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The evolution of transanal surgery for obstructed defecation syndrome: Mid-term results from a randomized study comparing double TST 36 HV and Contour TRANSTAR staplers

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ABSTRACT

A randomized study was carried out to compare the mid-term outcome of transanal rectal resection with the CCS-30 TRANSTAR and two TST36 staplers in patients with obstructed defecation syndrome.

After selection, patients were randomly assigned to 2 groups:104 underwent a TRANSTAR operation and 104 a transanal rectal resection with two TST36 staplers. Patients were followed up with clinical examination, and defecography.

Cumulative complication rate was significantly higher in TRANSTAR operation ($P = 0.019$). All symptoms and defecographic parameters significantly improved ($P < 0.001$), without differences.

Costs were significantly lower with double TST ($P = 0.035$). Recurrence rates were 6.2% in TRANSTAR group and 11.4% with double TST ($P = 0.206$).

Two circular TST 36 staplers consent to obtain the same clinical and functional results than the CCS-30, with significantly lower complication rate and costs.

1. Introduction

The transanal rectal resection using the curved CCS-30 multifire Contour R Transtar ™ stapler (TRANSTAR operation) gives good mid-term results in patients with rectal intussusception and rectocele,[1,2] consenting the removal of large amount of prolapsed tissue without residual lateral flaps, which are considered as the main cause of bleeding and urgency.[3] However the technique has some actual limitations, related to the design of the stapler: the limited vision and the difficulty to control the correct positioning of the rectal wall in the casing may cause dehiscence of the staple line, or spiral resection,[4] rectal perforation, or rectovaginal fistula,[5] creation of mediastinal and retro-intraperitoneal emphysema.[6]

The new circular TST36 stapler has an open case with a mega window, that consents a good view of the operating field, the control of the resectable volume of tissue and the closure of staples. In a comparative study the new device showed a tensile strength of staples superior to the most used other devices.[7]

In a recent multicentric study the TST36 was used in patients with prolapsed hemorrhoids and obstructed defecation syndrome (STARR PLUS operation) with good short-term results: 5% bleeding, 2.5% anastomotic dehiscence and 0.6% fecal urgency.[8]

The mean volume of resected tissue was 13.3 cm^3, the same obtained with the conventional PPH-STARR operation, performed with two PPH-01 staplers, but significantly lower than the about 26 cm^3 of tissue resected with the TRANSTAR operation.[1] This great limitation, that do not consent to completely resect large prolapses, could be overcome by using two H-V 36 staplers, than theoretically have a resective potential similar to the CCS-30 stapler.

The aim of this randomized study was to compare the medium-term clinical and functional results of CCS 30 and two H-V 36 staplers in two homogeneous groups of patients with obstructed defecation syndrome, caused by internal rectal prolapse (or intussusception) and rectocele, with complication rate as primary outcome measure.

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2. Methods

2.1. Study population and inclusion criteria

Patients were recruited, and selected on the basis of a previously described protocol, based on 6 items,[1] as we briefly report below:

1) validated ODS[9] and continence scores,[10]
2) evaluation of quality of life with the validated SF36 Health Survey score,
3) proctological and gynaecological examinations, and proctoscopy with validated Pescatori's grading of internal rectal prolapse,[11]
4) colonoscopy, to exclude concomitant colorectal diseases,
5) anorectal manometry to evaluate the integrity of anal sphincters,
6) colpocystodefecography with opacification of small bowel to exclude concomitant enterocele, or cystocele.

On the basis of this diagnostic protocol, patients selected for the study all had:

- 2nd, or 3rd Pescatori 's degree rectal prolapse, or rectal intussusception
- rectocele >5 cm
- ODS score >15 and continence score <3
- resting pressure >40 mm/Hg, and squeeze pressure >100 mm/Hg

Exclusion criteria were:

- previous transanal surgery
- pudendal neuralgia, puborectalis syndrome
- anorectal infection, proctitis, chronic diarrhea
- ODS score <15, continence score >3
- resting pressure <40 mm/Hg, squeeze pressure <100 mm/Hg
- concomitant anal fissure, enterocele, compressing the rectum during evacuation efforts, symptomatic cystocele, or genital 3rd degree prolapse (Half Way System)[12]
- psychiatric diseases
- absolute contraindications to surgery.

