



# Functional outcomes of intersphincteric resection in low rectal tumors

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## ABSTRACT

**Objective:** Currently, sphincter-saving procedures are increasingly performed in the treatment of low rectal cancers. This study aimed to evaluate the outcomes of patients who underwent intersphincteric resection.

**Material and Methods:** This was a single-center, retrospective, cross-sectional study. We evaluated the electronic data files of 29 patients who had intersphincteric resections at our institute between 2008 and 2018. Bowel function outcomes were assessed prospectively using Wexner incontinence score. Histopathological, surgical and functional outcomes were analyzed.

**Results:** Mean age of nine female and 20 male patients included in the study was  $55.8 \pm 12.8$  (30-76) years. A tumor-free surgical margin was achieved in all patients. Anastomotic leakage was detected in two patients. Mean Wexner incontinence score of 20 patients who still had functional anastomosis was 8.35, whereas 65% of the patients (n= 13) had a good continence status. There was no relationship between the continence status and sex, tumor distance from anal verge, T stage, distal surgical margin, and lymph node involvement. Twenty-one patients underwent primary coloanal anastomosis and eight patients underwent two-stage coloanal anastomosis.

**Conclusion:** In the treatment of distal rectal cancer, adequate oncological surgery and relatively acceptable functional outcomes can be obtained with intersphincteric resection technique in suitable patients.

**Keywords:** Fecal incontinence, rectum cancer, rectum resection, outcome assessment

## INTRODUCTION

For more than a century, abdominoperineal resection has been the standard surgical treatment option for rectal cancer located close to the anal canal (1). However, a persistent stoma significantly reduces patients' quality of life (2). Owing to advances in oncology and surgical techniques, several new techniques have been described aimed at preserving gastrointestinal continuity and improving functional outcomes. As a result, the intersphincteric resection (ISR) technique, defined in 1994, has been widely accepted (3,4). Based on the principle of dissection of the anatomical plane between the internal and external anal sphincters, this technique saves the patient from permanent colostomy. Partial functional loss is expected after partial or total excision of the internal sphincter, which is an important part involved in continence mechanism (5). Although there are conflicting results in the literature, studies on functional outcomes show that anal function is preserved satisfactorily in most cases after ISR (6-8).

The aim of this study was to report the functional outcomes after ISR.

## MATERIAL and METHODS

This was a single-center retrospective study conducted at a university hospital in Turkey. The study involved patients with low rectal cancer located at <4 cm from the anal verge and who underwent ISR between January 2008 and December 2018.

Surgical electronic data files, histopathological results, and Oncology Department's follow-up files of patients were retrospectively evaluated. Fecal continence conditions of the patients were evaluated prospectively by phone calls or during outpatient clinic visits. Continence was evaluated using the Wexner continence score.

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Wexner continence scores above eight were considered as poor functional outcome (4).

All patients were operated on by two colorectal surgeons with a standard open total mesorectal excision (TME) technique. Annually, an average of 80-100 rectal cancer surgeries is performed in our clinic. The exclusion criteria for ISR were invasion of the levator ani muscle, anal incontinence, and patient preference. Hand sewn coloanal anastomosis technique was used for all anastomoses. Bowel preparation was undertaken, and prophylactic antibiotics were administered routinely.

The patients were divided into two groups, i.e., primary anastomosis group and delayed anastomosis group. In the primary anastomosis group, coloanal anastomosis was performed in the same session, and a protective stoma was routinely used. In the delayed anastomosis group, 5 cm of the colon's segment was exteriorized from the anus in the first session. In the delayed anastomosis group, a protective stoma was not routinely used, and it was performed as surgeon's choice in only two patients. After 7-10 days, the exteriorized segment was excised, and delayed coloanal anastomosis was performed (two-stage Turnbull-Cutait coloanal anastomosis).

The study protocol was approved by the local ethics committee (Medical Research Ethics Committee, Approval Number 19-7T/39) and was conducted in accordance with the principles of the Declaration of Helsinki. Data were analyzed using IBM SPSS v.21.0 software package for Windows. Categorical data were assessed by Fisher's exact test, and numerical data were assessed by Mann-Whitney U test.

