Disappointing long-term outcomes after stapled trans-anal rectal resection (STARR) for obstructed defecation

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Abstract

Purpose: To assess both short and long-term functional outcomes and quality of life of patients treated with stapled trans-anal rectal resection (STARR) for obstructed defecation syndrome (ODS).

Methods: 46 patients with ODS, due to rectocele and/or rectal intussusceptions were treated with STARR. Data collected included demographics, OR time, pain score using visual analog scale (VAS), and complications. The study included defecographic assessment and anal manometry [Urge to defecate volume (UTDV) and maximum tolerable volume (MTV)], both were done preoperative and 1 year postoperative. Modified obstructed-defecation questionnaire (MODS), patient assessed constipation-quality of life (PAC-QOL) score and Cleveland clinic foundation (CCF) continence score were all recorded preoperative and every 6 months during follow-up.

Results: Mean age was 48.4 years. 45 patients had mild postoperative pain (VAS: 1-2). Only one male patient had severe pain (VAS: 7). Three patients developed stenosis at the staple line 6 months postoperative and were dilated manually. Follow-up period range was (18 – 48) and median follow-up period was 42 month. Recurrence rate was 6.5% after 18 months, 10.8% after 36 months and 13 % after 42 months. Significant reduction in maximal tolerable volume (MTP) and urge to defecate volume (UTDV) was recorded. Modified obstructed-defecation questionnaire (MODS) and PAC-QOL showed significant improvement after 6 months and this improvement was maintained for 18 months then rapid decline till the end of follow up period.

Conclusions: STARR is a safe surgical procedure that effectively restores anatomy and function of the anorectum in patients with ODS. This correction improves functional and QOL scores, however high rate of symptomatic recurrence and QOL score decline are expected after 18 months.

Keywords: STARR, ODS, outcomes.

Background:

Obstructed defecation syndrome (ODS), is a common multi-factorial disease characterized by the presence of normal desire to defecate but with unsatisfactory fecal evacuation attempts.[1] Symptoms of ODS that lead to impaired quality of life include feeling of incomplete evacuation, excessive straining during defecation, the need for digital vaginal or perineal assistance, insertion of fingers into the anal canal and the use of enemas or suppositories to defecate.[2,3] Patients might have structural abnormalities such as rectocele or distal rectal intussuception, and/or functional alterations such as non relaxing puborectalis or spastic external sphincter contractions.

Treatment of ODS should start by conservative measures and biofeedback treatment. Surgery should be reserved for patients with structural abnormalities if all the conservative treatments failed.

To complicate matters, approaches proposed to resolve ODS (transanal, transperineal, or transvaginal) have important limitations; and there is no evidence-based agreement on the best surgical approach for dealing with ODS.

Radiological investigations showed that subclinical obstructed defecation can be compensated by three basic mechanisms; a) transverse extension of the rectum forming rectocele, b) longitudinal extension forming perineal descent and c) pelvic expulsion forming prolapsed piles. However these mechanisms work only if the rectum is capable of creating an endo-luminal pressure gradient more than the residual closure pressure of the anal sphincter.[4]

With prolonged obstruction the previously described anatomical alteration will occur leading to extreme thinning and laxity of muscular coat of the rectum with loss of the normal rectal compliance leading to inability of the rectum to support pressure for defecation with the development of rectal invagination that gradually increases till it obstructs the normal passage of the stool.[4,5]

Stapled transanal rectal resection (STARR), has been proposed by Longo for treatment of ODS. It involves a double-stapling technique to produce a transanal full-thickness rectal resection with the goal of correcting structural abnormalities associated with ODS as it leads to restoration of rectal flow, normal rectal wall thickness and compliance, correction of rectocele and correction of rectal intussusceptions.[6,7]

Many publication demonstrated safety and efficacy of the procedure among patients of ODS. Published results reported early symptomatic improvement, however, the literature is lacking long term follow-up for these cases. We report the results of long term functional outcome and quality of life of patients treated with STARR for ODS due to structural abnormalities.

Specific aims:

To address both short and long term functional outcome and quality of life of patients treated with STARR for ODS due to structural abnormalities.

