Stapler-assisted trans-anal surgery for the treatment of outlet obstruction syndrome

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Abstract: Outlet obstruction syndrome (OOS) is related to anatomic alterations, such as rectocele, enterocele and distal intussusception which may be associated with functional disorders, such as paradoxical puborectalis contraction. Patients unresponsive to conservative treatment are eligible for surgical correction of the specific anatomic defect. Recently, new techniques of stapler-assisted trans-anal surgery have been proposed as an alternative to traditional trans-anal operations. This prospective study was undertaken with the aim of assessing the efficacy and postoperative morbidity of two trans-anal stapled techniques (stapled trans-anal prolapsectomy or stapled trans-anal rectal resection, STARR) which were selectively performed in patients with OOS, based on the specific clinical, manometric and defecographic findings. From January 2004 to December 2006, 31 female patients (median age = 58.2 years: range = 27-77 years) underwent surgery at the Division of General Surgery, Colo-Rectal Disease Unit of San Martino Hospital in Genoa. Patients had preoperative colonoscopy, anorectal manometry, defecography, and a complete standardized questionnaire was completed preoperatively and at every six-month follow-up visit aimed at assessing the obstructed defecation score (ODS), the degree of symptoms (Gravity Disease Score = GDS), as well as the quality of life (PAC-QoL), and the satisfaction index by means of a visual analogue scale (VAS: 0-10). A complete re-assessment was performed after one year, including anorectal manometry and defecography. Six patients underwent stapled trans-anal prolapsectomy and 25 underwent STARR (double-STARR in seven, and single anterior STARR in 18 patients). All patients had a regular postoperative course. They had follow-up visits for a median period of 12 months (range: 4-27 months); 23 patients completed clinical and instrumental follow-up at one year, with a significant improvement of post-operative scores of outlet obstruction; moreover, 3 of them (13%) judged their final clinical outcome as excellent, and 18 (80%) as good or moderate. As regards anorectal manometry, pre- and postoperative resting and squeeze pressures were not different thus excluding any postoperative damage to the anal sphincter; conversely, an improvement of rectal sensation was observed in 15 patients (79%) as suggested by the decrease of rectal sensitivity threshold volumes (P = 0.01) and maximum tolerable volume (P < 0.01); moreover, in 7 out of 19 patients (36.8%) the balloon expulsion test became positive. With regard to postoperative defecography, normal findings were observed in 11 patients (61,2%) with a significant reduction of rectocele (P < 0.001); persistent abnormal findings were observed in 7 patients (38,8%). The accurate preoperative assessment and the selective trans-anal correction of rectocele and/or intussusception determined a significant improvement of outlet obstruction scores coupled with a normalization of defecographic and manometric findings, which was most relevant in patients undergoing STARR, without any serious postoperative complication.

Key words: Outlet obstruction syndrome; Obstructed defecation; Rectocele.

INTRODUCTION

Outlet Obstruction Syndrome (OOS) mainly affects adult female patients (80-90%) presenting with difficulty in rectal emptying with painful efforts, prolonged time spent in the bathroom, insertion of fingers into vagina and/or the anal canal, laxative and/or enema abuse, and occasional bleeding. From the anatomic standpoint, various defects are detectable, such as rectocele, enterocele and internal mucosal prolapse with or without distal intussusception. Functional alterations may coexist, such as paradoxical puborectalis contraction or spastic external sphincter contraction which are likely to respond to biofeedback traning.[1-4] Patients unresponsive to conservative treatment (1.5 l/day of water, high-fiber diet, biofeedback training) are eligible to surgical correction of the specific anatomic defect (i.e., vaginal or perineal levatorplasty, laparotomic or laparoscopic rectopexies, resection-rectopexy, Delorme's transrectal excision).[5-11] Actually, surgical correction has achieved satisfactory results in 58% to 90% of patients in the short-middle term clinical follow-up, with favourable response in less than 50% in extended follow-up (6-7 years).[12-14] Recently, thanks to the development of stapler-assisted trans-anal surgery (such as stapled hemorrhoidopexy), new procedures have been proposed as an alternative to traditional trans-anal techniques for the treatment of OOS, which proved effective at least in short-term follow-up with a low postoperative complication rate.[15-16]

