Table 2 Pathological findings

		TINGE		T. U.S.A.
	Total	110		12
	7,€48)∺	v = 10		(n (= 21)
Histological type				
Well differentiated	.16	3	4 2.	10*
adenocarcinoma	.10		1.	12
	29			01
Moderately	. 29		14	9
differentiated				
adenocarcinoma				
Poorly differentiated	3	1	. 2.	0
adenocarcinoma		J.:.		
Invasion to surrounding				
organs ,				
Yes	21	5	11	5*
No	27	5	. 6	16*
Perineural invasion	*			
Yes	20	6	9	5†
No	28	4	8 .	16†
Venous invasion				
Yes	12	5	7	0* †
No	36	5	10	21*†
Lymphatic invasion		, ,		
Yes	10	3	6	1*
No	38	7	11	20*
Abscess formation around				77
recurrent tumour	18.			
Yes	e .		3	4 :
No	40	۵	14	17
			. '7'	17.

^{*}P < 0.050 versus f1, †P < 0.050 versus f0 (χ^2 test).

f0 or f1 fibrosis, and well differentiated adenocarcinoma in those with f2 fibrosis. Patients with f2 fibrosis had significantly lower rates of perineural (P=0.049) and venous (P<0.001) invasion than those with f0 fibrosis, and significantly lower rates of invasion to surrounding organs (P=0.011) and venous (P=0.001) and lymphatic (P=0.016) invasion than patients with f1 fibrosis.

The overall 5-year survival rate was 52 per cent (25 of 48 patients), with 5-year survival of none, four and eight patients with f0, f1 and f2 fibrosis respectively. The overall survival of patients with f2 fibrosis was significantly greater than that of patients with f0 fibrosis (P = 0.003).

To simplify the analysis, the histological type (well *versus* moderately or poorly differentiated) and degree of fibrous tissue (f2 *versus* f0-1) were grouped into two categories. A favourable overall survival after TPES correlated significantly with a higher level of sacrectomy (P = 0.036), absence of lymphatic invasion (P = 0.031) and circumferential fibrosis (P = 0.039). In multivariable analysis, circumferential fibrosis (P = 0.031) and low serum carcinoembryonic antigen levels (P = 0.044) were independent factors for a favourable outcome (*Table 3*).

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Table 3 Univariable and multivariable analysis for overall survival using the Cox proportional hazards regression model

	Univariable analys	is . Mültiyariable ar	alysis.
		Pods min	
Dukes' classification	0.059	2.86 (1.00, 8.17)	0.050
for primary growth			
(A, B versus C)			
Surgery for recurrent	0.066		0-614
tumour (no versus	Pet at a place for		
yēs)			
Serum CEA level (< 20	0.131	2.87 (1.03, 7.97)	0.044
versus ≥ 20 ng/ml)			
Simultaneous	0.944		0.845
hepatectomy (no			
versus yes)	0.000	ter en en en en en en	0.295
Level of distal	0.036		0.295
sacrectomy (< S3 versus > S3)			
Histological type (well	0.187		0.624
versus moderately,	0.107		0.024
poorly differentiated)			
Perineural invasion (no	0.117		0.725
versus yes)			
Venous invasion (no	0.079		0.947
versus yes)			
Lymphatic invasion (no	0.031		0.915
versus yes)			
Degree of fibrous	0.039	3-19 (1-11, 9-12)	0.031
tissue (f2 versus			J
f0-1)			

Values in parentheses are 95 per cent confidence intervals. CEA, carcinoembryonic antigen. Odds ratios given only for significant variables.

Discussion

Tumours surrounded by fibrous tissue in locally recurrent rectal cancer are associated with a better 5-year survival rate than those with no surrounding fibrosis.

Several factors have been suggested as prognostic indicators after surgical resection of recurrent rectal cancer fixed in the pelvis. The most important single factor has generally been accepted to be the achievement of an R0 resection^{8–10}. The present authors have reported previously that TPES with R0 resection resulted in a 5-year relapse-free survival rate of 49 per cent, although no patient who had R1 or R2 resection survived for 4 years⁴.

Although fibrotic tissue around a recurrent tumour sometimes makes it difficult to determine the preoperative extent of the disease¹¹, it is an interesting histological feature. This tissue is distinct from the stromal or desmoplastic reaction to tumour invasion, which has been reported to be a prognostic predictor in primary rectal cancer¹². The fibrotic area that extends widely around the fixed recurrent tumour appears to lack cancer cells. A similar 'fibrous tissue-encapsulating tumour' is

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often encountered in hepatocellular carcinoma¹³⁻¹⁵ and in metastatic liver tumours from colorectal primary cancers^{16,17}. It has been reported that the fibrous tissue is related to decreased tumour invasiveness and is an indicator of improved survival after resection¹³⁻¹⁷. There have been no reports of the clinical significance of fibrous tissues in locally recurrent rectal tumours.

The pathogenesis of fibrosis surrounding the recurrent fixed tumour has not been elucidated. It is unclear whether this fibrous tissue formation is promoted by radiotherapy, chemotherapy or previous pelvic surgery, and there were insufficient patients in the present series to justify multivariable analyses to examine the influence of these factors. Alternatively, fibrous tissue might be formed around the tumour by an active host response¹⁸. Inflammatory cell infiltration at the border between the tumour and non-cancerous tissue has been demonstrated to be a favourable prognostic indicator in primary gastric and colorectal cancers^{19,20}, and the fibrous tissue surrounding fixed recurrent tumours may represent part of a defensive immune inflammatory mechanism.

Previous studies have suggested staging systems for locally recurrent rectal cancer according to the degree of fixation to surrounding structures^{8,21–23}, but none has been universally adopted^{8,9}. As indicated by the present data, the degree of fibrosis may be an important prognostic factor and perhaps valuable in the selection of high-risk patients who would benefit from adjuvant treatment after TPES.

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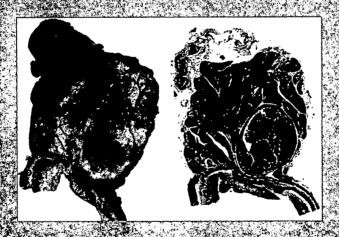
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Papillary tumour of the common bile duct

A 77 year old man with obstructive jaundice had a polypoidal mass occupying the lumen of the distal common bile duct on ERCP and intraductal ultrasound. Biopsies revealed papillary proliferation with excessive mitotic activity. He underwent a pylorus preserving pancreaticoduodenecromy. There was a $40 \times 30 \times 20$ mm tumour within the lumen of the common bile duct; extending across the papilla into the duodenum (T: tumour, B: bile duct; P pancreas, D' duodenum). Microscopy (H&E stain × 1) revealed a well-circumscribed, intraductal papillary tumour with focal intestinal interaplasia and clear cell change. There was market nuclear pleomorphism, but no stromal invasion. Papillary carcinomas of the extrahepatic bile ducts behave as in situ carcinomas, tavasion is a late event and prognosis is excellent.



