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Patient Satisfaction and Symptomatic Outcomes Following Stapled Transanal Rectal Resection for Obstructed Defecation Syndrome

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Background. Obstructed defecation syndrome (ODS) is recognized as a functional (e.g., anismus) and anatomic (e.g., rectocele and rectal intussusception) defecatory disorder of the pelvic floor. This study was designed to evaluate outcomes and patient satisfaction following stapled transanal rectal resection (STARR) for the surgical treatment of ODS.

Materials and Methods. Between May 2006 and July 2009, 37 patients underwent STARR for correction of ODS secondary to rectocele and internal intussusception. Demographic data and postoperative outcomes were tabulated. Symptomatic outcomes were assessed by comparing pre- and postoperative subsets of the Wexner constipation scoring system, and quality outcomes were evaluated with patient satisfaction surveys.

Results. Thirty-seven female patients with a mean age of 52.9 ± 11.2 y underwent STARR. All patients had clinically significant rectocele as evidenced on defecography and 81.1% had concomitant internal rectal intussusception. Postoperative complications occurred in 13 patients (35.1%). Two of these patients required re-intervention: dilation of stricture and transanal excision of staple granuloma. Mean quality of life follow-up occurred at 20.3 ± 6.6 mo (median: 20 mo, range: 9–36 mo). Mean preoperative and postoperative constipation subset scores were 11.1 ± 3.6 and 4.6 ± 3.9 , respectively ($P < 0.00001$). Overall outcome was reported as “excellent” or “good” in 71.9% of patients, “adequate” in 15.6%, and “poor” in 12.5%. When asked if they would undergo the procedure again, 81.3% responded affirmatively.

Conclusions. The STARR procedure results in improved symptomatic outcomes, high patient satisfac-

tion, and an acceptable complication rate. In selected patients, this minimally invasive approach was an acceptable procedure for the surgical correction of ODS secondary to rectocele and intussusception. © 2011 Elsevier Inc. All rights reserved.

Key Words: constipation; defecography; obstructed defecation syndrome (ODS); outcomes; patient satisfaction; pelvic muscle rehabilitation (PMR); rectal intussusception; rectocele; stapled transanal rectal resection (STARR).

INTRODUCTION

Obstructed defecation syndrome (ODS) is a prevalent disorder of defecation that significantly affects the quality of life and daily activities of many patients [1]. ODS affects nearly 50% of patients with chronic constipation [2], and these patients represent the largest subgroup presenting with constipation as their principal complaint.

Characteristic symptoms include a sense of incomplete evacuation, excessive straining, frequent visits to the toilet, laxative abuse, regular use of enemas, and digital maneuvers of the vagina and/or rectum to accomplish evacuation. Patients may spend several hours each day to attempt complete evacuation and often complain of persistent urgency. The pathophysiology of ODS is complex and is thought to result from both functional and anatomical disturbances. The functional abnormalities (e.g., anismus, dyssynergic defecation, and non-relaxation syndrome) involve dysfunction of the external anal sphincter and puborectalis muscles during defecation. The anatomical abnormalities include rectocele, rectal intussusception (internal rectal prolapse), mucosal prolapse, genitourinary prolapse, and enterocele.

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Surgical restoration of the rectal anatomy may provide significant improvement in the patient's symptoms and quality of life. Although various surgical procedures have been described, there is no consensus on the most effective modality [3], as most methods are limited by the complexity of the operation and associated high rates of complications [4]. One of the most recent techniques for the treatment of ODS is stapled transanal rectal resection (STARR), initially described by Longo [5]. The goal of this procedure is to correct the structural abnormalities of rectocele and internal intussusception through use of a double-stapling technique to facilitate a full-thickness transanal rectal resection. We have offered this technique since 2006 to appropriately selected patients with corresponding anatomical abnormalities of ODS. The aim of this study was to assess patient outcomes in regards to complications, symptomatic relief, and patient satisfaction following the STARR procedure for ODS.

