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ORIGINAL ARTICLE

Stapled transanal rectal resection for the treatment of rectocele associated with obstructed defecation syndrome: a large series of 262 consecutive patients

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Abstract

Background This study aims to investigate functional results and recurrence rate after stapled transanal rectal resection (STARR) for rectocele associated with obstructive defection syndrome (ODS).

Methods A study was conducted on patients with ODS symptoms associated with symptomatic rectocele ≥ 3 cm on dynamic defecography who had STARR at our institution between 01/2007 and 12/2015. Data were prospectively collected and analyzed. ODS was evaluated using the Wexner constipation score. Primary outcomes were functional results, determined by the improvement in 6-month postoperative Wexner constipation score, and 1-year recurrence. Secondary outcomes were operative time, time to return to work, pain intensity measured using the visual analogue scale (VAS), patient satisfaction, and overall postoperative morbidity and mortality at 30 days.

Results Two-hundred-sixty-two consecutive female patients [median age 54 years (range 20–78)] were enrolled in the study. The median duration of follow-up was 79 months (range 30–138). Sixty (23%) patients experienced postoperative complications, but only 9 patients required reinterventions for surgical hemostasis ($n=7$), fecal diversion for anastomotic leakage ($n=1$), and recto-vaginal fistula repair ($n=1$). Only 1 intraoperative complication (stapler misfire) was reported, and there were no deaths. There was a statistically significant ($p<0.001$) reduction in the median (range) Wexner constipation score from 19 (14–24) preoperatively to 9 (5–15) 6 months postoperatively. Only 10 (4%) patients experienced recurrence and only 3 of them required additional reintervention. Patient satisfaction at 1 year was excellent in 86%, good in 13%, and poor in 1% of patients.

Conclusions STARR is a safe, effective, and minimally invasive technique for the treatment of rectocele associated with ODS.

Keywords STARR · Stapled transanal rectal resection · Rectocele · Transanal surgery · Obstructive defecation syndrome · ODS · Pelvic floor disease

Introduction

The incidence of obstructed defecation syndrome (ODS) is not well defined in the literature and it is probably underestimated [1]. ODS commonly affects female with difficult, painful, or incomplete evacuation; the desire for a perineal support, odd posture, digital vaginal or anal insertion to evacuate and bleeding after defecation are common symptoms. Quality of life is usually impaired and the patient often becomes laxative and/or enema dependent: unfortunately this treatment becomes less effective over time [2, 3].

Obstructed defecation syndrome is often caused by the existence of complex anatomical and physiological disturbances, the two most common of which are rectocele and recto-rectal or recto-anal intussusception [1, 2, 4]. Rectocele is a herniation of the anterior rectal wall into the posterior vaginal wall. It may be isolated or associated with other conditions like recto-anal intussusception or anismus [1, 2].

Surgeons advocated various techniques for the treatment of symptomatic rectocele using transvaginal, transperineal,

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transanal, and transabdominal approaches, and a combination of these approaches has been, recommended [1]. However, the optimal technique has still to be identified [3].

Using the same principle as stapled hemorrhoidopexy, stapled transanal rectal resection (STARR) excises redundant tissue to restore normal anatomy and function and has emerged as a minimally invasive surgical treatment for ODS [1, 2]. Two PPH01® circular staplers are used: the first to anteriorly reduce the intussusception and the bulging of rectocele, thus correcting the anterior rectal wall muscle defect, the second to posteriorly correct the intussusception [1, 3, 4].

Promising results for both safety and functional efficacy, with low morbidity rates, were initially reported with the use of the STARR in the treatment of ODS caused by internal rectal prolapse [2]. However, conflicting results with unsatisfactory functional results and morbidity such as bleeding, rectovaginal fistula, chronic pain, urge symptoms and fecal incontinence, called into question the safety and the efficacy of the STARR procedure in the treatment of ODS patients [2, 3].

This prospective study aims to evaluate functional results, and recurrence rate after STARR for rectocele associated with ODS.

