Safety of Laparoscopic Intracorporeal Rectal Transection With Double-Stapling Technique Anastomosis

Seiichiro Yamamoto, MD, PhD, Shin Fujita, MD, PhD, Takayuki Akasu, MD, PhD, and Yoshihiro Moriya, MD, PhD

Abstract: To assess the feasibility and analyze the short-term outcomes of laparoscopic intracorporeal rectal transection with double-stapling technique anastomosis, a review was performed of a prospective registry of 67 patients who underwent laparoscopic sigmoidectomy and anterior resection with intracorporeal rectal transection and double-stapling technique anastomosis between July 2001 and January 2004. Patients were divided into 3 groups: sigmoid colon/rectosigmoid carcinoma, upper rectal carcinoma, and middle/lower rectal carcinoma. A comparison was made of the short-term outcomes among the groups. The number of cartridges required in bowel transection was significantly increased in patients with middle/lower rectal carcinoma, and significant differences were observed in the length of the first stapler cartridge fired for rectal transection. Furthermore, mean operative time and blood loss were also significantly greater in the middle/lower rectum group; however, complication rates and postoperative course were similar among the 3 groups. No anastomotic leakage was observed. Laparoscopic intracorporeal rectal transection with double-stapling technique anastomosis can be performed safely without increased morbidity or mortality.

Key Words: laparoscopic low anterior resection, rectal transection, double-stapling technique, complication, colorectal carcinoma

(*Surg Laparosc Endosc Percutan Tech* 2005;15:70–74)

More than 10 years have passed since the first report of laparoscopic colectomy by Jacobs et al[1] in 1991. With regard to long-term oncological safety, which is the most important concern for laparoscopic surgery (LS) for malignancies, there have been no reports indicating that LS is inferior to conventional open surgery (OS).[2–5] On the other hand, because LS requires surgical techniques that are different from those of OS, even a surgeon with considerable experience in OS cannot readily perform LS.

In particular, LS for rectal carcinoma is very difficult surgery from a technical standpoint, and consequently many randomized, controlled trials have excluded patients with middle/lower rectal carcinoma. This is because of concerns over the safety of the procedure, ie, the risk of complications associated with the laparoscopic procedure and the risk of tumor cell spillage because of traumatic manipulation of the tumor. Previous studies have reported an anastomotic leakage rate of 5.7% to 21% in patients who underwent laparoscopic low anterior resection (Lap-LAR), and some authors have recommended a covering ileostomy as a routine in Lap-LAR cases.[6–12] It remains uncertain which cases of rectal carcinoma are appropriate for laparoscopic surgery.

Since our first laparoscopic colectomy for colorectal carcinoma in 1993, approximately 280 laparoscopic resections for colorectal malignancies have been carried out at our institution. Most of our early experience was confined to early (Tis or T1) colorectal cancer located at the cecum, ascending colon, sigmoid colon, or rectosigmoid due to technical problems and concerns regarding port site and peritoneal recurrences. In June 2001, we unified our surgical and postoperative management procedures and expanded our indications for laparoscopic colectomy to include advanced colorectal cancers (ie, T2 lesions and beyond) located anywhere in the colon and/or rectum.

In 1980, Knight and Griffen[13] described the double-stapling technique (DST), which offered great advantages in that it permitted low rectal anastomoses to be performed with great ease. The aim of the present study was to assess the feasibility and analyze the short-term outcomes of laparoscopic intracorporeal rectal transection with DST anastomosis, one of the most demanding and stressful techniques in laparoscopic colorectal surgery, in selected patients with sigmoid colon and rectal carcinoma, who all underwent LS at our hospital after June 2001.

PATIENTS AND METHODS

Patients

At the Division of Colorectal Surgery of the National Cancer Center Hospital in Japan, 156 nonrandomized consecutive patients underwent laparoscopic colorectal resections between July 2001 and January 2004. During this period, 67 patients were treated by laparoscopic sigmoidectomy and anterior resection with DST anastomosis. Because the safety of LS in cancer patients remains to be established, candidates for laparoscopic surgery were patients who were preoperatively diagnosed with T1 or T2. Additionally, LS cases also included patients with sigmoid colon or upper rectal carcinoma who were preoperatively diagnosed with T3 but wished to undergo LS, as well as those for which palliative resection was

Received for publication March 25, 2004; accepted November 26, 2004.
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considered necessary. Exclusion criteria for LS were tumors larger than 6 cm, a history of extensive adhesions, severe obesity (body mass index >32 kg/m^2), intestinal obstruction, and refusal to undergo LS. The preoperative workup consisted of a clinical investigation, barium enema, total colonoscopy, chest x-ray, abdominal ultrasonography, and computed tomography.

LS was contraindicated for patients with preoperative diagnoses of T3 and T4 tumors in the middle and lower rectum because, with the current instrumentation, it was difficult to perform laparoscopic procedures without grasping and manipulating the bowel or mesorectum near the tumor; our concern was that this would result in accidental tumor spillage. Furthermore, lateral lymph node dissection combined with total mesorectal excision remains the standard surgical procedure for patients with T3 and T4 lower rectal carcinoma in Japan, and lateral lymph node dissection by laparoscopy is still an unexplored frontier.[14–16] As a result, some patients were found to have T3 cancer only after histopathological examination of the surgical specimens. Preoperative or postoperative radiation therapy was not performed in this series because of the low local recurrence rate in patients with T1–T3 lower rectal carcinoma without preoperative radiation.[14,16]

Patients were divided into 3 groups: sigmoid colon/rectosigmoid carcinoma, upper rectal carcinoma, and middle/lower rectal carcinoma. For the patients with rectal carcinoma, a primary rectal carcinoma was defined according to its distance from the anal verge as determined by colonoscopy. The tumors were grouped into lower rectum (0–7 cm), middle rectum (7.1–12 cm), and upper rectum (12.1–17 cm). We combined patients with middle and lower rectal carcinoma as a group because laparoscopic techniques for rectal transection and DST anastomosis were almost same: anastomosis located below peritoneal reflection.[7] Patients with lesions located within 2 cm of the dentate line who underwent laparoscopic intersphincteric rectal resection and hand-sewn coloanal anastomosis were excluded from the present study. This surgical technique has been described previously.[17] Conversion to open surgery was defined as any incision greater than 7 cm, excluding cases in which the incision was enlarged due to a large specimen size that could not be removed with a 7-cm incision.

Laparoscopic Technique

Laparoscopic resection techniques have previously been described, with minor modifications.[7,17] Initial port placement was performed using the open technique, and pneumoperitoneum was induced using carbon dioxide. Two 5-mm ports were then inserted in the left lower midabdominal and the left lower quadrant regions, and 2 other 12-mm ports were inserted in the mid-lower and the right midabdominal regions under laparoscopic guidance.

