progressed on or after ≥1 previous line of treatment in the locally-advanced unresectable or metastatic setting. The HER2+ BTC cohort will enroll 12 response-evaluable patients. If >2 responses are observed, the cohort will be expanded to 30 patients. HER2-mutated BTC patients may also be enrolled in a 30-patient cohort for HER2-mutated solid tumors. The primary objective is antitumor activity with confirmed ORR by investigator assessment as the endpoint. Secondary efficacy endpoints include disease control rate, duration of response, PFS, and OS. For eligibility, HER2 alterations can be demonstrated by 1. HER2 overexpression/amplification in tumor tissue by prior IHC/ISH or 2. by HER2 amplification/mutation in a prior or on-study NGS assay of ctDNA or prior tissue NGS assay. Patients will receive TUC 300 mg orally twice a day and Tras 8 mg/kg intravenously on Cycle 1 Day 1 then 6 mg/kg every 21 days from Cycle 2 Day 1. Disease assessments per RECIST 1.1 are every 6 weeks for the first 24 weeks, then every 12 weeks. Quality of life will be evaluated every 2 cycles using EQ-5D-5L. Sites are currently enrolling within Europe, US, and Asia-Pacific.

Clinical trial identification: NCT04579380.

Editorial acknowledgement: Natalie Pizzimenti, MS (MMS Holdings, Ann Arbor, MI), provided medical writing and editorial support in accordance with Good Publication Practice (GPP3) guidelines.

Legal entity responsible for the study: Seagen Inc.

Funding: This study is sponsored by Seagen Inc., Bothell, WA, USA in collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Ind., Kenilworth, NJ, USA.

Disclosures: T. Bekaii-Saab: Honoraria (self): Royalties: Uptodate; Advisory / Consultancy: Consulting (to institution): Ipsen, Arcus, Pfizer, Seattle Genetics, Bayer, Genentech, Incyte, Eisai and Merck. , Consulting (to self): Stemline, AbbVie, Boehringer Ingelheim, Janssen, Daichii Sankyo, Natera, TreosBio, Celularity, Exact Science, Sobi, Beigene, Kanaph, Astra Zeneca, Deciphera, MJH Life Sciences, Aptitude Health, Illumina and Foundation Medicine, IDMC/DSMB: Fibrogen, Suzhou Kintor, Astra Zeneca, Exelixis, Merck/Eisai, PanCan and 1Globe. ; Research grant / Funding (institution): Agios, Arys, Arcus, Atreca, Boston Biomedical, Bayer, Eisai, Celgene, Lilly, Ipsen, Clovis, Seattle Genetics, Genentech, Novartis, Mirati, Merus, Abgenomics, Incyte, Pfizer, BMS.; Licensing / Royalties: WO/2018/183488: HUMAN PD1 PEPTIDE VACCINES AND USES THEREOF — Licensed to Imugene, WO/2019/055687: METHODS AND COMPOSITIONS FOR THE TREATMENT OF CANCER CACHEXIA — Licensed to Recursion. F. Jin: Travel / Accommodation / Expenses: Merck, Merck, Merck; Shareholder / Stockholder / Stock options: Merck, Merck, Merck; Full / Part-time employment: Merck, Merck, Merck. J. Ramos: Shareholder / Stockholder / Stock options: Seagen Inc; Full / Part-time employment: Seagen Inc. S. Tan: Shareholder / Stockholder / Stock options: Seagen; Full / Part-time employment: Seagen. Y. Nakamura: Research grant / Funding (institution): Taiho Pharmaceutical, Guardant Health, Chugai Pharmaceutical.

https://doi.org/10.1016/j.annonc.2022.04.164

P-75 Digestive tumours in the elderly during COVID pandemic

A. Benzazoua, S. Ghomari-Bezzar

Medical Oncology Department, CHU Tlemcen, Laboratoire Toxicomed, Medicine Department, Universite de Tlemcen, Tlemen, Algeria

Background: Digestive tumours in the elderly are among the most frequent tumours. The diagnostic and therapeutic management is identical to that of the young subject for people in good health. In order to best adapt the treatment, a geriatric evaluation is necessary especially during the SARS COV 2 pandemic period.

