International Journal of Colorectal Disease (2025) 40:66
https://doi.org/10.1007/s00384-025-04838-5

RESEARCH

MRI navigation surgery for T4b rectal cancer using multiple minimally invasive surgical approaches

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Accepted: 16 February 2025

Abstract

Background These days, various surgical techniques such as trans-anal, trans-perineal total mesorectal excision, and transvaginal natural orifice transluminal endoscopic surgery have been utilized with flexibility, which was not possible before the laparoscopic era.

Methods From January 2014 to January 2023, 40 cases of c(yc)T4b rectal cancer underwent local curative surgery laparoscopically at Kansai Medical University Hospital. In 25 consecutive cases, we adopted multiple approaches (trans-anal total mesorectal excision, transvaginal natural orifice transluminal endoscopic surgery, trans-perineal total mesorectal excision, or prone position first abdominoperineal excision) to remove the deepest part of the tumor indicated by MRI last as the specimen-oriented surgery. The remaining 15 patients underwent top-to-bottom surgery based on standard surgery. The primary endpoint was the local recurrence rate of the specimen-oriented surgery group compared to that of the standard surgery group.

Results The specimen-oriented surgery group had a median follow-up of 3.9 (0.4–7.4) years with no local recurrence, while the standard surgery group had a median follow-up of 1.5 (0.7–3.7) years with 5 of 15 patients (33%) experiencing more local recurrence than specimen-oriented surgery group ($p=0.005$). Comparison of the local recurrence (+) and (−) groups showed significant differences in pCRM positive rate, neoadjuvant therapy, tumor size, and approach (specimen-oriented surgery vs. standard surgery) in univariate analysis ($p<0.05$). Still, no significant differences were found in the multivariate analysis.

Conclusions In the laparoscopic setting, local cure of c(yc)T4b rectal cancer requires a different strategy than open surgery, and specimen-oriented surgery may be a promising procedure.

Keywords Low rectal cancer · Abdominoperineal excision · Circumferential resection margin · Trans-anal total mesorectal excision · Beyond TME · Specimen-oriented surgery

Background

Radical surgery for c(yc)T4b rectal cancer can achieve R0 (microscopic no residual tumor) resection only after concomitant resection of other organs. Furthermore, a negative pathological circumferential resection margin (pCRM > 1 mm) is proposed to avoid local recurrence. In the case of middle to low rectal T4b cancer located deep in the pelvis, it is not easy to a secure pCRM > 1 mm with minimal resection using conventional laparotomy; therefore, beyond total mesorectal excision (TME) [1, 2] (standard abdominoperineal excision (APE) [3], extra levator abdominoperineal excision (ELAPE) [4], posterior pelvic exenteration (pPE), and total pelvic exenteration (TPE) has been frequently used.

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Published online: 14 March 2025

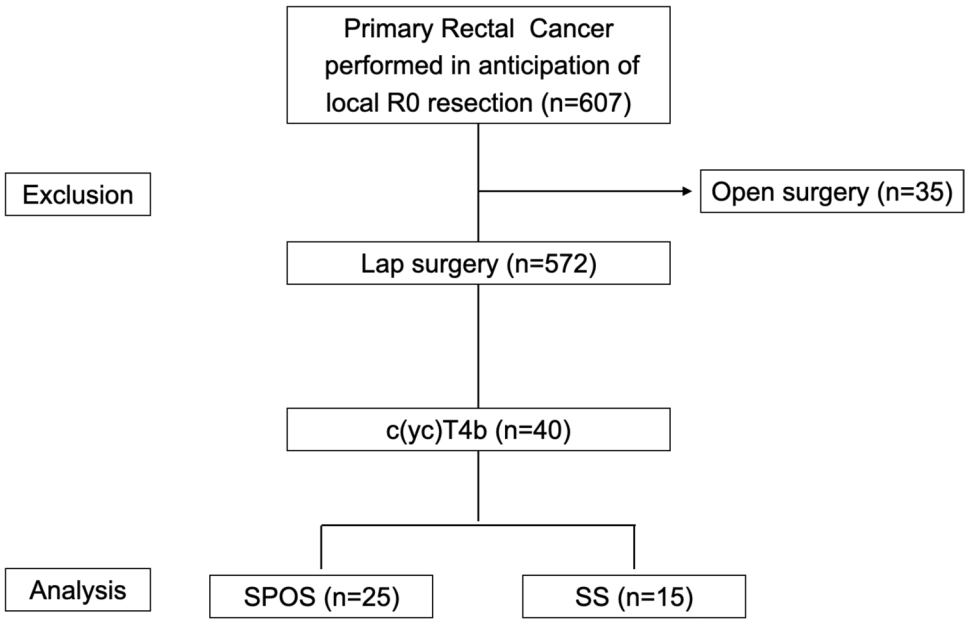

Fig. 1 Patient flow chart

We consider the surgery with combined resection using these procedures as standard surgery (SS).

Recent advances in MRI diagnosis have revealed the accuracy of c(yc)T-factor diagnosis of the tumor [5, 6] and suggested the possibility of less invasive resection of the tumor lesion [4]. Therefore, a technique with minimum resection of the tumor lesion planned preoperatively without excess or deficiency is proposed to ensure a pCRM-negative specimen, e.g., partial resection of adjacent organs (extended TME [4]).

