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Safety and Long-term Duration Effect of Procedure for Prolapse and Haemorrhoids

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Abstract

Aim: The object was to review our experience of the Procedure for Prolapse of Haemorrhoids (PPH) in the treatment of haemorrhoidal disease (HD), to assess results and document the need for reoperations and the long-term outcomes.

Methods: Eight hundred and forty patients with symptomatic grades II-IV HD, mean age 52.4 years, were surgically managed from 1/1999 to 9/2013. One hundred and fifteen displayed comorbidity of other anal pathology. All patients underwent PPH or double PPH, combined with accessory anal procedures in 104 cases. The distance from the dentate line to stapled line and the width of resected doughnut was recorded. Postoperative complications were encountered.

Results: The mean measured distance of the stapled to dentate line was 2.6cm and an incomplete/divided doughnut was found in 32 patients (3.8%). The mean hospital stay was 1.2 days. Early procedure-related complications arose that necessitated reintervention in 21 patients (2.5%). Thirty-eight patients (4.52%) developed late procedure-related complications that required surgery, with 28 (3.33%) displaying the most important recurrence. All patients were clinically examined at 1, 4 and 12 weeks, and were scheduled to be monitored annually for three years, after which they were instructed to contact us with any anorectal problem; 684 have been followed up for more than three years. Patient satisfaction at 12 weeks was high (98.33%). Quite low stapling caused severe pain or stenosis. Inadequate mucosectomy was related to stenosis or recurrence.

Conclusions: Experience of PPH in the treatment of grades II-III and selected IV HD confirms it as a safe and effective procedure with sustained favourable results. Recurrence after surgery is usually attributed to advanced disease or a too high stapled line and incomplete resected doughnut.

Key words: *Haemorrhoids; mucosal prolapse; stapled haemorrhoidopexy*

Introduction

Symptomatic haemorrhoidal disease (HD) is one of the most common anorectal disorders [1]. The origin of haemorrhoids is generally believed to be the external dislocation of the anorectal mucosa due to fragmentation of Park's ligament followed by swelling of the anal haemorrhoidal cushions, which may cause oedema, bleeding, mucosal or faecal soiling, itching, perianal pain, and a predisposition towards thrombosis [2-6]. It is the aforementioned sequence of alterations that demonstrates the complexity of the treatment of HD, justifying the attempt to restore normal anatomic conditions [2,7]. However, haemorrhoidal descent has also been described as a part of a not well defined process initiated by disordered relaxation of the internal anal sphincter (IAS) which impedes drainage of the anorectal vascular plexus and causes local hypertrophy with subsequent prolapse of the rectal mucosa [8].

Although conventional haemorrhoidectomy (CH) [7,9-11] treats haemorrhoidal prolapse effectively, it carries potentially hazardous complications, including sepsis, anal stenosis, bleeding, sphincter damage and incontinence, and is much feared by patients above all because of the ensuing postoperative pain [4,8]. This affects all its variants (Ligasure [12], Diathermy [13], Harmonic scalpel [14]). Antonio Longo in 1998 [15] advocated the Procedure for Prolapse and Haemorrhoids (PPH), also known as stapled haemorrhoidopexy, which revolutionized surgical treatment of symptomatic haemorrhoids. It has since gained wide acceptance as an effective, safe and less painful procedure, leaving no anodermal wounds, and it is associated with faster

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convalescence [3,16-22]. The method involves interruption of the feeding haemorrhoidal arteries, circumferential resection of excess haemorrhoidal and rectal mucosa at a non-sensitive area above the dentate line, and a mucomucous anastomosis fixed at the rectal wall [6,20]. In this technique, the stapling device works by repositioning the mucosa and the haemorrhoidal cushions higher (anopexy), aiming at reducing the venous engorgement and local inflammation and improving the venous reflux [6,8,15,20], as opposed to haemorrhoidectomy techniques that only excise abundant tissue. With the PPH, the haemorrhoids are not removed and the haemorrhoidal cushions are not excised so as to respect their role in aiding continence [1].

Since its early introduction, our surgical team has adopted PPH. The relative lack of long-term data from at least three years of follow-up in series with a large cohort of patients who had undergone PPH urged us to review our 15-year experience of this procedure. The object was both to interpret outcomes and to assess the durability of the method. Intentionally, we evaluated results, addressed complications and the need for reoperations, and investigated important learning points.

Patients and methods

Eight hundred and forty patients with Goligher grades II-IV symptomatic HD (males: 450, females: 390), mean age 52.4 years (ranging from 23 to 79), underwent stapled surgery from 1/1999 to 9/2013. One hundred and fifteen patients displayed comorbidity of other anal diseases excluding perianal skin components (Table 1). Patients excluded from the study were those with colorectal tumours, inflammatory bowel disease, solitary rectal ulcer, rectoanal intussusception or obstructed defaecation syndrome, rectocele, excessive scarring from previous perianal surgery and reduced sphincter contraction or others with prolapse confined to a single quadrant, congenital coagulation deficiency or on anticoagulation therapy, as well as patients who had no attending person at home.

