

## **Starr Surgery In ODS: A Case Series Of 500 ODS Patients Operated At India's Largest Proctology Clinic**

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# Starr Surgery In ODS: A Case Series Of 500 ODS Patients Operated At India's Largest Proctology Clinic

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## Abstract

**Background:** Chronic Constipation or obstructive defecation syndromes (ODS) is a frequently reported clinical problem. The incidence rate of ODS is high in India. The objective of the study was to evaluate the safety and effectiveness stapled transanal rectal resection (STARR) surgery in Indian ODS patients.

**Methods:** In this retrospective observational case series, ODS patients were clinically examined preoperatively and post STARR surgery at 15 days, 1, 3, 6 months and at 1 year. All patients were evaluated for improvement in signs and symptoms by Patient Assessment of Constipation-Quality of Life Questionnaire (PAC-QOL).

**Results:** A total of 500 ODS patients (female 55%) were associated with one or more anatomical abnormalities such as only rectocele 40 (8%), rectocele and recto-rectal intussusception combined 435 (87%) and only recto-rectal intussusception 1 (0.2%). The mean surgery time was 30 minutes and mean hospitalization was for 24 hours. Most of the patients resumed their normal activities by day 5 post surgery. There was significant improvement in daily complaints such as defecation frequency, straining intensity, extended time in defecation, pain or discomfort, use of laxatives, and digitation at the end of one year. The mean PAC-QOL score was improved from 2.52 to 0.61 at one year. The overall improvement was 76%. Approximately 6% patients have not responded to STARR surgery. The STARR surgery found to be safe in ODS patients.

**Conclusion:** Our case series of 500 patients confirms the effectiveness of STARR surgery in patients with ODS and particularly in female ODS patients, in achieving improvement of symptoms, low recurrence rate, improved quality of life and minimal postoperative complications.

**KEYWORDS:** Obstructive defecation syndrome, Stapled transanal rectal resection, Recurrence rate

## INTRODUCTION

Chronic constipation is a frequently reported complaint, having a major economic impact as well as adverse effects on quality of life, affecting 2-30% of western world population (1). Obstructive defecation accounts for the cause of 25-50% of cases of chronic constipation (1, 2). Other reports suggest significantly higher levels of obstructed defecation in the elderly, especially above the age of 65 with females being affected more than males with a ratio of 2.2: 1 (3). Many studies have shown the higher prevalence in non-Caucasian compared to Caucasian population (4).

Obstructed defecation is defined as per the Rome III guidelines, based on the infrequent defecation, straining on bowel movements, incomplete evacuation, and hard stool (5). Obstructed defecation is caused by pelvic dyssynergy, rectocele, rectal intussusception, enterocele, pelvic organ prolapse, and overt rectal prolapse (6), representing either a defect of pelvic support or abnormal function of the pelvic floor musculature (7).

The success rate of other surgical approaches such as transvaginal, transperineal, or transanal ranges from 80–95% (8). However, these procedures reportedly have high recurrence rates, adverse safety profiles and may not be the treatment of choice for patients with simultaneous anatomical abnormalities (8, 9). “Stapled Transanal Rectal Resection” (STARR) procedure was introduced by Longo in 2001. As per the 2005 consensus report, surgical intervention such as STARR should be considered in patients who failed to respond to conservative therapy (e.g. medical management) and obstructed defecation is associated with anatomical abnormalities such as rectocele, rectal intussusceptions and mucosal prolapse. The complications can be bleeding, hematoma, urinary

retention, severe pain, dehiscence, infection, recto-vaginal fistula, and fecal urgency (10). However, it is emphasized that STARR surgery should be performed by the experts to minimize the complication rate as STARR procedure is considered to be have long learning curve (11). Various clinical studies (case series and registries) have established the effectiveness of STARR procedure in patients with obstructive defecation syndrome (ODS) in terms of improved function and better quality of life for patients (12, 13, 14, 15).

The objective of the study was to evaluate the safety and effectiveness of STARR procedure in Indian ODS patients. This would be one of the largest case series on STARR procedure in ODS patients.

