

## Integrated Treatment With Stapled Haemorrhoidopexy and Proctonorm® of Haemorrhoidal Disease

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**Abstract.** *Background/Aim:* This retrospective study was performed in patients undergoing Stapled Haemorrhoidopexy (SH) who were post-operatively treated with Proctonorm® with the aim of assessing its effect on early and late haemorrhoidal-related symptoms. *Patients and Methods:* Forty-six males and 54 females received Proctonorm® (one tablet twice daily for 14 days) and Ketoprofene R (200 mg, one tablet twice daily, as requested). *Results:* “Early Complication Score” (0-12) two days after surgery was  $2.02 \pm 1.03$ ; pain VAS (Visual Analogue Scale) (0-10) was  $1.21 \pm 0.89$ , and the number of anti-inflammatory tablets was  $4.24 \pm 1.06$ . At 40-day post-operative assessment, seven patients had post-operative complications with “Late Complication Score” (0-20) of  $0.34 \pm 0.68$ . At six-month follow-up, a high index of patient satisfaction (VAS= $9.39 \pm 0.24$ ) was self-reported with 75% reduction in CSS (Constipation Scoring System) ( $1.95 \pm 2.58$ ) compared to preoperative scores; “Late Complication Score” was 0. *Conclusion:* The specific target activity of Proctonorm® at the microcirculatory level may be effective in patients undergoing SH in order to reduce the inflammatory response of residual haemorrhoids while waiting for stable resolution of symptoms within one or two weeks.

Haemorrhoids represent one of the most frequent proctological diseases, ranging in the adult population from 4-34% (1). Bleeding during or soon after evacuation, anal pain and/or discomfort, and haemorrhoidal prolapse are the most common findings. According to the “Unitary Theory of Rectal Prolapse”, haemorrhoids are determined by an internal rectal

prolapse that can be limited to the rectal mucosa (mucosal prolapse) or involve the muscle wall (full-thickness rectal prolapse) as well (2). During defecation, this internal prolapse can descend down to the anal canal, up to or even beyond the anal verge, thus pushing-out anorectal mucosa and haemorrhoids. This dynamic prolapse weakens over time the supporting structures, such as Treitz’s and Parks’ ligaments, with a progressive sliding down of the haemorrhoids which is primarily due to the internal recto-anal prolapse.

Stapled haemorrhoidopexy (SH), by correcting the inherent internal rectal prolapse, achieves less post-operative pain, superior functional recovery with earlier return to normal activities, and improved patient satisfaction compared to Conventional Haemorrhoidectomy (CH), but it can also ameliorate the symptoms of obstructed defecation, frequently reported in these patients, thus representing a standard of treatment (3-11). Notwithstanding the clear advantages of SH over CH, some early post-operative complications still negatively affect patient’s outcome mostly regarding pain or symptoms related to oedematous and/or congested haemorrhoidal anal cushions that may still remain after SH, such as: bleeding, thrombosis of external piles, hitching, anal soiling, and urinary retention. As a matter of fact, and differently from CH, the persistence of haemorrhoidal cushions in patients undergoing SH as well as their, although transient, iatrogenic damage due to the anal canal stretching secondary to the Circular Anal Dilator (CAD) that is left into the anal canal for the whole duration of the procedure, may be responsible of early post-operative symptoms that reduce compliance to the operation (12, 13).

So, although the stapled procedure reduces vascular supply to the haemorrhoids and, by excising the redundant rectal mucosa, reduces and fixates the prolapsed haemorrhoidal tissue higher-up in its former physiologic and anatomic site (haemorrhoidopexy), at least one or two weeks are required before inflammation and oedema of the residual haemorrhoidal plexus fade away. Traditionally, these symptoms are managed for a few days with Non-Steroidal

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*Key Words:* Haemorrhoidal prolapse, stapled haemorrhoidopexy.

Anti-Inflammatory Drugs (NSAID); however, considering both their inherent collateral effects as well as their less than specific modality of action, a targeted medical approach might be much more effective. In this view, the modality of action of Proctonorm® looks quite attractive because it's largely used for managing symptoms of haemorrhoidal disease thanks to its peculiar composition (Bromelain, Ginkgolect® 80 mg/cpr; Leucoselect® 100 mg/cpr;  $\alpha$ -lipoic acid 400 mg/cpr). Actually, this product has a specific target at the microcirculation level by increasing capillary resistance, reducing vascular permeability with local anti-inflammatory, anti-oedema, and analgesic effect, thus preventing local tissue irritation, serum and mucosal discharge (anal soiling) (14-18).

