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Evaluating the Surgeons' Perception of Difficulties of Two Techniques to Perform STARR for Obstructed Defecation Syndrome: A Multicenter Randomized Trial

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Abstract

Background. After initial enthusiasm in the use of a dedicated curved stapler (CCS-30 Contour Transtar) to perform stapled transanal rectal resection (STARR) for obstructed defecation syndrome (ODS), difficulties have emerged in this surgical technique. *Objective.* First, to compare surgeons' perception of difficulties of STARR performed with only Transtar versus STARR performed with the combined use of linear staplers and Transtar to cure ODS associated with large internal prolapse and rectocele; second, to compare the postoperative incidence of the urge to defecate between the 2 STARR procedures. *Design and Setting.* An Italian multicenter randomized trial involving 25 centers of colorectal surgery. *Patients.* Patients with obstructed defecation syndrome and rectocele or rectal intussusception, treated between January and December 2012. *Interventions.* Participants were randomly assigned to undergo STARR with a curved alone stapler (CAS group) or with the combined use of linear and curved staplers (LCS group). *Main Outcome Measures.* Primary end-points were the evaluation of surgeons' perception of difficulties score and the incidence of the "urge to defecate" at 3-month follow up. Secondary end-points included duration of hospital stay, rates of early and late complications, incidence of "urge to defecate" at 6 and 12 months, success of the procedures at 12 months of follow-up. *Results.* Of 771 patients evaluated, 270 patients (35%) satisfied the criteria. Follow-up data were available for 254 patients: 128 patients (114 women) in the CAS group (mean age, 52.1; range, 39-70 years) and 126 (116 women) in LCS group (mean age, 50.7 years; range, 41-75 years). The mean surgeons' perception score, was 15.36 (SD, 3.93) in the CAS group and 12.26 (SD, 4.22) in the LCS group ($P < .0001$; 2-sample t test). At 3-month follow-up, urge to defecate was observed in 18 (14.6%) CAS group patients and in 13 (10.7%) LCS group patients ($P = .34$; Fisher's exact test). These values drastically decrease at 6 months until no urge to defecate in all patients at 12 months was observed. At 12-month follow-up, a successful outcome was achieved in 100 (78.1%) CAS group patients and in 105 (83.3%) LCS group patients ($P = .34$; Fisher's exact test). No significant differences between groups were observed in the hospital stay and rates of early or late complications occurring after STARR. *Conclusions.* STARR with Transtar associated with prior decomposition of prolapse, using linear staplers, seems to be less difficult than that without decomposition. Both procedures appear to be safe and effective in the treatment of obstructed defecation syndrome resulting in similar success rates and complications.

Keywords

colorectal surgery, evidence-based medicine/surgery, NOTES

Introduction

Obstructed defecation syndrome (ODS) is a very common clinical disorder that obliges the patients, mostly middle-aged women, to spend several hours in the bathroom in attempts, mostly unsuccessful, to defecate.[1]

The cause of ODS may be a functional disorder secondary to a spastic pelvic floor syndrome or an anatomic rectal

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Table 1. Renzi Validated Scoring System for Obstructed Defecation Syndrome (ODS-S).[a]

Symptoms/Variables	0	1	2	3	4
Excessive straining	Never	Rarely	Sometimes	Usually	Always
Incomplete rectal evacuation	Never	Rarely	Sometimes	Usually	Always
Use of enemas/laxative	Never	Rarely	Sometimes	Usually	Always
Vaginal/perineal distal pressure	Never	Rarely	Sometimes	Usually	Always
Abdominal discomfort/pain	Never	Rarely	Sometimes	Usually	Always

[a]Never, never; rarely, <1/month; sometimes, <1/week, ≥1/month; usually, <1/d; ≥1/wk; always, ≥1/d.

alteration, such as a rectocele or rectal intussusception,[2] which may be treated by surgical correction.

