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BRIEF ARTICLE

Stapled transanal rectal resection for obstructed defecation syndrome associated with rectocele and rectal intussusception

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Abstract

AIM: To evaluate the safety and efficacy of stapled transanal rectal resection (STARR), and to analyze the outcome of the patients 12-mo after the operation.

METHODS: From May 2007 to October 2008, 50 female patients with rectocele and/or rectal intussusception underwent STARR. The preoperative status, perioperative and postoperative complications at baseline, 3, 6 and 12-mo were assessed. Data were collected prospectively from standardized questionnaires for the assessment of constipation [constipation scoring system, Longo's obstructed defecation syndrome (ODS) score system, symptom severity score], patient satisfaction (visual analogue scale), and quality of life (Patient Assessment of Constipation-Quality of Life Questionnaire).

RESULTS: At a 12-mo follow-up, significant improvement in the constipation scoring system, ODS score system, symptom severity score, visual analog scale and quality of life ($P < 0.0001$) was observed. The symptoms of constipation improved in 90% of patients at 12 mo after surgery. The self-reported definitive outcome was excellent in 15 (30%) patients, fairly good in 8 (16%), good in 22 (44%), and poor in 5 (10%).

CONCLUSION: STARR can be performed safely without major morbidity. Moreover, the procedure seems to be effective for patients with obstructed defecation associated with symptomatic rectocele and rectal intussusception.

Key words: Stapled transanal rectal resection; Obstructed defecation syndrome; Rectocele; Rectal intussusception

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INTRODUCTION

Obstructed defecation syndrome (ODS) is characterized by a spectrum of symptoms including difficult evacuation, excessive straining during defecation, sensation of incomplete evacuation, prolonged time to defecate, anal

pain, bleeding, and the use of external assistance to aid defecation. It has been estimated that approximately 20% of adult female population suffered from the syndrome[1,2]. The etiology of ODS is likely to be multifactorial, resulting from the interaction of functional and anatomic factors that influence the rectoanal evacuatory mechanism[3]. Furthermore, the most common clinical signs and pathophysiologic alterations associated with ODS are rectocele (RE) and rectal intussusception (RI)[4].

To date, a variety of surgical techniques including transvaginal, transperineal, transanal, and combined abdominal and vaginal approaches have been described for the treatment of ODS. However, there is no method achieving overall superiority because of different patterns of complications and high rate of recurrence. Based on the stapled hemorrhoidopexy procedure, Longo[5] proposed an alternative technique for patients with ODS caused by RE and RI called stapled transanal rectal resection (STARR). The novel technique is carried out sequentially using double circular stapler devices (PPH01, Ethicon Endo-Surgery), anteriorly and posteriorly, to restore normal rectal anatomy by strengthening rectovaginal septum and resecting redundant rectum.

STARR has been implemented rapidly and described as an effective cure for RE, RI, prolapsed hemorrhoids and even solitary rectal ulcer[6-9]. In addition, observations from several case series and multi-center trials have demonstrated a clinical benefit of the procedure in short-term follow-up[10-14]. Nevertheless, some unique and troublesome complications were also documented by a few case reports[15-18]. The current study was designed to determine the safety and efficacy of STARR in treatment of ODS related to symptomatic RE and RI, and to perform an analysis of outcomes of the patients 12 mo after surgery

MATERIALS AND METHODS

From May 2007 to October 2008, 50 female patients with ODS caused by RE and/or RI underwent STARR. Before the surgery, patients were asked about symptoms of constipation and previous histories of anorectal or gynecologic surgery. Apart from the comprehensive history, the presence and extension of any anatomical or functional abnormality were evaluated by means of a clinical examination and appropriate physiological investigations such as proctoscopy, colonoscopy, colonic transit time study, defecography and anorectal manometry. All the patients were operated on by the same surgical team, using the original techniques reported previously[6] without modifications. The protocol was approved by the ethical committee of our institution and all patients gave informed written consent.

Inclusion criteria

Patients with persistence of at least three specific symptoms of ODS (feeling of incomplete evacuation, prolonged painful straining, frequent calls to defecate, excessive toilet time, digital assistance, pelvic pain or pressure, rectal bleeding, soiling, or a feeling of prolapse). Additionally, conservative treatment with diet (1.5 L/d water, high-fiber diet), laxatives (10 g/d lactulose), enemas and/or physiotherapy had been tried in all patients without success. Moreover, there was radiologically-proven RE $\geqslant$ 3 cm, or RI < 4 cm on straining, or significant rectal barium trapping after defecation.

