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ORIGINAL ARTICLE

Hemorrhoid laser procedure (HeLP) for second- and third-degree hemorrhoids: results from a long-term follow-up analysis

Nicola Crea[1] · Giacomo Pata[2] · Mauro Lippa[1] · Andrea Marco Tamburini[3] · Abdul Halim Berjaoui[1]

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Abstract

We aimed to analyze the results of 5-year consecutive use of the hemorrhoidal laser procedure (HeLP) in patients with second- to third-grade hemorrhoids with minimal or moderate mucosal prolapse. A total of 189 patients were treated between April 2012 and October 2017. We reported perioperative complications, postoperative pain, improvement of hemorrhoids grade, and relapse of hemorrhoidal disease (HD). Improvement of symptoms was assessed using the Patient Global Improvement (PGI) Scale. No severe intraoperative complications were observed. The median follow-up was 42 months (range 6–62 months). Pain after surgery was absent in 94% of patients. No cases of rectal tenesmus or alterations of defecation habits were reported. Symptoms and HD improvement reached a "plateau" at 3 to 6 months following surgery. We observed a significant decrease in HD degree, occurrence of bleeding, pain, itching, and acute HD. Complete resolution of HD was reported in > 60% of patients 1 year after surgery. The individual level of improvement in symptoms was consistent (very much and much improved, according to PGI-I score) for about 90% of patients during the follow-up. This study confirmed that the HeLP is a safe, painless, and effective procedure for the treatment of HD in selected cases.

Keywords Hemorrhoid laser procedure · Help · Patient Global Improvement Scale · Minimal invasive procedure

Introduction

Hemorrhoidal disease (HD) is a very common disease still representing a major medical and socioeconomical issue today [1, 2]. The prevalence in the USA and in Europe ranges between 4.4 and 36% [3–5]. Hemorrhoidal disease has multifactorial etiology and many controversies still remain regarding its pathogenesis. Furthermore, symptoms related to HD and its tolerance can be consistently different among patients [6, 7].

The most frequent clinical presentation consists of bleeding, pain, soiling, mucosal prolapse, and reduced quality of life [8]. The treatment of hemorrhoids has evolved during the last three decades and new painless, effective, minimally invasive procedures have been proposed, associated with low risk of anal channel damage. At present, a consistent variety of techniques is available; hence, a tailored-surgery is desirable [6–11].

In this light, a successful HD treatment should focus on patients' characteristics and symptoms, particularly on those affecting their quality of life (QoL). Interestingly, a recent study on this topic included a systematic and thorough evaluation of patients' QoL as an essential aspect of an effective procedure [6]. In the last years, a non-excisional surgical technique named hemorrhoidal laser procedure (HeLP), proposed at first by Giamundo et al [12], has been successfully performed in several hospitals. The indication for HeLP is symptomatic second- to third-degree hemorrhoids with minimal or moderate mucosal prolapse [6, 12, 13]. With this technique, a laser device produces the shrinkage of the terminal branches of the superior hemorrhoidal artery. It is normally performed as an office procedure and no general anesthesia is required.

Our study analyzed the results of 5-year systematic use of HeLP procedure in selected patients. We evaluated the outcome in terms of hemorrhoid shrinkage, clinical

✉ Nicola Crea
creanico@gmail.com

[1] Department of General Surgery, Sant'Anna Clinic Institute, Via del Franzone 31, Brescia, Italy

[2] General Surgery 2 Unit, University Hospital ASST Spedali Civili of Brescia, P.le Spedali Civili 1, 25125 Brescia, Italy

[3] Gastrointestinal Surgery, San Raffaele Scientific Institute, Milan, Italy

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improvement, and quality of life amelioration using the Patient Global Impression of Improvement (PGI-I) Scale.

