

Factors affecting sphincter-preserving resection treatment for patients with low rectal cancer

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Abstract. The aim of the present study was to identify the factors associated with the use of sphincter-preserving resection (SPR) surgery for the treatment of low rectal cancer. A total of 330 patients with histopathologically confirmed low rectal cancer were divided into two groups, namely the abdominoperineal resection (APR) and sphincter-preserving (SP) groups. For SPR factor analysis, the χ^2 test was performed as the univariate analysis, while a logistic regression test was conducted as the multivariate analysis. Of the 330 patients, 192 cases (58.18%) received SPR surgery and 138 cases (41.82%) underwent an APR. Univariate analysis results revealed that the sphincter-preserving factor was significantly associated with age, gender, ethnicity, body mass index (BMI), total infiltrated circumference, distance of the tumor from the anal verge (DTAV), depth of invasion and tumor grade ($P < 0.05$). However, there were no statistically significant associations with family medical history, diabetes history, venous tumor embolism, growth type, tumor length, lymphatic metastasis and level of preoperative carcinoembryonic antigen ($P > 0.05$). Multivariate analysis indicated that the sphincter-preserving factor was strongly associated with DTAV and the depth of invasion, with significant statistical difference ($P < 0.05$). Therefore, selecting SPR surgery for patients with low rectal cancer is dependent on age, gender, ethnicity, BMI, the total infiltrated circumference, DTAV, depth of invasion and tumor grade. In addition, DTAV and the depth of invasion are independent risk factors for the selection of SPR surgery.

Introduction

With improvements in living standards, colorectal cancer has become one of the most common malignant tumors worldwide. In China the morbidity of rectal cancer is 24 individuals per hundred thousand and it rose by 4% in the past decade. It also ranks third amongst the other cancers in morbidity. The incidence rate of rectal cancer, and particularly low rectal cancer, has increased, accounting for 60-75% (1). Abdominoperineal resection (APR) has remained the standard surgical procedure for the treatment of low rectal cancer (2). However, certain patients are unable to undergo APR treatment due to their inability to tolerate the lower quality of life caused by the permanent anal rechanneling following the procedure. Through carrying out preoperative neoadjuvant chemotherapy and with the development of surgical techniques, it is now possible to perform sphincter-preserving resection (SPR) on cases of low and ultra-low rectal cancer (3,4). SPR can improve postoperative quality of life, and there is no difference compared with APR treatment in terms of the degree of radical surgery required (5). Therefore, to a certain extent, SPR has replaced APR in becoming the first choice treatment for cases of low rectal cancer (6). However, the decision with regard to the selection of APR or SPR surgery for treatment remains controversial. Thus, the aim of the present study was to investigate the associated factors of selecting SPR surgery for the treatment of low rectal cancer. As it is known, the radical resection treatment of high and midrectal cancers has been standardized. Both of these methods are performed by receiving sphincter preservation surgery, in which the former ones can be treated by partial mesorectal excision and the later by total mesorectal resection (7,8). However, for surgical therapy the low rectal cancer remains controversial. In the past, some patients receive APR as the standard surgical procedure (9) whereas others benefit from sphincter preservation (2).

Materials and methods

Patients and clinicopathological parameters. Between June 2006 and December 2009, a total of 330 patients, admitted to the Affiliated Tumor Hospital of Xinjiang

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Medical University (Ürümqi, China) with histopathologically-confirmed low rectal cancer, were enrolled in the study. Rectal cancer with a distance of the tumor from the anal verge (DTAV) of 3-7 cm was defined as low rectal cancer (10). All patients received radical surgery. Clinicopathological features, including age, gender, ethnicity, body mass index (BMI), history of diabetes, family medical history, level of preoperative carcinoembryonic antigen (CEA), total infiltrated circumference, DTAV, depth of invasion, tumor grade, venous tumor embolism, growth type, tumor length and lymphatic metastasis were fully reviewed. The tumor-node-metastasis (TNM) stage was determined according to the American Joint Committee on Cancer/International Union Against Cancer TNM staging system of colorectal cancer (11). The following criteria were used to exclude patients: Preoperative adjuvant chemotherapy (18 cases), preoperative radiotherapy (8 cases), preoperative chemoradiotherapy (59 cases), confirmed metastasis (63 cases) and rejection of APR treatment (13 cases). The study was approved by the Medical Ethics Committee of the Affiliated Tumor Hospital of Xinjiang Medical University (no. W201324). Informed consent was obtained from all the patients prior to their participation in the study.

