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ように剥離を骨盤底に進める．肛門側予定切離線で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5cm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，J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口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 (1.14~42.97)	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

表4　Complication in Curved cutter cases

Gender	AGE	Location	Preope Complication	Anastomotic leakage	Anasto Site from AV (cm)	Time	Blood Loss
M	65	RS	Obesity (BMI 31)	—	70	220	20
M	58	RS	Obesity (BMI 31)	Major Leak	70	266	50
M	67	Rb	DM	Minor Leak	40	273	300
M	73	RS	Obesity (BMI 28)	Minor Leak	80	225	40
M	76	RS	Gastric ulcer	—	100	220	5
M	62	RS		—	90	240	15
M	55	RS		—	160	237	5
M	59	RS	DM	—	140	246	50
F	82	Rb		—	25	243	150

DM, diabetes mellitus; AV, anal verge.

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．

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5cm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，腟後壁)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，口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

表5　直腸切離器械の特徴

直腸クランプ		Endovascular clip	φ12 mm Surgical Port から挿入可能	腸管把持力が弱い 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
直腸切離	鏡視下用	ENDO GIA UNIVERSAL™ ENDO CUTTER™ ECHERON™	φ12 mm Surgical Port から挿入可能開腹用器械より本体が小さいので鏡視下での操作が容易	Multi stapling の可能性あり 縫合長の長い器械は操作制限あり
	開腹用	Curved Cutter™	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
		TL-30™ TA-45™ ACCESS 55™	一括縫合が可能	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
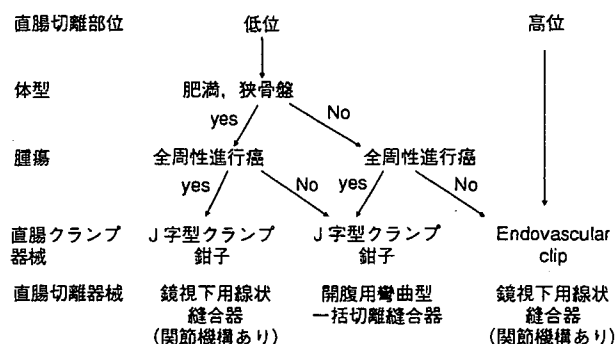

図1　教室における直腸切離器械の選択

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

Norio Saito, Takanori Suzuki, Masanori Sugito, Masaaki Ito, Akihiro Kobayashi, Toshiyuki Tanaka,
Masahito Kotaka, Hirokazu Karaki, Takaya Kobatake, Yoshiyuki Tsunoda, Akio Shiomi, Masaaki Yano,
Nozomi Minagawa, and Yuji Nishizawa

Division of Colorectal and Pelvic Surgery, Department of Surgical Oncology, National Cancer Center Hospital East, 6-5-1 Kashiwanoha, Kashiwa, Chiba 277-8577, Japan

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.

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 in 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 follow-up.[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 bladder-sparing 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 bladder-sparing 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; $n = 1$) 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 monitor-

ing 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
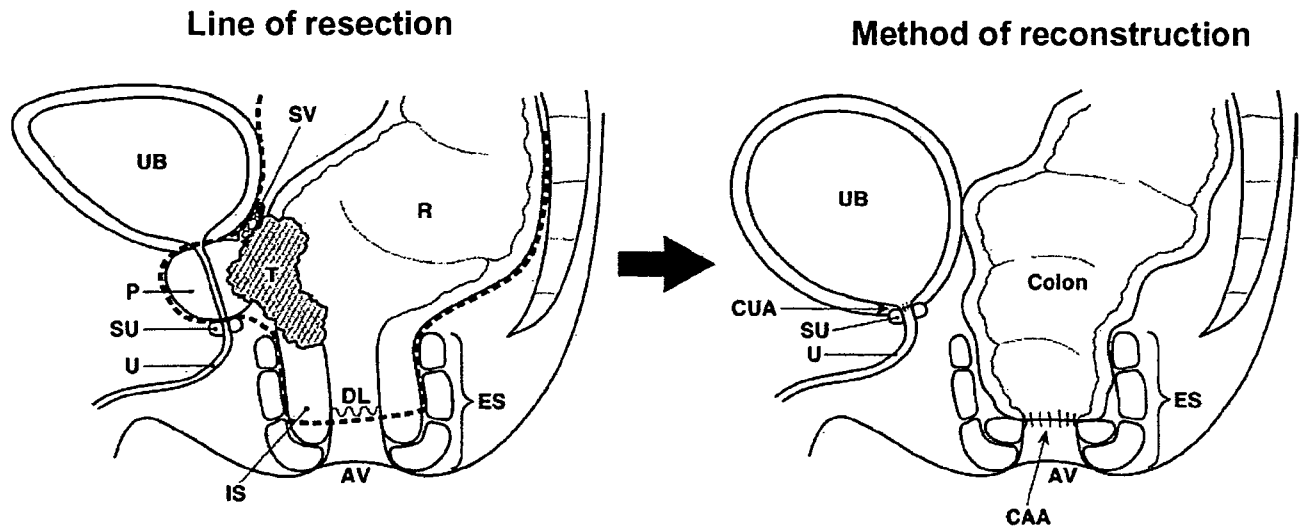
Method of reconstruction

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*, colo-anal 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; 250mg/m^2/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 node-positive. 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

Patient no.	Age (years)	Invaded organs	Surgical procedure	Reconstruction	
				Urinary	Fecal
Primary					
1	60	P · SV	ISR + RP	CUA	CAA
2	60	P · 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 · SV	APTR + RP	CUA	Stoma
11 (Post AR)	26	P · 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, colo-anal anastomosis; DST, double stapling technique

Table 2. Histopathology and prognosis

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

Table 3. Postoperative urinary functions (more than 12 months after surgery)

