Randomized Phase III Study of FOLFOX Alone and with Pegilodecakin as Second-line Therapy in Patients with Metastatic Pancreatic Cancer (SEQUOIA).

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Background: Effective therapies are limited for advanced metastatic pancreatic ductal adenocarcinoma (PDAC) patients (pts) who have progressed after 1st line gemcitabine-based chemotherapy (Gem). FOLFOX has clinical benefit in Gem-refractory PDAC pts. A phase 1 trial demonstrated promising activity with pegilodecakin (PEG; pegylated IL-10) and FOLFOX in Gem-refractory PDAC pts, providing rationale for the phase 3 trial (SEQUOIA; NCT02923921). **Methods:** SEQUOIA is a randomized phase 3 study of FOLFOX alone or with PEG in Gem-refractory PDAC pts. Pts were randomized 1:1, excluding pts with prior surgery and radiation, and received FOLFOX (*dI*-Leucovorin [400 mg/m^2], oxaliplatin [85 mg/m^2] followed by bolus 5-FU [400 mg/m^2], and a 46-48 hr infusion of 5-FU [2400 mg/m^2]) on day 1 of a 14-day cycle up to 12 cycles. PEG + FOLFOX arm received PEG (0.4 mg/d if $\leq$80kg and 0.8mg/d if $>$ 80 kg) on Days 1-5 then Days 8-12 + FOLFOX. Pts could continue PEG monotherapy (0.8mg/d if $\leq$ 80 kg and 1.6 mg/d if $>$ 80 kg) after FOLFOX discontinuation. Primary objective was OS. Secondary objectives included PFS, ORR per RECIST 1.1, and safety. Assuming OS HR of 0.74, the study was powered to 85% at 2-sided α = 0.05 with ~566 pts to detect superiority of PEG + FOLFOX. **Results:** As of Sept 9, 2019, 567 pts were randomized to PEG + FOLFOX (283) or FOLFOX (284). The majority (94.7%) had 1st line Gem+nab paclitaxel. The mOS was similar between FOLFOX + PEG arm [5.8 months] and FOLFOX arm [6.3 months] with HR = 1.045 (95% CI [0.863, 1.265], p = 0.6565). No statistical difference was observed for PFS, mPFS was 2.1 months in both arms with HR = 0.981, (95% CI [0.808, 1.190], p = 0.8144). ORR was 4.6% on the PEG+FOLFOX arm and 5.6% on the FOLFOX arm. Grade $\geq$3 adverse events that were 5% higher on the PEG+FOLFOX arm included thrombocytopenia (25.2% vs. 3.6%), anemia (16.2% vs. 4.0%), neutropenia (29.5% vs. 22.7%), and fatigue (17.6% vs. 10.8%). **Conclusions:** The addition of PEG to FOLFOX did not improve efficacy (OS, PFS, ORR) in advanced PDAC pts who have progressed after 1st line Gem-containing therapy. Safety findings were consistent with previous data observed from PEG + chemotherapy; toxicity was manageable and tolerable. Clinical trial information: NCT02923921. Research Sponsor: Eli Lilly and Company.

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HALO 109-301: A randomized, double-blind, placebo-controlled, phase 3 study of pegvorhyaluronidase alfa (PEGPH20) + nab-paclitaxel/gemcitabine (AG) in patients (pts) with previously untreated hyaluronan (HA)-high metastatic pancreatic ductal adenocarcinoma (mPDA).

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Background: HA is a major component of the tumor microenvironment (TME) in PDA. PEGPH20 degrades tumor HA, remodeling the TME. In PDA models, PEGPH20 has shown antitumor activity and increased TME delivery of anticancer agents to improve efficacy. A randomized phase 2 study showed promising results for PEGPH20+AG (PAG) in mPDA and identified HA accumulation as a biomarker. We present results from a phase 3 study (NCT02715804) of PAG for pts with HA-high mPDA. **Methods:** Pts ≥18 years with untreated HA-high mPDA were randomized (stratified by geographic region) 2:1 to PAG or placebo+AG (AG). HA status was prospectively determined with VENTANA HA RxDx Assay, with HA-high defined as ≥50% staining of a tumor sample. Treatment was administered IV in 4-wk cycles (3 wks on, 1 wk off) until progression or intolerable adverse events (AEs): PEGPH20 3.0 μg/kg twice wkly for Cycle 1 and once wkly (QW) thereafter, A 125 mg/m^2 QW and G 1000 mg/m^2 QW. Prophylactic enoxaparin 1 mg/kg was given daily for thromboembolism (TE) risk. The primary endpoint was overall survival (OS); secondary endpoints included progression-free survival (PFS), objective response rate (ORR) and safety. Response was independently assessed per RECIST v1.1. The estimated sample size was ~500 pts to detect a hazard ratio (HR) for OS of 0.67 (93% power, 2-sided α = 0.05) after 330 deaths. **Results:** As of 20 May 2019, 494 pts were randomized with 492 (327 for PAG and 165 for AG) included in ITT analyses (2 pts excluded due to site violations). Baseline characteristics were balanced for PAG vs AG. After 330 deaths, median OS for PAG vs AG was 11.2 vs 11.5 mo (HR 1.00, 95% CI 0.80–1.27; P = 0.97); median PFS was 7.1 vs 7.1 mo (HR 0.97, 95% CI 0.75–1.26); confirmed ORR was 34% vs 27%. Grade (G) 3+ AEs (PAG vs AG) included neutropenia (44% vs 47%), thrombocytopenia (21% vs 16%) and fatigue (16% vs 10%); G3+ rates were 6% vs 7% for TE events, 5% vs 2% for bleeding events and 13% vs 5% for musculoskeletal events. **Conclusions:** PAG did not improve clinical outcomes vs AG. The PAG safety profile was consistent with that of previous studies. Clinical trial information: NCT02715804. Research Sponsor: Halozyme.

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639 Rapid Abstract Session, Fri, 7:00 AM-7:45 AM and Poster Session (Board #A4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

A randomized, multicenter, phase II trial of gemcitabine (G), cisplatin (C) +/- veliparib (V) in patients with pancreas adenocarcinoma (PDAC) and a known germline (g)BRCA/ PALB2 mutation.

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Background: gBRCA 1,2 mutations occur in 5-8% PDAC. Platinum and poly-ADP ribose polymerase inhibitors (PARPi) effective in BRCA-mut cancers. Phase I GC + V high RR 78%; combination may delay resistance in PDAC (O'Reilly, Cancer, 2018). Herein, we evaluate GC +/- V in a multi-national, randomized phase II trial. **Methods:** Eligibility: Untreated germline (g)BRCA, PALB2 mut PDAC; measurable stage III/IV; ECOG 0-1. Randomized 1:1 Arm A or B. Treatment: Arm A: G 600 mg/m2 IV, C 25 mg/m2 IV, d3 and 10, V 80 mg PO BID day 1-12, all q 3 weeks or Arm B: GC only. Primary endpoint: RECIST 1.1 response rate (RR). Simon 2-stage per arm: null hypothesis 10% vs promising 28%; type I, II error 10%. Secondary endpoints: progression-free survival (PFS), OS (m), disease control rate (CR+PR+SD), safety and correlative analyses. PFS, OS compared between arms using log-rank test and RR, DCR using Fisher's exact test between arms. **Results:** N = 52 enrolled 01/14-11/18. N = 2 withdrew Arm B. N = 50 for ITT. Male = 22 (44%), Female = 28. Median age = 64 years (range 37-82). BRCA1 N = 12, BRCA2 N = 35, PALB2 N = 3. Stage III N = 8; Stage IV N = 42. Hematologic Toxicity: Arm A vs Arm B: Gd 3-4 neutropenia 13 (48%) vs 7 (30%); Gd 3-4 platelets 15 (55%) vs 2 (9%); Gd 3-4 anemia 14 (52%) vs 8 (35%). Non-hematologic toxicity similar Arm A vs B. Exploratory analyses (combined Arms): Med OS if $>$ 4 m platinum $\rightarrow$ PARPi: 23 m (95%CI 6.5-53.9). Med OS by BRCA: BRCA1: 14 m (8.1- 18.5); BRCA2: 20.2 m (12.3- 24.4). Med OS by ECOG: ECOG 0: 23 m (13.8- 24.5); ECOG 1: 14.3 (8.1 vs 16.4). Two-year OS rate for entire cohort: 30.6% and 3-year OS: 17.8%. **Conclusions:** GC +/- V very active in gBRCA/PALB2 mut PDAC with high RR, PFS, OS with both A, B significantly exceeding threshold RR. Improved DCR arm A vs B, but with greater heme toxicity A vs B. Study confirms GC as reference treatment in gBRCA/PALB2 with durable survival in subset. Funding: National Cancer Institute, CTEP, Lustgarten Foundation, AbbVie. Clinical trial information: NCT01585805. Research Sponsor: CTEP, Other Foundation.

	Arm A (GC+V) N = 27	Arm B (GC) N = 23	P-Value
RR, %	20 (74.1)	15 (65.2)	0.55
DCR, %	27 (100)	18 (78.3)	0.02
Median PFS (95%CI), mo	10.1 (6.7-11.5)	9.7 (4.2- 13.6)	0.73
Median OS (95%CI), mo	15.5 (12.2-24.3)	16.4 (11.7-23.4)	0.6

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640 Poster Session (Board #G15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

The clinical utility of the 2017 Fukuoka Guidelines and 2015 American Gastroenterological Association Guidelines for the management of intraductal papillary mucinous neoplasms.

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Background: Mucinous cystadenocarcinoma are malignant and mucinous pancreatic cysts (PC) have malignant potential. The management of PC remains controversial despite consensus guidelines. This study aims to evaluate the clinical utility of the 2017 Fukuoka Guidelines (FG) and 2015 American Gastroenterological Association Guidelines (AGA-G) for the management of PC. **Methods:** 212 patients who underwent EUS for PC between 2010 and 2017 were identified. The FG and AGA-G were used to define worrisome and high-risk cyst features. Receiver Operating Characteristic (ROC) curve was used to define sensitivity (SN), specificity (SP), positive predictive value (PPV) and negative predictive value (NPV). **Results:** 141 of 212 patients had IPMNs.EUS-FNA was performed in 76.5% with no reported complications. Median follow-up was 4.2 years. The majority of the IPMNs were in the pancreatic head (44.7%) or body (39.7%) while only 15.6 % were in the tail. Using the FG, 46.1% had at least one worrisome feature (FG-W) and 7.1% had at least one high risk feature (FG-HR). Using the AGA-G, 28.4% had at least one HR feature (AGA-HR1) and 1.4% patients had two or more risk factors (AGA-HR2). A change in cyst character (increase of $>$ 5 mm in 2 years, development of a solid component, or new pancreatic duct dilation) was noted in 43.2% patients. The median time to cyst change was 21 months. For prediction of cyst changes, the FG-W had a SN of 45.8%, SP of 55.4%, PPV 45%, and NPV 56%. FG-HR had a SN of 14.3%, SP of 53.2%, PPV 1.7%, and NPV 91.8%. AGA-HR1 had a SN of 35.3%, SP of 51.5%, PPV 20%, and NPV 69.9%. AGA-HR2 had a SN of 0%, SP of 54.2%, PPV 0%, and NPV 97.3%. No difference was seen in cyst change or development of high risk or worrisome features with CEA $>$ 192 vs. $<$ 192 ($p = 0.99$). During follow up, 14 patients died, but only one patient died of pancreatic cancer. **Conclusions:** FG and AGA-G are difficult to validate because malignant cyst transformation is rare. There was no correlation between any cyst characteristics on EUS and cyst changes. FG-W had the best performance in predicting changes. Surgical candidates should be carefully selected, as these guidelines have a limited clinical utility. Research Sponsor: None.

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641 **Poster Session (Board #G16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Determining when endoscopic ultrasound (EUS) changes management for patients with pancreatic cystic neoplasms.

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Background: Pancreatic cystic neoplasms (PCNs) are being incidentally detected at an increased rate due to the widespread use of CT and MRI. CT and MRI cannot always differentiate between malignant and benign PCNs. EUS is an emerging tool that provides higher quality descriptions of pancreatic cysts and can be used to differentiate between benign and malignant features. Considering that EUS is a resource dependent tool, we hope to identify the PCN cases in which EUS changes management. **Methods:** We conducted a retrospective case-control chart review evaluating patients, who were diagnosed with pancreatic cysts and underwent EUS for analysis between January 1, 2010 and December 31, 2017. We determined whether EUS correctly identified high-risk features (HRFs) relative to CT/MRI and whether EUS upstaged or downstaged the CT/MRI diagnosis to change overall patient management. **Results:** EUS was found to have a high specificity ($>$ 95%) for all high-risk features identified in the AGA and FG guidelines and a low sensitivity ($<$ 70%) for all high risk features except cyst size $>$ 3cm (82.35%) and mural nodule $<$ 5mm (100%). EUS was found to change management in 29.4% of cases (18.2% upstaged, 11.2% downstaged). EUS screening led to a total of three adenocarcinoma diagnoses, in which two were reported to be invasive. **Conclusions:** The high specificity of EUS supports its use in the differentiation of high risk PCNs identified on cross-sectional imaging. Its low sensitivity indicates that the reliance on operator experience may be a substantial limitation resulting in inconclusive diagnoses. In conclusion, considering that EUS is successful in changing patient management of PCNs, it should be readily referred when any HRF is identified on cross-sectional imaging. Research Sponsor: None.

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642 **Poster Session (Board #G17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Evaluation of ICD codes and phecodes for the identification of pancreatic cancer in a large genomic database.

Chelsea Anne Isom, Eric R. Gamazon, Marcus Chuan Beng Tan; Vanderbilt University Medical Center, Nashville, TN; Vanderbilt University, Nashville, TN; Mitchell Cancer Institute, The University of South Alabama, Mobile, AL

Background: Large genomic databases linked to electronic health records promise to shed light on molecular mechanisms underlying rare diseases, such as pancreatic cancer. However, accurately identifying patients with the desired phenotype can be challenging. This is particularly the case for pancreatic tumors, since ICD codes do not distinguish between pancreatic adenocarcinoma (PDAC) and pancreatic neuroendocrine tumors (pNET). Previous studies have shown that ICD codes aggregated by phenotype, known as "phecodes", have a higher accuracy in identifying specific phenotypes than ICD codes themselves; however, their performance in identifying cancers of the pancreas has not been studied. **Methods:** From a large deidentified genomic database, two queries were performed to identify all adults with pancreatic cancer for a GWAS study, one using ICD-9/10 codes and the other using phecodes. The medical records for all patients identified from both queries were then reviewed to confirm the presence and histologic type of pancreatic cancer. **Results:** Of the 91,985 genotyped adults in the database, ICD-9/10 codes identified 1,247 patients with pancreatic cancer, compared with only 422 patients identified by the phecode query. All patients in the phecode cohort were also found in the ICD cohort. Of the 1,247 patients in the ICD cohort, 760 were confirmed to have pancreatic cancer on review of the health records (594 with PDAC, 166 with pNET) whereas in the phecode cohort, only 251 were confirmed to have pancreatic cancer (159 with PDAC, 92 pNET). The positive predictive value (PPV) for PDAC in the ICD query was 47%, compared with 38% for the phecode cohort. The ICD and phecode cohorts had similarly low numbers of pre-malignant cystic tumors (5% in each cohort) and other periampullary cancers (3%). **Conclusions:** In this large genomic database, the use of ICD-9/10 codes for pancreatic cancer was able to identify nearly three times as many patients with pancreatic cancer and had a higher PPV compared to using phecodes. Therefore, ICD codes, rather than phecodes, should be used to identify patients with pancreatic cancer for subsequent genotyping analysis, though caution is required because the PPV is still low. Research Sponsor: None.

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643 Poster Session (Board #G18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Weight loss as an untapped early detection marker in pancreatic cancer.

Jonathan J. Hue, Sarah C. Markt, Ravi Kumar Kyasaram, John Shanahan, Goutham Rao, Jordan Michael Winter; University Hospitals Cleveland Medical Center, Cleveland, OH; Case Western Reserve University, Cleveland, OH; University Hospitals Seidman Cancer Center, Cleveland, OH

Background: Pancreatic cancer has the worst survival of common cancers and there are no reliable early detection tests. While prior reports link unintentional weight loss (>5% decrease from baseline) to pancreatic cancer, there has never been a study documenting the frequency of this presenting sign using raw patient weight data. **Methods:** Patients at our institution with a pancreatic neoplasm (n=288) were queried using ICD-9 code 157.9 and ICD-10 code C25.9. Retrospective review identified 95 patients with pancreatic ductal adenocarcinoma and two or more prediagnosis weights (>7 days apart). Date of diagnosis was defined by the date of positive biopsy or encounter with surgical or medical oncology. Standard statistical analysis was performed. **Results:** Among the 95 patients, there was a slight preponderance of female (65.3%) and Caucasian (54.7%) patients. The median age at diagnosis was 71 (range: 41-90) and the median BMI was 25.6 kg/m^2 (range: 15.4-49.5). 9.5% presented with clinical stage I disease, 27.3% with stage II, 9.5% with stage III, and 53.7% with stage IV. Within 1 year of diagnosis (range: 9-365 days), median weight loss was 7.1% of body weight (range: 0.2-34.5%). In this period, 71.6% of patients lost greater than 5% body weight and 32.6% lost over 10% (Table). In the 6 months before diagnosis (range: 9-180 days), median weight loss was 6.4% (range: 0.2-24.2%). A subgroup analysis of early (I, II) and late stage (III, IV) patients showed that those with late stage at presentation lost significantly more prediagnosis weight compared to the early stage patients (median 8.2% vs 5.6%, p=0.02) in a median of 175 days. Prior to diagnosis of late stage patients, 80.0% lost over 5% body weight and 38.3% lost over 10%. **Conclusions:** Diagnosis of pancreatic cancer is preceded by weight loss in the majority of cases, even at an early stage. Monitoring unintentional weight loss in otherwise asymptomatic patients may be an inexpensive and practical way to detect pancreatic cancer. Research Sponsor: University Hospitals Ventures.

	All patients (n=95)	Early stage (n=35)	Late stage (n=60)
5-10%	38.9%	34.3%	41.7%
10-15%	17.9%	17.1%	18.3%
>15%	14.7%	5.7%	20.0%
>5%, total	71.6%	57.1%	80.0%

Percent weight loss within 1 year of diagnosis.

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644 Poster Session (Board #G19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pathological examination of CT findings of tumor infiltration to the periarterial plexus in pancreatic cancer.

Takashi Miyamoto, Yusuke Yamamoto, Teiichi Sugiura, Yukiyasu Okamura, Takaaki Ito, Ryo Ashida, Katsuhisa Ohgi, Katsuhiko Uesaka; Division of Hepato-Biliary-Pancreatic Surgery, Shizuoka Cancer Center, Nagaizumi, Japan; Division of Hepato-Biliary-Pancreatic Surgery, Shizuoka Cancer Center, Shizuoka, Japan

Background: The radiographic diagnosis of tumor infiltration into the periarterial plexus in pancreatic cancer is important because it is related to the classification, however, it is difficult to distinguish the abnormal shadow along the artery caused by inflammation or cancer infiltration. The aim of this study is to investigate CT values of the abnormal shadow along artery could distinguish between inflammation and tumor invasion. **Methods:** Study 1: Of 26 patients who underwent DP-CAR between 2009 and 2018, we analyzed 19 patients who had dynamic CT and obtained sagittal slice taken 120 seconds after injection with less than 2.5 mm slice thickness. At first, we measured CT values at upper and lower point of CeA and CHA each sagittal slice using CT. Next, we evaluated tumor invasion at the upper and lower plexus of CeA and CHA in each section of the pathological specimen, and evaluated the relationship between the tumor invasion and the CT value. Study 2: Using these 19 patients and 40 patients who underwent DP for PDAC between 2010 and 2014, we analyzed the relation between CT value and long-term states. **Results:** Study 1: CT value was totally measured at the 606 points using 19 patients who underwent DP-CAR. At the 490 points, we did not observe cancer infiltration and fibrosis. At the 70 points, we observed fibrosis without cancer cells. At the 46 points, we observed cancer infiltration. CT value was significantly higher in the tumor infiltration group than that in the without cancer infiltration and fibrosis group ($P < 0.01$). Study 2: The best cut-off of CT value of the presence of cancer infiltration was 44.9 HU using ROC curve (AUC = 0.861). The median survival time of patients who had the points of CT value $>$ 44.9 HU around arteries was significantly shorter than that of patients who did not have the points of CT value $>$ 44.9 HU (2.17 vs. 4.55 years, p = 0.03). **Conclusions:** The CT value around the arteries was significantly higher in the points of pathological tumor infiltration than that in the points of fibrosis without cancer cells. The best cut-off CT value of the presence of cancer infiltration around arteries was 44.9 HU, and the presence of the point of CT value $>$ 44.9 HU around arteries was associated with poor survival. Research Sponsor: None.

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645 Poster Session (Board #G20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Detection of circulating tumor DNA in pancreas cancer.

Daniel King, Ash A. Alizadeh, George A. Fisher; Stanford University, Palo Alto, CA; Stanford Cancer Institute, Stanford, CA; Stanford University, Stanford, CA

Background: Pancreas cancer remains a leading cause of cancer-related death. Improved detection of early relapse or early failure of chemotherapy also has the potential to further improve outcomes. Exploring circulating tumor DNA (ctDNA) in this setting is an area of active investigation. **Methods:** We previously developed an approach, CAPP-Seq, combining high-depth sequencing with several strategies of error-suppression to identify minute amounts of circulating tumor DNA. We then trained and validated a new capture panel for pancreas cancer from 640 tumors from three data sources (TCGA, ICGC, UTSW), targeting 265 kb of the genome. We enrolled two cohorts of patients with pancreatic cancers at Stanford Cancer Center: (1) patients with localized tumors undergoing resection with curative intent, and (2) patients with unresectable or metastatic disease undergoing systemic therapy. **Results:** As of August 2019, we recruited 131 patients with at least one blood collection, with 63% having resectable disease and 27% having advanced disease; 59 patients had 2 or more blood collections. Stage distribution included 34% stage I, 33% stage II, 18% III, 16% IV disease. Approximately 15% had normal CA19-9 levels. Deep sequencing (4,000x unique depth) of an initial set of resected pancreatic tumors and matched germline specimens identified 1-6 non-synonymous coding mutations per case (median=3, n=14), with the most frequently mutated genes involving *KRAS* (79%), *TP53* (50%), *SMAD4* (29%). Among newly diagnosed treatment-naïve patients with resectable adenocarcinoma (n=9), we detected ctDNA in 4 patients (44%) prior to surgery including with AFs ranging from 0.27% - 0.88%. Subsequent sequencing will compare patients with and without neoadjuvant therapy prior to resection, selection of unresectable patients across a larger range of tumor burden and across multiple timepoints, and integration of large-scale copy number variant detection using low-pass whole-genome sequencing. **Conclusions:** Circulating tumor DNA monitoring with CAPP-Seq shows promise for improved detection of PDAC. Two key applications include early detection of minimal residual disease after resection and early assessment of response to chemotherapy. Research Sponsor: Stanford Cancer Institute.

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646 **Poster Session (Board #G21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Impact of biliary metal and plastic stents on preoperative staging for pancreatic cancer.

Hachem Hachem, Sanjay S. Reddy, Jeffrey Tokar, Eileen O'Halloran, Jennifer Higa, Abby Sapp, Albert Civitarese, Michael Bartel; Fox Chase Cancer Center, Philadelphia, PA

Background: Multiple studies have shown the superiority of biliary metal compared with plastic stents for pre-operative (preop) biliary drainage in pancreatic cancer (PDAC). Despite the importance of preop cross-sectional imaging, particularly in the era of neoadjuvant treatment, there is no data on the impact of such stents on the quality of preop cross-sectional imaging. We hypothesis, that biliary metal stents negatively impact the accuracy of preop cross-sectional imaging in pancreatic cancer, with unknown impact for the adequacy of surgical candidacy. **Methods:** Data of all patients undergoing pancreatic resection for PDAC between 1/1/2012 and 1/1/2018 was retrospectively abstracted. Clinical staging based on preop cross-sectional imaging following biliary stent placement (within 2 months prior surgical resection) was compared with the surgical pathology (staging gold standard). Accuracy of clinical and surgical pathology staging was compared. Logistic regression was performed to control for biliary stent type, neoadjuvant treatment and patient baseline characteristics including BMI and type of imaging. **Results:** 312 patients underwent pancreatic resections. 118 patients required preop biliary drainage in setting of PDAC, including 92 ERCPs of which 83 were successful (46 plastic and 37 metal stents). 76 patients underwent neoadjuvant chemoradiation therapy. Surgical pathology revealed following stages: 0 n = 4, 1A n = 5, 1B n = 8, 2A n = 20, 2B n = 24, 3 n = 1, 4 n = 14. 96% underwent preop CT and 4% MRI pancreas protocol imaging. Exact correlation between clinical and surgical pathology was present in only 48% of cases (57% plastic, 46% metal stent), with 28% of clinical T overstaging, 4% clinical T understaging, 16% clinical N understaging and 4% unable to stage due to artefacts. More importantly, 8% patients were incorrectly staged to be surgical candidates (14% plastic, 6% metal). Controlling for stent type, neoadjuvant treatment and BMI did not impact preop cross-sectional imaging accuracy. **Conclusions:** Despite their impact on preop cross-imaging biliary metal stents did not negatively impact the accuracy and patient selection for surgical candidacy compared with biliary plastic stents in PDAC. Research Sponsor: None.

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647 **Poster Session (Board #G22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Efficacy of chemotherapy for patients with unresectable or recurrent pancreatic adenosquamous carcinoma: A multicenter retrospective analysis.

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Background: Pancreatic adenosquamous carcinoma (PASC) is a rare variant of pancreatic ductal adenocarcinoma (PDAC). Although unresectable or recurrent PASC is usually treated by systemic chemotherapy, there are few reports which show the efficacy of chemotherapy. The aim of this study was to evaluate the efficacy of chemotherapy for patients (pts) with unresectable or recurrent PASC. **Methods:** We collected data retrospectively from 24 Japanese institutions. The selection criteria were as follows: 1) histologically or cytologically proven PASC (non-surgical specimens were eligible if squamous cell carcinoma (SCC) was detected), 2) unresectable or recurrent disease treated with 1st line chemotherapy between April 2001 and December 2017. **Results:** This study included 138 pts with median age of 66 years (range: 36-85). About 60% of pts were diagnosed with biopsy and only SCC was detected in 13.0% of pts. Median overall survival (mOS) was 6.7 months (M), median progression free survival (mPFS) was 2.8 M, and the 1-year survival rate (1YSR) was 26.7%. For the 102 metastatic or distal recurrent pts with PS of 0-1, patient characteristics were as follows: ≥76 years old, 9 (8.8%); PS of 0, 39 (38.2%); number of metastatic sites ≥2, 25 (24.5%). The treatment efficacies (The objective response rates(%)/mPFS(M)/mOS(M)/1YSR(%)) of the 5 major regimens were Gemcitabine(GEM) (n=45, 4.4%/2.2M/4.8M/28.1%), GEM+nab-PTX (n=24, 29.2%/2.9M/7.6M/23.1%), GEM+S-1 (n=9, 11.1%/5.1M/9.9M/25.4%), FOLFIRINOX (n=7, 14.3%/2.5M/7.5M/14.3%), and S-1 (n=7; 28.6%/2.6M/5.0M/28.6%), respectively. One patient with liver metastasis underwent conversion surgery after GEM+nab-PTX and achieved long survival. CRP ≥3.0mg/dl, CA19-9 ≥1000 U/ml, residual primary site, and monotherapy had a significant correlation with poor survival in multivariate analysis. **Conclusions:** Although combination chemotherapy regimens such as FOLFIRINOX and GEM+nab-PTX are now available, the prognosis of metastatic PASC remains poor. Development of more effective treatment options is required. Research Sponsor: None.

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648 Poster Session (Board #H1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pancreatic cancer (PaC)-specific health-related quality of life (HRQoL) with maintenance olaparib (O) in patients (pts) with metastatic (m) PaC and a germline *BRCA* mutation (g*BRCA*m): Phase III POLO trial.

Michael J. Hall, Talia Golan, Pascal Hammel, Michele Reni, Eric Van Cutsem, Teresa Macarulla, Joon Oh Park, Daniel Hochhauser, Dirk Arnold, Do-Youn Oh, Anke C. Reinacher-Schick, Giampaolo Tortora, Hana Algül, Eileen Mary O'Reilly, David McGuinness, Karen Cui, Seongjung Joo, Hyun Kyoo Yoo, Nikunj Patel, Hedy L. Kindler; Fox Chase Cancer Center, Philadelphia, PA; The Oncology Institute, Sheba Medical Center at Tel-Hashomer, Tel Aviv University, Tel Aviv, Israel; Hôpital Beaujon (AP-HP), Clichy, and University Paris VII, Paris, France; IRCCS Ospedale, San Raffaele Scientific Institute, Milan, Italy; University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; Vall d'Hebrón University Hospital and Vall d'Hebrón Institute of Oncology, Barcelona, Spain; Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; University College London Cancer Institute, London, United Kingdom; Asklepios Tumorzentrum Hamburg AK Altona, Hamburg, Germany; Seoul National University Hospital, Seoul, South Korea; St Josef-Hospital, Ruhr University Bochum, Bochum, Germany; Azienda Ospedaliera Universitaria Integrata Verona, Verona and Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy; Klinikum Rechts der Isar, Comprehensive Cancer Center Munich-TUM and Department of Internal Medicine II, Technische Universität München, Munich, Germany; Memorial Sloan Kettering Cancer Center, New York, NY; AstraZeneca, Cambridge, United Kingdom; AstraZeneca, Gaithersburg, MD; Merck & Co., Inc., Kenilworth, NJ; The University of Chicago, Chicago, IL

Background: In POLO (NCT02184195), maintenance O significantly improved progression-free survival vs placebo (P) in pts with a gBRCAm and mPaC without compromising HRQoL (Hammel *Ann Oncol* 2019). We report additional predefined exploratory HRQoL data from the PaC-specific EORTC QLQ-PAN26 questionnaire. **Methods:** Pts were randomized to O (300 mg bid; tablets) or P. QLQ-PAN26 was completed at baseline (BL), after 1, 2, 3 + 4 weeks (wk) of treatment, every 4 wks until progression, at discontinuation, and 30 days after last dose. Scale range = 1–100 (higher score = greater symptoms); a 10-point change was predefined as clinically meaningful. Adjusted mean change from BL (CFBL) was analyzed by mixed model for repeated measures; time to sustained clinically meaningful deterioration (TSCMD) by log-rank test. **Results:** Analyses included the 89/92 O- and 58/62 P-arm pts with BL data (overall compliance: 97.8% vs 98.3%). Symptom scores were well balanced in both groups at BL and remained low and stable over time (Table). There were no clinically meaningful between-group differences in adjusted mean CFBL symptom scores. TSCMD in symptoms were not significantly different with O vs P. **Conclusions:** HRQoL was preserved with maintenance O, as shown by a low and stable PaC symptom burden over time, with no difference vs P. These data support the clinical benefit of O in pts with a gBRCAm and mPaC. Clinical trial information: NCT02184195. Research Sponsor: AstraZeneca and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

	Mean score ± standard deviation				Adjusted mean CFBL (to 6 m)		Median TSCMD, m		
	BL	Wk 4	Wk 8	Wk 16					
	O;P	O;P	O;P	O;P	O;P	Difference (*P* value)	O	P	HR* (95% CI; *P*value)
Pancreatic pain	15±16; 13±13	18±18; 15±18	17±17; 16±24	18±18; 19±26	4.0; 6.4	-2.4 (0.34)	11.0	6.0	0.81 (0.48-1.36; 0.42)
Jaundice	7±13;5±12	6±11;6±13	6±12;6±16	6±10;5±12	0.7;0.5	0.2 (0.89)	16.6	NR	1.18 (0.60-2.32; 0.64)
Feeling bloated	20±26; 14±24	20±24; 15±23	20±23; 19±26	19±22; 17±27	3.5;2.0	1.5 (0.62)	14.7	6.5	0.91 (0.52-1.58; 0.74)
Indigestion	20±28; 16±23	15±20; 8±17	16±20; 12±22	17±20; 6±17	-2.9;-7.7	4.8 (0.05)	20.9	NR	1.21 (0.62-2.33; 0.58)
Dry mouth	27±31; 16±27	19±25; 12±22	21±26; 16±28	22±24; 14±27	-2.1;-5.5	3.4 (0.26)	26.2	NR	0.71 (0.36-1.43; 0.34)

*HR < 1 favors O. m, months; NR, not reached

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649 Poster Session (Board #H2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Scoring model with serum albumin and CA19-9 in advanced pancreatic cancer in second-line treatment: Results from the NAPOLEON study.

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Background: Patients with metastatic pancreatic cancer refractory to first-line chemotherapy (CTx) have limited treatment options. Moreover, it is unclear what kind of patients could be brought about survival benefit by 2nd-line CTx after refractory to gemcitabine+ nab-PTX (GnP) or FOLFIRINOX. **Methods:** This analysis was performed as part of a multicenter retrospective study of GnP or FOLFIRINOX in patients with unresectable pancreatic cancer (NAPOLEON study) conducted by 14 centers in Japan. From December 2013 to March 2017, 255 patients with advanced or recurrent pancreatic cancer received GnP or FOLFIRINOX as 1st-line CTx. Excluding censored cases in first-line treatment, 156 and 77 patientsreceived 2nd-line CTx and best supportive care (BSC), respectively. Variables at the refractory or intolerant to the 1st-line treatment were used to investigate correlation with prognosis by Cox regression model. Then, we made scoring system using the prognostic factors to reveal the benefit of 2nd-line CTx. **Results:** Median post-progression survivals (PPSs) were 5.2 months in 2nd-line CTx group and 2.7 months in BSC group, respectively (hazard ratio [HR]; 0.42, 95% confidence interval [CI]; 0.31-0.57, $p<0.01$). According to the Cox regression model, serum Alb level of less than 3.5 g/dL (HR; 1.98, 95% CI; 1.33–2.96, $p<0.01$) and CA19-9 level of greater than 1,000 U/mL (HR; 1.87, 95% CI; 1.25–2.80, $p<0.01$) were independent predictive factors. The scoring system for PPS was designed using these factors, which was obtained by summing up serum Alb ($\geq$ and $<$ 3.5 g/dL allocated to scores 0 and 1) and CA19-9 ($<$ and $\geq$ 1,000 U/mL allocated to scores 0 and 1) at disease progression in patients with 2nd-line CTx group. Patients with score 0 and 1 displayed significantly favorable PPSs in comparison with BSC group; however, there was no significant difference in PPS between patients with score 2 and BSC group (Table). **Conclusions:** Survival benefit of 2nd-line CTx was observed in patients with the score 0 and 1, but not in the score 2. Research Sponsor: None.

No. of factors	n	median OS	HR	95% CI	p
BSC	77	2.7	1	-	-
Score 0	37	8.1	0.26	0.16-0.41	< 0.01
Score 1	54	4.8	0.49	0.33-0.71	< 0.01
Score 2	22	2.8	0.94	0.57-1.56	0.82

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650 Poster Session (Board #H3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Prognostic factors associated with short-term survival (STS) in advanced pancreatic cancer (APC): A multicenter analysis from the CHORD consortium.

Sakshi Mehta, Miguel Cardoso, Christina Kim, Dawn Elizabeth Armstrong, Ravi Ramjeesingh, Daniel John Renouf, Shahid Ahmed, Yoo-Joung Ko, Mohammed Harb, Shiying Kong, Winson Y. Cheung, Brandon M. Meyers; Juravinski Cancer Centre, Hamilton, ON, Canada; Dept of Medical Oncology, CancerCare Manitoba, Winnipeg, MB, Canada; Dr. H. Bliss Murphy Cancer Centre, St. John's, NF, Canada; Nova Scotia Cancer Centre, Dalhousie University, Nova Scotia, NS, Canada; BC Cancer Agency, Vancouver, BC, Canada; University of Saskatchewan, Saskatoon, SK, Canada; Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON, Canada; Moncton Hospital, Moncton, NB, Canada; Alberta Health Services, Calgary, AB, Canada

Background: The survival of patients (pts) with APC (locally advanced/metastatic) is slowly improving; however, in some pts it remains extremely short. Few studies have evaluated the clinical, pathologic and treatment characteristics associated with STS in APC. **Methods:** Pts with APC (between 2011-2017) were included in the analysis. Descriptive analyses were conducted for demographic, tumor and treatment characteristics between pts who survived ≤ and > 90 days using Wilcoxon rank-sum test and Chi-square test for continuous and categorical variables respectively. Multivariable logistic regression was performed to identify association between pts' characteristics and STS. **Results:** A total of 580 pts were included in the analysis: median age 68, 53% male, 92% metastatic and 53% ECOG 0/1. STS ≤90 days occurred in 152 pts (26.2%), with 65.1% not receiving any chemotherapy. Median overall survival for STS was 49 days vs. 276 for non-STS. At least 1 cycle of chemotherapy was administered to 358 pts; mean duration of first-line chemotherapy for pts with STS ≤90 was 1.5(SD 2.5) cycles (N=53), compared to 7.6(SD 11.1) cycles (N=305) for pts surviving > 90 days. Prognostic factors associated with STS <90 days were neutrophil:lymphocyte ratio, LDH, metastatic disease, ECOG and not receiving chemotherapy (Table). Other clinical factors (BMI, smoking history, diabetes) and laboratory values (platelet, baseline CA19-9, estimated GFR) were not prognostic. **Conclusions:** In a multicenter database of Canadian academic centers, <2/3 of pts received at least 1 cycle of chemotherapy. Prognostic factors associated with STS include routine laboratory values, not receiving chemotherapy, ECOG and the presence of metastatic disease. Further evaluation of factors related to not receiving chemotherapy, and why chemotherapy is discontinued could improve the outcomes of pts with STS. Research Sponsor: None.

Variable	≤90 days OR (95% CI) p-value <0.05*, <0.0001**
neutrophil:lymphocyte ratio ≥5	2.88 (1.73-4.82)**
Bilirubin >21	1.41 (0.77-2.55)
Albumin <40	1.37 (0.59-3.16)
LDH >230	2.02 (1.11-3.69)*
ECOG >=2+	3.64 (1.39-9.5)*
Metastatic disease	10.97 (2.36-51)*
Not receiving chemotherapy	4.11 (2.26-7.5)**

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651 Poster Session (Board #H4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Improved surgical margins with neoadjuvant versus adjuvant chemotherapy in clinical stage I resectable pancreatic adenocarcinoma: A National Cancer Database study.

Geoffrey Bellini, Samit Kumar Datta, Nicholas Sich, Maharaj Singh, James Leighton Weese, Federico Augusto Sanchez, Nalini Guda, Wesley Allan Papenfuss, Aaron Chevinsky; Aurora St. Luke's Medical Center, Milwaukee, WI; Aurora Health Care, Milwaukee, WI; Dental School, Marquette University, Milwaukee, WI; Aurora Cancer Care, Advocate Aurora Health, Milwaukee, WI; GI Associates, Milwaukee, WI

Background: A strengthening consensus exists for neoadjuvant therapy (NAT) in borderline resectable pancreatic adenocarcinoma (PA), but the utilization of NAT in resectable stage I PA remains controversial. Many cancer centers are using NAT for these patients (pts), but others continue to offer upfront surgery and adjuvant therapy (AT). We hypothesized that NAT would improve margin negative resection in clinical stage I resectable PA. **Methods:** We utilized the IRB approved 2016 national cancer database for pancreas to establish a cohort of stage I PA pts. We divided this subset into pts who underwent NAT vs AT. We compared demographics. Primary endpoint was surgical margins. **Results:** 10,453pts from 2004 to 2016 had clinical stage I resectable PA: 8483pts (81.1%) AT and 1970pts (18.9%) total or partial NAT. There was a statistical difference in age (64.9 $\pm$ 9.9years NAT and 66.2 $\pm$ 9.9years AT, $p<0.001$), but no difference in Charlson comorbidity score (p=0.1693). NAT pts had significantly higher margin negative resection rates (84.5%) than AT pts (79.4%) ($p<0.0001$). Final pathologic staging was available for 10,237 pts: 8369 (81.8%) AT and 1868 (18.2%) NAT. Significantly fewer pts were upstaged on final pathology to stage II or greater (73.5%) in the NAT group than the AT group (84.1%) ($p<0.001$). **Conclusions:** NAT leads to significantly higher margin negative rates for resectable clinical stage I PA than surgery followed by AT. The majority of pts for both groups were upstaged suggesting that we continue to clinically understage the majority of pts. Overall, total or partial NAT for clinical stage I resectable PA provides a better chance for margin negative resection. Further study in the form of a randomized control trial is necessary. Research Sponsor: None.

Clinical Stage 1 PA Pts.			
	Adjuvant	Neoadjuvant	p-value
Surgical Margins			
Positive	1751 (20.6%)	305 (15.5%)	<.0001
Negative	6732 (79.4%)	1665 (84.5%)	
Pathologic Upstaging			
No	1329 (15.9%)	495 (26.5)	<.0001
Yes	7040 (84.1%)	1373 (73.5%)	
Final Pathologic Stage			
Stage 0	4 (0.05%)	15 (0.8%)	
Stage 1	1325 (15.8%)	480 (25.7%)	
Stage 2	6781 (81.0%)	1316 (70.5%)	
Stage 3	117 (1.4%)	32 (1.7%)	
Stage 4	142 (1.7%)	25 (1.3%)	

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652 **Poster Session (Board #H5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

An institutional series of early-onset pancreatic cancer (EOPC): Clinical outcomes and genetic and supportive care referral patterns.

Kunal C. Kadakia, Sally Jeanne Trufan, Megan Jagosky, William Mills Worrilow, Bradley W. Harrison, Katherine Broyhill, Nicole Lee Gower, Harris Coley, Jimmy J. Hwang, Laura W. Musselwhite, Reza Nazemzadeh, Seungjean Chai, John Stuart Salmon, Edward S. Kim, Mohamed E. Salem; Levine Cancer Institute, Atrium Health, Charlotte, NC; Atrium Health, Charlotte, NC; Levine Cancer Institute-Atrium Health, Charlotte, NC; Levine Cancer Institute, Carolinas Medical Center, Charlotte, NC; Levine Cancer Institute, Charlotte, NC

Background: The incidence of EOPC is rising and is associated with substantial implications for affected individuals and their families. Little is known about the extent of physician referrals of these patients (pts) to genetic, supportive care, and hospice services. **Methods:** Pts with EOPC (≤50 years) were identified using the institutional tumor registry for years 2011-2018 and retrospectively reviewed. Clinical data and rates of referral to supportive, genetic and hospice services were retrieved. Descriptive analyses were performed with 25-75% interquartile ranges (IQR) where appropriate. Overall survival (OS) was assessed using Kaplan-Meier curves and Cox Proportional Hazards modeling. **Results:** In total, 113 pts with EOPC and a median age of 47 years (range, 28-50) were analyzed. Of these 113 pts, 43% were female, 27% were black, and 45% had metastatic disease at initial presentation. The most commonly administered first line chemotherapy was FOLFIRINOX, with gemcitabine/nab-paclitaxel reserved for the second line. The median OS of pts with metastatic disease was 5.8 compared to 15.8 months for those without metastases. Only 28% of pts were referred to genetic services, and 72% of these underwent genetic testing. Out of the genetically tested pts, pathogenic germline mutations were confirmed for 33%. Of the original 113 pts, 41% received concurrent palliative care, which was provided at a median of 2.4 mos. (IQR, 0.7-6.8) preceding death. The median time between last chemotherapy administered and death was 2 mos. (IQR, 1-4.4), with 23% receiving treatment within the last month of life. Only 55% used hospice services prior to death for a median duration of 0.5 mos. (IQR, 0.2-1.4). **Conclusions:** Our study suggests that there is a tendency for late utilization of supportive and hospice care in pts with EOPC, possibly due to the desire of both pts and physicians to be more aggressive given the young age. Larger studies are warranted to elucidate barriers to concurrent supportive care, and whether formation of specialized young patient supportive care clinics would aid this situation and to avoid the use of unnecessary chemotherapy near the end of life. Research Sponsor: None.

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653 Poster Session (Board #H6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Real-world eligibility of advanced pancreatic (APC) patients for maintenance olaparib.

Atul Batra, Winson Y. Cheung, Patricia A. Tang; Tom Baker Cancer Center, Calgary, AB, Canada; Tom Baker Cancer Centre, University of Calgary, Calgary, AB, Canada

Background: The POLO trial demonstrated an improvement in progression free survival (PFS, 7.4 months vs. 3.8 months; hazard ratio, HR, 0.53; 95% confidence interval, 95% CI, 0.35 to 0.82; P=0.004) with olaparib compared to placebo, as maintenance therapy in APC patients with germline BRCA 1/2 mutations with disease control after 16 weeks (DC16) of platinum-based first-line therapy. This study aims to identify the proportion of real-world APC patients eligible for olaparib, and to determine the PFS and overall survival (OS) after DC16. **Methods:** APC patients treated with first-line FFX in Alberta were identified (2011-2018). We conducted an analysis of baseline characteristics to identify factors associated with DC16. **Results:** We identified 165 APC patients treated with FFX with unknown BRCA 1/2 status, of which 56% were males and median age at diagnosis was 59 years (interquartile range 38-75 years). Of these, 72 (44%) had DC16. Normal LDH and ALP, and albumin more than 35 g/L were associated with a higher likelihood of having DC16 (table). The PFS of patients with DC16 was significantly higher than those with DC<16 weeks (9.3 vs 2.5 months, HR=0.22, 95% CI 0.15-0.32, P<0.001). In patients who had DC16, median PFS and OS from that point were 5.6 months and 17.9 months, respectively. **Conclusions:** Less than half of real-world patients treated with first-line FFX would be eligible for olaparib by the criteria of DC16 with FFX. Median PFS after DC16 is 5.6 months with FFX in patients with unknown BRCA 1/2 status. This provides a baseline for future trials evaluating maintenance strategies. Patients with APC and higher disease burden (higher ALP and LDH) and low albumin are less likely to have DC16.
Research Sponsor: None.

				Logistic Regression	
Characteristic	**DC <16 weeks (n=93)**	**DC16 (n=72)**	**P-value**	**Odds Ratio**	**P-value**
Age	57.7±8.9 years	58.6±8.8 years	0.54		
Sex	51(55%)	41(57%)	0.79		
Male					
ECOG PS	3(9%)	4(14%)	0.23		
0	30(91%)	24(86%)			
1					
ECOG PS					
0	3(9%)	4(14%)	0.23		
1	30(91%)	24(86%)			
Biliary Stenting					
Yes	17(18%)	15(21%)	0.68		
Hb	40(43%)	15(21%)	**0.003**	2.14(0.92-4.99)	0.08
< 120 g/L					
Albumin	65(70%)	15(21%)	**<0.001**	6.88(3.08-15.36)	**<0.001**
< 35 g/L					
ALP	84(90%)	49(68%)	**<0.001**	0.32(0.12-0.88)	**0.03**
> ULN					
LDH	47(53%)	13(19%)	**<0.001**	0.35(0.15-0.84)	**0.02**
> ULN					

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654 Poster Session (Board #H7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Safety and efficacy of chemotherapy in older adults with locally advanced and metastatic pancreatic ductal adenocarcinoma (PDAC).

Lorena Ostios-Garcia, Patricia Saade, Joseph Elan Grossman, Leanne Lanniello, Andrea J. Bullock; Beth Israel Deaconess Medical Center, Hematology/Oncology Division, Boston, MA; Brigham And Women's Hospital, Pulmonary and Critical Care, Department of Medicine, Boston, MA; Beth Israel Deaconess Medical Center, Boston, MA

Background: PDAC is often diagnosed in patients (pts) ≥75yrs. However, older adults comprise a small proportion of subjects in prospective trials, and there is little reported on the safety and efficacy of chemotherapy in this population. **Methods:** Records were reviewed on all pts ≥75yrs treated with chemotherapy for locally advanced and metastatic PDAC at a single institution from April 2010 - March 2018. Response rate (RR), progression free survival (PFS), overall survival (OS) and toxicities were compared among the different regimens, and among pts < or ≥80yrs. Survival was estimated with the Kaplan-Meier method and compared by log-rank test. Univariate analyses were performed by Fisher's exact test and multivariate analyses by a Cox-regression model to identify factors associated with PFS and OS in this population. **Results:** 67 pts were treated, median age 81yrs (range: 75-90), stage III (34, 51%) and IV (33, 49%). Chemotherapy regimens included: gemcitabine alone (39), gemcitabine/nab-paclitaxel (17), gemcitabine/vinorebine (1), FOLFOX (8) and FOLFIRINOX (2). 59 (88%) pts required dose adjustments due to toxicity; no differences by age or regimen. RR, PFS, and OS did not differ by age or regimen (Table), although sample size was small. Age >80yrs was associated with reduced PFS (p 0.03). On univariate analyses liver metastases and performance status (PS)>1 were associated with reduced OS; PS>1 was associated with reduced OS on multivariate analysis. **Conclusions:** Among pts with locally advanced and metastatic PDAC ≥75yrs, there were no differences in RR, PFS or OS by chemotherapy regimen. PS was the only variable associated with reduced OS. Older adults with PS 0-1 are likely to benefit from chemotherapy for non-resectable PDAC.Research Sponsor: None.

Best overal response, PFS and OS.

Best Response, N (%)	Gem	Gem/Nab	Gem/V	FOLFOX	FOLFIRINOX
Complete Response	0	0	0	0	0
Partial Response	4 (10)	5 (29)	0	2 (25)	1 (50)
Stable Disease	16 (41)	6 (35)	1 (100)	2 (25)	1 (50)
Progressive Disease	12 (31)	4 (24)	0	3 (38)	0
Not Evaluated	7 (18)	2 (12)	0	1 (13)	0
Disease control, N (%)	20 (51)	11 (65)	1 (100)	5 (63)	2 (100)

Median of PFS: 8 months
Median of OS: 11 months

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655 Poster Session (Board #H8), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Gemcitabine and nab-paclitaxel in older adults with metastatic pancreatic cancer: Are two doses per cycle enough?

Arthur Winer, Elizabeth A. Handorf, Efrat Dotan; NYU Langone Medical Center, New York, NY; Fox Chase Cancer Center, Philadelphia, PA

Background: The dosing of Gemcitabine and Nab-Paclitaxel (GA), a frontline regimen to treat metastatic pancreatic cancer (mPC), is frequently altered from the traditional dosing schedule (TDS) of day 1, 8, and 15 of a 28 day cycle to a modified dosing schedule (MDS) of 2 doses/cycle. Previous work showed that overall survival (OS) was similar between patients (pts) treated with the MDS vs the TDS. We sought to analyze a larger real-world database to assess these trends. **Methods:** We retrospectively analyzed de-identified pts with mPC ≥ 65 y/o treated with GA in the Flatiron Health nationwide EHR-derived database. Demographics, treatments (tx), and outcomes were collected. Pts were grouped as either starting with the TDS or MDS. Analysis included time on treatment (TOT) as well as OS. A Cox model was used to test non-inferiority of the MDS vs the TDS for both TOT and OS, adjusting performance status, age, race, gender, and line of therapy (LOT). The upper bound for non-inferiority was a Hazard Ratio (HR) = 1.2. **Results:** 1497 pts were treated between 1/1/14-5/31/19; 883 pts with the TDS and 614 with the MDS. Median TDS age was 72 (65-85) and MDS was 73 (65-84) ($p<0.001$). 1237 pts received first- line GA; 60% received the TDS, 40% the MDS. The use of the TDS vs MDS did not vary significantly by LOT, gender, or race, but more pts with a PS of ≥2 received the MDS (p=0.03). In the first-line, outcomes were better for the TDS vs the MDS (unadjusted median TOT 5.3 vs 3.2 mo, $p<0.001$, OS 9.2 vs 5.3 mo; $p<0.001$), with consistent results in the ≥ second-line. The MDS did not meet its non-inferiority boundary: first-line TOT HR=1.4 [95% CI 1.2-1.6]; second+ line TOT HR=1.3 [95% CI 1.0-1.7]; first-line OS HR=1.6 [95% CI 1.4-1.8]; second+ line OS HR=1.3 [95% CI 1.0-1.8]. Results were consistent when additionally stratified by PS 0-1 vs 2+. **Conclusions:** In this large real-world cohort, first-line GA tx with a MDS did not meet criteria for non-inferiority for TOT and OS vs a TDS in older adults with mPC. With the caveats of potential confounding that exist in a de-identified retrospective database, these results suggest that dose intensity may be important in pts with mPC. Further prospective studies are necessary to ensure we utilize effective tx strategies in older adults with mPC. Research Sponsor: None.

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656 Poster Session (Board #H9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Clinical outcomes of FOLFIRINOX and gemcitabine-nab-paclitaxel for metastatic pancreatic cancer in the real-world setting.