The Ethical Committee approved the study protocol. All patients gave written informed consent. All patients were operated on by the same surgical team, using the techniques described below, with no modifications.

2.2. Surgical technique

Enema washing was done in the afternoon of the day before surgery, a bladder catheter was introduced and the patient received routine antibiotic prophylaxis, with a single shot of cefotaxime (2g) plus metronizadole (500 mg), immediately after the induction of anaesthesia. The procedures were performed under caudal anaesthesia, with the patient in the lithotomy position.

2.2.1. TRANSTAR

After positioning the dilator CAD38, and applying 4 sutures to the prolapsed tissue, the CCS-30 Contour R Transtar ™ (Ethicon-Endosurgery, Inc, Pomezia, Italy) curved stapler was placed in the 3 o'clock position and fired, in order to create a radial section line in the rectal wall.

The same procedure (removing the stapler, replacing the cartridge, capturing the prolapsed rectal wall by a continuous suture, positioning the stapler, closing and firing the device) was repeated from 2 to 11 o'clock, 11 to 8 o'clock, 8 to 5 o'clock and 5 to 1 o'clock and the entire specimen was removed. Finally the stapler line was inspected for hemostasis, using the anoscope, and stitches were applied when necessary.

All fresh surgical specimens were measured and sent for histologic examination.

2.2.2. Double STARR PLUS

The H-V 36 circular stapler (TST STARR Plus, Touchstone International Medical Science co. LTD, Suzhou, China) has an external diameter of 36 mm, with housing volume tripled when compared with the traditional PPH −01 stapler, and extimated in about 35.5 cm^3, with 34 staples of 4,2 mm open height. The two trademarks Mega-Windows™ and Barrier-free™ open case are designed for a better vision and control.

The 2-windows 36 mm anal dilator was introduced in the anal canal and fixed with 4 2-0 silk stitches to the skin. The parachute technique with 4 Prolene 2-0 running suture at 2, 5, 7, 10 o'clock was used, allowing a symmetrical traction of the maximum amount of tissue consented by the house stapling. Then the first TST 36 HV stapler was positioned closed and the staples fired. The same technique was used with the second stapler, for the resection of residual posterior rectal prolapse.

The volume of the two resected specimens was measured with the method, described by Naldini et al. (measuring the increase of liquid level in a cup filled of water).[7]

2.2.3. Postoperative management

The patient was started on a clear liquid diet from the first postoperative day. Antibiotics were continued during the hospital stay and the anus was inspected twice a day. Paracetamol 500 mg plus codeine 30 mg tablets (Coefferalgan R, UPSA Medica, Milan, Italy) were used for postoperative pain control, on patient's demand.

2.3. Outcome measures

Primary outcome measure was the cumulative rate of complications. Secondary outcome measures were: failure rate, defined as residual mucosal rectal prolapse, with an ODS score >5, operative time, hospital stay, postoperative pain assessed using a Visual Analog Scale (VAS: with a score from 0 = no pain to 10 = maximum pain), time to return to normal activity, outcome of surgery on the ODS score, quality of life on the SF36 Health Survey questionnaire, costs, and patient satisfaction score. Clinical examination was scheduled 7 days and 1, 3, 6, 12 and 16 months after the operation. A simple defecography was done six months after surgery. Due to the limited budget, the anorectal manometry was repeated 12 months after surgery only in patients with fairly good or poor results at Satisfaction Index.

