Original Article

Is Neoadjuvant Chemoradiotherapy Necessary for the Patient with Low-lying cT2N0 Rectal Cancer?

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T2 rectal cancer;
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Purpose. The value of preoperative chemoradiotherapy for patients with low-lying cT2N0M0 rectal cancer is controversial; it is usually performed for anal sphincter preservation in these patients. The aim of the study was to evaluate the actual sphincter preservation rate and prognosis in patients with low-lying cT2N0M0 rectal cancer given preoperative chemoradiotherapy.

Methods. Between January 2008 and December 2016, 48 patients who underwent radical surgery of low-lying rectal adenocarcinoma (≤ 6 cm from the anal verge) with clinical stage T2N0M0 were retrospectively enrolled in this study. Patients were categorized (PCRT+ vs. PCRT-) according to preoperative chemoradiotherapy application. The clinicopathologic features, sphincter preservation rate, and prognosis of the two groups were analyzed.

Results. Forty-eight patients (24 males and 24 females) with a mean age of 66.33 years were identified. Preoperatively, the PCRT+ group had significantly shorter tumor distance from the anus (3.86 ± 1.58 vs. 4.9 ± 1.37 cm, $p = 0.0216$). The operation procedure and method were similar between groups. Significantly more stoma were created and fewer lymph nodes harvested in the PCRT+ group. The groups did not differ significantly in sphincter preservation rate, primary tumor size, distal margin of the resected tumor, margin involved rate, post-operative complications, or mortality. Mean follow-up time from diagnosis was 67.02 ± 29.92 months. The groups did was not differ significantly in disease recurrence or overall, disease-free, or cancer-specific survival.

Conclusions. Preoperative chemoradiotherapy did not increase sphincter preservation or survival in patients with low-lying cT2N0 rectal cancer, but was associated with a higher rate of temporary stoma.

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The main aims of rectal cancer treatment are loco-regional control and improvement in overall and disease-free survival. Currently, the standard treatment for rectal cancer consists of radical surgery with total or partial tumor-specific mesorectal excision. Short-course radiotherapy or long-course chemoradiotherapy may be administered preoperatively, depending on the location of the tumor in the rectum and

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the disease stage.[1] In terms of disease stage, preoperative chemoradiotherapy (PCRT) or radiotherapy is indicated for locally advanced cT3 and/or N + rectal tumors[2] to improve local control.[3] According to the latest National Comprehensive Cancer Network (NCCN) guidelines for stage I rectal cancer (i.e., T1/T2 and N0), transanal local excision is an acceptable option in T1 patients with favorable clinical and histological features; in T2 patients, transabdominal resection is indicated.[4] For patients with very low-lying rectal tumors, the standard treatment for patients with distal cT2 rectal adenocarcinoma who cannot undergo a low anterior resection (LAR) is abdominoperineal resection (APR).[5] It is generally expected that PCRT will preserve the sphincter in patients who require abdominoperineal resection. Previous studies suggest that tumor downstaging and shrinkage after PCRT may increase the likelihood of sphincter preservation in rectal cancer patients.[3,6] Given its high toxicity, PCRT is difficult to justify for patients with cT2N0 rectal cancer, in whom it has not been associated with considerable oncological improvement.[7,8] Nevertheless, PCRT might be applicable in some cases in order to avoid APR when LAR is otherwise unfeasible. The aim of the present study was to evaluate the rate of sphincter preservation in patients with low-lying cT2N0 rectal tumors receiving PCRT to avoid APR.

