

# 「腹腔鏡下大腸癌手術に関する研究」 終了報告

研究代表者

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## Laparoscopic Surgery for Stage 0/I Rectal Carcinoma

### Short-term Outcomes of a Single-Arm Phase II Trial

Seiichiro Yamamoto, MD, PhD,\* Masaaki Ito, MD, PhD,† Junji Okuda, MD, PhD,‡ Shoichi Fujii, MD, PhD,§  
Shigeki Yamaguchi, MD, PhD,¶ Kenichi Yoshimura, PhD,|| Kenichi Sugihara, MD, PhD,\*\*  
and Masahiko Watanabe, MD, PhD†† for the Japan Society of Laparoscopic Colorectal Surgery

*Ann Surg* 2013;258: 283–288)

## Short-term outcomes of laparoscopic intersphincteric resection from a phase II trial to evaluate laparoscopic surgery for stage 0/I rectal cancer: Japan Society of Laparoscopic Colorectal Surgery Lap RC

Shoichi Fujii · Seiichiro Yamamoto · Masaaki Ito · Shigeki Yamaguchi · Kazuhiro Sakamoto · Yusuke Kinugasa · Yukihito Kokuba · Junji Okuda · Kenichi Yoshimura · Masahiko Watanabe

Surg Endosc

DOI 10.1007/s00464-012-2317-1

## Long-term survival outcomes following laparoscopic surgery for clinical stage 0/I rectal carcinoma

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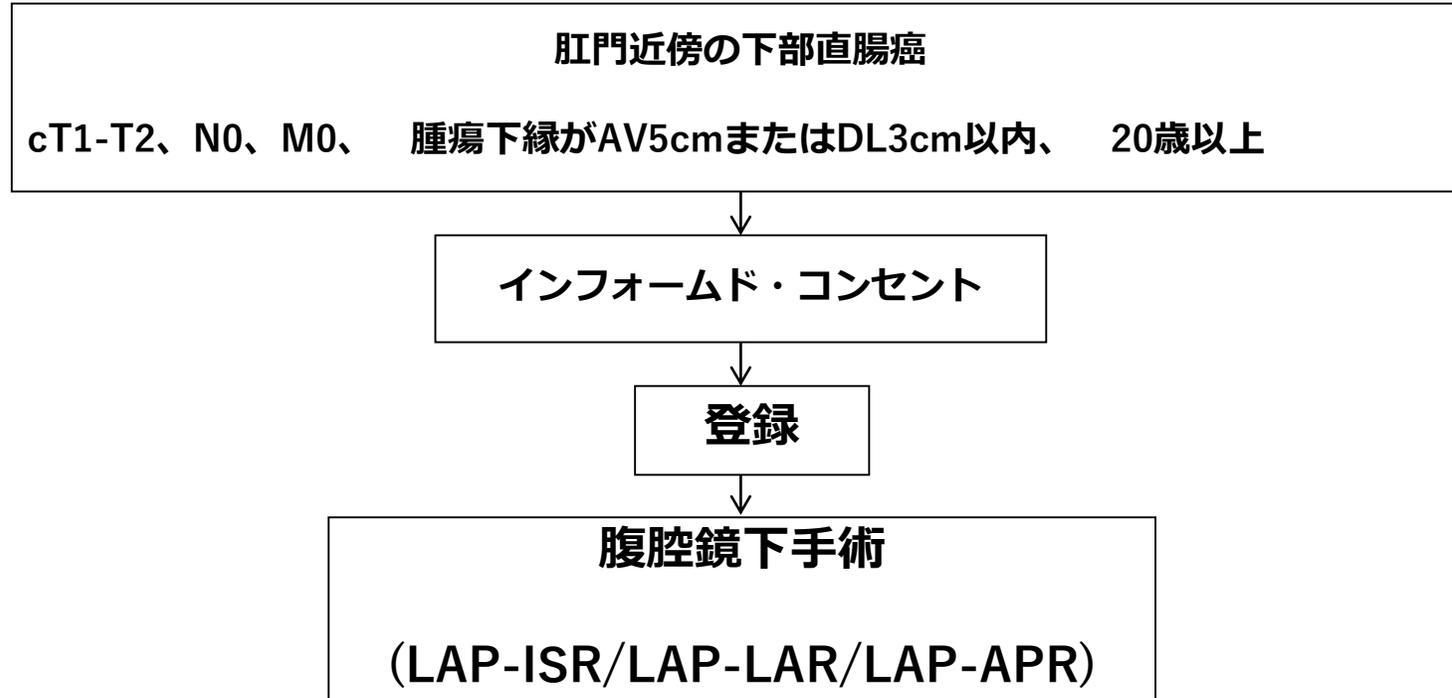
*Ann Gastroenterol Surg.* 2020;4:294–300.

## Open Versus Laparoscopic Resection of Primary Tumor for Incurable Stage IV Colorectal Cancer

### A Large Multicenter Consecutive Patients Cohort Study

Koya Hida, MD, PhD,\*†† Suguru Hasegawa, MD, PhD,\* Yousuke Kinjo, MD,\* Kenichi Yoshimura, PhD,† Masafumi Inomata, MD, PhD,‡ Masaaki Ito, MD, PhD,§ Yosuke Fukunaga, MD, PhD,|| Akiyoshi Kanazawa, MD, PhD,¶ Hitoshi Idani, MD, FACS, PhD,# Yoshiharu Sakai, MD, FACS, PhD,\* Masahiko Watanabe, MD, FACS, PhD,\*\* and the Japan Society of Laparoscopic Colorectal Surgery

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Primary endpoint :

3年累積局所再発率

- ①無再発生存期間
- ②全生存期間
- ③排便機能、排尿機能  
性機能、QOL
- ④肛門温存率
- ⑤有害事象発生割合

## 予定登録数と研究期間

予定登録数：300例。登録期間：3年。追跡期間：登録終了後3年。解析期間：1年。総研究期間：7年。

## Long-term Survival and Functional Outcomes of Laparoscopic Surgery for Clinical Stage I Ultra-low Rectal Cancers Located Within 5 cm of the Anal Verge

### *A Prospective Phase II Trial (Ultimate Trial)*

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*Ann Surg* • Volume 281, Number 2, February 2025

**TABLE 1.** Clinical Characteristics of the Patients

Characteristic	
Total number of patients	299
Gender - n (%)	
Male	187 (62.5)
Female	112 (37.5)
Age - y; median, range	65 (30-87)
ECOG PS - n (%)	
0	274 (91.6) 1/4
1	25 (8.4) 1/4
Body mass index - kg/m <sup>2</sup> , median, range	22.7 (15.9 - 38.6)
History of surgery, n (%)	79 (26.4)
Tumor location from anal verge, cm, median, range	4.0 (0-5.5)
Tumor location from dentate line, cm, median, range	2.0 (-1.5-4.0)
clinical T stage	
T1	169
T2	130
Preoperative CEA level, ng/mL, median, range	2.1 (0.4-27.4)
Preoperative CA19-9 level, U/mL, median, range	8.0 (0.1-244.0)

