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Hemorrhoidal laser procedure: short- and long-term results from a prospective study

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Treatment

Abstract

BACKGROUND: We report the results of 2-year regular use of the hemorrhoidal laser procedure (HeLP) in 97 patients with symptomatic second- to third-grade hemorrhoids with minimal or moderate internal mucosal prolapse.

METHODS: Data on duration of the procedure, perioperative complications, postoperative pain, downgrading of hemorrhoids, resolution or persistency, and recurrence of hemorrhoidal disease (HD) were prospectively collected.

RESULTS: No significant intraoperative complications occurred. The median follow-up was 15 months. Postoperative pain was null in most patients. There were no cases of rectal tenesmus or alteration of defecation habits. Symptoms and HD downgrading reached a "plateau" at 3 to 6 months after the HeLP. At this evaluation, frequency of bleeding, pain, itching, and hemorrhoidal acute syndrome decreased by 76% to 79%. HD grade showed a significant reduction. HD recurrence rate was 5% at 2 years.

CONCLUSIONS: Our study demonstrates that the HeLP is a safe, effective, and painless technique for the treatment of symptomatic second- to third-grade hemorrhoids with minimal or moderate mucosal prolapse, ideally suitable as ambulatory treatment.

Hemorrhoids are a common anorectal condition. They affect millions of people around the world and represent a major medical and socioeconomic problem.[1,2] The most common symptoms include rectal bleeding, pain, anal irritation, anal mass prolapse, and a disrupted quality of life.[3,4] In the United Kingdom, hemorrhoids were reported to affect 13% to 36% of the general population.[5] However, this estimation may be higher than actual prevalence because the community-based studies mainly relied on self-reporting and patients may attribute any anorectal symptoms to hemorrhoids. Because of its high incidence among the adult population, a painless and effective surgical treatment for hemorrhoidal disease (HD) represents a timely issue for colorectal surgeons. In spite of continuous progress in that field, many controversies still remain

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about the appropriate surgical therapy: excision, ligation, dearterialization, and stapled or conventional procedures? At present, the most common surgical procedures for HD are the excision–ligation, first described by Milligan-Morgan et al,[6] and the closed variant technique, proposed by Ferguson et al.[7] However, postoperative pain is commonly experienced in both cases.[8] The introduction of mini-invasive surgical procedures yielded better control of the symptoms with less postoperative pain, challenging the conventional procedures. Morinaga et al[9] described a new surgical procedure for HD named the hemorrhoidal artery ligation (HAL). Later, Sohn et al[10] proposed the transanal hemorrhoidal dearterialization (THD). Both the techniques are based on the identification and ligation of all the terminal branches of the superior rectal artery, through a specific proctoscope associated with a Doppler transducer. These procedures cause the reduction of blood flow to the hemorrhoidal tissue, thus determining decongestion and shrinkage of the hemorrhoidal cushions. The decreased tension helps the connective tissue regeneration, the reduction of the prolapse, and the improvement of the hemorrhoidal symptoms.

Recently, Giamundo et al[11,21] proposed a new nonexcisional surgical technique called the hemorrhoidal laser procedure (HeLP). It pursues the same goal of the THD and HAL, that is, the mini-invasive treatment of symptomatic second- to third-grade hemorrhoids with minimal internal mucosal prolapse.[12] With the HeLP procedure, the shrinkage of the terminal branches of the superior hemorrhoidal artery is achieved by a specific laser device. Usually, no kind of anesthesia is required.

Our prospective study reported the results after 2 years of regular use of HeLP in patients with symptomatic second- to third-grade hemorrhoids with minimal or moderate internal mucosal prolapse.

Patients and Methods

From April 2010 to June 2012, 97 patients underwent the HeLP procedure at the Department of General Surgery, San Camillo Clinic Institute, Brescia, Italy. This study was approved by the internal ethical committee. The written informed consent was obtained by all patients enrolled in the study. All subjects were preoperatively studied through medical history evaluation, routine blood tests, and physical examinations (digital examination and/or anoproctoscopy). The HeLP procedure was proposed only in case of symptomatic second-degree hemorrhoids or third-degree hemorrhoids with minimal or moderate internal mucosal prolapse at preoperative evaluation and failure of conservative treatment. The assessment of the prolapse was made on the basis of digital rectal examination and anoscopy. Defecography was requested in cases of severe prolapse or symptoms of obstructed defecation syndrome (outlet obstruction). The exclusion criteria from the study were younger than 18 or older than 75 years; fourth-degree hemorrhoids and third-degree hemorrhoids with moderate/severe prolapse at preoperative anoproctoscopy; previous surgery for HD; thrombosis of hemorrhoidal cushions; fecal incontinence (Wexner fecal incontinence score >7)[13,14]; obstructed defecation syndrome; previous surgical anastomosis lower than 5 cm from the dental line; anal stenosis, anal fissures, or fistulas; acute inflammatory bowel diseases; and current therapy with anticoagulant drugs. Before surgery, a colonoscopy was performed in all patients to rule out sources of bleeding different from HD—as recommended by the common guidelines for screening of colorectal disease.[15] Goligher classification[15] for hemorrhoids were used for preoperative and postoperative staging purposes.