Materials and Methods

Patients

Between January 2008 and December 2016, a total of 2,449 patients were diagnosed with rectal cancer at the Chi-Mei Hospital and Changhua Christian Hospital. Patients with low-lying cT2N0 rectal cancer, defined as tumors located 0-6 cm from the anal verge with a pathologic diagnosis of adenocarcinoma (clinical stage T2N0M0), were enrolled in this study. Of these patients, 48 underwent definitive treatment at our hospital. Each patient had a colonoscopy and biopsy to locate the tumor and to confirm the histologic diagnosis. The clinical stage of the tumor was determined before treatment via computed tomography scan, magnetic resonance imaging (MRI) of the abdomen and pelvis, or endorectal ultrasound. If necessary, a chest computed tomography scan and liver ultrasound were performed to exclude the presence of distant metastases. Twenty-eight patients received PCRT followed by radical surgery; the other 20 patients underwent radical surgery only. We analyzed the clinicopathologic characteristics and demographic features, such as age, gender, preoperative carcinoembryonic antigen (CEA) level, tumor distance from the anus, operative procedure, operative methods, post-operative stoma creation, sphincter preservation rate, tumor size, distal margin of the resected tumor, margin involvement rate, number of harvested lymph nodes, number of metastasized lymph nodes, peri- and post-operative complications, mortality, recurrence pattern, and prognosis. All patients were followed for at least three years from the date of diagnosis. The end of follow-up was 31 March 2019. All data in this study were obtained from the Cancer Registry Database, the Cancer Center of Chi-Mei Hospital/Changhua Christian Hospital, and patient charts.

Preoperative chemoradiotherapy (PCRT+) group

In those receiving PCRT, the radiation dose was 45-50.4 Gy/25 fractions (daily dose 1.8 Gy) delivered to the pelvis over a period of five weeks by using linear accelerators with an energy of 6 MV or 10 MV (GE Healthcare, Chicago, Il, USA). The radiation field was as follows: the upper limit was the L5 spine bone level, the lateral field was 1.5 cm lateral from the bony pelvis in order to include the pelvic lymph nodes, and the lowest level extended down to cover the whole rectum and the tumor bed. Three-dimensional or intensity modulated radiation therapy was used for treatment planning. Concurrently with radiation, the chemotherapy of fluorouracil was administered as a 120-hour continuous infusion at a dose of 1,000 mg/m^2/d during the first and fifth weeks of radiotherapy.

Surgical technique

All surgery was performed following the rules of

sharp dissection under direct vision with resection of the total mesorectum. Two major types of surgery were used: 1) abdominoperineal resection with a permanent colostomy and 2) low anterior resection with colorectal or usually coloanal anastomosis. Diverting stoma was left to the surgeon's decision. For lower rectal cancer, 2 cm of distal margin measured macroscopically was considered as adequate, or a distal margin that was tumor free for ultra-low rectal lesions (< 4 cm from the anal verge) according to microscopic evaluation. Surgery was planned for 6-8 weeks following the end of chemoradiotherapy in the PCRT+ group. Patients underwent mechanical bowel preparation before surgery. Intravenous antibiotics were administered 30 minutes before the operation and continued for 48 hours after surgery. Digestive tract reconstruction was performed by circular stapling devices or was hand-sewn.

Statistical analysis

Continuous data were represented as the mean ± the standard deviation (SD), and comparisons between groups were made using a two-sample t-test. Categorical data were presented by count and percentage and compared using a chi-square or Fisher's exact test, as indicated. The survival curves were presented using the Kaplan-Meier method, using the log-rank test to compare the differences between groups. All data were analyzed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Kaplan-Meier curves were plotted using STATA (version 12; Stata Corp., College Station, TX, USA). Statistical significance was set at a $p < 0.05$.

Results

Patients and clinical data

A total of 48 patients with low-lying cT2N0 rectal cancer were enrolled in this study. Of these, 28 received PCRT followed by radical surgery; the other 20 patients received radical surgery only. All patients received regular observation and follow-up in our outpatient department. Although the 2 groups showed no statistical difference in gender, age at diagnosis, or preoperative CEA, the PCRT+ group has significant short tumor distance from the anus (3.86 ± 1.58 vs. 4.90 ± 1.37, $p = 0.0216$). In the PCRT+ group, 18 patients (64.29%) underwent LAR with sphincter preservation and 10 (35.71%) underwent APR; in the PCRT- group, 17 patients (85%) underwent LAR with sphincter preservation and 3 (15%) underwent APR. All patients in the PCRT- group had an R0 resection with clear distal and circumferential margins. Two patients (7.14%) in the PCRT+ group had circumferential margins involved. Additional clinical data are shown in Table 1. Patients in the PCRT+ group had significantly fewer lymph nodes harvested ($p = 0.0233$). The other observed parameters showed no significant differences between the two groups.

