Original Article

Incidence and risk factors of low anterior resection syndrome with validation of low anterior resection syndrome score questionnaire among the Egyptian patients

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ABSTRACT

Background: Since the priority for patients with rectal tumors is a complete cure from the disease with free safety margins for tumor removal and complete control of systemic disease, postoperative squeals, which may last for life, have been overlooked. It was important to study the quality of life after surgery and chemoradiotherapy, especially the impact on bowel functions, in order to improve them and give psychological support to the patient.

Patients and Methods: This is a single-center prospective cohort study held in the Surgery Department from December 2017 to December 2022. It included 120 patients who had surgery for rectal tumors. Only patients who filled out the low anterior resection syndrome (LARS) score questionnaire, which was correlated to scores of the three subscales of EORTC QLQ-C30 v3 (The European Organisation for Research and Treatment of Cancer-Quality of Life Questionnaire Core 30 version3), were included.

Results: One hundred twenty patients were included, 40 patients had no LARS, 45 patients had minor LARS, and 35 patients had major LARS. LARS score was highly significantly higher with a *P value* less than 0.001 in patients with old age, high BMI, low rectal and T4 tumors, open surgery, hand-sewn coloanal anastomosis, intersphincteric resection surgery, total mesorectal excision, patients who had neoadjuvant and adjuvant therapy.

Conclusion: The LARS questionnaire is a valid and reliable tool to evaluate LARS among Egyptian patients. Risk factors of discrimination can be found in those patients.

Key Words: Anterior resection, diarrhea, low anterior resection syndrome, rectal tumors.

Received: 7 June 2024, **Accepted:** 2 July 2024, **Published:** 4 October 2024

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ISSN: 1110-1121, October 2024, Vol. 43, No. 4: 1511-1519, © The Egyptian Journal of Surgery

INTRODUCTION

With advances in surgical treatment for rectal cancer and the impact of radiochemotherapy on tumor size and resectability, the number of sphincter-sparing procedures has increased, as has the rate of patients with bowel dysfunction[1-3]. This significant consequence ranges from partial and infrequent to total incontinence, with increased frequency and urgency, or constipation and incomplete emptying, all of which are classified as low anterior resection syndrome (LARS)[4,5].

Many tools have been used to evaluate the postoperative changes in bowel functions, such as the Wexner score for fecal incontinence and the QLQ-C30 scales.

Recently, in literature, the LARS score has been evaluated for its validity by translation of the LARS questionnaire into many languages worldwide.

In Egypt, studying LARS is not clear. In this study, we evaluated the LARS, its incidence and risk factors, and whether the LARS questionnaire can be used as a valid test for its evaluation or not.

Rationale: the incidence of rectal tumors has been rising over the last few decades. Most cases were followed up at the Oncology Department. LARS occurrence after surgery is not well studied in Egypt. The evaluation of its symptoms and risk factors is not clear. There is an overlap between it and symptoms due to the side effects of chemoradiotherapy. This study evaluated the incidence and risk factors of LARS and how to evaluate them using the LARS questionnaire.

Hypothesis: the LARS score questionnaire is a valid tool for the evaluation of LARS. LARS is more common with low rectal tumors.

Aim of work: to improve quality of life after resection of rectal tumors.

Objectives: to study symptoms, risk factors, and incidence of LARS and to assess the validity of the LARS score questionnaire.

DOI: 10.21608/EJSUR.2024.296025.1097

PATIENTS AND METHODS:

This study is a single-center prospective cohort study conducted in the General Surgery Department from December 2017 to December 2022. It included 120 patients with rectal tumors who were 18 years old or older and had tumor resection surgery. Both sexes were included. Patients were followed up after surgery, and data were collected from General Surgery and Oncology Departments records. Patients were classified into three groups (no LARS group, minor LARS group, and major LARS group). Patients below 18 years old, those with abdominoperineal surgery, emergency surgery, temporary stoma, patients with dementia or recurrence, and nonresponders to questionnaires were excluded. The study protocol was approved by the Institutional Research Board (IRB) with registration ID #11280-4\12-2023 in adherence to the Helsinki Declaration of 1975, as revised in 2000 and registered in clinical trials by ID number NCT06314945 on March 15, 2024. Informed written consent was taken from all participants.