Patient no.	Reconstruction	Voiding	VV (ml)	RV (ml)
1	CUA	Spontaneous, continence	350	0
2	CUA	Spontaneous, continence	250	0
3	CUA	Spontaneous, continence	300	20
4	CUA	Spontaneous, continence	150	15
5	CS	Incontinence	Catheterization	
6	CS	Incontinence	Catheterization	
7	CS .	Incontinence	Catheterization	
8	CUA	Spontaneous, continence	250	10
9	CS	Incontinence	Catheterization	

CUA, cysto-urethral anastomosis; VV, voided urine volume; RV, residual urine volume; CS, cystostomy

Table 4. Postoperative fecal evacuation functions (more than 12 months after surgery)

Patient no.	Continence	Stool frequency	Feces-flatus discrimination	Urgency	Soiling
2	(+)	3/day	Good	(−)	Night-time (−) Day-time (−)
4	(+)	3–5/day	Good	(±)	Night-time (−) Day-time (−)
8	(+)	5/day	Good–Fair	(±)	Night-time (±) Day-time (−)

at night was occasionally experienced during the first year postoperatively, but this improved in the second year. Excretory urography demonstrated excellent urinary function bilaterally with no evidence of hydronephrosis. Retrograde cystography did not show reflux in any of the five patients (Fig. 2). The four patients who underwent catheter-cystostomy passed urine via an inserted catheter. This voiding style was similar to that of patients with an ileal conduit; however, no special outfits were needed after catheter-cystostomy. Unfortunately, erectile function was not able to be preserved in any of the patients.

Of the three patients who underwent ISR with radical prostatectomy, none experienced major soiling or incontinence, although one patient suffered occasional minor soiling for about 1 year after closure of the diverting stoma. These patients passed fewer than five bowel movements per day and could discriminate feces from flatus by 1 year after stoma closure (Table 4). Anal function tended to improve slowly during the second year after surgery. Stoma closure is planned for the remaining patient.

Discussion

Locally advanced rectal cancer with adherence to, or involvement of the adjacent organs is not uncommon. En bloc excision of locally invasive rectal cancer

without extrapelvic metastases can be curative, and TPE is still the conservative surgical option for locally advanced pelvic tumors, to achieve negative surgical margins in selected patients. This radical procedure was originally performed in the Ellis Fischel Cancer Center in the 1940s and was first reported by Brunschwig in 1948 as "a palliative operation for advanced cervical cancer"[23]. This formidable intervention carried with it high morbidity and mortality rates[5,6]. However, recent published series have reported mortality rates of lower than 10%, even with long-term follow-up[4,6,24,25]. Unfortunately, morbidity rates are still relatively high. TPE involving en bloc removal of the rectum, urinary bladder, distal ureters, and reproductive organs frequently requires diversion of urinary and anal functions, such as combined sigmoid colostomy and ileal conduit placement. TPE resulting in double stomas severely compromises the quality of life of these patients. Thus, orthotopic neobladder surgery is often attempted as an alternative for patients undergoing radical cystectoprostatectomy for bladder cancer, to enable voiding via the urethra with urinary continence[7,21]. Sphincter-preserving operations with colo-anal anastomoses are also attempted for patients with distal rectal cancer.

We believe that even more limited excision is feasible and preferable if the tumor can be removed en bloc. In patients with locally advanced rectal cancer and invasion limited to the prostate or seminal vesicles, extended
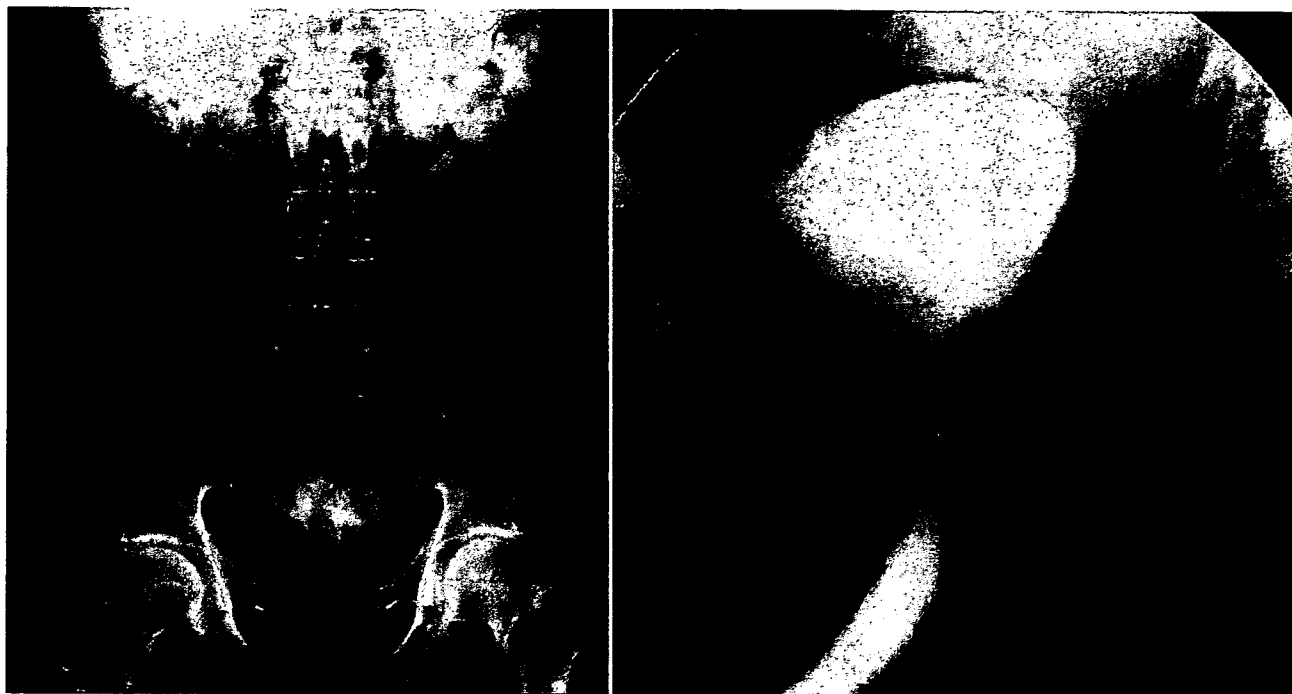
Fig. 2. Postoperative urogram findings in patients who underwent cystourethral anastomosis showed no evidence of hydronephrosis or reflux. Left Patient 1, 40 months after surgery.