Fabio Franco, Jose Ignacio Martin Valades, David Marrupe, Juan Carlos Camara, David Gutierrez Abad, Ana Lopez-Alfonso, Brezo Martinez-Amores, Ana Leon, Mar Perez, Ignacio Juez, Alicia Hurtado, Ana Ruiz-Casado; Hospital Universitario Puerta de Hierro-Majadahonda, Madrid, Spain; Fundacion Jimenez Diaz/Universidad Autonoma, Madrid, Spain; Hospital Universitario Móstoles, Mostoles, Spain; Hospital Universitario Fundación de Alcorcón, Madrid, Spain; Hospital Universitario de Fuenlabrada, Madrid, Spain; Infanta Leonor Hospital, Madrid, Spain; Hospital Universitario Rey Juan Carlos, Madrid, Spain; Oncology Department and Translational Oncology Division, University Hospital Fundacion Jimenez Diaz, Madrid, Spain; Hospital Universitario Infanta Leonor, Madrid, Spain; Hospital Universitario Fundación de Alcorcón, Alcorcon, Spain

Background: Randomized clinical trials have established new chemotherapeutic standards of care for metastatic pancreatic cancer, namely FOLFIRINOX (FFX) and gemcitabine + nab-paclitaxel (GNP) after demonstrating a significant and relevant increase of overall survival. However, there are some important uncertainties regarding how many patients are candidate to each of the two new regimens in the real life and how is the pattern of use in the elderly population. **Methods:** This is a retrospective study. Departments of Pharmacy of 7 Spanish hospitals generated the listings of patients (pts) treated in first line with these new regimens (FFX or GNP). Non-metastatic patients were excluded. An exploratory analysis was performed in the elderly population. **Results:** From Jan 2012 to Dec 2017, a total of 119 pts (M/F 58/42 %) were treated. Med age 63 y (38-83 y), 99% adenocarcinoma. 40% located in the head of pancreas. ECOG 87% 0-1. 89% had liver mets. In the 1st line 49.6% were treated with FFX and 50.4% with GNP. 53% of the pts could receive a 2nd line (82% after FFX 75% after GNP). The median OS was 12 months with no statistically significant differences between both regimens (12,7m for FFX vs 10,2 m for GNP). Elevated Ca 19.9 levels and Neutrophil-Lymphocyte ratio (NLR) increased the risk of death. Patients who received both regimens in first/second line had a median OS longer than 15 months whichever the sequence. 32 patients (27%) were older than 70 yo. 13 (41%) were treated with FFX and 19 (59%) with GNP. The median OS for patients older than 70 was 9.5m versus 12.3m for patients younger than 70. **Conclusions:** In our setting the use of FFX and GNP for treating metastatic pancreatic cancer is quite similar. Superiority could not be demonstrated for any of the schemes in first-line. Overall survival was determined by basal Ca 19.9 and NLR. Patients receiving both regimens (FFX or GNP) in first/second line whichever the sequence, exhibited the best survival rates. In our series elderly patients had poor survival rates. Research Sponsor: None.

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657 **Poster Session (Board #H10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Survival outcomes based on sequence of therapy using FOLFIRINOX and nab-paclitaxel + gemcitabine in metastatic pancreatic ductal adenocarcinoma.

Kelsey Baron, Christopher Duane Nevala-Plagemann, Justin Moser, Benjamin Haaland, Xuechen Wang, Ignacio Garrido-Laguna; Division of Internal Medicine, Intermountain Medical Center, Murray, UT; Huntsman Cancer Institute, University of Utah, Salt Lake City, UT; Honor Health Research Institute, Scottsdale, AZ; University of Utah, Salt Lake City, UT

Background: Optimal sequence of therapy for patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) is unknown. FOLFIRINOX (FFX) and Gemcitabine + Nab-paclitaxel (AG) are standard first line (1L) therapies. They have never been prospectively compared. Therefore, we retrospectively compared the overall survival (OS) of patients treated with 1L AG and second line (2L) FFX compared to those treated with 1L FFX and 2L AG. **Methods:** Patients with mPDAC treated with 1L FFX followed by 2L AG, or vice versa were identified using the Flatiron Health EHR-derived nationwide database. To avoid immortal time bias, patients who received no 2L were included. OS from the initiation of 1L was compared with Kaplan Meier curves and log rank analysis. A cox model, stratified by deciles of propensity score (PS), was used to estimate the effect of treatment on OS with adjustment for differences between the groups. **Results:** 3,042 patients were identified. 2001 patients received 1L AG. Among these patients, 1446 received 2L FFX, and 555 received no 2L. 1041 patients received 1L FFX. Among these patients, 496 received 2L AG, and 545 received no 2L. Median OS and 1-year OS for those treated with 1L AG followed by 2L FFX or no therapy was 6.1 months (95% CI:5.6 – 6.5) and 25% (95% CI: 0.23 – 0.28). Median OS and 1-year OS for patients treated with 1L FFX followed by AG or no therapy was 8.7 months (95% CI: 7.9 – 9.2) and 36% (95% CI: 0.33 – 0.39). The propensity stratified hazard ratio between these two groups was 0.76 (95% CI: 0.69 – 0.83), favoring 1L FFX. Median OS for patients treated with 1L FFX and 2L AG versus 1L AG and 2L FFX was not significantly different (12.0 m vs. 12.5 m; HR 1.04; 95% CI: 0.90 - 1.20). **Conclusions:** In this analysis of real-world data, 1L FFX was associated with increased OS in propensity analysis. For patients who received both FFX and AG, median OS was similar, regardless of the sequence. Research Sponsor: None.

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658 Poster Session (Board #H11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Effects of duration of initial treatment on postoperative complications in pancreatic cancer.

Naoya Takeda, Suguru Yamada, Hideki Takami, Fuminori Sonohara, Masamichi Hayashi, Isaku Yoshioka, Kazuto Shibuya, Koshi Matsui, Katsuhisa Hirano, Toru Watanabe, Yuuko Tohmatsu, Nana Kimura, Shozo Hojo, Shigeaki Sawada, Tomoyuki Okumura, Takuya Nagata, Yasuhiro Kodera, Tsutomu Fujii; Department of Surgery and Science, Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Toyama, Japan, Toyama, Japan; Nagoya University Graduate School of Medicine, Gastroenterological Surgery, Nagoya, Japan; Department of Surgery and Science, Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Toyama, Japan; Univ of Toyama, Toyama, Japan

Background: Early studies raised concerns over whether preoperative treatment led to postoperative complications or even death. In contrast, recent studies have reported that initial treatment (IT) prior to resection of pancreatic ductal adenocarcinoma (PDAC) is safe, with no significant increase in overall morbidity or mortality, despite evidence for more advanced disease. In this study, we analyzed the clinical impact of chemotherapy or chemoradiotherapy as IT, focusing on treatment duration, on morbidity and mortality in patients with resected PDAC. **Methods:** We enrolled 509 consecutive patients, with 417 in the upfront surgery group and 92 in the IT group. The IT group was subdivided into 72 patients treated for $<$ 8 months and 20 treated $\geq$8 months. We compared rates of postoperative Clavien–Dindo grade $\geq$III complications between the groups. Multivariate logistic regression analysis was used to find independent predictors of complications. **Results:** The upfront surgery and IT groups did not significantly differ in overall postsurgical complications. The rate of postoperative pancreatic fistula was significantly less in the IT group. Rates of other complications did not significantly differ, except for severe infection and delayed gastric emptying. Initiation of adjuvant chemotherapy was later in the IT group than in the upfront surgery group (43.2 vs 57.8 days, $P < 0.001$). In contrast, rates of overall complications significantly differed between the $<$ 8 months and $\geq$8 months IT groups, although their background clinical factors did not differ. In multivariate analysis, operative procedure (distal pancreatectomy and distal pancreatectomy with celiac axis resection) (odds ratio [OR] 6.950, $P = 0.0416$) and IT $\geq$8 months (OR: 4.508, 95%, $P = 0.0156$) were independent predictive factors for postoperative complications. **Conclusions:** The incidence of postoperative complication was similar between the upfront surgery group and the IT group, however, it was significantly higher in the $\geq$8 months IT group in patients who underwent PDAC resection. Research Sponsor: None.

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660 Poster Session (Board #H13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Observational retrospective evaluation of treatment with liposomal irinotecan plus fluorouracil/leucovorin for metastatic pancreatic cancer patients: An Italian large real-world analysis.

Antonio Pellino, Chiara Manai, Valeria Merz, Mario Scartozzi, Michele Milella, Ferdinando De Vita, Lorenzo Antonuzzo, Clizia Zichi, Maria Antonietta Satolli, Michele Panebianco, Silvia Noventa, Guido Giordano, Floriana Nappo, Camilla Zecchetto, Marco Puzzoni, Vanja Vaccaro, Annalisa Pappalardo, Elisa Giommoni, Davide Melisi, Sara Lonardi; Department of Clinical and Experimental Oncology, Medical Oncology 1 Unit, Istituto Oncologico Veneto IOV-IRCCS, Padua, Italy; Unit of Medical Oncology, University of Verona Hospital Trust, Verona, TN, Italy; Medical Oncology Department, University Hospital, University of Cagliari, Cagliari, Italy; Medical Oncology, Azienda Ospedaliera Universitaria Integrata, Verona, Italy; Division of Medical Oncology, Department of Precision Medicine, University of Study of Campania "L. Vanvitelli", Naples, Italy; Medical Oncology, Azienda Ospedaliero-Universitaria Careggi, Florence, Italy; Department of Oncology, University of Turin, Ordine Mauriziano Hospital, Turin, Italy; Department of Medical Oncology, University of Turin, Turin, Italy; Medical Oncology Unit, Clinical Cancer Center, IRCCS-AUSL di Reggio Emilia, Reggio Emilia, Italy; Medical Oncology Unit, Casa di Cura Poliambulanza, Brescia, Italy; Fondazione IRCCS Casa Sollievo della Sofferenza, UO di Oncologia Medica, San Giovanni Rotondo, Italy; Unit of Medical Oncology, University of Verona Hospital Trust, Verona, Italy; Medical Oncology 1, IRCCS Regina Elena National Cancer Institute, Rome, Italy; Medicine - Digestive Molecular Clinical Oncology Research Unit, University of Verona, Verona, Italy

Background: In the NAPOLI I phase III trial, Nanoliposomal irinotecan (nal-IRI) plus 5-fluorouracil/leucovorin (5-FU/LV) showed better outcome compared to 5FU/LV in patients with metastatic Pancreatic Cancer (MPC) progressed to 1st- line gemcitabine-based therapy. Aim of this study is to explore the real-world efficacy and safety of 5FU/LV-nal-IRI by a compassionate use programme and to identify potential prognostic factors that could affect survival in this setting. **Methods:** This is a retrospective multi-center analysis including patients with MPC who received 5FU/LV-nal-IRI after failure of a gemcitabine-based therapy. Survival analyses were carried out by the Kaplan-Meier method. Univariate and multivariate analyses were performed by using the log-rank test and the Cox regression. **Results:** A total of 296 pts (median age, 69 years, range 30-82; 50% male; ECOG PS 0, 44%) were treated at 11 Italian institutions from June 2016 and November 2018. 34% of the pts have been previously resected on their primary tumor, and 76% received gemcitabine-nabpaclitaxel as 1st - line treatment. 5FU/LV-nal-IRI has been administered as 2nd - line in 72% of the pts, while in 23% of the cases as 3rd - line or more. The median OS was 7.1 months [95% confidence interval (CI) 6.1 - 8.1] and the median PFS was 3.3 months (95% CI 2.9 - 3.6). At six months, OS and PFS rate were 53.4% and 31.4% respectively. ORR was 12% and DCR was 40%. 52% of pts received more than 4 cycle with dose reduction in 148 pts (50%). Most common grade 3 toxicities were neutropenia (14%), diarrhea (11%), anemia (3%), nausea (3%), fatigue (3%), mucositis (2%) and vomiting (1%). Baseline characteristics associated with better OS were ECOG PS 0, normal CEA, neutrophil-to-lymphocyte ratio ≤5 and haemoglobin ≥11 g/dL. **Conclusions:** These real-world data confirm the efficacy and safety of 5FU/LV-nal-IRI in patients with MPC progressed to a gemcitabine-based therapy, with outcome comparable to NAPOLI-1 even in a less selected population and with more active 1st - line combination therapy. In this cohort, well known prognostic markers has been confirmed, as expected. Research Sponsor: None.

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661 Poster Session (Board #H14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Efficacy of second-line chemotherapy after standard combination chemotherapy in patients with metastatic pancreatic cancer: The results from the NAPOLEON study.

Masaru Fukahori, Yoshinobu Okabe, Mototsugu Shimokawa, Taiga Otsuka, Futa Koga, Yujiro Ueda, Junichi Nakazawa, Azusa Komori, Shiho Arima, Akitaka Makiyama, Hiroki Taguchi, Takuya Honda, Tomoyuki Ushijima, Keisuke Miwa, Taro Shibuki, Kenta Nio, Yasushi Ide, Norio Ureshino, Kenji Mitsugi, Tsuyoshi Shirakawa; Division of Gastroenterology, Department of Medicine, Kurume University School of Medicine, Kurume, Japan; National Kyushu Cancer Center, Fukuoka, Japan; Department of Medical Oncology, Saga Medical Center Koseikan, Saga, Japan; Department of Hepatobiliary and Pancreatology, Saga Medical Center Koseikan, Saga, Japan; Department of Hematology and Oncology, Japanese Red Cross Kumamoto Hospital, Kumamoto, Japan; Department of Medical Oncology, Kagoshima City Hospital, Kagoshima, Japan; Department of Medical Oncology and Hematology, Oita University Faculty of Medicine, Yufu, Japan; Digestive and Lifestyle Diseases, Kagoshima University Graduate School of Medical and Dental Sciences, Kagoshima, Japan; Department of Hematology/Oncology, Japan Community Health Care Organization Kyushu Hospital, Kitakyushu, Japan; Department of Gastroenterology, Saiseikai Sendai Hospital, Satsumasendai, Japan; Nagasaki University Hospital, Nagasaki, Japan; Kurume University, Fukuoka, Japan; Kurume University Hospital, Kurume, Japan; National Cancer Center Hospital East, Kashiwa, Chiba, Japan; Department of Medical Oncology, Sasebo Kyosai Hospital, Sasebo, Japan; Department of Internal Medicine, Karatsu Red Cross Hospital, Karatsu, Japan; Department of Medical Oncology, Saga-Ken Medical Center Koseikan, Saga, Japan; Department of Medical Oncology, Hamanomachi Hospital, Fukuoka, Japan; Department of Gastrointestinal and Medical Oncology, National Hospital Organization Kyushu Cancer Center, Fukuoka, Japan

Background: Gemcitabine plus nab-paclitaxel (GnP) and FOLFIRINOX (FFX) have been established as standard first-line combination chemotherapy (CTx) for patients with metastatic pancreatic cancer (MPC). However, the efficacy of second-line CTx and the significance of combination CTx in clinical practice are unclear. We therefore investigated the efficacy of second-line CTx in patients with MPC. **Methods:** Data were collected from CTx-naive MPC patients treated with first-line combination CTx at 14 hospitals in the Kyushu area of Japan from December 2013 to June 2018. The median overall survival (mOS) from second-line treatment was compared between patients who received second-line CTx (CT group) and those who received best supportive care (BSC group). Furthermore, in the CT group, the mOS was compared between the patients who received combination CTx and those who received mono-CTx. To control potential bias in the selection of second-line treatment, we also conducted a propensity score-adjusted analysis. **Results:** A total of 255 patients received GnP or FFX as first-line CTx. Of these, there were 156 (61%) in the CT group and 77 (30%) in the BSC group. The number of patients who received FFX/GnP as first-line CTx was 79 (51%)/77 (49%) in the CT group and 15 (20%)/62 (80%) in the BSC group, respectively ($P < 0.01$). The mOS in the CT group was significantly longer than that in the BSC group (5.2 vs. 2.7 months; hazard ratio [HR] 0.42; 95% confidence interval [CI] 0.31-0.57; $p < 0.01$ and 5.2 vs. 2.6 months; adjusted HR 0.39; 95% CI 0.28-0.55; $p < 0.01$). In the CT group, 89 (57%) patients received combination CTx, and 67 (43%) received mono-CTx. There was no significant difference in the mOS between the combination CTx and mono-CTx patients (5.5 vs. 4.4 months; HR 0.88; 95% CI 0.62-1.26; p = 0.88 and 5.6 vs. 4.4 months; adjusted HR 0.85; 95% CI 0.56-1.30; p = 0.47). **Conclusions:** Among patients with MPC receiving second-line treatment, the CT group had a significantly longer mOS than the BSC group, but combination CTx conferred no improvement in the survival duration compared with mono-CTx. Research Sponsor: None.

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662 Poster Session (Board #H15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Comparison of clinicopathological characteristics and prognosis of borderline resectable pancreatic cancer according to the location of the primary tumor.

Tsuyoshi Takeda, Takashi Sasaki, Takafumi Mie, Takaaki Furukawa, Ryo Kanata, Akiyoshi Kasuga, Masato Matsuyama, Masato Ozaka, Naoki Sasahira; Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan

Background: Little is known about the clinicopathological and prognostic differences between borderline resectable (BR) pancreatic head (Ph) and pancreatic body/tail (Pbt) cancer. Therefore, we conducted this study to compare the clinicopathological features and prognosis of BR pancreatic cancer (PC) according to the location of the primary tumor. **Methods:** We retrospectively investigated consecutive patients with BR PC who initiated neoadjuvant chemotherapy (NAC) between March 2015 and April 2019. We compared clinicopathological characteristics and prognosis between Ph and Pbt cancer. Furthermore, multivariate survival analysis was performed using cox proportional hazard model. **Results:** A total of 104 patients with BR PC (median age 68, male 49%) were included in this study. The location of the tumor was Ph 72 and Pbt 32, respectively. The initial regimen of NAC was nab-paclitaxel/gemcitabine in 102 and gemcitabine in 2, respectively. The median cycle of NAC was 4. Median age, sex, primary tumor size, performance status, neutrophil to lymphocyte ratio, and serum level of carbohydrate antigen 19-9 at the time of the initiation of NAC were not significantly different between Ph and Pbt cancer, while the modified glasgow prognostic score (mGPS) was lower in Pbt cancer (mGPS = 0; 78% vs. 94%, p = 0.05). R0/R1 resection rate (81% vs. 69%, p = 0.21) and median survival time (928 days vs. NA, p = 0.13) were also not different between Ph and Pbt cancer. Multivariate survival analysis revealed that R0/R1 resection (HR, 0.11; $p < 0.01$) and Ph (HR, 2.29; p = 0.03) were independent prognostic factors for survival in patients with BR PC. **Conclusions:** Although R0/R1 resection rate was similar between BR Ph and Pbt cancer, Pbt cancer had a higher rate of mGPS score of 0 compared to Ph cancer. Furthermore, R0/R1 resection (HR, 0.11) and Ph (HR, 2.29) were independent prognostic factors for survival in patients with BR PC. Research Sponsor: None.

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663 Poster Session (Board #H16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

A real-world evidence analysis of periampullary cancers in an academic hospital in Chile.

Luis Villanueva, Gonzalo Navarrete, Ivan Gallegos, Valentina Castillo, Francisco Dodds, Jaime Gonzalez, Olga Barajas, Rodrigo Vasquez, Barbara Nuñez, Monica Ahumada; Hospital Clinico Universidad de Chile, Santiago, Chile

Background: Periampullary cancers can originate in the pancreas, duodenum, bile duct or structures of the ampullary complex. The treatment of choice in early stages is pancreatoduodenectomy. The management post-surgery can depend on the histology pattern, and the overall survival can vary in different subgroups. **Methods:** A retrospective cohort study. We examined patients (pts) with invasive periampullary cancer undergoing pancreatoduodenectomy at the Hospital Clinico Universidad de Chile between 2002 to 2018. We analyzed epidemiological, clinical, surgical, and histological data. OS and the hazard ratio (HR) were established by GraphPad Prism 8.0. **Results:** Thirty-seven cases were registered. Twenty-two (59%) pts were men. The mean age was 62.5 (43-83 years). The histological subtypes were: 15 pts (40.5%) intestinal group (IN), 20 pts (54%) pancreatobiliary group (PB), 1 pt (2.7%) mixed and 1 pt (2.7%) signet ring cell type. A full concordance between histology and immunohistochemistry (CK20, CK7, CDX2, MUC1, and MUC2) patterns was 66% of the PB group, and 0% of the IN group. The stage IB was most frequent in all of the group (36,4%). The most frequent stages were IB (66,6%) in the IN type and IIIA (46%) in the PB type. The level of Ca19-9 was higher the PB group than IN group (629.7 versus 41.5 U/ml, respectively). Seven pts received postoperative adjuvant treatment such as FOLFOX, capecitabine, and gemcitabine. The median OS was 133,5 months (mo) in the intestinal group and 32,6 mo in PB group (P-value = 0.021). The HR was 0.38 (95% CI of ratio 0.1332 to 1.084). The 5-year OS was 75,2% and 45,7% in the IN and PB group, respectively. **Conclusions:** Periampullary cancer remains very challenging because it is a rare malignancy and present diverse histological pattern. These factors influence the behavior and OS of the disease. Our results showed clinically and statistically relevant differences in the staging, levels of Ca19-9, and OS of the IN and PB subtypes. Our patients received few post-operatory therapies such as chemotherapy; this factor could influence the OS in the high-risk group. According to our data, a personalized treatment by histological type should consider in this disease. Research Sponsor: None.

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664 Poster Session (Board #H17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Comparing survival outcomes for neoadjuvant therapy versus adjuvant therapy in the management of stage 1 pancreatic adenocarcinoma: A National Cancer Database study.

Samit Kumar Datta, Geoffrey Bellini, Maharaj Singh, Nicholas Sich, James L. Weese, Federico Augusto Sanchez, Nalini Guda, Wesley Allan Papenfuss, Aaron Chevinsky; Aurora Health Care, Milwaukee, WI; Aurora St. Luke's Medical Center, Milwaukee, WI; Marquette Dental School, Milwaukee, WI; Advocate Aurora Health, Milwaukee, WI; Aurora Cancer Care, Advocate Aurora Health, Milwaukee, WI; GI Associates, Milwaukee, WI

Background: We are in the midst of a paradigm shift in the treatment of stage 1 pancreatic ductal adenocarcinoma (PDAC) from surgery first followed by adjuvant therapy (AT) to Neoadjuvant therapy (NAT) first followed by surgery and this is reflected in the current NCCN guidelines as well. Data comparing these two modalities are limited. AIM: To compare long term survival between Surgery + AT and NAT + Surgery in a large National Cancer Database for stage 1 PDAC. **Methods:** We identified patients with the NCDB with surgically resected AJCC clinical stage 1, 1A, and 1B PDAC between 2004-2016. Patients were stratified into two groups to assess outcomes: AT and NAT. Patients with incomplete survival and sequence of therapy were excluded. Baseline demographic data, 90-Day Mortality, Median survival, and Hazard ratios (HR) for survival was evaluated. **Results:** 9017 pts with Clinical stage 1, 1A, 1B PDAC between 2004-2016 were identified. Of these 7453 pts had surgery followed by AT; and 1564 pts had NAT followed by surgery. There was a statistically significant difference in age (66.0±9.9 years for AT vs. 64.7±9.78 years for NAT, p < 0.001) but no difference in Charlson Comorbidity Scoring (p = 0.618) or sex (p = 0.073). 90-Day Mortality was 0.35% in the AT group compared to 0.83% in the NAT group (p = < 0.001). Median survival was 28.5 (95% CI 26.5-29.9) months in the NAT group compared to 25.4 (95% CI 24.7-26.1) months in the AT group. With AT as the reference group for survival, there was a HR of 0.904 (95% CI 0.845-0.968, p = 0.003) for NAT. **Conclusions:** In this retrospective cohort of patients, NAT was associated with increased overall survival. However, NAT was associated with an increased 90 day mortality. A randomized, controlled trial is necessary to further support the superiority of NAT in the management of stage 1 PDAC. Research Sponsor: None.

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665 Poster Session (Board #H18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Impact of dose reductions on clinical outcomes among patients (pts) with metastatic pancreatic cancer (mPC) treated with liposomal irinotecan (nal-IRI) in oncology clinics in the United States.

Paul Cockrum, Andy Surinach, George P. Kim, Daniel Mercer, Jim M. Koeller, Rebecca A. Miksad; Ipsen Biopharmaceuticals, Cambridge, MA; Genesis Research, Hoboken, NJ; George Washington University, Division of Hematology & Oncology, Washington, DC; Univ of Texas Health Sci Ctr, San Antonio, TX; Flatiron Health, New York, NY

Background: The recommended starting dose for nal-IRI is 70mg/m^2 (free base, equivalent to 80 mg/m^2 salt-based dosing). This study evaluates the impact of nal-IRI dose reductions on clinical outcomes. **Methods:** Using the nationwide Flatiron Health electronic health record-derived database, de-identified data were extracted and analyzed for adult mPC pts treated with nal-IRI Jan 2014-Jan 2019 and who initiated treatment at approximately the recommended dose (RD), 70mg/m2 +/- 5mg. Initial dose was derived from structured medication records, prioritizing administrations. The cumulative dose (CD) of nal-IRI over the first six weeks of treatment, the presence of dose reductions (DR) – (a decrease ≥ 7mg/m2), overall survival (OS) from treatment initiation, and duration of treatment (DoT) were assessed. **Results:** 257 mPC pts treated with nal-IRI (median age: 68y, IQR: 61 - 73) were identified initiating therapy at approximately the RD. 26.5% (N = 68) of pts experienced a DR during treatment. Mean 6-week CD was 175.8 mg/m^2 (SD: 77.9) among pts with no DR. For pts with DR, mean CD was 191.8 mg/m^2 (53.2). Median DoT was 6.1 wks (IQR: 2.1 – 15.3). Pts that experienced a DR had a longer median DoT: 15.1 wks (7.1 – 23.0) vs 4.3. wks (2.1 – 12.1) for pts with no DR. Overall Median OS (mOS) was 4.2 months (95% CI: 3.7 – 5.4). mOS for DR pts was 7.2 mos (95% CI: 5.5 – 9.7) and 3.7 mos (3.0 – 4.1) for pts who did not experience a DR. **Conclusions:** This real-world analysis suggests that reducing the dose of subsequent administrations of nal-IRI during treatment is associated with pts remaining on therapy longer, experiencing a larger CD, and a with longer OS. Additional real-world prospective studies are necessary to characterize the impact of nal-IRI dosing on clinical outcomes. Research Sponsor: Ipsen Biopharmaceuticals.

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666 Poster Session (Board #H19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Real-world patterns of care among patients with metastatic pancreatic cancer (mPC).

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Background: Pancreatic cancer is the third deadliest cancer in the US and mPC has a 2.9% 5-year survival. The analyses herein describe treatment patterns, trends in usage, and overall survival (OS) in mPC. **Methods:** Using the Flatiron Health EHR-derived database, data were extracted and analyzed for patients with mPC (pts) between Jan 1, 2014 and Jun 30, 2019. The database includes de-identified data from over 280 cancer clinics (~800 sites of care) representing more than 2.2 million U.S. cancer patients available for analysis, with 80% of pts from community centers and 20% from academic centers. Lines of therapy in the metastatic setting are derived from structured medication records. OS from metastatic diagnosis was reported using the Kaplan-Meier method. **Results:** 7,666 pts with mPC were identified. 5,687 (74.2%) received therapy in the metastatic setting. Pts who didn't receive therapy in the metastatic setting were more likely to be older ($p < 0.0001$) and less likely to have been diagnosed initially with stage IV disease ($p < 0.0001$) than pts who were treated. The frequency of (1L) regimens were gemcitabine plus nab-paclitaxel (GnP) 46.8%, FOLFIRINOX (FFX) 24.1%, gemcitabine monotherapy 9.3%, and FOLFOX 3.8%. Gemcitabine monotherapy use was 12.9% in 2014 and 7.3% in 2018. GnP (31.4%), FFX (12.3%), FOLFOX (11.4%), and liposomal irinotecan (nal-IRI) + 5-FU/LV (10.2%) were the most frequent second line (2L) regimens. Between 2015 and 2018 nal-IRI based regimens increased from 6% to 17.6% in 2L. In the third line (3L) setting nal-IRI + 5FU/LV (19.3%), GnP (12.1%), FOLFOX (11.4%), and FFX (9.1%) were the most common treatments. Aggregate median OS (mOS) for treated pts was 8.1 mos (95% CI 7.8 – 8.4), and mOS for untreated pts was 2.8 mos (2.6 – 3.0), $p < 0.0001$. **Conclusions:** Survival for mPC is improving and practice patterns are changing. GnP is the most commonly used 1L regimen, followed increasingly by nal-IRI + 5-FU/LV in 2L and 3L. Further studies are necessary to understand the treatment gaps for pts with mPC. Research Sponsor: Ipsen Biopharmaceuticals.

Line Number	Regimen	N	% (of line)
1	GnP	2662	46.8
1	FFX	1368	24.1
1	Gemcitabine	531	9.3
1	FOLFOX	217	3.8
2	GnP	683	31.4
2	FFX	267	12.3
2	FOLFOX	248	11.4
2	nal-IRI + 5-FU/LV	221	10.2
3	nal-IRI + 5-FU/LV	144	19.3
3	GnP	90	12.1
3	FOLFOX	85	11.4
3	FFX	68	9.1

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667 Poster Session (Board #H20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Impact of prior irinotecan exposure on outcomes of metastatic pancreatic cancer (mPC) patients.

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Background: Published data suggests prior exposure to irinotecan infers a lower likelihood of benefit to liposomal irinotecan. This analysis seeks to expand this hypothesis by evaluating U.S. patterns of care to understand how prior irinotecan therapy impacts outcomes in mPC. **Methods:** Using the Flatiron Health database, data were extracted and analyzed for treated mPC patients (pts) in the 2L+ setting between Jan 1, 2014 and Jun 30,2019. Therapies of interest included: gemcitabine/ nab-paclitaxel (GnP), FOLFOX, FOLFIRI, FOLFIRINOX (FFX), and liposomal irinotecan/ 5-FU/LV (nal-IRI). The reference date for each treatment group was the date of treatment initiation. Prior irinotecan was defined as any irinotecan given in a prior regimen in mPC diagnosis. Cox proportional hazard (PH) methods were used to calculate mortality hazard ratios (HRs). HRs were adjusted to account for demographics and relevant covariates. Pts with prior exposure to irinotecan were used as the reference population for the Cox PH model (an HR $<$ 1 represents worse survival for exposed pts relative to the unexposed). **Results:** N = 1,978 were included in this analysis. The median age at treatment initiation, and the proportion of pts previously treated with irinotecan are reported in table. Crude mortality was: GnP pts, HR 0.93 [95% CI: 0.77 – 1.11, adjusted HR, 0.94, 0.76 – 1.15]; nal-IRI pts, HR 0.81 [0.64 – 1.02, adjusted HR: 0.89, 0.67 – 1.19]; HR for FOLFOX was 0.55 [0.38 – 0.78, adjusted HR: 0.51, 0.33 – 0.79]. HRs are not reported for FFX and FOLFIRI due to the small numbers with prior irinotecan exposure. **Conclusions:** In mPC, prior irinotecan treatment may not preclude benefit from later treatment with nal-IRI or GnP as can be seen from the adjusted and unadjusted HRs. These findings are hypothesis-generating and need to be considered in the context of wide CI's, retrospective nature and the limitations of such data. Further study is required to understand the less-favorable signal observed with FOLFOX and prior irinotecan.Research Sponsor: Ipsen Biopharmaceuticals.

Therapy	N	Age at treatment initiation, years, median (IQR)	Prior irinotecan, N(%)
GnP	755	64 (58 - 70)	560 (74.2%)
Nal-IRI	446	67 (62 - 74)	128 (28.7%)
FOLFOX	353	69 (63 - 76)	46 (13%)
FOLFIRI	113	69 (63 - 75)	8 (7.1%)
FFX	311	66 (60 - 72)	5 (1.6%)

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668 **Poster Session (Board #H21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Changes in glucose tolerance after pancreatectomy in patients with pancreatic ductal adenocarcinoma.

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Background: Diabetes mellitus (DM) is reported to be related to pancreatic ductal adenocarcinoma (PDAC). Long-standing DM is a risk factor for PDAC, meanwhile, quite a few patients with PDAC develop DM as a paraneoplastic disorder and some papers reported that DM affected prognosis for PDAC. In this study, we investigated pre- and post-operative glucose tolerance in patients with pancreatectomy for PDAC or other disease. **Methods:** This single-center prospective study included 69 patients with pancreatectomy (40 pancreaticoduodenectomy (PD) and 29 distal pancreatectomy (DP)) who received 75-g oral glucose tolerance test (OGTT) and glucagon test pre- and one month postoperatively. Plasma glucose, insulin, and C-peptide (CPR) at 0-, 30-, 60-, and 120-min during OGTT; and 0- and 6-min during glucagon test were obtained. These data and survival outcomes were analyzed. **Results:** There were 20 (29%) PDAC patients: 12 (30%) in PD group and eight (28%) in DP group. Nine patients with PDAC (45%) and seven patients (18%) without PDAC demonstrated DM type in preoperative OGTT. After pancreatectomy, 11 patients (55%) with PDAC and seven patients (15%) without PDAC experienced improvement in OGTT (P=0.0005). Greater improvement in homeostasis model assessment insulin resistance that were obtained by OGTT and used to measure insulin resistance, was noted after surgery in PDAC patients compared with non-PDAC patients (-1.4 vs -0.5 in PD group, P=0.07; -0.8 vs +0.06 P=0.05 in DP group). Delta CPRs obtained by glucagon test were significantly decreased postoperatively (3.0 to 1.1 ng/mL, P<0.0001 in PD group; 3.3 to 1.8 ng/mL, P<0.0001 in DP group). In survival analysis, fasting plasma glucose >110 mg/dL (HR 3.9, 95%CI 1.5-10, P=0.005) and the average of plasma insulin > 25 μIU/mL during OGTT (HR 0.36, 95%CI 0.14-0.93, P=0.035) were significant prognostic factor for PDAC. **Conclusions:** Pancreatectomy impaired insulin secretion and improve insulin resistance especially in PDAC patients. About half of PDAC patients demonstrated the improvement of glucose tolerance after surgery. Of note, glucose tolerance differed between PDAC and other disease, and affect the survival outcome for PDAC patients. Research Sponsor: None.

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669 Poster Session (Board #H22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

A multicenter clinical randomized phase II study of investigating duration of adjuvant chemotherapy with S-1 (six versus 12 months) for patients with resected pancreatic cancer: PACS-1 study.

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Background: Although adjuvant chemotherapy with S-1 has improved overall survival and progression-free survival (PFS) in patients with resected pancreatic cancer, the duration evaluation of adjuvant chemotherapy with S-1 have not established yet. **Methods:** We did a randomized, multicenter, phase 2 trial undertaken at 15 hospitals in Japan. Patients who were Eastern Cooperative Oncology Group performance states of 0 or 1 and aged 20 years or older were eligible. Patients with resected pancreatic cancer were randomly assigned (in a 1:1 ratio) to receive S-1 [40 mg, 50 mg, or 60 mg according to body-surface area, orally administered twice a day for 28 days followed by a 14 day rest, every 6 weeks [one cycle], for up to four cycles (6 months)] or up to eight cycles (12 months). The primary end point was overall survival rate. Secondary endpoints included PFS and safety. **Results:** The population consisted of 82 patients in the S-1 for 6 months group and 82 patients in the S-1 for 12 months group. The 2-year overall survival rate was 71.4% in the S-1 for 6 months group and 65.4% in the S-1 for 12 months, and the median overall survival was 31.0 months in the S-1 for 6 months group and 26.3 months in the S-1 for 12 months group [hazard ratio (HR) 1.23, 95% confidence interval (CI) 0.76-1.99, p = 0.377]. The PFS at 2 years was 56.8% in the S-1 for 6 months group, and 51.2% in the S-1 for 12 months. The HR for recurrence of S-1 for 6 months, compared with S-1 for 12 months, was 1.23 (95%CI 0.76-1.99, p = 0.392). Twenty-nine (35.3%) patients in the S-1 for 6 months group and 46 (56.0%) in the S-1 for 12 months group discontinued treatment before completion. In regard to patients completed treatment, the S-1 for 12 months group showed tendency to favorable prognosis on PFS compared with the S-1 for 6 months group (log-rank test; p = 0.175). **Conclusions:** In patients with resected pancreatic cancer, adjuvant chemotherapy with S-1 for 12 months is not superior to that for 6 months in terms of median overall survival and PFS. For patients who can tolerate adjuvant chemotherapy with S-1 for 6 months well, continuing treatment for up to 12 months may improve the prognosis. Research Sponsor: None.

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670 **Poster Session (Board #J1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Real-world rates of hematology lab abnormalities and associated cost among metastatic pancreatic cancer (mPC) therapeutic regimens.

Gabriela Dieguez, Andy Surinach, Daniel Mercer, Paul Cockrum, George P. Kim, Pamela Pelizzari; Milliman, Inc., New York, NY; Genesis Research, Hoboken, NJ; Ipsen Biopharmaceuticals, Cambridge, MA; 22nd and I Street, NW, Washington, DC; Milliman, New York, NY

Background: Low hematologic counts are a common, costly side effect of chemotherapy. This observational study examines rates and associated cost to treat. **Methods:** Data on adverse events (AEs) were extracted from the clinical Flatiron Health database for mPC patients (pts) from 01/2014-01/2019. Anemia, neutropenia, and lymphopenia occurrence was assessed via diagnosis codes and structured lab data. Costs due to AEs were derived from a claims analysis of mPC pts from 2013-2017 in Medicare Limited Data Set claims. Mean adjusted incremental costs (ICs) were estimated by comparing 30-day costs of pts with and without AEs, with controls selected among pts without AEs with the same regimen and line of therapy, when at least 80 cases/controls were identified. **Results:** 4592 treated mPC pts were identified (median age at diagnosis: 68y, IQR: 61 – 75). 1138 pts were treated with FOLFIRINOX (FFX) in first-line (1L), 2295 pts with 1L gemcitabine plus nab-paclitaxel (gem-nab), 218 pts with second-line (2L) FOLFOX, 56 pts with 2L FOLFIRI, and 178 pts with 2L liposomal irinotecan (nal-IRI) based therapy. Observed rates of anemia and neutropenia are shown in the table below. Lymphopenia rates were similar across regimens and ICs were not statistically significant. ICs for patients with any grade anemia were $3864, $3818, $3536, $3978, and $2963 for FFX, gem-nab, FOLFOX, FOLFIRI, and nal-IRI treated pts, respectively. ICs for pts with any grade neutropenia were $2382 for FFX, $2440 for gem-nab, $2688 for FOLFOX, $3551 for FOLFIRI and $2307 for nal-IRI. **Conclusions:** Any grade anemia ICs ranged from $2963 [$1544, $4400] (nal-IRI) to $3978 [$2241, $5817] (FOLFIRI), and any grade neutropenia ICs ranged from $2307 [$703, $4313] (nal-IRI) to $3551 [$1227, $6039] (FOLFIRI). Pts treated with nal-IRI had similar any grade AE rates but lower ICs, which suggest lower severity of AEs. These results are consistent with Flatiron Health's lower rates of grades 3+ neutropenia and anemia. Research Sponsor: Ipsen Biopharmaceutical Inc.

	Any Grade Anemia	Grades 3+ Anemia	Any Grade Neutropenia	Grades 3+ Neutropenia
1L FFX	84.7%	11.2%	40.8%	18.1%
1L GEM-NAB	86.4%	17.9%	38.2%	16.1%
2L FOLFOX	82.6%	6.4%	25.7%	11.0%
2L FOLFIRI	91.1%	19.6%	37.5%	19.6%
2L NAL-IRI	88.8%	7.3%	27.0%	8.4%

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671 Poster Session (Board #J2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM and Poster Walks, Fri, 4:45 PM-5:30 PM

Long-term outcome after combined carbon-ion radiotherapy and chemotherapy for locally advanced pancreatic cancer.

Makoto Shinoto, Hidenari Hirata, Hiroaki Suefuji, Shingo Toyama, Minoru Ueda; Ion Beam Therapy Center, SAGA HIMAT Foundation, Tosu, Japan

Background: Carbon-ion radiotherapy (C-ion RT) has the potential advantages in terms of improved dose localization and enhanced biological effectiveness compared to conventional radiotherapy or proton therapy. C-ion RT is expected to contribute to the prolongation of survival in patients with pancreatic ductal adenocarcinoma (PDAC). We started C-ion RT for pancreatic cancer at SAGA HIMAT since April 2014. The aim of this study is to evaluate the long-term clinical results of C-ion RT for locally advanced PDAC. **Methods:** From April 2014 to March 2018, 144 patients with pancreatic cancer were treated with definitive C-ion RT. 80 patients who were confirmed as unresectable locally advanced PDAC were included in this retrospective analysis. C-ion RT was performed with 55.2 Gy (RBE) at 12 fractions in 3 weeks. Overall survival (OS) and prognostic factors were analyzed. Toxicities were evaluated using the CTCAE ver. 5.0. **Results:** The median follow-up period for survivors was 38 (range 13-59) months from the initiation of C-ion RT. In all patients, planned C-ion RT was completed. Induction chemotherapy was performed in 64 patients (80%) and the median duration time was 3 (range 1-19) months. Seventy patients (86%) underwent concurrent chemotherapy with gemcitabine or S-1. 2y-, 3y-, and 4y-OS from C-ion RT were 47% (95%CI, 37-59%), 25% (95%CI,16-37%), and 18% (95%CI, 10-30%), respectively. 2y-, 3y-, and 4y-OS from initial treatment were 55% (95%CI, 45-66%), 33% (95%CI, 24-45%), and 20% (95%CI, 12-32%). Multivariate analysis showed that PS 1-2, CA19-9 $\geq$350, and the absence of concurrent chemotherapy were independent prognostic factors on OS. Only seven patients (9%) experienced grade 3 toxicities that were gastrointestinal ulcer/bleeding (n = 4), anorexia (n = 1), leukopenia (n = 1), and neutropenia (n = 1). There was no grade 4 or 5 toxicity. **Conclusions:** C-ion RT for locally advanced PDAC was effective and well-tolerated. Research Sponsor: None.

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672 **Poster Session (Board #J3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Neoadjuvant therapy (NAT) and its role for pancreatic adenocarcinoma (PC) in the current era: Institutional experience.

Emily Walzer, Mengying Deng, Elizabeth A. Handorf, Aryeh Blumenreich, Lauren Pease, Marianna Dorta, Kristen Sorice, Shannon M. Lynch, Namrata Vijayvergia, Efrat Dotan; Temple University Hospital, Philadelphia, PA; Fox Chase Cancer Center, Philadelphia, PA; Lewis Katz School of Medicine at Temple University, Philadelphia, PA

Background: PC affects 57,000 people in the U.S. annually with poor long-term outcomes. NAT for localized disease has increasingly been used but lacks robust prospective data. We investigated the disease course and outcomes for patients (pts) undergoing NAT versus upfront surgery for PC at a high-volume academic center. **Methods:** Utilizing our IRB-approved retrospective database of metastatic PC pts (year 2000-2017), we identified pts who presented with localized disease and were considered for surgery and present the baseline tumor and treatment characteristics here. Fisher's exact and Wilcoxon Rank-Sum tests were used for categorical data and Kaplan Meier (KM) curves for survival data when comparing those who had upfront surgery versus surgery following NAT. **Results:** 352 pts with localized disease at diagnosis were included in our analysis with median age of 65 y (range 38-89) and 45% females. NAT was used in 225 (64%) pts while 109 pts (31%) had upfront surgery and 18 pts (5%) received no treatment. Adjuvant therapy was given to 77% of pts after upfront surgery and 48% of pts after surgery following NAT. NAT regimen consisted of chemotherapy (CTx) and radiation for 48%, CTx alone for 8% and radiotherapy alone for 44% of pts. Of those receiving CTx, 24% received triple agent while 51% and 25% received dual and single agent therapy. Pt factors (age, CCI, gender, BMI, smoking status, race) did not differ between those receiving upfront surgery and surgery following NAT but upfront surgery was associated with a lower stage at diagnosis ($p < 0.0001$). Surgical resection after NAT occurred in 79 pts (35%) with median overall survival of 26.3m vs 19.7m ($p = 0.06$) in those who had upfront surgery. Survival rates at year 1, 3, and 5 years were 94%, 34%, and 8% for those with NAT followed by surgery vs 76%, 17%, and 11% for those with upfront surgery ($p = 0.06$). **Conclusions:** Use of NAT is prevalent, yet only 35% of pts make it to surgical resection. Survival was improved for pts who underwent resection following NAT versus upfront, although the difference was not statistically significant. Additional research is warranted to define the optimal NAT approach for pts with borderline resectable PC. Research Sponsor: None.

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673 Poster Session (Board #J4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

First-line drug selection versus sequential treatment in advanced pancreatic cancer: Does it really matter? Multi-institutional Canadian perspective.

Ivan Barrera, Neha Papneja, Jill Ranger, Abhishek Papneja, Petr Novotny, Shahid Ahmed, Gerald Batist, Petr Kavan; Jewish General Hospital, McGill University, Montreal, QC, Canada; Department of Medicine, University of Saskatchewan, Saskatoon, SK, Canada; Jewish General Hospital-Segal Cancer Center, University of McGill, Montreal, QC, Canada; Jewish General Hospital-Segal Cancer Center, Montreal, QC, Canada; University of Saskatchewan, Saskatoon, SK, Canada; Segal Cancer Centre-Jewish General Hospital, McGill University, Montreal, QC, Canada; McGill University, Montréal, QC, Canada

Background: Folfirinox (FFX) and Gemcitabine with nab-Paclitaxel (GN) are both proven to be superior to Gemcitabine (G) in the first line treatment (1LTx) for advanced pancreatic cancer (APC). Yet, the optimal 1LTx selection nor sequential Tx (ST) has not been fully established. Therefore, the best choice for 1LTx is a matter of debate often influenced by access to drugs. This analysis was conducted to compare outcomes based on 1Ltx selection and ST in APC. **Methods:** We assessed patients (pts) with APC who received either FFX or GN as 1LTx during 2010-2019 at three Canadian institutions. As well as the ST used. The main objective was to assess survival. Kaplan method and log-rank test were used for survival curves. **Results:** This retrospective study included 231 pts; 1LTx included 143 pts on FFX and 88 pts on GN. FFX pts were predominantly male; 89(62.2%) vs 46(52.3%) and slightly younger (median age 62 vs 66) than GN. WHO performance status (PS) of 0 were 38 (28.4%) vs 14 (16.5%) and 1 were 90 (67.2%) vs 65 (76.5%) respectively. There were more grade 3-4 toxicity in FFX vs GN group: GI 55 (38.5%) vs 15 (17%) and hematologic 51 (35.4%) vs 20 (22.7%) respectively. Grade 3-4 neutropenia rates were similar in both regimens. The median PFS of FFX was 5.5 months (95% CI: 5.0-6.7) vs 5.1 (95% CI: 3.8-7.1) with GN (p=0.37). The median OS with FFX was 9.3 months (95% CI: 7.5-11.1) vs 10.2 (95% CI: 6.8-11.3) with GN (p=0.81). There were not statically significant. Table shows Tx frequency across 4LTx. 2LTx and beyond regimens included G, GN, FFX, Capecitabine, Irinotecan liposome plus 5-FU, Irinotecan and clinical trials. **Conclusions:** Our results revealed that pts who received 1LTx FFX or GN had similar PFS and OS even though 1LTx FFX group was younger with better PS, allowing to continue 2-4LTx more frequently when compare with 1LTx GN group. Therefore, 1LTx selection appear to have more impact in our pts rather than ST, whereas GN is less toxic and seems a preferable 1LTx choice for most pts. FFX could be reserved for young high-performance pts. Research Sponsor: Educational and research grant provided by CELGENE Canada.

	1LTx (N=231)	2LTx N=102/231 (44%)	3LTx N=30/102 (29.4%)	4LTx N=7/102 (6.8%)
FFX	143 (62%)	60.8%	67%	71.4%
GN	88 (38%)	39.2%	33%	28.6%

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674 Poster Session (Board #J5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Distinct clinical characteristics of young-onset pancreatic cancer patients.

Suleyman Yasin Goksu, Syed Mohammad Ali Kazmi, Nina Niu Sanford, Todd Anthony Aguilera, David Hsieh, Aravind Sanjeevaiah, Udit Verma, Radhika Kainthla, Leticia Khosama, Mary Claire Maxwell, Benjamin David Fangman, Jonathan Scott Bleeker, Muhammad Shaalan Beg, Muslim Atiq; The University of Texas Southwestern Medical Center, Dallas, TX; The University of Texas Southwestern, Dallas, TX; Sanford Health, Sioux Falls, SD

Background: Young-onset pancreatic adenocarcinoma (YOPC) is uncommon but there are limited studies for these patients. We used a population based registry to compare the characteristics and outcomes of young-onset vs. older patients with pancreatic adenocarcinoma. **Methods:** We selected the patients with pancreatic adenocarcinoma from the SEER registry diagnosed between 2004 and 2015. Cases with age of diagnosis less than 50 were termed young-onset pancreatic cancer. Stage 4 patients were excluded. We compared baseline characteristics of YOPC vs. older using Chi-square. Kaplan Meier and Cox regression were used for survival analysis of these patients. **Results:** Of 28,904 patients, 1,415 (4.9%) had YOPC while 27,489 (95.1%) were older. YOPC were more likely to have stage 3 compared to older patients with PC (31.6% vs. 25.3%). YOPC had a higher rate of surgery than older patients (40% vs. 29.1%, $p < 0.001$), were more likely to be male, black and of Hispanic ethnicity. The primary tumor location was not different between the two groups. Overall survival (OS) was higher in YOPC versus older patients (12 vs. 9 months, $p < 0.001$). The analysis of multivariable Cox regression confirmed that there is a significant association between survival and YOPC group after adjusting for stage, grade, gender, ethnicity, surgery and race (HR 1.23, 95% CI: 1.13-1.33, $p < 0.001$). **Conclusions:** Patients with non-metastatic YOPC represent a group of patients with distinct clinical characteristics. YOPC have a higher rate of surgery and better overall survival compared to older patients. Research Sponsor: None.

Characteristics	< 50 years (%) 1,415 (4.9)	≥50 years (%) 27,489 (95.1)	*p-value*
Primary part; Head	985 (69.6)	19,273 (70.1)	*0.136*
Body	132 (9.3)	2,924 (10.6)	
Tail	88 (6.2)	1,426 (5.2)	
Other	210 (14.8)	3,866 (14.1)	
Surgery; Yes	566 (40)	8,009 (29.1)	*< 0.001*
No	842 (59.5)	19,381 (70.5)	
Stage; I	152 (10.7)	4,276 (15.6)	< 0.001
II	817 (57.7)	16,255 (59.1)	
III	446 (31.6)	6,958 (25.3)	

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675 Poster Session (Board #J6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Clinicopathological features of pancreatic cancer-related diabetes.

Michael Lee, Hui-Li Wong, Erica S. Tsang, Sean McKay Fenlon Addison, James T. Topham, Joanna Karasinska, Steve Kalloger, Jonathan M. Loree, David F. Schaeffer, Daniel John Renouf; BC Cancer, Vancouver, BC, Canada; Royal Melbourne Hospital, Melbourne, Australia; BC Cancer Agency, Vancouver, BC, Canada; Pancreas Centre BC, Vancouver, BC, Canada; Department of Pathology & Laboratory Medicine Vancouver General Hospital, Vancouver, BC, Canada

Background: Epidemiological studies suggest pancreatic ductal adenocarcinoma (PDAC) may be strongly interrelated with diabetes. However, little is known about the clinicopathological features of pancreatic cancer related diabetes. **Methods:** A retrospective chart review was undertaken of all patients with advanced PDAC treated with at least one cycle of palliative chemotherapy at BC Cancer, Vancouver between Jan 2012- Dec 2015. Diagnosis of diabetes was determined by consultation documentation and/or fasting glucose $>$ 7mmol/L or HbA1c $>$ 48mmol/L. Peri-pancreatic diabetes is defined as diabetes diagnosis $<$ 3 years prior to PDAC diagnosis. **Results:** 578 patients were identified with median age 66 (49-81), 54.6% male, 39.5% non-smoker and 63.5% ECOG 0/1. 27.3% confirmed diabetics, of which 75.8% (119/157) have peripancreatic diabetes. At initial diagnosis, 11.2% were deemed upfront resectable, 44.0% borderline/locally advanced, and 55.1% metastatic. Median overall survival (OS) for the cohort based on stage of disease at initial diagnosis for borderline, locally advanced and metastatic was 22 months (16.1-27.9), 12 months (10.1-13.9) and 6 months (5.0-7.0) respectively. There was no association with diabetes status and OS noted (p = 0.58). Statistical differences were noted in BMI (24.1 v 26.1, p = 0.003), and proportion of Charlson comorbidity index (CCI) of 2 (2.2 v 88.3%, p $<$ 0.01) between non-diabetic and diabetic patients respectively. Statistical difference between peripancreatic diabetes compared to long-term diabetes were noted in resectable status (18.6 v 7.6%, p = 0.048), weight loss $>$ 2kg (78.6 v 60.5%, p = 0.035), hypertension (25.9 v 59.8%, p = 0.002) and dyslipidemia (18.5 v 42.7%, p = 0.024). **Conclusions:** The majority of patients diagnosed with advanced PDAC with diabetes appeared to develop diabetes within 3 years prior to diagnosis. Further studies to assess the potential role of pancreatic cancer screening investigations in newly diagnosed diabetics are warranted. Research Sponsor: None.

