Review

STARR: indications, results and safety. Review of literature

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Abstract: Treatment of obstructed defecation (OD) is extremely challenging. Patients with symptoms of OD may demonstrate certain anatomic abnormalities on defecography, such as rectal intussusception, rectal prolapse, and recto- or enterocele. Internal rectal prolapse (rectal intussusception) and rectocele are frequent clinical findings in patients suffering from refractory constipation. However, there is still no clear evidence whether the STARR procedure (stapled transanal rectal resection) provides a safe and effective surgical option for symptom resolution in ODS patients In this paper we reviewed the literature to summarize the surgical outcomes and postoperative complications following STARR procedure considering the largest multicentric studies published in literature.

Key words: STARR; Obstructed defecation; Rectal prolapse; Intussusception; Literature review.

INTRODUCTION

Stapled transanal rectal resection (STARR) is indicated for obstructed defecation syndrome (ODS), a complex and multifactorial condition. ODS is more common in women, particularly multiparous women, than in men.[1-3]

ODS is characterised by the urge to defecate but an impaired ability to expel the faecal bolus. Symptoms include unsuccessful faecal evacuation attempts, excessive straining, pain, bleeding after defecation, and a sense of incomplete faecal evacuation. Rectocele (herniation of the rectum into the vagina), internal rectal mucosal prolapse and rectal intussusception may also be associated with ODS. Genital prolapse, enterocele and non-relaxing puborectalis may also coexist.[4]

It has been estimated that approximately 20% of adult female population suffered from the syndrome. The etiology of ODS is likely to be multifactorial, resulting from the interaction of functional and anatomic factors that influence the recto-anal evacuatory mechanism.

Conservative treatment such as diet, biofeedback or pelvic floor retraining improves symptoms in the majority of patients with ODS. Surgery may be considered in patients for whom conservative treatments have failed and where there is an underlying structural abnormality such as rectocele.[1-4]

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.[1]

Based on the stapled hemorrhoidopexy procedure, it has been proposed an alternative technique for patients with ODS caused by rectocele (RE) and rectal intussusception (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.3 In addition, observations from several case series and multicenter trials have demonstrated a clinical benefit of the procedure in short-term follow-up.[5] Nevertheless, some unique and troublesome complications were also documented by a few case reports.[4]

SURGICAL TECHNIQUE

The STARR procedure uses two circular staplers (PPH01, Ethicon Endo-Surgery) to produce a circumferential transanal full-thickness resection of the lower rectum.1,5 The combination of the two stapled resections aims to correct the structural abnormalities associated with obstructed defecation syndrome (ODS), i.e. rectal intussusception, rectocele and mucosal prolapse

A circular anal dilator is introduced into the anal canal and secured with skin sutures. Up to four sutures are placed in the anterior rectal wall at intervals above the ano-rectal junction in a semicircular manner. A retractor is then positioned to protect the posterior rectal wall. The first circular stapler is introduced into the rectum and the open head positioned above the level of the most proximal suture. The stapler is closed and fired to perform the anterior rectal resection.

The procedure is repeated for the posterior rectal resection. Two or more semicircular sutures are placed posteriorly above the anorectal junction. The anterior rectum is protected with a retractor. The second circular stapler is introduced into the rectum with the open head positioned above the level of the most proximal suture. The stapler is closed and fired to perform the posterior rectal resection.[1-5]

SURGICAL OUTCOME

Enthusiastic results have been reported after STARR in the first sample limited short-term studies with good to excellent outcomes in up to 90% of patients.[5]

Subsequently different multicenter trials either have been published in order to assess efficacy and safety of STARR procedure.[5-13]

The European Stapled Transanal Rectal Resection Registry was initiated in January 2006. Data were collected prospectively on effectiveness (symptom severity and obstructed defecation scores), quality of life, incontinence, and safety profile at baseline, 6 weeks, 6 months, and 12 months. At the review performed in May 2008, a total of 2,838 patients were entered into the registry, of whom 2,224 had reached 12 months of follow-up. Mean age was 54.7 years. A total of 2,363 patients (83.3%) were female. A significant improvement was seen in obstructive defecation and symptom severity scores and quality of life between baseline and 12 months (obstructed defecation score: 15.8 vs. 5.8, respectively, $P < 0.001$; symptom severity score: 15.1 vs. 3.6, respectively, $P < 0.001$). Complications

were reported in 36.0% and included defecatory urgency (20.0%), bleeding (5.0%), septic events (4.4%), staple line complications (3.5%), and incontinence (1.8%). One case of rectal necrosis and one case of rectovaginal fistula were reported.[6]