We used a translated form of the original LARS questionnaire. It was downloaded from the network and translated by two different Egyptian native Arabic translators. A third translator evaluated it blindly for Egyptian Arabic translation. Patients who underwent surgery for rectal tumors and who were followed up at the Oncology Department after finishing their adjuvant therapy course were contacted to fill out the questionnaire as well as an Arabic-translated copy of the EORTC QLQ-C30 v3 questionnaire. An assistant was provided for illiterate and blind patients. Surgery data was obtained from general surgery department records.

The LARS questionnaire consisted of five questions. Its score ranged from 0 to 42. Scores of 0-20 meant no LARS, 21–29 meant minor LARS, and 30-42 meant major LARS. They evaluated the following parameters: the nature of incontinence (flatus, liquid seepage, liquid incontinence, solid incontinence), the incontinence type (active awareness, passive nonawareness, urge incontinence), the quantity of loss, the frequency of incontinence episodes, and accompanying complaints such as abdominal/pelvic pain and obstructed defecation.

Three scales from the Arabic-translated version of the EORTC QLQ-C30 v3 questionnaire were filled out by the patient at the same time. The quality of life scale consisted of two questions; each question had a score from 0 to 7. The score calculated by the equation: Global health status/ quality of life: S={(RS−1) range}×100, RS (I1+I2+I3+….) \n (s: score, RS: raw score, I: item, n: number). Two symptom subscales were used: the diarrhea and the constipation subscales. Each one had a single question with a score from 1 (not at all) to 4 (very much); their score was calculated by the equation S={(RS−1) range}×100 (s: score, RS: raw score). To evaluate the LARS questionnaire's reliability, a test–retest evaluation was done after 2 weeks by 72 patients. According to the LARS score, there were three groups: no LARS (40 patients), minor LARS (45 patients), and major LARS (35 patients).

Outcome measures

Sociodemographic data, for example, age, sex, medical disease, and BMI, were evaluated in the three groups. Surgical data as surgical technique (open or laparoscopic assisted), surgery type [AR, LAR, ultralow anterior resection (ULAR), and intersphincteric resection (ISR)], type of anastomosis (colorectal or coloanal), mesorectal excision (partial or total), and anastmotic technique (hand sewn or stappled). Oncologic outcomes were also assessed as adjuvant, neoadjuvant therapy, and tumor size (T stage).

Statistical design

The collected data were computerized and statistically analyzed using the SPSS program (Statistical Package for Social Science), version 27.0 (Armonk, NY: IBM Corp, 2020). Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as the mean±SD. A *P value* of less than 0.05 indicates significant results, and a value of less than 0.001 indicates highly significant results. Bland-Altman plot was used for the calculation of the degree of agreement.

RESULTS:

Sociodemographic data and medical history are shown in (Table 1). Table 1 showed that the age of the studied participants ranged between 30 and 75 years, with a mean of 49.6 years. More than half of them were males (68.2%). BMI ranged between 20 and 36, with a mean of 24.8 kg/ m2. More than half of the participants did not have any medical disease (62.5%). Diabetes was found to be the most frequent medical disease among the studied group (19.2%).

The relationship between the LARS score and different parameters among the studied groups is shown in (Table 2). Table 2 showed that there were highly significant relations between LASR score and anastomosis type, mesorectal excision, neoadjuvant chemotherapy, anastomotic technique, surgery type, and tumor size (T stage). Also, there was a significant relationship between the score and a medical disease, adjuvant chemotherapy, and surgical technique.

The LARS score was found to be significantly higher among hepatic patients, patients above 45 years old, those who had coloanal anastomosis, total mesorectal excision (TME), receiving neoadjuvant and adjuvant chemotherapy, those who underwent open technique and hand sewing anastomosis, those who underwent ISR and ULAR surgeries, and those with stages T3, T4.

Tables 3 and 4 showed that there was a significant positive correlation between LARS score and age, BMI, and the occurrence of diarrhea. However, there was a significant negative correlation between the score and quality of life.

Different parameters discrimination among different LARS groups are shown in (Table 5). Test–retest reliability is shown in (Table 6), which indicates that there was excellent agreement between both LARS tests (interclass coefficient=0.99, 95% confidence interval=0.998–0.999), and in (Fig. 1), which is a Bland–Altman plot with 95% limits of agreement showing the difference between the LARS score at the first and second tests.