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676 **Poster Session (Board #J7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Changing the landscape of germline testing in patients with pancreatic adenocarcinoma.

Aly Athens, Lisa Amacker-North, Kelly Warsinske, Kunal C. Kadakia, Edward S. Kim, Mohamed E. Salem, Sara Elrefai; Levine Cancer Institute-Atrium Health, Charlotte, NC; University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Levine Cancer Institute, Charlotte, NC; Georgetown Lombardi Comprehensive Cancer Center, Washington, DC

Background: Results from the POLO trial demonstrated the benefits of PARP inhibition in patients (pts) with germline *BRCA*-mutated metastatic pancreatic cancer (PC). In 2018, ASCO and NCCN updated their guidelines to recommend that pts with a personal history of PC undergo germline testing. We examined referral patterns and frequency of germline pathogenic variants in pts with PC. **Methods:** A retrospective review was performed of PC pts seen at the Levine Cancer Institute (LCI) Center for Genetics between January 2010 and September 2019. Descriptive analyses were completed on demographics and appointment outcomes. **Results:** A total of 201 PC pts were referred; 20 canceled and 14 no-showed their appointment. The remaining 167 were seen and included in this analysis. Most pts (59%) were referred after July 2018. The median age was 65 years (range 32-90) and 19% were $<$ 50 years. The majority of pts were female (61%). Race was most often reported as white (72%) followed by black (20%). Reported family histories were as follows: 28 (17%) claimed at least one first-degree relative with PC; 54 (32%) claimed a first, second, or third-degree relative with PC; 24 (14%) had no known family history of PC; and 95 (57%) claimed a first-degree relative with another cancer (breast [37], prostate [25], colon [18], ovarian [9], uterine [6], and gastric [2]). Germline testing was pursued by 138 (83%) pts: 25 (18%) were found to have a pathogenic variant and 50 (36%) a variant of uncertain significance. Pathogenic variants were most commonly identified in *ATM* (24%), *BRCA2* (20%), *PALB2* (12%), and *CDKN2A* (8%). Variants were also observed in *DIS3L2, HOXB13, MITF, MUTYH* (heterozygote), *NTHL1* (compound heterozygote), *RAD50, PRSS1,* and *SDHA*. Among pts that had a pathogenic variant, cascade testing was performed in 11 families (44%) for 29 individuals. **Conclusions:** Our data suggest that the referral of PC pts to genetics has increased following updated ASCO/NCCN guidelines. However, improved adherence to genetic counseling is needed. *ATM* and *BRCA2* were the most common germline mutations observed. More effort to increase awareness of genetic testing and its potential implications for pts and their families is warranted and might reduce cancellations and missed visits. Research Sponsor: None.

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678 Poster Session (Board #J9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Implementation of systematic genetic counseling (GC) and multigene germline testing (MGT) for pancreatic cancer (PC) patients (pts).

Matthew B. Yurgelun, Anu B. Chittenden, Chinedu I. Ukaegbu, Kimberly Perez, Audrey P. Madigan, Shraddha Gaonkar, James M. Cleary, Andrew Aguirre, Brian M. Wolpin, Sapna Syngal; Dana-Farber Cancer Institute, Boston, MA

Background: MGT identifies cancer susceptibility gene variants in 4-10% of unselected PC pts. Such data have prompted national guidelines to recommend GC and MGT of all PC pts, but the benefits and barriers to implementing systematic testing are unknown. This study's aim was to study the implementation of universal GC for all PC pts seen in an academic oncology practice. **Methods:** In 12/2016, all Dana-Farber Cancer Institute (DFCI) gastrointestinal oncologists were recommended to refer all PC pts for GC and MGT. In 10/2018, workflows were changed such that PC patients were automatically scheduled for GC consultation on the same day as their initial oncologic evaluation (unless patients opted out), rather than relying on provider referral. Clinical and germline data were collected on a consecutive cohort of PC pts undergoing GC and MGT from 3/1/2017-3/31/2019. Two additional months (4/1/2019-5/31/2019) were collected for clinical quality assessment purposes. **Results:** 1305 (48.3/month) PC pts were seen for oncologic new patient visits, 318 (25.1%; 12.1/month) of whom underwent GC. Rates of GC/MGT increased significantly after the 10/2018 workflow change (8.2 PC pts/month [17.2% of all new PC pts seen] versus 20.3 PC pts/month, [40.9% of all new PC pts seen]; $p<0.01$). Of the 318 PC pts who underwent GC, 29 (9.1%; 95% CI 6.4-11.9%; 2.2% of all PC pts seen) were found to carry germline PC susceptibility gene mutations on MGT. Rates of mutation carrier identification increased after the clinical workflow change from 0.79 mutation carriers/month (1.6% of all new PC pts seen) to 1.75 mutation carriers/month (3.5% of all new PC pts seen). The majority of identified mutation carriers have either received therapy targeted towards their germline mutation or are undergoing first-line palliative systemic therapy with potential for future targeted therapy. **Conclusions:** Clinical implementation of routine GC/MGT in PC pts is feasible and results in the detection of mutations that are actionable for PC pts and at-risk family members. Systematized workflows for GC evaluation not reliant on active referral result in markedly higher uptake of MGT and mutation carrier identification. Clinical trial information: NCT03060720. Research Sponsor: U.S. National Institutes of HealthDana-Farber Cancer Institute Department of Medical Oncology Research Award.

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679 Poster Session (Board #J10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM and Poster Walks, Fri, 4:45 PM-5:30 PM

Development and validation of a pancreatic cancer prediction model from electronic health records using machine learning.

Limor Appelbaum, Jose Pablo Cambronero, Karla Pollick, George Silva, Jennifer P. Stevens, Harvey J. Mamon, Irving D. Kaplan, Martin Rinard; Beth Israel Deaconess Medical Center, Boston, MA; Massachusetts Institute of Technology, Cambridge, MA; Dana-Farber Cancer Institute, Boston, MA

Background: Pancreatic Adenocarcinoma (PDAC) is often diagnosed at an advanced stage. We sought to develop a model for early PDAC prediction in the general population, using electronic health records (EHRs) and machine learning. **Methods:** We used three EHR datasets from Beth-Israel Deaconess Medical Center (BIDMC) and Partners Healthcare (PHC): 1. "BIDMC-Development-Data" (BIDMC-DD) for model development, using a feed-forward neural network (NN) and L2-regularized logistic regression,randomly split (80:20) into training and test groups. We tuned hyperparameters using cross-validation in training, and report performance on the test split. 2. "BIDMC-Large-Data" (BIDMC-LD) to re-fit and calibrate models. 3. "PHC-Data" for external validation. We evaluate using Area Under the Receiver Operating Characteristic Curve (AUC) and compute 95% CI using empirical bootstrap over test data. PDAC patients were selected using ICD9/-10 codes and validated with tumor registries. In contrast to prior work, we did not predefine feature sets based on known clinical correlates and instead employed data-driven feature selection, specifically importance-based feature pruning, regularization, and manual validation, to identify diagnostic-based features. **Results:** BIDMC-DD included demographics, diagnoses, labs and medications for 1018 patients (cases = 509; age-sex paired controls). BIDMC-LD included diagnoses for 547,917 patients (cases = 509), and PHC included diagnoses for 160,593 patients (cases = 408). We compared our approach to adapted and re-fitted published baselines. With a 365-day lead-time, NN obtained a BIDMC-DD test AUC of 0.84 (CI 0.79 - 0.90) versus the previous best baseline AUC of 0.70 (CI 0.62 - 0.78). We also validated using BIDMC-DD's test cancer patients and BIDMC LD controls. The AUC was 0.71 (CI 0.67 - 0.76) at the 365-day cutoff. NN's external validation AUC on PHC-Data was 0.71 (CI 0.63 - 0.79), outperforming an existing model's AUC of 0.61 (CI 0.52 - 0.70) (Baecker et al, 2019). **Conclusions:** Models based on data-driven feature selection outperform models that use predefined sets of known clinical correlates and can help in early prediction of PDAC development. Research Sponsor: None.

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680 Poster Session (Board #J11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Case series examining somatic test results for patients with hereditary cancer syndromes associated with gastrointestinal cancer risk.

Kristen Pauley, Cathryn Koptiuch, Samantha Greenberg, Gammon Amanda, Christopher Nevala-Plagemann, Jennie Vagher, Whitney Espinel, Glynn Weldon Gilcrease, Wendy Kohlmann, Ignacio Garrido-Laguna; Huntsman Cancer Institute, University of Utah, Salt Lake City, UT; Huntsman Cancer Institute, Salt Lake City, UT; University of Utah and Huntsman Cancer Institute, Salt Lake City, UT

Background: Somatic tumor testing may identify germline pathogenic variants (PV) associated with cancer predisposition syndromes. Labs differ whether they offer somatic only or paired germline analysis. Methods used by somatic testing labs, even those that include germline analysis, differ from designated germline labs that have optimized the identification of germline PV. **Methods:** Chart reviews were performed for patients who had testing through both somatic and designated germline laboratories. Cases with discrepant results in which germline PV were not detected by the somatic laboratory are summarized. **Results:** Nine cases with discrepant results. Five had paired germline testing and 4 somatic testing only. All 9 patients met the criteria to undergo designated germline testing, either for Lynch syndrome (3) or *BRCA1/2* testing (6), based on personal and/or family history. Designated germline testing identified 4 *MLH1*, 1 *BRCA1*, 2 *ATM,* 1 *MUTYH* and 1 *RAD50* PV not reported by the somatic labs' tumor or germline analysis; 2 MLH1 PV were called variants of uncertain significance by somatic testing but classified as PV by ClinVar and designated germline labs. Three PV identified by designated germline labs are targets for PARP inhibitors and resulted in different treatment options. Three of the *MLH1* PV were identified in patients meeting Lynch Syndrome test criteria while 1 was identified in a patient meeting *BRCA1/2* criteria. Among the 5 other patients meeting *BRCA1/2* test criteria, 3 had PV in breast cancer genes (2 *ATM*, 1 *BRCA1*) and 2 had PV in other cancer genes (*MUTYH* and *RAD50*) not reported by the somatic labs, highlighting the importance of panel testing. **Conclusions:** Methods used by somatic labs, regardless of inclusion of germline analysis, are not equivalent to those of designated germline labs. Overlooked germline PV may miss identification of hereditary syndromes and targeted therapy opportunities (e.g. Anti-PD1 immunotherapy, PARP inhibitors). Patients meeting criteria for genetic evaluation should be referred for designated germline testing regardless of somatic testing outcomes. Research Sponsor: U.S. National Institutes of Health.

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681 Poster Session (Board #J12), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Survival and quality of life after isolated upper abdominal perfusion with chemofiltration (UAP-F) for stage III and IV pancreatic cancer.

Karl R Aigner, Sabine Gailhofer, Emir Selak, Kornelia Aigner; Medias Klinikum Burghausen, Burghausen, Germany

Background: In order to increase response and survival rates of advanced pancreatic cancer at good quality of life, UAP-F was clinically tested. We report on feasibility, safety, overall survival and quality of life of 79 patients in stage III and 142 patients in stage IV submitted to UAP with subsequent chemofiltration for lowering of systemic drug exposure. **Methods:** This technique is achieved with stop-flow balloon catheters introduced via the femoral artery and vein. The arterial balloon is placed below the celiac axis and proceeded beneath the diaphragm after injection of a three-drug combination consisting of cisplatin (CDDP), adriamycin (ADM) and mitomycin (MMC). Because of tenfold increased cytotoxicity of ADM and MMC, the perfusion is performed under hypoxic condition. Perfusion time is 15 minutes followed by 30 – 45 minutes of chemofiltration. **Results:** Median survival was 12.1 months and 8.7 months in stage III and IV respectively. One-year survival was 49.4 % and 37 % for stage III and IV, and 3-years survival 21.7 % and 7.7 % for stage III and IV respectively. Cisplatin levels in the arterial circuit amounted to 60.000 ng/ml and 6.000 ng/ml in the venous line. Resolution of ascites was achieved within two therapies in 33/36 cases with UAP-F. Toxicity was generally mild, not exceeding WHO grade II and amounted to grade III or IV only in patients after prior severe systemic chemotherapy. **Conclusions:** Upper abdominal perfusion with chemofiltration is a safe technique for advanced cancers of the pancreas, increasing survival time and maintaining quality of life. Research Sponsor: None.

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682 Poster Session (Board #J13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Extent of lymph node resection and effect on pancreatic cancer overall survival.

Brian Cox, Nicholas Manguso, Humair Quadri, Jessica Crystal, Katelyn Mae Atkins, Jaewon Lee, Andrew Eugene Hendifar, Mitchell Kamrava, Richard Tuli, Jun Gong, Alexandra Gangi; Cedars Sinai Medical Center, Los Angeles, CA; Cedars-Sinai Medical Center, Department of Surgery, Los Angeles, CA; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Cedars-Sinai Medical Center, Los Angeles, CA; Memorial Sloan Kettering Cancer Center, New York, NY; City of Hope, Duarte, CA

Background: Lymph node (LN) metastases affect overall survival (OS) in pancreatic cancer (PC). However, a LN sampling threshold does not exist. We examined the impact of nodal sampling on overall survival (OS). **Methods:** Patients with Stage I-III PC ≥55 years old who underwent curative resection from 2004-2016 were identified from the National Cancer Database (NCDB). After adjusting for age, gender, grade, stage, and Charlson-Deyo score, multiple binomial logistic regression analyses assessed the impact of the LN ratio (LNR) on OS. LNR was defined as the number of positive LN over the number of LN examined. Regression analyses, a Cox-Regression, and a Kaplan-Meier survival curve assessed how many LN should be sampled. **Results:** A total of 13,673 patients, median age 69 years (55-90), were included. Most were Caucasian (86.6%) males with Charlson-Deyo scores ≤ 1 (90.3%) and moderately to poorly differentiated PC (90.1%). Median number of LN examined was 15 (1-75) with a median of 1 positive LN (0-35). As expected, increased number of positive LNs was associated with reduced OS, $p < 0.001$. After data normalization, an increasing LNR was associated with a 12-fold likelihood of death [OR: 11.9, $p < 0.001$ (CI 6.0, 23.7)]. Subsequent regression models established evaluation of ≥ 16 LNs as the greatest predictor of OS. A regression model evaluating < or ≥ 16 lymph nodes was performed to ascertain the effects of age, gender, ethnicity, grade, stage, and LN examined on OS. The logistic regression model correctly classified 74.5% of cases with a specificity of 99.6% ($p < 0.001$). Examination of < 16 LN, Caucasian race, grade, stage, and higher Charlson-Deyo scores were significantly associated with decreased OS. If ≥ 16 LNs were examined, patients had a 1.5-fold likelihood of better OS, $p < 0.001$ (CI 1.4, 1.6). An adjusted Cox Regression showed increased HR of 1.2, $p < 0.001$ (CI 1.1, 1.2) and an unadjusted Kaplan Meier survival curve predicted ≥ 16 LN examined are associated with an increase in OS of 2.8 months [log-rank: 32.0, $p < 0.001$]. **Conclusions:** Patients undergoing curative intent resection for PC should have adequate nodal sampling. Stratification of patients by LNR may provide useful information of OS. Examination of ≥ 16 LNs impacts OS in patients with Stage I-III PC. Research Sponsor: None.

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683 Poster Session (Board #J14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Goals of care designations in advanced pancreatic cancer patients undergoing palliative chemotherapy.

Matthew Anaka, Minji Lee, Elisa Lim, Sunita Ghosh, Winson Y. Cheung, Jennifer L. Spratlin; University of Alberta, Edmonton, AB, Canada; University of Calgary, Calgary, AB, Canada; Cross Cancer Institute/University of Alberta, Edmonton, AB, Canada; BC Cancer Agency, Vancouver, BC, Canada; Alberta Health Services, Edmonton, AB, Canada

Background: Discussion of goals of care (GoC) is a key part of quality care for patients with palliative cancer. Numerous studies have shown that documentation of GoC in this population remains low. In 2014, Alberta Health Services launched a health-system wide initiative to provide patients with physical copies of their GoC designation intended to be available at all health-system interactions. Here we describe rates of GoC documentation in the period surrounding this initiative. **Methods:** This is a retrospective cohort analysis of 240 patients with locally advanced or metastatic pancreatic cancer treated with palliative chemotherapy from 2012-2015 in Alberta, Canada. Data were obtained from outpatient electronic medical record documentation and the provincial cancer registry. **Results:** 63.8% (153/240) of patients had a documented GoC discussion, with 60.4% (145/240) receiving a specific GoC designation. 59.6% (143/240) of patients were referred to palliative care, with 32.5% (78/240) seen by palliative care physician. Of 334 individual GoC discussions documented, 38.6% (129/334) were by medical oncologists, 2.3% (10/334) were by radiation oncologists, 27.2% (91/334) were by palliative care, and 19.2% (64/334) were by other inpatient physicians during hospital admissions. At least 9.6% (32/334) referenced discussions that occurred prior to initial consultation with an oncology physician. **Conclusions:** The majority of pancreatic cancer patients undergoing palliative chemotherapy had a documented GoC designation during the study period. Providing patients with physical copies of their GoC designation may therefore represent a simple but effective means of increasing GoC documentation in the outpatient oncology setting. Research Sponsor: None.

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684 Poster Session (Board #J15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Risk factors for severe neutropenia among pancreatic cancer patients receiving nab-paclitaxel and gemcitabine combination therapy.

Kazuyoshi Kawakami, Genta Ito, Takeshi Aoyama, Takashi Yokokawa, Masashi Nakamura, Masato Ozaka, Naoki Sasahira, Hayato Kizaki, Masayuki Hashiguchi, Toshihiro Hama, Satoko Hori; Department of Pharmacy, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan; Division of Drug Informatics, Faculty of Pharmacy, Keio University, Tokyo, Japan; Department of Gastroenterology, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan

Background: Albumin-bound paclitaxel (nab-paclitaxel) and gemcitabine combination therapy (GnP therapy) significantly extends overall survival in patients with metastatic pancreatic cancer, compared to conventional gemcitabine monotherapy. However, severe neutropenia (Grade $\geq$ 3) occurred in 67.6% of patients in the Japanese phase I/II trials of GnP therapy, and is often a limiting factor. The purpose of this study was to identify the risk factors for severe neutropenia in pancreatic patients receiving GnP therapy in clinical settings. **Methods:** A retrospective study of 222 consecutive patients with pancreatic cancer who received GnP therapy at the Cancer Institute Hospital from December 2014 to December 2016 was conducted. Univariate and multivariate analyses were used to compare blood test values and patients' characteristics between patients with no neutropenia or Grade 1/2 (non-serious) neutropenia and those with Grade $\geq$ 3 (severe) neutropenia. **Results:** There were 19 patients (8.6%) with modified FOLFIRINOX in the previous treatment history. The median doses of nab-paclitaxel and gemcitabine were 192.5 mg (range 134-277.5) and 1,545 mg (range 1,000-2,220), respectively. Severe neutropenia and febrile neutropenia occurred in 118 patients (53.2%) and 15 patients (6.8%), respectively. Multivariate logistic regression analysis indicated that ANC (absolute neutrophil count) $<$ 3.03 x 10^3 /μL (OR: 4.806, 95% CI: 2.416-9.558, p = 0.000), T-Bil $\geq$ 0.6 mg/dl (OR: 1.964, 95% CI: 1.040-3.708, p = 0.037) and CRP $<$ 0.13 mg/dl (OR: 2.607, 95% CI: 1.331-5.106, p = 0.005) were significant risk factors for severe neutropenia. The incidence rate of severe neutropenia was 85.7% (18/21) in patients with all three identified factors, while it was 27.7% (13/47) in patients with none of them. Age was not a risk factor in either univariate or multivariate analysis. **Conclusions:** Low ANC, high T-Bil, and low CRP were found to be risk factors for severe neutropenia in patients receiving GnP therapy. It would be desirable to monitor patients with these risk factors carefully, even if their values are within the standard ranges. Research Sponsor: None.

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685 Poster Session (Board #J16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

The role of neoadjuvant chemotherapy in elderly patients with borderline or locally advanced pancreatic cancer: Is it safe and feasible?

Atsushi Oba, Christopher Hanyoung Lieu, Cheryl Lauren Meguid, Sarah Lindsey Davis, Alexis Diane Leal, Tom Purcell, Gentry Teng King, Karyn A. Goodman, Tracey E. Schefter, Ana Luiza Gleisner, Steven Arthur Ahrendt, Stephen Leong, Wells A. Messersmith, Richard D. Shulick, Marco Del Chiaro; Department of Surgery, University of Colorado School of Medicine, Aurora, CO; University of Colorado Cancer Center, Aurora, CO; Albert Einstein Medical Center, Philadelphia, PA; Department of Radiation Oncology, University of Colorado School of Medicine, Aurora, CO

Background: For borderline resectable (BRPC) or locally advanced pancreatic cancer (LAPC), neoadjuvant (NAT) FOLFIRINOX or gemcitabine plus nab-paclitaxel (GnP) are standard treatment options and these regimens have shown a survival advantage over single-agent gemcitabine. However, the role of these modern therapeutic regimens in elderly patients is debatable. In this analysis, we evaluated the outcomes of neoadjuvant treatment (NAT) with combination chemotherapy in elderly patients. **Methods:** 230 consecutive patients who underwent neoadjuvant treatment for BRPC/LAPC discussed and planned for NAT at the University of Colorado Cancer Center from January 2011 to March 2019 were reviewed. 214 patients who received FOLFIRINOX (n = 143) or GnP (n = 71) were eligible for analysis. We divided all patients into three groups ($<$ 70, 70-74, $\geq$75 years) and compared the short-term and long-term outcomes. **Results:** Of 214 patients, patients $<$ 70 (n = 147) received FOLFIRINOX more frequently than the other groups ($p < 0.001$): FOLFIRINOX: 115 cases, GnP: 32 cases, 70-74 years (n = 33): FOLFIRINOX: 15 cases, GnP: 18 cases, and $\geq$75 years (n = 34): FOLFIRINOX: 13 cases, GnP: 21 cases. Resection rates were not statistically different between three groups ($<$ 70: 62%, 70-74: 70%, $\geq$75 years: 56%, p = 0.504). There was a slight trend towards worse survival in the two older groups (Median Survival Time [MST]: $<$ 70: 23.2 mo., 70-74: 19.5 mo., $\geq$75 years: 17.6 mo., p = 0.075) The FOLFIRINOX group was superior to GnP group in all three groups (MST: $<$ 70: 25.6 vs 18.2 mo., p = 0.017; 70-74: 33.2 vs 16.1mo., p = 0.029; $\geq$75 years: not reached vs 16.1 mo., p = 0.135). There were no toxic deaths or 30 day mortality after pancreatectomy in the study population. **Conclusions:** Neoadjuvant combination chemotherapy regimens were safe and feasible for elderly patients. Neoadjuvant therapy with FOLFIRINOX was associated with a survival advantage vs GnP and is an good option for fit and elderly patients $\geq$75 years. Research Sponsor: None.

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686 Poster Session (Board #J17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Adverse events (AEs) with maintenance olaparib in patients with a germline BRCA mutation (gBRCAm) and metastatic pancreatic cancer (mPaC): Phase III POLO trial.

Michele Reni, Hedy L. Kindler, Pascal Hammel, Eric Van Cutsem, Teresa Macarulla, Michael J. Hall, Joon Oh Park, Daniel Hochhauser, Dirk Arnold, Do-Youn Oh, Anke C. Reinacher-Schick, Giampaolo Tortora, Hana Algül, Eileen Mary O'Reilly, David McGuinness, Karen Cui, Katia Schlienger, Gershon Y. Locker, Talia Golan; IRCCS Ospedale, San Raffaele Scientific Institute, Milan, Italy; The University of Chicago, Chicago, IL; Hôpital Beaujon (AP-HP), Clichy, and University Paris VII, Paris, France; University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; Vall d'Hebrón University Hospital and Vall d'Hebrón Institute of Oncology, Barcelona, Spain; Fox Chase Cancer Center, Philadelphia, PA; Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; University College London Cancer Institute, London, United Kingdom; Asklepios Tumorzentrum Hamburg AK Altona, Hamburg, Germany; Seoul National University Hospital, Seoul, South Korea; St Josef-Hospital, Ruhr University Bochum, Bochum, Germany; Azienda Ospedaliera Universitaria Integrata Verona, Verona and Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy; Klinikum Rechts der Isar, Comprehensive Cancer Center Munich-TUM and Department of Internal Medicine II, Technische Universität München, Munich, Germany; Memorial Sloan Kettering Cancer Center, New York, NY; AstraZeneca, Cambridge, United Kingdom; AstraZeneca, Gaithersburg, MD; Merck & Co., Inc., Kenilworth, NJ; The Oncology Institute, Sheba Medical Center at Tel-Hashomer, Tel Aviv University, Tel Aviv, Israel

Background: In POLO (NCT02184195), maintenance olaparib was well tolerated and led to a significant progression-free survival benefit vs placebo in patients with a gBRCAm and mPaC whose disease had not progressed on first-line platinum-based chemotherapy (HR 0.53; 95% CI 0.35–0.82) (Golan *et al. NEJM* 2019). We analyzed common AEs and their management in POLO. **Methods:** Patients were randomized (3:2) to maintenance olaparib (tablets; 300 mg bid) or placebo until disease progression or unacceptable toxicity. AEs were graded using CTCAE v4.0. **Results:** Of 154 randomized patients, 151 were treated (olaparib, n=91; placebo, n=60) and included in safety analyses. Median treatment duration was 6.0 months (m) for olaparib and 3.7 m for placebo. Management of fatigue/asthenia, nausea, anemia and vomiting included supportive treatment and/or dose modification; few patients discontinued treatment due to AEs (Table). Of patients with anemia, 14 olaparib recipients received a blood transfusion while on study treatment; one olaparib recipient received epoetin beta. **Conclusions:** The AE profile of maintenance olaparib in patients with a gBRCAm and mPaC was consistent with that seen in other tumor types.Common AEs of fatigue/asthenia, nausea, anemia and vomiting occurred early, were manageable and led to few treatment discontinuations. Clinical trial information: NCT02184195. Research Sponsor: AstraZeneca and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

	Fatigue/ asthenia		Nausea		Anemia*		Vomiting	
	O	P	O	P	O	P	O	P
Patients with AE, n (%)	55 (60)	21 (35)	41 (45)	14 (23)	25 (27)	10 (17)	18 (20)	9 (15)
Grade 3; 4, n (%)	5 (5); 0	1 (2); 0	0; 0	1 (2); 0	9 (10); 1 (1)	2 (3); 0	1 (1); 0	1 (2); 0
Median time to first onset, m	0.49	0.79	0.16	0.79	1.25	1.15	0.95	1.25
AEs with a resolution date, n/N (%)	19/55 (35)	9/21 (43)	24/41 (59)	11/14 (79)	19/25 (76)	8/10 (80)	18/18 (100)	9/9 (100)
Median duration of first event,† m	4.14	1.25	1.51	0.77	1.48	0.33	0.05	0.03
Supportive therapy, n/N (%)	3/55 (5)	1/21 (5)	19/41 (46)	5/14 (36)	14/25 (56)	4/10 (40)	5/18 (28)	4/9 (44)
Dose interruption; reduction, n (%)	4 (4); 5 (5)	1 (2); 1 (2)	1 (1); 0	0; 0	9 (10); 4 (4)	0; 0	4 (4); 2 (2)	1 (2); 0
Discontinuation, n (%)	2 (2)	0	0	0	0	0	1 (1)	0

*Grouped term; †AEs with no end date censored at end of safety follow-up or data cut-off, as applicable. O, olaparib (N=91); P, placebo (N=60)

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687 Poster Session (Board #J18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Outcomes of advanced gastrointestinal (GI) cancer patients in relationship to opioid use: An individual patient data pooled analysis from eight clinical trials.

Omar M Abdel-Rahman Abdelsalam, Hatim Karachiwala, Jacob C. Easaw; Cross Cancer Institute, Edmonton, AB, Canada

Background: The current study aims at assessing the patterns of opioid use, and evaluating the impact of opioid use on survival outcomes among patients with advanced GI cancers who were included in eight clinical trials. **Methods:** De-identified datasets of eight clinical trials evaluating first-line systemic treatment for advanced GI cancers (NCT01124786; NCT00844649; NCT00290966; NCT00678535; NCT00699374; NCT00272051; NCT00305188; NCT00384176) were accessed from the Project Data Sphere platform. These trials evaluated patients with pancreatic, gastric, hepatocellular and colorectal carcinoma. Multivariable logistic regression analysis was used to evaluate factors predicting the use of opioids. Kaplan-Meier survival estimates were used to compare survival outcomes in each disease entity among patients who did or did not receive opioid treatment. Multivariable Cox regression analysis was used to assess the impact of opioid use on survival outcomes in each disease entity. **Results:** A total of 3441 participants were included in the current analysis. The following factors predicted a higher probability of opioid use within logistic regression analysis: younger age (P = 0.004), non-white race (P = 0.010), higher ECOG score ($P < 0.001$) and pancreatic primary site ($P < 0.001$). Use of opioids was consistently associated with worse overall survival in Kaplan-Meier survival estimates of each disease entity (for pancreatic cancer: P = 0.008; for gastric cancer: $P < 0.001$; for hepatocellular carcinoma: $P < 0.001$ and for colorectal cancer: $P < 0.001$). Within multivariable Cox regression analysis, opioid use was associated with worse overall survival among patients with pancreatic cancer (HR = 1.245; 95% CI: 1.063-1.459; P = 0.007), gastric cancer (HR = 1.725; 95% CI: 1.403-2.122; $P < 0.001$), hepatocellular carcinoma (HR = 1.841; 95 CI: 1.480-2.290; $P < 0.001$) and colorectal cancer (HR = 1.651; 95% CI: 1.380-1.975; $P < 0.001$). **Conclusions:** Opioid use is consistently associated with worse overall survival among patients with different GI cancers. Further studies are needed to evaluate the underlying mechanisms of this observation. Research Sponsor: None.

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688 **Poster Session (Board #J19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Perioperative complication rates following neoadjuvant therapy in pancreatic adenocarcinoma.

Christopher R. Deig, Blake Beneville, Amy Liu, Aasheesh Kanwar, Alison Grossblatt-Wait, Brett C. Sheppard, Erin W. Gilbert, Charles D. Lopez, Kevin G. Billingsley, Nima Nabavizadeh, Charles R. Thomas, Aaron Grossberg; Oregon Health & Science University, Portland, OR; Nova Southeastern University College Of Osteopathic Medicine, Davie, FL

Background: Whether upfront resection or total neoadjuvant therapy is superior for the treatment of potentially resectable pancreatic adenocarcinoma (PDAC) remains controversial. The impact of neoadjuvant treatment on major perioperative complication rates for patients (pts) undergoing resection for PDAC is commonly debated. We hypothesized that rates would be comparable among patients receiving neoadjuvant chemoradiation (neo-CRT), neoadjuvant chemotherapy alone (neo-CHT), or upfront surgery. **Methods:** This is a retrospective study of 208 pts with PDAC who underwent resection within a multidisciplinary pancreatico-biliary program at an academic tertiary referral center between 2011-2018. Data were abstracted from the medical record, an institutional cancer registry and NSQIP databases. Outcomes were assessed using χ^2, Fisher's exact test and two-tailed Student's t-tests. **Results:** 208 pts were identified: 33 locally advanced, borderline or upfront resectable pts underwent neo-CRT, 35 borderline or resectable pts underwent neoadjuvant-CHT, and 140 resectable pts did not undergo neoadjuvant therapy. There were no statistically significant differences in major perioperative complication rates between groups. Overall rates were 36.4%, 34.3%, and 26.4% for pts who underwent neo-CRT, neo-CHT alone, or upfront resection, respectively (p = 0.38). No significant difference were observed in complication rates (35.3% v. 26.4%; p = 0.19) or median hospital length of stay (10 days v. 10 days; p = 0.87) in pts who received any neoadjuvant therapy versus upfront resection. There were two perioperative deaths in the neo-CRT group (6.1%), zero in the neo-CHT group, and four in the upfront resection group (2.9%); p = 0.22. **Conclusions:** There were no significant differences in major perioperative complication rates, hospital length of stay, or post-operative mortality in pts who underwent neoadjuvant therapy (neo-CRT or neo-CHT alone) versus upfront surgery. Notably, neo-CRT had comparable perioperative complication rates to neo-CHT alone, which suggests neoadjuvant radiation therapy may not pose additional surgical risk. Research Sponsor: None.

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689 Poster Session (Board #J20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Efficacy and safety of second-line nab-paclitaxel plus gemcitabine (nab-P+GEM) after progression on first-line FOLFIRINOX in advanced pancreatic ductal adenocarcinoma (PDAC): Multicenter retrospective analysis.

Changhoon Yoo, Hyehyun Jeong, Heejung Chae, Jaekyung Cheon, Hong Jae Chon, Hyewon Ryu, Il-Hwan Kim, Jae Ho Jeong, Kyu-Pyo Kim, Baek-Yeol Ryoo; Department of Oncology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Division of Hematology and Oncology, Department of Internal Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, South Korea; Department of Medical Oncology, CHA Bundang Medical Center, CHA University, Seongnam, South Korea; Division of Hematology and Oncology, Department of Internal Medicine, Chungnam National University Hospital, Daejeon, South Korea; Department of Oncology, Haeundae Paik Hospital, Cancer Center, Inje University College of Medicine, Busan, South Korea; Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

Background: FOLFIRINOX is one of standard 1st-line regimens for patients (pts) with advanced PDAC. However, there is no globally established 2nd-line regimen after failure of FOLFIRINOX. Although gemcitabine-based regimens are recommended by multiple guidelines and widely used in daily practice, further analysis is needed to reveal the magnitude of clinical benefit with these regimens. Nab-P+Gem is another standard 1st-line regimen for PDAC, but there are limited data as 2nd-line therapy in PDAC. Therefore, we conducted multicenter retrospective analysis of 2nd-line nab-P+Gem after progression on FOLFIRINOX in pts with advanced PDAC. **Methods:** Between Feb 2016 and Feb 2019, a total of 103 pts with histologically documented PDAC who received nab-P+GEM after progression on 1st-line FOLFIRINOX were identified among 5 referral cancer centers in South Korea. **Results:** Median age was 60 years and 50 pts (49%) were male. All but one pts had ECOG performance status of 0-1 at the time of nab-P+GEM. At the time of nab-P+GEM, 25 (24%) and 78 (76%) patients had locally advanced and metastatic disease, respectively. Median overall survival (OS) and progression-free survival (PFS) with nab-P+GEM was 9.8 months (95% CI: 8.9-10.6) and 4.6 months (95% CI: 3.7-5.5), respectively. Among pts with measurable disease (n = 95), partial response and stable disease were achieved in 8 (8%) and 56 (54%), respectively. Median OS from the start of 1st-line FOLFIRINOX was 20.9 months (95% CI: 15.2-26.6). Most common adverse event of all grade was anemia (77%), followed by neutropenia (60%), fatigue (52%), thrombocytopenia (45%), and peripheral neuropathy (30%). Most common grade 3-4 adverse events were neutropenia (36%), anemia (9%), and peripheral neuropathy (8%). **Conclusions:** In medically fit pts with advanced PDAC who failed on 1st-line FOLFIRINOX, nab-P+GEM was effective and well tolerated as 2nd-line therapy. Research Sponsor: Celgene.

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690 **Poster Session (Board #K1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Tumor downsizing following neoadjuvant therapy for borderline-resectable pancreatic adenocarcinoma.

Joseph Arturo Reza, Alberto Monreal, Patrick Hunter Meyer, Swati Patel, Ahmed Zakari, Sebastian de la Fuente; AdventHealth Orlando General Surgery Residency, Orlando, FL; AdventHealth Orlando Institute for Surgical Advancement, Orlando, FL; Florida Hospital Cancer Institute, Orlando, FL; Florida Hospital Cancer Institute-Florida Hospital Medical Group, Orlando, FL

Background: Downstaging of pancreatic adenocarcinoma in patients presenting with nonmetastatic, unresectable disease has proven to be associated with improved clinical outcomes. Efforts at rescuing these patients to become surgical candidates are commonly attempted with a combination of systemic and radiation strategies. In this study, we aimed to determine tumor downsizing in patients that underwent neoadjuvant systemic therapy followed by a curative-intended surgical resection. **Methods:** A retrospective review of consecutive patients that underwent surgical resection for pancreatic adenocarcinoma following a course of neoadjuvant therapy was performed. Basic demographics, endoscopic ultrasound (EUS) findings, chemotherapy regimens and duration, rates of radiotherapy, type of surgical procedure and pathologic results were recorded. Tumor response to neoadjuvant therapy was established by correlating EUS- to pathologic tumor dimensions. Analysis of the data was done using Mann-Whitney U test, Pearson correlation and Chi-square when indicated. **Results:** A total of 97 patients were analyzed; 40 underwent neoadjuvant chemotherapy (13 patients also received concurrent radiation therapy). In those 57 patients that were resected upfront, EUS tended to underestimate tumor sizes significantly compared to pathologic dimensions, with an average difference between dimensions of 0.66 cm ($p = 0.0004$). Within the group treated with neoadjuvant chemotherapy, 90% of patients had downsizing at an average of 8% of tumor size. There were no differences in rates of tumor downsizing between FOLFIRINOX or Gemcitabine/Nac-paclitaxel treated patients. In addition, there were no correlations in margin status (R0) based on chemotherapy used, with both regimens achieving a similar rate of R0 resections (mean 61%). The type of chemotherapy regimen used did not affect the ratio of positive lymph nodes harvested. **Conclusions:** In patients that present with borderline resectable pancreatic adenocarcinoma, a course of neoadjuvant therapy results in tumor downsizing in a significant number allowing for margin negative resections. These results were seen regardless of the chemotherapeutic regimens utilized. Research Sponsor: None.

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691 **Poster Session (Board #K2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The surgical outcomes of borderline resectable or locally advanced pancreatic cancer.

Yukiyasu Okamura, Teiichi Sugiura, Takaaki Ito, Yusuke Yamamoto, Ryo Ashida, Katsuhisa Ohgi, Katsuhiko Uesaka; Division of Hepato-Biliary-Pancreatic Surgery, Shizuoka Cancer Center, Shizuoka, Japan

Background: Advances in multidisciplinary treatment for pancreatic cancer (PC) have increased surgical opportunities for initially unresectable locally advanced (UR-LA) or borderline resectable PC. In order to obtain a high rate of R0 resection, it is important to select an appropriate approach according to the infiltration site of the artery that can determine whether curative surgery is possible or not at early phase of the operation. **Methods:** From April 2012 to December 2018, 81 patients who were scheduled for curative resection for UR-LA or borderline resectable PC that contact the main artery (BR-A). In our institution, if a tumor is in contact with the superior mesenteric artery (SMA), we select the mesenteric approach. And if a tumor is in contact with the common hepatic artery (CHA) and/or celiac artery (CA), we open the lesser omentum and then dissect from the cranial side of pancreas to the diaphragm leg to judge the resectability before dividing the stomach. When arterial plexus infiltration is observed during surgery, we abandoned curative surgery or we performed combined resection of CHA and reconstruction if possible. **Results:** There were 69 BR-A and 12 UR-LA patients. Macroscopic curative resection was performed in 67 (83%) of 81 patients, and 14 patients were unresectable. Pancreatoduodenectomy was performed in 54 patients, distal pancreatectomy (DP) in 8, and DP with celiac axis resection in 7. There were 67 patients with vascular resection / reconstruction. R0 resection was obtained in 64 of 67 patients among curative resection. The median blood loss, operation time, and length of hospital stay were 714 mL, 439 minutes, and 19 days, respectively. The complications of Clavien-Dindo grade 3a or higher were observed in 18 patients (27%). There were no post-operative deaths. The 3-year survival rate after surgery was 70.3%, and there was no significant difference between BR-A and UR-LA (P = 0.701). The 3-year recurrence-free survival rate after surgery was 34.4%, which was not significantly different between the two groups (P = 0.816). **Conclusions:** A high R0 resection rate (96%) was obtained by an appropriate approach that can determine the resectability at early stage of operation, and high R0 rate leads to good outcomes. Research Sponsor: None.

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693 Poster Session (Board #K4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Phase Ib study of gemcitabine, nab-paclitaxel, and ficlatuzumab in patients with advanced pancreatic cancer.

Kimberly Perez, Colin D. Weekes, James M. Cleary, Thomas Adam Abrams, Lawrence Scott Blaszkowsky, Peter C. Enzinger, Marios Giannakis, Lipika Goyal, Jeffrey A. Meyerhardt, Douglas Adam Rubinson, Matthew B. Yurgelun, Danielle Stonely, Srivatsan Raghavan, Basil Bakir, Koushik Das, Jason Pitarresi, Andrew Aguirre, Michael N. Needle, Anil Rustgi, Brian M. Wolpin; Dana-Farber Cancer Institute, Boston, MA; Hematology/Oncology, Massachusetts General Hospital, Boston, MA; Massachusetts General Hospital, Boston, MA; Dana-Farber Cancer Institute/Partners Cancer Care, Boston, MA; Dana Farber Cancer Institute, Boston, MA; Dana-Farber Cancer Institute, Cambridge, MA; University of Pennsylvania, Philadelphia, PA; Aveo Oncology, Cambridge, MA; Columbia University Medical Center, New York, NY

Background: Paired-related homeodomain transcription factor 1 (Prrx1) isoforms are involved in pancreatic development, pancreatitis, and carcinogenesis. Hepatocyte growth factor (HGF) is a transcriptional target of Prrx1b. Ficlatuzumab is a recombinant humanized HGF antibody, that neutralizes HGF/c-Met binding and HGF-induced c-Met phosphorylation. In preclinical pancreatic ductal adenocarcinoma (PDAC) models, inhibition of Prrx1b-HGF signaling using ficlatuzumab and gemcitabine reduced primary tumor volume and eliminated metastatic disease. **Methods:** Patients (pts) with previously-untreated metastatic PDAC enrolled in a phase Ib dose escalation study with 3+3 design and two dose cohorts of ficlatuzumab (10mg/kg and 20mg/kg) administered intravenously every other week with gemcitabine (G; 1000mg/m^2) and nab-paclitaxel (A; 125mg/m^2) given 3 weeks on and 1 week off. This was followed by an expansion phase at the maximally tolerated dose (MTD) of the combination. **Results:** 24 pts (sex, 12M:12F; median age, 69 years [range, 51-82 years]) were enrolled. No dose-limiting toxicities were identified in the phase 1b (N = 6 pts) and ficlatuzumab at 20mg/kg with GA was advanced to the expansion phase (N = 18 pts). By RECISTv1.1 in the full study population, 7 (29%) pts had partial response, 15 (63%) had stable disease, and 2 (8%) could not be evaluated. Median progression-free survival was 8 months (range, 3-16 months), 4 pts are still on study treatment. The primary toxicities attributed to ficlatuzumab included hypoalbuminemia (grade 3, 21%; any grade, 91%) and edema (grade 3, 8%; any grade, 91%). Nine (38%) of the 24 pts discontinued study treatment due to these toxicities prior to disease progression. **Conclusions:** The combination of ficlatuzumab with gemcitabine and nab-paclitaxel is associated with durable treatment responses but also significant hypoalbuminemia and edema that may impair treatment tolerability. Serial blood samples were collected for circulating HGF measurements, and mandatory pretreatment biopsies were collected for tumor c-MET pathway activation and 3D organoid culture drug sensitivity testing. Clinical trial information: NCT03316599. Research Sponsor: AVEO Oncology.

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694 Poster Session (Board #K5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Effects of early discontinuation of adjuvant chemotherapy (EDAC) and the timing of treatment on outcomes in patients with early-stage pancreatic cancer (ESPC): Result from a population-based retrospective cohort study.

Javeria Muhammadzai, Michael Moser, Kamal Haider, John Shaw, Haji I. Chalchal, Donald Gardiner, Adnan Zaidi, Osama Ahmed, Yigang Luo, Bryan Brunet, Dueck Dorie-Anna, mussawar iqbal, Gavin Beck, Shahid Ahmed; College of Medicine, University of Saskatchewan, Saskatoon, SK, Canada; Department of Surgery, University of Saskatchewan, Saskatoon, SK, Canada; Saskatoon Cancer Centre, University of Saskatchewan, Saskatoon, SK, Canada; Allan Blair Cancer Centre, Regina, SK, Canada; Saskatoon Cancer Center, Saskatchewan Cancer Agency, Saskatoon, SK, Canada; Saskatchewan Cancer Agency, University of Saskatchewan, Saskatoon, SK, Canada; Saskatchewan Cancer Agency, Saskatoon, SK, Canada; Saskachewan Cancer Agency, Saskatoon, SK, Canada; ABCC, Regina, SK, Canada; University of Saskatchewan, Saskatoon, SK, Canada

Background: Although evidence suggests that a delay in initiation of adjuvant chemotherapy (AC) results in inferior outcomes in some cancers, little is known about its detrimental effects in patients with ESPC. Moreover, it is not known if EDAC has been associated with high risk of recurrence and poor survival. The current study aims to determine association between timing and completion of AC and outcomes in ESPC. **Methods:** Patients with ESPC who were diagnosed from Jan 2007 to Dec 2017 and underwent complete resection in the province of Saskatchewan were examined. Kaplan Meier methods and log rank tests were performed for survival analyses. Cox proportional multivariate analyses were performed for correlation with recurrence and survival. **Results:** A total 168 patients with ESPC were identified. 97 (57%) patients were excluded as they did not receive AC, were found to have metastatic disease, did not have curative surgery or had received preoperative chemotherapy. Of 71 eligible patients with median age of 69 years (IQR: 57-73), 52% were male, 31% had WHO performance status of 0 and 92% had a comorbid illness. 78% had pancreatic head tumor, 66% had T3 tumor and 63% had node-positive disease. Median time to start of AC from surgery was 73 days (IQR: 59-89). 32% were started AC within 60 days of surgery. 89% received single-agent chemotherapy and 25% received adjuvant radiation. 69% completed planned treatment. Median time to recurrence in group which completed treatment was 22 months (95%CI:15.8-28.2) vs. 9 months (3.3-14.7) if treatment was discontinued early ($P < 0.001$). Median overall survival of the group that completed treatment was 33 months (17.5-48.5) vs. 16 months (17.5-48.5) if it was stopped early ($P < 0.001$). On multivariate analysis, EDAC was significantly correlated with recurrent disease (HR = 3.0; 1.6-5.5), P = 0.0001 and inferior survival (HR = 3.2; 1.68-6.12), $P < 0.001$. No correlation between AC timing and survival was noted. **Conclusions:** Although timing of AC does not correlate with inferior outcomes, EDAC has been associated with high risk of recurrence and inferior survival in ESPC. Research Sponsor: College of Medicine, University of Saskatchewan.

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695 Poster Session (Board #K6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Multicenter retrospective observational study of pancreatic cancer with positive peritoneal lavage cytology intended for surgical resection.

Akiko Todaka, Satoshi Nara, Fuyuhiko Motoi, Soichiro Morinaga, Naoki Hama, Ryota Higuchi, Masaru Konishi, Hirofumi Shirakawa, Hidetaka Tsumura, Hiroyuki Okuyama, Hiroto Matsui, Kazuhiko Shioji, Keishi Sugimachi, Akinori Asagi, Nobumasa Mizuno, Akira Fukutomi, Junji Furuse; Division of Gastrointestinal Oncology, Shizuoka Cancer Center, Shizuoka, Japan; National Cancer Center Hospital, Tokyo, Japan; Department of Surgery, Tohoku University Graduate School of Medicine, Sendai, Japan; Kanagawa Cancer Center, Yokohama, Japan; National Hospital Organization Osaka National Hospital, Osaka, Japan; Tokyo Women's Medical University, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Surgery, National Cancer Center Hospital East, Kashiwa, Japan; Department of Hepato-Biliary-Pancreatic Surgery, Tochigi Cancer Center, Utsunomiya, Japan; Hyogo Cancer Center, Hyogo, Japan; Department of Clinical Oncology, Kagawa University Faculty of Medicine, Kagawa, Japan; Department of Gastroenterological, Breast and Endocrine Surgery, Yamaguchi University, Ube, Japan; Niigata Cancer Center Hospital, Niigata, Japan; Kyushu University Beppu Hospital, Beppu, Japan; Department of Gastrointestinal Medical Oncology, National Hospital Organization Shikoku Cancer Center, Matsuyama, Japan; Department of Gastroenterology, Aichi Cancer Center Hospital, Nagoya, Japan; Kyorin University, Tokyo, Japan

Background: Although macroscopically curative resection has been performed for pancreatic cancer with positive peritoneal lavage cytology (CY1), the prognosis is poor in most reports. In 2013, the JASPAC01 trial showed that S-1 was superior to Gemcitabine (GEM) as adjuvant chemotherapy for resected pancreatic cancer, and S-1 was also administered to the patients with CY1 who had undergone macroscopically curative resection. **Methods:** This is a multicenter retrospective observational study that collected data of the patients with pancreatic adenocarcinoma who were diagnosed with CY1 between 2007 and 2015 and had no other noncurable factors. **Results:** One hundred twenty-seven patients were enrolled from 14 institutions, and 3 were excluded due to liver metastasis or non-adenocarcinoma. The median age was 67 years old and almost patients had PS 0 or 1. Of the 124 patients, 114 underwent macroscopically curative resection and the median overall survival (OS) and recurrence free survival (RFS) were 16.7 and 7.2 months. Of the resected patients, 80 (70%) had no early recurrence and started postoperative adjuvant chemotherapy. Adjuvant chemotherapy regimens were S-1 in 43 patients (54%), GEM in 31 (39%) and others in 6 (7%). The median OS was 21.0 months with S-1 and 19.2 months with GEM (HR: 0.73, 95%CI: 0.44-1.22, P = 0.23), whereas the median RFS was 10.2 and 7.1 months (HR: 0.58, 95%CI: 0.36-0.95, P = 0.03), respectively. **Conclusions:** After the report of JASPAC01, most patients with pancreatic cancer with CY1 received macroscopically curative resection and treated with S-1 as adjuvant therapy, however the efficacy was insufficient. We should consider appropriate treatment strategies for patients with pancreatic cancer with CY1 intended for surgical resection. Research Sponsor: Shizuoka Cancer Center Medical Fund.

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696 **Poster Session (Board #K7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Use of gastrin vaccine to increase gamma-delta and NKT cells and alter pancreas tumor microenvironment to improve survival.

Jill P Smith, Nicholas Osborne, Rebecca Sundseth, Hong Cao, Martha D Gay, Robin D. Tucker, Alexander H Kroemer, Lynda Youngpeter Sutton, Allen Cato; Georgetown University, Department of Medicine, Washington, DC; Cato Research, Waltham, MA; Cato Research Ltd, Durham, NC; Georgetown University, Department of Pathology, Washington, DC; MedStar Georgetown University Hospital, Washington, DC; Cancer Advances, Inc, Durham, NC

Background: Pancreatic cancer (PC) has been called a "cold" tumor as it responds poorly to immune-based therapies. Strategies to render PC susceptible to immunotherapy are under investigation by methods that alter immune cell signatures such as increasing the population of double negative CD4-CD8-T-cells, or changing the polarization of tumor-associated macrophages (TAMs). Our current aim was to determine if a gastrin vaccine, Polyclonal Antibody Stimulator (PAS) influences double negative T-cell phenotype and polarization of TAMs to improve survival of PC. **Methods:** Two cohorts of C57BL/6 mice were injected either sc or orthotopically with syngeneic mT3 murine pancreatic cancer cells. After 1 week, groups were treated with PBS; PAS (100μg); PD-1 antibody (150μg); or the combination of PAS and PD-1 Ab. PAS was given ip at weeks 0, 1 and 3. Anti-PD-1 was given on days 0, 4, 8, 15 and 21. Spleens were collected from the sc experiment for T-cell surface analysis by flow cytometry. Orthotopic tumors were measured for growth rate, metastases, and stained for M1 (inos) and M2 (arginase) polarized TAMs, and mouse survival was analyzed. **Results:** PAS therapy increased expression of double negative T-cells. The percentage of gamma-delta T-cells in the ($CD3^+/CD4^-/CD8^-/CD44^-/CD62L^-$) TEMRA subpopulation of mice treated with PAS or combinations of PAS with PD-1 Ab were increased approximately 40% compared to PBS-treated controls or PD-1 Ab-treated mice. NKT cells from PAS-vaccinated mice were 2.5-fold higher than controls. M2+ TAMS were significantly decreased in tumors of PAS treated mice compared to PBS treated mice ($p = 0.017$). PAS monotherapy resulted in a nearly 10-fold increase in M1 TAMs relative to controls ($p = 0.002$). PAS monotherapy decreased tumor metastases by 69% and prolonged survival. Primary tumor growth decreased with PAS in combination with PD-1 Ab ($p=0.0025$). **Conclusions:** PAS decreases PC tumor growth and metastases by increasing CD4-CD8-, gamma-delta, and NKT T-cell populations. Furthermore, PAS monotherapy significantly increases M1 and decreases M2 TAMs. These immune cell changes with PAS vaccination may render tumors more susceptible to other cancer therapies and improve survival. Research Sponsor: U.S. National Institutes of Health, Pharmaceutical/Biotech Company.