The German STARR registry was designed as an interventional, prospective, multicenter audit. Primary outcomes included safety (morbidity and adverse events), effectiveness (ODS, symptom severity, and incontinence scores), and quality of life (PAC-QoL and EQ-5D) documented at baseline and at 6 and 12 months. Data of 379 patients (78% females, mean age 57.8 years) were included. Mean operative time was 40 min, mean hospitalization was 5.5 days. A total of 103 complications and adverse events were reported in 80 patients (21.1%) including staple line complications (minor bleeding, infection, or partial dehiscence; 7.1%), major bleeding (2.9%), and postsurgical stenosis (2.1%). Comparisons of ODS and symptom severity scores (SSS) demonstrated a significant reduction in ODS score between baseline (mean 11.14) and 6 months (mean 6.43), which was maintained at 12 months (mean 6.45), and SSS at preoperative and at 6- and 12-month follow-up (13.02 vs. 7.34 vs. 6.59; paired t test, $p < 0.001$). Significant reduction in ODS symptoms was matched by an improvement in quality of life as judged by symptom-specific PAC-QoL and generic ED-5Q (utility and visual analog scale) scores and was not associated with an impairment of incontinence score following STARR ($p > 0.05$). However, 11 patients (2.9%) showed de novo incontinence, and new-onset symptoms of fecal urgency were observed in 25.3% of patients.[7]

The STARR Italian Registry (SIR) collected data regarding preoperative assessment of patient and surgical outcome at 6 and 12 months using dedicated tools such as the Obstructed Defecation Syndrome Score (ODS-S), the Severity Symptom Score (SSS), and the Continence Grading Scale (CGS). Data on the quality of life were collected by Patient Assessment of Constipation Quality of Life (PAC-QoL) and the Euro Quality of Life-5 Domains Visual Analogue Scale (EQ-5D VAS). The SIR collected data on 2171 patients (1653 females, 76.1%; mean age 56.2 years; range 20- 96 years). A significant improvement ($P < .0001$) was seen between preoperative and 12-month follow-up in all scores: ODS-S (16.7 vs 5.0), SSS (15.6 vs 2.6), CGS (2.0 vs 0.7), PAC-QoL (51.0 vs 22.1), and EQ-5D VAS (57.5 vs 85.7). Complications included defecatory urgency (4.5% at 12 months), bleeding (3.6%), perineal sepsis (3.4%), and one case of rectovaginal fistula (0.05%).[8]

Recently in a prospective multicenter Spanish trial Arroyo et al9 reported data on 104 patients diagnosed with ODS and treated with STARR. Mean operating time was 46.7 min. Haemorrhage at the staple line occurred in 55 patients (52.9 per cent). Three patients required surgical revision in the first 48 h owing to persistent bleeding. The median postoperative pain score was 2.4 on a scale from 1 to 10. Mean hospital stay was 2.2 days. The mean constipation score improved from 13.5 before surgery to 5.1 at 1-year follow-up ($P = 0.006$). Twenty-three patients reported faecal incontinence at 4 weeks after surgery, but only nine still had minor residual incontinence by 1 year. At a median follow-up of 26 (range 12-72) months, ODS had recurred or persisted radiologically and/or clinically in 11 patients.

Interestingly the ODS II study group randomized 119 women patients who suffered from obstructed defecation with associated rectocele and rectal intussusception to stapled transanal rectal resection or biofeedback training. Fourteen percent (8/59) stapled transanal rectal resection and 50 percent (30/60) biofeedback training patients withdrew early. Eight (15%) patients treated with stapled transanal rectal resection and 1 (2%) biofeedback patient experienced adverse events. One serious adverse event (bleeding) occurred after stapled transanal rectal resection. Scores of obstructed defecation improved significantly in both groups as did quality of life (both $P < 0.0001$). Successful treatment was observed in 44 (81.5%) stapled transanal rectal resection vs. 13 (33.3%) evaluable biofeedback training patients ($P < 0.0001$). Functional benefit was observed early and remained stable during the study. The authors concluded that stapled transanal rectal resection was more effective than biofeedback training for the resolution of obstructed defecation symptoms, and improved quality of life, with minimal risk of impaired continence.[10]

