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RAPID COMMUNICATION

Sphincter-preserving R0 total mesorectal excision with resection of internal genitalia combined with pre- or postoperative chemoradiation for T4 rectal cancer in females

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Abstract

AIM: To evaluate the impact of chemoradiation administered pre- or postoperatively on prognosis in females following R0 extended resection with sphincter-preserving total mesorectal excision (TME) for locally advanced rectal cancer and to assess the association between chemoradiation and intra- and postoperative variables.

METHODS: Twenty-one females were treated for locally advanced but preoperatively assessed as primarily resectable rectal cancer involving reproductive organs. Anterior resection with TME and excision of internal genitalia was combined with neo- or adjuvant chemoradiation. Two-year disease-free survival analysis was performed with the Kaplan-Meier method and log-rank test. The association between chemoradiation and other variables was evaluated with the Fisher's exact test and Mann-Whitney test.

RESULTS: Survival rate decreased in anaemic females (51.5% *vs* 57.4%), in patients older than 60 years (41.8% *vs* 66.7%) with poorly differentiated cancers (50.0% *vs* 55.6%) and tumors located $\leqslant$ 7 cm from the anal verge (42.9% *vs* 68.1%) but with the lack of importance. Patients with negative lymph nodes and women chemoradiated preoperatively had significantly favourable prognosis (85.7% *vs* 35.7%; P = 0.03 and 80.0% *vs* 27.3%; P = 0.01, respectively). Preoperative chemoradiation compared to adjuvant radiochemotherapy was not significantly associated with the duration of surgery, incidence of intraoperative bowel perforation and blood loss $\geqslant$ 1 L, rate of postoperative bladder and anorectal dysfunction, and minimal distal resection margin. It significantly influenced minimal radial margin (mean 4.2 mm *vs* 1.1 mm; $P < 0.01$).

CONCLUSION: Despite involving internal genitalia, long-term disease-free survival and sphincter preservation may be achieved with combined-modality therapy for females with T4 locally advanced rectal carcinoma. Neoadjuvant chemoradiation does not compromise functional results and may significantly improve oncological outcomes probably due to enhanced radial clearance.

Key words: Locally advanced rectal cancer; Anterior resection; Total mesorectal excision; Hysterectomy; Chemoradiation

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INTRODUCTION

Since the introduction of total mesorectal excision (TME) by Heald *et al*[1], an optimal local control for rectal cancer and improved patient survival have been achieved comparing with traditional resection. In contrast, patients with locally advanced primarily unresectable tumors have a dismal prognosis. They require combined-modality therapy because of significant benefit from radiation, chemotherapy or both[2]. Neoadjuvant combined radiochemotherapy can increase sphincter preservation to 27%-64% and R0 resectability rate to 73%-90%,

which results in long-term disease-free survival in up to 73% patients[3-5]. For patients with locally advanced but primarily resectable rectal cancer more individual approach is postulated[6].

The aim of our study was to evaluate the impact of clinico-pathological factors and chemoradiation administered pre- or postoperatively on prognosis in females following R0 extended resection with sphincter-preserving TME for primarily resectable locally advanced rectal cancer and to assess the association between chemoradiation protocol and intra- and postoperative variables.

MATERIALS AND METHODS

Patients

From January 1997 to December 2003, twenty-one female patients with histologically confirmed rectal cancer involving internal reproductive organs were operated on with curative intent (R0) and entered the study. The mean age of patients was 61.52 ± 6.49 years, median 63 (range, 47-73) years. Preoperative staging diagnosed T4 lesion infiltrating female internal genitalia in all cases. Neither involvement of other organs nor fixation to the pelvic wall was shown. Thus, tumors were assessed as locally advanced but primarily resectable. The mean tumor site was 7.90 ± 1.70 cm from the anal verge, median 7 cm (range, 5-12 cm). All females were treated with combined-modality therapy: radiation, chemotherapy and extended surgery. Table 1 summarises the main characteristics of patients, tumors and chemoradiation.