On these grounds, a retrospective study was performed in patients undergoing SH with CPH34 HV (Chex™, Frankenman International Limited, Hong Kong, China) who were postoperatively treated with Proctonorm® with the aim of assessing its effect regarding early and late haemorrhoidal related symptoms, such as: post-operative pain, haemorrhoidal bleeding, thrombosis, anal soiling, and residual haemorrhoidal disease.

## Patients and Methods

The clinical charts of 100 patients with symptomatic third- or fourth-degree haemorrhoids who underwent SH at the Colo-Proctology Unit, Casa di Cura San Camillo - Forte dei Marmi, Lucca - Italy between 2017 and 2018 were reviewed. The study group consisted of 46 males and 54 females with a mean age of 54.3 years (SD=11.7 years; range=24-80 years). All patients underwent complete preoperative proctologic examination, with flexible colonoscopy performed according to age, risk factors for colorectal cancer, and associated bowel symptoms. The clinical characteristics of patients are reported in Table I. Patients underwent a one-day surgical procedure, with a preoperative self-administered rectal enema on the evening before and the morning of the operation; no antibiotic prophylaxis was given. Each patient gave his/her written informed consent and all procedures performed in this study were in accordance with the ethical standards of National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Preoperative clinical data included: i) specific symptoms of haemorrhoids such as: pain (Visual Analogue Scale, VAS=0-10); ii) bleeding; iii) haemorrhoidal prolapse/swelling; iv) Wexner's Constipation Scoring System (CSS=0-30), and v) Goligher's classification of haemorrhoids (III or IV degree) (19). Perioperative data included: i) operative time; ii) intraoperative assessment of the extent of internal rectal prolapse; iii) associated procedures, such as: excision of skin tags, excision of anal fissure, fistulotomy/fistulectomy, *etc.*; iv) technical failures of the stapler; v) specimen sizes (length, height, and volume). Post-operative self-assessment of pain was recorded by means of a traditional VAS scale (0-10). Moreover, the number of tablets the patient actually consumed was computed. Early and late post-operative complications were checked after two, 40 days, and six months by means of a validated questionnaire of colo-proctologic complications (20).

Table I. Clinical characteristics of patients (N=100).

	N	%
Age, yrs		
Mean (SD)	54.3 (11.7)	
Range	24-80	
Gender		
Males, n(%)	46	46
Females, n(%)	54	54
Specific preoperative symptoms		
Pain score (VAS: 0-10)		
Mean (SD)	4.7 (2.3)	
Range	0-10	
Bleeding, n. (%)	80	80
Haemorrhoidal prolapse, n. (%)	82	82
Constipation, n. (%)	54	54
Soiling, n. (%)	11	11
Diarrhoea, n. (%)	7	7
Goligher's Classification		
III	18	18
IV	82	82
Preoperative CSS (0-30)		
Mean (SD)	7.8 (3.1)	
Range	1-15	
Previous anorectal surgery	16	16

SD: Standard deviation; CSS: Constipation Scoring System according to Wexner (19).

Residual prolapse was defined as the reduction, without disappearance, of prolapsed tissue (haemorrhoids and/or rectal prolapse) six months after the operation with or without associated symptoms of haemorrhoidal diseases such as: anal pain (spontaneous and/or post-defecation: VAS=0-10), bleeding, local discomfort, and/or anal soiling. The grade of satisfaction (VAS=0-10), and the CSS score (range=0-30) were assessed, as well.

**Surgical details.** Patients usually underwent spinal anaesthesia, and were placed in a lithotomic position with a Trendelenburg's tilt. Controlled digital stretching was performed initially with two fingers (index fingers) introduced carefully inside the anus and performing moderate traction laterally (gradually separating the two index fingers) and in an antero-posterior direction with fingers stretched (taking care not to hook the muscles of the pelvic floor). Then, the fingers were moved in a circular motion around the anus to gently break the inner sphincter fibres. Afterwards, two fingers on each hand were inserted in a repeating circular motion to increase anal dilatation. Then, the lubricated circular anal dilator (CAD) was inserted with an obturator, an integral part of the CPH34 HV™ kit (CHEXTM). This was sutured to the perianal skin with four stitches. Once the obturator was removed, an intraoperative assessment of the rectal prolapse was accomplished in order to define whether it involved more than half of the length of the CAD. A surgical anoscope was then inserted into the lumen of the CAD and a 2-0 Prolene purse-string suture was undertaken about 4 to 5 cm above the dentate line, to make a suture line at the end of the procedure approximately 2 to 3 cm proximal to the dentate line. The head of the circular stapler was introduced fully open proximal to the purse-string, which was tied with a closing knot; the ends of the suture were then pulled through the lateral holes of

