Trifluridine/tipiracil vs regorafenib as salvage-line treatment in patients with metastatic colorectal cancer: A multicenter retrospective study

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Introduction: Trifluridine/tipiracil (TAS-102) and Regorafenib (REG) have shown promising activity in patients with heavily pretreated metastatic colorectal cancer (mCRC). The aim of this study was to compare the efficacy and safety of TAS-102 and REG alone in patients with mCRC refractory to standard chemotherapies.

Methods: From May 2014 to December 2017, 135 patients with mCRC were treated with TAS-102 or REG as salvage-line therapy. Efficacy, safety and clinical outcomes were retrospectively evaluated. Inclusion criteria were histologically confirmed colorectal adenocarcinoma; refractory or intolerant to fluoropyrimidine, oxaliplatin, irinotecan, anti-VEGF therapy and anti-EGFR antibody (for tumours with wild-type RAS); measurable or evaluable lesion; age ≥ 20 years; Eastern Cooperative Oncology Group performance status (ECOG PS) 0 to 2; and written informed consent. The clinical outcomes were evaluated using the Cox’s proportional hazard models.

Results: Among 135 patients, 77 received TAS-102 (median age 77 y, male 49%, ECOG PS 0 62%, RAS wt 43%) and the other 58 received REG (median age 66 y, male 53%, ECOG PS0 64%, RAS wt 51%). With a median follow-up of 5.8 months (range, 1.5 to 19.0), median progression-free survival was statistically longer in the TAS-102 group than in the REG group (TAS-102 2.9 vs REG 2.0 months; HR = 0.591, p = 0.0035). No significant difference in overall survival between TAS-102 and REG (TAS-102 10.4 vs REG 9.2 months; HR = 1.14, p = 0.57) was observed.

Conclusion: TAS-102 and REG showed equivalent survival benefit in the treatment of mCRC which had progressed after standard therapies.