Table 1: Baseline sociodemographic data and medical history of the studied group

Variables	Studied group (*N*=120) [*n* (%)]
Sex	
Female	38 (31.7)
Male	82 (68.2)
Age	
Mean±SD	49.6±11.2
Range	30–75
BMI	
Mean±SD	24.8±2.9
Range	20–36
Medical disease	
Normal	75 (62.5)
Cardiac	4 (3.3)
Diabetic	23 (19.2)
Diabetic and hypertensive	3 (2.5)
Hepatic	2 (1.7)
Hypertensive	13 (10.8)

Table 2: Relationship between low anterior resection syndrome score and different parameters among the studied group

Variables	Studied group (*N*=120)	Test	*P*
Age			
<45 years	18 (8–27.25)	–4.383	<0.001 (HS)
>45 years	29 (21–36)		
Sex			
Female	29 (18.25–34.25)	–1.595	0.111 (NS)
Male	21 (8.75–29.25)		
Tumor location			
0–5 cm	29 (21–39)	33.49	<0.001 (HS)
6–10 cm	21 (9–26.5)		
>10 cm	9 (8–21)		
Medical disease			
Normal	21 (8–29)		
Cardiac	32 (30–37.5)	17.78	0.003 (S)
Diabetic	30 (21–38)		
Diabetic and hypertensive	21 (21)		
Hepatic	34.5 (29–34)		
Hypertensive	23 (19–31)		
Anastomosis type			

Coloanal	29 (21–37.5)	–4.882	<0.001 (HS)
Colorectal	19 (8–24)		
Mesorectal excision			
Partial	18 (8–23.5)	–5.835	<0.001 (HS)
Total	29 (21–38)		
Neoadjuvant therapy			
No	19 (8–28)	–4.339	<0.001 (HS)
Yes	29 (21–36.5)		
Adjuvant chemotherapy			
No	19 (8–27)	–2.764	0.006 (S)
Yes	26 (19–36)		
Surgical technique			
Laparoscopic assisted	21 (8–28.2)	–3.292	0.001 (S)
Open	29 (21–36)		
Hand sewing or stapler			
Hand sewn	34 (27–39)	–6.626	<0.001 (HS)
Stapler	19 (8–25)		
Surgery type			
AR	18 (8–23.5)	41.96	<0.001 (HS)
ISR	39 (30.75–40)		
LAR	21.5 (17.25–29)		
ULAR	32 (28–38)		
Staging			
T1	8 (7.25–26.25)	29.85	<0.001 (HS)
T2	19 (8–29)		
T3	29 (21–38)		
T4	36 (26.75–38.5)		

Data expressed as median (interquartile range)
HS, highly significant; ISR, intersphincteric resection; S, significant; ULAR, ultralow anterior resection.

Table 3: The correlation between low anterior resection syndrome score and EORTC QLQ-C30 v3 scales score, age and BMI

	LARS score	
Variables	*r*	*P*
Age	0.388	<0.001
BMI	0.297	0.001
QOL	−0.907	<0.001
Diarrhea	0.830	<0.001
Constipation	−0.066	0.474

LARS, low anterior resection syndrome; QOL, quality of life.

Table 4: Relationship between different low anterior resection syndrome grades and quality of life among the studied group

Variables	No LARS (*N*=40)	Minor LARS (*N*=45)	Major LARS (*N*=35)	*P* value
QOL				
Median	8	24	38	<0.001 (HS)
IQR	7–16	21–29	35–40	
Diarrhea				
Median	0	33.3	100	<0.001 (HS)

IQR	–	33.3–66.6)	–	
Constipation				
Median	0	0	0	0.181 (NS)
IQR	–	–	–	

IQR, interquartile range; LARS, low anterior resection syndrome; QOL, quality of life.