Symptoms, including prolapse in 700 cases (83.3%) and repeated bleeding in 658 (78.3%), followed by mucous discharge or soiling (22.6%), itching or pain (20.5%) and haemorrhoidal thrombosis (7.5%), lasted from 5 months up to 32 years (mean 5.1 years). A variety of previous treatments for their haemorrhoids was reported by 47 patients and constipation was encountered in 316 (37.6%). Clinical evaluation included proctological examination and rectosigmoidoscopy. Patients >55 years of age or with rectal bleeding that could not be solely attributed to haemorrhoids underwent a complete colonoscopy. Rectoanal manometry was occasionally used to exclude a possible impaired function of the sphincter; endoanal ultrasound, not available in our institute, was even more rarely required. Preoperatively, whole bowel preparation was restricted to patients with chronic constipation. Perioperative antibiotics were administered only to patients at high risk of endocarditis or prosthetic infection, to immunosuppressed patients, to those with repaired anastomotic defects, and to emergent patients with thrombosed haemorrhoids.

Table 1. *Clinical characteristics of 840 patients with HD*

HD Grade	Co-morbid anorectal pathology	
II: 94	Rectal mucosal prolapse	50
III: 616	Fistulae	14
IV: 130	Fissure	35
	Polyp	16
	Skin components*	152

**Skin tags or grade IV haemorrhoids with skin involvement*

Seven hundred and ninety-four patients underwent PPH and 46 double PPH (DPPH) under general (765), epidural (58) or spinal (17) anaesthesia, with the patient in lithotomy position. Eight hundred patients underwent elective surgery, whereas 40 had emergent surgery for thrombosed (28) or bleeding (12) haemorrhoids. Seven electively treated patients were redo cases who had undergone an unsuccessful staple operation for their haemorrhoids at other institutes. In cases of excessive haemorrhoidal mucosal prolapse occupying more than half of the circular anal dilator (CAD), we performed a DPPH or a primary PPH followed by a scheduled repeated PPH (RPPH) after at least four months. Patients with large external components were submitted to PPH along with a low excision of residual external nodules (modified haemorrhoidectomy). PPH was combined with 104 accessory anal procedures in 94 patients. At the end of surgery, we further excised skin tags in 80 patients (Table 2).

A database was maintained for all patients undergoing PPH to allow tracking of outcomes. An arbitrary division of the study period into two consecutive periods of time was chosen; the first, 1999-2006, included 440 patients (Group I) and the second, 2007-2013, comprised the remaining 400 (Group II).

Technique

PPH was performed using the PPH01™ or preferably the PPH03™ stapler device (Ethicon Endosurgery®). In brief, after good strapping of the gluteal fold and sufficient sphincter dilatation, the transparent CAD, equipped with the obturator, is introduced with small circular movements and positioned high enough to allow repositioning of mucosal haemorrhoidal prolapse and visibility of the whole dentate line. After obturator removal, a running purse-string with 2-0 Prolene® (Ethicon, Inc.) including

Table 2. *Surgical procedures in 840 patients with HD*

Index Surgery				Staged surgery
PPH	DPPH	Accessory anal procedures		Scheduled RPPH
N=794	N=46	N=184		N=11
		Haemorrhoidectomy (modified)*	46	
		Partial internal sphincterotomy*	27	
		Fistulectomy*	14	
		Polypectomy*	13	
		Fissurectomy	4	
		Excision of skin tags	80	

**Included 10 patients with two procedures*

rectal submucosal bites was placed 5 cm over the dentate line. These bites were taken with step-by-step repositioning of the introduced anoscope. The 33 mm circular stapler was then completely opened and introduced transanally with its head positioned beyond the suture, and the suture was firmly tightened with three closing knots onto its anvil. The suture was externally retracted during progressive screwing of the stapler device to its absolute limit. In females, the posterior vaginal wall was checked to avoid its entrapment in the staple line. Subsequently, the stapler is fired and withdrawn. The anastomotic stapled line was carefully inspected by anoscopy; any bleeding point was accurately controlled and suture-ligated with 3-0 Vicryl (Ethicon, Inc.) or diathermied or injected with adrenaline. Any corresponding staple line deficit was similarly oversewn. The mean distance from the dentate line to the staple line at the midline of the posterior wall and the completeness and width of the resected doughnut were registered. All excised specimens were sent for histologic examination.

Results

Three hundred and twenty patients (38%) needed supplementary haemostatic sutures while 28 (3.33%) required staple-line reinforcement absorbable sutures (3-0 polyglactin). The mean measured distance of the staple line was 2.6 cm from the dentate line, ranging between 1 and 4 cm. The resected doughnut was found to be incomplete/divided, or as having a width $\leq$1 cm in 32 patients (3.8%), which corresponded with an incomplete staple line in just 13 cases (1.54%).

