HSD106

Metastatic Colorectal Cancer (mCRC) Patients Treated With Later Lines of Treatment (LOTs): A Retrospective Analysis by Race and Ethnicity in the United States (US) Community Oncology Setting

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BACKGROUND AND RATIONALE

- There are an estimated 152,810 new cases of CRC and an estimated 53,010 deaths in the US expected in 2024.[1] Approximately 50% to 60% of patients diagnosed with CRC develop metastatic disease.[2,3]
- Although sequencing of therapies has been evaluated in clinical trials, literature on sequencing of therapies in the real world is limited.[4-6]
- REGO and trifluridine/tipiracil (FTD/TPI) have been shown to extend overall survival in patients with mCRC who are refractory to standard therapies.[7] REGO and FTD/TPI have been found to have similar efficacy, but real-world data on sequencing of these therapies have mainly been generated in non-US populations.[8,9]
- The objective of this study was to analyze data from community oncology practices to understand patient characteristics, treatment patterns, and clinical outcomes among patients who received REGO or FTD/TPI for mCRC in the US community setting and the differences between racial and ethnic minority groups

METHODS

STUDY DESIGN

- Retrospective, observational cohort study of adult patients with mCRC initiating REGO or FTD/TPI in any line within The US Oncology Network between 01 September 2015 and 30 November 2022. Study-eligible patients were followed longitudinally until 31 May 2023, last patient record, or date of death, whichever occurred first.

DATA SOURCE

- Data were sourced through query of The US Oncology Network's iKnowMed (iKM) electronic health record (EHR) system.
- The US Oncology Network includes 1,300 affiliated physicians operating in over 480 sites of care across the US, with approximately 1.2 million US cancer patients treated annually.[10]
- Additional vital status information was obtained from the Social Security Administration's Limited Access Death Master File.

Inclusion criteria	Exclusion criteria
• Patients with a diagnosis of mCRC and aged ≥18 years at first diagnosis of CRC • Initiated REGO or FTD/TPI during the study identification period and after metastatic date; index date is considered the earliest date of initiation • Received care (including ≥2 office visits) at a US Oncology Network site during the follow-up period, utilizing the full EHR capacities of the iKM database at the time of treatment, and whose data were accessible for research purposes	• Patients enrolled in an interventional clinical trial during the study observation period • Receipt of an anticancer treatment indicated for another primary cancer diagnosis (except basal cell carcinoma and squamous cell carcinoma) during the study observation period

DATA ANALYSIS

- Descriptive methods were used to describe patient, clinical, and treatment characteristics.
- Line of therapy (LOT) was assigned using an algorithm based on a previously published method.[11]

RESULTS

PATIENT CHARACTERISTICS

- Among 2,684 mCRC patients initiating REGO or FTD/TPI in any LOT, 1,599 were White and 556 were from racial and ethnic minority groups (Black, Hispanic or Latino, or Asian).
- The mean ages were 63 and 62 years, respectively, in white patients and racial and ethnic minority patients (**Table 1**).
- The median duration of follow-up was 6.5 and 6.2 months, respectively, in White patients and racial and ethnic minority patients (**Table 1**).
- The median time from metastatic diagnosis of CRC to index date was 20.9 months for white patients and 19.8 months for racial and ethnic minority patients (**Table 1**).

Table 1. Demographic and clinical characteristics of patients with mCRC who initiated REGO and/or FTD/TPI by race and ethnicity

Variable	Minority patients (n=556)	White patients (n=1,599)
Age at baseline (years)		
Mean (SD)	61.6 (11.5)	63.1 (11.6)
Min, max	30, 90+	27, 90+
Age group at baseline, n (%)		
65+	208 (37.4)	707 (44.2)
<65 years	348 (62.6)	892 (55.8)
Gender, n (%)		
Male	305 (54.9)	883 (55.2)
Ethnicity, n (%)		
Hispanic or Latino	159 (28.6)	0 (0.00)
Not Hispanic or Latino	359 (64.6)	1,599 (100.0)
Not documented	38 (6.8)	0 (0.0)
Duration of follow-up (months)		
Median (min, max)	6.2 (0.5, 85.0)	6.5 (0.3, 90.9)
IQR	3.3, 10.9	3.6, 12.0
ECOG at baseline (± 30 days from index date), n (%)		
0	53 (9.5)	181 (11.3)
1	252 (45.3)	774 (48.4)
2+	46 (8.3)	188 (11.8)
Not documented	205 (36.9)	456 (28.5)
Time from metastatic CRC diagnosis to index date (months)		
Median (min, max)	28.2 (0.0, 113.2)	20.9 (0.0, 245.7)
Initial cancer diagnosis, n (%)		
Colon cancer	439 (79.0)	1,160 (72.5)
Rectal cancer	117 (21.0)	439 (27.5)
Distant metastatic sites, n (%)		
Bone	17 (3.1)	46 (2.9)
Liver	171 (30.8)	572 (35.8)
Lung	108 (19.4)	302 (18.9)
Other	95 (17.1)	256 (16.0)

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TREATMENT PATTERNS

- White patients most frequently initiated REGO in LOT4 (15.7%) and FTD/TPI in LOT4 (17.1%), while racial and ethnic minority patients most frequently initiated REGO in LOT3 (16.2%) and FTD/TPI in LOT4 (18.5%) (**Table 2**).
- The most common prior chemotherapy regimens were FOLFIRI-based (White, 60%; racial and ethnic minority, 66%) and FOLFOX-based regimens (White, 50%; racial and ethnic minority, 54%) (**Table 2**).
- The majority of patients had previous exposure to anti-VEGF therapy (White, 80%; racial and ethnic minority, 81%), of which bevacizumab was the most common agent (White 78%, racial and ethnic minority 80%) (**Table 2**).