2.4. Statistical analysis

Continuous data are shown as arithmetic means and SD, and qualitative data as absolute and percent frequencies. The statistical software package SPSS 16.0 for Windows XP R

(SPSS Inc. Chicago,IL, USA) was used. The sample size estimation was based on comparison of complication rates in the two groups using Chi-square test with continuity correction at a significance level of $\alpha = 0.05$ (95% confidence) and power of 0.80; a sample size of 104 patients for each group was sufficient to detect a difference from 15 to 5% in the cumulative complication rate. For secondary outcome measures a two sample *t*-test for unpaired data, ANOVA for repeated measures, and Chi Square test were used, as appropriate. Differences were considered significant at $P < 0.05$.

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2.5. Stopping rules

Patients who did not strictly adhere to the pre and/or post-operative protocol were excluded from the study.

2.6. Assignment

Patients were randomly assigned to TRANSTAR, or double STARR PLUS group using random permuted blocks with sizes varying from four to six and sequentially numbered. Sealed envelopes with a random number table were produced.

2.7. Blinding procedures

The treatment was assigned by a nurse on the ward before the operation. Another nurse in the operating room recorded the duration of the operation, and the length and weight of fresh removed tissue.

Pathologists were blinded regarding the operative technique used by the surgical team.

Postoperative measurements were done together by one of the authors (SA) and a blind assessor (a third nurse in the outpatient's department).

3. Results

3.1. Preoperative data

Randomization allocation is shown in Fig. 1.

From January 2014 to May 2016, out of 297 women with ODS, 208 (mean age 55.9 years, range 27–77) were selected, with clinical examination, constipation score, colonoscopy, anorectal manometry, and perineography and randomly assigned to 2 groups: 104 patients (mean age 54.8 years, range 27–77) underwent stapled transanal rectal resection with curved multifire stapler (TRANSTAR group) and 104(mean age 57.1 years, range 31–74) had the same operation with two circular TST36 staplers (double STARR PLUS group). Reasons for exclusion were: 30 previous transanal surgery, 14 puborectalis syndrome, 12 ODS score <15, 10 resting pressure <40 mm/Hg, 8 cystocele/genital prolapse,4 concomitant enterocele, 3 concomitant anal fissure, 2 pudendal neuralgia, 2 psychiatric diseases, 2 proctitis, 2 general contraindications to surgery.

3.1.1. Clinical examination and colonoscopy

Sixty-three (60.6%) TRANSTAR patients and 65 (62.5%) in the double STARR PLUS group were multiparous (mean parity 2.67 ± 0.74 and 2.63 ± 0.61; $P = 0.80$); 28 (26.9%) TRANSTAR