#### **MATERIAL AND METHODS**

In this retrospective study, clinical data collected as part of standard care surgical practice were analyzed. This was a case series of the first 500 ODS patients who underwent STARR procedure between period 2009 to 2013 who have completed more than 1 year of follow up. This is a single surgeon, single institution case series. Patients were treated under the aegis of Dr. Ashwin Porwal's Healing Hand Clinic, Pune, one of the leading proctology clinics in India. Dr. Ashin Porwal was the main surgeon for each case and one of 3 surgeons acted as assistants for some surgeries.

All symptomatic ODS patients with one or more anatomical abnormalities, who failed to respond to conservative therapies (e.g. biofeedback and medications), are considered for the surgery. ODS and associated abnormalities were diagnosed on the basis of clinical examination, MRI defecography, colonoscopy, and anorectal manometry. Longo's ODS score used to establish the severity of the ODS. Patients with active

anorectal infection, concurrent severe anorectal pathology, proctitis (inflammatory bowel disease, radiation), enterocele at rest (low, stable), or chronic diarrhoea was excluded from the STARR procedure. Additionally, patients with previous transanal surgery (rectal anastomosis), presence of foreign material adjacent to the rectum (mesh), and concurrent psychiatric disorder were also not considered for the STARR.

STARR procedure was done as per the technique developed by Antonio Longo. It comprised of double-stapled circumferential resection of the lower rectum together with any associated rectocele, intussusception or mucosal prolapse with use of use of two circular staplers (PPH03 and PPH01, Ethicon Endosurgery, USA) (Figure 1).

Patients were clinically assessed at 15 days, 1, 3, 6 months and 1 year postoperatively. Patients were evaluated for overall satisfaction and improvement by Longo's ODS score system. Patient Assessment of Constipation-Quality of Life Questionnaire (PAC-QOL), which is self-reported questionnaire, was used to assess the patient's quality of life. Adverse event data were collected at each follow up visit.

Statistical analysis was performed using paired *t*-test for continuous variables and Wilcoxon's signed-rank test for quantitative variables (Longo's Score and PAC-QOL). A *P* value < 0.05 was considered statistically significant. Others were presented in percent value.

## **RESULTS**

A total of 500 ODS patients underwent STARR surgery between 2009 and 2013 at the clinic. The mean age of the patient population was  $47 \pm 16.21$  years. Female patients, 275 (55%), were the predominant population.

Rectocele with recto-rectal intussusception was present in 435 (87%) patients. Rectocele alone was present in 40 (8%) patients (Figure 1). Recto-rectal intussusception alone was present in only 1 patient (0.2%) (Table 1). The mean surgery time was 30 minutes and mean hospitalization was 1 day. Patients have resumed their normal activities by an average of 5 days post operatively (Table 1).

In addition to STARR surgery, fistulectomy was performed in 11 (2.2%) patients and skin tag excision was performed in 9 (1.8%) patients. The clinical presentations of patients were improved postoperatively (Figure 3 and Figure 4).

The changes in ODS are shown in Table 2. The mean values are presented. These were defecation frequency, straining intensity, extension of time in defecation, sensation of incomplete of evacuation, recto/ perineal pain/ discomfort, activity reduction per week, use of laxatives/enemas and digitation. All signs and symptoms were improved significantly at the end of each follow up period. None of the patients required the use of enemas and digitation at the end of one year of follow up (Table 2). The mean Longo's Score significantly decreased from 24.53 preoperatively to 4.51 at the end of 1 year follow up ( $P < 0.05$ ) (Table 2).

The quality of life was improved as assessed by PAC-QOL. The overall PAC- QOL mean value was reduced from 2.52 at baseline to 0.62 at 1 year follow up. The overall improvement in PAC- QOL was 76% at 1 year following surgery (Table 3).

The rate of adverse events (AEs) was in between 3 -15% at postoperative day 15, most of which resolved significantly at the end of 3 months (0 – 4%), and 1 year (0 – 5%) postoperatively (Table 4). The most commonly

observed AEs were pain, urgency, burning, and bleeding were resolved without medication. 59 (11.5%) patients reported mild pain and 72 (14.4%) patients reported urgency at postoperative day 15. The incidence of these symptoms reduced to 8 (1.6%) and 2 (0.4%) respectively at the end of 1 year. Other adverse events such as burning in 50 (10%) patients, bleeding in 19 (3.8%) patients, and loose motion in 18 (3.6%) patients that were present at postoperative day resolved completely at 1 year. Overall patient satisfaction from STARR surgery at the end of 12 months was 94%.

