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Clinical Outcome of the ACCORD 12/0405 PRODIGE 2 Randomized Trial in Rectal Cancer.

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Abstract

PURPOSE The ACCORD 12 trial investigated the value of two different preoperative chemoradiotherapy (CT-RT) regimens in T3-4 Nx M0 resectable rectal cancer. Clinical results are reported after follow-up of 3 years. PATIENTS AND METHODS Between November 2005 and July 2008, a total of 598 patients were randomly assigned to preoperative CT-RT with CAP45 (45-Gy RT for 5 weeks with concurrent capecitabine) or CAPOX50 (50-Gy RT for 5 weeks with concurrent capecitabine and oxaliplatin). Total mesorectal excision was planned 6 weeks after CT-RT. The primary end point was sterilization of the operative specimen, which was achieved in 13.9% versus 19.2% of patients, respectively (P = .09). Clinical results were analyzed for all randomly assigned patients according to the intention-to-treat principle. Results At 3 years, there was no significant difference between CAP45 and CAPOX50 (cumulative incidence of local recurrence, 6.1% v 4.4%; overall survival, 87.6% v 88.3%; disease-free survival, 67.9% v 72.7%). Grade 3 to 4 toxicity was reported in four patients in the CAP45 group and in two patients in the CAPOX50 group. Bowel continence, erectile dysfunction, and social life disturbance were not different between groups. In multivariate analysis, the sterilization rate (Dworak score) of the operative specimen was the main significant prognostic factor (hazard ratio, 0.32; 95% CI, 0.21 to 0.50). CONCLUSION At 3 years, no significant difference in clinical outcome was achieved with the intensified CAPOX regimen. When compared with other recent randomized trials, these results indicate that concurrent administration of oxaliplatin and RT is not recommended.

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