Methods: We conducted a retrospective descriptive study in the medical oncology department of the University Hospital of Tlemcen. Our objective is to determine the epidemiological and clinical characteristics of patients aged 70 years and over, treated for a digestive tumour, namely colorectal (CR) and non-colorectal (NCR), during the COVID pandemic, for the period from 2020 to 2021.

Results: Fifty patients were included (28 CR vs 22 NCR). The mean age was 76 years with a predominantly male sex ratio (20H/8F CR vs 14H/8F NCR). Nearly half of the cases (46%) were diagnosed at a metastatic stage (10 CR vs 13 NCR), 28% at a localised stage (10 CR vs 4 NCR) and 26% at a locally advanced stage (8 CR vs 5 NCR). The majority of patients had a preserved general condition WHO 0-I in 29 patients (18 RC vs 11 NCR) and a normal BMI (24 RC vs 17 NCR). Undernutrition with hypoalbuminemia was noted in 4 patients (2 CR vs 2 NCR). 30 patients had a low G8 score Regardless of stage, chemotherapy and/or targeted therapy was prescribed at standard doses in 17 patients (11 CR vs. 6 NCR) and reduced dose in 19 patients (8 CR vs. 11 NCR). No adjuvant therapy was offered due to the early stage in 4 patients. Supportive care was offered in 4 patients (1 CR vs 3 NCR). After progression, second-line treatment was offered in 5 patients (1 CR vs 4 NCR) at full dose (1 CR vs 2 NCR) and reduced dose (0 CR vs 2 NCR). Survival at 6 months is estimated at 16/50 (32%) (6/28 CR vs 10/22 NCR), at 12 months 10/50 (20%) (8/28 vs 2/22) and at 24 months for 1 CR patient (2%).

Conclusions: Digestive tumours in the elderly are frequent, nutritional management and geriatric assessment is necessary for better management.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosures: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.165

P-76 Phase II study of FOLFIRI plus ramucirumab with recurrent colorectal cancer refractory to adjuvant chemotherapy with oxaliplatin/fluoropyrimidine (RAINCLOUD)

N. Sugimoto[1], K. Nakata[2], M. Miyo[3], S. Yoshioka[4], Y. Kagawa[5], A. Naito[6], M. Tei[7], H. Tamagawa[8], K. Konishi[9], H. Osawa[10], T. Shingai[11], K. Danno[12], N. Nishida[1], G. Sato[13], T. Shimokawa[14], N. Miyoshi[13], H. Takahashi[13], M. Uemura[15], H. Yamamoto[13], K. Murata[16], Y. Doki[17], H. Eguchi[13]

[1]Department of Medical Oncology, Osaka International Cancer Institute, Osaka, Japan; [2]Sakai City Medical Center, Sakai, Japan; [3]Department of Surgery, National Hospital Organization Osaka National Hospital, Osaka, Japan; [4]Yao Municipal Hospital, Osaka, Japan, Osaka, Japan; [5]Department of Surgery, Kansai Rosai Hospital (Department of Surgery, Japan Organization of Occupational Health and Safety, Kansai Rosai Hospital), Amagasaki, Japan; [6]Department of Surgery, Osaka Police Hospital, Osaka-shi, Japan; [7]Department of Surgery, Osaka Rosai Hospital, Osaka, Japan; [8]Department of Gastrointestinal Surgery, Otemae Hospital, Osaka-shi, Japan; [9]Department of Surgery, Hyogo Prefectural Nishinomiya Hospital, Nishinomiya, Japan; [10]Department of Surgery, Japan Community Healthcare Organization Osaka Hospital, Osaka-shi, Japan; [11]Department of Gastroenterological Surgery, Osaka Saiseikai Senri Hospital, Osaka, Japan; [12]Department of Surgery, Minoh City Hospital, Minoh, Japan; [13]Department of Gastroenterological Surgery, Graduate School of Medicine, Osaka University, Suita, Japan; [14]Wakayama Medical University, Wakayama, Japan; [15]Osaka University Graduate School of Medicine, Osaka, Japan; [16]Department of Surgery, Kansai Rosai Hospital, Amagasaki, Japan; [17]Osaka University Graduate School of Medicine, Osaka, Japan

