Original Article

The Risk Factors of Anastomotic Leakage and Influence of Fecal Diversion after Resection of Rectal Cancer

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Key Words
Rectal cancer;
Anastomotic leakage;
Diverting stoma

Purpose. The most important surgical complication following rectal resection with anastomosis is symptomatic anastomotic leakage. This study investigated factors in anastomotic leakage and the effect of fecal diversion after resection of middle and low rectal cancers.
Methods. Prospective data collection from patients with rectal cancer at 16 cm or less from anal verge was reviewed and risk factors of anastomosis investigated. The relationship between anastomotic leakage and clinicopathologic variables was determined using logistic regression analysis. Multivariate analysis with a logistic regression model was done to determine independent factors of anastomotic leakage.
Results. From January 1993 to June 2003, 999 rectal cancer patients received elective radical resection and anastomosis. Fifty-three of these patients experienced anastomotic leakage. Univariable analysis revealed that age > 70 years old ($P = 0.008$), tumor location between 6-12 cm ($P = 0.026$), and surgery with ultra-LAR ($P = 0.002$) were significantly associated with increased anastomotic leakage. Multivariate analysis showed only older patients ($P = 0.009$) and operation method ($P = 0.002$) were independent factors for the development of anastomotic leakage; tumor of the middle rectum (6-12 cm) had borderline significance ($P = 0.078$). Thirty percent (n = 3/10) of patients with diverting stoma and 100% (n = 43/43) of patients without diverting stoma needed reoperation to treat abdominal sepsis.
Conclusion. Older rectal cancer patients, or those who have had anastomosis at the anorectal junction or dentate line, have increased risk of anastomotic leakage. A diverting stoma seems not to decrease incidence of anastomotic leakage, but may decrease the necessity of reoperation and provide a positive oncological impact if leakage occurs.
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The most important surgical complication following rectal resection with anastomosis is symptomatic anastomotic leakage, especially after resection of middle and low rectal cancers. Anastomotic leakage is also a major cause of postoperative morbidity and mortality in patients with rectal cancer undergoing sphincter preservation surgery.[1,2] Leakage rates from 2.8% to more than 15% have been reported by several investigators.[1-12] Many factors may be associated with the risk of and the outcomes from an-

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astomotic leakage, including patient condition, tumor characteristics and surgical technique. Identification of risk factors for leakage may lead to preventive measures. The intraoperative test for identifying the integrity of anastomosis, fecal diversion, and pelvic drainage have been reported by several authors to decrease the serious effect of anastomotic leakage.[12-17]

The aim of this study was to analyse the factors that may influence the incidence of anastomotic leakage after resection of middle and low rectal cancer with anastomosis.

Patients and Methods

Prospective data collection of consecutive patients with colorectal cancer started at the opening of the Colorectal Surgery Service in our hospital in 1959. The database includes patient's age, sex, family history of colorectal cancer, major medical conditions, previous major surgery, location, size, histological characteristics of the tumor, operation and complications, recurrence and survival. The patients have been regularly followed up.

The subjects of the present study, 999 rectal cancer patients with tumors at or below 16cm from anal verge, received resection and anastomosis in Taipei Veterans General Hospital from January 1993 to June 2003. Patients who did not have anastomosis, or who received preoperative chemoradiotherapy (PCRT), were excluded from the study. Tumor location was measured from the lower border of the tumor to anal verge with rigid sigmoidoscopy and was classified as low when the distance was < 6 cm, middle when 6-12 cm, and upper when > 12 cm. The operation was defined as an anterior resection (AR) when the anastomosis was performed above the peritoneal reflection, a low anterior resection (LAR) when anastomosis was constructed below the peritoneal reflection, and an ultra-low anterior resection (Ultra-LAR) when the anastomosis was located at the level of the anorectal junction near pelvic outlet or at dentate line.

Standard procedures for resection of rectal cancers were followed. Adequate mesorectal excision with a 2-4 cm distal clear margin for anterior or low anterior resection and total mesorectal excision (TME) for ultra-low anterior resection was adopted as the standard surgical technique for the curative treatment for rectal cancer. The mobilization of the rectum was achieved by sharp dissection and autonomic nerve preservation under direct vision so that the rectal fascia propria, which enclosed the mesorectum, was kept intact. All patients underwent radical resection with intact preservation of rectal fascia propria in specimens, intended a 4 cm but at least 2 cm distal clear margin was preserved. End-to-end colorectal or coloanal anastomosis (straight or J pouch), either by using circular staplers or hand suture technique, was applied. The diversion colostomy or ileostomy was performed either when the anastomosis was difficult to accomplish as judged by the surgeon, the anastomosis was ultra-low, or there were incomplete doughnuts or leakage in air-tight test. Pelvic drains, placed behind the anastomosis in the presacral space, were always used. There were 155 patients given diverting stoma, either by colostomy or ileostomy.