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697 Poster Session (Board #K8), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Phase II study of preoperative chemotherapy with nab-paclitaxel and gemcitabine followed by chemoradiation for borderline resectable or node-positive pancreatic ductal adenocarcinoma.

Emerson Yu-sheng Chen, Garth William Tormoen, Adel Kardosh, Nima Nabavizadeh, Bryan Foster, Skye C. Mayo, Kevin G. Billingsley, Erin W. Gilbert, Christian Lanciault, Aaron Grossberg, Kenneth Gregory Bensch, Erin Maynard, Eric C. Anderson, Brett C. Sheppard, Charles R. Thomas, Charles D. Lopez, Gina M. Vaccaro, OHSU Gastrointestinal Cancer Disease Group; Oregon Health & Science University, Portland, OR; Portland VA Medical Center, Portland, OR

Background: Pre-operative therapy for resectable pancreatic ductal adenocarcinoma (PDAC) may eliminate micro-metastatic disease early and help achieve negative surgical margins. The present study is based on the hypothesis that gemcitabine/nab-paclitaxel chemotherapy followed by chemo-radiation with fluoropyrimidine is a feasible and efficacious pre-operative treatment for borderline resectable or node-positive PDAC. **Methods:** This is a single-arm phase II trial to evaluate pre-operative treatment with 2 cycles of gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 on days 1, 8, 15 every 28 days followed by 50.4 Gy of intensity-modulated radiation therapy over 28 fractions with concurrent 5-fluorouracil or capecitabine prior to pancreatic resection. Patients were eligible if they met borderline resectable criteria or had abnormal regional nodes visible on contrast CT. After surgery, they were eligible to receive up to 4 additional cycles of gemcitabine/nab-paclitaxel. The primary endpoint was the R0 resection rate. Secondary endpoints included response to pre-operative therapy, overall toxicities, relapse-free survival, and overall survival. **Results:** Nineteen of 24 screened patients have been enrolled. Median age was 68, 10 (53%) were female, and 4 (21%) were non-Caucasian. Eleven (78%) had head of pancreas cancers, 13 (68%) exhibited both arterial and venous involvement, and 12 (63%) had positive clinical nodes. All 19 patients received 2 months of gemcitabine/nab-paclitaxel, of which 17 patients continued to chemo-radiation (1 developed metastatic disease and 1 moved out of state). In the interval between chemo-radiation and surgery, 3 developed metastatic disease, 1 became unresectable, 1 withdrew from study, and 1 was deemed too frail for surgery. Nine have undergone successful pancreatic resection, and 2 are pending resection. **Conclusions:** Pre-operative gemcitabine/nab-paclitaxel followed by chemo-radiation with fluoropyrimidine is feasible in patients with borderline resectable PDAC and represents another strategy to FOLFIRINOX-based therapy. A planned interim analysis is ongoing. Clinical trial information: NCT02427841. Research Sponsor: CelgeneOther Foundation.

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698 **Poster Session (Board #K9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Phase II clinical trial of novel agent PBI-05204 in patients with metastatic pancreatic adenocarcinoma (mPDA).

Marc Thomas Roth, Dana Backlund Cardin, Erkut Hasan Borazanci, Margaux Steinbach, Vincent J. Picozzi, Alexander Rosemurgy, Raymond Couric Wadlow, Robert A. Newman, Jordan Berlin; Vanderbilt-Ingram Cancer Center, Nashville, TN; HonorHealth Research Institute, Scottsdale, AZ; Virginia Mason Hospital and Medical Center, Seattle, WA; Florida Hospital Tampa, Tampa, FL; Virginia Cancer Specialists, Fairfax, VA; MD Anderson Cancer Ctr, Houston, TX

Background: Survival statistics for mPDA are dismal and with limited treatment options novel agents are needed to improve disease outcomes. PBI-05204 (Phoenix Biotechnology, Inc., San Antonio, TX) is a modified supercritical carbon dioxide extract of *Nerium oleander* leaves. Oleandrin, the extract's major cytotoxic component, has demonstrated anti-tumor activity in various tumor cell lines. In a human PDA orthotopic model, this preparation reduced tumor burden as monotherapy. Pharmacodynamic studies suggest that PBI-05204's mechanism of action is through inhibition of the PI3k/Akt/mTOR pathway. **Methods:** A phase II single-arm, open-label study to determine the efficacy of PBI-05204 in patients (pts) with mPDA refractory to standard therapy was conducted. The primary endpoint was overall survival (OS) with the hypothesis that 50% of pts would be alive at 4.5 months. Secondary objectives included safety, progression-free survival (PFS), and overall response rate. Pts received oral PBI-05204 daily until progressive disease (PD), unacceptable toxicity, or pt withdrawal. Radiographic response was assessed every two cycles. **Results:** Forty-one pts were enrolled; two never received treatment and one was found to have a neuroendocrine tumor after pathological re-evaluation, leaving 38 pts for analysis. Median age at time of enrollment was 65.0 years. The median time from initial diagnosis to treatment was 16.9 months. The primary reason for withdrawal was PD (45.2%). Ten pts were alive at 4.5 months (26.3%) with a mPFS of 56 days (corresponding to first restaging). One objective response (2.6%) was observed for 162 days. Grade ≥3 treatment-emergent adverse events occurred in 63.2% of pts with the most common attributed to drug (all grades) being fatigue (36.8%), vomiting (23.7%), nausea (18.4%), decreased appetite (18.4%), and diarrhea (15.8%). **Conclusions:** PBI-05204 did not meet its primary endpoint for OS in this study. Recent preclinical data indicate an efficacious role for PBI-05204 against glioblastoma multiforme when combined with chemotherapy, such as temozolomide, and radiotherapy. A randomized Phase II trial is currently being designed. Clinical trial information: NCT02329717. Research Sponsor: Phoenix Biotechnology, Inc., San Antonio, TX.

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699 Poster Session (Board #K10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

A pilot clinical trial of p53/p16-independent epigenetic therapy for pancreatic ductal adenocarcinoma (PDA).

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Background: PDA treatment is limited to cytotoxic drugs. A key factor limiting their efficacy is *TP53* mutations, omnipresent in PDA, which counter apoptosis-mediated cell kill. We evaluated a novel epigenetic approach using decitabine (Dec) to inhibit DNA methyltransferase 1 (DNMT1) and effect cancer cell cycle exits by epithelial-differentiation, combined with tetrahydrouridine (THU) to inhibit cytidine deaminase (CDA) and thereby permit oral bioavailability and solid-tissue distribution of Dec. **Methods:** Open-label single-arm, IRB-approved clinical trial at Cleveland Clinic and University Hospitals for patients with metastatic PDA that had progressed on prior chemotherapy, ECOG PS of 0-2. Treatment was oral, weight-based, with Dec 10-20 mg, and THU 500-1000 mg daily, 5 days/week. Primary endpoint was DNMT1 protein levels at 16-week vs baseline biopsies. **Results:** From Apr to Aug 2017, we enrolled 13 patients. Median age was 65 (range 44-74) years; 7 (54%) males; 11 (85%) Caucasians. Median time from diagnosis was 13 (3.9-53.5) months, with a median of 2 (1-3) prior lines of therapy. Baseline ECOG PS was 0/1 in 12 (92%) patients. All patients started study drugs; median time on treatment was 35 (4-63) days, and on study 72 (25-105) days. The most frequent adverse events attributable to the study drugs were anemia (n=5), and anorexia, dehydration, nausea, fatigue, febrile neutropenia and decreased lymphocyte count, in 3 patients each; no deaths. Eight (62%) patients underwent evaluation scans at 8 weeks, showing stable disease in 1 patient and progression in 7. Common reasons for coming off of study drugs were progression (n=6), physician discretion (n=3), and adverse events (n=2). Overall, 6 patients died; median survival was 3.1 months, and patients did not reach the 16-week biopsy. Shifts in blood counts, a sensitive indicator of Dec systemic activity, were unexpectedly mild, and plasma CDA enzyme activity was increased versus other cancer and normal controls. **Conclusions:** This first-of-its-kind study demonstrated feasibility and safety of the novel oral epigenetic therapy. Systemically elevated CDA in these patients requires higher doses of THU; a trial accordingly refined is planned. Clinical trial information: NCT02847000. Research Sponsor: Case Comprehensive Cancer Center.

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700 Poster Session (Board #K11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

An exploratory study of metformin (Met) with or without rapamycin (Rapa) as maintenance therapy after induction chemotherapy in patients (Pts) with metastatic pancreatic adenocarcinoma (PDA).

Katherine M. Bever, Erkut Hasan Borazanci, Elizabeth Thompson, Annie Wu, Jennifer N. Durham, Meizheng Liu, Cara Wilt, Wei Fu, Jeffrey P. Leal, Ana De Jesus-Acosta, Hao Wang, David Cosgrove, Lei Zheng, Daniel A. Laheru, Daniel D. Von Hoff, Elizabeth M. Jaffee, Jonathan Powell, Dung T. Le; The Sidney Kimmel Comprehensive Cancer Center and Bloomberg-Kimmel Institute for Cancer Immunotherapy at Johns Hopkins, Baltimore, MD; HonorHealth Research Institute, Scottsdale, AZ; Department of Biostatistics at the Johns Hopkins University School of Medicine, Baltimore, MD; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; Vancouver Cancer Center, Compass Oncology, Vancouver, WA; Translational Genomics Research Institute, Phoenix, AZ

Background: Few studies have examined maintenance therapy in unselected pts with metastatic PDA (mPDA). mTOR signaling is central to several oncogenic pathways in PDA and also has a role in T cell differentiation and activation, and we hypothesized a role for mTOR inhibition (mTORi) in the maintenance setting. **Methods:** This was a randomized open-label study conducted at 2 sites. Eligible pts had mPDA with stable disease for ≥6 months on chemotherapy and ECOG PS 0/1. Pts were randomized 1:1 to Met 850mg BID alone (Arm A) or with Rapa 4mg daily (Arm B), stratified by prior FOLFIRINOX. Baseline and on-treatment PET scans and peripheral blood mononuclear cells were obtained for exploratory analyses. **Results:** 23 pts were randomized. Median age was 64 (range 34-77) and 82% had ECOG PS 1. 12 of 23 received prior FOLFIRINOX; 8 received >1 prior line of therapy. 22 subjects (11 per arm) were treated per protocol. Treatment related adverse events of Grade ≥3 were seen in 0% vs 27% of pts in Arm A vs B and were all asymptomatic hematologic or electrolyte abnormalities that were not clinically significant. Median PFS/OS were 3.5 (95% CI: 2.9-9.2)/13.2 mos (95% CI: 7.8 to not reached) respectively, with 2 yr OS rate of 37% (95% CI: 21-66%); there were no differences between treatment arms. As expected in the maximally debulked setting, no responses were observed by RECIST; however, decreases in FDG avidity and/or CA199 were observed in several long-term survivors. Better survival was associated with low baseline neutrophil to lymphocyte ratio, baseline lack of assessable disease by PET, and with expansion of dendritic cells following treatment. Compared to Met alone, Met + Rapa was associated with decreased mTOR activity on some immune cell subsets and decreased metabolic fitness, but this was not correlated with outcome. **Conclusions:** Met +/- rapa maintenance for mPDA was well-tolerated and several pts achieved stable disease associated with exceptionally long survival. Further prospective studies are needed to clarify the role of mTORi in the maintenance setting and to enhance pt selection for such approaches. Clinical trial information: NCT02048384. Research Sponsor: Stand Up To Cancer.

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702 **Poster Session (Board #K13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Multicenter phase I/II study of intravenous gemcitabine + nab-paclitaxel combined with intraperitoneal paclitaxel for pancreatic ductal adenocarcinoma patients with peritoneal metastasis.

Suguru Yamada, Tsutomu Fujii, Tomohisa Yamamoto, Hideki Takami, Isaku Yoshioka, So Yamaki, Fuminori Sonohara, Kazuto Shibuya, Fuyuhiko Motoi, Satoshi Hirano, Yoshiaki Murakami, Hitoshi Inoue, Masamichi Hayashi, Yasuhiro Kodera, Mitsugu Sekimoto, Sohei Satoi; Nagoya University Graduate School of Medicine, Gastroenterological Surgery, Nagoya, Japan; Department of Surgery and Science, Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Toyama, Japan; Department of Surgery, Kansai Medical University, Hirakata, Japan; Department of Surgery, Tohoku University Graduate School of Medicine, Sendai, Japan; Department of Gastroenterological Surgery II, Faculty of Medicine, Hokkaido University, Sapporo, Japan; Department of Surgery, Institute of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan; Department of HBP and Breast Surgery, Ehime University Graduate School of Medicine, Ehime, Japan

Background: Pancreatic ductal adenocarcinoma (PDAC) patients with peritoneal metastasis (peritoneal deposits and/or positive peritoneal cytology) have an extremely poor prognosis, and an effective treatment strategy remains elusive. **Methods:** The aim of this study were to determine the recommended dose (RD) for a combination of intravenous (IV) gemcitabine, intravenous nab-paclitaxel, and intraperitoneal (IP) paclitaxel in chemotherapy-naive PDAC patients with peritoneal metastasis and to evaluate the clinical efficacy and safety. Gemcitabine and nab-paclitaxel was administered IV combined with paclitaxel IP on days 1, 8 and 15, followed by 1 week of rest. The frequency of dose-limiting toxicity was evaluated and the RD was determined. The primary endpoint of the phase II part was 1-year overall survival (OS) rate. The secondary endpoints were antitumor effect, symptom relief effect, safety and OS. **Results:** In the phase I part, RD for IV gemcitabine, IV nab-paclitaxel and IP paclitaxel were determined as 800 mg/m^2, 75 mg/m^2, and 20 mg/m^2, respectively. A total of 46 patients were enrolled in the phase II part and drugs were delivered at the RD. All patients had positive intraperitoneal cytology and 29 patients (63.0%) had the peritoneal dissemination. The median treatment period was 6.0 (0-22.6) months. The response rate and disease control rate were 45.7% and 95.7%, respectively. Ascites disappeared in 40.0% and cytology turned negative in 67.4%. Median CA19-9 decrease ratio was 84.4 (16.9-99.1) %. The median survival time was 12.8 (3.1-32.7) months, and the 1-year survival rate was 52.2%. Finally, conversion surgery was performed in 8 (17.4%) patients and those who received conversion surgery survived significantly longer than those who did not (not reached vs. 11.7 months, P = 0.0070). Grade 3/4 hematologic toxicities occurred in 76.0% and nonhematologic adverse events in 15.0%, of which 6.5% were bowel obstructions. **Conclusions:** This regimen has shown promising clinical efficacy with acceptable tolerability in chemotherapy-naive PDAC patients with peritoneal metastasis. Clinical trial information: 000018878. Research Sponsor: None.

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703 Poster Session (Board #K14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Radiation as a single modality treatment in localized pancreatic cancer.

Walid Labib Shaib, Katerina Mary Zakka, Asser Shahin, Fares Yared, Jeffrey M. Switchenko, Christina Wu, Mehmet Akce, Olatunji B. Alese, Pretesh R. Patel, Mark William McDonald, Bassel F. El-Rayes; Winship Cancer Institute of Emory University, Atlanta, GA; Emory University, Atlanta, GA; Department of Medicine, Lebanese University, Beirut, Lebanon; Emory University, Department of Biostatistics and Bioinformatics, Atlanta, GA; Ohio State University Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, Columbus, OH; Winship Cancer Institute, Atlanta, GA; Emory Winship Cancer Institute, Atlanta, GA; Indiana University School of Medicine, Indianapolis, GA; Winship Cancer Institute, Emory University, Atlanta, GA

Background: Locally advanced pancreatic cancer (LAPC) is managed with multimodality therapy. A subset of patients with LAPC are not good candidates for aggressive treatment. The aim here is to evaluate the outcomes of single modality radiation therapy for LAPC using the National Cancer Database (NCDB). **Methods:** Data was obtained between years 2004 and 2013. Pancreatic ductal adenocarcinoma (PDAC) patients with unresectable local disease were identified excluding patients who received chemotherapy or surgery. Univariate and multivariable analyses identified factors associated with patient outcome. Kaplan-Meier analysis and Cox proportional hazards models were used for patient characteristics and overall survival (OS). **Results:** A total of 6,590 patients were included; 480 (6.9%) received radiation therapy only and 6470 (93.1%) received no treatment. Mean age was 73.5 (range, 28-90) years, with the majority being White (N = 5685; 83.2%) and female (N = 3779; 54.4%). Poorly differentiated histology and tumors $\geq$ 4 cm ($>$ T3 stage) accounted for 47.8% and 52.7%, respectively. The median dose of radiation was 39.6 Gy. Stereotactic body radiation (SBRT) was given in 64 patients and external-beam/Intensity modulated radiotherapy (IMRT) in 416 patients. Charlson-Deyo score of +1 was seen in 34.4% of patients who received no treatment, 32.8% of patients who received SBRT and in 29.8% of patients who received external-beam IMRT. Radiation therapy was associated with improved OS compared to no treatment in univariate and multivariable analyses controlling for sex, Charlson-Deyo score, age, tumor size, amongst other covariates. Median OS for patients who received SBRT, external-beam/IMRT or no radiation was 8.6, 6.7 and 3.4 months; respectively ($P < 0.001$). There is a significant difference in 12-month OS for the SBRT cohort (31.9%; 95% CI 20.9%-43.5%) compared to patients who received no radiation (15.1%; 95% CI 14.2%-16.0%), similarly seen on multivariable analysis (HR 0.50; 95% CI 0.38-0.65; $P < 0.001$). **Conclusions:** The current study is the first to evaluate the efficacy of radiation as single modality therapy in LAPC. The results suggest a potential benefit for radiation therapy alone, in comparison to no treatment. Research Sponsor: None.

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704 Poster Session (Board #K15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Phase III, international, randomized trial of adjuvant *nab*-paclitaxel plus gemcitabine (*nab*-P + G) versus gemcitabine (G) for resected pancreatic cancer (APACT): Recurrence patterns.

Vaibhav Sahai, Josep Tabernero, Eric Van Cutsem, Michele Reni, Margaret A. Tempero, Eileen Mary O'Reilly, Jordan Berlin, Hanno Riess, David Goldstein, Mingyu Li, Brian Lu, Stefano Ferrara, Philip Agop Philip; University of Michigan, Ann Arbor, MI; Vall d'Hebron University Hospital and Vall d'Hebron Institute of Oncology, Barcelona, Spain; University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; IRCCS Ospedale, San Raffaele Scientific Institute, Milan, Italy; School of Medicine, University of California, San Francisco, San Francisco, CA; Memorial Sloan Kettering Cancer Center, New York, NY; Vanderbilt-Ingram Cancer Center, Nashville, TN; Charité Universitätsmedizin, Berlin, Germany; Nelune Cancer Centre, Prince of Wales Hospital and University of New South Wales, Randwick, NSW, Australia; Celgene Corporation, Summit, NJ; Karmanos Cancer Center, Detroit, MI

Background: APACT did not meet the primary endpoint of independently assessed disease-free survival (DFS) with *nab*-P + G vs G; overall survival showed a nominal improvement. Here, we report recurrence patterns by resection status. **Methods:** A total of 866 treatment-naive patients (pts) with histologically confirmed pancreatic cancer, R0/R1 resection, CA19-9 $<$ 100 U/mL, and ECOG PS $\leq$ 1 received 6 cycles of *nab*-P + G or G on days 1, 8, and 15 Q28 days. Stratification: resection (R0/R1); lymph node status (LN+/−); geographic region. Disease recurrence was per investigator review of CT/MRI scans. **Results:** Of 571 (66%) pts with investigator-assessed DFS events (median follow up, 35.4 mo), 543 had radiographic progression with 764 recurrent lesions ($\geq$ 20 events: liver, 271; unspecified abdominal organ, 152; lung, 130; surgical bed, 70; mesenteric nodes, 54). Most pts (73%) had only abdominal, 61% had only distant, and 10% had only local recurrence (Table). Although more pts with R1 vs R0 status had recurrence (72% vs 60%), patterns were generally similar, and local recurrence was similarly low. **Conclusions:** Most recurrences in APACT were distant and in abdomen (liver). Recurrence patterns were generally similar in pts with R0 and R1 status, with low rates of local recurrence. These data may help make more informed pt management decisions. Additional data on patterns by baseline characteristics will be presented. Clinical trial information: NCT01964430. Research Sponsor: Celgene Corporation.

Parameter	R0 (n = 661)	R1 (n = 205)	Total (N = 866)
Scans, median (range), n	7 (1 - 18)	6 (1 - 17)	7 (1 - 18)
Pts with recurrence, n (%)	396 (60)	147 (72)	543 (63)
Region, n (%)[a,b]			
Abdomen	315 (80)	125 (85)	440 (81)
Abdomen only	285 (72)	113 (77)	398 (73)
Chest	100 (25)	32 (22)	132 (24)
Chest only	72 (18)	21 (14)	93 (17)
Pelvis	4 (1)	1 (1)	5 (1)
Pelvis only	3 (1)	0	3 (1)
Head/neck	2 (1)	1 (1)	3 (1)
Head/neck only	1 ($<$ 1)	1 (1)	2 ($<$ 1)
Unclear	5 (1)	1 (1)	6 (1)
Local/distant, n (%)[b]			
Distant only	244 (62)	87 (59)	331 (61)
Local only	44 (11)	13 (9)	57 (10)
Unknown only	73 (18)	32 (22)	105 (19)
Any combined	35 (9)	15 (10)	50 (9)
Time to recurrence, median, mo			
All	11.0	10.4	11.0
Distant only	8.6	10.7	8.9
Local only	16.7	11.4	14.5
Any combined	11.8	10.4	11.1

[a] A pt can have $>$ 1 region.

[b] % of pts with recurrence.

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705 Poster Session (Board #K16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Attenuated regimen of biweekly gemcitabine/nab-paclitaxel in patients aged > 65 years with advanced pancreatic cancer (APC).

Hasan Rehman, Jeffrey Chi, Nausheen Hakim, Shreya Prasad Goyal, Coral Olazagasti, Jyothi Jose, Linda Moriarty, Wasif M. Saif; Northwell Health Cancer Institute, Lake Success, NY

Background: Treatment with gemcitabine/nab-paclitaxel confers a survival benefit over gemcitabine monotherapy in APC. However, such treatment can be associated with significant toxicities especially in older patients and carries practical disadvantages related to a weekly schedule along with financial cost. We retrospectively analyzed patients > 65 years of age with APC who received a modified biweekly regimen of gemcitabine/nab-paclitaxel to evaluate efficacy and toxicity. **Methods:** Patients aged > 65 years with chemo-naive APC and ECOG PS < 2 were studied. Patients were treated with a modified regimen of gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 every 2 weeks on days 1 and 15 of a 28-day cycle. Patients were evaluated for progression-free survival (PFS) and overall survival (OS) with analyses performed using Kaplan-Meier method. Adverse events were recorded on the day of chemotherapy. CA19-9 was measured every cycle and restaging scans were performed every two cycles. **Results:** Seventy-three patients (median age: 73; range: 66 - 93) were treated with biweekly gemcitabine/nab-paclitaxel as first-line treatment. The median OS and PFS were 9.1 months and 4.8 months respectively. 66% of patients received growth factor support based on ASCO guidelines and no patients developed neutropenic fever. The incidence of grade > 3 toxicity for neutropenia, anemia, thrombocytopenia, and neurotoxicity were 2%, 7%, 3%, and 5% respectively. Dose reductions of gemcitabine/nab-paclitaxel were required in 10% and 4% patients respectively. **Conclusions:** In patients > 65 years of age with APC, a modified regimen of biweekly gemcitabine/nab-paclitaxel was found to be effective when compared with historical control from the MPACT study. This regimen allowed for less dose reductions, reduced healthcare costs from additional appointments, travel-related cost, as well as favorable side effect profile while maintaining efficacy. Though retrospective in nature, this study underlines the need for further investigation, particularly in elderly patients with APC and poor performance status. Better tolerability may allow for combination with a third agent, such as a targeted or immunotherapy. Research Sponsor: None.

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706 **Poster Session (Board #K17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Single institutional analysis of resectable pancreatic cancer.

Jeff Wiisanen, Patrick Navin, Moustafa El Khatib, William R Bamlet, Sean P. Cleary, Robert R. McWilliams, Mark J. Truty, Thanh P. Ho, Mindy L. Hartgers, Siddhartha Yadav, Amit Mahipal; Mayo Clinc, Rochester, MN; Mayo Clinic, Rochester, MN; Beaumont Health, Royal Oak, MI

Background: In recent years, there has been a shift towards neo-adjuvant treatment (NAT) of non-metastatic pancreas cancer in the hopes of improving negative margin rate, lymph node negativity, recurrence and survival. Even patients deemed resectable based on NCCN criteria are receiving NAT but data for these patients remains limited. This current study evaluated the outcomes of patients diagnosed with resectable pancreatic adenocarcinoma. **Methods:** Patients were retrospectively identified through the Mayo Clinic, Rochester SPORE pancreatic cancer registry as well as search of the electronic medical record via Advanced Cohort Explorer from May 2011 to 2016. Baseline demographics, tumor characteristics, treatments rendered, and outcomes were collected. Variables were analyzed for association with recurrence from time of surgery and survival from time of diagnosis using Kaplan-Meier curves and Cox proportional hazards regression. **Results:** A total of 520 patients with resectable pancreatic adenocarcinoma were identified. 72 patients received upfront chemotherapy with 44 (61.1%) proceeding to surgical resection. 62 patients received upfront chemotherapy followed by radiation with 33 (53.2%) proceeding to surgical resection. 12 patients received upfront radiation alone with 7 (58.3%) proceeding to surgical resection. 374 patients did not receive any NAT with 293 (78.3%) proceeding to surgical resection. In total, 377 (72.5%) went to resection. Median time to recurrence from surgery was 27.7 months vs. 21.7 months for NAT and upfront resection, respectively (HR 0.87, 95% CI 0.60-1.72, p = 0.48). Median overall survival from diagnosis for those receiving NAT was 40.6 months vs. 24.7 months for those receiving upfront resection (HR 0.62, 95% CI 0.41-0.92, p = 0.02). **Conclusions:** This study shows an approximate 16 month improvement in overall survival of patients receiving upfront NAT for resectable pancreatic adenocarcinoma. This might be due to a better selection of patients. It also highlights that not all patients with resectable cancer undergo resection. Further studies are warranted to identify why resectable patients are not proceeding to resection and which specific NAT approaches benefit patients the most. Research Sponsor: None.

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707 **Poster Session (Board #K18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The development of therapeutic cancer vaccine for pancreatic cancer.

Hiroki Yamaue, Motoki Miyazawa, Masahiro Katsuda, Manabu Kawai, Seiko Hirono, Ken-Ichi Okada, Yuji Kitahata, Masaki Ueno, Shinya Hayami; Second Department of Surgery, Wakayama Medical University, School of Medicine, Wakayama, Japan; Second Department of Surgery, Wakayama Medical University, Wakayama, Japan

Background: A previous phase II/III trial using a single cancer peptide vaccine derived from vascular endothelial growth factor receptor (VEGFR)2 for patients with advanced pancreatic cancer did not demonstrate the overall survival (OS) benefit (Yamaue et al. Cancer Sci 2015). However, for the next trial, we conducted a multicenter phase II study using multipeptide cocktail vaccine named OCV-C01 derived from a novel higher immunogenic antigen KIF20A, VEGFR1 and VEGFR2 combined with gemcitabine in postoperative adjuvant setting. **Methods:** A single-arm multicenter phase II study was performed on 30 patients with pancreatic ductal carcinoma who underwent pancreatectomy. At each 28-day treatment cycle, patients received weekly subcutaneous injection of OCV-C01 for 48 weeks, and gemcitabine was administered intravenously at 1,000 mg/m2 on days 1, 8, and 15 for 24 weeks. Patients were followed for 18 months. The primary endpoint was disease-free survival (DFS) and secondary endpoints included safety, OS and immunological assays on peptide-specific cytotoxic T lymphocyte (CTL) activity and KIF20A expression in resected pancreatic cancer. **Results:** The median DFS was 15.8 months (95% confidence interval (CI), 11.1-20.6), and the DFS rate at 18 months was 34.6% (95% CI, 18.3-51.6). The median OS was not reached and the OS rate at 18 months was 69.0% (95% CI, 48.8-82.5). The administration of OCV-C01 was well tolerated. In the per protocol set, there were significant differences in DFS between patients with and without KIF20A-specific CTL responses ($p = 0.027$), and between patients with and without KIF20A expression in resected pancreatic cancer tissues ($p = 0.014$). In addition, all four patients who underwent R0 resection with KIF20A expression had no recurrence of pancreatic cancer with KIF20A-specific CTL responses. **Conclusions:** OCV-C01 combined with gemcitabine was tolerable with a favorable median DFS of 15.8 months. In cancer vaccine treatment, positive expression of targeted antigen was essential, and postoperative adjuvant setting was more suitable than advanced state of cancer. Clinical trial information: UMIN000007991. Research Sponsor: Health and Labour Sciences Research Grants of the Ministry of Health Labour and Welfare in Japan.

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708 Poster Session (Board #K19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pancreatic ductal adenocarcinoma (PDAC), BRCA: Detailed analysis and outcomes of cohort from Memorial Sloan Kettering Cancer Center (MSK).

Parisa Momtaz, Catherine Anne O'Connor, Joanne F. Chou, Marinela Capanu, Kenneth H. Yu, Anna M. Varghese, Wungki Park, Alice Zervoudakis, Jia Li, Geoffrey Yuyat Ku, Diane Lauren Reidy, Marina Shcherba, James J. Harding, Zoe Goldberg, Ghassan K. Abou-Alfa, Zsofia Kinga Stadler, Erin E. Salo-Mullen, Eileen Mary O'Reilly; Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York City, NY; Memorial Sloan Kettering Cancer Center/Weill Cornell Medical College, New York, NY; Memorial Sloan Kettering Cancer Center, Department of Medicine, Gastrointestinal Oncology, New York, NY; Winthrop Oncology Hematology Associates, Mineola, NY; Yale School of Medicine, Yale University, New Haven, CT; Memorial Sloan Kettering Cancer Center, Rockville Centre, NY; Clinical Genetics Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Given encouraging responses of platinum agents and poly-ADP ribose polymerase inhibitors (PARPi) in *BRCA* mutated (mut) PDAC, we sought to identify patients (pts) with *BRCA* mut PDAC treated at MSKCC and to evaluate outcome. **Methods:** Institutional database at MSK with IRB approval was queried for PDAC germline (g) or somatic (s) *BRCA1/2* mut. Genomic profiling, clinicopathologic characteristics and outcomes were collected. Overall survival (OS) from diagnosis was estimated using Kaplan-Meier method. **Results:** n = 126 with *BRCA1/2* mut PDAC were identified between 1/2011-12/2018. n = 77 (61%) male and median age of 62 (range 24-85) at diagnosis. n = 78 (62%) had g*BRCA* mut (n = 21 *BRCA1*; n = 57 *BRCA2*). n = 54 (43%) had a family history of *BRCA*-related malignancies; 35pts (28%) with a personal history of other *BRCA*-associated malignancy. n = 66 (52%) AJCC stage IV; of these 43pts (65%) received platinum-based therapy with a partial response (PR) in 35pts (81%); median duration 7 months (m) (range 0.5-39m). n = 40 (32%) received $\geq$ 4 lines of therapy (range 1-6 lines). n = 44 (35%) received PARPi and 11% (n = 14) received immunotherapy. Median OS for the entire cohort 32.1 m (95% CI 23.9, 42.6). Median OS for stage I-II 49.9m (95% CI 38.5,-); stage III 43m (95% CI 33.9,-) and stage IV 19.1m (95% CI 19.1 16.1,25.8). We did not observe a statistically significant difference in OS between *BRCA1* vs *BRCA2* pts. **Conclusions:** *BRCA* mut PDAC constitutes a small but likely distinct biologic subgroup. Improved OS was notable relative to historical data, possibly due to the integration of platinum and PARPi therapy and possibly due to contribution from disease biology. Research Sponsor: None.

Stage at Diagnosis (n = 126)	
I-II	39 (31%)
III	21 (17%)
IV	66 (52%)
Age by decade g*BRCA* mut at Diagnosis (n = 78)	
30s	5 (6%)
40s	8 (10%)
50s	24 (31%)
60s	27 (35%)
70s-80s	14 (18%)
Surgery (n = 126)	
Yes	48 (38%)
No	78 (62%)
Adjuvant chemotherapy (n = 31)	
Platinum	13 (42%)
Non-platinum	18 (58%)
Response first-line platinum Stage IV (n = 43)	
CR	1 (2%)
PR	35 (81%)
SD	4 (9%)
POD	3 (7%)
Response to PARPi (at any line) (n = 44)	
PR	15 (34%)
SD	16 (36%)
POD	13 (30%)

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709 **Poster Session (Board #K20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase I study of olaparib in combination with capecitabine-based chemoradiation (CRT) in patients (pts) with locally advanced pancreatic cancer (LAPC).

T.R. Jeffry Evans, Martin McKinlay Eatock, Liz-Anne Lewsley, Caroline Kelly, Elaine McCartney, Aileen Duffton, Peter Houston, Claire Harrison, Colin Purcell, Miranda Ashton, Alanna Morton, Jill Graham, Anthony J. Chalmers, Fiona Thomson, Chantevy Pou, Alan Bilsland, Susie Cooke, David McIntosh, Derek B. Grose; University of Glasgow, Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom; Belfast City Hospital, Belfast, United Kingdom; University of Glasgow, Glasgow, United Kingdom; Cancer Research UK Clinical Trials Unit, Glasgow, United Kingdom; Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom; N Ireland Cancer Center, Belfast, United Kingdom; Northern Ireland Cancer Centre, Belfast, United Kingdom; Wolfson Wohl Cancer Research Centre, Institute of Cancer Sciences, University of Glasgow, Glasgow, United Kingdom

Background: Olaparib is a potent inhibitor of PARP-1, which has a critical role in signalling DNA single strand breaks (SSB) as part of the base excision repair pathway, and may have radiosensitizing effects due to impaired resolution of radiation induced SSB. We hypothesize that O may potentiate the effects of X-CRT in pts with LAPC. **Methods:** Eligible pts with LAPC, ECOG <1, tumor diameter $<$ 6cm, with stable disease (SD) or response after 12 weeks' induction chemotherapy, were treated with 1 of 4 escalating doses of O given bid po starting on day -3, and then in combination with X (830 mg/m2 bid) and radiation (50·4 Gy in 28 fractions) all administered Mon-Fri. Dose limiting toxicities (DLT) were determined on clinical and lab toxicity assessments (NCI-CTC AE v4.03) performed weekly from the start of O until completion of O plus X-CRT (i.e. 6 weeks). Dose escalation continued with a rolling-six design until the Maximum Tolerated Dose (MTD) was reached. Blood samples for PK analyses of O and PD measurement (inhibition of PARP activity) were collected on day -3 (O monotherapy) and during week 1 of O + X-CRT. **Results:** 18 pts, (9 m, 9 f, ECOG 0/1 [n=6/12]), age range 49-81 (median=70) years, with histologic (14) or cytologic (4) proven LAPC, had received induction chemotherapy with gemcitabine [GEM] (n=2), GEM + X (12), or FOLFIRINOX (3) with partial response (n=4) or stable disease (14). Pts received 50 (3), 100 (4), 150 (6), or 200 (5) mgs bid of O with X+CRT. DLTs were observed in 2 pts (both at 200mgs bid): 1 pt with grade 3 nausea (on optimal anti-emetics) and grade 3 fatigue, 1 pt with grade 3 anorexia. 6 pts were subsequently recruited at 150mgs bid with no DLTs. No pts had complete response, 2 pts had partial response (1 pt each at 100 and 150 mgs bid) and 1 pt (at 100 mgs bid) had progressive disease; the remaining 14 pts had SD. **Conclusions:** The recommended dose (RP2) of O is 150mgs bid when given in combination with X + CRT in LAPC. Recruitment of up to 12 pts with borderline operable LAPC at the RP2 is ongoing. PK analyses of O, PD studies (PARP inhibition – PBMCs; cytokeratin 18 – serum; γH2AX foci – hair follicles), and exploratory predictive marker studies (tumor – NGS; RNA exome sequencing) are ongoing. Clinical trial information: ISRCTN10361292. Research Sponsor: Cancer Research UKPharmaceutical/Biotech Company.

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710 Poster Session (Board #K21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Efficacy of SBP-101, in combination with gemcitabine and nab-paclitaxel, in first-line treatment of metastatic pancreatic ductal adenocarcinoma.

Dusan Kotasek, Adnan Nagrial, Sumit Lumba, Niall C. Tebbutt, Thomas J. George, Sheri Lynn Smith, Suzanne Gagnon, Michael T. Cullen, Michael J. Walker; University of Adelaide, Adelaide, SA, Australia; Blacktown Hospital Cancer and Haematology Centre, Blacktown, NSW, Australia; John Flynn Private Hospital Cancer and Haematology Centre, Tugun, QLD, Australia; Olivia Newton-John Cancer and Wellness Centre, Ãƒ‚Â‚Ã‚Â Heidelberg Repatriation Hospital, Heidelberg, Australia; University of Florida Health Cancer Center, Gainesville, FL; Courante Oncology, Excelsior, MN; Sun BioPharma Inc, Jamestown, RI; Sun BioPharma, Inc., Waconia, MN

Background: SBP-101, a polyamine metabolic inhibitor, inhibited growth in 6 human pancreatic ductal adenocarcinoma (PDA) cell lines and 3 murine xenograft tumor models of human PDA. SBP-101 monotherapy in heavily pre-treated PDA patients (> 2 prior regimens, N=4) showed a median survival of 5.9 months at the optimal dose level. Purpose: To assess the safety, tolerability, PK, and efficacy of SBP-101 in combination with gemcitabine (G) and nab-paclitaxel (A) in patients with previously untreated metastatic PDA. **Methods:** In a modified 3+3 dose escalation scheme, subcutaneous injections of SBP-101 were dosed at 0.2, 0.4 or 0.6 mg/kg days 1-5 of each 28-day cycle. G (1000 mg/m^2) and A (125 mg/m^2) were administered intravenously on Days 1, 8, and 15 of each cycle. Safety and tolerability were evaluated by clinical and laboratory assessments. PK was evaluated on day 1 of cycle 1. Efficacy was assessed by CA19-9 levels, objective response as assessed by RECIST criteria, progression-free survival (PFS) and overall survival (OS). **Results:** Fifteen patients have been enrolled in 3 cohorts (1: N=4, 2: N=7, 3: N=4) and received up to 6 cycles of treatment (7 subjects are ongoing in cohorts 2 and 3). The most common adverse events related to SBP-101 are fatigue (N=4), nausea (N=2) and injection site pain (N=2). There is no evidence of SBP-101-related bone marrow suppression or peripheral neuropathy. One patient in cohort 2 developed grade 3-4 reversible liver enzyme elevation. PK parameters in cohort 1 were below the limits of detection at most time points, but plasma C_{max} and AUC_{0-t} were measurable in cohorts 2 and 3. In those cohorts, CA19-9 levels decreased 76-95% in 7 of 8 evaluable subjects (1 additional subject TBD), with 5 patients achieving partial responses (4 ongoing) and 1 achieving stable disease. Median PFS and OS have not yet been reached. **Conclusions:** Preliminary results suggest SBP-101 is well tolerated when administered with G and A. Signals of efficacy support continued development of SBP-101 in combination first-line treatment for PDA. Clinical trial information: NCT03412799. Research Sponsor: Sun BioPharma, Inc.

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711 **Poster Session (Board #K22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Modified FOLFIRINOX versus sequential chemotherapy (FOLFIRI/FOLFOX) as second-line treatment for advanced pancreatic adenocarcinoma: A real-world analysis.

Shun Tezuka, Makoto Ueno, Satoshi Kobayashi, Manabu Morimoto, Shuhei Nagashima, Yusuke Sano, Hiroyuki Asama, Kuniyuki Kawano, Satoshi Tanaka, Taito Fukushima; Kanagawa Cancer Center, Yokohama, Japan; Department of Gastroenterology, Hepatobiliary and Pancreatic Medical Oncology Division, Kanagawa Cancer Center, Yokohama, Japan; Kanagawa Cancer Hospital, Yokohama, Japan

Background: Therapy options for second-line treatment of advanced pancreatic adenocarcinoma (PDAC) are limited and preferred regimens have not been established. This study compared the efficacy and safety of modified FOLFIRINOX (mFFX) and sequential chemotherapy (FOLFIRI/FOLFOX) as second-line treatment for advanced PDAC. **Methods:** This was a retrospective single-center analysis of all patients who received mFFX or sequential chemotherapy between December 2014 and May 2019 as second-line treatment for advanced PDAC. The sequential arm included all patients intended to be treated with sequential chemotherapy even if finished with either FOLFIRI or FOLFOX. For efficacy analysis, progression-free survival (PFS), overall survival (OS), and response rate (RR)of all the patients, excluding those with locally advanced pancreatic cancer (LAPC), were evaluated. For safety analysis, we evaluated the incidence of grade ≥3 adverse events in all the patients. **Results:** Seventy-four patients (mFFX 44; sequential 30) were included.The patients characteristics (mFFX/sequential) are as follows:median age 64/67 years, performance status (ECOG) 0 50%/53%, and LAPC 16%/13%. In contrast to sequential therapy, the mFFX group showed better OS and RR. However, there was no significant difference between mFFX and sequential therapy in PFS (median 4.4 [95% confidence interval (CI) 1.8-7.9] vs. 4.6 [95% CI 2.0-6.2] months; hazard ratio [HR] 0.88 [95% CI 0.51-1.56]; p = 0.657), OS (median 10.6 [95% CI 5.9-13.8] vs. 8.5 [95% CI 5.0-12.2] months; HR 0.71 [95% CI 0.37-1.41]; p = 0.318), and RR (8.1% vs. 3.8%; odds ratio 1.94 [95% CI 0.19-19.87]; p = 1.000). In the safety analysis, grade ≥3 rates of neutropenia, febrile neutropenia, and anorexia were 36.4%, 6.8%, and 16.0%, respectively, with mFFX and 0%, 0% and 3.3%, respectively, with sequential chemotherapy. **Conclusions:** Whereas certain trends were observed, there were no significant differences in efficacy between mFFX and sequential chemotherapy. Considering the incidence of grade ≥3 adverse events with mFFX, sequential chemotherapy could be considered as one of the second-line treatment options for advanced PDAC. Research Sponsor: None.

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712 **Poster Session (Board #L1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Phase Ib/II open-label, randomized evaluation of 2L atezolizumab (atezo) + BL-8040 versus control in MORPHEUS-pancreatic ductal adenocarcinoma (M-PDAC) and MORPHEUS-gastric cancer (M-GC).

Do-Youn Oh, Jaffer A. Ajani, Yung-Jue Bang, Hyun Cheol Chung, Jill Lacy, Jeeyun Lee, Teresa Macarulla, Gulam Abbas Manji, Eileen Mary O'Reilly, Simon Allen, Nedal Jaffer Abdulla Al-Sakaff, Hila Barak, Jilpa Patel, Jan Peter Pintoffl, Colby Shemesh, Wei Zhang, Xiaosong Zhang, Ian Chau; Seoul National University Hospital, Seoul, South Korea; The University of Texas-MD Anderson Cancer Center, Department of Gastrointestinal Medical Oncology, Houston, TX; Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, South Korea; Smilow Cancer Hospital, Yale University, New Haven, CT; Division of Hematology-Oncology, Department of Medicine, Samsung Medical Center, Seoul, South Korea; Vall d'Hebrón University Hospital and Vall d'Hebrón Institute of Oncology, Barcelona, Spain; Columbia University Medical Center and New York-Presbyterian Hospital, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY; Genentech, Inc., South San Francisco, CA; F. Hoffmann-La Roche Ltd., Basel, Switzerland; Roche Pharma AG, Grenzach-Wyhlen, Germany; The Royal Marsden Hospital NHS Foundation Trust, London and Surrey, United Kingdom

Background: The MORPHEUS platform comprises multiple Ph Ib/II trials to identify early efficacy signals and safety of treatment (tx) combinations across cancers. Due to the immune-mediated effects of BL-8040, a high-affinity antagonist for CXCR4, it was tested with atezo (anti-PD-L1) in pts with advanced/metastatic (m) PDAC and GC. **Methods:** In 2 separate randomized trials, pts with mPDAC or advanced/mGC who progressed on 1L chemo received either atezo + BL-8040 (BL-8040 1.25 mg/kg SC D1-5, then BL-8040 1.25 mg/kg SC TIW + atezo 1200 mg IV Q3W) or control tx (M-PDAC: mFOLFOX-6 or gemcitabine + *nab*-paclitaxel; M-GC: paclitaxel + ramucirumab). Primary endpoints were investigator-assessed ORR per RECIST 1.1 and safety. **Results:** Efficacy from evaluable pts followed for ≥18 wks in M-PDAC and ≥8 wks in M-GC is summarized in the table; 24-wk M-GC data will be presented. There were 15 safety-evaluable pts in each M-PDAC arm, as well as 13 in the atezo + BL-8040 and 12 in the control arm of M-GC. Gr 3-5 AEs were seen in 47% of pts on atezo + BL-8040 and 67% on control in M-PDAC, and 77% on atezo + BL-8040 and 67% on control in M-GC. Tx-related SAEs in M-PDAC occurred in 7% of pts on atezo + BL-8040 and 20% on control, and in M-GC, in 8% of pts on control. No Gr 5 AEs occurred in atezo + BL-8040 arms. Tx-related AEs led to 7% and 8% of pts discontinuing tx in the M-PDAC and M-GC control arms, respectively, and 15% discontinuing BL-8040 in M-GC due to Gr 3 injection-related reactions. Biomarker and PK data will be presented. **Conclusions:** Atezo + BL-8040 had limited efficacy for PDAC or GC. Tx-related AEs with atezo + BL-8040 were consistent with each agent's known safety profile. Clinical trial information: NCT03281369; NCT03193190. Research Sponsor: F. Hoffmann-La Roche, Ltd.

	M-PDAC (18-wk cutoff)		M-GC (8-wk cutoff)	
	Atezo + BL-8040	Control	Atezo + BL-8040	Control
Efficacy-evaluable pts (n)	14	15	13	12
Confirmed ORR, n (%; 95% CI)	0 (0; 0-23)	0 (0; 0-22)	2 (15; 2-45)	2 (17; 2-48)
CR, n (%; 95% CI)	0 (0; 0-23)	0 (0; 0-22)	0 (0; 0-25)	0 (0; 0-26)
PR, n (%; 95% CI)	0 (0; 0-23)	0 (0; 0-22)	2 (15; 2-45)	2 (17; 2-48)
SD, n (%; 95% CI)	1 (7; 0-34)	6 (40; 16-68)	1 (8; 0-36)	8 (67; 35-90)
Median PFS (95% CI), mo	1.6 (1.4, 1.9)	2.5 (1.4, 4.5)	Not mature	
Median OS (95% CI), mo	5.2 (3.3, 8.3)	6.8 (2.3, 9.7)	Not mature	

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713 **Poster Session (Board #L2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Phase Ia, first-in-human study of AbGn-107, a novel antibody-drug conjugate (ADC), in patients with gastric, colorectal, pancreatic, or biliary cancers.

Andrew H. Ko, Andrew L. Coveler, Benjamin L. Schlechter, Tanios S. Bekaii-Saab, Brian M. Wolpin, Jeffrey William Clark, Yi-Lin Cheng, Ting-Ying Cheng, Peter J. Langecker, Shih-Yao Lin; UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; Seattle Cancer Care Alliance/University of Washington, Seattle, WA; Beth Israel Deaconess Medical Center, Boston, MA; Mayo Clinic, Phoenix, AZ; Dana-Farber Cancer Institute, Boston, MA; Massachusetts General Hospital, Boston, MA; Abgenomics International, Los Altos, CA; Los Gatos Pharmaceuticals, Monte Sereno, CA; AbGenomics International, Taipei, Taiwan

Background: AbGn-107 is an ADC directed against AG-7 antigen, a Lewis A-like glycol-epitope expressed in 24-61% of gastric (G), colorectal (CRC), pancreatic (PDA), and biliary (BIL) cancers. Based on promising antitumor activity of AbGn-107 in both *in vitro* and *in vivo* preclinical studies, we performed a Phase Ia trial in pts with the aforementioned GI malignancies. **Methods:** Standard 3+3 dose escalation was used. Key eligibility criteria: locally adv or metastatic G, CRC, PDA, or BIL cancer, previously treated, ECOG PS 0-1; positive AG-7 expression was not required. Two dosing intervals were tested: AbGn-107 administered i.v. Q4 weeks (at doses ranging from 0.1-1.2 mg/kg) and Q2 weeks (at doses from 0.8-1.0 mg/kg). DLTs were based on grade 3/4 hematologic and non-heme AEs occurring during the initial 4-week rx window. Pts were treated until dz progression or unacceptable toxicity, with tumor assessments Q8 weeks. 1o objectives: safety and MTD; 2o objectives: PK, immunogenicity, and efficacy defined by ORR (RECIST 1.1). **Results:** 35 patients were enrolled across 6 dose levels (median age 61.5 yo (range 40 – 81); G (0)/CRC (12)/PDA (20)/BIL (3); median # lines of prior rx = 3 (range 1-7). Safety: 5 pts experienced Grade 3 or 4 neutropenia, all at higher dose levels, with 1 episode of febrile neutropenia. Other frequent drug-related AEs, mostly grade 1/2, inc. fatigue (29%), nausea (20%), and diarrhea (14%). DLTs include grade 4 CK elevation (n = 1) at 0.8 mg/kg Q4W and grade 3 arthralgias (n = 1) at 1.2 mg/kg Q4W. MTD was not reached at either 1.2 mg/kg Q4W or 0.8 mg/kg Q2W; the 1.0 mg/kg Q2W cohort will complete enrollment in Oct 2019. Efficacy: Median duration of treatment = 56 days (range, 8 – 225 days); best response observed to date is stable dz lasting $>$ 6 months at 0.8 mg/kg Q4W and Q2W cohorts (n = 1 each). **Conclusions:** Overall, AbGn-107 appears well-tolerated with encouraging prelim signs of efficacy (prolonged dz control) in non-biomarker selected pts with advanced GI cancers. Pre-screening for high AG-7 expression is underway for subjects with G, CRC, PDA, and BIL cancers for the cohort expansion phase of this study, which will be open across multiple sites in U.S. and Taiwan. Clinical trial information: NCT02908451. Research Sponsor: Abgenomics.

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714 **Poster Session (Board #L3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The role of immunotherapy on the survival of pancreatic cancer patients.

Saber Ali Amin, Michael Baine, Jane L. Meza, Chi Lin; University of Nebraska Medical Center, Omaha, NE

Background: Immunotherapy has revolutionized the treatment landscape of many malignancies, but its therapeutic role in pancreatic cancer (PC) remains unclear. The objective of this study is to investigate the impact of immunotherapy on the overall survival of PC patients stratified by definitive surgery of the pancreas using the National Cancer Database (NCDB). **Methods:** Patients with pancreatic adenocarcinoma were identified from NCDB. Cox proportional hazard models were employed to assess the impact of immunotherapy on survival after being stratified by surgery and adjusted for age of diagnosis, race, sex, place of living, income, education, treatment facility type, insurance status, year of diagnosis, and treatment types such as chemotherapy and radiation therapy. **Results:** Of 252,280 patients who were analyzed, 214,632 (85.08%) had definitive surgery, and 37,638 (14.92%) did not get definitive surgery of the pancreas. In the surgery group, 351 (0.93%) received immunotherapy and 37,287 (99.07%) did not while in the no surgery group, 838 (0.39%) received immunotherapy and 213,804 (99.61%) did not. In the multivariable analysis, patients who received immunotherapy had significantly improved OS both in the no surgery group (HR: 0.886, CI: 0.655-0.714; $P < 0.0001$) and in the surgery group (HR: 0.846, CI: 0.738-0.971; $P < 0.0001$) compared to patients who did not receive immunotherapy. Treatment with chemotherapy plus immunotherapy was associated with significantly improved OS (HR: 0.871, CI: 0.784-0.967; $P < 0.009$) compared to chemotherapy without immunotherapy in the no surgery group, while it was not significant in the surgery group. Chemoradiation plus immunotherapy was associated with significantly improved OS (HR: 0.787, CI: 0.684-0.906; $P < 0.0009$) in the no surgery group and (HR: 0.799, CI: 0.681-0.938) in the surgery group compared to chemoradiation alone. **Conclusions:** In this study, the addition of immunotherapy to chemoradiation therapy was associated with significantly improved OS in PC patients with or without definitive surgery. The study warrants further future clinical trials of immunotherapy in PC. Research Sponsor: None.