# 術中術後合併症

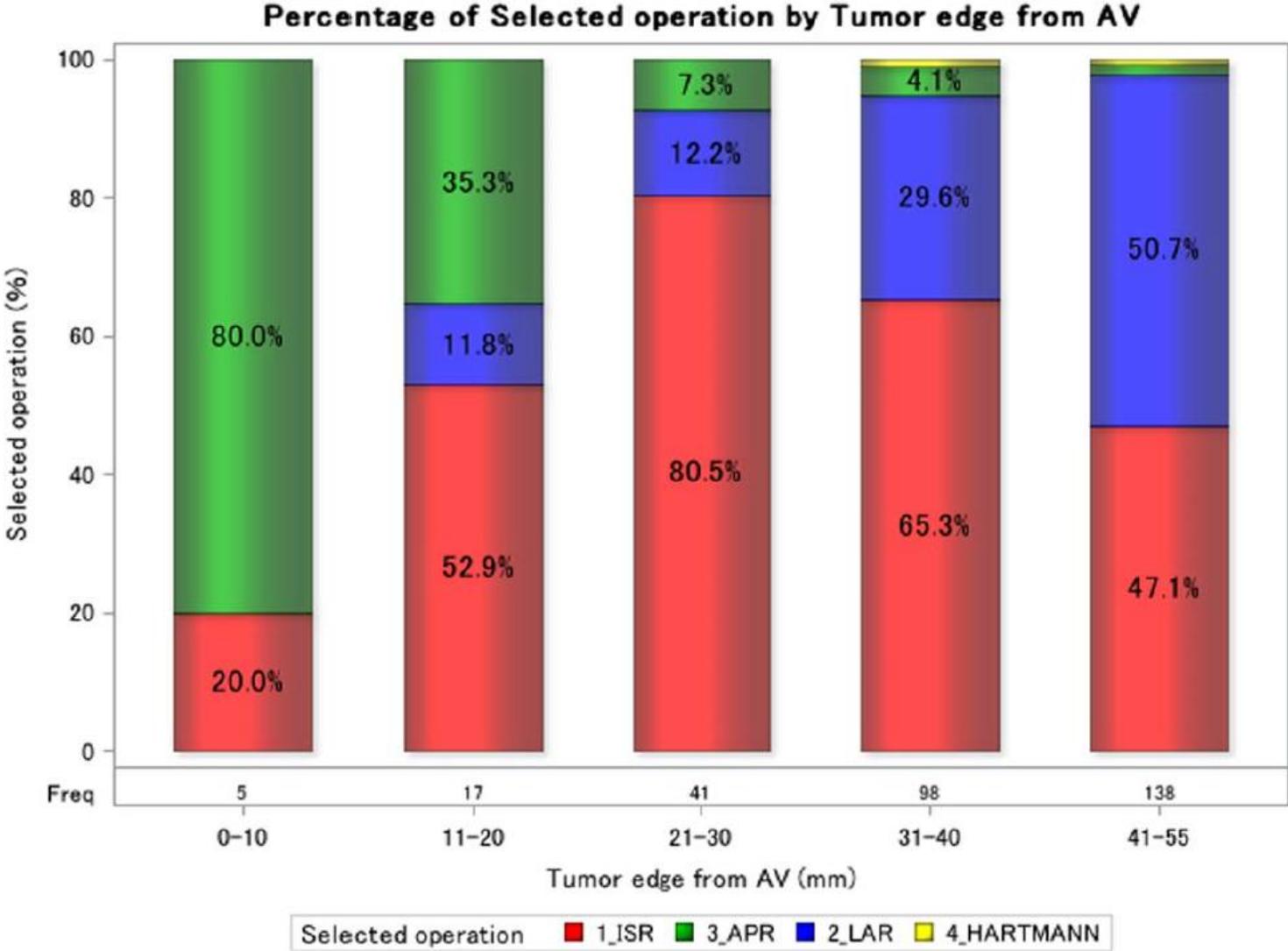
**TABLE 2.** Operative Results

Laparoscopic procedures - n (%)	
Low anterior resection	106 (35.5)
Intersphincteric resection	172 (57.5)
Abdominoperineal resection	19 (6.4)
Hartmann operation	2 (0.7)
Range of lymph node dissection	
High tie	158 (52.8)
Low tie	141 (47.2)
Splenic flexure mobilization, n (%)	
Yes	92 (30.8)
No	207 (69.2)
Type of anastomosis	
Stapler	106 (35.5)
Hand-sewn	172 (57.5)
Type of reconstruction	
Straight	232 (77.6)
Side-to-end	43 (14.4)
Coloplasty	3 (1.0)
Diverting stoma - n (%)	
Ileostomy	244 (81.6)
Colostomy	8 (2.7)
Transanal tube insertion	
Yes	127 (42.5)
No	172 (57.5)
Operative time, median (range), min	286 (96-656)
Blood loss, median (range), mL	34 (0-740)
Conversion - n (%)	0 (0)
Intraoperative adverse event, n (%)	
Injury of vessels	4 (1.4)
Injury of small intestine	3 (1.0)
Injury of the colon or rectum	5 (1.7)
Injury of the urinary tract	3 (1.0)
Injury of vagina	2 (0.7)
Thromboembolism	3 (1.0)