This prospective study was performed in consecutive patients with OOS with the aim of assessing the efficacy and postoperative morbidity of two trans-anal stapled techniques (stapled trans-anal prolapsectomy and stapled trans-anal rectal resection, STARR) which were selectively performed based on the specific clinical, manometric and defecographic findings: stapled prolapsectomy was performed when the main anatomic defect was represented by internal mucosal prolapse and/or recto-anal intussusception while STARR was undertaken in patients whose rectocele was the most remarkable finding.

PATIENTS AND METHODS

From January 2004 to December 2006, 31 consecutive female patients with OOS (median age = 58.2 years: range = 27-77 years) were recruited with informed consent in this prospective clinical study which was performed at the Division of General Surgery, Colo-Rectal Disease Unit of San Martino Hospital in Genoa. Patients had preoperative colonoscopy, anorectal manometry and defecography. When colonic inertia was suspected, colonic transit time study using radiopaque markers was performed in order to detect slow colonic transit. A complete standardized questionnaire was completed preoperatively and at every six-month follow-up visit in order to assess obstructed defecation score (ODS), degree of symptoms (Gravity Disease Score = GDS), as well as the quality of life (PAC-QoL), and the satisfaction index by means of a visual analogue scale (VAS: 0-10).[17-18] Intra- and postoperative complications (such as: bleeding, haematoma, intractable pain, local infection, recto-vaginal fistula, anastomotic stenosis, urinary tract infection or retention, outlet obstruction symptoms, urge to defecate, incontinence to flatus) were recorded. Clinical follow-up was

performed every six months, and a complete re-assessment was undertaken after one year, including anorectal manometry and defecography. Moreover, a qualitative self-assessment was determined considering the clinical outcome as *excellent* when patients were symptom-free; *good* when they had 1-2 episodes/month of use of laxatives without digital assistance, use of enema, or bleeding; *moderate* when they had more than 2 episodes/month of laxative use, and *poor* when their symptoms were unchanged as compared to the preoperative period. As regards statistical evaluation, all analyses were performed using SPSS for Windows (SPSS Inc., Chicago, IL) statistical software; t-test for paired data was used to compare the scores of questionnaires, and Fisher exact test to compare pre- and post-operative manometric and defecographic findings.

Anorectal manometry: With the patient lying in the left lateral position and the hips flexed 90 degrees, a manometric probe, consisting of a silastic tube with an external diameter of 3 mm and bearing six open-ended-tip transducers with continuous water perfusion (Medtronic) was inserted into the anus. The transducers were in the anal canal, and an inflatable latex balloon was mounted on a polyvinyl tube at 5 cm from the anal verge. The transducers were connected via amplifiers to a multichannels computerized unit (*PC Poligram VIII* - Synectics Medical - USA) showing pressure/time curves in real-time. The main parameters which were assessed included: length of the anal canal, maximal anal resting pressure (MARP), maximal anal squeezing pressure (MASP), rectal sensitivity threshold volume (RSTV), objective recto-anal inhibitory reflex (RAIR), and maximum tolerable volume (MTV); moreover, the balloon-expulsion test was performed at the end of the manometric study.[19]

Defecography: Dynamic radiologic rectal evacuations were performed as described by Andromanakos et al.[20] Three hours before the exam the patient was given hydrosoluble contrast by mouth in order to check the small bowel and exclude the co-existence of enterocele. The rectum and vagina were filled with different barium contrast medium. Radiographs were taken in the lateral projection at rest, during and after straining until the complete evacuation of the contrast; anterior-posterior projections were acquired in selected cases in order to exclude any lateralization of the anatomic defect. Defecography was used to document the extent of rectoanal intussusception according to Wexner's classification (1st degree: < 10 mm infolding on the rectal wall; 2nd degree: > 10 mm infolding extending into the anal canal) and the size (in mm) and shape of rectocele according to Marti's classification (Type I: digitiform rectocele; Type 2: big sacculation with anterior rectal mucosal prolapse; Type 3: rectocele associated with intussusception and/or prolapse of the rectum).[21-22]

