

Internal Delorme vs. STARR procedure for correction of obstructed defecation from rectocele and rectal intussusception



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PURPOSE: "Outlet obstruction" is a complex functional disorder compelling patients to exhausting ineffective attempts to void. This study was designed to compare the effectiveness and a safety of the endorectal proctopexy (internal Delorme) vs STARR procedure in two groups of patients.

METHODS: A total of 66 patients with rectocele and associated mucosal prolapse or anorectal intussusception between January 2006 and June 2010 were randomly assigned to Group # 1 Endorectal proctopexy with levatorplasty (ERPP) and Group # 2 STARR. Patients were assessed one week, six and twelve months after the operation. Operative time, postoperative pain, day of discharge and late complications was recorded. The time of recovery of work was also assessed. The continence score was updated with a constipation questionnaire. Quality of life after the operation and the overall grade of satisfaction were assessed and compared with radiological findings. All patients were reassessed after one year.

RESULTS: The results in the two groups of patients show no significant difference between ERPP and STARR: the improvement in symptoms is similar but significant and well definite in both groups with a low incidence of postoperative complications. STARR procedure is just faster to perform even if more expensive. Dyspareunia slightly improved mainly in ERPP group, due probably to scar distention.

CONCLUSION: The results of our experience indicate a significant improvement of symptoms with both techniques. The overall incidence rate of postoperative complications is low and similar between the two groups. As economical consideration, ERPP is less expensive.

KEY WORDS: Rectocele, Intussusception, Obstructed defecation, Transanal surgery

Introduction

The term "outlet obstructive constipation" or "obstructive defecation" (ODS) describes a functional disorder

resulting from pathophysiologic and anatomic changes in the peritoneum of the pelvic floor and pelvic organs¹ Obstructed defecation plays a paramount role in the pathogenesis of chronic constipation as commonly reported in the literature²

It is a complex functional disorder compelling patients to exhausting ineffective attempts to void: it is a challenging clinical problem, whose pathophysiology remains not clearly defined. Functional disorders such as spastic pelvic floor syndrome with a failure to relax or paradoxical contraction of the anal sphincters muscles can cause the symptoms of ODS or anatomical rectal anomalies as rectal intussusception (RI) and/or rectocele (RE).

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Rectocele is a non painful disorder, due to the herniation of the anterior rectal wall into the vagina that occurs almost exclusively in women. It is considered to be part of a genital prolapse³ and it is mostly asymptomatic since up to 80 per cent of patients are incidentally diagnosed⁴.

It is often associated with ano-rectal symptoms as difficulty in evacuation and/or the need of perianal or vaginal digitation which are frequently aggravated by rectal intussusception. Other symptoms of this disease include feeling of incomplete evacuation, excessive straining during defecation, the need for digital vaginal or perineal assistance, and the use of enemas or suppositories to defecate.

Different approaches were reported in order to correct symptomatic rectocele including trans-vaginal, trans-anal, trans-abdominal as well as combined techniques and the use of graft materials by gynecologist to reinforce tissue reconstruction^{5,6}.

Transanal repair: commonly considered more promising in the correction of anorectal symptoms supported by an increased efficiency in defecation and a good radiological correction of the defect.⁷ This technique was used from the beginning in the perspective of a good effectiveness, safety and a quick recovery of patients.

More recently a surgical approach known as STARR (stapled transanal rectal resection) has been proposed by A. Longo as a novel alternative for treatment of ODS⁸. Since it showed promising results in the short time follow-up there is only one randomized clinical trial based on a limited number of patients and some reports of non acceptable severe postoperative complications and an increased incidence of recurrence in the long-term follow-up: a high rate of symptomatic recurrence and QOL score decline are expected after 18 months⁹. The procedure is associated in some patients with persistent urge incontinence and with a substantial number of reoperations¹⁰. Moreover the technique is expensive since it requires the use of two stapling guns and the circular stapler is not reloadable.

Effective and cheap alternatives to STARR are: a) Transvaginal repair, that is reported to have poor results for ODS correction; b) combined transanal/transvaginal approach that we experimented in a comparative study to STARR and c) endorectal proctopexy (Internal Delorme). Due to a cost-saving policy that limited the use of stapler devices the role of this procedure was recently reconsidered.

