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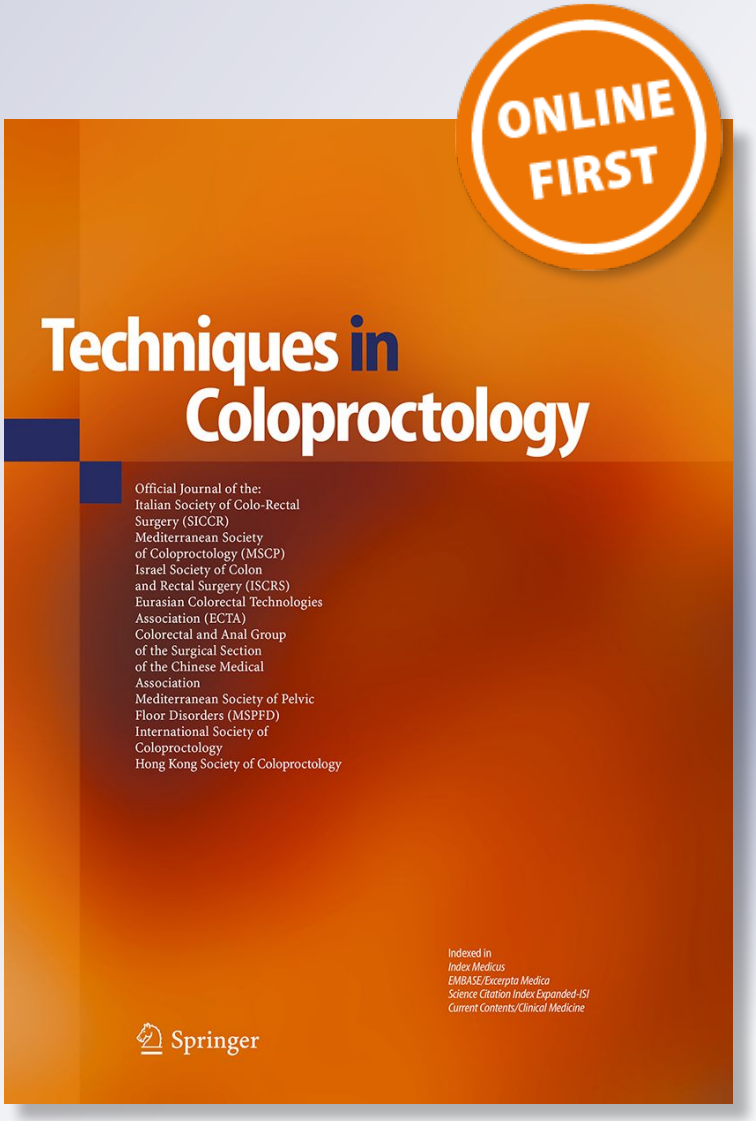
Techniques in Coloproctology
Official Journal of SICCR, MSCP, ISCRS, ECTA, Colorectal Anal Group of Surgical Section of Chinese Medical Association, MSPFD

ISSN 1123-6337

Tech Coloproctol
DOI 10.1007/s10151-017-1696-7



Springer

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MULTIMEDIA ARTICLE

Treatment of obstructed defecation syndrome due to rectocele and rectal intussusception with a high volume stapler (TST STARR-plus)

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Received: 7 November 2016 / Accepted: 24 September 2017

Abstract

Background In recent years, stapled transanal resection (STARR) has been adopted worldwide with convincing short-term results. However, due to the high recurrence rate and some major complications after STARR, there is still controversy about when the procedure is indicated. The aim of this study was to assess the safety, efficacy and feasibility of STARR performed with a new dedicated device for tailored transanal stapled surgery.

Methods All the consecutive patients affected by obstructed defecation syndrome (ODS) due to rectocele or/and rectal intussusception, who underwent STARR with the TST STARR-Plus stapler, were included in a prospective study. Pain, Cleveland Clinic Score for Constipation (CCCS) and incontinence, patient satisfaction, number of hemostatic stitches, operative time, hospital stay and perioperative complications were recorded. Postoperative complications and recurrence were also reported.