MATERIALS AND METHODS

The procedures followed in this study were in accordance with the Helsinki Declaration of 1975. From May 2006 through July 2009, 1,580 patients were evaluated at our institution for complaints related to constipation and/or rectocele. Preoperative evaluation included a subset of the Wexner constipation questionnaire [1], physical examination, anorectal physiology studies, and defecography. Similar to the obstructed defecation syndrome score (ODS-S) created by Renzi *et al.* [6], we created a modified constipation score to evaluate the severity of each patient's symptoms at initial presentation. This modified score was based on a subset of six questions from the Wexner constipation scoring system: (1) frequency of bowel movements, (2) difficulty or excessive straining, (3) incomplete evacuation, (4) time required for a bowel movement, (5) number of failed bowel movements in a day (24 h period), and (6) need for digital, laxative, or enema assistance (Table 1). Preoperative responses were compared with postoperative responses to evaluate intermediate-term symptom relief following STARR (minimum follow-up: 9 mo).

Physiology studies included anorectal manometry, rectal sensation, balloon expulsion, and electromyography (EMG). Anorectal manometry was performed *via* pull-through technique as described by Allen *et al.* [7] utilizing the four-lumen balloon tip ARM4 anorectal manometry catheter (T-DOC Company LLC, Wilmington, DE) with four side-hole recording sites. Recto-anal inhibitory reflex was recorded at the minimum volume necessary to elicit the response. Serial air inflation of the balloon tip probe was performed to assess rectal sensation (i.e., first sensation, first urge to defecate, and maximum tolerable volume). A balloon expulsion test was performed *via* a balloon tip probe that was inflated with 100 cc of air as described by Rao *et al.* [8]. EMG analysis of puborectalis muscle fiber recruitment was performed using surface electrodes (Mediwatch PLC, Warwickshire, UK) to assess sphincter muscle activity at rest and during activity, as described by Siroky [9] and O'Donnell *et al.* [10]. Patients who were identified as having a functional disorder based on anorectal physiology studies underwent pelvic muscle rehabilitation (PMR, a modified biofeedback program) before STARR was offered.

All patients underwent cindefecography (defecography) prior to STARR to assess the morphology and physiology of the structures involved in defecation [11]. Rectocele grade was determined according to the classification proposed by Marti *et al.* [12], grade I = small (≤ 2 cm), grade II = moderate (2.4 cm), and grade III = large (> 4 cm). In our patient population, the STARR procedure was offered to patients

who had failed conservative management with any size of rectocele and/or rectal intussusception, as suggested by Gagliardi *et al.* [11].

Between May 2006 and July 2009, a total of 37 patients were selected to undergo STARR for ODS secondary to rectocele with or without intussusception. Consensus conference guidelines (June 2005, Rome, Italy) were followed for selection of patients for the STARR procedure [3]. STARR was performed at The Methodist Hospital or St. Joseph Medical Center Hospital in Houston, TX by two board-certified colon and rectal surgeons (EMH and TBP) with special STARR credentials (course undertaken in a porcine animate lab (Ethicon Endo-Surgery, Inc., Cincinnati, OH) and proctorship of the initial case). Potential complications (e.g., pelvic sepsis, pain, postoperative bleeding, tenesmus, stricture, and urinary retention) [13] were described to the patient prior to surgery and informed consent was obtained. The STARR procedure was performed as previously described under general anesthesia with the patient in lithotomy position [14]. All patients underwent enema preparation and received a single dose of preoperative prophylactic antibiotics. Two STR10 staplers were used for each procedure (Ethicon Endo-Surgery Inc., Cincinnati, OH). Figure 1 displays the steps involved in the STARR procedure.

Patient data were entered into a de-identified database. Clinical evaluation was performed at 0.5, 1, 3, 6, and 12 mo postoperatively (minimum of 3 mo in all patients). Patient satisfaction with the surgical result was classified as "excellent" with practically no defecation problem, "good" with occasional defecation problem, "adequate" with several defecation problems affecting lifestyle, or "poor" with significant defecation problems significantly affecting lifestyle. A telephone survey included a constipation questionnaire subset and a question regarding whether the patient would undergo the surgery again, based on her surgical result. The constipation score subset was calculated as described earlier (Table 1).