Patients and methods:

From August 2005 to August 2008, 46 patients with ODS, (30 females and 16 males) were included in this study. Surgeries were done in both Alexandria University Hospital And Karmoz Health Insurance Hospital in Alexandria. Inclusion criteria included patients with symptoms of obstructed defecation due to structural abnormalities (rectocele and/or rectal intussusception) that failed to respond to conservative measures.[8] Normal continence (Wexner continence score[9] <4) and at least score of 9 on modified obstructed-defecation syndrome **Table(1)** were mandatory in all patients enrolled in this study. Exclusion criteria comprised inflammatory bowel disease, colorectal neoplasms, and severe anal stenosis.

The Ethics Committees of Alexandria University approved the study protocol. All patients participating in the study gave preoperative written informed consent.

Preoperative clinical evaluation consisted of: A questionnaire for the presenting symptoms, bleeding per rectum, pregnancies, episiotomy, and previous pelvic or anal surgeries. Clinical examination of the perineum, rectum, and vagina to diagnose any associated abnormalities and evaluate the perineal descent. Proctoscopy was performed for all patients to evaluate any concomitant anorectal disease and colonoscopy was done if inflammatory bowel disease or malignancy was suspected.

The validated modified obstructed-defecation syndrome patient questionnaire, constipation-quality of life (PAC-QOL) score[10] and CCF continence score,[9] were recorded.

Defecography was performed before surgery and one year postoperative. The rectum was filled with 200 ml of a suspension of barium sulfate paste, and the patient was positioned on a toilet seat with a radiolucent rim. Radiographic pictures were taken at rest and at defecation attempt.

Pescatori classification was used for rectal intussusception (first degree when detectable below the anorectal ring on straining, second degree when it reached the dentate line, and third degree when it reached the anal verge)[11] and shape of rectocele was classified according to the Marti classification (Type 1: digitiform rectocele; Type 2: big sacculation with anterior

rectal mucosal prolapse; Type 3: rectocele associated with intussusception and / or rectal prolpase).[12]

Rectocele was defined as any anterior or posterior bulge outside the line of the rectal wall >2 cm, occurring during rest and at attempted defecation. Intussusception was defined as the circumferential infolding of the rectal mucosa more than 3 mm during evacuation. Abnormal perineal descent was noted if the anorectal junction was situated at more than 3 cm below the pubococcygeal line at rest or at more than 5 cm below the pubococcygeal line during evacuation.

Anorectal manometry using perfusion catheter systems (Synectics, Stockholm, Sweden) was done for all patients with evaluation of mean urge-to-defecate volume (UTDV), and maximum tolerable volume (MTV).

STARR procedure was performed under general anesthesia with the patient in the lithotomy position using two (PPH-01™; Ethicon Endo-Surgery, Inc., USA). The procedure was designed to achieve a transanal full-thickness resection of the lower rectum. Resected "doughnuts" obtained during surgery were measured.

Operative data collected included, operative (OR) time, estimated operative blood loss (EBL) and bleeding from the suture line.

Patients were discharged within the first 24 hours with a prescription of oral metamizol 1 g/8 hours coupled with oral ketorolac 10 mg/8 hours, and stool softeners.

At the first follow-up visit after 1 week, the level of postoperative pain was evaluated on visual analogue scale (0 to 10).

Patients were followed up every 6 months till the end of the study. During the follow up visits, proctologic examination was done to evaluate the clinical correction of the rectocele or intussusception and the anastomotic line for local complications (stenosis, granulomas, or mucosal prolapse). Also, digital rectal examination was performed to evaluate anal sphincter tone. Variables recorded in the follow up visits included modified obstructed-defecation syndrome patient questionnaire, constipation-quality of life (PAC-QOL) score and CCF continence score. Defecogram was done after 1 year to evaluate the incidence of rectocele, intussusception, sigmoidocele, and abnormal perineal descent in both improved and unimproved groups. Anorectal manometry was done after 1 year to evaluate mean urge-to-defecate volume (UTDV), and maximum tolerable volume (MTV).

Statistical analysis:

Quantitative variables were expressed as mean ± standard deviation. Qualitative variables were expressed as frequency and percent. The data consisting of repeated measures across multiple time points during the period of observation were compared using the one way-ANOVA test, and association of qualitative non independent values were verified by the McNemar test with Bonferroni correction. Comparison between preoperative and postoperative manometric data was done using Wilcoxon's rank-sum test for paired data. Statistical significance was established at $p < 0.05$.