In the past 15 years, transanal resection of the rectum with staplers (STARR) has become one of the most frequently performed surgical procedures to cure ODS when secondary to rectocele and/or rectal intussusception.[3-6] STARR has proven to be an effective procedure in these patients, although different patterns of complications have been reported.[7-9]

The most common surgical technique to perform this procedure is based on the sequential use of 2 circular staplers. For several years, however, a new curved stapler, the CCS-30 Contour, known as "Transtar," has been made available and utilized.[10-14]

After initial enthusiasm for this new device, difficulties have emerged in the surgical technique. This led some surgeons to experiment with variants to the surgical technique of STARR with Transtar. Among these variants, the additional use of linear staplers for splitting the rectal prolapse into 2 halves, has gained a rapid diffusion among Italian colorectal surgeons. Although this technical change is considered to simplify the STARR with Transtar procedure and is associated with a reduction of the postoperative urge to defecate, there are no studies available on these issues.

There were 2 primary objectives for this trial: (1) to compare surgeons' perception of difficulties of STARR performed with only Transtar versus STARR performed with the combined use of linear staplers and Transtar to cure ODS associated with large internal prolapse and rectocele and (2) to compare the postoperative incidence of the urge to defecate between the 2 STARR procedures.

Methods

Design and Setting

We hypothesized that STARR using the linear and curved staplers would be perceived as less difficult to perform by surgeons than STARR performed with the curved alone stapler; furthermore, we hypothesized that STARR using the linear and curved staplers would be associated with a less frequent incidence of the postoperative urge to defecate. The study was an Italian multicenter randomized trial; it was not supported by any commercial company and had the approval of the Ethics Committee of Federico II University of Naples. All patients gave written informed consent to take part in the study. The design of the study followed CONSORT (Consolidated Standards of Reporting Trials) guidelines. Prior to start the trial, the protocol of the study was published on the website http://www.siucp.org on a dedicated page for the prospective studies and randomized trials (http://www.siucp.org/trials.aspx). All the surgeons involved in this study were randomly chosen between the members of Italian Unitary Society of Coloproctology (SIUCP) agreed to participate in the trial, who were trained in stapled transanal techniques, had experience in the STARR procedure with 2 circular staplers and showed variable confidence with the employment of the Transtar semicircular stapler.

Participants

All patients referred for ODS in any of the 25 centers involved were considered for enrolment.

To confirm the diagnosis, all these patients underwent a clinical evaluation by a questionnaire inquiring about their history/symptoms, proctologic examination, endoscopic evaluation, and cinedefecography. A gynecological evaluation was also performed for all female patients. The validated Renzi Scoring System for Obstructed Defecation Syndrome (ODS-S)[15] (Table 1) was also used.

Inclusion Criteria. Patients were eligible for study participation if they met the following criteria: ODS score ≥12; rectal intussusception (intussusception ≥10 mm) and/or rectocele extending 3 cm or more from the rectal wall contour, as shown by cinedefecography; and failure of 6 months of medical therapy.

Exclusion Criteria. Patients were excluded if they had undergone previous anal and rectal surgery, or had suffered from anal cancer, anal fissure and fistula, inflammatory bowel disease, intestinal inertia, anismus, associated II/III degree genital prolapse, and symptomatic cystocele.

The patients on antidepressants, anxio- lytics, and antipsychotic medications and those with a previous diagnosis of psychological disorders were also excluded.

Surgical treatment was proposed for all the patients who met the inclusion criteria. At that time, a further selection of all the patients was performed. With the patient in lithotomic position and after subaracnoid/general anesthesia, a dedicated circular anal dilator (CAD) was positioned to expose the internal rectal prolapse. The latter was considered as "large" when its volume spontaneously reached at least half of the length of the CAD. Only patients presenting a large internal rectal prolapse, as defined above, were considered eligible for the study.

Randomization

Eligible patients were assigned to undergo STARR with a curved alone stapler (CAS group) or with the combined use of linear and curved staplers (LCS group) based on a computer-generated randomization scheme with block size varying from 4 to 6 and maintained at each center in opaque envelopes numbered sequentially. The assignment was carried out by a nurse extracting the next envelope in sequence.