The left colon was initially mobilized laterally to medially until the left ureter and superior hypogastric nerve plexus were identified. The mobilization of splenic flexure was performed if necessary. Usually, Japanese patients have a long sigmoid colon, and if the surgeon preserves 1 or 2 arcades of marginal vessels of sigmoid colon by division of sigmoidal arteries between superior rectal artery and marginal vessels, mobilization of splenic flexure becomes unnecessary; thus, splenic mobilization was performed in only about 20% of our patients. Then, a window was made between the mesocolon containing the arch of the inferior mesenteric vessels and the superior hypogastric nerve plexus, starting at the bifurcation, with support from an assistant holding the sigmoid mesocolon ventrally under traction and to the left using a 5-mm bowel grasper through the left lower quadrant port. After the dissection, proceeding to the origin of inferior mesenteric artery, taking care not to injure the superior hypogastric nerve plexus and the roots of the sympathetic nerves, intracorporeal high ligation of the inferior mesenteric artery was performed. After cutting the inferior mesenteric vein and left colic artery, mobilization of the rectum and mesorectum was performed. The avascular plane between the intact mesorectum anteriorly and the superior hypogastric nerve plexus, right and left hypogastric nerves, and Waldeyer fascia posteriorly was entered by sharp dissection and extended down to the level of the levator muscle for middle and lower rectal carcinomas, taking care to protect the pelvic nerves. For proximal sigmoid colon carcinoma, the mesentery at the promontory was excised routinely using ultrasonic shears (laparoscopic coagulating shears [LCS], Ethicon Endo-Surgery Inc, Cincinnati, OH) or an endolinear stapler (Endo GIA Universal, Tyco Healthcare, Auto Suture Co, US Surgical Corp, Norwalk, CT). For rectosigmoidal and upper rectal lesions, mesorectal tissue extending down to 5 cm below the tumor was excised routinely using LCS. Middle and lower rectal tumors were treated by total mesorectal excision. Immediately before rectal transection, laparoscopic rectal clamping was performed just above the anticipated point of rectal transection, using a bowel clamping device (Fig. 1) introduced through the 12-mm mid-lower port. A distinct advantage of this device is that the bowel clamp at the head of the device can be easily bent intraabdominally without reducing the grasping strength. Rectal washout was performed routinely using 1000 mL of a 5% povidone-iodine solution. Rectal transection was then performed by a multiple-firing technique, using Endo GIA Universal staples, introduced through the 12-mm right midabdominal port.[18] If the rectal transection was not completed after the first cartridge, the stapler line for the second cartridge was carefully positioned on the anal side stapler line of the first cartridge. The third and fourth firings were performed in the same way. A 4- to 5-cm incision was then made over the mid-lower 12-mm port site, and the bowel was exteriorized under wound protection and divided with appropriate proximal clearance. After inserting the anvil head of the circular stapler into the end of the proximal colon, the proximal colon was internalized and the incision was closed. Intracorporeal anastomosis under a laparoscopic view was performed by means of the DST, using a circular stapler (ECS 29 or 33 mm, Ethicon Endo-Surgery Inc). After the insertion of the body of the circular stapler into the anus, the puncturing cone was pushed through the midpoint of the linear staple line. In patients in whom 2 or more linear stapler cartridges were used for rectal transection, the puncturing cone was pushed near the crossing point of the first and second stapler lines.

The anastomotic air leakage test was performed if the "doughnuts" were incomplete. Patients with a low anastomosis within 1 cm from the dentate line and incomplete doughnuts

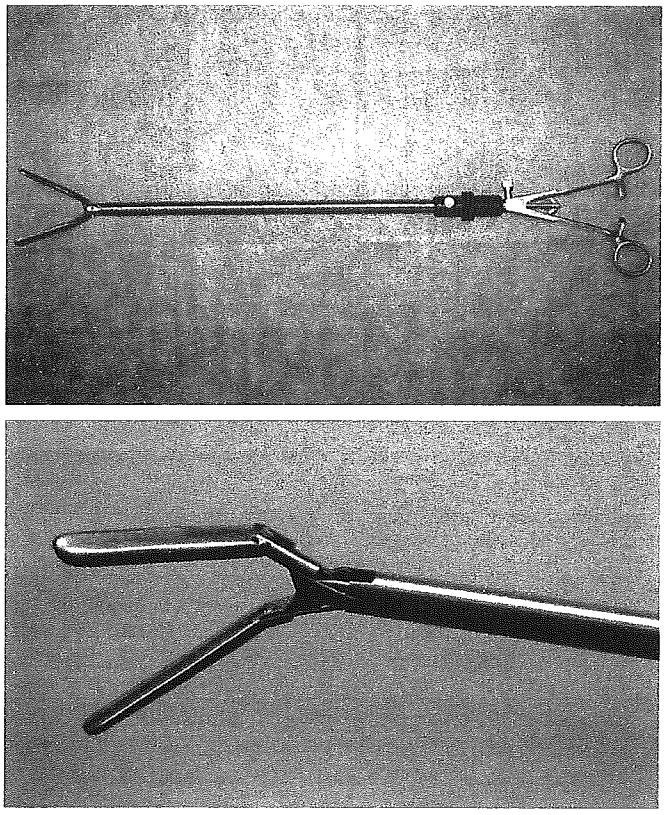

FIGURE 1. Bowel clamping device. A distinct advantage of this device is that the bowel clamp at the head of the device can be easily bent intraabdominally without reducing the grasping strength.

underwent a covering ileostomy. However, the decision to perform a protective ileostomy in this series was based on much looser criteria than those used in OS to avoid major anastomosis complications that could lead to a permanent stoma or a fatal outcome, especially in the early LS cases of lower rectal carcinoma.

Study Parameters

The parameters analyzed included gender, age, body mass index, prior abdominal surgery, operative time, operative blood loss, number of stapler cartridges fired and the length of the first stapler cartridge for rectal transection, conversion rate, days to resume diet, length of postoperative hospital stay, and both intraoperative and postoperative complications within 30 days of surgery. Pathologic staging was performed according to Duke's stage.

Statistical Analysis

Statistical analysis was performed using the χ^2 test, Kruskal-Wallis test with Bonferroni correction, and repeated-measure analysis of variance (ANOVA) with the Scheffe method when appropriate. A P value of <0.05 was considered significant.

RESULTS

The patient demographics are summarized in Table 1. No significant differences were observed in baseline characteristics among the 3 groups. In the middle/lower rectum group, anastomosis was performed <3 cm from the dentate line in 7 patients and >3 cm but below the peritoneal reflection in 3 patients. We performed an anastomotic air leakage test in 2 patients with lower rectal carcinoma and did not find any sign of air leakage; however, both patients underwent a protective ileostomy. Overall, a protective ileostomy was required in 4 patients, and a transverse coloplasty pouch was created in 1 patient.

The number of patients in relation to the number of stapler cartridges used for rectal transection in each group is shown in Table 2. The number of cartridges required during bowel transection was significantly increased in patients with middle/lower rectal carcinomas compared with the other groups. Similarly, significant differences were observed in the length of the first stapler cartridge fired for rectal transection (Table 3). In patients with middle/lower rectal carcinomas, the length of the first stapler cartridge was 45 or 30 mm, and it was 45 or 60 mm for proximal lesions.