In Group 1, postoperative pain was managed on demand with intravenous pethidine hydrochloride 1.5 mg per Kg body-weight as part of another study. Their mean Visual Analogue Scale (VAS) 0-10 pain score at the 1st postoperative day was 3.2 (range 2-7) and at the 7th 1.0 (range 0-3), regardless of whether they had undergone a concomitant procedure. Regarding Group II, no routine pain score was measured in uncomplicated cases and analgesic injections, such as paracetamol 1 g or parecoxib sodium 40 mg, were administered. Two hundred and sixteen patients in Group I patients (49%) and 202 in Group II (50.5%) did not require any analgesics. Other patients received 1-7 analgesic injections (mean, 1.4).

Patients resumed normal diet on the first postoperative day and were discharged once they were free of severe pain, but no sooner than at least 12 hours after surgery, and regardless of whether evacuation had occurred. Only fifteen patients were discharged 12 hours after surgery, all of whom were in good physical and mental health with simple grade II HD and resided near the hospital.

No deaths were recorded. The mean hospital stay was 1.2 days (0.5-4). After discharge, patients were prescribed oral analgesics such as paracetamol or paracetamol-codeine only when necessary. Patients who received I.V. antibiotics were also prescribed some oral analogue for five days. Constipated patients were given paraffin oil or oral laxatives. All patients returned to pain-free defaecation and normal or preoperative activity within 10 days. All were scheduled to be clinically examined at 1, 4 and 12 weeks and one year, and were monitored annually for at least three years. Thereafter, they were instructed to contact us at any time if they experienced symptom recurrence or any anorectal problem.

Histologically, resected doughnuts in 620 cases (73.8%) demonstrated the presence of mucosa, submucosa, and even parts of rectal muscularis propria, with or without haemorrhoidal tissue. In the remaining patients, small parts of smooth muscle fibres were additionally found. All polyps and anal lesions excised were benign.

Postoperative follow-up

Throughout the entire study period (6-184 months), we had follow-up information at our disposal, which was

complete for individuals followed up for at least three years, with the exception of four patients who died of causes unrelated to the procedure and 16 others who abandoned the annual examination or were lost to follow-up. Intentionally, every possible complication or favourable effect related to the procedure was investigated and listed. Four weeks after surgery, 32 patients with preoperative huge haemorrhoids, excessive mucosal prolapse and sensory impairment reported that they felt a remarkable improvement in the sensitivity of their anal canals and in functional control. When reviewed at 12 weeks, 50 patients out of 316 (15.8%) with pre-existing constipation reported that PPH had improved their symptoms of difficult rectal evacuation since they required less straining and had less frequent need of common laxatives. Six patients with no functional problem, examined in particular since they experienced severe postoperative pain and belonged to those with inadequate resected specimen, were found to have mild anastomotic stenosis. At 12 weeks, 826 patients (98.33%), including the six PPH stricture patients, reported that they were satisfied with the procedure, while 14 (1.66%) were dissatisfied. Failure of regression of the external component was the major source of dissatisfaction.

Among the dissatisfied patients, 12 suffering from constipation reported no deterioration, while two bedridden patients complained of their condition having worsened. Only two patients who displayed no deterioration had scarce muscle fibres in their resected specimens. Five patients, including the two bedridden, had redundant sigmoid or poorly compliant rectum as revealed later by endoscopy and/or rectoanal manometry (data not shown). In anoscopy, all dissatisfied patients had a stapled anastomosis positioned well above the dentate line.

We annually recorded all cases with residual skin tags or recurrence confirmed clinically during the first three postoperative years and beyond. At the 12-month review, nine patients had residual tags; only six with large tags requested their removal. Significantly, during the first 3-year follow-up period, 23 HD recurrences were recorded: 18 soon after index surgery (16 reoperated within the first year) and five after 1-3 years. After the first three years, 30 patients requested a clinical evaluation for complaints that they considered might be related to the procedure, but in only eight was a possible procedure-related complication found, among whom five new HD recurrences (four to six years). In terms of the follow-up period, 684 patients have been observed for more than three years.

Early complications

We had no septic complications requiring a stoma. Usual early procedure-related complications (<15 days) requiring early reoperation developed in 21 patients (2.5%), with the most important being immediate bleeding (0.95%) that demanded prompt intervention. Eighty-four other patients experienced various complications that were easily managed with conservative means or were spontaneously resolved; the most significant was severe pain, usually from low stapling, recorded in 22 cases (2.6%) (Table 3). Specific early findings that needed 1-3 months before becoming completely apparent, such as residual or persisting prolapse, were not encountered. In total, 21 early reoperations were performed on patients of whom 13 were from Group I and eight from the Group II. An analysis of early complications and reintervention is beyond the objectives of this trial.

Analysis of late and long term complications

Late (>15 days) and long-term complications are listed in Table 4. Forty-eight patients (5.71%) required one late reoperation after the index procedure for various anorectal symptoms, of whom 38 (4.52%) underwent reintervention for stapler-related reasons. Nobody underwent an early reoperation. In all, 28 late reoperations were performed among Group I and 20 among Group II. In respect of the need for late reoperations within the first year of index surgery, we encountered 15 reoperations during the first (1999-2006) and 12 reoperations during the second (2007-2013) period.

