Methods: This is a retrospective study including 31 patients diagnosed and treated for locally advanced or metastatic pancreatic cancer, at the medical oncology department at Habib Bourguiba university hospital in Sfax, between 2011 and 2017. LMR was calculated by using the equation: LMR = absolute lymphocyte count/absolute monocyte ratio. Value cutoffs were adopted to discriminate patients as follows: low LMR $<$ 4.6 and high LMR$\geq$4.6.

Results: The median age of our patients was 60 years (36 -77). A male predominance was observed (61%). The average consultation time was 2.7 months, and the most common reason was abdominal pain (87%) followed by the onset of jaundice (29%). Nine patients had a performance status (PS) $\geq$2. On imaging, the average tumor size was estimated at 4.5 cm. The presence of metastases was observed in 16 patients (51.6%). Chemotherapy was indicated in 19 patients, as a neoadjuvant situation (38%) and in 51% in case of metastatic disease. A high LMR was found in 9 patients (29%). The mean overall survival was 7 months. Survival at 1 and 2 years were 12.9% and 3.2% respectively. The LMR $<$ 4.6 was associated with a worse overall survival (OS) at 1 year (3.2% vs 13%, p =0.002). The other poor prognostic factors were PS $\geq$2, high CA19-9 level and stage IV (p=0.001, p=0.021 and p=0.027 respectively).

Conclusions: The findings from our study suggest that low LMR is associated with worse OS in Tunisian patients with advanced pancreatic cancer, in addition to the other prognosis factors.

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P-7 Encorafenib and cetuximab in patients with metastatic, BRAF V600E-mutated, colorectal cancer: Update on the first real-world study in Germany and Austria – BERING CRC

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Background: For the therapy of previously treated BRAF V600E-mutant metastatic colorectal cancer, the combination of encorafenib with cetuximab represents a new standard of care. The combination of encorafenib plus cetuximab was approved in the EU in June 2020. The approval was based on positive results from the BEACON CRC trial, which demonstrated a median overall survival (OS) of 8.4 mo (second data cut off 9.3 mo) and an objective response rate of 20% (both data cut offs). The observed tolerability profile was consistent with the known safety profile of each agent. Since data from controlled clinical trials are based on a selected patient population, the present non-interventional study (NIS) investigates the use of encorafenib + cetuximab under real-world conditions in a broader patient population.

Trial design: BERING CRC is an ongoing, multi-national, multi-centric, prospective, longitudinal NIS. It represents the first NIS to investigate the real-world use of the targeted therapy encorafenib + cetuximab in BRAF V600E-mutant metastatic colorectal cancer after prior systemic treatment in Germany and Austria. The project aims to enroll up to 500 patients from 90 German and Austrian sites with a total study duration of approx. 6 yrs. From Sep 2020 to Feb 2022, 72 patients have been included from 80 open sites. The study follows patients treated according to the SmPCs (Summary of Product Characteristics) and the primary objective is to assess the 1-year OS rate. Additional analyses include efficacy, quality of life, safety and tolerability of encorafenib + cetuximab treatment. The influence of prognostic factors on efficacy, safety and tolerability will also be analyzed.

Clinical trial identification: NCT04673955.

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P-8 Long-term survival in patients with pancreatic cancer (PAC) treated with liposomal irinotecan in combination with 5-fluorouracil and leucovorin (nal-IRI+5-FU/LV)

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Background: PAC is an aggressive disease with 85% of patients being diagnosed at a locally advanced or metastatic (mPAC) stage; the prognosis is poor, as only 10% survive beyond 5 years after diagnosis. Current treatments include the use of gemcitabine (GEM)-based therapies in first line, followed by liposomal irinotecan (nal-IRI+5-FU/LV) after failure. Despite poor survival outcomes, some patients survive $>$1 year from the start of nal-IRI+5-FU/LV. No clear recommendations exist for the optimal treatment sequence with no precise characteristics or molecular markers to help select a chemotherapy regimen or personalized treatment. Nevertheless, a nomogram derived from the pivotal NAPOLI-1 trial identified 8 factors that were significantly associated with overall survival, including baseline Karnofsky score (KPS), albumin (g/dL), neutrophil-to-lymphocyte ratio (N/L), liver metastasis, CA19-9 (U/mL), disease stage at diagnosis, body mass index (kg/m2), treatment arm (nal-IRI+5-FU/LV). While the identification of these factors has greatly helped in determining who will be a long-term survivor, they are not exhaustive and there is a need to further identify predictive markers. This abstract will report some published experiences of long-term survivors following nal-IRI+5-FU/LV treatment.

Methods: A descriptive analysis on the experiences of patients with mPAC who were treated with nal-IRI+5-FU/LV from several countries and who are considered long-term survivors ($>$1 year from start of nal-IRI treatment) was conducted.

