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Safety and efficacy of transanal prolapse resection with a new 36mm stapler device (TSTstarr +)

Results of a prospective multicenter assessment study

Transanal stapler resections have been established in recent years as a safe and effective method for the treatment of advanced haemorrhoidal disease and obstructed defecation syndrome at / with intussusception and rectocele [1,2]. Recurrences or failures may be due to an insufficient resection volume, at very large prolapse. For particularly large haemorrhoids, a 33mm standard stapler occasionally appears too small and for a common STARR surgery (Stapled Transanal Rectal Resection) two 33mm staplers are necessary. For this reason, a new (36mm) stapler was developed by the industry, which makes it possible to remove either mucosal cuffs with very large volumes at stapled hemorrhoidopexy or perform a complete transanal resection of an internal rectal prolapse with only one stapler. A special feature is specified by the manufacturer that the built-in mechanism adjusts the closed staple height (0.75mm-1.8mm) to the thickness of the resected tissue ("Tissue Selecting Therapy" - TST). Thus, the stapler can be used either for a mucosal resection or a full - thickness resection.

In this multicenter study it should now be tested at 7 German proctologic centers, whether this new stapling instrument (36mm TSTstarr+, Touchstone International Medical Science Co., Ltd, Suzhou, China) is safe and can be used efficiently.

Material and Methods

In the period from 01.09.2013 to 31.06.2014 prospectively all patients were recorded in the mentioned 7 study centers, where surgery was performed with the TSTstarr+. All patients were informed about the participation in the study and they gave their consent. The study has been approved by the local ethics committees of the participating hospitals. As an operational diagnosis both, large grade three hemorrhoids and an obstructed defecation syndrome (ODS) with internal rectal prolapse were possible. The rectal cuff could be drawn into the stapler either by a purse-string suture or by parachute sutures. The study excluded patients who had already had proctologic operations and in particular patients who had already been stapled before and who had relevant proctologic comorbidities. Preoperatively, the results of a clinical examination and an endosonography of the sphincter apparatus were at hand. An anal manometry was only optional. The Cleveland Clinic Incontinence Score (CCIS) for incontinence and the Altomare-ODS score was determined preoperatively. Both scores were determined again one and six months after surgery. The pain score was recorded using numerical and visual analogue scale, VAS (0-10). Follow-up examinations were performed after 14 days, after one month and after 6 months. Hemostatic sutures for bleeding of the staple suture line, operation time, hospital stay and perioperative complications were recorded.

Statistics

The data analysis was performed using SPSS 18.0.

The data from the CCIS and ODS scores were analyzed by T-Test of related variables.

Surgical Technique

The surgery was always performed in the lithotomy position and was carried out either in general anesthesia or spinal anesthesia.

The TSTstarr+ stapler (Touchstone International Medical Science Co. Ltd., Suzhou, China) has a housing length of 6 cm with an internal volume of more than 35cm³ and a blade diameter of 28mm. It carries 34 staples with a height of 4.2 mm in open condition and a closure range of 0,75-1,8mm.

Analogous to the stapled hemorrhoidopexy [3] the 4 stay-sutures for the Circular Anal Dilator (CAD) are made after desinfection of the perianal region. After dilatation of the anus with the 36mm obturator, the introduction of CAD occurs together with the obturator. After evaluation

of the initial findings (Fig.1), the CAD is fixed with the previously applied sutures. In haemorrhoids and prolapse of the rectum <50% into the CAD, a purse-string suture with 2-0 Prolene 3 cm above the edge of the CAD respectively 5-6 cm above the Linea dentata is applied (Fig.2). The suture-ends are then pulled with the suture hook through the stapler chamber. Now the prolapse can be drawn under vision into the staple chamber. The stapler is then closed and the posterior wall of the vagina is palpated to detect and prevent its inclusion into the stapler. Then the stapler is released. After opening the stapler with a little more than half a turn, a click is heard. Then the stapler can be removed. The resected tissue is checked for completeness (Fig.3). The stapler suture is inspected (Fig.4). The correct staple suture is located at the apex of the hemorrhoidal plexus. If bleeding occurs from the suture line, locking single puncture-sutures with 2-0 Vicryl are applied at the bleeding sites. After hemostasis the CAD can be removed and the operation is completed (Fig. 5).