Methods

Between April 2012 and October 2017, 189 patients underwent the hemorrhoidal laser procedure (HeLP) for symptomatic HD at the Department of General Surgery, S. Anna Clinical Institute, Brescia, Italy. All patients included in the study gave their informed consent for this procedure, treatment of data, and follow-up. All the procedures were performed according to the ethical standards of our internal committee and with the 1964 Helsinki declaration and its amendments or comparable ethical standards.

Before surgery, all patients were studied by medical history assessment, blood test, and clinical examination.

A 4-point visual-verbal scale (VRS) was applied to evaluate the presence of pain: no pain was recorded as 0; 1 point corresponded to infrequent discomfort not affecting daily life; 2 was a pain defined as "moderate" and interfering normal activities; 3 points were assigned to "severe" pain.

Anoscopy was routinely employed for anal channel evaluation.

Colonoscopy was performed preoperatively in cases of bleeding not HD related, as indicated by the colorectal screening guidelines [14–16].

The proctological assessment at the first outpatient date consisted of hemorrhoidal grade evaluation both in normal condition and during Valsalva maneuver.

Goligher hemorrhoid classification [16] was used, both for preoperative and postoperative evaluation.

Non-protruding hemorrhoids during the Valsalva maneuver were considered as first degree; those protruding and self-reentering as second degree; those protruding and manually reentering as third degree; those not reentering as fourth degree HD.

Inclusion criteria for treatment were symptomatic second- to third-degree hemorrhoids with low or moderate prolapse, after ascertained failure of conservative medical treatments. We did not propose the HeLP procedure in case of obstructed defecation syndrome (ODS), third degree with severe mucosal prolapse, or fourth-degree HD at preoperative assessment. In such cases, a failure of that treatment would be expected. Acute or recent hemorrhoidal thrombosis, anal stenosis, fistulas, and active inflammatory bowel disease represented further exclusion criteria for HeLP.

The indication to the HeLP procedure also took into account the patient's description of symptoms, preferences, and expectations.

We confirmed (or denied) the indications to the procedure during a second visit carried out at the time of preadmission.

The institutional review board has approved this study.

Surgical technique

All the procedures were carried out by two equally trained and skilled surgeons using the HeLP kit from Biolitec AG-CeramOptec (Bonn, Germany) and following the surgical technique previously described [12, 17].

All operations were performed without general, spinal, or injective local anesthesia; only topical anesthesia (EMLA® cream) was applied; aware sedation was used on patient's demand. The HeLP procedure was performed as office procedure and all patients were discharged 4 h after treatment. No intestinal preparation was required; two enemas (one the evening before surgery and the other few hours before surgery) were administered. Analgesic drugs were used only on demand (usually paracetamol or ketorolac).

Information about procedure duration, perioperative complication, postoperative pain, downgrading of HD, resolution, or recurrence of disease was collected.

Major bleeding was defined as any bleeding requiring surgical hemostasis.

The 4-point visual-verbal scale was applied to evaluate the perioperative and postoperative pain.

The grade of postoperative improvement was evaluated as proposed by De Nardi et al. by the seven-point Patient Global Impression of Improvement (PGI-I) Scale [18]: very much improved = 1, much improved = 2, minimally improved = 3, no change = 4, minimally worsened = 5, much worsened = 6 and very much worsened = 7. The follow-up included clinical evaluation, digital rectal examination, and anoscopy 2 and 4 weeks after surgery, 3, 6, and 12 months postoperatively, and annually thereafter. At 3, 6, 12 months, and then yearly after surgery, patients reported their improvement by the PGI-I Scale.

No patients were lost at follow-up both thanks to continuous contact by our surgical team and patients' manager nurse.

Statistical analysis

The chi-square test was used to compare categorical variables. Odds ratios (OR) and 95% CI were calculated when required. The Mann-Whitney *U* test was used to compare continuous variables not normally distributed (presented as median, interquartile range (IQR), and range). Normality of variables distribution was determined using the D'Agostino-Pearson test. A p value < 0.05 was considered as statistically significant. All tests were two sided. Statistical analysis was performed with

statistical software for biomedical research (McCalc® Software for Windows).

