

ORIGINAL RESEARCH ARTICLE

## Long-term assessment of anorectal function after extensive resection of the internal anal sphincter for treatment of low-lying rectal cancer near the anus

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### Abstract:

**Objectives:** Intersphincteric resection (ISR) for low-lying rectal cancer (LRC) may induce major problems associated with anorectal function. In this study, we assessed the severity of ISR-induced impairment in anorectal function. **Methods:** In total, 45 patients followed up regularly  $\geq 2$  years after diverting ileostoma closure were eligible. The patients underwent ISR (n=35) or conventional coloanal anastomosis without resection of the internal anal sphincter (IAS) (n=10) for treatment of LRC from January 2000 to December 2011. We retrospectively compared anorectal function [stool frequency, urgency, Wexner incontinence scale (WIS) score, and patient satisfaction with bowel movement habits on a visual analog scale (VAS) score] for  $\geq 2$  years after stoma closure between the two groups. **Results:** The median follow-up period was 4.0 years (range, 2.0-6.5 years). Of the total, 17 (48.6%) patients who underwent ISR had poor anorectal function, including two with complete incontinence. Significant differences were found between the groups in the incidence of urgency ( $p=0.042$ ), WIS score ( $p=0.024$ ), and defecation disorder with a WIS score of  $\geq 10$  ( $p=0.034$ ) but not in stool frequency. Based on the VAS score, 45.7% of patients who underwent ISR were dissatisfied with their bowel movement habits ( $p=0.041$ ). **Conclusions:** Extensive resection of the IAS has negative short- and long-term effects on anorectal function.

### Keywords:

low rectal cancer, intersphincteric resection, long-term outcomes of anorectal function

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### Introduction

Intersphincteric resection (ISR) for low-lying rectal cancer (LRC) was reported by Schiessel et al.<sup>1)</sup> in 1994 as a sphincter-preservation technique, and it has made sphincter preservation possible for more patients with LRC near the anus. While the oncological outcomes of ISR do not differ from those of abdominoperineal resection (APR)<sup>2-5)</sup>, long-term functional outcomes and quality of life (QOL) after ISR have not been adequately studied. A few studies of the long-term functional outcomes and QOL after ISR have targeted Asian races, including the Japanese<sup>6-10)</sup>. Among studies performed in Western countries, a systematic review by Martin et al.<sup>11)</sup> showed that perfect continence was achieved in about half of patients who underwent ISR, but that fecal incontinence, which ranged from incontinence to mild soil-

ing to solid stool, occurred in 11%-63% of patients. Thus, many patients undergoing ISR have preoperative anxiety about the possible development of postoperative anorectal dysfunction. Regardless of race, an acceptable QOL after surgery is as important as good oncological results for patients undergoing ISR. Before choosing to undergo ISR, patients with LRC should consider whether the problems associated with postsurgical anorectal function are preferable to life with a colostomy. Especially for older patients whose activity of daily living is worsening, whether to perform ISR should be carefully considered.

The aim of this longitudinal study was to clarify the magnitude of the effect of extensive resection of the internal anal sphincter (IAS) on the long-term outcomes of anorectal function after ISR so that patients with LRC, including older patients, can take informed decisions regarding ISR.

## Methods

### Patients

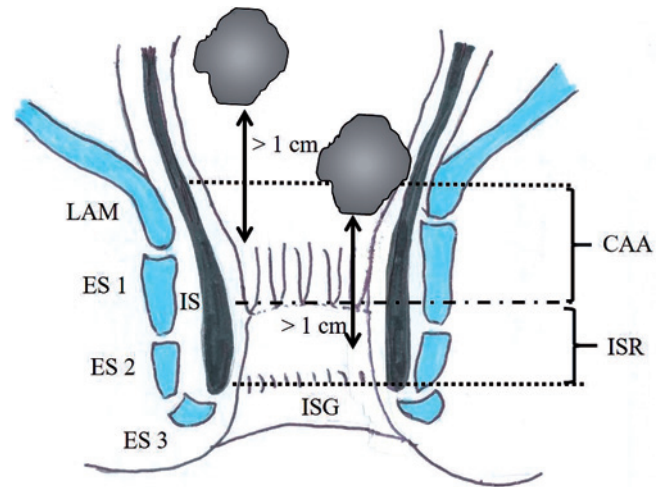
This study was approved by the Ethics Committee at the Toho University Medical Center Omori Hospital (No. 25-213).