Tumor distance from the anal verge was measured with a rigid rectoscope. All patients were staged with preoperative magnetic resonance imaging, and anal sphincter invasion was excluded. None of the lesions were suitable for local excision. Patients with Stage 2 or Stage 3 disease received preoperative long-term radiotherapy (RT) and concurrent chemotherapy. The total dose of RT was 50.4Gy with 1.8Gy/fraction to the gross tumor and 45Gy to pelvic lymph nodes. For concomitant chemother-

apy, capecitabine was administered orally at a dose of 825 mg/m<sup>2</sup> twice daily throughout the radiation therapy or 5 fluorouracil 380 mg/m<sup>2</sup> and leucovorin 20 mg/m<sup>2</sup> were administered every 28 days (days 1-4) for two cycles. All patients underwent standardized TME.

## RESULTS

Twenty-nine patients, including 20 males and nine females, were included in the study. The characteristics of the patients included in the study are shown in Table 1. When evaluated in terms of the indications for surgery, two patients had in situ carcinoma that was not suitable for local excision. All of the other patients had well or moderately differentiated adenocarcinoma. Long-term neoadjuvant chemoradiotherapy was administered to 21 patients. When measurement was performed using a rigid rectoscope, mean distance of the tumor from the anal verge was 3.51 ± 0.63 cm. Distal and circumferential surgical margins were tumor-free in all patients. The excision of the posterior vaginal wall was performed in one patient with suspicion of tumor invasion. On pathological examination, mean distal surgical margin distance was 1.79 ± 0.7 cm. Pathological complete response (ypT0N0) was achieved in two patients. The number of removed lymph nodes was 14.6 ± 8.4 (4-32). Postoperative histopathological results are shown in Table 2.

Eight patients underwent delayed coloanal anastomosis, and 21 patients underwent primary coloanal anastomosis. Anastomotic leakage was not detected in the delayed anastomosis group, whereas anastomotic leakage was detected in two (9.5%) patients in the primary anastomosis group. The difference between the rates of anastomotic leakage was not statistically significant (p= 0.517).

Twenty out of the 29 patients still had functional anastomosis, which is shown in Figure 1. Fecal continence status was assessed by reaching all of these twenty patients. In the primary anastomosis group, 14 patients had a functional stoma because five patients had mortality and two patients had a permanent stoma due to anastomotic stricture.

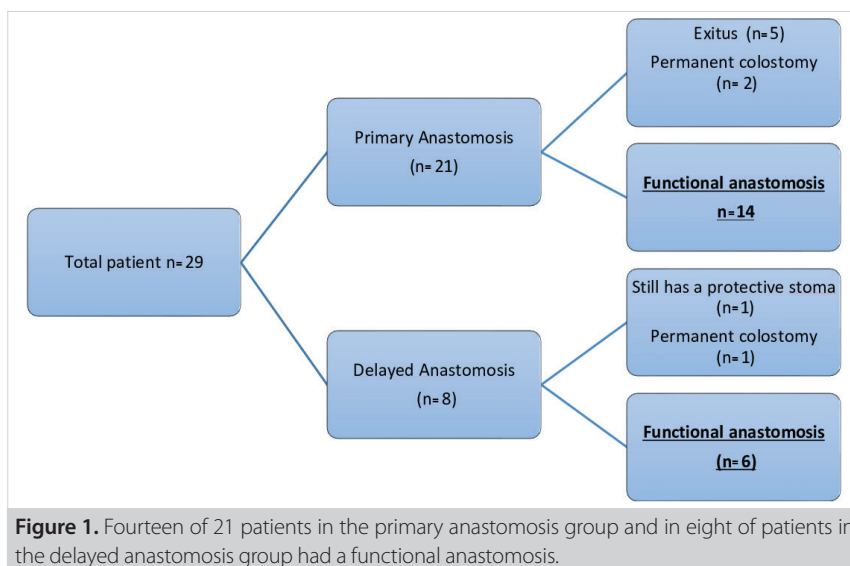
**Table 1.** Patient characteristics

	Primary Anastomosis (n= 21)	Delayed Anastomosis (n= 8)	Total (n= 29)	
Age (years)	55.47 ± 12.7	56.75 ± 12.2	55.83 ± 12.8	Range (30-76)
Sex (Female/male)	8/13	1/7	9/20	31.0%/69.0%
Tumor distance from anal verge (cm)	3.57 ± 0.6	3.37 ± 0.7	3.51 ± 0.6	Range (2.0-4.0)
Neo-adjuvant Chemo-radiotherapy (Yes/No)	12/9	7/1	19/10	65.5%/34.5%
Distal surgical resection margin (cm)	1.81 ± 0.7	1.74 ± 0.5	1.79 ± 0.7	Range (0.3-3.0)
Number of dissected lymph nodes	14.52 ± 8.0	14.62 ± 9.4	14.55 ± 8.4	Range (4-32)
Anastomotic leak	2	0	2	6.9 %
Length of stay (days)	10.47 ± 4.8	12.12 ± 1.3	10.93 ± 4.36	Range (5-30)