Results

A total of 189 patients were enrolled in the study (111 men, 58.7%), from April 2012 to October 2017, with a median age of 45 years (range 18–73 years).

Altogether, 101 patients (53.4%) had second-grade hemorrhoids and 88 (46.6%) had third-grade hemorrhoids.

The most frequent preoperative symptoms were bleeding (109 cases, 58%) and pain (31 cases, 16%) (Table 1). Persistent hemorrhoidal acute syndrome (HAS) (defined as the presence of pain, mucosal discharge, and bleeding lasting for 5–7 consecutive days at least 2 times/year during the past 2 years) was recorded in 22 patients (11.5%).

The HeLP median duration time was 20 min (IQR 18–23 min; range 15–35 min). Ten to 14 arterial branches were detected and closed with the laser. In 13 patients (7%), we recorded a minor intraoperative bleeding that was effectively treated with the laser in almost all cases (3 cases required reabsorbable sutures to secure hemostasis). All patients were dismissed 4 h after surgery and were able to return to usual daily activities within 48 h. Eleven patients (6%) required oral analgesic drugs for 24–48 h after the HeLP (paracetamol 1000 mg every 12–8 h).

The median follow-up was 42 months (range 6–62 months).

One week after surgery, 86% of patients showed grade 0 pain on VRS and the remaining 14% reported grade 1. Improvement of symptoms over the follow-up period was significant as displayed in Table 1.

Significant hemorrhoid downgrading was recorded 1 month after the procedure: the incidence of third-grade HD decreased from 46.6 to 20.1% ($p < 0.0001$) that of second-grade HD did from 53.4 to 42.9% ($p = 0.052$). This trend was confirmed during the entire follow-up, as reported in detail in Table 1. One month after treatment, 37% of patients got HD downgraded to first grade. A further improvement was recorded in subsequent checks, reaching the plateau (around 60–65%) 12–24 months after HeLP ($p < 0.0001$ when compared to preoperative rate). All patients with HD reduction also reported preoperative symptoms improvement. The improvement of symptoms was recorded also in patients who did not have any HD downgrading; in particular 3 years after HeLP only 18 out of the 41 patients (43.9%) still suffering from II–III-degree hemorrhoids reported any HD-related symptom (persisting bleeding, pain, or itching) compared to 167/189 (88.3%) patients before the treatment ($p < 0.0001$).

No patient suffered from rectal tenesmus, stenosis of the anal canal, or alteration of defecation habits. No patient underwent other surgical procedures during follow-up.

Patients' perception of clinical improvement was significant at each follow-up appointment: it was graded as "very much or much improved" by nearly 95% of cases at 3–6 months and by nearly 90% at 12–60 months postoperatively. Minimal improvement or no change was reported by 3–5.7% of patients at 3–6-month follow-up, and by 7% thereafter. Detailed data are reported in Fig. 1.

Discussion and conclusions

The current study confirmed the result of previous trials [17, 18]: the HeLP is a secure and effective procedure for the treatment of HD being also associated with low pain rate after surgery and low frequency of persistent or recurring disease. The novelty of this study is the long-term follow-up (84% of patients had at least 1 year postoperative evaluation), since several former studies just report short- or medium-term outcomes [11–13, 18].

We observed an excellent persistence of the improvement of HD-related symptoms. Over the past few decades, the excisional techniques, i.e., Milligan-Morgan and Ferguson hemorrhoidectomies, were considered the most effective procedures for HD treatment, even if burdened with postoperative pain and several complicationsc [7–13, 18–27].

In the last years, supported by the results of the HeLP, the "vascular" theory has been gaining increasing consent in the understanding of the pathogenesis of HD, alongside the "mechanical" theory [18–21].

