

# Intersphincteric Resection for Distal Rectal Cancer, Oncological and Function Outcomes (Short-Term Follow-Up)

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## Abstract

**Background:** Intersphincteric resection (ISR) is a sphincter-sparing procedure for treating distal rectal cancer.

**Aim of the work:** Evaluation of oncological and functional outcomes after ISR.

**Patients and methods:** A prospective study comprising twenty patients with distal (low) rectal cancer discovered and treated between 2021 and 2024. All patients received neoadjuvant therapy, after which they were evaluated for eligibility for ISR. Following this, they were assessed and monitored for outcomes.

**Results:** The median follow-up period was  $16.4 \pm 2.26$  months, ranging from 12 to 20 months. One patient (5%) died. Two patients (10%) experienced local recurrence (LR). Disease-free survival (DFS) was found in 17 patients (85%). Postoperative morbidity was found in the form of pelvic abscess (5%), anastomotic leak (5%), wound infection (30%), rectovaginal fistula (5%), anal stenosis (5%), and transient voiding and erectile dysfunction (15%). Functional outcomes were assessed using the Wexner score with median scores of 11, 7.5, and 5.5 at 3, 6, and 12 months, respectively, showing significant improvement over time. Good functional outcomes were noted in 14 patients (70%), while six (30%) had poor outcomes.

**Conclusion:** ISR is a viable, practical, and feasible option for LRC with satisfactory oncological and functional outcomes.

**Keywords:** Intersphincteric resection (ISR); Low rectal cancer (LRC); Neoadjuvant chemoradiotherapy (NCRT)

## 1. Introduction

Colorectal cancer is the third common cancer in the world. Surgery for rectal cancer has evolved since 1907, when Miles announced his radical operation, abdominoperineal resection (APR), and described it as a treatment for distal rectal tumors.<sup>1</sup>

Due to the pelvic width limitation and the need for a 5cm distal free margin, abdominoperineal resection (APR) is traditionally performed. However, APR often leads to a poor quality of life (QoL) in the form of a permanent stoma, making it unacceptable for many patients.<sup>2</sup>

Recently, the 2cm or even 1cm rule of distal resection margin (DRM), after better understanding of tumor spread and lymphatic

drainage patterns, advances in surgical technologies such as improved stapling devices techniques, the discovery of the importance of the total mesorectal excision (TME) and optimal circumferential resection margin (CRM) which offer an effective control of LR and improve survival rates. In addition, NCRT plays a significant role in reducing the tumor size. All these factors promote anal-preserving surgeries and decrease the need for APR in certain cases.<sup>2,3</sup>

Efforts have been made to enhance this approach. In 1994, Schiessel et al<sup>4</sup> introduced ISR followed by handsewn coloanal anastomosis (CAA) as an anal-preserving procedure for LRC located close to the anus. This method has demonstrated fair postoperative results, particularly in maintaining postoperative continence.<sup>5</sup>

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ISR is defined as an anal-preserving operation, performed through both abdominal and anal approaches in principle respect of TME, and involves partial or complete removal of the internal anal sphincter (IAS). This technique is prescribed particularly for LRC (defined as a tumor 6 cm or less from the anal verge). 5 ISR can be performed in three variations: partial (removal of upper third of IAS), subtotal (removal of upper two-thirds of IAS), or total ISR (complete removal of IAS) for type I, II, III LRC described by Ruller, provided no infiltration to the intersphincteric plane (ISP).<sup>6</sup>

Many studies indicate that oncological outcomes of ISR are acceptable. However, medical concerns about functional outcomes are still challenging. ISR may result in some sort of anal dysfunction, which is mainly due to loss of the rectum.<sup>7,8</sup>

This study aimed to evaluate the oncological and functional outcomes of ISR after a short follow-up period.

## 2. Patients and methods

We conducted this paper on twenty patients presented to our outpatient clinic with LRC, fulfilling our criteria in the years of the study.

Place and years of the study:

Said Jalal Hospital and Maadi Military Hospital between 2022 and 2024.

Inclusion and exclusion Criteria:

Patients with distally located tumors who meet the selection criteria for ISR are included. According to the Ruller classification, this includes types I, II, and III LRC. Eligible patients must have a tumor located no more than 2 cm from the anorectal junction and should possess normal sphincter function. Conversely, patients with clinically T4, have type IV LRC (tumors that invade the external anal sphincter and ISP), or have poor anal function, are contraindicated for the procedure.