Operative and postoperative results are shown in Table 4. Mean operative time and blood loss were significantly greater in the middle/lower rectum group. All the operations were completed laparoscopically. We did not experience any accidental intestinal perforations at or near the tumor site. Liquid and solid food was started at a median of 1 and 3 postoperative days in all groups. The median length of postoperative hospitalization was 8–9 days. No significant differences were observed in the postoperative course among the 3 groups. All patients were discharged home.

The postoperative complications are listed in Table 5. There were no perioperative mortality and no anastomotic leakage. Reoperation of a laparoscopic division of an adhesive band for a postoperative small bowel obstruction was necessary in 1 patient with sigmoid colon carcinoma. No significant differences were observed in complication rates among the 3 groups.

TABLE 1. Patient's Characteristics*

	Sigmoid Colon/ Rectosigmoid	Upper Rectum	Middle/Lower Rectum
No. of patients	36	21	10
Sex ratio (male:female)	22:14	10:11	8:2
Age (y)	59 (30–79)	59 (37–73)	60 (47–76)
Body mass index (kg/m^2)	23.5 (18.9–29.0)	24.1 (17.5–32.4)	23.8 (19.5–26.4)
Prior abdominal surgery (%)	6 (17)	5 (24)	5 (50)
Duke's stage			
A	27	16	7
B	1	0	0
C	7	3	3
D	1	2	0

*Values are means (range), $P > 0.05$.

TABLE 2. Number of Patients in Relation to the Number of Stapler Cartridges Fired for Rectal Transection*

No. of Stapler Cartridges Fired	Sigmoid Colon/Rectosigmoid†	Upper Rectum†	Middle/Lower Rectum
1	25	8	0
2	9	12	2
3	2	1	6
4	0	0	2

*$P < 0.01$ between groups, Kruskal-Wallis test.
†$P < 0.01$ versus middle, lower rectum/Boneferroni test.

DISCUSSION

In the present study, short-term outcomes were compared among different tumor sites in patients who underwent laparoscopic intracorporeal rectal transection with double-stapling technique anastomosis. The closer the tumor site was to the anus, the more the number of stapler cartridges needed for rectal transection increased and the use of a longer Endo GIA Universal stapler cartridge was significantly restricted, suggesting that rectal transection for Lap-LAR in patients with middle/lower rectal carcinomas may be a difficult and stressful procedure. In the present study, however, the complication rate did not increase despite lower anastomotic sites. With thorough and careful intracorporeal rectal transection and DST anastomosis, the safety of Lap-LAR may be established.

Minimum invasiveness is often noted as one of the merits of LS in comparison with OS for colorectal cancer.[19–23] But even recently, some studies have reported that minimal or no short-term benefits were found with LS compared with standard OS.[24–26] Reviewing these reports raises a question about the conversion rate. Even granting that LS has a lower surgical invasiveness than OS, there is a possibility that the treatment outcomes of LS will be contaminated by the treatment outcomes of OS, when the conversion cases are included in the LS group, based on the intention-to-treat principle. In the study by Weeks et al,[26] who reported a conversion rate of 25%, LS showed only minimal short-term quality-of-life benefits compared with OS in an intention-to-treat analysis, probably due to the high conversion rate. Moreover, they pointed out that patients assigned to laparoscopy-assisted colectomy who required intraoperative conversion to open colectomy had slightly poorer quality-of-life outcomes than patients who successfully underwent minimally invasive resection, and that the length of postoperative hospital stay in the LS group requiring conversion was longer than that in patients assigned to OS (7.4 vs. 6.4 days), although statistical analysis was not performed regarding these points. If the conversion patients did not show a worse outcome than those undergoing OS, patients who might benefit from LS should be considered as candidates for LS. Further studies are necessary to evaluate postoperative and oncological outcomes of patients assigned to laparoscopy-assisted colectomy who then require intraoperative conversion.

The results of the current study suggested that laparoscopic approaches to middle/lower rectal carcinoma do not compromise early postoperative recovery, such as days to oral feeding and length of hospitalization. Previous studies reported an anastomotic leakage rate of 5.7% to 21% in patients undergoing Lap-LAR.[6–12] Some authors have recommended a covering ileostomy as a routine step in Lap-LAR.[6,10,27] At present, patients with a preoperative diagnosis of T1–T2, middle/lower rectal carcinoma are required to decide whether they prefer to undergo OS or LS, after being given full information at our institution.

TABLE 3. Length of the First Stapler Cartridge Fired for Rectal Transection*

Length of the First Stapler Cartridge (mm)	Sigmoid Colon/Rectosigmoid†	Upper Rectum†	Middle/Lower Rectum
60	34	16	0
45	2	5	7
30	0	0	3

*$P < 0.01$ between groups, Kruskal-Wallis test.
†$P < 0.01$ versus middle/lower rectum, Boneferroni test.

TABLE 4. Operative and Postoperative Results

	Sigmoid Colon/Rectosigmoid	Upper Rectum	Middle/Lower Rectum
Operative time,* min (range)	221 (135–348)†	244 (190–328)‡	315 (190–392)
Blood loss,* mL (range)	29 (6–161)†	24 (10–198)†	124 (17–265)
Conversion	0	0	0
Liquid intake, d (range)	1 (1–4)	1 (1–3)	1 (1)
Solid food, d (range)	3 (2–5)	3 (3–4)	3 (2–4)
Hospital stay, d (range)	8 (7–12)	8 (7–11)	9 (7–17)

*$P < 0.01$ between groups, repeated-measure analysis of variance.
†$P < 0.01$ versus middle/lower rectum, Scheffe test.
‡$P < 0.05$ middle/lower rectum, Scheffe test.

TABLE 5. Morbidity and Mortality*

	Sigmoid Colon/ Rectosigmoid	Upper-Rectum	Middle/Lower Rectum
Mortality	0	0	0
Morbidity			
Wound sepsis	2	1	0
Bowel obstruction	1	0	1
Urinary tract infection	1	0	0
Abscess	0	0	1
Neurogenic bladder	0	1	0
Anastomotic leakage	0	0	0
Total	4	2	2

*$P > 0.05$.

In this study, the authors evaluated the safety of laparoscopic rectal transection using an endolinear stapler, which is one of the most technically difficult procedures in Lap-LAR. To date, we have not observed serious complications, such as anastomotic leakage. However, this surgical procedure remains technically difficult. We consider that this method should not be attempted if it is not performed by a laparoscopic surgical team with sufficient experience in LS. Regarding a surgical procedure that can be placed between OS and Lap-LAR, Vithiananthan et al[28] reported a hybrid method. In their procedure, they mobilized the left-sided colon and completed high ligation of the inferior mesenteric vessels with the use of the pneumoperitoneum, and then, from the inferior midline incision measuring 8 cm or longer, they performed rectal mobilization, mesorectal division, rectal transection, and anastomosis by DST using the OS tools. They noted that the mean incision length was 11.1 cm, which is longer than in Lap-LAR but shorter than in OS and that the patients treated with this method showed a significantly faster postoperative recovery than those treated with OS. Hand-assisted laparoscopic surgery may also be another treatment option.[29] However, compared with the standard Lap-LAR technique evaluated in this study, both of these methods may need a larger incision. With the surgeon's proficiency in the surgical procedure and the improvement in and development of instruments, the safety of standard Lap-LAR will probably be established; however, it is important to remember that this surgical technique cannot be employed at an early stage of the learning curve of laparoscopic surgery.