The "vascular" theory demonstrates that the arterial overflow in the superior hemorrhoidal arteries would lead to dilatation of the hemorrhoidal venous plexus, based on the anatomical findings of arteriovenous hemorrhoidal shunting system without capillary interposition. On the other side, the "mechanical" theory sustains that the muscular fibroplastic supportive tissue of the hemorrhoidal plexus would degenerate in subjects suffering from hemorrhoidal disease [18–21].

In recent years, some non-excisional techniques have been used. In particular, the attention has been focused on THD and HAL. These are based on the decrease of the arterial flow in the hemorrhoidal cushions obtained with the ligation, under Doppler guidance, of the terminal divisions of the hemorrhoidal arteries [10, 11].

More recently, Brusciano [28] proposed a laser-based non-excisional procedure (laser hemorrhoidoplasty), showing promising results [28].

The HeLP was suggested as an innovative mini-invasive procedure where the shrinking of the terminal branches of the superior rectal artery and the sealing of the arterial flow were obtained using the laser device [6, 10, 11]. Many papers have pointed out that this surgical technique is effective and with low postoperative pain and morbidity [6, 12, 13, 17, 18].

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

Symptoms (any grade)	Preop (189pts) *n* (%)	1 month (189 pts) *n* (%)	3 months (189 pts) *n* (%)	6 months (189 pts) n (%)	1 year (159 pts) *n* (%)	2 years (134 pts) *n* (%)	3 years (120 pts) *n* (%)	4 years (109 pts) *n* (%)	5 years (97 pts) *n* (%)
Bleeding	109 (57.8)	47 (24.9) $^{\#}p < 0.0001$	21 (11.1) $^{\#\#}p < 0.0001$	18 (9.5)	16 (10) $^{*}p < 0.0001$	14 (10.4)	12 (10) $^{**}p < 0.0001$	11 (10)	11 (11) $^{***}p < 0.0001$
Pain	31 (16.4)	16 (8.5) $^{\#}p = 0.03$	6 (3.2) $^{\#\#}p < 0.0001$	5 (2.6)	5 (3.1) $^{*}p = 0.0001$	4 (2.9)	3 (2.5) $^{**}p = 0.0003$	3 (2.7)	4 (4.1) $^{***}p = 0.0049$
Itching	27 (14.3)	11 (5.8) $^{\#}p = 0.01$	5 (2.6) $^{\#\#}p = 0.0001$	4 (2.1)	4 (2.5) $^{*}p = 0.0003$	3 (2.2)	*3* (2.5) $^{**}p = 0.0013$	3 (2.7)	3 (3.1) $^{***}p = 0.0065$
HAS	22 (11.5)	9 (4.8) $^{\#}p = 0.028$	4 (2.1) $^{\#\#}p = 0.0006$	4 (2.1)	3 (1.9) $^{*}p = 0.0011$	3 (2.2)	3 (2.5) $^{**}p = 0.0086$	3 (2.7)	3 (3.1) $^{***}p = 0.03$
HD grade									
I	0	70 (37) $^{\#}p < 0.0001$	105 (55.5) $^{\#\#}p < 0.0001$	107 (56.7)	98 (61.7) $^{*}p < 0.0001$	88 (65.7)	79 (65.8) $^{**}p < 0.0001$	69 (63.3)	59 (60.8) $^{***}p < 0.0001$
II	101 (53.4)	81 (42.9) $^{\#}p = 0.052$	65 (34.5) $^{\#\#}p = 0.0003$	64 (33.8)	40 (25.1) $^{*}p < 0.0001$	30 (22.4)	26 (21.7) $^{**}p < 0.0001$	27 (24.8)	26 (26.8) $^{***}p < 0.0001$
III	88 (46.6)	38 (20.1) $^{\#}p < 0.0001$	19 (10) $^{\#\#}p < 0.0001$	18 (9.5)	21 (13.2) $^{*}p < 0.0001$	16 (11.9)	15 (12.5) $^{**}p < 0.0001$	13 (11.9)	12 (12.4) $^{***}p < 0.0001$

[#] Between preop and 1-month f.u.