Surgical Procedures

The procedures were performed with subarachnoid or general anesthesia with the patient in lithotomic position. In compliance with the health policy of their respective institutions, each investigator could freely select the surgical preparation measures (antibiotic prophylaxis, physical preparation of colon) and the type of postoperative management (choice and regimen of antibiotic and/or analgesic therapy) to adopt.

Curved Alone STARR Procedure. This procedure reproduces the surgical technique proposed by Antonio Longo, and first described by Renzi et al[10] in 2008. A rechargeable CCS-30 Contour Transtar stapler kit (Ethicon-Endosurgery, Pomezia, Italy) was utilized. After a delicate anal massage, a circular anal dilatator (CAD) was introduced into the anus and secured to the perianal skin by 4 stitches. Using a piece of gauze held by a pincer, the rectal wall involved in the rectocele and/or rectal intussusception was drawn into the CAD to identify the prolapsing tissue to be removed. On the edge of the prolapsing rectal wall, 5 short running sutures were apposed circumferentially, like parachute cords, to obtain total control of the selected prolapsing tissue. Subsequently, another single stitch was apposed at 3 o'clock position involving the entire length of the prolapsing rectal wall and was knotted tightly. Keeping this stitch in traction, the stapler was positioned and the first shot fired. This maneuver opened the prolapsing rectal wall laterally, allowing the surgeon to start the circumferential resection of the prolapsing rectal wall by subsequent firing of the stapler. After firing the last shot and removing the stapler, any subsequent bleeding was stopped by hemostatic stitches. Finally, the CAD was removed, leaving a piece of gauze positioned in the rectum for a few hours.

Linear and Curved STARR Procedure. The procedure was performed in a specular manner to that described above until the circumferential positioning of the short running suture on the wall of the prolapse (Figure 1A). In this case there were 6 sutures and they were arranged to allow the positioning, at 3 o'clock and at 9 o'clock positions, of 2 linear staplers ETS-45 (Ethicon-Endosurgery, Pomezia, Italy) (Figure 1B and C). This maneuver determined the decomposition of rectal prolapse into 2 halves, upper and lower (Figure 1D). The resection of these 2 halves of the prolapse was obtained by subsequent firing of the rechargeable CCS-30 Contour Transtar, first on the superior halve (Figure 1E and F) and then on the inferior halve of rectal prolapse (Figure 1G and H). As in the curved alone STARR, after firing the last shot any bleeding was stopped by hemostatic stitches and the CAD was removed, leaving a piece of gauze positioned for a few hours. Specimens are shown in Figure 1I and L.

Surgeons' Perception of Difficulties Questionnaire

Using a dedicated surgeons' perception of difficulties questionnaire, constructed following the model of the one previously used and validated by Geis et al,[16] all the surgeons were asked to rate the degree of difficulty of each procedure immediately after its execution. The questionnaire (Table 2) consists of 4 items and was graded with a score ranging from 1 to 5 in order of increasing difficulty.

Timing and Outcome Measures

The primary end-points were the evaluation of the surgeon's perception of difficulties score and the incidence of "urge to defecate" at 3-month follow-up.

The secondary end-points were the mean operative time, number of Transtar recharges used, average dimension of the surgical specimens, duration of hospital stay, rates of early and late complications, incidence of "urge to defecate" at 6 and 12 months, and success of the procedures at 12 months of follow-up. Procedures were considered successful when an ODS-S ≤ 9 was achieved.