Results Forty-five consecutive patients (median age 50; range 24–79) were included in the study. Median resected volume was 15 cm^3 (range 12–19 cm^3) with a median height of surgical specimen of 5.6 cm (range 4.5–10 cm). The mean CCCS decreased from 17.26 (± 3.77) to 5.42 (± 2.78) postoperatively ($p < 0.001$). Patient satisfaction grade was excellent in 14 patients (31.1%), good in 25 (55.5%), sufficient in three (6.7%) and poor in three patients (6.7%). No major complications occurred. Five patients (11%) reported urgency after 30 days and two patients (4%) after 12 months. The Cleveland Clinic Incontinence score did not significantly change. At a median follow-up of 23 months (range 12–30 months), only three patients (6.7%) reported recurrent symptoms of obstructed defecation comparable to those reported at baseline.

Conclusions TST STARR-Plus seems to be safe and effective for the treatment of ODS due to rectocele and rectal intussusception, and technical improvement could reduce the risk of some complications. However, careful patient selection is still the best means of preventing complications.

Keywords Obstructed defecation · STARR · Rectal prolapse · Surgical stapling · Rectal resection · Rectocele intussusception

Introduction

Obstructed defecation syndrome (ODS) is the definition of a common and heterogeneous condition found in patients with defecatory dysfunction and constipation. Many anatomical and physiological abnormalities underlying ODS have been described, although sometimes the complex mechanisms underlying them were not fully understood. These disorders are frequently encountered in clinical practice and affect at least 18% of the population [1]. Rectocele and

Electronic supplementary material The online version of this article (doi:10.1007/s10151-017-1696-7) contains supplementary material, which is available to authorized users.

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Published online: 23 October 2017

intussusception are of multifactorial origin and have in turn been identified as aggravating factors of ODS [2].

In recent years, stapled transanal resection (STARR) has been adopted worldwide with convincing short-term results. Several multicenter trials have demonstrated that STARR significantly improves constipation with low morbidity and high comfort for patients [3–5]. However, the procedure has been associated with a high recurrence rate and some major complications [6, 7]. As a consequence, although STARR is increasingly being accepted as an important option for surgical treatment of ODS, there is still controversy about clinical and functional outcomes.

Considering that a larger resection could help to prevent or delay recurrence and that better technology could help to reduce some important complications, such as perioperative bleeding, technical improvement of the device seem to be required.

The aim of the study was to assess the safety, the efficacy and the feasibility of STARR performed by a new dedicated device for tailored transanal stapled surgery.

Materials and methods

All the consecutive patients admitted from November 2012 to May 2014 who underwent STARR with the TST STARR-Plus (Touchstone International Medical Science Co., Ltd. Suzhou, China) were prospectively enrolled in the present study. Indications for STARR with the TST STARR-Plus included patients with ODS symptoms with rectocele and/or symptomatic recto-anal intussusception, evidenced by clinical and radiological evaluation, with impaired quality of life and failure to respond to conservative measures (diet, laxatives, enemas or rehabilitation when indicated). Patients with non-relaxing puborectalis muscle, inflammatory bowel disease (IBD), major anal incontinence (Wexner Incontinence Score > 3), anal strictures, mental disorders or general contraindications to surgery were excluded. A clinical evaluation with digital exploration, proctoscopy, tridimensional endoanal ultrasound (3D-EAUS), cinedefecography or magnetic resonance (MR) defecography and anorectal manometry were performed in every patient before surgery. Sigmoidoscopy was performed in young patients with anal bleeding and a complete colonoscopy in patients over the age of 50 or in younger patients with a family history of colorectal cancer. All patients gave detailed informed consent. Follow-up was performed by outpatient visits at 7 days, 30 days, 6 months and 12 months after surgery and consisted in physical exam and administration of the following questionnaire on the part of the surgical team members: pain was measured with a Visual Analogue Scale (VAS, 1–10) before the operation and at every follow-up evaluation; the Cleveland Clinic Constipation Score (CCCS) and the Cleveland Clinic Incontinence Score (CCIS) of each patient were calculated before surgery and 7 days, 30 days, 6 months and 12 months after surgery.