Excretory urography shows no hydronephrosis. Right Patient 4, 6 months after surgery. Retrograde cystogram demonstrates a relatively small capacity (about 280 ml) and no reflux

colorectal resection with partial preservation of the bladder and anal sphincter may be possible, provided cancer-free margins can be achieved. Balbay et al. wrote: "Bladder-sparing surgery to treat patients with locally invasive colorectal carcinoma provides good local control without sacrificing survival. Selected men in whom CT and intraoperative evaluation identifies only localized involvement of the prostate or seminal vesicle appear to be reasonable candidates for bladder-sparing procedures"[22]. These procedures without ISR were first reported by Campbell et al. in 1993. In their experience of two patients, en bloc excision yielded negative surgical margins with no evidence of local recurrence at 1-year follow-up examination, and the patients displayed satisfactory control of intestinal and voiding function[22,27]. Although no long-term follow-up evaluation was reported, if adequate surgical margins can be achieved without total cystectomy, local and distant failure rates will not be diminished by cystectomy and urinary diversion.

In the present series, negative surgical margins were obtained in all patients by using en bloc resection combined with radical prostatectomy, even in the three patients with local pelvic recurrence of colorectal cancer. No standards for the treatment of locally recurrent rectal cancer have been established. Local recurrence close to or involving nearby pelvic organs after APR

often cannot be resected with negative margins unless TPE is performed. Fortunately, negative surgical margins were obtained by bladder-sparing surgery in these three patients with local recurrence involving the prostate or seminal vesicles, or both. Despite our concerns about the risk of local recurrence after limited excision to preserve the superior or inferior bladder vessels to supply the residual bladder, no local recurrence was seen during follow-up (median, 26 months). Moreover, the patients who underwent CUA reported satisfactory control of voiding function. Their voiding style was similar to that of patients with an ileal neobladder. Unfortunately, the remaining four patients required cystostomy after preservation of the membranous urethra was deemed impossible because of probable cancerous invasion. These patients voided via an inserted catheter without special outfits, much like patients with an ileal conduit. An obvious difference between neobladder surgery and bladder-sparing surgery is that the neobladder is made using intestine, which presents inevitable long-term complications such as mucinous production, nutritional abnormalities, metabolic acidosis, skeletal demineralization, and the risk of malignant transformation in the intestinal segment[27,29]. No such problems are associated with the bladder-sparing surgery we described because the original bladder is preserved.

Anal sphincter-preserving surgery using ISR or ultra LAR was performed in 4 of these 11 patients, 3 of whom reported satisfactory control of anal function, while the others reported occasional minor soiling and other functional disturbances such as urgency, fragmentation, and frequent bowel movements. In our experience, and that of other authors, curability and acceptable anal function can be achieved with ISR in patients with very low rectal tumors[12-17]. Attempts should be made to preserve the anal sphincter, partially or completely, whenever possible.

In this series, the bladder was preserved successfully in eight men, by performing prostatectomy without compromising local control, even though these patients had been considered candidates for standard TPE. Bladder-sparing surgery seems to be an appropriate procedure for patients with locally advanced colorectal cancer involving the prostate or seminal vesicles, or both, without urinary bladder invasion, extensive pelvic nodal metastasis, or distant metastasis. Exploration was necessary to determine if limited en bloc resection of invasive rectal cancer was feasible, since discrimination between cancerous involvement and inflammatory adhesions is very difficult intraoperatively, although preoperative imaging examinations such as CT, MRI and PET can be helpful. We recommend careful intraoperative examination using frozen sections to evaluate the extent of pelvic invasion, and to determine whether limited resection is possible. However, intraoperative decisions based on frozen sections may carry some risk, since tumor exposure can occur and convert a potentially curative resection into a noncurative resection. However, if the bladder and anal sphincter are spared, the procedures described offer several advantages over TPE. We think that these procedures may yield improved functional results without compromising local control. More experience and longer follow-up evaluations are necessary to define the operative morbidity, risk of recurrence, and functional results associated with these surgical procedures.

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超低位直腸癌における
肛門括約筋部分温存手術の適応と方法

Partial and sphincter-preserving operation in patients with very low rectal cancer

齋藤　典男[*]　杉藤　正典[**]　伊藤　雅昭[**]　小林　昭広[**]　西澤　雄介[**]
Norio Saito　　Masanori Sugito　　Masaaki Ito　　Akihiro Kobayashi　　Yusuke Nishizawa

●要旨●外科的肛門管に及ぶ肛門にきわめて近い超低位進行直腸癌の標準手術は，腹会陰式直腸切断術である。

しかし最近では，内肛門括約筋の切除を主とする肛門括約筋部分温存手術により，直腸切断術の回避が可能とされる報告も認められるようになった。本稿では肛門括約筋部分温存術の適応と，その実際の手術手技について要点を解説した。また本手術法による長期成績は未だ不明な点もあるため，本法を実施するにあたり相当な慎重さが要求されることも述べた。

● key words：外科的肛門管，直腸切断術，肛門括約筋部分温存手術，内肛門括約筋，外
肛門括約筋

はじめに

近年の下部直腸癌の手術では，手術手技や機器の発達により肛門温存術が増加している。しかし，外科的肛門管やその近傍の超低位直腸癌症例では，腹会陰式直腸切断術（APR）が標準手術法であり永久人工肛門が必要となる。この理由として，①この部位の癌では坐骨直腸窩や肛門挙筋に沿うリンパ節転移の可能性，②肛門温存が手技的にきわめて困難であること，③肛門括約筋切除により排便機能が廃絶する可能性が大変に大きいこと，などがあげられていたためである。しかし最近では，肛門にきわめて近い超低位直腸癌（肛門縁から腫瘍の下縁が5cm以内に存在する）に対し，外肛門括約筋を可能な限り温存しながら内肛門括約筋を切除する手術（intersphincteric resection：ISR）が臨床応用されるようになり，その結果が報告されている[1~5]。これまでの報告によると，①の項目については否定的であり[6][7]，また③の術後排便機能はさまざまな排便障害は存在するものの容認できる結果であ

