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Correlation of mesothelin expression with recurrence in colorectal cancer (CRC) patients

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Background: Mesothelin (MSLN) is a membrane bound protein that can promote survival, proliferation and invasion of cancer cells. Our previous work had shown a significant association between MSLN expression on resected localized CRC (Stage I-III) and future development of peritoneal carcinomatosis (PC) (p < 0.001). MSLN expression in early stage CRC was also associated with an inferior overall survival. We expanded this work by examining an additional cohort of patients at West Virginia University (WVU), WV, USA.

Methods: This is a retrospective study of patients with localized CRC who underwent surgical resection from 2005-2019 at WVU. The patients were categorized into two groups based on whether they had a recurrence. Metastatic group comprised of patients who recurred and control group constituted patients who did not have a recurrence after a minimum of 5 years of surveillance. Metastatic group is further subdivided into 2 subgroups; SOM: patients who developed metastases in solid organs only; PC group: patients who developed PC at any time. MSLN staining with immunohistochemistry was performed using Rockland (MN1) mouse monoclonal antibody and scored based on intensity (0, 1+, 2+, and 3+) and percent positivity (0: 50%). MSLN total score was defined as the sum of intensity and percent positivity, with a total score of 3 or greater considered "positive" for MSLN expression. Fisher's exact test was performed to determine the association of MSLN score and future recurrence of CRC.

Results: Out of a total of 484 patients diagnosed with localized CRC, 88 patients had a recurrence. Out of 88 patients, SOM and PC groups comprised 48 (54%) and 19 (22%) patients respectively while 21 patients (24%) had local recurrence. Control group comprised 126 patients. MSLN staining was completed on 70 patients in the entire cohort and the results are presented here. Among 70 patients, 14 patients had a recurrence in either solid organs (n-9) or peritoneum (n-5) and 56 patients did not recur. Positive MSLN score was demonstrated on resected CRC tissues in 8 out of 14 patients who had a recurrence; Five of them from the SOM group (5 out of 9 patients (55.6%)) and 3 from the PC group (3 out of 5 patients (60%)). Contrastingly, only 16 out of 56 patients (28.5%) in the control group had a positive MSLN score. Based on Fisher's exact test, a near significant association was observed between positive MSLN score and future development of cancer recurrence (p: 0.06). No statistical significance was observed between positive MSLN score and location of metastases (SOM vs PM) likely due to limited sample size.

Conclusions: A higher proportion of patients who had a recurrence (SOM+PC groups) had a positive MSLN score on their resected CRC specimens compared to the patients who did not recur (control group) (p: 0.06). MSLN staining results on the remaining patients is ongoing. Precision medicine informatics to identify patients at highest risk of development of future recurrence is key to personalize treatment for patients with colorectal cancer.

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Impact of regorafenib dose optimization on clinical outcomes compared to best supportive care and TAS-102 in the treatment of relapsed/refractory metastatic colorectal cancer

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Background: In a randomized controlled trial (RCT) ReDOS of relapsed/refractory metastatic colorectal cancer (mCRC) patients, regorafenib dose optimization (rego 80+), starting at 80 mg/day with 40 mg weekly increments to the standard dose of 160 mg/day, was found to improve tolerability and clinical outcomes compared to regorafenib at standard dose (rego 160), 160 mg/day for 21 days of a 28-day cycle. This network meta-analysis (NMA) aims to further investigate the impact of rego 80+ on efficacy and safety compared to best supportive care (BSC) and trifluridine/tipiracil (TAS-102).

Methods: RCTs included in the NMA were identified via a systematic literature review conducted in April 2021. A feasibility assessment was performed to ensure that the included trials did not differ significantly with respect to treatment effect modifiers.

Bayesian fixed effect NMAs were performed to simultaneously synthesize hazard ratios (HRs) for overall survival (OS) and progression-free survival (PSF) and odds ratios for safety endpoints of interest, and their respective 95% credible intervals (Crl). The HRs from the NMA were applied to the rego 80+ OS and PFS Kaplan Meier Curves from the ReDOS trial to estimate predicted median OS and PFS for each treatment.

