EE639

Real-World Healthcare Resource Utilization in Patients With Metastatic Colorectal Cancer Treated With Trifluridine/Tipiracil Plus Bevacizumab or With Regorafenib

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OBJECTIVE

- To describe real-world healthcare resource utilization (HCRU) in patients with previously treated metastatic colorectal cancer (mCRC) receiving trifluridine/tipiracil with bevacizumab (FTD/TPI+BEV) or regorafenib (REG).

CONCLUSIONS

- In this real-world study, mean monthly HCRU, including outpatient, inpatient, and emergency room (ER) visits, was similar between patients with mCRC treated with FTD/TPI+BEV and patients treated with REG, suggesting equivalent HCRU across cohorts.

Background

- mCRC remains a leading cause of cancer-related mortality worldwide.[1]
- Few well-tolerated treatment options are available for patients with mCRC who are refractory to first-line and second-line treatment.[2,3]
- FTD/TPI+BEV and REG are approved treatments for mCRC in the third-line setting or later.[2,3]
- FTD/TPI+BEV and REG have different toxicity profiles, supportive care needs, and, for BEV, administration routes, which may influence HCRU, although data are limited.[2,3]
- Understanding the real-world HCRU associated with these therapies is critical for informing treatment decisions, optimizing care delivery, and guiding health economic evaluations.

Methods

Study design

- This retrospective study of US claims data from the Komodo Healthcare Map database included patients with mCRC who received FTD/TPI+BEV or REG between January 1, 2021, and May 31, 2024.
- Index date was defined as the first qualifying treatment claim for FTD/TPI+BEV or REG among patients who satisfied all inclusion criteria.
- A baseline period of 18 months prior to the index date was used to characterize the study population.
- Patients were followed from their index date until death, disenrollment, or end of study period—whichever occurred first.

Patients and cohorts

- Patients were included if they met the following criteria:
  - A diagnosis claim for CRC between January 1, 2016, and August 30, 2024, with a metastatic diagnosis code within 30 days before, on the same date, or any time after first eligible CRC claim.
  - Treatment with FTD/TPI+BEV or REG after the mCRC diagnosis date and between January 1, 2021, and May 31, 2024. For combination therapy, patients must have received ≥1 claim for FTD/TPI and ≥1 claim for BEV within 28 days of each other (with the date of latter claim for FTD/TPI or BEV considered the first qualifying claim).
  - Patients with prior treatment (nonindex therapy) for mCRC (chemotherapy, anti–vascular endothelial growth factor therapy, or targeted therapy) during the baseline period.
  - No claims for either FTD/TPI+BEV or REG during the baseline period.
  - No other primary cancer diagnoses prior to the index date.
  - Continuous enrollment in medical and drug insurance plans during the baseline period (enrollment gap up to 45 days allowed).
  - Aged ≥18 years at index date.
- Index cohorts were defined as (1) patients receiving FTD/TPI+BEV and (2) patients receiving REG.

Outcomes and statistical analyses

- Patient demographics were evaluated at index, and clinical characteristics were evaluated during the baseline period.
- All-cause, mCRC-related, and adverse event (AE)–related healthcare visits per patient per month (PPPM) were evaluated during postindex follow-up.
  - mCRC and AE-related HCRU was captured by claims with an mCRC or prespecified AE diagnosis in any (principal or secondary) diagnosis position.
  - AEs of interest were limited to those identifiable via code-based algorithms and included anemia, arterial embolism event, asthenia/fatigue, dysgeusia, gastrointestinal perforation, hand-foot syndrome, hypertension, leukopenia, myocardial infarction, neutropenia, intestinal obstruction, proteinuria, stomatitis, stroke, and thrombocytopenia.
- Continuous variables were described using means, SD, medians, and interquartile ranges, whereas frequencies and percentages were used for categorical variables.

Results

Study population and patient characteristics

- The study included 1585 patients treated with FTD/TPI+BEV and 1494 with REG.
- Patient demographic and clinical characteristics were similar between cohorts (**Tables 1 and 2**).
- Median age was 57.0 years for patients treated with FTD/TPI+BEV vs 58.0 years for patients treated with REG; 56.4% vs 56.8% of patients were male, and 44.9% vs 40.6% were White (**Table 1**).
- The highest proportion of patients treated with FTD/TPI+BEV had their index year in 2023 (40.8%); for patients treated with REG, the most frequent index year was 2021 (44.8%).
- The majority of patients in each cohort had commercial insurance (58.9% for FTD/TPI+BEV and 50.7% for REG).

