Conclusions: Single organ pulmonary metastasis has better impact on PFS and OS in mCRC patients treated with FOLFIRI and VEGF inhibitors as second-line chemotherapy.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosures: K. Yamaguchi: Honoraria (Institution): Taiho pharm; Speaker Bureau / Expert testimony: Daiichi Sankyo, Eli lily Japan, Bristol Mayers Sqibb. E. Shinozaki: Honoraria (self): Merck biopharma. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.124

P-34 Does the chemotherapeutic efficacy of trifluridine/tipiracil plus bevacizumab change depend on pre-treatment vascular endothelial growth factor inhibitors?

H. Osumi[1], O. Akira[1], K. Shimozaki[1], I. Nakayama[1], T. Wakatsuki[1], D. Takahari[1], K. Chin[1], K. Yamaguchi[2], E. Shinozaki[1]

[1]Cancer Institute Hospital of Japanese Foundation for Cancer Research, Ariake, Japan; [2]Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan

Background: Trifluridine/tipiracil (FTD/TPI) plus bevacizumab (BEV) is widely used as one of salvage line treatment options in metastatic colorectal cancer (mCRC) patients. In Japan, three vascular endothelial growth factor (VEGF) inhibitors, BEV, ramucirumab (RAM), and aflibercept (AFL), are approved for mCRC patients with second-line chemotherapy including irinotecan. It remains unclear the effect of the difference of pretreatment VEGF inhibitors in clinical outcomes of FTD/TPI plus BEV.

Methods: Consecutive mCRC patients who were treated with FTD/TPIplus BEV were retrospectively enrolled. Disease control rate (DCR), progression-free survival (PFS), overall survival (OS), and safety were compared according to the pretreatment VEGF inhibitors. Subgroup analyses of prognostic and predictive efficacy markers were performed.

Results: In total,156 patients (median age, 61.5 years) were included. The DCR was 52.6%, median PFS was 4.2 months (3.2-4.9), and median OS was 12.9 months (10.7-15.3). A total of 73 (46.8%), 50 (32.0%), and 33 patients (21.2%) were treated with FOLFIRI +BEV, RAM, or AFL, respectively. DCR, PFS, OS showed no significant differences between three groups. The most common grade 3 or 4 AEs were neutropenia (29.1%), proteinuria (16.0%) respectively. There were also no significant differences about grade 3 or 4 adverse events rates between three groups.Multivariate analysis revealed poor performance status and liver metastasisas an independent predictor for shorter both PFS and OS (Liver metastasis, PFS: P = 0.002, OS: P = 0.001, Performance status, PFS: P = 0.001, OS: P = 0.00002).

Conclusions: Chemotherapeutic efficacy and safety of FTD/TPIplus BEV did not differ regardless of the pre treatment VEGF inhibitors.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosures: K. Yamaguchi: Honoraria (Institution): Taiho pharm; Speaker Bureau / Expert testimony: Daiichi Sankyo, Eli lily Japan, Bristol Mayers Sqibb. E. Shinozaki: Honoraria (self): Merck biopharma. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.125

P-35 An observational study of health-related quality of life (HRQoL) with electronic patient-reported outcome (ePRO) monitoring during nivolumab therapy for advanced gastric cancer as the 3rd or later line treatment: NIVO-G QoL study

H. Kawakami[1], S. Oyamada[2], Y. Horie[3], S. Fumita[4], N. Izawa[3], T. Miyaji[5], T. Kawaguchi[6], T. Yamaguchi[7], T. Nakajima[8]

[1]Kindai University Faculty of Medicine, Osakasayama, Japan; [2]JORTC Data Center, Tokyo, Japan; [3]Department of Clinical Oncology, St. Marianna University School of Medicine, Kawasaki, Japan; [4]Kindai university Nara hospital, Ikoma, Japan; [5]Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan; [6]Tokyo University of Pharmacy and Life Sciences, Hachioji, Japan; [7]Tohoku University Graduate School of Medicine, Sendai, Japan; [8]Department of Early Clinical Development, Kyoto University Graduate School of Medicine, Kyoto, Japan

Background: Nivolumab is the first immune checkpoint inhibitor that proves efficacy in advanced gastric or gastroesophageal junction cancer and is approved as the 3rd or later line treatment. However, the patients (pts)'s HRQoL has not been evaluated in this setting. We thus investigated how adverse events (AEs) affect HRQoL decline during nivolumab treatment and assessed the feasibility of symptom monitoring at home using the patient's own smartphone.

Methods: Eligible pts were aged ≧20 years with ECOG-PS of 0-2, diagnosed as advanced gastric cancer, and were scheduled to receive nivolumab every two weeks as the 3rd or later line treatment. Pts assessed symptomatic AEs by themselves with PRO-CTCAE and HRQoL with FACT-Ga weekly through ePRO system using pts' own smartphones or rental devices. Objective AEs were evaluated with NCI-CTCAE v5 at the time of consultation. The observation period was 12 weeks. The primary endpoint was the association between each AE and HRQoL decline. The impact of AE deterioration on HRQoL decline was determined by the longitudinal data analysis using a general linear model. The response variable was FACT-Ga total score changes from baseline for each time point. Explanatory variables were FACT-Ga total score at baseline, time point, and composite grade of each AE based on PRO-CTCAE. After ePRO monitoring, the pts completed the questionnaire about its usability.