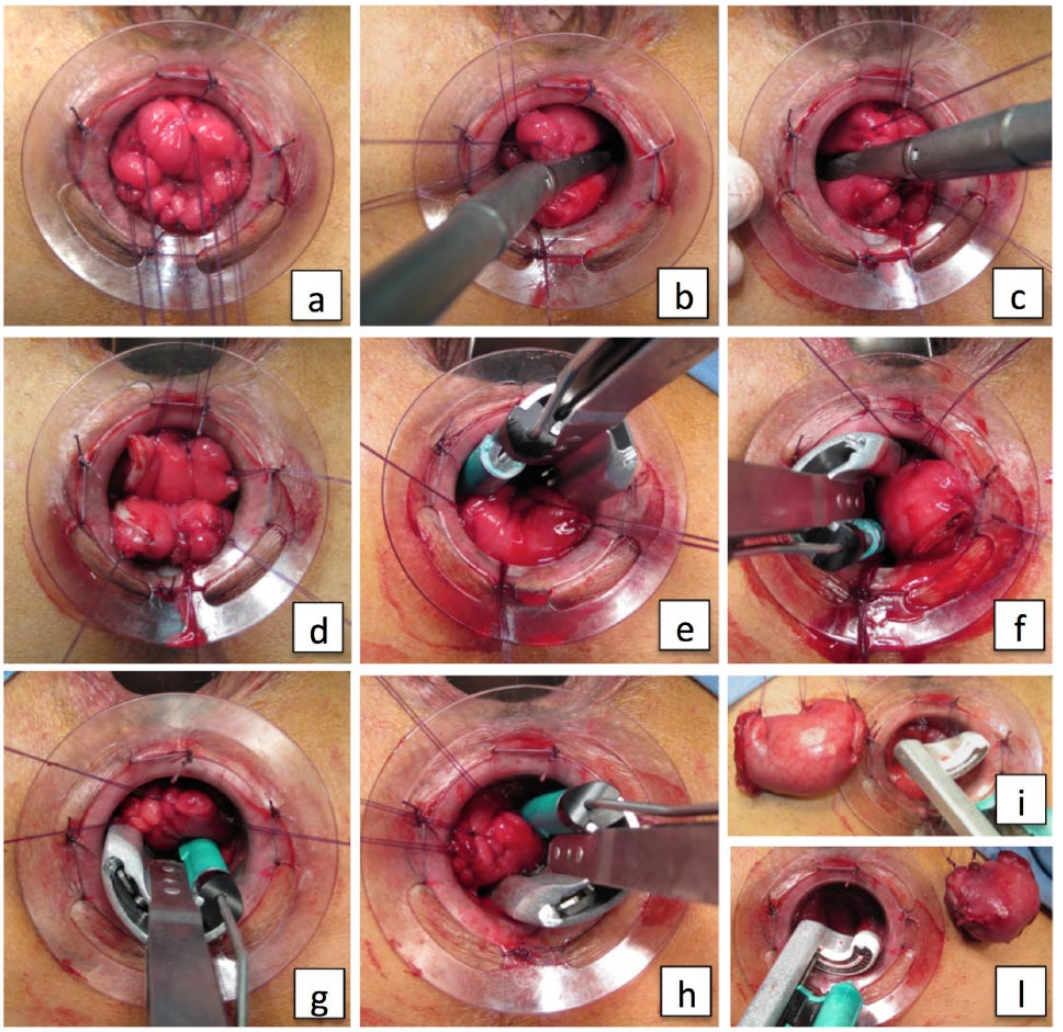

Figure 1. Linear and curved stapled transanal rectal resection (STARR) procedure.

Table 2. Surgeons' Perception of Difficulties Questionnaire.

	1	2	3	4	5
Exposure of the operating field	Very easy	Easy	Moderate	Difficult	Very difficult
Positioning of the staplers	Very easy	Easy	Moderate	Difficult	Very difficult
Execution of the rectal resection	Very easy	Easy	Moderate	Difficult	Very difficult
Intraoperative complication management	Very easy	Easy	Moderate	Difficult	Very difficult

Data Entry and Collection Methodology

In each institution, a single investigator, not involved in the selection and allocation of patients or in the surgical procedures, was delegated to collect the intraoperative data and follow-up the patients. To facilitate data entry, a dedicated registry was designed for this purpose and assigned to each center. The registry included, apart from the demographics of each patient, all the intraoperative and postoperative data useful for the analysis of the outcomes. In this way, all the intra and postoperative data of each center were collected and transcribed in a digital format. Finally, all the collected results from each institution were mailed to another single blinded investigator for analysis and interpretation. All recruited patients were blinded to the assigned operative procedure.