In conclusion, the findings of the present study demonstrate that laparoscopic intracorporeal rectal transection with DST anastomosis can be performed safely without increased morbidity or mortality. Even at present, there are few prospective, randomized trials investigating the short-term and oncological outcomes in patients with middle/lower rectal carcinoma, perhaps mainly because Lap-LAR has not been widely performed compared with LS for colon/upper rectal carcinoma due to the technical difficulties. The radical resection of middle/lower rectal cancers is a procedure that requires advanced technical skills in OS, to say nothing of Lap-LAR; however, we believe that use of Lap-LAR for middle/lower rectal carcinoma will expand with improvements in technology and surgeons' experience in the near future.

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Surg Oncol Clin N Am
14 (2005) 225–238

SURGICAL
ONCOLOGY CLINICS
OF NORTH AMERICA

Total Pelvic Exenteration with Distal Sacrectomy for Fixed Recurrent Rectal Cancer

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Four percent to 33% of patients with rectal cancer develop locoregional relapse after undergoing radical surgery with curative intent. Without treatment, the mean survival time for patients with local recurrence is only approximately 8 months, an associated severe symptomatic disease—especially pain—occurs, and their quality of life becomes remarkably deteriorated, probably with a miserable prognosis [1–4].

For cases with locally recurrent rectal cancer (LRRC), external beam radiotherapy, intraoperative radiotherapy, chemotherapies, and surgical treatments have been used singly or as part of a multimodality approach over the last several decades, resulting in certain outcomes that are not yet satisfactory [5–21]. For the purpose of attaining thorough margin-free resection, what we have been performing actively as our standard curative approach for fixed recurrent tumor (FRT) is radical resection with removal of affected neighboring organs and pelvic walls, including the sacrum, as originally reported by Wanebo and Marcove [6]. This article describes the surgical indications, contraindications, surgical techniques, oncologic outcomes, and complications of total pelvic exenteration with distal sacrectomy (TPES).

Patterns of growth in the pelvis

By cause and growth pattern of local recurrence, LRRC can be classified into three main categories.

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Anastomotic recurrence and perianastomotic recurrence

These suture line recurrences after low anterior resection are caused by implantation of cancer cells into the stump of anastomosis or insufficient resection of the rectal wall or mesorectum (Fig. 1). In the case of extramural invasion, however, it is difficult to distinguish between these two recurrences. When there is no extramural invasion or neighboring organ invasion, the basic surgical procedure is abdominoperineal resection (APR).

Perineal recurrence

Perineal recurrence is a recurrence that occurs after APR near the pelvic floor or perineal wound. From its early stage, perineal recurrence invades the coccyx, gluteal maximus muscle, or pelvic wall. Surgical margin-free resection seldom can be obtained by local excision alone. Many patients need resection of the pelvic wall or intrapelvic organs.

Pelvic recurrence

By occupied site, pelvic recurrence (Fig. 2) can be subdivided into anterior, lateral, and dorsal recurrences. Anterior pelvic recurrence is an LRRC that invades the anterior organs (ie, urogenital organs). For resecting this recurrent tumor, the basic surgical procedure is total pelvic exenteration (TPE). In women, if there is no obvious bladder invasion, it is possible to preserve urinary organs. This recurrence frequently is caused by insufficient resection for T4 rectal cancer. Lateral pelvic recurrence occurs because of lateral lymph node metastasis after total mesorectal excision or insufficient lateral node dissection. It begins to infiltrate the pelvic wall in its early stage. Dorsal pelvic recurrence is presacral extramural recurrence after APR or low

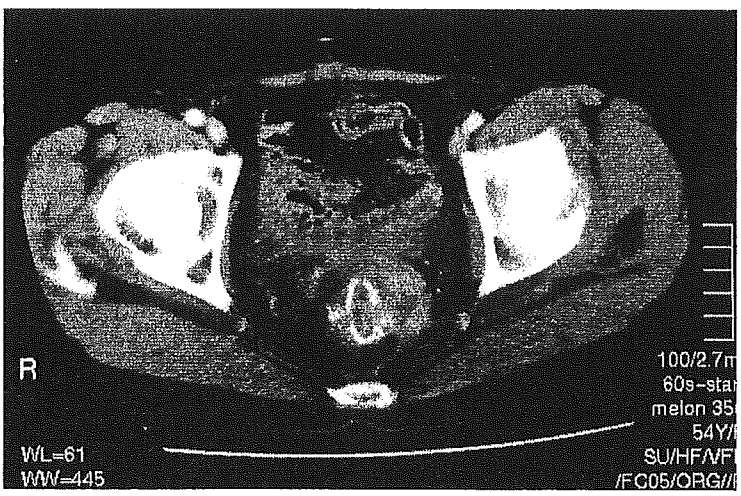

Fig. 1. Perianastomotic recurrence. A 54-year-old female patient underwent TPES for her FRT with 556 mL blood loss and no complication. At initial surgery 4 years ago, she received low anterior resection with D3 lymph node dissection and postoperative 60 Gy radiotherapy.