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特集

◆ 直腸癌に対する腹腔鏡手術の問題点 ◆

直腸癌に対する腹腔鏡手術における縫合不全の危険因子 ―縫合器、吻合器とその操作を中心に―

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Risk Factors For Anastomotic Leakage After Laparoscopically Assisted Anterior Resection in Patients with Rectal Cancer: Yamagishi S*1, Fujii S*1, Momiyama M*1, Nagano Y*1, Ota M*2, Ichikawa Y*2, Kunisaki C*1, Ike H*1, Ohki S*2 and Shimada H*2 (*1Yokohama City University Medical Center, Gastroenterological Center, *2Department of Gastroenterological Surgery, Yokohama City University Graduate School of Medicine, Yokohama, Japan)

Background: Anastomotic leakage is the most severe complication following rectal resection. The aim of this study was to evaluate risk factors of clinical anastomotic leakage after laparoscopically assisted anterior resection for rectal cancers.

Methods: A total of 65 consecutive operations involving anastomosis of the rectum performed from 1997 to 2006 were reviewed. The associations between clinical anastomotic leakage and 12 patient-, tumor-, surgical-, and device-related variables were studied by univariate and multivariate analysis. Result: The anastomotic leakage was seen in 12.3% (8 of 65). Univariate analysis showed that men (p=0.046) and a new dividing device (p=0.046) were significant factors of anastomotic leakage. The new dividing device remained significant after multivariate analysis (OR 7.00, p-value= 0.036). In the former period, the new dividing device was the risk factor of anastomotic leakage, but not in the latter period. This study also revealed that multi-stapling was not a risk factor for anastomotic leakage.

Conclusion: In the laparoscopic surgery, because there are many types and use frequencies of the device, it is important to be well informed of the characteristic and safe directions, and to use an accustomed device.

Key words: Anastomotic leakage, Laparoscopically assisted surgery, Rectal cancer

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はじめに

大腸癌に対する腹腔鏡下手術は,1991年 Jacobsの報告¹⁾以来,低侵襲性や整容性から急速 に普及し,わが国では1992年から導入された. 当初は早期がんが適応とされてきたが,進行がん にも適応が拡大され、現在では側方郭清が不必要な下部直腸癌にも適応とされている。直腸癌に対する腹腔鏡下手術の利点は、骨盤という限られた閉鎖腔の中でも、術者、助手全員が拡大視効果により解剖の把握が可能となることにより、安全に剥離、授動が行えることである²⁾.しかし、肥満者や狭骨盤症例、8 cm を越える巨大腫瘍などでは操作性が制限される。このような症例は直腸の剥離操作は可能であるが、直腸切離前の肛門側腸管の洗浄および切離器械については、簡便で確実な腹腔鏡用器械が少なく、開腹術と比較して操作

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が困難である.本稿では直腸癌の腹腔鏡下手術に おける再建操作,器具の選択の観点から,縫合不 全の危険因子について検討したので報告する.

1. 適 応

教室では1993年より早期癌に対する腹腔鏡下手術を導入し、2000年よりN(-)、MP,2002年よりSE,2003年よりN1と局所再発や遠隔転移を加味して段階的に適応拡大してきた。現在の直腸癌に対する適応は、腫瘍径8cm以下、直腸RSは進達度SE,N1とし、直腸Ra,Rbにおいては側方郭清の適応がないRaのMP,RbのSMまでとしている。狭窄が高度で術前に病変口側の情報が得られないもの、気腹が不可能な症例も適応外としている。

2. 対象

1997年4月から2006年8月までに教室で施行した直腸RSを含む直腸癌の腹腔鏡手術症例65例を対象として、縫合不全の危険因子を検討した.

3. 手術方法

1) ポートの配置と小切開部:5ポートで、カメラポートは臍直下(開腹用腸管切離器械の使用時は臍直上に設定)、術者は右側腹部上下のポート、助手は左側腹部上下のポートを使用する.
2) 中枢側リンパ節郭清と血管処理:D3郭清を基本とし、早期癌では下腸間膜動脈(IMA)温存のD3、進行癌ではIMA根部で処理している.自律神経は全温存.3)後腹膜剥離:内側アプローチにて後腹膜下筋膜上層を剥離し、左尿管、左精巣/卵巣動静脈を温存する.4)左側結腸授動:SD Junction付近から外側剥離し、内側からの剥離面と連続させる.5)直腸授動:自律神経を温存しながら、直腸固有筋膜を破らない直腸固有筋膜を切離し直腸の外膜を露出する.

6) 腸管洗浄:腸管切離直前の腸管洗浄のための

クランプ器械は、切離線が高位の症例や骨盤が広 く操作性の良好な症例には endovascular clip を 使用する. 低位や狭骨盤, 肥満など操作性の不良 な症例は、腸管クランプ前に下腹部正中に約5 cm の小切開をおき、J字型腸管クランプ鉗子を 腹腔内に挿入して気密を保ち、再気腹後に通常の 開腹での方法と同様に病変の肛門側をクランプ し、腸管洗浄する.7)直腸切離:腸管クランプ 鉗子として endovascular clip を使用した場合は 鏡視下用器械で切離し, 」字型腸管クランプ鉗子 の場合は開腹用器械で切離する. 8) 開腹操作: 臍直下創部を延長して小切開創とし、直腸を体外 へ誘導しロ側腸管を切離して標本を摘出する. 下 腹部正中に小切開創がある場合は、同部から直腸 を誘導する. 9) 再建: 再気腹後に腹腔内にて double stapling 法で吻合する.

4. 検討項目

検討1: 術後縫合不全を合併した症例としなかった症例に群別し、その危険因子について単変量解析,多変量解析を用いて解析した.

検討2: 開腹手術用の直腸切離器械(彎曲型一 括切離縫合器)の使用経験から、症例を前期と後 期に分けて解析した.

検討3:直腸切離時に同一の鏡視下用線状縫合器を使用した症例46例を対象に、複数回切離が縫合不全の危険因子となるか検討した.

共変量項目は以下とした。患者因子:性別,年 齢,糖尿病の有無,栄養状態(PNI),占拠部位。 手術因子:術者,IMA根部切離の有無,手術時 間,出血量,肛門縁から吻合までの距離.器械因 子:腸管切離器械,Circular staplerの種類。

5. 解析

単変量解析は Student's t-test と Fisher の直接確立法を用いて解析した. 多変量解析は, 単変量解析で p-value < 0.8 の項目を共変量項目とし,ロジスティック回帰分析を用いて統計学的有意差検定を施行した. 検定は p-value < 0.05 を有意とした. 単変量解析は Statview J-5.0 を用い,多

表 1 Patient characteristics

	No. cases (n=65)
Gender	
Male: Female	44:21
Age	64.1 ± 9.3
Location	
RS/Ra/Rb	38/17/10
Disease	
Carcinoma	59
Carcinoid	6
Stage	
0	6
I	40
II	5
IIIa	9
IIIb	4
Anastomotic leakage	
with/without	8(12.3%)/57

変量解析は Dr. SPSS-Ⅱを用いた.

6. 結果

腹腔鏡手術を施行した 65 例の占拠部位は RS が 38 例, Ra が 17 例, Rb が 10 例で, 縫合不全合併率は 12.3% (8/65) であった (表 1). 縫合不全症例のうち再手術にて人工肛門を造設した症例は 4 例 (50%) であった.

検討1: 縫合不全群 (n=8) と, 非縫合不全群 (n=57) の単変量解析による比較では, 縫合不全は男性に多く (p=0.046), 直腸切離器械の検討では開腹用彎曲型一括切離縫合器: Cに縫合不全が多く合併した (p=0.046) (表2). 縫合不全に対する多変量解析で独立した危険因子として選出されたのは, 開腹用直腸切離器械の彎曲型一括切離縫合器: Cであった (Odds ratio 7.00, p-value=0.036) (表3).

