PATIENT BASELINE CHARACTERISTICS IN THE PROMETCO STUDY: A REAL-WORLD, PROSPECTIVE LONGITUDINAL COHORT ON THE CONTINUUM OF CARE OF METASTATIC COLORECTAL CANCER

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PROMETCO

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INTRODUCTION

- Tumour shrinkage and disease control are the primary treatment goals for patients with metastatic colorectal cancer (mCRC).[1] When not possible, emphasis lies in slowing disease progression and prolonging survival[1]
- While advances in the treatment of mCRC have improved survival to an average of 30 months in randomised clinical trials,[1] there is still a paucity of data applicable to real-world patient populations
- PROMETCO (NCT03935763) is the first international, prospective real-world study to investigate the continuum of care in the mCRC patient population, collecting data on all patients regardless of treatment
- PROMETCO will evaluate the overall survival of patients with mCRC, the patterns, effectiveness and safety of mCRC treatments, the reasons behind changes or discontinuation in treatment, adherence to treatment guidelines, healthcare resource utilisation and patient-reported outcomes (PROs)
- One major goal is to capture the patient and physician perspectives with the aim of improving/maintaining quality of life and treatment management

AIM

- To present initial baseline characteristics of the first 277 patients by biomolecular status from the PROMETCO trial, as per the cut-off date

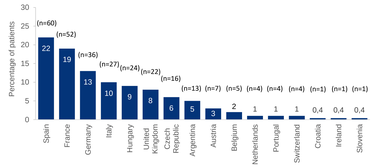
RESULTS

Overall study population

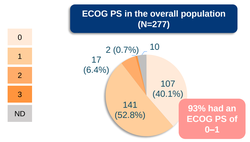
Baseline demographics

	All (N=276)*
Age, years Mean	66
Median (min, max)	67 (33, 86)
Sex, n (%) Female	121 (44)
Male	155 (56)

*Missing data in 'All'=1



ECOG PS¶



- 248 (93%) patients in the overall study population had an ECOG PS of 0–1
- Values were similar in the *RAS/BRAF* and MSI groups (centre/right columns of the poster, respectively)

¶Percentage based on n observed per group (i.e. not including ND values)

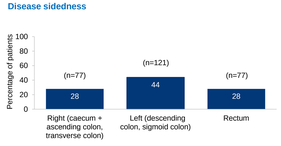
Baseline disease characteristics

- The majority of patients had <3 metastatic sites, with synchronous metastases being the most prevalent
- Metastatic liver and lung disease had the highest incidence, while a higher prevalence of left-sided disease was seen overall

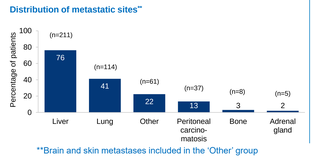
Disease characteristic	All (N=277)
Number of metastatic sites‡, n (%) <3 ≥3	243 (88.4) 32 (11.6)
Type of metastasis§, n (%) Synchronous Metachronous	184 (66.7) 92 (33.3)
Time between mCRC diagnosis and PROMETCO inclusion, months Median (min, max)	22 (4, 104)

‡N=275 due to missing data; §N=276 due to missing data

Disease sidedness



Distribution of metastatic sites**

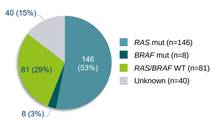


**Brain and skin metastases included in the 'Other' group

RAS/BRAF status¥

- Please note that the *BRAF* mutant and *RAS/BRAF* mutant groups did not yet have sufficient numbers to make an interpretation

Baseline demographics



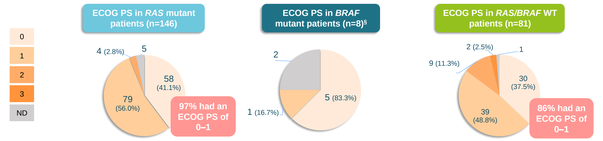
	All (N=276)*	*RAS* mutant (n=146)	*BRAF* mutant (n=7)†	*RAS/BRAF* WT (n=81)
Age, years Mean Median (min, max)	66 67 (33, 86)	67 68 (35, 86)	64 63 (57, 74)	64 66 (33, 84)
Sex, n (%) Female Male	121 (44) 155 (56)	74 (51) 72 (49)	4 (57) 3 (43)	23 (28) 58 (72)

*Missing data in 'All'=1; †missing data for *BRAF* mutant=1

- The *RAS/BRAF* wild type (WT) group had a higher proportion of males (58/81; 72%)

¥40 (15%) had an unknown *RAS/BRAF* status, and two patients were *RAS/BRAF* mutant

ECOG PS¶



¶Percentage based on n observed per group (i.e. not including ND values); §did not yet have sufficient numbers to make an interpretation

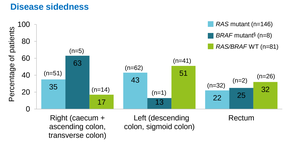
Baseline disease characteristics

- *RAS/BRAF* data on metastatic sites, type, distribution and sidedness mirrored the overall population

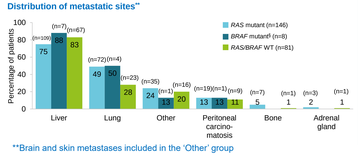
Disease characteristic	All (N=276)*	*RAS* mutant (n=146)	*BRAF* mutant (n=8)§	*RAS/BRAF* WT (n=81)
Number of metastatic sites‡, n (%) <3 ≥3	243 (88.4) 32 (11.6)	125 (86.2) 20 (13.8)	7 (87.5) 1 (12.5)	76 (93.8) 5 (6.2)
Type of metastasis, n (%) Synchronous Metachronous	184 (66.7) 92 (33.3)	99 (67.8) 47 (32.2)	3 (37.5) 5 (62.5)	55 (67.9) 26 (32.1)
Time between mCRC diagnosis and PROMETCO inclusion, months Median (min, max)	22 (4, 104)	21 (4, 104)	23 (7, 28)	22 (6, 89)