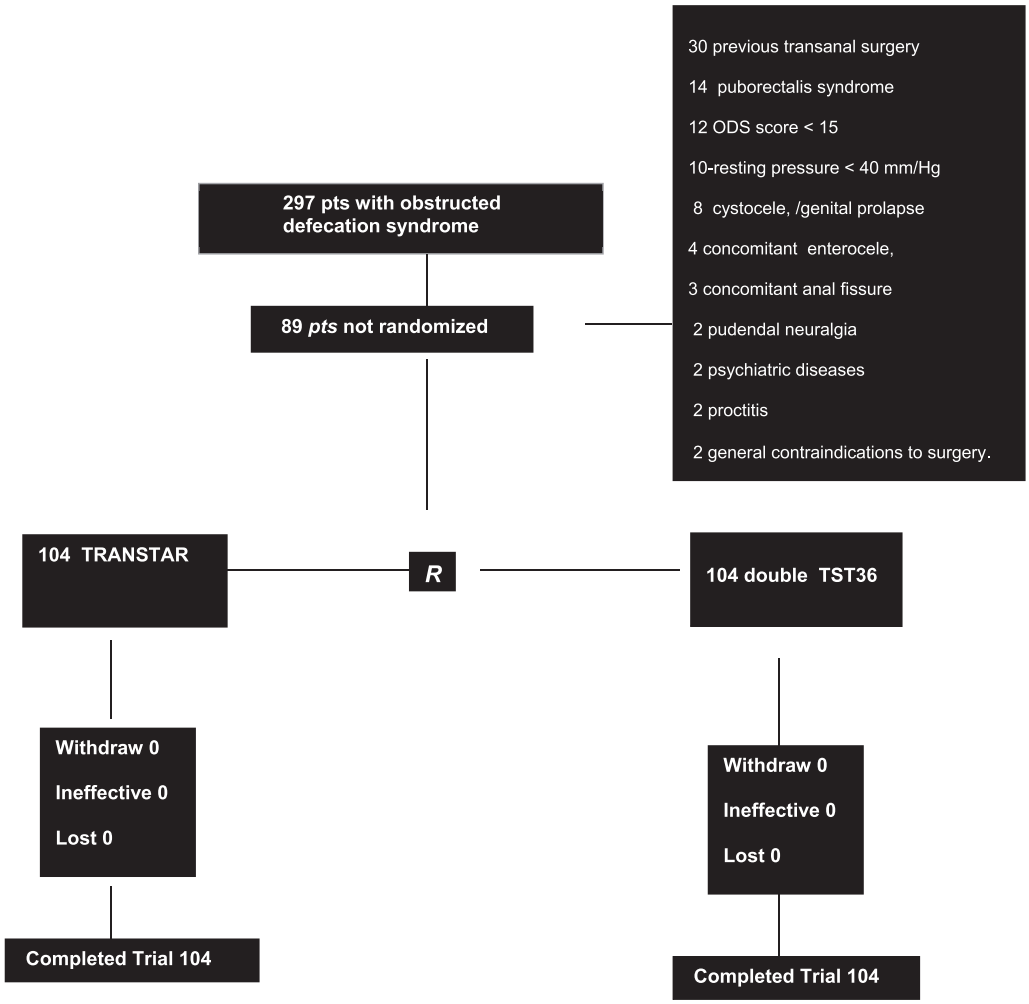

Fig. 1. Randomization allocation. No patients were lost to follow-up and all eligible patients were analyzed. R randomization, FU follow-up, pts patients.

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Table 1
Pre and post-operative (one year) anal/rectal symptoms in patients of TRANSTAR and double STARR PLUS groups: values expressed as number (%) for symptoms and mean (SD) for scores.

	TRANSTAR n = 104		double STARR PLUS n = 104	
	preop	postop	preop	postop
Pain	59 (56.7)	8 (7.7)	57 (54.8)	6 (5.8)
Rectal Bleeding	42 (40.4)	6 (5.8)	43 (41.3)	2 (1.9)
Tenesmus	39 (37.5)	0	40 (38.5)	1 (0.9)
Mucorrhoea	20 (19.2)	0	18 (17.3)	0
Continence score[7]	0.49 (0.20)	0.51 (0.19)	0.50 (0.18)	0.51 (0.21)

Chi-square with continuity correction for evaluation of symptoms and ANOVA for repeated measures for continence score were used. All symptoms were significantly reduced after surgery, without differences between the 2 groups, while values of continence score were not modified (P = 0.78).

patients and 29 (27.9%) in the double STARR PLUS group had previously been operated by hysterectomy. The incidence of preoperative symptoms is reported in Tables 1 and 2. A 2nd degree rectal prolapse was found in 58/104 (55.8%) patients in the TRANSTAR and 57/104 (54.8%) in the double STARR PLUS group (P = 0.84): the others had 3rd-degree IRP.

3.1.2. Anorectal manometry

No significant differences were found between the 2 groups in mean resting and squeeze pressures, rectal compliance and threshold volume (Table 3a).

3.1.3. Colpocystodefecography with opacification of the small bowel

As shown in Table 3b, no significant difference was found in the 2 groups before surgery.