Materials and methods

Study design

Patients were recruited between January 2007 and December 2015. Data were collected prospectively. Signed informed consent was obtained from every patient after approval from the local ethics committee in accordance with the principles of the Declaration of Helsinki.

Inclusions and exclusions

Patients with ODS symptoms and symptomatic rectocele ≥ 3 cm on dynamic defecography were recruited for the study and had STARR. Patients who had had previous anal or colorectal surgery, fecal incontinence, occult sphincter damage, severe pelvic dyssynergia, anismus, inflammatory bowel disease, rectocele < 3 cm, as well as general contraindications for surgery, were excluded.

Preoperative work up and preparation

All cases were discussed in a colorectal multidisciplinary meeting. After careful clinical examination, patients were evaluated using the Wexner constipation score [4], Cleveland Clinic Incontinence Score, anorectal manometric studies, proctoscopy, and dynamic defecography.

Before surgery, patients were offered conservative therapy including dietary modification if necessary, fibers, and laxatives. Pelvic floor rehabilitation were offered to those with dyssynergia.

On the morning of surgery, patients received a single phosphate enema. Prophylactic antibiotics (1 gm 3rd generation cephalosporin (Cefotaxime)) were given at induction of anaesthesia.

Surgical technique

Patients were placed in the lithotomy position under spinal or general anesthesia. An examination under anesthesia was performed to confirm the preoperative findings and the size of the rectocele.

A circular anal dilator (CAD) was introduced into the anal canal secured to the perianal skin with four 0 silk stay sutures (Fig. 1a). Three parachute sutures were placed and ligated in the anterior rectal wall above the prolapse apex at 12, 10, and 2 o'clock (Fig. 1b). The first PPH stapler was introduced and the posterior rectal wall was protected with a spatula while the vagina was protected by an Allis clamp that pulled up the posterior vaginal wall (Fig. 1c). The ends of the previously ligated sutures were delivered through the side channels in the stapler; tension was applied to these threads, making sure that the posterior vaginal wall was not incorporated and finally, the stapler was closed and fired. Similarly, the second PPH stapler was fired after placement of three parachute sutures at 6, 4, and 8 o'clock (Fig. 1d, e).

From 2007 to 2010, two Proximate® "PPH-01" staplers (Ethicon Endosurgery, Inc., Somerville, NJ, USA) were used, while from 2011 to 2015, two Proximate® "PPH-03" staplers (Ethicon Endosurgery, Inc., Somerville, NJ, USA) were used.

The staple line was carefully inspected for bleeding, stopped if present by 3-0 Vicryl® (Polyglactin 910) (Ethicon, US, LLC., Cincinnati, OH, USA) full-thickness hemostatic sutures. If needed, two further sutures were applied to embed the redundant tissue that sometimes was left at the level of the junctions between the two suture lines, the so-called "dog ears".

At the end of the procedure, the CAD was removed, leaving an absorbable hemostatic gelatine sponge and a Dufour catheter with its balloon inflated with 30 ml of physiological saline in the rectum. The catheter was removed after 12 h. All surgical specimens obtained during the procedure were sent for histopathological examination.

Postoperative care, follow-up, outcomes, and definitions

Postoperatively, patients were managed according to the enhanced recovery after surgery (ERAS) protocol [5].