These days, various surgical techniques such as trans-anal (ta), trans-perineal (tp), total mesorectal excision (TME) [7–9] procedures also have been advanced, and surgical positions such as the prone approach and lithotomy position have been utilized with flexibility [10, 11]. Furthermore, we can use indocyanine green (ICG) fluorescent image technology to detect blood flow, lymphatic drainage, and ureteral path quickly [12–14], allowing for safely preserving sphincter function and ureteral preservation in the case of complicated resection of other organs.

We have considered specimen-oriented surgery (SP0S), proposed by Nikberg et al. [15], in which the extent of resection should be planned based on MRI findings without being restricted to conventional procedures. Lesions are resected without excess or deficiency by flexibly combining various surgical techniques, which can provide maximum combination radical cure and minimal invasiveness.

This study aimed to examine the effects of SPOS for c(yc)T4b rectal cancer on local recurrence compared to the SS.

Methods

Inclusion and exclusion criteria (Fig. 1)

Of the 607 cases of primary rectal adenocarcinoma resection experienced in our department from January 2014 to January 2023, 572 were LAP cases, and 35 were open surgery cases, of which c(yc)T4b cases for local R0 resection were 40 among 572 LAP cases (7.0 %). This study excluded open surgery cases and cases resected for hemostasis or pain control. Patients with c,yc, and pStageVIC were also excluded. In this series, rectal cancer was defined as whose tumor(s) were located more distally than the promontory of the sacral bone on MRI T2 sagittal images, regardless of the distance from the anal verge, according to the Japanese Classification of Colorectal, Appendiceal, and Anal Carcinoma [16]. To know the surgical effects on the local control, even in the c(yc)StageIVA, IVB cases (TNM 8th edition), the indication for surgery was cT4b rectal cancer diagnosed with preoperative imaging including CT and MRI, with a prognosis of at least 2 years for both groups and with pCRM-negative (pCRM > 1 mm) resection or at least local R0 resection possible.

We conducted the SPOS and examined its postoperative local recurrence rate compared to that of SS performed by a surgeon with more than 30 years of experience at the same period.

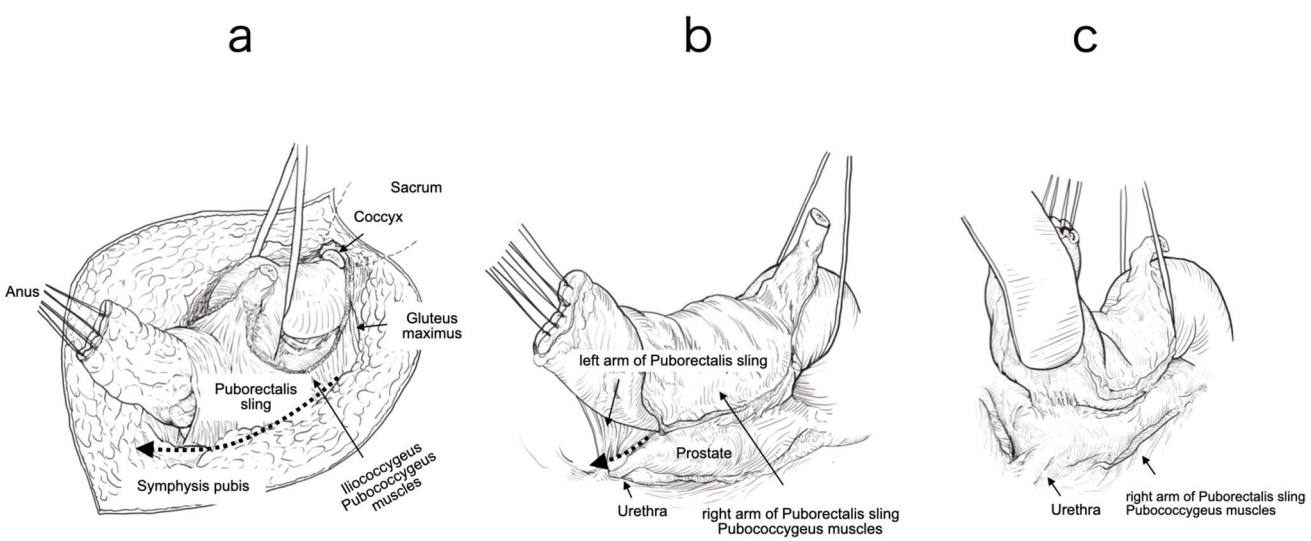

Fig. 2 Schema of the surgical procedure of the perineal phase of a prone position first abdominoperineal excision (pfAPE) of a left lateral to anterior tumor in a male patient. In the pfAPE, the operation was started at the perineal part in the prone jackknife position. The incision and dissection of subcutaneous fat surrounding the levator ani muscles' outer surface were performed. The puborectalis sling was exposed as anteriorly as possible. After disarticulating the coccyx, we adjusted the range of the incision line of the levator ani muscles according to findings in preoperative MRI T2 images. A demarcation line was recognizable between the fascia toward the prostate or vagina and the mesorectum, which allowed the separation of the mesorectum from the anterior organs by blunt dissection and tunneling. (**a**) We passed a vessel tape after tunneling. An incision of the levator ani muscles around the puborectalis sling, including the MRI indicating the deepest part of the tumor with the surface of the puborectalis sling as anterior as possible, was performed while pulling up the cranial and caudal rectum to the tumor lesion. (**b**) If necessary, we partially resected the vagina or adopted prostate shaving in combination, using a near-infrared ray catheter (NIRC). (**c**) connecting the dissection plane with a perianal incision, the specimen could be lifted; the peritoneal reflection could be reached in most cases

Definition of laparoscopic specimen-oriented surgery and laparoscopic standard surgery

Specimen-oriented surgery (SPOS): Treatment strategy based on preoperative MRI imaging to resect the most profoundly involved area of tumor last, a combination of conventional laparoscopic surgery with ta(tp)TME, transvaginal natural orifice transluminal endoscopic surgery (vNOTES), and prone position first abdominoperineal excision (pfAPE (Fig. 2)), was used.

