RWD239

Advancing Colorectal Cancer (CRC) Research in Japan: Insights from Electronic Health Record (EHR)-Derived Data in Japan

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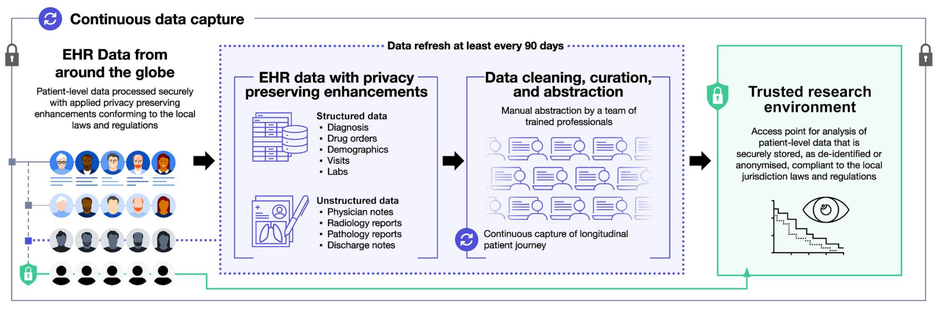
Background

- Understanding real-world patient characteristics, treatment patterns, and outcomes for colorectal cancer (CRC) in Japan has been limited by the lack of comprehensive, recent, and longitudinal data[1]
- Using EHR-derived real-world data (RWD), we examined patient clinical and demographic characteristics, biomarker testing rates and treatment patterns in a real-world Japanese cohort

Methods

- **Data source:** The Flatiron Health Research Database, an electronic health record (EHR)-derived, deidentified database comprising patient-level data originating from over 5 million patients around the world, including the US, Germany, UK, and Japan, and curated following the approach in Figure 1[2,3]

Figure 1. Flatiron Health Research Database Data Curation Approach



- **Eligibility criteria:** The study included 1,534 patients in Japan with a confirmed diagnosis of CRC (ie, abstraction-confirmed pathology, stage, etc.) between January 1, 2011 and March 31, 2025
- **Analyses:** We summarized the characteristics of the overall and metastatic CRC cohorts using descriptive statistics. Variables examined included:
  - **Clinical characteristics:** Age at diagnosis, birth sex, histology, clinical or pathological group stage, disease site, and Eastern Cooperative Oncology Group performance status (ECOG PS) score at first treatment
  - **Interventions**: Biomarker testing rates and results; treatment patterns utilizing Flatiron Health's oncology expert-defined, rules-based line of therapy variable

Results

Patient demographic and clinical characteristics for the overall CRC cohort and metastatic CRC cohort are presented in Table 1.

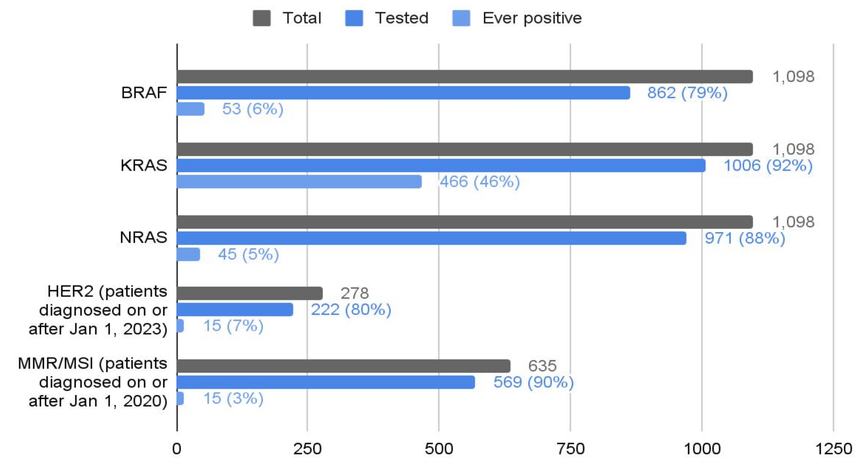
Table 1. Patient Characteristics

Characteristic	Overall (N=1534)	Metastatic CRC (N=1098)
Age, median (IQR), y	64 (54,71)	64 (53,71)
Sex, No. (%)		
Male	902 (59%)	641 (58%)
Histology, No. (%)		
Adenocarcinoma	1534 (100%)	1098 (100%)
Group stage[a], No. (%)		
Stage 0-I	148 (10%)	23 (2%)
Stage II	250 (16%)	105 (10%)
Stage III	386 (25%)	239 (22%)
Stage IV	709 (46%)	709 (65%)
Unknown	41 (3%)	22 (2%)
Disease Site, No. (%)[b]		
Left colon	620 (40%)	480 (44%)
Rectum	515 (34%)	305 (28%)
Right colon	390 (25%)	310 (28%)
Unknown	<=10	<=10
ECOG PS at first treatment, No. (%)[c]		
0	736 (48%)	510 (33%)
1	167 (11%)	141 (9%)
2+	28 (2%)	27 (2%)
Unknown	603 (39%)	420 (27%)

