Background: At present, distant metastasis remains the main cause of failure for locally advanced rectal cancer (LARC), efficient short-course radiotherapy (SCRT) combined with neoadjuvant chemotherapy is an attempt of optimizing pre-operative treatment.

Methods: We did this randomized, phase III study in multiple centers in China. Patients with middle or lower rectal adenocarcinomas, staged cT3-4 and/or N1-2 by MRI, were randomly assigned to receive 5 Gy × 5 and 4 courses of CAPOX (experimental group) or 50 Gy in 25 fractions concurrently with capecitabine (control group). TME in both groups was performed 6-8 weeks later, then two or six courses of CAPOX and/or 5-FU based chemotherapy were prescribed in experimental or control group, respectively. The purpose of this interim analysis was focusing on the comparision of primary enrolled 100 patients.

Results: Initially enrolled 100 patients, 51 in experimental group and 49 in control group were analyzed, with MRF = 27.5% vs. 30.6%, MRI based T1c = 92.2% vs. 98.0%, N1c = 74.5% vs. 77.6%, and EMVI scores = 52.9% vs. 65.3% in each group. The completion rates of neoadjuvant treatment were 98.0% vs. 100% (p = 0.325), with incidences of grade III-IV toxicity 17.6% vs. 4.1% (p = 0.076) in each group, respectively. 80 patients completed surgery and 7 patients (all in experimental group) chose “watch-and-wait” policy due to clinical complete remission (cCR) after neoadjuvant treatment. 92.9% and 89.5% of patients in experimental and control group had R0 resection (p = 0.593), while 26.2% and 5.3% of them achieved ypT0N0 (p = 0.011), respectively. The completion rates of adjuvant chemotherapy were 76.2% vs. 65.8% (p = 0.305) in each group, respectively. On the whole, the patients who had received 6 cycles of chemotherapy accounted for 62.7% vs. 49.0% (p = 0.000) in experimental and control group, and there were 76.5% and 49.0% of patients who could complete all planned treatments in each group, respectively.

Conclusions: The interim analysis revealed the acute toxicity and surgical complication were acceptable and comparable in both groups, however, the people in experimental group showed better treatment completion.

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