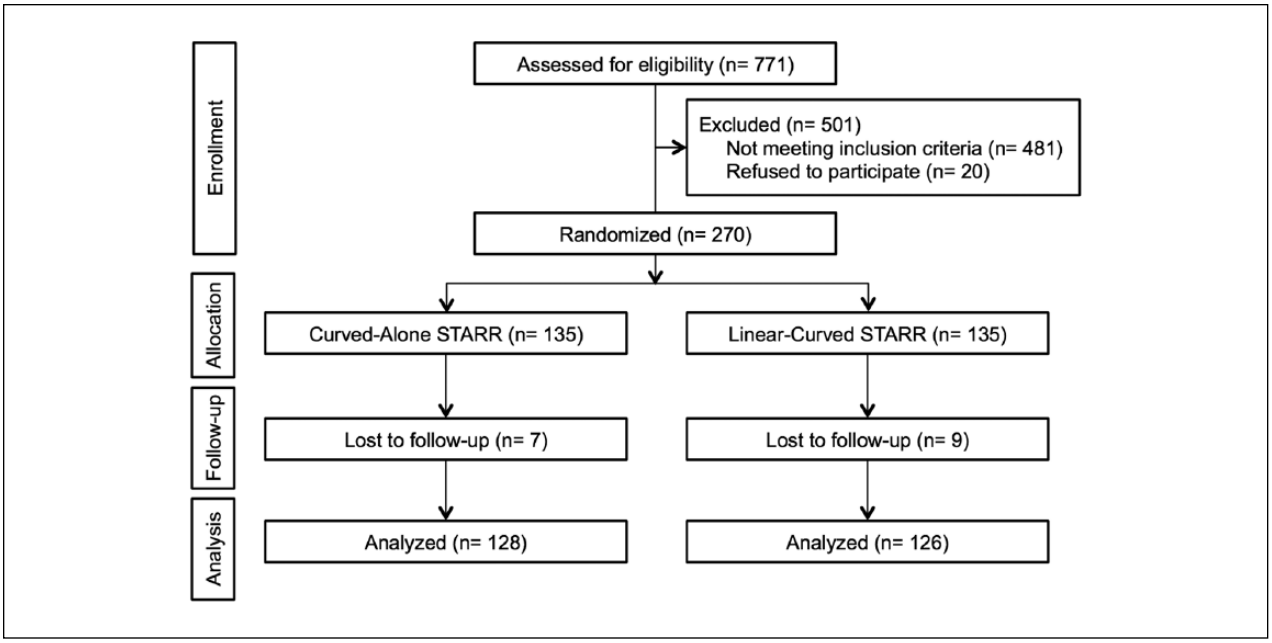

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

Sample Size and Statistical Analysis

The number of patients included in the study was based on the sample size estimation for our primary end-point. A retrospective analysis of early outcome in patients who had undergone STARR with Transtar suggested a 15% rate of urgency at 3-month follow-up. We hypothesized that a 5% rate could be achieved in STARR with the combined use of linear and curved staplers. We estimated that 125 patients would be required in each group for the study to have a power of 80% to detect a difference of 10% in the urgency rates between the two groups at a significance level (α) of .05 (2-tailed test), if such a difference truly existed. We allowed for the possibility of incomplete data and included a total of 270 patients in this study.

Statistical analysis was performed with Excel 2010 (Microsoft, Redmond, WA), using the programs InStat and StatMate (Graph-Pad Software, San Diego, CA). Results were expressed as the mean with standard deviation of the mean in parenthesis or as the median with range in parenthesis, according to distribution. Data were compared between groups using the 2-sample *t* test, the paired *t* test, Mann-Whitney test, and Fisher exact probability test, as indicated. Differences were considered statistically significant for $P < .05$.