Table 5: Different parameters among different low anterior resection syndrome groups

Variables	Group I: no LARS (*N*=40) [*n* (%)]	Group II: minor LARS (*N*=45) [*n* (%)]	Group III: major LARS (*N*=35) [*n* (%)]	*P* value
Age				
<45 years	26 (65)	11 (24.4)	3 (8.6)	<0.001 (HS)
>45 years	14 (35)	34 (75.6)	32 (91.4)	
Sex				
Female	10 (25)	13 (28.9)	15 (42.9)	0.222 (NS)
Male	30 (75)	32 (71.1)	20 (75.1)	
Tumor location				
0–5 cm	6 (15)	24 (53.3)	28 (80)	<0.00 (HS)
9–10 cm	21 (52.5)	18 (40)	6 (17.1)	
>10 cm	13 (32.5)	3 (6.7)	1 (2.9)	
Medical disease				
Normal	32 (80)	29 (64.4)	14 (40)	0.006 (S)
Cardiac	0	0	4 (11.4)	
Diabetic	3 (7.5)	8 (17.8)	12 (34.3)	
Diabetic and hypertensive	0	2 (4.4)	1 (2.9)	
Hepatic	0	1 (2.2)	1 (2.9)	
Hypertensive	5 (12.5)	5 (11.1)	3 (8.6)	
Anastomosis type				
Coloanal	12 (30)	31 (68.9)	30 (85.7)	<0.001 (HS)
Colorectal	28 (70)	14 (31.1)	5 (14.3)	
Mesorectal excision				
Partial	34 (85)	13 (28.9)	6 (17.1)	<0.001 (HS)
Total	6 (15)	32 (71.1)	29 (82.9)	
Neoadjuvant therapy				
No	26 (65)	11 (24.4)	6 (17.1)	<0.001 (HS)
Yes	14 (35)	34 (75.6)	29 (82.9)	
Adjuvant chemotherapy				
No	14 (35)	7 (15.6)	4 (11.4)	0.02 (S)
Yes	26 (65)	38 (84.4)	31 (88.6)	
Surgical technique				
Laparoscopic assisted	26 (65)	22 (48.9)	10 (28.6)	0.007 (S)
Open	14 (35)	23 (51.1)	25 (71.4)	
Hand sewing or stapler				
Hand sewn	2 (5)	18 (40)	29 (82.9)	<0.001 (HS)
Stapler	38 (95)	27 (60)	6 (17.1)	
Surgery type				
AR	27 (67.5)	10 (22.2)	4 (11.4)	<0.001 (HS)

ISR	0	2 (4.4)	10 (28.6)	
LAR	11 (27.5)	24 (53.3)	9 (25.7)	
ULAR	2 (5)	9 (20)	12 (34.3)	
Staging				
T1	12 (30)	1 (2.2)	3 (8.6)	<0.001 (HS)
T2	26 (65)	17 (37.8)	8 (22.9)	
T3	2 (5)	22 (48.9)	17 (48.6)	
T4	0	5 (11.1)	7 (20)	

ISR, intersphincteric resection; LARS, low anterior resection syndrome; ULAR, ultralow anterior resection.

Table 6: Degree of agreement between the first and second low anterior resection syndrome tests among the studied group

Variables		ICC	95% CI	*P* value
LARS score				
First time	24.33±10.6	0.99	0.998–0.999	0.727
Second time	24.36±10.7			

ICC, interclass coefficient; LARS, low anterior resection syndrome.