3.2. Operative data

The ASA score was 2.6 ± 0.4 in the TRANSTAR and 2.6 ± 0.5 in the double STARR PLUS group (P = 1.0). The mean (SD) number of reloads for the CCS-30 in TRANSTAR group was 5.0 (0.5). There was no operative mortality. Mean operating time, hospital stay, VAS score during hospitalization and daily doses of analgesics did not differ in the two groups (Table 4).

3.3. Histologic examination

The mean resected volume of the specimen was 30.8(4.1) vs 27.1 (3.5) cm^3 in TRANSTAR and double STARR PLUS group, respectively (P = 0.055). All specimens had muscle fibres. No histological abnormalities were detected in either group, except for the presence of vaginal tissue in one specimen.

3.4. Follow-up data

No patient was excluded from analysis for not complying with the protocol during the 16 months follow-up period.

3.4.1. Primary outcome

Cumulative complication rate was 13.5% (9 bleeding, 3 acute urinary retention, 1 anastomotic dehiscence, 1 tear of the vagina) in TRANSTAR group and 4.8% (3 bleeding, 2 suture line leakages) with double STARR PLUS (P = 0.019). The vaginal lesion, caused by entrapping the vaginal wall in the stapler device, was found at the end of the operation, was located on the posterior vaginal wall, with a diameter of 6 mm, and was directly repaired with 3-0 absorbable stitches, with no after-effects. The anastomotic dehiscence required a reoperation, while staple line leakages where directly sutured during the operation. The postoperative bleedings were self-limitating and treated conservatively, avoiding additional operations. Two patients with acute urinary retention required short-term urinary catheterization.

Table 2
Pre and post-operative (one year) ODS score (from 0 to 31)[5] in patients of TRANSTAR and double STARR PLUS groups: values expressed as mean (SD).

	TRANSTAR n = 104		double STARR PLUS n = 104	
	preop	postop	preop	postop
Mean time spent at the toilet	2.90 (0.47)	0.44 (0.51)	2.95 (0.61)	0.43 (0.55)
Attempts to defecate per day	2.58 (0.52)	0.45 (0.48)	2.64 (0.55)	0.36 (0.38)
Anal/vaginal digitation	2.87 (0.35)	0.43 (0.50)	2.87 (0.56)	0.42 (0.52)
Use of laxatives	2.65 (0.42)	0.61 (0.50)	2.67 (0.50)	0.59 (0.51)
Use of enemas	3.23 (0.48)	0.46 (0.49)	3.14 (0.68)	0.47 (0.52)
Incomplete/fragmented defecation	2.59 (0.45)	0.53 (0.51)	2.68 (0.54)	0.50 (0.49)
Straining at defecation	2.42 (0.44)	0.33 (0.36)	2.32 (0.45)	0.34 (0.43)
Stool consistency	1.75 (0.39)	0.27 (0.36)	1.87 (0.49)	0.28 (0.41)
Total	20.99 (1.89)	3.52 (1.22)	21.14 (1.95)	3.39 (1.57)

ANOVA for repeated measures was used. No significant differences among patients of the 2 groups were found. All parameters were significantly reduced after surgery (P < 0.001).

Table 3a
Pre and post-operative (one year) ano-rectal manometry data in patients of TRANSTAR and double STARR PLUS groups: values expressed as mean(SD).

Finding	Preoperative		Postoperative	
	TRANSTAR n = 104	double STARR PLUS n = 104	TRANSTAR n = 26	double STARR PLUS n = 20
Resting Pressure (mmHg)	66.2 (7.1)	64.8(6.9)	65.7 (7.0)	62.9 (7.2)
Squeeze Pressure (mmHg)	120.3 (11.9)	118.5 (12.4)	119.8(12.3)	117.1 (12.9)
Rectal compliance (mm/Hg)	5.5 (1.1)	5.6(0.9)	5.3 (1.4)	5.2(1.5)
Threshold Volume (ml)				
Distension	50.0 (5.8)	49.5(6.0)	48.7(6.2)	48.5 (6.1)
Defecatory desire	90.2 (10.4)	89.9 (10.1)	88.6 (10.3)	88.1 (9.7)
Maximum tolerable	171.1(20.4)	173.6(21.5)	169.7(20.1)	168.9 (19.9)

ANOVA test was used and no significant change from pre to postoperative data for TRANSTAR vs double STARR PLUS groups was found ($p > 0.50$).