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715 **Poster Session (Board #L4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Role of para-aortic lymph node sampling in pancreatic cancer surgery.

Yusuke Kazami, Hiromichi Ito, Yoshihiro Ono, Takafumi Sato, Yosuke Inoue, Yu Takahashi; Department of Digestive and HBP Surgery, Cancer Institute Hospital, Japanese Foundation for Cancer Research, Tokyo, Japan; Japanese Foundation for Cancer Research, Tokyo, Japan

Background: In the management of pancreatic cancer, para-aortic lymph node (PALN) metastasis is regarded as distant metastasis, and systemic treatment is recommended. However, imaging study is not perfect to detect all PALN metastasis and the management of intraoperatively discovered PALN has been controversial. We hypothesized that sampling of PALNs on exploration could allow us to avoid pancreatic resection for patients who would not benefit. In this study, we evaluated the incidence and the effect on the long-term outcomes for patients with potentially resectable pancreatic cancer. **Methods:** Three hundred and ninety-two patients who had PALNs sampled upon potentially resectable pancreatic cancer from 2005 through 2014 were included in the study. All patients were appropriately staged preoperatively with CT/MRI and those with suspected PALN metastasis were not considered as candidates for resection. The patients whose resections were aborted because of liver metastasis or peritoneal dissemination discovered on exploration, or those who died within 30-days after the operation were not included. Evaluated outcomes were incidence of PALN metastasis and their recurrence-free and overall survivals (RFS, OS). **Results:** The patients' median age was 74 years, and 58.6% was man. 67.8% had tumors at pancreatic head. Preoperative chemotherapy was given only on 16 patients (3.2%). Among 392 patients with PALNs sampled, 53 (13.5%) patients had metastasis; Resection was completed on 40 patients and resection was aborted on the rest. Among patients who underwent pancreatic resection, median RFS and OS were 10 and 12 months for patients with PALN metastasis, compared to 17 and 26 months for those without PALN metastasis ($p < 0.001$ for RFS and $p < 0.001$ for OS). The 5-year-OS rates for patients with/without PALN metastasis were 5.9% and 25% ($p < 0.001$). Among 53 patients with PALN metastasis, OS were not different between the patients who underwent resection and those who did not (median 13 months vs 17 months, $p = 0.06$), and there were no recurrence-free survivors. **Conclusions:** PALN sampling and evaluation before committing to resection is useful to identify the patients who can unlikely benefit and to avoid unnecessary morbid operation. Research Sponsor: None.

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716 **Poster Session (Board #L5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase I/II study combining a TMZ-CD40L/4-1BBL-armed oncolytic adenovirus and nab-paclitaxel/gemcitabine chemotherapy in advanced pancreatic cancer: An interim report.

Benjamin Leon Musher, Brandon George Smaglo, Wasif Abidi, Mohamed Othman, Kalpesh Patel, James Jing, Nir Stanietzky, Jinyu (Jim) Lu, Amanda Brisco, Jessica Wenthe, Benjamin Brenner, Emma Eriksson, Ann M. Leen, Susan G. Hilsenbeck, Gustav J. Ullenhag, Eric Keith Rowinsky, Bambj Grilley, Angelica Sara Ingrid Loskog; Baylor College of Medicine, Houston, TX; Georgetown Lombardi Comprehensive Cancer Center, Washington, DC; Uppsala University, Uppsala, Sweden; Smith Breast Center At BCM, Houston, TX; Akademiska Sjukhus, Uppsala, Sweden; Rgenix, Inc., New York, NY

Background: Pancreatic ductal adenocarcinoma (PDAC) has been highly resistant to immunotherapeutics to date. LOAd703, an oncolytic adenovirus with transgenes encoding TMZ-CD40L and 4-1BBL, has been shown to lyse tumor cells selectively, induce anti-tumor cytotoxic T-cell responses, reduce myeloid-derived suppressor cell (MDSC) infiltration, and induce tumor regression in preclinical studies. **Methods:** In this phase I/II trial, patients with unresectable or metastatic PDAC are treated with LOAd703 intratumoral injections and standard nab-paclitaxel/gemcitabine (nab-P/G) chemotherapy. Starting on cycle 1 day 15 of nab-P/G, LOAd703 is injected with image guidance into the primary pancreatic tumor or a metastasis every 2 weeks for 6 injections. In the event of sustained tumor control, subjects are eligible to receive 6 more injections. Three dose levels of LOAd703 are being investigated using a BOIN dose escalation design. Primary endpoints are safety and feasibility. Secondary endpoints include response rate and overall survival. **Results:** To date, 13 subjects are evaluable for safety and feasibility. Three patients were treated at dose 1 (5x10e10 VP), 4 subjects at dose 2 (1x10e11 VP), and 6 subjects at dose 3 (5x10e11 VP). The most common adverse events (AEs) attributed to LOAd703 have been fever, chills, nausea, and increased transaminases. AEs have been transient and grade 1-2, with the exception of a grade 3 transaminase elevation in 1 subject receiving dose 3 (the only dose-limiting toxicity observed thus far). During protocol treatment, circulating MDSCs decreased in 8/13 subjects while effector memory T-cells increased in 10/13. ELISPOT analyses showed a rise in tumor antigen-specific T-cells in 10/13 subjects. At the lowest dose level, best response was stable disease, and 6/10 patients who received higher LOAd703 doses have had partial responses. Only 1 patient has had progressive disease as best response. **Conclusions:** Adding LOAd703 to nab-P/G has been safe and feasible. Treatment-emergent immune responses have been demonstrated in most subjects, with a notable proportion having objective anti-tumor responses. Clinical trial information: NCT02705196. Research Sponsor: LOKON pharma, Other Foundation.

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717 **Poster Session (Board #L6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Efficacy and safety of nab-paclitaxel plus S-1(nab-P/S-1) versus nab-paclitaxel plus gemcitabine (nab-P/Gem) for first-line chemotherapy in advanced pancreatic ductal adenocarcinoma (aPDAC): A randomized study.

Yuan Zong, Zhi Peng, Xicheng Wang, Lin Shen, Jun Zhou; Department of Gastrointestinal Oncology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education/Beijing), Peking University Cancer Hospital and Institute, Beijing, China; Department of Gastrointestinal Oncology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education), Peking University Cancer Hospital and Institute, Beijing, China; Department of Gastrointestinal Oncology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education), Peking University Cancer Hospital & Institute, Beijing, China; Beijing Cancer Hospital and Institute, Beijing, China

Background: Nab-P/Gem significantly improved survival compared with gem in patients (pts) with metastatic PDAC, but the ORR was limited to 23% with increased myelosuppression. Two phase II trials demonstrated high ORR of 50.0-53.1% with nab-P/S-1 and showed less hematologic toxicity. **Methods:** A randomized (1:1) phase II trial was conducted. Eligibility required treatment-naïve pts with unresectable PDAC. Pts received nab-P 125mg/m^2on day 1 + S-1 80-120mg orally per day on day 1-7 every 2 weeks or nab-P 125mg/m^2+ Gem 1000mg/m^2 on days 1,8 every 3 weeks. With an increase of ORR from 25% to 50%, 100 pts were required for 90% power at a two-sided significance level of 0.05. We enrolled 40 pts for a pilot study. Primary endpoints were ORR and 6-month PFS rate. Secondary endpoints were ORR of primary lesion, DCR, PFS, OS and safety. **Results:** 40 pts were enrolled between 06/2018 and 06/2019, including locally advanced (27.5%) and metastatic (72.5%) PDACs. 42.5% were male and the median age was 61 (range, 36-75) years old. The median duration of treatment was 2.3 months in nab-P/S-1 (n = 20) and 2.7 months in nab-P/Gem (n = 20). In the intention-to-treat (ITT) population, the ORR and DCR were 35.0% vs 25.0% (*P*= 0.49) and 70.0% vs 70.0%, respectively.The ORR of primary lesion was 30.0% vs 25.0% (*P*= 0.72). In the evaluable pts (nab-P/S-1 n = 18, nab-P/Gem n = 18), the ORR, DCR and the ORR of primary lesion were 38.9% vs 27.8%, 77.8% vs 77.8% and 35.3% vs 29.4%, respectively.With the median follow-up of 5.0 (range 0.3-11.4) months, the median PFS and 6-month PFS rate was 6.3 vs 5.7 months and 56.1% vs 36.2%(*P*= 0.61) for nab-P/S-1 and nab-P/Gem, respectively. The median OS have not reached. Grade 3/4 toxicities occurred in 30.0% nab-P/S-1 and 30.0% nab-P/Gem: leukopenia/neutropenia(15.0% vs 25.0%), febrile neutropenia (0 vs 5.0%), rash (0 vs 5.0%) and diarrhea (10.0% vs 0). **Conclusions:** Compared with nab-P/Gem, nab-P/S-1 had higher ORR, ORR of primary lesion and longer PFS without significant difference. Nab-P/S-1 developed a trend towards less hematologic toxicity. Follow up for survival is ongoing. Clinical trial information: 03636308. Research Sponsor: None.

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718 **Poster Session (Board #L7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Neoadjuvant gemcitabine and nab-paclitaxel followed by concurrent capecitabine/radiation in borderline resectable (BR) pancreatic cancer: A single-institution experience.

Niraj K. Gupta, Kirpal Singh, Murad Aburajab, Vinay Mathavan, Mazen Al-Satie, Timothy Glass, Christopher A. Leagre, Michael Rowe, Thomas Tigges, Robert H. Liebross, Chad Davis, Sweta Tandra, Vas Tumati, Jianmin Tian, Brandon Martinez, Joshua Dowell, Kristen Kay Schmidt, Vincent Flanders, St Vincent Cancer Care; St. Vincent Cancer Care, Carmel, IN; St. Vincent Hospital, Indianapolis, IN; St Vincent Cancer Care, Indianapolis, IN; St Vincent Cancer care, Indianapolis, IN; St Vincent Cancer Care, Carmel, IN; Cancer Care Grp, Carmel, IN; St Vincent Care, Indianapolis, IN

Background: Neo-adjuvant therapy is becoming a preferred approach in the management of BR pancreatic cancer patients. There is no consensus on an ideal treatment regimen. We report our experience with a combination of nab-Paclitaxel/Gemcitabine followed by concurrent Capecitabine and radiation treatments in BR pancreatic cancer patients. **Methods:** A prospectively maintained database of patients with BR pancreatic cancer undergoing neo-adjuvant treatments at our cancer center between 01/2013- 11/2017 was reviewed. Patients were treated with Gemcitabine(1gm/m2) and nab-paclitaxel (125mg/m2) given on D1-8-15 every 28 days. Pts. were re-assessed after two cycles and the responding pts received two additional cycles. Pts. who continued to respond after four cycles were treated with capecitabine (825mg/m2) and radiation treatments(50.4Gy). **Results:** A total of 32 patients with PS 0/1 were treated. Median age was 59 yrs (42-76), 19 Males and 13 females. After 2 cycles of Gem/nab-paclitaxel, none of the pts. had progressive disease. Thirty patients (93%) were able to complete all four cycles of Gem/nab-paclitaxel. Twenty nine (90%) received capecitabine and radiation treatments. Imaging to assess response was done 4 weeks after completing radiation and the results were were; 2 CR, 11 PR, 14 SD, 2 PD. Surgery was performed 6-8 weeks after completing radiation. Twenty six (81%) underwent planned resection, 2 had PD, 3 declined surgery and 1 had significant decline in PS. Twenty two out of Twenty six patients undergoing surgery had a R0 resection (80%). Grade-III/IV toxicities with the neo-adjuvant treatments were seen in 41% and 7 % of the pts., respectively. No thirty day post-op mortality, pancreatic leaks or re-operations were observed. The median PFS among all patients was 11.7 months, 2 yr OS 49% and median OS was 27.6 months, compared to 23.4 months, 65% and median OS not reached, in patients who underwent surgical resection. **Conclusions:** Nab-Paclitaxel and Gemcitabine followed by Capecitabine and radiation is an effective neo-adjuvant treatment strategy with acceptable toxicity-profile for patients with BR pancreatic cancer. Research Sponsor: None.

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719 **Poster Session (Board #L8), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A study of preoperative FOLFIRINOX in potentially curable pancreatic cancer.

Hamed Javan, Tamim Niazi, Tsafrir Vanounou, Jean-Sebastien Pelletier, Richard Dalfen, Magali Lecavalier-Barsoum, Gerald Batist, Petr Kavan; McGill University, Montréal, QC, Canada; Jewish General Hospital, McGill University, Montreal, QC, Canada; Jewish General Hospital, Montreal, QC, Canada; Segal Cancer Centre-Jewish General Hospital, McGill University, Montreal, QC, Canada

Background: Although Folfirinox (FFX) prolonged survival in metastatic and adjuvant setting, the role of preoperative FFX is still controversial. Our aim is to evaluate how surgery after neoadjuvant FFX with or without radiotherapy (RT) affects the clinical outcome in these patients. **Methods:** This is a single arm, open-label, phase 2 prospective study. Based on resectability criteria (NCCN-V.1.2017), patients prospectively were divided into 3 groups of resectable, borderline resectable (BR), locally advanced (LA). Patients received 6 cycles of preoperative FFX. Patients with adequate response, underwent resection. Continuation of chemotherapy or radiation was given to the patients who were deemed unresectable after 6 cycles. Primary objective is time to progression (TTP), and secondary objectives are safety, R0/R1 resection rate, response rate (RR) and overall survival (OS). **Results:** 20 consecutive patients with pancreatic adenocarcinoma enrolled. The frequency of each group was 4, 8, 8 patients, respectively. Median age was 64 years old (range, 49-78). 45% of patients had primary tumor in head or uncinate process. 25% of cases presented with normal CA 19-9 value. 85% (17/20) of patients completed the preoperative treatment. Folfirinox was given within median of 11.5 weeks (range, 8-17) and median of 6 cycles (range, 1-7). Median relative dose intensity (RDI) was 85.89%. Grade III-IV (G3+4) adverse event (CTCAE-4.03) observed in 47.4% (9/19). RR (RECIST) was 89% (16/18). Best response was partial response (PR) and stable disease (SD) with 22.2% (4/18) and 66.7% (12/18). Resection rate was 64.3% (9/14, 1 case scheduled for resection). R0 and negative lymph node (LN) achieved in 87.50% (7/8) and 62.50% (5/8) of patients. Complete pathological response (cPR) was seen in one patient 12.5% (1/8) who preoperatively reported as SD. Patients TTP and OS will be reported during the meeting. **Conclusions:** Preoperative FFX was associated with high clinical and pathological response rate translating in high resection rate in majority of BRPC and LAPC, and appears to be a safe treatment strategy. Patients received higher FFX dose intensity than it was reported in adjuvant setting. However, these results need to be assessed in a randomized trial. Clinical trial information: NCT03167112. Research Sponsor: None.

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720 **Poster Session (Board #L9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Efficacy and safety of mFOLFIRINOX in patients with borderline resectable and locally advanced unresectable pancreatic cancer: Intention-to-treat population analysis.

Inhwan Hwang, Changhoon Yoo, Kyu-Pyo Kim, Jae Ho Byun, Jae Ho Jeong, Heung-Moon Chang, Baek-Yeol Ryoo; Asan Medical Center, University of Ulsan, Seoul, South Korea; Department of Oncology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Department of Radiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

Background: Borderline resectable pancreatic cancer (BRPC) and locally advanced unresectable pancreatic cancer (LAUPC) are heterogeneous disease entity with various prognosis. Based on the phase III PRODIGE trial, (m)FOLFIRINOX has been widely used for the management of patients with BRPC and LAUPC. Considering the lack of large phase 3 trial of (m)FOLFIRINOX for BRPC and LAUPC, real-life evidences of (m)FOLFIRINOX are needed. **Methods:** In this retrospective analysis, 199 patients who received at least one dose of (m)FOLFIRINOX between February 2013 and January 2017 were included. Endpoints of this study were objective response rates (ORR), surgical resection rate, progression-free survival (PFS) and overall survival (OS). **Results:** Median age was 60 years (range, 33-79) and 62.3% of patients were male. Pancreas head (n=112, 56.3%) was the most common primary tumor site, followed by body (n=42, 21.1%) and multifocal (n=34, 17.1%). By an independent radiology review, patients were classified to BRPC (n=75, 37.7%) and LAUPC (n=124, 62.3%). With median 40.3 months (95% CI, 36.7-43.8) of follow-up duration in surviving patients, ORR was 26.6% (n=53), median PFS and OS were 10.6 months (95% CI, 9.5-11.7) and 17.1 months (95% CI, 13.2-20.9), respectively. There was no difference in PFS and OS between BRPC and LAUPC (median PFS, 11.1 months [95% CI, 8.8-13.5] vs. 10.1 months [95% CI, 8.4-11.8], p=0.47); (median OS, 18.4 months [95% CI, 16.1-20.8] vs. 17.1 months [95% CI, 13.2-20.9], p=0.50). Curative-intent surgery (R0 and R1) was done in 63 patients (33.2%, 49 for R0 and 14 for R1) after treatment with (m)FOLFIRINOX. Resection rates were 58.2% in BRPC patients and 19.4% in LAUPC patients ($p<0.001$). In patients who underwent curative-intent surgery, median disease-free survival since surgery was 10.4 months (95% CI, 8.3-12.5) and there was no difference according to the baseline disease extent (BRPC vs. LAUPC): 10.0 months (95% CI, 7.5-12.5) vs. 12.0 months (95% CI, 3.7-20.3), p=0.37. **Conclusions:** (m)FOLFIRINOX is effective therapy for BRPC and LAUPC patients. Significant proportion of patients could receive curative-intent surgery. Research Sponsor: None.

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721 **Poster Session (Board #L10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Comparing total cost of care for Medicare FFS patients with pancreatic cancer by chemotherapy regimen.

Jared Hirsch, Gabriela Dieguez, Paul Cockrum; Milliman, Inc., New York, NY; Ipsen Biopharmaceuticals, Cambridge, MA

Background: To analyze total cost of care for patients with pancreatic cancer by FDA-Approved/NCCN Category 1 regimen. **Methods:** Cancer episodes were identified using a methodology similar to the Medicare Oncology Care Model (OCM) in the 2014-2016 100% Medicare Limited Data Set (LDS) claims files. Index dates were established for chemotherapy claims that did not occur within 6 months of another chemotherapy claim for all Medicare fee-for-service beneficiaries. Cancer episodes were defined as the 6-month period following an index date. Each episode was assigned a cancer type based on the plurality of cancer ICD 9/10 diagnosis codes that occurred on chemotherapy claims in the episode. Episode costs were calculated from claim paid amounts, and DME and other Part B spending was estimated using episodes created in the 5% Medicare LDS files using the same methodology. We analyzed total episode costs for three FDA-Approved/NCCN Category 1 pancreatic cancer regimens: gemcitabine plus nab-paclitaxel (gem-nab), FOLFIRINOX (FFX), and liposomal irinotecan (nal-IRI). **Results:** We identified 110,618 cancer episodes in 2016, of which 4,018 were for pancreatic cancer (average age at index: 71.3 years). Pancreatic cancer patients in these episodes were treated with gem-nab (45% of episodes), FFX (14%), and nal-IRI (4%). The main cost drivers across all regimens were Part B chemotherapy, other Part B drugs and inpatient services. Episode costs were $41,749, $42,086, and $45,851 for patients receiving gem-nab, FFX, and nal-IRI, respectively. Part B chemotherapy costs were $13,065 (gem-nab), $3,095 (FFX), and $18,472 (nal-IRI); other Part B drug costs were $7,343 (gem-nab), $17,013 (FFX), and $10,479 (nal-IRI); and inpatient service costs were $9,044 (gem-nab), $9,069 (FFX), and $5,108 (nal-IRI). **Conclusions:** Total episode costs for pancreatic cancer care were similar among three FDA-Approved/NCCN Category 1 regimens, but the components of cost varied. Episodes with Nal-IRI had the largest Part B chemotherapy costs and the lowest inpatient service costs. Episodes with FFX and gem-nab had similar inpatient service costs, which were higher than episodes with nal-IRI. Episodes with FFX had the highest other Part B drug costs. Research Sponsor: Ipsen Biopharmaceuticals Inc.

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722 **Poster Session (Board #L11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The impact of pancreatic cancer resection in the era of effective systemic treatment.

Yaacov Richard Lawrence, Ofer Margalit, Galia Jacobson, Liat Hamer, Uri Amit, Naama Halpern, Einat Shacham Shmueli, Ben Boursi, Yuri Goldes, Daniel Azoulay, Talia Golan, Zvi Symon; Sheba Medical Center, Ramat Gan, Israel; Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Chaim Sheba Medical Center, Ramat Gan, Israel; The Oncology Institute, Sheba Medical Center at Tel-Hashomer, Tel Aviv University, Tel Aviv, Israel

Background: Surgical resection is the only curative modality in pancreatic cancer, yet the vast majority of patients undergoing surgery succumb of their disease. No randomized studies have been performed to assess the survival impact of the procedure. We hypothesized that in the era of effective systemic treatments, the survival advantage of surgical resection would be lessened. **Methods:** A meta-analysis of published phase III clinical trials in pancreatic cancer in both the post resection adjuvant setting and the locally advanced metastatic setting, based upon indirect aggregate data. Data was stratified based upon the systemic agents used. Patients from trials arms for which there were not complementary data sets with/without surgical resection were excluded. Primary endpoint was 3 year overall survival (OS). **Results:** Trials were published between 1997 and 2018. A total of 2722 patients were included in the data analysis, of whom 1645 underwent tumor resection and 814 were metastatic. Median follow-up was 40 months. Analyses were performed of five systemic options with / without tumor resection. Across the trials averaged 3 yr OS was 0%, 0.8%, 0%, and 3.8% for 5FU, gemcitabine, gemcitabine + capecitabine, & FOLFIRINOX respectively; and 18.1%, 30.0%, 37.9%, 42.5%, and 62.5% for the same systemic treatments delivered following surgical resection. Hence the additive impact of surgical resection on absolute 3 yr OS was only 18.1% in the absence of systemic treatment, but 30.0%, 37.1%, 42.5% and 58.8% in the presence of 5FU, gemcitabine, gemcitabine + capecitabine, FOLFIRINOX respectively. **Conclusions:** Within the limitations of this analysis, it appears that our hypothesis was incorrect, and that the opposite is true. The introduction of effective systemic therapies has greatly increased the impact of pancreatic surgery on long-term survival in pancreatic cancer. Consequently, every effort should be made to bring patients to curative resection. Research Sponsor: None.

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723 **Poster Session (Board #L12), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Phase II trial of BPM31510-IV plus gemcitabine in advanced pancreatic ductal adenocarcinomas (PDAC).

Madappa N. Kundranda, David Propper, Paul S. Ritch, James Strauss, Manuel Hidalgo, Roopinder Gillmore, Rangaprasad Sarangarajan, Niven R. Narain, Michael A. Kiebish, Leonardo O Rodrigues, Elder Granger, Ramesh Ramanathan, Angela Tatiana Alistar, Lynne A. Bui, Sant P. Chawla, Anna A. Niewiarowska; Banner MD Anderson Cancer Center, Gilbert, AZ; St Bartholomew's Hospital, London, United Kingdom; Medical College of Wisconsin, Milwaukee, WI; Mary Crowley Cancer Research Center, Dallas, TX; Weill Cornell Medicine, New York, NY; Royal Free, London, United Kingdom; BERG, LLC, Framingham, MA; Mayo Clinic, Phoenix, AZ; Atlantic Health System, Morristown, NJ; Global Cancer Research Institute, Inc., San Jose, CA; Sarcoma Oncology Research Center, Santa Monica, CA; Vita Medical Associates, Fountain Hill, PA

Background: BPM31510-IV is an Ubidecarenone (CoQ10) drug-lipid conjugate nanodispersion targeting metabolic machinery in cancer, shifting bioenergetics from lactate dependency towards mitochondrial OxPhos to generate ROS and activate apoptosis. An MTD of BPM31510-IV in combination with gemcitabine was established at 110mg/kg in a Phase I clinical trial, which determined the dose for the Phase 2 investigation. **Methods:** Eligible patients (aged ≥ 18 y) with relapsed/refractory PDAC to standard treatment (ST) and met inclusion/exclusion criteria were recruited. Patients received 110mg/kg IV BPM31510 in combination with gemcitabine in a 144-hour infusion. Tumor response was evaluated at week 10 and then every 8 weeks. Study endpoints assessed were Overall Response Rate (ORR), Overall Survival (OS), Progression-Free Survival (PFS), Time to Progression (TTP), Tumor Response using Adaptive Molecular Responses (multi-omic molecular profiling), changes in CA 19-9 levels and patient reported Quality of Life (QOL) using the validated FACT-HEP PRO. A comprehensive multi-omic profiling for identification of biomarkers for patient stratification was explored. **Results:** Of the 35 patients enrolled to receive therapy, 18 patients met criteria of an adequately treated cohort (ATC- received BPM31510-IV + gemcitabine for 30 days over 2 cycles and had a RECIST 1.1 evaluation) while remaining (n = 17) had progressive disease (PD). Half of the ATC population (n = 9/18, 50%) achieved best ORR of stable disease (SD); 10/18 (55 %) demonstrated SD as best response at target lesions and 8/18 demonstrated SD at end of Cycle 2. The mTTP was 121 days (70 – 147, 95% CI); PFS 118 days (70 – 131, 95% CI) and OS 218 days (131 – 228, 95% CI), respectively. Overall, BPM31510-IV was well tolerated; the most common AE's were GI related. **Conclusions:** The efficacy signal observed in this heavily pretreated population in addition to the toxicity profile warrants further clinical investigation of BPM31510-IV + gemcitabine in advanced PDAC. Clinical trial information: NCT02650804. Research Sponsor: BERG LLC.

Parameters	BPM31510 + Gemcitabine (N = 18)
Age (years) - Median (Range)	64.5 (38 - 79)
Sex - n (%)	
Female: Male	7 (38.9): 11 (61.1)
ECOG PS - n (%)	
0	10 (55.5)
1	8 (44.4)
No. of Prior Therapies - n (%)	
1	5 (27.7)
≥2	13 (72.2)

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724 **Poster Session (Board #L13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Randomized phase II trial of chemoradiotherapy with S-1 versus combination chemotherapy with gemcitabine and S-1 as neoadjuvant treatment for resectable pancreatic cancer (JASPAC 04).

Hirochika Toyama, Teiichi Sugiura, Akira Fukutomi, Hirofumi Asakura, Yuriko Takeda, Kouji Yamamoto, Satoshi Hirano, Sohei Satoi, Ippei Matsumoto, Shinichiro Takahashi, Soichiro Morinaga, Makoto Yoshida, Yasunaru Sakuma, Hidetaka Iwamoto, Yasuhiro Shimizu, Katsuhiko Uesaka; Division of Hepato-Biliary-Pancreatic Surgery, Kobe University Graduate School of Medicine, Kobe, Japan; Division of Hepato-Biliary-Pancreatic Surgery, Shizuoka Cancer Center, Shizuoka, Japan; Division of Gastrointestinal Oncology, Shizuoka Cancer Center, Shizuoka, Japan; Radiation and Proton Therapy Center, Shizuoka Cancer Center, Shizuoka, Japan; Department of Biostatistics Yokohama City University School of Medicine, Yokohama, Japan; Department of Gastroenterological Surgery II, Faculty of Medicine, Hokkaido University, Sapporo, Japan; Department of Surgery, Kansai Medical University, Hirakata, Japan; Department of Surgery, Kindai University, Osaka-Sayama, Japan; National Cancer Center Hospital East, Kashiwa, Japan; Kanagawa Cancer Center, Yokohama, Japan; Department of Medical Oncology, Sapporo Medical University, Sapporo, Japan; Department of Surgery, Jichi Medical University, Tochigi-Shimotsuke, Japan; Division of Metabolism and Biosystemic Science, Department of Medicine, Asahikawa Medical University, Asahikawa, Japan; Department of Gastroenterological Surgery, Aichi Cancer Center Hospital, Aichi, Japan

Background: Although neoadjuvant treatment (NAT) has been widely employed for resectable pancreatic ductal adenocarcinoma (PDAC), it is still unclear what kind of regimen is recommended. The aim of the study is to investigate which chemoradiotherapy (CRT) with S-1 or combination chemotherapy with gemcitabine (GEM) and S-1 is more promising as NAT for resectable PDAC in terms of effectiveness and safety. **Methods:** Patients with resectable PDAC were enrolled and randomly assigned into either CRT group or chemotherapy group. In the CRT group, a total radiation dose of 50.4 Gy in 28 fractions was administered and S-1, at a dose of 30, 40 or 50 mg according to the body surface area, was orally provided twice a day on the same day of irradiation. In the chemotherapy group, GEM was intravenously administered at a dose of 1000 mg/m^2 on day 1 and 8 and S-1 was orally provided at a dose of 30, 40 or 50 mg according to the body surface area twice daily on day 1 to 14 followed by one week reset. Patients in the chemotherapy group received two cycles of this regimen. Surgery was performed between 15 and 56 days after the last day of NAT. The primary endpoint was 2-year progression-free survival (PFS) rate. With 50 patients in each group, the study had 80% power assuming a threshold 2-year PFS rate of 25% and an expected 2-year PFS rate of 40% at 0.05 one-sided alpha. The trial was registered with the UMIN Clinical Trial Registry as UMIN000014894. **Results:** From April 2014 and April 2017, 103 patients were enrolled from 11 institutions in Japan. One was excluded because of ineligibility, therefore 51 patients in CRT group and 51 patients in chemotherapy group constituted the intention-to-treat analysis. The 2-year PFS rate was 45% (90% CI, 33-60%) in the CRT group and 55% (43-65%) in the chemotherapy group (p = 0.52). The hazard ratio for chemotherapy to CRT was 0.78 (0.46-1.31). The median survival time was 37.7 (95% CI, 30.3-NE) in the CRT group and NE (29.9-NE) in the chemotherapy group (p = 0.30). There was no treatment-related death in both groups. **Conclusions:** Combination chemotherapy with GEM and S-1 may be more promising compared with CRT with S-1 as NAT for resectable PDAC. Clinical trial information: UMIN000014894. Research Sponsor: Pharma-Valley Center, Shizuoka Industrial Foundation.

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725 **Poster Session (Board #L14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Clinical outcome of initially unresectable pancreatic cancer patients: Conversion surgery after modified FOLFIRINOX or gemcitabine nab-paclitaxel.

Yuta Ushida, Yosuke Inoue, Hiromichi Ito, Yoshihiro Ono, Takafumi Sato, Yu Takahashi; Japanese Foundation for Cancer Research, Tokyo, Japan

Background: Although pancreatic cancer (PC) is unfavorable clinical entity, the prognosis of resectable PC has been improving due to perioperative chemotherapy. Meanwhile, the prognosis of unresectable (UR) PC remains poor. In highly selected patients, however, conversion surgery (CS) has been performed with good outcome. Indication criteria of CS remain unestablished because the number of patients who underwent CS was very small in each institution. **Methods:** From 2014 to 2018, 485 consecutive patients with UR-PC who received modified FOLFIRINOX (mFFX) / Gemcitabine Nab-Paclitaxel (GnP) chemotherapy were reviewed. Among them, patients with disease control for more than 8 months were enrolled and divided into two groups; patients who underwent CS (CS group) and patients who did not undergo CS (non-CS group). We compared clinical characteristics and survival outcomes between groups. Our surgical indications were as follows: 1) Decreasing trend in CA19-9, 2) With response for chemotherapy in image, 3) Disease control more than 8 months, 4) Decision in Cancer board as for metastatic cases. **Results:** In UR-PC patients, 358 patients had distant metastasis (MPC) and 127 patients had locally advanced (LA) PC. The overall survival (OS), progression free survival (PFS) and conversion rate of LAPC were significantly better than MPC (OS; 21 vs. 13 months, PFS; 12 vs. 7 months, Conversion rate; 16 vs. 5 %, $p < 0.001$). Chemotherapy regimen (mFFX/GnP) had no significant difference in survival outcome. Between CS group (n = 39) with non-CS group (n = 160), age, sex, body mass index, location of lesion, CEA, CA19-9, regimen of chemotherapy and histology had no significant differences. The median survival time of CS group was significantly better than that of non-CS group (OS; NA vs. 21 months, $p < 0.001$, PFS; 24 vs. 14 months, $p = 0.01$). In CS group, median operative duration was 509 minutes, blood loss was 735 ml, hospital stay was 26 days, and there was no 90-days mortality case. **Conclusions:** In our retrospective study, CS for UR-PC can be safely performed, and among carefully selected patients, reasonable short and long term outcomes can be obtained without acceptable morbidity rate. Research Sponsor: None.

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726 Poster Session (Board #L15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

A prospective trial of elemental enteral feeding in patients with pancreatic cancer cachexia (PANCAX-1).

Andrew Eugene Hendifar, Gillian Gresham, Haesoo Kim, Michelle Guan, Jar-Yee Liu, Brian Minton, Diane Bhuiyan, Ruby Langeslay, Andre Rogatko, Jun Gong, Veronica Placencio-Hickok; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Cedars-Sinai Medical Center, Los Angeles, CA; Cedars-Sinai Medical Center, West Hollywood, CA; City of Hope, Duarte, CA

Background: Unintentional weight loss affecting > 85% of pancreatic cancer (PC) patients contributes to low therapeutic tolerance, reduced quality of life, and overall mortality. Optimal treatment approaches have not been developed. We hypothesize that peptide-based enteral nutritional support in cachectic advanced PC patients, receiving palliative chemotherapy, results in improved weight, lean body mass (LBM), and hand-grip strength. **Methods:** Pancreatic adenocarcinoma patients with cachexia (> 5% unintentional weight loss within the previous 6 months) were provided a jejunal tube peptide-based diet for 3 months. Primary outcome was weight stability (0.1kg/BMI unit decrease). Secondary outcomes included changes from baseline in LBM, bone mineral density (BMD), total body fat mass (BFM), handgrip strength, physical activity (Fitbit), and CA19-9 and CRP. Planned interim analysis was performed after 14 patients completed treatment. **Results:** From 31 consenting patients, 16 were evaluable for the primary outcome. Patients receiving enteral therapy were 39% male, median age 69 (Range: 41 to 89 years), and 74% ECOG 1. A summary of change in outcomes at 3 months from baseline is shown in Table. The primary endpoint of weight stability in 10 (62.5%) patients was met, thus completing study. Overall survival was 6.5 months (n=31) and 9.9 months for evaluable patients (n=16). Weight stability was statistically associated with LBM (Pearson's correlation: 0.87, $p<0.001$), but not survival (HR: 0.94, 95% CI 0.32, 2.83, p=0.92). **Conclusions:** Peptide-based enteral feeding resulted in weight stability and improvements in lean body mass and physical function. Further randomized trials assessing nutritional support in advanced patients are warranted. NIH/NCATS Grant # UL1TR000124. Clinical trial information: NCT02400398. Research Sponsor: U.S. National Institutes of Health.

Mean change in outcomes.

Outcome	Mean	SD
Weight (kg)	1.3	5.8
BMI (kg/m^2)	0.5	1.7
LBM (g)	1273.1	4078.0
BMD (g/cm^2)	-0.01	0.02
BFM (g)	-602	2794
CRP	-9.78	37.6
CA 19-9	-233.7	43118.5
Handgrip (kg)	1.2	4.0
Daily steps	976.5	1844.0

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727 Poster Session (Board #L16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Outcomes and efficacy of neoadjuvant chemoradiation versus chemotherapy in localized pancreatic cancer.

Asmita Chopra, Jacob C. Hodges, Adam Olson, Steven A. Burton, Kenneth K. Lee, Nathan Bahary, Aatur D. Singhi, Brian A. Boone, Michael T. Lotze, Melissa E. Hogg, Herbert Zeh, Amer H. Zureikat; Department of Surgery, University of Pittsburgh, Pittsburgh, PA; Wolff Center at UPMC, Pittsburgh, PA; Department of Radiation Oncology, University of Pittsburgh, Pittsburgh, PA; Department of Medical Oncology, University of Pittsburgh, Pittsburgh, PA; Department of Pathology, University of Pittsburgh, Pittsburgh, PA; Department of Surgery, West Virginia University, Morgantown, WV; Department of Surgery, North Shore Hospital, Chicago, IL; Department of Surgery, University of Texas Southwestern Medical Center, Dallas, TX

Background: Neoadjuvant therapy is increasingly used for pancreatic cancer (PDA). The comparative efficacy of neoadjuvant chemotherapy (NC) versus chemoradiation (NCRT) remains uncertain. We aimed to compare NC and NCRT on survival outcomes and pathologic endpoints of PDA. **Methods:** Single-center analysis of PDAs treated with NC or NCRT between 2008-2018. Average treatment effects (ATE) were estimated after matching cases to controls using Mahalanobis distance nearest-neighbor matching. Competing risk survival analysis and inverse probability weighted estimates (IPWE) were used for disease free survival (DFS) and overall survival (OS) respectively. **Results:** Of 418 patients (median age 67yrs, 51% females), 327 received NC and 91 received NCRT. NCRT patients had more locally advanced disease, cross-over NC regimens (gemcitabine & 5-FU based), longer neoadjuvant therapy duration, open surgery and vascular resection (all $p < 0.05$). NCRT was associated with lower LN positivity, LNR, LVI and PNI, higher R0 rates, and higher near complete and complete pathologic responses (all $p < 0.05$, table). After adjustment, NCRT was associated with a significant reduction in LN positivity [95%CI = (-)0.41-(-)0.07; p = 0.007] and LVI [95%CI = (-)0.36-(-)0.03; p = 0.02]. While NCRT was associated with improved OS on UVA (25.5 vs. 21.6 months; p = 0.04), it was not significantly associated with OS by IPWE after adjusting for adjuvant therapy [95%CI = (-)5.02-16.3; p = 0.3] or DFS on competing risk analysis (95%CI = 0.78-1.31; p = 0.96). **Conclusions:** Although NCRT is associated with improved pathologic surrogates, it is not associated with improved survival in PDA. Research Sponsor: None.

Variables	NC (N = 327)	NCRT (N = 91)	p-value (UVA)	p-value (MVA)
T size (cm)	2.5 (2.0, 3.2)	2.5 (1.6, 3)	0.13	0.46
Lymph node ratio (LNR)	0.05 (0.0, 0.14)	0.03 (0.0, 0.12)	**0.04**	0.14
LN positive	230 (70.3)	47 (51.6)	**0.001**	**0.007**
Positive Margin (R1<1mm)	173 (52.9)	34 (37.4)	**0.008**	0.22
Lymphovascular invasion (LVI)	240 (76.7)	49 (57.0)	**< 0.001**	**0.02**
Perineural invasion (PNI)	274 (85.1)	64 (70.3)	**0.002**	0.21
Near-complete/ complete response	12(3.8)	11 (14.1)	**< 0.001**	0.13
DFS (months)	15.1 (10.7, 24.5)	17.0 (11.2, 31.5)	0.056	0.96
OS (months)	21.6 (14.3, 35.4)	27.5 (14.9, 54.9)	**0.042**	0.3

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729 **Poster Session (Board #L18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Establishment of patient-derived tumor xenograft (PDX) model as artificially-created liver metastasis using cryopreserved pancreatic ductal adenocarcinoma.

Kenjiro Kimura, Ryota Tanaka, Ryosuke Amano, Shoji Kubo, Hiroaki Tanaka, Kazuya Muguruma, Kosei Hirakawa, Masaichi Ohira; Department of Hepato-Biliary-Pancreatic Surgery, Osaka City University Graduate School of Medicine, Osaka, Japan; Department of Gastroenterological Surgery, Osaka City University Graduate School of Medicine, Osaka, Japan; Kashiwara Municipal Hospital, Kashiwara, Japan

Background: Translational research using patient-derived tumor xenograft (PDX) model is progressing rapidly, and is also becoming widespread in pancreatic cancer research. The purpose of this study was to establish the liver transplant PDX model as artificially-created liver metastasis with cryopreserved primary pancreatic ductal adenocarcinoma(PDAC). **Methods:** The primary PDAC from 10 patients were cryopreserved and transplanted into NSG mice using liver pocket method. For engraftment and similarity evaluation, H&E staining and immunohistochemical staining such as Ki-67, p53, SMAD4, and MUC1 were performed. **Results:** Patient-derived xenograft was succeeded in 6 cases (60%), 10 mice (33.3%). Ki-67 index of primary PDAC and the interval of cryopreservation were significantly related to successful engraftment, respectively ($p = 0.003$, $p = 0.007$). **Conclusions:** In this study, we succeeded in establishing a liver transplant PDX mouse model as a preclinical platform. The factors such as Ki-67 index and the interval of cryopreservation would affect the successful establishment. Research Sponsor: None.

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730 **Poster Session (Board #L19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Prognostic and predictive value of circulating tumour DNA (ctDNA) by amplicon-based next generation sequencing (NGS) of advanced pancreatic cancer (APC) in a phase I trial of oxaliplatin capecitabine and irinotecan (OXIRI) triplet chemotherapy.

Amanda Oon Lim Seet, Su Pin Choo, David Wai-Meng Tai, Justina Yick Ching Lam, Tira Jing Ying Tan, Daniel Shao-Weng Tan, Aaron C. Tan, Yvonne Chang, Balram Chowbay, Matthew C.H. Ng; National Cancer Center, Singapore, Singapore; Curie Oncology, Singapore, Singapore; National Cancer Center Singapore, Singapore, Singapore; National Cancer Centre, Singapore, Singapore; National Cancer Centre Singapore, Singapore, Singapore

Background: Tumoral KRAS mutations ($KRAS^{mt}$) are detected in ~80% of APC and associated with a negative prognosis. Digital droplet PCR (ddPCR) has high sensitivity for circulating $KRAS^{mt}$but narrower gene coverage. NGS using hybrid-capture methods has reported ctDNA $KRAS^{mt}$in ~30% of patients (pt). We previously presented clinical results of the Phase I trial of OXIRI (GI ASCO 18 #411). We now present the first prospective evaluation of ctDNA in APC by an amplicon-based NGS approach in this Phase I trial. **Methods:** Paired ctDNA and CA19-9 samples were taken at baseline, C2D1, C3D1 and end of trial. A targeted panel with error-correction (Lucence Diagnostics) was used to detect for *mt*in KRAS, TP53, SMAD4, CDKN2A, CTNNB1, GNAS, APC and MYC. CT scans were performed every 2 cycles. Survival curves by Kaplan Meier were compared by mutational status, ctDNA and CA19-9 response using the log-rank test. Spearman correlation of ctDNA and CA19-9 changes was performed. **Results:** $ctDNA^{mt}$was detected at baseline in 19/23 (83%) samples, comprising KRAS 17/23 (73%), TP53 (61%), SMAD4 (48%) and CDKN2A (30%). $KRAS^{mt}$and $SMAD4^{mt}$ conferred a negative prognosis for overall survival with a hazard ratio of 4.2 (CI: 1.6-10.4; p = 0.01) and 2.8 (CI: 0.9-8.65; p = 0.01) respectively. Drop in ctDNA and CA19-9 was associated with a trend for longer progression free survival at C2D1 (both) and C3D1 (ctDNA only). Radiological partial response (PR) was associated with lower ctDNA in 5/5 pt and CA 19-9 in 4/5 pt. Decrease in ctDNA and CA19-9 was associated with disease control (PR/SD) at C2D1 in 11/14 pt and 10/10 pt; at C3D1 in 11/12 pt and 6/7 respectively. No significant correlation between the amplitude of CA19-9 and ctDNA changes was found. **Conclusions:** ctDNA could be detected in 83% of pts of whom $KRAS^{mt}$rates were similar to reports using tissue NGS. Determination of $RAS^{mt}$and $SMAD4^{mt}$in ctDNA may aid in the prognostication of pts and decrease in ctDNA levels may predict for treatment benefit, similar in extent to CA 19-9. This may be particularly useful in non-CA19-9 secreting APC as an adjunct to imaging. Clinical trial information: NCT02368860. Research Sponsor: National Medical Research Council Singapore.

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731 **Poster Session (Board #L20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

DNA-damage repair deficiency (dDDR) and response to nanoliposomal irinotecan (nal-IRI) in metastatic pancreatic ductal adenocarcinoma (mPDAC).

Sameeha Rau, Andrea P. Espejo Freire, Gretel Terrero, Manisha Jayandra Patel, Benjamin Woodress Rush, Caio Max Sao Pedro Rocha Lima, Peter Joel Hosein; University of Miami Miller School of Medicine, Miami, FL; University of Miami-Miller School of Medicine, Jackson Memorial Hospital, Miami, FL; Jackson Health System, Miami, FL; Wake Forest Baptist Health, Hematology and Oncology-Heme Onc Fellowship Program, Winston Salem, NC; NRG Oncology and Wake Forest University Baptist Medical Center, Winston-Salem, NC; University of Miami Sylvester Comprehensive Cancer Center, Miami, FL

Background: Chemotherapy is the standard of care for patients with mPDAC but there are no biomarkers to aid in treatment selection. Nal-IRI with 5-fluorouracil/folinic acid (FUFA) improves survival over FUFA in the second-line treatment of mPDAC. Nal-IRI is a topoisomerase inhibitor and its action produces DNA damage leading to cell death. We hypothesize that tumors with dDDR, a process that is altered in a subset of patients with PDAC, may be more sensitive to the effects of nal-IRI. **Methods:** Utilizing the IRB-approved pancreas cancer databases at the University of Miami and Wake Forest University, we identified patients with mPDAC treated with nal-IRI and FUFA who had germline and/or somatic mutation testing. We conducted a retrospective chart review to extract demographic and clinical characteristics including treatments received, response, and survival. **Results:** Among 31 patients identified, the median age was 66y and 47% were female. Nine patients had a DDR mutation; 6 germline and 3 somatic. Median progression-free survival (PFS) in patients with any germline or somatic DDR mutation was 3.2m vs 3.9m for those without (log-rank p = 0.7). When restricted to germline DDR mutations only, the median PFS was not reached with germline dDDR vs 4m for those without (log-rank p = 0.22). Presence of dDDR was associated with a higher clinical benefit rate (CBR = partial response + stable disease); a DDR mutation was present in 36% of patients who showed clinical benefit vs 15% in those without clinical benefit (p = 0.21). **Conclusions:** DDR mutations appear to define a subset of patients with mPDAC who may be more sensitive to nal-IRI and FUFA. The PFS and CBR were numerically but not statistically superior, especially in patients with germline DDR mutations. Larger data sets and longer follow-up are needed to confirm this trend. Research Sponsor: None.

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732 Poster Session (Board #L21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Homologous recombination deficiency (HRD) by BROCA-HR and survival outcomes after surgery for patients (pts) with pancreatic adenocarcinoma (PC): A single institution experience.

Amy E. Chang, David Bing Zhen, Marc Radke, Kelsey K. Baker, Andrew L. Coveler, Kit Man Wong, Venu Gopal Pillarisetty, Mary Weber Redman, Elizabeth Swisher, E. Gabriela Chiorean; University of Michigan, Ann Arbor, MI; University of Washington School of Medicine, Seattle, WA; Fred Hutchinson Cancer Research Center, Seattle, WA; Seattle Cancer Care Alliance/ University of Washington, Seattle, WA; University of Colorado, Denver, CO; University of Washington, Seattle, WA; SWOG Statistical Center; Fred Hutchinson Cancer Research Center, Seattle, WA; University of Washington/Seattle Cancer Care Alliance, Seattle, WA; University of Washington and Fred Hutchinson Cancer Research Center, Seattle, WA

Background: 5-7% of PC pts exhibit deleterious germline mutations (MUT) in HR tumor suppressor genes *BRCA1* and *BRCA2*. BROCA-HR is a targeted capture and massively parallel sequencing assay designed to detect all mutation classes including gene rearrangements, copy number variations, and gene aberrations within the Fanconi Anemia-BRCA HR, non-homologous end joining (NHEJ) DNA repair, and DNA mismatch repair pathways. BROCA-HR has been successfully used in breast and ovarian cancer pts for overall prognosis and prediction of response to platinum-based therapies. While *BRCA1/2* MUT may confer survival advantage for PC pts if treated with platinum-chemotherapy, the survival impact of HRD is less well defined. **Methods:** We retrospectively identified 100 consecutive pts who underwent surgical resection for suspected PC at University of Washington Medical Center between 1999 and 2008. Formalin-fixed paraffin embedded resected tumors were sequenced using BROCA-HR. HRD was grouped based on the following deleterious genetic mutations: 1) *BRCA1*, *BRCA2*; 2) core HRD: *BARD1*, *BRIP1*, *RAD51C*, *RAD51D*, *PALB2*, *CDK12*, *NBN*; 3) non-core HRD: *ATM*, *ATR*, *ATRX*, *BAP1*, *BLM*, *CHEK1/2*, *ERCC*, *FANC A/C/D2/E /F/G/L*, *MRE11*, *RAD50/51/51B*, *RIF1*, *SLX4*; 4) HR proficient. Overall survival (OS) was measured from diagnosis until death or last follow-up. **Results:** 95 pts had histologically confirmed PC, and 81 pts had adequate tumor DNA for analysis. Six pts (7%) had *BRCA1/2* MUT (n = 5), or *BRCA1* methylation (n = 1), 1 pt (1%) had non-BRCA core HRD (*PALB2* MUT), 7 pts (9%) had non-core HRD: *ERCC* (2), *CHEK2* (2), *ATR*, *RAD51D*, and *FANCA* MUT (1 each). Median OS was: all pts 1.93 yrs (95% C.I. 1.53, 2.16), *BRCA1/2* pts 3.09 yrs (95% CI 0.41, 12.21), all core HRD pts 1.21 yrs (95% CI 0.41, 12.21), all core and non-core HRD pts 1.89 yrs (95% CI 0.57, 4.96), HR proficient pts 1.93 yrs (95% CI 1.51, 2.15). There were no OS differences between pts with HRD vs those HR proficient. **Conclusions:** HRD is common (17%) but does not affect OS for pts with resected PC. Prospective clinical trials should test neo/adjuvant therapies including platinum chemotherapy and PARP inhibitors for pts with HRD. Research Sponsor: U.S. National Institutes of Health.

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733 Poster Session (Board #L22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Loss of Rnf43 to accelerate KRAS-mediated neoplasia in a clinically relevant genetically engineered mouse model of pancreatic adenocarcinoma.

Abdel Nasser Hosein, Gita Dangol, Takashi Okumura, Lotfi Abou-Elkacem, Anirban Maitra; University of Texas MD Anderson Cancer Center, Houston, TX

Background: The genetic heterogeneity of pancreatic ductal adenocarcinoma (PDAC) demands a personalized molecular-targeted treatment approach. While activating *KRAS* mutations are a near ubiquitous event in PDAC pathogenesis, 5-10% of cases display deleterious driver mutations in the Wnt-signaling negative regulator, ring finger 43 *(RNF43)*. Despite this characterization there are no personalized treatment options for this subset of patients. **Methods:** We have developed a genetically engineered mouse model (GEMM) of PDAC, driven by an activating mutation in *Kras* and deletion of *Rnf43* under control of a pancreas specific promoter (KRC). Mice were followed for survival outcomes and histological changes which were compared to a *Kras* driven PDAC GEMM (KC). Mice underwent serial magnetic resonance imaging (MRI), with and without dynamic contrast enhanced (DCE) imaging, to evaluate cystic tumor morphology and contrast enhancement during tumor progression. Single cell RNA sequencing (scRNAseq) was also performed to assess changes in single cell populations during tumor progression. Lastly, we established *ex vivo* cultures from KRC and KC tumors and performed bulk RNA-sequencing (RNAseq) and *in vitro* pharmacology studies. **Results:** KRC mice displayed a decrease in overall survival and higher incidence of both high grade pre-neoplastic lesions and invasive PDAC compared to KC mice. Serial MRI revealed increased cystic morphology of KRC mice during tumor progression with increasing DCE intensity. scRNAseq of KRC tumors from moribund mice displayed two distinct populations of both macrophages and fibroblasts, similar to our previous report of *Kras/Tp53* and *Kras/Ink4a* driven GEMMs. Lastly, primary cultures from KRC tumors demonstrated increased expression of Wnt-related genes by RNAseq and increased sensitivity to small molecule porcupine inhibition relative to KC cell lines, demonstrating functional Wnt dependence of the KRC system. **Conclusions:** *Rnf43* is a bona fide tumor suppressor gene in PDAC. This GEMM is a novel platform for drug discovery in *RNF43*-mutated PDAC with the eventual goal of implementing a precision oncology approach in these patients. Research Sponsor: UT MD Anderson Pancreatic Cancer Moonshot Initiative.

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734 **Poster Session (Board #M1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Tumor infiltration and cytokine biomarkers of prostate stem cell antigen (PSCA)-directed GOCAR-T cells in patients with advanced pancreatic tumors.

