Aflibercept as a second line chemotherapy in metastatic colorectal cancer. One centre experience.

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Background:
A III-phase clinical trial has demonstrated benefit in global survival using **aflibercept** in combination with **FOLFIRI** in patients with metastatic colorectal cancer (mCRC) who progressed after being treated with oxaliplatin despite receiving previously either anti-EGFR or antiangiongenics. The main objective of our study is to analyze the benefit of this combination in the daily clinical practice, tolerance and correctly manage of associated side effects.

Methods:
During 19 months (from March 2013 until December 2014) we treated 20 patients with FOLFIRI plus aflibercept each every 15 days as a second line chemotherapy treatment for mCRC. Efficacy and safety outcomes were analyzed. Toxicities were assessed using the Common Terminology Criteria for Adverse Events 4.3

Results:
Patients median age was 60 years (28-72). All were classified as ECOG 0-1.
Each patient received oxaliplatin as a first line treatment. Also prior use of bevacizumab was reported in 12 patients (60%) and anti-EGFR in 5 patients (25%). 70% of them had mutated RAS status and 30% wild-type RAS status. The median number of cycles given was 10 (2-42).
Aflibercept dose reduction was required in 6 patients (30%), and therapy discontinuation due to toxicity in 2 (10%), 1 as a consequence of hypertension and 1 as diarrhea. In all patients, some kind of grade treatment-related adverse events occurred. Most frequently 3-4 grade toxicity observed were: asthenia (20%), neutropenia (20%), hypertension (20%), diarrhea (15%), stomatitis (15%), palmar-plantar erythrodysesthesia (10%) and proteinuria (5%).
In patients evaluable for response, the response rate was 40% and the disease control rate of 73%. In a follow-up median time of 9 months, the progression-free survival median time was 6,5 months (2-23), and it was similar between mutated-RAS (6 months) and wild-type-RAS (7 months). In the moment that the analysis took place, only 35% of patients had progressed to treatment and 18 of them (90%) were alive.

Conclusion(s):
In our patient series, FOLFIRI and aflibercept combination achieves a high clinical percentage benefit independently of RAS status or prior therapy received. Observed side effects were consistent to previous III-phase trial, and the main causes of aflibercept discontinuation therapy were hypertension and diarrhea.

WCGC 2015
266--P
Clinical Colon Cancer
Beatriz González
DOI: 10.3252/pso.eu.17wcgc.2015
Poster presented at: 12TH WORLD CONGRESS ON Gastrointestinal CANCER 1–4 JULY 2015 BARCELONA, SPAIN