Standard surgery (SS): It is a surgical technique that replaces the abdominal phase of a typical open abdominal surgery with a laparoscopic technique and treatment strategy based on preoperative MRI or CT imaging to perform top-to-bottom surgery using standard pelvic exenteration (total pelvic exenteration (TPE), posterior pelvic exenteration(pPE)), standard APE (APE), extended standard APE for combined partial resection of anterior organs (extAPE).

Preoperative chemoradiotherapy

Twenty-nine out of 40 patients (72.5%) received neoadjuvant (chemo) radiotherapy (CRT): 20 in the SPOS group and 9 in the SS group. The CRT consisted of 45–50.4 Gy of radiation delivered by a three-field approach with daily doses of 1.8 Gy on weekdays to the pelvis (45 Gy), including the field of lateral pelvic lymph nodes (LLNs), followed by a 5.4 Gy boost to the primary tumor and perirectal tissue (50.4 Gy). Concomitantly, S-1 (80 mg/m^2, Taiho Pharmaceutical Co., Ltd. Tokyo, Japan) was administered 40–60 mg/twice a day/body from day 1 to day 25–28 of radiotherapy with weekend breaks.

CRT was not performed in five patients in the SPOS group or six in the SS group. In the SPOS group, two patients requiring partial cystectomy and reconstruction, one patient with chronic renal failure, one patient with bowel obstruction with upper rectal cancer, and one patient with low rectal cancer harboring concomitant primary lung cancer had not received CRT to avoid postoperative complications.

In the SS group, three patients required partial cystectomy and reconstruction; one patient performed low anterior resection (LAR) with a wide range of left side colon who had not received CRT. Two patients underwent chemotherapy alone.

Patient characteristics (Fig. 1, Table 1)

From January 2014 to January 2023, forty consecutive cases of c(yc)T4b primary rectal adenocarcinoma who underwent laparoscopic resection accompanying

Table 1 Patients' characteristics of SPOS and SS groups

Procedure		SPOS	SS	*p*
N		25	15	
Age (yo)	Median (range)	70.0 (47–79)	72 (38–86)	n.s
Gender	M/F	18/7	8/7	n.s
BMI (kg/m^2)	Median (range)	22.5 (14.6–36.6)	21.8 (15.9–28.3)	n.s
ASA-PS	1/2/3	4/17/4	1/13/1	n.s
AV(cm)	Median (range)	4.0 (0–16)	9.0 (0–20)	n.s
Tumor size (mm)	Median (range)	30 (0–90)	60 (1–95)	0.005
Invasion organs	LA/Se/Co/PX/Pr/B/V/Ut/Ov/Ot	11/9/7/6/6/5/4/3/2/1¶	6/2/0/1/1/6/3/3/1/8§	n.s
Neoadjuvant therapy	(C)RT/CT/None	20/0/5	9/2/4	n.s
c(yc)Stage	IIC/IIIC/IVA/IVB	14/0/8/3	7/5/3/0	0.018
Duration from the end of NT to Op. (day)	Median (range)	54 (42–156)	96.5 (67–155)	0.006
Major Op. procedure	spTPE/extAPE/APE/pPE/Hartmann/LAR	3/4/7/2/4/5	1/2/4/1/1/6	n.s
Combination operative techniques	ta(tp)TME/vNOTES/pfAPE/NIRC	8/2/7/3	0/0/0/1	<0.01
Duration of Op. (min)	Median (range)	472 (223–801)	409(242–885)	n.s
Blood loss (mL)	Median (range)	235 (13–1370)	89 (7–1981)	0.017
pStage	I/IIA/IIC/IIIBIIIC/IVA/IVB/X	3/12/3/1/1/2/2/1	1/2/4/0/4/3/1/0	n.s
pCRM	≤ 1 mm / >1 mm	5/20	9/6	0.017
R	1/0	0/25	5/10	0.002
Postoperative observation period (year)	Median (range)	3.9 (0.4–7.4)	1.5 (0.7–3.7)	0.003
Local recurrence	(+)/(−)	0/25	5/10	0.005

SPOS, specimen-oriented surgery; *SS*, standard surgery; *Op. procedure*, operation procedures; *BMI*, body mass index; *ASA–PS*, American Society of Anesthesiologists physical status; *AV*, tumor distance from the anal verge; *Tumor size*, tumor maximum size; *c(yc)Stage*, preoperative TNM Stage (TNM 8th edition); *Duration from the end of NT to Op.*, duration between the end of neoadjuvant therapy and operation; *Duration of Op.*, duration of operation; *pCRM*, pathological circumferential resection margin; *R1/0*, microscopic residual/no residual tumor; *M*, male; *F*, female; *(C)RT*, (chemo) radio therapy; *CT*, chemotherapy; *pStageX*, pathological complete remission; Invaded organs (LA/Se/Co/PX/Pr/B/V/Ut/Ov/Ot), (Levator ani muscles/ Seminal vesicle/Coccyx/ Pelvic plexus/Prostate/Bladder/Vagina/Uterus/Ovary/Others (¶, Sigmoid Colon+Small intestine+ Abdominal wall; §, Sigmoid colon 3, Small intestine 2, Appendix 1, Periosteum of the Sacral bone 1, Ureter1)); *spTPE*, sphincter-preserving total pelvic exenteration; *APE*, abdominoperineal excision; *extAPE*, extended APE; *pPE*, posterior pelvic exenteration; *Hartmann*, Hartmann's operation; *LAR*, low anterior resection; *ta(tp) TME*, trans-anal (trans-perineal) total mesorectal excision; *vNOTES*, transvaginal natural orifice transluminal endoscopic surgery; *pfAPE*, prone position first abdominoperineal excision; *NIRC*, near-infrared ray catheter

