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First-line (1L) treatment patterns in advanced gastric, gastroesophageal junction, and esophageal adenocarcinoma (GC/GEJC/EAC): Data from the Spanish AGAMENON-SEOM registry

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Background: Data on treatment patterns and outcomes in patients with advanced gastroesophageal adenocarcinoma in daily clinical practice are scarce. Using real-world data from the Spanish AGAMENON-SEOM registry, this retrospective study assessed patient characteristics, treatment patterns, and outcomes for 1L advanced GC/GEIC/FAC

Methods: Adult patients diagnosed with locally advanced unresectable or metastatic GC/GEIC/EAC between 2008 and 2021 were identified from 34 centers. This analysis only included patients who received ≥1 cycle of 1L polychemotherapy. Primary endpoints included description of demographic and clinical characteristics at initial diagnosis (equivalent to 1L therapy initiation), 1L treatment patterns, progression-free survival (PFS) and overall survival (OS) from 1L therapy initiation. Secondary endpoints included subgroup analyses in patients with human epidermal growth factor receptor 2 (HER2)-negative status and in patients who met the eligibility criteria of the CheckMate 649 study (Janjigian YY et al, Lancet 2021;398:27-40) and were treated with FOLFOX or XELOX (hereafter, CheckMate 649-matched subgroup). The proportion of patients who received second-line (2L) or third-line (3L) therapy and the reasons for not receiving subsequent therapy were explored.

Results: Overall, patients initiating 1L treatment (n=3.110) had a median (range) age of 65 (20-89) years, were mostly male (71.0%), had an ECOG performance status (PS) of 1 (61.7%) or 0 (23.7%), and had normal (>35 g/dL) basal albumin levels (64.8%). The most prevalent comorbidities were diabetes (15.3%) and chronic cardiopathy (11.6%). The most common primary tumor location was the stomach (77.7%) versus GEJ (13.4%) or esophagus (8.7%). 5.6% of patients had unresectable locally advanced disease and 94.4% of patients had metastatic disease, primarily synchronous (77.6%); the number of metastastic sites was unknown in 13 (synchronous) and 4 (metachronous) patients. The most frequent metastatic locations were lymph nodes (46.4%) or peritoneum (43.7%). In the HER2-evaluable population (n=2,650), 73.3%of patients had HER2-negative tumors. Clinical characteristics of patients in the HER2negative (n=2,385; includes 460 patients with unknown HER2 status) and CheckMate 649-matched (n=383) subgroups were generally similar to those of the overall population. The most common 1L treatments for HER2-negative tumors were FOL-FOX6 (20%) and XELOX (19%). In the overall population, 1,588 patients received 2L therapy and 218 patients received 3L therapy. The primary reason for patients not receiving 2L or 3L therapy was poor ECOG PS (68.0% and 79.8%, respectively). At a median follow-up of 57.0 months in the overall population (n=3,037), the median (95% confidence interval [CI]) PFS and OS were 6.0 (5.8-6.2) and 10.8 (10.4-11.2) months, respectively. Median OS was 10.1 (95% CI 9.7-10.5) months in the HER2negative subgroup (n=2,346). At a median follow-up of 32 months in the CheckMate 649-matched subgroup, median (95% CI) PFS and OS were 6.4 (5.7-7.2) and 11.7 (10.6-12.8) months, respectively.

Conclusions: In this real-world observational study of the Spanish AGAMENON-SEOM registry, PFS and OS outcomes for 1L treatment of advanced GC/GEIC/EAC were comparable to those of historical studies. With an estimated median OS of < 1 year from 1L therapy initiation, better treatment options for patients with advanced GC/GEIC/EAC remain an unmet need and deserve further investigation.

Clinical trial identification: NCT04958720.

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Different regimens of the 1st line chemotherapy in patients (pts) with metastatic anal cancer: Results of the multicenter observational study

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Background: Combination of paclitaxel with carboplatin and cisplatin with fluoropyrimidines are the standards of the 1st and 2nd lines of treatment in pts with metastatic anal cancer. Regimen mDCF (docetaxel 40 mg/m2 d1, cisplatin 40 mg/m2 d1, 5-FU 2400 mg/m2 46-h d1-3, two-weekly) showed promising activity in the 1st line in the nonrandomized study. We performed an analysis of a prospective multicentric database of metastatic anal cancer pts to evaluate the efficacy of different regimens as 1st line systemic treatment in a real-life clinical practice setting.

Methods: We analyzed a database of pts with metastatic anal cancer in 3 cancer centers in Russia. The primary endpoints were progression free survival (PFS) and overall response rate (ORR). Analysis was performed with the SPSS v.20 software package.

Results: The study included 68 pts with metastatic anal cancer. Sixty three (93%) pts received systemic treatment; female - 87%, average age - 68 years (20-83), ECOG 0-1/2/3/NA - in 22%/33%/31%/13%; synchronous metastases - in 30%; local relapse or primary tumor - in 60%; radiotherapy or chemoradiotherapy of primary tumor were previously? administered in 70%; lung metastases in 18%, liver - 38%, retroperitoneal lymph nodes metastases - 27%; peritoneal metastases - in 3% pts; average number of metastatic zones - 2 (1-5); metastasectomy was performed in 32% pts. The first line was weekly paclitaxel and carboplatin (CP) in 29 (46%), mDCF - in 10 (16%), platinum compounds with fluoropyrimidines (CF) - in 18 (29%), others regimen - in 6 (9%). Median PFS was 6 months in CP group, 3 months - in CF group, 10 months - in mDCF group, and 3 months - in other regimens group (HR 1,02, 95% CI 0,76-1,37, p=0,8); ORR was 9%, 10%, 50%, 0%, respectively (p=0,01).

Conclusions: In the 1st line mDCF regimen shows the best ORR and numerically the longest median PFS, which warranted conducting of prospective randomized study to compare mDCF and paclitaxel with carboplatin.

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Prognostic impact of single organ pulmonary metastasis in metastatic colorectal cancer patients treated with FOLFIRI and vascular endothelial growth factor inhibitors as second-line chemotherapy

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Background: The impact of single-organ metastases to lung on progression free survival (PFS) and overall survival (OS) in patients with metastatic colorectal cancer (mCRC) has not been studied. Recognizing the differences in prognosis and chemotherapeutic efficacy by metastatic organs can help optimize treatment strategy.

Methods: Consecutive mCRC patients who were treated with second-line FOLFIRI and vascular endothelial growth factor (VEGF) inhibitorswere retrospectively enrolled. Overall response rate (ORR), PFS, OS were assessed according the presence of single organ pulmonary metastasis.

Results: A total of 289 patients were treated with FOLFIRI +VEGF inhibitors.26 patients (9.0%) have a single organ pulmonary metastasis. Characteristic of patients with single organ pulmonary metastasis were tended to be high frequency of left sided primary site (P = 0.076) and significantly low level of tumor markers at initiation of chemotherapy (CEA: P = 0.0044, CA19-9: P = 0.00008). Patients with single organ pulmonary metastasis had significantly longer PFS and OS than those without (Median PFS: 29.6 months vs 6.1 months P = 0.00025, Median OS: 35.3 months vs 18.7 months P = 0.0001). In multivariate analysis, single organ pulmonary metastasis was independent predictor of longer PFS and OS (PFS: HR 0.36, P = 0.0009, OS: HR 0.28, P = 0.0004).

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