Table 2. Treatment patterns of patients with mCRC that initiated REGO and/or FTD/TPI by race and ethnicity

Variable	Minority patients (n=556)	White patients (n=1,599)
Drug initiated first, n (%)		
Both	4 (2.2)	20 (3.7)
FTD/TPI	91 (49.7)	243 (45.3)
REGO	88 (48.1)	273 (50.9)
REGO LOT, n (%)		
LOT1	16 (2.9)	35 (2.2)
LOT2	32 (5.8)	80 (5.0)
LOT3	90 (16.2)	230 (14.4)
LOT4	83 (14.9)	251 (15.7)
LOT5	56 (10.1)	189 (11.8)
LOT6	27 (4.9)	106 (6.6)
LOT 7-10	27 (4.9)	117 (7.3)
LOT 10+	3 (0.5)	7 (0.4)
Not Documented	222 (39.9)	584 (36.5)
FTD/TPI LOT, n (%)		
LOT1	16 (2.9)	29 (1.8)
LOT2	36 (6.5)	102 (6.4)
LOT3	100 (18.0)	232 (14.5)
LOT4	103 (18.5)	274 (17.1)
LOT5	72 (13.0)	227 (14.2)
LOT6	38 (6.8)	124 (7.8)
LOT 7-10	37 (6.7)	123 (7.7)
LOT 10+	3 (0.5)	9 (0.6)
Not Documented	151 (27.2)	479 (30.0)
Prior systemic therapies (received after mCRC date), n (%)		
Anti-VEGF[a]	452 (81.3)	1,271 (79.5)
Bevacizumab monotherapy	9 (1.6)	44 (2.8)
Immuno-oncology[b]	10 (1.8)	34 (2.1)
Anti-EGFR therapy[c]	154 (27.7)	531 (33.2)
FOLFOXIRI-based[d]	20 (3.6)	66 (4.1)
FOLFIRI-based[e]	369 (66.4)	955 (59.7)
FOLFOX-based[f]	299 (53.8)	809 (50.1)

[a] Bevacizumab, ramucirumab, ziv-aflibercept. [b] Atezolizumab, avelumab, cemiplimab, durvalumab, ipilimumab, nivolumab, or pembrolizumab. [c] Cetuximab or panitumumab. [d] Fluorouracil, leucovorin, irinotecan, oxaliplatin; may be in combination. [e] Fluorouracil, leucovorin, irinotecan; may be in combination, cannot include oxaliplatin. [f] Fluorouracil, leucovorin, oxaliplatin; may be in combination, cannot include irinotecan.

TREATMENT CHARACTERISTICS

- Treatment durations of REGO and FTD/TPI were similar between White and minority patients, with longer durations achieved when a respective drug was used earlier in treatment sequencing (**Table 3 and Table 4**).

Table 3. Regimen duration of patients with mCRC who have >1 order of REGO and/or FTD/TPI by race and ethnicity

Variable	Minority patients (n=556)	White patients (n=1,599)
REGO regimen duration (months)		
Median (min, max)	1.87 (0.07, 15.67)	1.64 (0.07, 22.54)
FTD/TPI regimen duration (months)		
Median (min, max)	2.04 (0.07, 19.19)	2.07 (0.07, 24.28)

Table 4. Regimen duration of patients with mCRC who initiated both REGO and FTD/TPI by race and ethnicity

Variable	Minority patients (n=556)	White patients (n=1,599)
REGO regimen duration based on sequence (months)		
REGO initiated first, median (min, max)	1.87 (0.07, 15.67)	2.02 (0.07, 13.77)
REGO initiated second, median (min, max)	1.81 (0.07, 9.53)	1.41 (0.07, 22.54)
FTD/TPI regimen duration based on sequence (months)		
FTD/TPI initiated first, median (min, max)	2.60 (0.07, 17.08)	2.63 (0.07, 22.67)
FTD/TPI initiated second, median (min, max)	1.76 (0.07, 16.03)	1.69 (0.07, 19.55)

CONCLUSIONS

LIMITATIONS

- The iKM system is used for clinical practice reasons, not solely for research.
- Exact date of oral medication discontinuation may not be assessed at high completeness using structured data.

KEY TAKEAWAYS

- Within The US Oncology Network database, baseline demographic and clinical characteristics were similar between White and racial and ethnic minority group.
- There appears to be a trend of earlier initiation of REGO among minority patients. Prior systemic therapies received and duration of REGO and FDT/TPI therapy were similar between the groups.
- Further research on clinical outcomes in White and racial and ethnic minority populations is necessary.

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