Results

A total of 771 patients with ODS were evaluated between January and December 2012. As shown in the flow diagram (Figure 2), 270 patients (35.0%) satisfied selection criteria and were randomly assigned to CAS or LCS. Data from 16 patients (5.9%) were lost to follow-up, so they were excluded from the study.

Baseline and Perioperative Data

The CAS group consisted of 128 patients, 114 women (89.0%) and 14 men (10.9%), with a mean age of 52.1 years (SD, 5.97; range 39-70 years); the LCS group consisted of 126 patients, 116 women (92.0%) and 10 men (7.9%), with a mean age of 50.7 years (SD, 5.81; range 41-75 years). Of the 114 women in the CAS group, 19 (16.6%) were nulliparous. Twenty-nine women (25.4%) had undergone a previous hysterectomy. Of the 95 women who had given birth, 42 (44.2%) had had at least 1 vaginal delivery. Of these, 26 (61.9%) had had at least 1 episiotomy. Of the 116 women in the LCS group, 21 (18.1%) were nulliparous; 27 (23.2%) had undergone a previous hysterectomy. Of the 95 women who had given birth, 35 (36.8%) had had at least 1 vaginal delivery. Of these, 15 (42.8%) had had at least 1 episiotomy.

The 2 groups did not differ with regard to preoperative ODS-S scores: ODS-S = 14.4 (SD 3.4) for CAS group versus 15.2 (SD 3.6) for LCS ($P = .06$, 2-sample *t* test). Preoperative cinedefecography data are summarized in Table 3.

The mean operative time was 35.6 minutes (SD, 7.8) in the CAS group and 34.7 minutes (SD, 10.5) in the LCS group ($P = .40$; 2-sample *t* test).

The mean Surgeon Perception Score, reported in detail in Figure 3, was 15.36 (SD, 3.93) in the CAS group and

Table 3. Results of Preoperative Cinedefecography in Patients With Obstructed Defecation Syndrome Undergoing STARR With a Curved Stapler or With Curved and Linear Staplers.

	CAS (N = 128); n (%)	LCS (N = 126); n (%)	P[a]
Dynamic perineal descent	96 (75.0)	90 (71.4)	.57
Rectal intussusception	105 (83.5)	107 (84.9)	.61
Recto-rectal intussusception	30 (28.5)	26 (24.2)	.65
Recto-anal intussusception	75 (71.4)	81 (75.7)	.36
Rectocele	104 (81.2)	100 (79.3)	.75
Sigmoidocele[b]	7 (5.4)	6 (4.7)	>.99
Enterocele	2 (1.5)	2 (1.5)	>.99

Abbreviations: STARR, stapled transanal rectal resection; CAS, curved alone stapler; LCS, linear and curved staplers.
[a]Fisher's exact probability test.
[b]First degree.

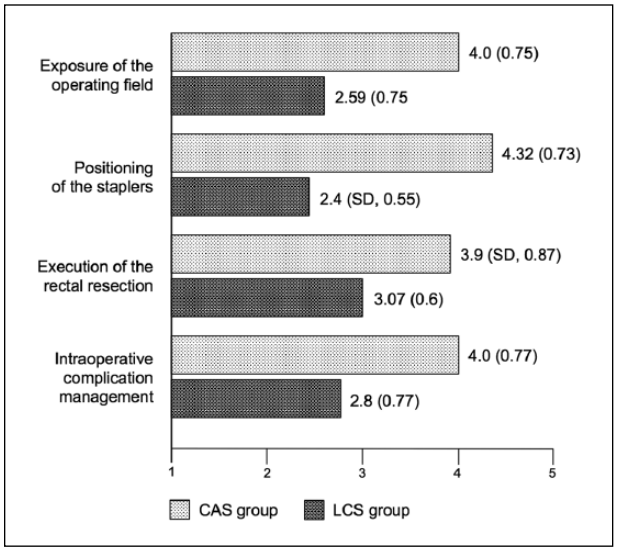

Figure 3. Results for each domain of surgeons' perception of difficulties questionnaire in patients with obstructed defecation syndrome undergoing STARR with a curved stapler or with curved and linear staplers. Data are as mean with standard deviation in parentheses. STARR, stapled transanal rectal resection; CAS, curved alone stapler; LCS, linear and curved staplers. Difference between the 2 groups was statistically significant for each domain ($P < .001$; 2-sample *t*-test).