Surgical pattern. Open surgery using the total mesorectal excision (TME) (12) technique was successfully performed on all 330 patients. Of these, 192 cases (58.18%) received SPR and 138 cases (41.82%) underwent APR. All postoperative incisional margins were pathologically confirmed as negative.

Postoperative therapy. Radiotherapy was applied to all the patients with rectal cancer of $pT_3N_0M_0$ or $pT_{1-3}N_{1-2}M_x$. The chemotherapy scheme of FOLFOX6 was administered intravenously injected with intravenously infused 130 mg/m² oxaliplatin (L-OHP) that lasted 3 h on the first day, an intravenously infused 300 mg/m² calcium folinate (CF) injection, an intravenously injected 400 mg/m² 5-FU injection and a 2,400 mg/m² 5-FU continuous intravenous infusion by a micropump for 48 h, for 14 days per cycle and for 12 cycles in total. For the recurrence therapy, the scheme of FOLFIRI was performed at 2 weeks per therapeutic circle until the dose became intolerable or invalid. This was performed on the first day with an intravenously infused 350 mg/m² Irinotecan (CPT-11) injection, an intravenously infused 300 mg/m² CF injection, a 400 mg/m² 5-FU injection that was intravenously injected and a 2,400 mg/m² 5-FU continuous intravenous infusion by a micropump for 48 h. For the patients who exhibited drug resistance, the chemotherapy scheme of XELOX was used. This therapy consisted of the following on the first day: an intravenously infused 130 mg/m² L-OHP injection for 3 h, 1,000 mg/m² capecitabine tablets, po., twice a day, from the first to the fourth day, 3 weeks per cycle and for nine cycles in total. These treatment criteria were according to the Ministry of Health of China (13).

Follow-up assessments. All the patients enrolled in the study were registered at the hospital and complete personal follow-up files of the patients with explicit pathological diagnoses were established. Following surgery, the patients were followed-up once every 3 weeks within the first 6 months,

once every 3 months for the subsequent two years and once every 6 months thereafter until they succumbed to the disease or their contact information was lost. Two follow-up procedures were performed, namely outpatient or inpatient review and a telephone follow-up, which included information regarding postoperative chemotherapy, postoperative radiotherapy, chemotherapy regimens, therapeutic course count, side effects, recurrence and survival time. A digital examination was performed each time. Other inspection methods carried out regularly included computerized tomography scans (GE Discovery CT750 HD, GE Healthcare Biosciences, Pittsburgh, PA, USA), magnetic resonance imaging (1.5-T General Electric Medical Systems, Signa®, Milwaukee, USA), electronic colonoscopy (PCF-200, Olympus®, Tokyo, Japan) and CEA level measurements.

Statistical analysis. Using the SPR procedure as the dependent variable, univariate analysis was performed with the χ^2 test and Fisher's exact test. Multivariate correlation analysis was carried out with the logistic regression test. In addition, survival analysis was performed using the log-rank test. All statistical tests were conducted using SPSS 19.0 software (IBM SPSS, Armonk, NY, USA). $P \leq 0.05$ was considered to indicate a statistically significant difference.

Results

SPR procedure. Of the 192 patients who received SPR surgery, 16 cases underwent a unilateral inguinal lymphadenectomy due to visible lymphadenectasis and nine cases experienced a bilateral inguinal lymphadenectomy. A number of the key steps involved in the SPR surgery are shown in Fig. 1.

Local recurrence results. Of the 330 patients, 192 cases (58.18%) received an SPR and 138 cases (41.82%) underwent APR surgery. In the three-year follow-up period, the total local recurrence rate in the pelvic cavity was 4.24%. The local recurrence rate of the APR group was 3.62% (5/138), while the rate was 4.69% (9/192) in the SP group, with no statistically significant difference ($P > 0.05$; Table I).

Univariate correlation analysis for SPR surgery with associated clinicopathological features. For patients with low rectal cancer, the univariate analysis results revealed that the sphincter-preserving factor was associated with age, gender, ethnicity, BMI, total infiltrated circumference, DTAV, depth of invasion and tumor grade, with significant statistical difference ($P < 0.05$). However, no statistically significant associations were observed with the family medical history, diabetes history, venous tumor embolism, growth type, tumor length, lymphatic metastasis and preoperative CEA level ($P > 0.05$; Table II).

Multivariate correlation analysis for SPR surgery with associated clinicopathological features. Multivariate correlation analysis indicated that the sphincter-preserving factor was closely associated with DTAV and the depth of invasion, with significant statistical difference ($P < 0.05$). Consequently, DTAV and the depth of invasion were determined to be independent risk factors for SPR (Table III).