Surgical Techniques: Preoperatively a cleansing enema was given, and the patient received a routine antibiotic prophylaxis (single shot cefotaxime 2 g and metronidazole 500 mg intravenously) immediately after the induction of anaesthesia. The operation was always performed under spinal anaesthesia with the patient in lithotomic position.

Stapled Trans-Anal Prolapsectomy: According to the technique described by Longo for the treatment of hemorrhoids,[15] the anal verge was gently dilated with one and then two fingers, and the lubricated dilator with obturator (CAD) of the PPH-03™ kit (Ethicon Endo-Surgery, Inc., Pratica di Mare - Rome, Italy) was introduced and left in place for 60 seconds. Four radial stitches were applied to the perineal skin and knotted in order to hold the CAD in place. After removing the obturator, the operative anoscope was introduced within the CAD, and one purse-string including mucosa and submucosa was prepared with Prolene 2-0 (Ethicon, Somerville, NY, USA) 2.0 cm above the dentate line. The PPH-3 circular stapler was opened and its head was placed above the purse-string which was knotted and the ends of the sutures were brought through the specific holes of the stapler. Keeping the end of the sutures in traction, the stapler was closed, fired, and then gently withdrawn thus performing prolapse resection with rectopexy. The haemostasis was accurately controlled by supplementary haemostatic sutures of the anastomotic ring with Vicryl 3-0 (Ethicon, Somerville, NY, USA). After 5-10 minutes of careful observation to check for bleeding, a piece of gauze was positioned into the anorectal canal for 4 to 6 hours, and the CAD was removed.

Stapled Trans-Anal Rectal Resection (STARR): The preliminary operative phases were similar although a different kit was used (PPH-01™; Ethicon Endo-Surgery, Inc., Pratica di Mare - Rome, Italy). The posterior rectal wall was protected by a retractor, inserted in the lower hole on the CAD 33 and pushed along the anal canal and lower rectal ampulla. The anoscope (PSA 33) was introduced into the CAD 33 and two half (180°; from 9 to 3 hours) purse-strings with Prolene 2-0 (Ethicon, Somerville, NY, USA), including prolapsed rectal wall with mucosa, submucosa and rectal muscle wall, were inserted 2 cm above the dentate line, 1-2 cm apart, to include the top of rectocele. Should the anterior rectocele only be resected, the two purse-strings were a little wider, from 8 to 4 hours instead of 9 to 3 hours. The PPH-1 circular stapler was opened and its head was placed above the purse-strings which were knotted and the ends of the sutures were brought through the specific holes of the stapler. Before firing the stapler, the posterior vaginal wall was carefully checked with fingers and a vaginal valve was introduced to prevent mucosa entrapment. Keeping the end of the sutures in traction, the stapler was closed, fired, and then withdrawn. A minimal mucosal bridge with a staple connecting the two edges of the anterior anastomosis was sometimes found and cut by scissors. The haemostasis of the anterior stapled line was completed with haemostatic stitches using Vicryl 3-0 (Ethicon, Somerville, NY, USA). The procedure was repeated in the posterior rectal wall, with the retractor inserted into the upper hole of the dilator. Two half (180°) purse-strings with Prolene 2-0 were prepared in the posterior rectal wall above the dentate line including mucosa, submucosa and rectal wall, to reduce the posterior intussusception. Subsequent surgical manoeuvres were similar to the previous phase and, after careful inspection for bleeding, the operation was concluded by positioning a piece of gauze into the anorectal canal for 4 to 6 hours, and the CAD is removed. All removed tissue was always carefully checked and sent for definitive histologic assessment.