The medical records of patients who had undergone ISR for treatment of LRC without preoperative chemoradiation therapy (pre-CRT) at the Toho University Medical Center Omori Hospital from January 2000 to December 2011 were retrospectively evaluated. At our institution, although ISR is indicated for lesions located <5 cm from the anal verge, the following lesions are contraindications for ISR: clinical stage T4 cancer, clinical stage N2-3 cancer, lateral lymph node involvement, and distant metastasis. For all patients, ISR was initially performed by the perineal approach. ISR was performed as open surgery until March 2006 and laparoscopically thereafter. Additionally, patients with LRC who received pre-CRT were excluded from this study because pre-CRT for advanced rectal cancer may be a negative factor for anorectal function after surgery for LRC<sup>12-15</sup>. Our goal was to clarify the clinical impact of extensive resection of the IAS for earlier-stage tumors for which pre-CRT could not be administered.

### Surgical procedure and follow-up

The surgical technique for transanal rectal dissection has been described previously<sup>16</sup>. The procedure should be converted to APR if direct invasion of the external anal sphincter muscle or levator ani muscle is suspected during dissection of the internal and external anal sphincter muscles. Transanal rectal dissection was performed by T.T., K.F., and H.S. The ISR procedure resected the IAS by dissecting the intersphincteric space. In this study, the mucosa and the IAS were incised circumferentially at least 1 cm distal from the lower edge of the tumor, taking care to preserve the IAS as much as possible. In ISR, the distal line of resection was between the dentate line and the intersphincteric groove. Rectal dissection beyond the dentate line but within 1 cm from the dentate line with coloanal anastomosis was defined as a conventional coloanal anastomosis (conventional CAA) (Figure 1).

After surgery, the patients were followed up regularly at the outpatient department of our institution, and anorectal function was investigated at 6 months and 1, 2, 3, 4, and  $\geq 5$  years after diverting ileostoma closure. Patients were given a standardized questionnaire regarding daily stool frequency, fecal urgency (incapacity to restrain for >5 minutes), complete fecal incontinence, the Wexner incontinence scale (WIS) score, and patient satisfaction on a visual analog scale (VAS). Assessment of anorectal function was stopped in patients who died, required a definitive stoma for anastomotic complications, developed distant metastasis and/or local recurrence, or developed psychiatric disorders such as dementia.



**Figure 1.** Surgical procedure.

ISG: intersphincteric groove, AV: anal verge, DL: dentate line, ES1: deep part of external sphincter, ES2: superficial part of external sphincter, ES3: subcutaneous part of external sphincter, IS: internal sphincter, ISR: intersphincteric resection, conventional CAA: conventional coloanal anastomosis

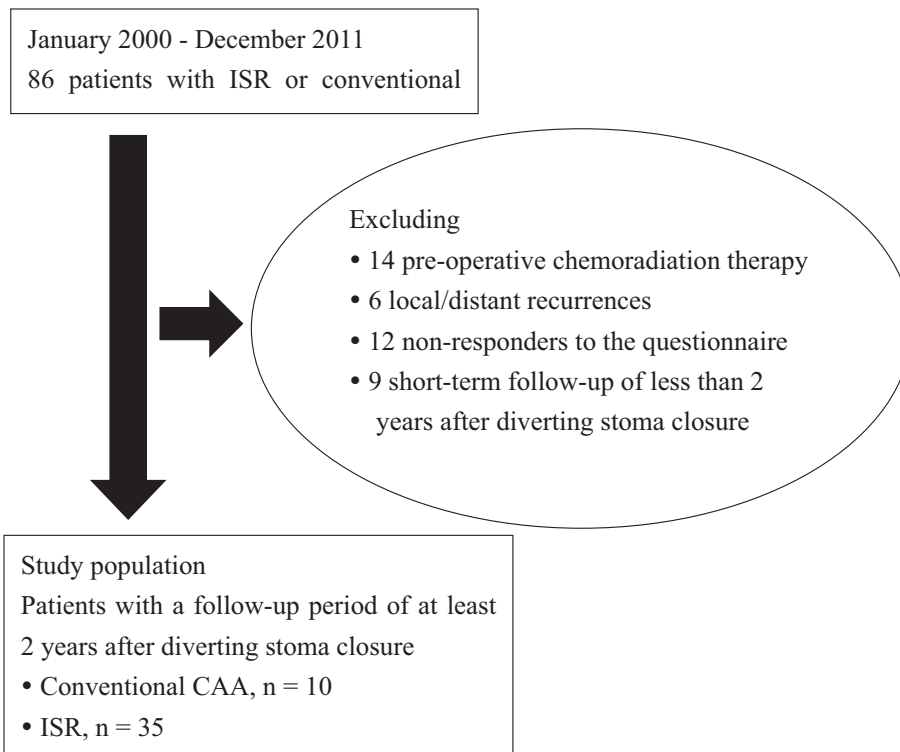
(a): In conventional CAA, the distal line of resection was above the dentate line but within 1 cm from the dentate line. (b): In ISR, the distal line of resection was between the dentate line and the intersphincteric groove, and the dentate line and the intersphincteric groove was included in the resection.

