EXPERIENCE OF REGORAFENIB USE IN METASTATIC COLORECTAL CANCER

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INTRODUCTION
Regorafenib for the treatment of patients with previously treated metastatic colorectal cancer (mCRC)

PURPOSE
To evaluate the efficacy and safety of regorafenib treatment in patients with mCRC

MATERIAL AND METHODS
✓ Retrospective observational study
✓ mCRC patients treated with regorafenib (September 2015-2017)
✓ Collected variables: age, sex, ECOG, KRAS gene status, treatment line, number of cycles, dose reduction
✓ Efficacy endpoints: progression-free survival (PFS) and overall survival (OS) obtained by the Kaplan-Meier method
✓ Safety: collected adverse effects (AE)
✓ Descriptive statistical analysis: SPSS® Statistics program V22.0

RESULTS

<table>
<thead>
<tr>
<th>Patients</th>
<th>n=13 (7 men; 6 women)</th>
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<tbody>
<tr>
<td>Age</td>
<td>Median=57 years (41-77)</td>
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| Initial ECOG | 0=38,46 %
               | 1=38,46%
               | 2=23% |
| KRAS gene | Mutated=50,8%
              | Wild-type=30,8%
              | Undetermined=3,8% |
| Protocol | Regorafenib 160 mg once daily for 21 days, every 28 days |
| Line     | 3rd=46,2%
              | >4th=53,8% |
| Dose reduction | 30,8% |
| Nº of cycles | Mean=2.75±1.22 cycles |
| Treatment discontinuation | n=9 progression
                                      n=3 deterioration of general health
                                      n=1 toxicity |

Efficacy

- PFS 3.0 months (95%CI 2.52-3.47)
- OS 8.3 months (95%CI 1.07-15.51)

Safety

AE any grade
- Hand-foot skin reaction
- Hypertension
- Neutropenia
- Mucositis
- Nausea

AE grade 3-4
- 1
- 1

CONCLUSION
✓ The SLP obtained is greater than what was described in the pivotal trial CORRECT (3.0 versus 1.9 months). This was possibly due to the longer time it took to determine the radiological response.
✓ The SG was also higher (8.3 versus 6.4 months) → limitation of the sample size.
✓ The AE described were similar to those published in the literature.

References: Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomized, placebo-controlled, phase 3 trial.