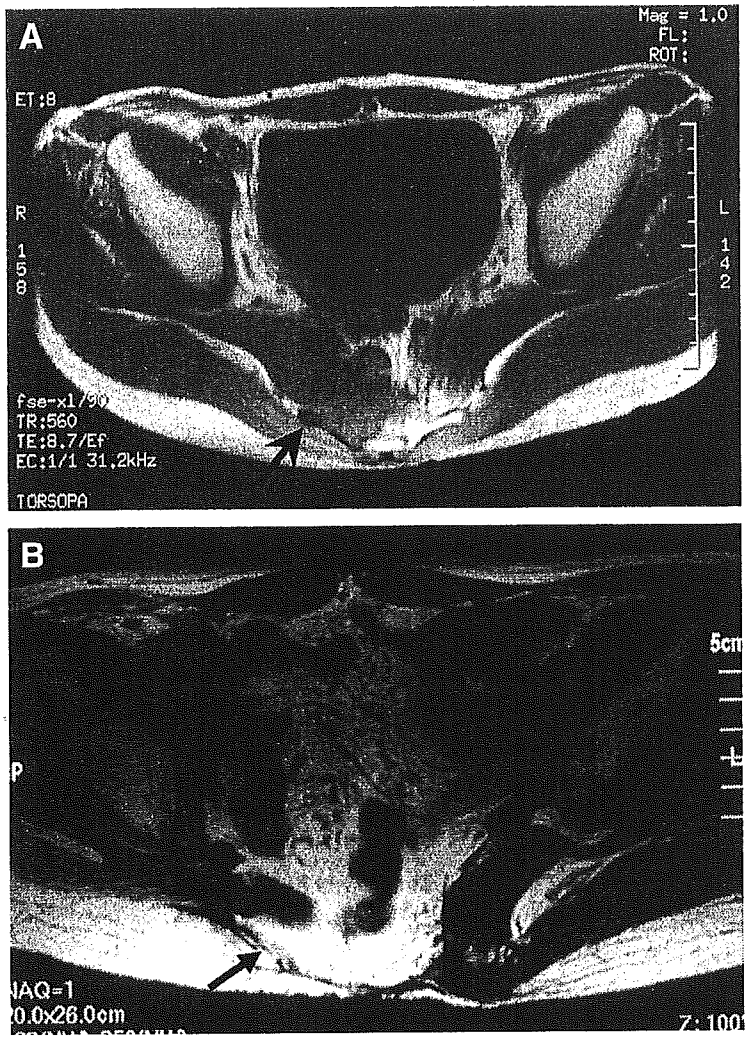

Fig. 2. (*A*) Dorsolateral pelvic recurrence with sacral bone invasion. A 47-year-old male patient underwent TPES for his FRT (*arrow*) with 673 mL blood loss and no complication. At initial surgery 1.5 years ago, he received low anterior resection. (*B*) Postoperative MRI. The patient is alive without re-recurrence 4 years after TPES.

anterior resection that invades the pelvic wall. It forms itself into FRT from its early stage. The cause of this recurrence may be extramesenteric lymphatic spread, insufficient resection of the mesorectum, or a cut into the mesorectum during operation. This pattern of recurrence is common patterns.

Why total pelvic exenteration with distal sacrectomy is the standard surgery for fixed recurrent tumor

Therapeutic policies for LRRC vary remarkably. The probable reasons for this are as follows: (1) there are various LRRCs, ranging from mobile recurrences to huge masses that occupy the pelvis, (2) an inappropriate surgical intervention may cause an iatrogenic cancer spread, leading to impaired quality of life, and (3) although treatments other than complete resection may not bring cure, the invasiveness of surgeries such as TPES is

considered excessive. In non-fixed recurrent tumors, complete resection can be achieved more often with limited surgery, such as APR or low anterior resection, and the outcomes are relatively favorable. LRRC grows within the narrow pelvis, and when the tumor size becomes larger to some extent, it can invade the pelvic wall easily and appear in the form of FRT. A challenge for the surgeon is the surgical treatment for FRTs with lateral or dorsal involvement, which comprises a larger percentage.

Such fixation is infrequently confined to one site and is of small range; many of those cases show fixations to the components surrounding the LRRC (eg, bony pelvis, including sacrum and coccyges; non-bony pelvis, including coccygeus muscle, piriform muscle, internal iliac vessels, inferior hypogastric plexus, sacral nerve plexus, obturator internus muscle, and sacrospinous and sacrotuberous ligaments; and residual anterior organs in the pelvis). Their anatomic planes are distorted, and it is difficult to determine and hold uninvolved margins during resection. For FRT cases, composite resection is inevitably required to encompass potentially involved pelvic walls, especially the distal sacrum. Only this strategy enables the R0 extirpation en bloc. Especially after APR, the LRRC grows while being sandwiched between the anterior organs and sacrum. Wanebo and Marcove [6] tackled this difficult problem using the new technique of abdominosacral resection, followed by several surgeons in 1980s [8,9,10,12].

Techniques to preserve the anterior organs and inferior hypogastric plexus for surgical treatment of FRT have been reported [16]. Those approaches, however, are likely to reduce local radicality, because the anatomic pathway around the autonomic nerve plexuses and ureter disappears and is replaced by scar tissue caused by initial surgery, especially after extended surgery. FRT in the deep pelvis also is often fixed more extensively than expected before surgery, which also justifies our experience-based strategy that TPES is positioned as the standard surgery for FRT. This technique is considered to be demanding and formidable because of high rates of mortality and morbidity [6,12,13,19]; consequently, combination of limited resection and intraoperative radiotherapy is likely to become standard in the treatment of FRT [17,22–29]. Whether an emphasis is placed on composite resection or multimodality treatment, surgeons have the same view that the key treatment to obtain local control and survival benefit is R0 surgery [22,28–31]. Is it really possible to carry out R0 resection for FRT by conventional surgery? Having been able to ensure R0 resection for FRT and develop secure surgical techniques, we consider that there are no therapies superior to TPES in treating FRT.

Evaluation by imaging and patient selection

Once the diagnosis of LRRC is made, detailed study should be conducted in terms of surgical indication from two aspects: (1) whether distance metastasis

is present and (2) to what extent the tumor spreads within the pelvis. Extrapelvic disease is searched for by the whole body CT scan. MRI and F-18-fluorodeoxy glucose position emission tomography (FDG-PET) are also useful in detecting extrapelvic disease and distinguishing between recurrent disease and scar tissue. CT, MRI, and FDG-PET are useful in distinguishing between solitary and multifocal recurrences in the pelvis and between anterior organ involvement and dorsolateral pelvic wall involvement.

We investigated a total of 196 consecutive patients who underwent laparotomy to remove LRRC between 1983 and 2003. The study excluded patients whose recurrent rectal cancer developed after local excision. We performed a limited surgery, such as APR, in 62 patients, TPE in 41, and TPES in 69. The remaining 24 patients had unresectable LRRC. Clinical and pathologic characteristics of 69 patients are listed in Table 1.

Patients with documented distant metastasis are not candidates for surgical treatment, because the curative potential is low and their life expectancy is not long enough to evaluate treatment outcome. With regard to surgical indication, we conducted TPES for FRT localized in the pelvis. Locally unresectable diseases include tumors that grow into sciatic notch,

Table 1
Clinical and pathologic characteristics of 69 patients

Characteristics	Number
Median age (range) (y)	57 (29–73)
Sex	
Male	55
Female	14
Body mass index (range)	22.9 (15.0–28.7)
Median time to local recurrence (range) (mo)	23 (7–118)
Liver metastasis	
No	65
Yes	5
Initial surgery	
Sphincter-preserving surgery; SPS	33
Abdominoperineal resection; APR	36
Radiotherapy for primary rectal cancer	
Yes	4
No	65
Radiotherapy for local recurrence before re-resection	
Yes	32 (median, 50 Gy; range, 30–80 Gy)
No	37
Dukes classification for primary growth	
A	4
B	18
C	47
Histologic type	
Well-differentiated adenocarcinoma	26
Moderately	34
Poorly	9

encase the external iliac vessels, extend to the sacral promontory, obstruct the bilateral ureters, and cause leg edema secondary to lymphatic or venous obstruction [30,31]. For patients with one or two liver metastases amenable to surgical resection, however, concomitant hepatectomy with surgical treatment of LRRC may be warranted. Lung metastasis and other extrapelvic diseases are excluded from surgical indications.

