**TPS3646** **Poster Session**

# mFOLFOX6 + bevacizumab + PD-1 monoclonal antibody vs. mFOLFOX6 in locally advanced pMMR/MSS CRC: A multicenter, randomized controlled phase III study (BASKETIII).

Jun Huang, Ping Liu, Zheng Liu, Wan He, Zhenyu Lin, Chao Dong, Shasha Ruan, Fang He, Yandong Zhao, Zhimin Liu, Fengyun Pei, Qijun Yao, Menghan Wang; Department of Colorectal Surgery, The Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China; Third Affiliated Hospital of Kunming Medical University, Kunming, China; Department of Colorectal Surgery, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; Shenzhen People's Hospital, Shenzhen, China; Department of Oncology Center, Affiliated Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; The First Affiliated Hospital of Kunming Medical University, Kunming, China; Department of Clinical Oncology, Renmin Hospital of Wuhan University, Wuhan, China; Department of Radiation Oncology, the Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China; Department of Pathology, The Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China; Department of General Surgery(Coloproctology), the Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China; Department of Colorectal Surgery, the Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China; The Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China

**Background:** Immunotherapy has shown promising therapeutic effects in mismatch repair-deficient or microsatellite instability-high (dMMR/MSI-H) colorectal cancer (CRC). However, for patients with mismatch repair-proficient or microsatellite stable (pMMR/MSS) CRC, the efficacy of single-agent PD-1 monoclonal antibody remains limited. Previous studies reported that combining anti-angiogenic drugs with PD-1 monoclonal antibody might improve the efficacy of immunotherapy. Our BASKETII study (NCT04895137) demonstrated that the neoadjuvant therapy regimen of mFOLFOX6 combined with Bevacizumab and sintilimab significantly enhanced the immunotherapy sensitivity of pMMR/MSS locally advanced CRC (LACRC), resulting in improved pathological complete response (pCR) rates and higher R0 resection rates. **Methods:** BASKETIII is a multicenter, randomized controlled, phase III study with a parallel design conducted in China. This trial aims to evaluate whether the neoadjuvant therapy regimen of mFOLFOX6 combined with Bevacizumab and sintilimab can further improve survival outcomes, and maintain the higher pCR rate and acceptable safety profile compared to mFOLFOX6 in pMMR/MSS LACRC patients. Eligible participants will be randomly assigned in a 1:1 ratio to either the experimental group or the control group. Participants in the experimental group will receive the neoadjuvant therapy regimen of mFOLFOX6 + Bevacizumab + sintilimab. The first five doses will follow the mFOLFOX6 combined with Bevacizumab and sintilimab regimen, and the sixth dose will receive only mFOLFOX6 and sintilimab but without Bevacizumab, in order to avoid delay of surgery. Participants in the control group will receive the neoadjuvant therapy regimen of mFOLFOX6 alone. Participants in both groups will undergo radical surgical treatment after neoadjuvant therapies. Participants who achieve pCR based on postoperative pathology will be regularly followed up. Participants who do not achieve pCR will receive adjuvant therapy with a maxim of six doses and will be regular followed up after the final dose of adjuvant therapy. The primary outcome of this study is to evaluate the 3-year disease-free survival (DFS). The key inclusion criteria include histologically confirmed adenocarcinoma of the colon or upper rectum; tumor biopsy immunohistochemical identified pMMR or MSS identified through next-generation sequencing or polymerase chain reaction; Clinical staging of cT4NxM0. The main exclusion criteria include evidence of distant metastasis beyond the pelvic region; history of pelvic or abdominal radiotherapy; multiple CRC or multiple primary tumors; history of immunotherapy and other malignancies within the past 5 years. A total of 122 patients are planned to be enrolled in this study. This study is registered with ClinicalTrials.gov (NCT06791512) and is recruiting. Clinical trial information: NCT06791512. Research Sponsor: National Natural Science Foundation of China.