496P Short-term radiotherapy plus chemotherapy versus long-term chemoradiotherapy in locally advanced rectal cancer (STELLAR): A planned interim analysis

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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 x 5 and 4 courses of CAPOX (experimental group) or 50 Gy in 25 fractions concurrently with capcitabine (control group). TME in both groups was performed 6-8 weeks later, then two or six courses of CAPOX as post-operative chemotherapy was prescribed in experimental or control group, respectively. The purpose of this interim analysis was focusing on the comparison of primary enrolled 100 patients.

Results: Initially enrolled 100 patients, 31 in experimental group and 49 in control group were analyzed, with MRF = 27.5% vs. 30.6%, MRI-based T, 92.2% vs. 98.0%, N, 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 pT0N0 (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 76.3% 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.

Clinical trial identification: NCT02533271.

Legal entity responsible for the study: National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College.

Funding: Collaborative Innovation Center for Cancer Medicine [No. XT2015-03].

Disclosure: All authors have declared no conflicts of interest.