Surgical Technique and Postoperative Management

All procedures were performed using the HeLP kit from Biolitec AG–CeramOptec (Bonn, Germany). A dedicated 23-mm diameter proctoscope was inserted into the rectum, with the patients in lithotomy position. Through the small window at the proctoscope distal part, the Doppler transducer was used to identify the terminal branches of the superior hemorrhoidal artery, approximately 3 cm above the dentate line. Once the arterial flow was identified, all branches were closed using a laser optic fiber (5 pulses of 1.2 seconds each with a .6-second pause at the power of 13 W) that replaced the Doppler probe in the same small proctoscope window. By the reintroduction of the Doppler transducer, the actual closure of the artery was checked and, if necessary, a new sequence of 2 laser shots was delivered in the same point.

All operations were carried out without general or local anesthesia; conscious sedation was usually unnecessary. Nonsteroidal anti-inflammatory drugs, usually ketorolac, were administered intravenously only on demand; antibiotic prophylaxis was routinely adopted. The HeLP was performed as office procedure. No intestinal preparation was needed; 2 enemas (on the evening before the procedure and in the early morning of the procedure) were administrated. All patients were discharged within a few hours after surgery.

Data on duration of the procedure, perioperative complications, postoperative pain and downgrading of HD, resolution or persistency, and recurrence of disease were prospectively collected. Major bleeding was defined as any bleeding causing hemoglobin reduction of 3 g/dL or more or requiring transfusion of 2 red blood cell units or more.

Postoperative pain was evaluated using a 4-point verbal rating scale (VRS) (none, mild, moderate, and severe). Absence of pain was recorded as zero in the evaluative scale. ''Mild pain'' was attributed to an occasional disturbance not affecting daily life and activities at follow-up; it corresponded to 1 point in the evaluative scale. ''Moderate pain''

(corresponding to 2 points) was regarded as a pain that interfered with normal activities after discharge. The pain was considered "severe" (3 points) when it hampered normal daily activity. At each evaluation, we also recorded the presence of scars and rubber band on the anal canal mucosa, the recurrence of symptoms, and performed an accurate proctoscopic examination (for classification of eventual persistent or recurrent HD).

All patients were evaluated 1 and 4 weeks postoperatively and then at 3, 6, and 12 months after surgery for the first year and annually thereafter.

Statistical Analysis

Statistical analysis was carried out using the chi-square test or Fisher exact test, when appropriate, for categorical variables. Odds ratios and 95% confidence interval were calculated when required. The Mann–Whitney *U* test was used to compare continuous variables not normally distributed (presented as median and interquartile range [IQR]). Normality of the distribution of variables was determined using the D'Agostino–Pearson test. A *P* value less than .05 was considered as statistically significant. All tests were 2 sided. Statistical analysis was performed with statistical software for biomedical research (McCalc Software for Windows; version 10.2.0.0).

Results

The median age of the patients enrolled in the study (53 men and 44 women) was 47 years (IQR 36 to 59 years; range 28 to 74 years). Overall, 51 patients (53%) had second-grade hemorrhoids and 46 (48%) had third-grade hemorrhoids. The most frequently reported symptoms (of any grade of intensity and frequency) were bleeding in 63 (65%) cases, pain in 27 (28%), and itching in 21 (22%). Recurrent hemorrhoidal acute syndrome (HAS) was recorded in 31 (32%) cases (Table 1). The HAS was defined by the presence of pain, mucous discharge, and bleeding lasting for 5 to 7 consecutive days at least 2 times/y during the past 2 years.

