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Neoadjuvant chemotherapy with oxaliplatin and capecitabine versus chemoradiation with capecitabine for locally advanced rectal cancer with uninvolved mesorectal fascia (CONVERT): Initial results of a multicenter randomised, open-label, phase III trial

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Background

Combined chemoradiation therapy is currently the standard practice for locally advanced rectal cancer (LARC) with uninvolved mesorectal fascia (MRF). The CONVERT study compares neoadjuvant chemotherapy with CapeOx alone to standard chemoradiotherapy (CRT) with Capecitabine for these patients.

Methods

Patients between June 2014 and October 2020 with LARC within 12 cm from the anal verge and uninvolved MRF were randomly assigned to receive 4 cycles of CapeOx chemotherapy alone (nCT arm) or CRT with concurrent Capecitabine (nCRT arm). Primary endpoint is local regional failure free survival.

Results

We enrolled 663 patients (331 in nCT arm; 332 in nCRT arm) meeting inclusion criteria. 86.3% of patients accomplished full dose of neoadjuvant therapy in nCT arm compared to 91.0% in nCRT arm (P= 0.074). 52.8% of patients accomplished full dose of adjuvant chemotherapy in nCT arm compared to 44.1% in nCRT arm (P= 0.065). The pCR rate and good downstaging (ypStage 0 to 1) rate in nCT arm and nCRT arm was 11.0% vs. 13.8% (P= 0.333), and 40.8% vs. 45.6% (P= 0.265), respectively. nCT significantly reduced perioperative distant metastases compared with nCRT (0.7% vs. 3.1%, P= 0.034). Two patients in nCT arm and 5 patients in nCRT arm achieved complete clinical response and were treated with a non-operative approach. Less preventive ileostomy were observed in nCT arm (52.2 vs. 63.6, P= 0.008). The two arms had similar short-term toxicity and postoperative complications. Similar results were observed in subgroup analysis.

Conclusions

nCT achieved similar pCR and good downstaging rate with less peri-operative distance metastasis and preventive colostomy compared to nCRT. This regimen could serve as a potential alternative to CRT in LARC with uninvolved MRF. Long-term follow-up is needed to confirm these results.Table: LBA22

	All patients		*P* value
	nCT	nCRT	
Age Median(Range)	60.1 (31-77)	60.1 (28-77)	0.852
Clinical T4(%)	27.8	25.6	0.529
Clinical staging III (%)	67.7	71.8	0.260
pCR(%)	11.0	13.8	0.333

	All patients		*P* value
	nCT	nCRT	
pCR+cCR(%)	11.7	15.4	0.205
ypT0-1N0M 0(%)	16.9	19.2	0.500
ypStage 0 to 1 (%)	40.8	45.6	0.265
TRG 0-1(%)	24.0	38.6	⊠0.001
TRG 0-2(%)	60.1	77.1	⊠0.001
R0 resection (%)	99.6	99.6	0.999
Sphincter preservation (%)	94.9	94.3	0.760
Preventive diverting ileostomy (%)	52.2	63.6	0.008
Peri-operative distant metastasis (%)	0.7	3.1	0.034
Any grade 3/4 adverse events(%)	12.3	8.3	0.109
Any postoperative complications(%)	17.7	24.1	0.065

Clinical trial identification

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Legal entity responsible for the study

The authors.

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Disclosure

All authors have declared no conflicts of interest.