This study was designed to compare the effectiveness and safety of the endorectal proctopexy (internal Delorme) vs STARR procedure in two groups of patients.

Methods

A total of sixty-six patients who underwent surgery for rectocele and associated mucosal prolapse or anorectal

intussusception between January 2006 and June 2010 were prospectively examined. All patients were female and the mean age was 68.5 (range 52-85).

All patients underwent proctological examination including proctoscopy and a careful rectal and vaginal examination. Patients were scheduled for colpocystodefecography and anorectal manometry. An MRI was performed in the suspicion of enterocele.

Criteria of inclusion were the persistence of at least two symptoms after a period of medical treatment: incomplete evacuation, perineal heaviness, painful straining, need of digitation, evacuation with enemas, vaginal bulging. Radiological symptoms were: presence of rectocele, anorectal prolapse, and incomplete barium voiding. The presence of either a complete rectal prolapse or cystocele, enterocele and uterine prolapse were considered exclusion criteria such as paradoxical puborectalis contraction and incontinence. Patient with a suspected slow transit constipation (confirmed by positive transit time study) were also excluded.

A detailed patients record was maintained on the basis of a) clinical symptoms; b) Wexner continence score (range 0-20) evaluation; c) a validated health survey SF36 questionnaire (Italian version) This latter is a self-administered instrument based on 36 condition specific questions about the quality of life. The questions are divided into 4 subsections for physical discomfort, psycho-social discomfort, worries and concerns, satisfaction. The reported results of last one, an overall satisfaction scale, were classified as poor (0-4), acceptable (5-8), good (9-12), excellent¹³⁻¹⁶.

Patients enrolled for the study were divided into two groups by using a computer-generated list for randomization: the code enclosed in a numbered envelope corresponding to one of the two techniques was shown at the beginning of the operation to the surgeon.

All patients were operated by the same senior staff surgeon (MG) as day-surgery procedures under epidural or general anesthesia.

Postoperative complications were defined as "immediate" within the first postoperative month and "late" after the first month.

Patients were assessed one week, six and twelve months after the operation. Anything concerning operative time, postoperative pain, day of discharge and late complications was recorded. The time of recovery of work was also assessed.

The continence score was updated with a constipation questionnaire and the patients were also asked to fill out the simplified questionnaire on quality of life after the operation and to provide informations about their overall grade of satisfaction (excellent, good, satisfactory or poor). This subjective opinion was compared with radiological findings. All patients were reassessed after one year.

All data were recorded and collected by an independent observer not from the surgical team and the assessed outcome was not blinded.

Group n. 1 Endorectal proctopexy with levatorplasty (ERPP)

After inserted and fixed with four stitches a special disposable purse device (ZKHQ-33.5 Purse Device Changzou Kangdi Medical Stapler Co, China) an adrenaline saline solution was injected into the submucosa. The dissection was performed by diathermy starting about 2 cm above the dentate line and the mucosal layer was progressively separated with a gentle traction by the inner muscle and pulled down. A careful hemostasis was accomplished by using bipolar forceps. The dissection was continued circumferentially until a satisfactory height of the cylinder was obtained; four stitches, one for each quadrant, were placed from the distal margin of the dissected mucosal layer with three or four steps to the proximal margin. Once this repeated suture is completed the mucosal layer was excised and the anastomosis pulled in. The anastomotic line was carefully inspected and some absorbable stitches were placed between the previous. A levatorplasty was always associated to the procedure.

Group n. 2 STARR:

After the induction of a spinal anesthesia patients were placed in lithotomy position. The anal verge was dilated with two fingers and a lubricated dilator (CAD) of the PPH03 kit (Ethicon Endosurgery Inc. Pratica di Mare, Roma, Italy) was introduced and hold in the position by 4 stitches in the cardinal points. After removing the obturator, an operative anoscope (PSA33) was introduced and a retractor was inserted in order to protect the posterior rectal wall. Two or three half-purse-string (from 9 to 3 hours) of 2/0 prolene (Ethicon, Sommerville NY) were placed including the mucosa, the submucosa and the muscle rectal wall, starting 2 cm above the dentate line to the top of the rectocele. The anterior suture was accomplished by using the PPH03 stapler that was inserted opened through the CAD and placed above the knotted sutures. The posterior wall of the vagina was carefully inspected after the stapling head was closed and, finally, the gun was fired and extracted. The same procedure was repeated for the posterior rectal wall by using a novel instrument and after placing 1 or 2 prolene half-purse-strings. The anastomosis was carefully examined over the entire circumference checking for bleeding; some X absorbable stitches including the staple line were used for bleeders. All the specimens were extracted, examined and sent to the pathologist.