No cases of recto-vaginal fistula or staple line insufficiency are reported. Two (0.4%) patients had bleeding on postoperative day 3 not responding to non-operative treatment. The patients returned to the operating room for anorectal exam under anesthesia with ligation of bleeding from the staple line.

Staple line stricture was seen in 30 male patients. There were no identified strictures in female patients. Post STARR staple line stricture developed in 5 (1%) patients at week 4, in 15 (3%) patients at week 5 and in 10 (2%) patients at week (Table 5). Patients who developed staple line stricture at the end of 2 months underwent 3 quadrant stricturoplasty under anesthesia. Six patients developed recurrent strictures at 6 weeks after stricturoplasty. They were subjected to stricturoplasty again followed by weekly wide bore proctoscopy for 6-8 weeks to prevent stricture recurrence. They did not develop stricture recurrence during 3 months of follow up.

## **DISCUSSION**

Most of the published literature regarding STARR procedure are from developed nations in Europe and America. Although the epidemiology

data are not available for India and the prevalence of ODS is considered to be high in India. However, clinical studies have not been published so far. Our case series of 500 ODS patients could lead the way for effective treatment for unacknowledged disease, ODS, in the Indian population.

The profile of Indian ODS patients was similar to the earlier published literature, in terms of a high incidence in female patient population. However, compared to other published series, the ratio of females to males was relatively low. This may be due to a lack of awareness and because of associated anatomical abnormalities such as rectocele and recto-rectal intussusception. Patients selected for STARR were not responsive to conventional therapies such as medical therapy, dietary modifications, biofeedback, etc.

The safety and effectiveness of STARR have been reported by many studies (16, 17, 18, 19, 20). The duration of follow up in these studies was between 23 to 34 months. In all studies, the signs and symptoms associated with ODS were reduced after STARR procedure. On examination, the authors noted significant reduction of rectocele and intussusception in all patients (16, 18, 20). Similarly, we found a significant improvement in signs and symptoms present before STARR surgery.

The significant improvement in patient satisfaction score (>94%) is similar to earlier published literature (16, 17, 19, 20). The European registry had also showed significant improvement in various quality of life scores at the end of 1 year (13). Four randomized control clinical trials (RCTs) have presented the similar clinical findings post STARR surgery. The mean operating time (30 minutes) and mean length of stay (24 hrs) was also similar to other published studies. Additionally, time to

resumption of normal activities in our study was also 5 days, which is comparable to other studies.

Adverse events during the first few weeks after surgery such as urgency, frequency, and mild pain observed in our study was 3-15% at postoperative day 15 and resolved at 1 year follow up. The published literature has shown a similar adverse event profile for STARR procedure. Other studies also have shown the good to excellent clinical outcomes for short term follow up evaluation (16-20). German STARR registry data of 379 ODS patients showed significant reduction in ODS symptoms and improvement in quality of life as judged by symptom-specific PAC- QOL and generic ED-5Q (utility and visual analog scale) score (21). We found our study results such as operation time and safety profile are similar German STARR registry. The recurrence rate or no response to STARR surgery rate has been reported as 2-10% of cases. Our study results also fall in the same range of percentage of patients who had not responded to STARR surgery.

In our experience, certain key steps are critical for a better clinical outcome of STARR surgery. The correction of rectal intussusception is very critical. The surgeon should be very selective in applying stay sutures for lateral wall (9 o'clock and 3 o'clock positions). Staple line should be placed 3cm above the dentate line in males and up to 4 cm above dentate line in females.

This is one of the largest case series published so far, on the safety and effectiveness of STARR procedure in the Indian ODS patient population. The results of our study once again establish the usefulness of STARR for a better clinical outcome in ODS patients. As highlighted in the consensus

report, the differentiating factors for a better clinical outcome would be the proper surgical technique using two circular staplers as well as patient selection. The procedure has evolved over the period of years as having the clinical outcome. However, the long term data on STARR has not yet been published and it would be important to know the long term safety and effectiveness of the STARR procedure.