Preoperative preparation and staging:

A comprehensive history, along with clinical and physical examinations, was conducted. This included a digital rectal examination, measurement of carcinoembryonic antigen (CEA) levels, a full colonoscopy, and chest and pelvic-abdominal MRI/CT scans. Additionally, a preoperative functional questionnaire was administered, along with frequency assessment tools such as the Wexner score to evaluate preoperative anal function. NCRT is administered for locally advanced tumors (T3 or pathological lymph nodes) as recommended by the National Comprehensive Cancer Network (NCCN) guidelines. A reassessment using rectal MRI is performed 6 to 8 weeks after NCRT. Patients meeting the criteria for our study will undergo

surgical resection after providing informed consent.

### Surgical procedure

Surgery was performed approximately 6 to 8 weeks after NCRT, as prescribed by Schiessel, following these steps:

#### Abdominal Step (supine position):

This procedure can be performed using an open or a laparoscopic approach. Ligation of both the Inferior Mesenteric Artery (at its origin) and vein (at the duodenojejunal junction) is carried out, followed by complete mobilization of the splenic flexure of the colon. Next, a sharp dissection is performed along the "holy plane," a term coined by Dr. Heald (avascular plane between mesorectal and pelvic fascia). This is crucial for achieving an effective TME and avoiding damage to surrounding nerves. Dissection extended to the pelvic floor. (Figure 1).

#### Transanal Step (lithotomy position):

A lone star retractor or using multiple sutures to fix the anal mucosa away to the gluteal region for better exposure, then an Incision was started 1cm distal to the tumor as a free margin in a circular manner and dissected along the ISP till connecting the abdominal dissection proximally, followed by complete removal of the rectum through the anus. (Figure 2).

#### Restoration of the bowel continuity.

A handsewn CAA with absorbable suture is done in all patients to restore bowel continuity.

Creation of a temporary protective ileostomy or transverse colostomy.

As almost all of the patients have received NCRT, we prefer the creation of protective ileostomy or transverse colostomy that can be then closed after 2\_3 months.

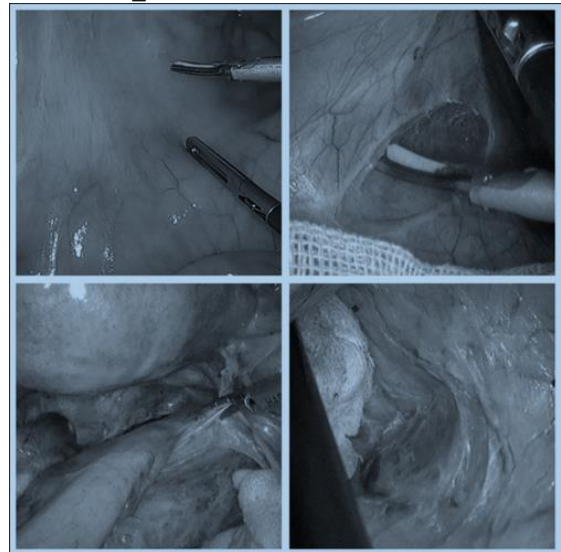


Figure 1. Laparoscopic approach for the abdominal part of ISR.

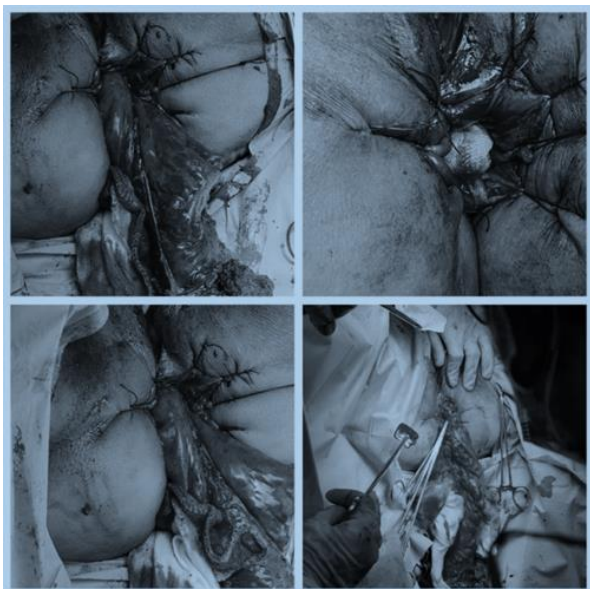


Figure 2. Transanal approach of ISR.