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Table 3b
Pre and post-operative (6 months) defecographic data: values expressed as mean (SD). In patients of TRANSTAR and double STARR PLUS groups.

	TRANSTAR n = 104		doubleSTARR PLUS n = 104	
	preop	postop	preop	postop
Intussusception thickness: mm				
Anterior	3.64 (0.30)	2.29 (0.32)	3.68 (0.26)	2.27 (0.27)
Posterior	3.34 (0.31)	2.14 (0.25)	3.47 (0.29)	2.15 (0.26)
Intussusception descent: mm				
Anterior	29.38(2.48)	16.84 (1.95)	29.25(2.50)	16.36 (1.84)
Posterior	26.20(2.31)	17.10 (1.90)	25.92(1.95)	16.78(1.77)
Rectocele depth: cm	3.85 (0.30)	1.12 (0.22)	3.93 (0.24)	1.08 (0.16)

ANOVA test was used. Preoperatively no significant differences among patients of the 2 groups were found. All parameters were significantly reduced after surgery ($P < 0.001$).

3.4.2. Secondary outcomes

The mean period of inability for normal activity was 16.3 (8.0) and 15.5 (7.1) days respectively ($P = 0.399$). Anal/rectal symptoms and ODS scores significantly improved after the operation in both groups ($P < 0.001$), with no worsening of anal continence (Tables 1 and 2). The incidence of fecal urgency was 14.6% in TRANSTAR group and 23.9% with double STARR PLUS ($P = 0.102$). This complaint was absent before surgery and disappeared in all cases. Postoperative anorectal manometry data in patients with fairly good, or poor results at Satisfaction Score showed a trend of a reduction of both rectal compliance ($P = 0.06$) and maximum tolerable volume ($P = 0.09$) in double STARR PLUS group (Table 3a).

Postoperative defecography showed a significant ($P < 0.001$) improvement of all parameters, without significant differences between the 2 groups (Table 3b). The SF36 Health Survey score significantly improved in both groups ($P < 0.01$) without differences (Table 5). Table 6 reports the patients' Satisfaction Score, with no significant differences within the two groups.

As shown in Table 7, TRANSTAR operation was significantly more expensive than double STARR PLUS operation ($P = 0.035$) Recurrence rates at 16 months were 6.2% in TRANSTAR group and 11.4% with double STARR PLUS ($P = 0.206$).

Table 6
Overall patient satisfaction index in patients of TRANSTAR and double STARR PLUS groups: values expressed as number (%).

	TRANSTAR n = 104	doubleSTARR PLUS n = 104	p[a]
Excellent	20 (19.2)	24 (23.1)	0.55
Good	58 (55.8)	60 (57.7)	0.68
Fairly good	19 (36.3)	15 (14.4)	0.81
Poor	7 (6.7)	5 (4.8)	0.03

[a] By Chi-square test.

4. Discussion

In the last 15 years the surgical treatment of obstructed defecation, due to rectal intussusception and rectocele, or to prolapsed hemorrhoids and internal rectal prolapse, has expanded at a fast rate with the design of new staplers, and the description and application of new surgical techniques and thousand of operations have been done all over the world, with good results, but even with pitfalls and drawbacks. Apart the economic evaluation, the main reason for the constant search of new surgical devices was the evidence of high risk of residual disease (and recurrence of symptoms) in patients with large preoperative rectal prolapse, and/or rectocele, due to the limited capacity of the stapler casing.