Sphincter preservation

The final sphincter preservation rate was 64.29% in the PCRT+ group and 85% in the PCRT- group ($p = 0.2067$). Twenty-four patients in the PCRT+ group and 8 patients in the PCRT- group had stoma creation after the operation (85.71% vs. 40%, $p = 0.0013$). After exclusion of APR patients with permanent stomy, the patients in the PCRT+ group had significantly more temporary stomy than those in the PCRT- group (13/18, 72.22% vs. 4/17, 23.53%, $p = 0.0110$) (Table 2).

Recurrence and survival

All 48 patients were followed for a mean period of 67.02 ± 29.92 months; the PCRT+ group was followed for 68.44 ± 29.51 months and the PCRT- group was followed for 65.04 ± 31.15 months ($p = 0.7022$; Table 3). Seven patients (72/85, 25.00%) in the PCRT+ group and 5 patients (5/20, 25.00%) in the PCRT- group developed local or distant recurrences ($p > 0.9999$). In the PCRT+ group, 1 patient had local recurrence and 6 patients had distant metastasis. In the PCRT- group, 2 patients developed local recurrence and 3 patients developed distant metastasis. The PCRT+ group had a 1-, 3-, 5-, and 7-year overall survival rates of 100%, 85.71%, 68.86%, and 61.20%, respectively;

Table 1. Demographic profiles of patients with cT2N0M0 lower rectal cancer

N(%)	PCRT+ (N = 28)	PCRT- (N = 20)	*p* value
Gender			0.2416
Male	16 (57.14)	8 (40.00)	
Female	12 (42.86)	12 (60.00)	
Age (years)			
Median (Q1, Q3)	65.5 (56.50, 78.00)	67.50 (57.50, 74.50)	0.8924
Mean ± SD (range)	66.39 ± 11.75 (46.00-84.00)	66.25 ± 9.36 (48.00, 79.00)	0.9642
Preoperative CEA			
Median (Q1, Q3)	1.9 (1.46, 4.00)	2.35 (1.55, 4.10)	0.6327
Mean ± SD (range)	10.24 ± 36.25 (0.80-194.10)	44.57 ± 139.63 (0.30-595.00)	0.2951
Distance from anal verge (cm), mean ± SD (range)	3.86 ± 1.58 (0.00-6.00)	4.90 ± 1.37 (0.00-6.00)	0.0216
Operation procedure			0.1114
LAR	18 (64.29)	17 (85.00)	
APR	10 (35.71)	3 (15.00)	
Operative methods			0.4640
Open	20 (71.43)	12 (60.00)	
Laparoscopic	2 (7.14)	4 (20.00)	
da Vinci	6 (21.43)	4 (20.00)	
Tumor diameter			0.0742
≤ 3 cm	21 (75.00)	10 (50.00)	
> 3 cm	7 (25.00)	10 (50.00)	
Length of distal resection margin (cm), mean ± SD (range)	2.09 ± 1.50 (0.5-5.0)	1.81 ± 0.92 (0.5-4.5)	0.4286
Involvement of CRM (%)	2 (7.14)	0 (0.00)	0.5035
Number of LNs harvested, mean ± SD (range)	10.07 ± 5.24 (0.00-18.00)	15.00 ± 8.09 (4.00-36.00)	0.0233
Number of LNs involved, mean ± SD (range)	0.36 ± 1.06 (0.00-5.00)	1.00 ± 1.97 (0.00-7.00)	0.1960
Pathology T status			
T0	2 (7.14)	0 (0)	0.6253
T1	5 (17.86)	0 (0)	0.1291
T2	15 (53.57)	14 (70)	0.3964
T3	6 (21.43)	6 (30)	0.7353
Pathology N status			
N0	24 (85.71)	13 (65)	0.1818
N1	3 (10.71)	5 (25)	0.3594
N2	1 (3.57)	2 (10)	0.7624
Pathology stage			
0	2 (7.14)	0 (0)	0.6253
I	17 (60.71)	10 (50)	0.6580
IIA	5 (17.86)	3 (15)	> 0.999
IIIA	2 (7.14)	2 (10)	> 0.999
IIIB	2 (7.14)	5 (25)	0.1890
Adjuvant therapy			
CRT	0 (0)	6 (85.71)	0.0032
Chemotherapy	3 (75)	1 (14.29)	0.6309
Complications			> 0.9999
Yes	2 (7.14)	1 (5.00)	
No	26 (92.86)	19 (95.00)	
Surgical mortality	0 (0.00)	0 (0.00)	-

