

Hemorpex System Procedure (HPS®) for Hemorrhoidal Disease: 10 Years Follow-Up of 396 Patients

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Abstract

Background: HemorPex System (HPS®) is a surgical technique used for hemorrhoidal disease, combining ligature of the superior hemorrhoidal artery branches and mucopexy. Several studies have been published in Literature about HPS, but they lack of a long follow-up period. Aim of this study was to analyze the results of this technique after a 10-years follow-up.

Methods: Surgical reports of 396 patients operated at Policlinico San Martino (Genoa, Italy) from 2003 to 2009 were reviewed. Long-term follow-up was realized with telephone interview and patients were asked about satisfaction of surgery, the need to undergo a second procedure or medical treatment for relapse of symptoms.

Results: 225 males (57%) and 171 females (43%) with mean age of 53 years were operated with HPS®. 63% of patients had grade III hemorrhoids, 28% grade II and 9% grade IV. Mean operative time was 28 min (range 8-75 min). 392 procedures (99%) were performed under local anesthesia. 94% of the patients were discharged in the same day of operation. Questionnaire has been compiled in 213 cases. Forty-one patients (19%) stated subjectively satisfied with the HPS®'s results. 14 patients (6.5%) were totally satisfied and 27 (12.5%) partially satisfied. 62% of patients (133 cases) needed a second surgical procedure. Within totally-satisfied group, 11 patients were grade II (78.5%) and 3 were grade III (21.5%). Among 27 partially-satisfied patients, one (3.5%) was grade IV, 14 (52%) grade III and 12 (44.5%) grade II. When examined as a whole, 35% of 64 patients with grade II hemorrhoids stated satisfaction and 17% complete satisfaction, compared with 13% of 128 patients with III grade piles (2% totally satisfied).

Conclusions: HPS® for the treatment of hemorrhoidal disease seems to offer promising results. Patients satisfaction decreases with the rising of hemorrhoidal disease grade. Elderly patients seem to be the most satisfied from the procedure.

Keywords

Hemorrhoids, Hemor pex system (HPS), Muco-hemorrhoidopexy, Follow up

Introduction

Surgical treatment of hemorrhoidal disease still remains a matter of debate. Hemorrhoidectomy and stapled hemorrhoidopexy are burdened by postoperative pain, high costs and risk of severe complications or recurrences, respectively [1,2]. Conservative alternatives include de-arterialization procedures and mucopexy, developed in order to reduce postoperative pain and minimize surgical risk [3].

HemorPex System (HPS®) allows to realize combined ligature of the superior hemorrhoidal artery and mucopexy seems to offer good results in grade II and III hemorrhoidal disease [4].

Immediate and medium-term success seem encouraging but limited data have been published and few patients enrolled in single-center retrospective studies with short follow-up. Long-term results have not been investigated while maintenance of the satisfaction rate should be confirmed. Moreover the onset of remote complications can't be ruled out (e.g. acute diverticulitis [5]).

Aim of this paper was to evaluate a prolonged follow-up after HPS surgery, by the use of a retrospective 10-years revision of the first published clinical case study [6].



Figure 1: The HemorPex System: Fixed and rotating parts



Figure 2: The anterior part of rotating proctoscope.

Materials and Methods

HPS[®], developed by Angiologica BM S.r.L in San Martino Siccomario (PV Italy), consists of a disposable self-illuminated device through which pass manual suturing in order to obtain combined hemorrhoidal artery ligation and mucopexy (Figure 1 and Figure 2). The external fixed circular component contains an internal windowed rotating proctoscope. The window is 4 cm from the distal edge of the anoscope and this allows high suturing above hemorrhoids at the 1, 3, 5, 7, 9, 11 o'clock positions where terminal branches of the superior hemorrhoidal artery are interrupted with stitches and 3-cm mucosal plication starts.

Surgical reports of 396 patients operated at Policlinico San Martino (Genoa, Italy) from 2003 to 2009 were reviewed. This cohort of patients was part of a larger group of cases whose short term clinical results have already been published in a multicentric study [6].