The definition of anastomotic leakage in the present study was based on clinical finding of gas, pus or fecal discharge from the drain, pelvic abscess, peritonitis, discharge of pus per rectum or development of colocutaneous or rectovaginal fistula. Subclinical leakage was considered when there was leakage of water-soluble contrast media in enema examination before considering reversal of diversion.

Thirteen variables were analyzed to investigate the factors that might associate with the occurrence of anastomotic leakage. These included age, gender, systemic disease (none or presence of any major systemic disease, such as diabetes mellitus, hypertension, heart, liver, or kidney disease), tumor location, tumor invasion depth (T1-3 *versus* T4), TNM staging (stage I & II *versus* III&IV), lymphovascular or perineural invasion, quality of resection (curative *versus* palliative), operation methods (LAR *versus* Ultra-LAR and AR), type of anastomosis (hand sutured or stapled), fecal diversion, associated organ resection, and related surgical complications (such as stroke, arrhythmia, atelectasis of lungs, or pneumonia). The continuous variable age was dichotomized using the mean value as a cut-off point. Chi-square test was used for univariate analysis of the prognostic value of these variables. All variables that showed $P < 0.1$ were also entered into the

multivariate model. A P value less than 0.05 was considered statistically significant. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. Statistical analyses were performed using SPSS software (version 16.0 for Windows, SPSS, Chicago, IL, USA).

Results

Of the 999 patients, 53 patients experienced anastomotic leakage, an incidence of 5.3% (53 of 999 patients). Fourteen patients died within 30 days after operation or during hospitalization, a surgical mortality of 1.4% (14 of 999 patients). Only one mortality patient was in the leakage group.

Risk factors for anastomotic leakage

The patients were divided to two groups according to the presence of clinical anastomotic leakage. Table 1 shows a comparison between patients with and without anastomotic leakage, in terms of patient and tumor characteristics and treatment-related variables. Univariable analysis revealed that age of patient ($P = 0.008$ for age > 70 years old), tumor location ($P = 0.026$ for location between 6-12 cm), and operation method ($P = 0.002$ for ultra-LAR) were significantly associated with increased anastomotic leakage rate. Multivariate analysis revealed that only older patients and operation methods were independent factors for the development of anastomotic leakage. The risk of leakage was 2.2 times higher for patients > 70 years than for those ≤ 70 years ($P = 0.009$; 95% CI, 1.21-3.88). The risk was 3.1 times higher for anastomosis at the level of the anorectal junction or dentate line than for those below the peritoneal reflection but above the anorectal junction ($P = 0.002$; 95% CI, 1.53-6.22). Tumor of the middle rectum (6-12 cm) also showed borderline significance for increased risk of anastomotic leakage ($P = 0.078$). Results of multivariate analysis are shown in Table 2.

Diverting stoma

Only 30% (n = 3/10) of the leakage patients who had diverting stoma before leakage needed reoperation to treat the abdominal sepsis caused by leakage. In contrast, 100% (n = 43/43) of the patients who did not have diverting stoma before leakage needed reoperation to treat abdominal sepsis once leakage occurred (Table 3; $P < 0.001$).

Discussion

Clinical anastomotic leakage is one of the most serious complications of rectal cancer surgery. Although good results in terms of survival and local recurrence have been achieved in the treatment of patients with rectal cancer,[18] low colorectal anastomosis still has a high risk of leakage. Reports in the literature show that anastomotic leakage following resection of rectal cancer is associated with high morbidity and mortality rates.[1,8,19,20] In this series, the postoperative mortality rate after clinical anastomotic leakage was low (one patient), and no patient had leakage if anastomosis had been performed above the peritoneal reflection.

The present study found a clinical leakage rate of 5.3%. This rate is at the lower level of incidence reported by several investigators, which range from 2.8% to more than 15%.[1-12] The definition of leakage varies and clinical leakage differs from subclinical leakage. In our study, the diagnosis of anastomotic leakage was dependent on clinical presentation, and subclinical leakage was not thoroughly considered because contrast enema was not performed routinely after operation. This may explain the relative low leakage rate when compared to other reports.