### Functional assessment

All patients who were followed up for  $\geq 2$  years after diverting ileostoma closure were eligible for inclusion in this study. Anorectal function was measured with structured questionnaires at baseline, 1 year, and a long-term follow-up of  $\geq 2$  years after diverting stoma closure to assess the post-ISR improvement in impaired anorectal function over time, and changes from baseline were evaluated. The questionnaires addressed the daily stool frequency, fecal urgency (incapacity to restrain for >5 minutes), WIS score, and patient satisfaction with daily bowel movement habits based on the VAS score. In this study, perfect continence and complete incontinence were defined as a WIS score of 0 and 20, respectively. The functional outcome was considered as a defecation disorder when the WIS score was  $\geq 10$ <sup>17</sup>.

### Statistical analysis

Quantitative data are reported as median (range). Differences between the two groups were assessed with the chi-square test or Fisher's exact test as appropriate. Because stool frequency, urgency, WIS bowel function score, and VAS score were not normally distributed, nonparametric methods were used for analysis. Changes from baseline in bowel function and VAS scores at 1 year and at a long-term follow-up of  $\geq 2$  years after diverting stoma closure were compared using the Wilcoxon *t*-test for nonparametric paired data. A *p* value of <0.05 was considered statistically significant.



CAA = coloanal anastomosis, ISR = internal sphincteric resection

**Figure 2.** Patient selection.

## Results

### Study population

In total, 86 patients with LRC near the anus underwent sphincter-preserving surgery at our institution from January 2000 to December 2011. Of these, 41 patients were excluded from this study: 14 with pre-CRT, 6 with postoperative recurrence, 12 who did not respond to the questionnaire, and 9 with a follow-up period of <2 years after diverting stoma closure. Therefore, 45 patients (35 who underwent ISR and 10 who underwent conventional CAA without resection of the IAS) were eligible for this study (Figure 2).

### Patient characteristics

The clinical characteristics of the 35 patients who underwent ISR and the 10 patients who underwent conventional CAA without resection of the IAS are shown in Table 1. Of the 35 patients, 24 (68.6%) who underwent ISR underwent partial resection of the IAS. Reconstruction using a pouch was performed for only 12 (34.3%) of the 35 patients who underwent ISR because of bulky mesocolic fat tissue or a narrow pelvis. With regard to the histological findings, 15 (42.9%) patients were diagnosed with pathological stage III cancer and were followed up with oral 5-fluorouracil. A significant difference between the two groups was found only in the number of patients who underwent reconstruction using a pouch ( $p=0.029$ ).

**Table 1** Patients Characteristics.

	Conventional CAA (n = 10)	ISR (n = 35)	P
Gender, n			0.491
Male	7	22	
Female	3	13	
Age, y*	60.5 (48–75)	59 (33–77)	0.440
Approach, n			0.611
Open	5	23	
Laparoscopic	5	12	
Resection of the IAS, n			NE
Partial	0	24	
Total	0	11	
Reconstruction, n			0.029
Pouch	0	12	
Straight	10	23	
P Stage, n			0.063
I	5	8	
II	0	12	
III	5	15	
Complication at anastomosis, n			NE
Mucosal prolapse	0	3	
Stricture	0	2	
Follow-up period, years*	3.0 (2.1–5.3)	4.0 (2.0–6.5)	0.075

\*: median (range), CAA: coloanal anastomosis, ISR: intersphincteric resection, NE: not evaluated

**Table 2** Improvement in Anorectal Function after Intersphincteric Resection.

	ISR (n = 35)		p
	Baseline	Long-term	
Follow-up period* days after diverting stoma closure	448 (390–478)	1469 (748–2372)	-
Stool frequency per 24 hours*	2 (0.3–10)	1 (0.3–15)	0.354
Urgency, n (%)	19 (54.3)	13 (37.1)	0.082
Perfect continence, n (%)	5 (14.3)	6 (17.1)	0.129
Complete incontinence, n (%)	3 (8.6)	2 (5.7)	0.500
Defecation disorder, n (%)	24 (68.6)	17 (48.6)	0.309
WIS score*	10 (0–20)	9 (0–20)	0.048
VAS score*	5.05 (0.2–10.0)	7 (0–10.0)	0.025

\*: median (range), ISR: internal sphincteric resection, VAS: visual analog scale, WIS: Wexner incontinence scale

**Improvement in anorectal function over time**

To assess the post-ISR improvement in anorectal function over time, the change in anorectal function from baseline was measured at 1 year and at a long-term follow-up of ≥2 years after diverting stoma closure (Table 2). The median stool frequency per 24 hours, the WIS score, and the incidence of urgency, complete incontinence, and defecation disorder improved over time; a significant difference was observed only in the WIS score ( $p=0.048$ ). Additionally, the VAS score showed a significant improvement from baseline over time ( $p=0.025$ ).