**TABLE 3.** Postoperative Recovery, Perioperative Complications, and Delayed Complications

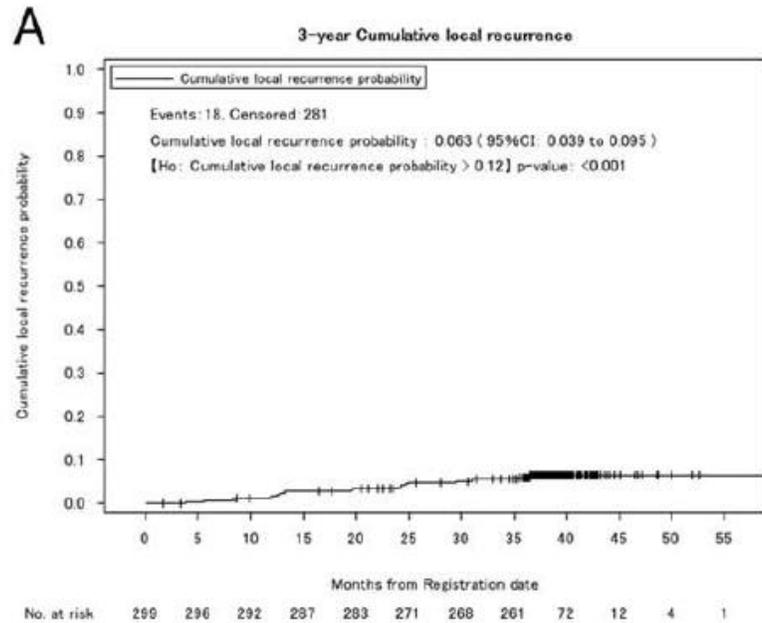
<b>n = 299</b>	
Time to pass first flatus, days, median (range)	1 (0-9)
Time to water intake, days, median (range)	1 (0-8)
Time to diet intake, days, median (range)	3 (1-20)
Perioperative complications	All grades (%) / Grade 3 or 4 (%)
Ileus	52 (17.4) / 6 (2.0)
Anastomotic leakage	25 (8.4) / 17 (5.7)
Urinary retention	12 (4.0) / 0 (0)
Surgical site infection	21 (7.0) / 13 (4.3)
Pelvic abscess	5 (1.7) / 4 (1.3)
Urinary tract infection	4 (1.3) / 2 (0.7)
Stoma related complications	5 (1.7) / 2 (0.7)
Postoperative bleeding	3 (1.0) / 0 (0)
Upper tract bleeding	1 (0.3) / 1 (0.3)
Delayed complications	
Ileus	9 (3.0) / 3 (1.0)
Anastomotic leakage	2 (0.7) / 2 (0.7)
Anastomotic fistula	3 (1.0) / 3 (1.0)
Anastomotic stenosis	27 (9.0) / 21 (7.0)
Pelvic abscess	1 (0.3) / 1 (0.3)
Urinary retention	3 (1.0) / 0 (0)
Rectal prolapse	8 (2.7) / 8 (2.7)

# 腫瘍の高さと施行術式

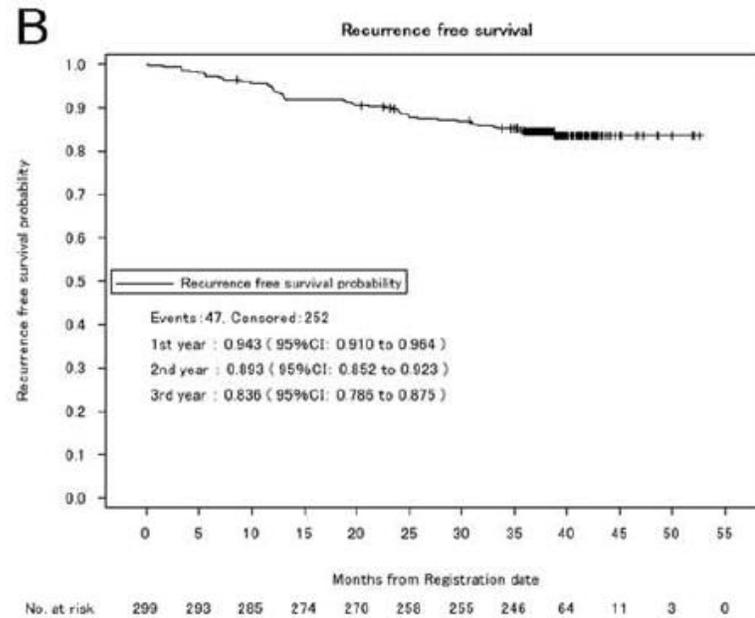


**FIGURE 1.** Tumor location and selected operation. The bar graph shows the tumor location and selected operation. For instance, the rates of APR, ISR, and LAR were 80.0%, 20.0%, and 0%, respectively, when the tumor was located within 10 mm from AV.

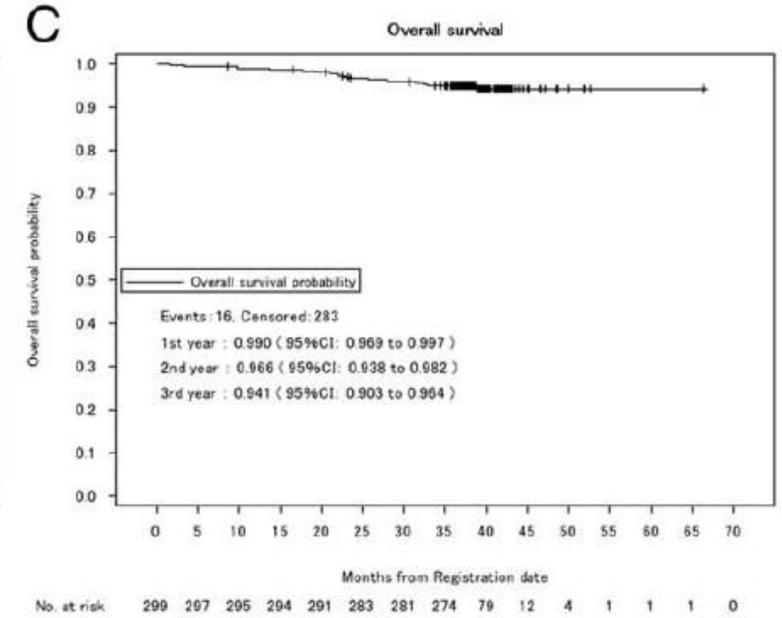
# 腫瘍学的結果



**3yr.LRR: 6.3%**



**3yr.RFS: 83.6%**



**3yr.OS: 94.1%**

# 術後肛門機能

**TABLE 4.** Incontinence Score

	<b>Preoperative</b>	<b>3 mo</b>	<b>6 mo</b>	<b>12 mo</b>	<b>24 mo</b>	<b>36 mo</b>
<b>Scorable</b>	<b>(n = 245)</b>	<b>(n = 193)</b>	<b>(n = 192)</b>	<b>(n = 180)</b>	<b>(n = 148)</b>	<b>(n = 133)</b>
Incontinence score						
Mean	1.2	11.5	10.3	9.2	8.4	7.9
Median	1	12	10	9	8	8
Range	0 to 8	0 to 20				
Collected (/Target* %)	96	78	77	74	59	55
Scoreable (/Collected %)	96	92	93	91	94	91
Distribution of Incontinence score, n (%)						
0 to 5	242 (99)	21 (11)	35 (18)	48 (27)	47 (32)	42 (32)
6 to 10	3 (1)	56 (29)	71 (37)	65 (36)	55 (37)	54 (41)
11 to 15	0 (0)	79 (41)	57 (30)	46 (26)	32 (22)	31 (23)
16 to 20	0 (0)	37 (19)	29 (15)	21 (12)	14 (10)	6 (5)

Date stands for the time after stoma closure following ISR.