RESULTS

Six patients underwent stapled trans-anal prolapsectomy and 25 underwent STARR (double-STARR in seven, and single anterior STARR in 18 patients). All but one patient, who developed a peripheric neuropathy of the sciatic nerve, had a regular postoperative course. They had follow-up visits for a median period of 12 months (range: 4-27 months); 23 patients completed clinical and instrumental follow-up at one year, and a significant improvement of the main scores of outlet obstruction was observed (Tab. 1). Moreover, three of them (13%) judged their final clinical outcome as excellent, 16 patients (69.5%) as good, two patients (8.6%) as moderate, with only two patients (8.6%) having poor results (Tab. 2).

TABLE 1. – *Preoperative and Postoperative scores in 31 patients operated for Outlet Obstruction.*

Items	Preoperative	12 months	P value
Frequency	1.09 (0.259)	0.35 (0.135)	0.001
Straining (intensity)	1.78 (0.108)	0.35 (0.119)	0.000
Straining (time)	1.83 (0.081)	0.48 (0.124)	0.000
Sense of rectal fullness	2.83 (0.120)	0.74 (0.237)	0.000
Rectal pain	2.13 (0.269)	0.26 (0.180)	0.000
Reduction of daily activity	1.83 (0.469)	0.26 (0.191)	0.001
Use of laxatives	3.87 (0.678)	1.96 (0.567)	0.002
Use of enema	2.74 (0.654)	0.48 (0.326)	0.001
Manual assistance	1.65 (0.493)	0.30 (0.183)	0.006
Failure	3.09 (0.301)	0.74 (0.229)	0.000
Feeling of incomplete evacuation	3.83 (0.174)	1.00 (0.295)	0.000
Painful evacuation effort	0.91 (0.288)	0.22 (0.177)	0.010
Daily urge for defecation	0.22 (0.125)	0.09 (0.87)	n.s.
Rectal bleeding	1.30 (0.277)	0.22 (0.108)	0.002
Continence Grading Scale	0.30 (0.183)	0.17 (0.136)	n.s.
PAC-QOL (unsatisfactory index)	50.13 (4.352)	13.22 (2.973)	0.000
PAC-QOL (satisfactory index)	0.83 (0.306)	10.13 (1.118)	0.000
VAS satisfactory index	3.52 (0.444)	7.39 (0.396)	0.000

Values are expressed as means with standard errors.

As regards anorectal manometry, pre- and postoperative resting and squeezing pressures were not different thus excluding any postoperative damage to the anal sphincter; conversely, an improvement of rectal sensation was observed in 15 out of 19 patients (79%) as suggested by the decrease of rectal sensitivity threshold volumes (P = 0.01) and maximum tolerable volume (P < 0.01); moreover, in 7 out of 19 patients (36.8%) the balloon expulsion test became positive. In postoperative defecography normal findings were observed in 11 out of 18 patients (61.2%) while persistent abnormalities were observed in 7 patients (38.8%) (n = 3, second degree rectocele; n = 1, internal mucosal prolapse; n = 3, second degree rectocele with internal mucosal prolapse). As compared to preoperative defecographic findings, anterior rectocele was significantly reduced from 96 percent to 12 percent of patients (P < 0.001) while intussusception was reduced, although not significantly, from 48 percent to 20 percent.