Eleven cases with residual grade II haemorrhoids were classified as treatment failures; they were downstaged from grade IV, scheduled for RPPH at primary PPH and reoperated within 4-6 months. Grade III haemorrhoids persisted in seven patients with single stapling and suffering from resisting constipation; stapling was high, resulting in inadequate mucosectomy in all cases, and five were reoperated within the first year after surgery. Ten other cases (seven with single stapling and high anastomosis) later recurred. The latter had incomplete doughnuts and an incomplete staple line that needed some sutures at index surgery to be complete. All 28 cases accounted for a total recurrence rate of 3.33%. No one belonged to the subgroup of redo cases initially comprised in the study. The meantime of confirmed recurrence was 14.7 months (range, 1-64). No haemorrhoidal crisis or troublesome bleeding was recorded. Intraoperative findings included mobile or rather mobile prolapse with single or multiple haemorrhoids ≤ 3 in all residual or persisted cases and four with late recurrence; congested or thrombosed isolated haemorrhoids in two with mobile (within the first month after surgery) and six with fixed prolapse (within 18 and 60 months after surgery). All cases were willing to undergo the same procedure. All were successfully treated by RPPH in instances of mobile prolapse (22 patients: 18 residual/persisting cases, 4 late recurrences) or RPPH plus low excisional surgery in cases

Table 3. *Postoperative complications in 840 patients with HD and reoperations after PPH/DPPH*

Early complications (<15 days)	Early reoperations	Patients		Percentage
Bleeding requiring revision*	Suturing, diathermy	8		
Thrombosed external haemorrhoid*	Evacuation of clot	8		
Residual skin components*	Excision	4	21	2.5
Dehiscence of staple line*	Suturing, excision of nodules	1		
3-day pain VAS score >5*		22**		
Mild incontinence (lasting < 2 months)*		8***		
Oedema-ecchymosis-haematoma*		9		
Intermittent daily dripping at defaecation		16		
Acute urinary retention		38	84*****	10
Post-spinal anaesthesia headache		2		
Difficult evacuation (all constipated)	Resolved within 2-3 months	6		
Faecal urgency		3****		
Stapler-related reason for complications*		60		7.14
Overall reoperations (stapler-related)		21		2.5

**Assumed to be caused by PPH; **Low anastomosis in 14 cases, excision of ext. nodules in six; ***Included three patients with PIS and four with muscle fibres in specimens; ****Included two with muscle fibres in specimens; *****Included 18 with ≥2 complications.*

of fixed prolapse (6 late recurrences) at a median of 18.6 months (range 4-68) after index surgery. Finally, six patients requested excision of residual skin tags, not considered as recurrences, which was intentionally performed under local anaesthesia in an outpatient setting about 12 months after surgery.

Fourteen others needed further minimal surgery for various anorectal findings, such as anal papilla, thrombosed

Table 4. *Postoperative complications in 840 patients with HD and reoperations after PPH/DPPH*

Late complications (>15 days)	Late reoperations	Patients	Percentage
Persisting prolapse Residual prolapse HD recurrence* Recurrent prolapse	RPPH/RPPH+excision**	28 (16)***	3.33
Residual skin tags*	Excision	6 (6)	0.71
Mild anastomotic stricture/stenosis*		6	0.71
Anal papilla*	Excision	3 (1)	0.35
Mucous cyst in staple line*	Excision	1 (1)	0.12
Thrombosed external haemorrhoid	Evacuation of clot	4 (2)	0.47
Anal fissure	PIS	3	0.35
Anal abscess-fistula	Drainage/excision	3 (1)	0.35
Delayed faecal urgency		4	0.47
Soiling/pruritus ani		12	1.43
Stapler-related reason for complications*		44	5.23
Stapler-related reason for reoperations		38	4.52
Overall reoperations		48	5.71

**Assumed to be caused by PPH; ** Scheduled (11 patients) and non-scheduled (17 patients) RPPH; ***Numbers in parentheses correspond to patients reoperated at or within the first year of index surgery*

haemorrhoid, staple line mucus cyst and anal abscess-fistula or fissure, months or years after index surgery. In our experience, delayed presentation of fissures or fistulas/abscesses or even new haemorrhoids emerging after many years could not be clearly related to the procedure.

Anastomotic stenosis at 12 weeks, noted as thin adhesions at the stapled line, was encountered in six patients (0.71%) with advanced disease; all had inadequate width of resected doughnut. Three cases of cone-shaped anus displaying a poorly-recognized dentate line at emergent surgery, which resulted in a low anastomosis (1cm from dentate line), showed evidence of smooth muscle fibres in their specimens. A further three had a low anastomosis lying less than 2cm above the dentate line (1.2-1.8cm). All six belonged to the group which suffered 3-day pain $\geq$5, but none presented any functional problems later. In all cases, treatment by means of digital dilatation was successfully achieved.