Several factors, such as age, gender, and characteristic of the tumor or methods of operation may be related to the incidence of leakage. Other possible factors, such as body mass index, tumor diameter, shape of advanced tumor (Borrmann's type), and American Society of Anesthesiologists (ASA) score, could not be analyzed from our limited database.

Among patient-related factors, male gender is generally accepted as a risk factor for anastomotic leakage.[1,8,21] In the present study, male gender showed borderline significance by univariate study but no statistical significance by multivariate analysis. Gender group sizes in our study were unequal (F/M: 297/702) and this may be due to the special background of our

Table 1. Univariate analysis of predictive factors for anastomotic leakage in 999 patients undergoing resection of rectal cancer

Variables	Anastomotic leakage (%)		*P**	OR	95% CI
	Yes (n = 53)	No (n = 946)			
Age, years					
≤ 70	21(3.7)	553(96.3)			
> 70	32(7.5)	393(92.5)	0.008	2.14	1.22-3.77
Gender (M/F)					
Female	10(3.4)	287(96.6)			
Male	43(6.1)	659(93.9)	0.08	1.87	0.93-3.78
Systemic disease					
Absence	23(4.5)	492(95.5)			
Presence	30(6.2)	454(93.8)	0.224	0.71	0.41-1.24
Tumor location					
> 12 cm	3(1.7)	172(98.3)			
6-12 cm	46(6.3)	689(93.7)	0.026	3.83	1.18-12.45
< 6 cm	4(4.5)	85(95.5)	0.200	2.70	0.59-12.33
Tumor invasion depth					
T1,T2,T3	50(5.6)	843(94.4)			
T4	3(2.8)	103(97.2)	0.239	0.49	0.15-1.60
TNM staging					
I&II	34(6.4)	495(93.6)			
III&IV	19(4.0)	451(96.0)	0.096	0.61	0.35-1.09
Lymphovascular or perineural invasion					
No	45(5.1)	841(94.9)			
Yes	8(7.1)	105(92.9)	0.374	1.42	0.65-3.10
Quality of resection					
Curative	46(5.4)	813(94.6)			
Palliative	7(5.0)	133(95.0)	0.862	0.93	0.41-2.10
Operation method					
LAR	39(4.7)	789(95.3)			
Ultra-LAR	14(12)	103(88)	0.002	2.75	1.44-5.27
AR	0(0)	54(100)	0.997	0.00	0.00
Anastomosis type					
Hand suture	3(2.1)	143(97.9)			
Staple	50(5.9)	803(94.1)	0.070	2.97	0.91-9.65
Fecal diversion					
No	43(5.1)	801(94.9)			
Yes	10(6.5)	145(93.5)	0.490	1.285	0.63-2.61
Associated organ resection					
No	38(5.2)	698(94.8)			
Yes	15(5.7)	248(94.3)	0.737	1.111	0.60-2.06
Surgical complication					
Absence	51(5.2)	926(94.8)			
Presence	2(9.1)	20(90.9)	0.430	1.82	0.41-7.98

CI = confidence interval; OR = odds ratio; LAR = low anterior resection; AR = anterior resection;

*As determined by logistic regression

hospital which is a veterans hospital.

Older age and ultra-LAR remained as independent factors associated with anastomotic leakage in multivariate analysis, as has been found in other studies.[1,8,12,21] Tumors located 6-12 cm from anal verge had a significantly high rate of anastomotic leakage by univariate analysis, but in multivariate analysis became borderline significant. Tumor location in the middle or lower third, with subsequent low anastomosis, is generally accepted as a risk factor for anastomotic leakage.[19,22] Poor general condition and potentially compromised microcirculation may explain the higher incidence of anastomotic leakage. For low tumor and low anastomosis in particular, tissue ten-

Table 2. Multivariate analysis of risk factor for anastomotic leakage

	Odds ratio	95% Confidence interval	*P** values
Age, years			
≤ 70			
> 70	2.17	1.21-3.88	0.009
Gender			
Female			
Male	1.37	0.63-2.98	0.431
Tumor location			
> 12 cm			
6-12 cm	2.93	0.89-9.71	0.078
< 6 cm	1.26	0.25-6.35	0.782
Operation method			
LAR			
Ultra-LAR	3.08	1.53-6.22	0.002
AR	0.00	0.00	0.997
Anastomosis type			
Hand suture			
Staple	2.34	0.65-8.37	0.192

*As determined by logistic regression
LAR = low anterior resection; AR = anterior resection

Table 3. The influence of time of diverting stoma on reoperation rate after anastomotic leakage

	When diversion performed		*P** values
	Before AL (n = 10)	After AL (n = 43)	
Re-operation			
No	7(70.0)	0(0.0)	< 0.001
Yes	3(30.0)	43(100.0)	

*As determined by Fisher's exact tests
AL: Anastomotic leakage

sion, poor circulation at anastomosis ends, and difficulty of technique may explain the higher incidence of leakage.