Results

All patients included in the study suffered from obstructed defecation and/or constipation. At the preoperative manometric assessment none of the patient was in-

continent. The minimum follow-up after surgery was 12 months (range 12-32). Twenty-eight patients had grade A rectocele and thirty-eight had grade B all associated with mucosal prolapse or anorectal intussusception: in the 100% of patients a perineal descent was observed. Barium persistence after voiding was present in 100% of pts. The proportion of retained contrast was not indicated by the radiologist. Preoperative symptoms observed were reported in Table I.

In STARR group there was an improvement of the most symptoms at 6 months follow-up (Table II): only eleven out 30 patients (36.6%) complained of persistent incomplete evacuation, eight (13.3%) reported a sensation of perineal heaviness and one still used daily suppositories or enemas to defecate. No patient needed to digitate to void the rectum; as well an increased rate of dyspareunia from 10 to 13.3% was recorded.

The comparison between pre and postoperative symptoms is reported (Table II). A statistical significance is evidenced; dyspareunia is postoperatively increased but not significant. At one year follow-up results of treatment slightly worsen with an increase of perineal heaviness and use of laxatives: the overall evaluation of results is anyway significantly positive.

In the ERPP group about 11,1 % complained for incomplete evacuation six months after treatment, 22,2% for perineal heaviness and only two patients needed to use daily laxatives or suppositories. The incidence of postoperative dyspareunia was low, 6 out 36 patients. At one year follow-up the incidence of incomplete evacuation increased while a slight worsening in other symptoms was observed. The overall improvement in symptoms was, anyway, strongly significant.

The overall incidence rate of complications was 20% (6 patients) for STARR group and 19.4% (7 patients) for ERPP group without statistical significance (Table III). An overall radiological postoperative assessment was performed in 60 patients only and showed a complete correction of the rectocele in 37 pts (61.6%). The evidence of postoperative mucosal prolapsed/residual intussusception was about 13.3% (8 out 60 pts). One patient (1.6%) in ERPP group showed barium entrapment after the surgical correction (Table II).

The level of satisfaction of patients, after six months, was high with 48 out 66 indicating "excellent" or "good"

TABLE I - Patient's Features

Preoperative symptoms	
ODS (rectal prolapse/intuss ± rectocele)	66/66
Mean Age	68,5 (range 52-85)
Perineal heaviness	66/66 (100%)
Daily use of enemas/supp.	54/66 (81.8%)
Need of digitating	30/66 (45.4%)
Dyspareunia	12/66 (18.1%)

TABLE II - Pre and post operative symptoms and statistical significance in STARR group (30 pts)

	Preoperative	6 months	1 year
Incomplete evacuation	30/30 (100%)	11/30 (36.6%) p < 0,0001	15/30 (16.6%) p < 0.0001
Perineal heaviness	30/30 (100%)	4/30 (13.3%) p < 0,0001	6/30 (20%) p < 0.0001
Daily use of enemas/supp.	26/30 (86.6%)	1/30 (3.3%) p < 0,0001	14/30 (13.3%) p < 0,0001
Need of digitating	15/30 (50%)	0/30 p < 0,0001	0/30 p < 0,0001
Dyspareunia	3/30 (10%)	4/30 (13.3%) n.s. (1.0000)	5/30 (16.6%) n.s.(0.7065)

TABLE III - Pre and post operative symptoms and statistical significance in ERPP group (36 pts)

	Preoperative	6 months	1 year
Incomplete evacuation	36/36 (100%)	4/36 (11.1%) p < 0,0001	6/36 (16.6%) p < 0.0001
Perineal heaviness	36/36 (100%)	8/36 (22.2%) p < 0,0001	9/36 (25%) p < 0.0001
Daily use of enemas/supp.	28/36 (77.7%)	2/36 (5.5%) p < 0,0001	6/36 (22.2%) p < 0.0001
Need of digitating	15/36 (41.6%)	0/36 p < 0,0001	0/36 p < 0.0001
Dyspareunia	9/36 (25 %)	6/36 (16.6%) n.s. (0,26)	4/36 (11.1%) n.s.(0.67)