検討2:開腹用彎曲型一括切離縫合器について 詳細に検討すると,使用開始の最初の4例中3 例に連続的に縫合不全を認めた(ただし3例と も保存的に治癒). 問題点を検討すると,切離, 縫合の際に腸管の緊張を解除せずにファイヤーし ていたので,ファイヤーの際には Tension Free で行うこととした. この操作を徹底し,その後の

表 2 Results of univariate analysis of possible risk factors for anastomotic leakage

	Cases with leakage (n=8)	Cases without leakage (n=57)	p value
Gender			
Male : Female	8:0	36:21	0.046
Age (≥60)	6	39	> 0.999
DM	1	5	0.561
PNI (<45)	0	6	> 0.999
Location			
RS/Ra/Rb	4/2/2	34/15/8	0.717
Surgeon			
A/B/C/D	6/2/0/0	38/8/5/6	0.539
IMA divided	7	40	0.427
Operation time (≧240 min)	6	40	>0.999
Blood loss (≥200 ml)	2	13	> 0.999
Dividing device			
A/B/C	4/1/3	42/6/9	0.046
Circular stapler			
A/B	7/1	50/7	>0.999
Distance from AV (<70 mm)	5	20	0.243

DM, diabetes mellitus; PNI, Prognostic Nutritional Index; IMA, inferior mesenteric artery; AV, anal verge.

表 3 Odds ratio for statistically significant variables after multivariate analysis

Variable	Odds ratio (95% CI*)	p-Value
Dividing Device		0.113
B/A	14.0 (0.69~283.78)	0.086
C/A	$7.00(1.14\sim42.97)$	0.036

A: 視下用線状縫合器, B: A, C 以外の縫合器,

C: 開腹用彎曲型一括切離縫合器, 95% CI*: 95% Confidence interval

5 例には縫合不全を認めなかった (表 4). そこで、開腹用彎曲型一括切離縫合器で直腸切離した症例のうち縫合不全を合併した 3 例が含まれる前期症例 44 例と、それ以降の後期症例 21 例に期間を分け、縫合不全群と非縫合不全群を比較検討した。前期症例での検討では、単変量、多変量解析ともに直腸切離器械で開腹用彎曲型一括切離縫合器が独立した縫合不全危険因子として選択さ

F

Anasto Site Blood Preope Anastomotic AGE Location Time Gender from AV (cm) Complication leakage Loss 70 220 20 M 65 RS Obesity (BMI 31) 58 RS Obesity (BMI 31) Major Leak 70 266 50 M 40 273 300 67 Rb DMMinor Leak M 80 225 40 73 RS Obesity (BMI 28) Minor Leak M 100 220 5 M 76 RS Gastric ulcer 90 62 RS 240 15 M RS 160 237 5 M 55 59 RS DM 140 246 50 M

表 4 Complication in Curved cutter cases

DM, diabetes mellitus; AV, anal verge.

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れた(Odds ratio 40.5, p value=0.007). しかし, 後期症例の検討では, 直腸切離器械は選択されず, 独立した危険因子は選出できなかった.

Rb

検討3:同一の鏡視下用線状縫合器(関節機構あり)を使用した症例の検討では、術後縫合不全合併は4例(8.7%)に認め、直腸切離の際の器械使用回数が3回以上の症例は3例(75%)だった.一方、縫合不全を合併しなかった症例のうち3回以上使用したのは13例(31%)で、複数回使用した症例に術後縫合不全を合併していたが、統計学的には有意差は認めなかった(p=0.114).

7. 考察

開腹直腸癌手術の術後縫合不全の合併率は 7.3 ~12%と報告され³~8),腹腔鏡下手術での合併率は 6.4-20.0%と報告されている9~15). また,腹腔鏡下手術と開腹手術に関する RCT の報告では,術後縫合不全を含む合併症発生率に差はなかったと報告されている16~19). 今回の検討では術後縫合不全合併率は 12.3%であったが,後期症例 21 例を対象とすると合併率は 9.5%だった. 縫合不全症例のうち,人工肛門造設術を施行した症例は 4 例(50%)であった.手術関連死亡症例はなかった.

直腸癌の開腹手術における術後縫合不全の危険 因子は、①下部直腸癌症例(吻合部が肛門縁から 5 cm 以下)、②男性、③術前放射線療法の既往、 ④術中に合併症を有する症例、などが報告されて いる3~7). 今回の検討では、開腹用直腸切離器械 の彎曲型一括切離縫合器が術後縫合不全の独立し た危険因子として選択されたが、最初の連続した 3例に合併しており、未熟な操作が原因の1つと 考えられた. 患者因子としては, 3例中2例は肥 満を有する男性で、1例は糖尿病を合併していた (表4). 合併症の経験から,以下の点を改善し た. 周囲臓器の巻き込みを意識して直腸に緊張を かけた状態で中間ロックするが、縫合、切離する 際にもこの緊張を解除することなくファイヤーし ていたので、ファイヤーの際には Tension Free で行うこととした. これにより後期症例で開腹用 彎曲型一括切離縫合器を使用した5例には縫合 不全を認めず、改善点の効果と器械操作の手技が 安定したためと思われた. また, 開腹用彎曲型一 括切離縫合器は確実に1回で切離,縫合できる という利点はあるが、本体が大きく視野が不良と なり、とくに肛門側前壁の臓器(精嚢腺、膣後壁) などの挟み込みが懸念される. 開腹用器械である TL-30TM, TA-45TM などの彎曲型一括切離縫 合器より小さい器械もあるが,縫合,切離が同時 でないため、ロ側腸管の確実なクランプが問題点 として残る. 一方, 腹腔鏡用器械では縫合長の長 いものは切離部へのアプローチが困難であり、複 数回使用になる危険性が高まるが、器械本体は小 さいので視野の観点からは良好であると思われる (表5). 教室では直腸切離器械の選択について は、直腸切離部位が高位であれば endovascular

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表 5 直腸切離器械の特徴

直腸クランプ		Endovascular clip	φ 12 mm Surgical Port	腸管把持力が弱い
			から挿入可能	角度の調節等の操作性に難あり
				斜めにかかると腸管全てをクランプ
				できないことがある
		J字型クランプ鉗子	把持力が強く腸管の展開	器械挿入時に下腹部に小切開をおき
			が可能	気密保持に工夫が必要
直腸切離	鏡視下用	(ENDO GIA	ϕ 12 mm Surgical Port	Multi stapling の可能性あり
		UNIVERSAL™	から挿入可能開腹用器械	縫合長の長い器械は操作制限あり
		ENDO CUTTER™	より本体が小さいので鏡	
		\ ECHERON™	視下での操作が容易	
	開腹用	Curved Cutter TM	一括切離縫合が可能	器械挿入時に下腹部に小切開をおき
				気密保持に工夫が必要
				器械本体が大きく操作制限あり
		$\int TL-30^{TM}$	一括縫合が可能	器械挿入時に下腹部に小切開をおき
		TA-45 TM		気密保持に工夫が必要
		\ ACCESS 55TM		器械本体は Curved Cutter より小さ
				いが切離,縫合が同時でない

clip でクランプして鏡視下用線状縫合器(関節機構あり)で切離している. 低位の場合は体型, 腫瘍進行度を加味してクランプ鉗子と直腸切離器械を選択している (図 1).