Background: The RAISE study demonstrated the superiority of FOLFIRI plus ramucirumab (Ram) to FOLFIRI in second-line metastatic colorectal cancer (CRC) patients progressed after oxaliplatin, fluoropyrimidine with bevacizumab. But no evidence of FOLFIRI plus Ram for patients who were pretreated oxaliplatin, fluoropyrimidine without an anti-angiogenesis antibody. Therefore, we prospectively investigated the efficacy and toxicity of FOLFIRI plus Ram after CRC patients refractory to adjuvant chemotherapy with oxaliplatin plus fluoropyrimidine.

Methods: RAINCLOUD study was a multicenter single-arm phase II trial. Key eligibility criteria were as follows: histologically or cytologically confirmed colorectal cancer, confirmed recurrent colorectal cancer, refractory to fluoropyrimidine, refractory or intolerant of oxaliplatin without pretreated anti-angiogenesis therapy, had measurable or non-measurable lesion, PS=0 or 1, had adequate coagulation function, 20 years or older. FOLFIRI plus Ram were administered as follows; each 2-week cycle, patients received either 8 mg/kg ramucirumab intravenous infusion, followed by the FOLFIRI regimen (150～180 mg/m^2 intravenous irinotecan concurrent with 200 mg/m^2 intravenous leucovorin followed by 400 mg/m^2 fluorouracil given as an intravenous bolus then 2400 mg/m^2 given as a continuous infusion over 48 h). Primary endpoint of this study was progression-free survival (PFS). Secondary endpoints were overall survival (OS), overall response rate (ORR), disease control rate (DCR) and safety. The number of patients was set at 48 based on the threshold and expected median PFS values were 3.9 months and 6.9 months, respectively, with a one-sided alpha error of 0.05 and power of 0.80. This study was conducted in MCSGO (Multicenter Clinical Study Group of Osaka, Colorectal Cancer Treatment Group).

Results: A total of 48 patients were enrolled from 15 sites between September 2017 and September 2020. Patient characteristics: Median age 63.5 years (25～77), male / female 25 / 23, ECOG PS0/1 44/4, sidedness right/left 10/38, and RAS WT/MT/UN 13/33/2. Median PFS was 6.2 months (90% CI: 5.6-8.6), so primary endpoint was met. PFS rates of 6M and 12M were 54.1% (95% CI: 41.4-70.8) and 23.8% (95% CI: 14.0-40.6), respectively. Median OS was 21.2months (95% CI: 17.4-NA). The ORR and DCR were 41.7 % and 81.3 %, respectively. The incidence of grade 3/4 adverse events over 5% were neutropenia (43.8 %), leucopenia (10.4 %), and hypertension (8.3 %). No unexpected adverse events and treatment related death were observed.

Conclusions: Our data suggested that FOLFIRI plus Ram was effective and tolerable for patients with recurrent colorectal cancer refractory to adjuvant chemotherapy with oxaliplatin plus fluoropyrimidine. The results of the pre-planned translational research will be available soon.

Clinical trial identification: Clinical trial information: UMIN000028677.

Legal entity responsible for the study: The authors.

Funding: Eli Lilly.

Disclosures: Y. Kagawa: Speaker Bureau / Expert testimony: Bayer Co., Ltd., Chugai Pharmaceutical Co., Ltd., Yakult Honsha Co., Ltd., Sanofi Co., Ltd., Eli Lilly Japan Co., Ltd., Taiho Pharmaceutical Co., Ltd., Takeda Pharmaceutical Co., Ltd., Merck Co., Ltd.. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.166