PCRT, preoperative chemoradiotherapy; SD, standard deviation; CEA, carcinoembryonic antigen; LAR, low anterior resection; APR, abdominoperineal resection; CRM, circumferential resection margin; LN, lymph node; CRT, chemoradiotherapy.

Table 2. Sphincter preservation and stoma creation profiles of patients with cT2N0M0 lower rectal cancer

N (%)	PCRT+ (N = 28)	PCRT- (N = 20)	*p* value
APR	10 (35.71%)	3 (15.00%)	0.2067
Post-operative stoma creation	24 (85.71%)	8 (40%)	0.0013
Permanent stoma (%)	11 (11/28, 39.29%)	4 (20.00%)	0.3324
Temporary stoma (%)	13 (13/18, 72.22%)	4 (4/17, 23.53%)	0.0110
Stoma free	4 (4/18, 22.22%)	12 (12/17, 70.59%)	0.0106
Unexpected permanent stomy	1/18 (5.56%)	1/17 (5.88%)	> 0.9999
Sphincter preservation rate	64.29% (18/28)	85% (17/20)	0.2067

PCRT, preoperative chemoradiotherapy; APR, abdominoperineal resection.

Table 3. Recurrence and survival in patients with cT2N0M0 lower rectal cancer

N (%)	PCRT+ (N = 28)	PCRT- (N = 20)	*p* value
Follow-up (months), mean ± SD (range)	68.44 ± 29.51 (19.60-121.27)	65.04 ± 31.15 (9.83-121.30)	0.7022
Recurrence	7 (25.00)	5 (25.00)	> 0.9999
Local recurrence	1 (3.57)	2 (10.00)	0.7624
Distant metastasis	6 (21.43)	3 (15.00)	0.8513
Overall survival rate, mean (95% CI)			
1 year	1.00 (-, -)	0.9474 (0.6812, 0.9924)	-
3 year	0.8571 (0.6629, 0.9438)	0.9474 (0.6812, 0.9924)	0.2801
5 year	0.6886 (0.4684, 0.8323)	0.9474 (0.6812, 0.9924)	0.0147
7 year	0.6120 (0.3664, 0.7866)	0.6316 (0.2670, 0.8522)	0.9182
Disease-free survival rate, mean (95% CI)			
1 year	0.8571 (0.6629, 0.9438)	0.8471 (0.5968, 0.9480)	0.9240
3 year	0.7483 (0.5432, 0.8713)	0.7374 (0.4782, 0.8818)	0.9335
5 year	0.7483 (0.5432, 0.8713)	0.7374 (0.4782, 0.8818)	0.9335
7 year	0.7483 (0.5432, 0.8713)	0.7374 (0.4782, 0.8818)	0.9335
Cancer-specific survival rate, mean (95% CI)			
1 year	1.00 (-, -)	1.00 (-, -)	-
3 year	0.9286 (0.7435, 0.9816)	1.00 (-, -)	-
5 year	0.8454 (0.6365, 0.9395)	1.00 (-, -)	-
7 year	0.8454 (0.6365, 0.9395)	0.8333 (0.2731, 0.9747)	0.9426