In ODS and prolapse of the rectum > 50% in the CAD (Fig.6) six stay-sutures in parachute technique at 12, 2, 4, 6, 8, 10 o'clock LP are applied [4] (Fig.7). The suture-ends are then pulled with the suture hook through the stapler chamber. Now the prolapse can be drawn under vision into the stapler chamber (Fig.8, 9). The stapler is then closed and the posterior wall of the vagina is palpated to detect and prevent its entrapment. Then the stapler is released. After opening the stapler with a little more than half a turn, a click is heard. Then the stapler can be removed. The resected tissue is checked for completeness (Fig.10). The stapler suture is inspected, the internal rectal prolapse should be completely removed (Fig.11). In case of bleeding from the suture line, securing single puncture-sutures with 2-0 Vicryl are applied. After hemostasis the CAD can be removed and the operation is completed.

All operations were performed by experienced coloproctological surgeons who had previously had appropriate training in the above standardized technique.

Results

From September 1st 2013 to June 31st 2014, 103 consecutive patients (67 women, 36 men) were included in the study. The complete data of these patients could be acquired till the 6-month follow-up. The indication for surgery in 48 patients was an advanced haemorrhoidal disease and in 55 patients - ODS with rectal intussusception (thereof 52 women).

The average operative time was 30 minutes (10-53 minutes). The average hospital stay was 3,4 days (1-10 days).

The length of all resected specimens averaged 4.3 cm, the weight averaged 14.5 g. The resected specimen in STARR technique with a prolapse > 50% of the CAD had the average length of 5,1 cm and the average weight was at 17,2 g.

The average value of the preoperative VAS-score was at 0,6. Six hours postoperatively the average value of the VAS - score was 3,2 and after 24 hours at – 2,8. 24 hours after surgery, 39 patients (38%) needed additional analgetics during the hospital stay.

In 2 weeks, the average VAS - score was 1,9. 38 patients (37%) were still taking analgetics. In a month, the average VAS - score was 0,8. 9 patients (8%) were still taking analgetics. Six months after surgery, no patient complained of pain at the surgical area.

The ODS- score after Altomare (5), which was detected with patients with ODS (n = 55), was preoperatively at 12,2 (\pm 9.2), a month after surgery it was 6.8 (\pm 5.5) and after six months it was 5.4 (\pm 5.2) ($p < 0.01$) (Fig. 12).

The Cleveland Clinic Incontinence Score (6) of the patients was low preoperatively, at 5,7 (\pm 5.3), in one month it was 4.3 (\pm 4.0) and after six months it was 3.2 (\pm 3, 0). The changes did not have statistically significant difference (Fig. 13).

As part of the data acquisition, intraoperative and postoperative problems were detected (Tab.1). Three times the introduction of the stapler was described as difficult. In 22 cases, mechanical problems were specified, always as a matter of difficult stapler closure. In 4 cases an intraoperative partial dehiscence of the stapler suture occurred, which had to be sutured. 3 intraoperative hematomas occurred; all affected patients were taking anticoagulants. Averagely 2 hemostatic sutures were necessary per operation at the staple suture line.

There were 4 relevant postoperative hemorrhages, which had to be revised. 3 acute urinary retentions had to be temporarily treated by transurethral catheter. There was one haemorrhoidal thrombosis, which was treated with a Milligan-Morgan haemorrhoidectomy. An extensive perineal hematoma was treated conservatively.

In the first two weeks postoperatively, there were 4 postoperative hemorrhages, in two of them a surgical revision was necessary. One staple suture dehiscence was sealed by repeated coloscopic insertion of an Endo-Vac sponge.

4 weeks after the operation, one hemorrhage occurred, which had to be amended surgically. Overall, thus, 7 operative revisions for postoperative hemorrhages (6.7%) and 1 Milligan-Morgan haemorrhoidectomy for haemorrhoidal thrombosis took place. In the first 6 months after the stapler operation 5 Milligan Morgan excisions were performed, because of a residual prolapse or an early recurrence (4.8%). Further relapses did not occur.

In addition, in the four week control, 22 patients stated Urge symptoms with reduced warning time for defecation (21%), after 6 months these symptoms were complained by only 5 patients (4.8%). Incontinence did not occur.

The most serious complication was the previously mentioned stapler suture dehiscence treated by endoluminal vacuum therapy.

Discussion

With the introduction of new technical equipment and new surgical techniques, it must be determined by careful observation, if these devices fit into the clinical routine. The advantage, which is touted for this device, is the better adaptation of the stapler-height to the resected tissue (Tissue-Selecting-Therapy TST). That means, no matter how thick the resected mucosal or rectal full thickness cuff is, the stapleline compresses the anastomosed tissue correctly. The stapled sutureline may not be insufficient and no relevant bleeding may occur from the stapled sutureline. From the 103 cases recorded, intraoperative partial dehiscence occurred in 4 cases (3 full thickness resections, 1 mucosal ring). These were detected intraoperatively and closed transanally by means of simple interrupted sutures. Postoperatively there were no complications in these patients. One patient developed a postoperative partial stapled suture- insufficiency (after full thickness resection in STARR technique), which could be sealed by endoluminal vacuum therapy. Stapling insufficiency may, therefore, occur as in the classical surgical procedures, with stapled haemorrhoidopexy and STARR operation [7]. The security suggested by the advertised TST technology should therefore not be seen as a guarantee of one hundred percent safe anastomosis. Also in relation to the postoperative hemorrhages, subject to revision, the rate in this study of 6.7% corresponds to the data from the literature with an postoperative hemorrhage rate of 5-12% [8,9].