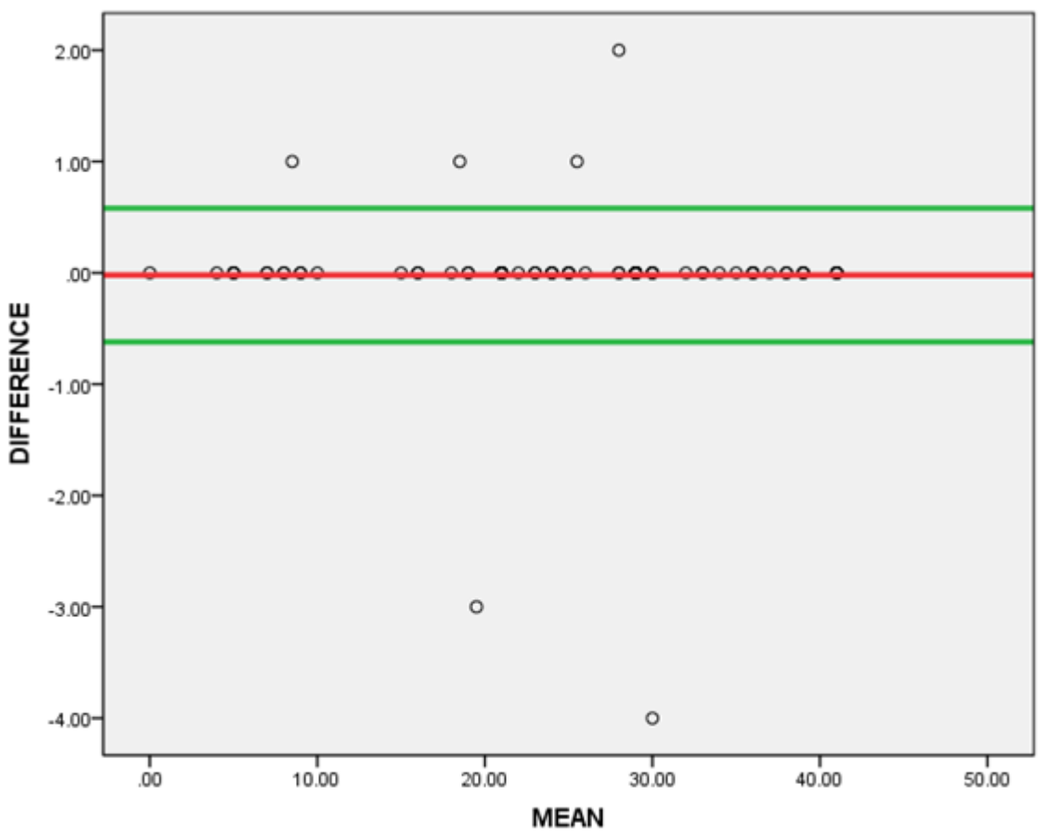

Fig. 1: Bland–Altman plot showing the difference between LARS score at the first and second test. LARS, low anterior resection syndrome.

DISCUSSION

Oncologic results for rectal adenocarcinoma have improved as a result of enhanced surveillance, chemotherapy, radiation, and surgical procedures. Rectal cancer patients can now escape the permanent colostomy performed in abdominoperineal resection by undergoing LAR with TME instead. As a result, an increasing number of patients are treated with sphincter-sparing surgery. In general, surgeons think that patients want to avoid a permanent colostomy, and patients expect that by retaining their sphincter, their bowel function will not change dramatically after rectal resection or that the effects will be temporary. However, an increasing body of evidence suggests that the vast majority (up to 90%) of patients endure long-term reductions in quality of life as a result of LAR symptoms[6].

Assessment of LARS is quite hard. It depends on the patient's symptoms; many patients are lost during follow-up, and no standard tool is used to diagnose it. Previous reports used a variety of instruments to assess functional bowel outcomes, including the Cleveland Clinic Florida Fecal Incontinence Score (Wexner incontinence score), the St Marks' Fecal Incontinence Grading Score, the Rockwood Fecal Incontinence Severity Index, and the Fecal Incontinence Quality of Life Scale. However, these scores were designed to identify simple incontinence and are too restricted and specialized to assess complex dysfunctions such as LARS[7].

Emmertsen and Laurberg[8] introduced "the LARS score" in Danish in 2012. The LARS score is a patient-reported outcome measure used to assess the severity of bowel dysfunction following rectal surgery. It scores the key symptoms of LARS, which include incontinence (flatus and liquid stool), frequent bowel movements, stool fragmentation/clustering, and urgency. The original Danish version was translated into English, and the English version has been translated into 16 languages, with nine (Danish, English, Swedish, Spanish, German, Chinese, Moroccan Arabic, Turkish, and Lithuanian) being formally recognized. Validation in many languages will allow for worldwide uniform LARS reports regardless of native language. Furthermore, reports from various places in the world will boost the comprehension of LARS and can help with the LARS score as a well-validated international assessment tool[7].

The purpose of this study was to translate the English version of the LARS score into Egyptian Arabic and assess its validity in Egyptian rectal cancer patients by comparing the results to the EORTC QLQ-C30 v3 questionnaire. Additionally, the incidence and risk factors for LARS were assessed.