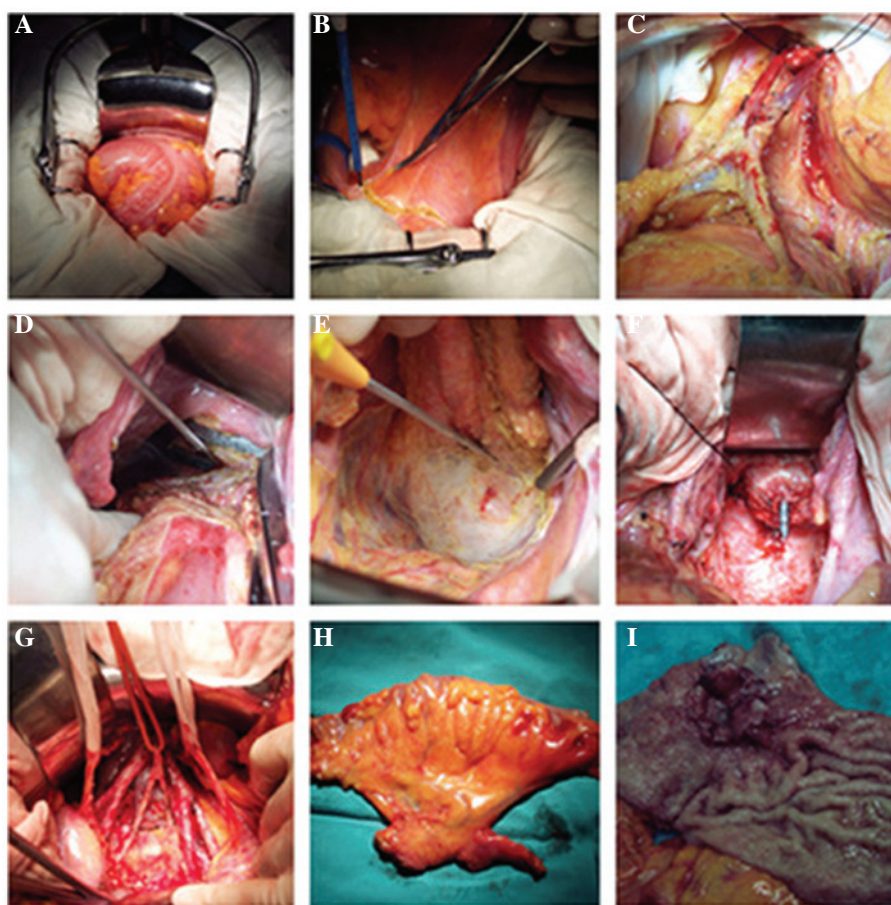


Figure 1. A number of the key procedures included in the sphincter-preserving resection surgery. (A) Abdominal dissection; (B) opening of the mesentery; (C) ligation and incision of the inferior mesenteric artery and vein; (D) separation of the superior rectal spaces; (E) separation of the inferior rectal spaces; (F) insertion and fixation of a tubular anastomosis into the distal incised end of the rectum; (G) bilateral inguinal lymphadenectomy; (H) tissue excision extension and (I) tumor mass.

Discussion

The TME technique proposed by Heald in 1982 (14) has been regarded as the gold standard for the treatment of rectal cancer. The TME technique significantly decreases the local postoperative recurrence rate of rectal cancer (15). In certain cases, selecting the surgical method is difficult due to the specific tumor location of low rectal cancer. Retaining anal function following radical surgery, local recurrence rate control and improving postoperative quality of life have caused the selection of the appropriate surgical method for the treatment of low rectal cancer to be increasingly studied (16). The local recurrence rate is an important index for evaluating the efficacy of the SPR outcome for low rectal cancer, and this has been extensively studied. In previous studies, Peeters *et al* reported a local recurrence rate of ~10% (17), while You *et al* reported a local recurrence rate of 6.9% (18), and in the study by Sun and Wang, a local recurrence rate of 6.71% was determined (19). In the present study, the local recurrence rate in the pelvic cavity of patients with low rectal cancer was 4.24%, which was 3.62 and 4.69% in the APR and SP groups, respectively, with no statistically significant difference ($P>0.05$). Thus, the SPR surgical method did not increase the local recurrence rate of low rectal cancer. This conclusion is similar to the majority of previous studies (20,21). Consequently, the selec-

tion of SPR surgery for the treatment of low rectal cancer primarily depends on the accurate preoperative assessment of the clinicopathological features of the patient, which are beneficial to design a more reasonable surgical scheme.