All the procedures were performed without anesthesia and only 11 (11%) patients required analgesics (usually ketorolac intravenously) for pain relief. The operations took a median time of 18 minutes (IQR 15 to 25; range 12 to 40 minutes). A median number of 10 (IQR 7 to 12; range 5 to 13) artery branches were identified and treated with the laser device in each patient. No significant intraoperative complications or adverse events occurred. We observed minor intraoperative bleeding in 9 (10%) cases, who were successfully treated with the laser. No blood transfusion was required in any patient. In 3 cases (3%), a re-absorbable hemostatic suture was placed to stop an artery bleeding. These 3 patients were discharged after 24 hours, whereas the rest were discharged within 6 hours after the procedure. All patients were immediately able to resume their normal daily living activities. The median follow-up was 15 months (IQR 10 to 18; range 6 to 30 months). One day postoperatively, 80 patients (83%) disclosed grade 0 to 1 pain on VRS. The remaining subjects (18%) had moderate pain during the first 24 to 36 hours postoperatively and were successfully treated with oral painkillers (usually ketorolac). Median pain at 1 week postoperatively was 0 (IQR 0 to 1; range 0 to 2) on VRS. One week after HeLP, 79 (81%) patients showed at proctoscopy fibrin deposits covering the mucosa in all the sites of laser shots, whereas 18 (19%) subjects had only few signs of the laser beam. One month postoperatively, no scars were present at proctoscopy in any patient. No major complications were observed. Median pain at 1 month postoperatively was 0 (IQR 0 to 1; range 0 to 2) on VRS. Moderate anorectal pain was still reported by 13 (13%) patients 1 month postoperatively. In particular, pain during defecation was recorded in 6 (6%) cases, after defecation in 4 (4%), and without relation to defecation in 3 (3%) cases. Nine (9%) of these patients needed analgesic drugs occasionally. No relationship was observed between pain and preoperative HD grade (8 of 13 patients exhibited third-grade HD, $P = .37$). Ten of these 13 patients (77%) had anorectal pain related to HD preoperatively. This observation

Table 1 Pre- and postoperative symptoms and HD grade of the patients who underwent the HeLP

Symptoms (any grade of intensity)	Preoperative (97 pts), n (%)	1 mo (97 pts), n (%)	3 mo (97 pts), n (%)	*P**	6 mo (97 pts), n (%)	1 y (68 pts), n (%)	2 y (33 pts), n (%)	*P*†
Bleeding	63 (65)	25 (25.7)	16 (16.5)	<.0001	14 (14.4)	9 (13.2)	4 (12.1)	1
Pain	27 (27.8)	13 (13.4)	6 (6.1)	<.0001	5 (5.1)	3 (4.4)	2 (6)	1
Itching	21 (21.6)	9 (9.3)	6 (6.2)	.0037	4 (4.1)	3 (4.4)	2 (6)	1
HAS	31 (32)	8 (8.2)	7 (7.2)	<.0001	6 (6.1)	4 (5.8)	2 (6)	1
HD grade				<.0001				.81
First	0	39 (40.2)	46 (47.4)		45 (46.4)	35 (51.5)	16 (48.5)	
Second	51 (52.5)	45 (46.4)	44 (45.4)		45 (46.4)	28 (41.2)	13 (39.5)	
Third	46 (47.5)	13 (13.4)	7 (7.2)		7 (7.2)	5 (7.3)	4 (12)	

HAS = hemorrhoidal acute syndrome; HD = hemorrhoidal disease; HeLP = hemorrhoidal laser procedure; pts = patients.
*Between preoperative data and 3 months postoperatively.
†Between 6 and 24 months postoperatively.

resulted in high significance (odds ratio 13; 95% confidence interval 3 to 53; $P = .0002$). Twenty-five (26%) patients still reported rectal bleeding related to persistent HD (58% improvement). No patient was bothered by rectal tenesmus or defecation habits alteration. One month after the HeLP, 72 (74%) patients showed downgrading of the hemorrhoids: 33 of 46 (72%) patients with preoperative third-grade HD improved to second grade and 39 of 51 (77%) patients changed from second-grade HD to first grade. The improvement rate was not significantly related to preoperative HD grade ($P = .76$). All patients who presented HD reduction reported any improvement of preoperative symptoms. In a further 3 of 46 (7%) patients with preoperative third-grade HD and 7 of 51 (14%) patients with preoperative second-grade HD, the improvement of symptoms was not associated with hemorrhoid size reduction ($P = .4$). The overall improvement of symptoms was 85%.

Improvement of symptoms and modification of HD grade at the 1-, 3-, 6-, 12-, and 24-month follow-up are reported in the Table 1. Significant improvement of symptoms and reduction of HD grade were recorded until 3 months postoperatively. At this evaluation, frequency of bleeding, pain, and itching decreased by 75%, 78%, and 71%, respectively. HAS incidence decreased by 78% and HD grade showed a significant reduction (1 grade reduction in >85% of patients). Symptom intensity and frequency and HD grade reached a "plateau" at 3 to 6 months after the HeLP and did not change significantly thereafter (Table 1). HD recurrence rate was 5% at 2 years. No significant complications were recorded at longer follow-up, in particular stenosis of the anal canal.