The PPH-STARR operation was the first technique to be shown by many rectrospective and prospective studies to be a safe and effective procedure, and the same was reported with the TRANSTAR procedure: at one-year follow-up there was no difference between the two operations, regarding the clinical and functional outcomes, but results after TRANSTAR seemed to be more stable in time, due to the larger amount of resected tissue than PPH-STARR[13]

In a multicenter study Renzi et al. achieved 86.2% of successful

Table 4
Operative and early postoperative data in patients of TRANSTAR and double STARR PLUS groups: values expressed as mean (SD).

	TRANSTAR n = 104	double STARR PLUS n = 104	p	95% CI
Operative Time: min	30.7 (4.9)	29.6 (3.4)	0.062	- 0.04 < 2.24
Volume of resected rectal wall: cm3	30.8 (4.1)	27.1 (3.5)	0.055	2.66 < 4.74
Pain[a]	3.6 (0.7)	3.4 (0.5)	0.019	/
Dose of paracetamol/codeine: mg/day[b]	1000.0 (150.0)	950.5 (185.3)	0.067	/
Hospital stay: days	2.5 (0.5)	2.4 (0.6)	0.967	- 0.05 < 0.25
Time to return to normal activity: days	16.3 (8.0)	15.5 (7.1)	0.399	- 1.34 < 2.94

Statistics by two-sample *t*-test and ANOVA for repeated measures for pain and analgesics.
[a] Mean (SD) daily value of Visual Analog Scale during the hospital stay.
[b] Mean daily dose during the hospital stay.

Table 5
Pre and post-operative (one year) SF36 Health Survey questionnaire in patients of TRANSTAR and double STARR PLUS groups: values are expressed as mean (SD).

	TRANSTAR n = 104		double STARR PLUS n = 104	
	preop	postop	preop	postop
Limitations physical activities	15.0 (1.3)	20.5 (1.6)	14.6 (1.4)	21.3 (1.9)
Limitations social activities for physical, or emotional problems	5.9 (0.9)	6.5 (0.7)	5.7 (0.9)	6.5 (0.6)
Limitations usual role activities for physical problems	5.4 (0.9)	6.4 (0.6)	5.3 (0.8)	6.6 (0.6)
Bodily pain	4.7 (0.7)	3.5 (0.9)	4.7 (0.6)	2.9 (0.7)
General mental health	6.9 (0.8)	4.9 (1.0)	6.8 (0.8)	4.1 (0.7)
Limitations usual role activities for emotional problems	4.0 (0.6)	4.9 (0.6)	4.0 (0.7)	5.2 (0.6)
Vitality	34.1 (2.4)	33.2 (2.2)	34.4 (2.5)	33.1 (2.1)
General health perceptions	13.0 (1.2)	11.5 (1.0)	13.3 (1.3)	11.1 (0.9)
Total	89.0(2.8)	91.5(3.1)	88.8 (3.7)	90.7 (3.3)

ANOVA for repeated measures was used. Preoperative data did not differ in the 2 groups. Surgery significantly improved quality of life in both groups ($P < 0.01$), without differences.

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Table 7
Costs of the operation (euro) in patients of TRANSTAR and double STARR PLUS groups: values are expressed as mean (SD).

	TRANSTAR n = 104	double STARR PLUS n = 104	P[a]	95% CI
Materials	1378 (40.5)	860 (45.3)	0.068	506.32 < 529.68
Operative room and hospital stay	1440 (172.0)	1380(148.5)	0.871	16.32 < 103.67
Total	2818 (179.7)	2240(150.1)	0.035	533 < 623

[a] By two-sample *t*-test.

outcome with CCS30 in patients with ODS within 6 months after the operation.[14]

In our hands the curved CCS-30 Contour Transtar showed some advantages over the two traditional PPH-01 circular staplers, consenting a better anatomical cure of the rectal prolapse, with a significantly larger amount of resected rectal wall, in terms of size and weight, and significantly reduced intussusception thickness and descent and depth of the rectocele at defecography: these better anatomical results reflected in a significantly lower risk of recurrence at 3 years (P = 0.035).[1] In the same study we demonstrated by a multivariate analysis, that the preoperative size of the rectal intussusception is the most important predictive factor for recurrence.[1]

Finally the absence of lateral flaps on the rectal wall with TRANSTAR reduced the incidence of transient postoperative fecal urgency, that is one of the most important problem of PPH-STARR.