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**Table 1. Patient demography**

Total number of patients	n=500
Age (years)	47 years ( $\pm 16.21$ )
Male	225 (45 %)
Female	275 (55%)
Male to female ratio	0.82:1
ODS Patient mapping	500
Only rectocele	40 (8%)
Only recto-rectal intussusception	1 (0.2%)
Rectocele + recto-rectal intussusception	435 (87%)
subcutaneous fistula	11 (2.2%)
skin tags	9 (1.8%)
Surgery details	
STARR only	480 (96.0%)
STARR + fistulectomy	11 (2.2%)
STARR + skin tag excision	9 (1.8%)
Surgery time, mean	30 minutes (range 22-37 min)
Length of hospital stay, mean	1 day (range 1-3 days)
Resumption of normal activities, mean	5 days (range 4-7 days)

**Table 2. Improvement in baseline signs and symptoms**

	Preoperatively	15 Day	1 Month	3 Month	6 Month	1 Year
Defecation Frequency	1.46	1.79	1.24	1.03	0.65	0.52
Straining Intensity	2.26	1.43	1.06	0.89	0.68	0.54
Extension of time in defecation	2.36	1.41	0.96	0.73	0.70	0.59

Sensation of incomplete of evacuation	2.69	2.41	1.82	1.33	1.03	0.75
Recto/perineal pain/discomfort	2.82	1.83	1.46	1.28	0.98	0.78
Activity reduction per week	2.28	1.34	1.01	0.82	0.73	0.62
Laxatives	4.53	2.25	1.43	1.33	0.99	0.71
Enemas	1.41	0.00	0.00	0.00	0.00	0.00
Digitation	4.73	0.00	0.00	0.00	0.00	0.00
Longo's score	24.53	1.46	8.98	7.41	5.78	4.51
Wilcoxon signed ranks test and paired samples <i>t</i> test, both $p < 0.05$						

**Table 3. Overall satisfaction score**

	Preoperatively	1 Month FU	3 Months FU	6 Months FU	1 Year FU
PAC-QOL (Mean)	2.52	1.25	0.98	0.63	0.61