Patient satisfaction was measured 12 months after surgery, by asking patients to define the result of the procedure as excellent, good, sufficient or poor. Hemostatic suture for bleeding at the staple line, operative time, length of hospital stay and perioperative complications (in the first 30 postoperative days) were recorded. Postoperative complications or sequelae were also reported.

Device features The TST STARR-Plus stapler (Touchstone International Medical Science Co., Ltd, Suzhou, China) has an external diameter of 36 mm and a housing volume of more than 35 cm^3. This high volume system allows to remove an adequate amount of tissue with a single firing. The TST STARR-Plus features large windows (Mega-Windows TM) and an open case (Barrier-Free TM) that allows incorporation of more tissue and a better view of the surgical field and the tissue to resect.

Surgical technique (see video)

All the procedures were performed by surgeons with experience in stapled transanal surgery (GN, DM, JM). Surgical procedures were performed under spinal or general anesthesia with the patient in the lithotomy position. After introduction of a circular anal dilator (CAD), the prolapsed rectal wall was drawn into the CAD, to identify the amount of prolapsing tissue to be removed. The amount of tissue to be resected is assessed based on the amount found prolapsing into the CAD. The goal is to completely free the CAD from prolapsed tissue. To this purpose, it is necessary to resect twice the length of the amount of tissue blocking the CAD by prolapsing through it. For example, if the prolapsing tissue reached the rim of the CAD, considering that the length of the CAD was 3 cm, the surgeon needed to resect 6 cm of tissue to unblock the CAD. The parachute technique was used, with six double sutures at 1, 3, 5, 7, 9 and 11 o'clock (see video). This approach was preferred to a simple purse-string to allow to the surgeon to better manage the prolapse and traction. A vaginal valve was positioned, and the posterior vaginal wall was carefully checked with fingers before closing the stapler to prevent entrapment. The volume and length of each resected specimen was measured. The volume was determined by fluid displacement upon immersion of the resected tissue in a measuring cup filled by water. The postoperative analgesic protocol provided opioids on the day of surgery, NSAID-paracetamol in the following 3 days administered every 6–8 h and from the 4th postoperative day, NSAID-paracetamol if needed.

Statistical analysis: Data were prospectively recorded into a dedicated database; statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS

Table 1 Main preoperative and postoperative symptoms reported (if > 1 time per week)

Symptoms	Preoperative	Postoperative 30 days	Postoperative 12 months	Significance *p*
Feeling of incomplete evacuation	45 (100%)	4 (8%)	6 (13%)	0.0001
Need of digital assistance	33 (73%)	4 (8%)	5 (11%)	0.0001
Unsuccessful attempts	37 (82%)	3 (6%)	2 (4%)	0.0001
Use of laxatives or enemas	29 (65%)	9 (20%)	10 (22%)	0.0001
Painful evacuation effort	11 (24%)	7 (15%)	1 (2%)	0.003
Abdominal pain	6 (13%)	2 (4%)	2 (4%)	0.2