[##] Between preop and 3-month f.u.

*Between preop and 1-year f.u.

**Between preop and 3-year f.u.

***Between preop and 5-year f.u.

The choice of the more indicated procedure should be made considering different factors such as preoperative Goligher grading, symptoms, presence, and severity of prolapse and patients' expectations. As suggested by Giamundo [6], there is poor correlation between hemorrhoidal grading, severity, and improvement of symptoms. This finding was confirmed also by our experience.

In this light, we also chose the HeLP in patients with symptomatic second-degree hemorrhoids (after failure of medical treatment) even if this option could be debatable, considering the possibility of rubber band ligation or sclerotherapy [6].

Furthermore, the presence at preoperative assessment of moderate mucosal prolapse, only requiring occasional manual reduction, does not represent an absolute contraindication to HeLP [6]. In fact, in these patients, the decision to perform different surgical procedures (such as hemorrhoidectomy, PPH, and hemorrohoidopexy) should be considered too invasive.

One of the most significant advantages of HeLP when compared to more invasive methods is the absence of anal wounds, which significantly reduces the postoperative pain and discomfort. In addition, it only generates minimal damage to mucosal and submucosal tissue [29, 30]. The preservation of the anal anatomy and physiology should not be ignored. Noteworthy, impaired anal function, including fecal incontinence, pelvic floor incoordination, and defecation disorders, has been reported following traditional HD surgical treatments [5] with necessity of pelvic rehabilitation [31].

The anticipated reduction of postoperative pain and alleviation of symptoms makes this procedure highly appreciated by patients. Early and mid-term results have shown high success and improvement of symptoms rates [25].

When compared to other more invasive procedures (Milligan-Morgan or stapled hemorrhoidopexy or even PPH), the HeLP may have the advantage of reducing the incidence of severe complications. In contrast, the good long-term results in terms of HD symptoms may be associated with little higher recurrence rates compared to conventional hemorrhoidectomy in case of higher hemorrhoidal grade [5]. As such, in addition to the advantages in terms of rapid decrease of pain and bleeding and quicker return to daily activities, patients must be informed of this eventuality, especially in case of 3rd-degree hemorrhoids with moderate mucosal prolapse.

As discussed by Giamundo [6], the HeLP procedure may have advantages when compared with ligation: it could be performed without general or spinal anesthesia as office procedure and is painless since the laser is applied around 2.5 cm above the dentate line (that is relatively insensitive).

When compared with THD or HAL, a major difference consists of the number of arterial branches treated: 10 to 14 arteries are detected and shrinked with laser while only 6 to 8 with the ligation. In fact, while THD uses a 6–8-MHz Doppler, the HeLP uses a 20-MHz Doppler device that is strongly accurate in detecting the arterial branches of the superior rectal artery. In addition, as confirmed by Giamundo et al. [30] in a recent multicentric prospective paper, the HeLP is a quite easy technique to perform for trained surgeons who attended the theoretical and live-surgery course, after an estimated 10-procedure learning curve.

A point of strength of the present study is the consistent number of subjects included with a long-term follow-up. According to our experience, two key points of the HeLP must be stressed: the absence of the need for anesthesia (only topical anesthetic ointment) and a very low postoperative pain rate. These two aspects lead to possible discharge within a few hours after surgery.