\*Target¼[Diverting stoma(+) → Stoma closure(+)] or [Diverting stoma(+) → Using own anus] or [Diverting stoma(+) → Stoma creation] (n = 268).

# 術後排尿・性功能

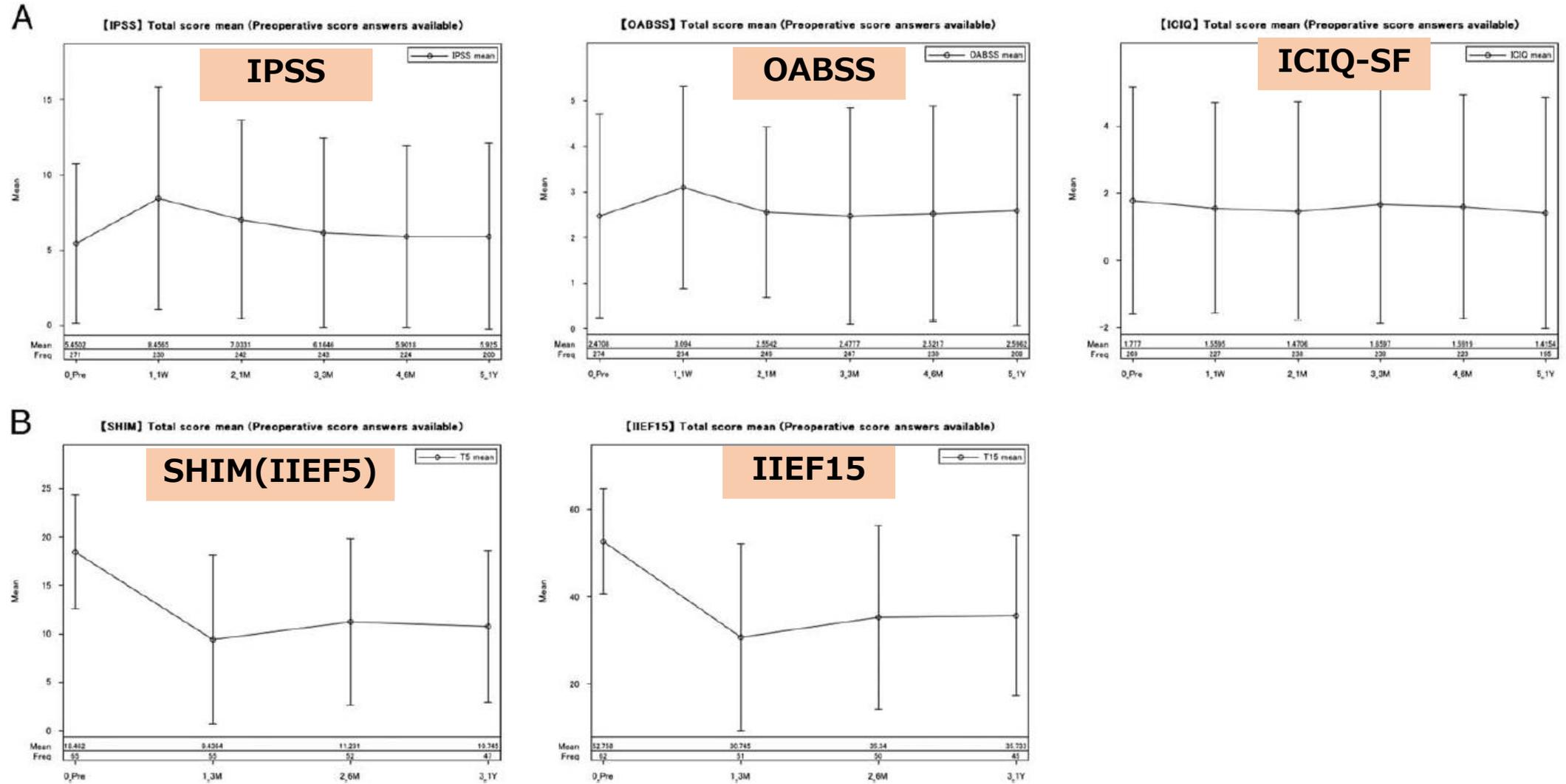


FIGURE 3. A and B, Postoperative urinary and sexual functions.

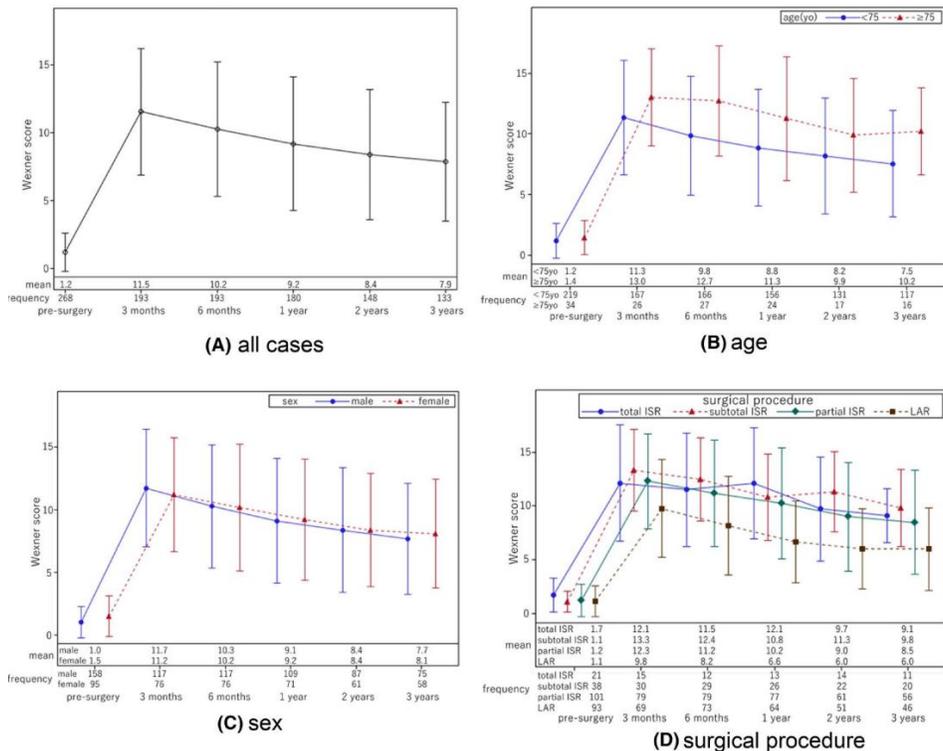
## Conclusions:

This study demonstrated that laparoscopic surgery for clinical stage I very low rectal cancers within 5 cm of the anal verge provides feasible long-term oncological outcomes, a high rate of anal preservation, and moderate preservation of anal function.