Specific problems, such as faecal urgency and pruritus ani/soiling, were observed in 16 constipated patients who routinely received laxatives before and after surgery. In comparison to their previous situation, 12 elderly patients (of whom nine were women) complained of persistent soiling or pruritus ani. Eight patients experienced less discomfort; two belonging to the group of dissatisfied patients found the situation virtually unchanged, while the condition in another two deteriorated after a transient improvement. Four others experienced delayed faecal urgency. No one suffered more pain immediately after stapling and only two with pruritus and one with urgency had some muscle fibres in their resected specimens. All these patients were relieved temporarily by conservative means, and their symptoms resolved or subsided within 4-6 months.

Discussion

Long-term patient satisfaction after PPH, especially for grade II and grade III HD, is high in most trials and reaches as much as 95.4% [17-19,22]. However, an unsatisfactory outcome is significantly related to post-PPH symptoms such as prolapse, bleeding, pain, new onset of faecal urgency, soiling and local discomfort [5,8,17]. Some complications after PPH are similar to CH, but most are specifically technique-related [1,10,11,17,23,24]. Recent review papers and meta-analyses [8,9,20,21,25] have aroused considerable interest as to the long-term outcomes following PPH.

The procedural overall complication rate and the need for late stapler-related reoperations for anorectal symptoms is a frequently mentioned issue. Among the observed rates and reasons for early reintervention, we note the overall reoperation rate of 3.8% in Jongen's [21] review of 1233 cases; the most important reason for early reintervention is bleeding, more likely to occur after PPH for grade IV HD, reaching the rate of 13.3% [18,26]. Published recurrence rates range from 2 to 25.9% [13] and reoperation rates for recurrence are reported at between 7 and 16% [27]. In our experience, the overall reoperation rates for early and late complications are 2.5 and 5.71% respectively, which are in keeping with published data [21]. Similarly, rates of staple line dehiscence (0.12%), HD recurrence (3.33%), persisting skin tags or anoderm needing further surgery (1.18%) and overall stapler-related reoperations for failed or complicated PPH (7%) correlate with those given in other reports [3,20,21].

Persistent or long-term pain or faecal urgency after low stapling have been reported by some authors, drawing considerable attention to the procedure [2,7,9,13,25,26,28,29]. The incidence of chronic pain ranges from 1.6 to 31% in the studies reporting this complication [23,25,28,30]. Cheetham et al. [26] reported the higher incidence of post-PPH persistent pain and faecal urgency, but their results have not been confirmed by any other study. Many authors [2,8,23] cited stapling of the sensitive anoderm and anastomosis too close to the dentate line as the main causes of pain. Chronic pain has also been attributed to muscle entrapment in the staple line, although it may present without muscle incorporation [23,26]. Other causes implied are persistent HD, sphincter or rectal spasm, high anal resting pressure, anastomotic dehiscence, anal fissure, anorectal sepsis and retained staples [10,17,23,25,28,30]. Chronic proctalgia may respond to oral nifedipine [30] or, rarely, may require transanal injections of steroid and local anaesthetic, electrostimulation or even excision of the staple line and manual refashioning of the anastomosis [23]. Faecal urgency, if present, is mostly an early symptom which is nearly always transitory and tends to disappear 6-8 weeks after PPH [13,26]. Some authors implicated postoperative reduced rectal capacity [8] and decreasing distal rectal compliance [28] in the frequency of tenesmus and faecal urgency. Biofeedback training has been tried with little success in such cases [4]. This complication can be prevented by avoiding the use of PPH in patients with reduced rectal compliance or increased rectal sensation on physiology testing and, possibly, in selected patients with grade IV HD [23]. In the experience of this trial, stapling was not clearly related to postoperative anal discomfort symptoms such as painful defaecation or chronic pain and urgency, thus excluding one of the concerns with the use of PPH. Low stapling, usually without muscle impingement, was eventually associated with increased pain which resolved uneventfully during the first week after surgery.

PPH did not affect functional sphincter length or the rectoanal inhibitory reflux [23,28,29]. However, minor and temporary incontinence may arise after PPH [7,23,26], as noted in eight of our patients, including three with a

simultaneous partial internal sphincterotomy. This manifestation may be induced by a low staple line or by excessive stretching of the anal sphincter in surgery [23,28]. Anal sphincter defects after PPH are likely to contribute to passive incontinence and add to persistent faecal urgency, especially in women [28]. In cases of a weak sphincter, damage or sub-stenosis caused by previous anal surgery, there is a high risk of stapler use causing a latent faecal incontinence to become clinically manifest [4,23]. Comparative clinical evaluation showed that even when minor injuries of the IAS are diagnosed, symptoms subside within 2-8 weeks and lesions should be adequately compensated so as not to cause permanent incontinence [2,7,29]. This correlates with the early observations of Altomare and colleagues' [29], although lesions of the IAS at ultrasonography were not confirmed. Sphincter repair is rarely needed and was performed in only two out of 65 reoperations after PPH in a series [25]. Preoperative anal manometry and ultrasonography may help to detect patients with less compliant rectum and weak sphincters, thus minimizing the risk of post-PPH incontinence [23].