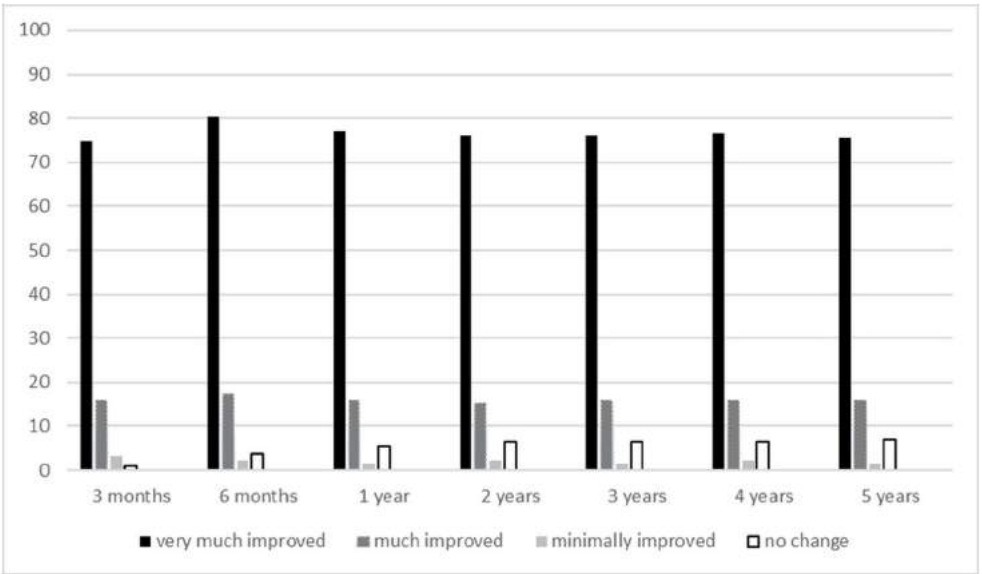

Fig. 1 Patient Global Improvement (PGI) score during the follow-up

As proposed by De Nardi et al. [18], we applied the PGI-I to evaluate the patients' opinion about improvement or relapse after surgery. Bleeding, pain, and other HD-related symptoms were rapidly improved after the procedure and maintained during the follow-up.

Moreover, we recorded a significant and long-lasting HD downgrading. We observed that HD degree and symptoms are poorly correlated and symptom improvement could be also observed in patients who did not have any HD downgrading. This finding is in line with previously reported data. [17–30]

We acknowledge that the PGI-I has been applied mainly after surgical procedure for urinary incontinence and prolapse [32, 33], but it proved a reliable scale to evaluate the clinical effect of different surgical treatments, such as in case of HD [18]. More than 90% of patient rated their postoperative condition as very much or much improved. No patient experienced worsening compared to preoperative situation. Our good long-term results, including low rate of recurrence, low postoperative complications, and high patients' satisfaction, encouraged us to continue using HeLP instead of other minimally invasive procedures.

In conclusion, this study confirmed that the HeLP is a safe, painless, and effective procedure for the treatment of HD in selected cases. Multicentric studies with larger number of cases and longer follow-up are required to confirm our findings and ascertain the advantages of this procedure over traditional mini-invasive procedures.

We also acknowledge that comparison of HeLP with the aforementioned minimally invasive techniques in a trial setting would be of paramount interest to draw firm conclusions.

Authors' contributions All authors gave the same contribution in terms of data collecting, statistical analysis, and surgical performance.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval The institutional review board has approved this study.

Consent to participate All patients included in the study gave their informed consent for this procedure, treatment of data and follow-up. All the procedures were performed according to the ethical standards of our internal committee and with the 1964 Helsinki declaration and its amendments or comparable ethical standards.

Consent for publication Not applicable.

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Doppler-guided hemorrhoidal dearterialization with laser (HeLP): indications and clinical outcome in the long-term. Results of a multicenter trial

Paolo Giamundo[1,8] · Andrea Braini[2] · Giuseppe Calabrò[3] · Nicola Crea[4] · Paola De Nardi[5] · Fabio Fabiano[6] · Mauro Lippa[4] · Alessandro Mastromarino[7] · Andrea M. Tamburini[5]

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Abstract

Background Doppler-guided hemorrhoidal laser procedure consists of sutureless closure of terminal branches of the superior hemorrhoidal artery by laser energy. Clinical results of patients treated with this procedure were analyzed at the completion of 2-year follow-up. Primary endpoint was resolution of symptoms and secondary endpoints were recurrence rate, type of recurrences, re-operation rate, and potential predictive factors for failure.

