Clinical outcome of liposomal irinotecan after progression on prior chemotherapy in pancreas cancer

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Background: In the NAPOLI-1 trial, nanoliposomal irinotecan (nal-IRI) plus 5-fluorouracil/leucovorin (5-FU/LV) was shown to improve overall survival compared to fluorouracil alone for patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. In that trial, Asian patients experienced more hematological toxicity and subsequent dose modification. There has been limited information on the clinical benefit and toxicity of this regimen in a real-world setting. Herein, we assessed real-world experience of nal-IRI plus 5-FU/LV in patients with advanced pancreatic cancer after gemcitabine failure.

Methods: The medical records were retrospectively reviewed to investigate the therapeutic efficacy and safety profile of nal-IRI plus 5-FU/LV in patients with gemcitabine refractory pancreatic cancer treated in our institution. Patients received nal-IRI (80 mg/m², equivalent to 70 mg/m² of irinotecan base) with fluorouracil and folinic acid every 2 weeks. Chemotherapy dose adjustments was allowed. Median dose intensity was assessed by calculating a percent of target dose achieved in the average cycle for each patient.

Results: Thirty-eight patients received nal-IRI plus 5-FU/LV between May 2015 and July 2020. The median age was 65 years, and males were 55.3%. A total of 29 (76.3%) and 9 (23.7%) patients had received less than two and two or more lines of chemotherapy before enrollment, respectively. At a median follow up of 5.5 months, median overall survival was 6.5 months (95% confidence interval [CI] 4.5-8.5) and median progression-free survival was 2.98 months (95% CI 1.7-4.3). The objective response rate and disease control rate were 5.3% and 55.3%, respectively. Chemotherapy doses were reduced or delayed in 26 (68.4%) patients and median relative dose intensity was 0.87. Twenty-eight (73.7%) patients experienced any grade 3 or 4 adverse events. Most common grade 3 or 4 adverse event was neutropenia (60.5%) and most non-hematologic adverse events were under grade 2.

Conclusion: Our study confirmed that the effectiveness of nal-IRI plus 5-FU/LV as a well-tolerated regimen in treatment of advanced gemcitabine-refractory pancreatic cancer.