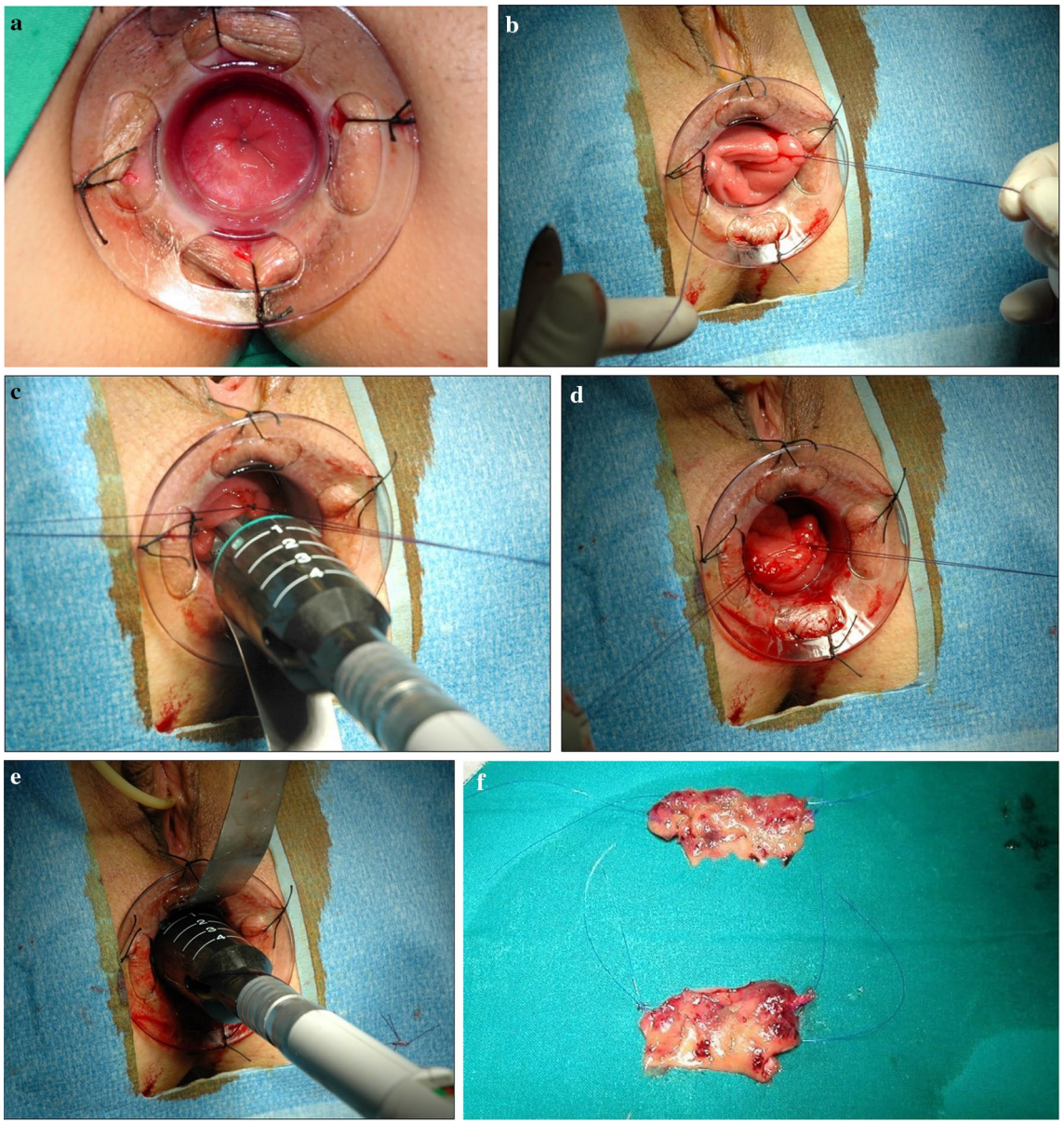

Fig. 1 STARR procedure: **a** Introduction of circular anal dilator; **b** Three parachute suture of the anterior prolapsing tissue, first row; **c** Insertion of first PPH01 stapler; **d** Posterior parachute sutures and anterior staple line; **e** Insertion of second PPH01 stapler. Resected anterior and posterior half of rectal wall; **f** Resected anterior and posterior half of rectal wall

Analgesics were administered on demand in the form of 1 g paracetamol tablets. No routine postoperative radiological imaging was performed. Patients were followed up in the outpatient department at 1, 2 and 4 weeks postoperatively. 6 months postoperatively, patients were evaluated with the Wexner constipation score. Follow-up was then continued every 6 months and lasted until June 2017.

Primary outcomes were functional results and 1-year recurrence. Functional results were determined by the improvement in the Wexner constipation score at 6 months. Secondary outcomes were operative time, time to return to work, pain intensity, patient satisfaction, and 30-day morbidity and mortality. Complications were classified according to the Clavien-Dindo classification of surgical complications [6].

