Aim: The FOLFOX with bevacizumab regimen has been established as a standard first-line therapy for metastatic colorectal cancer (mCRC), and the OPTIMOX1 study suggested that a stop and go strategy for oxaliplatin reduced peripheral sensory neuropathy. We had already evaluated the efficacy of OPTIMOX1 plus bevacizumab in patients (pts) with mCRC (CRAFT study, Tezuka et al, Invest New Drugs 2013). CapeOx is one of the standard treatments for mCRC that has been proven to be as effective as the FOLFOX regimen. Thus we assessed the efficacy and safety of the combination of intermittent CapeOx + Bevacizumab as a first-line therapy in patients with mCRC in this trial.

Methods: Eligibility criteria included ECOG PS: 0 – 1, no peripheral neuropathy (<Grade 1). Patients received CapeOX (oxaliplatin 130mg/m2, capecitabine 2000mg/m2 + bevacizumab 7.5mg/kg) q3 weeks for 5 cycles, maintenance without oxaliplatin for 5 cycles, and reintroduction CapeOX + bevacizumab for 5 cycles until progression. Primary endpoint was progression-free survival (PFS). Results: Between March 2011 and August 2013, 55 pts were enrolled. Baseline characteristics were median age of 67 years (range, 20 – 83); PS 0/1 (49/6 pts); male/female (33/22 pts), colon/rectum (28/27 pts) and metastatic lesion liver/lung/lymph nodes (32/18/21 pts). A total of 47 pts were evaluated as Par Protocol Set population. 38 pts moved from initial CapeOX to maintenance capecitabine. 20 pts moved to CapeOx reintroduction. Median PFS was 12.4 months (95%CI, 7.7 – 17.1) and Median TTF was 8.3 months (95%CI, 4.5 – 12.1). Best overall response rate was 50.9%. Median capecitabine courses were 5 cycles (range 1 – 5). Oxaliplatin reintroduction rate was 52%. The causes of reintroduction failure were disease progression (3 pts), successful liver resection (2 pts), peripheral sensory neuropathy grade 2 (1 pt). Main grade 3/4 toxicities: neutropenia, anemia, peripheral neuropathy, hand-foot syndrome, and hypertension in 1 patient.

Conclusions: This study met its primary endpoint PFS. It was longer than the CRAFT study. CapeOx with intermittent oxaliplatin is indicated to reduce incidence of severe neutropenia and peripheral sensory neuropathy. The results suggested that our treatment strategy was well tolerated and effective for first-line therapy in mCRC, and maintenance of duration for 5 cycles was reasonable.

Disclosure: All authors have declared no conflicts of interest.