るとされている。

また腫瘍学的な予後も，比較的良好な結果が得られている。そこで本稿では，当施設で実施しているISRとこれに加えた外肛門括約筋部分合併切除（partial external sphincteric resection：PESR）などの肛門括約筋部分温存手術の適応と方法について述べることにする。

肛門管の局所解剖と各手術法の切除線

1. 局所解剖

肛門括約筋部分温存手術を行うにあたって，肛門管の解剖に精通することが重要となる。肛門管の局所解剖についてはすでに報告しているため[12~14]，ここでは簡単に述べることにする（図1）。解剖学的肛門管は肛門縁（anal verge：AV）から歯状線（dentate line：DL）までであるが，臨床的に取り扱う肛門管は実際に狭くなった部分の全体を外科的肛門管（平均3～5cm）として呼んでいる。肛門から手指を挿入した場合，AVから約1cm程度の部位に輪状の浅い陥凹を示す溝が存在し，これは内肛門括約筋の終末部と外肛門括約筋皮下部の内側上縁の境界に相当する括約筋間溝（intersphincteric groove：ISG）である。
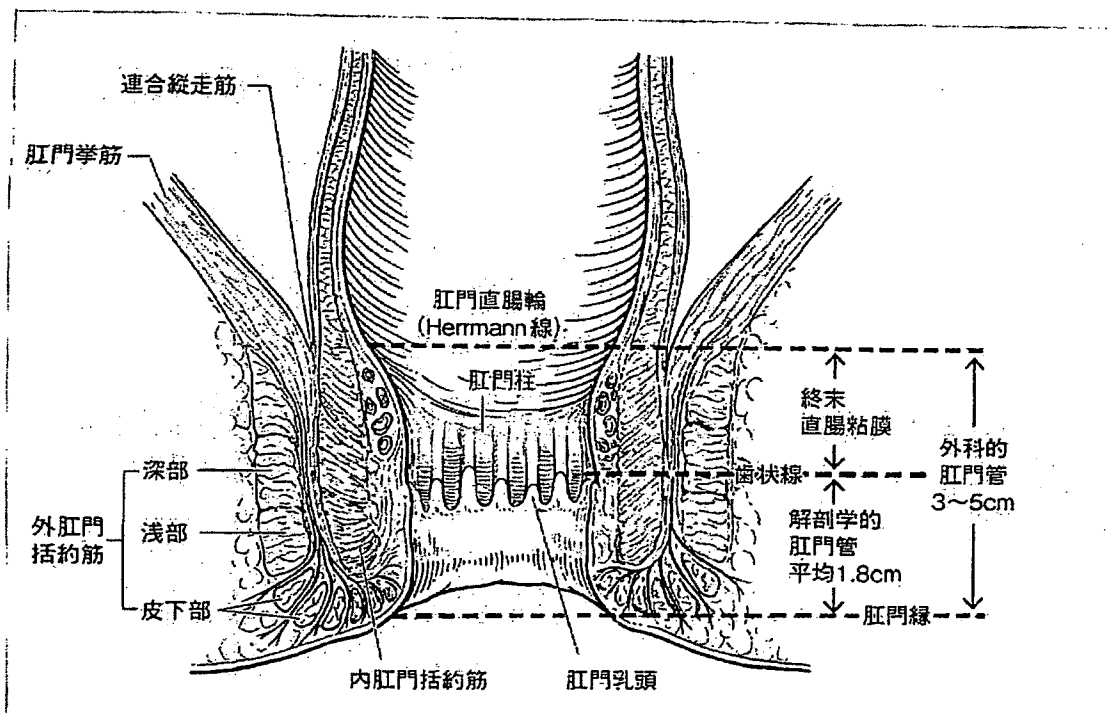
図1 肛門管の構造

この口側は狭い管状部となり，これを通過するとドーム状の広い部位となる。ここが肛門直腸輪（恥骨直腸筋付着部上縁）で，ほぼHerrmann線と一致する。直腸の内輪状筋はこの部位付近より肥厚を始めISGで終末となり，これが内肛門括約筋（internal sphincter；IS）で平滑筋である。外肛門括約筋（external sphincter；ES）は肛門管外側を筒状に取り巻く横紋筋であり、皮下部、浅部、深部から構成され，肛門管の持続的閉鎖作用を有する。内外肛門括約筋の間には疎な組織として認識される連合縦走筋（conjoined longitudinal muscle；CLM）が存在し，これは直腸の縦走筋と肛門挙筋の一部が融合して放射状に分岐して広がる線維性筋組織である。肛門管は，このように大切な機能を有する筋組織によって包まれている。

2. 各術式の切除線（図2）

APRの回避を目的とした当施設における肛門括約筋部分温存手術は内肛門括約筋の切除線により⑥total intersphincteric resection（total ISR，⑥subtotal ISR，⑥partial ISR．⑥各ISRに種々のpartial external sphincteric resection（PESR）を加えたもの（ISR＋PESR）に大別される。PESRはさらに細かく分類されるが，本稿では省略することにする。各術式の切除線を図2に示すが，これらの各術式の選

択は腫瘍の肛門側下縁の位置と腫瘍浸潤の最深部の部位で決定される。つまり，distal marginとradial marginをどこの部位に設定するかにより決定されるものである。これにはAV，ISG，DL，IS，CLM，ESなどと腫瘍の位置関係が重要となる。図3にAPR標本のルーペ像を示すが，この症例の場合はISRおよびISR＋PESRでも十分なsurgical marginsが得られることがわかる。本術式の適応については，次の項目で述べる。

