with neoadjuvant chemoradiotherapy and study. Zachary 2, Sivananthan Gokulan 3, Kroeker Daniel 2, 4, Wightman Robert 4, Nashed Maged 5. Canada, 2University of Manitoba, Winnipeg, Canada, 4University of Manitoba, Manitoba, University of Manitoba, Winnipeg, Canada.

Therapy (NACRT) is the standard preoperative treatment for patients with locally advanced rectal adenocarcinoma (LARC) which is followed by radical surgery. 10-25% of patients achieve pathological complete response (ypCR). There is uncertainty with regards to the prognostic value of achieving ypCR. In addition, the prognostic value of fluoropyrimidine-containing adjuvant chemotherapy (AC) after radical surgery is still an area for debate. In this retrospective study, we aimed at identifying prognostic markers of tumour recurrence and survival of patients with LARC who were treated with NACRT and surgery.

Methods: We included patients with LARC, diagnosed in Manitoba between January 2007 and December 2012 who were treated with NACRT followed by radical surgery. The patients were identified from the Provincial Cancer Registry database. Data on patient demographics, tumour characteristics, treatment, and outcomes were collected.

Conclusion: Patients with LARC who received NACRT and achieved ypCR were less likely to have recurrence and also had a better survival. Therefore, efforts should be made to maximize pathological response to neoadjuvant therapy. In this study, adjuvant chemotherapy was associated with improved survival. Further analysis is required to determine if the subgroup of patients who achieved ypCR derive any survival benefit from AC or if chemotherapy could be safely omitted for them.
Abstract

Introduction: The FOLFOXIRI regimen is highly active in metastatic colorectal cancer, but the activity in pts with non-metastatic locoregionally advanced rectal cancer remains to be defined. This study evaluated the activity and safety of adding a modified FOLFOXIRI regimen prior to pre-operative chemoradiotherapy (CRT) in patients (pts) with high-risk rectal cancer who were treated at a tertiary oncology center.

Methods: Eligible pts with potentially operable rectal cancers that were deemed to have a significant risk of positive surgical margin (T3 or T4 disease, or tumour infiltrating peri rectal fat, surrounding structures of the peritoneum, or any T-stage with lymph node involvement. Must be staged M0), were treated with 4 cycles of FOLFOXIRI with GCSF support, followed by concurrent capcitabine 825mg/m2 b.d and pelvic RT at a total dose of 50.4 Gy in 28 fractions over 5 weeks. Total mesorectal excision (TME) surgery was planned at 8-10 weeks after CRT. All patients underwent staging with MRI pelvis, endorectal ultrasound, CT chest/abdo/pelvis or whole-body PET-CT.

Results: We report the result of the first 20 pts enrolled into this study. The median age was 60 (range: 43-89 years), male female ratio = 15:5. The stage distribution at enrollment was: T3N0M0 (n = 2), T3N1M0 (n = 10), T4N1M0 (n = 3), T4N2M0 (n = 3). One pt was withdrawn from study because of bowel perforation following 1 cycle of FOLFOXIRI. Of the 19 evaluable pts who completed all planned neoadjuvant therapy, the objective responses included (WHO criteria) partial response (n = 12, 63%), stable (n = 5, 26.3%) and progressive (n = 2, distant mets). Of the 14 pts underwent surgery (2 pts refused, two were inoperable due to distant mets, 1 is pending surgery), 2 pts had pathological complete response (pCR), 13 pts had negative margins (92.8% out of 14 pts) and 1 had close margin. 3 pts had permanent stoma from abdominal peritoneal resection (n = 2), pelvic exenteration (n = 1). 11 pts who had surgery were down-staged when comparing the baseline with the final pathological stage: Overall stage down-staged in 78.5% out of 14pts, T-stage down-staged in 6 pt (42.8%), N-stage down-staged in 9 pt (64.2%). Allis encountered during neoadjuvant therapy included: Gr 3 vomiting (n = 1), non-neutropenic fever Gr 3 (n = 1), infection (n = 1), bowel perforation (n = 1). Post-operatively, 1 pt had Gr 3 radiation cystitis, 1 pt had Gr 3 post-operative bleeding. There were no treatment-related deaths or perioperative mortality.

Conclusion: Neoadjuvant FOLFOXIRI followed by CRT is a feasible approach. The rate of pCR and rate of conversion from threatened circumferential resection margin to clearance of margin were at least comparable to our retrospective data on CRT alone in 135 pts (Yeung et al, Hong Kong Med J. 2016;22:546–55). Enrollment will continue until a target of 30 pts has been reached.

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