Exclusion criteria

Exclusion criteria were in accordance with the consensus statement published by the Pioneers group[4] and the consensus recommendations by Corman *et al*[19]. These included patients with good response to conservative treatment, slow transit constipation, enterocele, sigmoidocele, cystocele, genital prolapse, external rectal prolapse, pelvic floor dyssynergia, proctitis, active perineal infection, chronic diarrhoea, inflammatory bowel disease, neoplasia, anorectal stenosis and previous anterior resection with rectal anastomosis, and patients with anal incontinence (Cleveland Clinic Florida; Wexner Score > 7) and foreign material (such as mesh) adjacent to the rectum or with mental disorder. Furthermore, RE < 3 cm or RI $\geqslant$ 4 cm on straining was not considered straightforward candidates for the STARR procedure. Also excluded were those with general contraindications for surgery and those who declined surgical treatment.

Study design

All patients had detailed data on preoperative status, perioperative and postoperative complications. A clinical assessment was performed at baseline and at 3, 6, and 12 mo after surgery. The magnitude and degree of ODS were quantified by constipation scoring system (CSS)[20]. The validated CSS consists of eight items and the overall score ranges from 0 (normal) to 30 (severe constipation). In addition to CSS, the severity of disordered defecation was also quantified by Longo's ODS score system (Table 1) and the symptom severity (SS) score (Table 2). The summed global scores of ODS and SS range from 0-40 and 0-36, respectively, in which a higher score indicates more severe symptoms. Moreover, the index of patient satisfaction was evaluated by a visual analog scale (VAS: with a score from 0 to 10), and a higher score suggests an improvement in patient satisfaction with the surgery. Patient Assessment of Constipation-Quality of Life Questionnaire (PAC-QoL), a self-reported questionnaire, was used to measure the quality of life of patients[21,22]. The validated PAC-QoL is composed of 28 items grouped into four subscales: physical discomfort, psychosocial discomfort, worries and concerns, and satisfaction. The first three subscales were used to assess the patient dissatisfaction index, with an overall score ranging from 0 to 96 (where lower scores correspond to better quality of life). The satisfaction subscale includes four items with a global score ranging from 0 to 16, so that each patient's self-reported definitive outcome was defined as either poor (0-4), fairly good (5-8), good (9-12), or excellent (13-16)[23].

Table 1 Longo's ODS score system

ODS-score (0-40)									
Defecation frequency	1-2 def/ 1-2 d	0	2 def /wk or 3 def or attempts/d	1	1 def/wk or 4 def or attempts/d	2	< 1 def/wk or > 4 def or attempts/d		3
Straining									
Intensity	No, light	0	Moderate	1	Intensive	2			
Extension			Short time	1	Prolonged	2			
Sensation of inco-mplete evacuation	Never	0	≤ 1 time/wk	1	2 times/wk	2	> 2 times/wk		3
Recto/perineal pain/discomfort	Never	0	≤ 1 time/wk	1	2 times/wk	2	> 2 times/wk		3
Activity reduction per week	Never	0	< 25% of activity	2	25%-50% of activity	4	> 50% of activity		6
Laxatives	Never	0	< 25% of def	1	25%-50% of def	3	> 50% of def	5 Always	7
Enemas		0		1		3	5		7
Digitation		0		1		3	5		7

ODS: Obstructed defecation syndrome.

Table 2 Symptom severity score

Symptoms	None	Very short time	Some time	Most of the time	All of the time
Need laxatives/enemas	0	1	2	3	4
Unsuccessful attempts to open bowels	0	1	2	3	4
Low frequency of bowel movements	0	1	2	3	4
Pain on opening bowels	0	1	2	3	4
Bleeding on bowel opening	0	1	2	3	4
Incomplete bowel opening	0	1	2	3	4
Increased time or straining to open bowels	0	1	2	3	4
Incontinence/soiling	0	1	2	3	4
Difficulty to withstand urge to open bowels	0	1	2	3	4

Table 3 Previous anorectal or gynecologic surgery in patients undergoing STARR *n* (%)

Operation	Patients
Milligan-Morgan hemorrhoidectomy	11 (22)
Fistulectomy	1 (2)
Fistulotomy	1 (2)
Closed lateral subcutaneous sphincterotomy	1 (2)
Stapled hemorrhoidopexy	1 (2)
Episiotomy	13 (26)
Hysterectomy	9 (18)
Abdominal delivery	7 (14)

STARR: Stapled transanal rectal resection.