PCRT, preoperative chemoradiotherapy; SD, standard deviation; CI, confidence interval.

the corresponding rates in the PCRT- group were 94.74%, 94.74%, 94.74%, and 63.16%, respectively (Fig. 1). The 7-year overall survival rate did not differ significantly between the two groups ($p = 0.9182$). As shown in Figs. 2 and 3, the 7-year disease-free and cancer-specific survival rates in the PCRT+ group (74.83% and 84.54%, respectively) were not significantly higher ($p = 0.9335$ and $p = 0.9426$, respectively) than those of the PCRT- group (73.74% and 83.33%, respectively).

Discussion

It is generally expected that patients receiving PCRT will experience more tumor shrinkage than those who do not receive it, and the therapy will increase sphincter preservation in patients whose anatomical features make rectal operations difficult. Tumor shrinkage may reduce the tumor bulk and facilitate withdrawal of the tumor from the anal verge, increasing the operative space for further surgical interventions.[4] Sphincter preservation in low rectal cancer is more challenging than in mid and upper rectal cancer. Thus, PCRT is anticipated to aid in sphincter preservation, especially in low rectal cancer. Many researchers have, however, reported controversial results regarding the influence of PCRT on sphincter preservation.[3,6,10-13] Although many personal series reported an increased sphincter preservation rate after PCRT,[11-13]

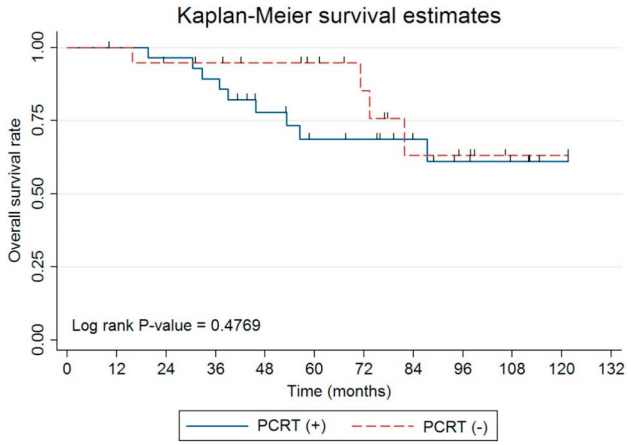

Fig. 1. Kaplan-Meier estimates of overall survival for patients with low-lying cT2N0 rectal cancer by receipt of preoperative chemoradiotherapy (PCRT).

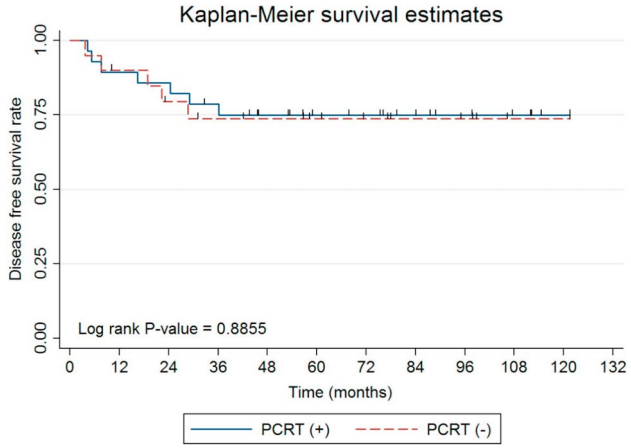

Fig. 2. Kaplan-Meier estimates of disease-free survival for patients with low-lying cT2N0 rectal cancer by receipt of preoperative chemoradiotherapy (PCRT).

two representative randomized controlled trials failed to confirm this result.[3,10] Meta-analyses of randomized trials likewise revealed no difference in the rates of sphincter preservation between patients with and without PCRT.[13,14] Similarly, a recent Cochrane review of 6 randomized trials found no positive effect of PCRT on the rate of sphincter preservation.[15] The topic remains controversial and not well been evaluated because many studies of the effect of PCRT on sphincter preservation include all types of rectal cancer.[3,6,10-13] Sphincter preservation is also a complex topic in low rectal cancer patients, because many factors influence sphincter preservation; these include age, sex, non-fixed tumor, operating institution, and