Table 1. Patient demographics at index

Demographic	FTD/TPI+BEV (n=1585)	REG (n=1494)
Age, median (IQR), years	57.0 (50.0-63.0)	58.0 (52.0-64.0)
Age group, n (%), years		
18-45	230 (14.5)	151 (10.1)
46-64	1049 (66.2)	990 (66.3)
≥65	306 (19.3)	353 (23.6)
Sex, n (%)		
Female	677 (42.7)	629 (42.1)
Male	894 (56.4)	849 (56.8)
Unknown/missing	14 (0.9)	16 (1.1)
Race/ethnicity, n (%)		
Asian or Pacific Islander	86 (5.4)	86 (5.8)
Black or African American	193 (12.2)	246 (16.5)
Hispanic or Latino	185 (11.7)	204 (13.7)
White	711 (44.9)	607 (40.6)
Other	78 (4.9)	72 (4.8)
Unknown/missing	332 (20.9)	279 (18.7)
Payer, n (%)		
Commercial	933 (58.9)	758 (50.7)
Managed Medicaid	333 (21.0)	362 (24.2)
Medicare	49 (3.1)	53 (3.5)
Medicare Advantage	268 (16.9)	318 (21.3)
Unknown/missing	2 (0.1)	3 (0.2)
Region, n (%)		
Northeast	344 (21.7)	310 (20.7)
Midwest	401 (25.3)	284 (19.0)
South	564 (35.6)	627 (42.0)
West	272 (17.2)	264 (17.7)
Unknown	4 (0.3)	9 (0.6)
Index year, n (%)		
2021	342 (21.6)	669 (44.8)
2022	385 (24.3)	472 (31.6)
2023	646 (40.8)	306 (20.5)
2024	212 (13.4)	47 (3.1)

BEV, bevacizumab; FTD/TPI, trifluridine/tipiracil; REG, regorafenib.

Table 2. Clinical characteristics during the 18-month preindex baseline period

Characteristic	FTD/TPI+BEV (n=1585)	REG (n=1494)
Therapies received prior to index, n (%)		
Chemotherapy	1555 (98.1)	1467 (98.2)
Fluoropyrimidine	1498 (94.5)	1400 (93.7)
Oxaliplatin	1428 (90.1)	1311 (87.8)
Irinotecan	995 (62.8)	921 (61.6)
Anti-VEGF therapy	1322 (83.4)	1098 (73.5)
BEV	1320 (83.3)	1088 (72.8)
Other	17 (1.1)	52 (3.5)
Other targeted therapy	556 (35.1)	540 (36.1)
EGFR	517 (32.6)	502 (33.6)
dMMR/MSI-H	48 (3.0)	54 (3.6)
BRAF	39 (2.5)	20 (1.3)
Other	17 (1.1)	17 (1.1)
CCI, median (IQR)	**8.0 (7.0-9.0)**	**8.0 (7.0-9.0)**
Comorbidities included in the CCI, n (%)[a]		
Metastatic solid tumor	1573 (99.2)	1480 (99.1)
Mild liver disease	932 (58.8)	855 (57.2)
Peripheral vascular disease	488 (30.8)	472 (31.6)
Chronic pulmonary disease	328 (20.7)	342 (22.9)
Diabetes with chronic complication	196 (12.4)	220 (14.7)
Diabetes without chronic complication	189 (11.9)	210 (14.1)
Renal disease	165 (10.4)	195 (13.1)
Congestive heart failure	104 (6.6)	172 (11.5)
Other comorbidities of interest, n (%)		
Hypertension	979 (61.8)	1022 (68.4)
Cardiovascular disease	798 (50.3)	789 (52.8)
Obesity	515 (32.5)	518 (34.7)
Venous thromboembolism	405 (25.6)	366 (24.5)
History of tobacco use, n (%)	269 (17.0)	263 (17.6)