Permission to access patient data was allowed by Hospital Health Management of and by C. Iachino MD, previous Day Surgery Department Head in Policlinico San Martino, who performed the vast majority of operations (98%). Intra operative reports were registered. Recovered personal data were used for the purpose of conducting an interview. Long-term follow-up was realized with telephone interview. Resident surgeons asked about satisfaction (totally satisfied, partial satisfaction and dissatisfied), the need to

Table 1: Clinical demographic data.

Total	396
Sex	
Male	225 (57%)
Female	171 (43%)
Grade of piles	
II	111 (28%)
III	249 (63%)
IV	36 (9%)

Table 2: Patient satisfaction.

Age Range	Cases (%)	Satisfied (%)	Totally Satisfied (%)
< 30	37 (17.5%)	4 (11%)	-
30-39	31 (14.5%)	5 (16%)	2 (6.5%)
40-49	34 (16%)	6 (17%)	3 (8.5%)
50-59	30 (14%)	6 (20%)	1 (3.5%)
60-69	33 (15.5%)	4 (12%)	1 (3%)
≥ 70	48 (22.5%)	16 (33%)	7 (14.5%)

undergo a second procedure or medical treatment for relapse of symptoms (pain, rectal bleeding or prolapse).

Results

225 males (57%) and 171 females (43%) with mean age of 53 years (range: 17-94 years) were operated with HPS[®]. Utilizing Goligher's classification [7,8], 63% of patients had grade III hemorrhoids, 28% grade II and 9% grade IV. Demographic data are listed in Table 1.

Mean operative time was 28 min (range 8-75 min) and 392 procedures (99%) were performed under local anesthesia with the standard six-sutures technique employing Vicryl[®] 00 in 87% of cases (PDS[®] 00 in 7.5%; Maxon[®] 00 in 3.2% and Prolene[®] 00 in 2.5%).

Ninety-four percent of the patients were discharged in the same day of operation; only 24 had to stay in the Hospital (mean: 1.75 days; range: 1-9 days). Minimum postoperative interval was 10 years (range: 10-16 years).

Standardized questionnaire has been compiled in 213 cases (53% with 47% of drop-out), of which 64 patients (30%) grade II hemorrhoids, 128 (60%) grade III, and 21 (10%) grade IV. Data about patient satisfaction are listed in Table 2. Forty-one patients (19%) stated subjectively satisfied with the HPS[®]'s results. In particular, 14 patients (6.5%) were totally satisfied and 27 (12.5%) partially satisfied (symptomatic patients who underwent medical/outpatient treatment per disease relapse).

Within totally-satisfied group, 11 patients were grade II (78.5%) and 3 were grade III (21.5%). Among 27 partially-satisfied patients, one (3.5%) was grade IV, 14 (52%) grade III and 12 (44.5%) grade II. When

examined as a whole, 35% of 64 patients with grade II hemorrhoids stated satisfaction and 17% complete satisfaction, compared with 13% of 128 patients with III grade piles (2% totally satisfied). Only 4% of patients in grade IV were satisfied.

Statistic analysis showed a statistically significant difference ($p < 0.0001$) in patient satisfaction between each hemorrhoids grade; in particular grade II hemorrhoids patients were more generally satisfied ($p < 0.0001$) and, moreover, more totally satisfied ($p < 0.047$) than grade III and IV patients.

62% of patients (133 cases) needed a second surgical procedure, most of them within the first 48 months (110 cases, 82%). Risk of "surgical" recurrence was related to the grade of disease: 30 patients (46%) with grade II, 85 (66%) with grade III, and 18 (85%) with grade IV were operated again. There was a statistically significant difference ($p < 0.038$) between each hemorrhoids grade: grade II patients were positively related to no "surgical" recurrence, while grade IV patients were positively related to revisional surgical procedure.

Length of the operation as well as suture material were unrelated with satisfaction rate ($p > 0.1$). Satisfied patients were noticeably older than overall cohort, possibly because mean age 65 years (range 34-84 years), but there was not statistic significant relation to age patient ($p > 0.1$). Anyway, with advancing age, clinical results seem to improve.

