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Early tumor shrinkage versus early response as a predictor for overall survival (OS) in patients with metastatic colorectal cancer (mCRC) treated with triplet chemotherapy regimens (TCR).

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Abstract:

**Background:** TCR with fluoropyrimidines, oxaliplatin(O) and Irinotecan (I) have shown better efficacy in term of response and survival in mCRC. Early tumor shrinkage (ETS), defined as ≥ 20% shrinkage in tumor size per RECIST criteria, have shown to be a predictive for progression free survival and overall survival in mCRC in patients treated with anti-EGFR therapy. We report here the predictive potential of ETS in patients with mCRC treated on our prospective phase I-II trial of the combination of Capecitabine (C), O, I, and bevacizumab (B). **Methods:** Eligible patient had locally advanced unresectable or mCRC. Patients received 5-8 cycles of the combination of C: 1,000 mg/m2 bid day1-14, O: 130 mg/m2 IV day 1, I: 150 mg/m2IV day 1 and B: 7.5 mg/kg bodyweight IV on day 1. Cycles repeated every 21 days. Patients with response or stable disease were then maintained on the combination of C and B till progression. Patients on the TCR had radiological assessment for response after cycles 2, 5, and 8 and then every 3 cycles. Tumor measurement according to RECIST criteria and at each CT evaluation was recorded for every patient. **Results:** 54 patients enrolled. Median age 52 years (range 23-74). 28 (52%) were males. Performance status 0/1/2 were 11.3%/66%/19%. 9.4% received prior adjuvant chemotherapy. 54.7% had multi-organ involvement. Median follow up was 23 months. 45 patients evaluable for response. Response evaluation: CR: 4.4%, PR: 60%, SD 31% for a clinical benefit of 95.4%. 33% qualified for early response (CR or PR at 1stevaluation), 40% qualified for ETS. Median PFS and OS for the whole group was 16 (95% CI: 15.6-25.3) and 28 months (95% CI: 23.9-33.63) respectively. PFS and OS for patients achieving early tumor shrinkage vs no was 25 months and not reached vs. 9 and 22 months respectively(p=0.006 for both), and for early responders was 28 and 28 months vs. 9 and 28 months (p=0.02 and 0.5 respectively). **Conclusions:** Both ETS and response evaluation by RECIST criteria at 1st evaluation are predictor of PFS while only ETS predict OS in mCRC patients treated with TCR.

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