各手術法の適応について

最初に肛門括約筋部分温存手術の適応について，その概要を表1に示す。原則的に腫瘍下縁がAVより1～5cm以内のType 1，2の腫瘍までの症例が原則であり，低分化型腺癌とType 4は除外する。Type 3は要注意である。その他に年齢では75歳前後までとし，術前に正常範囲内の排便状態を有する症例としている。また本手術法は標準手術とは異なることを説明し，承諾の得られた症例に施行している。以下に各手術法の適応について述べる。

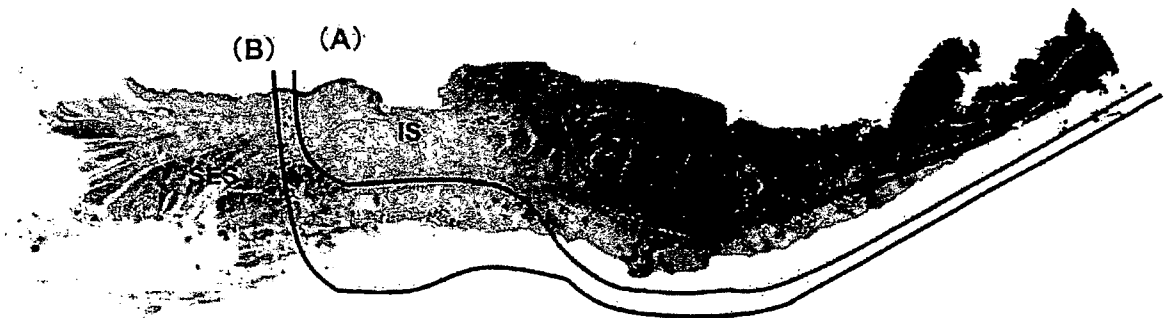### 1. total ISR

連合縦走筋（CLM）内を剝離して外肛門括約筋を温存し，肛門側は括約筋間溝（ISG）で切除して内肛
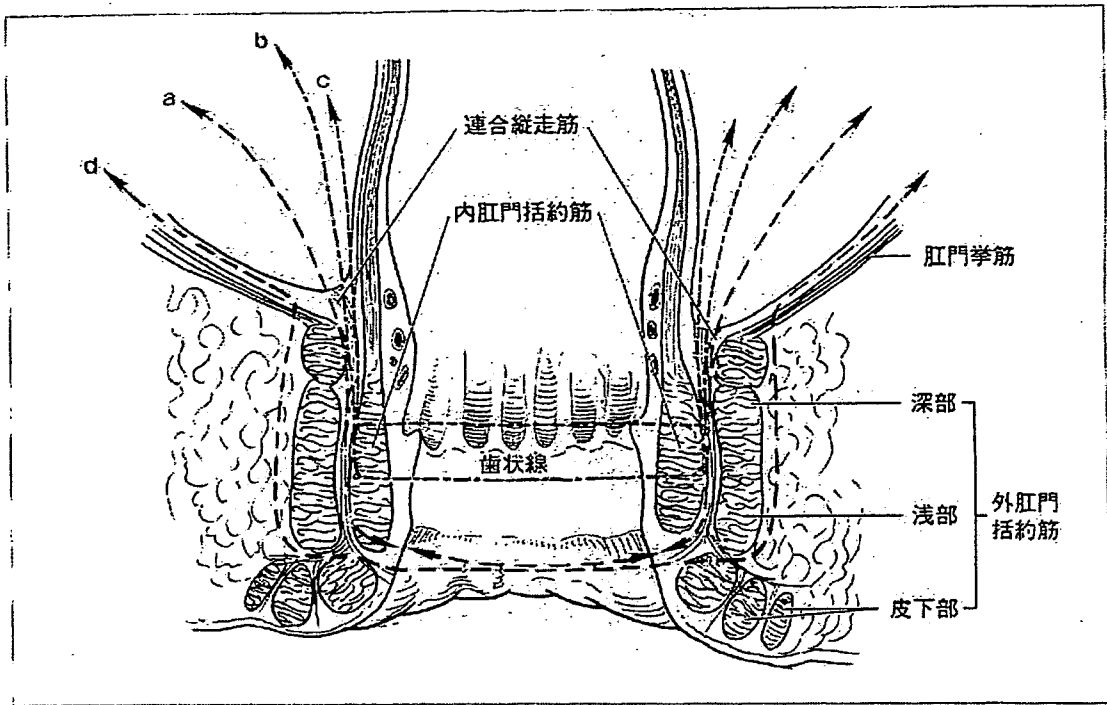
図2 術式分類
a：total ISR　b：subtotal ISR　c：partial ISR　d：total ISR ＋ PESR の例

(A)：ISR（Internal sphincteric resection）
(B)：ISR+PESR（Partial external sphincteric resection）

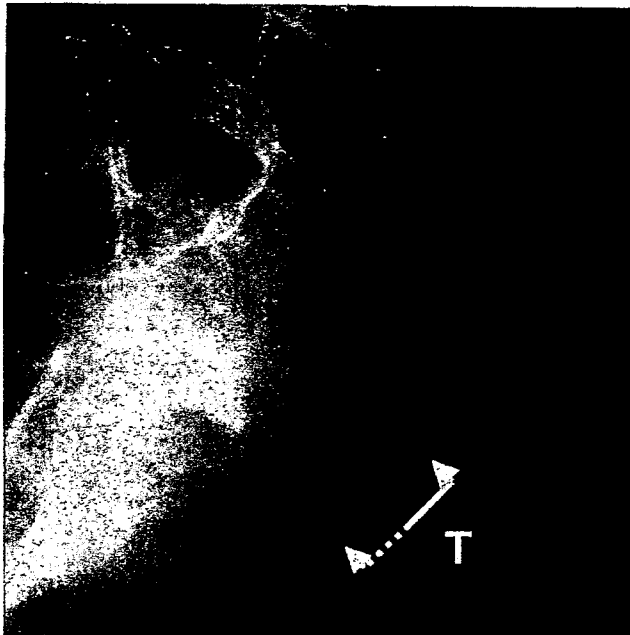

IS：Internal sphincter
SES：Subcutaneous part of external sphincter

図3　APR 標本を用いた括約筋部分温存手術の切除線

表 1　肛門括約筋部分温存手術の適応

Location
　anal verge（AV）より 5 cm 以内の腫瘍で，下縁が AV より10mm 以上口側に存在
Tumor Stage
　主に T3までで，一部の T4を含む
Type
　Type1，Type2で Type3 は要注意，Type4は除外
その他
　P/D，mucinous Ca. は除外することが多い
　Age—原則的に75歳前後まで
　正常範囲内の排便状態を有する
　IC で承諾が得られている