The study included 120 patients, 31.7% females and 68.2% males. The mean age was 49.6±11.2. Those patients were classified into three groups: group I included 40 patients (no LARS), group II included 45 patients (minor LARS), and group III included LARS scores that were more common in males. This agrees with the study by Kim *et al*.[9]. LARS score had a positive relation with age. It was higher among patients above 45 years old, which was similar to the study by Essangri *et al*.[10]. The incidence of LAR syndrome was also higher among hepatic patients. This can be attributed to the liver being the most common site of secondaries in colorectal carcinoma. We also found that higher LARS scores were associated with higher BMI. This can be due to the difficulty of surgery in obese patients with a higher incidence of surgical complications and higher morbidity.

In our study, the LARS score was highly significantly higher in low rectal tumors less than or equal to 5 cm from anal verge with *P value* less than 0.001 and in ISR with *P value* less than 0.001. No LARS group had AR in 67.5%, LAR in 27.5%, ULAR in 5%, and 0% in ISR with the AR had the highest incidence. Minor LARS group had 22.2, 53.3, 20, and 4.4%, respectively, with the LAR had the highest percentage. Major LARS had 11.4, 25.7, 34.3, and 28.6%, respectively, with the highest percentage in ISR because the lower the tumor location, the more difficult the surgery and the more the affection of the sphincter.

In the study by Akizuki *et al*.[7], there were 45% in LAR, 26% in AR, 22% in ULAR, and 7% in ISR. However, they did not discriminate against LARS groups in their results.

We found that the LARS score was highly significantly higher in patients with coloanal anastomosis, open surgery, hand-sewn anastomosis, and TME with *P value* less than 0.001. This is in accordance with Hain *et al*. study[11]. Open surgery, coloanal anastomosis, and hand-sewn anastomosis had longer operative duration with a longer sphincter retraction during surgery, which results in a weak sphincter. They also have a higher risk of bleeding. TME affects the lymphatic drainage of the rectum and increases operative time and manipulation.

LARS was found to increase with a higher T stage (T3 and T4), with a highly significant *P value*. The incidence of LARS was higher among patients who had adjuvant and neoadjuvant therapy. This was similar to Eid *et al*. study[12]. Neoadjuvant and adjuvant therapy cause radiation enteritis, destruction of lymphatic tissue, and increased comorbidity in patients.

Akizuki *et al*.[7] used one scale questionnaire (quality of life) in their study. Essangri *et al*.[10] have estimated the validity of the LARS score questionnaire by correlation to five scales of the QLQ-C30 questionnaire. Carpelan *et al*.[13] used the European Organisation for Research and Treatment of Cancer-quality-of-life questionnaire-C30 and QLQ-CR29 questionnaires.

In a similar study for validation of the English version of the LARS questionnaire among the UK patients, Juul and colleagues used six scales of the EORTC QLQ-C30 and the LARS score questionnaires. Our results were very similar to them. Sixty percent of their patients were men, and the mean age was 69.8. They found that LARS incidence was higher with TME, neoadjunant, and adjuvant therapy. Quality of life was higher in the no LARS group and lower in the major LARS group. Tumors within 5 cm from the anal verge had exclusively high scores. Their test–retest reliability had 95% limits of agreement. They differed from our study in that they included patients with temporary stoma, and the majority of their cases had T0–2 tumors, but they attributed this to chance. Also they did not discriminate the type and technique of surgery, and the type and the technique of anastomosis[14].

We saw that the LARS questionnaire did not contain all the parameters of QLQ-C30 and QLQ-CR29. They also did not correlate constipation despite its evaluation in the LARS questionnaire as obstructed defecation. So, we test the validity of the LARS questionnaire using three scales of the EORTC QLQ-C30 v3 (quality of life scale, diarrhea scale, and constipation scale).

We found that there was a significant positive correlation between the LARS score and the occurrence of diarrhea. However, there was a significant negative correlation between the score and quality of life. This agrees with the previous studies. Relation with constipation was not significant.

We also tested the reliability of the LARS questionnaire as some patients filled it out again two weeks after the first test, which showed excellent agreement.

CONCLUSION

The LARS score questionnaire is a reliable and valid test for the evaluation of LARS among Egyptian patients who had surgery for rectal cancer. The incidence of LARS is higher with age above 45 years old, hepatic patients, high BMI, T3 and T4 tumors, neoadjuvant and adjuvant therapy. It also increases with open surgery, low rectal tumor surgery, coloanal anastomosis, hand-sewn anastomosis, and TME.

CONFLICT OF INTEREST

There are no conflicts of interest.

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