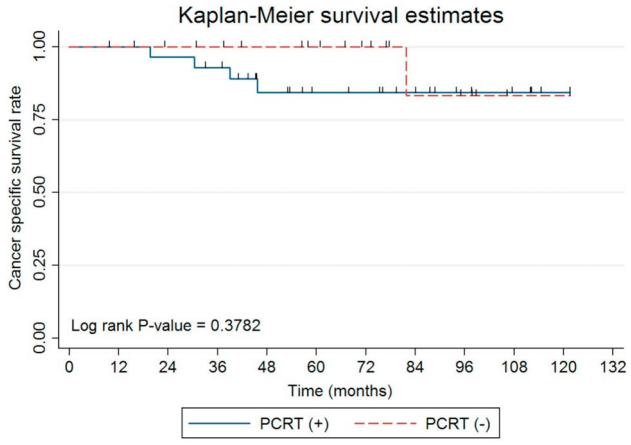

Fig. 3. Kaplan-Meier estimates of cancer-specific survival for pT3N0M0 low-lying cT2N0 rectal cancer by receipt of preoperative chemoradiotherapy (PCRT).

the surgeon's experience.[16-18]

PCRT is rarely used to treat early-stage disease; according to NCCN guidelines, patients with cT2N0 distal rectal cancer do not require neoadjuvant therapy. However, when a patient refuses APR, is there an alternative? In the only published trial that specifically addressed this issue, Rengan and colleagues[19] demonstrated that, in patients with distal cT2N0 rectal cancer who require APR, preoperative pelvic irradiation improved sphincter preservation without any apparent cost to local control or survival. The aim of the current study was to clarify the role of PCRT in sphincter preservation and prognosis for patients with cT2N0 rectal cancer. Our data suggested that PCRT did not improve sphincter preservation in patients with low rectal cT2N0M0 compared to those who received surgery only. Overall, 64.29% of those in the PCRT+ group and 85.00% in the PCRT- group were able to undergo LAR/coloanal anastomosis. Up to 72.22% of those in the PCRT+ group needed a temporary stoma after the operation, compared with 23.53% of those in the PCRT- group. In the PCRT- group, the stoma-free rate was significant higher after primary anastomosis (70.59% vs. 22.22%, $p = 0.0106$). Most of the patients in the PCRT- group had no stoma creation after the operation. In each group, only 1 patient had an unexpected permanent stomy due to poor anastomosis healing after anastomotic leakage.

After a mean follow-up of 67.02 ± 29.92 months,

the recurrence rate was the same for the two groups (25.00% vs. 25.00%, $p > 0.9999$). In our series, 6.25% of patients (3/48) developed local recurrence (1 in the PCRT+ group, 3.57%; 2 in the PCRT- group, 10.00%; $p = 0.7624$) and 18.75% of patients (9/48) developed distant metastasis (6 in the PCRT+ group, 21.43%; 3 in the PCRT- group, 15.00%; $p = 0.8513$). The PCRT+ group appeared to have a lower risk of local recurrence, although the difference did not reach statistical significance. We observed no significant difference in overall, disease-free, or cancer-specific survival between the two groups.