Joanne Shaw, Brandon Ballard, Xiaohui Yi, Aditya Malankar, Matthew R. Collinson-Pautz, Carlos Roberto Becerra, Joseph Paul Woodard, Aaron E. Foster; Bellicum Pharmaceuticals, Inc., Houston, TX; Baylor University Medical Center, Dallas, TX

Background: PSCA is a cell surface protein overexpressed in approximately 60% of pancreatic cancers. BPX-601 is an autologous GOCAR-T cell therapy engineered to express a PSCA-CD3ζ CAR and the MyD88/CD40 (iMC) costimulatory domain activated by rimiducid (Rim), designed to boost CAR-T performance in solid tumors. The safety and activity of BPX-601 activated with Rim in $PSCA^+$ metastatic pancreatic cancer is being assessed in a Phase 1/2 clinical trial, BP-012 (NCT02744287). **Methods:** Phase 1 of BP-012 is a 3+3 dose escalation of BPX-601 (1.25-5 $x10^6$/kg) administered on Day 0 with a single, fixed-dose of Rim (0.4 mg/kg) on Day 7 in subjects with previously treated $PSCA^+$ metastatic pancreatic cancer. All 5 subjects in cohort 5B received Flu/Cy lymphodepletion followed by BPX-601 (5 $x10^6$/kg) and Rim. BPX-601 kinetics, PBMC phenotype, and serum cytokines were assayed by qPCR, flow cytometry, and cytokine multiplex, respectively. Baseline and on-treatment biopsies were evaluated by RNAscope *in situ* hybridization. **Results:** BPX-601 cells expanded in all subjects and persisted up to 9 months (median 42 days). Transient reduction in BPX-601 vector copy number and total T cell count concurrent with Rim infusion, supports margination of activated BPX-601 cells. Increased serum cytokines, such as IFN-γ and GM-CSF, were observed following BPX-601 infusion with further elevation after Rim activation. All subjects with evaluable on-treatment biopsies had infiltration of BPX-601 cells (n = 3) proximal to tumor cells 7-15 days after Rim, but not in an end of treatment biopsy $>$ 200 days after Rim (n = 1). Stratification by best response (RECIST 1.1) revealed stable disease in 3 subjects and progressive disease in 2 subjects was potentially associated with distinct cytokine signatures. **Conclusions:** BPX-601 GOCAR-T cells expand and persist in patients with $PSCA^+$ metastatic pancreatic cancer and infiltrate metastatic lesions. A peripheral cytokine signature was observed following BPX-601 infusion. Select cytokines were enhanced after GOCAR-T cell activation and may correlate with clinical response. A cohort of subjects exploring serial administration of Rim is open for enrollment. Clinical trial information: NCT02744287. Research Sponsor: Bellicum Pharmaceuticals, Inc.

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735 Poster Session (Board #M2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Real-world outcomes in pancreatic adenocarcinoma (PDAC) and persona types with implications for standard of care (SOC) therapy (Tx).

Emanuel Petricoin, Michael J. Pishvaian, Patricia DeArbeloa, Daniel Barg, Dzung Thach, Jonathan Robert Brody, Lynn McCormick Matrisian, Vincent Chung, Andrew Eugene Hendifar, Sameh Mikhail, Davendra Sohal, Edik Matthew Blais; George Mason University, Fairfax, VA; The University of Texas, MD Anderson Cancer Center, Houston, TX; Perthera, Inc., Mclean, VA; The Sidney Kimmel Cancer Center at Thomas Jefferson University, Philadelphia, PA; Pancreatic Cancer Action Network, Manhattan Beach, CA; City of Hope, Duarte, CA; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; The Ohio State University Comprehensive Cancer Center, Arthur G. James Cancer Hospital, Columbus, OH; Cleveland Clinic, Cleveland, OH

Background: Molecular profiling (MP) for PDAC has gained increased acceptance and we previously demonstrated that targeting actionable mutations can improve patient (pt) outcomes. However, the correlations of diverse patterns of molecular alterations with outcomes following SOC Tx are largely unknown. **Methods:** We analyzed longitudinal outcomes of 1355 PDAC pts who underwent MP and received SOC Tx. "Persona" types were established based on the molecular characteristics of each pt using unsupervised clustering, as well as a supervised review defined by our molecular tumor board, following classifications reported in previous studies. Progression-free survival (PFS) for each type was assessed based on the choice of first-line Tx (i.e. FOLFIRINOX [FFX] vs. gemcitabine + nab-paclitaxel [GA]). Statistical comparisons were made against all other types within a specific Tx group. **Results:** The prognostic/predictive value of the persona types for 1st-line Tx revealed distinct differences in outcomes (Table). As expected, the DDR deficiency type was associated with a significantly improved PFS for pts treated with FFX but not for GA. In addition, pts in the cell cycle type had a worse PFS compared to other persona types for both FFX and GA. Using this platform, we will further subdivide the persona types into molecular subtypes and associate these with pt outcomes. **Conclusions:** Our analyses demonstrate that specific molecular persona types exist in PDAC pts and can be linked to Tx outcomes. Ultimately, knowing the persona type/subtype early in a pt's Tx course may help personalize Tx to improve outcomes. Research Sponsor: The Pancreatic Cancer Action NEtwork, Pharmaceutical/Biotech Company.

Median PFS with first-line Tx in months (n=# of patients) across persona types; NR = not reached.

Persona Type	GA: mPFS (n); p-value		FFX: mPFS (n); p-value	
DDR def	8.2 (59)	0.55	19.2 (54)	**0.0011**
Cell cycle	5.6 (83)	**0.0013**	7.0 (98)	**7.5e-05**
KRASmut & p53mut	7.5 (60)	0.14	9.3 (74)	0.96
SWI/SNF	8.4 (24)	0.73	9.0 (30)	0.21
p53wt	8.7 (26)	0.091	9.7 (13)	0.94
Replicative stress	7.7 (29)	0.96	11.7 (23)	0.54
KRASwt	8.8 (13)	0.15	NR (11)	0.76
PI3K/AKT/mTOR	5.4 (15)	0.11	NR (12)	0.27
Wnt pathway	13.9 (10)	0.15	12.4 (16)	0.11
STK11	8.6 (10)	0.74	10.3 (10)	0.53
BRAFmut	7.7 (5)	0.72	7.5 (13)	0.19

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736 Poster Session (Board #M3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Gene expression profiling of unresectable pancreatic cancer patients treated with gemcitabine, nab-paclitaxel, metformin, and dietary supplements (DS).

Vincent Chung, Paul Henry Frankel, Stephen Shibata, Isa Mambetsariev, Holly Yin, Tamara Mirzapoiazova, Bolot Mambetsariev, Prakash Kulkarni, Dean Lim, Daneng Li, Joseph Chao, Marwan Fakih, Andrea Bild, Raju K. Pillai, Orn Adalsteinsson, Steven Hirsh, Ravi Salgia; City of Hope, Duarte, CA; City of Hope Comprehensive Cancer Center, Duarte, CA; City of Hope Natl Medcl Ctr, Duarte, CA; City of Hope National Medical Center, Duarte, CA; Life Extension, Fort Lauderdale, FL

Background: Pancreatic cancer commonly causes weight loss and many patients take supplements to improve nutrition but also for any potential anticancer properties. We conducted a pilot trial evaluating a standardized combination of dietary supplements, metformin and gemcitabine plus nab-paclitaxel chemotherapy. **Methods:** The supplements were custom designed by a nutritionally trained oncologist. 17 supplements were given as 12 pills and 2 smoothie packets divided twice per day. Patients began metformin on day (D)-6 to evaluate GI tolerance before starting the DS on D-3. On D1, gemcitabine and nab-paclitaxel chemotherapy was administered at standard doses. Serum samples were collected D-6, C1D1, C3D1 and at the end of treatment. RNA was extracted from PBMC samples and a total of 48 samples were analyzed from 19 patients. NanoString Human Immune Profiling and PanCancer Pathways were performed to evaluate changes in gene expression with treatment. **Results:** The differential expression of genes was small with dietary supplements alone and in combination with chemotherapy. After 2 months of treatment, 17 genes were upregulated while 4 genes were down regulated. At the time of tumor resistance, 33 genes were upregulated while 17 genes were downregulated. We observed down-regulation of tumor suppressor gene expression with upregulation in growth factor pathways. Interestingly, SPRY2 mRNA expression was also up regulated which functions as a negative feedback regulator of multiple receptor tyrosine kinases. **Conclusions:** Increasing number of genes were upregulated with continued treatment. The most common pathway affected was cell cycle and apoptosis. During the initial supplement run-in period from D-6 to C1D1, IL-8 mRNA expression was upregulated the most. IL-8 is a neutrophil chemotactic factor secreted by cells involved in the innate immune response as well as pancreatic cancer cells associated with a pro-inflammatory state. Treatment with gemcitabine and nab-paclitaxel decreased the IL-8 mRNA expression. Additional studies with longer course treatment with supplements alone would be required to explore its impact on differential gene expression. Research Sponsor: Biomedical Research and Longevity Society, Inc.

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737 Poster Session (Board #M4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Comparison of gemcitabine delivery and tumor response in a pressurized pancreatic retrograde venous infusion versus systemic infusion in an orthotopic murine model.

Diego Vicente, Jayanth Shankara Narayanan, Partha Ray, Louis F. Chai, Suna Erdem, Matthew Carr, Benedict Capacio, Bryan Cox, David Jaroch, Steven C. Katz, Rebekah Ruth White; Moores Cancer Center, San Diego, CA; Roger Williams Cancer Center, Providence, RI; TriSalus Life Sciences, Westminster, CO

Background: Pancreatic ductal adenocarcinoma (PDAC) is associated with limited response to systemic therapy (ST). Elevated tumor interstitial fluid pressures (IFP) inhibit penetration of ST. Regional Pressure Enabled Drug Delivery has recently demonstrated improved response for liver tumors in a clinical trial. However, this delivery method has not been evaluated in PDAC. We compared gemcitabine (Gem) by systemic delivery vs. a novel pressurized Pancreatic Retrograde Venous Infusion (PRVI) method in an orthotopic PDAC mouse model. **Methods:** PDAC murine cell line (KPC4580P) tumors were transplanted onto the pancreatic tail of C57BL/6J mice. Groups of 15 mice were randomly assigned to PRVI Gem, PRVI saline (Control), or intraperitoneal Gem (Systemic) groups. Five mice from the PRVI and Systemic groups were randomly selected after one hour post infusion to evaluate Gem tumor concentrations by liquid chromatography - tandem mass spectrometry (ng/mg), and the remainder of mice were euthanized after 7 days to evaluate treatment response. **Results:** Tumor concentrations of Gem were significantly higher following PRVI compared to Systemic (128 vs. 19, $p < 0.01$) at one hour after treatment. Seven days after treatment, PRVI Gem mice demonstrated lower mean tumor volume (mm^3) than Systemic Gem and Control mice (274 vs. 857 vs. 629, $p < 0.01$), respectively. Histologic evaluation of tumors demonstrated decreased cellularity in the PRVI Gem mice compared to Systemic and Control mice (35 vs. 78 vs. 71%, $p = 0.01$), respectively. No differences were seen in Ki67% or immune cell infiltrate between groups. **Conclusions:** PRVI delivery resulted in increased PDAC Gem concentrations and improved treatment responses with decreased tumor burden and cellularity. These findings suggest that pressurized regional chemotherapy infusion overcomes the elevated PDAC IFP and justifies additional translational pre-clinical studies with other chemotherapeutics (including immunomodulating antibodies) with different physicochemical properties. Research Sponsor: TriSalus Life Sciences, Westminster, CO.

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738 Poster Session (Board #M5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pharmacogenomic blood-based assay to predict chemotherapy response and survival in pancreatic cancer.

Kenneth H. Yu, Brian McCarthy, William H. Isacoff, Brandon Cooper, Andrew Bartlett, Jennifer Park, Fay Purcell, Devan McCarthy, Eileen Mary O'Reilly; Memorial Sloan Kettering Cancer Center/Weill Cornell Medical College, New York, NY; Adera Biolabs, Germantown, MD; Univ of California, Los Angeles, CA; University of Maryland Greenebaum Comprehensive Cancer Center, Baltimore, MD; Adera Biooncology, LLC, Germantown, MD; Memorial Sloan Kettering Cancer Center, New York, NY; The Pancreatic Cancer Center of Los Angeles, Los Angeles, CA

Background: Pancreatic adenocarcinoma (PDAC) is for most patients a refractory disease. Modern cytotoxic chemotherapeutics (C) are not yet optimal for inducing responses and extending life. We are developing a blood-based pharmacogenomic (PGx) assay profiling circulating tumor and invasive cells (CTICs) to predict sensitivity and resistance to C. **Methods:** The PGx assay was studied in two cohorts of patients (pts) presenting for frontline C therapy of metastatic PDAC. Cohort 1 is from an ongoing prospective study (planned n=80); pts are enrolled prior to receiving either FOLFIRINOX or gemcitabine (Gem)/nab-paclitaxel (Nab-P). Cohort 2 (n=50) consists of pts enrolled prior to receiving bespoke combinations of C agents informed by the assay. 6 mL of peripheral blood was collected from pts at baseline and while on C therapy. CTICs were isolated by previously described collagen invasion assay, total RNA was extracted and gene-expression analysis was performed. PGx models for seven C agents used in PDAC were applied, and correlated to treatment received. Pts were classified as sensitive if C received were predicted to be effective and resistant if not. Objective endpoints were PFS and OS. **Results:** Cohort 1 patients who received sensitive first-line C combinations experienced significantly longer time to progression (TTP) v resistant (Table). In Cohort 2, the PGx assay was predictive of TTP and OS when used across multiple lines of therapy, with a two-year survival of 38%. Greater OS was observed in Cohort 2 pts receiving heterogenous C regimens more highly correlated to those predicted by the PGx assay. **Conclusions:** The PGx assay has promising predictive performance in both standard and personalized C regimens. A prospective, directed trial comparing these approaches is warranted. Clinical trial information: NCT03033927. Research Sponsor: U.S. National Institutes of Health.

Cohort 1 (n=45)			**Cohort 2 (n=50)**			
Median age	65		Median age	62		
Gender (M/F)	25/22		Gender (M/F)	26/24		
Treatment			Frontline regimen contains			
FOLFIRINOX	17		5-FU	43	Oxaliplatin	21
Gem/Nab-P	30		Mitomycin-C	16	Nab-P	31
TTP, frontline (mo)			Irinotecan	23	Gem	20
Sensitive	7.6		Cisplatin	11		
Resistant	4.3	p=0.03	TTP, any line (mo)			
OS (mo)			Sensitive	5.3		
Sensitive	14.9		Resistant	3.3	p=0.03	
Resistant	11.8	NS	OS (mo)			
			Sensitive	24.8		
			Resistant	15.8	p=0.05	

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740 Poster Session (Board #M7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Translational analysis from SCALOP trial: CCL5 as a prognostic biomarker and a potentially actionable target in locally advanced pancreatic cancer (LAPC).

Somnath Mukherjee, Simone Lanfredini, Catrin Cox, Asmita Thapa, Sophie Hughes, Fiona Bangs, Frances Willenbrock, Charlotte Wilhelm-Benartzi, Aswin George Abraham, Rob Owens, Ahmad Sabbagh, Tim Maughan, Chris Hurt, Eric O'Neill; University of Oxford, Oxford, United Kingdom; Centre for Trials Research, Cardiff, United Kingdom; Oxford University, Oxford, United Kingdom; Wales Cancer Trials Unit, Cardiff, United Kingdom; Oxford University Hospital NHS Trust, Oxford, United Kingdom; Weston Park Hospital, Sheffield, United Kingdom; Centre for Trials Research, Cardiff University, Cardiff, United Kingdom

Background: SCALOP was a multi-centre phase II RCT where 114 patients with LAPC were received 3 cycles of Gemcitabine and Capecitabine (GEMCAP) and those with stable/responding disease (n = 74) were randomised to Gem-RT or Cap-RT. The trial showed superiority of Cap-RT**.** Baseline blood samples of randomised patients were analysed for 35 circulating biomarkers. In vivo study was undertaken with candidate biomarker (CCL5) to test actionability. **Methods:** Patient bloods were tested using R&D multiplexed magnetic Luminex assays and IGF-1, TGF-b1 and b-NGF DuoSet ELISA. Orthotropic $Kras^{G12D}$;$P53^{R172H}$;PDX^{cre} (KPC) tumors were implanted in Bl6-mice and treated with Gem, CCR5-inhibitor (CCR5i) maraviroc (MV), PD1 inhibitor (PD1i), PD1i+MV alone and in combination with MRI guided small animal Radiotherapy (RT). Immunophenotyping was performed by IHC and Aurora Cytek spectral flow cytometry. **Results:** Baseline biomarker data was available on 63/74 randomised patients. Of the 35 biomarkers tested, only CCL5 was found to be significantly associated with OS with a median OS of 18.5 (95% CI: 11.76-21.32) vs 11.3 (9.86-15.51) months (low vs high), and HR 1.37 (95% CI:1.04-3.65; p = 0.037) in the Cox multivariable model. Treatment of orthotopic KPC tumors revealed that combination of MV+PD1i+RT resulted in tumour growth inhibition and a switch of tumour macrophages from M2 to M1 accompanied by increase in infiltration of cytotoxic CD8+ Tcells and NK cells. **Conclusions:** Previous pre-clinical studies reported CCL5-CCR5 axis as a poor prognostic marker and a possible cause of immune-resistance in pancreatic cancer. Herein we have demonstrated in prospectively collected clinical trial blood samples that high circulating CCL5 is associated with poor prognosis in LAPC. CCR5 inhibitor in combination with RT+PD1i may overcome immune-resistance, and should be tested in clinical trials. Clinical trial information: 96169987. Research Sponsor: SCALOP trial.

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741 **Poster Session (Board #M8), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Homologous recombination deficiency (HRD) scoring in pancreatic ductal adenocarcinoma (PDAC) and response to chemotherapy.

Grainne M. O'Kane, Rob Denroche, Sarah Louise Picardo, Amy Zhang, Spring Holter, Robert C. Grant, Michael Allen, Yifan Wang, Anna Dodd, Stephanie Ramotar, Shawn Hutchinson, Mustapha Tehfe, James Joseph Biagi, Julie Wilson, Faiyaz Notta, Sandra Fischer, George Zogopoulos, Steven Gallinger, Jennifer J. Knox; Princess Margaret Cancer Centre, Toronto, ON, Canada; Ontario Institute for Cancer Research, Toronto, ON, Canada; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Ontario institute for Cancer Research, Toronto, ON, Canada; Samuel Lunenfeld Research Institute, Toronto, ON, Canada; Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, Toronto, ON, Canada; McGill University, Montréal, QC, Canada; Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; Centre Hospitalier Universite de Montreal- Hopital Notre Dame, Montreal, QC, Canada; Queen's University, Cancer Centre of Southeastern Ontario, Kingston, ON, Canada; Toronto General Hospital, University Health Network, Toronto, ON, Canada; McGill University Health Centre, Montréal, QC, Canada; Toronto General Hospital, Toronto, ON, Canada

Background: Whole genome sequencing (WGS) can reveal patterns of substitution base signatures and structural variation consistent with tumours deficient in homologous recombination repair. We evaluated the published HRDetect score and a novel HRD hallmark score (HS) in patients receiving combination chemotherapy (cCT) on the COMPASS trial for advanced PDAC. **Methods:** The HRD-HS incorporates 10 genomic characteristics of HRD-PDAC with a score ≥ 4 defining HRD. HRD-HS and an HRDetect score $\geq$0.7 were applied to WGS data and overall survival (OS) and response (ORR) evaluated. Sensitivity and specificity were ascertained. **Results:** As of 05/19, 205 eligible patients (pts) were enrolled and 186 received cCT including modified FOLFIRINOX n = 108 (58%) or cisplatin/gemcitabine n = 2 (1%) and gemcitabine/nab-paclitaxel n = 76 (41%). HRD-HS had a sensitivity of 87.5% and specificity of 100% in detecting HRD-PDAC. In contrast, HRDetect ($\geq$0.7) had sensitivity of 51.9% and specificity of 100%; sensitivity increased to 73.7% when using a cutoff score of $\geq$0.99. 23/186 (12%) pts were classified as HRdetect^{hi} and median OS was 15.3months (mo) vs 8.7mo in HRDetect^{lo} pts (HR 0.44 95% CI 0.27-.70, p = 0.009). In platinum treated pts, median OS was 18.1mo (HRDetect^{hi}) vs 9.3mo (HRDetect^{lo}) (HR 0.38 95%CI 0.21-0.69, p = 0.02). HRD-HS predicted the longest median OS for platinum of 21.0mths. ORR in HRDetect^{hi} was not different to HRDetect^{lo} pts treated with cCT, however in those receiving platinum the ORR was 50% vs 19% respectively ($p < 0.001$). Of the false positives by HRDetect, 46% had a non-BRCA1 tandem duplicator phenotype (TDP). The TDP group comprised 8% of all patients enrolled. HRD-PDAC was caused by inactivation of *BRCA1/2*, *PALB2*, *RAD51C* and *XRCC2;* all germline variants were pathogenic. Pathogenic *ATM* and *CHEK2* germline variants were present in 3 pts with evidence of a second somatic hit or LOH, none of these identified as HRD by either classifier nor considered a TDP. **Conclusions:** HRD-HS most correctly identified HRD-PDAC however the HRDetect score classifies additional patients sensitive to cCT, especially platinum. The TDP cohort may be responsive to DNA damaging agents warranting further evaluation. Clinical trial information: NCT02750657. Research Sponsor: Ontario Institute Cancer Research, Pancreatic Cancer Canada.

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742 Poster Session (Board #M9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Clinical significance of MUC4 isoforms in pancreatic cancer patients.

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Background: Pancreatic adenocarcinoma (PC) is a highly aggressive cancer with a 5-year survival rate around 9% with majority of patients diagnosed at advanced stage. Prior studies describe transcriptomic alterations during tumorigenesis, of which novel and progressive expression of mucins are significant. Mucins are large secreted or membrane-tethered glycoproteins that have been shown to be of pathogenic importance in PC. **Methods:** We explored differential expression and survival outcomes based on mucin expression using TCGA PC patients (n = 150). RNA-Seq. reads were realigned to all known mucin splice variant (SV) sequences. Hazard ratios (HR) were calculated for all SVs (n = 123), and SVs with significant HRs were plotted on Kaplan-Maier survival curves comparing expression about the median. The MUC4 SV (MUC4Δ6) was selected for validation in patient tumor samples (n = 17) due to PC tumor cell-specific expression and in-frame deletion of a single exon. After discovery of significant mucin SVs, we designed a gold-nanoparticle (GNP) assay to specifically detect MUC4Δ6 in circulation from PC patient plasma. **Results:** In the absence of significant mucin-based survival differences, we expanded our analysis to include mucin SV transcripts. Through hazard and survival analyses, we identified 3 MUC1 SVs with better survival (SV1 HR = .61, p = .033; SV2 HR = .64, p = .05; SV3 HR = .62, p = .04), and one each of MUC4 (HR = 1.93, p = .028) and MUC16 (HR = 1.90, p = .027) with worse prognosis. In a validation cohort, we found 10 samples had a high cellularity (HC) gene signature. Expression of MUC4Δ6 was 4804.7 copies/100,000 GPI copies in the HC population and expressors above the median had a median survival of 397 days compared to1964.5 days (p = .191) in low expressors. Our novel GNP assay detected MUC4Δ6 transcripts at minimum concentrations of 100 fM with a synthetic RNA. Uniquely, our assay detects the MUC4Δ6 SV but not wild-type variant. **Conclusions:** We were able to determine that expression of specific mucin SV are prognostic in PC patients. We developed technology to detect MUC4Δ6 transcript in circulation using a novel GNP assay. Future studies will seek to stabilize the nanoparticles and modify them for potential diagnostic purposes in a clinical setting. Research Sponsor: U.S. National Institutes of Health.

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743 Poster Session (Board #M10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Whole genome and transcriptome analysis and the link between insulin receptor aberration and diabetes in PDAC.

Michael Lee, James T. Topham, Steve Kalloger, Shehara Ramyalini Mendis, Erica S. Tsang, Joanna Karasinska, Jonathan M. Loree, David F. Schaeffer, Daniel John Renouf; BC Cancer, Vancouver, BC, Canada; Pancreas Centre BC, Vancouver, BC, Canada; Department of Pathology & Laboratory Medicine Vancouver General Hospital, Vancouver, BC, Canada; BC Cancer Agency, Vancouver, BC, Canada

Background: Pancreatic ductal adenocarcinoma's (PDAC) association with diabetes development remains poorly understood. The insulin receptor (*INSR*) can divert insulin signaling from metabolic to oncogenic pathway activation through alternative splicing of *INSR* in several cancer types. **Methods:** 54 treatment naïve patients with metastatic PDAC underwent fresh tumour biopsy in the BC Cancer Personalized Oncogenomics (POG) and PanGen studies (NCT02155621, NCT02869802) for whole genome (WGA) and transcriptome analysis (RNASeq). Copy status and expression of *INSR* were correlated with T2DM status, Moffitt subtypes, and overall survival (OS). The findings were then correlated with 92 resected PDAC from the International Cancer Genome Consortium (ICGC). **Results:** 13/54 (24%) had confirmed T2DM at enrollment, and had poorer OS compared to non-diabetic PDAC patients, independent of Moffitt subtype, HR 3.2 (1.5-6.5), p =0.001. Diabetics were more likely to have hypertension (64 v 11%, p $<$0.001), dyslipidemia (57 v 16%, p=0.013), and to be older (61.5 v 58 years, p=0.014) and smokers (71.4 v 21.6%, p=0.015). WGA revealed significant enrichment of heterozygous *INSR* copy loss in T2DM (69%) compared to all other patients (24%; p=0.03) and an enrichment of *INSR* copy loss for metastatic PDAC relative to resected PDAC in ICGC (35 v 18%, p=0.03). Heterozygous *INSR* copy loss (n = 17/54) was an independent predictor of worse OS (10.8 v 15.1 months, HR 2.29 (1.20-4.36), p=0.012), and it interacted with diabetes status (p=0.023). Moffitt basal (vs. classical) subtype (n = 17/54, of which 8/17 have *INSR* copy loss) was also an independent predictor of OS with HR 4.3 (2.1-8.7), p$<$0.001. Whilst there was no interaction between *INSR* status and Moffitt subtype on OS (p=0.727), *INSR* expression is lower in basal subtype, p$<$0.001. **Conclusions:** Presence of T2DM in our cohort is an independent predictor of worse OS, consistent with published literature. Alteration in the insulin signalling pathway with heterozygous copy loss of *INSR* was associated with poorer prognosis, diabetes development and overlapped with Moffitt basal subtype. Research Sponsor: Terry Fox Research Institute, BC Cancer Foundation, Pancreas Centre BC.

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744 Poster Session (Board #M11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pancreatic cancer intratumoral microbiome and characteristics within paired patient samples.

Sonal Suresh Noticewala, Daniel Lin, Ramez Kouzy, Anirban Maitra, Lauren Elizabeth Colbert, Cullen M. Taniguchi; University of Texas MD Anderson Cancer Center, Houston, TX; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: While most studies evaluating the microbiome in gastrointestinal cancers analyze stool, little is known about the microbiota of the peri-tumoral and intra-tumoral environment. Here, we evaluated the intra-tumoral and peri-tumoral (duodenum and normal pancreas) microbiome for paired duodenal, normal pancreas and resected tumor specimens from pancreatic cancer patients. The purpose of this study was to describe the similarities and differences within patient microbiota. **Methods:** Fifteen specimens from 5 patients with pancreatic cancer were collected during surgical resection. Genomic bacterial DNA was extracted from these specimens and underwent 16S rRNA sequencing. Alpha (Inverse Simpson) and beta diversity were calculated, and relative abundances of individual bacterial species were compared. Sorensen distance was used the evaluate the spread in beta diversity between paired sample types. **Results:** Of the five patients who underwent resection, the following baseline characteristics were obtained: median age = 65 years (range 55 -80 years), 2/5 patients were treated with gemcitabine/abraxane, 3/5 patients were treated with oxaliplatin, irinotecan, fluorouracil, and leucovorin (FOLFIRINOX); 4/5 patients received pre-operative radiation. 16s sequencing analysis of the pancreatic tumor showed the dominant genus to be *Escherichia/Shigella* (10.6%). *Bradyrhizobium* (10.1 %) was dominant in the normal pancreas. *Escherichia/Shigella (*14.3%) was abundant in the duodenum. There was a trend towards higher alpha diversity in tumor vs. normal duodenum/ pancreas (p = 0.12). Sorensen distance was statistically different between sample types (p = 0.004), with duodenal samples most consistent (distance = 67.82), and tumor vs. normal pancreas (81.86) and tumor vs. other tumor samples the most heterogeneous (78.5). **Conclusions:** This pilot data suggests that the pancreatic tumor microbiome is distinct from the normal pancreas and duodenal microbiome, which indicates tumor specific bacteria should be studied. In future studies, intra-tumoral microbiome may be more relevant to associations with outcomes and treatment response than stool or intestinal microbiome studies. Research Sponsor: None.

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745 **Poster Session (Board #M12), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Clinical significance of monitoring *KRAS* in tissue and plasma of pancreatic cancer patients.

Fumiaki Watanabe, Koichi Suzuki, Toshiki Rikiyama; Jichi Medical University, Saitama, Japan

Background: *KRAS* monitoringprovides valuable information for early diagnosis and prediction of treatment outcome in colorectal cancer. *KRAS*mutation is observed in only half of colon cancer patients, whereas it is detected in 90% of pancreatic cancer patients. Therefore, investigating tumor DNA in plasma by *KRAS* monitoringmay be even more valuablein pancreatic cancerpatients. In this study, we elucidated the clinicalsignificance of *KRAS*monitoring in pancreatic cancer patients during treatment. **Methods:** *KRAS*in tumor tissues was analyzed for mutations by Scorpion ARMS or RASKET in 83 patients with pancreatic tumors. *KRAS*in plasma was analyzed for mutations(G12D, G12V, G12C, G12A, G12S, G12R, G13D, Q61L, and Q61H) using droplet digital polymerase chain reaction in 88 patients who underwent the curative surgery (N = 45) or the chemotherapy (N = 33) and who had *KRAS* mutation in their tissues. **Results:** *KRAS*mutation in tumor tissues was detected in 74 of 83 patients (89.2%). These 74 patients showed significantly poorer prognosis (MST; 32) than the seven patients without mutation (p = 0.03), whose MST were 193. Monitoring of*KRAS*in plasma revealed *KRAS*mutation in 35 of 88 patients (39.8%). In patients who underwent the chemotherapy (N = 33), 2years OS of patients who detected *KRAS*mutation in plasma (N = 23) was 16.4% and them which not detected it (N = 10) was 53.3% (p = 0.18). But in the curative resection group (N = 45), 3years OS of patients who detected *KRAS*mutation in plasma (N = 12) was 16.7% and them which not detected it (N = 33) was 68.2% (p = 0.00). **Conclusions:** *KRAS*mutation in tissue and plasma could be a valuable predictive and prognostic biomarker in pancreatic cancer patients. Research Sponsor: Jichi medical university saitama medical center.

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746 Poster Session (Board #M13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

CEACAM6 as a candidate biomarker for pelareorep sensitivity in pancreatic adenocarcinoma (PDAC).

Anne M. Noonan, Jacob Yount, Jason David, Mindy Hoang, Colin W. Stets, Tanios S. Bekaii-Saab, Ying Huang, Wendy L. Frankel, Cynthia Dawn Timmers, John L. Hays, James Lin Chen; The Ohio State University Comprehensive Cancer Center, Arthur G. James Cancer Hospital, Columbus, OH; The Ohio State University, Columbus, OH; The Ohio State Comprehensive Cancer Center, Columbus, OH; Mayo Clinic, Phoenix, AZ; The Ohio State University, Division of Hematology, Columbus, OH; The Ohio State University Wexner Medical Center, Columbus, OH

Background: Pelareorep is a proprietary formulation of live, replication-competent, naturally occurring Reovirus Type 3 Dearing strain. A randomized phase II trial of pelareorep in combination with carboplatin and paclitaxel in first-line treatment of metastatic PDAC (NCT01280058) was performed. Although pelareorep did not improve the primary endpoint of progression-free survival compared to carboplatin and paclitaxel alone, impressive durable responses were seen in the pelareorep arm in some patients (pts). Further, prior studies have noted the immunomodulatory carcinoembryonic antigen-related cell adhesion molecule (CEACAM6/CD66c) as a receptor for specific viral subtypes. We thus speculated that altered CEACAM6 levels may be predictive for pelareorep sensitivity. **Methods:** Pre-treatment tissue biopsies were collected prior enrolment for all 73 pts on study. Evaluable pts with transcriptomic data was available for only 31 pts. RNA was purified from FFPE tissue and gene expression analysis was performed using SensationPlus FFPE Amplification and WT labelling kit and the Human Transcriptome Array 2.0. CEACAM6 protein expression was determined by immunohistochemistry. Differential gene expression and survival analysis using were performed in R/Bioconductor. Appropriate corrections for multiplicity were performed. **Results:** When comparing extraordinary responders in the pelareorep treated arm to those with poor outcomes, low levels of CEACAM6 mRNA expression were associated with prolonged PFS in pelareorep-treated pts (adjusted p = 0.05). This effect was not seen in non-pelareorep treated pts. The luminal, but not the cytoplasmic immunohistochemistry score, was highly correlated with mRNA expression levels of CEACAM6, p = 0.001. Modulation of CEACAM6 in vitro and in vivo are underway. **Conclusions:** CEACAM6 may be a candidate biomarker of sensitivity to pelareorep and, in theory, could improve viral trafficking of this compound in tumor cells. Clinical trial information: NCT01280058. Research Sponsor: U.S. National Institutes of Health, William Hall Fund for Liver and Pancreatic Cancer Research.

	PFS Median (95% CI)	Log-rank test
Arm A (n = 17) (median CEACAM = 5.24)		
CEACAM ≥5.24	5.72 (2.50-8.25)	0.05
CEACAM < 5.24	10.32 (2.17-30.55)	
Arm B (n = 14) (median CEACAM = 4.73)		
CEACAM ≥4.73	4.30 (0.92-6.34)	0.35
CEACAM < 4.73	7.36 (1.05-16.46)	

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747 Poster Session (Board #M14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Clinical and molecular profiling of locally advanced compared with metastatic pancreatic adenocarcinoma.

Sarah Louise Picardo, Grainne M. O'Kane, Sandra Fischer, Amy Zhang, Robert Edward Denroche, Gun Ho Jang, Anna Dodd, Robert C. Grant, Barbara Grunwald, Shari Moura, Elena Elimova, Rebecca M. Prince, George Zogopoulos, Faiyaz Notta, Julie Wilson, Steven Gallinger, Jennifer J. Knox; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Princess Margaret Cancer Centre, Toronto, ON, Canada; Toronto General Hospital, University Health Network, Toronto, ON, Canada; Ontario institute for Cancer Research, Toronto, ON, Canada; Ontario Institute for Cancer Research, Toronto, ON, Canada; Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, Toronto, ON, Canada; University of Texas MD Anderson Cancer Center, Houston, TX; Princess Margaret Cancer Centre, University of Toronto, Toronto, ON, Canada; McGill University Health Centre, Montréal, QC, Canada

Background: It is unclear whether locally advanced pancreatic cancer (LAPC) should be treated similarly to metastatic pancreatic cancer (MPC). Clinical trials often exclude LAPC. We compare clinical and genomic characteristics of LAPC and MPC. **Methods:** Patients with LAPC and MPC were enrolled in the COMPASS trial (NCT02750657). Clinical, demographic and survival data was collected (cut off 8/31/19). WGS, RNAseq and modified Moffitt classification was performed. **Results:** Patients with LAPC (n = 28) and MPC (n = 180) did not differ in terms of age, gender, smoking or diabetes history. Patients with LAPC had lower BMI (p = 0.005) and lower baseline Ca19-9 (p = 0.02) than those with MPC. LAPC/MPC tumors had similar rates of KRAS, p53, CDKN2A and SMAD4 mutations and similar levels of ploidy, indels and neoantigens. There were increases in single nucleotide variants (p = 0.026) and structural variants (p = 0.04) in MPC compared with LAPC. No LAPC tumors were homologous recombination deficient (HRD) or KRAS wild type (WT), compared with 14 (8%) HRD and 16 (9%) KRAS-WT MPC. All LAPC were classical subtype compared with 77% MPC (p = 0.0052). OS data is shown in the table. MPC classical subtype tumors had improved OS compared with basal-like tumors (p = 0.008). Patients with MPC and p53 mutation trended towards worse OS compared with those without p53 mutation (p = 0.07); this was not seen in LAPC. There was a significant correlation between time on chemotherapy and OS in LAPC (p = 0.002) and MPC ($p < 0.0001$). **Conclusions:** Patients with LAPC have similar molecular profiles to those with MPC with similar rates of altered drivers. LAPC tumors are more likely to be Moffitt classical subtype and have similar OS to classical subtype MPC. LAPC patients benefit from local therapy; all patients benefit from increased time on chemotherapy. These data suggest that patients with LAPC should be treated similarly to those with classical subtype MPC but should be offered local therapy when possible. Clinical trial information: NCT02750657. Research Sponsor: Government of Ontario, Other Foundation.

		Median OS (weeks)	Significance
Overall OS	LAPC	42.49	
	MPC	31	p = 0.06
Classical subtype	LAPC (n = 28)	42.49	
	MPC (n = 132)	32.14	p = 0.18
LAPC SMAD4	SMAD4 mutated	47.07	
	SMAD4 WT	40.35	p = 0.09
LAPC local therapy	Yes (n = 10)	56.64	
	No (n = 18)	38.21	p = 0.04

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748 Poster Session (Board #M15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

The potential of Tenascin C in the tumor-nerve microenvironment to enhance perineural invasion and correlate with locoregional recurrence-related poor prognosis in pancreatic ductal adenocarcinoma.

Satoru Furuhashi, Takanori Sakaguchi, Ryuta Muraki, Ryo Kitajima, Mayu Fukushima, Makoto Takeda, Yoshifumi Morita, Hirotoshi Kikuchi, Mitsutoshi Setou, HIROYA TAKEUCHI; Hamamatsu University School of Medicine, Hamamatsu, Japan

Background: Perineural invasion (PNI) is commonly seen in pancreatic ductal adenocarcinoma (PDAC) and worsens the postoperative prognosis. However, the detail mechanisms of PNI in PDAC remain unclear. Tenascin C (TNC), an extracellular matrix glycoprotein, is abundant in cancer stroma and modulates tumor progression. In this study, we hypothesized that TNC could enhance PNI in PDAC. The aim of this study was to investigate the roles of TNC in the tumor-nerve microenvironment of PDAC. **Methods:** We immunohistochemically examined TNC expression in 78 resected PDAC specimens. TNC staining intensity in perineural sites at the invasive front was classified as low or high, by comparison with adjacent non-cancerous tissues in the same section. The relationships between TNC expression and clinicopathological features were retrospectively analyzed. Furthermore, interactions between cancer cells and nerves after supplementation with TNC were investigated using in vitro co-culture model with a PDAC cell line and neonatal mouse dorsal root ganglion (DRG). **Results:** High perineural TNC expression at the invasive front, seen in 30 (38%) patients, was associated with the presence of PNI ($p = 0.006$), pathological T stage ≥ 3 ($p = 0.01$), and postoperative locoregional recurrence ($p = 0.002$). It was independently associated with postoperative, poor recurrence-free survival in multivariate analysis ($p = 0.045$). In the in vitro co-culture model, TNC supplementation significantly enhanced both neurotropism of PDAC cells and tumor tropism of a DRG. On the other hand, when PDAC cells and a DRG were cultured separately, TNC did not affect cancer cell proliferation or neural outgrowth. Furthermore, the knockdown of Annexin A2, which is known to be a receptor for TNC, cancelled the neurotropism of PDAC cell toward DRGs. **Conclusions:** Strong perineural TNC expression was a prognostic indicator of locoregional recurrence-related poor prognosis. The neurotropism of PDAC induced by TNC and TNC-Annexin A2 signaling pathway could be the potential therapeutic target for PDAC by regulating PNI. Research Sponsor: kaken.

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749 Poster Session (Board #M16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Molecular genetic changes in solid pseudopapillary neoplasms (SPN) of the pancreas.

Elisa M. Rodriguez-Matta, Gerardo Colon-Otero, Amanda Hemmerich, Eric Allan Severson; Univeristy of Puerto Rico School of Medicine, San Juan, PR; Mayo Clinic, Jacksonville, FL; Foundation Medicine, Inc., Cambridge, MA

Background: Solid Pseudopapillary Neoplasms (SPNs) of the pancreas are rare accounting for 1-2% of all pancreatic tumors. Previous studies had shown that a pathogenic mutation of the *CTNNB1* gene is present in over 90% of the SPN tumors with very limited information available on the specific molecular changes present in SPN. Here we report the results of next generation genetic testing of a large series of SPN tumors from the Foundation Medicine database. **Methods:** Foundation Medicine database from 07/2012 to 04/2019 was reviewed. A total of 31 cases of SPN tumors were identified out of 12,892 cases of pancreatic cancers. Information collected included demographic information on the patients as well as tumor analysis for next generation genetic sequencing of 315 genes associated with cancer with FoundationOne or 324 genes associated with FoundationOneCDx. Microsatellite stability status and tumor mutation burden were determined. **Results:** Twenty nine out of 31 cases (93%) had a *CTNNB1* mutation. Seventy percent of the *CTNNB1* mutations were on position 32 (14 cases, 41%) or in position 37 (9 cases, 29%). Other sites of CTNNB1 mutations included position 34 (3 cases, 9.6%), position 2 (2 cases, 6.4%) and position 38 (1 case, 3.2%). Two cases did not have a *CTNNB1* mutation, one had a *CDKN2A* mutation and the other had no detectable mutations. Most cases had additional mutations aside from the *CTNNB1*, the most common were *TP53* (3 cases, 9.6%) and *LRP1B* (2 cases, 6.4%). Other accompanying mutations were seen just once. Twenty-five percent of these cases had actionable gene mutations, each found in one case including: *MSH2, BRCA2, ATM, XRCC3, ATRX, PTEN, ESR1*, *CDKN2, and PIK3CA*. **Conclusions:** Next generation genetic testing of SPN tumors is of clinical benefit since it identifies actionable mutations in 29% of the cases. Research Sponsor: None.

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750 Poster Session (Board #M17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Early progression (progr) in patients (pts) with metastatic pancreatic cancer (mPaC) and a germline BRCA mutation (gBRCAm): Phase III POLO trial of olaparib (O) versus placebo (P).

Teresa Macarulla, Hedy L. Kindler, Pascal Hammel, Michele Reni, Eric Van Cutsem, Michael J. Hall, Joon Oh Park, Daniel Hochhauser, Dirk Arnold, Do-Youn Oh, Anke C. Reinacher-Schick, Giampaolo Tortora, Hana Algül, Eileen Mary O'Reilly, David McGuinness, Karen Cui, Katia Schlienger, Gershon Y. Locker, Talia Golan; Vall d'Hebrón University Hospital and Vall d'Hebrón Institute of Oncology, Barcelona, Spain; The University of Chicago, Chicago, IL; Hôpital Beaujon (AP-HP), Clichy, and University Paris VII, Paris, France; IRCCS Ospedale, San Raffaele Scientific Institute, Milan, Italy; University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; Fox Chase Cancer Center, Philadelphia, PA; Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; University College London Cancer Institute, London, United Kingdom; Asklepios Tumorzentrum Hamburg AK Altona, Hamburg, Germany; Seoul National University Hospital, Seoul, South Korea; St Josef-Hospital, Ruhr University Bochum, Bochum, Germany; Azienda Ospedaliera Universitaria Integrata Verona, Verona and Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy; Klinikum Rechts der Isar, Comprehensive Cancer Center Munich-TUM and Department of Internal Medicine II, Technische Universität München, Munich, Germany; Memorial Sloan Kettering Cancer Center, New York, NY; AstraZeneca, Cambridge, United Kingdom; AstraZeneca, Gaithersburg, MD; Merck & Co., Inc., Kenilworth, NJ; The Oncology Institute, Sheba Medical Center at Tel-Hashomer, Tel Aviv University, Tel Aviv, Israel

Background: In POLO (NCT02184195), maintenance O was associated with significant progr-free survival benefit vs P in pts with a gBRCAm and mPaC (Golan *NEJM* 2019). Early progr or death (within 4 months [m]) occurs in ~35−45% of pts on standard-of-care first-line (1L) chemotherapy for mPaC (Conroy *NEJM* 2011; von Hoff *NEJM* 2013); however, predictive factors are currently unknown and early progr has not been addressed in the maintenance setting. We examined factors potentially associated with early progr in POLO. **Methods:** Following ≥16 weeks of 1L platinum-based chemotherapy (PBC) without progr, pts were randomized to maintenance O (tablets; 300 mg bd) or P until progr or unacceptable toxicity. Early progr was defined as progr (by blinded independent central review) or death within 4 m of randomization. A stepwise logistic regression model included baseline (BL) factors age, albumin, lactate dehydrogenase (LDH), global health status (GHS) and physical functioning (PhysF) as continuous variables, and discrete variables listed in the Table. **Results:** 62/154 randomized pts (40%) were defined as early progressors (EP; Table). Due to missing BL data, the multivariate analysis included 127 pts (56 EPs [44%]). Lower BL PhysF score (continuous) was significantly associated with early progr (*P*= 0.02); no difference for partial/complete response (PR/CR) vs stable disease (SD). **Conclusions:** While small sample size limited analysis power, PhysF score was the only BL factor significantly associated with early progr in pts with a gBRCAm and mPaC in the POLO trial of maintenance O vs P. Clinical trial information: NCT02184195. Research Sponsor: AstraZeneca and Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Inc, Kenilworth, NJ, USA.

n (%)	Pts	EP		Pts	EP		Pts	EP
						ECOG status		
Olaparib	92	33 (36)	***BRCA2*m**	104	45 (43)	**0**	103	44 (43)
Placebo	62	29 (47)	***BRCA1*m, both**	46	17 (37)	**1**	48	18 (38)
1L PBC			**1L PBC duration**			**GHS**		
FOLFIRINOX variants	129	49 (38)	**≤6 m**	101	44 (44)	**< median (75.0)**	70	32 (46)
Gemcitabine/cisplatin, other	23	13 (57)	**> 6 m**	51	18 (35)	**≥ median**	77	28 (36)
PhysF			**1L PBC best response**			**Age**		
< median (86.7)	88	41 (47)	**PR/CR**	76	32 (42)	**< 65 y**	113	43 (38)
≥ median	59	19 (32)	**SD**	76	30 (39)	**≥65 y**	41	19 (46)
Randomization y						**Metastases**		
2015	25	14 (56)	**Male**	84	32 (38)	**Liver**	104	45 (43)
2016	42	16 (38)	**Female**	70	30 (43)	**Other**	38	14 (37)
2017	40	13 (33)						
2018-19	47	19 (40)						

y, year

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751 Poster Session (Board #M18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Pancreatic adenosquamous carcinoma: Clinical associations, treatment, and outcomes.

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Background: Pancreatic adenosquamous carcinomas (PASC) are rare malignancies, with limited evidence regarding best treatment options. The Mayo Clinic Pancreatic Cancer SPORE Registry was utilized to compare/contrast outcomes for pancreatic cancers with a squamous component to pancreatic ductal adenocarcinoma (PDAC). **Methods:** Patients were identified from the SPORE Registry (2000-2019), were reviewed and confirmed by expert pathologists. Demographic and clinical information was ascertained from medical records and risk factor questionnaires. A case control study of patients with PASC vs PDAC was constructed. PASC patients were also followed for outcome and treatment records were extracted. **Results:** Of 2,584 total patients with pancreatic cancers, 45 cases of PASC and 2,438 with PDAC were identified. There were no differences in age (median 69 vs 67 years, p=0.42), sex (male 64.4vs 56.6%, p= 0.29), BMI (27.41 vs 27.78 kg/m2, P=0.50), or ever-smoking (61.0 vs 55.3%, P=0.47), with a borderline association with reported diabetes (17.8 vs 29.9%, p =0.08). Compared to PDAC, PASCs were more likely to involve the body/tail (48.9 vs 33.2%, p= 0.02) and had poorer overall survival, adjusted for age, gender, and stage (median 7.1 m vs 12.8m, HR 1.89, p=0.0004). Of 9 PASC pts treated with neoadjuvant intent, 4 were surgically resected, median survival was 7 months. Eleven pts underwent upfront surgery, with variable adjuvant treatments. Median OS post- surgery was 18m (range 7-51). Of 14 patients presenting with metastatic disease, median survival was 4.5 m (range 1-22). With regard to systemic chemotherapy, for neoadjuvant or metastatic disease median duration of treatment was 3 months (range 0.5-7m) for Gemcitabine + nab-paclitaxel (N=9) and also 3 months (range 2-6m) for FOLFIRINOX (N-13). **Conclusions:** The diagnosis of PASC carries an even poorer outcome than pancreatic adenocarcinoma. Tumors are more likely to arise in the distal pancreas, and patients may be less likely to report associated diabetes. Limited antitumor activity was noted with multi-agent chemotherapeutic regimens. Prospective trials will be needed to clarify choice of regimen in the future. Research Sponsor: None.

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752 Poster Session (Board #M19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Prognostic utility of inflammation biomarkers in a PDAC trial involving the human anti-CTGF antibody pamrevlumab.

Mark D. Sternlicht, Dongxia Li, Viet-Tam Nguyen, Mairead Carney, Duo Zhou, Kenneth E. Lipson, Elias Kouchakji, Vincent J. Picozzi, Ewa Carrier, Todd W. Seeley; FibroGen, Inc., San Francisco, CA; Virginia Mason Hospital and Medical Center, Seattle, WA

Background: Pancreatic ductal adenocarcinomas (PDAC) often exhibit desmoplasia, elevated CTGF (connective tissue growth factor) expression and inflammation. The influence of inflammation on patient outcomes was examined in a dose-ranging trial of the anti-CTGF antibody pamrevlumab in combination with a fixed regimen of gemcitabine and erlotinib in locally advanced or metastatic PDAC patients (NCT01181245; Picozzi et al. J Cancer Clin Trials 2017 2:123; n = 75). **Methods:** The prognostic utility of pre-treatment plasma levels of C-reactive protein (CRP), transforming growth factor β1 (TGFβ1), albumin, CTGF and CA 19-9 were assessed by univariate and multivariate Cox analysis. Demographic parameters, treatment cohort, and pamrevlumab exposure determined on treatment day 15 were also evaluated, as were changes in biomarker levels over the first four weeks of treatment. **Results:** Elevated baseline CTGF and CRP were prognostic for shorter overall survival (OS) by univariate analysis (HR = 3.2 for CRP $>$ 10 mg/L, p= 0.00002 and HR = 1.6 for CTGF $>$ 10 ng/mL, p= 0.045). In a five-factor multivariate Cox model that included CRP and TGFβ1 as continuous Ln-transformed variables, performance status, age, and pamrevlumab treatment cohort, cohort assignments associated with increasing pamrevlumab exposure predicted improved OS (HR = 0.87, p= 0.03). Removing CRP from this model reduced the prognostic utility of pamrevlumab cohort assignment and exposure, indicating an important contribution of inflammation to interpretation of treatment outcome. Changes in inflammation biomarkers over the course of treatment were also evaluated, but were not prognostic in this study. **Conclusions:** In multivariate Cox models, assessment of pre-treatment CRP levels improved ability to detect significant differences in PDAC patient survival outcomes associated with pamrevlumab treatment. Our results emphasize the utility of accounting for pre-treatment CRP levels as an independent prognostic factor in PDAC treatment effect models. Research Sponsor: FibroGen.

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753 Poster Session (Board #M20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM and Poster Walks, Fri, 4:45 PM-5:30 PM

Noninvasive comprehensive genomic profiling from plasma ctDNA in pancreatic cancer patients.