Table II. *Intra- and early post-operative findings (N=100 patients).*

	Mean (SD)	N	%
Operative time, min			
Mean	20.1 (3.9)		
Range	15-27		
Haemostatic stitches, n.			
Mean	1.1 (1.3)		
Range	0-4		
Technical failures of the device		0	0
Specimen measures			
Length, mm	89.3 (11.9)		
Height, mm	35.8 (1.3)		
Volume, ml	10.4 (1.5)		
Associate surgical procedures			
No, n. pts. (%)		68	68
Yes, n. pts. (%)		32	32
Anal fissure, (n. procedures)		22	
Skin tags excision, (n. procedures)		9	
Fistulotomy/fistulectomy, (n. procedures)		4	
Condiloma, (n. procedures)		2	
Early post-operative assessment (2 days after surgery)			
Early post-operative score (0-12)	2.02 (1.03)		
Pain (VAS=0-10)	1.21 (0.89)		
NSAID (n. tablets)	4.24 (1.06)		
Late post-operative assessment (40 days after surgery)			
Late post-operative score (0-20)	0.34 (0.68)		
Post-operative complications		7	7
Anal pain (spontaneous/post-defecation)		2	2
Bleeding		1	1
Acute urinary retention		2	2
Urgency		0	0
Thrombosis of residual haemorrhoids		0	0
Others		2	2
Re-operation (within 30 days)		0	0
Follow-up at six months			
Late post-operative score (0-20)	0		
Satisfaction Index (VAS=0-10)	9.39±0.24		
CSS (0-30)	1.95±2.58		
Residual haemorrhoids		1	1

SD: Standard deviation.

the instrument. The ends of the sutures were then fixed externally using a clamp and a gentle digital pressure on the sutures was maintained while tightening the stapler to draw the prolapsed rectal wall into the stapler casing. Hence, the stapler was fired in order to perform the prolapsectomy and rectopexy, having completed all necessary check to avoid recto-vaginal fistula. Once the stapler was removed, the integrity of the mucosal cylinder removed (doughnut) was checked by measuring into the operative room the specimen measures (length, mm; height, mm; and volume, ml with a graduated ampulla half filled with water), and then sent for histological examination. Haemostatic stitches were placed along the suture line in re-absorbable material (Vicryl 3-0) when required, and their number was recorded into the operative description. After prolonged observation to check for haemostasis, an absorbable plug was placed into the anal canal, thus concluding the intervention.

*Medical post-operative treatment.* Beyond standard hygienic and dietetic recommendations (adequate water and fiber supply, oral lactulose to improve bowel evacuation; no post-operative enema, etc.) patients received oral therapy with Proctonorm® (1 tablet twice daily for 14 days) and Ketoprofene R (200 mg, one tablet twice daily, as requested) coupled with gastric protection.

## Results

All patients underwent SH in one-day surgery; the mean operative time was 20.1 min (3.9 SD); hemostatic stitches (mean=1.1; SD=1.3) were given only in a minority of patients (n=34); no technical failure of the device did occur. Associated procedures were accomplished in 32 patients for anal fissures

(n=22), skin tags excision (n=9), fistulotomy/fistulectomy (n=4), and condyloma (n=2) (Table II).

Regarding post-operative complications, “Early Complication Score” [0-12] assessed two days after surgery was equal to  $2.02 \pm 1.03$  (mean $\pm$ SD); the VAS assessment of pain was  $1.21 \pm 0.89$ , and the number of tablets of NSAID was  $4.24 \pm 1.06$ . At 40-day post-operative assessment, two patients complained of post-operative pain for more than three days; rectal bleeding was managed conservatively in one; acute urinary retention requiring bladder catheterization was reported in two patients, and miscellaneous problems in two other patients; “Late Complication Score” [0-20] was  $0.34 \pm 0.68$  (mean $\pm$ SD).