The assessment of post-operative defecographic findings stratified by type of surgery showed that residual rectocele and intussusception were more frequent after stapled transanal prolapsectomy than after STARR (both anterior or double). Patients in the former group had residual rectocele and intussusception in two out of four cases (50%) while those undergoing single anterior STARR had residual intussusception in two out of ten patients (20%), and those

TABLE 2. – *Subjective evaluation of the outcome of surgery of 25 patients at one-year follow-up.*

Subjective evaluation of the outcome of surgery	n. pts	%
Excellent	3	13.0%
Good	16	69.5%
Moderate	2	8.69%
Poor	2	8.69%

undergoing double STARR had residual rectocele and intussusception in one out of four patients (25%). As regards post-operative manometric assessment, the improvement of rectal sensation was more frequently achieved by STARR than by stapled prolapsectomy, as suggested by persistently increased rectal sensitivity threshold volumes and maximum tolerable volumes in 33 percent of patients undergoing stapled prolapsectomy (1 out of 3) as compared to 9 percent of patients undergoing single anterior STARR (1 out of 11) and complete normalization of manometric parameters in all five patients undergoing double STARR.

DISCUSSION

Outlet Obstruction Syndrome (OOS) is a clinically relevant and emerging problem which mainly affects adult female patients (80-90%) referring with difficulty in rectal emptying with painful efforts, long time spent in bathroom, insertion of fingers into vagina and/or the anal canal, laxative and/or enema abuse, and occasional bleeding. This syndrome should not be confused with constipation related to colonic inertia or associated with irritable bowel syndrome, as they are characterized by a slow transit time of radio-opaque markers.[1] The pathophysiology of OOS is still far to be clearly understood because anatomic defects, such as rectocele, enterocele, internal mucosal prolapse with or without distal intussusception, may be associated with functional alterations, such as paradoxical puborectalis contraction or spastic external sphincter contraction.[1-4] Noteworthy, none of these alterations is regarded as pathognomonic because: 1) an anterior rectocele has been shown in 20 to 81 percent of asymtomatic females or with constipation; 2) only 23 to 70 percent of unselected patients with a rectocele have symptoms related to obstructed defecation; 3) clinical outcome after surgery is not strictly related to the complete repair of rectocele, and 4) notwithstanding rectocele repair, 30% al 72% of patients have still persistent difficulty with defecation.[12] The same considerations may be true for internal intussusception, a frequent find-

ing on defecography observed in 13 to 50 percent of control patients and in 28 to 50 percent of patients with OOS.[23-27]

Preoperative evaluation of patients with OOS should include a detailed clinical history by means of validated questionnaires, such as the Constipation Scoring System and the Continence Grading System, to allow a postoperative assessment of the effectiveness of treatment, and diagnostic investigations (defecography, anorectal manometry) to define the specific anatomic and functional abnormalities; colonoscopy should exclude concomitant colo-rectal disease.[16-18]

Patients should usually undergo preliminary conservative treatment (1.5 l/day of water, high-fiber diet, use of bulk laxatives); when paradoxical puborectalis contraction or descending perineum is confirmed, biofeedback training is valuable because in 30 to 38 percent of patients a prolonged clinical improvement has been reported.[28-31] Unresponsive patients are eligible to different surgical options for the repair of the specific anatomic defect, proven the absence of primarily colonic constipation.[32] Moreover, patients with impaired sphincter function should be excluded due to the high risk of inducing definitive postoperative incontinence; actually, postoperative anorectal manometry in patients treated by means of traditional trans-anal surgery demonstrated a significant reduction of maximum anal resting and squeezing pressures ($P = 0.043$) which may be related to anal stretching by the retractor, with damage of the anal sphincter complex, although a partial recovery was observed within two years after surgery.[33-35]

Different surgical options have been proposed, such as: vaginal or perineal levatorplasty, open or laparoscopic rectopexies, resection-rectopexy, and Delorme's transrectal excision.[5-11] Some surgeons and urogynecologists are in favour of traditional transperineal anterior repair of rectal wall with levatorplasty, while rectocele with concomitant cystocele is best repaired by transvaginal anterior levatoplasty with posterior colporrhaphy; postoperative dyspareunia is frequently reported, with a negligible improvement of obstructed defecation symptoms.[36-39] The abdominal approach seems the best for the high type rectocele, as it makes possible combined treatment of rectal and urogynecologic alterations, and is also indicated in case of rectocele associated with enterocele, especially in young women.[40] For low lying rectocele which is usually associated with OOS, the transanal repair is employed by colorectal surgeons and it seems to be more effective than traditional transperineal or vaginal operation in obstructed defecation symptoms improvement.