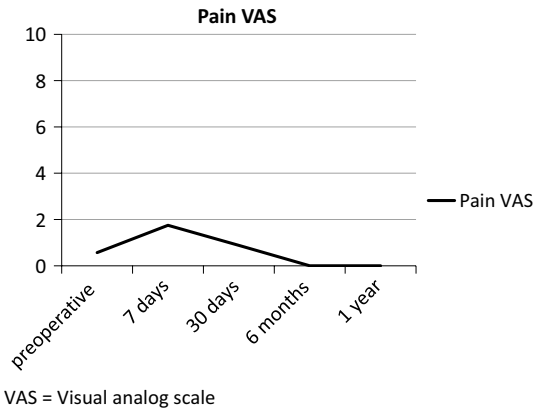

Fig. 1 VAS score for pain

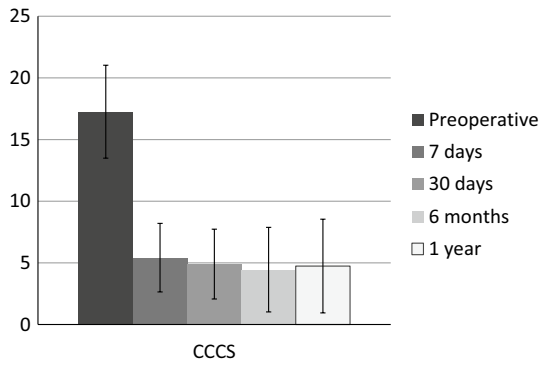

Fig. 2 Cleveland Clinic Constipation Score (CCCS)

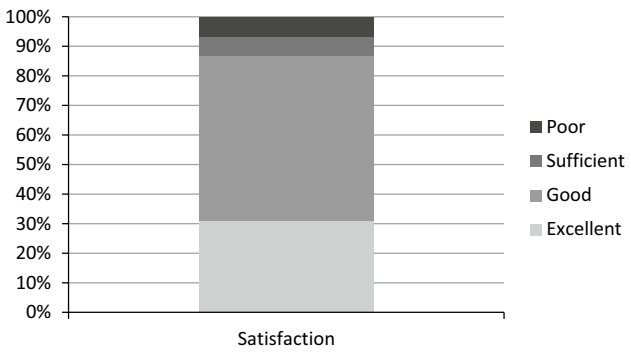

Fig. 3 Patient satisfaction rate after 12 months

13, Chicago, IL, USA). The difference between pre- and posttreatment data was analyzed by a *t* test. The difference was considered statistically significant for p values < 0.05.

Results

From November 2012 to May 2014, 45 consecutive patients (all females), with a mean age of 50.1 years (range 24–79), were enrolled in the study. Seven patients had previously undergone gynecological surgery (hysterectomy, in one case associated with cystopexy). The median operative time was 30.9 min (range 15–60 min) with a median hospital stay of 2.6 days (range 1–7 days). The median resected volume was 15 cm^3 (range 12–19 cm^3) with a median height of the surgical specimen of 5.6 cm (range 4.5–10 cm). No patient was lost to follow-up. Preoperative and postoperative ODS symptoms are reported in Table 1. The total mean preoperative VAS value was 0.57 (± 1.23), with mean values of 1.75 (± 1.58), and of 0.88 (± 1.29), 0 and 0 at 7 days, 30 days, 6 months and 12 months (Fig. 1). Eight patients (17.7%) required additional analgesics during the hospital stay. At 7 and 30 days after surgery, 11 (24.4%) and two (4.4%) patients, respectively, still needed analgesics occasionally. The CCCS decreased from 17.26 (± 3.77) preoperatively to 5.42 (± 2.78), 4.9 (± 2.83), 4.45 (± 3.43) and 4.74 (± 3.84) at 7 days, 30 days, 6 months and 12 months after surgery ($p < 0.001$) (Fig. 2). Patient satisfaction was excellent in 14 patients (31.1%), good in 25 (55.5%), sufficient in three (6.7%) and poor in three patients (6.7%) (Fig. 3). In 14 patients (31.1%), the surgeon reported the need of additional sutures on the staple line, with a median number of 1.7 sutures for each patient (range 0–7). A mild hematoma occurred in one patient (2.2%), but did not require treatment. No patient had an incomplete suture line or mechanical problems with the stapler. The CCIS was calculated for every patient changed from 0.24 (± 0.52) preoperatively to 0.2 (± 0.4), 0.37(± 0.88), 0.33 (± 0.7) and 0.2 (± 0.4) at 7 days,

30 days, 6 months and 12 months after surgery, respectively, with no statistically significant difference ($p > 0.05$) (Fig. 4).