Surgery

Multivisceral excisions with curative intent were done by a multidisciplinary team of surgeons and gynaecologists. All operations were performed or closely supervised by the senior authors: the consultant of surgical oncology (J.F.) and the consultant of gynaecological oncology (Professor J.K.). All resection margins were postoperatively stated as microscopically free of cancer by pathological examination. All patients underwent anterior resection of the rectum with sphincter preservation strictly according to the total mesorectal excision method. Sharp dissection of pelvic fascia was performed carefully under direct vision down to the pelvic floor. Because of cancer involvement, the internal female reproductive organs were removed with the rectum in one tissue block. In eighteen females hysterectomy with bilateral salpingo-oophorectomy was performed. Three women underwent an additional excision of posterior vaginal wall. Straight end to end bowel reconstruction was performed using double-stapling technique. In order to prevent the anastomosis proximal diversion was used. Defunctioning transversostomy was closed after 12-24 wk.

Chemoradiation

For ten patients neoadjuvant 50.4 Gy irradiation (25 × 1.8 Gy + 5.4 Gy boost) and two five-day cycles of chemotherapy with 5-fluorouracil (325 mg/m^2) and folinic acid (20 mg/m^2) by intravenous bolus injection were administered, followed by surgery after 4-6 wk and postoperative four cycles of chemotherapy. In the remaining eleven females a standard adjuvant radiochemotherapy (5-fluorouracil/folinic acid- based systemic treatment in six five-day courses added to 50.4 Gy radiation) was given. Impact of chemoradiation protocol on survival and its association with intra- and postoperative variables (surgery duration, blood loss, bowel perforation, bladder disturbances, anorectal dysfunction, minimal distal and radial margin) were analysed.

Table 1 Baseline characteristics of patients, tumors, treatment and survival

Parameter	*n* (%)	Survival rate (%)	*P*
Age ⩽ 60 yr	9 (42.8)	66.7	NS
> 60 yr	12 (57.2)	41.8	
Tumor site > 7 cm	15 (71.4)	68.1	NS
⩽ 7 cm	6 (28.6)	42.9	
Differentation grade			NS
Well/moderate	12 (57.2)	55.6	
Poor	9 (42.8)	50.0	
Anemia: absent	18 (85.7)	57.4	NS
present	3 (14.3)	51.5	
Lymph node-status: (-)	7 (33.3)	85.7	< 0.05
(+)	14 (66.7)	35.7	
Chemoradiation			
Preoperative	10 (47.6)	80.0	< 0.05
Postoperative	11 (52.4)	27.3	

NS: not significant.

Follow-up

The mean follow-up duration was 20.6 (range, 9-34) mo. It was scheduled every three months during the first postoperative year and every six months thereafter. Physical examination, blood tests, serum markers, barium enema, gynaecological examination, endoscopy, chest radiograph and abdominal ultrasound were done. In every supposition of cancer recurrence more precise investigation using endorectal sonography, CT-scanning or radioisotope imaging was performed. Besides chemoradiation impact of patient's age, tumor site, differentiation grade, lymph node-status and presence of anaemia on survival was evaluated.

Statistical analysis

The data were analysed using software StatSoft Inc, STATISTICA for Windows ver. 5.5 A, Tulsa, OK, USA. For considered range of parameters, median and mean values with standard deviation were calculated. To examine the impact of individual factors on long-term outcome, two-year disease-free survival analysis was performed. Females not alive due to any cause and alive with any evidence of local recurrence or distant metastases were defined as not disease-free survivors. Survival was estimated by the Kaplan-Meier method. Differences between curves were analysed with log-rank test (Cox-Mantel). To compare nominal variables Fisher's exact test was performed, for continuous variables the Mann-Withney *U*-test was used. Probability level of 0.05 was accepted as a significance limit.