Pain intensity was measured using the Visual Analogue Scale (VAS) (0 = no pain, 10 = worst pain). Severe postoperative pain was defined as a VAS score > 7. Patient satisfaction at a 1 year postoperatively were categorized as excellent, good, and poor.

Variables studied and statistical analysis

Basic demographic data were recorded including age and sex as well as the operative time, length of hospital stay, time required for complete healing, pain score on VAS, patient satisfaction, postoperative morbidity, and mortality. Data were analyzed using SPSS® (Statistical Package for Social Science version 21 for Microsoft Windows, Chicago IL, USA). The statistical review of the study was performed by a biomedical statistician. Continuous data were expressed as a mean ± (SD) or median (range) according to normality. The paired *t* test was performed to compare preoperative and postoperative Wexner constipation score. A p value of <0.05 was considered statistically significant.

Results

Patient characteristics

Two-hundred-sixty-two consecutive female patients [median age 54 years (range 20–78 years)], with a symptomatic rectocele ≥ 3 cm on dynamic defecography, were enrolled. Thirty-seven (14%) patients had had a hysterectomy. Sixty-five (25%) patients used maneuvers to facilitate defecation. Figure 2 shows the recruitment process and patients included. Median operative time was 42 min (range 35–60 min). All patients reported ODS symptoms. There were no statistically significant differences in terms of complications or recurrences in the group of patients treated with PPH01 versus PPH03 (Table 1).

Perioperative mortality and morbidity

There were no deaths. There was only one intraoperative complication: a stapler misfire. Sixty (23%) patients experienced postoperative complications including: temporary urgency ($n=27$), urinary retention ($n=18$) (both treated

Table 1 Postoperative complications and recurrence with PPH01 and PPH03

	PPH01 (2007–2010)	PPH03 (2011–2015)	p value
Total# of interventions	113	149	NS
Temporary urgency	12	15	NS
Urinary retention	10	8	NS
Staple line bleeding	6	6	NS
Rectovaginal fistula	1	0	NS
Retrorectal hematoma	0	1	NS
Anastomotic leakage	1	0	NS
Recurrences	5	5	NS

