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Risk Factors Associated With Sphincter-Preserving Resection in Patients With Low Rectal Cancer

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Abdominoperineal resection (APR) and sphincter-preserving resection (SPR) are the two primary surgical options for rectal cancer. Retrospectively we collected rectal cancer patients for SPR and APR observation between 2005 and 2007. The patient-related, tumor-related, and surgery-related variables of the SPR and APR groups were analyzed by using logistic regression techniques. The mean distance from the anal verge (DAV) of cancer is significantly higher in SPR than that in APR ($P < 0.001$). In cancers with DAV <40 mm (SPR, 40 versus APR, 110), multivariate analysis shows that surgeon procedure volume (odds ratio [OR] = 0.244; 95% confidence interval [CI]: 0.077–0.772; $P = 0.016$) and neoadjuvant radiotherapy (OR = 0.031; 95% CI: 0.002–0.396; $P = 0.008$) are factors influencing SPR. In cancers with DAV ranging from 40 mm to 59 mm (SPR 190 versus APR 50), analysis shows that patient age (OR = 2.139; 95% CI: 1.124–4.069; $P = 0.021$), diabetes (OR = 2.657; 95% CI: 0.872–8.095; $P = 0.086$), and colorectal surgeon (OR = 0.122, 95% CI: 0.020–0.758; $P = 0.024$), are influencing factors for SPR. The local recurrence and disease-free survival reveal no significant difference. A significant difference exists in DAV, surgeon specialization, procedure volume, age, diabetes, and neoadjuvant radiotherapy between SPR and APR.

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Abdominoperineal resection (APR) with permanent colostomy and sphincter-preserving resection (SPR) of the rectum are the two primary surgical options for the curative treatment of rectal cancer. With the introduction of the concept of total mesorectal excision (TME), combined with the significant effects of adjuvant radiochemotherapy and surgical staplers, SPR indication has been significantly expanded compared with APR in low or ultra-lower rectal cancer.

For patients with rectal cancer, sphincter preservation (SP) is often as important as curing cancer. Surgeons need to determine whether a patient with lower rectal cancer is suitable for SP. However, a standard method of determining patient suitability is unavailable because this judgment depends on the different individual experiences of surgeons.

In addition to the distance of the tumor from the anal verge (DAV), other important factors such as the patient's individual condition, oncologic consideration, technical feasibility, and the surgeon's personal experience, are reported as risk factors that may influence the SP rate.[1–3] This study aims to determine the significance of these factors on achieving SPR in a single large-volume institution.

Methods

We retrospectively collected consecutive data of rectal cancer patients in Changhai Hospital, Shanghai, China. A total of 938 patients underwent rectal resection between January 2005 and December 2007, including 744 SPRs, 164 APRs, and 30 Hartmann's resections. Patients who underwent transanal excision were not included. The SP rate was 79.3%. In the majority of patients, DAV was measured by the surgeon during preoperative rigid proctoscopy, with the patient in the lateral position. We screened rectal cancer cases with DAV lower than 60 mm as "low rectal carcinoma" to control tumor location bias. The surgical procedure strictly followed the TME principle, as described by Heald.[4] Transanal excision and Hartmann's resection were not discussed in this article. Patients were followed-up, and the local recurrence and disease-free survival were compared.

Patient-related, tumor-related, and surgery-related characteristics, which can be obtained before the operation, may influence the SP rate; therefore, these data were analyzed. The patient-related variables include sex, age, body mass index (BMI), diabetes mellitus, smoking/alcohol abuse, hypertension, and other concomitant disease (e.g., coronary heart disease, infarction of the brain, asthma, or chronic obstructive pulmonary disease). The tumor-related variables include serum carcinoembryonic antigen levels, carbohydrate antigen 19-9 levels, tumor histology and differentiation, and distant metastasis. The surgery-related variables include neoadjuvant radiotherapy, surgeon procedure volume, colorectal surgeon, emergent operation, and resection of other organs. Surgeon procedure volume was determined through analysis of the mean number of rectal cancer operations performed by each surgeon per year (2005–2007) and categorized by using the following range: low volume, <10 rectal resections per year; medium volume, 10 to 50 rectal resections per year; and high volume, >50 rectal resections per year.