The potential risk of stricture after rectal wall resection [23,31] causes concern regarding PPH. If the surgeon performs the purse-string lower than usual and excises most of the haemorrhoids, he takes more risks in terms of potential fibrosis of the upper anal canal [23]. Furthermore, stricture is possibly related to pre-PPH sclerosing injections [23]. In this series, this complication was observed in just 0.71% of cases. It arose from quite low stapling, resulting in inadequate mucosa resected. However, digital or balloon dilatation of such diaphragm-like stenoses is effective, although most patients may also respond to medical treatment and fibre supplements [23]. In the Ng's series of 3711 patients [32] surgical repair was required in 1.4% of cases.

Another concern is the feasibility and effectiveness of PPH in Grade IV HD [4,33]. The procedure was designed to reduce mucosal prolapse, not to remove the skin-covered external component in most cases of grade IV HD [13]. Consequently, the same procedure cannot be applied to grade III and grade IV HD; it must be modified or employed selectively for patients with grade IV HD [5,13]. However, although PPH can be technically difficult if the haemorrhoids are massively enlarged and are prolapsing circumferentially through the anal canal, we concur with many authors [19-21,27,34] who suggest that these cases can be selectively elected for the procedure. In such cases, we do not hesitate to take the purse-string directly over the prolapsed mucosa instead of using the anoscope. Furthermore, excision of the residual external components is an essential part of the operation. In our experience, these patients could gain greater benefit from the procedure, acquiring better functional control of their anal canals, as achieved by 32 of our patients with huge haemorrhoids. Easier rectal evacuation after removal of the loose redundant mucosa could accomplish similar results, as suggested by Pescatori [35].

A limitation of traditional staplers is the discrepancy between the capacity of the case and the amount of the prolapse to be removed [5]. A technical modification to PPH using separated traction stitches and the same stapler, known as the "Single Stapler Parachute Technique" (SSPT) [1], has been proposed for large prolapse that occupies more than half the length of the CAD or is particularly irregular or asymmetric. New staplers have recently been introduced that allow stapler housing of greater capacity and a higher number of agraphes to prevent against dehiscence and bleeding [5,28]. Others have recommended Stapled Transanal Rectal Resection (STARR) [36] or have proposed larger staples (4.8 mm instead of 3.5 mm) for more extensive resections [5]. In our opinion, CH should be reserved for grade IV haemorrhoids which are not suitable for PPH or DPPH combined with low excision of residual nodules, such as those with chronic external components or a history of perianal surgery.

A major concern relates to the durability of PPH. Mucosectomy and mucopexy in PPH are performed above the haemorrhoids; this implies that they could remain at follow-up in part, but they should be asymptomatic and no longer prolapse [1,4,5,19]. The presence of residual or recurrent prolapse can derive from incorrect indication for surgery, from an inadequate resective approach, or from technical errors made during surgery [1,3,5,20-22,37]. True prolapse is more likely the result of failure of the stapling technique to remove an adequate volume of the prolapsing tissue [1,5,20]. In fact, the traditional Longo procedure alone may expose a subgroup of patients whose prolapse occupies as much as or more than half the length of the CAD, or is particularly irregular or asymmetric to an increased risk of residue [1,5]. A possible risk factor of recurrence is the use of PPH in all cases of grade IV HD, especially those with fibrous and fixed components; higher complication and reintervention rates than its use for grade III HD may be expected [13,19,21,33]. One more important factor that may correlate with early recurrence is the height of the stapled line in relation to the dentate line [5]; if the stapled line is too high above the apex of the haemorrhoidal complex, this would not be sufficiently lifted. Notably, in their studies investigating the anatomy and haemodynamics of the anorectal vascular plexus in HD, Aigner and colleagues [6,38] found additional branches of the feeding arterial vessels coursing variably through the rectal wall far below the ligation line of the PPH and Haemorrhoidal Artery Ligation (HAL) techniques. They also pointed out that HD may have increased arterial inflow, which does not show

significant change following PPH. They suggested that not only should the extent of haemorrhoidal prolapse be considered when choosing the appropriate treatment but also the state of vascularization of the transitional zone. However, the postoperative outcome does not depend exclusively on the complete interruption of the arterial inflow; the complete reposition of the haemorrhoidal prolapse and thereby the improvement of the venus reflux out of the haemorrhoidal cushions might be more important [15,24,35].

To minimize the possibility of recurrent prolapse, appropriate inclusion criteria and a well-performed stapled operation, calibrated on the sufficient amount of the haemorrhoidal prolapse to be excised, combined with an immediate correction of the persistent prolapse or complementary excision of residual haemorrhoids should be performed [5]. Some surgeons tend to place absorbable sutures [5] or even a horizontal mattress suture [19] at the staple line to obtain additional prolapse lifting against recurrence. Ng [39] postulated a low purse-string of 2-3 cm, but this option seems to be less justified when taking everything into account. However, transection at the proposed level safeguards against pain and stenosis as well as severe IAS injuries. Finally, PPH demands a significant learning curve while increased surgical experience is associated with a trend towards lower recurrence rates [5,9,21-23,40].