combined resection of adjacent organs with curative intent in the Department of Gastrointestinal Surgery of Kansai Medical University Hospital were included. Among all patients, SPOS was indicated in 25 patients and SS in 15. Surgeries were performed in two teams that consistently performed SPOS and SS (Table 1).

There were no significant differences in age, gender, BMI, ASA-PS, tumor height from the anal verge (AV), neoadjuvant therapy, duration of operation, or pStage between the two groups, but the SPOS group had more advanced preoperative staging (c(yc)Stage) and more blood loss than SS group and less duration from the end of neoadjuvant therapy to the operation, smaller tumor size.

Invasion organs were not different between the groups.

Procedures and combination techniques of SPOS (Table 2)

The principle to resecting the invading lesion of c(yc)T4b rectal cancer was the MRI indicating the deepest part of the tumor should be resected last without excess or deficiency. It was based on the anatomic landmarks and tumor location based on preoperative diagnosis, and it was used to minimize functional damage by ensuring pCRM >1 mm with minimal resection. In principle, the sphincter-preserving surgery involved reaching the site of maximum tumor invasion from the cephalad, lateral, and caudal sides "multi-directional approach" followed by the dissection of Denonvillier's fascia or the rectovaginal septum on the anal side of the tumor and divided the invading organ with a stapler. Then, the rectum was divided with a stapler (Fig. 3, Video at http://links.lww.com/DCR/B711) [12].

Table 2 Operative procedures, combination techniques and organs with combined resection

Procedure		Beyond TME ($n=16$)				ext TME ($n=9$)		Total
		spTPE	ext APE	APE	pPE	Hartmann	LAR	
n		3	4	7	2	4	5	25
M/F		3/0	3/1	5/2	0/2	4/0	3/2	18/7
AV (cm)		7.5 (7.0–8.0)	0 (0–2.0)*	0 (0–2.5)**	11.5 (7.0–16.0)	7.0 (3.0–16.0)	6.0 (4.0–8.0)	3.0 (0–16.0)
Combination Tec	Lap	3	4	7	2	4	5	25
	ta(tp) TME	1	2	4	-	-	1	8
	vNOTES	-	1	-	1	-	-	2
	pfAPE	-	3	4	-	-	-	7
	NIRC	-	2	-	1	-	-	3
Organs with combined resection	LA	-	4	7	-	-	-	11
	Seminal vesicle	3	1	-	-	2	3	9
	Co	-	3	4	-	-	-	7
	PX	3	2	-	-	-	1	6
	Prostate	3	2	-	-	-	1	6
	Bladder	3	-	-	-	2	-	5
	Vagina	-	1	-	2	-	1	4
	Uterus	-	1	-	2	-	-	3
	Ovary	-	-	-	2	-	-	2
	Others	-	-	-	-	1	-	1
pCRM ≤ 1 mm		-	2	2	-	1	-	5
pT4b/3/2/x		2/1/0/0	1/3/0/0	0/4/2/1	1/1/0/0	2/2/0/0	0/5/0/0	6/16/2/1

ext TME, extended total mesorectal excision; *spTPE*, sphincter-preserving total pelvic exenteration; *APE*, abdominoperineal excision; *extAPE*, extended APE; *pPE*, posterior pelvic exenteration; *Hartmann*, Hartmann's operation; *LAR*, low anterior resection; *Lap*, conventional laparoscopic surgery; *ta(tp) TME*, trans-anal (trans-perineal) total mesorectal excision; *vNOTES*, transvaginal natural orifice transluminal endoscopic surgery; *pfAPE*, prone position first abdominoperineal excision; *NIRC*, near-infrared ray catheter; *LA*, levator ani muscles; *Co*, coccyx; *PX*, pelvic plexus; *Others*, sigmoid colon + small intestine + abdominal wall; *pTx*, pathological complete remission

In cases where multi-directional dissection is difficult during top-to-bottom surgery, such as when the tumor is extensive, taTME or vNOTES was used in combination with the top-to-bottom surgery. If rectal cancer is contiguous to the bladder lumen by MRI or cystoscopy at the initial visit, we selected spTPE after CRT (Video 1).

In the SPOS group, we did not adopt "standard" APE or "ELAPE." Still, we underwent specimen-oriented APE according to the extent of the tumor diagnosed by the preoperative MRI controlling the resection area of tumor invading levator ani muscles to obtain pCRM > 1 mm. The combined resection of the levator ani muscles was first performed in two team approaches using tpTME (tpAPE) in four cases from June 2017 to August 2018. In October 2018, we adopted the pfAPE in seven cases (Fig. 2, Video at http://links.lww.com/ DCR/B437 [13]), which was more accessible than tpTME when anterior organs were combined for resection.