Results:

Preoperative data and demographics

The study included 30 females and 16 males with male to female ratio 1:1.87. Mean age of patients in this study was 48.4 ± 10.7 years (range, 29-68). All 30 females were multiparous. Nineteen of them had at least one vaginal delivery with episiotomy, while 11 females never had vaginal delivery.

Preoperative clinical symptoms included sense of incomplete evacuation in 40 patients, constipation in 38 patients, digitations in 14 patients, using of water enema in 24 patients and manual support of the perineum in 10 patients. Anorectal examination revealed associated 3rd or 4th degree hemorrhoids in 7 patients, perineal descent in 6 patients, fissure in 3 patients and skin tags in 4 patients. All preoperative clinical data are summarized in **Table(2)**.

Defecography **Figure(1)** revealed rectocele in 27 female patients (20 Marti Type 2 and 7 Marti Type 3). Rectal intussusceptions without rectoceles were found in 16 males and 3 females (Pescatori first degree in 10 patients and second degree in 9 patients) **Table(3)**.

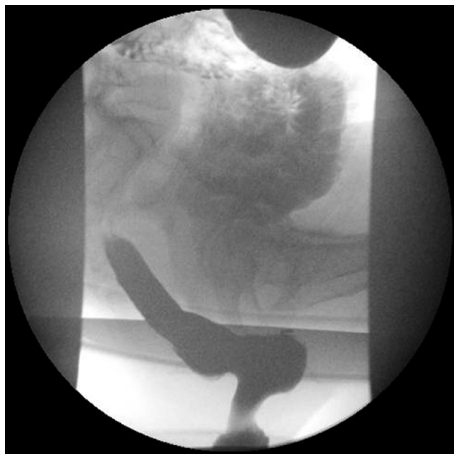

Figure (1): Defecogram showing Anterior rectocele.

Operative data:

Mean operative (OR) time was 48.4 ± 9.6 minutes and estimated operative blood loss was less than 40 cc/ patient in all cases.

3/0 vicryle stitches (Ethicon, Inc. USA) were used to control bleeding from the suture line in 42 patients (36 patients from anterior half and 13 patients from posterior half). Resected rectal wall varied in length from 3-6.5 cm with a mean length of 4.6 ± 1.1 cm. All patients were discharged in the first postoperative day.

Postoperative:

After one week, 45 patients had minimal postoperative pain (VAS: 1-2). Only one male patient had sever pain (VAS of 7), this patient had the dentate line partially entangled in the staple line.

Urine retention was reported in one patient and was treated by urinary catheter; catheter was removed after 12 hours. Urinary tract infection occurred in one patient and chest infection in 2 patients. No incidence of postoperative bleeding, pelvic sepsis or rectovaginal fistulae. No postoperative mortality. Three patients developed stenosis at the staple line after 6 months and they all responded to manual dilatation.

Follow-up:

According to the date of operation, the median follow-up period was 42 month. After 6 months, constipation improved in 31 patients and remained unchanged in 7 patients with no newly developed cases of constipation, however 5 patients (10.7%) and 6 patients (13 %) redeveloped constipation after 36 and 42 months respectively.

No recurrence of symptoms was reported till 12 months. Recurrent marked obstructed defecation with sense of incomplete rectal evacuation, the need of laxatives, enemas or self digitations to evacuate occurred in 3/46 patients (6.5%) after 18 months, 5 patients (10.7%) after 36 months and 6 patients (13%) after 42 months. By clinical examination, proctoscopy, and defecography of these patients; rectocele type 2 was found in 3 patients and rectal intussusceptions in 3 patients.

Multivariate analysis revealed that sex, vaginal delivery, episiotomy were not risk factors for recurrence. However, preoperative digitations, number of parities and longer duration of follow up proved to have significant correlation with symptom recurrence ($P= 0.015$, $P<0.01$ and $P=0.031$ respectively).