Discussion

Dearterializing mucopexy with HPS® for the treatment of hemorrhoidal disease seems to offer promising results, for its short learning curve, low grade of postoperative complications, fast recovery and competitive costs. The procedure is standardized, fast, exempt from serious adverse events and cheaper if compared with stapled hemorrhoidopexy. Short-term clinical results were encouraging, especially in early stages of disease.

Clinical experience started in 2003 and in 2009 Iachino published the first report amounting to 1112 cases from a prospective multicenter non-randomized study [7] but data related to 719 cases (65%) with complete 3-years follow-up. Main indication was grade III (65%) and grade II (25%) hemorrhoids, and just in 10% grade IV. HPS® procedure was mainly performed under local anesthesia (92%) with daily hospitalization (97%). Postoperative complications, although with not negligible incidence (30%), were slight severe and lowered to 4.4% after 60 days. After 1 year, promising results were recorded for grade II and III (1.6% and 3.4% of recurrences, respectively) although clinical relapse was commonly observed in grade IV (37.5%).

Tagliabue confirmed this high recurrence rate in grade IV: 28.5% after 6 months, moreover 76% of patients were included with grade II hemorrhoids in her cohort of 116 cases [9]. Even here, HPS® technique showed good compliance with mean VAS score of 2 (± 1) and postoperative complication were uncommon; nevertheless in 3.4% of cases, a second operation for late bleeding control became necessary.

In non-randomized prospective study from Basile [4], 85% of 100 enrolled patients were classified grade II and 15% grade III. Operation resulted fast (mean duration 16 min) and no intraoperative complications were registered. VAS scoring was 3 ± 1 . Bladder catheterization was necessary in 22.4% of males but seemed due to spinal anesthesia. After 2 years, despite 44% of drop out at survey, 85.7% of patients were satisfied and "conventional" surgery was necessary just in 8% of recurrence.

Pagano [10] has extended indication for use HPS® in grade IV hemorrhoids: 30% of 126 cases (70% grade III). He renamed MuRAL (mucopexy-recto-anal-lifting) the procedure with a mean duration of 29.5 minutes (longer in grade IV) and quite painless (VAS 1.9 in the third postoperative day). Urinary retention was always observed associated with spinal anesthesia (18%). Fecal urgency often observed after 3 weeks (18.8%) disappeared at 1 year. At this time up to 88% of patients declared excellent (31.1%) or good (57.4%) satisfaction with 4.1% or recurrences.

We interviewed 53% of operated patients. Satisfaction rate significantly decreased over time (19% after 10 years) and was related to pile grade. 35% of patients with grade II hemorrhoids declared satisfaction, 13% with grade III and 4% with grade IV. In addition to subjective assessment of the results, re-do surgery rate (62%) depend on clinical classification too: 46% of grade II, 66% of grade III and 85% of grade IV.

Traditional hemorrhoidectomy and stapled hemorrhoidopexy ensure lower rates of disease relapse (respectively 3% and 7%) than dearterializing mucopexy does. We have to say that the latter procedure is not equivalent to a prolassectomy, therefore we should not directly compare these two types of surgical interventions. The reason of high relapse of disease could stand in the anatomical and functional variability of hemorrhoidal plexus: Despite vascular ligation, venous plexus could refill the piles and bring to high rate of relapse.

HPS® procedure, therefore, does not seem to ensure acceptable results for grade IV hemorrhoids. With patient aging, satisfaction rate enhances, reaching 33% over 70 years. This final point, beyond the option of local anesthesia with daily hospitalization, safety and

tolerance, might mean that HPS® should be proposed as a treatment option for older patients.

In conclusion, HPS® procedure is a safe and light technique, feasible also in older people. Long term results are disappointing, but could be cynically attractive precisely for the elderly population, with a reduces life expectancy, nevertheless with more comorbidities, thus excluding heavier procedures. In our country Liguria, first place to mean age in Italy [11], this assumption would be very attractive.

Conflict of Interest

The authors declare that they have no conflict of interest.

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