a：注腸造影所見（T；tumor）

b：大腸内視鏡所見（直腸内反転像）

図4　症例1

門括約筋を全摘し，結腸肛門吻合を行う術式である。
本法の適応は，外科的肛門管より口側で腫瘍がT3で
あってもよいが外科的肛門管に及ぶ腫瘍はT2までで
あり，肛門管に存在する腫瘍下縁が歯状線（DL）お
よびその直上に及ぶ症例である。

2.　subtotal ISR

本法は内肛門括約筋全摘とは異なり，肛門側の内肛
門括約筋の一部を温存する術式であり，肛門側切除線
はDLとISGとの間に存在する。本法の適応は，肛
門管内の腫瘍下縁がDLより口側1cm以内に存在す
る場合である。他の条件は，total ISRの場合と同様
である。

3.　partial ISR

本法は内肛門括約筋の一部が切除される術式であ
り，肛門側切除線はDLの直上からその1cm程度口
側の間となる。本法の適応は，腫瘍下縁がDLより口
側1cm以上の肛門管から肛門管上縁の間に存在する
場合である。その他の条件は，totalおよびsubtotal
ISRの場合と同様である。本法には，従来から行われ
ていた結腸肛門吻合（いわゆるCAA）が一部含まれ
ることになる。

4.　ISR＋PESR

本術式では，内肛門括約筋と外肛門括約筋の皮下部

を除く部分的な外肛門括約筋が一緒に切除される。し
たがって，さまざまな程度の外肛門括約筋が温存（皮
下部は全温存）される。この術式では，内肛門括約筋
に対してはtotal ISRとなることが多い。しかし，腫
瘍下縁の位置により，内肛門括約筋の一部が温存され
る場合もある。腫瘍の最深部が，肛門管のどの部位に
存在するかにより異なるわけである。つまり肛門管内
で腫瘍がT3またはT4（外肛門括約筋に浸潤）とな
る部位で大きく異なるわけであり，また前述した腫瘍
の下縁の位置で異なることになる。

上述した各術式の選択にあたり，術前および術中に
おける腫瘍の浸潤度診断が重要となる。術前では直腸
指診や内視鏡による腫瘍下縁の位置の計測と判定が，
また直腸肛門管MRI画像による浸潤度診断などがき
わめて重要である。注腸造影所見のみでは，肛門管の
十分な描出が不可能なこともあり不十分である。以下
に症例を提示する。

〈症例1〉

図4は56歳，男性の注腸造影像と内視鏡像であり，
注腸像では腫瘍下縁の部位と肛門管の関係の把握が難
しい。内視鏡と直腸指診による計測で，Type 2の腫
瘍の下縁はAVより4cmであった。図5に本症例の
MRI画像を示す。腫瘍と内・外肛門括約筋および肛
門挙筋の関係が描出され，腫瘍の浸潤範囲は内肛門括
約筋内であり，肛門挙筋および外肛門括約筋には浸潤
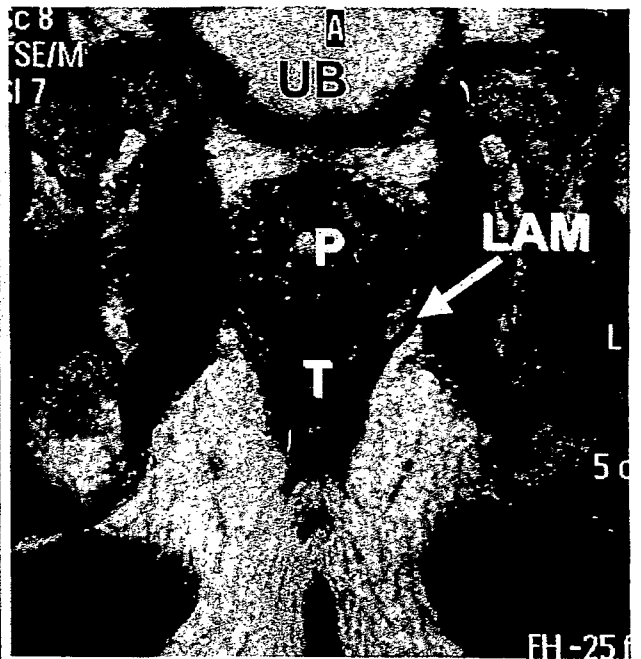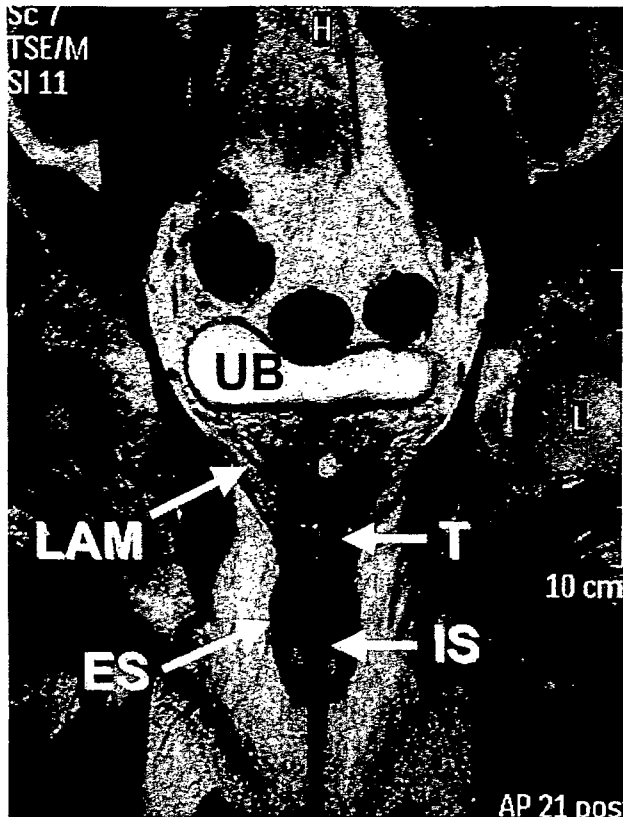
UB：urinary bladder
LAM：levator ani muscle
IS：internal sphincter
ES：external sphincter
P：prostate