Danielle Sara Bitterman, Kristin Sedgwick Price, Emily E. Van Seventer, Jeffrey William Clark, Jill N. Allen, Lawrence Scott Blaszkowsky, David P. Ryan, Christine Elissa Eyler, Jennifer Yon-Li Wo, Theodore S. Hong, Ryan David Nipp, Eric Roeland, Janet E. Murphy, Ryan Bruce Corcoran, Colin D. Weekes, Aparna Raj Parikh; Department of Radiation Oncology, Massachusetts General Hospital, Boston, MA; Guardant Health, Inc., Redwood City, CA; Massachusetts General Hospital, Boston, MA; Hematology/Oncology, Massachusetts General Hospital, Boston, MA; Massachusetts General Hospital Cancer Center, Boston, MA

Background: The use of comprehensive genomic profiling (CGP) is increasing in pancreatic ductal adenocarcinoma (PDAC) as knowledge improves regarding molecular drivers of tumorigenesis and effective targeted therapies emerge. However, adequate tissue sampling is often limited. Plasma-based CGP offers a non-invasive approach to assess biomarkers that may impact treatment decisions. **Methods:** We retrospectively evaluated genomic and clinical data from 97 PDAC patients with circulating tumor DNA (ctDNA) testing from 9/2016-8/2019 (Guardant Health, Inc.). ctDNA analysis included single nucleotide variants (SNV), fusions, indels and copy number variations (CNV) of up to 74 genes. ctDNA results were assessed across clinical variables. We evaluated for actionable alterations. **Results:** A total of 114 samples were obtained from 97 patients for ctDNA testing. ctDNA alterations were detected in 82% (93/114) of all samples, including 90% (18/20) at diagnosis, 88% (59/67) at progression, and 56% (10/18) while on stable therapy. ctDNA alterations were found at each stage of PDAC: in 25% (1/4) of samples with resectable disease, 75% (3/4) with borderline resectable disease, 82% (9/11) with locally advanced disease, and 85% (81/95) with metastatic disease. One or more *KRAS* alterations were detected in 55% (51/93) of patients with alterations present. The median maximum mutant allele frequency was similar between the cohort of patients with *KRAS* detected (0.55%) versus not detected (0.70%). 8% (8/97) of patients had potentially actionable alterations (2 activating *BRAF* SNVs, 1 *ERBB2* CNV, 1 *ERBB2* activating SNV, 1 *KRAS* G12C, and 3 indels in Homologous Recombination Deficiency genes). Median turnaround time was 8 days. 51% (49/97) of patients had both plasma-based CGP and tissue-based CGP. Of these patients, tissue-based CGP showed $\geq$ 1 alterations detected in 82% (40/49), test failure in 14% (7/49), and no alterations detected in 4% (2/49). **Conclusions:** Plasma-based CGP detected ctDNA alterations in 90% of samples tested at diagnosis and 82% of all samples. Potentially actionable mutations were found in 8% of patients, with prompt processing time allowing for rapid decision making. Research Sponsor: None.

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754 **Poster Session (Board #M21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Exceptional responses to ipilimumab/nivolumab (ipi/nivo) in patients (pts) with refractory pancreatic ductal adenocarcinoma (PDAC) and germline BRCA or RAD51 mutations.

Gretel Terrero, Terri Pollack, Daniel A. Sussman, Albert Craig Lockhart, Peter Joel Hosein; Jackson Health System, Miami, FL; Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine, Miami, FL; University of Miami Miller School of Medicine, Miami, FL; University of Miami Sylvester Cancer Center, Miami, FL; University of Miami Sylvester Comprehensive Cancer Center, Miami, FL

Background: Immune checkpoint inhibitors (ICI's) have not shown meaningful clinical activity in unselected pts with PDAC. BRCA-deficient tumors have increased genomic instability, including increased tumor mutation burden (TMB), more tumor-infiltrating immune cells, and enrichment of a T cell-inflamed signature. We hypothesized that pts with mutations in BRCA or other homologous recombination repair genes may be sensitive to ICI's. **Methods:** Utilizing the IRB-approved PDAC database at the University of Miami, we identified pts with relapsed/refractory PDAC with pathogenic germline mutations who were treated with combination ICI's (ipi 1mg/kg and nivo 3mg/kg every 21 days followed by nivo 240mg every 2 weeks). **Results:** Five pts were identified (1 BRCA1, 2 BRCA2, 1 RAD51C and 1 RAD51D). Among the 3 evaluable pts, there was one complete response (CR), one partial response (PR) and one had progressive disease (PD). The pt with a CR had BRCA1; he had resection followed by adjuvant gem/cape and had a biopsy-proven recurrence in the lung and retroperitoneum 1y after the end of adjuvant therapy. He received ipi/nivo at recurrence and achieved a CR, ongoing for 17m on nivo maintenance. The patient with a PR had RAD51C; he was diagnosed with mPDAC and received FOLFIRINOX for 6m, followed by olaparib on a trial for 12m. Upon PD, the disease quickly progressed on 5FU/liposomal irinotecan, gemcitabine/nab-paclitaxel/cisplatin and FOLFIRINOX. He then started ipi/nivo with immediate improvement in pain and tumor markers. A radiological PR was seen after 2 doses and is ongoing for 3m with continued clinical and tumor marker improvement. The 3rd evaluable pt had BRCA2 and had PD with an exponential rise in tumor markers accompanied by clinical deterioration. Response data on the final two pts were pending at the time of submission and will be presented at the meeting. **Conclusions:** In this biomarker selected cohort, 2 out of 3 evaluable pts with PDAC had impressive responses to ipi/nivo. PDAC has generally been refractory to ICI therapy but this series suggests that this subgroup may be responsive to ICI's. Further evaluation is warranted. Research Sponsor: None.

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755 Poster Session (Board #M22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Patterns of failure after adjuvant stereotactic body radiation therapy in patients with pancreatic cancer with close or positive margins.

Ankur Patel, Joshua L. Rodríguez-López, Nathan Bahary, Amer H. Zureikat, Steven A. Burton, Dwight Earl Heron, Adam C. Olson; Department of Radiation Oncology, UPMC Hillman Cancer Center, University of Pittsburgh School of Medicine, Pittsburgh, PA; Department of Medical Oncology, UPMC Hillman Cancer Center, University of Pittsburgh School of Medicine, Pittsburgh, PA; Department of Surgical Oncology, UPMC Hillman Cancer Center, University of Pittsburgh School of Medicine, Pittsburgh, PA

Background: There is no consensus on treatment volumes for stereotactic body radiation (SBRT) in patients with pancreatic cancer (PCa). Herein, we report patterns of failure following adjuvant SBRT for close/positive margins in patients with pancreatic cancer, which may inform appropriate target volume design for SBRT. **Methods:** An IRB-approved retrospective review of patients with PCa treated with adjuvant SBRT for close/positive margins from 2009-2018 was conducted. Patterns of failure were assessed by review of imaging and were defined as local (LF), regional (RF), local and regional (LRF), or distant (DF). The Kaplan-Meier method was used to calculate long-term failure rates. In-field failures were defined as LFs completely within the PTV (planning target volume). The location of LFs was compared to the RTOG consensus volumes for adjuvant treatment of PCa to determine if conventional radiation volumes would have included the LF. **Results:** Seventy-six patients were treated with adjuvant SBRT for close (51.3%) or positive (48.7%) margins, with a median follow-up of 17.0 months (interquartile range [IQR] 7.4-28.3 mos.). Adjuvant SBRT was delivered at a median of 2.2 months after surgery (IQR 1.7-3.0 mos.). Most patients (81.6%) received 36 Gy in 3 fractions. The median PTV volume was 17.8 cc (IQR 12.3-25.2 cc). Upon examination of first failure sites, crude rates of isolated LF, isolated RF, isolated LRF, and DF +/- LF or RF were 9.2%, 6.6%, 2.6%, and 56.6% respectively; 2-year rates were 12.4%, 11.5%, 7.0%, and 66.5%, respectively. Thirty-two patients (42.1%) developed a LF at some point during follow-up. Of 28 LFs with available plans and imaging, 21.4% were in-field failures, while the remainder were completely outside (60.1%) or partially outside (17.9%) the PTV. Most LFs outside the PTV (90.9%) would have been encompassed by the RTOG consensus target volumes for postoperative conventional radiation. **Conclusions:** In patients with PCa who receive adjuvant SBRT for close/positive margins, the majority of LFs are outside the PTV. Future trials involving SBRT or hypofractionated radiation should consider expansion of treatment volumes if feasible. Research Sponsor: None.

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756 **Poster Session (Board #N1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Evaluation of the ratio of plasma fibrinogen to platelet in resectable pancreatic cancer.

Yusuke Arakawa, Mitsuo Shimada, Yuji Morine, Satoru Imura, Tetsuya Ikemoto, Yu Saito, Shinichiro Yamada, Masato Yoshikawa, Katsuki Miyazaki; Tokushima University, Tokushima, Japan; Department of Surgery, Tokushima University, Tokushima, Japan

Background: Several prognostic factors were reported in pancreatic cancer such as neutrophil lymphocyte ratio (NLR), platelet lymphocyte ration (PLR) modified GPS. Fibrinogen platelet ratio (FPR) was reported as one of the prognostic factor of resectable gastric cancer (Surgery today 2019). In this report, the FPR was evaluated in patients with resectable pancreatic cancer. **Methods:** Between 2004 and 2019, one hundred and sixty-three patients in our institution with curative resection for pancreatic cancer were enrolled in this retrospective study. The cases of non-curative resection were excluded. The FPR was calculated with the preoperative plasma fibrinogen and the platelet counts. Cut-off value was decided with ROC curve. The patients were divided into high and low FPR group according to cut-off value. **Results:** The cut-off value of FPR was 25.51. In age, gender, BMI, operative factors including operative type, amount of blood loss and operative time, there was no significant difference between these two groups. Patients in low FPR group had significantly better overall survival (OS) rates and relapse-free survival (RFS) rates compared with high FPR group ($p < 0.05$). On multivariate analysis, the high FPR, CA19-9 $>$ 300 U/ml and receipt of adjuvant chemotherapy were independent risk factor of post-operative recurrence. **Conclusions:** The FPR might be a prognostic factor of patients with resectable pancreatic cancer. Research Sponsor: None.

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757 Poster Session (Board #N2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

PD-L1 expression, tumor mutational burden, and microsatellite instability status in 746 pancreas ductal adenocarcinomas.

Amanda Hemmerich, Claire I. Edgerly, Daniel Duncan, Richard Huang, Natalie Danziger, Garrett M. Frampton, Julia Andrea Elvin, Jo-Anne Vergilio, Jonathan Keith Killian, Douglas I. Lin, Erik Williams, Siraj Mahamed Ali, Prasanth Reddy, Vincent A. Miller, Clarence Owens, Charlotte Brown, Brian M Alexander, Jeffrey S. Ross, Eric Allan Severson, Shakti H. Ramkissoon; Foundation Medicine, Inc., Cambridge, MA; Foundation Medicine, Cambridge, MA; Foundation Medicine, Inc, Morrisville, NC; Foundation Medicine Inc., Cambridge, MA; Foundation Medicine, Inc, Cambridge, MA

Background: Pancreas ductal adenocarcinomas (PDA) has a 5-year survival rate of 6% with a need for new therapeutic options. The approval of pembrolizumab for some gastrointestinal cancers shows the potential of immunotherapy (IMT) in PDA. We evaluated the IMT-associated biomarkers of PD-L1 expression, tumor mutational burden (TMB), microsatellite instability (MSI) and *PD-L1* amplification in PDAs. **Methods:** 746 formalin-fixed paraffin embedded samples were evaluated for PD-L1 IHC using the Dako 22C3 pharmDx assay and scored using tumor proportion score (TPS). The cases had comprehensive genomic profiling (CGP) via DNA sequencing, using a hybrid-capture next-generation sequencing assay (FoundationOne and FoundationOneCDx) for genomic alterations (GAs), TMB, and MSI. **Results:** PD-L1 was positive (TPS $\geq$ 1%) in 29% (214/746) and negative in 71% (532/746). 43/214 (20%) of positive cases were high positive (TPS $\geq$ 50%). TMB (590 cases) had a mean of 3.20, 3.46, and 3.61 mutations/Mb for PD-L1 negative, positive, and high positive groups. 3 hypermutated (TMB $\geq$ 20) were negative for PD-L1 expression. 3/581 cases were MSI-high with a high TMB score (average 23.53 mutations/Mb). 2 MSI-high cases were negative for PD-L1 and 1 was high positive. *PD-L1* amplification was not detected (0/746). Only *BCOR* was significantly different between PD-L1 high positive and PD-L1 negative tumors (Table). **Conclusions:** Of 729 PDA cases, 29% were positive (TPS $\geq$ 1%) for PD-L1 expression while only 6% of all cases showed a high level of PD-L1 expression on tumor cells. TMB high (3/729) and MSI-High (3/729) cases were rare. Only 2 of the TMB high cases were also MSI-high. *PD-L1* amplification was not detected. Comparing GAs in PD-L1 high positive vs negative cases was only significantly different for *BCOR*. Further investigation is needed to see if a combined positive score of PD-L1 expression may identify a subset of patients with PDA who are more likely to respond to IMT. Research Sponsor: None.

Gene	High Positive PD-L1 (TPS ≥50%, n= 43)	Negative PD-L1 (TPS <1%, n=532)	p-value
KRAS	41	499	1
TP53	36	422	0.5608
CDKN2A	27	320	0.8715
CDKN2B	17	133	0.0463
MTAP	12	100	0.161
ARID1A	7	57	0.3082
SMAD4	8	176	0.0608
AKT2	5	22	0.0432
BCOR	5	7	0.001
DNMT3A	3	29	0.7246

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758 **Poster Session (Board #N3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Analysis of pancreatobiliary adenocarcinoma (PBC) treatment response and resistance utilizing circulating tumor DNA (ctDNA).

Madhulika Banerjee, Alejandro Recio Boiles, Sumana Veeravelli, Jorge Andres Leiva, Kathylynn Saboda, Denise Roe, Ali McBride, Hani M. Babiker; University of Arizona College of Medicine, Tucson, AZ; University of Arizona Medical Center, Tucson, AZ; Strake Jesuit College, Houston, TX; University of Arizona Cancer Center, Tucson, AZ; University of Arizona, Tucson, AZ

Background: Accurate disease monitoring in PBC is instrumental for optimal therapeutic decision-making. CA 19-9 is the most utilized biomarker, though it has limited sensitivity/specificity and cannot be used in CA 19-9 non-secretors (n-S). ctDNA is a potentially helpful monitoring aid and surrogate for PBC n-S. Serial ctDNA could identify emerging resistant driver mutations. Our study prospectively examined ctDNA in PBC patients receiving treatment and retrospectively correlated it with clinical response. **Methods:** We performed genomic testing of ctDNA from metastatic PBC patients' plasma from 11/2016 to 08/2019. This included 77 patients, of those, 18 had >1 ctDNA measurement with 49 correlative data points in total. Demographics, serial CA 19-9 levels and imaging results were collected. ctDNA analysis by parallel sequencing of amplified target genes (74) using Guardant360 was obtained. We correlated imaging and CA 19-9 responses with molecular alterations in patients receiving systemic chemotherapy. Descriptive statistics and logistic regression of the data was performed. **Results:** Of those included, median age was 66 yo, 50% male, and 92% pancreatic ductal adenocarcinoma. Baseline ctDNA showed 103 mutations including *TP53* 12.6%, *KRAS* 9.7%, *MET* 6.8%, *APC*, *ARID1A and NF1* 4.8% each, and others < *3%*. 44% of patients were n-S with 75% having both *TP53* and *KRAS* mutations. *APC*, *ARID1A, and NF1* were only present in n-S. 91% vs 90% *KRAS* and 84% vs 78% *TP53* of n-S and secretors (S), respectively, had correlation between ctDNA levels and imaging response. S *TP53* and *KRAS* mutations correlated to CA19-9 levels and scans in 78% and 70% responses. New *TP53* subclonal variant mutations were the most common resistance mutations for all progressions (75%). A logistic regression model of imaging progression on change in CA19-9 secretion and *TP53* or *KRAS* expression was not statistically significant. **Conclusions:** Baseline ctDNA level changes (*TP53* and *KRAS*) can potentially act as a biomarker of response in PBC, specifically in n-S. *TP53* subclonal mutations were the most common resistant alterations at progression and can be explored as future targets. This is being explored in larger prospective trials. Research Sponsor: None.

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759 Poster Session (Board #N4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Impact of *CDKN2A/b* status in pancreatic cancer (PC).

Kaitlin Annunzio, Claire Griffiths, Igli Arapi, Matthew Lasowski, Arun K. Singavi, Kulwinder Dua, Abdul H. Khan, Paul S. Ritch, Mandana Kamgar, James P. Thomas, William Adrian Hall, Beth Erickson, Susan Tsai, Kathleen K. Christians, Douglas B. Evans, Raul Urrutia, Aniko Szabo, Ben George; Medical College of Wisconsin, Milwaukee, WI; Medical Colllege of Wisconsin, Milwaukee, WI; Medical College of Wisconsin and Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI; Froedtert & the Medical College of Wisconsin, Milwaukee, WI

Background: PC is a lethal disease with limited treatment options. We utilized Comprehensive Genomic Profiling (CGP) to identify putative prognostic and/or predictive biomarkers. **Methods:** We retrospectively reviewed PC patients (pts) at our institution who underwent CGP utilizing the Foundation One assay. CGP was performed on hybrid-capture, adaptor ligation-based libraries for up to 315 genes plus 47 introns from 19 genes frequently rearranged in cancer. PC pts were categorized by clinical stage – localized (resectable and borderline resectable PC; LPC), locally advanced (LAPC) and metastatic (mPC). Effect of gene alterations (GAs) with at least 10% prevalence were analyzed. The marginal effect of each gene on radiographic response and survival outcomes was estimated using proportional odds and multivariate Cox regression analysis, respectively, adjusting for stage. **Results:** Ninety-three pts were identified - median age was 63, 55% were male, and 50% were smokers. Clinical stage at diagnosis was LPC, LAPC and mPC in 42 (45%), 23 (25%) and 28 (30%) pts, respectively. The most commonly altered genes were *KRAS* (94%), *TP53* (75%), *CDKN2A* (41.2%) and *SMAD4* (32.9%). All patients were microsatellite stable and the median tumor mutational burden was 1.7. 5-FU (52%) or Gemcitabine (46%) based chemotherapy combinations were utilized as the first systemic therapy. Median overall survival for patients with LPC, LAPC and mPC were 30.7, 28.8 and 9.6 months respectively. Thirty-eight (91%) pts with LPC underwent curative intent surgery compared to 15 (65%) pts with LAPC ($p = 0.019$). Thirty-five (95%) pts with wild type (WT) *CDKN2A* and 47 (94%) pts with WT *CDKN2B* underwent curative intent surgery compared to 13 (65%) and 1(14%) pt(s) with GAs in *CDKN2A* and *CDKN2B* respectively ($p = 0.003$ and $p < 0.0001$ respectively). The response to chemotherapy was statistically significantly higher in pts with WT *CDKN2A* (53%) and *CDKN2B* (48%) compared to pts with GAs in *CDKN2A* (19%) and *CDKN2B* (12%) ($p = 0.03$ and $p = 0.05$, respectively). **Conclusions:** GAs in *CDKN2A/B* may have a predictive and possibly a prognostic impact. The clinical validity and biological relevance of these findings need to be further explored in larger studies. Research Sponsor: U.S. National Institutes of Health.

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760 Poster Session (Board #N5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Utilization of somatic comprehensive genomic profiling (CGP) to identify patients (pts) with pancreatic cancer (PC) that harbor germline DNA damage repair (DDR) gene alterations.

Matthew Lasowski, Samantha Stachowiak, Igli Arapi, Kulwinder Dua, Abdul H. Khan, William Adrian Hall, Beth Erickson, Susan Tsai, Kathleen K. Christians, Douglas B. Evans, Raul Urrutia, Paul S. Ritch, Mandana Kamgar, James P. Thomas, Ben George; Medical College of Wisconsin, Milwaukee, WI; Medical Colllege of Wisconsin, Milwaukee, WI; Medical College of Wisconsin and Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, WI; Froedtert & the Medical College of Wisconsin, Milwaukee, WI

Background: Somatic and germline DDR gene alterations in PC have been postulated to positively predict response to DNA damaging cytotoxic agents. Due to the relatively high prevalence of germline DDR gene alterations, germline testing is recommended in all pts with PC. We examined whether somatic CGP can be used to reliably identify PC pts that merit germline testing. **Methods:** We retrospectively reviewed the electronic medical records of PC pts who underwent both somatic CGP (utilizing the Foundation One assay) and germline testing. DDR gene mutations were categorized as somatic-pathogenic, somatic-variant of uncertain significance (VUS), germline-pathogenic and germline-VUS. For somatic testing, DNA was extracted from formalin fixed paraffin embedded (FFPE) clinical specimens and CGP was done on hybrid-capture, adaptor ligation based libraries to a mean coverage depth of $>$ 600 for up to 315 genes plus 47 introns from 19 genes frequently rearranged in cancer. Germline genetic testing was performed on submitted blood or saliva samples, utilizing commercial assays; next generation or Sanger sequencing of all coding regions and adjacent intronic nucleotides were performed. **Results:** Ninety-three pts had somatic CGP data, 51 (55%) pts had both somatic CGP and germline data available. Among the 51 pts with both germline and somatic data available, DDR gene alterations that were somatic-pathogenic, germline-pathogenic, somatic-VUS and germline-VUS were present in 7 (13.7%), 7 (13.7%), 23 (45.1%) and 16 (31.4%) pts, respectively. Of the 7 pts with somatic-pathogenic alterations, 5 (71%) had a concordant germline alteration and of the 7 pts with germline-pathogenic alterations, 5 (71%) had a concordant somatic alteration. Of the 23 pts with somatic-VUSs, 12 (52%) had a concordant germline VUS and of the 16 pts with germline-VUSs, 12 (75%) had a concordant somatic VUS. **Conclusions:** Both somatic and germline DDR gene alterations are common in PC pts. Despite the relatively high concordance rate between somatic and germline pathogenic DDR gene alterations, somatic CGP will miss approximately one fourth of the germline DDR gene alterations. Research Sponsor: None.

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761 Poster Session (Board #N6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Association of SMAD4 loss with response to neoadjuvant chemotherapy with the autophagy inhibitor hydroxychloroquine in patients with pancreatic adenocarcinoma.

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Background: *SMAD4*, a tumor suppressor gene, is inactivated or deleted in 60-90% of pancreatic adenocarcinomas (PDA). Loss of SMAD4 allows tumor progression by limiting cell cycle arrest and apoptosis and increasing metastases. SMAD4 deficient PDA cells are resistant to radiotherapy by upregulation of autophagy, a cell survival mechanism that allows intracellular recycling of macromolecules and organelles. Hydroxychloroquine (HCQ) is a known autophagy inhibitor, suggesting that HCQ treatment in SMAD4 deficient PDA may prevent therapeutic resistance induced by autophagy upregulation. **Methods:** We retrospectively analyzed the SMAD4 status of PDA patients enrolled in two prospective clinical trials evaluating preoperative HCQ. The first dose escalation trial demonstrated the safety of preoperative gemcitabine with HCQ (NCT01128296). More recently, a randomized trial of gemcitabine/nab-paclitaxel +/- HCQ evaluated Evans Grade histopathologic response (NCT01978184). Immunohistochemistry of resected specimens for SMAD4 was previously performed. Patients not treated at the max HCQ dose (n = 5), not resected (n = 2) or with SMAD4 staining unavailable were excluded (n = 10). The effect of SMAD4 loss on response to HCQ and chemotherapy was studied for association with clinical outcome. Fisher's exact test and log-rank test were used to assess response and survival. **Results:** 52 patients receiving HCQ with neoadjuvant chemotherapy and 24 patients receiving neoadjuvant chemotherapy alone were studied. Of the HCQ group, 25 patients had SMAD4 loss (48%), compared with 15 control patients (63%, p = 0.32). 76% of HCQ treated patients with SMAD4 loss obtained a histopathologic response $\geq$2A, compared to only 37% with SMAD4 intact (p = 0.006). In the control group, loss of SMAD4 was associated with a nonsignificant detriment in 3 year OS (25% vs. 78%, p = 0.3) that was less apparent in patients treated with HCQ (46% vs. 47%, p = 0.18). **Conclusions:** The addition of HCQ to neoadjuvant chemotherapy in PDA may improve treatment response in patients with SMAD4 loss. Further study of the relationship between SMAD4, autophagy and treatment outcomes in PDA is warranted. Research Sponsor: U.S. National Institutes of Health.

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762 Poster Session (Board #N7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Analysis of associations of CXCR3 ligands with immune microenvironment and aggressiveness in murine and human pancreatic ductal adenocarcinoma.

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Background: The complex milieu of cytokines within pancreatic ductal adenocarcinoma (PDAC) promotes tumor progression and immune suppression thereby contributing to the dismal prognosis of patients with PDAC. However, the roles of many cytokines, including CXCR3 ligands, in PDAC have not been thoroughly investigated. **Methods:** Bioinformatics analyses of PDAC microarray and TCGA datasets were used to identify cytokines overexpressed in PDAC, their association with patient survival as well as the expression of cognate cytokine receptors. Comparative analysis of cytokine expression in $Kras^{LSL\text{-}G12D}$-$P53^{LSL\text{-}R172H}$-Pdx1-Cre (KPC) and $Kras^{LSL\text{-}G12D}$-Pdx1-Cre (KC) murine PDAC models were used to validate these findings. Pathway and CIBERSORT analyses were employed to determine mechanistic basis of altered survival associated with cytokines of interest. **Results:** Of the 149 cytokines analyzed, CXCR3 ligands CXCL9 and CXCL10 were highly and consistently overexpressed in PDAC datasets. Concurrently, CXCL9, CXCL10 and PF4 were overexpressed in the aggressive KPC murine model compared to the indolent KC model. CXCR3 showed robust expression in PDAC in microarray, TCGA and IHC analyses. Interestingly, high expression of CXCR3 ligands was associated with shorter overall survival ($p = 0.04$ for CXCL9, 10 and 11 and $p = 0.02$ for PF4) while high expression of CXCR3 was associated with increased overall survival ($p = 0.03$). Pathway analysis of genes correlated with CXCR3 and/or its ligands showed that CXCR3 ligands may promote T-cell exhaustion ($p < 0.001$). Finally, CIBERSORT analysis of TCGA data demonstrated that high CXCR3 expression was associated with increased CD8 T-cell and naïve B-cell signatures and loss of plasma cells signatures. High CXCR3 ligand expression was associated with increased CD8 T-cell, and M1 macrophage, and loss of NK-cell signatures($p < 0.05$). **Conclusions:** CXCR3 ligands are overexpressed in PDAC and are associated with poor survival, likely related to alterations in tumor immune infiltrate/activity and may represent targets to augment anti-tumor immunity. Research Sponsor: U.S. National Institutes of Health.

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763 **Poster Session (Board #N8), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Serum glycoproteomic-based liquid biopsy for the detection of pancreatic ductal adenocarcinoma.

Pashtoon Murtaza Kasi, Ling Shen, Prasanna Ramachandran, Kaitlynn Moser, Gege Xu, Padraig Buckley, Daniel Serie, Carlito Lebrilla, Hui Xu, Carlos Hou Fai Chan; Mayo Clinic, Jacksonville, FL; InterVenn Biosciences, Redwood City, CA; Venn Biosciences Corporation, Redwood City, CA; Brigham and Women's Hosp, Brookline, MA

Background: Non-invasive biomarkers with high sensitivity and specificity would be of great value for patients with Pancreatic Ductal Adenocarcinoma (PDAC). This would aid in early detection and serve other purposes that 'liquid biopsies' are being explored in. Besides circulating tumor DNA (ctDNA) and methylation markers, glycosylation markers hold great potential promise. We developed a novel workflow using high-resolution quantification of site-specific protein glycosylation by liquid chromatography and tandem mass spectrometry to evaluate the clinical utility of glycoprotemics signature for patients with PDAC. **Methods:** Serum samples from newly diagnosed PDAC patients and controls were obtained from a commercial biobank (Indivumed, Hamburg, Germany), and a panel of 504 glycan motifs, representing 73 previously reported proteomic markers, was determined. Age-adjusted generalized linear regression models were used to evaluate the differential abundance of each marker, and stepwise variable selection was used for model construction. **Results:** We analyzed 45 PDAC and 136 control samples. PDAC patients (60% male) had a mean age of 67 ($\pm$11) years. with 4.4%, 71.1%, 4.4%, and 20% at stage 1, 2, 3,4, respectively. Controls were women with benign histology after pelvic mass surgery; with a mean age of 61 ($\pm$11) years. Twenty-six glycoproteomic markers showed statistically highly significant differential abundance among cases and controls ($p<1e-4$ each) and were highly reproducible(Pearson's $r > 0.85$), which were glycoforms in proteins that have previously been found to be associated with PDAC. Fourteen of these markers displayed >0.8 area under the curve of the receiver operating characteristic (AUC). Multivariate logistic regression modeling with backward selection yielded a classification model with an AUC of 0.94 (95% CI: 0.89-0.99), sensitivity of 91% (95% CI: 75-97%) and specificity of 86% (95% CI: 81-92%). **Conclusions:** Circulating glycoproteomic biomarkers may be useful in the early detection and clinical management of PDAC patients; offering a new platform to explore and validate. Research Sponsor: InterVenn.

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764 **Poster Session (Board #N9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The effect of TGF-β on PD-L1 expression on PDAC TAMs.

Katarzyna Trebska-McGowan, Liza Makowski, Marcus A. Alvarez, Rita Kansal, S. Mazher Husain, Ajeeth K. Pingili, Evan Scott Glazer; University of Tennessee Health Science Center, Memphis, TN

Background: Pancreatic Ductal Adenocarcinoma (PDAC) has less than a 10% five year survival and will become the second leading cause of US cancer mortality in the next decade. Immunotherapy, such as checkpoint inhibition against anti-Programmed death-ligand 1 (PD-L1) has not been successful in the treatment of PDAC patients. Both tumor associated macrophages (TAMs) and the TGF-β protein are ubiquitous in PDAC tumors. We hypothesize that TGF-β increases the overall number of TAMs and degree of PD-L1 expression of TAMs in PDAC. **Methods:** Our lab has a mouse pancreatic cancer cell line derived from a genetically engineered mouse model (KPC mice that spontaneously form PDAC tumors that are similar to human PDAC). We orthotopically implanted this cell line into the pancreas of immunocompetent C57BL/6 (B6) mice. In groups of 5 each, mice were treated with saline (control) or TGF-β. We investigated tumor burden, the number of TAMs ($CD45^+$, $CD11b^+F4/80^{hi}$, $Ly6C^-$, $Ly6G^{-/lo}$) in the tumors with flow cytometry and the percentage of TAMs expressing PD-L1 in the pancreas and metastatic lesions in the liver. **Results:** As a percent of leukocytes in the tumor, PDAC liver metastases had more TAMs compared to tumors in the pancreas (33 ± 5% vs 10 ± 4%, P = 0.001). Compared to controls, TGF-β treatment significantly increased the percent of PD-L1 expressing TAMs (32 ± 6 % vs 12 ± 5%, P = 0.013, see Figure) in the pancreas but no effect was evident on TAM density. In liver metastases, treatment with TGF-β decreased the overall TAM density (P = 0.039) but did not affect the number of PD-L1 positive TAMs. **Conclusions:** TGF-β plays pivotal role in the progression of PDAC and demonstrates context dependent activity. Our results suggest that an immunosuppressive effect mediated by PD-L1 expression on TAMs may be initiated by TGF-β. Future investigations will focus on understanding the role of the PDAC – TAM interaction to develop effective immune therapies for PDAC patients.
Research Sponsor: SSAT - Society for Surgery of Alimentary Track.

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765 Poster Session (Board #N10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Genomic associations in metastatic pancreatic cancer (mPC).

Anil Kumar Rengan, Efrat Dotan, Karthik Devarajan, Namrata Vijayvergia; Temple University Hospital, Philadelphia, PA; Fox Chase Cancer Center, Philadelphia, PA

Background: mPC is an aggressive cancer, and molecular profiling provides further insight into pathogenesis and treatment. We sought to illustrate the molecular landscape of mPC in relation to post-metastatic survival and VTE incidence. **Methods:** With IRB approval, we retrospectively analyzed charts of mPC patients who underwent molecular profiling. Fisher's exact test (categorical) and Mann-Whitney test (continuous) were used to compare groups. Log-rank test, Cox proportional hazards model and weighted Cox regression were used for survival analysis. **Results:** Between 2009 and 2018, 98 out of 502 mPC patients (19.5%) underwent molecular testing. Of these, 70% were tested after 2015. The most common mutations were in KRAS (79.2%), TP53 (59.0%), CDKN2A (35.9%), BRCA (16.4%), PIK3CA (9.4%) and SMAD4 (7.4%). Concurrent KRAS and TP53 mutations were found in 62.3% of patients. KRAS mutation was positively associated with Jewish ancestry (OR 2.3; $p < 0.05$), and TP53 mutation was positively associated with younger age at diagnosis (63.5 vs. 67 years; $p < 0.05$). KRAS and TP53 mutations were negatively associated with tobacco use (OR 0.43 and 0.3, respectively; $p < 0.05$). There was no association between any mutation and metastatic site. Both KRAS and TP53 mutations were positively associated with VTE (OR 2.55 and 2.71, respectively; $p < 0.05$). Interestingly, TP53 mutation portends worse survival (HR 3.85; $p < 0.05$) whereas CDKN2A mutation confers improved survival (HR 0.55; $p < 0.05$). No patient received targeted therapy for their specific mutations. **Conclusions:** Molecular testing is becoming more prevalent in the mPC treatment paradigm. Among our cohort, concurrent KRAS and TP53 mutations were frequently identified. Incidence rates of the most common mutations were similar to those observed in prior literature. KRAS and TP53 mutations were associated with higher incidence of VTE. TP53 mutation was associated with poorer prognosis. Research Sponsor: None.

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766 Poster Session (Board #N11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Survival outcomes of pancreatic intraepithelial neoplasm (PanIN) versus intraductal papillary mucinous neoplasm (IPMN) associated pancreatic adenocarcinoma.

Timothy McGinnis, Leonidas Bantis, Rashna Madan, Prasad Dandawate, Sean Kumer, Timothy Schmitt, Ravi Kumar Paluri, Anwaar Saeed, Anup Kasi; University of Kansas Cancer Center, Westwood, KS; University of Kansas Health System, Kansas City, KS; University of Alabama at Birmingham, Birmingham, AL; University of Kansas Medical Center, Kansas City, KS

Background: Pancreatic intraepithelial neoplasms (PanINs) and intraductal papillary mucinous neoplasms (IPMNs) are common pancreatic adenocarcinoma precursor lesions. However, data regarding their respective associations with prognosis is lacking. **Methods:** We retrospectively evaluated 72 resected pancreatic adenocarcinoma cases at the KU Cancer Center between Aug 2009 and March 2019. Patients were divided into either one of two groups, PanIN or IPMN, based on the results of the surgical path report. We compared baseline characteristics, overall and progression free survival between the two groups, as well as OS and PFS based on local or distant tumor recurrence. **Results:** 52 patients had PanIN and 20 patients had IPMN. Demographic and baseline characteristics are as follows (PanIN/IPMN): Median age 62.5/69; Gender (male) 63%/65%; ECOG status (0-1) 98%/85%; pancreatic head tumors 87%/70%; pancreatic body tumors 6%/15%; pancreatic tail tumors 7%/15%; Abnormal CA19-9 at diagnosis 79%/67%; Comorbidity Index 5/5 respectively. Median PFS was 26.2 months (95% CI: 21.4-31.0) for PanIN and 74.3 months (95% CI: 15.7-132.9) for IPMN [p = 0.004]. Median OS was 70.3 months (95% CI: 35.4-105.2) for PanIN and 78.8 months (95% CI: 33.2-124.4) for IPMN [p = 0.013]. Within the PanIN group, median OS after recurrence was 71.3 months (95% CI: 68.8.-73.4) for local recurrence and 46.7 months (95% CI: 39.2-54.2) for distant recurrence [p = 0.330]. **Conclusions:** Patients who had a IPMN associated pancreatic cancer had better PFS and OS when compared to patients with PanIN associated pancreatic cancer. In patients with PanIN associated cancer that recurred, OS was better with local recurrence compared to distant recurrence but did not meet statistical significance. The results need to be validated in a larger cohort. Research Sponsor: None.

Characteristics	PanIN (n = 52)	IPMN (n = 20)
Median age (years)	62.5 (42-85)	69 (54-77)
Gender (%)		
Female	19 (37%)	7 (35%)
Male	33 (63%)	13 (65%)
ECOG Status		
0-1	51 (98%)	17 (85%)
2 or higher	1 (2%)	3 (15%)
Tumor Location		
Head	45 (87%)	14 (70%)
Body	3 (6%)	3 (15%)
Tail	4 (7%)	3 (15%)
CA19-9 at time of diagnosis		
Normal (< 37)	7 (21%)	4 (33%)
Abnormal	26 (79%)	8 (67%)

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767 **Poster Session (Board #N12), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Association of neutrophil, platelet, and lymphocyte ratios with prognosis in metastatic pancreatic cancer.

Jessica Allen, Colin Cernik, Suhaib Bajwa, Anwaar Saeed, Anup Kasi; University of Kansas Medical Center, Kansas City, KS; University of Kansas Cancer Center, Westwood, KS; University of Kansas, Kansas City, KS

Background: High mortality associated with pancreatic ductal adenocarcinoma (PDA) warrants research into prognostic factors. We examined the relationship between the daily rate of change of CA19-9 over the first 90 days of treatment (DRC90) and pretreatment levels of neutrophils, lymphocytes, and platelets with overall survival (OS) and progression free survival (PFS) in patients with stage IV PDA that received chemotherapy. **Methods:** We retrospectively evaluated 102 locally advanced and metastatic PDA patients treated at KU Cancer Center between Jan 2011 and Sep 2019. We compared the ratio of pretreatment absolute neutrophil count to pretreatment absolute lymphocyte count (NLR) and the ratio between pretreatment platelet count to pretreatment absolute lymphocyte count (PLR) with OS and PFS. We also compared DRC90 to OS and PFS. Log-rank trend test using the mean of NLR, PLR, and DRC90 as the threshold for two groups within each variable. **Results:** Baseline demographics are shown in the table. Pts with $\geq$ mean NLR (4.6) had significantly lower OS [p = 0.0444] and PFS [p = 0.0483] than Pts below the mean. Pts with PLR $\geq$ mean (3.9) did not have significantly different OS [p = 0.507] or PFS [p = 0.643] than Pts below the mean. Pts with DRC90 $\geq$ mean (-1%) did not have significantly different OS [p = 0.342] or PFS [p = 0.313] than Pts below the mean. **Conclusions:** Pts with NLR $\geq$ mean (4.6) had significantly lower OS and PFS than Pts with NLR below the mean. This implies the possibility of NLR as a prognostic marker in PDA that could guide treatment approach but needs validation in a larger cohort. Research Sponsor: None.

Characteristics	NLR < 4.6 (n = 66)	NLR > 4.6 (n = 35)
Age (median)	65.5	62
Gender: Male/Female	62% / 38%	60% / 40%
ECOG status 0-1	60 (90.1%)	33 (94.3%)
Tumor location		
Head	49 (74.2%)	15 (42.3%)
Body	9 (13.6%)	11 (31.4%)
Tail	7 (10.6%)	9 (25.7%)
Neck	1 (1.5%)	0 (0.0%)
CA19-9 at time of diagnosis		
Normal (< 38)	11 (16.7%)	3 (8.6%)
Abnormal	54 (81.8%)	32 (91.4%)
Treatment Received		
FOLFIRINOX	40 (60.6%)	20 (57.1%)
Gemcitabine/albumin-bound Paclitaxel (Abraxane)	16 (24.2%)	11 (31.4%)
Gemcitabine	4 (6.1%)	0 (0.0%)
Other	6 (9.1%)	4 (11.4%)

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768 Poster Session (Board #N13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Impact of surveillance among patients with resected pancreatic cancer following adjuvant chemotherapy.

Selina Wong, Lovedeep Gondara, Daniel John Renouf, Howard John Lim, Sharlene Gill; BC Cancer Agency, Vancouver, BC, Canada; British Columbia Cancer Agency, Vancouver, BC, Canada

Background: Pancreatic adenocarcinoma carries a poor prognosis and high risk of recurrence even after surgery and adjuvant chemotherapy (AC). Guidelines recommend against routine surveillance imaging due to lack of evidence supporting a survival benefit. With current first-line chemotherapy options, it is unclear whether surveillance scans allow for early detection of asymptomatic disease and therefore an opportunity to offer fit patients chemotherapy. We describe the patterns of surveillance in patients followed at a Canadian provincial cancer agency and determine whether routine imaging after AC is associated with receipt of palliative chemotherapy (PC). **Methods:** A retrospective review was completed to identify patients treated at British Columbia (BC) Cancer centres between January 1, 2010 and December 31, 2016 who had undergone curative intent resection and received at least one cycle of AC. Baseline characteristics, number of scans done after completing AC to recurrence, and PC were collected. Logistic regression analysis was performed. **Results:** A total of 151 patients followed at BC Cancer were identified. Patients who recurred within 28 days after AC were excluded, leaving 142 patients, of which 115 patients had recurrence. We defined 2 cohorts based on number of scans done between completion of AC and recurrence: those with 0-1 scans were "symptomatic" recurrences (22 patients, median age 68y, 64% female, and 91% node-positive) and those with $>$ 1 scan were "surveillance" recurrences (93 patients, median age 64y, 43% female, and 81% node-positive). Patients who underwent surveillance scans were more likely to receive PC at time of recurrence, though statistical significance was not reached (OR 2.11, 95% CI 0.75-6.58, p = 0.17). **Conclusions:** Despite guidelines, the majority of patients treated in BC underwent surveillance imaging. Within the limits of our sample size, we demonstrated a trend towards increased likelihood of receiving PC in patients who receive surveillance scans following AC. With efficacious PC options available, studies to determine whether receipt of PC in asymptomatic recurrences detected on imaging translates into improved survival and/or quality of life are warranted. Research Sponsor: None.

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769 Poster Session (Board #N14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Clinical outcomes of first-line FOLFIRINOX versus gemcitabine plus nab-paclitaxel in metastatic pancreatic cancer at the Yale Smilow Healthcare System.

Timil Patel, Thejal Srikumar, Joseph Anthony Miccio, Jill Lacy, Stacey Stein, Jeremy S. Kortmansky, Carol Staugaard, Melissa Gambaccini, Alfredo Axtmayer, Michael Cecchini; Yale School of Medicine, New Haven, CT; Department of Therapeutic Radiology, Yale School of Medicine, New Haven, CT; Yale New Haven Hospital, New Haven, CT

Background: FOLFIRINOX (FFX) and Gemcitabine plus *nab*-paclitaxel (GN) are established first line (1L) therapies for metastatic pancreatic cancer (MPC) but real-world data on their comparative effectiveness is limited. **Methods:** All cases of MPC treated with 1L FFX or GN at Yale Smilow Cancer Hospital and the affiliated community care centers (CCC) from January 2011 – April 2019 were reviewed. Patient (pt) demographics, prior therapy, initial and subsequent dose reductions (DR), time to treatment discontinuation (TTD), overall survival (OS), and second line (2L) treatment data were manually abstracted from the electronic medical record. Categorical and continuous variables were compared between 1L FFX and GN cohorts via the Chi-squared and Wilcoxon rank-sum tests. Median OS was calculated by the Kaplan-Meier method. **Results:** We identified 363 MPC pts treated with 1L FFX or GN; 269 (74%) pts were treated with FFX and 94 (26%) with GN as 1L therapy. 204 (56%) pts were treated at the main campus and 159 (44%) at a CCC. Demographics and baseline characteristics (FFX/GN) were as follows: gender (male) 55% / 41%; race (white) 82% / 77%; age $<$ 76 90% / 71% ($P < 0.001$). 332 (91%) of pts received no prior therapy; 21 (6%) had prior surgery plus adjuvant gemcitabine and 10 (3%) had surgery alone. 98% of FFX-treated pts were treated with upfront DR, compared to 78% of GN-treated pts ($P= 0.003$). 78% and 53% of FFX-treated and GN-treated pts, respectively, had subsequent DR ($P< 0.001$). Median TTD was 4.8 months with FFX and 3.4 months with GN ($P= 0.0029$) and the median OS was 11.3 months with FFX versus 7.2 months with GN ($P < 0.0001$). After 1L, 33% and 61% of FFX- and GN-treated pts, respectively, received no further chemotherapy ($P< 0.001$). **Conclusions:** In the largest manually abstracted retrospective analysis to date, MPC pts treated with 1L FFX were younger, more likely to receive 2L therapy, and had increased survival compared to pts treated with GN. The OS of pts treated with FFX was similar to the OS reported by Conroy et al despite upfront dose attenuations in 98% of pts. A randomized trial is needed to confirm optimal sequencing of chemotherapy in MPC. Research Sponsor: None.

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770 **Poster Session (Board #N15), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Timing and location of palliative care consultation in metastatic pancreatic cancer: A retrospective, single-center observational study.

Timil Patel, Joseph Anthony Miccio, Thejal Srikumar, Elizabeth Horn Prsic, Kerin B. Adelson, Dmitry Kozhevnikov, Komal Patel, Jill Lacy, Michael Cecchini; Yale School of Medicine, New Haven, CT; Department of Therapeutic Radiology, Yale School of Medicine, New Haven, CT; Yale New Haven Hospital, New Haven, CT

Background: Patients (pts) receiving treatment for metastatic pancreatic cancer (MPC) experience significant symptoms, treatment related side effects and psychosocial burdens. The ASCO guidelines recommend early palliative care consultation (PCC) to improve quality of life and survival. However, limited real-world data is available regarding the timing of PCC, hospice enrollment and location of death (LOD) in pts with MPC. **Methods:** We conducted a retrospective observational analysis of pts treated with chemotherapy for MPC at the Yale Smilow Cancer Hospital and affiliated community care centers (CCC) from January 2011 to April 2019. Patient demographics, treatment dates, initial PCC, enrollment of hospice at the time of death and LOD were manually abstracted from the electronic medical record. Univariate and multivariable logistic regression analyses were conducted to predict for PCC and death outside the hospital. **Results:** Of 363 pts identified with MPC who received chemotherapy, 38% (138) had a PCC. 67% (93) of patients' initial PCC was in the hospital versus 33% (45) in the outpatient setting. The median time from the start of first-line chemotherapy to the first PCC was 5.2 months (interquartile range [IQR] 1.2 – 12.9). The median time from the first PCC to death was 1.5 months (IQR 0.5 – 4.42). At the time of our analysis, 300 pts had died and of those 76% (229) were enrolled on hospice at the time of death while 24% (71) were not. With respect to LOD, 47% (139) of pts died at home with hospice, 31% (94) at an inpatient hospice facility and 22% (67) died in the hospital. Female gender was associated with an increased likelihood of a PCC (HR 1.78, 95% CI 1.07-2.94, P = 0.026). Pts treated at a CCC were less likely to have a PCC (HR 0.21, 95% CI 0.12-0.36, $P < 0.001$). A PCC was not associated with a higher likelihood of death outside the hospital (HR 1.31, 95% CI 0.75-2.29, P = 0.346). **Conclusions:** Although most pts with MPC enroll in hospice, PCC is generally underutilized. In fact, many pts receive PCC near the end of life and in the hospital. Further studies are warranted to determine how best to incorporate early PCC to maximize supportive care for pts with MPC. Research Sponsor: None.

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771 Poster Session (Board #N16), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Prognostic value (PV) of pathologic response (PR) to neoadjuvant chemotherapy (NC) alone in resected pancreatic cancer (PDAC): Initial analysis.

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Background: As neoadjuvant Rx for resected PDAC often includes chemoradiation, the PV of PR includes its impact. We began analysis of the impact of NC alone in this setting. **Methods:** Patients (pts) were identified from the Virginia Mason Pancreaticobiliary Cancer Database. Inclusion criteria: 1) Dx 1/2010 - 3/2019; 2) Path dx PDAC stage I-III; 3) NC (any type) as sole neoadjuvant Rx; 4) complete surg path data; 5) longitudinal OS known. Exclusion criteria: 1) neoadjuvant chemoradiation; 2) unknown NC (outside providers only). Histologic response was scored as follows: (0=complete response, 1 ≥95% response, 2=50-95% response, 3<50% response). **Results:** Results for 134 pts are in Table. Median (med) f/u was 33 months (mo). In univariate analysis, all path features examined were statistically significant re med/5-yr OS. In multivariate analysis, risk increased with tumor size (HR 1.9, 95% CI 1.1-3.2) and tumor differentiation (HR 1.8, 95% CI 1.1-3.1) independent of other variables. **Conclusions:** 1) In univariate analysis, all PR features after NC had PV for med/5-yr OS, especially tumor size and histologic response score. NC type was not significant. 2) In multivariate analysis, risk increased with tumor size and tumor differentiation.3) This data needs extension to a bigger pt base/correlation with other variables (Ca 19.9, postop Rx, recurrence pattern etc.) for greater utility (now underway). 4) This approach may aid postop Rx decision -making in this setting. Research Sponsor: Vriginia Mason Pancreaticobiliary Cancer Fund.

Group	# Pts (%)	Med OS (mo) (95% CI)	5-year OS (%) (95% CI)
All	**134**	**38 (32-48)**	**34 (24-44)**
T size (cm)			
≤ 3	51 (38)	47 (34-61)	42 (29-55)
> 3	83 (62)	29 (20-38)	17 (5-35)
		p<0.001	
Node status			
Neg	52 (39)	93 (33-NR)	54 (37-69)
Pos	82 (61)	34 (29-41)	19 (9-32)
		p<0.01	
Stage			
0-2A	53 (40)	93 (33-NR)	53 (36-68)
2B-3	81 (60)	33 (29-41)	20 (10-33)
		p<0.05	
Margin			
Neg	113 (84)	41 (33-51)	36 (25-48)
Pos	21 (16)	30 (16-48)	20 (4-42)
		p<0.05	
Histologic response			
0/1 (≥ 95%)	29 (22)	93 (27-NR)	53 (23-76)
2/3 (< 95%)	105 (78)	37 (30-48)	30 (20-42)
		p<0.001	
Tumor Diff			
Well/Mod	85 (63)	48 (33-61)	42-(27-56)
Poor	49 (37)	28 (30-48)	22 (9.3-37)
		p<0.01	
NC type			
Gem based	101 (75)	41 (33-52)	37 (25-49)
5-FU based	15 (11)	32 (16-61)	24.(8-44)
Both	18 (14)	29 (16-NR)	NR
		NS	

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772 Poster Session (Board #N17), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Prognostic significance of familial pancreatic cancer after surgery.

Koji Tezuka, Yukiyasu Okamura, Teiichi Sugiura, Takaaki Ito, Yusuke Yamamoto, Ryo Ashida, Katsuhisa Ohgi, Katsuhiko Uesaka; Division of Hepato-Biliary-Pancreatic Surgery, Shizuoka Cancer Center, Shizuoka, Japan

Background: Familial pancreatic cancer (FPC) is defined as two first-degree relatives with pancreatic cancer. It is known that the risk of developing pancreatic cancer increases in those who have a family history of pancreatic cancer in first-degree relatives. However, prognostic significance of FPC after surgery is not fully understood. **Methods:** Patients who underwent pancreatectomy for pancreatic ductal carcinoma between January 2008 and December 2016 were retrospectively reviewed. The prognostic significance of FPC was analyzed. **Results:** A total of 423 patients underwent pancreatectomy for pancreatic ductal carcinoma. FPC was identified in 32 (7.6%) patients. Recurrence occurred in 72% of all resected cases and in 88% of resected FPC cases. Multivariate analysis revealed FPC (hazard ratio [HR] 1.60; P=0.026), CA19-9 $\geq$300 U/ml (HR 1.54; P=0.001), lymph node metastasis (HR 2.10; P$<$0.001), microscopic venous invasion (HR 1.64; P$<$0.001), nerve plexus invasion (HR 1.39; P=0.010), R1 resection (HR 1.65; P=0.010), and lack of adjuvant chemotherapy (HR 2.27; P$<$0.001) as independent predictors for recurrence-free survival (RFS). The univariate analysis revealed that FPC is significantly associated with worse overall survival (OS) (P=0.018). The multivariate analysis showed that FPC was not an independent predictor of OS. This cohort was divided into 314 patients (FPC: 18 patients, non-FPC: 296 patients) who received adjuvant chemotherapy (AC group) and 109 patients (FPC: 14 patients, non-FPC: 95 patients) received no adjuvant chemotherapy (no AC group). In AC group, FPC is an independent predictor for RFS (HR 3.03; P$<$0.001) and OS (HR 2.23; P=0.018). In no AC group, FPC is not a predictor for RFS and OS. **Conclusions:** This study may show that FPC has a significant impact on RFS and OS after resection in patients who received adjuvant chemotherapy. Research Sponsor: None.

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773 Poster Session (Board #N18), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

An assessment of the total cost of pancreatic cancer using real-world evidence.