**Long-term outcomes of anorectal function**

Long-term anorectal function was evaluated at a median of 4.0 years (range, 2.0-6.5 years). There was a significant difference in the incidence of urgency between the two groups ( $p=0.020$ ) but not in the stool movement frequency or incidences of perfect continence and complete incontinence. Additionally, there was a significant difference in the median WIS score between patients who underwent conventional CAA (1.5; range, 0-11) and those who underwent ISR (9.0; range, 0-20;  $p=0.024$ ). More patients who underwent ISR complained of the need to wear a pad ( $p=0.043$ ) and implement lifestyle alterations ( $p=0.029$ ) than did patients who underwent conventional CAA without resection of the IAS. Moreover, defecation disorder (WIS score ≥10) was found in only 1 (10.0%) patient in the conventional CAA group, whereas 17 (48.6%) patients in the ISR group developed defecation disorder ( $p=0.034$ ) (Table 3).

Satisfaction with bowel movement habits was measured with the VAS. Although 90.0% of the patients who had undergone conventional CAA without resection of the IAS reported high satisfaction (VAS score of ≥7), only 54.3% of the patients who had undergone ISR were satisfied with their bowel movement habits ( $p=0.041$ ) (Table 4).

**Table 3** Long-term Outcomes of Anorectal Function after Conventional Coloanal Anastomosis and Intersphincteric Resection.

	Conventional CAA (n = 10)	ISR (n = 35)	p
Stool movement frequency*	1.0 (0.3–5.0)	1.0 (0.3–15)	0.320
Urgency, n (%)	0	13 (37.1)	0.020
Perfect continence, n (%)	2 (20.0)	6 (17.1)	0.794
Complete incontinence, n (%)	0	2 (5.7)	0.922
WIS score*	1.5 (0–11)	9 (0–20)	0.024
Fecal incontinence, n (%)	6 (60.0)	25 (71.4)	0.858
Gas incontinence, n (%)	6 (60.0)	25 (71.4)	0.858
Need to wear a pad, n (%)	3 (30.0)	25 (71.4)	0.043
Lifestyle alteration, n (%)	2 (20.0)	21 (60.0)	0.029
Defecation disorder, n (%)	1 (10.0)	17 (48.6)	0.034

\*: median (range), CAA: coloanal anastomosis, ISR: intersphincteric resection, WIS: Wexner incontinence scale

**Table 4** Long-term Satisfaction with Bowel Habits Measured by Visual Analog Scale.

	Conventional CAA	ISR	p
VAS			
<5 (%)	1 (10)	7 (20.0)	
5–7 (%)	0	9 (25.7)	0.041
7≤ (%)	9 (90)	19 (54.3)	

VAS: visual analog scale, CAA: coloanal anastomosis, ISR: intersphincteric resection

**Discussion**

ISR has broadened the choices of sphincter-preserving procedures for selected patients with LRC. However, impaired anorectal function after ISR remains a major problem, even if the anus is preserved. Akagi et al.<sup>18)</sup> reported that whereas perfect continence was found in 13.9%-86.3% of patients after ISR, 0.0%-5.9% of patients who underwent ISR required a colostomy. Reported risk factors associated with anorectal dysfunction after ISR include pre-CRT<sup>12,19)</sup>, total resection of IAS<sup>19,20)</sup>, the tumor level and height of the anastomosis<sup>17)</sup>, and age<sup>21)</sup>. In particular, pre-CRT has been considered to be a significant negative factor for anorectal function after ISR because of ischemic and fibrous changes in the pelvis tissue induced by irradiation<sup>13)</sup>. In this study, we excluded patients who received pre-CRT and were thus able to assess the long-term anorectal function of selected patients who underwent ISR and CAA without resection of the IAS to clarify the magnitude of extensive resection of the IAS for earlier-stage tumors. Our data show that extensive resection of the IAS adversely affects the long-term outcomes of anorectal function after surgery, even if pre-CRT is not administered, and suggest that ISR might alter continence. After conventional CAA, the rectal capacity amounts to only 20% of normal<sup>22)</sup>. Therefore, reconstruction using a pouch may be useful for frequent bowel movements

after ISR. Hallböök et al.<sup>23)</sup> reported that J-pouch anastomosis was associated with better bowel function than straight anastomosis. Bretagnol et al.<sup>24)</sup> reported that frequency, urgency, the WIS score, and the Fecal Incontinence Severity Index were significantly better following colonic J-pouch reconstruction than following straight CAA. In the present study, however, the daily stool frequency of patients who underwent ISR was similar to that of patients who underwent conventional CAA without resection of the IAS with a median follow-up period of about 4 years. As Heriot et al.<sup>25)</sup> and Schiessel et al.<sup>26)</sup> stated, a high stool frequency may be a transient problem after ISR.