Methods Bleeding was assessed on a score from 0 to 4 (none = 0; < 1/month = 1; 1/week = 2; > 1/week = 3; 3–4/week = 4), frequency of hemorrhoid-related symptoms with a score of 0–3 (2/year = 1; 3–5/year = 2; < 5/year = 3). Constipation and fecal incontinence were assessed by means of validated scores. Quality of life and pain at defecation were assessed using a visual analog scale of 0–10 (0 = worst possible–10 = best possible quality of life and 0 = no pain–10 = worst pain imaginable, respectively). Recurrence rate and need for re-operation were reported. Potential predictive factors of failure were analyzed by means of univariate analysis.

Results Two-hundred-eighty-four patients (183 males, 101 females; mean age: 47.5 years) were included in the trial; 8 patients were lost at follow-up. Analysis of 276 patients who completed the 2-year follow-up showed an overall resolution of symptoms in 89.9% (248/276) of patients. Statistically significant improvement of quality of life, pain reduction, bleeding and frequency of acute symptoms were reported. Of 28 patients with persistent or recurrent symptoms, 12 had pain (4.35%), 10 had bleeding (3.6%) and 6 had increasing prolapse at defecation (2.2%). Eleven out of twenty-eight patients required additional surgery. Constipation and III–IV grade hemorrhoids were associated with statistically significant higher failure rates ($p = 0.046$ and 0.012, respectively). Better results were reported in patients reporting preoperative high-grade pain at evacuation.

Conclusions The Doppler-guided hemorrhoidal laser procedure showed efficacy at long-term follow-up. It can be considered as 'first-line' treatment in patients with low-grade hemorrhoids suffering from bleeding, pain and recurrent acute symptoms in whom conservative treatment failed.

Keywords Laser · Hemorrhoids · Sutureless dearterialization · Minimally invasive treatment · HeLP

✉ Paolo Giamundo
pgiamundo@gmail.com

[1] Department of Colorectal Surgery, Policlinico di Monza, Monza, Italy

[2] Department of General Surgery, AAS5 Friuli occidentale, Pordenone, Italy

[3] Humanitas Gavazzeni Institute, Bergamo, Italy

[4] Department of General Surgery, Sant'Anna Clinic, Brescia, Italy

[5] Gastrointestinal Surgery, IRCCS San Raffaele Scientific Institute, Milan, Italy

[6] Department of General Surgery, Evangelic International Hospital, Genoa, Italy

[7] Vascular Surgery, San Salvatore Hospital, L'Aquila, Italy

[8] Via Rolfi 4/E, 12069 Santa Vittoria d'Alba, CN, Italy

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Doppler-guided hemorrhoidal dearterialization (HeLP) is a form of dearterialization for the treatment of symptomatic hemorrhoids. The HeLP procedure can be considered a reappraisal of the original hemorrhoidal dearterialization ligation (HAL) proposed by Morinaga in 1995 [1]. Both techniques are based on the assumption that the cause of enlargement of the hemorrhoidal venous plexus and related symptoms lies in the blood overflow coming from the superior hemorrhoidal arteries into the hemorrhoidal veins.

Compared to previously described dearterialization procedures, HeLP has the potential advantage of being less invasive; the Doppler-guided laser energy selectively shrinks the most distal and superficial branches of the superior hemorrhoidal arteries without the need for sutures and without damaging the surrounding tissue. Since the procedure is associated with very minimal pain, anesthesia is deemed unnecessary and sedation or loco-regional anesthesia is administered only in a few selected cases. Thus, HeLP can be performed as an out-patient procedure. A prospective multicenter trial was initiated in January 2016 in seven different centers. The short-term clinical results and the analysis of a subgroup of 144 patients at one-year follow-up have been reported in our previous publication [2]. The aim of the current prospective study was to implement the trial by assessing clinical results and analyzing potential predictive factors of failure at the completion of the 2-year follow-up for all patients.