Surgical technique

Polyethylene glycol electrolyte solutions were given for preoperative bowel preparation, and patients received routine broad-spectrum antibiotics immediately after the induction of anesthesia. The operation was always performed under spinal anesthesia with the patient in a lithotomic position. According to recommendations for the performance of STARR[6], two circular PPH-01™ staplers (Ethicon Endo-Surgery) were used. Briefly, the anal canal was gently dilated, then the circular anal dilator (CAD33) introduced and secured with silk sutures. Three semi-circumferential purse-string sutures were positioned in the anterior rectum at approximately 1, 2, and 3 cm above the haemorrhoidal apex. The first PPH-01 stapler was inserted and the posterior rectal wall was protected with a spatula. The ends of sutures were delivered through the specific holes of the stapler, and tension was applied to prolapse the removed tissues into the stapler housing, making sure that the posterior vaginal wall had not been incorporated, the stapler was closed and fired. By the same procedure, two semi-circumferential purse-string sutures and a second PPH-01™ stapler were performed on the posterior rectal wall. Subsequent bleeding from the staple line was controlled with full-thickness 2-0 Vicryl™ stitches, and "posterior staple bridge" was divided with scissors.

Statistical analysis

Statistical analysis was performed using paired *t* test for continuous variables, and Wilcoxon's signed-rank test for quantitative variables. The total scores of CSS, ODS, SS, VAS and PAC-QoL were expressed as mean values with 95% confidence intervals (CI). A P value < 0.05 was considered statistically significant.

RESULTS

There were 50 female patients (median age, 53.7 years; range, 30-70 years). As shown in Table 3, 43 (86%) patients had experienced 1-5 vaginal deliveries, 13 (26%) had experienced at least one episiotomy, and 36 (72%) had undergone prior anorectal or gynecologic surgeries. All the patients had symptoms of outlet obstruction (Table 4). Median operating time was 28 min (range,

Table 4 Presenting symptoms and early complications in patients undergoing STARR *n* (%)

Symptoms	Incidence	Early complications	Incidence
Excessive straining	43 (86)	Defecatory urgency	21 (42)
Feeling of incomplete evacuation	42 (84)	Bleeding[3]	4 (8)
Rectal bleeding[1]	32 (64)	Incontinence to flatus	3 (6)
Rectoperineal discomfort	23 (46)	Acute urinary retention	2 (4)
Abdominal distension	21 (42)	Severe pain	2 (4)
Abdominal pain	20 (40)	Anal fissure	1 (2)
Feeling of rectal obstruction	16 (32)	Rectovaginal fistula	0
Laxatives[2]	34 (68)	Perianal sepsis	0
Enema	20 (40)	Staple line dehiscence	0
Rectal or vaginal digitation	17 (34)	Mortality	0

[1]> 1 episode/wk; [2]> 2 episodes/mo; [3]No treatment was required.

Table 5 Intermediate complications in patients undergoing STARR *n* (%)

Symptoms	3 mo	6 mo	12 mo
Defecatory urgency	5 (10)	3 (6)	1 (2)
Incontinence to flatus	1 (2)	1 (2)	1 (2)
Incontinence to feces	1 (2)	1 (2)	1 (2)
Chronic pain	2 (4)	1 (2)	1 (2)
Constipation	4 (8)	5 (10)	5 (10)
Rectal stenosis	0	0	0
Rectal diverticulum	0	0	0

20-50 min). The mean vertical height of the resected specimen was 3.8 cm (range, 2.5-4.8 cm) anteriorly and 2.0 cm (range, 2.0-4.0 cm) posteriorly; the mean horizontal length was 5.9 cm (range, 4.6-7.2 cm) anteriorly and 4.4 cm (range, 3.2-5.3 cm) posteriorly. The only intraoperative incident was subsequent bleeding from the anastomotic ring, which occurred in 92% of cases and was secured with hemostatic stitches.