Open and closed procedures have been proposed. The principles of open methods are: to resect superabundant layer of rectocele and anterior rectal wall prolapse: to restore solidity of the anterior rectal wall by means of submucosa and muscularis plication and by contemporary fibrosis induced from submucosa surgical trauma; a longitudinal plication by transverse suture of the rectal wall in the dissection area has been proposed by Khubchandani et al.[41] and Sullivan et al.[42] while transversal plication by longitudinal suture has been suggested by Sarles.[43] The most common closed technique for trans-anal rectocele repair (i.e., obliterative suture) has been proposed by Block et al.[44] As regards the outcome of patients, the improvement of obstructed defecation ranges from 62 to 84 percent with closed Block technique, up to 78 to 92 percent with open techniques by Sarles, Sullivan e Khubchandani.[45] However, postoperative complications are rather frequent, as suggested by an Italian multicentric study: postoperative bleeding (7.8%), dehiscence of endorectal suture (5%), distal rectal stenosis (2%), recto-vaginal fistula (1.4%) and acute urinary retention (3.5%).[46]

Recently, thanks to the development of stapler-assisted trans-anal surgery (such as, the stapled hemorrhoidopexy proposed by Longo [15]), new procedures have been proposed as an alternative to traditional trans-anal techniques for the treatment of OOS, which proved effective at least in short-term follow-up with a low postoperative complication rate.[16] The STARR procedure is performed using two circular staplers (PPH-01™), the first to anteriorly reduce the intussusception and the anterior rectocele, thus correcting the anterior rectal wall muscle defect, and the second to posteriorly correct the intussusception.

In the present experience, trans-anal prolapsectomy and STARR were adapted to the clinical and anatomic and functional findings in the specific patient, the former being performed when the most relevant defect was represented by internal mucosal prolapse and/or recto-anal intussusception while single anterior STARR (limited to anterior rectal wall, from 8 to 4 hours) was undertaken in patients whose anterior rectocele was the most remarkable finding, and double STARR in patients with anterior and posterior rectocele. Actually, trans-anal prolapsectomy allowed only a partial correction of the anatomic defect, with a high rate of recurrent rectocele and intussusception detected at defecography coupled with a less than optimal normalization of manometric findings. Conversely, both anterior and double STARR could achieve a persistent correction of rectocele and intussusception coupled with normalization of manometric parameters.

As regards post-operative complications, no serious bleeding, recto-vaginal fistula or local infection did occur; this low morbidity rate seems to be related to the careful haemostasis of the anastomotic ring, and to the proper use of retractor and vaginal valve in order to avoid any entrapment of adjacent viscera, mostly associated enterocele or the posterior wall of vagina. Moreover, no significant reduction of maximal anal resting pressure and maximal anal squeezing pressure was observed as compared to traditional trans-anal surgery, which can be related both to the reduced operative time (20 to 25 minutes) and minimal anal divulsion produced by the use of CAD 33 (36 mm) as compared to Park's rectal retractor which has been associated with transient sphincteric impairment.[33-35]

CONCLUSIONS

The results of this prospective clinical study suggest that:

1) more than 90% of patients had a satisfactory surgical result of OOS with stapler-assisted trans-anal surgery, coupled with a negligible postoperative morbidity;

2) the clinical resolution of symptoms was associated with an improvement of functional parameters in over 80% of patients, with normal defecographic findings in more than 60% of patients;

3) although the symptoms of OOS were significantly improved with either operations, trans-anal prolapsectomy allowed only a partial correction of the anatomic defect, with a high rate of recurrent rectocele and intussusception detected at defecography as well as less than optimal normalization of manometric findings, while STARR achieved a persistent correction of rectocele and intussusception coupled with normalization of manometric parameters.

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