Results: NAPOLI-1 survival data are replicated in the clinical practice and several data are already published (Drugs 2020). A retrospective observational database study evaluating patients treated with nal-IRI between Nov-2015 and Jul-2020, was presented during ASCO-GI (Kim 2021). This analysis from $>$280 cancer clinics in the US that examined 1-year survival for 699 patients treated with nal-IRI—based regimens showed that, when compared to NAPOLI-1, these patients were older, had more prior lines of therapy, and worse ECOG PS, but a similar treatment exposure. Despite these characteristics, the 1-year OS among patients who received at least 4 treatment cycles was similar to the intent-to-treat (25%) and per-protocol (34%) treated patients in NAPOLI-1. Among all patients, 1-year OS was 17.2% (14.3-20.7), 31.5% (22.1—41.3) for patients treated in first line, 16.4% (12.2 -21.1) in second line, and 12.2% (7.5 -18.0) in third line. Among those who received at least 4 and 8 cycles, the 1-year OS estimates were 29.1% (24.0-34.3) and 47.9% (39.7-55.7), respectively. Additionally, four published clinical cases of patients with unfavorable profiles at baseline were successfully treated with nal-IRI+5-FU/LV without any specific common factors (except age $<$ 60 years old). Additional experiences coming from other countries will be presented during the congress.

Conclusions: A subset of mPAC patients may derive exceptional benefit from nal-IRI+5-FU/LV. The currently presented evidence from real-world data and specific clinical cases highlight the need to identify and better characterize predictive factors for long-term survival. Future studies elucidating predictive factors of response to nal-IRI+5-FU/LV are needed to enable better patient selection.

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P-9 Gallbladder cancer in the United States: Identifying factors associated with failure to treat

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Background: Adjuvant chemotherapy (AC) should be considered for all patients with surgically resected T1b-T3, high-risk (node-positive) gallbladder cancer (GBC). However, in the United States, few patients receive AC. We sought to identify physician- and patient-specific factors associated with and reasons for low AC use for high-risk T1b-T3 GBC.

Methods: We performed a retrospective review of the National Cancer Database from 2004-2017, identifying patients with T1b-T3 GBC who underwent surgical resection. Exclusion criteria were non-surgical management; death within 60 days of definitive surgery; T1a, T4, or metastatic disease; and receipt of neoadjuvant therapy. To identify a cohort in which all patients should be candidates for AC, our analysis focused on patients with T1b-T3, node-positive disease. Receipt or recommendation of AC within 90 days of definitive surgical procedure was described; for patients for whom AC was not recommended or received, the reason was noted. Trends in AC recommendation rate were evaluated using the Cochrane-Armitage test. Five-year overall survival (OS) by lymph node status and AC receipt were described with Kaplan-Meier and Cox proportional hazards modeling.

Results: 2,765 patients with T1b-T3 GBC met study criteria. Of these, 30% (n=832) had positive lymph nodes and 27% (n=755) had positive resection margins. Most were older than 65 years of age (61%), non-Hispanic White (65%), female (70%), and had a Charlson Comorbidity Index of 0 (70%). Of those with positive lymph nodes, 53% (n=436) were recommended and received AC, 31% (n=254) were not recommended AC because "chemotherapy is not indicated for this condition," 4% (n=32) were not recommended AC due to patient risk factors, and 14% (n=110) did not receive recommended AC due to patient death, patient refusal, or unknown reason. Rate of AC recommendation for patients with node-positive disease significantly increased throughout the study period, from 58% in 2004 to 71% in 2017 (p£0.05). Odds of AC recommendation for node-positive patients were increased in the more recent time frame (2012-2017 vs 2004-2011; OR 1.79, CI 1.33-2.41) and for younger patients (ages 18-64 vs 55-64; OR 1.83, CI 1.3-2.58), but decreased with age >65 (vs 55-64; OR 0.46, CI 0.32-0.68). While the 5-year OS of node-positive patients who did not receive CT was 17% throughout the study period, the 5-year OS of node-positive patients who received CT was prolonged in the more recent time period: from 20% in 2004-2011 to 28% in 2012-2017 (p=0.06).

Conclusions: For patients with node-positive T1b-T3 GBC, AC recommendation rate increased over time, and was associated with prolonged OS. However, low AC use was most frequently related to the physician perception that "chemotherapy is not indicated." In contrast, poor performance status and patient refusal were only rarely responsible for low AC use. Our data suggest that physician-dependent factors are the predominant driver of failure to treat patients with high-risk GBC - namely, that physicians believe AC is not indicated for these patients. Improving physician education is likely key to improving AC rates and survival outcomes for patients with node-positive T1b-T3 GBC.