Early complications are summarized in Table 4. The most common morbidity after surgery was defecatory urgency, and the incidence was 42% during the first postoperative week. Bleeding occurred in 4 (8%) patients, but the symptom was minor and no further surgical intervention was required. Other recorded complications were acute incontinence to flatus (6%), acute urinary retention (4%), severe pain (4%) and anal fissure (2%). No staple line dehiscence, massive rectal hemorrhage, rectovaginal fistula, perianal sepsis and postoperative mortality occurred.

In addition, the postoperative complications were followed up for one year. As shown in Table 5, the frequency of defecatory urgency decreased dramatically with time and was 10% at 3-mo, 6% at 6-mo and merely 2% at 12-mo follow-up. Incontinence to flatus was a problem in only 1 (2%) elderly patient at a 3-mo follow-up. Moreover, the patient developed incontinence and remained unchanged during a 12-mo follow up. Another 2 (4%) cases had chronic pain during 3 mo after resection, whereas one resolved at a 6-mo follow-up. Forty-six (92%) patients had a clinical benefit at 3 mo, however, constipation recurred in one patient at 6 mo after the STARR procedure. At a follow-up of 12 mo, the symptoms of constipation improved in 45 (90%) patients. No rectal stenosis and rectal diverticulum occurred.

The variation of the CSS, ODS, SS and VAS scores are presented in Figure 1A-D. Overall, a significant reduction in CSS, ODS and SS scores was observed at 12 mo as compared with baseline [CSS score at baseline *vs* 12 mo: 15.58 (95% CI: 14.40-16.76) *vs* 5.68 (95% CI: 4.34-7.02); ODS score: 17.54 (95% CI: 16.13-18.95) *vs* 5.92 (95% CI: 4.31-7.53); SS score: 15.22 (95% CI: 13.91-16.53) *vs* 4.52 (95% CI: 3.29-5.75); $P < 0.0001$]. The differences indicated that patients undergoing STARR had an improvement in the symptoms of obstructed defecation. Additionally, the VAS score at 12 mo was more markedly increased than that at baseline [VAS score at baseline *vs* 12 mo: 4.07 (95% CI: 3.79-4.35) *vs* 7.59 (95% CI: 7.10-8.08), $P < 0.0001$]. The results were consistent with the improvement in CSS, ODS and SS scores, and suggested that patients undergoing STARR also had an obvious improvement of patient satisfaction. Summarized data from the individuals showed that the PAC-QoL score at 12 mo was significantly lower than that at baseline [PAC-QoL (dissatisfaction index) at baseline *vs* 12 mo: 47.78 (95% CI: 44.25-51.31) *vs* 8.14 (95% CI: 6.13-10.15), $P < 0.0001$]. Furthermore, the self-reported definitive outcome was excellent in 15 patients (30%), fairly good in 8 (16%), good in 22 (44%), and poor in 5 (10%). These observations demonstrated that most of the patients (90%) undergoing STARR had noticeable improvement in both the quality of life and the index of satisfaction.

DISCUSSION

ODS is an emerging and challenging clinical problem, the pathophysiology of which remains to be clearly defined. RE and RI, however, are the two most frequent anatomic defects associated with ODS. Although various surgical procedures have been described for the treatment of the syndrome, many of these are unsuitable for patients accompanied with RE and RI[24]. Notably, STARR has been demonstrated as an alternative operation and a relatively noninvasive surgical technique for ODS caused by RE and RI. The novel procedure aims to correct rectocele, resect internal prolapse, restore anatomy, correct rectal volume, and improve function[10]. Nevertheless, limited evidence has been available about the safety and short-term efficacy of STARR so far[23,25,26].