Urinary function recovers to the preoperative level within 1 month after surgery, although sexual function does not fully recover to the preoperative level beyond 6 months, which should be clearly explained to the patients.

# A multicentre prospective study of anal function after laparoscopic ultra-low rectal cancer surgery using a mixed-effects model

Makoto Takahashi<sup>1</sup> | Kazuhiro Sakamoto<sup>1</sup> | Yuichiro Tsukada<sup>2</sup> | Shingo Kawano<sup>1</sup> | Jun Watanabe<sup>3</sup> | Yosuke Fukunaga<sup>4</sup> | Yasumitsu Hirano<sup>5</sup> | Hiroki Hamamoto<sup>6</sup> | Masanori Yoshimitsu<sup>7</sup> | Hisanaga Horie<sup>8</sup> | Nobuhisa Matsuhashi<sup>9</sup> | Yoshiaki Kuriu<sup>10</sup> | Shuntaro Nagai<sup>11</sup> | Madoka Hamada<sup>12</sup> | Shinichi Yoshioka<sup>13</sup> | Shinobu Ohnuma<sup>14</sup> | Tamuro Hayama<sup>15</sup> | Koki Otsuka<sup>16</sup> | Yusuke Inoue<sup>17</sup> | Kazuki Ueda<sup>18</sup> | Yuji Toiyama<sup>19</sup> | Satoshi Maruyama<sup>20</sup> | Shigeki Yamaguchi<sup>21</sup> | Keitaro Tanaka<sup>6,22</sup> | Motoko Suzuki<sup>23</sup> | Toshihiro Misumi<sup>23</sup> | Takeshi Naitoh<sup>24</sup> | Masahiko Watanabe<sup>25</sup> | Masaaki Ito<sup>2</sup> | Ultimate Trial Group



## Conclusions:

Anal function in very low rectal cancer deteriorates postoperatively, but then gradually improves over 3 years and eventually reaches an acceptable level.

The study also indicated a higher risk of poor postoperative anal function after ISR and in patients aged  $\geq 75$  years.

It is important to inform patients of these facts before surgery and to ensure that patients fully understands this information.

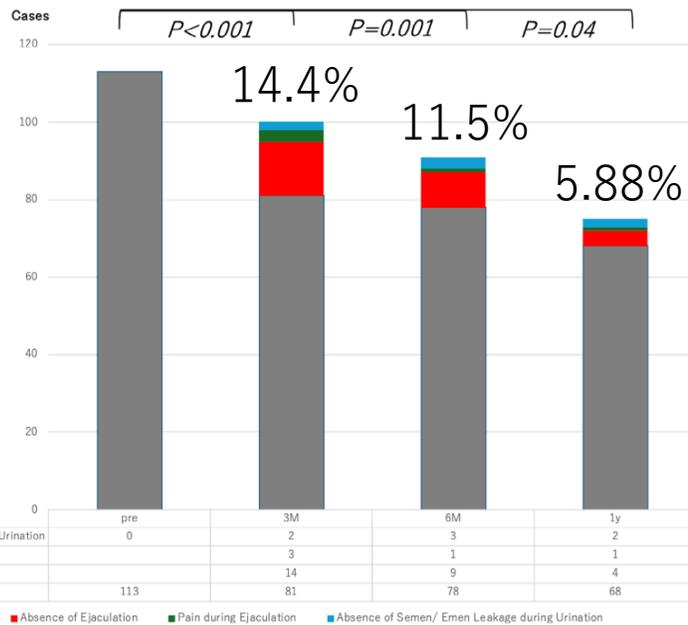
**TABLE 5** Multivariate analysis using a mixed-effects model. ISR ( $p < 0.01$ ) and age  $\geq 75$  years ( $p = 0.03$ ) were identified as significant independent factors for a worsened Wexner score.

Effect	Estimate	Standard error	p-value
<u>Age (years) (<math>\geq 75 / &lt; 75</math>)</u>	-1.28	0.58	0.03
Sex (male/female)	0.07	0.40	0.87
<u>Surgical procedure (ISR/LAR)</u>	2.37	0.43	<0.01
Operating time (min) ( $\geq 300 / < 300$ )	-0.25	0.42	0.55
Blood loss (mL) ( $\geq 35 / < 35$ )	0.16	0.43	0.71
Anastomotic leakage (yes/no)	-0.17	0.72	0.81

# Longitudinal follow-up of sexual function after surgery for ultra-low rectal cancers located within 5 cm of the anal verge: A multicentre collaborative study

Yasuhiro Ishiyama<sup>1</sup> | Yasumitsu Hirano<sup>1</sup> | Yuichiro Tsukada<sup>2</sup> | Jun Watanabe<sup>3,4</sup> |  
 Yosuke Fukunaga<sup>5</sup> | Kazuhiro Sakamoto<sup>6</sup> | Hiroki Hamamoto<sup>7</sup> |  
 Masanori Yoshimitsu<sup>8</sup> | Hisanaga Horie<sup>9</sup> | Nobuhisa Matsushashi<sup>10</sup> | Yoshiaki Kuriu<sup>11</sup>  
 Shuntaro Nagai<sup>12</sup> | Madoka Hamada<sup>13</sup> | Shinichi Yoshioka<sup>14</sup> | Shinobu Ohnuma<sup>15</sup> |  
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 Masahiko Watanabe<sup>25</sup> | Motoko Suzuki<sup>26</sup> | Toshihiro Misumi<sup>26</sup> | Masaaki Ito<sup>2</sup> |  
 Ultimate Trial Group in Japan Society of Laparoscopic Colorectal Surgery

## Longitudinal analysis of temporal changes in ejaculatory function



## Conclusions:

We evaluated sexual function after surgery in patients with cT1-2, NOM0 lower rectal cancers.

IIEF-15 scores were the lowest at 3 months postoperatively, which gradually recovered; however, scores remained lower than the preoperative levels at 1 year.

Ejaculatory function showed limited recovery at 12 months postoperatively.

Given the implications of these results, it is imperative to ensure widespread awareness of erectile dysfunction risk among both surgeon and patient populations before surgery for rectal cancer.