Data analysis was performed using Stata ver. 9.2 (Stata Corp., College Station, TX). Statistical analysis for difference in preoperative and postoperative constipation score subset was performed using the Wilcoxon rank-sum test, with significance level set at $\alpha = 0.05$. In order to assess for differences in patient characteristics between both surgeons, a two-tailed unpaired Student's *t*-test was employed.

RESULTS

Stapled transanal rectal resection was performed in 37 female patients (Table 2) with a mean age of 52.9 ± 11.2 years (range 31–74 years). The majority of patients had prior pelvic surgery, including hysterectomy ($n = 31$, 83.8%), rectocele repair ($n = 9$, 24.3%), and urinary bladder suspension procedures ($n = 8$, 21.6%). In addition, six patients (16.2%) had a previous history of anorectal surgery (e.g., hemorrhoidectomy). All patients had constipation for a minimum of 12 mo. All patients had failed conservative measures, including dietary modification and behavior counseling.

Thirteen patients (35.1%) with a significant component of anal dyssynergia and non-relaxation of the pelvic floor identified on anal physiology studies underwent and failed PMR (Table 3).

Preoperative anatomical evaluation revealed that all patients had large or symptomatic rectocele with retained stool on defecography. Concomitant internal intussusception was present in 30 patients (81.1%).

Six patients (16.2%) had a significant enterocele identified and underwent STARR with laparoscopic surveillance. Figure 2 shows the postoperative appearance of

TABLE 1
Questionnaire Subset for Evaluation of ODS

Questions	Score and value of response
(1) Frequency of bowel movements	0 = 1–2 times per 1–2 d 1 = 2 times per wk 2 = Once per wk 3 = Less than once per wk 4 = Less than once per mo
(2) Difficulty or excessive straining	0 = Never 1 = Rarely 2 = Sometimes 3 = Usually 4 = Always
(3) Incomplete evacuation	0 = Never 1 = Rarely 2 = Sometimes 3 = Usually 4 = Always
(4) Time required for a successful bowel movement	0 = Less than 5 min 1 = 5–10 min 2 = 10–20 min 3 = 20–30 min 4 = Greater than 30 min
(5) Number of failed bowel movements in a day (during a 24 h period)	0 = Never 1 = 1–3 attempts 2 = 3–6 attempts 3 = 6–9 attempts 4 = Greater than 9 attempts
(6) Need for assistance	0 = Without assistance 1 = Laxative use 2 = Digital or enema use

the rectum following STARR. The median length of hospital stay was 1 d. Analysis revealed no significant difference in patient outcomes between the two surgeons.

Thirteen patients (35.1%) developed minor complications during 90-d post-operative follow-up (six of these patients developed more than one complication), see Table 4. The complications included transient episodes of bleeding ($n = 6$, 16.2%) and/or tenesmus/pain ($n = 5$, 13.5%); development of granuloma at the anastomosis site ($n = 2$, 5.4%); dyspareunia ($n = 2$, 5.4%); persistent constipation ($n = 2$, 5.4%); transient fecal incontinence ($n = 2$, 5.4%); persistent rectocele ($n = 1$, 2.7%); stricture ($n = 1$, 2.7%); and urinary retention ($n = 1$, 2.7%). Two patients (5.4%) required re-intervention: dilation of stricture in one and transanal excision of staple granuloma in another. There were no major complications such as pelvic abscess, anastomotic leak, or rectovaginal fistula.

Follow-up evaluation occurred *via* telephone at a mean of 20.3 ± 6.5 mo (median 20 mo, range 9–36 mo) following STARR. Five patients (13.5%) were lost to long-term follow-up. There was a significant improvement in the overall constipation score subset: 11.1 ± 3.6 (range 0–17) preoperatively compared with 4.6 ± 3.9 (range 0–14) postoperatively ($P < 0.00001$). Significantly improved

patient outcomes were observed in each of the six components of the questionnaire: frequency of bowel movements ($P < 0.003$), difficulty or excessive straining ($P < 0.00001$), incomplete evacuation ($P < 0.00001$), time required for a bowel movement ($P < 0.0001$), number of failed bowel movements in a 24 hr period ($P < 0.00001$), and need for assistance ($P < 0.0007$). Overall outcome was reported as “excellent” in 16 patients (50.0%), “good” in seven patients (21.9%), “adequate” in five patients (15.6%), and “poor” in four patients (12.5%). When asked in retrospect if they would undergo the procedure again, 26 (81.3%) responded affirmatively. Of note, nine of these patients (34.6%) experienced postoperative complications.

