P-61 Impacts of salvage chemotherapy after nivolumab therapy (NIVO): A REVIVE substudy

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Background: The primary endpoints met in the REVIVE study have been previously reported, demonstrating the chemotherapeutic efficacy after the progression on NIVO therapy in patients with advanced gastric cancer (AGC). Therefore, the current study evaluated the survival from the NIVO therapy initiation in all registered participants of the REVIVE trial.

Methods: The REVIVE trial was a prospective, multicenter, observational study evaluating the efficacy and safety of chemotherapy for NIVO-refractory or NIVO-intolerant patients with AGC (UMIN000032182). We primarily register the patients who underwent NIVO therapy as primary registration, and the patients formally were registered as formal registration. The previously reported main study analyzed data of formally registered patients who underwent chemotherapy with irinotecan, trifluridine/tipiracil hydrochloride, or oxaliplatin combination regimens. In this study, patients who discontinued NIVO therapy for any reason at data cutoff among primarily registered patients were selected. The survival of patients who received the best supportive care (cohort A) was compared to those included in the main study (cohort B).

Results: Of 395 primarily registered patients, 108 patients in cohort A and 199 patients in cohort B were included, respectively. Those receiving other chemotherapeutic regimens (N = 47) or continuing NIVO therapy (N = 38) were excluded. Median overall survival (OS) and time to treatment failure (TTF) were 9.3 (95% confidence interval [CI], 8.3—10.2) and 1.8 (95%CI, 1.6—2.2) months at 234 and 307 events, respectively, from the initiation of NIVO therapy in the whole population. The objective response rate (ORR) and disease control rate (DCR) were 9.1% and 43.0%, respectively. Patients in cohort B had significantly better prognosis in OS (median, 12.2 vs. 4.8 months; hazards ratio [HR], 0.43 [95%CI 0.34—0.57]; $p < 0.01$). However, the difference in short-term efficacies was not observed: ORR, 6.5% vs. 10.6%; DCR, 38.0% vs. 45.7%; and median TTF, 1.9 vs. 1.8 months (HR, 1.06 [95%CI 0.84—1.35]; $p = 0.62$) (cohort A vs. B). The post-progression survival (PPS) from the date of NIVO therapy discontinuation was significantly better in cohort B than in cohort A (median PPS, 8.1 vs. 1.9 months; HR, 0.22 [95%CI 0.17—0.30]; $p < 0.01$). The proportion of patients who received the best supportive care after NIVO therapy was similar, regardless of the effectiveness of NIVO therapy (transition rate: 25% in complete response or partial response [responders, N = 28] and 33% in stable or progressive disease [non-responders, N = 267]). The difference of OS from the initiation of NIVO therapy in responders was not observed between cohorts A and B; however, the OS of cohort B in non-responders was significantly longer than that of cohort A (median OS, 10.8 vs. 4.8 months; HR, 0.60 [95%CI 0.52—0.69]; $p < 0.01$).

Conclusions: Salvage chemotherapy as much as possible after NIVO therapy could improve the AGC prognosis.

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P-62 Characterization and management of cholangiocarcinoma in a tertiary hospital with a high volume of patients

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Background: The objective of this study is to evaluate the epidemiological characteristics, potential risk factors and local/systemic treatments in a tertiary care hospital with a high volume of patients.

Methods: Unicentric retrospective study; The patients were seen in consultation from January 2020 to January 2022, this being the end date of follow-up. Demographic variables related to tumor, treatment, and death were also collected. For descriptive statistics, percentages with frecuencies and medians were used. Survival was estimated using Kaplan-Meier plots. The SPSS 20.0 program was used for stadistical analysis.

Results: Data from a total of 44 patients were collected. 70.7% men and 29.3% women. All Caucasian. The highest incidence peak was in the decade between 50 and 60 years (59%), with the rest of the cases in the decade between 40 and 50 years. There was no significant history of prior smoking, alcohol consumption, prior pancreatitis, history of cholangistitis, or heavy metal exposure. However, in our series two personal antecedents stand out: 1) 48% of the patients were type 2 diabetics and 23% type 1 diabetics and 2) 61.3% of the patients prior to diagnosis had periodontal disease. 90.2% of the histology was adenocarcinoma, 53.7% of the tumors being resectable, the rest presenting advanced disease. In the case of local surgery, partial hepatectomy with lymphadenectomy was the most used (68%), capecitabine the adjuvant treatment of choice in operated patients (82.3%) and the treatment scheme for advanced disease Cisplatin in combination with Gemcitabine (82.9%), obtaining partial response in 54.5%, stabilization in 18.2% and disease progression in 27.3% in the first tumor evaluation performed. NGS was performed on 100% of the patients, finding potentially actionable mutations: KRAS G12C mutation in 2 patients, IDH mutation in 1 patient, and microsatellite instability in 2 patients. Regarding germline mutations, these were performed in 12 patients due to family history, finding mutations related to the ATM gene (2), BRCA2 (1) and p53 (1) in 4 of them.

Conclusions: The oncological results observed in our series are comparable to those described in the literature. Its etiology is uncertain, advancing the age of diagnosis and requiring the study of more predictive and prognostic factors. Our study reaffirms the role of NGS in this disease, with the intention of increasing future treatment options in this pathology.

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P-63 Efficacy, safety and prognostic subgroups for outcome with regorafenib in patients with refractory metastatic colorectal cancer in the real-world setting: The CORE study

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Background: CORRECT trial has shown a survival benefit for regorafenib over placebo in patients with metastatic colorectal cancer (mCRC) that progressed after standard therapies. We evaluated survival, safety and prognostic subgroups in patients treated with regorafenib in a real-life setting.

Methods: Retrospective, multicenter, observational study of patients (pts) with mCRC treated with Regorafenib (REG) after failure to standard therapies as part of routine clinical practice at 7 hospitals from the Galician Research Group on Digestive Tumors (GITuD).

Results: We recorded 130 pts treated with REG between September 2013 to December 2019. Median age was 63 years (range 27-79), 94.6% ECOG PS0-1, 55.4% RASmt and 1.5% BRAFmt, 18% time since initial diagnosis 3 metastatic locations and 75% liver metastases. Prior therapy included a median of 3 lines of treatment (range