#### Postoperative assessment:

Patients postoperatively transmitted to ICU then to the ward after stabilization of their condition. Postoperative complications are documented and scheduled for assessment. Patients with positive pathological lymph nodes receive adjuvant chemotherapy. Follow-up includes evaluating anal function using the Wexner score, as well as assessing for LR throughout the 24-month study period.

#### Statistical analysis:

Data were collected, revised, coded, and entered into the Statistical Package for Social Science (IBM SPSS), version 27. The comparison between groups regarding qualitative data was done using the Chi-square test and/or Fisher's exact test. The p-value was considered significant if it was more than 0.05.

### 3. Results

Sociodemographic and post-operative morbidity:

The total number was 20 cases: 12 males (60%) and 8 females (40%). The mean age was  $47.75 \pm 11.02$ , ranging from 24\_65 years. All patients received neoadjuvant therapy. The average distance of the lower edge of the tumor after NCRT was  $5.6 \pm 0.82$  cm, with a range of 4 to 7 cm. Operation approaches were Laparoscopic in 4 cases (20%) and 16 cases (80%). The type of ISR conducted was subtotal in 2 cases (10%) and partial in 18 cases (90%). The Mean postoperative hospital stay was  $7.95 \pm 2.38$  and ranged from 5\_12 days. Early postoperative complications are illustrated in Figure 3.

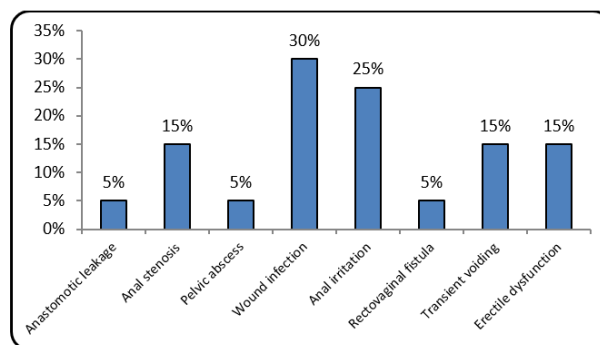


Figure 3. Schematic data of early postoperative outcome.

#### Oncological outcomes:

The mean CRM was  $10.35 \pm 1.76$  and ranged from (7\_13 mm), and all CRMs were free. The mean DRM was  $17.85 \pm 2.74$  and ranged from 12 to 22 mm, and all distal margins were free from tumors. Complete R0 was achieved in all cases (100%). Table 1 illustrated pathological results in study patients.

Table 1. Pathological results in studied patients.

TOTAL NO.= 20		
CRM (MM)	Mean $\pm$ SD	$10.35 \pm 1.76$
	Range	7 – 13
POSITIVE CRM	Free margin	20 (100%)
DISTAL MARGIN (MM)	Mean $\pm$ SD	$17.85 \pm 2.74$
	Range	12 – 22
(T- STAGE)	(T1)	4 (20%)
	(T2)	16 (80%)
(N- STAGE)	(N0)	13 (65.0%)
	(N1)	6 (30.0%)
	(N2)	0 (0.0%)
	(N3)	1 (5.0%)
M STAGE	M0	0 (100%)
STAGE	Stage I	13 (65%)
	Stage II	0 (0%)
	Stage III	7 (35%)
COMPLETE RESECTION (R0)	R0	20 (100%)

Median follow-up was  $16.4 \pm 2.26$  months and ranged from 12 to 20 months. Adjuvant chemotherapy was given to 8 cases (40%). LR was observed in two patients (10%). DFS was 85% and 15% not survive (LR or metastasis). Mortality was in one patient (5%). Table 2 illustrated oncological outcomes.

Table 2. Oncological outcomes in studied patients.