DISCUSSION

Obstructed defecation syndrome is a complex disorder that may be attributed to a combination of both physiologic and anatomic abnormalities. Historically, surgical options for the treatment of ODS secondary to rectocele and internal intussusception have yielded variable results and a consensus on the gold standard for treatment has yet to be established. Our goal was to evaluate the results of the STARR procedure for ODS in regards to patient satisfaction and postoperative symptomatic outcome. According to a search on the ClinicalTrials.gov website for STARR as an intervention, there are four completed trials and three trials that are currently recruiting. This study represents one of the first data series reported from North America.

Postoperative constipation scores revealed improvement in all components. We used a subset of six questions from the Wexner constipation scoring system [1] to quantify the severity of constipation in each patient. These questions were chosen because they facilitated pre- and postsurgical evaluation of symptoms, and they afforded straightforward and accurate completion by the patients. The extremely significant improvement between pre- and post-evaluation with the six-component questionnaire subset ($P < 0.00001$) was attributed to the significant improvement in the six individual components ($P < 0.003$ for each component). These findings reflect the goal of STARR—to restore the capacity and compliance of the rectum by resecting the prolapse and repairing the rectocele [3]. The results of the current study are comparable to those of other studies employing the Wexner constipation scoring system for pre- and post-STARR assessment of ODS symptomatology [15, 16], see Table 5. The greatest improvements across all studies were in the components of incomplete evacuation and difficulty with or excessive straining.

For the patient satisfaction question, we used the same terminology employed by Renzi *et al.* for the response

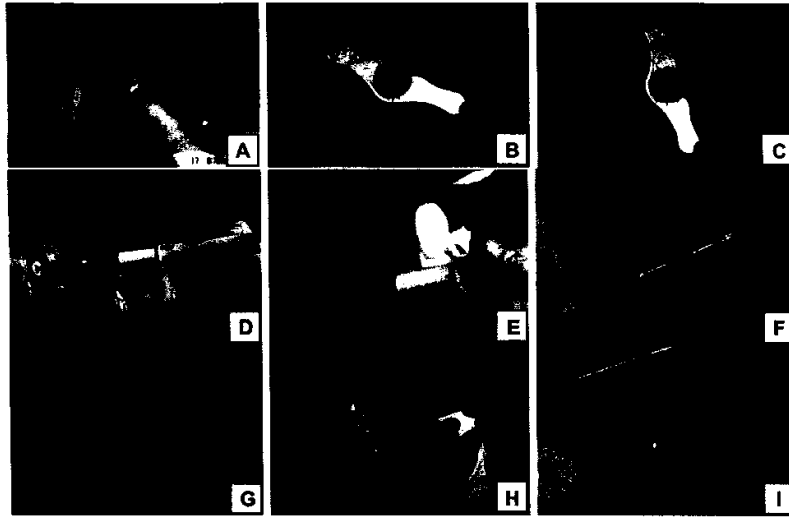


FIG. 1. Staged transanal rectal resection (STARR) procedure. (A) Introduction of circular anal dilator and small sponge. (B) Semi-purse-string of the anterior prolapsing tissue, first row. (C) Parachute sutures, second and third rows. (D) Insertion of first STR10 staple. (E) Confirming exclusion of posterior vaginal wall. (F) Resected anterior portion of prolapsing segment. (G) Posterior parachute sutures and anterior staple line. (H) Insertion of second STR10 staple. (I) Resected posterior half of rectal wall.