We decided on the operative procedure based on the radiologist's MRI reports, diagnosed by two radiologists with more than 25 years and 10 years of experience. When there were differences of opinion among the radiologists and surgeons, we discussed them at a preoperative conference and chose the procedure. Although it is sometimes challenging for mesorectal fascia (MRF) evaluation only with T2W-MRI, the DWI corresponding to T2W was referred to without the apparent diffusion coefficient (ADC) map [17–19].

Table 2 summarizes SPOS into two categories, beyond TME: total combined excision of other organs and extended TME: partial excision to ensure pCRM > 1 mm.

Endpoints

The primary endpoint was the local recurrence rate of the SPOS group compared to that of the SS group, and the secondary endpoint was to examine the effect of SPOS on the local recurrence with multiple logistic regression analysis. We defined the local recurrence as any suspicious tumor lesion progressing or new developing within the pelvis after primary surgery for rectal cancer.

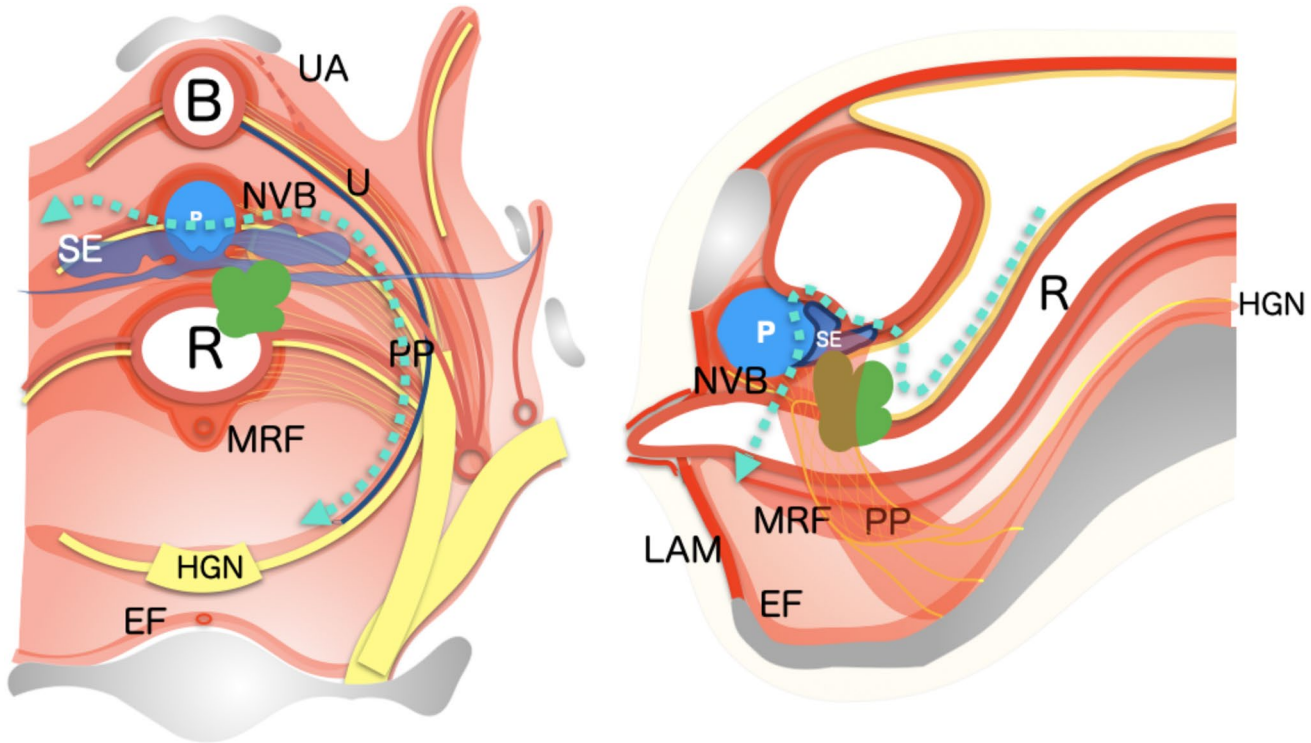

Fig. 3 Extended total mesorectal excision. Combined resection of the seminal vesicle. Ext TME: In many cases in male patients, pCRM can be secured by resectioning the seminal vesicles together. If the TME dissection is performed circumferentially on the distal side of the seminal vesicles following bilateral resection of vas deference, a specimen with sufficient pCRM can be obtained by the transection of seminal vesicle and ampulla at the oral side of ejaculatory duct (see literature 12 for details). B, bladder; NVB, neurovascular bundle; U, ureter; P, prostate; SE, seminal vesicle; R, rectum; MRF, mesorectal fascia; HGN, hypogastric nerve; PP, pelvic plexus; EF, endopelvic fascia; LAM, levator ani muscles

Statistical analysis

Descriptive statistics are displayed as frequencies for categorical variables and medians with the data from lowest to highest values for continuous variables. Univariate analysis was performed using the $\chi 2$, Student *t*, or Mann–Whitney *U* tests. Local recurrence–free survival was measured from the date of primary rectal surgery until the date of recurrent detection with CT examination, which was calculated using the Kaplan–Meier method, and the statistical difference was calculated using the generalized Wilcoxon test. *P* values less than 0.05 were considered statistically significant. Calculations were performed using Stat-Flex (ver7.0 for Windows11, Artec, Osaka, Japan).

This manuscript was written following STROBE guidelines.