NS not significant

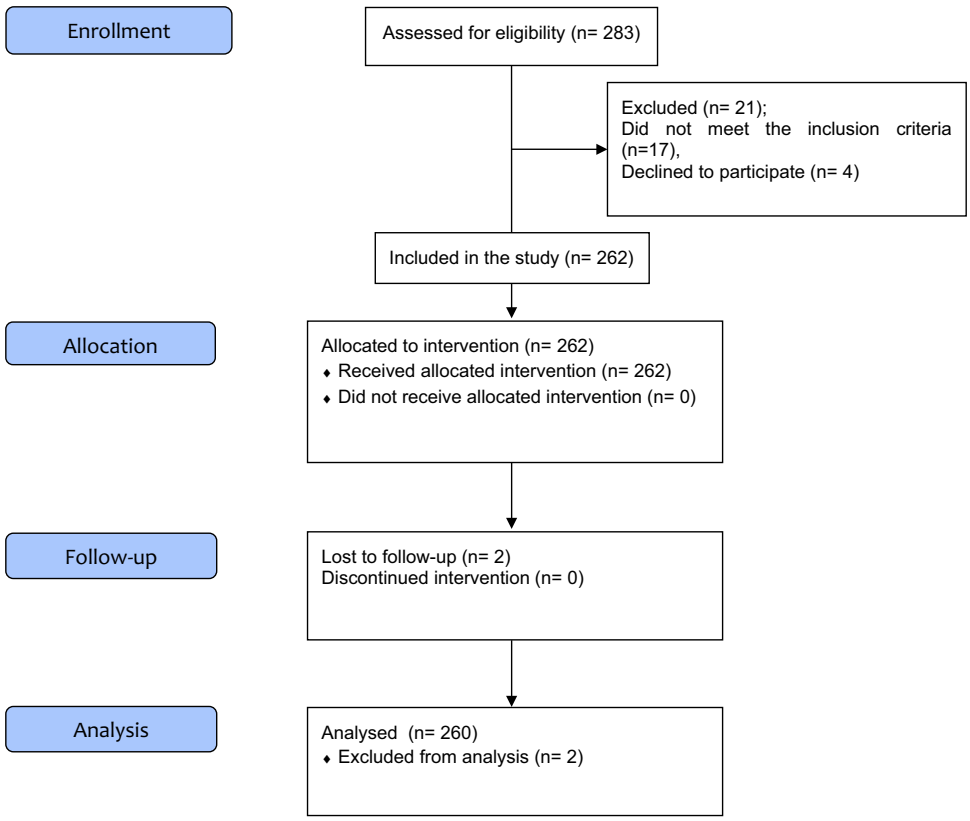

Fig. 2 A flow chart illustrating the recruitment process

Table 2 Postoperative complications, treatment, and Clavien-Dindo classification

Complications	No (%)	Treatment	Clavien-Dindo classification
Total #			
Temporary urgency	27	Conservative	Grade I
Urinary retention	18	Conservative	Grade I
Staple line bleeding	12	5 patients; conservative with blood transfusion 7 patients; reintervention	Grade II Grade IIIB
Rectovaginal fistula	1	Advancement flap	Grade III B
Retrorectal hematoma	1	Conservative	Grade I
Anastomotic leakage	1	Fecal diversion	Grade III B

Table 3 Postoperative course; time to return to work and length of hospital stay

	Median (range)
Length of hospital stay	3 days (range 2–9days)
Time to return to work	15 days (range 5–30 days)

conservatively), staple line bleeding ($n=12$), anastomotic leakage (AL) from the anterior staple line ($n=1$), retro-rectal hematoma ($n=1$), and rectovaginal fistula (RVF) ($n=1$).

Nine (15%) patients required reinterventions for surgical hemostasis ($n=7$), fecal diversion for AL ($n=1$), and repair of RFV ($n=1$). The rectovaginal fistula repair was made with an advancement flap. Patients who experienced staple line bleeding but did not require surgical reintervention were treated with blood transfusions. The retrorectal hematoma was treated with both blood transfusions and antibiotic therapy. Postoperative complications, treatment and Clavien-Dindo classifications are shown in Table 2.

Length of hospital stay and time to return to work

The median (range) length of hospital stay was 3 (2–9) days and the median time to return to work was 15 (5–30) days. (Table 3).

Functional results, recurrence, and patients' satisfactions

The median (range) duration of follow-up was 79 (30–138) months. Two patients were lost to follow-up. Wexner constipation score was reduced from 19 (14–24) preoperatively to 9 (5–15) 6 months after surgery (p value <0.001).

By the end of the follow-up (June 2017), 221 (85%) patients had no symptoms, and 247 (95%) patients reported at least significant improvement. Two-hundred-twenty (84%) patients at 1-week follow-up reported pain on VAS ranging from 1 to 3, but 30 (12%) patients had VAS scores of 4–6, and 10 (4%) patients had a score >7. Satisfaction after a year was excellent in 86%, good in 13%, and poor in 1% of patients. No patients reported dyspareunia. After 1 year 12 (5%) patients still used maneuvers to facilitate defecation. Ten (4%) patients experienced recurrence, with only 3 of them requiring reintervention. All were treated with ventral rectopexy.

Discussion

We found STARR to be safe and effective with a low recurrence rate. High success rates were also reported by Ommer et al. [7] with perineal levatorplasty (74%) and Shafik et al. [8] with transvaginal rectal resection (94%) but both these techniques were associated with high rates of dyspareunia. Melich et al. [9] proposed a new transvaginal approach combined with levatorplasty and biological graft insertion, but reported mild dyspareunia (11%) after the repair.

In a systematic review, Maher et al. [10] concluded that transanal repair of the posterior vaginal defect was better than transvaginal repair in terms of awareness of prolapse and recurrence, however, the STARR procedure was not included in the meta-analysis.