The influence of stapled anastomosis is still controversial. Most studies have showed no statistically significant difference in surgical complications between stapled and hand-sutured anastomosis.[4,10] In our univariate analysis results, stapled anastomosis showed a trend to a higher leakage rate, but the difference did not reach statistical significance.

Other patient-related parameters (such as presence of any major systemic disease), tumor-related parameters (including tumor invasion depth, TNM staging, lymphovascular or perineural invasion), and surgery-related parameters (including quality of resection, fecal diversion, associated organ resection, and related surgical complications) were not identified as risk factors of anastomotic leakage in the present study. These factors have not been generally accepted risk factors for anastomotic leakage in most studies.[4,5,7-9,11,12,21-23]

The role of a temporary diverting stoma in patients undergoing low anterior resection remains controversial.[24-26] Some reports have shown that proximal diversion is not able to protect from anastomosis dehiscence,[2,27] but other reports have shown significant decrease in the incidence of clinically relevant leakage and the risk of reoperation.[28,29] Diverting stoma is the best strategy to minimize the consequence of severe pelvic sepsis caused by anastomotic leakage.[10] In the present study, although the presence of diverting stoma made no significant difference in leakage rates, the reoperation rate in patients with diverting stoma was significantly decreased.

The pathologic mechanism responsible for the oncological impact of anastomotic leakage is currently attributed to the release of exfoliated cancer cells remaining in the bowel lumen of patients with colorectal cancer at the time of operation.[30,31] In addition, the inflammatory response to anastomotic leakage may enhance the tumor spread and metastasis.[32,33] Anastomotic leakage results in delayed mucosal healing, and provides a way that the exfoliated tumor cells can implant on a high vascular surface for tumor growth or distant spreading. These mechanisms may account for the association between poorer survival and anastomotic leakage.[34-36]

It seems that diverting stoma may convert the clinical leakage to a subclinical leakage, prevent local or systemic septic reaction, and thereby provide a better prognosis. Once clinical leakage occurs in patients without diverting stoma, local and systemic septic reaction cannot be avoided. The adverse consequences of leakage and a poor prognosis can be expected. Therefore, it is critical to identify at-risk patients to perform diverting stoma in high risk anastomosis.

Conclusion

We have found that rectal cancer patients who are

older, or who have had anastomosis at the anorectal junction or dentate line, have increased risk of anastomotic leakage. A diverting stoma does not appear to decrease the incidence of anastomotic leakage. However, diverting stoma may decrease the necessity of reoperation and provide a positive oncological impact if leakage occurs.

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原　著

直腸癌手術病人吻合處滲漏之危險因子及造口的影響

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目的　吻合處的滲漏可說是直腸癌術後影響最大的併發症。此篇研究是爲了研究本院直腸癌手術病人可能造成吻合處滲漏的危險因子及造口對吻合處滲漏的影響。

方法　收集距離肛門口 16 公分以內的直腸癌病人資料。這些病人的臨床及病理的資料與吻合處滲漏的關係將予以分析。

結果　從 1993 年一月到 2003 年六月共有 999 位直腸癌病人接受手術切除及腸道吻合。發生吻合處滲漏的病人有 53 位。年紀大於 70 歲、中段直腸癌及低位吻合處的病人，於是否影響滲漏之單變異分析中達顯著差異。只有年紀大於 70 歲及低位吻合處的病人，於多變異分析中達顯著差異。吻合處滲漏發生時，預先做造口可明顯降低需要再次手術的比率。

結論　年紀大於 70 歲及吻合處位於肛門和直腸交界或是齒狀線上是直腸癌術後病人發生吻合處滲漏的危險因子。預先做造口並無法降低吻合處滲漏發生的機會，卻可降低再次手術的比率和提供較好的預後。

關鍵詞　直腸癌、吻合處滲漏、造口。