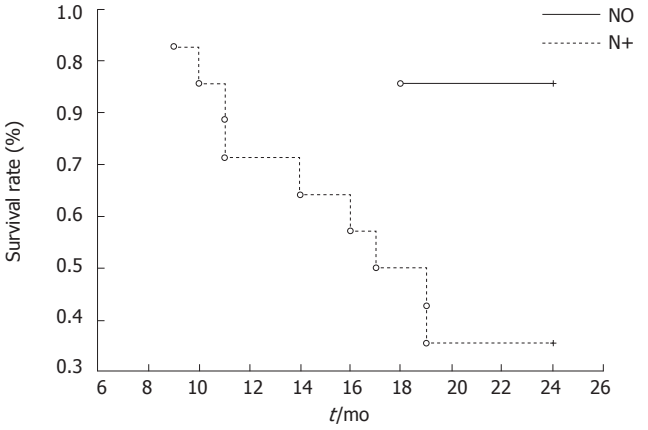

Figure 1 Association between lymph node-status and survival ($P < 0.05$) (log-rank test). N0: lymph node negative patients; N+: lymph node positive patients.

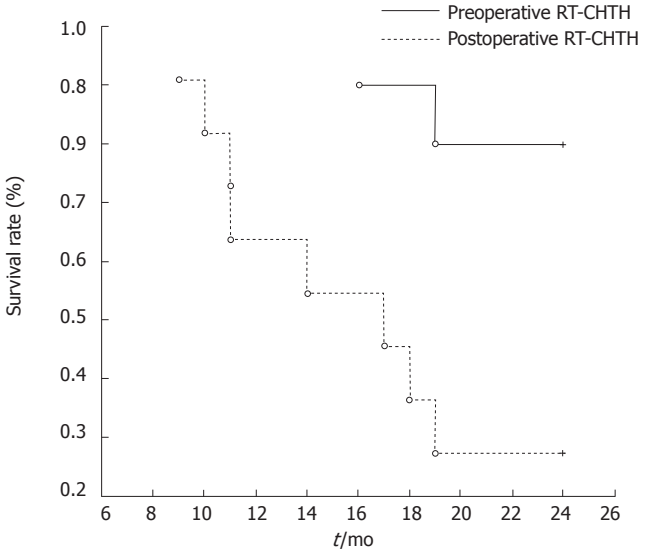

Figure 2 Association between chemoradiation and survival ($P < 0.05$) (log-rank test). Preoperative RT-CHT: patients treated with preoperative chemoradiation; postoperative RT-CHT: patients treated with postoperative chemoradiation.

Table 2 Impact of chemoradiation on intra- and postoperative variables

Parameter	Preoperative	Postoperative	*P*
Surgery duration	155 min	137 min	NS
Intraoperative blood loss ⩾ 1 L	1	1	NS
Intraoperative bowel perforation	Absent	Absent	-
Postoperative bladder disturbances	3	2	NS
Postoperative anorectal dysfunction	6	5	NS
Minimal distal clearance	10.6 mm	9.5 mm	NS
Minimal radial clearance	4.2 mm	1.1 mm	< 0.01

NS: not significant.

RESULTS

Survival analysis

There was no postoperative death. Twenty-four months after resection eleven females were still alive without any evidence of cancer recurrence, two-year disease-free survival rate was 53%. Survival was enhanced in women at the age of less than or equal to 60 years and non-anaemic patients with well or moderately differentiated tumors sited above 7 cm from the anal verge, but with a lack of importance. Significantly poorer survival was noticed in females with lymph node metastases (log-rank, $P = 0.03038$) (Figure 1). Prognosis was significantly favourable for patients treated with preoperative chemoradiation (log-rank, $P = 0.01231$) (Figure 2). There were seven node-positive patients in each group according to chemoradiation protocol. Survival analysis is shown in Table 2.

Chemoradiation and intra- and postoperative variables

Chemoradiation schedule did not significantly influence the volume of intraoperative blood loss, incidence of intraoperative bowel perforation, rate of postoperative bladder disturbances, incidence of postoperative anorectal dysfunction and surgery duration: mean 155 (range, 106-187) min *vs* mean 137 (range, 98-182) min. Postoperative chemoradiation was related to decreased minimal distal clearance: mean 9.5 (range, 9.1-33.9) mm *vs* mean 10.6 (range, 9.2-36.7) mm but with the lack of importance. Preoperative chemoradiation was associated with significantly enhanced minimal radial clearance: mean 4.2 (range, 3.6-7.2) mm *vs* mean 1.1 (range, 0.9-1.4) mm (Mann-Withney, $P < 0.01$).