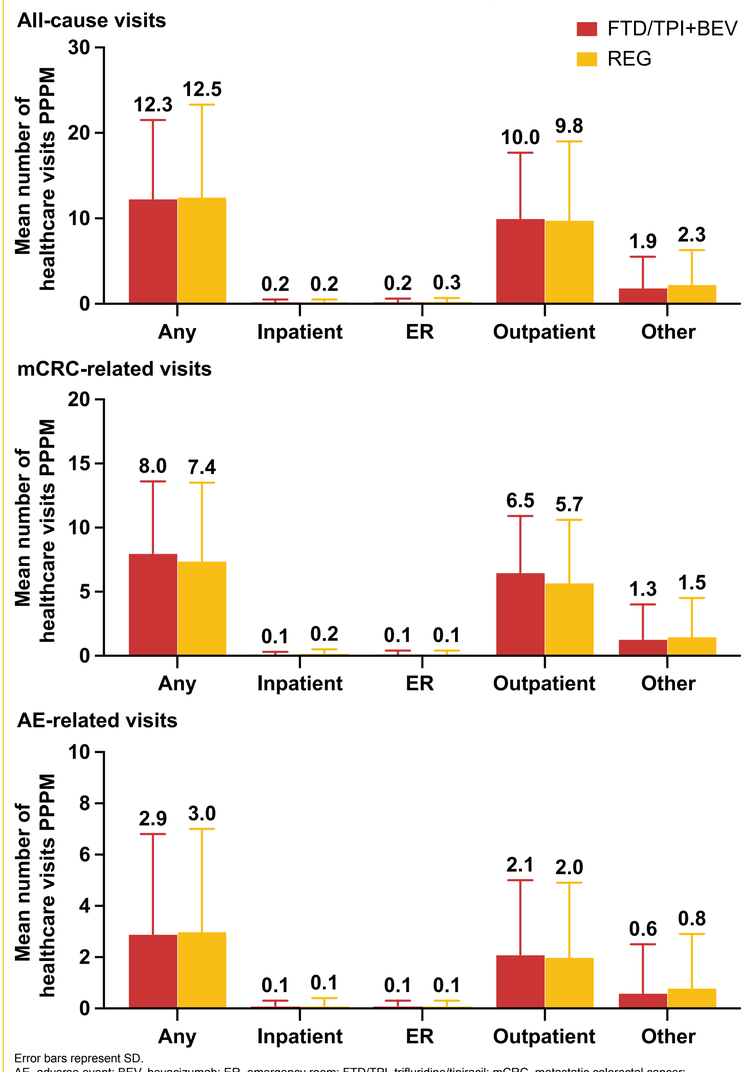
[a]Only comorbidities observed in >10% of patients in either cohort are presented.
BEV, bevacizumab; BRAF, B-Raf proto-oncogene, serine/threonine kinase; CCI, Charlson Comorbidity Index; dMMR, deficient mismatch repair; EGFR, epidermal growth factor receptor; FTD/TPI, trifluridine/tipiracil; MSI-H, microsatellite instability-high; REG, regorafenib; VEGF, vascular endothelial growth factor.

- Median Charlson Comorbidity Index score was 8.0 for patients in both cohorts; metastatic solid tumor, moderate or severe liver disease, and hypertension were the most common comorbidities in both cohorts (**Table 2**).
- Prior BEV use was reported in 83.3% of patients treated with FTD/TPI+BEV vs 72.8% of patients treated with REG.
- Other prior targeted therapy use was reported in 35.1% of patients treated with FTD/TPI+BEV vs 36.1% of patients treated with REG, including 32.6% vs 33.6%, respectively, with prior epidermal growth factor receptor therapy use.
- Overall, 35.1% of patients treated with FTD/TPI+BEV and 34.8% treated with REG had an AE of interest during treatment; the most common AEs were asthenia (in 10.5% of patients with FTD/TPI+BEV and in 14.5% of patients with REG) and anemia (in 8.5% of patients with FTD/TPI+BEV and in 8.2% of patients with REG). Discontinuation due to AEs occurred in 21.9% of patients with FTD/TPI+BEV and in 21.2% with REG.

HCRU during follow-up

- Mean (SD) follow-up was 217.6 (185.0) days for FTD/TPI+BEV and 240.4 (214.6) days for REG.
- Mean (SD [median]) number of total all-cause healthcare visits PPPM during follow-up was 12.3 (9.2 [9.7]) for FTD/TPI+BEV and 12.5 (10.8 [9.7]) for REG. This included mean outpatient (10.0 vs 9.8), inpatient (0.2 vs 0.2), and ER visits (0.2 vs 0.3).
- Results were similar for mean mCRC-related visits (all visits, for FTD/TPI +BEV vs REG: 8.0 vs 7.4; outpatient, 6.5 vs 5.7; inpatient, 0.1 vs 0.2; ER, 0.1 vs 0.1) and AE-related visits (all visits, for FTD/TPI+BEV vs REG: 2.9 vs 3.0; outpatient, 2.1 vs 2.0; inpatient, 0.1 vs 0.1; ER, 0.1 vs 0.1).

Figure 1. Mean number of all-cause, mCRC-related, and AE-related healthcare visits PPPM during follow-up



Error bars represent SD.
AE, adverse event; BEV, bevacizumab; ER, emergency room; FTD/TPI, trifluridine/tipiracil; mCRC, metastatic colorectal cancer; PPPM, per patient per month; REG, regorafenib.

Limitations

- This study utilized a claims dataset, which may be subject to coding errors and incomplete data that may lead to a degree of misclassification of treatments and HCRU in this study.
- Claims data do not capture important clinical information, such as disease severity, performance status, or treatment response, which may influence HCRU.
- AE-related visits in this study are restricted to those visits associated with the prespecified AEs and may not capture the full scope of AE-related HCRU.
- Differences in index year between cohorts may have resulted in uneven follow-up times and impacted HCRU, because clinical practices may have evolved over time.
- The COVID-19 pandemic may have affected results in this study due to changes in social behavior or healthcare access that occurred during the observation period.

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