Results: Three global or US-only RCTs (ReDOS, CORRECT, RECOURSE) and three Asianonly RCTs (TERRA, Yoshino 2012, and CONCUR) were included in the NMA. When all trials were analyzed, rego 80+ was associated with statistically significant improvements in OS and PFS vs. BSC (HR [95% Crl]: 0.49 [0.33, 0.73] and 0.35 [0.24, 0.53], respectively) and numerically favorable improvements in OS and PFS vs. rego 160 (0.72 [0.49, 1.05] and 0.84 [0.56,1.25]), and TAS-102 (0.71 [0.47, 1.08] and 0.78 [0.52, 1.18]). Median OS (95% confidence interval [CI]) was estimated to be 9.8 (7.5, 11.9) months for rego 80+, 7.5 (4.6, 11.9) months for rego 160, 7.5 (4.4, 11.9) months for TAS-102, and 6.4 (2.5, 10.3) months for BSC. Median PFS (95% CI) was 2.80 (2.0, 2.5) months for rego 80+, 2.07 (1.89, 5.85) months for rego 160, 1.98 (1.8, 5.76) months for TAS-102, and 1.89 (1.17, 2.16) months for BSC. For grade 3+ adverse events (AEs), BSC was the most favorable, with the exception of increased aspartate transaminase (AST). Compared to rego 160, rego 80+ was numerically favorable in all AEs analyzed including hand-foot skin reactions (HSFR), diarrhea, fatigue, hypertension, and increased AST. Compared to TAS-102, rego 80+ had higher incidence of HSFR, comparable fatigue and hypertension, and numerically lower incidence of diarrhea, increased AST, neutropenia, febrile neutropenia, leukopenia, and anemia, All NMA findings were consistent when Asian-only trials were excluded from the analyses.

Conclusions: Findings from this NMA indicate that rego 80+ provides additional survival benefits (over standard dose rego 160) when compared to BSC and TAS-102; with gains of median OS of 3.4 months (~50% risk reduction), and 2.3 months (~30% risk reduction), respectively. Results also suggest that rego 80+ delays disease progression in comparison. With its more favorable safety profile, rego 80+ should be considered a preferred option for optimizing clinical outcomes in patients with relapsed/refractory mCRC.

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Microsatellite instability and HER2 status in radically resectable locally advanced esophago-gastric adenocarcinoma: A single-center experience

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Background: Peri-operative systemic chemotherapy significantly improved the prognosis of patients with resectable locally advanced gastric cancer (LAGC) but, despite that, relapse-related death remains a major challenge. Neoadjuvant chemotherapy (NAC) plays a crucial role and is currently recommend by international guidelines. Several biomarkers, including human epidermal growth factor receptor-2 (HER2) and mismatch repair (MMR) or microsatellite instability (MSI) are crucial for treatment decision in metastatic setting. However, currently, no biomarkers can guide the choice of NAC in clinical practice. In addition, most of available data derived from surgical specimens, harboring potential confusing factors after NAC. Our aim was to evaluate correlations between MSI and HER2 status and clinical outcomes in resectable LAGC treated with perioperative chemotherapy.

Methods: We conducted a retrospective cohort study of resectable LAGC patients treated with NAC and surgery +/- adjuvant chemotherapy from 2006 to 2018, for whom endoscopic pre-NAC and surgical post-NAC samples were available. A uniform small cohort of patients receiving adjuvant chemotherapy only was added for general prognostic analyses. Clinical parameters were collected including patient and tumor characteristics. Determinations of HER2 and MMR status were carried out on endoscopic pre-NAC and surgical samples. Pathologic complete response (pCR) rate, Overall survival (OS) and event-free survival (EFS) were estimated and evaluated for association with histologic downstaging and MSI status using Cox proportional hazard

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models. Moreover, in dMMR cases, a custom in-house Next-Generation Sequencing (NGS) (Ion Torrent S5) panel was performed, assessing mutational status of 26 tumorgenes (EGFR, MET, ALK, RET, KRAS, NRAS, HRAS, BRAF, KIT, PDGFR α/β , GNAQ, GNA11, PIK3CA, AKT1, MAP2K1, MAP2K2, TP53, ERBB2, SMAD4, PTEN, STK11, CTNNB1, NOTCH1, POLE, ESR1).