TOTAL NO.= 20		
FOLLOW-UP PERIOD IN MONTHS	Mean $\pm$ SD	$16.4 \pm 2.26$
	Range	12 – 20
LR	No	18 (90%)
	Yes	2 (10%)
LR TREATED BY	APR	1 (50%)
	Colostomy	1 (50%)
DISTANCE METASTASIS	No	18 (90%)
	Yes	2 (10%)
DFS	Not survive	3 (15%)
	Survive	17 (85%)
MORTALITY	No	19 (95%)
	Yes	1 (5%)
RECEIVE ADJUVANT CT	No	12 (60%)
	Yes	8 (40%)

#### Functional outcomes:

The median Wexner score at 3, 6, and 12 months was 11, 7.5, and 5.5, respectively. Also, the mean score at 3, 6, and 12 months was  $11.15 \pm 2.26$ ,  $8.15 \pm 3.07$ , and  $5.90 \pm 3.02$ , with a significant decrease in the Wexner score over the months of follow-up. Figure (4).



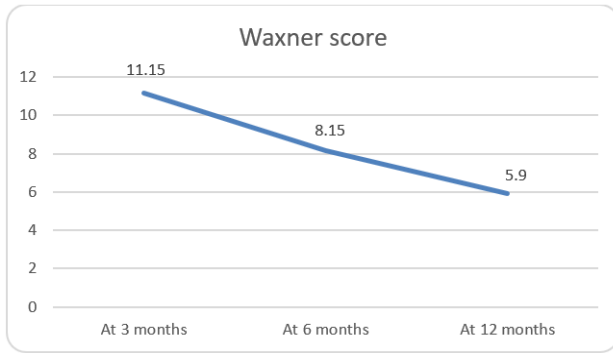


Figure 4. Wexner score of the studied patients after surgery at 3, 6, and 12 months

Incontinence to solid was found in one patient (5%), to liquid in 3 patients (15%), and to flatus in 7 patients (35%). Difficulty feces/flatus discrimination 10 patients (50%), stool fragmentation (more than 2 evacuations in one hour). 6 patients (30%). Alternation of lifestyle in 7 patients (35%) wearing a pad was found in 6 patients (30%). Figure (5).

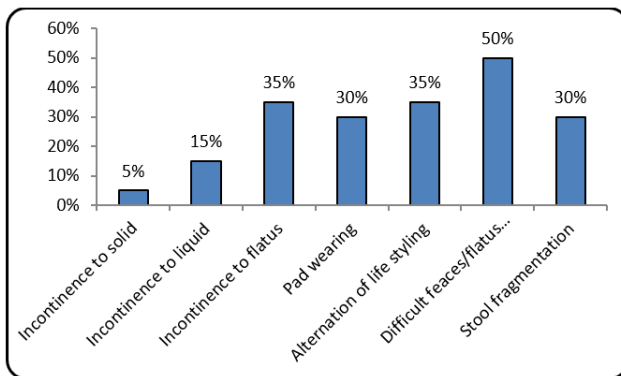


Figure 5. Chart of function outcomes

Analysis of outcomes patients (oncological and function):

In summary, we categorized the outcomes into good and poor oncological and functional results. Poor oncological outcomes were observed in patients who developed LR after surgery, with 2 patients affected (10%).

Poor functional outcomes occurred in patients who did not regain normal anal function or who experienced a significant decrease in their Wexner score compared to those who showed notable improvement. We noted that 14 patients (70%) had good functional outcomes, while 6 patients (30%) had poor outcomes. Additionally, we classified patients who developed LR and were treated with APR or colostomy as having poor functional outcomes by the end of the study.

#### 4. Discussion

Recently, APR should only be considered when the tumor infiltrates the sphincter complex and in preexisting unsatisfactory sphincter function, as regular TME technique and preoperative NCRT resulted in a lower rate of LR with good

conservation of postoperative genitourinary function.<sup>9</sup> And both Swedish and Dutch rectal cancer trials show that NART increases survival benefits, tumor down-staging in 40%, a decrease in LR by 60%, and an increase in R0 resection by 90% after surgery.<sup>10</sup> In our study, 100% of cases received NCRT according to guidelines, as all presented to our clinic with clinical mesorectal lymph node involvement. A complete pathological response was not achieved, but down-staging enables complete resection R0 in 100% of cases.

There is no postoperative mortality. The only mortality case was due to recurrence and metastasis and represented 5% of cases. Martin et al.<sup>11</sup> conducted a retrospective meta-analysis that showed postoperative mortality was 0.8% (ranged from 0% to 6%) and morbidity was 25.7% in form of anastomotic leakage, bowel ileus, sepsis and bleeding. Bediako et al.<sup>12</sup> retrospective study reported postoperative mortality (12%) and morbidity (41%) at 30 days postoperative.