Surgical technique

TPE for primary pelvic malignancy is performed by first dividing loose connective tissues, such as the Retzius, retrorectal, and obturator spaces, and then dissecting along the parietal pelvic fascia. In recurrent cancer cases, however, those spaces disappear and are replaced by dense scar tissue. Because of this condition, TPES for FRT is a challenging procedure. The operation is performed in the following order.

Abdominal phase

The patient is placed in the lithotomy position. After detaching adhesions caused by initial surgery, the surgeon confirms the localization of the recurrent tumor within the pelvis and the absence of extrapelvic diseases and then makes a final decision to proceed to TPES. First, the Retzius space is opened. The endopelvic fascia and pubo-prostatic ligaments can be identified bilaterally and divided using electric cautery to expose the levator ani muscle. The dorsal vein complex together with the divided endopelvic fascia is bunched with the forceps and doubly tied and divided.

Next, the level of sacral amputation is determined. The anterior area from the aortic bifurcation to the sacral promontory is exposed to enter the anterior surface of the sacrum. The dissection is made using electric cautery down to the distal sacrum, at which point sacral amputation is planned, as is resection of the thickened Waldeyer's fascia with the presacral venous plexuses and scar tissue. During this process, bleeding occurs more or less; however, hemostasis can be obtained using combination of electric cautery and gauze pack. The area from the common iliac artery to the bifurcation between the internal and external iliac arteries is exposed. During dissection of the obturator space while preserving the obturator nerve, components of the sacral nerve plexus, such as the lumbosacral nerve and S1 and S2 sacral nerves, can be identified. Marking the S2 sacral nerve with a rubber loop ensures recognition of sacral nerves during sacrectomy (Fig. 3).

The next step is resection of the internal iliac vessels. The way to manipulate the internal iliac vessels is as follows. First, the trunk of the internal iliac artery is doubly tied and divided at the distal portion of the branching of the superior gluteal artery. Second, several branches that perforate the pelvic wall are divided. Finally, the trunk of the internal iliac vein is doubly tied and divided. Blood loss during TPES mostly occurs from

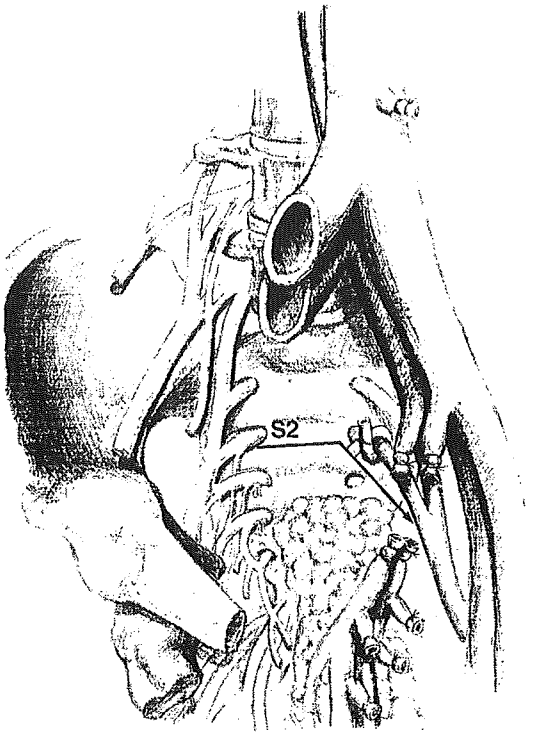

Fig. 3. Line of sacrectomy and marked second sacral nerve.

the venous plexus [31]. By taking the appropriate steps to avoid congestion of the venous plexus at the earliest possible opportunity, the operation can be performed with a minimum amount of blood loss from the venous plexus. Resection of the internal iliac veins is the most important part of this operation, and it requires advanced technical skills and careful maneuvers. FRT extends along the internal iliac vessels more frequently than the primary rectal cancer [32]; bilateral resection of the internal iliac vessels is one of the pivotal steps in TPES. Combined resection of the internal iliac vessels during the abdominal phase greatly contributes to reducing blood loss during sacrectomy.

Perineal phase

Incision of the perineal skin conforms to APR. The levator ani muscle is divided at its attachment and a connection is made through to the pelvic cavity. If the perineal phase is performed after the venous plexus is resected, a considerable amount of blood loss will occur from congested veins around the urogenital diaphragm. The perineal phase should occur before ligation of the trunk of the internal iliac veins so that the phase can be performed with less blood loss.

Sacral phase

The patient is placed in the prone position after temporary closure of abdominal wound. At that point, the padded operating frame for laminectomy

is used to prevent an increase in abdominal or vertebral venous pressure. Bleeding caused by the increase of vertebral venous pressure makes sacral amputation complicated. The median incision is made approximately 10 cm longer toward the head from the planned line of sacral amputation. The gluteus maximus muscle is detached from the sacrum so that the posterior surface of the sacrum can be exposed fully. The next step of this phase involves detaching the sacrotuberous and sacrospinous ligaments and piriform muscle that fix the sacrum. After dissecting these structures, the sacral nerve plexus also can be checked.

The surgeon inserts an index finger into the pelvic cavity from the lower edge of the sacroiliac joint and checks the dissected level of the anterior surface of the sacrum to determine the level of sacral amputation. The medial sacral crest is scraped, laminectomy is performed, and the root of the second sacral nerve is identified. The caudal end of the dura usually extends to around the lower edge of the S2. The dura, together with the cauda equine, is tied and divided. The surgeon performs sacral amputation using chisel and hammer at a stretch (Fig. 4). Hemostasis is performed quickly using electric cautery and bone wax. In men, after checking the stump of the urethra, the urethra is closed tightly to prevent transurethral infection. The origins of the gluteus maximus muscle, the subcutis, and the skin are closed tightly.

Urinary diversion, prevention of pelvic sepsis, and wound closure

The patient is placed in the lithotomy position. Reconstruction of the urinary tract using ileal conduit and colostomy is performed. Mobilization of the right colon from the cecum to the hepatic flexure enables construction of a high urostoma. After constructing the ileal conduit, an ileoileostomy

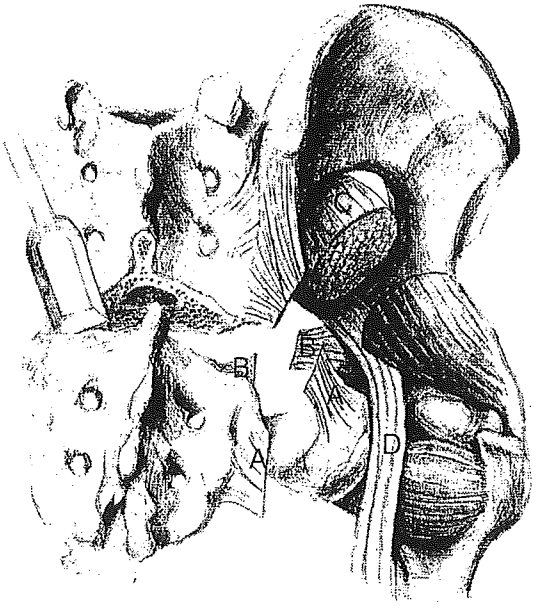

Fig. 4. Sacral amputation in prone position. (*A*) Sacrotuberous ligament. (*B*) Sacrospinous ligament. (*C*) Piriform muscle. (*D*) Sciatic nerve.

should be lifted up above the pelvic brim and fixed to the mesentery so that it will not fall in the pelvic cavity. This procedure is invariably required to prevent anastomotic leakage secondarily caused by pelvic sepsis, especially after radiotherapy. If the greater omentum is long enough with favorable blood flow, omentoplasty into the pelvic cavity should be performed. In patients who have recurrent tumor invading the perineal skin, it is necessary to combine a wide resection of the perineal skin. In such cases, reconstruction should be performed with a musculocutaneous flap [20,30]. It is appropriate that gastrostomy be performed before closing the abdomen, because enteroparalysis continues for a while after TPES. A thick drain is placed in the pelvis, and then the abdomen is closed.