options (excellent, good, adequate, and poor), but created a 4-point Likert scale for evaluating success instead of using the post-STARR constipation score [15]. We assessed success of the procedure from the self-reported point of view of the patient's satisfaction with the

Patient demographics	
Gender	Female: 37 (100%)
Age	52.9 ± 11.2 y (range 31–74 y)
Comorbidities	
Psychopathology	Depression: 14 (37.8%)
Other anorectal pathology	Internal hemorrhoids: 24 (64.9%)
Previous surgical history	
Hysterectomy	31 (83.8%)
Rectocele repair	9 (24.3%)
Bladder suspension	8 (21.6%)
Anorectal surgery (i.e., hemorrhoidectomy)	6 (16.2%)

All patients had evidence of rectocele and/or intussusception and had failed conservative measures (including dietary modification and behavioral counseling) prior to being offered STARR.

procedure. The response descriptors are easily understood by the patient and may prove consistent if assessed over time in a serial fashion. Sixteen patients (50.0%) described their overall surgical results as excellent, whereas four patients (12.5%) described them as poor. We did not find any significant factors in the pre- or postoperative analysis to account for the negative feedback from the latter group of patients. When asked if in retrospect they would undergo the procedure again, 26 patients (81.3%) responded affirmatively (this included 9 of the 13 patients who experienced postoperative complications). Although self-reported patient outcomes are an inexact measure, this positive response rate in the face of some minor complications (69.2%) is indicative of overall positive satisfaction following STARR.

Six patients (16.2%) had a known preoperative finding of enterocele and underwent STARR under laparoscopic surveillance. There were no complications such as cross contamination, wound infection, or hernia in these patients. While enterocele has been thought to be a contraindication to STARR due to the potential for small bowel injury [1], use of laparoscopic guidance, as first described by Petersen *et al.* [17], facilitated reduction and removal of the small bowel from the pelvis to enable direct

TABLE 3

Preoperative Evaluation of Patients	
Anal physiology studies	
Anal dyssynergia and non-relaxation of pelvic floor	13 (35.1%)
Preoperative anatomical evaluation (as noted on defecography)	
Rectocele - grade I (small, ≤ 2 cm)	6 (16.2%)
Rectocele - grade II (moderate, 2-4 cm)	22 (59.5%)
Rectocele - grade III (large, >4 cm)	9 (24.3%)
Internal rectal intussusception	30 (81.8%)

visualization and avoidance of inadvertent injury during activation of the stapling device.

Thirteen patients (35.1%) developed complications following STARR, which is higher than the previously reported complication rate of 17.6% (15 of 85 patients) described by Gagliardi *et al.* [11]. However, most of the complications reported in our series were minor and resolved with dietary and behavioral measures (90.9%). Similar minor complications (e.g., pain, urinary retention, and fecal incontinence) have been reported in multicenter European trials [11, 14, 18-20]. However, we did not experience any of the previously reported severe complications, such as pelvic sepsis [11], rectovaginal fistula [21-23], or bleeding requiring re-admission [14]. There were no hospital readmissions, and our reoperation rate of 5.4% compared favorably to the 19% to 37% that has previously been reported [11].

We did not identify any male patients who met the criteria for this study. Several male patients with rectocele and/or intussusception who presented to our clinic were found to have pelvic dyssynergia and entered a PMR program as per protocol. They responded to PMR therapy and, therefore, were not candidates for the STARR.

TABLE 4

Surgical Complications Following STARR During 90-d Follow-Up

Type of complication	Number of patients (%)
Transient episodes of bleeding*	6 (16.2%)
Transient episodes of tenesmus (pain)**	5 (13.5%)
Development of anastomotic granulation tissue	2 (5.4%)
Dyspareunia	2 (5.4%)
Persistent constipation	2 (5.4%)
Transient fecal incontinence*	2 (5.4%)
Persistent rectocele	1 (2.7%)
Stenosis	1 (2.7%)
Urinary retention*	1 (2.7%)

*Resolved with conservative management. Overall, 13 patients experienced complications (six [46.2%] experienced more than one complication).

