Transanal anopexy with HemorPex System (HPS) is effective in treating grade II and III Haemorrhoids: long term results.

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Abstract: Haemorrhoidal disease is a common proctologic disorder. The HemorPex System (HPS) is an innovative surgical technique based on muco-haemorrhoidopexy without Doppler guidance. Purpose: The aim of this study is to evaluate the HemorPex System (HPS) efficacy on grade II and grade III haemorrhoidal patients. Methods: 100 patients affected by grade II and grade III haemorrhoidal disease were included in the study and operated by means of the HemorPex System (Angiologica, Italy) without Doppler support. The proposed procedure consists in the re-positioning of the haemorrhoidal cushions in their anatomical place by means of sutures applied circumferentially in the six supposed position of the superior haemorrhoidal artery terminal branches. These sutures determine a plication of the mucosa and could determine the closure of the terminal branches of the superior haemorrhoidal artery. A few parameters were compared preoperatively and postoperatively: pain, bleeding, prolapse and hygienic difficulties. Results: Operative time was 16 ± 5 minutes; pre-treatment observed symptoms improved considerably after the procedure: pain from 44,8% to 10,4%; bleeding from 56,7% to 13,4%; prolapse from 44,8% to 14,9% and hygienic difficulties from 23,8% to 0,4% . Conclusions: HemorPex System (HPS) is an innovative technique for the treatment of grade II and grade III haemorrhoidal disease. From the data collected in this study this technique depicts itself as a fast, low pain and economic approach to the haemorrhoidal disease which is also granted with good long term results. Key words: Haemorroids, HemorPex System (HPS), Muco-haemorrhoidopexy without Doppler guidance.

Introduction

Haemorrhoidal disease represents the most common proctologic disorder, affecting approximately 5% of the general population with a peak prevalence noted between 45 and 65 years of age [1,2]. The etiologic and pathophysiologic theories of haemorrhoidal disease confirm its multifactorial character. The vascular hyperplasia, the varicose veins and the anal mucous membrane sliding theory are many factors contributing to the growth of haemorrhoidal piles; the impact of Treitz’s muscle disruption and mucosal prolapse are also included [3]. The haemorrhoidal cushions are fibrovascular structures containing an arteriovenous network between the terminal branches of the superior rectal artery and subepithelial venous plexus (corpus cavernosum recti), connective tissue and smooth muscle; they are located at left lateral, right anterior, and right posterior positions (at 3,
7, 11 o’clock) with the patient in the anatomical lithotomy position, and are important for continence.

Goligher’s classification [4] is useful to graduate the severity of haemorrhoidal disease. This clinical traditional classification includes grade I haemorrhoids which is represented by haemorrhoidal cushions protrusion in the anal canal lumena as a result of venous congestion due to defecation stress; grade II haemorrhoids which is represented by cushions protrusion up to anal border but is spontaneously reduced; grade III haemorrhoids which need manual repositioning and, finally, grade IV haemorrhoids which cannot be reduced digitally into the anal canal.

As years go by, several surgical techniques followed one upon the other. The traditional surgical approaches to haemorrhoidal disorders are represented by Milligan Morgan open haemorrhoidectomy or by Ferguson closed haemorrhoidectomy, Longo proposal of stapled mucoprolassectomy introduced the concept of the utility of lifting the prolapsing mucosa instead of simply excising it [5]. These invasive surgical techniques, even though effective in most cases, however are not devoid of complications like bleeding, serious infections, stenosis, pain, distress, prolapse, need for general anesthetic approach, longer operation time, post-operative hospital stay and convalescence. Therefore new mini invasive approaches were researched. Morinaga [6] in 1995 was the first to describe Doppler-guided haemorrhoidal artery ligation. The center of this non-excisional technique was the artery ligation in order to decrease the inflow to haemorrhoidal piles and so improve the prolapse. The superior rectal artery terminal branches variable course was studied for ligating sutures correct placement. In addition to the Goligher’s conventional positions of 3, 7, 11 o’clock, other studies were conducted. Kolbert and all and Toh et all in their studies affirmed that there is a fourth haemorrhoidal artery that is consistently found in the left anterior one o’clock position (1, 3, 7, 11 o’clock) [7,8]. Other authors [9-13] asserted there were additional superior rectal artery branches that provide the corpus cavernosum recti entering the rectal wall (1, 3, 5, 7, 9, 11 o’clock). Apart from their circumferential disposition also the sagittal position together with the depth of those haemorrhoidal artery terminal branches are highlighted as a critical factor for the appropriate suture placement. From the clinical results of high dearterialization series it appears that if the sutures are applied in high position as described by so called THD technique and no mucopexy is carried out, recurrent bleeding is frequently observed [14,15].

