

Methods: This is a retrospective study including 31 patients diagnosed and treated for locally advanced or metastatic pancreatic cancer, at the medical oncology department at Habib Bourguiba university hospital in Sfax, between 2011 and 2017. LMR was calculated by using the equation: $LMR = \text{absolute lymphocyte count/absolute monocyte ratio}$. Value cutoffs were adopted to discriminate patients as follows: low $LMR < 4.6$ and high $LMR \geq 4.6$.

Results: The median age of our patients was 60 years (36–77). A male predominance was observed (61%). The average consultation time was 2.7 months, and the most common reason was abdominal pain (87%) followed by the onset of jaundice (29%). Nine patients had a performance status (PS) ≥ 2 . On imaging, the average tumor size was estimated at 4.5 cm. The presence of metastases was observed in 16 patients (51.6%). Chemotherapy was indicated in 19 patients, as a neoadjuvant situation (38%) and in 51% in case of metastatic disease. A high LMR was found in 9 patients (29%). The mean overall survival was 7 months. Survival at 1 and 2 years were 12.9% and 3.2% respectively. The $LMR < 4.6$ was associated with a worse overall survival (OS) at 1 year (3.2% vs 13%, $p = 0.002$). The other poor prognostic factors were PS ≥ 2 , high CA19-9 level and stage IV ($p = 0.001$, $p = 0.021$ and $p = 0.027$ respectively).

Conclusions: The findings from our study suggest that low LMR is associated with worse OS in Tunisian patients with advanced pancreatic cancer, in addition to the other prognosis factors.

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P-7 Encorafenib and cetuximab in patients with metastatic, BRAF V600E-mutated, colorectal cancer: Update on the first real-world study in Germany and Austria – BERING CRC

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Background: For the therapy of previously treated BRAF V600E-mutant metastatic colorectal cancer, the combination of encorafenib with cetuximab represents a new standard of care. The combination of encorafenib plus cetuximab was approved in the EU in June 2020. The approval was based on positive results from the BEACON CRC trial, which demonstrated a median overall survival (OS) of 8.4 mo (second data cut off 9.3 mo) and an objective response rate of 20% (both data cut offs). The observed tolerability profile was consistent with the known safety profile of each agent. Since data from controlled clinical trials are based on a selected patient population, the present non-interventional study (NIS) investigates the use of encorafenib + cetuximab under real-world conditions in a broader patient population.

Trial design: BERING CRC is an ongoing, multi-national, multi-centric, prospective, longitudinal NIS. It represents the first NIS to investigate the real-world use of the targeted therapy encorafenib + cetuximab in BRAF V600E-mutant metastatic colorectal cancer after prior systemic treatment in Germany and Austria. The project aims to enroll up to 500 patients from 90 German and Austrian sites with a total study duration of approx. 6 yrs. From Sep 2020 to Feb 2022, 72 patients have been included from 80 open sites. The study follows patients treated according to the SmPCs (Summary of Product Characteristics) and the primary objective is to assess the 1-year OS rate. Additional analyses include efficacy, quality of life, safety and tolerability of encorafenib + cetuximab treatment. The influence of prognostic factors on efficacy, safety and tolerability will also be analyzed.

Clinical trial identification: NCT04673955.

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P-8 Long-term survival in patients with pancreatic cancer (PAC) treated with liposomal irinotecan in combination with 5-fluorouracil and leucovorin (nal-IRI+5-FU/LV)

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Background: PAC is an aggressive disease with 85% of patients being diagnosed at a locally advanced or metastatic (mPAC) stage; the prognosis is poor, as only 10% survive beyond 5 years after diagnosis. Current treatments include the use of gemcitabine (GEM)-based therapies in first line, followed by liposomal irinotecan (nal-IRI+5-FU/LV) after failure. Despite poor survival outcomes, some patients survive >1 year from the start of nal-IRI+5-FU/LV. No clear recommendations exist for the optimal treatment sequence with no precise characteristics or molecular markers to help select a chemotherapy regimen or personalized treatment. Nevertheless, a nomogram derived from the pivotal NAPOLI-1 trial identified 8 factors that were significantly associated with overall survival, including baseline Karnofsky score (KPS), albumin (g/dL), neutrophil-to-lymphocyte ratio (N/L), liver metastasis, CA19-9 (U/mL), disease stage at diagnosis, body mass index (kg/m²), treatment arm (nal-IRI+5-FU/LV). While the identification of these factors has greatly helped in determining who will be a long-term survivor, they are not exhaustive and there is a need to further identify predictive markers. This abstract will report some published experiences of long-term survivors following nal-IRI+5-FU/LV treatment.

Methods: A descriptive analysis on the experiences of patients with mPAC who were treated with nal-IRI+5-FU/LV from several countries and who are considered long-term survivors (>1 year from start of nal-IRI treatment) was conducted.

Results: NAPOLI-1 survival data are replicated in the clinical practice and several data are already published (Drugs 2020). A retrospective observational database study evaluating patients treated with nal-IRI between Nov-2015 and Jul-2020, was presented during ASCO-GI (Kim 2021). This analysis from >280 cancer clinics in the US that examined 1-year survival for 699 patients treated with nal-IRI-based regimens showed that, when compared to NAPOLI-1, these patients were older, had more prior lines of therapy, and worse ECOG PS, but a similar treatment exposure. Despite these characteristics, the 1-year OS among patients who received at least 4 treatment cycles was similar to the intent-to-treat (25%) and per-protocol (34%) treated patients in NAPOLI-1. Among all patients, 1-year OS was 17.2% (14.3-20.7), 31.5% (22.1-41.3) for patients treated in first line, 16.4% (12.2-21.1) in second line, and 12.2% (7.5-18.0) in third line. Among those who received at least 4 and 8 cycles, the 1-year OS estimates were 29.1% (24.0-34.3) and 47.9% (39.7-55.7), respectively. Additionally, four published clinical cases of patients with unfavorable profiles at baseline were successfully treated with nal-IRI+5-FU/LV without any specific common factors (except age < 60 years old). Additional experiences coming from other countries will be presented during the congress.

Conclusions: A subset of mPAC patients may derive exceptional benefit from nal-IRI+5-FU/LV. The currently presented evidence from real-world data and specific clinical cases highlight the need to identify and better characterize predictive factors for long-term survival. Future studies elucidating predictive factors of response to nal-IRI+5-FU/LV are needed to enable better patient selection.

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