A correct evaluation of the symptoms and assessment of recurrence features are of primary importance in the choice of reintervention technique to be applied. If the prolapse is mobile, it is possible that the index surgery was not properly performed or that the indication for surgery was wrong; if the prolapse is chronically fixed, initial surgery was probably not the main reason for recurrence [5]. In the case of mobile prolapse with multiple haemorrhoids ($\geq$3), the choice may be reintervention with stapler by means of RPPH [5,25,40,41]. PPH combined with complementary excisions is applied in instances of mobile prolapse with some residual haemorrhoid. On the contrary, CH should be preferred choice in cases of fixed prolapse or with 1-3 large haemorrhoids [4,5]. For post-PPH recurrence, as well as for advanced HD, Boccasanta et al. [36] proposed the use of STARR outside its specific indications, but this might be an overtreatment. Recurrent prolapse in our cases was mostly mobile and mainly ascribed to inadequate mucosa resected at primary surgery (residual/ persisting cases) which were successfully treated by RPPH, or to incorrect technique with incomplete doughnuts (late recurrences) which were similarly treated by RPPH, combined or not, with complementary excisions. Nevertheless, not all of our patients were followed up for at least three years; hence, the possibility of new recurrences arising in the future cannot be dismissed.

In contrast to CH which involves the anal canal alone, PPH involves the lower rectum with a "blind" resection close to the vagina, the prostate and the Douglas pouch [8]. Apart from the expected morbidity, serious complications following PPH, such as a rectovaginal fistula, rectal perforation, perineal or pelvic sepsis and rectal obliteration, have been rarely reported [8,23,31,42]. A recent systematic review on PPH attributed all major complications to surgical errors [18]. Devastating complications originate from misplacement of the purse-string in relation to the dentate line (too high) and the depth of biting (too deep bites), and the drawing in of too much tissue into the stapler housing [21,23,28,31]. We were fortunate not to have encountered any of these complications.

The basic notion that the submucosa purse-string suture should be placed at a distance of 5 cm above the dentate line is supported by the authors; on completion, the stapling line should lie 2 to 3 cm proximate to the dentate line [16,37]. Since the early days of performing the procedure, we have adopted and routinely used several key learning points. First, maintaining strict inclusion criteria is essential. Ensuring correct positioning of the dilator to facilitate visibility of the whole dentate line is of paramount importance and safeguards against an eventful procedure. Tightening of the purse-string firmly on the anvil and addressing the stapler so as to parallel the rectal axis are also crucial, otherwise stapling becomes more ineffective than ever. If firm tightness is not feasible, the procedure is converted to an open haemorrhoidectomy. Precise synchronicity of a progressive introduction of the stapler and the closing of its jaws can sufficiently control the amount of rectal mucosa and submucosa to be resected. Checking of the vaginal wall before engaging the stapler helps to correct the actual direction of the instrument and safeguards against a possible rectovaginal fistula. The staple line should be checked and defects should be promptly repaired. Further key points include performing DPPH for excessive anal prolapse and selected grade IV haemorrhoids which are not fixed; excision of haemorrhoidal components that have failed to shrivel after PPH so as to ensure a more radical result and to relax anastomotic tightness and prevent dehiscence; performing an early RPPH for persisting prolapse or understaged disease; finally, routinely excising concomitant skin tags or redundant anoderm. The data presented in this study confirm that this practice is reasonable.

In a previously published report [40], we had a look at the impact of the learning curve upon the need for late reoperations for anorectal symptoms, and observed a significant reduction during the second period of time (2007-2013) as compared to the first (1999-2006) concerning both the first year after index surgery (p=0.0553) and the whole periods of time (p=0.0305). Our observations are in keeping with those reported in other relevant studies [9,18,21-23].

As concerns the durability of treatment, long-term outcomes after PPH and CH have been recently investigated in systematic reviews and meta-analyses that showed higher incidence of stenosis after CH [2,4] and recurrence after PPH [8-11,13,22-24,41], or even the similar overall need for surgical and non-surgical reintervention after the two procedures [18]. Higher incidence of residual haemorrhoids or recurrence after PPH is presented in studies that included patients with grade IV HD [5,9-11,22,32]; long-term results in grade II and III HD tend to be equal for both PPH and CH techniques [28,33]. Unfortunately, there is a lack of information in studies analysed regarding the degree of haemorrhoids treated and the technical characteristics, such as the placement of the purse-string, the level of staple line, the completeness of the mucosectomy ring and the use of double stapling, as well as bowel habits, all of which may influence the outcome after PPH. However, the choice of whether to accept the cost of a possible higher recurrence rate so to take advantage of all other benefits of PPH lies with the patient [1,22]. In our opinion, CH should be reserved for certain cases with grade IV haemorrhoids, especially those with fixed external component or with perianal scarring.