DTAV is regarded as the most important factor for the determination of anal preserving surgery methods by the majority of researchers (22,23). Colorectal cancer has the particular biological characteristic of upwards growth along the intestinal wall (24). However, the downward growth is generally within 2.0 cm and growth of >2.0 cm presents in only 3% of cases (25,26). A consensus was recently reached that a distal normal bowel resection of >2.0 cm was sufficient for treatment (27). According to the US National Comprehensive Cancer Network guidelines (revised in 2005), resecting a 1-2-cm section of the distal rectal cancer in cases where the DTAV is <5 cm is feasible. Based on the characteristics of colorectal cancer anatomy, disconnecting the ligament can extend the intestinal canal by 3-5 cm (28), which greatly increases the success rate of low anastomosis procedures. At present, according to clinical experience and literature reports (22,29,30), a DTAV of 5 cm is the boundary for the selection of SPR surgery treatment. Rectal cancer with a DTAV of 5-7 cm has a relatively high rate of sphincter preservation since the intestinal tube is sufficient in length for convenient anastomosis. In the present study, a DTAV of

Table I. Three-year local recurrence rate in the APR and SP groups.

Group	Cases, n	Local recurrence, n (%)	χ^2	P-value
SP	192	9 (4.69)	0.224	0.636
APR	138	5 (3.62)	-	-

APR, abdominoperineal resection; SP, sphincter-preserving.

Table II. Univariate analysis results of SP with associated clinicopathological features for patients with low rectal cancer.

Clinicopathological features	Cases, n	SP group, n (%)	APR group, n (%)	χ^2	P-value
Gender					0.003
Male	168	88 (52.38)	80 (47.62)	4.733	
Female	162	104 (64.20)	58 (35.80)		
Age, years					0.002
≤ 40	34	10 (29.41)	24 (70.59)	13.004	
41-60	134	81 (60.45)	53 (39.55)		
≥ 61	162	101 (62.34)	61 (37.66)		
Tumor length, cm					0.317
< 4	146	84 (57.53)	62 (42.47)	2.298	
4.0-5.0	132	82 (62.12)	50 (37.88)		
> 5.0	52	26 (50.00)	26 (50.00)		
Ethnicity					0.011
Han	278	170 (61.15)	108 (38.85)	6.393	
Uyghur	52	22 (43.31)	30 (46.69)		
Growth type					0.290
Ulcerative	191	108 (56.54)	83 (43.46)	2.476	
Mass	125	78 (62.40)	47 (37.60)		
Infiltrating	14	6 (42.86)	8 (57.14)		
Tumor grade					< 0.001
Well	38	25 (65.79)	13 (34.21)	16.198	
Moderate	182	120 (65.93)	62 (34.07)		
Poorly/anaplastic	110	47 (42.73)	63 (57.27)		
Lymphatic metastasis					0.458
N0	204	124 (60.78)	80 (39.22)	1.560	
N1	81	43 (55.56)	38 (44.44)		
N2	45	25 (51.85)	20 (48.15)		
Depth of invasion					0.001
T1/T2	84	59 (70.24)	25 (29.76)	14.645	
T3	126	79 (62.70)	47 (37.30)		
T4	120	54 (45.00)	66 (55.00)		
DTAV, cm					< 0.001
3- < 5	124	11 (8.87)	113 (91.13)	198.518	
5-7	206	181 (87.86)	25 (12.14)		
Total infiltrated circumference (cycle)					< 0.001
$< 1/2$	115	80 (69.57)	35 (30.43)	17.878	
$1/2$ - $< 3/4$	124	75 (60.48)	49 (39.52)		
$\geq 3/4$	91	37 (40.66)	54 (59.34)		
Preoperative CEA, μg					0.891
< 5	219	128 (58.45)	91 (41.55)	0.019	
≥ 5	111	64 (57.66)	47 (42.34)		

Table II. Continued.

Clinicopathological features	Cases, n	SP group, n (%)	APR group, n (%)	χ^2	P-value
Venous tumor embolus					0.746
No	317	185 (58.35)	132 (41.65)	0.105	
Yes	13	7 (53.84)	6 (46.16)		
Diabetes history					0.844
No	286	167 (58.39)	119 (41.61)	0.039	
Yes	44	25 (56.82)	19 (43.18)		
BMI					0.030
<25	181	115 (63.54)	66 (36.46)	4.723	
≥25	149	77 (51.68)	72 (48.32)		
Tumor family history					0.727
No	266	156 (58.25)	110 (41.75)	0.122	
Yes	64	36 (56.25)	28 (43.75)		

APR, abdominoperineal resection; SP, sphincter-preserving; DTAV, distance of the tumor from the anal verge; CEA, carcinoembryonic antigen; BMI, body mass index.

