

(13.3%). Surveillance imaging performed was by CT scanning in all cases (46.7% as routine, 6.7% if not done previously, 6.7% on occasions); none of the responders used FDG-PET (0%) or liver-MRI (0%). During surveillance, tumour marker (CA 19.9) was tested 6-monthly (66.7%), 3-monthly (40.0%), or annually (26.7%). Most (62.5%) stated that routine follow-up after curative treatment should be performed, but that clear evidence determining the impact on patient's outcome was required.

Conclusions: Pre-surgical staging with 18FDG-PET is not yet routine. Surveillance after curative treatment varies between institutions, both in terms of investigations performed (if any) and duration. Further guidance is required to establish standardised practice.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosures: A. Lamarca: Advisory / Consultancy: Advisory and consultancy honoraria from Eisai, Nutricia Ipsen, QED, Roche, Servier, Boston Scientific, Albireo Pharma, AstraZeneca, Boehringer Ingelheim and GENFIT; Speaker Bureau / Expert testimony: Speaker honoraria from Merck, Pfizer, Ipsen, Incyte, AAA, QED, Servier, AstraZeneca and Eisai; Research grant / Funding (self): Member of the Knowledge Network and NETConnect Initiatives funded by Ipsen. Roche; Travel / Accommodation / Expenses: Travel and educational support from Ipsen, Pfizer, Bayer, AAA, Sirtex, Novartis, Mylan and Delcath. D. Palmer: Advisory / Consultancy: Servier, Celgene. J. Valle: Advisory / Consultancy: AstraZeneca. All other authors have declared no conflicts of interest.

<https://doi.org/10.1016/j.annonc.2022.04.175>

P-86 First-line nivolumab (NIVO) plus chemotherapy (chemo) vs chemo in patients with advanced gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma (GC/GEJC/EAC): CheckMate 649 Chinese subgroup analysis 2-year follow-up

L. Shen¹, Y. Bai², X. Lin³, W. Li⁴, J. Wang⁵, X. Zhang⁶, H. Pan⁷, C. Bai⁸, L. Bai⁹, Y. Cheng¹⁰, J. Zhang¹¹, H. Zhong¹², Y. Ba¹³, W. Hu¹⁴, R. Xu¹⁵, W. Guo¹⁶, S. Qin¹⁷, N. Yang¹⁸, J. Lu¹⁹, C. Amaya Chanaga²⁰, S. Soleymani²⁰, T. Liu²¹

¹Peking University Cancer Hospital & Institute, Beijing, China; ²Herbin Medical University, Heilongjiang, China; ³Fujian Medical University Union Hospital, Fuzhou, China; ⁴The 1st Hospital of Jilin University, Changchun City, China; ⁵Henan Cancer Hospital, Zhengzhou, China; ⁶The Affiliated Hospital of Qingdao University, Qingdao, China; ⁷Sir Run Shaw Hospital, Hangzhou, China; ⁸Peking Union Medical College Hospital, Beijing, China; ⁹China P.L.A. General Hospital (301 Hospital), Beijing, China; ¹⁰Jilin Cancer Hospital, Changchun, China; ¹¹Liaoning Cancer Hospital and Institute, Shenyang, China; ¹²Zhejiang Cancer Hospital, Hangzhou, China; ¹³Tianjin Medical University Cancer Institute and Hospital, Tianjin, China; ¹⁴The First People's Hospital of Changzhou, Changzhou, China; ¹⁵Medical Oncology Cancer Center, Sun Yat-Sen University, Guangzhou, China; ¹⁶Fudan University Shanghai Cancer Center, Shanghai, China; ¹⁷Eastern Theater General Hospital, QinHuai District Medical Area, China; ¹⁸Hunan Cancer Hospital, Changsha Shi, China; ¹⁹Jiangsu Cancer Hospital, Nanjing, China; ²⁰Bristol Myers Squibb, Princeton, United States; ²¹Zhongshan Hospital Fudan University, Shanghai, China