TABLE IV - Post operative symptoms and statistical significance in ERPP vs STARR group after 1 year follow-up

	ERPP	STARR	p value
Incomplete evacuation	6/36 (16.6%)	5/30 (16.6%)	p = 1.0000
Perineal heaviness	9/36 (25%)	6/30 (20%)	p = 0.7704
Daily use of enemas/supp.	6/36 (22.2%)	4/30 (13.3%)	p = 0.7454
Need of digitating	0/36 (50%)	0/30	p = 1.0000
Dyspareunia	6/36 (11.1 %)	5/30 (16.6%)	p = 1.0000
Complications (%)	19,4% (7 pts)	20% (6 pts)	p = 1.0000
Mean operative time (min)	65	40	p = < 0,05

results. These opinions were compared to the radiological results of the follow-up. Only 5 patients with mucosal prolapse and/or rectocele complained for persistence of obstructed defecation symptoms while 3 reported fair results although a good correction of rectocele was accomplished (Table V).

Clinical reassessment of symptoms after one year was compared with preoperative findings in both groups: a persistent improvement of anorectal symptoms was

reported. In comparing the results in the two groups of patients there is no significant difference between ERPP and STARR: the improvement in symptoms is similar but significant and well definite in both groups with a low incidence of postoperative complications. STARR procedure is just faster to perform even if more expensive. Dyspareunia slightly improved mainly in ERPP group, due probably to scar distention. A comparison of results and the statistical significance is reported in Table I.

Discussion

The optimal therapy for internal intussusception of the rectum is unknown because the cause of the problem is unknown¹¹. Conservative management is recommended in all but the most severely symptomatic patients¹².

It is currently thought that the cause of the patient's symptoms is multifactorial since the so called OOC (obstructive outlet constipation) or OD (obstructive defecation) is the result of changes in the position and configuration of the different pelvic organs: rectocele and rectal intussusception coexist in up to 44% of patients and symptoms of intussusception and rectocele are difficult to differentiate.

The most common complaints in symptomatic patients are obstructed defecation, digitation to empty the rectum and vaginal lump¹³.

Attempts at classification of the abnormalities based only on anatomical changes¹⁴ are not useful without a clinical correlation since they can also be observed also in asymptomatic patients. The choice of treatment of these conditions is closely related to patient's symptoms in the opinion that anatomical correction of the defect will improve rectal evacuation. Thus the outcome of surgical treatment is inevitably influenced by patients' selection¹⁵. An extensive review of the literature by Heriot¹⁶ demonstrated that poor results of the early studies were probably due to an unselective approach. It has been widely assumed that while surgical repair of rectocele alone is successful in functional outcome in 70-90% of patients it is largely unsatisfactory to resolve symptoms despite a good structural correction of the defect so that the recruitment of patients plays an essential role¹⁷⁻²¹.

Moreover a conservative treatment of isolated rectocele through adoption of a specific diet as well as the use of laxatives or enemas and biofeedback²² can improve the quality of the life and in these cases a surgical option is considered only for failure of such therapy. Concerning the surgical technique, it is well known that gynecologists use a transvaginal approach with a high success rate in correction of the wall defect but poor results for bowel and sexual functions²³.

Transanal repair is commonly considered more promising in the correction of anorectal symptoms supported by an increased efficiency in defecation and a good radiological correction of the defect²⁴. Heriot, however, in his conclusions, support the transanal approach as safe and effective alternative for rectocele repair. This superiority significantly increased after the introduction of the stapling device; in addition enthusiastic opinions about a transanal correction of the rectocele and associated obstructed defecation are reported with the STARR technique, an operation for removing the distal part of hypotensive and dysfunctional rectum by a double stapling²⁵.

Using this technique, however, Dodi et al reported a high rate of recurrence (50%) and a significant incidence

of complications such as fecal urgency, incontinence, tenesmus, anastomotic stenosis -and even a recto-vesical fistula²⁶.

In a review based on German STARR registry in 2008 Schwander and Frust concluded that the role of the STARR "has to be assessed by careful and prospective evaluation of long term functions, symptoms resolution and quality of life"²⁷.