**Table 2.** Postoperative histopathological results

		n (29)	(%)
Stage			
	0 (Tis)	2	6.9
	PCR	2	6.9
	I	5	17.2
	II A	10	34.5
	II B	3	10.3
	II C	0	0
	III A	2	6.9
	III B	3	10.3
	III C	0	0
	IV A	2	6.9
PNI (+)		8	27.6
LVI (+)		3	10.3
Satellite tumor (+)		2	6.9
R0 resection		29	100

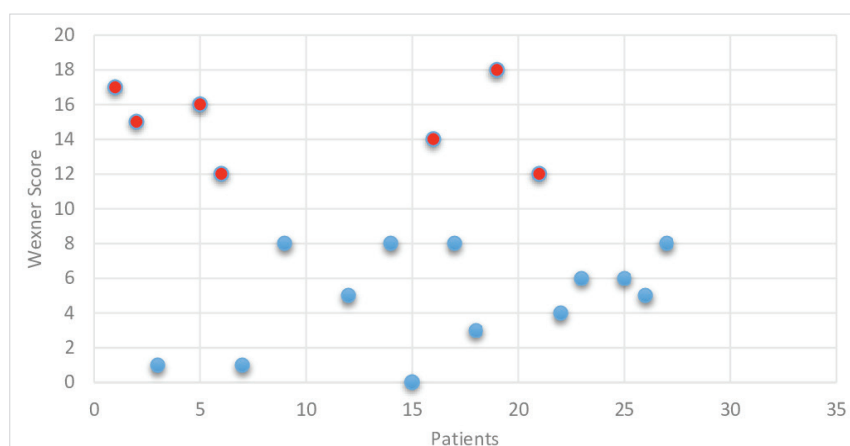
PCR: Pathologic complete response, PNI: Perineural invasion, LVI: Lymphovascular invasion.



In the delayed anastomosis group, six patients had a functional anastomosis as diverting stoma closure had not yet been performed in one individual at the time of the study and one had permanent stoma due to local recurrence. Mean Wexner incontinence score of all patients was 8.35 (0-17) (Figure 2). While 65% of the patients (n= 13) had a good continence status, 35% (n= 7) had poor continence status (Wexner score > 8). According to univariate analysis, no relation was found between continence status and sex (p= 0.651), distance of the tumor from the anal

verge (p= 0.608), T stage (p= 0.370), distal surgical margin distance (p= 0.439), and lymph node involvement (p= 0.587).

The rate of severe incontinence in the delayed anastomosis group was 33.3% (n= 2) and 35.7% (n= 5) in the primary anastomosis group (Table 3). No statistically significant difference was found between the two groups in terms of incontinence scores (p= 0.660). The relationship of the variables with severe fecal incontinence was presented in the Table 4."



**Figure 2.** The distribution of Wexner scores (Red dots shows the patients with severe fecal incontinence).

**Table 3.** Wexner incontinence scores according to type of anastomosis

		Primary Anastomosis (n= 14)	Delayed Anastomosis (n= 6)	p
Wexner score		8.21 ± 5.53	8.67 ± 6.15	0.873
Type of incontinence	Solid	0.71 ± 0.91	0.83 ± 1.16	
	Liquid	1.64 ± 1.00	1.83 ± 1.32	
	Gas	2.93 ± 1.26	2.83 ± 1.16	
	Wears ped	1.07 ± 1.43	1.33 ± 1.75	
	Lifestyle alteration	1.93 ± 1.38	1.83 ± 1.47	
Severe incontinence <sup>a</sup>		5/14 (35.7%)	2/6 (33.3%)	0.660

<sup>a</sup>Wexner score > 8 defined as severe incontinence.

**Table 4.** The relationship of the variables with severe fecal incontinence (Logistic regression analysis)

	Odds ratio	95% Confidence interval	p
Age	0.861	0.75-0.99	<b>0.036</b>
Sex	0.352	0.024-5.221	0.448
Tumor distance from anal verge	0.515	0.054-4.895	0.563
Distal surgical resection margin	2.049	0.386-10.881	0.4
Type of anastomosis <sup>b</sup>	0.954	0.054-16.861	0.974

<sup>b</sup>Delayed (Turnbull Cutait)/Primary coloanal anastomosis.