鏡視下用線状縫合器により複数回で直腸切離された症例に縫合不全が合併したという報告があり²⁰⁾,危険因子とされる.本稿では同一器械(鏡視下用線状縫合器:関節機構あり)を使用した症例を対象とし,直腸切離の際の器械使用回数が縫合不全の危険因子となるか検討した.術後縫合不全は3回以上の multi stapling 症例が75%と多く(縫合不全合併4例中3例),合併しなかった症例では31%で2倍以上の差を認めるが,統計学的には有意差は認めなかった(p=0.114).複数回使用になることの問題点は,切離方向がずれて直線状の切離ラインが形成できない点であり,たとえ3回以上であっても一直線であれば縫合不全の危険因子とはならないと思われる.

術後縫合不全の危険因子とされる男性^{4~7)}については、今回の検討では単変量解析で有意差を認めたが、多変量解析では選択されなかった.しかし、縫合不全症例は全例男性であり、やはり危険因子と思われる.理由については解剖学的に女性より狭骨盤であること⁴⁾、最近ではホルモンの違いで腸管の微小血管循環が影響されているとの報

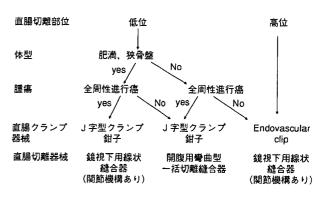


図1 教室における直腸切離器械の選択

告もある²¹⁾. 開腹手術と同様に, 腹腔鏡下手術でもやはり狭骨盤は難易度が高く, とくに直腸切離器械の選択に注意が必要である.

術後縫合不全は重篤な合併症の1つであり, 症状によっては緊急で一時的人工肛門造設術を施 行しなければならない.合併症の発生を予防する ためには,確実な解剖の把握が重要で,手術中の 注意点は,口側腸管の血流の確認,肛門側腸管の 十分な剥離と切離部位の設定,吻合部に緊張がか からない左側結腸の授動などが重要である.その うえで,腹腔鏡下手術においては器械の種類を利 用頻度が高いので,その特性や安全な使用法を熟 知し,慣れた器械を使用することが重要であり, 新規導入する器械については,操作が安定するま では、より慎重に取り扱うべきと考える.

結 語

今回,腹腔鏡下手術における術後縫合不全の危 険因子を検討したが,腹腔鏡下手術特有の縫合不 全危険因子はなかった.手術器械を新規導入し, 操作が安定するまでに吻合部合併症が起こってお り,より慎重な使用が望まれる.自動縫合器には それぞれに長所・短所があり,安全な手術のため にはどの器械にも十分に慣れておくことと,症例 に応じて使い分けを見極めることが重要であると 思われた.

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Predictors of Successful Salvage Surgery for Local Pelvic Recurrence of Rectosigmoid Colon and Rectal Cancers

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Abstract

Purpose. We investigated the predictors of successful resection of recurrent tumors and improved survival in patients with local pelvic recurrence of rectosigmoid colon and rectal cancer.

Methods. We analyzed the clinicopathological factors of 94 patients who underwent treatment between 1993 and 2002 for the local pelvic recurrence of curatively resected primary rectosigmoid colon and rectal adenocarcinoma.

Results. Of the 94 patients, 48 underwent salvage surgery and 46 were treated conservatively. The survival rate of the patients who underwent salvage surgery was significantly higher than that of those treated conservatively (P < 0.0001). Logistic regression analysis revealed that the following factors were significantly associated with successful salvage surgery: tumor differentiation (well or moderately; P < 0.04), a long interval between the initial operation and the detection of recurrence (P < 0.03), and negative lymph node status at the initial operation (P < 0.02). The Cox proportional hazard model revealed the following predictors of better survival after surgery: tumor differentiation (well and moderate), negative lymph node status at the initial operation (pN0), and a perianastomotic pattern of recurrence.

Conclusion. The predictors of successful salvage surgery are the tumor differentiation and nodal status of the primary tumor, the interval between the initial operation and the detection of recurrence, and the pattern of tumor recurrence.

Key words Salvage surgery · Rectal cancer · Local recurrence

Introduction

Local recurrence (LR) after curative resections for colon and rectal cancer is still a major problem. The incidence of LR after radical surgery for colon and rectal cancer ranges widely from 3% to 50%, ¹⁻⁵ and 70%–80% of recurrences are detected within 2 years of the primary operation. Recurrent rectal cancer carries an extremely poor prognosis, with a median survival time of only 7 months without surgical resection. Presently, 75%–90% of the patients with LR die within 5 years after its detection.

The methods of treating LR are not standardized. In contrast to the acceptance of hepatic and pulmonary resection for isolated colorectal cancer metastasis, there is no general agreement about the surgical approach to locally recurrent rectal cancer. In many patients with LR, radiotherapy or chemotherapy brings about only temporary relief of the condition, and a few patients who undergo further surgery with curative intent attain longer survival time. Moreover, salvage surgery often requires radical procedures such as pelvic exenteration associated with substantial morbidity and occasional mortality. Thus, it is essential to identify those patients who could benefit from resection, with a chance of improved survival and local control, whereas preventing unnecessary morbidity and mortality in those less possibly to benefit from surgery.

We conducted this study to identify the predictors of successful resection of recurrent tumors and improved survival in patients with the local pelvic recurrence of curatively resected rectosigmoid colon and rectal cancers.

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Methods

Between 1993 and 2002, 94 consecutive patients who had previously undergone potentially curative resection of rectosigmoid colon or rectal cancer were treated for local pelvic recurrence at the National Cancer Center Hospital East, in Japan. There were 54 men and 40 women, ranging in age from 37 years to 83 years (median 61 years). The median length of follow-up after the diagnosis of LR was 21.3 months (range 2–142 months). The primary cancer had originated in the rectosigmoid colon in 21 patients and in the rectum in 73 patients. Of the 94 patients, 11 were referred from other institutes for LR (of rectosigmoid colon cancer in two and rectal cancer in nine). None of the 94 patients had received any neoadjuvant therapy for their primary cancer, although 62 patients received adjuvant chemotherapy after their initial operation because of positive lymph node metastases. Here, potentially curative resection was defined as radical resection, including total mesorectal excision, with macroscopic and microscopic negative margins. All cases of recurrent rectosigmoid colon or rectal cancer were detected on regular follow-up examinations with computed tomography (CT) and magnetic resonance imaging (MRI), focusing on the liver or pelvis, chest X-ray, and colonoscopy or barium enema. The medical records of these patients were retrospectively reviewed. Local pelvic recurrence was defined as any tumor recurrence in the pelvis or perineum with or without concomitant distant metastasis. Successful re-resection was defined pathologically as clear surgical margins.

The criteria used to select patients for surgical resection with curative intent included an age lesser than 75 years with good performance status, no distant metastasis, and an expected tumor-free margin. If the metastatic lesion could be resected radically, surgical resection for LR was considered.