Abbreviations: IQR, interquartile range
[a]Aggregated group stage based on clinical and pathological stage data
[b]Counts are rounded to the nearest 5 to allow for masking of small counts for patient privacy.
[c]Patients with ECOG PS coded as 0-1 and 1-2 are reported as ECOG PS1 and 2, respectively

Results (continued)

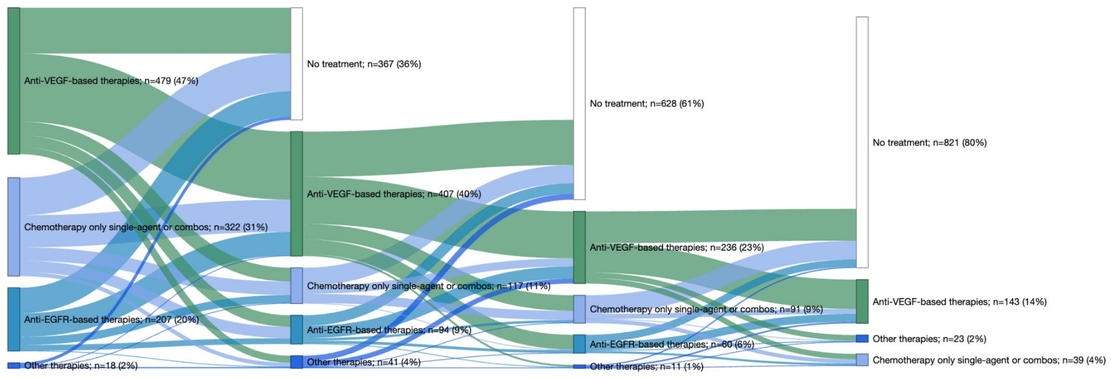
Figure 2. Biomarker Testing and Positivity Rates among mCRC patients



Note: BRAF, KRAS and NRAS testing rates were calculated for all patients regardless of diagnosis date. HER2 and MMR/MSI testing rates were calculated for a subset of patients diagnosed on or after Jan 1, 2023 and Jan 1, 2020, respectively, to account for the timing of approval in Japan and assumed lead time for adoption in the real-world setting. Positivity rates were calculated as the percentage of patients who ever tested positive among a denominator of patients with a record of receiving the biomarker test.

- The majority of patients (80%~) received standard-of-care CRC biomarker tests
- Biomarker testing and positivity rates were similar across disease sites, with the exception of higher KRAS-positivity observed in patients with disease in the right colon (56%) vs left colon (40%)

Figure 3. Treatment Patterns among patients with mCRC (1L~4L)



- Of 822 patients with Stage I~III disease at initial diagnosis, 756 (92%) received primary surgery; 158 (70%) patients with Stage III colon cancer (n=225) received adjuvant therapy
- Of 1098 patients with metastatic disease (both de novo and recurrent metastasis), 1026 (93%) received first-line systemic therapy
- The most commonly administered regimens in the top three therapy classes were:
  - **Anti-VEGF-based therapy**: bevacizumab + FOLFOX in 1L (43%), bevacizumab + FOLFIRI in 2L (31%), bevacizumab + tipiracil/trifluridine in 3L (52%)
  - **Chemotherapy only**: CapeOx +/- capecitabine in 1L (43%), FOLFIRI in 2L (29%), tipiracil/trifluridine in 3L (68%)
  - **Anti-EGFR-based therapy**: panitumumab + FOLFOX in 1L (80%), panitumumab + irinotecan in both 2L (29%) and 3L (76%)

Conclusions and Future Directions

- This is the first known study to examine detailed clinical characteristics, biomarker profiles, and treatment patterns, in a real-world cohort of patients diagnosed with CRC in Japan, using an EHR-derived real-world database
- The database contained clinical variables (group stage, disease site, histology etc.) with high completeness, and the characteristics and biomarker profile of this Japanese CRC cohort were largely consistent with clinical expectations[4-6]
- Secure analyses of EHR-derived, deidentified, patient-level Japanese RWD in a trusted research environment[7], in compliance with local legal and ethical requirements, will enable future research on real-world effectiveness and multinational evidence generation in furtherance of global CRC care

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