gastrointestinal tumours, colorectal

MULTICENTER PHASE II TRIAL OF NEOADJUVANT CHEMOTHERAPY WITH MFOLFOX6 FOR STAGE II/III RECTAL CANCER WITH A T3/T4 TUMOR FACT TRIAL


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Aim: The efficacy and safety of neoadjuvant chemotherapy with modified FOLFOX6 (mFOLFOX6) for stage II/III rectal cancer patients with a T3/T4 tumor is still unknown.

Methods: Inclusion criteria in this multicenter phase II study as follows; Stage II/III (Rai/Rb) rectal cancer patients with a T3/T4 tumor, aged 20–80 years old, Eastern Cooperative Oncology Group performance status of 0–1. A planned patient population set is 50. The primary endpoint is preoperative response rate, and the secondary endpoints are histological effect, R0 resection rate, pCR rate, down-staging rate, neoadjuvant therapy completion rate, toxicity, the incidence of postoperative complications, and 3-year disease-free survival. Computed tomography was performed after 4 courses of mFOLFOX6. Patients with disease progression (DP) underwent resection of the primary lesion, while those without DP received another 2 courses of treatment. Treatment was discontinued when resection was not possible in patients with DP.

Results: Registered patients from August 2011 to July 2013 totaled 53 (male n = 41, female n = 12) with a mean age of 60 (38–77). The number of patients with T3 and T4 tumors was 42 and 10, and patients at stages II and III were 10 and 42, respectively. One patient withdrew due to consent retraction. Median relative dose intensity of mFOLFOX6 therapy was 93.2% for L-OHP, 5-FU, and l-LV. Treatment completion was achieved in 96.2% and 84.6% for 4 and 6 courses, respectively, and withdrawal was due to patient’s discretion, not adverse events. Preoperative response rate was 51%. Surgery was performed in 78.8% of patients. Serious (grade ≥3) toxicity included neutropenia (n = 5), leukopenia (n = 1), thrombocytopenia (n = 1), febrile neutropenia (n = 1), nausea (n = 1), vomiting (n = 1), and peripheral neuropathy (n = 2). The rates of R0 resection, pCR, and sphincter preservation were 91.0%, 10.3%, and 82.9%, respectively. The down staging rate was calculated as 2%. Postoperative complications included suture failure (n = 3), wound infection (n = 2), pneumonia (n = 1), and intestinal obstruction (n = 1).

Conclusions: In a short period observation, neoadjuvant chemotherapy using mFOLFOX6 is a safe and efficacious treatment option for rectal cancer, especially locally advanced disease.

Disclosure: All authors have declared no conflicts of interest.