Table III. Multivariate correlation analysis of SPR surgery with associated clinicopathological features for patients with low rectal cancer.

Variable	β -value	SE	Wald value	P-value	OR	95% CI
DTAV	4.714	0.473	99.526	<0.001	111.539	44.176-281.625
Depth of invasion ^a						
T2 X13			11.234	0.004		
T3 X13 (1)	0.892	0.432	4.271	0.039	2.441	1.047-5.689
T4 X13 (2)	1.900	0.582	10.669	0.001	6.686	2.138-20.910

^aDepth of invasion is an introduced dummy variable to produce the multivariate analysis. DTAV, distance of the tumor from the anal verge; SE, standard error; OR, odds ratio; CI, confidence interval; SPR, sphincter-preserving resection. X is an independent variable of the Logistic regression analysis. X13 stands for the 13th independent variate. Two dummy variables were introduced in the Logistic regression analysis. These are T3 vs. T2 and T4 vs. T2. T2 is the internal reference.

3-7 cm was selected, since a DTAV of <3 cm can markedly decrease the effect of radical surgery. Rectal cancer with a DTAV of >5 cm was shown to have a higher rate of sphincter preservation (87.86%) compared with cases where the DTAV was 3-5 cm (8.87%), and the difference was statistically significant ($P<0.05$). Furthermore, multivariate analysis revealed that the DTAV is an independent risk factor for treatment with SPR surgery in patients with rectal cancer.

A consensus has not been reached on whether the depth of invasion is an independent risk factor for SPR surgery in patients with low rectal cancer. However, the majority of studies (22,29,31,32) support the hypothesis that the depth of invasion is an independent risk factor. The studies report that the rectum below the peritoneum has no serosa layer covered. Rectal tumors are able to infiltrate into the tissue outside the rectum and pelvis, which increases the difficulty of SPR surgery and increases the local recurrence rate (33,34). In the present study, univariate and multivariate analyses indicated that the rate of sphincter preservation was associ-

ated with the depth of invasion, and statistically significant differences were observed ($P<0.05$). Thus, the deeper the rectal tumor infiltrate, the lower the rate of sphincter preservation. Furthermore, univariate analysis results revealed that the sphincter-preserving factor was strongly associated with the total infiltrated circumference, which was similar to the results of a study by Cong (22). According to the growth characteristics of the malignant tumor, the longer the growth cycle and the wider the tumor infiltrates, the more difficult the surgery becomes. When rectal cancer infiltration reaches close to a complete cycle of the rectum, the depth of invasion is primarily in the T3 or T4 stage, and the adjacent tissue of the intestinal tube may be infiltrated. Consequently, SPR surgery becomes too difficult to be implemented.

Xinjiang Uygur Autonomous Region in the northwest of China comprises numerous ethnic groups that have different diets, living habits and plateau environments. Therefore, ethnicity was an important research parameter in the current study. However, the results of the present study demonstrated

that SPR surgery success was not associated with ethnicity. Liu *et al* (35) reported that the rates of obesity in the Kazak and Uygur ethnic populations were 40.1 and 28.9%, respectively, which were markedly higher compared with the Han ethnicity (18.4%). The increase in surgical difficulty as a result of obesity may decrease the rate of sphincter preservation in patients from the Uygur ethnicity (36,37). Furthermore, on an economical and cognitive level, rectal cancer in Uygur populations is generally diagnosed much later in the disease stage, resulting in a larger tumor size and deeper invasion, which greatly influences the rate of sphincter preservation (38-40). In the present study, univariate analysis demonstrated that the sphincter-preserving factor was significantly associated with gender, BMI, age and tumor grade. The reasons for this may be as follows: i) The male pelvis is narrower and smaller, which increases the difficulty of the surgery for patients with rectal cancer; ii) young patients tend to be diagnosed at a later stage of the disease; thus, there is more extensive invasion of adjacent tissue; iii) obesity increases the surgical difficulty, particularly with regard to sphincter preservation; and iv) a low differentiated rectal tumor may lead to deeper tumor invasion (41,42).

In conclusion, there are numerous risk factors with regard to sphincter preservation for patients with low rectal cancer. The sphincter-preserving factor was demonstrated to be associated with certain clinicopathological features, including DTAV and the depth of invasion. Therefore, careful preoperative evaluation of the associated risk factors may be beneficial for selecting the precise surgical pattern (SPR or APR) and ensuring an accurate surgical procedure, which may subsequently enhance the rate of sphincter preservation and improve the quality of life of patients with low rectal cancer.

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