SAFETY

Previous studies have shown a clinical benefit of the STARR procedure for ODS However, limited effect and some serious complications were also described.[4]

Some authors reported persistence of symptoms in over 40% of patients and lack of improvement in over 30% of patients. Besides, reintervention may be needed in over 10% either for postoperative complications or recurrence of the disease.[14,15]

The risk of adverse events and poor outcome following STARR may be increased by concomitant pelviperineal impairments such as anismus, enterocele and sigmoidocele that are contraindications to the procedure.[14]

Postoperative bleeding occurred in the above mentioned trials in 2-5% of patients; besides Arroyo reported bleeding at the staple line in over 50% of patients. A manual suture to reinforce the staple line minimizes the risk of bleeding after STARR. Delayed bleeding may be caused by a granuloma which may be surgically removed.[15,16]

Gagliardi5 reported postoperative pelvic pain in about 10% of patients; Arroyo reported an average of 2.1 postoperative VAS score.9 The pathogenesis of post-STARR proctalgia may be due to retained staples, reduced rectal compliance secondary to full-thickness resection and the double staple line and finally entrapment of innervated striated muscle fibers. Excision of the suture scar, pelvic floor rehabilitation, neurosacral stimulation have been proven to be effective in some selective cases.[15-17]

Accumulating evidences have shown that defecatory urgency was the most common complaint in the immediate and intermediate recovery periods after STARR reported in over 20% of patients.[19] In a recent randomized controlled trial, Boccasanta et al reported that incidence of fecal urgency was 34.0% in the STARR group.[19] 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. Urgency and low rectal compliance after STARR may be successfully treated with pelvic floor rehabilitation.[15,19-21]

De novo fecal incontinence has been reported in up to 20% of patients in the above mentioned multicentric trials. Fecal incontinence may be due to a device-related fragmentation of the internal sphincter, a complication already reported after PPH.[15,19-21] Moreover, fecal incontinence may be neurogenic, due either to vaginal multiparity or chronic straining leading to pudendal neuropathy or to previous hysterectomy, with damage of the pericervical plexus involving anorectal innervation.[22,23]

Transanal electrostimulation and sacral neuromodulation may help in treating such conditions. Bulking agents, and levatorplasty have also been successfully used.24-27

Exceptional complications such us rectovaginal fistula, total rectal obliteration, rectal wall hematoma, perforation with fecal peritonitis, retroperitoneal sepsis potentially life

threatening, requiring surgery and often a diverting stoma have also been reported in literature.[28-33]

INNOVATIONS AND BREAKTHROUGHS

STARR procedure with PPH 01 has limitations in the amount of rectal wall that can be resected; furthermore, the use of a circular stapler also requires retraction of the opposite rectal wall with a retractor. In addition, resection is performed 'blind' after trans-anal insertion of the stapler. A new device has been designed to overcome these difficulties. The Contour Transtar stapler (Ethicon Endo-Surgery; Cincinnati) is designed to allow tailored modulation of the amount of rectal wall to be resected and to improve open visualization of the procedure .the Contour Transtar stapler™ (Ethicon Endo-Surgery, Inc.).

Recently, Jayne et al33 in a prospective multicentric trial compared 150 constipated patients treated with either PPH-STARR (n = 68) or Contour Transtar (n = 82).The mean size of the resected specimen was 27 cm2 in the PPH-STARR group and 46 cm2 in the CT group ($P < 0.001$). Morbidity was 7.3% (n = 5) in the PPH-STARR group and 7.5% (n = 6) in the CT group. Neither septic complications nor surgical re-interventions were observed. The most common complication was minor postoperative bleeding in 2 cases in both groups. Postoperative pain was more frequent after contour TRASTARR (3.5%versus 1.4%).

Constipation Scores (CCS) were similar in the 2 groups (15.50 in the PPH-STARR group and 15.70 in the CT group preoperatively and decreased significantly to 8.25 and 8.01 at 12-months after surgery.[33]

Meurette 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 TRANSTARR remains to be observed.

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