Results

Comparison of the surgical procedures and the rates of R1 and pCRM ≤ 1 mm between the SPOS and SS groups (Table 1)

Standard laparoscopic surgery (SS) group

In 15 patients who underwent local radical surgery at c(yc) T4b, there was one case of spTPE, 2 of APE with combined resection other than the levator ani muscles in the lithotomy position, and 4 of standard APE. Eight patients underwent extended TME surgery with simultaneous resection of invaded organs, of which one underwent pPE, one underwent Hartmann's operation, and 6 underwent LAR. In all cases, ta(tp)TME, tpAPE, pfARE, and vNOTES were not used. Nine cases were pCRM positive (1 ≤ mm), and five cases were histological tumor exposure on the surface of the resected specimen (R1). Five cases encountered local recurrence.

Specimen-oriented surgery (SPOS) group (Tables 1 and 2)

Of the 25 patients, 16 underwent beyond TME, and nine underwent extended TME surgery. In the beyond TME surgery, there were 3 cases of spTPE, 4 cases of extended APE with combined resection other than the levator ani muscles and the coccyx using tpTME (one case) or pfAPE (three cases), and 7 cases of APE (tpAPE in 3 cases, pfAPE in 4 cases). There was one case for each pfAPE with tpTME in extended APE and APE. Two patients underwent pPE.

Nine patients underwent extended TME with partial resection of invaded organs, of which 4 underwent Hartmann's operation, and 5 underwent LAR. No patient lost both urinary and sphincter function.

Five cases of the SPOS group were pCRM ≤ 1 mm. Two cases of extAPE requiring prostate shaving, two cases of APE, and one case of Hartmann's operation with combined resection of the bladder wall and sigmoid colon had pCRM of 1 mm or less but had R0. In the first two cases of extAPE (pT3, pT4b one case each), the distance between the prostate surface and the MRI indicating the deepest part of the tumor was 0.5 mm and 0.1 mm in clinical CRM. In the two cases of APE (pT3, 2 cases), the pCRM was 0.5 mm and 1 mm on the left side of the rectum covered by the puborectalis sling. The last case had an abscess in the mesorectum, and the pCRM was 1 mm at the dissection surface on the sacral bone (pT4b). One case of prostate shaving encountered urethral injury requiring suture repair. The pT4 was six among 25 cases, and 2 were pCRM ≤ 1 mm. The pT2 tumor was 0 cm from the anal verge in two cases. pT3 was in 16 cases, but the pCRM of the patients, if they had chosen TME, was not speculated. We have not experienced pathological tumor exposure on the dissection plane in the SPOS group.

Examination of the effect of SPOS on the local recurrence (Tables 1 and 3)

The pCRM positive rate (≤ 1 mm) and R1 rate in the SPOS group were significantly lower than the SS group(5/25 vs 9/15, 0/25 vs 5/15), and all surgeries performed in the SPOS were R0. The postoperative observation period was significantly longer in the SPOS group (Table 1).

The SPOS group had a median follow-up of 3.9 (0.4–7.4) years with no local recurrence, while the SS group had a median follow-up of 1.5 (0.7–3.7) years with 5 of 15 patients (33%) experiencing more local recurrence than SPOS group ($p = 0.005$) (Table 1). To examine the effect of SPOS on local recurrence, a comparison of the local recurrence (+) and (−) groups showed significant differences in pCRM positive rate, neoadjuvant therapy, tumor size, and approach

Table 3 Comparison between local recurrence (+) and (−) groups

Local recurrence		(+)	(−)	*p* (univariate)	*p* (multivariate)
N		5	35		
Approach	SS/SPOS	5/0	10/25	0.005	n.s
Age (yo)	Median (range)	68 (52–79)	70 (38–86)	n.s	n.s
Gender	M/F	2/3	24/11	n.s	n.s
BMI (kg/m^2)	Median (range)	17.4 (16.6–28.3)	22. 5(14.6–36.6)	n.s	n.s
ASA-PS	1/2/3	1/3/1	4/27/4	n.s	n.s
AV (cm)	Median (range)	10 (3.0–20)	5 (0–26)	n.s	n.s
c(yc)Stage	IIC/IIIC/IVA/IVB	3/1/1/0	18/4/10/3	n.s	n.s
Neoadjuvant therapy	(C)RT/CT/None	2/2/1	27/0/8	0.002	n.s
Major Op. procedure	LAR/Hartmann/pPE/APE/extAPE/spTPE	2/0/1/1/0/1	9/5/2/10/6/3	n.s	n.s
Tumor size (mm)	Median (range)	65 (50–80)	35 (0–95)	0.04	n.s
Duration of Op. (min)	Median (range)	524 (242–629)	433 (223–885)	n.s	n.s
Blood loss (mL)	Median (range)	98 (16–98)	197 (7–1981)	n.s	n.s
Tumor differentiation	muc/por/tub1/tub2	0/0/2/3	1/1/17/16	n.s	n.s
N. metastatic LN	Median (range)	0 (0–1)	0 (0–5)	n.s	n.s
pCRM	≤ 1 mm, > 1 mm	4/1	10/25	0.04	n.s
R	1/0	2/3	3/22	n.s	n.s
pStage	I/IIA/IIC/IIIB/IIIC/IVA/IVB/X	0/1/2/0/1/1/0/0	4/13/5/1/4/4/3/1	n.s	n.s

