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Radiotherapy of rectal cancer

Preoperative radio therapy and local excision of rectal cancer with immediate radical re-operation for poor responders $^{\updownarrow}$

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ABSTRACT

Background and purpose: To report an early analysis of prospective study exploring preoperative radiotherapy and local excision in rectal cancer.

Materials and methods: Mucosa at tumour edges was tattooed. Patients with cT1-3N0 tumour <3-4 cm were treated with either 5×5 Gy + 4 Gy boost (N = 31) or chemoradiation (50.4 Gy + 5.4 Gy boost, 1.8 Gy per fraction + 5-fluorouracyl and leucovorin; N = 13). Thirteen patients from the short-course group were unfit for chemotherapy. The interval from radiation to full-thickness local excision was 6 weeks. The protocol called for conversion to a transabdominal surgery in case of ypT2-3 disease or positive margin.

Results: The postoperative complications requiring hospitalization were recorded in 9% of patients. The rate of pathological complete response was 41%. The rate of patients requiring conversion was 34%; however, 18% actually underwent conversion and the remaining 16% refused or were unfit. During the 14 months of median follow-up, local recurrence was detected in 7% of patients and all underwent salvage surgery. Of 19 patients in whom initially anterior resection was likely, 16% had abdominoperineal resection performed for a conversion or as a rescue procedure.

Conclusion: Our study suggests that the short-course radiation prior to local excision is a treatment option for high-risk patients.

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Full-thickness local excision of rectal cancer is an attractive treatment for a number of reasons. Firstly, it prevents a permanent stoma in patients who would otherwise require abdominoperineal resection. Secondly, when compared with abdominal surgery, the risk of postoperative morbidity is lower [1–3]. In addition, sometimes local excision is the only surgical option for elderly patients

with co-morbidity who are unfit for transabdominal operation. The third reason is a better anorectal function compared to low anterior resection [1,3]. Lastly, local excision procedure does not impair sexual and urinary functions.

The prevailing opinion is that local excision should be limited to small T1N0 tumours with favourable histology [3]. The results of the use of local excision and postoperative radiation for more advanced lesions have been disappointing [4]. It seems, that preoperative radio(chemo)therapy provides an opportunity for expanding the applicability of local excision to more advanced tumours. Approximately 350 patients treated with preoperative radio(chemo)therapy and local excision have been described in the literature [2,3,5–22]. The reported results are encouraging;

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however, they are difficult to be interpreted and generalized due to a variety of highly selective entry criteria and the retrospective nature of most studies. In addition, the reference populations were rarely described. The mean numbers of patients treated per year were low – most often less than 3.

To explore this issue in a systematic fashion, we have launched a prospective multicentre study. The rationale for designing our trial (Fig. 1) has been described previously in detail [5]. In short, two selection levels are the basic underlying principles in this trial. The first selection is based on the tumour size; it must be initially resectable with local excision, i.e. a tumour should not be larger than 3-4 cm. The second selection depends on a response to radiation. This is because; there is a correlation between radiosensitivity and inherited low aggressiveness of rectal cancer. In addition, there is a high correlation between radioresponsiveness of primary tumour and radioresponsiveness of mesorectal nodal disease (which might be left behind after local excision). If pathological complete response of primary tumour or downstaging to ypT1 category occurs after radiation, the risk of mesorectal nodal disease and local recurrence is low. For these reasons, in patients downstaged to ypT0-1 category, the local excision might be considered as a final treatment. For patients with more radioresistant cancer, the risk of mesorectal nodal disease is high and prognosis is less satisfactory; thus, immediate conversion to an abdominal surgery is needed. In this context, preoperative irradiation is not only a treatment, but also a selection test. The Lyon R96-02 randomised study suggests that the escalation of preoperative radiation dose is a promising approach to enhance the applicability of local excision [9]. Optimal schedule of preoperative radiotherapy is unknown in patients undergoing local excision. For these reasons, we launched the randomised trial that compared the short-course schedule with the chemoradiation using dose escalation in both schemes. Presently, the number of randomised patients is too low and follow-up is too short to compare these two treatments. In addition, in order to increase the number of patients, we included into the analysis those who were not randomised, but received treatment according to the protocol. However, this created biased study results. The aim of this report is to present early analysis that showed results that had not been previously reported in the literature.

Patients and methods

The study was approved by the ethics committee. All patients signed informed written consent. The eligibility criteria included the biopsy-proven good or moderately differentiated adenocarcinoma less than 3-4 cm as assessed by digital examination and by endorectal sonography (EUS) or by pelvic magnetic resonance (MR). The proximal pole of tumour should not be higher than 8-9 cm from the anal verge in case of anterior wall involvement or not be higher than 10-12 cm in case of posterior wall involvement. Tumours should be clinically staged (c) as T1, but only flat raised or ulcerated or as cT2 or as borderline cT2-3 (irregular outer margin of muscularis propia but no obvious perirectal fat invasion). In addition, there was no evidence of mesorectal nodal metastases as assessed by EUS and pelvic computed tomography (CT) or by MR and there was no evidence of distant metastases on chest Xray and abdominal CT or sonography. Although, cT1 lesions may be managed with local excision alone, we included flat raised or ulcerated cT1 lesions, as this type of tumour growth is associated with worse prognosis compared to cT1 exophytic lesions [23]. Patients with poorly differentiated pathology (G3) were excluded. Colonoscopy was mandatory. Assuming that a local excision would not have been carried out, the most likely type of surgery (abdominoperineal resection or anterior resection) was prospectively recorded.



Fig. 1. Protocol schema.

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