Regarding follow-up data at six months after the operation, a high index of patient satisfaction (VAS=9.39 $\pm$ 0.24 SD) was self-reported with a consistent reduction (75%) of CSS ( $1.95 \pm 2.58$  SD) as compared to preoperative scores; moreover, the “Late Complication Score” [0-20] was equal to 0; finally, one patient had still mucosal prolapsed tissue on straining.

## Discussion

SH certainly represents an effective surgical treatment of haemorrhoids not only for the technical details of the operation, which avoids any wound in a very sensitive area such as the anus and perianal skin but, also, for its new pathophysiological concept aimed at the correction of the internal rectal prolapse thought to determine the sliding down of the haemorrhoids from the anal canal. Actually, this operation simply “lifts” haemorrhoids back into their original anatomic site by means of the circular excision of a variable volume of rectal wall (mucosa-submucosa with contiguous muscular fibres); this is accomplished by means of a circular stapler that allows both the transverse transection of rectal tissue as well as the end-to-end anastomosis at least 2-3 cm from the dentate line (17).

The advantages of SH over CH was confirmed by sound clinical data with less post-operative pain, superior functional recovery and earlier return to normal activities, improved patient satisfaction coupled with a significant improvement of obstructed defecation symptoms (3-11). However, notwithstanding the haemorrhoidopexy and reduced vascular supply to the haemorrhoids, their conservation may sometime reduce patient’s compliance due to a transient inflammation/congestion of residual haemorrhoidal cushions with bleeding, thrombosis of external piles, hitching, anal soiling, and urinary retention which may be related also to the added local iatrogenic effect of the operative procedures, especially in the advanced stages of haemorrhoidal disease (12, 13). Traditionally, these symptoms have been managed for a few days with Non-Steroidal Anti-Inflammatory Drugs (NSAID) although a more selective pharmacologic approach might be much more effective and appealing.

Our preliminary findings suggested the substantial clinical advantage of the integrated treatment with Proctonorm® given in the early post-operative period for controlling residual haemorrhoids-related symptoms, just when they may be more frequent. As a matter of fact, very low “Early Post-Operative Score” ( $2.01 \pm 1.03$ ), self-assessment of pain (VAS= $1.21 \pm 0.89$ ) and, mostly, a small number of tablets of NSAID to manage early post-operative pain were reported. This favorable trend was also confirmed at 40-day assessment with very low scores of “Late Post-Operative Complications” ( $0.34 \pm 0.68$ ) and a few overall complications (7%), as well as at six-month follow-up with a very high satisfaction index ( $9.39 \pm 0.24$ ).

Actually, compared to our previous multicentric clinical experience on 621 consecutive patients undergoing stapled haemorrhoidopexy for haemorrhoids between 2012 and 2014, there was an almost three-fold reduction of spontaneous/post-defecation anal pain (from 7.2-2%) and anal bleeding was reduced from 3.7% to 1%; acute urinary retention reduced from 4.2-2%, and no attack of thrombosis of residual piles or urgency did occur (21). These findings are remarkable even when compared to the large clinical experience of Ng *et al.* (7) who reported minor complications in 12.3% of patients in 3,711 patients undergoing stapled haemorrhoidopexy, including acute retention of urine (4.9%), bleeding (4.3%), and significant post-operative pain requiring re-admission (1.6%). The comparison with the meta-analysis of Sutherland *et al.* (8) is even more impressive, because post-operative bleeding requiring medical consultation was reported in 5% to 13% of patients; urinary retention in 1.8% to 5% of patients and, mostly, thrombosis of residual haemorrhoids occurred in 1.8% to 15% of patients.

Hence, the specific activity of Proctonorm® at the microcirculation level and its local anti-inflammatory effect, due to an increased capillary resistance, reduced vascular permeability, and analgesic effect, that prevent tissue and mucosal irritation may be effectively used in patients undergoing SH in order to reduce the inflammatory response of residual haemorrhoids related not only to their persistence but, possibly, to their increase by surgical manoeuvres while waiting for their stable resolution within one or two weeks.

## Conflicts of Interest

This study received no grant and each Author declares that he/she has no conflict of interest.

## Authors’ Contributions

Reboa Giuliano: Study planning, surgical treatment, manuscript review. Gipponi Marco: Study planning, statistical analysis, manuscript editing and review. Fregatti Piero: Clinical follow-up, data management. Depaoli Francesca: Clinical follow-up, data management.

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Received May 10, 2019

Revised June 11, 2019

Accepted June 13, 2019