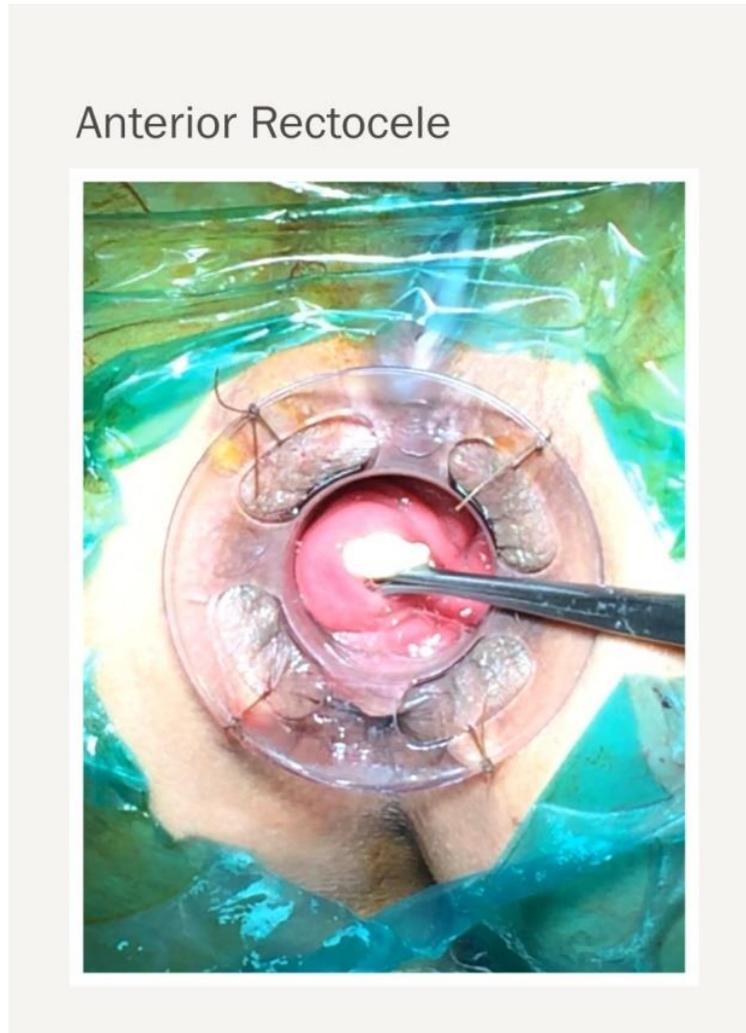
**Table 4. Complications reported**

	15 days – N (%)	1 months – N (%)	3 months – N (%)	6 months – N (%)	1 yr – N (%)
Pain	59 (11.5%)	20 (4%)	10 (2%)	10 (2%)	8 (1.6%)
Burning	50 (10%)	29 (5.8%)	5 (1%)	2 (0.4%)	0
Urgency	72 (14.4%)	47 (9.4%)	7 (1.4%)	4 (0.8%)	2 (0.4%)
Bleeding	19 (3.8%)	16 (3.2%)	1 (0.2%)	1 (0.2%)	0
Loose Motions	18 (3.6%)	12 (2.4%)	7 (1.4%)	2 (0.4%)	0

**Table 5. Staple line stricture reported**

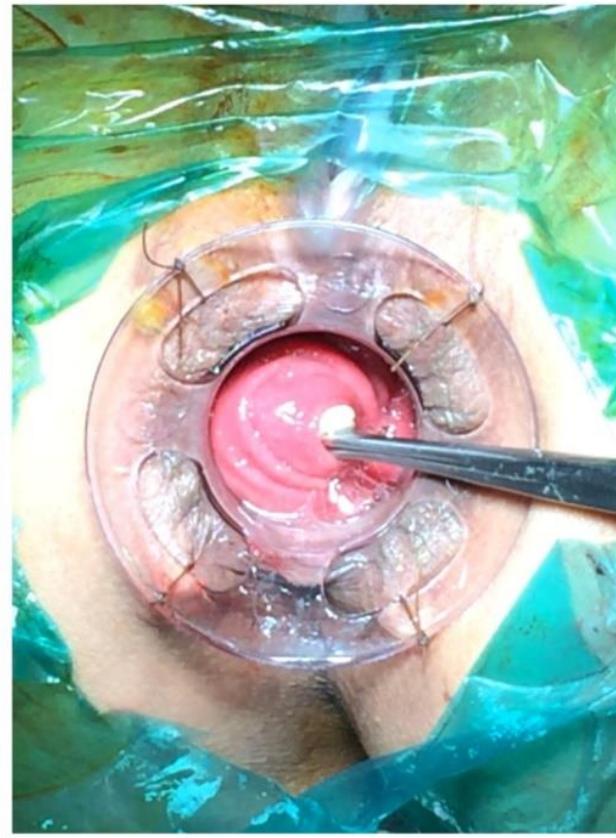
	4 wks – N (%)	5 wks – N (%)	6 wks – N (%)
Patients	5 ( 1%)	15 (3 %)	10 (2%)

**Figure 1.**



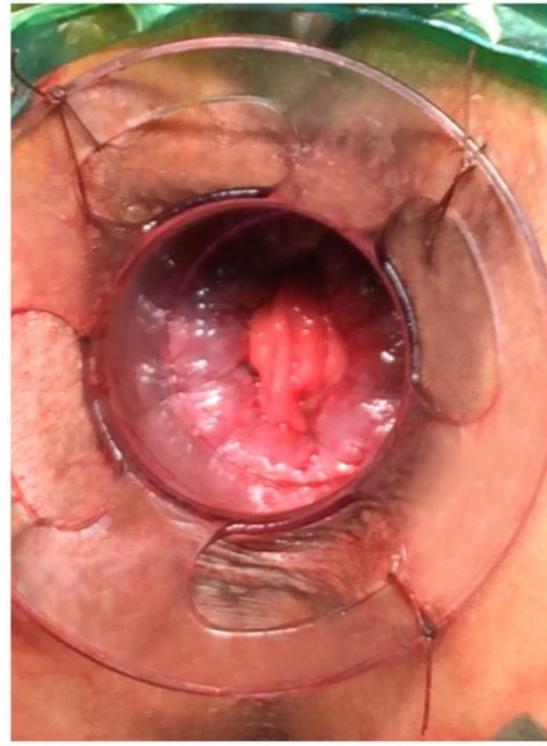
**Figure 2.**

## Recto Rectal Intussusception



**Figure 3.**

After Surgery :  
No internal mucosal prolapse



**Figure 4.**

After Surgery : No Recto Rectal  
Intussusception and No Rectocele

