

EFFICACY AND SAFETY OF TRIFLURIDINE/TIPIRACIL IN PATIENTS WITH METASTATIC COLORECTAL CANCER: REAL WORLD DATA

Patier-Ruiz I¹, Fernández-Fraga F¹, Moreno-García M¹, Díez-Fernández R¹, Molina-García T¹
¹ Pharmacy Service, Hospital Universitario de Getafe, Madrid (Spain)

BACKGROUND AND IMPORTANCE

Trifluridine/tipiracil (TAS-102) has been included as a drug with a doubtful clinical benefit according to the ESMO-MCBS scale (values=1-2) in the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.

AIM AND OBJECTIVES

The objective of this study is to evaluate the effectiveness and safety of TAS-102 in mCRC in real-world use.

MATERIALS AND METHODS

Observational, retrospective, descriptive study in which all patients with diagnosis of mCRC who received treatment with TAS-102 from January 2017 to April 2019 were included. Demographic (sex and age) and clinical variables (RAS gene mutation, primary tumor location, duration of treatment, progression-free survival (PFS) and adverse events) were analyzed. Progression was analyzed according to Response Evaluation Criteria In Solid Tumors (RECIST v1.1).

RESULTS

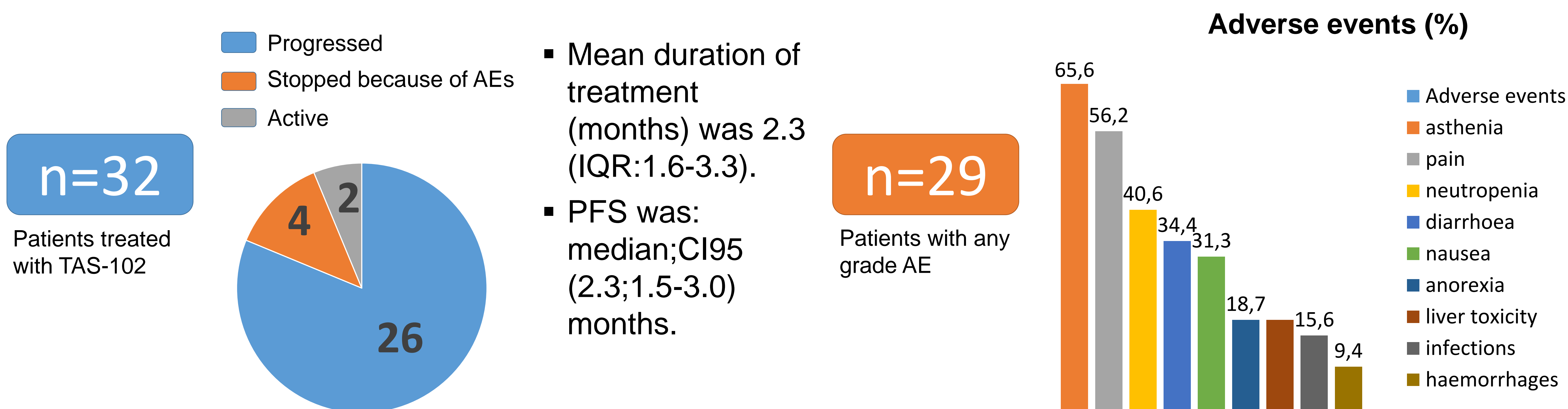
32 patients with mCRC were included. Mean age was 69.4 years (IQR:61.7-75.4). RAS wild-type was detected in 53.1% of patients. Primary location was 71.9% colon (43.5% unspecified, 30.5% left, 26% right), 25% rectum and 3.1% both.

3.1% of the patients had received two previous lines of treatment, 68.8% three and 28.1% four (schemes with capecitabine±oxaliplatin, FOLFOX, FOLFIRI and regorafenib). The addition of anti-VEGFR/EGFR therapy was not considered a differentiated scheme.

All patients had progressed to fluoropyrimidines, 96.9% progressed to irinotecan and 53.1% to cetuximab. 100% of patients received biological therapy. Bevacizumab was administered to 90.6% of patients, aflibercept to 59.4%, and cetuximab/panitumumab to 53.1%.

Mean duration of treatment (months) was 2.3 (IQR:1.6-3.3). At the time of data collection, 81.2% had progressed, 12.5% stopped because of toxicity and 6.2% still on regimens. PFS was: median;CI95 (2.3;1.5-3.0) months.

Any grade adverse events occurred in 90.6% of the patients. These were asthenia (65.6%), pain (56.2%), neutropenia (40.6%; differentiated in 38.5% grade-3, 46.1% grade-2, 15.4% grade-1), diarrhea (34.4%), nausea (31.3%), anorexia (18.7%), liver toxicity (18.7%), infections (15.6%) and hemorrhages (9.4%).



CONCLUSIONS AND RELEVANCE

In our study, patients treated with trifluridine/tipiracil presented toxicity and a PFS similar to that observed in the pivotal clinical trial (2.0[1.9-2.1]). TAS-102 is a low clinical benefit option in mCRC.

References:

- Mayer RJ et al. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. *N Engl J Med* 2015;372:1909-19. <https://doi.org/10.1056/nejmoa1414325>.
- ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) Available at: <https://www.esmo.org/guidelines/esmo-mcbs>

Conflict of interest: nothing to disclose

Email: Ignacio.patier@salud.madrid.org