

Accord12_0405 prodige 2 Phase III Trial Neoadjuvant Treatment In Rectal Cancer. Results After 3 Years Of Follow up.

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Purpose/Objective(s): This study aims at analysis the main clinical results of the ACCORD12 trial in rectal cancer after 3 years of follow-up.

Materials/Methods: Between 11/2005 and 07/2008, 598 patients were included in trial. Inclusion criteria was : adenocarcinoma of rectum accessible to digital examination staged T3 Nx M0 (or T2 Nx distal anterior rectum). Randomization was between two neoadjuvant treatments with radiochemotherapy (RT-CT) : Cap45 (RT 45 Gy + capecitabine) and Capox50 (RT 50 Gy + cape. and oxaliplatin). Main end point was sterilization of the operative specimen and was in favor of the Capox50 group (1). Secondary end points were local control, survival and toxicity. Bowel function was analysed with a questionnaire and a global score (1 very poor to 7 excellent). Late radiation toxicity was evaluated using the CTC-NCIV3.0 classification. A total of 253 patients received adjuvant chemotherapy usually with FOLFOX 133 in Cap45, 120 in Capox50).

Results: In the ITT population, with a median follow-up of 36 months, main carcinologic results were calculated using the Kaplan-Meier method (Table 1). Subgroup analysis and prognostic factors will be presented at time of meeting. There was no difference in late grade 3 radiation toxicity. There was no grade 4 toxicity.

Conclusions:The Capox50 regimen did not improve significantly local control and survival. There was no difference in toxicity. It was shown previously that Capox50 was increasing Dworak score 3-4 on the operative specimen. The STAR 1 randomized trial (2) in a similar randomized study (685 patients) and only the addition of oxaliplatin showed increased G3-4 toxicity due to oxaliplatin with no impact on the operative specimen. Combining these data it is possible to propose Cap50 (RT 50 Gy/25F/5w-capecitabine) as a convenient and efficient neoadjuvant regimen for T3 Nx M0 patients.

References :

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3 year - Oncologic results

<i>End point</i>	<i>Cap45 (299 pts)</i>	<i>Capox50 (299 pts)</i>
Loc. Recurrence	6 % (16 pts)	4% (14 pts)
Disease free survival	69 %	74 %
Overall survival	88 %	88 %
Bowel function (median score) [range]	5 [1-7]	5 [1-7]
Any grade 3-4 rad. toxicity	2.7 %	1.4 %