To evaluate the efficacy of PCRT, we should focus on local recurrence-free survival; however, as Fig. 4 shows, there was no significant statistical difference between the two groups. The 3 patients (1 in PCRT+ vs. 2 in PCRT-) with local recurrence had pathological features as follows. 1) All of these tumor size were < 3 cm and 2 patients received APR. Two patients had tumors < 1 cmfrom the anal verge (at the dentate line) and 1 patient had tumor distance of 5 cm from the anal verge. 2) One patient in the PCRT+ group with involvement of the circumferential resection margin (CRM) developed local recurrence. The 9 patients (6 in PCRT+ vs. 3 in PCRT-) with distant metastasis had the following pathological features. In the PCRT+ group, 6 patients had distant metastasis and 2 patients had lymph node metastasis by pathological report. In the PCRT- group, 3 patients had distant metastasis and 2 patients had lymph node metastasis by pathological report. Comparing these 2 groups, 4 patients from the PCRT+ group had lymph node metastasis and 2 of these patients had distant metastasis (50%, 2/4); however, 7 patients in the PCRT- group had lymph node metastasis, 2 of whom had distant metastasis (28.57%, 2/7) (Table 4). The presence of lymph node metastasis in the PCRT+ group may mean that the rectal tumor was chemoradiation-resistant and not diminished by PCRT. The radiochemoresistance of nodal metastasis from rectal cancer is associated with a high potential for developing distant metastasis.[20] This feature may explain why patients with pathologic lymph node metastasis in the PCRT+ group had a greater likelihood of distant metastasis.

The accessibility of rectal cancer to evaluation by pelvic MRI with contrast makes possible preoperative assessment of the depth of tumor penetration and the presence of local lymph nodal metastases. In our PCRT- group, the accuracy of the MRI for T2 was 14/20 (70%) and for N0 was 13/20 (65%). The result was comparable with that of a previous study.[21] To

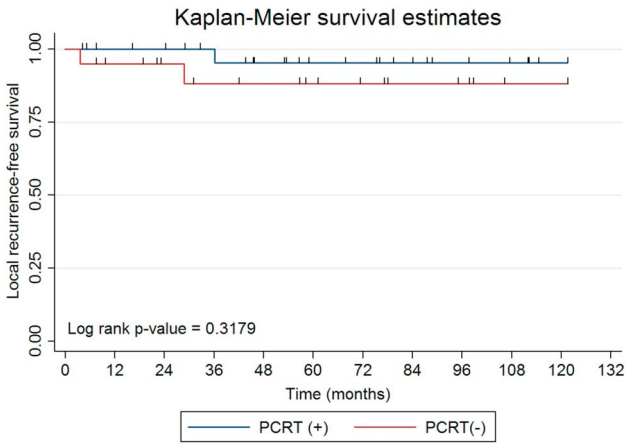

Fig. 4. Kaplan-Meier estimates of local recurrence-free survival for patients with low-lying cT2N0 rectal cancer by receipt of preoperative chemoradiotherapy (PCRT).

Table 4. Pathology features of local recurrence and distant metastasis by treatment assignment

	PCRT+ (N = 28)	PCRT- (N = 20)
Local recurrence (N = 3)	1	2
Tumor size < 3 cm	1 (100%)	2 (100%)
APR	1 (100%)	1 (50%)
Tumor located at dentate line	1 (100%)	1 (50%)
Involvement of CRM	1 (100%)	0 (0%)
Distant metastasis (N = 9)	6	3
Pathology lymph node metastasis	2 (2/4, 50%)	2 (2/7, 28.57%)

PCRT, preoperative chemoradiotherapy; APR, abdominoperineal resection; CRM, circumferential resection margin.
Total pathologic lymph node metastasis in both groups: 4 in PCRT+; 7 in PCRT-.

reduce local recurrence, we should improve surgical techniques, especially in very low lying rectal cancer. To date, total mesorectal excision (TME), based on dissection of the presacral plane and removal of the intact mesorectum, represents the gold standard treatment for rectal cancer. The widespread adoption of this technique has resulted in decreasing local recurrence and improving survival. With both the open or the laparoscopic approach, the main challenge is to complete TME in low rectal lesions through a sphincter-saving procedure with negative distal margins, good quality specimens, and reduced morbidity. CRM is the closest distance between the radial resection margin and the tumor tissue by either the direct tumor spread, the areas of neural or vascular invasion, or the nearest involved lymph node. In our PCRT+ group, 2 patients had CRM involvement. Both were male patients and their tumors were located 1 cm and 2 cm away from the anus, respectively. Both tumors were located at the anterior wall of the rectum and their postoperative pathological stage was pT3N0M0. Due to the limitation of the narrow pelvis of male patients,[22] the tumor location at the anterior wall of the low rectum,[23] and tissue edema after radiotherapy, it was difficult to distinguish the boundary with the prostate during the operation. In low rectal cancer, CRM is positive in more than 30% of patients if an APR is performed, and in 10.7% if a LAR is performed. CRM involvement increases the more distally the tumor is located.[24] These were the reasons that could lead to CRM involvement.

