EVALUATION OF EFFICACY AND SAFETY OF REGORAFENIB IN METASTATIC COLON CANCER

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BACKGROUND

Treatment with regorafenib is an alternative third-line therapy for patients with metastatic colon cancer. This new treatment option was marketed in 2013, so it should be checked whether the efficacy and safety in routine clinical practice are equivalent to those reported in pivotal trials.

PURPOSE: To assess the efficacy and safety of regorafenib in the treatment of metastatic colon cancer in routine clinical practice in a tertiary hospital.

MATERIAL AND METHODS

Study

Observational
Descriptive
Retrospective (until June 2016)

Patients

Adults
Metastatic colon cancer
Treatment with Regorafenib

Variables

Age and gender
Therapeutic indication
Overall survival (OS)
Progression-free survival (PFS)
Adverse reactions
Dose reduction

Endpoints

Primary efficacy endpoints: OS and PFS
Safety profile

Data were recorded from Computerized Clinical History and Pharmaceutical Dispensing Software.

RESULTS

Ten patients, 6 (60%) men and 4 (40%) women, were studied. Mean age was 60.8 years. All patients were diagnosed with metastatic colon cancer. Mean OS was 5.25 months and mean PFS was 2.55 months. Notified adverse reactions were: hand-foot syndrome (4), diarrhea (2), asthenia (6), decreased intake (4), mucositis (2) and emetic syndrome (2). All patients had at least one adverse event and 80% required a full dose reduction for toxicity and/or bad tolerance.

CONCLUSIONS

Results of efficacy of regorafenib in metastatic colon cancer therapy in routine clinical practice were inferior to those reported in pivotal trials (6.4 months OS in CORRECT vs 5.25 months).

Safety profile was similar to that described in data sheet, however frequency of patients requiring dose reduction (80%) was higher than expected.

In conclusion, comparing older alternatives efficacy (Regorafenib PFS 1.9 months, Panitumumab PFS 1.9 months, Cetuximab PFS 3.7 months, Best supportive care PFS 1.2 months), the use of an alternative in third-line treatment for metastatic colon cancer should be based on its safety profile and patient tolerance.

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