Results: We selected 76 out 90 patients, with a median age at diagnosis of 61 years. Fifty-nine patients received NAC, while 17 were treated with adjuvant chemotherapy alone. Overall, dMMR/MSI-H counted for 8% of cases, entirely consistent between endoscopic and surgical samples. Six percent of tumors were HER2 positive on endoscopic tumor assessment and 4% on surgical samples. Tumor downstaging was observed in 52.5% of the population, with 3 pCR (5.1%), none of them in MSI-H cancers. According to MSI status and pCR, EFS and OS were better for MSI-H patients and MSS achieving pCR compared to MSS without pCR [EFS NR vs NR vs 30.0 months (95% CI 16.8 — NR.), P=.08; OS NR vs NR vs 39.6 (95% CI 27.6 — NR) P=.10]. Considering the entire population, EFS and OS were analyzed according to MSI status with a better outcome for MSI-H patients [EFS NR vs 48.0 months (95% CI 25.2 — 229.4), P=.121; OS NR vs 62.4 (95% CI 28.8 — 229.4) P<.143]. The most common alteration in MSI-H cases was TP53 mutation (4/6), other mutations detected were KRAS, SMAD4, ERBB2, BRAF, PIK3CA, RET and PTEN.

Conclusions: Our work confirms the positive prognostic effect of MSI-H in the curative setting of LAGC, not correlated with the rate of pathologic tumor response to NAC. Prospective ad-hoc trial focused on dMMR/MSI-H and more accurate molecular profiling are strongly needed in resectable LAGC.

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Inhibition of phosphoprotein phosphatase 2A (PP2A) sensitizes pancreatic cancer to PARP inhibitors by modulation of homologous recombination repair

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Background: Pancreatic cancer remains one of the most difficult to treat cancers with a 5-years survival of less than 6%, representing one of the most lethal types of cancer, recent research has shown that PP2A inhibitors (LB-100) sensitize pancreatic cancer to chemotherapy and radiation. In addition, the finding from clinical trial study demonstrated that the effectiveness of single-agent Talazoparib for treatment of patients with and without germline BRCA1/2 mutation in ovarian, breast, small cell lung and Pancreatic cancers. The aim of this work was to I. investigate activity of LB-100 against pancreatic cancer cells as monotherapy and in combination with PARP inhibitions (Talazoparib). II. Investigate the mechanism by which LB-100 and Talazoparib effect pancreatic cancer cells by studying effect of drugs on cell cycle and modulation of cell cycle regulatory proteins and assess the role of treatment combination in control DSB and HR repair through modulation of ATM phosphorylation.

Methods: Human pancreatic cancer cell lines Panc-1, MIA-Pa-Ca-2 and BxPC-3 were obtained from European Collection of Authenticated Cell Culture (ECACC) and grown in either Dulbecco's modified Eagle medium (DMEM) (MiaPaCa-2 and Panc-1) or RPM medium (BxPC-3) with 10% FBS. Cell cultures were maintained in an atmosphere of 5% CO2/95% air at 37 C. PP2A activity was measured by PP2A Immunoprecipitation phosphatase assay Kit (Millipore), cell cytotoxicity were measured by MTT assay, cell cycle determined by flow cytometry. Western blot techniques were used to assess levels of proteins associated with regulation of cell cycle (Cdc2, p-Cdc2, and Cdc25c), apoptosis (caspase3) and DNA damage (γ-H2AX). Data are expressed as the mean \pm (SEM) and analysed by an analysis of variance (ANOVA).

