

EFFECTIVENESS OF REGORAFENIB IN THE TREATMENT OF METASTATIC COLORECTAL CANCER IN SELECTED PATIENTS

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OBJECTIVES

The aim of this study is to analyze the effectiveness of regorafenib in the treatment of mCRC in a selected population per protocol compared with data of CORRECT study.

METHODS

Retrospective observational study. All patients with mCRC in treatment with regorafenib, in a tertiary hospital, were included. Variables were: demographic (age, sex), clinicals (KRAS wild-type, cycles of treatment, reduced dose, reported adverse events) and effectiveness (median duration of treatment). Information sources used were electronic records of medical history.

INCLUSION CRITERIA

- ECOG = 0
- Failed treatment with fluoropyrimidine, oxaliplatin and irinotecan based chemotherapy, an anti-VEGF therapy and, if KRAS wild type, an anti-EGFR therapy,
- Survival expectancy greater than 3 months

RESULTS

10 patients were included with an average age of 55 (70% men, 30% women), 30% patients with KRAS wild-type vs 70% mutant, 3,7 median of lines previous of treatment. Needed reduced dose or suspected temporarily 80% (8/10). Median of cycles were 2,5 cycles (2-5). All patients scheduled for realization of PET at 2-3 months of treatment, showed disease progression. All patients experienced adverse events (AEs). 40% reported AE grade 3-4: (Astenia (3 patients), hand-foot syndrome (2 patients), diarrhea (1 patient) Other AE with grade 1-2: mucositis, high blood pressure and anorexia.

		Nº Patients (N=10)
MUTACION	KRAS wild-type	3
	K-ras mutation	7
DURATION OF TREATMENT (median (min,max))		2,9 month (2,5)
DOSE REDUCTION/TEMPORARY SUSPENSION	YES	8
REACTION GRADE 3-4	YES	4

CONCLUSIONS

Our patients were treated a median of 2.9 months similar to the reported in EPAR of EMA (2.8 months). The total percentage of adverse events registered were superior (100% vs. 93%) and inferior the percentage of adverse events grade 3-4 (40 vs. 54%) in our sample with respect to Correct study. It seems that the selection of patients, in clinical practice, does not improve the results obtained in clinical trials. Herefore we consider it necessary to closely monitor patients treated with regorafenib.

*Grothey A, Van Cutsem E, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Bouché O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, Goldberg RM, Sargent DJ, Cihon F, Cupit L, Wagner A, Laurent D; CORRECT Study Group. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet*. 2013 Jan 26;381(9863):303-12. doi: 10.1016/S0140-6736(12)61900-X. Epub 2012 Nov 22.