In our experience, STARR can be performed safely without major morbidity. The only intraoperative incident was subsequent bleeding from the staple line which happened in 92% of patients. Given that a full thickness segment of rectal wall was excised by the STARR staplers, the anastomotic ring should be meticulously checked and carefully secured with stitches whenever necessary. The current dada documented 4 (8%) cases with mild bleeding from the staple line postoperatively,

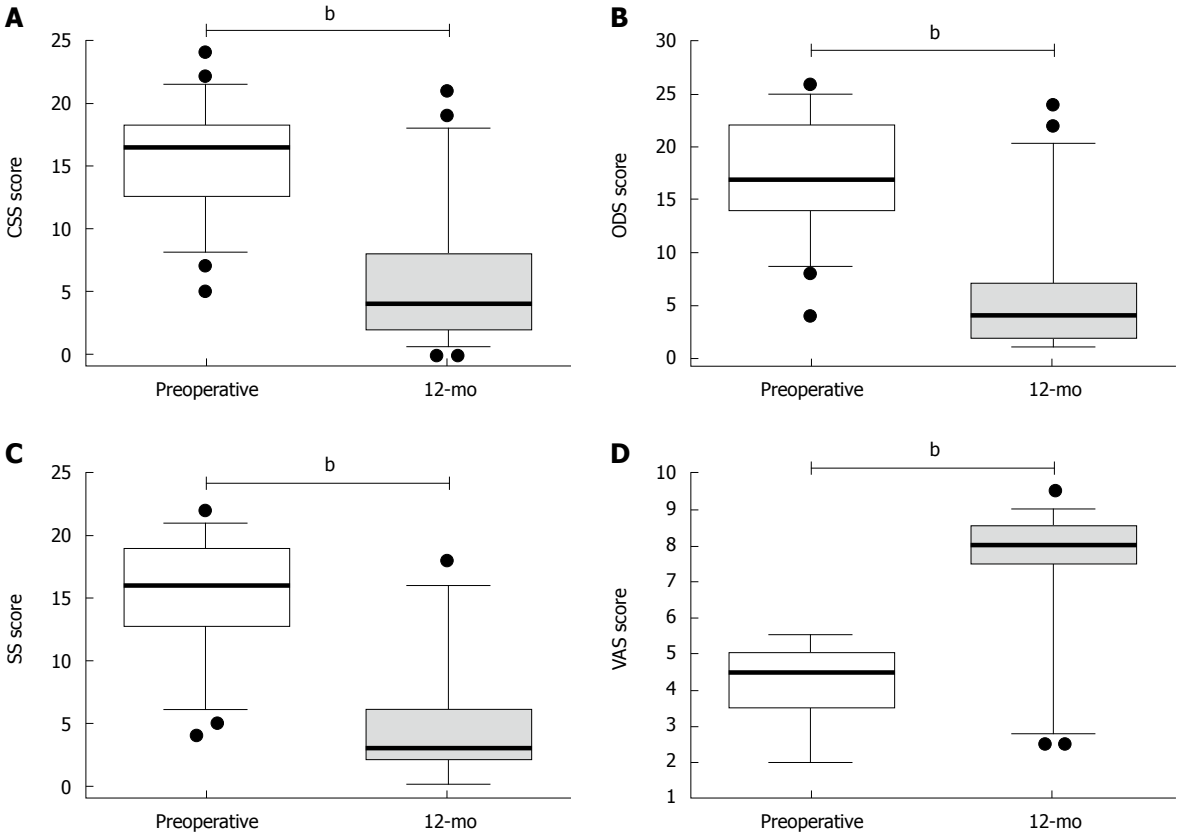

Figure 1 Comparison of scores at baseline and at a 12-mo follow-up. A: Comparison of constipation scoring system (CSS) scores; B: Comparison of Longo's obstructed defecation syndrome (ODS) scores; C: Comparison of symptom severity (SS) scores; D: Comparison of visual analog scale (VAS) scores. A significant reduction in the CSS, ODS, SS and VAS scores was observed at 12 mo after surgery as compared with baseline (paired *t* test , $^{b}P < 0.0001$).

but no one required further surgical intervention. Additionally, no severe complications associated with bleeding such as massive rectal hemorrhage and secondary anastomotic sepsis occurred in this study. Furthermore, no patient had recto-vaginal fistula. It may be because to a large extent, that much attention was paid to avoiding any entrapment of the posterior wall of vagina in the process of operation. Even though a few worrisome complications[15-18] including staple line dehiscence, rectal diverticulum, pelvic infection and even fulminating necrotizing pelvic fasciitis occurred following the STARR procedure in some studies, none of our patients developed any of the complications.