Changes in ODS, PAC-QOL and continence score are shown in **Table(4)**. There was significant reduction in the mean ODS score after 6 months and this reduction was maintained after 12 and 18 months, however these scores started to increase steadily after 24 months to 42 months (ODS score at baseline vs. 6 months: 20.13 vs. 4.98, $p<0.001$). Similarly, mean PAC-QOL score increased from a mean of 30.3 preoperative to 52.6 after 6 months postoperative; ($p< 0.001$). Again, this increase in PAC-QOL score was sustained for 24 months then it started to decrease till 42 months **Table(4)**.

Although there were 5 patients who complained from temporary incontinence to flatus for 3 months, all of them had vaginal delivery and episiotomy, yet the CCF continence scores after 6 months was not significantly different from the preoperative values. This continence score was sustained for the whole follow-up period.

As regard anal manometry, there were significant reduction in MTP and UTDV indicating increasing rectal sensitivity **Table(5)**.

Table (1): Modified obstructed-defecation syndrome patient questionnaire.

Question and response options	**Score**			
1. Medication to evacuate (enemas or suppositories)	0	1	2	3
2. Difficulties to evacuate	0	1	2	3
3. Digitation to evacuate	0	1	2	3
4. Return to toilet to evacuate	0	1	2	3
5. Feeling of incomplete evacuation	0	1	2	3
6. Straining to evacuate	0	1	2	3
7. Time needed to evacuate	0	1	2	3
8. Lifestyle alteration	0	1	2	3

Each point is scored according to frequency of the symptom (Questions 1 to 6: 0 = never, 1= less than once weekly, 2= 1-6 times weekly, 3= every day; Question 7: 0 = less than 5 minutes, 1= 6-10 minutes, 2= 11-20 minutes, 3= more than 20 minutes; Question 8: 0= no alteration of life style, 1= mild alteration, 2= moderate alteration and 3= significant alteration of life style). The total score is in the range of 0 (best) to 24.

Table (2): Clinical presentations of patients.

Symptoms	No.	Signs	No.
Incomplete evacuation	40	Hemorrhoids	7
Constipation	38	Perineal descent	6
Digitations	14	Fissure	3
Using of water enema	24	Skin tags	4
Manual support	10		

Table (3): Etiology of obstructed defecation in the study group.

	Rectocele		Rectal intussusceptions	
	Marti type 2	Marti type 3	Pescatori first degree	Pescatori second degree
Females	20	7	2	1
Males	0	0	8	8

Table (4): ODS and Quality of life changes after STARR procedure.

	Preop.	18 months	36 months	42 months
ODS	11.56 ± 2.3	2.2 ± 2.5	3.7 ± 2.8	4.9 ± 3.1
PAC-QOL	52.6 ± 11.1	30.3 ± 3.8	40.9 ± 10.5	45.3 ± 9.9
CCF- CS	2.8± 0.7	1.8± 0.6	1.8± 0.6	1.8± 0.6

Table (5): Manometric changes 1 years after STARR procedure.

	Preoperative mean ±SDV	1 year postoperative mean ±SDV	P value
UTDV (cc)	115.1 ± 10.6	92.7 ± 5.8	<0.01*
MTV (cc)	301.2 ± 27.1	211.4 ± 20.9	<0.001*

** = significant value, SDV = standard deviation*

Discussion:

Obstructed defecation is a broad term used to describe the condition of patients with defecatory dysfunction and constipation. Anatomical changes that may cause obstructed defecation include rectocele, rectal intussusception and enterocele. The initial management of obstructed defecation is dietary with adequate fluid and fiber intake. Biofeedback can be considered if available. If these fail, most surgeons recommend operative repair.

It has not yet been clearly established which surgical technique is the most effective. But it has been demonstrated that patient selection should be very careful because only symptomatic rectocele or intussusceptions justifies surgical treatment. It should be explained to patients that only the symptoms caused by these pathologies will improve.[13,14] Other associated manifestations, such as irritable colon[15] or pudendal neuropathy, are not modified by operation, so they may persist.

The stapled transanal rectal resection (STARR) is one of the recent surgical options. The goal of STARR is to resect the internal rectal prolapse and concomitantly repair rectocele by means of staplers to restore normal rectal anatomy and function.

In this trial we tried to assess the safety of STARR together with both short term and long-term functional outcome and its effect on the quality of life.