10.26 (SD, 4.22) in the LCS group; the difference was found to be statistically significant ($P < .0001$; 2-sample *t* test).

The median number of Transtar recharges used, except the preloaded one, was 6.02 (range, 5-8) for the CAS group and 4.45 (range, 4-6) for the LCS group; the difference was found to be statistically significant ($P < .0001$; Mann-Whitney test). The mean specimen dimensions were as follows: in the CAS group 7.9 cm (SD, 2.3) long × 13.5 cm (SD, 2.7) wide; in the CLS group 8.0 cm (SD, 3.0) long × 6.8 cm (SD, 2.3) wide for the anterior part of the rectal prolapse and 7.8 cm (SD, 2.5) long × 7.0 cm (SD, 2.5) wide for the posterior part.

The median length of postoperative stay was 48 hours (range, 28-72 hours) in the CAS group and 48 hours (range 24-72 hours) in the LCS group ($P = .66$; Mann-Whitney *U* test).

Postoperative Data

At 3-month follow-up, the urge to defecate was observed in 18 (14.6%) CAS group patients and in 13 (10.7%) LCS group patients ($P = .34$; Fisher's exact test). These values drastically decreased at 6 months until we can observe no urge to defecate in all patients at 12 months.

At 12-month follow-up, mean ODS-S was 6.76 (SD, 2.72) in the CAS group and 6.65 (SD, 2.89) in the LCS group ($P = 076$; 2-sample *t* test). Comparing the preoperative and postoperative mean ODS-S, a significant improvement in both groups was observed at 12 months ($P < .0001$ in each group; paired *t* test). A successful outcome was achieved in 100 (78.1%) CAS group patients and in 105 (83.3%) LCS group patients ($P = .34$; Fisher's exact test).

Complications

No significant differences between the groups were seen in rates of early or late complications occurring after STARR (Table 4).

Discussion

Ever since STARR was proposed to the scientific community as a surgical procedure for the treatment of ODS, this procedure has never ceased to arouse heated debate among surgeons. The surgical technique, much appreciated by some and opposed by others, has been the battleground of an entire generation of colorectal surgeons both in Italy, where STARR was first proposed, and elsewhere.

Table 4. Early and Late Complications in Patients With Obstructed Defecation Syndrome Undergoing STARR With a Curved Stapler or With Curved and Linear Staplers.

	CAS (N = 128); n (%)	LCS (N = 126); n (%)	P[a]
Early complications			
Mild perineal hematoma[b]	25 (19.5)	22 (17.4)	.74
Acute urinary retention	21 (16.4)	23 (18.2)	.74
Bleeding[c]	7 (5.4)	9 (7.1)	.61
Perianal sepsis	0 (0.0)	0 (0.0)	
Mortality	0 (0.0)	0 (0.0)	
Late complications			
Incontinence to flatus[d]	11 (8.5)	13 (10.3)	.67
Dyspareunia[e]	0 (0.0)	0 (0.0)	

Abbreviations: STARR, stapled transanal rectal resection; CAS, curved alone stapler; LCS, linear and curved staplers.
[a]Fisher's exact probability test.
[b]No treatment was required.
[c]No transfusion was necessary.
[d]Spontaneously resolved within 6 months.
[e]Spontaneously resolved within 12 months.

The use of 2 circular staplers was for years the standard technique for performing STARR. Subsequently, a new dedicated stapler with a curved shape was developed. This device, the so-called Transtar, seemed to add certain advantages to the technique. In contrast to the circular staplers, the Transtar does not have a case limiting the volume of the specimen to resect. Thus, the surgeon is able to choose how much of the prolapsed rectal wall to remove. The new device therefore makes an individually tailored resection of the prolapsed rectal wall possible.