In our study, we employed the STARR procedure for the treatment of rectocele associated with ODS. STARR was first described as a treatment for patients with ODS in 2004 [11]. Both circular staplers used in STARR produced an anterior and posterior full-thickness resection of the rectal wall with the resolution of anatomical alterations like rectocele, intussusception, and rectal prolapse.

The European STARR registry [12] showed a high success rate of about 85% in the treatment of ODS with a complication rate of 36%. Harris et al. [13] compared a transvaginal technique to STARR and reported a similar success rate, a lower complication rate in the transvaginal group, a lower recurrence rate in the STARR group, and dyspareunia only in the transvaginal group.

Several authors, including Pescatori and Gagliardi [14], reported high complication rates after STARR. In our study, there was an overall complication rate of 23% but only 3 major complications (2%). As reported elsewhere in the literature [15–17] the most frequent postoperative complications in our series were bleeding and temporary urgency: most of these were managed conservatively.

Compared to Gagliardi et al. [18] we found a lower rate of reintervention of 3.8% due to complications and 1.2% due to recurrence of symptoms. Low rates of

complications and reintervention may be attributed to increased surgeon experience and implementation of a series of preventive measures, such as the reinforcement of staple line with manual suture to minimize the risk of bleeding, especially at the sites of "dog ears", which also minimizes the risk of AL [19], or the protection of the vagina during stapler firing by an Allis clamp to minimize the risk of rectovaginal fistula. Strict inclusion and exclusion criteria applied in our study are probably another reason we obtained these results.

Farouk et al. [20] analyzed the role of STARR in ODS and concluded that conventional treatments are not effective if rectocele is associated with ODS and STARR is a valid alternative. In our study, we observed the improvement of symptomatic rectocele with a significant reduction of the Wexner constipation score after the STARR procedure and patients did not experience dyspareunia after surgery.

Recently, Knowles et al. [16]. reporting on 5 systematic reviews, compared 5 different surgical techniques used in the management of chronic constipation (colon resection, rectal suspension, rectal excision, rectovaginal reinforcement, and sacral nerve stimulation). In the 47 studies reviewed, conducted on "rectal excisional techniques" including STARR and Delorme, the overall perioperative complication rate was 16.9% and the global satisfaction rate was 72%. Furthermore, those rectal excision procedures resulted in the lowest operation time (44 min). However, they did not comment on functional results. Overall satisfaction in our series was 86%, which is similar to the satisfaction rate reported by Knowles et al. [16] among patients who underwent "colon resection" which was the higher if compared with other techniques. On the other hand, our patients had a higher complication rate (23% vs 16.9%).

Functional results were carefully analyzed in a recent work by Schiano di Visconte et al. [21] with a 10-year follow-up after STARR. In this study, 40% of the patients experienced recurrence of ODS symptoms with a mean satisfaction rate of 21%, progressively decreasing through the years (43% at a 3-months follow-up and 36% at a 12 months). This work is an incentive for us to check if this trend in recurrence rates is unavoidable or if there is something that can be done to maintain the results of the intervention for a longer time. This trend has also been noticed by Guttadauro et al. [22] who reported 10 years of follow-up and noticed a gradual deterioration in outlet function in 10–30% of patients despite no "internal prolapse or rectocele recurrence".

Our study has some limitations. Firstly, it is a single-center experience. Secondly, it is an observational study without a control group comparing STARR with other transvaginal, transperineal, or transanal technique. Furthermore, a longer follow-up is needed to determine the long-term recurrence rate of ODS symptoms or rectocele.

Conclusion

STARR is a safe, effective, and minimally invasive technique for the treatment of rectocele associated with ODS. It is characterized by a very low recurrence rate, low postoperative pain and an early return to work. Precise and careful patient selection and evaluation are of key importance. STARR should be offered to symptomatic patients after failure of medical treatment.

Data availability The datasets during and/or analysed during the current study are available from the corresponding author on reasonable request.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained for the surgical procedure prior to their participation.

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