No major complications occurred. Urgency was reported in 12 patients (26.6%) at 7 days after surgery and in five patients (11.1%) at 30 days. Two of the patients with urgency at 30 days (4.4%) complained minor anal incontinence (gas or liquid stool) (CCIS of four for each incontinent patient). At 6 months after surgery, urgency was reported in four patients (8.9%), with an improvement of the two cases of minor anal incontinence (CCIS of 3 for each incontinent patient). At 12 months, only two patients (4.4%) still complained of urgency but without any disturbance of continence. Tenesmus was reported in one of the two patients that complained urgency at every follow-up. At a median follow-up of 23 months (range 12–30 months), only three patients (6.7%) reported recurrent symptoms of obstructed defecation comparable to baseline.

Discussion

The first published results of the STARR procedure showed that the functional and surgical results in patients affected by obstructed defecation related to rectocele and intussusception are excellent within and after 12 months [3, 8–12].

However, the reports about infrequent but possible major surgical complications (bleeding, retroperitoneal hematoma, pelvic sepsis, necrotizing pelvis fasciitis, rectovaginal fistulas) or unsatisfactory functional results (persistence or recurrence of the obstruction symptoms) meant that skepticism and debate around STARR continued. In fact, the risk of serious complications after surgery for benign disorders including hemorrhoids or ODS is not surprisingly considered unacceptable by many surgeons, and this strongly limits the trust in this type of procedures despite otherwise good results.

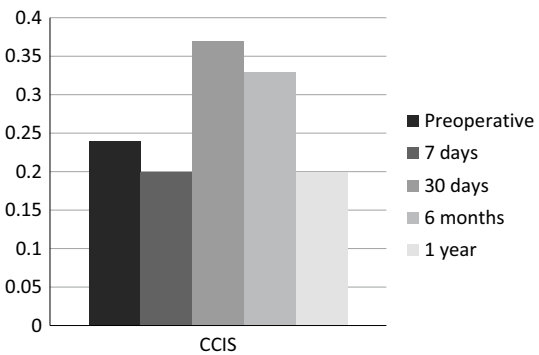

Fig. 4 Cleveland Clinic Incontinence Score (CCIS)

Although the merits of the technique are still debated, the STARR procedure rekindled interest in the surgical treatment of ODS, stimulating the need to find new solutions.

One of the main questions is whether or not a better technology could help to avoid or reduce complications. Excluding surgeons' technical errors (probably a significant number in the first period of the transanal stapler surgery experience) and stapler failure, it is necessary to distinguish between complications related to the use of a stapler, in which better technology could be determinant, and complications related to the transanal resection procedure, independent of stapler use.

Anastomotic line quality could theoretically help to reduce complications such as suture line bleeding or perirectal hematomas and the reduced need of additional stitches to perfect hemostasis, as reported in the present results, could avoid the risk that deep hemostatic stitches or sutures increase the possibility of further complications.

Moreover, some major complications could be avoided by using a surgical device that allows complete and continuous control of the procedure under direct vision, by regulating the height of the staples according to the amount of tissue to be resected and the rectal wall thickness and by a correct regulation of stapler closure to avoid an incomplete anastomosis.

The possibility of evaluating the amount of the prolapse intraoperatively with a disposable CAD before starting the procedure, together with the possibility of determining the optimal amount of the resection (from 2 to 8 cm) and performing the resection with a single device under direct vision with no need to use a second stapler or a reload (as with STARR and Transtar) seems to be optimal for a real tailored resection to minimize residual prolapse [13]. Studies that tried to compare a resection performed with double stapled STARR versus curved stapled STARR (Transtar with Contour CCS30) confirmed that a larger resection is possible with a curved stapler, but without commensurate improvement of qualitative outcome [14]. The idea that larger resection means a better result with a lower recurrence rate still has to be demonstrated.

On the contrary, complications such as urgency, alterations of continence or long-term recurrence are probably not affected by the device used, and are complications related to the procedure itself.