For all the patients, we recorded age, sex, interval between the initial operation and the detection of LR, pathological features of the primary tumor, pattern of recurrence, presence of distant metastasis at the time of LR, and survival. As evaluated by CT, MRI, and colonoscopy, the pattern of recurrence was divided into four types, namely, the perianastomotic site, defined as being contiguous with the suture line, with or without extramural spread; regional intrapelvic lymph nodes; surgical margins, defined as pathologically unclear distal or circumferential margins in the primary resection; and unclassified. All staging, including the anatomical site of the tumors, was assigned using TNM classifications as described by the International Union Against Cancer (UICC).8 For statistical analysis, we considered the following factors: age, sex, size (≤5.0cm or >5.0cm) of the primary tumor, pT and pN status at the initial operation, pathological differentiation of the primary tumor (well, moderately, or others), pattern of recurrence, concurrent metastasis, serum carcinoembryonic antigen (CEA) levels at the time of LR, and the time to recurrence. Logistic regression analysis was used to identify the predictors of successful salvage surgery. Survival in patients with LR was calculated using the Kaplan–Meier method with the log-rank comparison. The Cox proportional hazard model was used to identify the predictors of these outcomes. A P value of ≤ 0.05 was considered to be statistically significant.

Results

Details of the clinicopathological factors are shown in Table 1. LR was detected in the following sites: the perianastomotic site in 29 (30.9%) patients, the regional lymph nodes in 17 (18.0%), the surgical margin in 14 (14.9%), and unclassified in 34 (36.2%), with the subsequent curative resection rates of 62.1%, 29.4%, 42.8%, and 52.9%, respectively. The surrounding structures where invasion was expected on preoperative examinations were the uterus in seven patients, the sacrum in five, the bladder in four, the small intestine in four, the prostate in three, and the ovaries in two. Concurrent

Table 1. Patient and tumor characteristics

Age ^b (range)	60.5 (37–83)
Sex ^b (M/F)	54/40
Tumor size ^a (cm)	5.0 (2.0-17.0)
Location ^a	
Rectosigmoid colon	21 (22.3)
Rectum	73 (70.2)
Histological differentiation ^a	
Well	12 (12.8)
Moderate	66 (70.2 [°])
Poor	9 (9.6)
Others	7 (7.4)
pT status ^a	` '
pT2	41 (43.7)
pT3	43 (45.7)
pT4	10 (10.6)
pN status ^a	` ′
pN0	28 (29.8)
pN1	35 (37.2 [°])
pN2	31 (33.0)
Concurrent metastasis ^b	, ,
Absent	74 (78.7)
Present	20 (21.3)
Pattern of recurrence	, ,
Perianastomotic site	29 (30.9)
Regional lymph node	17 (18.0)
Surgical margin	14 (14.9)
Unclassified	34 (36.2)
Time to recurrence (months)	41 (1.4–79.6)

Values in parentheses are percentages, unless stated otherwise

^aAt initial treatment

bAt the time of local recurrence

distant metastasis was evident in 20 (21.3%) patients in the following sites: the liver in 11, the lung in 5, both the liver and the lung in 2, and the lymph nodes in 2. The median interval to recurrence was 14 months (range 1.4–79.6 months).

Of the 94 patients, 48 (51%) underwent salvage surgery, and 46 (49%) received other treatment. The following salvage operations were performed: abdominoperineal resection on 6 (12.5%) patients; low anterior resection on 10 (20.8%); pelvic exenteration on 10 (20.8%), as total in 5 and posterior in 5; and non-anatomical resection on 20 (41.6%), including 3 patients who underwent hepatectomy for liver metastases. The main reasons for conservative treatment were unresectable locally advanced tumors in 22 patients (48%) and multiple distant metastases in 14 patients (30%). Conservative treatment consisted of palliative surgery followed by chemotherapy in 7 (15.2%) patients and chemotherapy or radiotherapy or both, in 30 (65.2%) patients.

Complications resulted in extended hospitalization in 15 (31%) patients. These complications included surgical site infection, pelvic inflammatory disease, and problems related to anastomosis. There was one (2%) operation-related death secondary LR developed in three (6.3%) patients, and was treated with chemotherapy or radiotherapy.

The 5-year survival rate for the entire group was 22%, with a median survival time of 16 months (Fig. 1). The survival rate was the highest for patients who underwent salvage surgery (P < 0.0001).

According to the logistic regression analysis, the factors associated with successful salvage surgery were tumor differentiation of the primary cancer (well or moderately; P < 0.04), a long interval between the initial operation and the diagnosis of recurrence (P < 0.03), and negative lymph node status at the initial operation (P < 0.02; Table 2).

The survival curves according to the pattern of recurrence are shown in Fig. 2. The survival rate of patients with tumor recurrence at the perianastomotic site was significantly better than that of patients with recurrence at other sites (P < 0.04).

Univariate analysis of other prognostic factors that affected survival was performed using the log-rank test

Table 2. Predictors of successful salvage surgery, as identified by logistic regression analysis

	Hazard ratio	95% CI	P	
Tumor differentiation				
Others	1			
Well or moderately	4.94	1.00-20.6	0.04	
Time between initial op ≤1 year	eration and diagr	osis of recurr	ence	
>1 year	2.85	1.10-7.40	0.03	
Nodal status ^a				
pN2	1			
pN1	1.50	0.48-4.38	0.50	
pN 0	3.82	1.18-12.3	0.02	

CI, confidence interval

^aFrom reference [8]

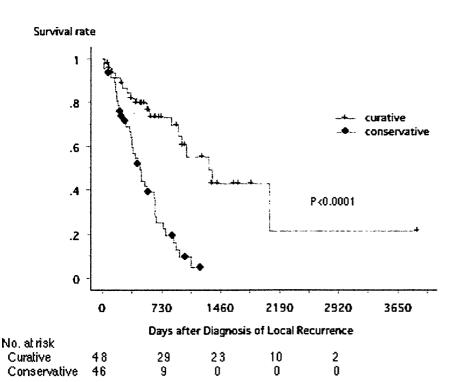


Fig. 1. Survival curve of patients according to treatment. The survival rate of patients treated conservatively was significantly worse than that of patients treated with salvage surgery (P < 0.000, log rank test)

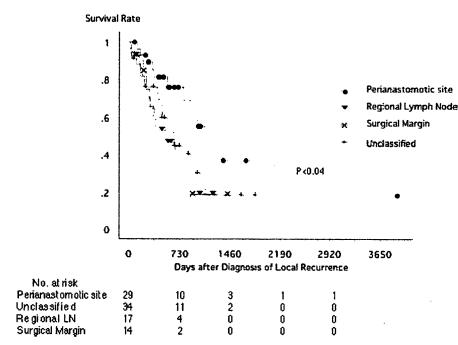


Fig. 2. Survival curve of patients according to different types of recurrence. Patient survival was significantly better in the perianastomotic site group than that in the other groups $(P < 0.04, \log rank test)$

Table 3. Predictors of survival from the time of diagnosis of local recurrence

	MST (month)	P
Age ^b		0.384
≤60	15.8	
>60	18.1	
Sex		0.466
Male	14.1	
Female	16.4	
Tumor size ^a (cm)		0.659
≤5.0	19.3	
>5.0	13.5	
Location ^a		0.736
Rectosigmoid junction	18.2	
Rectum	15.5	
Histological differentiation ^a		< 0.001
Well, moderate	17.1	
Others	6.6	
pT status ^a		0.213
pT2	15.9	
pT3	17.1	
pT4	5.1	
pÑ status ^a		0.009
pN0	18.8	
pN1	12.0	
pN2	13.5	
Concurrent metastasis ^b		0.155
Absent	16.0	0.100
Present	12.1	
CEA level ^b (ng/dl)	~	0.248
≤10	18.2	0.2.10
>10	16.1	
Time to recurrence (year)	10.1	0.049
≤1	12.0	0.047
>1	18.2	
	10.2	

MST, median survival time; CEA, carcinoembryonic antigen

(Table 3). Accordingly, the following factors were not related to patient survival: age, sex, size, location, pT status of the primary tumor, CEA level when LR was detected, and evidence of concurrent distant metastasis. Even in patients treated with surgery, concurrent distant metastasis did not contribute to survival (Fig. 3). In contrast, lymph node status, tumor differentiation, and time between the initial operation and the diagnosis of recurrence were related to patient survival. Ten patients had macroscopic negative but microscopic positive margins; however, this did not influence survival (data not shown).