In the present study, 5.7% of the patients who underwent ISR had complete incontinence (defined as a WIS score of 20), although patients who underwent conventional CAA without resection of the IAS did not. Additionally, 48.6% of the patients who underwent ISR developed defecation disorder, which was arbitrarily defined as a WIS score of  $\geq 10$ , and a significant difference was found between the two groups. Moreover, the median WIS score of the patients who underwent ISR was significantly higher than that of patients who underwent conventional CAA. Finally, compared with patients who underwent conventional CAA, most patients in the ISR group needed to wear a pad and make lifestyle alterations. Thus, most patients' daily lives were affected by extended resection of the IAS for treatment of LRC.

As many researchers have reported, patients who undergo ISR tend to accept their postoperative complications over time. Barisic et al.<sup>27)</sup> reported that although 11% of patients had fecal incontinence, the majority of patients had acceptable continence, and QOL scores were good for all functional and symptom components. Denost et al.<sup>17)</sup> demonstrated a significant negative correlation between the WIS score and follow-up duration in 101 patients who underwent ISR. Chi et al.<sup>28)</sup> reported that continence significantly improved over time based on the relationship between the WIS score and follow-up duration. In the present study, as the WIS score improved over time, the VAS score for bowel movement habits increased, and there was a significant negative correlation between the WIS and VAS scores. However, patients' satisfaction with bowel movement habits after ISR remains controversial. Kuo et al.<sup>29)</sup> noted that 91.0% of patients were satisfied with the functional outcome after ISR, although 38.0% of patients reported stool fragmentation, 23.8% of patients experienced nocturnal defecation, and 33.3% of patients required antidiarrheal medications. Gamagami et al.<sup>30)</sup> and Rullier et al.<sup>31)</sup> showed that extensive resection of the IAS had a good functional long-term outcome in half of the patients. In the present study, which targeted the Japanese population, 45.7% of the patients who underwent ISR were dissatisfied with their ISR-induced impairment in anorectal function, 37.1% of patients had urgency, and 48.6% had defecation disorder with a WIS score of  $\geq 10$  at the long-term follow-up. Although most surgeons might think that the patients who underwent ISR were satis-

fied that they avoided a permanent colostomy, we would like to emphasize the discrepancy between their satisfaction with their bowel movement habits and avoidance of a permanent colostomy.

The average life span of the Japanese population has lengthened to a great extent. In 2014, the life expectancy in Japan was 80.50 years for males and 86.83 years for females; these are the highest life expectancies worldwide. The average life span of the Japanese could still be increasing. More recently, some researchers reported that there was no difference in global QOL following ISR or CAA versus APR<sup>32-35)</sup>. Patients may not always obtain benefits from sphincter preservation for treatment of LRC near the anus, and we should recognize that global QOL is not worse after APR than ISR.

There were some limitations in this study. First, this was a retrospective single-center study of patients treated by three surgeons with a high level of experience; transanal rectal dissection requires a high level of experience. Second, the sample size was small, which may have introduced bias in the results. Therefore, a prospective study should be planned to clarify the magnitude of the effect of extensive resection of the IAS on the long-term outcomes of anorectal function after ISR. Finally, functional outcomes were assessed longitudinally using a questionnaire for patients who were followed up, but the questionnaire did not address the patients' QOL. Therefore, we cannot comment on the QOL in detail.

## Conclusion

In the present study, extensive resection of the IAS had a negative effect on both the short- and long-term outcomes of anorectal function in patients with LRC who had not received pre-CRT. However, most symptoms associated with impaired anorectal function were acceptable. They improved over time, and their acceptance increased concomitantly. However, despite avoiding a permanent stoma, about half of the patients were not satisfied with their daily bowel movement habits. ISR may be an option for a very select group of patients with LRC near the anus. In sphincter-preserving operations for treatment of LRC near the anus, IAS should be preserved to the greatest extent possible.

### Conflicts of Interest

The authors declare that there are no conflict of interest.

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