Stenosis in the anastomosis area have not been observed so far.

The purpose of the prolapse removal was achieved in 95%. The symptoms of obstructed defecation syndromes have improved significantly (Fig. 12). A repeatedly occurring fecal incontinence, which is quite possible for a 36 mm measuring stapler, with respectively relevant anal dilatation, could not be observed (Fig. 13).

The results of this prospective study coincide with the data of the Italian group of Naldini et al [10]. Merely the Urge symptoms in the study by Naldini et al. were much less frequently observed than in our study. In Naldini et al, 30 days postoperatively the Urge symptoms were only observed with 0.5% of the patients. We observed Urge symptoms with reduced warning time one month postoperatively in 22 patients (21%). Six months postoperatively, 5 patients still reported these disturbing symptoms (5%).

The costs for the new 36mm TSTstarr+ stapler are higher than those for the 33mm PPH stapler. However, one TSTstarr+ stapler is cheaper than two PPH 01 staplers, which are necessary for a standard STARR surgery. For large anal prolapse with internal rectal prolapse, this new device is suitable to respond flexibly to the intraoperative findings.

Depending on the findings, which spread into the CAD, a tailored resection can be made. By a correspondingly larger volume resection, the recurrence rate could be lowered.

This operation should only be carried out by coloproctologically experienced surgeons who have also experienced a corresponding hands-on training, in which the handling of this stapler was demonstrated. The closing of the stapler was often perceived as surprisingly difficult on thick rectal cuffs, releasing could well require force. Therefore appropriate modifications to the mechanics of the device have already been made by the manufacturer.

For coloproctologically experienced surgeons, the TSTstarr+ stapler is a quite useful complement to the transanal resection of mucosal or rectal full thickness cuffs. The better visual control of the prolapse drawn into the stapler through the large side openings has been rated as positive (Fig. 9).

Conclusion

The data collected in this study show that the new, larger 36mmTSTstarr+ stapler can be securely and effectively used for treatment of anorectal prolapse in advanced haemorrhoidal disease and Obstructed Defecation Syndrome. The complications encountered are similar to those of the previously popular stapler methods. However, this stapler can achieve larger resection volumes, with good postoperative results within a postoperative follow up period of 6 months.

Like all transanal stapler resections, this procedure should only be performed after adequate instruction and by appropriately experienced coloproctological surgeons. In order to confirm the initial positive results, longer observation studies must be conducted.

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Competing interests

The authors report the financial support of this study by Touchstone International Medical Science Co. Ltd..

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Summary

Introduction: A new stapler (TSTstarr+), 36mm in diameter, enables the resection of large mucosal cuffs in the technique of the stapler haemorrhoidopexy, as well as the circular resection of full-thickness rectal wall cuffs in the STARR technique.

Methods: In this multicenter observation study safety and efficiency of this device were prospectively recorded and assessed by means of 103 operated patients, with a follow-up period of 6 month.

Results: 7 Patients had to be surgically revised due to postoperative hemorrhages. Overall 5 haemorrhoidectomys after Milligan – Morgan at residual haemorrhoids were performed in the process. Further recurrences did not occur in the follow-up period. One postoperative staple-suture dehiscence was cured by endoluminal vacuum therapy.

Conclusion: The new 36mm TSTstarr+ stapler is a good and safe complement in the treatment of advanced grade three haemorrhoidal disease and internal rectal prolapse with ODS.

Keywords

Haemorrhoids – Obstructed Defecation – STARR – Stapled Hemorrhoidopexy – anorectal Prolapse

Tab. 1

Complications in 103 patients	
perioperative	patient number
mechanical problems	22 (21,3%)
stapleline dehiscence	4 (3,9%)
hematoma	3 (2,9%)
bleeding from stapleline, needed to be sutured	80 (77,6%)
postoperative	
bleeding	9 (8,7%)
urinary retention	3 (2,9%)
haemorrhoidal thrombosis	1 (0,9%)
perineal hematoma	1 (0,9%)
stapleline dehiscence	1 (0,9%) Endo-Vac Therapy
recurrence	
haemorrhoidectomy (Milligan Morgan)	5 (4,8%)
rectal prolapse	0 (0%)