The Cox proportional hazard model revealed that tumor differentiation (well and moderate), negative lymph node status (pN0), and pattern of recurrence (perianastomotic site) were predictors of better survival (Table 4).

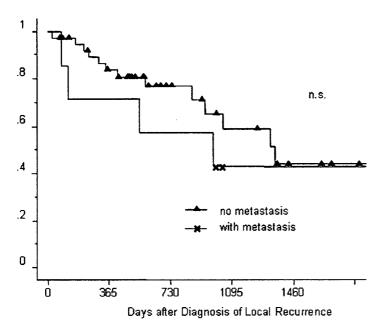
Discussion

The incidence of local pelvic recurrence after radical resection of rectosigmoid colon and rectal cancer remains high, despite improvements in surgical materials and techniques. The prognosis of these patients is poor, with an expected median survival of only 6–11 months if they are untreated. Pilipshen et al. reported that 89% of the patients with pelvic recurrence after resection of rectal cancer died, 7% were alive with local disease, and only 3.8% were free of disease after reoperation. However, there have been an increasing number of reports on the results of salvage surgery for isolated locoregional recurrence after initial radical

^aAt initial treatment

bAt the time of local recurrence

Survival rate



No. at risk					
no metastasis	41	29	18	9	4
with metastasis	7	4	4	1	1

Fig. 3. Survival curve of patients according to concurrent distant metastasis in those treated with surgery. No difference was observed between the groups (log rank test)

Table 4. Independent prognostic factors (Cox proportional hazard model)

Variable	Hazard ratio	95% CI ^c	P
Lymph node status ^a			
pÑ0	1		
pN1	2.52	1.13-5.63	0.02
pN2	3.08	1.39-6.83	0.006
Histological type ^a			
Well or moderately	1		
Others	3.86	1.77-8.21	< 0.001
Pattern of recurrence ^b			
Perianastomotic site	1		
Others	2.23	1.05-4.86	0.03

^aAt initial treatment

surgery for rectal cancer.^{10–16} For patients with locoregional recurrence, the rate of salvage surgery ranges from 30% to 50%, ^{13,17,18} and the 5-year survival rate after repeat resection ranges from 10% to 25%.^{7,11} Surgical resection provides a better chance of survival than other therapeutic approaches, but there are still risks of incomplete resection of the recurrent tumor, the early development of a second recurrence, and postoperative complications.^{17,18} Thus, to minimize unnecessary surgery, it is important to identify those patients most likely to benefit from this treatment.

Lopez-Kostner et al. 14 reported that female sex, treatment of the primary tumor by transanal local excision, and initial surgery at an outside institution were the only independent factors associated with a higher chance of receiving curative-intent surgery. Garcia-Aguilar et al.¹⁹ also used logistic regression analysis to identify the factors associated with curative outcome; and found that the earlier stages of the primary tumor, tumor differentiation, radical proctectomy with a sphincter-saving procedure in the initial surgery, and younger age at the diagnosis of recurrence were independent factors associated with the curative outcome of surgery. These factors are in agreement with the predictors of successful salvage surgery identified in the present study, which include well to moderate histological differentiation of the primary tumor, negative lymph node metastasis at the initial operation, and a long interval between the initial surgery and the detection of LR. As the inclusion criteria for statistical analysis differ between the present and previous studies, these data cannot be compared directly, although we can compare general trends.

Previous investigations have found that the detection of recurrence with careful follow-up resulted in an improved re-resection rate.^{20,21} However, Secco²² reported that an intensive and strict follow-up program was ineffective in improving the long-term survival of patients who underwent re-operation with curative intent.

^bAt the time of local recurrence

^{°95%} confidence interval

One noteworthy finding of the present study was that a short interval between the initial operation and the diagnosis of LR was a predictor of worse prognosis. This may indicate that there are specific biological features controlling the aggressive nature of a rapidly growing tumor.

Wanebo et al.¹⁰ found that neither the stage of the primary tumor nor the disease-free interval correlated with survival after the resection of recurrent rectal cancer. Hahnloser et al.¹¹ also reported that the demography of the patients and the factors related to the initial rectal cancer did not affect the outcome of patients with locally recurrent rectal cancer. In contrast, our univariate analysis indicated that lymph node status and tumor differentiation of the primary tumor were associated with patient survival. Cox regression analyses confirmed that lymph node status and the histological type of the primary tumor contributed to improved prognosis after resection of LR.

The pattern of recurrence was also a predictor of survival, with the perianastomotic site being the most common (30.9%) in the present study. Previous reports define anastomotic recurrence as recurrence within 2 cm of the suture line and with no extramural spread.^{3,16} The incidence of this type of recurrence ranges from 6% to 21%. ^{2,17,22,23} The higher rate of this pattern of recurrence recorded in our series is related to the fact that our definition of perianastomotic recurrence was more inclusive than that of previous reports.

An additional factor that may influence the outcome is distant metastasis. In our institute, the selection criteria for surgery for metastatic lesions were the possibility of an oncologically radical operation while preserving at least 40% of the normal hepatic parenchyma. The total number of hepatic metastases, their unilateral or bilateral presentation, and the existence of extrahepatic metastases were not considered to be exclusion criteria. Concurrent distant metastases were found in 21% of our patients with LR. According to previous reports, the presence of metastatic disease is a contraindication for surgery,^{24,25} although Gagliardi et al.⁵ reported that patients with small liver and peritoneal metastasis amenable to resection had an outcome similar to those with no metastasis. It is interesting that the presence of synchronous distant metastasis at the time of diagnosis of LR did not affect patient survival. Accordingly, we found that evidence of distant metastasis did not affect the survival rate. Therefore, patients with concurrent distant metastasis may also be candidates for surgical resection.

On the basis of these findings, salvage surgery is strongly recommended for patients with negative lymph node metastasis at their initial operation, well or moderate tumor differentiation of the primary tumor, and perianastomotic recurrence, even in the presence of distant metastasis. The decision to operate on patients who fall outside these criteria requires careful consideration to minimize unnecessary surgery.

In conclusion, salvage surgery for locally recurrent rectosigmoid colon and rectal cancer may be beneficial depending on the following pathological characteristics: tumor differentiation and nodal status of the primary tumor, the interval between the initial operation and the diagnosis of recurrence, and the pattern of recurrence.

