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**1228P Stage migration, changed treatment profile and survival impact in newly diagnosed oesophago-gastric cancer in Scotland during the COVID-19 pandemic: A national study**

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**Background:** COVID-19 has significantly disrupted cancer care. This may have impacted on staging, management and survival as health services worldwide had to adapt. Responding to the pandemic, the United Kingdom (UK) government declared a national lockdown on 23<sup>rd</sup> March 2020. This national study investigated the effect of the national response on oesophago-gastric (OG) cancers in Scotland, including time from referral to gastroscopy, staging at presentation, multidisciplinary team (MDT) treatment outcomes and overall survival.

**Methods:** This was a retrospective cohort study. Consecutive new patients presenting in NHS Scotland to five regional OG cancer MDTs covering 93.2% of the Scottish population between October 2019 and September 2020 were identified. Electronic health records were reviewed. The study period was divided into pre- and post-lockdown, based on the first UK national lockdown.

**Results:** 931 patients with biopsy-proven OG cancer were identified; 499 (53.6%) pre and 432 (46.4%) post-lockdown. Median age was 71 years (range 25-95) and 66% were male. There were 252 (27.1%) gastric and 679 (72.9%) oesophageal cancers. No clinically meaningful difference in median time to gastroscopy was observed post-lockdown (19 days vs 15 days,  $p < 0.001$ ), however, patients were more likely to present as an emergency (11.1% vs 8.2%,  $p = 0.014$ ). Post-lockdown, patients tended to poorer ECOG PS ( $p = 0.09$ ), were more symptomatic ( $p = 0.007$ ), and presented with higher stage disease (stage 4; 57.6% vs 49.3%). There was a significant shift to palliative intent treatment post-lockdown (76.2% vs 64.7%,  $p < 0.001$ ). Median overall survival post-lockdown was 7.6 months vs 10.1 months pre-lockdown (HR 1.24; 95% CI 1.06-1.43,  $p = 0.005$ ).

**Conclusions:** This national study highlights the impact of COVID-19 on OG cancer diagnosis and outcome in Scotland. Patients presented at a later stage and a shift towards palliative intent treatment was observed, with subsequent negative impact on overall survival. The reason for the observed stage migration of OG cancers is likely multifactorial, occurring prior to the diagnostic pathway and not simply due to a delay in performing gastroscopy.

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**1229P A multicenter phase II study of sotigalimab (CD40 agonist) in combination with neoadjuvant chemoradiation for resectable esophageal and gastroesophageal junction (GEJ) cancers**

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**Background:** Neoadjuvant chemoradiation (CRT) followed by surgical resection is a standard approach for patients (pts) with locally advanced esophageal/GEJ cancers. A pathologic complete response (pCR) is achieved in 22-23% of adenocarcinomas (AC)

and 42-49% of squamous cell carcinomas (SCC) and is associated with improved survival outcomes. Sotigalimab (sotiga) is a high affinity, potent CD40 agonist mAb capable of inducing and expanding anti-tumor immune responses by activating dendritic cells (DCs), T cells, NK cells, B cells, and M1 macrophages. This study examined the safety and efficacy of combining sotiga with neoadjuvant CRT in pts with esophageal/GEJ cancers.

**Methods:** Pts with resectable (T1-3, Nx) AC or SCC of the esophagus/GEJ were eligible. T1N0 and cervical tumors were excluded. Study treatment: carboplatin (AUC 2)/paclitaxel (PTX) (50 mg/m<sup>2</sup>) weekly x 5 with radiation 5040 cGy plus up to 4 doses of sotiga 0.3mg/kg IV prior to Ivor-Lewis esophagectomy. Primary efficacy endpoint was pCR.

**Results:** 34 pts were enrolled (safety pop). Histology: 76% AC, 24% SCC; clinical stage: II/III/IVA, 9%/68%/23%; location: GEJ 47%. AEs (> 20%) attributed to sotiga: nausea, chills, fatigue, cytokine release syndrome (CRS), pyrexia, vomiting, abnormal LFTs, thrombocytopenia, diarrhea, and pruritus; majority Grade 1-2. Grade  $\geq 3$  CRS was observed in 3 pts (9%). No pt withdrawals due to sotiga; no treatment-related deaths. 28 pts were evaluable for the primary endpoint (3 opted against surgery, 1 pt withdrew after PTX reaction, 1 unrelated death, 1 surgery still pending). Path responses: 10 pCR (36%), 16 pPR (57%), 18 major path resp ( $\leq 10\%$  residual tumor) (64%). 2 PD (7%), ORR 93%. pCR by histology: 7/23 AC (30%), 3/5 SC (60%). Post-tumor samples demonstrated increased infiltration and activation of DCs and monocytes compared to baseline.

**Conclusions:** Sotiga combined with neoadjuvant chemoradiation for esophageal/GEJ cancers was generally well tolerated and achieved pCR rates in both AC and SCC that compare favorably to historical data and are promising for this treatment strategy. Additional evaluations of clinical outcomes (including DFS, OS) and immune-based biomarkers are ongoing.

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