Surgical invasiveness and oncologic outcomes after total pelvic exenteration with distal sacrectomy

Margins were microscopically negative in 57 patients (83%) and positive in 12. A comparison between two periods (1983–1992 and 1993–2003) showed a mean blood loss decrease from 4229 to 2102 mL ($P < 0.001$), with a favorable learning curve (Table 2). There was no difference in operative time and hospital stay. The most common level of sacral amputation was the S3 superior margin in 26 cases, followed by the S3 inferior margin and S2 inferior margin (Table 3). Overall mortality and complication rates were 3% and 58%, respectively. There was no hospital death in the latter period. The most frequent complication was sacral wound dehiscence in 51%, followed by pelvic sepsis in 39%. The incidence of pelvic sepsis in the latter period decreased significantly to 27%, compared with 72% in the former period ($P = 0.038$). Enteroperineal fistulae were observed in four cases.

Survival curves show overall 3- and 5-year disease-specific survival rates of 58% and 40%, respectively. In 57 patients with R0, including 5 patients with hepatic metastasis, 3- and 5-year disease-specific survival rates were 67% and 49%, respectively, whereas there was no 4-year survivor in patients with margin-positive, which showed significantly poor prognosis ($P < 0.001$) (Fig. 5). There was no survival difference between patients with and without radiotherapy before re-resection. Fourteen patients had lateral node metastases around the internal iliac vessels. Of these 14 patients, 6 are alive and 3 were long-term survivors for 64, 71, and 141 months, respectively.

Table 2
Surgical invasiveness and hospital stay

Operative burden	Former period (1983–1992) mean $n = 18$	Latter period (1993–2003) mean $n = 51$	P-value
Operative time (min)	769 (370–990)	702 (480–1100)	NS
Blood loss (mL)	4229 (1800–16,300)	2102 (673–8468)	$P < 0.0001$
Hospital stay (d)	37.5 (23–200)	34 (21–257)	NS

Table 3
Level of distal sacrectomy and complications

Level of sacrectomy	Sepsis in pelvis	Ileus	Fistula[a]
Middle amputation			
S2 inferior margin (n = 12)	6	2	1
S2-3 (n = 26)	9	1	1
Low amputation			
S3 inferior margin (n = 16)	8	1	2
S3-4 (n = 10)	2	1	
S4 inferior margin (n = 5)	2		

[a] Fistula: enteroperineal fistula caused by anastomotic leakage.

Of 57 patients with R0 resection, 34 developed re-recurrence. The most common site was the lung (18 patients) followed by the pelvis (12 patients).

Oncologic outcomes reported in the literature

Factors such as type of surgery, combined therapy, and postoperative follow-up period are diversified, and comparison of reported oncologic outcomes for LRRC is of small significance. For example, a study that includes patients with recurrence after local excision naturally should show favorable outcome, whereas in a study conducted only with cases of FRT, unfavorable outcome can be predicted. Lopez-Kostner et al [33] reported a 5-year survival rate of 32% in 43 patients who underwent surgical treatment, 11 of whom developed recurrence after local excision. On the other hand, Bozzetti et al [18] showed a 5-year survival rate of less than 10% in patients who underwent surgery alone and pointed out a limitation of outcome after surgical treatment alone. Regarding 5-year survival after

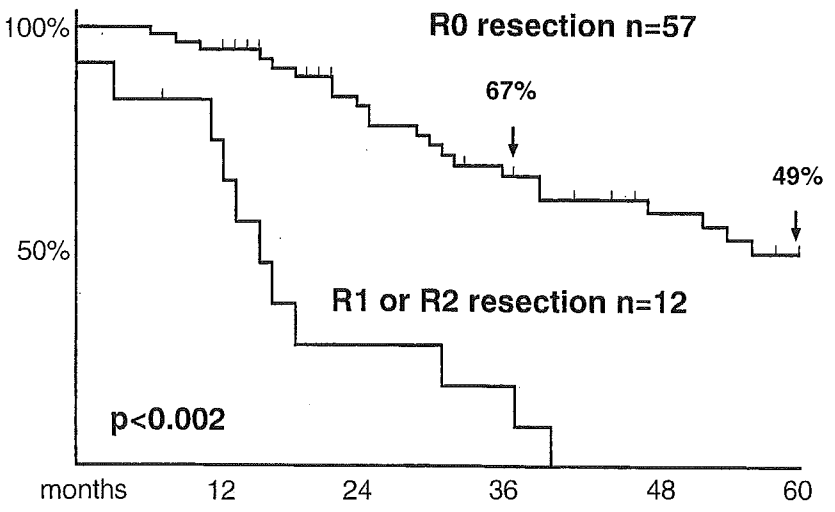

Fig. 5. Disease-specific survival curve. The difference between the two groups was significant ($P < 0.001$).

composite resection, Wanebo et al [19] reported a rate of 31%, Maetani et al [10] reported a rate of 25%, and Yamada et al [21] reported a rate of 18%. Those are not satisfactory outcomes. Incidence of local re-recurrence ranges from 27% to 61% [10,19,31].

As for outcome after multimodality therapy, there are many reports in which the ordinary dosages of radiation used preoperatively were 45 to 50 Gy. Intraoperative dosages of 10 to 15 Gy in R0 cases and 15 to 20 Gy in R-positive cases also were reported [24–29]. Valentini et al [24] reported a 5-year survival rate of 22%, and Mannaerts et al [23] reported a 3-year survival rate of 60%. In the series by Shoup et al [25], who investigated outcomes after resection plus intraoperative radiotherapy, patients with R0 had a median disease-free survival of 31 months and a median disease-specific survival of 66 months.

Lung metastasis and local re-recurrence account for nearly 90% of all re-recurrence patterns [31], and measures to prevent these two types of re-recurrence are important. Compared with 20 years ago, when the only effective antitumor agent was 5-fluorouracil, some effective antitumor agents (eg, CPT-11, UFT, capecitabine, and oxaliplatin) have become available. We think that surgical treatment, combined with composite resection and intraoperative radiotherapy, is indispensable for improving local control rates and that an effective chemotherapy regimen after re-resection is indispensable for inhibiting lung metastasis.

