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P-17 Real-life use and long-term effectiveness results from CIREL – the multi-centre, observational study on irinotecan-eluting transarterial chemoembolization in CRLM

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Background: Transarterial chemoembolization (TACE) using irinotecan-eluting beads as a treatment approach for patients with unresectable colorectal cancer liver metastases (CRLM) is finding use beyond treatment guidelines but real-life data from multi-centre studies are lacking. The CIrse REgistry for LifePearl microspheres (CIREL, NCT03086096) is a prospective, Europe-wide, multi-centre, observational study on the real-life clinical outcomes of LifePearlTM microspheres TACE (LP-irinotecan TACE). The study was conducted by the Cardiovascular and Interventional Radiological Society of Europe (CIRSE).

Methods: Eligible patients were adults with CRLM treated with LP-irinotecan TACE and were enrolled between February 2018 and August 2020. Baseline characteristics and treatment-related data were collected. The median follow-up inclusion according to reverse Kaplan-Meier was 19 months (95% CI: 17-23) during which data on overall survival (OS), progression-free survival (PFS), hepatic progression free survival (hPFS) and adverse events (AEs) graded according to CTCAE 4.03 were collected.

Results: 152 patients were enrolled in the study. Median age was 66 years and 39% were female. Eastern Cooperative Oncology Group was 0 in 59%; 1 in 34%; and $\geq$2 7%; liver involvement was 50% in 7% of patients. 84% had progressive disease at baseline. 42% received 1 line, 40% 2 or more lines and 18% no line of previous systemic therapy. 91 (60%) patients experienced 266 adverse events within 24 hours after a TACE session, of which 19 (7%) were grade 3 or higher in 12 (8%) patients. The complete treatment plan was administered in 80% of patients and no treatment-related deaths were reported. The median OS for the whole cohort was 13.0 months (95% CI 10.5-15.0), median hPFS was 6.2 months (95% CI 5.1-6.9) (hPFS rate at 9 months: 29%) and median PFS was 4.7 months (95% CI 3.8-5.3) (PFS rate at 9 months: 13%). We could observe statistically significant differences (p=0.005) in OS for different treatment strategies. When LP-irinotecan TACE was used as a first-line treatment or as consolidation after response to first-line treatment (41, 27%), the median OS was 17 months (95% CI 12.7-23.1). When it was used in combination with ablation (with curative intent) (19, 13%), the median OS was 17.1 (95% CI 10.5-NA). When chemo-refractory patients still eligible for further systemic treatment were treated with LP-irinotecan TACE (41, 27%), the median OS was 10.3 months (95% CI 7.5-14.0). Salvage treatment of chemo-refractory patients not eligible for further systemic treatment (46, 30%) resulted in the smallest median OS of 9.0 months (95% CI 6.8-13.0). For 5 (3%) patients LP-irinotecan TACE was used after response to second-line treatment.

Conclusions: The results from this large prospective multi-centre observational study show that in a real-world context, LP-irinotecan TACE is well tolerated with low occurrences of severe adverse events and patients with CRLM receiving LP-irinotecan have a median overall survival comparable to gold-standard systemic treatment for later lines.

Clinical trial identification: NCT03086096.

Legal entity responsible for the study: The authors.

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P-18 Prognostic association between (so over-expression of vascular) of vascular endothelial growth factor receptor and micro-vascular invasion in patients with hepatocellular carcinoma

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Background: Overexpression of vascular endothelial growth factor (VEGF) receptor promotes angiogenesis and vascular invasion in hepatocellular carcinoma (HCC). More strict patient selection for VEGF receptor targeted therapy based on evidence of micro vascular invasion may have prognostic benefit. In the present study, we aimed to investigate prognostic association between over expression of VEGF receptor and micro vascular invasion in patients with HCC.

Methods: We used a web-based gene survival analyzer Kaplan Meier Plotter (KMplotter) to demonstrate association between VEGF receptor expression and long-term outcomes in patients with HCC with and without micro vascular invasion. Overall survival rate was calculated in study cohorts which stratified by median expression level of VEGF (gene probe set 7422).

Results: A total of 293 patients with HCC were selected from an online KM plotter database and number of patients with and without micro vascular invasion were 90 and 209, respectively. The VEGF receptor over expression was significantly associated with increased risk of mortality in patients with micro vascular invasion (HR=2.84, 95% CI 1.30-6.23, p=0.006) (optimal threshold value of 6500) but not in patients without micro vascular invasion (HR=1.55, 95% CI 0.83-2.87, p=0.160) (no optimal threshold value). Furthermore, patients with micro vascular invasion who revealed VEGF receptor overexpression had significantly lower overall survival rate (26 months vs. 83 months, log-rank p=0.006) compared to patients without micro vascular invasion (71 months vs. 85 months, log-rank p=0.160).

Conclusions: VEGF receptor overexpression is associated with significantly lower overall survival rate in patients with HCC who have micro vascular invasion. Non-invasive detection of micro vascular invasion in patients with HCC may allow more strict patient selection for VEGF receptor targeted therapy.

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