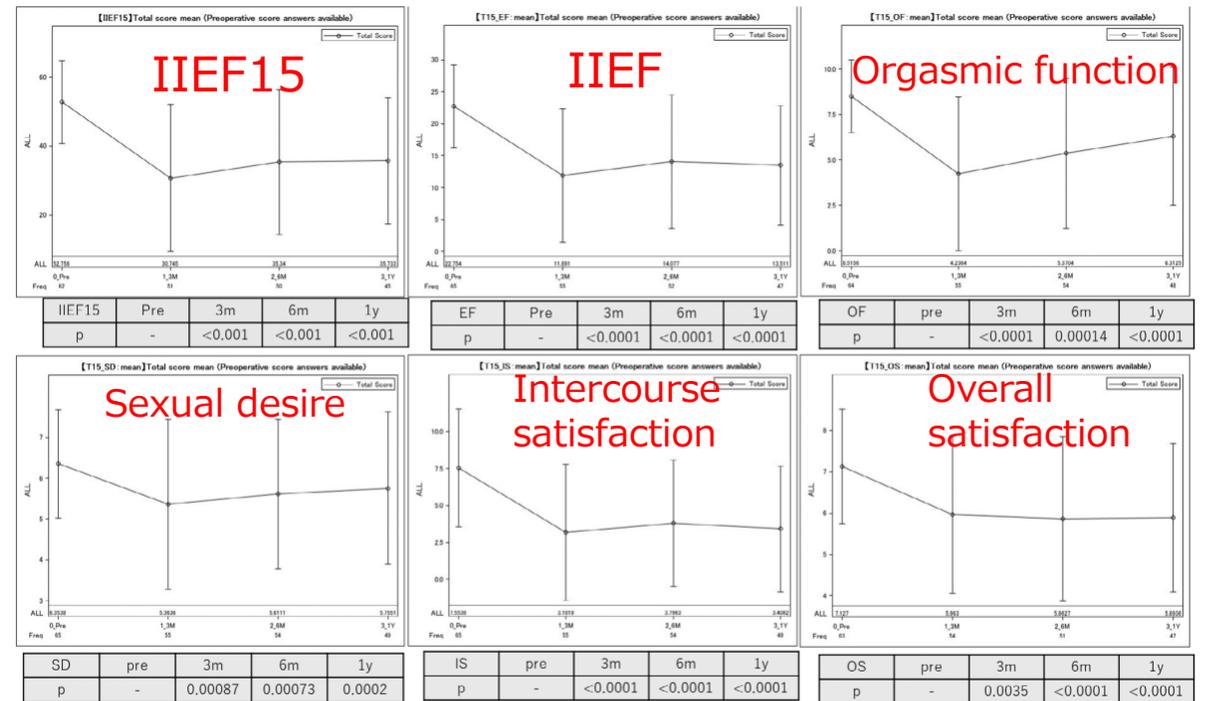


FIGURE 2 Longitudinal changes in erectile function (IIEF-15), EF, erectile function; IIEF-5, International Index of Erectile Function-5; IS, intercourse satisfaction; OF, orgasmic function; OS, overall satisfaction; SD, sexual desire.

# Quality of life after laparoscopic surgery for very low rectal cancer: A sub-analysis of the ultimate trial

Hiroki Hamamoto<sup>1</sup> | Keitaro Tanaka<sup>1,2</sup> | Yuichiro Tsukada<sup>3</sup> | Jun Watanabe<sup>4</sup> |  
 Yosuke Fukunaga<sup>5</sup> | Yasumitsu Hirano<sup>6</sup> | Kazuhiro Sakamoto<sup>7</sup> | Masanori Yoshimitsu<sup>8</sup> |  
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 Takeshi Naitoh<sup>24</sup> | Masahiko Watanabe<sup>25</sup> | Masaaki Ito<sup>3</sup> | Ultimate Trial Group in Japan  
 Society of Laparoscopic Colorectal Surgery

TABLE 3 Multivariate analysis using a mixed effects model. (a) Physical component summary, (b) Mental component summary, (c) Role/social component summary.

Effect	Estimate	Standard error	t Value	p	Lower 95% CI	Upper 95% CI
<b>(a)</b>						
ISR	0.8257	0.8193	1.01	0.3138	0.7824	2.4338
Stage III	2.6726	1.0114	2.64	0.0084*	0.6874	4.6577
Wexner 1 year ≥9	1.3632	0.8261	1.65	0.0993	0.2583	2.9847
<b>(b)</b>						
ISR	0.9191	0.8606	1.07	0.2859	0.7702	2.6083
Stage III	0.3349	1.0625	0.32	0.7527	1.7505	2.4203
Wexner 1 year ≥9	0.7176	0.8677	0.83	0.4084	0.9854	2.4207
<b>(c)</b>						
ISR	0.1665	1.439	-0.12	0.9079	2.6579	2.9909
Stage III	2.8902	1.7758	1.63	0.104	0.5953	6.3757
Wexner 1 year ≥9	3.673	1.4528	2.53	0.0116*	0.8216	6.5247

**Physical**  
**Mental**  
**Social**

Abbreviations: CI, confidence interval; ISR, intersphincteric resection.

\*Significant difference:  $p < 0.05$ .

## Physical

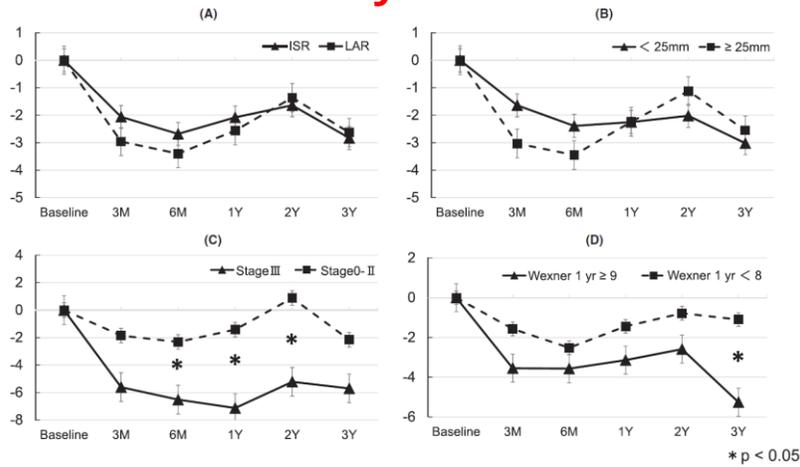


FIGURE 2 Subgroup analysis of PCS. (A) Surgical method (ISR vs. LAR), (B) tumour distance from AV (<25 mm vs. ≥25 mm), (C) pathological stage (Stage III vs. Stages 0-II), (D) Wexner score at 1 year (≥9 vs. <8). The difference between the two groups was statistically significant (\* $p < 0.05$ ). AV, anal verge; ISR, intersphincteric resection; LAR, low anterior resection; PCS, physical component summary.