Statistical Analysis

Univariate comparison of factors was performed by using χ^2 test of categorical variables and unpaired Student *t*-test of continuous variables. Multivariate analyses of factors associated with SPR were performed by using logistic regression. We used the statistical software (SPSS version 13.0; SPSS Inc., Chicago, IL, USA) for all statistical analyses. Statistical significance was considered if the two-sided P value was less than 0.05.

Results

From 2005 to 2007, 390 patients who underwent SPR (n = 230) or APR (n = 160) were identified to have DAV lower than 60 mm by using the TME technique. A total of 105 females (45.7%) were in SPR, and 62 females (38.8%) were in APR ($P = 0.175$). The average age of patients was 57.1 ± 13.0 years and 59.2 ± 12.6 years ($P = 0.122$) in SPR and APR, respectively. The mean DAV of rectal cancer was 42.3 ± 8.2 mm in SPR and 32.4 ± 11.1 mm in APR. These results are statistically significant ($P < 0.001$). The rate of defunctioning stoma in SPR was 68.3%.

Short-Term Peri-operative Outcomes

No postoperative mortality was noted for patients who underwent SPR. Postoperative morbidity was

Table 1 Follow-up data for 312 patients with low rectal cancer

	SPR (n = 181)	APR (n = 131)	*P* value
Follow-up rate, n (%)	181 of 230 (78.7)	131 of 160 (81.9)	
Median (range) follow-up, mo	37.1 (2–62)	39.0 (2–66)	
Estimated 5-year local recurrence rate, %[a]	6.8 (0.0)	8.2 (0.0)	0.830
Estimated 5-year disease-free survival rate, %*	75.4 (0.0)	74.9 (0.1)	0.498
Mean disease-free survival, mo[b]	59.4 (55.5, 63.4)	61.1 (59.7, 62.5)	

[a]Kaplan–Meier actuarial rates with standard error.

[b]Values in parentheses are 95% confidence intervals.

14.8% (n = 34), with an overall anastomotic leakage rate of 4.3% (n = 10). Postoperative mortality was 0.6% (n = 1) and postoperative morbidity was 15.6% (n = 25) in APR patients. This difference was not statistically significant ($P = 0.819$).

Long-Term Oncologic Outcomes

The data of 312 (80.3%) out of the 389 patients were available for the analysis of long-term oncological outcomes. A total of 77 (19.8%) patients failed to follow-up. The median follow-up period was 38.0 months for the 181 SPR patients and 38.5 months for the 131 APR patients. Local recurrence and disease-free survival in these 2 patient groups revealed no significant differences. Table 1 shows an overview of the oncological outcomes.

Figure 1 shows that APR was more frequently adopted than SPR in the treatment of rectal cancer with DAV lower than 40 mm, whereas SPR was more frequently adopted than APR in the treatment of rectal cancer with DAV between 40 mm and 59 mm. Therefore, our first comparison was made between the SPR and APR groups in rectal cancer with DAV <40 mm (SPR 40 versus APR 110) to control the bias of DAV. The second comparison was made between SPR and APR in rectal cancer with DAV ranging from 40 mm to 59 mm (SPR 190 versus APR 50).

In Rectal Cancers With DAV <40 mm (SPR 40 versus APR 110)

Univariate χ^2 test indicates that age and neoadjuvant radiotherapy were significantly different between SPR and APR (see Table 2). The SPR rate in patients younger than 50 years was 40.4% (19/47), which is significantly higher than that of patients aged 50 years to 70 years (20.5%, 16/78) or >70 years (20%, 5/25; $P = 0.036$). Eight of the 9 patients with neoadjuvant radiotherapy achieved SPR ($P < 0.001$).

Multivariate logistic regression analysis (see Table 3) indicates that surgeon procedure volume (OR = 0.244; 95% CI: 0.077–0.772; $P = 0.016$) is an influencing factor for SPR and was brought into the regression equation. Neoadjuvant radiotherapy is also an influencing factor for SPR (OR = 0.031; 95% CI: 0.002–0.396; $P = 0.008$). On the one hand, the SPR rate of the patients of high-volume surgeons was as high as 31.6% (31/98), although the tumor positions in the patients were very low. On the other hand, the SPR rates of the patients of medium- and low-volume surgeons were only 19.6% (9/46) and 0% (0/6), respectively.