BMI, body mass index; *ASA–PS*, American Society of Anesthesiologists physical status; *AV*, tumor height from the anal verge; *c(yc)Stage*, preoperative TNM Stage (TNM 8th edition); *Tumor size*, tumor maximum size; *Duration of Op.*, duration of operation; *N. metastatic LN*, the number of metastatic lymph nodes; *pCRM*, pathological circumferential resection margin; *R1/0*, microscopic residual/no residual tumor; *pStage*, pathological Stage (TNM 8th edition); *M*, male; *F*, female; *LAR*, low anterior resection; *Hartmann*, Hartmann's operation; *pPE*, posterior pelvic exenteration; *APE*, abdominoperineal excision; *extAPE*, extended APE; *spTPE*, sphincter-preserving total pelvic exenteration

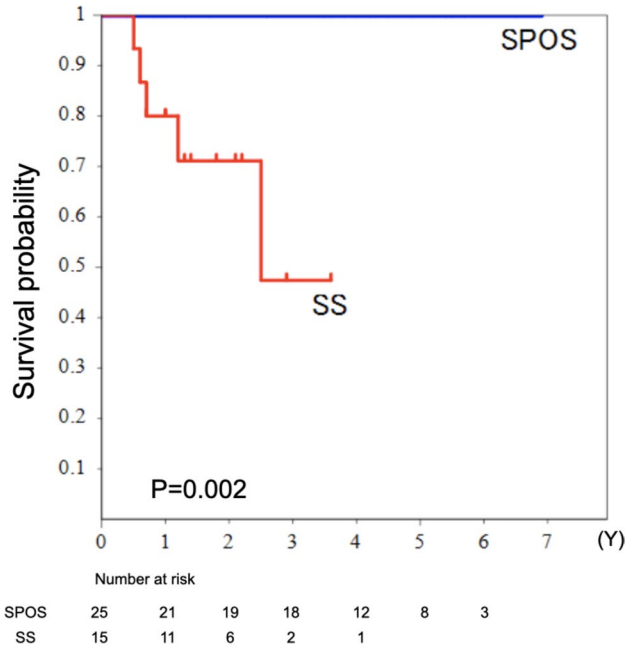

Fig. 4 Postoperative local recurrence–free survival between SPOS and SS groups in the Kaplan–Meier survival curve. There is no local recurrence in the SPOS group, and the 2-year local recurrence–free survival rate is 71.1% in the SS group ($p = 0.002$)

(SPOS vs. SS) in univariate analysis but no significant differences were found in multivariate analysis (Table 3).

Local recurrence–free survival of SPOS and SS (Fig. 4)

The Kaplan–Meier curve shows local recurrence–free survival of SPOS and SS. No local recurrence was observed in the SPOS group, and the 2-year local recurrence–free survival rate was significantly higher than that of SS with a shorter observation period ($p = 0.002$).

Discussion

An essential difference exists between a negative mesorectal fascia (MRF) involvement by MRI when planning TME surgery [15, 20, 21] and a positive MRF involvement by MRI in c(yc)T4b cases with combined resection of other organs [22–24]. In the former case, accurately pursuing the dissection plane would lead to a pCRM > 1 mm specimen with a high probability that the preoperative MRI can diagnose c(yc)CRM more than 1 mm from the MRF. In contrast, there is no dissection plane in the latter case, so the only way to obtain a pCRM > 1 mm specimen is to remove the surrounding organs combinedly based on the preoperative MIR using anatomic landmarks intraoperatively.

Although the extent and volume of organs to be removed vary widely depending on the extent of tumor invasion, the main focus of minimally invasive surgery (MIS) for c(yc) T4b rectal cancer is to ensure pCRM > 1 mm with minimal resection of adjacent organs, which is also the goal of the SPOS we have been using.

The basic concept of SPOS is to compensate for the weak points of LAP surgery as possible to combine the advantages of these recently developed techniques to achieve both a radical cure and preserve urinary systems and anal sphincter function of c(yc)T4b rectal cancer. Of course, it does not mean that SS is not a specimen-oriented surgery. However, SS intended to resect a large enough area to be included in the resection area, not to carve out an ideal specimen. How et al. recommend the exenteration for the tumors located above and below the puborectalis sling and anteriorly at the level of the prostate, as achieving a negative pCRM could not be reliably resolved through ELAPE [23]. In other words, unnecessary areas were extended, resulting in insufficient resection of the vital areas.

In the 11 cases of APE, their tumors were located 0 cm from the anal verge, and tpTME and pfAPE were adopted to control the resection volume of the levator ani muscles without excess or deficiency [10, 11, 25–28]. Especially when a tumor is closely attached to an anterior organ, we cannot secure pCRM > 1 mm unless the puborectalis sling is dissected as far forward as possible to the anterior aspect of the anterior organ while looking at anatomic landmarks (Fig. 2). Removing the levator ani muscles entirely in such cases has little effect on securing pCRM > 1 mm.

Of course, TPE may improve the pCRM of anterior wall lesions, which leads to sacrifice of the urinary function. Considering no significant difference in overall survival between extended TME and beyond TME for responders of neoadjuvant therapy, as Denost et al. pointed out [29], the significance of prostate shaving is worth considering. For this reason, near-infrared ray catheter (NIRC) was also used in 2 cases of extAPE to preserve the urinary tract as much as possible.

Registry data showed that the relative risk of local recurrence was significantly higher for ELAPE irrespective of a defined wide resection area than the standard APE without a definite extent of resection. Furthermore, considering the high number of wound-related complications [28], c(yc)T4b rectal cancer requiring combined resection of levator ani muscles should be controlled on a case-by-case basis based on the preoperative MRI [23, 28].