Reports on STARR in the literature include a minority of 2 to 3 male patients, ranging from 2.6% to 23.1% of all patients evaluated [15, 16, 24, 25]. With the exception of Ommer *et al.*, these studies did not stratify results or offer conclusions based on patient gender. One of the two male patients in the report by Ommer *et al.* experienced increased (worsening of) ODS score at 8 and 13 mo post-STARR, almost triple the mean score of the other patients at the same time points [24]. Given the dearth of data on male patients undergoing STARR for ODS, no meaningful conclusions can be drawn from the literature in regards to outcomes of this procedure in male patients.

Our primary goal was to report patient satisfaction, for which we chose to utilize a constipation score subset and patient satisfaction questionnaire as a global measure of self-reported operative outcome. Overall, the majority of patients, including nine of 13 patients who experienced complications, reported positive satisfaction with the results of STARR. The results of this study should be considered in the context of its limitations. We did not acquire QOL data at serial postoperative time intervals; future studies may benefit from such time points. Furthermore, we chose not to compare pre- and postoperative quantitative measures (e.g., anal physiology testing and defecography), as these measures are best suited for acquisition at predetermined intervals in a prospective series, enabling temporal changes to be correlated with functional status. There was no comparison arm, which would have allowed us to test whether the STARR is safer or more effective compared with a non-stapled therapy. Five patients (13.7%) were lost to follow-up assessment for quality of life and patient satisfaction; in regards to the 32 patients in whom post-STARR questionnaire data were available, four patients (12.5%) were queried less than 1 y postoperatively, which precluded us from



FIG. 2. Postoperative appearance of rectum following STARR.

TABLE 5

Changes in Objective Measures of ODS Symptomatology After STARR Based on the Wexner Constipation Scoring System [1]: Comparison of Current Study Results with Those Previously Reported

Parameter	Current study	Lenisa et al., 2009 [16]	Renzi et al., 2008 [15]
Number of patients (F/M)	37 (37/0)	75 (73/2)	30 (28/2)
Median post-STARR follow-up (mo)	20	12	6
Success rate ¹	Excellent: 50.0%; Good: 21.9%; Adequate: 15.6%; Poor: 12.5%	NR	Excellent: 31.0%; Good: 48.3%; Adequate: 6.9%; Poor: 13.8%
Constipation scale component ²	Post-STARR mean value - Pre-STARR mean value (difference)		
Frequency of bowel movements	0.5-1.5 (-1.0)*	1.4-2.6 (-1.2)*	0.5-0.5 (0)
Difficulty/excessive straining	1.4-2.8 (-1.4)*	1.5-3.6 (-2.1)*	1.2-3.2 (-2.0)*
Incomplete evacuation	1.2-2.4 (-1.2)*	1.4-3.7 (-2.3)*	1.6-3.4 (-1.8)*
Time required for bowel movements	0.4-1.5 (-1.1)*	NR	0.7-2.8 (-2.1)*
Number of failed bowel movements per day	0.5-1.6 (-1.1)*	1.3-3.3 (-2.0)*	0.5-1.7 (-1.2)*
Assistance	0.5-1.3 (-0.8)*	1.6-3.0 (-1.4)* ³	0.7-1.6 (-0.9)* ⁴

NR = not reported, STARR = stapled transanal rectal resection.

*P < 0.003.

¹Use of enemas/laxatives: 0 = never, 1 = rarely, 2 = sometimes, 3 = usually, 4 = always.

²Self-reported patient satisfaction in current study and based on postoperative obstructed defecation syndrome score in Renzi *et al.* study.

³Unless otherwise specified, the same scale used in Table 1 was used by all studies.

⁴Mean and standard deviation values indicate a different scale was used, but no mention in the reference.

ascertaining long-term patient outcomes and satisfaction for all patients.

The STARR procedure may be an acceptable surgical procedure in those with ODS secondary to rectocele and internal rectal intussusception. Through proper patient selection, a potential exists for significant symptomatic relief, a low complication rate, and a high rate of postoperative patient satisfaction. In addition, this procedure can be offered with laparoscopic guidance to those patients with a documented enterocele.

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