*Missing data in 'All'=1; §did not yet have sufficient numbers to make an interpretation; ‡N=275 due to missing data

Disease sidedness



Distribution of metastatic sites**

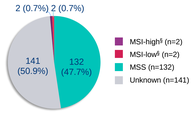


**Brain and skin metastases included in the 'Other' group

MSI status#

- Please note that the low/high MSI groups did not yet have sufficient numbers to make an interpretation

Baseline demographics

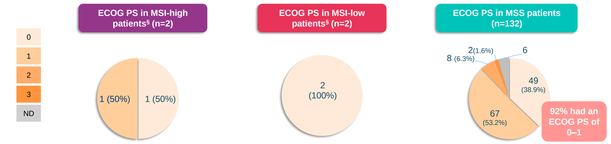


#‡141 patients had an unknown MSI status

	All (N=276)*	MSI-high§ (n=2)	MSI-low§ (n=2)	MSS^ (n=131)
Age, years Mean Median (min, max)	66 67 (33, 86)	60 60 (60, 60)	57 57 (49, 65)	66 67 (34, 86)
Sex, n (%) Female Male	121 (44) 155 (56)	1 (50) 1 (50)	0 (0) 2 (100)	59 (45) 72 (55)

*Missing data in 'All'=1; §did not have yet sufficient numbers to make an interpretation; ^Missing data for MSS=1

ECOG PS¶



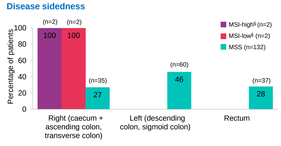
¶Percentage based on n observed per group (i.e. not including ND values); §did not yet have sufficient numbers to make an interpretation

Baseline disease characteristics

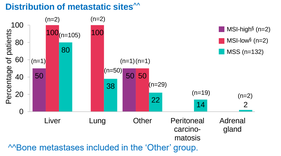
Disease characteristic	All (N=276)*	MSI-high† (n=2)	MSI-low§ (n=2)	MSS (n=132)
Number of metastatic sites‡, n (%) <3 ≥3	242 (88.3) 32 (11.7)	2 (100) 0	1 (50) 1 (50)	119 (90.2) 13 (9.8)
Type of metastasis†, n (%) Synchronous Metachronous	183 (66.5) 92 (33.3)	1 (50) 1 (50)	1 (50) 1 (50)	91 (68.9) 41 (31.1)
Time between mCRC diagnosis and PROMETCO inclusion, months Median (min, max)	22 (4, 104)	17 (10, 23)	43 (22, 66)	22 (4, 99)

*Missing data in 'All'=1; §did not yet have sufficient numbers to make an interpretation; ‡N=274 due to missing data; †N=275 due to missing data

Disease sidedness



Distribution of metastatic sites^^



^^Bone metastases included in the 'Other' group.

Abbreviations: CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; max, maximum; mCRC, metastatic colorectal cancer; min, minimum; MSI, microsatellite instability; MSS, microsatellite stable; ND, not determined; WT, wild-type.

METHOD

- Enrolment in PROMETCO began in March 2019. On 1 October 2020, baseline demographics and disease characteristics from 277 mCRC patients (of the 1000 expected) from 16 countries were analysed:
  - **Inclusion** criteria**:** adult patients with two disease progressions since the first diagnosis of metastatic disease who were willing to receive subsequent treatment
  - **Exclusion** criteria**:** patients enrolled in other clinical trials, those receiving treatment for other cancers or those with insufficient mental capacity
- Patients were categorised by their biomolecular status (*RAS/BRAF* or microsatellite instability [MSI]) and analysed by age, sex, Eastern Cooperative Oncology Group performance status (ECOG PS), metastatic status and location (side) of disease
- Descriptive statistics were employed to address the study objectives. Continuous variables have been summarised using mean, median and range. Categorical variables are reported as number and percentage of patients

TAKE-HOME MESSAGES

- Preliminary data from the PROMETCO trial provide key insights as to the baseline demographics, disease characteristics and molecular status of real-world mCRC patients
- *RAS/BRAF* molecular testing is routinely performed (with only 15% having an unknown status). However, for MSI molecular testing, there is a significant proportion with an unknown status (50.9%) which could potentially influence the choice of treatment and subsequent treatment sequencing
- The mean age at diagnosis for the overall study population is 66 years, which is in line with the high range reported in a systematic literature review of seven clinical studies (age range, 56–67)[2]
- Tumours on the right side occur less frequently (28.0–44.0%) than on the left, in this initial assessment of the population. This is in line with a subgroup analysis of 12 randomised trials (26.0–73.9%). Further analysis on a larger population will be interesting to determine sidedness/mutational status and how this affects treatment sequence and prognostic features[3]
- It is anticipated that PROMETCO will provide valuable data on overall survival, treatment patterns, effectiveness, safety, adherence to treatment guidelines, healthcare resource utilisation and PROs in this patient population

REFERENCES

1. Van Cutsem E, Cervantes A, Adam R, et al. Ann Oncol. 2016;27(8):1386–1422. **2.** Walter T, Hawkins NS, Pollock RF, et al. J Cancer Res Clin Oncol. 2020;146(10):2575-2587. **3.** Yin J, Cohen R, Jin Z, et al. [published online ahead of print, 2021 Jun 1]. J Natl Cancer Inst. 2021;djab112.

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