Background: NIVO + chemo demonstrated a clinically meaningful improvement in overall survival (OS) and progression-free survival (PFS) vs chemotherapy alone, along with acceptable safety, in a preplanned analysis of previously untreated Chinese patients from CheckMate 649 after 12 months of follow-up. Results were consistent with those for the overall study population with advanced GC/GEJC/EAC. Based on data from CheckMate 649, NIVO + chemo was approved as first-line treatment for advanced GC/GEJC/EAC in China and other countries. 2-year follow-up data for Chinese patients in CheckMate 649 is reported.

Methods: Adults with previously untreated, unresectable advanced or metastatic GC/GEJC/EAC were enrolled regardless of programmed death ligand 1 (PD-L1) expression. Patients with known HER2-positive status were excluded. Patients were randomized to receive NIVO (360 mg Q3W or 240 mg Q2W) + chemo (XELOX Q3W or FOLFOX Q2W), NIVO + ipilimumab, or chemo. Dual primary endpoints for NIVO + chemo vs chemo were OS and PFS by blinded independent central review in patients with PD-L1 combined positive score (CPS) ≥ 5 .

Results: 208 Chinese patients were concurrently randomized to NIVO + chemo (n = 99) or chemo (n = 106), including 156 (75%) with PD-L1 CPS ≥ 5 ; 88% had GC, 12% had GEJC, and no patients had EAC. At 25 months of minimum follow-up, NIVO + chemo continued to show clinically meaningful improvement in OS with median OS (95% CI) in patients with PD-L1 CPS > 5 of 15.5 months (11.9-21.1) for NIVO + chemo vs 9.6 months (8.0-12.1) for chemo (HR 0.56 [95% CI 0.38-0.81]); in all randomized patients the median OS (95% CI) was 14.3 months (11.5-16.5) for NIVO + chemo vs 10.3 months (8.1-12.1) for chemo (HR 0.63 [95% CI 0.46-0.86]). The median PFS (95% CI) in patients with PD-L1 CPS ≥ 5 was 8.5 months (6.0-14.0) for NIVO + chemo vs 4.3 months (4.1-6.5) for chemo (HR 0.51 [95% CI 0.34-0.76]); in all randomized patients, the median PFS was 8.3 months (6.2-12.4) for NIVO + chemo vs 5.6 months (4.2-6.8) for chemo (HR 0.57 [95% CI 0.41-0.80]). Objective response rate (ORR) in patients with PD-L1 CPS ≥ 5 was 68% vs 48% and median duration of response (DOR) was 12.5 months vs 6.9 months for NIVO + chemo vs chemo, respectively; ORR in all randomized patients was 66% vs 45% and median DOR was 12.5 months vs 5.6 months, respectively. Grade 3/4 treatment-related adverse events (TRAEs) occurred in 66%

and 50% of patients with NIVO + chemo vs chemo, and any-grade TRAEs leading to discontinuation were observed in 49% and 26% of patients, respectively.

Conclusions: NIVO + chemo continued to demonstrate clinically meaningful improvement in OS, PFS, and ORR and have a longer DOR vs chemo alone in previously untreated Chinese patients, along with acceptable safety. These results are consistent with those observed in the overall study population with advanced GC/GEJC/EAC from CheckMate 649.

Clinical trial identification: NCT02872116.

Editorial acknowledgement: All authors contributed to and approved the abstract, writing and editorial assistance was provided by Rajendra Damle, PhD, of Parexel International, funded by Bristol Myers Squibb.

Legal entity responsible for the study: Bristol Myers Squibb.

Funding: The study was supported by Bristol Myers Squibb.