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Bladder-Sparing Extended Resection of Locally Advanced Rectal Cancer Involving the Prostate and Seminal Vesicles

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Abstract

Purpose. Total pelvic exenteration (TPE) is the standard procedure for locally advanced rectal cancer involving the prostate and seminal vesicles. We evaluated the feasibility of bladder-sparing surgery as an alternative to TPE.

Methods. Eleven patients with advanced primary or recurrent rectal cancer involving the prostate or seminal vesicles, or both, underwent bladder-sparing extended colorectal resection with radical prostatectomy. The procedures performed were abdominoperineal resection (APR) with prostatectomy (n = 6), colorectal resection using intersphincteric resection combined with prostatectomy (n = 4), and abdominoperineal tumor resection with prostatectomy (n = 1). Local control and urinary and anal function were evaluated postoperatively.

Results. Cysto-urethral anastomosis (CUA) was performed in seven patients and catheter-cystostomy was performed in four patients. Coloanal or colo-anal canal anastomosis was also performed in four patients. There was no mortality, and the morbidity rate was 38%. All patients underwent complete resection with negative surgical margins. After a median follow-up period of 26 months there was no sign of local recurrence, and ten patients were alive without disease, although distant metastases were found in three patients. Five patients had satisfactory voiding function after CUA, and three had satisfactory evacuation after intersphincteric resection (ISR).

Conclusion. These bladder-sparing procedures allow conservative surgery to be performed in selected patients with advanced rectal cancer involving the prostate or seminal vesicles, without compromising local control.

Reprint requests to: N. Saito Received: April 13, 2006 / Accepted: January 12, 2007 **Key words** Locally advanced rectal cancer · Total pelvic exenteration · Bladder-sparing surgery · Local control

Introduction

Locally advanced rectal cancer sometimes invades the prostate, seminal vesicles, and trigone of the urinary bladder. Total pelvic exenteration (TPE) is the standard procedure performed for patients with this type of rectal cancer.1-7 Total pelvic exenteration involving en bloc removal of the rectum, urinary bladder, distal ureters, and reproductive organs may be performed with curative intent, with negative surgical margins.4 However, these patients often require one stoma for urinary diversion, such as an ileal conduit or a uretero-cutaneostomy,8-10 and an additional stoma for fecal diversion. This procedure results in double stomas and compromises quality of life severely, despite achieving acceptable locoregional control. Recent advances sphincter-saving surgery for lower rectal cancer have allowed colo-anal canal and colo-anal anastomoses to be performed without adversely affecting outcome. 11-17 Orthotopic neobladder construction has also become standard following cystoprostatectomy for invasive bladder cancer. $^{18-20}$ This procedure represents a feasible alternative for patients undergoing radical cystectoprostatectomy, allowing them to void via the urethra with urinary continence. Moreover, it is a well-accepted technique with excellent results on long-term followup. 18 Together, these advances may improve postoperative quality of life for patients with advanced rectal cancer requiring TPE,21 by enabling an operation to be preformed without a stoma or with only a single stoma. Until recently, bladder-sparing surgery was thought to be possible only for patients without invasion over a wide range of the bladder and the membranous urethra. However, extended colorectal resection with partial preservation of the bladder or anal sphincter, or both, may be possible if cancer-free surgical margins can be achieved. Campbell et al. recommended combined radical retropubic prostatectomy and proctosigmoidectomy as an alternative to TPE for patients with carcinoma of the rectum with isolated extension to the prostate gland or seminal vesicles.22 They also described two patients who underwent radical retropubic prostatectomy in conjunction with restorative proctosigmoidectomy for en bloc excision. These approaches have been explored as alternatives to TPE in patients with locally advanced primary rectal cancer at our institute since 2000. These procedures also have been performed recently in selected patients with local recurrence after rectal cancer surgery. This study examines the oncological findings of 11 patients who underwent bladdersparing surgery as an alternative to TPE. We evaluated the feasibility of, and rationale for bladder-sparing surgery in patients with advanced rectal cancer involving the prostate or seminal vesicles, or both.

Patients and Methods

Patients

The subjects were 11 men with advanced primary or recurrent rectal cancer involving the prostate or seminal vesicles, or both, who underwent extended bladdersparing colorectal resection between January 2001 and October 2005. The mean patient age at the time of surgery was 58.6 years (range, 26-72 years). Eight patients underwent surgery for primary tumors, and three underwent surgery for local recurrence after abdominoperineal resection (APR; n = 1), low anterior resection (LAR; n = 1), or anterior resection (AR; n = 1) 1) of advanced rectal cancer. In all cases, the preoperative diagnosis was primary or recurrent rectal cancer invading the prostate or seminal vesicles. Preoperative staging was conducted using computed tomography (CT), magnetic resonance imaging (MRI), colonoscopy, and barium enema. Positron emission tomography (PET) was also done preoperatively to exclude multiple metastatic disease. All patients had localized tumors involving the prostate or seminal vesicles without distant metastases or marked pelvic lymph node metastasis. There was no evidence of urinary bladder involvement in any of the patients. All resected specimens were examined macroscopically and microscopically to determine the radial and distal surgical margins and lymph node metastases. Involvement of the adjacent organs and margins of surgical resection, perioperative morbidity and mortality, and locoregional control were investigated in all patients. Urinary and anal functions were also evaluated postoperatively by careful monitoring of continence and voiding habits. Locoregional failure was defined as recurrence of rectal cancer within the pelvic cavity. Other recurrences were considered distant disease.

Surgical Technique for Primary Tumors

The left colon was mobilized and the inferior mesenteric artery was transected. The posterior and bilateral sides of the rectum were mobilized by total mesorectal excision (TME) with lateral lymph node dissection. The superior vesical arteries were preserved bi- or unilaterally. The pelvic nerve plexus and almost all of the internal iliac vessels, except for the bi- or unilateral superior vesical arteries, were sacrificed during lymph node dissection. The ureters were visualized and carefully protected throughout the procedure. At this time, the plane between the rectum and the base of the bladder was investigated. After confirming that these were no severe adhesions or obvious tumor involvement cephalad to the prostate, bladder-sparing surgery was deemed possible. We dissected the prostate and seminal vesicles using the usual method for radical prostatectomy, to preserve the urinary bladder. After the puboprostatic ligaments were incised sharply at the pubis and the dorsal vein complex was ligated using the bunching technique, the apex of the prostate was divided from the urethra. The prostatic vesical junction was also transected, and the entire prostate and seminal vesicles were separated from the bladder. Using the peranal approach for intersphincteric resection (ISR) or the perineal approach for APR, we performed en bloc removal of the rectum with the prostate and seminal vesicles. The membranous urethra and bladder were preserved and the bladder neck was reconstructed. An anastomosis between the urethra and bladder was done after confirmation of cancer-free margins in the resected specimen. When the membranous urethra was sacrificed for probable tumor involvement, a cystostomy was created for voiding with a catheter. Finally, a colo-anal anastomosis (CAA) with a diverting stoma or permanent colostomy was established. The diverting stoma was closed 3 months after radical surgery. The line of resection and final appearance of the reconstruction are shown in Fig. 1. Intraoperative histological examination was done using frozen sections if tumor invasion was suspected in the surgical margins, and the operative procedure was converted to TPE if cancer-free margins were not confirmed.