Comments

In our study, the HeLP procedure showed excellent long-term outcome in terms of resolution of hemorrhoid-related symptoms, postoperative pain, and low incidence of persistent or recurrent disease. These results support the "vascular" theory in the pathogenesis of HD.

In recent years, this theory has been getting broad consensus among surgeons.[7–12,16–21] It is based on the anatomical finding of arteriovenous hemorrhoidal shunting system with no capillary interposition. It also supports the possibility that the arterial overflow in the superior hemorrhoidal arteries should be responsible of the dilatation of the hemorrhoidal venous plexus.[16–21]

As a consequence, the reduction of blood flow to the hemorrhoids should lead to shrinkage of the hemorrhoidal piles and healing of supportive tissue and, therefore, symptom improvement.[7–12,16–21] The vascular theory does not replace the ''mechanical'' theory based on degeneration of the fibromuscular supportive tissue of the hemorrhoidal plexus but rather complements the former for better understanding and treatment of HD.

Following the vascular theory, 2 nonexcisional techniques for symptomatic hemorrhoids have been developed in the last few years, namely the THD and HAL.[9,10] Both of them are based on the reduction of the hemorrhoidal arterial flow that supports the hemorrhoidal plexus by means of Doppler-guided identification and ligation of the terminal branches of the superior rectal artery.

Best results were reported when dealing with patients bothered by second- to third-degree hemorrhoids. Conversely, the results obtained in case of fourth-grade hemorrhoids were unsatisfactory, with recurrence or persistence rate of 50% to 60%.[17,22,23]

As for the HeLP, the sensitive region below the dentate line is avoided, thus obtaining less postoperative pain and shorter length of hospital stay, in most cases as day surgery hospitalization.

The absence of the need for anesthesia must be emphasized. The HeLP can be performed as ambulatory treatment, and this is a great advantage over HAL and THD.

In addition, the effect of the laser beam on the arteries is highly selective, and the damage to the tissues and mucosa around the vessels is minimal compared with other techniques.[11,12] Significantly, scar tissue and retraction of the rectal mucosa are less common compared with the THD or HAL.[11,12,24,25]

On the other hand, this could explain the less evident healing effect on mucosal prolapse following this procedure, compared with the HAL or THD, where shrinkage of the rectal mucosa is more commonly observed. Thus, precise definition of inclusion criteria for HeLP treatment is of paramount importance. Specifically, such procedure is commonly reserved to patients having symptomatic second- to third-degree HD with minimal or moderate mucosal prolapse.

Following these restricted criteria, we achieved very interesting results. Our study showed that the postoperative pain was graded 0 to 1 on VRS by most patients. The improvement of preoperative symptoms was observed within 3 to 6 months postoperatively in more than 75% of patients and downgrading of the hemorrhoids (at least 1 grade reduction) in more than 85% of subjects. The absence of significant modification in the percentage of patients with second-grade HD from preoperative data to 6 to 12 months follow-up can be easily explained by equally effective reduction of hemorrhoids size both among third- and second-grade HD subjects.

Not only patients who presented HD reduction reported an improvement of preoperative symptoms but also patients without significant HD grade modifications could experience symptom relief. These findings were still present up to 2 years postoperatively. More specifically, at 1 and 2 years follow-up, more than 90% of patients reported a resolution of their initial symptoms.

Our results confirmed the good findings previously reported by others.[11,12] It would be interesting to know the recurrence rate of symptoms and HD size on long-term evaluation on the whole-study group.

A major limitation of this study is the lack of long-term follow-up because 2-year evaluation was available only

for 34% of our patients. However, all patients included in this study are still in follow-up for further future evaluations.

Conclusions

Often poor correlation can be observed between the presence of debilitating symptoms and the HD size. Severe-looking hemorrhoids with third- to fourth-degree prolapse can cause in some patients mild symptoms, whereas itching, bleeding, and recurrent acute pain can be associated with second- to third-grade hemorrhoids with initial prolapse.[3,4] In such cases, excisional techniques or stapled hemorrhoidopexy may be an overtreatment. Instead, in these cases, the HeLP procedure can be considered a more viable option when lifestyle modification and medical treatments have failed. Our prospective study demonstrated that the HeLP is a safe, effective, and painless technique for the treatment of symptomatic second- to third-grade hemorrhoids with minimal or moderate mucosal prolapse. Furthermore, this technique is mini-invasive, does not require any kind of anesthesia, and can be performed as ambulatory treatment.

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