Disclosures: L. Shen: Advisory / Consultancy: BMS/AstraZeneca/BI/MSD/Daiichi Sankyo/Roche; Research grant / Funding (institution): Yaojie Ankang (Nanjing) Technology Co., Ltd./Qilu Pharmaceutical, Baiji Shenzhou (Beijing) Biotechnology Co., Ltd./Zaiding Pharmaceutical, Beijing Xiantong Biomedical Technology Co., Ltd. C. Amaya Chanaga: Full / Part-time employment: Bristol-Myers Squibb. All other authors have declared no conflicts of interest.

<https://doi.org/10.1016/j.annonc.2022.04.176>

P-87 Clinical score to predict recurrence in patients with stage II and III colon cancer

D. Viñal, S. Martinez-Recio, D. Martinez Perez, D. Jimenez-Bou, I. Ruiz, J. Peña, G. Martin-Montalvo, M. Alameda, A. Rueda-Lara, L. Gutierrez-Sainz, M. Palacios, A. Custodio, I. Ghanem, J. Feliu, N. Rodriguez-Salas

Hospital Universitario La Paz, Madrid, Spain

Background: Colorectal cancer is the 3rd most common tumor worldwide. In patients with stage II and III colon cancer the prognosis is heterogeneous, and clinical and pathological characteristics, such as tumor budding, may help to further refine the recurrence risk. The aim of this study is to create a score to predict recurrence using clinical and pathological variables available in routine clinical practice and to select a subgroup of patients with excellent prognosis according to this score.

Methods: We included all of the patients with pathologically confirmed diagnosis of stage II and III colon cancer at Hospital Universitario La Paz from October 2016 to September 2020. All statistical analyses were carried out using SPSS v.25. We performed a univariate and multivariate Cox regression model for the endpoint Time to Recurrence (TTR). We built a prognostic score for recurrence assigning 1 point for each variable that remained $P < 0.10$ at the multivariate analysis.

Results: A total of 440 patients were included. 222 (50%) and 218 (50%) patients were diagnosed with stage II and III disease, and 48% were located in the right colon. After a median follow-up of 36 months (range, 0.1 to 56 months), 72 (16%) patients had a first tumor recurrence, and 80 (17%) patients died. Median TTR, and OS were not reached for the whole cohort. Univariate Cox regression analysis showed that T4, N2, R1, Stage III, bowel obstruction and perforation at diagnosis, lymphovascular and perineural invasion, high tumor budding, and deficient mismatch repair were significantly associated with TTR. Only T4 (hazard ratio (HR), 3.27 [95% confidence interval (CI): 1.52-7.00], $p < 0.01$), N2 (HR, 2.03 [95%CI, 0.99-4.16], $p = 0.05$), R1(HR, 3.58 [95%CI, 1.77-7.21], $p < 0.01$) and high tumor budding (HR, 2.80 [95%CI, 1.56-5.03], $p < 0.01$) remained with a p value < 0.10 at the last step of the multivariate cox regression model. Based on these characteristics, patients were assigned from 0 to 4 points. A total of 135, 97, 52, 16, and 4 had 0,1,2,3, and 4 points, respectively. Freedom from recurrence at 24 months in patients with 0 to 4 points was 95%, 79%, 68%, 54% and 33% ($p < 0.001$). The area under the ROC curve for tumor recurrence at 24 months was 0.771 (95%CI, 0.65-0.85), $p < 0.01$. We compared patients with score = 0 (n = 135; 44%) vs ≥ 1 (n = 169; 56%). Patients with score 0 had significantly longer median TTR (not reached (NR) in either group, $p < 0.01$), with a HR for disease recurrence of 0.13 (95%CI, 0.05-0.33), $p < 0.01$. 95%, and 72% of the patients were recurrence-free at 24 months in the score 0, and ≥ 1 groups, respectively.

Conclusions: In this study, we built a simple score to accurately predict tumor recurrence based on T4, N2, R1 and high tumor budding. Patients with a score = 0, that comprises 44% of the cohort, had an excellent prognosis. The positive results of this score need to be confirmed in a validation cohort.

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.2022.04.177>