## Mental

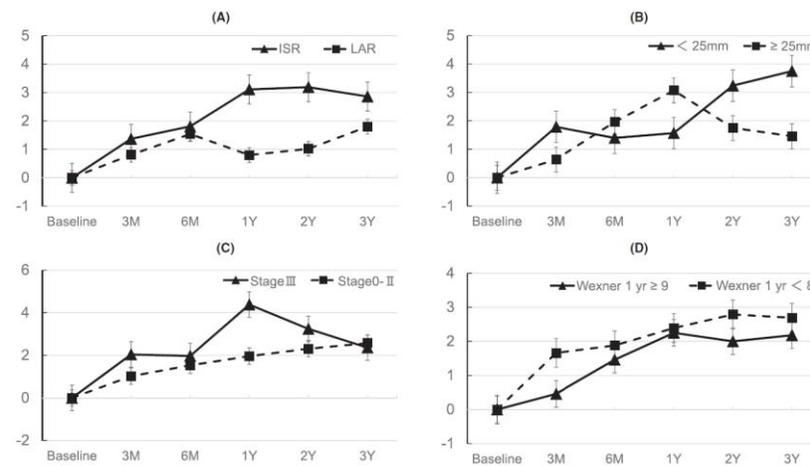


FIGURE 3 Subgroup analysis of MCS. (A) Surgical method (ISR vs. LAR), (B) tumour distance from AV (<25 mm vs. ≥25 mm), (C) pathological stage (Stage III vs. Stages 0-II), (D) Wexner score at 1 year (≥9 vs. <8). AV, anal verge; ISR, intersphincteric resection; LAR, low anterior resection; MCS, mental component summary.

## Social

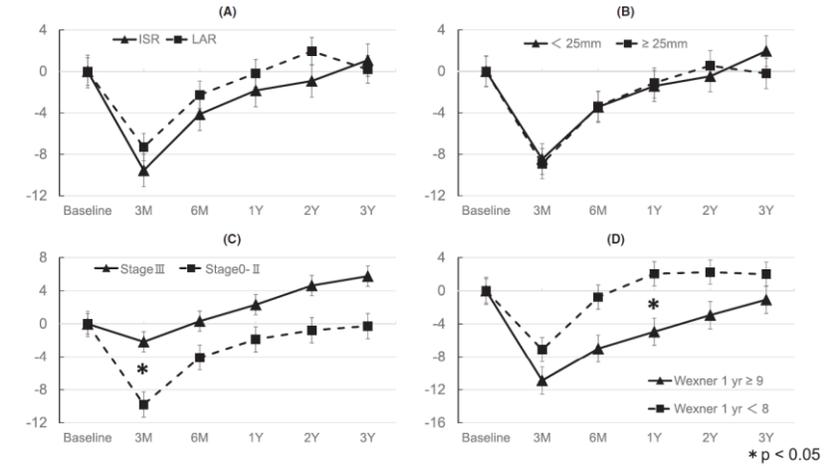


FIGURE 4 Subgroup analysis of RCS. (A) Surgical method (ISR vs. LAR), (B) tumour distance from AV (<25 mm vs. ≥25 mm), (C) pathological stage (Stage III vs. Stages 0-II), (D) Wexner score at 1 year (≥9 vs. <8). The difference between the two groups was statistically significant (\* $p < 0.05$ ). AV, anal verge; ISR, intersphincteric resection; LAR, low anterior resection.

## Conclusions:

Patients with stage III cancer experience prolonged physical challenges, whereas those with bowel dysfunction struggle with the social aspects of QOL. Clinicians should recognize that patients with stage III disease may require additional interventions to support physical recovery after surgery.

# Patient-Reported Outcomes and Surgical Results of Hand-Sewn Versus Stapled Anastomosis for Lower Rectal Cancer Located 4–5 cm From the Anal Verge: A Subanalysis of the Ultimate Study

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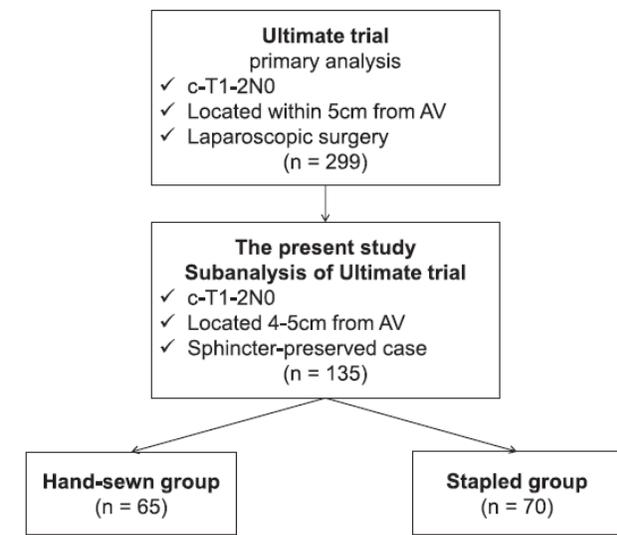


FIGURE 1 | Patient flow diagram. AV, anal verge.

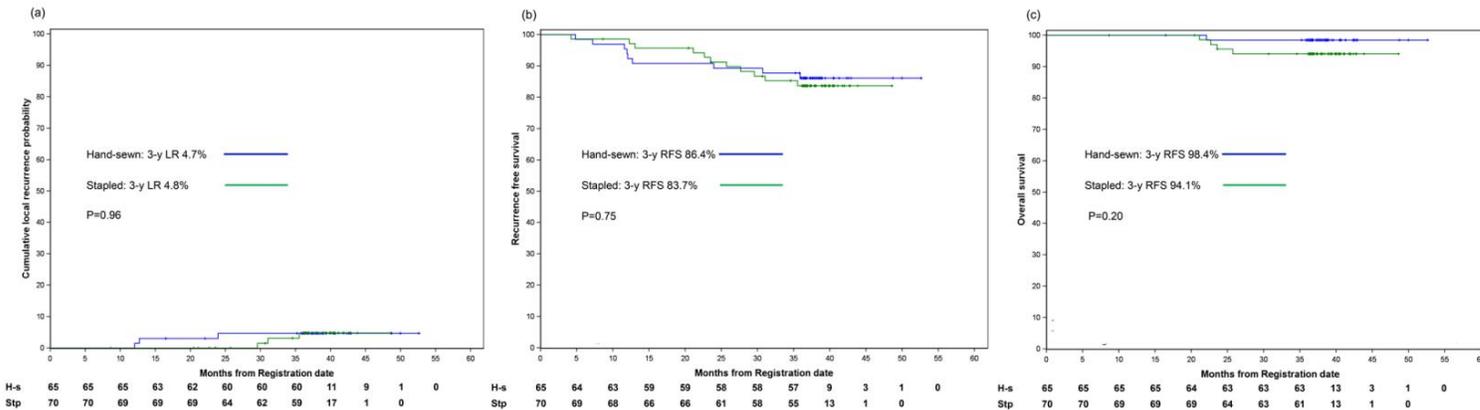
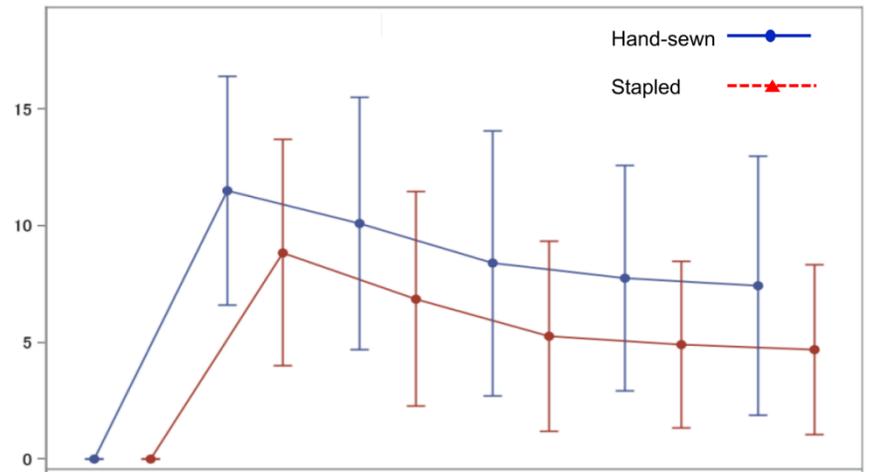