In Rectal Cancers With DAV Ranging From 40 mm to 59 mm (SPR 190 versus APR 50)

Univariate χ^2 test indicates that diabetes mellitus, surgeon procedure volume, and colorectal surgeon are associated with SPR (see Table 2). Patients with diabetes mellitus are less likely to achieve SPR. The SPR rate of the diabetes group was only 59.1% (13/22), which is lower than that of the nondiabetes group (81.2%, 177/218) (P = 0.030). The SPR rates of patients of high- and medium-volume surgeons were 79.5% (128/161) and 86.7% (52/60), respec-

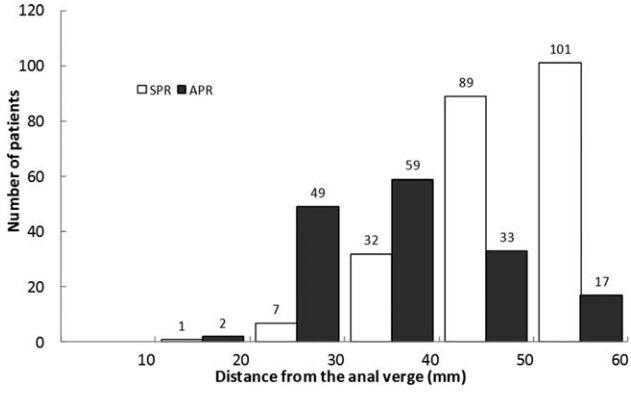

Fig. 1 Relationship between tumor distance from the anal verge and the two surgical options.

Table 2 Univariate χ^2 test of variables

Variable	Step one: DAV <40 mm				Step two: DAV 40–59 mm			
	SPR (n = 40)	APR (n =110)	χ^2	*P* value	SPR (n =190)	APR (n =50)	χ^2	*P* value
Sex								
Male	19	64	1.354	0.245	106	34	2.428	0.119
Female	21	46			84	16		
Age								
<50 years	19	28	6.628	0.036	48	6	4.779	0.092
50–70 years	16	62			109	31		
>70 years	5	20			33	13		
BMI								
<22.9	25	59	0.836	0.658	90	19	3.829	0.147[a]
22.9–25	5	17			42	9		
>25	10	33			55	22		
Smoking/alcohol abuse								
Present	8	24	0.057	0.81	40	15	1.793	0.18
Absent	32	86			150	35		
Diabetes								
Present	2	5	0.103	0.748	13	9	4.654	0.03
Absent	38	105			177	41		
Hypertension								
Present	6	18	0.04	0.84	39	9	0.158	0.691
Absent	34	92			151	41		
Other concomitant disease								
Present	9	32	0.642	0.423	60	22	2.715	0.099
Absent	31	78			130	28		
Neoadjuvant radiotherapy								
Present	8	1	15.722	<0.001	12	4	0.18	0.671
Absent	32	109			178	46		
Surgeon procedure volume								
Low	0	6	4.604	0.1	10	9	10.169	0.006
Medium	9	37			52	8		
High	31	67			128	33		
Surgeon								
Colorectal	40	104	1.074	0.3	181	41	10.037	0.002
Noncolorectal	0	6			9	9		
Emergent operation								
Present	3	5	0.091	0.763	11	2	0.021	0.884
Absent	37	105			179	48		
Other organs resection with suspicious metastasis								
Present	0	4	0.422	0.516	10	3	<0.001	1
Absent	40	106			180	47		
CEA								
Normal	20	59	0.189	0.663[a]	121	32	0.011	0.914[a]
Abnormal	18	45			62	17		
CA19-9								
Normal	31	86	0.15	0.697 [a]	151	34	0.916	0.338[a]
Abnormal	7	16			30	10		
Tumor histology								
Adenocarcinoma	31	94	0.133	0.247	162	39	1.759	0.184[a]
Mucinous adenocarcinoma	9	16			27	11		
Tumor differentiation								
High/Medium	28	80	0.176	0.674[a]	142	40	0.036	0.847[a]
Low/In-	5	18			17	5		
Depth of invasion by tumor								
T1	3	2	4.366	0.225[a]	12	1	3.54	0.316[a]
T2	14	41			56	12		
T3	19	63			101	34		
T4	3	4			16	3		

Table 2 Continued

Variable	Step one: DAV <40 mm				Step two: DAV 40–59 mm			
	SPR (n = 40)	APR (n =110)	χ^2	*P* value	SPR (n =190)	APR (n =50)	χ^2	*P* value
Distant metastasis								
Present	1	7	0.271	0.603	18	4	0.003	0.955[a]
Absent	39	103			171	46		

[a]The result of this variable was not collected in some cases, so these cases were not counted into the analysis of the χ^2 test.

tively, which were significantly higher than those of patients of low-volume surgeons (52.6%, 10/19; $P = 0.006$). Patients of colorectal surgeons were more likely to achieve SPR (81.5%, 181/222) compared with those of noncolorectal surgeons (50.0%, 9/18; $P = 0.002$).