## DISCUSSION

This study presented functional outcomes of 29 patients undergoing ISR for low rectal cancer. These results revealed that R0 resection could be achieved in all patients using the sphincter preservation technique, and a good functional outcome could be achieved at a rate of 65%. The treatment of rectal cancer is constantly evolving. TME and neoadjuvant therapies have been introduced into routine practice to reduce the high local recurrence rates in the treatment of rectal cancer. Abdominoperineal resection is still used as the gold standard treatment method in

many patients with distal rectal cancer (9,10). When adequate oncological outcomes are achieved, the efforts are directed to the development of new methods to avoid performing permanent colostomy in patients and achieve better functional outcomes. As a result of these investigations, Schiessel et al. have described ISR in very low rectal tumors (3).

Accurate patient selection is vital in ISR. The most important goal in rectal cancer surgery is to achieve a tumor-free surgical margin. Nowadays, ISR has been increasingly used with the reduction of acceptable distal surgical margin to 1 cm (11,12). In

terms of oncological outcomes, the most important indicator of rectal cancer surgery's quality is the circumferential and distal surgical margins. In a systemic review of 14 retrospective studies, it has been shown that a negative surgical margin could be achieved in 97% of patients undergoing ISR (13). In our study, mean distal surgical margin distance was  $1.79 \pm 0.72$  cm, and a tumor-free circumferential surgical margin was achieved in all patients. These data are consistent with the literature and indicate that ISR is an oncologically reliable method. In cases in which surgical margin adequacy is suspected, abdominoperineal resection should not be avoided.

There is no standard method for evaluating bowel function after ISR. In this study, we evaluated bowel function with Wexner incontinence score which offers an easily understandable and objective assessment of the patient (14). In this study, mean Wexner incontinence score of the patients was 8.35 (0-17). Different cutoff values have been used in the literature to define the severity of fecal incontinence with the Wexner score. As originally described by Rothbarth et al., a Wexner score of  $\geq 9$  is usually associated with complete gas incontinence and more than one fecal incontinence per month, and these patients experience limitations in their social lives (15). Upon considering a Wexner score of nine as a cutoff value for incontinence, 65% ( $n=13$ ) of the patients in our study had an good continence status, whereas 35% ( $n=7$ ) had poor continence. Although the mean of Wexner scores is 8.35, a score of 8 or less in 65% of patients may seem like a consistency. This can be explained by the fact that some patients have very high scores. The distribution of the patients' Wexner scores can be seen in Figure 2. It is important to manage patient expectations well and inform the patient accurately. Similar to most studies, ISR achieved not perfect but acceptable functional outcomes in our study. A cutoff frequency for acceptable functional outcome has not been defined. Saito et al. have considered a Wexner score less than 10 to be a "good" functional outcome and reported that 70% of the patients in their series had good continence after intersphincteric resection (16). In their series evaluating 101 patients, Denost et al. have found that the median Wexner incontinence score was 11 and 47.5% of the patients were classed as having a good functional result (Wexner score  $\leq 10$ ) (17). These functional results are not perfect but tolerable for many patients. Consequently, a realistic conversation should be made with the patients before surgery regarding acceptable outcomes. It must be explained that the average expectation will not be complete continence but will involve gas incontinence, partial soiling, and partial liquid incontinence in most patients. During the planning of the surgery, open discussion with the patient is required, mentioning that the procedure is an alternative to permanent colostomy and not to normal defecation (18).

Various researchers have reported considerably different continence outcomes after ISR. In our study, 65% of the patients had

an acceptable continence level. Some series have reported a good continence level in 29% of the patients, while others have reported good continence level in 76% of the patients (19-21). One of the main reasons for this difference is that many factors affect the continence status after rectal cancer surgery. As is known, loss of rectal reservoir, damage to autonomic nerves, and neoadjuvant radiotherapy are factors affecting continence status (19). In physiological studies, it has been shown that the basic loss of function in patients undergoing ISR is the decrease in resting pressure due to the loss of internal sphincter (22). It has been shown that the distance of the anastomosis level from the anal verge and the resection of more than half of the internal sphincter affects the continence status after ISR (23). In their study investigating the risk factors for fecal incontinence after ISR, Denost et al. have found that the factors affecting incontinence are the tumor being close to the anal ring and the anastomosis being closer than 2 cm to the anal verge. In our series, we did not find a statistically significant relationship between the level of anastomosis and the distance of the tumor to the anal verge and severe incontinence.

