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REAL-WORLD EFFECTIVENESS AND SAFETY PROFILE OF TRIFLURIDINE/TIPIRACIL (TAS-102) PLUS BEVACIZUMAB ON COLORECTAL METASTATIC CANCER

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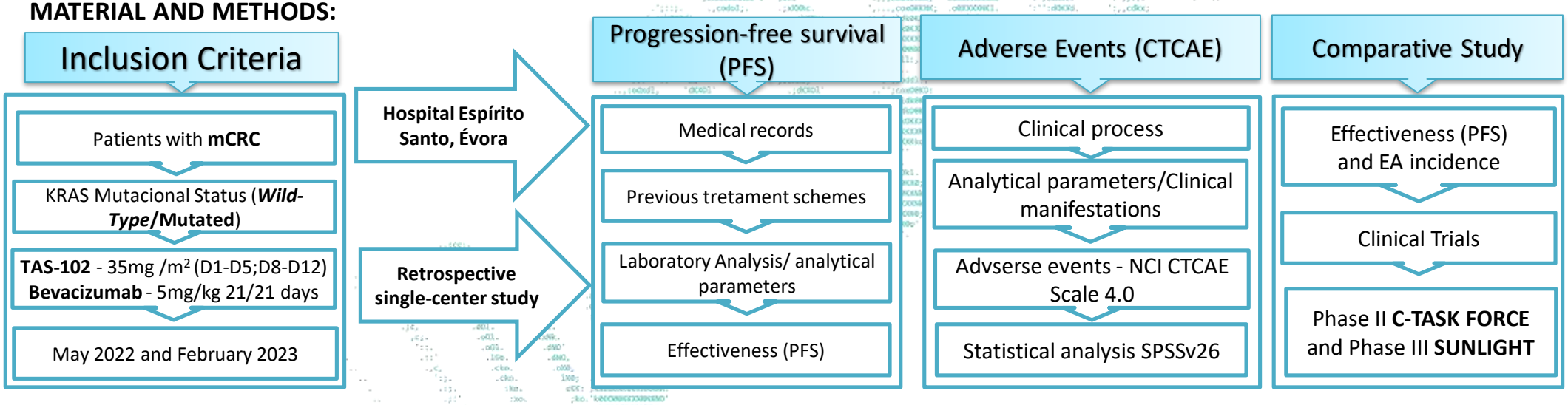
INTRODUCTION: Trifluridine/Tipiracil and Bevacizumab is a novel combination therapy for the treatment of adults with colorectal metastatic cancer (mCRC). Clinical Trials showed promissing efficacy and therapeutic superiority of this association, theoretically by increasing the plasmatic concentration of active drug metabolites, resulting in a increased toxicity.

OBJETIVES: We aimed to performed a retrospective real-world study to evaluate the effectiveness and toxicity profile of TAS-BEVA association in patients with mCRC.

MATERIAL AND METHODS:



RESULTS: Eligible population with **CRCm treated with TAS-BEVA, included 8** patients, 62% male, the average age was **66 years old** (48-84), ECOG≤1, **63%** KRAS *wild-type*. Patients was previously treated with 3 prior systemic treatment regimens for advanced disease and were treated in average **4,9 mouths** wtith **TAS-BEVA**. The population demographic, anthropometric and baseline disease characteristics are summarized on Table 1.

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Population Characteristics (n = 8)		
Gender	Female	3 (38%)
	Male	5 (62%)
Mean = 66 years-old (48-84)		
Age	>65 years	4 (50%)
	<65 years	4 (50%)
ECOG	PS 0	2 (25%)
	PS 1	6 (75%)
> 3 average systemic treatment regimens		
Previous Treatment	Anti-VEGF	7 (88%)
	Anti-EGFR	1 (12%)
KRAS Status	Wild-type	5 (63%)
	Mutated	3 (37%)

Table 1: Population Characteristics

Significant survival benefit of TAS-BEVA was observed. A median progression-free survival (PFS) of **5,1 months vs 3,7 and 2,2 months, SUNLIGHT and C-TASK FORCE Trials, respectively**. The comparison between the present study and the Clinical Trials that recommended the therapeutical association TAS-BEVA is represented on **Figure 1**.

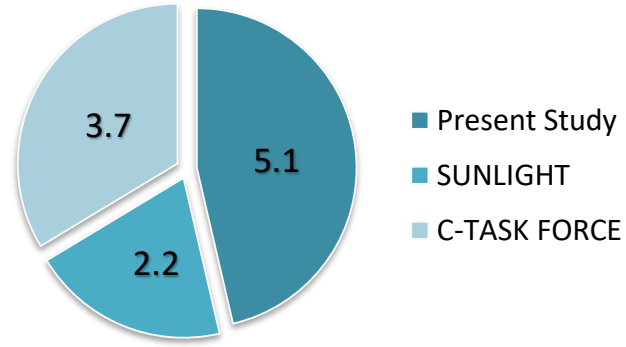

Figure 1: PFS Clinical Trials vs Present Study

	Present Study	C-TASK FORCE Trial	SUNLIGHT Trial
Adverse Events Grade>3	73%	72%	69%
Thrombocytopenia Grade <3	50%	12%	5%
Neutropenia Grade ≤3	100%	72%	38%
Neutropenia Grade>4	40%	16%	4%
Leucopenia Grade>3	80%	44%	-
Anemia	60%	16%	18%

Table 2: Security profile of TAS-Bevacizumab

DISCUSSION/CONCLUSIONS: The evaluation of **Real World Data** regarding new therapies is extremely important to guarantee the rational drug use assuring safety and efficacy of innovative therapies or those for which limited literature is available. In this study a higher incidence of **severe Adverse Events** was recorded in comparison to the Clinical Trials that leads to TAS-BEVA recommendation in guidelines. However, this study revealed a clinical benefit of the combined therapy with a median PFS of **5,1 months**, when compared to data described in C-TASK FORCE and SUNLIGHT Trials (3,7 and 2,2, respectively). The aim is to prospectively assess the veracity of the therapeutic superiority described in these trials.

REFERENCES:

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