The HemorPex System (HPS) consents, the repositioning of haemorrhoidal piles, by lifting up the prolapsed anorectal mucosa (muco-haemorrhoidopexy). Whereas the suturing is started immediately above the dentate line in the site were the terminal branches of the superior rectal artery emerge in the sub mucosa and carried out proximally, an occlusive effect on them cannot be excluded. The procedure is performed by using a rotating Proctoscope called HemorPex System (HPS) (Angiologica SAS, Italy) without Doppler support.

The aim of this study is to evaluate long term results of this innovative technique.

Materials and Methods

After obtaining approval by the local ethical committee, the study was started. In a 6 year time frame, from 2007 to 2013, at General Surgery Department – “Spirito Santo” General Hospital, in Pescara (Italy), 100 patients affected by grade II and grade III symptomatic haemorrhoidal disease not responsive to medical therapy, were recruited in the study and were submitted to haemorrhoidal disease surgical correction by HemorPex System (HPS).

Patients with thrombosed, fibrous and fixed external IV grade haemorrhoidal piles were excluded. All patients were informed and signed an informed consent.

Patient’s characteristics were estimated pre-operatively, intra-operatively and post-operatively. In the preoperative evaluation were contemplated: age, gender, haemorrhoidal disease severity grade pain, bleeding, prolapse, hygienic difficulties.

Intra-operative and post-operative complications were evaluated.
All patients underwent office routine examinations at 7 days and 30 days.
Long term follow-up was performed by telephone interview as well as direct examinations when needed.
Follow-up was possible on 67 patients over 100 (67%) with a follow-up time range of 3-67 months (average 39.01 months).

Surgical technique

All patients were operated by one of the author (MB) by means of the HemorPex System (HPS). The HPS is a single use device composed by a fixed part which remains in contact with the anoderma and the sensible mucosa of the anal canal and by a rotating operative part which includes the window through which the suture stitches are placed (Fig.1).

![Fig.1 The HemorPex System (HPS).](image)

All patients were submitted to spinal anesthesia.
Prior to the introduction of the anuscope a lubricated gauze is introduced into the anal canal to fully reduce the sliding mucosa. The operative anuscope is then introduced. A first stitch is placed and knotted on the mucosa protruding through the anuscope opening just above the dentate line, in the area where the artery runs submucosally: the suturing is then carried out proximally so that a good mucopexy is achieved. By moving only the distal rotating part of the anuscope the “window” faces a different aspect of the distal rectum without the need of withdrawing the whole instrument. The procedure is thus repeated on all six positions (at 1,3,5,7,9,11 o’clock); no doppler support is provided.

Results
Altogether 100 patients signed up in the study. There were 38 females (38%) and 62 males (62%). 67 patients (67%) attended the long term follow-up, the rest were lost; the average of follow up was 39,01 months, the median was 41 months (tab 1). The mean age was 49,16 years.

Tab 1. 67 Patients participated in follow up examination from 3 to 67 month (average=39,01; median=41).

Patients were affected by grade II (15%) and grade III (85%) haemorrhoidal disease; none of them was affected by IV grade haemorrhoids.

Pre-operative symptoms were: pain (44,8%), bleeding (56,7%), prolapse (44,8%), hygienic difficulties (23,8%).

The average surgical time was 16 min ± 5 min.

We did not observe any intra-operative complication.

All patients were dismissed within 24 hours from the procedure.

At discharge appropriate diet regimen, stool softeners and a prudential 2 days codeine-based medication were advised.

Long term follow-up results were: pain (10,4%), occasional bleeding (13,4%), occasional prolapse (14,9%), hygienic difficulties (0,4%), partial recurrence (1,4%), total recurrence (7,4). (tab 2.) In one case 14 months after the first treatment the removal of one pile by a limited excision under local anesthesia, was necessary and the patient has been free of symptoms since then (partial recurrence). We define as a total recurrences cases in which a new surgery was indicated either by us or by a different surgeon.

Total recurrence occurred in 5 patients. In 2 cases after 8 and 10 months excisional haemorrhoidectomy was performed on patients outside institution; in the three remaining cases recurrent prolapsing haemorrhoids were observed respectively at 24, 26 and 36 month from the first procedure (HPS) and surgically treated.
Tab. 2. Pre- and postoperative complications.

**Conclusion**

From our experience we can affirm that HemorPex System is an efficient surgical approach to haemorrhoidal disease treatment. This approach consented a substantial reduction in terms of pain (44.8% vs 10.4%), bleeding (56.7% vs 13.4%), prolapse (44.8% vs 14.9%), and hygienic difficulties (23.8% vs 0.4%); (gross data including recurrences).

In conclusion, we infer from our experience that HemorPex System, if applied with the correct indications, provides a safe, fast and inexpensive approach to the control of haemorrhoidal disease.

The authors declare that they have no conflict of interest.

The study has been approved by the appropriate ethics committee and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

**References**