In 1961, Turnbull from Cleveland and Cutait from Brazil independently described a delayed coloanal anastomosis after a pull-through procedure (24,25). With the advent of stapled anastomoses, this method has lost its popularity. The Turnbull-Cutait technique is currently used to prevent the formation of a permanent stoma in selected cases with pelvic sepsis due to anastomotic leakage, rectovaginal or rectourethral fistula, and perianal involvement in Crohn's disease (26). A systematic review of seven retrospective studies has demonstrated that the Turnbull-Cutait technique reduced the likelihood of opening permanent stoma while offering low rate of anastomotic leakage and pelvic morbidity along with reasonable fecal continence (27). The use of Turnbull-Cutait technique has recently gained currency in patients undergoing elective procedures. In a recent randomized controlled trial, Biondo and colleagues have compared the two-stage Turnbull-Cutait anastomosis with the primary anastomosis after ISR in cases with very low rectal cancer (28). They have demonstrated that postoperative complication rates and oncological and functional outcomes of the two groups at one year were similar. Based on the results of this multicenter randomized controlled trial, the authors have argued that a delayed coloanal anastomosis could be a valid alternative strategy to avoid transient stoma. In our study, a two-stage anastomosis was performed in eight patients, and the number of patients was insufficient to make a subgroup analysis.

Retrospective, single-center study design and small size of the study population are important limitations of the present study. Another limitation is that the assessment time of the patients was not homogeneous since the present study evaluated the current functional status of the patients, and the follow-up

durations were different among the patients. The strengths of the study are the prospective performance of functional assessment, accessibility of all the patients who survived, and being one of the most extensive patient series published in our country.

In conclusion, tumor-free surgical margins and acceptable functional outcomes can be achieved in suitable patients with ISR technique in the treatment of very low rectal cancer. ISR is an alternative that can save patients from permanent colostomy. It is essential to manage patient expectations and thoroughly inform the patient.

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**Ethics Committee Approval:** The study protocol was approved by (Ege University Medical Research Ethics Committee (Decision no: 19-7T/ 39, Date: 01/08/2019).

**Peer-review:** Externally peer-reviewed.

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**Conflict of Interest:** The authors have no conflicts of interest to declare.

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### ORJİNAL ÇALIŞMA-ÖZET

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## Alt rektum kanserlerinin intersfinkterik rezeksiyonunun işlevsel sonuçları

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### ÖZET

**Giriş ve Amaç:** Günümüzde alt rektum kanserlerinin tedavisinde sfinkter koruyucu işlemler giderek daha fazla uygulanmaktadır. Bu çalışmanın amacı, intersfinkterik rezeksiyon yapılan hastaların sonuçlarını değerlendirmektir.

**Gereç ve Yöntem:** Bu çalışma, tek merkezli, retrospektif ve kesitsel bir analizdir. 2008-2018 yılları arasında kliniğimizde intersfinkterik rezeksiyon uygulanan 29 hastanın elektronik veri dosyaları değerlendirildi. Bağırsak fonksiyonları prospektif olarak Wexner inkontinans skoru kullanılarak değerlendirildi. Histopatolojik, cerrahi ve fonksiyonel sonuçlar değerlendirildi.

**Bulgular:** Çalışmaya alınan dokuz kadın, 20 erkek hastanın yaş ortalaması  $55,8 \pm 12,8$  (30-76) yıl idi. Tüm hastalarda tümörsüz cerrahi sınır elde edilmişti. İki hastada anastomoz kaçağı saptandı. Halen fonksiyonel bir anastomozu olan 20 hastanın ortalama Wexner inkontinans skoru 8,35 idi. Hastaların 13'ünde (%65) iyi bir kontinans durumu mevcuttu. Kontinans durumu ile cinsiyet, tümörün anal verge uzaklığı, T evresi, distal cerrahi sınır ve lenf nodu tutulumu arasında ilişki saptanmadı. Yirmi bir hastaya primer koloanal anastomoz, sekiz hastaya iki aşamalı koloanal anastomoz uygulandı.

**Sonuç:** Distal rektum kanseri tedavisinde uygun hastalarda intersfinkterik rezeksiyon tekniği ile yeterli onkolojik cerrahi ve nispeten kabul edilebilir fonksiyonel sonuçlar elde edilebilir.

**Anahtar Kelimeler:** Fekal inkontinans, rektum kanseri, rektum rezeksiyonu, sonuç değerlendirmesi

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