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The impact of the multidisciplinary team (MDT) in the management of colorectal cancer (CRC)

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Background: The management of CRC is complex, particularly in metastatic disease, where it is crucial the definition of disease burden, the assessment of radiological response and the identification of the right timing for potential radical surgery or loco-regional treatments. A correct CRC evaluation and the subsequent choice of the most appropriate treatment strategy, need, therefore, a MDT involving surgeons, oncologists, radiologists, radiation oncologists, endoscopists, gastroenterologists and pathologists. Based on such considerations, we investigated the impact of the MDT meeting in the management of CRC at our Institution.

Methods: We retrospectively evaluated all the cases discussed at our MDT meeting between September 2019 and September 2021. We collected data, both pre- and post-MDT meeting, regarding radiology evaluation (disease control vs progression), surgical assessment (yes vs no) and radiotherapy evaluation (yes vs no). Primary endpoint was the overall rate of discrepancy in evaluation between pre- and post-MDT meeting.

Results: Between September 2019 and September 2021, 696 cases were presented at our MDT meeting. The median age was 65 years (24-86), 391 (56%) patients were male and 553 (79%) patients had metastatic disease at diagnosis. After MDT meeting, a total of 214 decisions were modified, for an overall discrepancy rate of 31%. In particular, among 377 cases discussed for radiology evaluation, 110 decisions (29%) were modified after a central imaging review: 80 cases initially evaluated as progressed disease before MDT meeting were defined stable after MDT meeting, for a discrepancy rate of 73%. Regarding the 246 cases discussed for surgical assessment on primary tumor and/or metastatic sites, treatment strategy changed in 86 cases (35%). More specifically, 16 cases (19%), evaluated unresectable before MDT meeting, were then considered resectable after MDT meeting. Finally, among the 71 cases discussed for radiotherapy evaluation, treatment strategy changed in 18 cases (25%).

Conclusions: Our analysis demonstrates a significant rate of discrepancy in radiology and/or surgical evaluation between pre- and post-MDT meeting. Our results show that a MDT allows a considerable modification in CRC management, maximizing the treatment strategy, in particular avoiding unnecessary changes in therapy and allowing surgery where possible.

Legal entity responsible for the study: The author.

Funding: Has not received any funding.

Disclosures: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.173



Can a patient navigator increase quality of life in colorectal cancer patients? The WeGuide trial

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Background: An estimated one-third of patients with cancer will experience clinically significant distress, manifesting as anxiety or depression that is associated with their diagnosis and treatment. This has been shown to negatively impact health outcomes and quality of life (QOL). Intrahospital processes are complex, involving a significant amount of paperwork and several stakeholders, creating overwhelming circuits which can add up to generating more anxiety. Patient navigators (PN) can help to overcome these barriers by helping in several dimensions: information management and mediation (organize clinical information, prepare appointments, engaging in patient-

healthcare professional communication), healthcare education and self-care (clarifying doubts about the therapeutic process, encouraging adherence to therapy) and on emotional and spiritual support (mobilizing social and family support, self-help groups). On this basis, the investigators designed the WeGuide trial, with the primary objective of assessing the impact of a PN in the QOL of patients with colorectal (CRC) cancer and also the utility of a PN from the patient's point of view.

Methods: Participants were recruited from Hospital de Santa Maria and were randomized 1:1 to receive a PN or not. Three questionnaires (EORTC QLQ-C30, Utility Likert Scale and Satisfaction Scale) were applied in four moments: at diagnosis, three months, six months (end of therapy) and nine months (first follow-up). Value Based Health Care (VBHC) concepts were also applied to assess the impact of a PN on patient's well-being and on the cost-effectiveness of CRC treatment in the health care system.

Results: We present the results of a preliminary analysis of 30 patients (of 160 needed). The PN group had a better Global Health Status with the average score increasing in 12.37% (p=0.05) when comparing the baseline to the last evaluation. Several other dimensions also improved in the same time period: physical functioning (6.40%; p=0.09), role functioning (10.18%; p=0.09), emotional functioning (8.49%; p=0.06) and cognitive functioning (10.16%; p=0.03). Symptom scales registered an absolute decrease in average, albeit not statistically significant in the current analysis. Regarding VBHC, medical appointments were considered to be more effective, patient visits to the emergency department were reduced and there was also a reduction in the number of trips to the hospital by optimizing the scheduling of procedures to the same day when possible. Patient safety could also be improved, with PN reporting to the responsible physician when alarm thresholds/symptoms had been noticed.

Conclusions: PN were useful to patients in this setting, promoting their QOL and their emotional well-being in spite of few observations. Looking at these indicators, the result of the positive impact on the patient's functional capacity comes from an improvement in the emotional component and, above all, in the cognitive capacity. We still have few observations to establish a concrete VBHC.

Legal entity responsible for the study: The authors.

Funding: Terra dos Sonhos is responsible for raising the necessary funds to implement this study. To achieve this objective, this non-profit organization has applied to several grants and has been awarded the BPI Capacitar Grant and, more recently, the Caixa Social Grant. In addition, WeGuide is also financed by some organizations sharing the same belief about this project. These include Saúde Prime, Fundação D. Pedro V, among others.

Disclosures: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.04.174



Pre-surgical staging and surveillance after curative treatment for pancreatic ductal adenocarcinoma (PDAC): Survey of practice in the United Kingdom (UK)

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 ${\bf Background:} \ {\bf Differences} \ \ {\bf in} \ \ {\bf pre-operative} \ \ {\bf staging} \ \ {\bf and} \ \ {\bf surveillance} \ \ {\bf after} \ \ {\bf curative} \ \ {\bf treatment} \ \ {\bf for} \ \ {\bf PDAC} \ \ {\bf hamper} \ \ {\bf interpretation} \ \ {\bf of} \ \ {\bf outcome} \ \ {\bf data}.$

Methods: This survey aimed to assess current practice and identify areas for improvement; it was circulated to members of the United Kingdom National Cancer Research Institute (NCRI) pancreatic cancer subgroup between 14/4-4/5 2021.

Results: A total of 23 responses were collected (medical oncologist 52.2%, surgeon 26.1%, radiation oncologist 13.0%, other 8.7%); the majority were Consultants (91.3%) working in tertiary care institutions (86.9%) who attended PDAC tumour boards (90.9%). For staging prior to curative surgery, all responders used computerised tomography (CT) (100%), and 61.1% used routine 18FDG positron emission tomography (PET) (16.7% used it only in specific occasions); only 38.9% used routine liver magnetic resonance imaging (MRI). In terms of surveillance following curative treatment, practice varied widely: 64.7% of responders considered imaging, tumour marker and clinical follow-up as routine practice after curative treatment, while 29.4% undertook follow-up without imaging; 5.9% did not offer any form of surveillance. Frequency of follow-up was either 6-monthly (60.0%), 3-monthly (26.7%), or variable (13.3%) and lasted for 5 years (73.3%), 2 years (6.7%), 3 years (6.7%), or other

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(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, Astra Zeneca 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



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

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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/GEIC/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 \geq 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 \geq 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 \geq 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/GEIC/EAC from CheckMate 649.

Clinical trial identification: NCT02872116

Editorial acknowledgement: All authors contributed to and approved the abstract, writing and editoiral 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



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

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Background: Colorectal cancer is the $3\underline{o}$ 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 regresión 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 \geq 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