Results: The results show that LB-100 decreased PP2A activity in all pancreatic cancer cells in dose dependent manner. LB-100 significantly decreased cell viability of Panc-1, MIA-Pa-Ca-2 and BxPC-3 with ICS0 (3.94 μM), 6.86 μM , and 10.87 μM) respectively. Interestingly adding 25 nm of Talazoparib further decreased ICS0 in all cells (1.88 μM), 5.24 μM and 5.83 μM). Treatment combination attenuated pancreatic cancer cells growth through caspase activation and G2/M cell-cycle arrest. Combination therapy impaired cellular repair and induced DNA double-strand breaks by inducing U-H2AX.

Conclusions: Our results suggest that treatment combination of LB100 and talazoparib in vitro inhibit cancer cells growth by modulation of the DNA damage response pathway and cell cycle checkpoint abrogation. The combination of PP2A inhibitor with PARP inhibitor has a synergistic effect in vitro. Further in vivo studies are needed to explore this combination as an effective option in the treatment of pancreatic cancer.

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Phase 2a study of NT-I7, a long-acting interleukin-7, plus pembrolizumab: Cohort of subjects with checkpoint inhibitor-naïve advanced pancreatic cancer

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Background: Pancreatic cancer (PaC) is immune-quiescent and resistant to single-agent checkpoint inhibitor (CPI). NT-I7 (efineptakin alfa) is a long-acting IL-7 that can increase T-cell infiltration in the tumor microenvironment (TME) and may enhance tumor responsiveness to CPI therapy. We hypothesize that the combination of NT-I7 and pembrolizumab may result in enhanced efficacy in CPI-naïve advanced PaC.

Methods: This is an open-label, phase 2a study in subjects with relapsed/refractory (R/R) tumors, including CPl-naïve R/R PaC. The study follows Simon's 2-stage minimax design to enroll 17 in the first stage, and 8 additional subjects in the second stage. Subjects received NT-I7 intramuscularly at 1200 µg/kg every 6 weeks (Q6W) plus pembrolizumab 200 mg intravenously Q3W. Antitumor activity based on Overall Response Rate (Q6R) was assessed by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and iRECIST. Biomarker analyses of peripheral blood and tumor biopsies were performed.

Results: As of 14-March-2022, 32 subjects were enrolled in the CPI naïve R/R PaC cohort. Median age was 66 years [31-81], with ECOG PS 0 (31%), 1 (69%). Twenty-eight (90.3%) subjects had \geq 2 prior therapies. All subjects had metastatic or locally advanced disease at enrollment. The median duration of follow-up was 3.7 months. Among 26 evaluable subjects, the ORR and disease control rate (DCR) were 4% (1/26) and 31% (8/26) by RECIST 1.1; 8% (2/26) and 35% (9/26) per iRECIST. In addition to 2 subjects with iPR, 9 subjects are still ongoing to follow up responders. It was observed that among subjects with \leq 1 liver mets vs \geq 2 liver mets, the ORR by iRECIST was 8.2% (2/11) vs 0; DCR was 63.7% (7/11) vs 13.3% (2/15) and PFS was 19.1 weeks vs 6.0 weeks. The ORR and DCR by iRECIST were 25% (1/4) and 75% (3/4) in 11; 13% (1/8) and 38% (3/8) in 2L. All subjects with responses continue treatment. NT-I7 treatment-related adverse events (trAEs) occurred in 23 (71.9%) subjects, 18 (56.2%) G1-2, 3 (9.4%) G3; 2 (6.3%) G4; no G5 trAEs were reported. No subjects discontinued from treatment due to trAE. A cPR subject with available biopsy had enhanced T-cell infiltration in the TME at week 5.

Conclusions: The chemotherapy-free combination of NT-I7 + pembro was well tolerated in heavily pretreated subjects with CPI-naïve R/R PaC. The encouraging antitumor activity showed that subjects with with ≤ 1 liver mets achieved clinical benefit from the combination of NT-I7 and pembro therapy. Biomarker analyses demonstrated improved peripheral and intratumoral T cell responses. These results support continued evaluation of NT-I7 + pembrolizumab in subjects with CPI-naïve R/R PaC

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