For these reasons TRANSTAR operation was preferred by many coloproctologists over the PPH-STARR,particularly in case of large prolapses and rectocele > 5 cm.

On the other side the TRANSTAR procedure was recognized to be not intuitive and easy to perform and not complication-free. In the European multicenter TRANSTAR study, 9% of intraoperative technical difficulties were reported and many studies showed the risk of serious early and late complications with the multifire technique, particularly perforations[5,6] and vaginal lesions,[1,] or rectovaginal fistula[5]

Finally the TRANSTAR operation is very expensive and costs of materials has become mandatory for the choice of surgical techniques in countries with a National Health Service. The TST 36 stapler was designed as a less expensive surgical alternative to PPH-STARR on patients with obstructed defecation, with the theoretic advantages to consent better vision and control of resection and to resect the same amount of tissue than two PPH01 staplers, using one stapler: these assumptions were confirmed by the study of Naldini et al[8] In a prospective German multicenter study the new TST 36 stapler was used in 110 patients (55 with rectal intussusception or rectocele, and 55 with advanced hemorrhoidal disease) with 3.6% of partial suture line dehiscence, 6.3% of reintervention for bleeding, one anastomotic dehiscence, and 4.5% recurrence.

In the same study a close correlation between the amount of resected rectal wall tissue and improvement of ODS Altomare's score [1] was found (P = 0.01).[15]

These good results prompt us to try to compare the new high volume stapler to the TRANSTAR procedure in patients with large third-degree internal rectal prolapse and rectocele > 5 cm. Two TST 36 staplers were necessary to warrant the same possibility of tissue resection than the multifire TRANSTAR operation.

Our results demonstrated that double STARR PLUS operation has the same clinical and functional results than TRANSTAR with no technical difficulty and significantly lower cumulative complication rate and costs.

The TRANSTAR Registry Study Group reported 11% of complications: 3% related to the staple line during the operation, and 8% postoperatively, particularly 5% of self-limited bleeding,[16] while Lenisa had 5% of partial dehiscence and 4% of spiraling of the staple line during the TRANSTAR operation, and therefore strongly recommended the intraoperative control of the staple line. Our results confirmed that the TRANSTAR operation is technically more difficult than the STARR PLUS operation and therefore requires sufficient experience in transanal stapled surgery, to avoid, or minimize the intraoperative complications related to the staple line, and the vaginal lesions.

As described by Naldini[7] and Petersen[11] we observed an high incidence of fecal urgency after STARR plus procedure, similar to the traditional PPH-STARR and higher than TRANSTAR (even if data were not significant). As described for PPH-STARR, even if our postoperative data in the double STARR PLUS group showed only a trend, not reaching the level of significance, the reasons of this transient complaint could be the reduced rectal compliance, and the modification of rectal sensitivity, due to the resection and the presence of residual lateral flaps, that is a standard for circular stapling. In our opinion the easy removal of the residual lateral flaps with hemostatic stitches during the STARR PLUS operation could reduce the incidence of this transient, but disabling symptom. The recurrence rate showed a trend to lower risk with TRANSTAR procedure,but, as observed for fecal urgency, the difference was not significant in the mid-term period.

In conclusion in patients with third grade rectal prolapse and rectocele deeper than 5 cm, the double STARR PLUS appears to be the best alternative to the TRANSTAR technique, consenting to obtain the same midterm clinical and functional results with less complications and money saving.

Longer follow up is necessary to assess is the not significant gap in the recurrence rate will reach the significance level.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.01.074.

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