Finally, in a multicentric randomized trial Lehur et al. report safety and effectiveness of the procedure compared to biofeedback in the resolution of ODS symptoms with an improved quality of life but the results of this study "must be interpreted with some cautions because of the high rate of withdrawal (50%) from the BF group"²⁸.

ERPP, basically derived from the Delorme procedure, can be considered a good alternative to STARR procedure in treatment of ODS. Berman et al treated 21 patients with a Delorme transrectal excision for internal prolapse with a symptomatic relief in 71% of cases²⁹ and Liberman et al. in 2000³⁰ published the results of a Delorme procedure for internal rectal prolapse as a favourable experience with an overall satisfaction of 75% patients; finally Dippolito et al³¹ reported a successful outcome in 92.3% patients in 2005 with an anterior modification of the technique. In 2006 Trompetto described a transanal Delorme procedure in a 54-years-old female which was asymptomatic three months after treatment³².

In our experience the two techniques were effective: there was a significant improvement of symptoms after surgery with a low rate of persistent incomplete evacuation and a marked resolution of the perineal heaviness; a significant improvement in the use of laxatives was observed and the need of digitating completely disappeared. These results were similar in the two groups and the difference was not significant. On the contrary an increase of pain during sexual intercourses was observed mainly after STARR procedure.

Compared to a good symptomatic relief, a difference between preoperative e postoperative radiological findings is evidenced, with a persistence of rectocele in 41,6% (ERPP 15 out 36 patients) and 26.6% (ERPP 8/30 patients) and an overall 13.3% with residual mucosal prolapse or intussusception in the two groups. These data are well evidenced in other experiences, such as Finco et al.³³ and Gosselink³⁴ showing poor correlations between radiological and clinical findings after surgery. The overall incidence rate of postoperative complications is low and there is no significant difference between the two groups.

Conclusions

The results of our experience indicate a significant improvement of symptoms with both techniques. The

endorectal proctopexy, internal Delorme, avoid the use of a stapler device allowing the excision of a higher mucosal cylinder while ensuring a muscle plication: it reduces the incidence of persistent obstructed defecation (4.3% vs. 20%)³⁵ tenesmus (3-40%)³⁶ and one year incidence of recurrence (5.7%) reported after stapled hemorrhoidopexy³⁷. As economical consideration this operation is less expensive and there is not a significant difference between the two groups in terms of recovery (15,8 vs 14,7 days) since these expenses are not balanced by an earlier return to work. Although a correct analysis is difficult this point must be taken into account when a more expensive technique is used.

Riassunto

OBIETTIVO: La sindrome da ostruita defecazione (ODS) è un disordine funzionale complesso che costringe i pazienti a estenuanti, quanto inefficaci tentativi di evacuare. In questo studio compariamo la proctopexi endorettale (Delorme interna) rispetto alla STARR nel trattamento dell'ODS.

METODI: Tra Gennaio 2006 e Giugno 2010 66 pazienti affette da rettocele con associato prolasso mucoso o intussuscezione rettale sono state assegnate a due gruppi di trattamento: proctopexi endorettale o STARR. Le pazienti sono state valutate a una settimana, sei e dodici mesi dopo l'intervento. Sono stati registrati il tempo operatorio, il dolore postoperatorio, la durata del ricovero, le complicanze tardive. Il grado di continenza è stato valutato con un questionario validato. La qualità della vita dopo chirurgia e il livello complessivo di soddisfazione sono stati registrati e comparati ai riscontri radiologici. Tutti le pazienti sono state rivalutate dopo un anno.

RISULTATI: I risultati nei due gruppi non hanno mostrato significative differenze tra le due tecniche: il miglioramento dei sintomi è risultato simile, consistente e ben definito in entrambi i gruppi, con un basso tasso di complicanze postoperatorie. La STARR è una procedura più veloce da eseguire, ma più costosa. La dispareunia tende a migliorare lievemente, soprattutto nel gruppo di pazienti sottoposte a proctopexi, probabilmente a seguito della distensione della cicatrice.

CONCLUSIONI: I risultati della nostra esperienza mostrano un significativo miglioramento dei sintomi con entrambe le tecniche. L'incidenza complessiva di complicanze postoperatorie è bassa e simile nei due gruppi. Dal punto di vista della spesa sanitaria, la proctopexi endorettale, è, a parità di risultati, una procedura più economica.

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