Most of the c(yc)T4b rectal cancer with widespread invasion to the anterior organs that require TPE have a sufficient distance from the anal verge to preserve anal function. The ability to dissect the Retzius fossa with LAP surgery and simultaneous dissection of the posterior aspect of the TME

avascular plane with taTME was instrumental in facilitating specimen mobilization and ensuring spTPE.

The SPOS group using various surgical techniques had significantly better pCRM > 1 mm and R0 rates, with no local recurrence. A comparison between the local recurrence (+)/(−) groups showed significant differences in pCRM positive rate, neoadjuvant therapy, tumor size, and SS/SPOS approach. Although there was no significant factor in the multivariate analysis, the number of patients was so small that the results of the multivariable analysis might be misinterpreted. Of course, the larger tumor size in the SS group compared to the SPOS group might have influenced the results of the present study. Still, the advantages of a technique that uses multi-directional resection as much as possible may be more beneficial for larger tumors. Furthermore, preoperative chemotherapy was used in two patients in the SS group, but the lack of radiotherapy might have been insufficient in terms of local control (Tables 1 and 3).

Despite these strategies, five patients were pCRM ≤ 1 mm in SPOS group, unrelated to insufficient resection of the levator ani muscles, and had no local recurrence during the 3.9-year observation period. In these cases, pCRM requires measurement of the distance from the dissected edge of levator ani muscles or the anterior wall organ, which is different from the change after formalin immersion of the TME dissected surface, so the equivalence of the pCRM cut-off values is questionable.

There are some limitations in this study. The present study is a single-center, non-randomized retrospective study of only 40 consecutive patients with heterogeneity who underwent local curative surgery for c,(yc)T4b rectal cancer.

As each group was operated by a different surgeon, other factors that were difficult to measure might have influenced observed outcomes. Due to the increase in our caseload, one skillful surgeon with more than 30 years of experience joined our department in April 2019 and performed a conventional top-to-bottom laparoscopic procedure for T4b rectal cancer. Therefore, the follow-up period of the SS group was significantly shorter than that of the SPOS group: 3.9 years in the SPOS group and 1.5 years in the SS group.

It is undoubtedly desirable to wait for more cases to accumulate and be reported after a longer follow-up, including the SS group. However, a combination of new minimally invasive surgical techniques (SPOS) may be more effective in local control of c(yc)T4b rectal cancer than expected and not only theoretically, which has led us to report it, although the number of cases and follow-up period is minimal.

Laparoscopic surgery, including robotic surgery, provides a good field of vision in the deep pelvis but has the disadvantage of not being able to freely set the resection site by pulling the organ with the human hand or a broad retractor entirely using flexible, tactile, necessary, and sufficient traction force such as open surgery, especially in case of a large tumor. It may be the reason why SS, a laparoscopic replacement of open surgery, is as difficult to perform for a large-size tumor. The most significant advantage of SPOS is the ability to set the resection line after maximizing the mobility of the cancer-invading area, which may have led to the results of the SPOS.

Miles devised an APE for rectal cancer based on what specimen should be removed from the autopsy [3]. If he were alive today, it is conceivable that he would have defined the extent of resection based on MRI diagnosis. The recent development of all surgical procedures, including laparoscopic surgery, has been developed to remove the necessary specimen with minimal invasiveness. Similarly, diagnostic imaging techniques have also advanced remarkably. With all the advancements in the surgical field, personalized medicine is undoubtedly the key to improving the outcome of c(yc)T4b rectal cancer. However, future multicenter studies should be required to confirm these findings with this study's limited number of patients.

Conclusions

In the laparoscopic setting, local control of c(yc)T4b rectal cancer requires a different surgical strategy than open surgery, and SPOS may be a promising procedure.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00384-025-04838-5.

Acknowledgements The content of this manuscript was presented in the symposium of the 120th annual Congress of Japan Surgical Society. The content of this manuscript was presented in the video symposium of the 78th general meeting of the Japanese Society of Gastroenterological Surgery. The authors thank Professor Leon Sakuma, who assisted in drawing the schema for the manuscript. The authors thank Professor Emeritus Tatsuo Sato, Institute of Science Tokyo, formerly Tokyo Medical and Dental University, who advised on the schemas from an anatomical point of view. The authors thank Professor Hidefumi Kinoshita in the Department of Urology and Andrology, Kansai Medical University, who was willing to help us with our research. The authors thank Professor Mitsugu Sekimoto in the Department of Surgery, Kansai Medical University, who was willing to help us with our research.

Author contributions Author contributions Conception and design: MH. Acquisition of the data: MH, FS, YM, MH, MK, SB, HK, KT Drafting and critical revision of the article: MH. Final approval: MH. All authors have read and approved the manuscript.

Data availability Although this study was conducted using an anonymized database, it was a single-center study; due to the nature of this research, participants did not agree for their data to be shared publicly, so supporting data is unavailable.

Declarations

Ethics approval The preoperative diagnosis and planning of the operation using MRI in this manuscript was approved by the Hospital Ethics Committee of Kansai Medical University (reference number #2017049: http://www.kmu.ac.jp/hirakata/hospital/2671t8000001356c.html).

Consents The patient's written consent for the published photos was obtained. In addition, written permission was obtained from all registered patients to use the information for research and paper activities.

Competing interests The authors declare no competing interests.

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