No serious adverse events were reported in this trial; however, around 10% of patients (5/46) experienced minor adverse events in the form of urinary retention, severe pain, and temporary flatus incontinence. Flatus incontinence was explained by sphincteric injury due to operative dilatation and pain occurred due to partial involvement of the dentate line in the suture line. No incidence of postoperative bleeding, pelvic sepsis or rectovaginal fistulae. No postoperative mortality. Three patients (6.5%) developed stenosis at the staple line after 6 months. Frascio et al[6] in their trial on 30 patients, reported no mortality or pelvic sepsis, and 4 % bleeding treated surgically. Boccasanta et al[16] reported urinary retention in (9%), bleeding in (4%) and stenosis in (4%) of patients after STARR procedure. The present results together with previous reports[7,17-20] indicate that in the hands of a properly trained surgeon, the STARR procedure is technically safe and reproducible.

There is scant information about persistent pain after STARR. Most studies report a low incidence, varying from 0.4% to 2%, that actually tends to resolve spontaneously within the first 3 postoperative months.[21] In the current study only 2.1% had persistent anal pain for 2 months. Persistent pain has been suggested to have several causes, such as inclusion of smooth muscle in the resected specimen, or an excessive tension of the anodem in patients with an important fixed external anal component.[22,23]

Boccasanta and colleagues[2] reported staple line bleeding of (30%) with PPH33-03 that necessitate staple line reinforcement by transfixive stitches. In this study, around 90% of patients required transfixive stitches with PPH33-03 stapler. Regarding postoperative bleeding requiring re-operation the literature reports an incidence of about 5%.[21] In the current study, no re-operation was needed.

As regard rectal sensitivity, replacement of the prolapsed mucosa after STARR improves this capability in patients with previously diminished sensitivity as evidenced by decreased UTDV and MTV in the current study. In addition, no significant changes are expected in pressures or the high-pressure zone length.

The current study shows the early functional benefit of the STARR procedure for ODS associated with rectocele and/or rectal intussusception. Maximum improvement was seen at the first post treatment evaluation after 6 months, and there was little change of symptoms between 6, 12 and 18 months, demonstrating that the effects of treatment were apparent almost immediately and lasted for 18 months.

No recurrence of symptoms was reported till 12 months, but there were recurrence in 3 patients after 18 months, 5 patients (10.7%) after 36 months and 6 patients (13 %) after 42 months. Lehur et al[24] reported successful treatment 81.5 % after surgery and this remained stable after follow-up for 12 months. While Arroyo et al[25] found radiologic and clinical correction of the rectocele and intussusception in 94.6% of the patients, with a recurrence of 5% after one year.

A significant improvement in quality of life scores were reported after 6 months and again, the mean scores showed no significant changes from 6 to 18 months; however after 18 months the mean scores started to show decline. The decline was significant after 42 months when compared to immediate postoperative results. Lehur et al[24] found significant improvement in both ODS and QOL scores after 12 months however, no longer follow up was available. Similarly, Jayne et al[7] found significant improvement in obstructive defecation and symptom severity scores and quality of life between baseline and 12 months. Again no longer follow-up available.

Dodi et al,[21] thinks that parity, spastic floor syndrome and psychoneurosis seem to be the risk factors predisposing to failure of STARR, which may be followed by early recurrence of symptoms requiring re-operation. In the current study there were no early recurrence that required re-operation but there was significant correlation between the rate of recurrence and preoperative digitations, parity, and longer duration of follow up. In all cases the recurrence started after more than a year. Up to our knowledge, this is the first report that mentions the correlations between the rate of recurrence and preoperative digitations, parity, and longer duration of follow-up.

There are still no enough studies with long-term follow-up to support our long term functional results and quality of life. However, up till we have more long term follow up studies. We think that recurrence after long time is a significant issue that should be discussed with the patient before surgery.

Conclusion:

STARR is a safe surgical procedure that effectively restores anatomy and function of the anorectum in patients with ODS. The procedure improves functional and QOL scores, however a progressive high rate of symptomatic recurrence and QOL score decline are expected with time. Preoperative digitations, parity and long follow up are risk factors for symptom recurrence.

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