Vincent J. Picozzi, Victoria G. Manax, Kelly Feehan, Zachary Wintrob, Michele Korfin, Giuseppe Del Priore, Robert Goldberg; Virginia Mason Hospital and Medical Center, Seattle, WA; PanCan, Manhattan Beach, CA; ROAKETIN Inc., Oneonta, NY; Tyme, New York, NY; Morehouse School of Medicine, Atlanta, GA; Center for Medicine in the Public Interest, New York, NY

Background: The aggregate health economic implications of pancreatic cancer are poorly understood, especially from the patient perspective. As a preliminary effort, we sought to better understand changes in type and quantity of medical expenditures over time, along with quality of life related costs, from this perspective. This preliminary research is part of a larger effort to understand how the introduction of new treatments affect both the outcome and costs of pancreatic cancer associated with care, patients, survivors, their families, and their communities. **Methods:** We analyzed patient-level data from the Medical Expenditure Panel Survey (MEPS, 1996-2017). All analyses were performed using R version 3.6.1 on Ubuntu 19.04. Averages were computed for the total health care costs, including prescription drug costs. Average individual annual cost estimates for the second year excluded individuals that were identified as having died prior to the first round of data collection in the second year. The individual patient level ratios of prescription drug cost to other medical expenses was also computed. All expenditures are adjusted for inflation using 2017 US dollars. Included subjects, N= 80 had a diagnosis of pancreatic cancer and available prescription data. Individual age and employment status were accounted for as covariates. **Results:** Between 1997 and 2017 inflation adjusted first and second year non-medication spending on pancreatic cancer care averaged $66,999.96 and $105,308.60 respectively. However, inflation-adjusted first and second year charges for hospitalizations and emergency visits fell between 2007-2017. Prescription drug as a proportion of total spending prescription drugs increased during the same time period. Lost work/school days declined between 2007 and 2017. **Conclusions:** Total inflation adjusted pancreatic cancer care expenses declined over the past decade even as drug costs increased. Quality of life costs declined as well. Further analysis is needed to evaluate the relationship between drug spending, total cost of care and quality of life. Research Sponsor: Tyme Inc.

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774 Poster Session (Board #N19), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM

Young-onset pancreas cancer (PC) in patients less than or equal to 50 years old at Memorial Sloan Kettering (MSK): Descriptors, genomics, and outcomes.

Anna M. Varghese, Isha Singh, Ritu Raj Singh, Marinela Capanu, Joanne F. Chou, Winston Wong, Zsofia Kinga Stadler, Erin E. Salo-Mullen, Christine A Iacobuzio-Donahue, David Paul Kelsen, Wungki Park, Kenneth H. Yu, Eileen Mary O'Reilly; Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York City, NY; Clinical Genetics Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, Department of Medicine, Gastrointestinal Oncology, New York, NY; Memorial Sloan Kettering Cancer Center/ Weill Cornell Medical College, New York, NY

Background: For individuals ≤ 50 years old, cancer incidence is increasing, particularly gastrointestinal and obesity related cancers (Sung, Lancet Public Health 2019). Limited details are known about young onset PC. Herein, we report the epidemiologic, pathologic, and molecular characteristics of PC in patients (pts) ≤ 50 years. **Methods:** MSK institutional database was queried for medical and treatment history, genomics, and outcomes in pts ≤ 50 years old diagnosed with PC between January 2008 and July 2018. Neuroendocrine cancers were excluded. Overall survival (OS) from date of PC diagnosis was estimated using Kaplan-Meier methods. **Results:** N = 450 pts ≤ 50 years old with a diagnosis of PC were identified. Ninety-six percent had adenocarcinoma, and 4% had acinar cell carcinoma/other histologies. Table summarizes demographics. Median OS was 16 months in the entire cohort and 11.3 months in stage IV disease. For N = 236 pts diagnosed after 2014, 119 (50%) underwent successful somatic testing with at least one alteration identified, and 21/119 tumors were RAS wild-type with identification of several actionable alterations (NRG1 fusions (n=2), NTRK fusions (n=2), IDH1 R132C (n=1), and microsatellite unstable tumors (n=1)). N = 114 pts had germline testing (routine after 2015), and 33/114 (29%) had pathologic germline alterations, including BRCA1/2 (n=18), CHEK2 (n=3), PALB2 (n=3), ATM (n=2), MLH1 (n=1), and MSH3 (n=1). **Conclusions:** Pathogenic germline alterations are present in a substantial percentage of pts with young onset PC, and actionable somatic alterations were seen frequently in the subgroup of young onset PC RAS-wild type tumors. These observations underpin the need for germline and somatic profiling in PC. Research Sponsor: None.

		N	%
Sex - Male / Female		254 / 196	56/44
Average age at diagnosis (range)		44.7 years(16-50)	
	< 30	9	2
	30-40	56	12
	40-45	109	24
	45-50	276	62
Average BMI (range)		26.1 (14.7-53.7)	
	< 18.5	23	5
	18.5-24.9	182	43
	25-29.9	137	32
	30-34.9	52	12
	>35	32	8
	Missing	24	
Tobacco history			
	Never	224	50
	Former / Current	213	47
	Unknown	13	3
Diabetes mellitus - Yes / No		76 / 374	17 / 83

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775 **Poster Session (Board #N20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Does aberrant hepatic arterial anatomy impact the complication rate or survival following resection of pancreatic adenocarcinoma?

Nicketti M Handy, Angelena Crown, Kimberly A. Bertens, Jesse Clanton, Adnan Alseidi, Thomas Biehl, William Scott Helton, Flavio G. Rocha; Virginia Mason Medical Center, Seattle, WA; University of Ottawa, Ottawa, ON, Canada; West Virginia University, Charleston, WV; Virginia Mason Hospital and Medical Center, Seattle, WA

Background: Patients with aberrant hepatic arterial anatomy (AHAA) are susceptible to tumor invasion and/or ligation during resection of the pancreatic head. The purpose of this study is to determine if AHAA negatively impacts perioperative outcomes or survival. **Methods:** All patients who underwent either pancreaticoduodenectomy or total pancreatectomy for pancreatic ductal adenocarcinoma (PDAC) between 2005 and 2014 at our center were retrospectively reviewed. Univariate logistic regression was used to compare outcomes between patients with conventional hepatic arterial anatomy to those with AHAA. Survival analysis was performed by Kaplan-Meier method with log rank test. **Results:** During the study period, 330 patients underwent resection for PDAC, 69 (20.9%) with aberrant hepatic arterial anatomy. The presence of AHAA does not significantly increase operative time (p= 0.110) or length of stay (p=0.518). The overall frequency of complications (49.3% vs 37.9%, p=0.088) was higher in the AHAA group, but not significantly so. Certain postoperative complications are more common in the AHAA group, namely superficial surgical site infection (18.8% vs. 8.8%, p=0.018) and pancreatic fistula (18.8% vs. 10.0%, p=0.042). However, deep SSI, need for blood transfusion, respiratory failure, DGE, bleed from GDA/pseudoaneurysm, biliary fistula, chyle leak, PV thrombus, fascial dehiscence, and reoperation are not statistically different between the two groups. There is a trend for reduced overall survival in the AHAA group that is not statistically significant (p=0.11). **Conclusions:** Aberrant hepatic arterial anatomy is encountered in greater than 20% of pancreatic surgery patients, and its presence may increase the rate of certain postoperative complications such as superficial surgical site infection and pancreatic fistula. Research Sponsor: None.

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776 **Poster Session (Board #N21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Retrospective analysis of institutional outcomes with FOLFIRINOX versus nab-paclitaxel plus gemcitabine in metastatic pancreatic cancer.

Amisha Singh, Rachna T. Shroff, Ali McBride; University of Arizona College of Medicine, Tucson, AZ; University of Arizona Cancer Center, Tucson, AZ

Background: With an estimated six percent five-year survival, metastatic pancreatic adenocarcinoma is one of the most lethal cancers in the United States. Previously, treatments with FOLFIRINOX (FFX) or gemcitabine plus nab-paclitaxel (G+A) have demonstrated improved overall survival versus gemcitabine alone. The purpose of this study is to compare institutional outcomes for the two regimens, FFX vs. G+A in metastatic pancreatic cancer. **Methods:** We conducted a retrospective review of medical records of all metastatic pancreatic cancer patients from 2010 to 2018 who received first line treatment with FFX or G+A at University of Arizona Cancer Center. **Results:** Thirty-five patients received combination treatment with G+A and 29 patients received FFX. Patient demographics: median age was 66 years in FFX vs 70 years in the G+A group; baseline CA-19-9 was 791 in FFX vs 738 in the G+A group. Median ECOG score was 1 for both groups. Median overall survival was 11.5 months in the FFX group (range 0-39 mos) vs 5 months in the G+A group (range 0-37 mos). Overall survival at 6 months was 75.9% vs 51.4% in FFX vs G+A groups respectively. Median progression-free survival was 6 months with FFX (range 0-25 mos) and 3 months with G+A (range 0-24 mos). Twenty-one of 29 patients in the FFX group pursued second line treatment, compared to 12 of 35 patients in the G+A group. Time to next treatment was 6 months in the FFX group vs 5 months in the G+A group. More adverse effects were noted with FFX, the most common being neuropathy and neutropenia, leading to treatment discontinuation due to adverse effects in 31% of patients, compared to 3% of patients in the G+A group. FFX patients required a higher median no. of office visits (35 visits vs 18 visits in the G+A group). **Conclusions:** FFX showed improved progression-free survival vs G+A; however, this could be due to more patients pursuing second line treatment in the FFX group. Compared to G+A, FFX patients had higher rates of treatment discontinuation due to adverse effects. FFX patients also required more office visits and further analysis is necessary to assess whether this resulted in poorer quality of life and increased total cost of care for patients treated with FFX. Research Sponsor: None.

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TPS777 **Trials in Progress Poster Session (Board #P20), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

The impact of early palliative care on the quality of life of patients with advanced pancreatic cancer: The IMPERATIVE study.

Stephanie Lelond, Harvey Chochinov, Paul Joseph Daeninck, Benjamin Adam Goldenberg, Lisa Lix, Susan McClement, Christina Kim; CancerCare Manitoba, Winnipeg, MB, Canada; University of Manitoba, Winnipeg, MB, Canada; Dept of Medical Oncology, CancerCare Manitoba, Winnipeg, MB, Canada; University of Manitoba, Manitoba Palliative Care Research Unit, Winnipeg, MB, Canada

Background: Pancreatic cancer is lethal. Chemotherapy can improve survival by months; however, many patients experience an overwhelming burden of cancer-associated symptoms and poor quality of life (QOL). Early palliative care (EPC) alongside standard oncologic care results in improved QOL and survival in patients with lung cancer. Although international guidelines recommend EPC for patients with advanced pancreatic cancer (PANC), the benefit is not known. Objectives: The primary objective is to test for change in QOL between baseline (BL) and 16 weeks (wk). Secondary objectives are to test for change between BL and 16 wk in (a) symptom control; and (b) depression and anxiety. **Methods:** This prospective case-crossover study of patients with PANC provides EPC plus standard oncologic care. Primary oncology clinics refer patients to an EPC team led by a palliative care physician and a clinical nurse specialist. BL questionnaires are completed prior to initial EPC assessment, then every 4 wk until wk 16. EPC visits are every 2 wk for the first month, every 4 wk until wk 16, and then as needed. QOL, symptom control, anxiety and depression are measured using the FACT-Hep tool, ESAS-r, HADS and PHQ-9, respectively. A generalized linear model will test for statistically significant change in scores between BL and 16 wk; chemotherapy (yes/no) is included as a confounding covariate; model fit will be assessed. A sample size of 20 patients provides 80% power after controlling for covariate effects. 40 patients will be enrolled to account for missing data. To date, 28 patients have enrolled and 17 have completed the intervention. Significance: The benefit of EPC for patients with PANC is not known, however, EPC is increasingly recognized internationally by patients and stakeholders as a critical intervention which may improve both QOL and satisfaction with care. The Canadian Partnership Against Cancer's report on the patient experience states "the best possible patient experience means all people with cancer have equitable access to high-quality person-centered palliative care". This study offers access to EPC and provides an environment in which the benefit of an integrated approach is evaluated. Research Sponsor: CancerCare Manitoba FoundationPharmaceutical/ Biotech Company.

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TPS778 **Trials in Progress Poster Session (Board #P21), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Demoralization and depression in pancreatic cancer patients.

Jar-Yee Liu, Veronica Placencio-Hickok, Brian Anderson, Paul Eliezer Oberstein, Andrew L. Coveler, Crystal S. Denlinger, Jun Gong, Andrew Eugene Hendifar; Cedars-Sinai Medical Center, Los Angeles, CA; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; University of California San Francisco, San Francisco, CA; Laura and Isaac Perlmutter Cancer Center, NYU Langone Health, New York, NY; Seattle Cancer Care Alliance/University of Washington, Seattle, WA; Fox Chase Cancer Center, Philadelphia, PA; City of Hope, Duarte, CA

Background: Demoralization is a maladaptive coping response to stressful situations characterized by thoughts of hopelessness, helplessness, and loss of meaning and purpose. Psychometrically, it is measured using the Demoralization-Scale II (DS-II), a validated questionnaire that yields a patient-reported quantification (scale 0-32) of demoralization. Previous studies involving patients with progressive disease have uncovered a strong positive correlation between demoralization and depression, respectively measured by the DS-II and Patient Health Questionnaire-9 (PHQ-9) surveys. Here, we aim to characterize demoralization and its relationship to depression in pancreatic cancer patients, a unique patient population in terms of its poor prognosis. We hypothesize that demoralization is highly prevalent in the pancreatic cancer patient population and strongly correlated with depression. **Methods:** Eligible patients with an active pancreatic cancer diagnosis, after consenting to an IRB approved protocol, will be administered the DS-II and PHQ-9 surveys to yield psychometric measurements for analysis. The primary objective of this project is to determine the association between demoralization (DS-II) and depression (PHQ-9) in pancreatic cancer patients. Secondary objectives include associations between demoralization and ethnicity, sexual orientation, suicidal ideation, education, cancer stage, and disease progression. Data will be analyzed via simple linear regression. An ANOVA will also be conducted using DS-II groups as the categorical variable and PHQ-9 scores as the continuous variable, and vice versa. This is a multi-institutional study to be conducted at Cedars-Sinai Medical Center, New York University, University of Washington, UC San Francisco, and Lewis Katz Schools of Medicine. Research Sponsor: None.

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TPS779 **Trials in Progress Poster Session (Board #P22), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Improving cascade genetic testing for families with inherited pancreatic cancer (PDAC) risk: The GENetic Education, Risk Assessment and TEsting (GENERATE) study.

Matthew B. Yurgelun, Chinedu I. Ukaegbu, C. Sloane Furniss, Barbara Kenner, Alison Klein, Andrew M. Lowy, Florencia McAllister, Maureen E Mork, Scott H. Nelson, Alison Robertson, Jill E. Stopfer, Meghan Underhill, Allyson J. Ocean, Lisa Madlensky, Gloria M. Petersen, Judy Ellen Garber, Scott Michael Lippman, Michael Goggins, Anirban Maitra, Sapna Syngal; Dana-Farber Cancer Institute, Boston, MA; Kenner Family Research Fund, New York, NY; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; UCSD Moores Cancer Center, La Jolla, CA; The University of Texas MD Anderson Cancer Center, Houston, TX; Mayo Clinic, Rochester, MN; Center for Cancer Genetics and Prevention, Dana-Farber Cancer Institute, Boston, MA; Weill Cornell Medical College, New York, NY; University of California San Diego, La Jolla, CA; Johns Hopkins University, Baltimore, MD; University of Texas MD Anderson Cancer Center, Houston, TX

Background: 4-10% of PDAC patients harbor pathogenic germline variants in cancer susceptibility genes, including *APC*, *ATM*, *BRCA1*, *BRCA2*, *CDKN2A*, *EPCAM*, *MLH1*, *MSH2*, *MSH6*, *PALB2*, *PMS2*, *STK11*, and *TP53*. For families with such pathogenic variants, the greatest potential impact of germline testing is to identify relatives with the same variant (cascade testing), thereby providing the opportunity for early detection and interception of PDAC and other associated cancers. Numerous factors limit cascade testing in real-world practice, including family dynamics, widespread geographic distribution of relatives, access to genetic services, and misconceptions about the importance of germline testing, such that the preventive benefits of cascade testing are often not fully realized. The primary aim of this study is to analyze two alternative strategies for cascade testing in families with inherited PDAC risk. **Methods:** 1000 individuals with a confirmed pathogenic germline variant in any of the above genes in a $1^{st}/2^{nd}$ degree relative and a $1^{st}/2^{nd}$ degree relative with PDAC will be remotely enrolled through the study website (www.GENERATEstudy.org) and randomized between two methods of cascade testing (individuals with prior genetic testing will be ineligible): Arm 1 will undergo pre-test genetic education with a pre-recorded video and live interactive session with a genetic counselor via a web-based telemedicine platform (Doxy.me), followed by germline testing through Color Genomics; Arm 2 will undergo germline testing through Color Genomics without dedicated pre-test genetic education. Color Genomics will disclose results to study personnel and directly to participants in both arms. All participants will have the option of pursuing additional telephone-based genetic counseling through Color Genomics. The primary outcome will be uptake of cascade testing. Secondary outcomes will include self-reported genetic knowledge, cancer worry, distress, decisional preparedness, familial communication, and screening uptake, which will be measured via longitudinal surveys. Enrollment is underway nationwide as of May, 2019. Clinical trial information: NCT03762590. Research Sponsor: Stand Up To Cancer-Lustgarten Foundation Pancreatic Cancer Interception Translational Cancer Research Grant (Grant Number: SU2C-AACR-DT25-17).

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TPS780 **Trials in Progress Poster Session (Board #Q1), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase I study of nanoliposomal irinotecan and 5-fluorouracil/folinic acid in combination with interleukin-1-alpha antagonist for advanced pancreatic cancer patients with cachexia (OnFX).

Katelyn Mae Atkins, Jun Gong, Mourad Tighiouart, Samuel J. Klempner, Richard Tuli, Veronica Placencio-Hickok, Andrew Eugene Hendifar; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Cedars-Sinai Medical Center, Los Angeles, CA; Massachusetts General Hospital, Boston, MA; Memorial Sloan Kettering Cancer Center, New York City, NY

Background: Patients with pancreatic cancer have the highest rate of weight loss among all advanced cancers. Of which, the majority develop cachexia, characterized by progressive and involuntary loss of weight and skeletal muscle mass. In preclinical studies, interleukin-1-alpha (IL-1α) antagonism has been found to neutralize tumor angiogenesis and onco-inflammation. Early phase single-agent studies in cancer cachexia have demonstrated increased lean body mass and decreased fatigue, pain, and appetite loss. The present study aims to establish the safety of an IL-1α antagonist (Bermekimab) in combination with nanoliposomal irinotecan (Nal-Iri) and 5-fluorouracil (5FU)/folinic acid (FA) in patients with advanced pancreatic adenocarcinoma and cachexia who have failed gemcitabine-based chemotherapy. **Methods:** This is a single arm, single center, phase I study. The primary objective is to assess the maximum tolerated dose (MTD) of Bermekimab in combination with Nal-Iri and 5FU/FA. MTD is defined as the dose such that the probability of dose-limiting toxicities at MTD is $\theta = 0.33$. The first cohort of up to 3 patients will receive 7.5 mg/kg Bermekimab, 50 mg/m2 nanoliposomal irinotecan, 2000 mg/m2 5FU, and 400 mg/m2 FA and the subsequent doses will be determined by the escalation with overdose control (EWOC) algorithm. Treatment is administered on days 1 and 15 of each 28-day cycle. Key inclusion criteria include: advanced or locally advanced pancreatic adenocarcinoma that has progressed through or intolerant of gemcitabine-based chemotherapy, cachexia defined as $>$ 5% unexplained weight loss 6 months prior to screening or as documented by physician, ECOG PS 0-2 or KPS $\geq$ 60%, and normal organ and marrow function. Secondary objectives are to assess weight, lean body mass, inflammatory cytokines, overall survival, progression free survival, patient quality of life, and functional status. Since January 2019, 23 patients have been screened and 21 enrolled. Clinical trial information: NCT03207724. Research Sponsor: Ipsen and XBiotech, Inc.

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TPS781 **Trials in Progress Poster Session (Board #Q2), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Apartinib in combination with S-1 for the second-line treatment of advanced pancreatic cancer (APC).

Junjie Hang, Lixia Wu, Ruohan Yin, Muhan Liu, Kequn Xu; Changzhou No.2 People's Hospital, Changzhou, China; Shanghai Zhabei District Central Hospital, Shanghai, China

Background: The prognosis for patients with advanced pancreatic cancer (APC) is extremely dismal. First-line treatment for APC is gemcitabine/5-FU-based chemotherapy with no standard second-line treatment. Anti-angiogenic therapy combined with chemotherapy have showed its effects in improving the outcomes in a variety of cancers. Apatinib is an oral tyrosine kinase inhibitor that selectively targets VEGFR2. Some preclinical studies and several case reports showed the anti-tumor effect of apatinib in pancreatic cancer, but there is no evidence from clinical trial to confirm it. This study aims to evaluate the efficacy and safety of apartinib in combination with S-1 as the second-line therapy for patients with APC. **Methods:** In this open-label, single-arm, randomized phase II study, we will recruit 30 patients with pathologically proven advanced pancreatic cancer after the failure of first-line chemotherapy. All patients are aged 18-70 years with ECOG PS 0-2 and will receive apatinib at an initial dose of 500mg/d on a continuous basis, and oral S-1 (60mg/d for BSA $< 1.25m^2$, 80mg/d for $1.25<$BSA $< 1.5m^2$, and 100mg for BSA $>1.5m^2$, orally) twice a day on days 1-14 of a 21-day cycle. Primary endpoint is PFS. Secondary endpoints include OS, duration of response, ORR and DCR. The safety of apartinib + S-1 will be evaluated by CTCAE v4.0. Translational research will be performed in blood (before and on-treatment): cytokine panel to explore predictive and prognostic biomarkers. Clinical trial information: NCT03662035. Research Sponsor: CSCO-Henrui Funding for Cancer Research.

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TPS782 **Trials in Progress Poster Session (Board #Q3), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A pilot study of intratumoral SD-101 (toll-like receptor 9 agonist), nivolumab, and radiotherapy for treatment of chemotherapy-refractory metastatic pancreatic adenocarcinoma.

Justin Chen, Jasmine Huynh, Arta Monjazeb, May Thet Cho, Edward Jae-Hoon Kim; University of California Davis Comprehensive Cancer Center, Sacramento, CA; UC Davis Comprehensive Cancer Center, Sacramento, CA; University of California Davis, Sacramento, CA

Background: Pancreatic adenocarcinoma is an aggressive disease projected to be the second leading cause of cancer-related death. A majority of patients have advanced disease on diagnosis. Combination chemotherapy is first-line for advanced disease but limited by toxicity and median survival under 1 year. SD-101 is a toll-like receptor 9 agonist that is injected intratumorally to increase immunogenicity in the tumor microenvironment. Localized radiation can further enhance this via antigen release and potential abscopal effects. Immunotherapy has revolutionized care for various solid organ malignancies but not yet for pancreatic cancer. Therefore, the combination of SD-101, localized radiation, and checkpoint inhibitor is a promising therapeutic strategy for metastatic pancreatic adenocarcinoma. **Methods:** Six patients with chemotherapy-refractory, liver-metastatic pancreatic adenocarcinoma will be evaluated for combination SD-101, radiation, and nivolumab. SD-101 is injected intratumorally into a liver metastasis on days 1, 8, 15, 29 with optional dosing days 43 and 57. Localized radiation (6-10 Gy per fraction) to the injected lesion will be given on days 1, 3, 5, 8, and 10. Nivolumab will be given at 240 mg every 2 weeks starting day 2 until progression or unacceptable toxicity. Blood samples will be collected at baseline and at regular intervals while on treatment. Biopsies will be obtained at baseline and on day 29. Primary objectives are to evaluate safety and tolerability, defined so if $\geq$5 patients reach day 29 without experiencing grade $\geq$3 treatment-related toxicity. Secondary objectives include preliminary efficacy as defined by disease control rate, duration of response, progression-free survival, and overall survival. Exploratory objectives include objective response rate and biomarker correlatives (T-cell clonality, tumor mutational burden, tumor infiltrative immune cell subsets, and immune-related gene expression profile). Blood and biopsy specimens will be analyzed using flow cytometry, qRT-PCR, RNA sequencing, and whole exome sequencing including immunohistochemistry on biopsy specimens. Clinical trial information: NCT04050085. Research Sponsor: Private, individual donorDrug-only support from Bristol-Myers Squibb and Dynavax.

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TPS783 **Trials in Progress Poster Session (Board #Q4), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

TRYbeCA-1: A randomized, phase III study of eryaspase in combination with chemotherapy versus chemotherapy alone as second-line treatment in patients with pancreatic adenocarcinoma (NCT03665441).

Pascal Hammel, Rossana Berardi, Eric Van Cutsem, Jaime Feliu, Richard Greil, Harpreet Singh Wasan, Jean-Philippe Metges, Peter Nygren, Pia J. Osterlund, Marcus Smith Noel, Thomas Seufferlein, Geert-Yan Creemers, Anu Gupta, Sophie Salesse, Nigel Biswas-Baldwin, Hedy Dion, Hagop Youssoufian, Felix Tomas Garzon, Iman El-Hariry, Manuel Hidalgo; Hôpital Beaujon (AP-HP), Clichy, and University Paris VII, Paris, France; Clinical Oncology, Polytechnic University of Marche, AOU Ospedali Riuniti, Ancona, Italy; University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; Translational Oncology Unit, Madrid, Spain; Department of Internal Medicine III with Hematology, Medical Oncology, Hemostaseology, Infectious Diseases, Rheumatology, Oncologic Center, Paracelsus Medical University, Salzburg, Austria; Hammersmith Hospital, Imperial College Health Care Trust, London, United Kingdom; Centre Hospitalier Regional Universitaire (CHRU) de Brest-Hopital Morvan, Brest, France; Uppsala University, Uppsala, Sweden; Helsinki University Central Hospital, Helsinki, Finland; James P. Wilmot Cancer Institute, University of Rochester, Rochester, NY; Department of Medicine I, Hospital of the University Ulm, Ulm, Germany; Catharina Hospital, Noord-Brabant Holland, Netherlands; Erytech Pharma Inc., Cambridge, MA; Erytech Pharma Inc., Lyon, France; Erytech, Boston, MA; Centro Nacional de Investigaciones Oncologicas, Madrid, Spain

Background: Second-line treatment options for advanced pancreatic adenocarcinoma are currently limited. Eryaspase, asparaginase (ASNase) encapsulated in red blood cells (RBCs) is an investigational product under development. Following infusion, asparagine and glutamine are actively transported into RBCs where they are hydrolyzed by the encapsulated ASNase. We have recently reported the outcome of a randomized Phase 2b study inpatients with advanced pancreatic cancer whose disease progressed following first-line treatment. Eryaspase in combination with gemcitabine monotherapy or FOLFOX combination therapy improved overall survival (OS) and progression free survival (PFS). The safety profile of eryaspase was acceptable. The results of this Phase 2b study provided a rationale for initiating this confirmatory Phase 3 pivotal trial (TRYbeCA-1). **Methods:** TRYbeCA-1 is a randomized, open-label Phase 3 trial (N = ~500) of eryaspase combined with chemotherapy in patients with adenocarcinoma of the pancreas who have failed only one prior line of systemic anti-cancer therapy for advanced pancreatic cancer and have measurable disease. Patients are randomized in a 1:1 ratio to receive gemcitabine/Abraxane or irinotecan-based therapy (FOLFIRI [FOLinic acid-Fluorouracil-IRInotecan regimen] or irinotecan liposome injection/5-fluorouracil/leucovorin) with or without eryaspase, administered as IV infusion on Day 1 and Day 15 of each 4-week cycle. Key eligibility criteria include performance status 0 or 1; stage III-IV disease; documented evidence of disease progression; available tumor tissue; and adequate organ function. The primary endpoint is OS. Key secondary endpoints include PFS and objective response rate, safety, quality of life, pharmacokinetics and pharmacodynamics, and biomarker research. A hazard ratio in OS of 0.725 is being targeted which represents a conservative estimate based on the Phase 2b data and is viewed as being highly clinically relevant. An IDMC will be established to review safety at regular intervals andto review efficacy data at the planned interim and final analyses. Clinical trial information: NCT03665441. Research Sponsor: Erytech.

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TPS784 **Trials in Progress Poster Session (Board #Q5), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Vitamin D receptor agonist paricalcitol plus gemcitabine and nab-paclitaxel in patients with metastatic pancreatic cancer.

Kimberly Perez, James M. Cleary, Thomas Benjamin Karasic, Srivatsan Raghavan, Osama E. Rahma, Jonathan Nowak, Erkut Hasan Borazanci, Michael Downes, Jeffrey A. Drebin, David A. Tuveson, David Tsai Ting, Richard Moffitt, Jen Jen Yeh, Andrew Aguirre, Ronald Evans, Daniel D. Von Hoff, Peter J. Odwyer, Brian M. Wolpin; Dana-Farber Cancer Institute, Boston, MA; University of Pennsylvania Abramson Cancer Center, Philadelphia, PA; Dana-Farber Cancer Institute, Cambridge, MA; Brigham and Women's Hospital, Boston, MA; HonorHealth Research Institute, Scottsdale, AZ; Salk Institute, La Jolla, CA; University of Pennsylvania, Philadelphia, PA; Cold Spring Harbor Laboratory, Cold Spring Harbor, NY; Massachusetts General Hospital, Boston, MA; SUNY Stonybrook, Stonybrook, NY; UNC Chapel Hill Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Translational Genomics Research Institute, Phoenix, AZ

Background: Patients(pts) with metastatic pancreatic cancer (PC) have a median survival of less than one year even with use of multiagent chemotherapy programs. Pancreatic tumors are composed of multiple cell types and a dense extracellular matrix that may support cancer cell proliferation and impede chemotherapy delivery. Cancer-associated fibroblasts (CAF's) in the tumor microenvironment secrete pro-inflammatory factors and components of the extracellular matrix. In PC laboratory models, engagement of the vitamin D receptor (VDR) by VDR agonists shifts CAFs toward a more quiescent phenotype with reduced tumor growth and improved chemotherapy penetration (Sherman. *Cell*, 2014). Paricalcitol is a synthetic VDR agonist used in patients with secondary hyperparathyroidism due to chronic kidney disease. A prior pilot study evaluated IV paricalcitol with gemcitabine (G) and nab-paclitaxel (A) before surgical resection in patients with resectable PC (NCT02030860). **Methods:** Pts with previously-untreated metastatic PC will be enrolled in a two-stage study consisting of a safety run-in and a randomized phase 2 study (NCT03520790). In the run-in stage, 36 pts will be randomized 1:1:1 to G (1000 mg/m^2) and A (125 mg/m^2) given 3 weeks on and 1 week off plus: (a) paricalcitol 25mcg IV thrice weekly, (b) paricalcitol 16mcg oral daily, or (c) placebo oral daily. Grade 3/4 hypercalcemia or genitourinary stones will be considered dose limiting toxicities.Pts will undergo paired pre- and on-treatment tumor biopsies to examine pharmacodynamic (PD) markers by bulk and single cell RNA sequencing and multiplex immunofluoresence.Assuming safety and supportive PD assessments, the phase 2 study will randomize an additional 76 pts to two treatment arms with GA plus: (a) paricalcitol or (b) placebo.Paricalcitol formulation (IV or oral) will be determined based on data from the run-in stage.The primary endpoint of the phase 2 study is overall survival, with a total of 100 pts needed to identify a hazard ratio of 0.6 with 80% power and one-sided alpha of 0.10.Secondary endpoints include safety, response rate, and progression free survival.Trial funding provided by SU2C, CRUK,Lustgarten Foundation, and AACR. Clinical trial information: NCT03520790. Research Sponsor: SU2C, Lustgarten Foundation, and AACR.

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TPS785 **Trials in Progress Poster Session (Board #Q6), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

PCRT16-001: Phase II study of PEGPH20 plus pembrolizumab for patients (pts) with hyaluronan (HA)-high refractory metastatic pancreatic ductal adenocarcinoma (mPDA).

E. Gabriela Chiorean, Paul S. Ritch, David Bing Zhen, Elizabeth Poplin, Ben George, Andrew Eugene Hendifar, Tomislav Dragovich, Andrew L. Coveler, Amy C. Stoll-D'Astice, Stephanie Edwards, Adam Rosenthal, Shelley M. Thorsen, Sunil R. Hingorani; University of Washington and Fred Hutchinson Cancer Research Center, Seattle, WA; Medical College of Wisconsin, Milwaukee, WI; University of Michigan, Ann Arbor, MI; Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; Froedtert & the Medical College of Wisconsin, Milwaukee, WI; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Banner MD Anderson Cancer Center, Gilbert, AZ; Seattle Cancer Care Alliance/University of Washington, Seattle, WA; Cancer Research and Biostatistics, Seattle, WA; Fred Hutchinson Cancer Research Center, Seattle, WA

Background: PDA is characterized by invasiveness and therapeutic resistance in part due to a desmoplastic stroma and an immunosuppressive microenvironment (*Provenzano PP, Hingorani S. Br J Cancer 2013*). PD1/PD-L1 inhibitors have no single agent activity in PDA, except for pts with mismatch repair defects. There is high need to overcome resistance to immune targeted therapies and develop biomarkers for pts selection. Stromal HA poses a physical barrier and protects tumor cells from immune surveillance (*Kultti A, et al Biomed Res Int 2014*). By remodeling the tumor stroma, PEGPH20 allows infiltration of cytotoxic T lymphocytes, and improves delivery of chemotherapy and PD1/PD-L1 antibodies (*Singha NC, et al Mol Cancer Ther 2015*). mPDA pts refractory to 1st line therapy have median overall survival (OS) of 6 mos. We hypothesize that stroma remodeling with PEGPH20 sensitizes PDA to immune therapy, and stroma and immunologic biomarkers will identify pts most likely to benefit. In this trial we will evaluate the efficacy, safety and translational biomarkers of PEGPH20 plus pembrolizumab in HA-high refractory mPDA. **Methods:** Eligible pts have ECOG PS 0-1, $\leq$ 2 prior therapies for mPDA, life expectancy $\geq$ 12 wks, able/willing to have tumor biopsies at baseline and after 6 wks of treatment. PEGPH20 dosing is 3 μg/kg iv QW and pembrolizumab 200 mg iv Q3W (2-4 hrs after PEGPH20 on wk 1) in 3-wk cycles. All pts receive prophylactic low molecular weight heparin. Primary endpoint: progression-free survival (PFS). Secondary endpoints: safety, OS, response rates. Translational endpoints: flow cytometry of peripheral and intratumoral immune cells, T-cell receptor sequencing, immune transcriptome, immune subsets IHC, circulating cytokines, serial plasma and tumor HA levels. For the primary endpoint of PFS, with a sample size of 31 evaluable pts, a one-sided α-level of 0.05, assuming 12 mos of accrual and 6 mos of follow-up, this study has 80% power to detect a difference between the null hypothesis median PFS 3 mos, versus the alternative hypothesis median PFS 6 mos. The study was activated in May 2019 and is open to accrual; 6 pts were enrolled as of 24Sept 2019. Clinical trial information: NCT03634332. Research Sponsor: Merck, Halozyme.

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TPS786 Trials in Progress Poster Session (Board #Q7), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM and Poster Walks, Fri, 4:45 PM-5:30 PM

Stereotactic MR-guided on-table adaptive radiation therapy (SMART) for locally advanced pancreatic cancer.

Parag Parikh, Daniel Low, Olga L. Green, Percy P. Lee; Henry Ford Cancer Institute, Detroit, MI; University of California Los Angeles, Los Angeles, CA; Washington University in St. Louis, Department of Radiation Oncology, St. Louis, MO; UCLA Jonsson Comprehensive Cancer Center, Los Angeles, CA

Background: Standard dose radiation therapy has been unsuccessful in inoperable pancreatic cancer; with a negative study (LAP07) for conventional chemoradiation and dropping of the stereotactic body radiation therapy arm in Alliance A021501. Recently, reports of using high dose ablative radiation therapy has been associated with increased survival in retrospective studies. Moreover, technological advances with MRI-guided radiation therapy offer improved targeting and the ability to change the radiation delivery on a daily fashion; allowing ablative radiation doses over one week. However, it is not clear whether this can be done safely on a multiinstitutional basis. **Methods:** We are conducting the largest prospective study of ablative radiation therapy in pancreatic cancer. The study is a single arm, multi-institutional phase II, industry sponsored study to investigate the safety and efficacy of Stereotactic, MR guided, on-table-Adaptive Radiation Therapy (SMART). Eligibility criteria include locally advanced and borderline resectable pancreatic cancer patients with ECOG PS of 0 or 1; who have non-metastatic disease after a minimum of 3 months of any systemic therapy; including investigational agents. Patients will receive MR-guided radiation therapy to a dose of 50 Gy / 5 fractions; with maximum tumor coverage delivered each fraction that allows keeping the gastrointestinal organs at risk to a dose of 33 Gy or less. Primary endpoint is grade 3 of higher gastrointestinal toxicity at 90 days. Secondary endpoints are overall survival at 2 years, distant progression free survival at 6 months, and changes in patient related quality of life at 3 and 12 months. Target sample size was calculated to show at a significance level 0.05, a reduction of the toxicity rate to 8% or lower by using SMART compared with 15.8%, the toxicity rate of conventionally delivered chemoradiation at a power level 0.8. Given an expected 15% drop-out, the enrollment goal is 133. Descriptive statistics will be used for secondary objectives. The study opened in January, 2019 and is currently opened at 4 centers; with other US and international sites pending. Sponsored by Viewray, Inc. Clinical trial information: NCT03621644. Research Sponsor: Viewray, Inc.

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TPS788 **Trials in Progress Poster Session (Board #Q9), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase I study to evaluate the safety and tolerability of AB680 combination therapy in participants with gastrointestinal malignancies.

Johanna C. Bendell, Gulam Abbas Manji, Shubham Pant, Dominic W. Lai, Jill Colabella, Wade Berry, Melissa Constance Paoloni, William J. Grossman, Eileen Mary O'Reilly; Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN; Columbia University Medical Center and New York-Presbyterian Hospital, New York, NY; University of Texas MD Anderson Cancer Center, Houston, TX; Arcus Biosciences, Inc., Hayward, CA; Arcus Biosciences, Hayward, CA; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Metastatic pancreatic ductal adenocarcinoma (mPDAC) expresses very high levels of CD73 among tumor types, and CD73 expression level is a known poor prognostic factor in PDAC. Adenosine, a product of AMP breakdown by CD73, is highly immunosuppressive against effector T & NK cells in the tumor microenvironment. AB680 is the first clinical-stage small-molecule CD73 inhibitor, which is highly potent, pharmacodynamically active, and safe in healthy volunteer dose escalation studies. Targeting the adenosine pathway in combination with standard of care regimens may have a more profound effect on activating and inducing sustained anti-tumor immunity. **Methods:** This is a Phase 1/1b, open-label, dose-escalation, and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of AB680 in combination with AB122 (anti-PD-1 antibody) and standard chemotherapy (nab-paclitaxel [NP] and gemcitabine [Gem]) in participants with first line (1L) mPDAC. In the dose-escalation Ph1 portion, increasing dose levels of AB680 are administered every 2 weeks (Q2W) in combination with AB122 (240 mg Q2W) and NP/Gem (Gem 1000 mg/m2 + NP 125 mg/m2 IV on Days 1, 8, and 15 of each 28-day cycle). Up to 30 participants may be evaluated in Ph1 dose-escalation. In the dose-expansion Ph1b portion, AB680 will be administered at the recommended dose for expansion in combination with AB122 and NP/Gem in up to 40 participants. Adverse events will be graded according to NCI CTCAE 5.0 and antitumor activity assessed using RECIST v1.1. **Conclusions:** This Ph1/1b study will be the first to target the adenosine axis using a highly potent small-molecule inhibitor of CD73, AB680, in 1L mPDAC in combination with standard of care chemotherapy (NP/Gem) and a PD-1 antibody (AB122). Future results will be shared in upcoming scientific conferences. Clinical trial information: NCT04104672. Research Sponsor: Arcus Biosciences, INc.

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TPS789 **Trials in Progress Poster Session (Board #Q10), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

Tyme-88-Panc Part 2: A randomized phase II/III of SM-88 with MPS as third-line in metastatic PDAC.

Shubham Pant, Sant P. Chawla, Vincent Chung, Giuseppe Del Priore, Dae Won Kim, Marcus Smith Noel, Paul Eliezer Oberstein, Allyson J. Ocean, Philip Agop Philip, Vincent J. Picozzi, Diane M Simeone, Andrea Wang-Gillam; University of Texas MD Anderson Cancer Center, Houston, TX; Sarcoma Oncology Research Center, Santa Monica, CA; City of Hope, Duarte, CA; Morehouse School of Medicine, Atlanta, GA; The University of Texas MD Anderson Cancer Center, Houston, TX; James P. Wilmot Cancer Institute, University of Rochester, Rochester, NY; Laura and Isaac Perlmutter Cancer Center, NYU Langone Health, New York, NY; Weill Cornell Medical College, New York, NY; Karmanos Cancer Institute, Detroit, MI; Virginia Mason Hospital and Medical Center, Seattle, WA; NYU Langone Health, New York, NY; Washington University School of Medicine in St. Louis, St. Louis, MO

Background: Patients with metastatic pancreatic cancer who have progressed on two prior lines of therapy have a poor prognosis with an overall survival in the range of 2-2.5 months. (Manax, et al. J Clin Oncol 37, 2019 suppl 4; abstr 226). There is currently no standard of care for these patients that has demonstrated improved outcomes. SM-88 (D,L-alpha-metyrosine; racemetyrosine [USAN]) is a proprietary dysfunctional tyrosine derivative and is the backbone of SM-88 used with MPS (Methoxsalen 10mg, Phenytoin 50mg and Sirolimus 0.5mg; all administered daily). SM-88 monotherapy was relatively well tolerated, with improvement in survival in select patients with heavily pretreated PDAC who achieved stable disease on therapy (HR 0.08, p = 0.02). Circulating tumor cells (CTC's) were prognostic and decreased on therapy with SM-88 potentially identifying a subgroup of PDAC that may be most likely to benefit from therapy (Noel et al. *Annal Oncol* V30, Suppl 4, 2019). Preliminary radiomic analysis of the largest metastases at baseline suggested the same benefits including a correlation with baseline CTCs, changes in CTCs on therapy and OS (Ocean et al, *Annal Oncol*, V30, Suppl 5, 2019). Here, we describe a randomized, open-label, phase 2/3 trial evaluating the efficacy of SM-88 + MPS vs physician's choice treatment as third line therapy for patients with metastatic PDAC. **Methods:** This is a multi-center Phase 3 study of patients ≥18 years with metastatic PDAC that progressed after 2 lines of chemotherapy (gemcitabine [gem] and 5-fluorouracil [5-FU] based) with an ECOG <2. Randomization will be 1:1 with 250 patients being stratified by site, ECOG, and choice of chemotherapy. SM-88 will be administered at a dose of 460mg twice daily (920 mg/day). Primary end point is Overall Survival (OS). Secondary end points include progression free survival, response rate, duration of response, pharmacokinetics, safety and CTCs. Clinical trial information: NCT03512756. Research Sponsor: Tyme Inc.

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TPS790 **Trials in Progress Poster Session (Board #Q11), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase II, open-label pilot study evaluating the safety and activity of Nal-IRI in combination with 5-FU and oxaliplatin in preoperative treatment of pancreatic adenocarcinoma (NEO-Nal-IRI Study) (NCT03483038).

Hiral D. Parekh, Jessica L. Cioffi, Kathryn Hitchcock, Ji-Hyun Lee, Z. Hugh Fan, Carmen Joseph Allegra, Steven J. Hughes, Jose Gilberto Trevino, David L. DeRemer, Thomas J. George; University of Florida Health Cancer Center, Gainesville, FL; University of Florida, Gainesville, FL; NSABP Foundation, Inc., and The University of Florida, Gainesville, FL; Georgia Regents Univ, Augusta, GA

Background: Neoadjuvant treatment for borderline resectable pancreatic cancer (PCa) is increasing in acceptability, but a standard regimen has yet to be established. Multiple studies have demonstrated feasibility and effectiveness of the FOLFIRINOX (5-fluorouracil, leucovorin, oxaliplatin and irinotecan) regimen in the perioperative setting. However, FOLFIRINOX often requires dose modifications, delays and growth factor support due to excessive toxicity which can complicate care delivery when given neoadjuvantly. Irinotecan liposomal injection (Nal-IRI) is FDA approved with a well-tolerated safety profile in relapsed, refractory metastatic PCa. The current study aims to substitute Nal-IRI for traditional irinotecan in the standard FOLFIRINOX regimen and to demonstrate safe and effective neoadjuvant delivery. **Methods:** This phase 2, open-label, multicenter single-arm study focuses on patients (pts) with borderline resectable PCa without metastatic disease. Other key eligibility criteria include age ≥18 years, resectability confirmed by multiD GI tumor board, adequate cardiac, renal, hepatic function and ECOG performance status of 0 to 1. Pts receive FOLFNal-IRINOX regimen as per Table every 2 weeks for four months followed by disease reassessment. Pts who remain surgical candidates will undergo surgical resection within 4 to 8 weeks following last dose of therapy. The primary endpoint is to assess safety and feasibility of regimen in perioperative setting. Secondary endpoints include R0 resection rate, clinical, biochemical and radiological response rate and patient-reported quality of life during treatment as measured by the NCI validated FACT-G scale. Enrollment continues to a maximum of 28 evaluable pts to demonstrate a reduction in historical 30 day postoperative complication rate. Clinical trial information: NCT03483038. Research Sponsor: IPSEN.

FOLFNal-IRINOX Regimen components given every 14 days.

Agent	Dose	Route/Duration
Nal-IRI	50 mg/m^2	IV over 90 minutes
Oxaliplatin	60 mg/m^2	IV over 120 minutes
Leucovorin	400 mg/m^2	IV over 120 minutes
5-fluorouracil infusion	2400 mg/m^2	IV continuous infusion for 46 hours

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TPS791 **Trials in Progress Poster Session (Board #Q12), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A phase II trial of pharmacological ascorbate, gemcitabine, and nabpaclitaxel for metastatic pancreatic cancer.

Pashtoon Murtaza Kasi, Kellie Bodeker, Daniel James Berg, Chandrikha Chandrasekharan, Saima Sharif, Brian J. Smith, Sandy-Vollstedt@uiowA.edu Vollstedt, Heather Brown, Meghan Chandler, Joseph J. Cullen; Mayo Clinic, Jacksonville, FL; The University of Iowa, Iowa City, IA; University of Iowa Hospitals and Clinics, Iowa City, IA; University of Iowa, Iowa City, IA; University of Iowa Hospitals and Clinics, Holden Comprehensive Cancer Center, Iowa City, IA; Department of Biostatistics, The University of Iowa, Iowa City, IA

Background: FOLFIRINOX or gemcitabine/nab-paclitaxel are both frontline chemotherapy options for patients with metastatic pancreas cancer. For most who cannot tolerate the triplet, the latter doublet is the preferred option. Through previous work by our group, pharmacologic ascorbate is known to synergize with gemcitabine; preliminary in vitro data from our group suggests a similar synergistic response with paclitaxel. Though ascorbate has been utilized in cancer therapy, few robust trials have investigated intravenous delivery of ascorbate to deliver plasma concentrations that are cytotoxic to tumor cells. Our prior studies have demonstrated ascorbate induces oxidative stress and cytotoxicity in pancreatic cancer cells; this cytotoxicity appears to be greater in tumor vs. normal cells. We hypothesize that production of hydrogen peroxide mediates the increased susceptibility of pancreatic cancer cells to ascorbate-induced metabolic oxidative stress, resulting in improved treatment outcomes, which has led to the development of the clinical trial (NCT02905578). **Methods:** All participants receive gemcitabine (1000 mg/m2 weekly) and nab-paclitaxel (125 mg/m2) on cycle days 1, 8, and 15 of a 28-day cycle. Participants are randomized to ± pharmacologic ascorbate (75-gram infusion 3x weekly) in addition to chemotherapy. Study therapy continues until tumor progression. The primary objective is to determine overall survival in patients when treated with combination gemcitabine, nab-Paclitaxel and high-dose ascorbic acid compared to gemcitabine and nab-paclitaxel in patients with non-resectable pancreatic cancer. Secondary objectives include determining objective response rate as well as progression free survival using RECIST 1.1 criteria employing a blinded reviewer for RECIST measurements. The study opened to accrual in 2018 with a goal of enrolling 65 participants. Oversight.Study is conducted under IND 105715 (J. Cullen, sponsor). The University of Iowa Biomedical IRB (IRB-01) serves as the IRB of record. Clinical trial information: NCT02905578. Research Sponsor: U.S. National Institutes of Health.

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TPS792 **Trials in Progress Poster Session (Board #Q13), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

PANOVA-3: A phase III study of tumor treating fields with nab-paclitaxel and gemcitabine for front-line treatment of locally advanced pancreatic adenocarcinoma (LAPC).

Vincent J. Picozzi, Teresa Macarulla, Philip Agop Philip, Carlos Roberto Becerra, Tomislav Dragovich; Virginia Mason Hospital and Medical Center, Seattle, WA; Vall d'Hebrón University Hospital and Vall d'Hebrón Institute of Oncology, Barcelona, Spain; Karmanos Cancer Institute, Detroit, MI; Baylor University Medical Center, Dallas, TX; Banner MD Anderson Cancer Center, Gilbert, AZ

Background: Tumor Treating Fields (TTFields) are a non-invasive, regional antimitotic treatment modality, which has been approved for the treatment of glioblastoma. TTFields at specific frequency (150-200 kHz) are delivered via transducer arrays placed on the skin in proximity to the tumor site. TTFields predominantly act by disrupting the formation of the mitotic spindle during metaphase. TTFields were effective in multiple preclinical models of pancreatic cancer. The Phase 2 PANOVA study, the first trial testing TTFields in pancreatic cancer patients, demonstrated the safety and preliminary efficacy of TTFields when combined with nab-paclitaxel and gemcitabine in both metastatic and LAPC. The Phase 3 PANOVA-3 trial (NCT03377491) is designed to test the efficacy and safety of adding TTFields to nab-paclitaxel and gemcitabine combination in LAPC. **Methods:** Patients (N = 556) with unresectable, LAPC (per NCCN guidelines) will be enrolled in this prospective, randomized trial. Patients should have an ECOG score of 0-2 and no prior progression or treatment. Patients will be stratified based on their performance status and geographical region, and will be randomized 1:1 to TTFields plus nab-paclitaxel and gemcitabine or to nab-paclitaxel and gemcitabine alone. Chemotherapy will be administered at standard dose of nab-paclitaxel (125 mg/m^2) and gemcitabine (1000 mg/m2 once weekly). TTFields (150 kHz) will be delivered at least 18 hours/day until local disease progression per RECIST Criteria V1.1. Follow up will be performed q8w, including a CT scan of the chest and abdomen. Following local disease progression, patients will be followed monthly for survival. Overall survival will be the primary endpoint and progression-free survival, objective response rate, rate of resectability, quality of life and toxicity will all be secondary endpoints. Sample size was calculated using a log-rank test comparing time to event in patients treated with TTFields plus chemotherapy with control patients on chemotherapy alone. PANOVA-3 is designed to detect a hazard ratio 0.75 in overall survival. Type I error is set to 0.05 (two-sided) and power to 80%. Clinical trial information: NCT03377491. Research Sponsor: Novocure.

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TPS793 **Trials in Progress Poster Session (Board #Q14), Fri, 12:00 PM-1:30 PM and 4:30 PM-5:30 PM**

A pilot study of liposomal irinotecan plus 5-FU/LV combined with paricalcitol in patients with advanced pancreatic cancer progressed on gemcitabine-based therapy.

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Background: Pancreatic ductal adenocarcinoma (PDAC) is predicted to be the second leading cause of cancer-related death by 2030, and is characterized by resistance to chemo- and radiotherapy and a highly fibrotic tumor microenvironment. Front-line therapies for advanced PDAC include FOLFIRINOX and gemcitabine/nab-paclitaxel with median overall survival ranging from 8.5 to 11 months. After progression on gemcitabine-containing therapy, 5-FU/LV/liposomal irinotecan is a standard second-line option, however outcomes are still poor. Retrospective studies demonstrate superior survival of advanced PDAC in patients with high serum levels of 25(OH) vitamin D. Notably, the PDAC tumor microenvironment is enriched in cancer-associated fibroblasts that favorably respond to vitamin D, prolonging survival in combination with chemotherapy in mouse models. Furthermore, vitamin D suppresses catabolism of irinotecan in gastrointestinal cancer cells, potentiating its efficacy. Therefore, we are conducing an investigator-initiated study of 5FU/LV/liposomal irinotecan with paricalcitol as second-line therapy in advanced PDAC. **Methods:** This is a pilot study of 5FU/LV/liposomal irinotecan combined with paricalcitol in patients with advanced PDAC progressed on gemcitabine-based therapy. All patients receive liposomal irinotecan, LV, 5-FU and paricalcitol. Liposomal irinotecan is given at 70 mg/m^2 IV over 90 minutes, LV at 400 mg/m^2 IV over 30 minutes, and 5-FU at 2400 mg/m^2 continuous IV infusion over 46 hours, on Day 1 of each 14-day cycle. Paricalcitol IV infusion will precede the above, given according to assigned cohort (75 mcg weekly or 7 mcg/kg weekly). The primary objective of this study is to determine the tolerability between two different dose levels of paricalcitol added to the combination regimen of 5-FU/LV/liposomal irinotecan in patients with advanced PDAC. Secondary objectives are measures of efficacy (ORR, PFS, OS, CA19-9 biochemical response rate). Clinical trial information: NCT03883919. Research Sponsor: IPSEN.

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