Multivariate logistic regression analysis (see Table 3) indicates that patient age (OR = 2.139; 95% CI: 1.124–4.069; $P = 0.021$) is an influencing factor for SPR and was brought into the equation. The factors diabetes mellitus (OR = 2.657; 95% CI: 0.872–8.095; $P = 0.086$) and colorectal surgeon (OR = 0.122; 95% CI: 0.020–0.758; $P = 0.024$) are also influencing factors for SPR. Patients aged younger than 50 years were more likely to achieve SPR (88.8%, 48/54) compared with patients aged between 50 and 70 years (77.9%, 109/140) and older than 70 years (71.7%, 33/46).

Discussion

APR with permanent colostomy and SPR are the main procedures for low rectal cancer. The former used to be the gold standard treatment for nearly all patients presenting carcinoma of the low rectum. However, the introduction of TME permits the sphincter-preserving removal of rectal cancer without compromising oncological radicality.[5] Furthermore, studies have shown that a tumor-free resection margin as short as 1 to 2 cm is oncologically safe. This finding, coupled with the technical feasibility of ultralow anastomosis, that has been obtained because of the introduction of surgical-stapling devices, has reduced the number of patients undergoing APR but increased that undergoing SPR.[6–8] For patients with rectal cancer, SP is often as important as curing cancer. Instead of being concerned with survival issues, patients are now concerned with the following issues: "Am I going to lose my anus?" and "Do I have to wear a bag for the rest of my life?" The questions concerning the optimal surgical treatment of low rectal cancer will be different.

The main operation problem of rectal cancer has been transferred to anal conservation. The SP technology has been proven a safe and effective procedure for low rectal cancer. The burden of proof has been to demonstrate that the outcome of sphincter-sparing surgery is equivalent to or even better than that of APR. However, a randomized trial has never been conducted to prove this claim. SPR can maintain bowel function and improve the quality of life of patients without requiring the use of colostomies.[9,10] Surgeons have gradually favored SPR over APR.[11,12] Most surgeons in our study prefer a two-staged SP approach, including the creation of a temporary stoma (with a rate of 68.3%) and stoma reversal during, or at the end of, adjuvant chemotherapy treatment. This practice pattern is supported by recent randomized controlled trials that compare SPR with or without a diverting stoma. These trials demonstrate improved outcomes (i.e., fewer anastomotic leaks, emergency operations for infection, abscess) with a temporary stoma.[13,14]

Several predictive factors have been identified in this study as to which patients with low rectal

Table 3 Multivariate logistic regression analysis of variables in rectal cancers

Group	Variable	OR	95% CI		*P* value
			Lower	Upper	
DAV <40 mm	Surgeon procedure volume	0.244	0.077	0.772	0.016
	Neoadjuvant radiotherapy	0.031	0.002	0.396	0.008
DAV 40–59 mm	Age	2.139	1.124	4.069	0.021
	Diabetes	2.657	0.872	8.095	0.086
	Colorectal surgeon	0.122	0.020	0.758	0.024

cancer are more likely to achieve SPR. Conventional knowledge dictates that the need for permanent colostomy is mainly driven by DAV.[15] This article has also demonstrated that DAV remains to be one of the most important factors in undergoing sphincter-preserving surgery. In low rectal cancers with DAV <60 mm, the mean DAV was 42.3 mm in the SPR group and 32.4 mm in the APR group, which is statistically significant ($P < 0.001$). In addition to DAV, we have identified several risk factors in which a significant difference exists between SPR and APR. The variables that reflect the technical expertise of the surgeon are shown to play a pivotal role in this study.