Prognostic factors and staging system

Several factors, such as type of initial surgery, tumor size, presence of symptoms, and serum carcinoembryomic antigen level, have been regarded as significant prognostic indicators, although a consensus has not been reached yet. Willet et al [11] and Wanebo et al [19] found improved resectability in patients who underwent initial low anterior resection compared with patients who had initial APR. If FRT developed after low anterior resection, however, there was no difference in resectability and survival between them [31]. Shoup et al [25] indicated that vascular invasion and R1/R2 resection are factors for poor prognosis. In either report, the most important factor is whether R0 resection was attained [19,24,25,27,31]. Researchers already have shown that in surgical treatment for primary rectal cancer, surgery-related and biologic factors are crucial [34]. Surgical margin status and complications are exclusively determined by a surgeon's technical skills. Complicated surgeries, such as TPES or abdominosacral resection, should be undertaken only in specialized centers with an experienced complex treatment team.

Suzuki et al [14] judged the degree of fixation to surrounding structures according to surgical and pathologic findings and proposed their own staging method. Valentini et al [24] also reported a similar staging system in

which they judged from CT scan imaging. They mentioned that degree of fixation is an independent prognostic factor. Wanebo et al [19] proposed a new staging system for stages TR1-2 to TR5, which are determined by extent of invasion. A staging system that uses degree of fixation or other prognostic factors is constructed so that treatment modalities for LRRC, especially surgical treatment, are placed in an appropriate position.

Summary

For primary rectal cancer, there is a difference in therapy between Western countries and Japan. In Western countries, initial surgery is total mesorectal excision or less limited surgery plus radiotherapy. For this reason, fibrosis caused by radiation occurs in the pelvis. On the other hand, in Japan, although preoperative radiotherapy is not given, total mesorectal excision or more extended surgery is performed as initial surgery, and the intrapelvic spaces are covered with postoperative scar tissue. In identifying an anatomic index and doing hemostasis, this scar tissue brings the surgeon more difficulty than the fibrosis caused by radiotherapy. Approximately half of our patients are irradiated preoperatively for recurrence. In those patients, operation is performed under an unfavorable condition because the fibrosis caused by radiation is added to the scar tissue caused by dissection. Composite resection, such as TPES, has been thought to be demanding and formidable because of high mortality and morbidity rates. Improvement of surgical techniques has allowed TPES to be completed with a blood loss of approximately 2000 to 3000 mL, however, which has resulted in a favorable learning curve with low morbidity and mortality rates.

We have excluded tumors that grow into the sacral promontory or sciatic notch from surgical indications. If high sacral amputation is performed, increased surgical invasiveness, more serious complications, and inevitable walking disorders are observed; as a result, a patient may have a remarkably deteriorated quality of life [6,9,12,19]. We have limited the level of sacral amputation in TPES to the S2 lower edge or below to preserve the second sacral nerve. Consequently, patients were able to have favorable quality of life after TPES, except for living with double stomas and temporary pain caused by resection of sacral nerves, and they were able to return to their original occupations [31,35].

If oncologic outcome obtained is superior to that after multimodality treatment, composite resection for FRT also may become an acceptable treatment. Finally, it should be noted that when extended surgeries, such as TPES, are performed for FRT, each of the departments concerned should review surgical indications and the surgeries must be worked on in the form of team medicine. One must realize that only through such process can negative resection margins be obtained as a great boon to patients.

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Original Paper

Postsurgical Surveillance for Recurrence of UICC Stage I Colorectal Carcinoma: Is Follow-up by CEA Justified?

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KEY WORDS:
UICC stage I colorectal carcinoma; Follow-up; Surveillance; CEA

ABBREVIATIONS:
Carcinoembryonic Antigen (CEA)

ABSTRACT

Background/Aims: This study was undertaken to investigate whether it will be possible to reduce the times and types of postoperative examinations for surveillance in patients with UICC stage I colorectal carcinoma. In addition, the value of CEA in postoperative surveillance is discussed.

Methodology: A review was performed of 541 patients who underwent curative resection for UICC stage I colorectal carcinoma between January, 1985 and December, 1998. Periodic check-up was routinely conducted to identify recurrence.

Results: The median follow-up was 82 months. The recurrence rate was 2.9% in the UICC stage Ia (pT1N0M0) group, and 5.6% in the Ib (pT2N0M0) group. Cancer-specific survival rates at 5 years were 99.3% and 97.6%, respectively ($p=0.0354$). Recurrences occurred more frequently in patients with lower rectal carcinoma ($p=0.0415$). Curative-intent salvage surgery was performed in 61.9% (13/21) for recurrent lesions. Between the patients who were CEA positive (13/21; 61.9%) and those who were CEA negative at the time of recurrence, there was no significant difference in the prognosis.

Conclusions: The incidence of recurrence was low after curative surgery in patients with UICC stage I colorectal carcinoma, and it is therefore possible to reduce times and types of postoperative examinations. CEA measurement alone appears to be sufficient.

INTRODUCTION

Currently, a main topic for discussion with regard to the surveillance after colorectal carcinoma surgery is whether intensive follow-up for detecting recurrence earlier and initiating the treatment of it practically contributes to the improvement in prognosis for colorectal carcinoma patients. In nonrandomized cohort studies and randomized studies, significant differences in the time of confirming recurrence, the surgical resectability of recurrent lesion, and the 5-year survival rate between intensive follow-up group and control group (traditional follow-up or no follow-up group) were reported (1-5). At the same time, there are other studies that have reported no significant difference in these points (6-12). However, in those previous studies, the numbers of cases that were reviewed ranged from 98 to 1247, and there were a variety of disease stages from UICC stages I through IV. One study reported that although the resectability after recurrence was higher by more than 10% in an intensive follow-up group than in the control group, no significant difference was obtained, probably due to the small number of cases (13). In two studies using meta-analysis that were reported lately, the 5-year survival rates were 9% to 14% greater in the intensive follow-up group than in the control group (14,15).

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Recently, advances in diagnostic techniques have enabled the detection of colorectal carcinoma at earlier stages in Japan (16). At our institution, the proportion of UICC stage I cases in all colorectal carcinoma patients receiving the first-line treatment was 14% (12/86) in 1980, but it increased to 25% (71/284) in 2000. It is important to conduct a cost-effective follow-up in view of the risk for recurrence (17,18). In fact, for UICC stage I colorectal carcinoma patients, the rate of recurrence is lower, and hence fewer times and screening examinations may be reasonable and warranted for the postoperative surveillance, compared with UICC stages II-IV colorectal carcinoma patients (19).

In the present study, we utilized the prospective follow-up database at a single institution to analyze the long-term outcomes of UICC stage I colorectal carcinoma patients, and to investigate whether it will be possible to reduce the times and types of screening examinations for postoperative surveillance. In addition, the present study discusses the value of CEA (carcinoembryonic antigen) in performing surveillance after curative surgery for UICC stage I colorectal carcinoma.

METHODOLOGY

Between January, 1985 and December, 1998,