Accumulating evidences have shown that defecatory urgency was the most common complaint in the immediate and intermediate recovery periods after STARR[26,27]. Consistently, our data showed that the incidence was 42% during the first postoperative week and 10% at 3-mo, 6% at 6-mo and merely 2% at a 12-mo follow-up. The frequency was decreased dramatically with time, indicating that the complication was largely self-limited. Contrary to Titu's observations[27], the complaint was not present with an obviously regular rhythm and symptom-relieving period character in our patients. Although the exact etiopathogenesis of defecatory urgency is unclear, it may reflect the inflammatory response related to the staple line, presence of irritable rectum, and reduced rectal capacity or compliance. The incidence of incontinence to flatus was 6% during the first week after surgery, but was only 2% at a 3-mo follow-up. The marked improvement manifested that it may be a procedure-related complication caused by transient sphincteric impairment during instrumentation. Nevertheless, one elderly patient with postoperative defecatory urgency was concomitant with incontinence during a 12-mo follow-up. The potential relationship between defecatory urgency and incontinence need to be further elucidated.

Even though there is no acknowledged and standardized assessment to quantitate ODS, a dedicated score represents an essential tool, which can be used for the clinical staging of ODS for subsequent surgery and for the evaluation of therapeutic results[28]. Therefore, the validated CSS, Longo's ODS score system, SS score, VAS, and the validated PAC-QoL were used for clinical assessment in this study. Compared with the preoperative results, an evident reduction in the CSS, ODS and SS scores was exhibited at 12 mo after surgery. The variation demonstrated the efficacy of STARR in relieving symptoms of obstructed defecation. Furthermore, the significant differences between preoperative and postoperative mean total scores of VAS and PAC-QoL indicated an improvement in both the patient satisfaction index and the quality of life. At a 12-mo follow-up, it was noteworthy that the self-reported definitive outcome was excellent in 15 patients (30%), fairly

good in 8 (16%), good in 22 (44%), and poor in 5 (10%). The symptoms of constipation improved in 45 (90%) patients. However, a few studies have reported the limited effect of STARR for the treatment of ODS[15,16]. The different inclusion/exclusion criteria, the limited expertise of STARR surgery and the absence of routine surgical practice may account for the discrepant results. In addition, the long-term benefits warrant further investigations.

Intriguingly, the Contour Transtar stapler™ (Ethicon Endo-Surgery, Inc.) device has been introduced more recently as a modification of the STARR procedure[29,30]. Transtar has the potential benefit of being able to tailor the amount of rectal wall to be resected. Meurette *et al*[31] suggested that it would be wise to select the STARR procedure for a predominant "isolated" RE and the Transtar procedure for a high grade RI. Therefore, further research into this area is required to optimize patient selection, and the difference in function and efficacy between STARR and Transtar remains to be observed.

COMMENTS

Background

Obstructed defecation syndrome (ODS) is one of the most widespread clinical problems which frequently affect middle-aged females. Rectocoele (RE) and rectal intussusception (RI) are the two most common clinical signs and anatomic defects associated with ODS. Stapled transanal rectal resection (STARR) is a new procedure for obstructed defecation due to RE and RI.

Research frontiers

Previous studies have shown a clinical benefit of the STARR procedure for ODS related to RE and RI in short-term follow-up. However, limited effect and some serious complications were also described. In this study, the authors demonstrated that STARR seems to be safe and effective for selected patients presenting with ODS caused by RE and RI.

Innovations and breakthroughs

This is an original study taking place in a single centre that describes the safety and feasibility of STARR for the management of ODS due to symptomatic RE and RI. The study confirms that this technique can be performed safely without major morbidity. Furthermore, the symptoms of constipation relieved in 90% of patients with significant improvement in both the quality of life and the index of satisfaction at 12 mo after surgery.

Applications

Although the current study indicates a short-term clinical benefit, a longer follow-up should be made to establish the true value of STARR. Moreover, further studies are needed to optimize patient selection and compare the efficacy of this technique with that of other surgical procedures for patients with ODS.

Terminology

STARR is a relatively noninvasive surgical technique using double circular stapler devices to resect a full thickness segment of rectal wall. The novel procedure has been utilized for the treatment of RE, RI, prolapsed hemorrhoids, solitary rectal ulcer and even rectal tumor.

Peer review

This work is well planned and structured. The authors report good short-term results with the STARR procedure for obstructed defecation due to a RE or RI.

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