DISCUSSION

Adjacent organ involvement is present in 10% rectal cancers and in 50%-57% of them fixation is caused by cancer infiltration[7,8]. For females with primarily resectable tumor involving internal genitalia the key factor to avoid oncological relapse is microscopically free R0 multivisceral excision[9,10]. Our findings are in accordance to recent studies, suggesting that aggressive approach and close surgico-gynaecological co-operation can provide sphincter preservation and excellent pelvic control resulting in improved long-term survival with acceptable risk of 0%-7.5% postoperative mortality and 12.5%-50.0% morbidity (mostly wound healing complications)[11-14].

Lymph node involvement is an unquestionable indicator of poor outcome. For node-positive patients five-year overall survival, two-year overall survival and disease-free survival rates are decreased to 25%, 43% and 33%, compared to 75%, 94% and 67% for patients with negative nodes, respectively[12-14]. We did not notice significant prognostic value of other clinical and pathological parameters, possibly due to the relatively small sample size. In contradiction to our results, negative predictive significance of blood loss ⩾ 1 L, patient's age > 62-64 years, increased CEA serum level, poor differentiation and the presence of anaemia before treatment have been found in other studies[14-17].

The only other factor significantly related to survival in our study was chemoradiation protocol. In spite of R0 resection chemoradiation given before surgery influenced favourable prognosis with a high level of statistical importance. Due to preoperative irradiation, the complete pathological response of resectable cancer in up to 20%

patients can be achieved, tumor may downsize in 64% cases, incidence of local recurrence may be reduced to 4%, 69% patients with lymph node metastases may be rendered node-negative, and finally, overall long-term and disease-free survival rates may be enhanced to 75% and 83%, respectively[18-20]. Moreover, the addition of preoperative chemotherapy independently increases tumor response improving survival[3,21,22]. Results of comparisons of neo- and adjuvant therapy are discrepant. A Swedish review of over 40 000 patients reported that preoperative schedule is more effective for survival benefit[23]. In contrast, in the Uppsala trial decreased risk of local relapse was noticed for the preoperative arm but five-year survival was not significantly improved[24]. However, this study evaluated short-course hypofractionated preoperative irradiation without concurrent chemotherapy. Results from the recent controlled randomised German trial suggest that neoadjuvant radiochemotherapy is related with less toxicity, does not produce higher postoperative morbidity and is better for local control than adjuvant chemoradiation but in fact does not significantly affect overall survival[25,26].

The reason for the important prognostic value of the chemoradiation protocol in our study may be its association with the extent of resection margins. When feasible, striving for 2 cm distal resection margin is advocated because of intramural tumor spread possibility. However, it does not exceed 1 cm for 90% rectal cancers[27]. Zhao *et al*[27] have reported maximum 12 mm distal intramural spread and 36 mm distal mesorectal spread. Thus, some authors claim that TME with a distal margin $\leqslant$ 1 cm does not seem to compromise oncological outcome, especially if resection follows combined-modality therapy[28]. In our patients, preoperative chemoradiation was not significantly related to distal margin probably due to the analysis only of the females selected for sphincter-saving resection. Importance of circumferential clearance for rectal cancer was firstly emphasised twenty years ago by Quirke *et al*[29]. Recently, during total mesorectal excision removal of radial margin at a minimum of 1 mm[30], 2 mm[31] and 3 mm[32] is postulated for adequate local control. In our series radiochemotherapy protocol was strongly associated with radial clearance and seven females not chemoradiated before surgery measured their circumferential margin $\leqslant$ 1 mm. The extent of resection margins for effective local control remains a matter of debate. However, our findings are supported by others, who noticed that the radial margin of $\leqslant$ 1 mm should be considered inadequate and positive[33]. Results of our study suggest, similarly to some others[34], that the main role of neoadjuvant combined-modality therapy for primarily resectable rectal cancer is not to enhance the distal margin but to increase the radial clearance and therefore improve local control and long-term survival.

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