The surgeon characteristics have always been considered an important factor of SP incidence, morbidity, and local recurrence of rectal cancer surgery. Anal conservation in the low rectal cancer setting is heavily dependent on two surgeon variables: specialization and technical expertise. The following points explain the importance of surgeon specialization: comprehension of the pathophysiology of rectal cancer and mode of spread; ongoing refreshment of knowledge by keeping abreast of the current literature and outcome of different treatments and surgical options; an appreciation for the role and contribution of neoadjuvant chemoradiation; keen observation of the functional results. Technical expertise is built upon the clear understanding of the pelvic anatomy, extensive surgical practice, and experiences with a variety of techniques.

Surgeon procedure volume is a reliable indicator of technical expertise. The procedure volume is also relevant with specialization. High-volume surgeons are most likely specialists in large centers who have treated a high number of colorectal carcinomas. High-volume surgeons also have more opportunities for advanced professional training and for consolidating the TME "learning curve" because their skills become refined by the large number of daily operations. Our study demonstrates that patients of high-volume surgeons and colorectal surgeons have high SPR rates. Patients of high-volume surgeons are more likely to achieve SPR (31.6%) in rectal cancer with DAV <40 mm. In rectal cancers with DAV ranging from 40 to 59 mm, the SPR rate of the colorectal surgeon group was as high as 81.5%. Other studies have obtained similar results.[16,17] On the basis of the data from a Canadian cancer registry,[18] a positive relation exists between colorectal-trained surgeons together with surgeon caseload, as well as the likelihood of patients undergoing SPR compared with APR. Purves *et al*. studied 477 patients undergoing surgery for rectal cancer and determined that patients treated by high-volume surgeons (>10 rectal resections per year) had significantly higher SPR rates (OR = 5.05) compared with patients treated by low-volume surgeons (1 to 3 resections per year).[19]

A relationship exists between surgeon procedure volume and SP. Likewise, a similar relationship exists between surgeon procedure volume and patient outcome.[20,21] These results emphasize the necessity of technical expertise in rectal cancer resections and demonstrate the importance of specialization in colorectal surgery and establishment of a standard TME technique. Given the implications of surgery type on the quality of life of patients, these results should be considered by both patients and providers when deciding on a suitable rectal cancer treatment. More information should be given regarding the correlation of improved short-term perioperative and long-term oncologic outcomes and high procedure volume to help patients determine the potential value of referral to high-volume surgeons with specialized skills.

Our results also indicate that DAV, surgeon specialization, procedure volume, age, diabetes mellitus, and neoadjuvant radiotherapy are important factors in patients who had relatively high tumors but still underwent APR and in patients with low tumors who underwent SPR. Opposing the belief of many surgeons, sex is shown to be not significant in this study.[22] These data provide evidence that DAV is not the only prognostic factor for SPR. Previous studies indicate that rectal carcinoma patients prefer to be involved in the decision-making process and to be informed about the risks of different treatment options.[23] By using these data, the treating physician can counsel patients better about the risk of permanent or temporary colostomy. This case is important when considering the use of critical and often scarce resources, such as enterostomal therapy nurses, for pre-operative consultation.

This study has several limitations. The primary limitation of this study is that only a single institution is used. Another limitation is that although growing evidence exists indicating that neoadjuvant radiotherapy does influence SP,[24–27] only a small number of patients (6.4%) received neoadjuvant radiotherapy in this study. Neoadjuvant treatment is not completely accepted in China because most Chinese patients believe that once a

tumor is discovered, an operation should be performed as soon as possible. For this reason, patients often express a strong desire to avoid neoadjuvant radiotherapy when doctors express the opposite view. In addition, the rate of patients lost during follow-up is high. Our institution is one of the largest colorectal carcinoma treatment centers in eastern China, and numerous patients come from provinces across the country. Given the nature of our institution and the reality that Chinese patients do not attach importance to follow-ups, several patients (19.8%) choose to follow-up with their local physician instead of returning to our institution. Although SPR for high rectal tumors results in good function, several studies indicate that SPR for low rectal tumors results in significant functional alterations that affect the quality of life.[28] However, the follow-up data did not include a reliable assessment of bowel function from the perspective of either patient or physician.

Conclusion

We have identified that a significant difference exists in DAV, surgeon procedure volume, surgeon specialization, age, diabetes mellitus, and neoadjuvant radiotherapy between SPR and APR group. The prognostic factors identified in this article are helpful in identifying patients who may be suitable for SPR. Future directions may include an extension of this work with more patients to create a preoperative nomogram that can effectively relate the individual factors. SPR is no longer a procedure parallel with, APR but should be considered a quality measure or an end point in addition to oncologic outcomes.

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