For these reasons, the main factor that influences the outcome still remains careful patient selection [15]. Gagliardi et al. [7] have suggested that the results were worse in patients with preoperative digitation, puborectalis dyssynergia, enterocele, larger rectocele, lower bowel frequency, and sense of incomplete evacuation. Another study demonstrated that factors for an unfavorable outcome after STARR included small rectal diameter, low sphincter pressure, and increased pelvic floor descent [16]. In fact, the correction

of the anatomical alteration (rectocele) excluding patients with additional functional or more complex anatomical dysfunction brought excellent results in the study performed by Zehler et al. [17]. An explanation of the positive results of the present study can also be related to the careful selection of patients. As reported in several large series, good patient selection can reduce morbidity to less than 5% [5, 18]. Moreover, we believe that technical improvements, standardization of the technique and significant attention to details may reduce the risk of postoperative chronic pelvic pain that was reported in up to 7% [5] after STARR procedure but in no patients in the present series.

Also painful defecation was adequately controlled after the procedure, more so than previously reported by other authors [3, 12].

The STARR procedure is an option only for patients who have symptomatic ODS in combination with clinical or radiological correlates such as rectocele or intussusception and who do not respond to conservative treatment. In our experience, less than 20% of patients with rectocele or intussusception need surgical treatment, in line with other authors [19, 20]. Of these patients, only some require a transanal rectal resection, and patients with predominantly functional alterations (including dyssynergia, rectal hyposensitivity and fecal incontinence) or different anatomical alterations (including multicompartment prolapse and descending perineum) would better be treated with other rehabilitative or surgical techniques.

Finally, a comparison of the resected tissue specimens of STARR performed with a high volume device with the ones performed with double PPH or Contour Transtar revealed significant qualitative differences, as shown in Table 2. It was previously reported that after a Contour CCS 30 Transtar procedure resected tissue is more symmetrical and larger in size compared to the STARR with two PPH-01 technique, but that there is no difference in postoperative pain and length of hospital stay [21]. The high volume stapler specimens are thinner, with a significantly different surface/volume ratio when compared to the other specimens, characterized by a large resected surface but with reduced fat tissue over the muscular layer, giving the impression of a less deep resection beyond the rectal wall, similar to the stapled hemorrhoidopexy procedure specimens. However, the real impact of the better quality specimen on outcome has still to be explored and clarified.

The study has several limitations. Inclusions and exclusion criteria including constipation score, presence of incontinence, preoperative studies and conservative treatment were not stringently defined. Therefore, ours is a carefully selected patient population for which this specific surgical approach was chosen by a group of experienced colorectal surgeons. The results of our study therefore may not be easily reproducible as patient selection is key both to improve results and minimize complications. Another limitation is in the length of follow-up. Since the prolapsed tissue is the effect of functional bowel disturbances and musculo-fascial defects, resecting the prolapse, while it clearly improves symptoms, it does not eliminate the risk of recurrence at long-term follow-up. Furthermore, a constipation score designed to assess the prevalence and severity of constipation on patients with slow transit and obstructed defecation was used. The use of a different scoring system more specific to ODS may have yielded different results [22, 23].

Table 2 Specimen features comparison between STARR with double PPH, Contour Transtar and TST STARR-Plus

	Double PPH-1[21]	CCS 30[21]	STARR-Plus
Surface (cm^2)	36.9	54.5	45
Volume (cc)	23.8	29.8	13.5
Surface/volume	1.55	1.82	3.5

STARR stapled transanal rectal resection, *PPH* procedure for prolapse and hemorrhoids, *CCS30* Contour Transtar

Conclusions

TST STARR-plus seems to be safe and effective for the treatment of ODS due to rectocele and rectal intussusception. The high volume open window case and the innovative technology of the stapler could reduce some postoperative complications and lower the recurrence rate. However, further studies are necessary to confirm these results.

Author's contribution GN, BF, IG, DM and JM were involved in study conception and design. BF, CM, IG, GLT and DM were involved in acquisition of data. GN, BF and JM were analyzed and interpreted the data. GN, BF and JM wrote the manuscript.

Compliance with ethical standards

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

Ethical approval Ethical approval for this type of study was not required in any of the participating institutions.

Informed consent Informed consent was obtained from all participants included in the study.

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