Despite these benefits, which have been reported in the literature,[10-15] after an initial enthusiasm for this new device some surgeons, who started to perform STARR using the Transtar, returned to using 2 circular staplers. The reasons may be many, but probably 3 are prevalent: (*a*) the greater difficulty of execution of STARR with Transtar compared to that with 2 circular staplers; (*b*) the emergence of new complications, such as the spiraling of rectal anastomosis, and the subsequent apprehension that ensued; and (*c*) the presence in the literature of similar short-term outcomes between STARR with circular staplers and STARR with Transtar that does not justify the use of this new technique with its consequent burden of a new learning curve.

Since 2007, with the goal of reducing the technical difficulties and the learning curve of the STARR with Transtar, some surgeons, first among them the coordinator of this multicenter trial (A.R.), have proposed and implemented a variant of the STARR with Transtar, as originally described. This variant provides an additional surgical intervention: the breakdown of the prolapse into 2 halves by the use of 2 linear staplers positioned and fired at 3 o'clock and 9 o'clock positions. Since the additional use of linear staplers in STARR with Transtar was proposed, this variant seemed to show 2 main features. First, it promptly appeared to some surgeons simpler to execute when compared with the classic technique. Second, from the retrospective analysis of the preliminary results in the outcome of patients who had undergone STARR with the mentioned technical variant, seemed to result a reduction in the incidence of postoperative urge to defecate, if compared with the standard procedure. Thus, it was speculated that a more homogeneous resection of the rectal prolapse and a less likely "spiraling" of rectal anastomosis, obtained with the additional use of the linear staplers, could be the reason of this finding, representing a further advantage and a further characteristic of superiority of the technical variant. On the basis of these considerations, this multicenter study was designed to evaluate (*a*) whether this perception "of lesser difficulty of execution" of STARR with the combined use of the linear staplers and Transtar occurred with only a few surgeons or, on the contrary, was shared by colorectal surgeons in the wider Italian community and (*b*) the role of this technical variant in containing the postoperative urge to defecate.

Although the mean operative time was similar in the 2 groups, the surgeons' perception of difficulties of STARR with Transtar versus STARR with linear staplers and Transtar demonstrated the overall perception of less difficulty when the STARR procedure is performed with the combined use of staplers. The difference in the mean overall surgeons' perception of difficulties score was statistically significant (15.36 in the CAS group and 10.26 in the LCS group) as well as the data in each domain of the questionnaire: exposure of the operating field, positioning of the staplers, execution of the rectal resection and intraoperative complication management.

Thus, taking into account the similar costs of the 2 procedures, the LCS technique could encourage the diffusion of the STARR with Transtar device even among the surgeons that, for the emerging technical difficulties, had previously discharged it. Concerning the other primary objective of the study, or rather the incidence of postoperative urge to defecate, no statistically significant difference at 3-month follow-up in urge to defecate was found between the 2 groups (14.6% in the CAS group vs 10.7% in the LCS group), suggesting that, apart from the spiraling of rectal anastomosis and the type of rectal resection, other considerable factors may be involved in the genesis of this surgical complication, such as, the reduced rectal capacity, per se, the increase of rectal sensitivity and the persistence of retained staples in the rectum.[16-19] Likewise, the 2 surgical procedures were associated with similar specimen dimension (considering the 2 specimens obtained in the LCS group as one), success rate, (78.1% in the CAS group vs 83.3% in the LCS group), similar length of hospital stay and early and late complication rates.

Conclusion

STARR with Transtar associated with prior decomposition of prolapse, using linear staplers, is less difficult than that without decomposition. The combined use of the linear and Transtar stapler to perform STARR allows a better exposure of the operating field, and facilitates the positioning of the staplers, the execution of the rectal resection and the management of intraoperative complications. Both procedures appear to be safe and effective in the treatment of obstructed defecation syndrome achieving similar success rates and are associated with similar complications. The employment of the linear staplers in the STARR with Transtar does not provide significant advantages in containing the incidence of postoperative urge to defecate.

Addendum

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Declaration of Conflicting Interests

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