Urinary and sexual dysfunction are notable issues after rectal surgery. Injury to sympathetic nerves may give rise to bladder instability and ejaculatory problems, while injury to the parasympathetic nerves results in detrusor instability and erectile dysfunction. Many studies verified that laparoscopic ISR is better for the visualization and preservation of these nerves.<sup>13</sup>

Compared to APR, Peng et al.<sup>14</sup> in their meta-analysis study, ISR showed 2.89 hospital stay days shorter and an increase in erectile and sexual dysfunction in the APR groups. Zedan et al.<sup>15</sup> reported voiding difficulties in 3.7%, erectile and ejaculatory dysfunction were in 14.6%, and 15.2% respectively. In our study, transient voiding occurred in three patients (15%), while erectile dysfunction was noted in three cases (15%).

The primary objective of rectal cancer surgery is to achieve clear surgical margins. CRM and DRM are the most predictive factors for cancer recurrence and the quality of rectal surgery. A systematic review of 14 retrospective studies showed that a negative surgical margin can be achieved in 97% of ISR.<sup>16</sup> DRM at least 1-2 cm is currently adequate for LRC; CRM should be at least 1mm.

Park et al.<sup>8</sup> reported no significant differences in survival or LR between ISR and APR. Numerous studies have explored the oncological aspect of ISR for LRC; they discovered that LR rate varied between 0% to 12%. Valentin et al.<sup>17</sup> reported LR was 12.5% for T2 staged. Saito et al.<sup>18</sup> LR was 10.3%. Kim et al.<sup>19</sup> LR was identified in 13 out of 301 patients with significant association with the pathological stage.

In our study, LR was observed in two patients (10%). The recurrence was found in the pelvic wall treated by palliative colostomy with

chemotherapy and along the anastomotic line that was treated with APR. DFS was 85% during the mean follow-up period of the study. Three cases did not survive; two cases developed LR, and one developed distant bone metastasis without LR.

Documenting these aspects (LR, DFS, and distant metastasis) is only for descriptive purposes, as they lack statistical significance due to the short follow-up period, high selection criteria, and the small number of patients studied. However, a Pathological state was significantly associated with recurrence, which is consistent with other studies at this point.

There is currently no standard method for evaluating bowel function after ISR. In our study, we assess bowel function using the Wexner score, which provides a simple, straightforward, and objective tool for understanding and measuring the patients' condition.

Saito et al.<sup>18</sup> reported that a Wexner score of less than 10 is associated with good functional results, with 70% of patients having good continence after ISR. Bozbiyik O et al.<sup>16</sup> Wexner's score was 8.35. Rothbarth et al.<sup>20</sup> reported that less than 9 is linked to gas incontinence and experiencing fecal incontinence more than once a month. Tokoro et al.<sup>21</sup> evaluated anal function after ISR; the mean was 11.5. His study noted an improvement in patients with partial ISR in contrast to patients with subtotal and total ISR.

Zidan et al.<sup>15</sup> retrospective study conducted on 164 patients the mean Wexner score was found to be 6. The reported rates of incontinence were 11%, 4.9%, and 4.3% for flatus, fluid, and solids, respectively. Fecal urgency was present in 17.7%, stool fragmentation in 18.9%, nocturnal soiling in 17.1%, and pad wearing in 23.8%.

In our study, the mean Wexner score associated with poor outcomes was 10, while those with good functional results had scores around 70%. The correlation analysis we conducted between poor and good anal function, considering factors such as age, gender, and type of ISR, was non-significant. However, we observed that poor function was more commonly found in older patients compared to younger ones and was associated with the subtotal ISR type. These findings may be limited by the small number of patients in the study and the short follow-up period.

#### 4. Conclusion

ISR is an intriguing alternative to the conventional APR. As a sphincter-preserving approach, it is a safe and valuable surgical option, offering favorable oncological and functional outcomes for carefully selected patients with LRC.

## Disclosure

The authors have no financial interest to declare in relation to the content of this article.

## Authorship

All authors have a substantial contribution to the article

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## Conflicts of interest

There are no conflicts of interest.

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