FIGURE 5 | Oncological results. (a) Cumulative local recurrence. 3-y LR, three-year cumulative local recurrence rate. (b) Recurrence free survival. 3-y RFS, three-year recurrence free survival rate. (c) Overall survival. 3-y OS, three-year overall survival rate.

## Conclusions:

Our findings suggest that compared with hand-sewn anastomosis, stapled anastomosis may lead to better anorectal function while maintaining comparable safety and oncological outcomes. stapled anastomosis may be the preferred surgical approach, particularly in cases where oncological safety is secured.



## Late anastomotic complication after laparoscopic surgery for clinical stage I low rectal cancers located within 5 cm of the anal verge: Sub-analysis of the ultimate trial

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### Conclusions:

Anastomotic stenosis and late fistula formation frequently emerge as secondary consequences of early AL, and represent significant complications linked to permanent stoma creation, often proving resistant to treatment.

Intestinal prolapse is a characteristic anastomotic complication of ISR that can be caused by excessive intestinal mobilization.

### Risk factor for anastomotic stenosis

		Event		Univariate p	Multivariable		
		No	Yes		p	Odds	95% CI
Sex	Male	151	22	0.03	0.09	2.42	0.86–6.8
	Female	100	5				
Age (years old)	64 or less	127	13	0.81			
	More than 64	124	14				
Performance status	0	235	25	0.84			
	1	16	2				
Body mass index		22.6 (15.9–34.0)	23.6 (17.3–32.8)	0.03	0.19	4.78	0.46–49.9
	History of cardiovascular disease	Absent	155	10	0.01	0.08	2.17
Present	96	17					
History of diabetes mellitus	Absent	217	25	0.37			
	Present	34	2				
Early anastomotic leakage	Absent	234	19	<0.0001	0.004	4.45	1.61–12.3
	Present	17	8				

- early anastomotic leakage

### Risk factor for permanent stoma

		Event		Univariate p	Multivariable		
		No	Yes		p	Odds	95% CI
pT	0-1	150	6	0.04	0.26	2.05	0.58–7.23
	2-	110	12				
pN	Negative	218	12	0.06	0.50	1.68	0.38–7.34
	Positive	42	6				
Tumor diameter (mm, range)		25 (0–85)	25 (10–60)	0.18			
Distance of lower edge of the tumor from AV (mm, range)		40 (10–60)	30 (10–50)	0.0011	0.004	1.10	1.03–1.18
Operative method	LAR	103	3	0.053	0.51	1.68	0.34–8.24
	ISR	157	15				
Early anastomotic leakage	Absent	240	13	0.004	0.09	4.44	0.80–24.7
	Present	20	5				
Late anastomotic stenosis and/or fistula	Absent	241	7	<0.0001	<0.0001	17.08	4.79–60.92
	Present	19	11				

- tumor distance from AV
- late anastomotic stenosis or fistula

### Risk factor for intestinal prolapse

		Event		Univariate p	Multivariable		
		No	Yes		p	Odds	95% CI
Sex	Male	166	7	0.13	0.21	3.48	0.39–30.94
	Female	104	1				
Age (years old)	64 or less	138	2	0.15	0.15	3.26	0.60–17.82
	More than 64	132	6				
Operative method	LAR	106	0	0.02	0.05	10096 116	NE
	ISR	164	8				
Bowel reconstruction method	Straight	227	5	0.11	0.24	2.71	0.54–13.57
	Others	43	3				
Take down of splenic flexure	No	185	0	<0.0001	0.003	18405 711	NE
	Yes	84	8				

- ISR
- splenic flexure takedown

# Ultimate Trial関連論文

主論文：短期成績、長期成績、主要な肛門・排尿・性機能 国がん東 伊藤：**Annals of Surgery**

副論文①：肛門機能に関するサブグループ解析 順天堂大学 坂本先生、高橋先生：**Colorectal Disease**

副論文②：排尿機能に関するサブグループ解析 がん研有明病院 福長先生：論文Revise後再投稿中

副論文③：性機能に関するサブグループ解析 埼玉医科大国際医療センター 平能先生、石山先生：**Colorectal Disease**

副論文④：QOLに関する詳細な解析 大阪医科薬科大 田中先生、濱元先生：**Colorectal Disease**

副論文⑤：肛門管近傍（AV41-55mm）のCAA/ISRとLARの違い 横浜市立大 渡邊先生、沼田先生：**Annals of Gastroenterological Surgery**

副論文⑥：有害事象もしくは手術から人工肛門閉鎖日が肛門機能に及ぼす影響 東海大学 山本先生：論文作成中

副論文⑦：晩期合併症に関して 広島市立安佐市民病院 下村先生：**Annals of Gastroenterological Surgery**

副論文⑧：腫瘍局在の違いによる治療成績の検討 東北大学 神山先生：論文作成中

副論文⑨：施設間差について 山口大学 鈴木先生（国がん東 塚田が引継ぎ）：論文作成中

副論文⑩：経肛門ドレーンが早期・晩期合併症、肛門機能に及ぼす影響 京都大 肥田先生、星野先生：**Updates in Surgery**

# 最後に

本委員会では  
大腸癌に対する腹腔鏡手術の臨床試験あるいは臨床研究に  
多くの施設の先生方よりご協力いただくことにより  
多くの腹腔鏡下大腸切除に関するエビデンスを  
日本から発信することができました。

多くの症例を登録いただき、あるいは試験成功にご尽力いただきました  
すべての先生方に心より感謝申し上げます。