Despite multiple alternatives having been proposed since the 1990s to treat HD with the objective of reducing the inconvenience of CH, such as rubber band ligation, photocoagulation, LASER and Doppler-guided haemorrhoidal artery ligation (DGHAL), no method is universally accepted as superior to the others. Reviewing literature on DGHAL combined with rectal mucopexy, which shares a common proposition with PPH, we found that the series reported [43-46] are small, comprising patients with early stage HD, lacking in long-term outcomes regarding possible recurrence, possibly leading one to question the use of the procedure in this setting. In two systematic reviews enrolling all published DGHAL cases, one [43] of which involved 17 articles including 1996 patients and the other [46] 28 studies comprising 2904 patients, the pooled recurrence rates for mucosal prolapse were 10.8% and 17.5%, respectively. The authors have no personal comparative data.

This review constitutes a retrospective analysis of results in a large cohort of patients with symptomatic haemorrhoids treated with PPH in a single institute over a long period of time. Although these data are affected by the presence of comorbidity and by the lack of controls, in our experience PPH is safe and effective in all grades of symptomatic HD. The durability of results of this approach is adequately confirmed by sustained relief of haemorrhoidal symptoms and the low reintervention rate for persistence or recurrence of haemorrhoidal prolapse. Consequently, the authors support that the place of the PPH in the treatment of HD is in no doubt.

Conclusion

PPH is safe and effective, offers high patient satisfaction, and provides sustained control of haemorrhoidal symptoms in the treatment of grades II, III and selected IV HD. Its safety shows consistent improvement with experience and technical upgrading. The success of the operation depends entirely on the reduction of the prolapse by the stapler. DPPH for excessive anal prolapse and non-fixed grade IV haemorrhoids and early RPPH for persisting prolapse or understaged disease as staged treatment achieve a final favourable and durable result. Recurrence of the haemorrhoidal prolapse is usually attributed to advanced disease or to a too high stapled line and incomplete resected ring.

Ethical Approval

Ethical approval was obtained by our Institutional Ethics Committee.

Conflict of interest

There is no conflict of interest.

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Ασφάλεια και Μακράς Διαρκείας Αποτελέσματα της Επέμβασης Βλεννογονική Πρόπτωση και Αιμορροϊδες

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Περίληψη

Σκοπός: Παρουσιάζουμε την εμπειρία μας στη χειρουργική αντιμετώπιση της αιμορροϊδικής νόσου (ΑΝ) με τη μέθοδο PPH (Procedure for Prolapse and Haemorroids) και αξιολογούμε απώτερα αποτελέσματα και επανεγχειρήσεις.

Μέθοδοι: Το διάστημα 1/1999-9/2013 840 ασθενείς μέσης ηλικίας 52.4 έτη χειρουργήθηκαν για συμπτωματική ΑΝ II-IV βαθμού, ενώ 115 είχαν και άλλη συνυπάρχουσα παθολογία πρωκτού. Όλοι υποβλήθηκαν σε PPH ή διπλή PPH, 104 δε σε συμπληρωματικές πρωκτικές εγχειρήσεις. Καταγράψαμε την απόσταση οδοντωτής γραμμής από αναστόμωση και πλάτος- ακεραιότητα χειρουργικού παρασκευάσματος. Καταγράψαμε τις μετεγχειρητικές επιπλοκές.

Αποτελέσματα: Η μέση απόσταση οδοντωτής γραμμής από αναστόμωση ήταν 2.6 cm ενώ ανεπαρκής εκτομή βλεννογονικού δακτυλίου υπήρξε σε 32 ασθενείς (3.8%). Η μέση διάρκεια νοσηλείας ήταν 1.2 ημέρες. Ως έχουσες ευθεία σχέση με την PPH και που απαίτησαν επανεγχείρηση υπήρξαν επιπλοκές πρώιμες σε 21 ασθενείς (2.5%) και απώτερες σε 38 (4.52%). Υποτροπή υπήρξε σε 28 ασθενείς (3.33%). Όλοι οι ασθενείς εξετάσθησαν μετεγχειρητικά την 1η, 4η και 12η εβδομάδα, ανά έτος για 3 έτη και ακολούθως αναλόγως αναγκών, ενώ 684 παρακολουθήθηκαν για περισσότερο από τρία έτη. Την 12η εβδομάδα, το ποσοστό ικανοποίησης από την εγχείρηση ήταν υψηλό (98.33%). Η πολύ χαμηλή αναστόμωση προκάλεσε άλγος ή στένωση, η δε ανεπαρκής βλεννογονική εκτομή στένωση ή υποτροπή.

Συμπεράσματα: Η εφαρμογή της PPH στη θεραπεία της αιμορροϊδικής νόσου βαθμού II-III και επιλεκτικά IV είναι ασφαλής και αποτελεσματική σε μακρά διάρκεια. Η υποτροπή οφείλεται συνήθως σε προχωρημένη νόσο, υψηλή αναστόμωση και ανεπαρκή εκτομή.

Λέξεις κλειδιά: *Αιμορροϊδες, βλεννογονική πρόπτωση, αιμορροϊδοπηξία*

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