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P-10 Standardization of a neoadjuvant therapy (NAT) pathway for pancreatic cancer across a geographically large and diverse healthcare system improves patient care and successful completion of NAT

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Background: Optimal management of patients with potentially resectable pancreatic ductal adenocarcinoma (PDAC) is controversial and variation exists within/across academic and healthcare systems. Herein we describe the initial results of a neoadjuvant therapy (NAT) pathway across one of New York's largest, most diverse health care systems.

Methods: The NAT pathway was established at Northwell Health in June 2019, consisting of an initial, single-day pancreas multi-disciplinary clinic (PMDC) visit, followed by NAT, interval scans and PMDC re-reviews at two and four months, prior to consideration of radiation and of surgical resection. We conducted an IRB-approved retrospective analysis of patients enrolled to this pathway. Primary endpoints included completion of NAT pathway and overall survival (OS). Kaplan-Meier analysis was used to estimate OS.

Results: The cohort consisted of 55 patients: 44% men, mean age 69.7 years, and 48% non-White. Surgical stage at diagnosis was locally advanced (LAPC; 49%), borderline resectable (BRPC; 35%) and resectable (RPC; 16%). NAT consisted of gemcitabine/nab-paclitaxel (GnP, 41%; 147 total cycles), FOLFIRINOX (36%; 167 total cycles), and a combination of both regimens (23%). Eighteen (33%) received radiotherapy (94%, SBRT) and 72% received >=50 Gy. Average duration of NAT pathway (from biopsy to surgery) was 5.9 mo (IQR 4.7-7.6 mo): average time from biopsy to C1 of NAT was 25 days (IQR 18-39 days), from C1 to post NAT completion imaging was 3.9 mo (IQR 3.5-4.8 mo) and from RT to surgery was 36.0 days (IQR 30.5-43.8 days). Of 55 patients who began the pathway, 24 (44%; 6% RPC, 53% BRPC, 41% LAPC) completed the pathway and underwent surgical exploration; 22 did not complete the pathway and 9 are currently undergoing NAT. Reasons for not completing NAT included metastasis (24%), transfer of care (12%), local progression (5.5%), and death (3.6%). Out of 24 patients who were surgically explored, 71% underwent successful resection (53% R0, 18% R1 < 1mm and 30% R1) compared to prior institutional resection rate in NAT patients of 17% (p=0.015). There were 11 deaths (20%) and median OS was reached at 17.7 mo (95% CI 7.9, 27.6): 16.3 mo 95% CI 7.2, 25.4) and 26.1 mo (95% CI 3.2, 49) for GnP and FOLFIRINOX, respectively. Patients enrolled in the NAT pathway had a higher rate of germline mutation testing (52% vs 30%, p=0.002). The percentage of patients that remained within the Northwell Health system for their post-NAT was higher among patients in the pathway, compared to prior (87% versus 44%).

Conclusions: Implementation of a standardized NAT approach at a large diverse healthcare system increased the percentage of PDAC patients who underwent surgical resection and improved patient retention rate. Our data lay the groundwork for further studies that will provide long term outcomes of NAT in these patients.

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P-11 Venous thromboembolism in colorectal cancer patients with BRAF mutation

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Background: Venous thromboembolism (VTE) is a frequent complication in colorectal cancer (CRC) patients. In these patients, some molecular biomarkers, such as KRAS mutation, have been associated with an increased risk of thrombosis. However, little is known about the characteristics of VTE associated with less prevalent molecular biomarkers. The aim of this analysis is to describe the characteristics of VTE of a cohort of ambulatory CRC patients harboring BRAF mutation.

Methods: We performed a retrospective review of consecutive patients with BRAF-mutated CRC attended in the Medical Oncology Department of 10 hospitals from the network of the Cancer & Thrombosis Section of the Spanish Society of Medical Oncology (SEOM). Between January 2014 and June 2018, 165 patients were identified and included in the analysis.

Results: Mean age was 63.47 years (standard deviation [SD] 11.50 years) and 46.7% (n=77) were men. With a median follow-up of 15 months (interquartile range [IQR] 9-25), forty patients (24.2%) developed a VTE (32.4% pulmonary embolism, 24.3% lower-extremity deep-vein thrombosis [DVT], 2.7% upper-extremity DVT, 16.2% visceral thrombosis, 18.9% catheter related-thrombosis, 5.4% others). Most patients had metastatic disease (90.0%) and was receiving systemic therapy (73.7%). Median time from CRC diagnosis to VTE was 5.06 months (IQR 2.85-10.81). 50.0% of events were diagnosed incidentally and 75.0% in the ambulatory setting. Most patients (87.5%) received anticoagulant treatment (low-molecular-weight heparins [LMWH] 33 patients, direct oral anticoagulants [DOACs] 1 patient, others 1 patient), 35.9% for more than 6 months. 6 patients (15.4%) experienced VTE recurrence and 7 patients