Several studies demonstrate the importance of CRM as an independent prognostic factor for local recurrence and long-term survival,[25-28] suggesting that CRM might be a strong predictor of long-term oncologic outcomes. According to the European Society for Medical Oncology (ESMO) Clinical Practice Guidelines for rectal cancer, CRM is defined as involved if it is ≤ 1 mm from the tumor-free margin, leading to an increased risk of local recurrence, distant metastases, and poorer survival.[29] For CRM-threatened cancer on baseline MRI, long-course preoperative chemoradiation is generally used. Performing a good TME might be especially challenging in the case of patients with a narrow pelvis, in male patients, and in those with obesity, even in those with early rectal cancer. Clinicians should not only consider the T/N status for indications of CCRT, but also CRM involvement. Only complete TME and CRM assessment can effectively reduce the chance of local recurrence and distant metastasis, and provide patients with a better long-term survival rate.

Our study had some limitations. First, the current study was retrospective and not a randomized control trial. Selection bias existed. Second, the sample size was relatively small. Third, sphincter function was not evaluated after sphincter-sparing procedure. Despite these shortcomings, the study provides valuable information to guide the use of PCRT in patients with low-lying cT2N0 rectal cancer.

Conclusion

The current standard treatment for patients with low-lying cT2N0 rectal cancer is transabdominal resection. In our series, PCRT did not increase the rate of sphincter preservation but was associated with a higher rate of temporary stoma.

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原　著

在臨床期別第一期 (cT2N0M0) 的低位直腸癌，術前輔助性同步電化療是否必要？

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目的　第一期 (cT2N0M0) 的低位直腸癌術前輔助性電化療對於患者來說，仍然是一個有爭議性的議題，尤其是在肛門括約肌保留的部分。這個研究的目的主要是在評估第一期 (cT2N0M0) 低位直腸癌患者，給予術前輔助性電化療對於實際肛門括約肌保存率及預後。

方法　我們以回顧性的方法研究了在 2008 年 1 月至 2016 年 12 月期間，臨床分期為 T2N0M0 的低位直腸癌患者 (距離肛門邊緣 ≤ 6 cm) 接受手術治療的患者。以術前輔助性電化療的有無將患者分為兩組 (PCRT+ 對比 PCRT-)，並分析兩組的臨床病理特徵、肛門括約肌保留率及預後。

結果　48 名平均年齡為 66.33 歲的患者 (24 名男性和 24 名女性) 包含在此研究中。在術前評估裡，與沒接受術前輔助性電化療組 (PCRT-) 相比，接受術前輔助性電化療組 (PCRT+) 的患者，原發腫瘤與肛門的距離明顯較短 (3.86 ± 1.58 對 4.9 ± 1.37，p = 0.0216)。兩組的手術步驟及方法並無差異，但接受術前輔助性電化療組 (PCRT+)，術後有較高的造口比率及較低的直腸系膜淋巴結摘取數量。兩組中的肛門括約肌保留比率、原發腫瘤大小、與切除腫瘤遠端距離、切除邊緣侵犯率、術後併發症及死亡率無顯著差異。自診斷後的平均追蹤時間為 67.02 個月 (± 29.92 個月)。兩組之間的復發率，總體存活率，無病存活率和癌症特異性存活率無顯著差異。

結論　術前輔助性電化療 (PCRT) 對於低位直腸癌 (cT2N0M0) 患者並沒有提高肛門括約肌保留的機會，但會伴隨著較高的暫時性造口比率。

關鍵詞　T2 直腸癌、術前同步電化療、肛門保留、手術造口、存活率。