Abstract # 56

Real world data on treatment patterns of advanced CRC in 3rd line and beyond

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BACKGROUND

Regorafenib (REG – FDA approved Sept. 2012) and trifluridine/tipiracil (TT – FDA approved Sept. 2015) are among therapeutic options endorsed by the NCCN for the treatment of patients with advanced colorectal cancer (CRC).[1] Available clinical trial data has not established whether recycling of prior regimens (oxaliplatin/irinotecan /5FU) with exchange of biologics (bevacizumab, ziv-aflibercept, cetuximab, panitumumab) is superior to changing class of therapy with oral well tolerated agents such as REG and TT. TT has been identified as the more cost-effective of the two in this setting.[2] Here, we examine the patterns of use REG and TT in this patient population using real world evidence from a diverse of commercially insured patients in the USA.

METHODS

The Eviti® Connect decision support tool allows prospective treatment plan review for commercial payers, capturing detailed information on the clinical features of the proposed treatment plan and the insured patient.[3] Treatment plans submitted from January 2011 to October 2019 (n-101,804) were filtered to include only those for the treatment of advanced CRC as 3rd line of therapy or greater. The overall number of requests by drug was analyzed across all submitted treatment plans, both those approved and unapproved for reimbursement. Subsequent analysis was then limited to those treatment plans that included REG or TT, and then further limited to those that were approved for reimbursement.

RESULTS

Over this interval, 6325 treatment plans for 3124 patients were submitted as third line or greater treatment. Excluding growth factors, anti-emetics, and leucovorin, REG and TT were the 9th and 13th most frequently requested drugs in this clinical setting. Irinotecan was the most frequently requested drug in this setting at >10x the frequency of REG. Ramucirumab was requested more often than REG, and pembrolizumab, nivolumab, and ziv-aflibercept were more requested than TT (Figure 1).

Of these 6325 submitted plans, 352 (5.5%) were REG or TT, of which 332 were approved as they were compliant with FDA and/or NCCN indications or were justified due to issues specific to the patient (Table 1).

	REG	TT	TOTAL
Approved by payer	203	129	332
Not approved	14	15	29
TOTAL	217	144	361

Table 1: Number of plans submitted for REG and TT

Although REG constituted the majority of the approved treatment plans, the use of TT has increased over time (Figure 2). Among the 25 patients in this data set who received both drugs sequentially, 13 started with REG and 12 started with TT.

The trials that led to FDA approval of REG and TT were neither head to head nor identical in design, but the populations were similar.[4,5] The reported tumor control and survival outcomes reported in the registration trials of REG and TT are comparable (Figure 3).

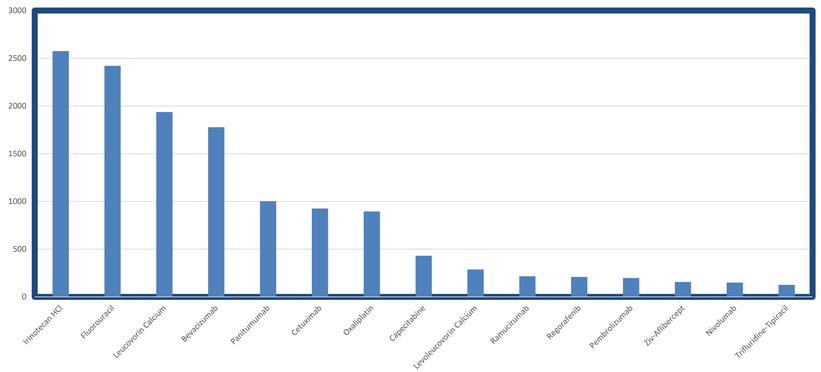

Figure 1: Drugs submitted in 3rd line or greater therapy of CRC

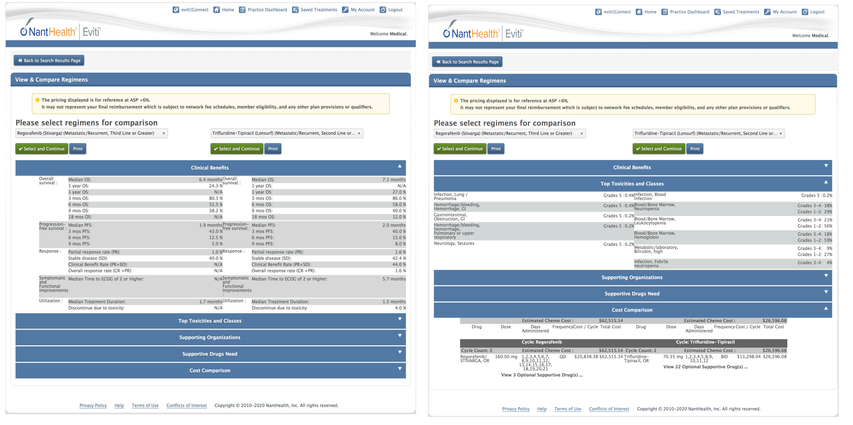

Figure 3: Reported clinical outcomes and estimated costs for use of REG and TT in CRC.[6]

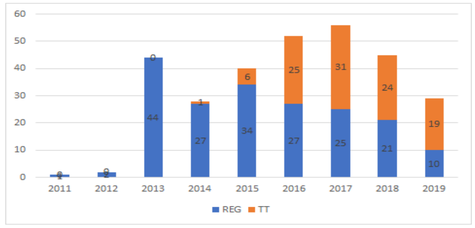

Figure 2: REG or TT - first use over time

CONCLUSIONS

Observed patterns of care in the 3rd line and later treatment of advanced CRC patients cannot be fully explained by clinical trial outcome differences, FDA/NCCN indications, or HEOR measures. Recycling of chemotherapy and biologics in the later line setting is common and occurs more frequently than switching to a drug regimen with proven activity in the resistant setting. Oral agents such as REG and TT appear to be underutilized in this setting. The lack of head to head data or biologic measures that identify optimal treatment selection among similar treatments may provide an opportunity for shared decision making or value-based care initiatives based on HEOR measures.

REFERENCES

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