図5 症例1；MRI 所見
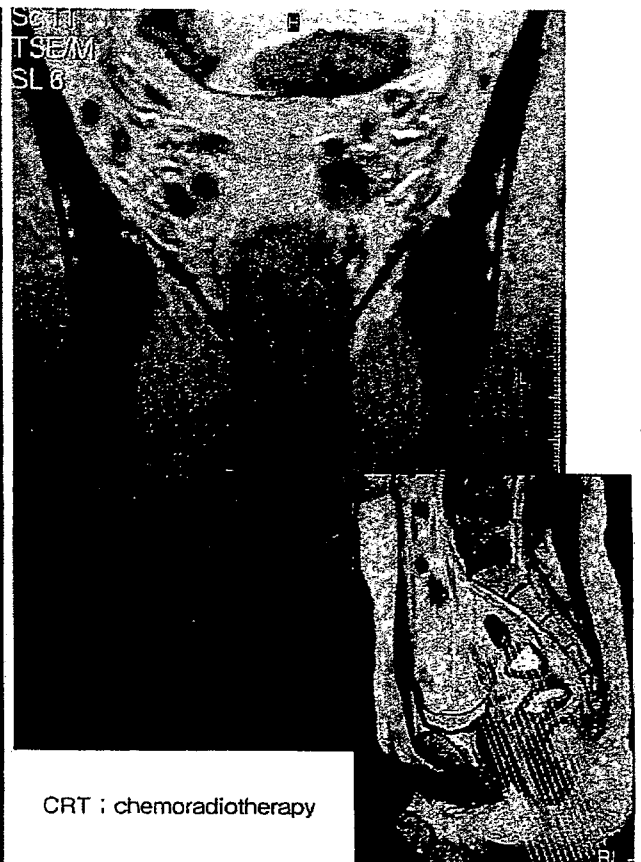
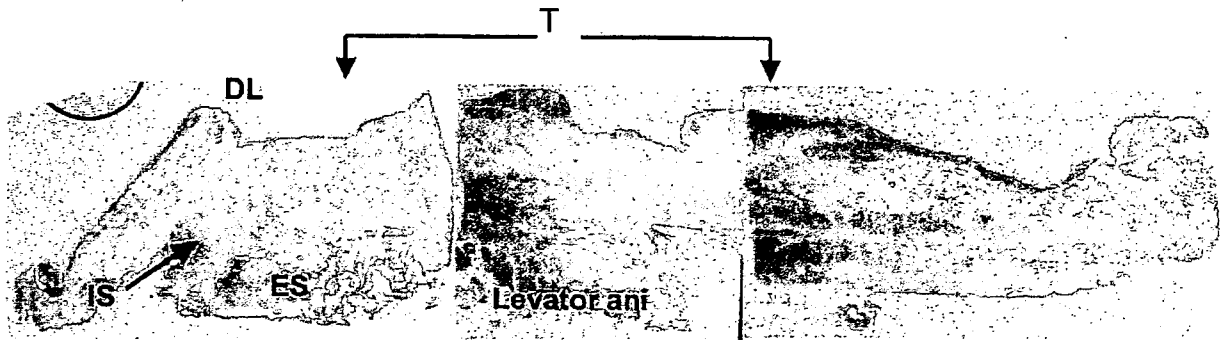CRT；chemoradiotherapy

a：pre-CRT

b：post-CRT

図6 症例2；MRI 所見

図7 切除標本のルーペ像 (total ISR + PESR 例, 症例2)

location : anorectal junction
size : 23×23mm
TNM : pT2, pN0, M0
histologic type : moderately differentiated adenocarcinoma
lymphatic invasion : none
venous invasion : low-grade
surgical margins : cancer-free (negative)
              : circumferential ; 7 mm
              : distal ; 15mm
DL : dentate line IS : internal sphincter ES : external sphincter T : tumor

所見を認めない。本症例の術式は, partial もしくは subtotal ISR で十分な根治的切除が可能と考えられる。

〈症例2〉

図6は症例2の MRI 画像である。術前放射線化学療法 (CRT) 前および後の画像であり, 左の CRT 後の所見では腫瘍左側で LAM および ES の一部と腫瘍との境界がはっきりしない。このため本症例では total ISR + PESR (左側) が施行された。本症例の切除標本ルーペ像を図7に示すが, 腫瘍は ES に浸潤所見を認めず, 十分過ぎる surgical margin が得られている。これは術前補助療法による変性のため, 正確な浸潤度診断が困難であったためである。このような過大手術に対しても, 注意を要する。
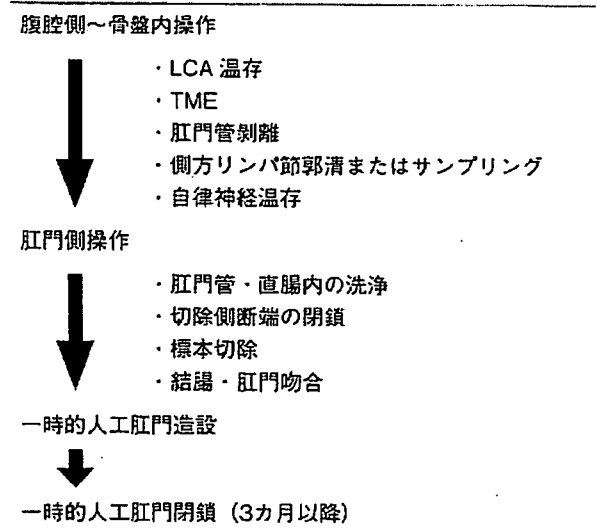
手術の実際