Adjuvant Therapy

Although preoperative radiochemotherapy for resectable rectal cancer is not standard protocol in Japan, four patients agreed to undergo preoperative radiochemo-

Line of resection

Method of reconstruction

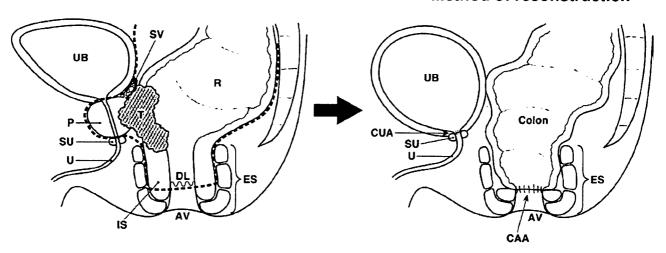


Fig. 1. Line of resection and method of reconstruction in the bladder-sparing surgery described in Materials and Methods. SV, seminal vesicle; UB, urinary bladder; P, prostate; SU, sphincter urethrae; U, urethra; R, rectum; T, tumor; DL,

dentate line; AV, anal verge; IS, internal sphincter; ES, external sphincter; CUA, cyst-urethral anastomosis; CAA, coloanal anastomosis

therapy according to our previous protocol. ¹⁶ These patients received 45 Gy over a 5-week period, followed by resection 2 weeks or more later. These four patients were also given 5-fluorouracil (5-Fu; 250 mg/m²/day) as a continuous infusion during radiotherapy to enhance the radiotherapeutic efficacy. Postoperative chemotherapy (5-Fu/Leucovorin (LV) therapy) was offered to patients if the final pathological specimen was nodepositive. If the margins were cancer-free without lymph node metastasis, chemotherapy was not given.

Follow-Up

Follow-up examinations were done every 3 months for 2 years postoperatively, then every 6 months thereafter. Patients underwent clinical examination, laboratory tests, including measurement of tumor markers, radiological investigations, including liver and pelvic CT, and chest radiography, and evaluation of continence status for urinary and anal function. These functional results were investigated using a questionnaire on the degree of satisfaction with voiding and bowel functions based on continence, frequency, soiling, and urgency, determined by the ability to defer evacuation for 15 min. These functions were evaluated 3, 6, 12 and 24 months postoperatively. Physiological assessment was also done using anal manometry and uroflowmetry. The median follow-up period was 26 months (range, 4-60 months). No patient was lost to follow-up.

In this series, statistical analyses were not performed because of the small number of patients.

Results

We performed bladder-sparing surgery for locally advanced rectal carcinoma in 11 men with a mean age of 58.6 years (range 26-72 years). Only one patient ultimately required TPE for a huge tumor invading the wide area of the urinary bladder, the prostate, and the anal sphincter. All 11 patients were originally considered candidates for TPE, and their clinical characteristics are shown in Table 1. They all had preoperative findings of primary or recurrent rectal cancer with extension into the prostate or seminal vesicles, or both. No extrapelvic metastases were found on pre- or intraoperative examination. Three patients underwent surgery only, five received preoperative radiochemotherapy, and three received postoperative chemotherapy. The types of bladder-sparing surgery performed were APR combined with radical prostatectomy in six patients, anal sphincter-preserving surgery (ISR: 3, ultraLAR: 1) combined with radical prostatectomy in four, and abdominoperineal tumor resection with radical prostatectomy in one. A diverting stoma was established in all of the patients who underwent anal sphincter-preserving surgery. CUA was performed in seven patients, and catheter-cystostomy was performed in four patients in whom the urethral sphincter muscle could not be preserved. Thus, these four patients had colo-anal anastomoses and CUAs instead of stomas. (Table 1). Although the operative procedures were not converted to TPE, a cystostomy was performed for four patients with intraoperative histo-

Table 1. Patients and surgical procedures

				R	econstruction
Patient no.	Age (years)	Invaded organs	Surgical procedure	Urinary	Fecal
Primary					
1	60	$P \cdot SV$	ISR + RP	CUA	CAA
2	60	$P \cdot SV$	APR + RP	CUA	Stoma
3	72	P	APR + RP	CUA	Stoma
4	66	P	ISR + RP	CUA	CAA
5	57	P	APR + RP	CS	Stoma
6	43	P	APR + RP	CS	Stoma
7	52	P	APR + RP	CS	Stoma
8	68	P	ISR + RP	CUA	CAA
Recurrent					
9 (Post LAR)	52	P	APR + RP	CS	Stoma
10 (Post APR)	54	$P \cdot SV$	APTR + RP	CUA	Stoma
11 (Post AR)	26	$P \cdot SV$	Ultra LAR + RP	CUA	Ultra LAR (DST)

P, prostate; SV, seminal vesicle; ISR, internal sphincteric resection; APR, abdominoperineal resection; LAR, low anterior resection; AR, anterior resection; RP, radical prostatectomy; APTR, abdominoperineal tumor resection; CUA, cysto-urethral anastomosis; CS, cystostomy; CAA, coloanal anastomosis; DST, double stapling technique

Table 2. Histopathology and prognosis

Patient no.		Invaded		Site of		
	Tumor stage	organs	Surgical margins	recurrence	Survival	
1	T3 N0 M0	_	Negative	Liver → resection	60mo ANED	
2	T3 N0 M0	 .	Negative		41 mo ANED	
3	T4 N0 M0	P	Negative		31 mo ANED	
4	T3 N2 M0		Negative	Liver → resection	30mo ANED	
5	T4 N0 M0	P	Negative	Lung (multiple)	27mo AWD	
6	T4 N0 M0	P	Negative	3 (1)	25 mo ANED	
7	T4 N2 M0	P	Negative		22 mo ANED	
8	T4 N0 M0	P	Negative		13mo ANED	
9	Recurrence	P	Negative		22 mo ANED	
10	Recurrence	SV	Negative		12mo ANED	
11	Recurrence	$P \cdot SV$	Negative		4mo ANED	

P, prostate; ANED, alive with no evidence of disease; AWD, alive with disease; mo, months

logical evidence of cancerous invasion of the membranous urethra.

There were no perioperative deaths, but five patients suffered perioperative complications. A cysto-urethral anastomotic leak developed in four patients, requiring catheterization through the site of the anastomosis for 3–24 weeks postoperatively; however, no urethral stricture developed. A wound infection developed in three patients, but resolved with local wound care.

All resected margins were examined pathologically and reported to be tumor-free; however, final pathological examination revealed involvement of the prostate or seminal vesicles in eight patients. According to pathological staging by TNM classification in the eight primary rectal cancers, four tumors were T4N0, one was T4N2, and three were T3N0. The three patients with recurrent tumors also underwent surgery with curative intent. Complete resection with negative surgical

margins was achieved in all patients with a primary or recurrent tumor.

After follow-up ranging from 4–60 months (median, 26 months), ten patients were alive without evidence of disease, and one was alive with disease. Recurrence developed in three patients, as a solitary liver metastasis in two and as multiple lung metastases in one. The two patients with solitary liver metastasis underwent curative partial hepatic resection, and the patient with multiple lung metastasis refused chemotherapy. None of the patients had local recurrence (Table 2).

Functional outcomes were evaluated in nine patients who were followed up for at least 12 months postoperatively (Table 3, 4). Five of the patients who underwent CUA were able to void via the urethra, with little or no residual urine (0–20 ml) and without the need for intermittent self-catheterization. All five patients had complete daytime urinary continence. Overflow incontinence