Results: Between April 2019 and April 2020, 30 pts were enrolled, out of which 29 were evaluable. Twenty pts had completed ePRO monitoring by the end of the observation period, of which 10 pts had still continued nivolumab. The median age of pts was 71 years, and 58% were male. 97% of the pts were PS 0-1 and treated after the third line of treatment. 37.9% of pts do not use their smartphones on a regular basis, and 52.4% were aware of the difficulty of using them. As a result, only 0.95% of the total timepoints were missing data due to no ePRO input, indicating good compliance. The median time until the definitive deterioration of the FACT-Ga total score was nine weeks (95%CI: 3-NA). AEs such as stomatitis ($p<0.0001$), dysgeusia ($p<0.0001$), pain ($p<0.0001$, malaise ($p<0.0001$, nausea ($p=0.0006$, depression ($p=0.0011$, insomnia ($p=0.0035$), loss of appetite ($p=0.0047$, shortness of breath ($p=0.0052$, and vomiting ($p=0.0123$) were associated with worsening HRQoL, but peripheral neuropathy, diarrhea, and constipation were not. For the questionnaire about the usability of ePRO, no pts answered "not satisfied", but only 33.4% of pts were answered "satisfied". While 33.4% of pts wanted to continue using ePRO, 22.2% did not.

Conclusions: Symptom monitoring with ePRO revealed that certain AEs may be responsible for the decrease in HRQoL in pts with advanced gastric cancer during the 3rd or later line nivolumab treatment. Although compliance in the ePRO input was sufficient, there are still challenges in implementing it in daily practice to meet pts expectations.

Legal entity responsible for the study: The authors.

Funding: The study was supported by Bristol Myers Squibb.

Disclosures: H. Kawakami: Honoraria (self): Taiho Pharmaceutical Co. Ltd, Ono Pharmaceutical Co. Ltd., Bristol-Myers Squibb Co. Ltd., Daiichi-Sankyo Co. Ltd.; Advisory / Consultancy: Daiichi-Sankyo Co. Ltd.; Research grant / Funding (institution): Taiho Pharmaceutical Co. Ltd, Bristol-Myers Squibb Co. Ltd, Eisai Co. Ltd., Kobayashi Pharmaceutical. Co., Ltd. N. Izawa: Honoraria (self): Chugai Pharmaceutical, Lillly, Takeda, Taiho Pharmaceutical, Daiichi Sankyo, Bristrol Myers Squibb. T. Miyaji: Research grant / Funding (institution): ONO PHARMACEUTICAL CO., LTD. T. Yamaguchi: Advisory / Consultancy: ONO PHARMACEUTICAL CO., LTD.; Speaker Bureau / Expert testimony: 3H Clinical Trial Inc.. T. Nakajima: Honoraria (self): Taiho Pharm; Research grant / Funding (self): Chugai Pharm, Taiho Pharm. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.126

P-36 Real-world outcomes in BRAFV600E metastatic colorectal cancer – the Glasgow experience

H. Gan[1], M. White[2], G. McGaffin[3], T. Lannagan[4], A. Campbell[4], J. Graham[1], O. Sansom[4], R. Wilson[2]

[1]Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom; [2]Institute of Cancer Sciences, University of Glasgow, Glasgow, United Kingdom; [3]Department of Clinical Genetics, Queen Elizabeth University Hospital, Glasgow, United Kingdom; [4]Cancer Research UK Beatson Institute, Glasgow, United Kingdom

Background: Approximately 8 - 10% of metastatic colorectal cancers (mCRC) have a BRAF V600E mutation. BRAF V600E mutant mCRC represents a distinct clinical subset with a poor prognosis. Previous treatment guidelines have been derived from subgroup analyses of non-designated BRAF V600E trials. Real world studies have shown that outcomes and treatment practices can vary widely. Here, we report on our regional practices and outcomes.

Methods: We undertook a retrospective analysis of all mCRC patients with confirmed BRAF V600E mCRC diagnosed in NHS Greater Glasgow and Clyde Health Board (Scotland, UK) between 01/01/2015 - 31/12/2020. Clinical and pathological features were obtained from electronic records. Univariate analysis of prognostic factors was performed using Kaplan Meier analysis and log-rank test. Multivariate analysis was performed using Cox regression.

Results: A total of 139 patients were identified for study with 1 excluded for missing follow up information. Median age at metastatic diagnosis was 69 years, with a female preponderance (59% female, 41% male). 31% of tumours also had deficient mismatch repair (dMMR) or high levels of microsatellite instability (MSI-H). Primary tumour site was mostly right-sided (n=102, 74%), with less left-sided (n=20, 15%) and rectal (n=15, 11%) tumours. 1 patient had 2 synchronous primaries (1 right colon and 1 rectal). 64% presented with de novo metastatic disease. For those with initial loco-regional disease, the median time to metastatic progression was 10 months. The most common metastatic sites were liver (54%), peritoneal (33%), lymph node (31%), and lung (28%). 36% of patients did not receive any systemic treatment, 36% received 1 line, and 28% received 2 or more lines of treatment. Most (69%) received a cytotoxic chemotherapy doublet as first-line treatment, and 6% received triplet cytotoxic chemotherapy. 7% received immunotherapy. Among the treated patients, only 19% received some form of targeted therapy over their full treatment course, usually a combination containing an anti-EGFR inhibitor. The median overall survival was poor at 7.2 months. Features significantly associated with shorter survival were