実際の本手術法の要点について表2に示すが, 以下に簡単に述べる。

1. 腹腔操作

通常の低位前方切除術に準じて行う。下腸間膜動脈の切離は, 吻合に用いる結腸の良好な血流を確保するために可能な限り左結腸動脈 (LCA) を温存する。吻合時に結腸の緊張が問題となる場合, LCA を犠牲

表2 手術の実際

腹腔側～骨盤内操作
・LCA 温存
・TME
・肛門管剝離
・側方リンパ節郭清またはサンプリング
・自律神経温存

肛門側操作
・肛門管・直腸内の洗浄
・切除側断端の閉鎖
・標本切除
・結腸・肛門吻合

一時的人工肛門造設

一時的人工肛門閉鎖 (3ヵ月以降)

にする。

2. 骨盤内操作

超低位前方切除の場合と同様に, total mesorectal excision (TME) を十分に行う。その後に外科的肛門管の剝離を行うのであるが, 図8のごとく肛門挙筋群が直腸・肛門管を取り巻く部位を十分に認識し, 慎重に肛門側へ剝離を行い肛門側へ可能な限りすすめる。腫瘍の浸潤度により剝離 (切離) 線が異なり, ISR の場合は内外括約筋内の CLM の層で剝離を行う。

骨盤鈎　　直腸　恥骨直腸筋

腸骨尾骨筋

恥骨直腸筋が
直腸に巻き付
くライン

恥骨尾骨筋

尾骨

図8　骨盤底から肛門側への剝離

AF

LAM

ES

AV

electric knife

residual anal canal

threads of purse string suture
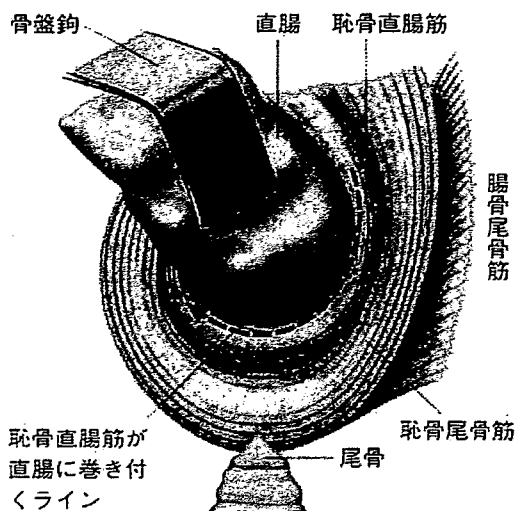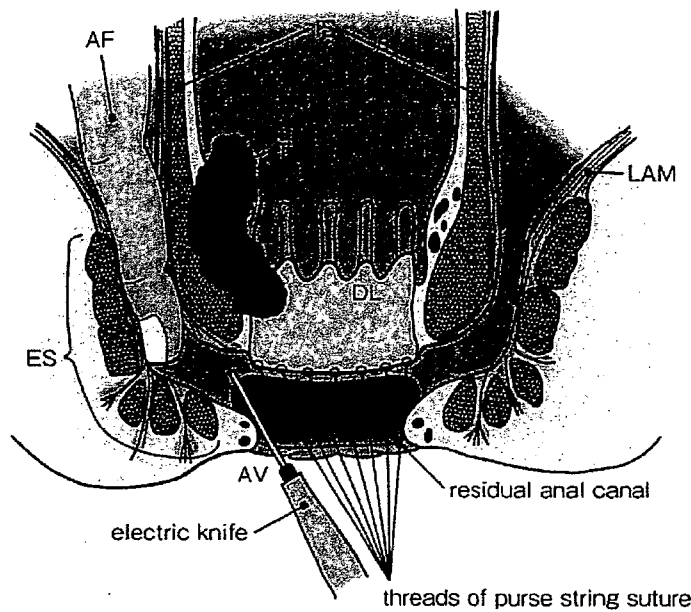
図9　肛門側操作

AF : assistant's finger-tips
T : tumor
ES : external sphincter
IS : internal sphincter
DL : dentate line
LAM : levator ani muscle
AV : anal verge

　PESR の場合は癌の最深部の部位により異なるが，
合併切除する外肛門括約筋の部位の外側に切離線を設
定して切り込む。これらの操作の終了後に，自律神経
を温存しながら側方郭清を実施する。

3.　肛門側操作

　最初の肛門側操作は，肛門管・直腸内の十分な洗浄
（2ℓ以上）である。このときの腸管のクランプは，
当然のことながら腫瘍の口側となる。洗浄後に開肛器
を用いて肛門管の展開を行い，腫瘍下縁と AV を確
認して肛門側切除線の設定を行う。distal margin を

どの位確保するかにより，total, subtotal, partial
ISR が決定される。各部位で内肛門括約筋を全周に切
離しながら，切除側肛門管断端を縫合閉鎖し，糸は支
持糸として残す（図9）。この操作により切除標本が
摘出される。骨盤腔内から肛門に向かって十分に洗浄
した後，口側結腸を肛門へ引き出して 3-0 吸収糸で
結腸・肛門管（肛門）吻合を全層で行う（平均20〜
24針程度）（図10）。なお，切離端の迅速病理検索で
cancer-free でない場合は，APR に変更することを
考慮する。