Materials and methods

A multicenter, longitudinal study of a cohort of patients treated with Doppler-guided hemorrhoidal dearterialization from January 2016 to November 2017 in seven different centers affiliated with the GILP (Italian Group Laser in Proctology) group was conducted. All patients complained of hemorrhoid-related symptoms unresponsive to conservative treatment. Patients with high-grade prolapse requiring manual reduction at each evacuation, confirmed at preoperative clinical and proctoscopic evaluation, were excluded from the study with the exception of four patients with IV degree hemorrhoids whose poor medical conditions contraindicated more invasive treatments. Patients were asked to complete a preoperative questionnaire regarding medical history and symptoms, including constipation and anal incontinence scores [3,4].

Bleeding was assessed on a scale of 0–4 (0 = no bleeding; 1 ≤ 1 episode per month; 2 ≤ 1 episode per week; 3 = 1 to 3 episodes per week and 4 = 4 or > 4 episodes per week). Pain was assessed using a visual analog scale (VAS) of 0–10 where 0 = no pain and 10 = the worst pain imaginable.

Subjective evaluation of quality of life (QOL) was assessed by means of a visual analog scale (VAS) of 0–10, where 0 the worst possible and 10 = the best possible QOL. Hemorrhoids were classified according to Goligher's grading system [5].

Written informed consent was obtained by all patients. The trial was conducted in accordance with the ethical standards reported in the Declaration of Helsinki. The procedure was the same as that described in prior publications [2, 6] and is part of routine surgical practice in all centers participating to the trial. Therefore, this type of study was deemed exempt from IRB approval in all the participating institutions.

Procedure

Using a specially designed proctoscope (kit for HeLP^{R}, Biolitec Biomedical Technology, Germany), 12 terminal branches of the superior rectal arteries were identified by means of a 20 MHz Doppler probe and sealed by means of laser energy approximately 2–3 cm above the dentate line. A diode laser platform (Leonardo Dual 45, Biolitec Biomedical Technology, Germany), delivering 13 W of pulsed laser energy at the wavelength of 980 nm allowed closure of the identified arteries (Fig. 1). Selective absorption of

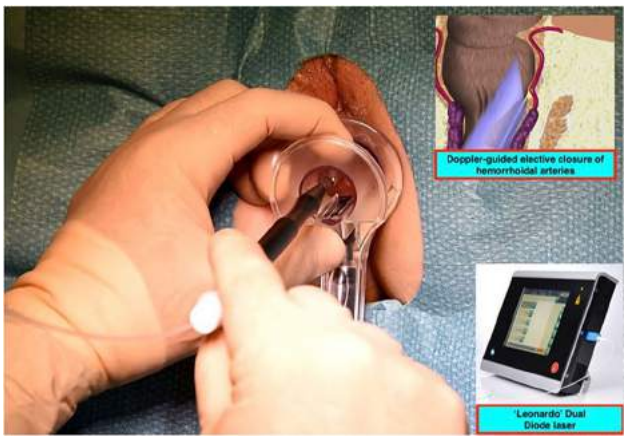

Fig. 1 Laser closure of hemorrhoidal arteries identified by Doppler

laser beam by chromophores of hemoglobin allowed shrinkage of the arteries, limiting the thermal effect on the surrounding tissue [6]. Follow-up was scheduled at 1, 6, 12, and 24 months after the procedure.

Preliminary results showing clinical outcome at 6 months and analysis of a subgroup of 144 patients at 12 months follow-up were the objectives of our previously published study [2]. To obtain homogeneous data, analysis in the current study focused on the clinical results obtained at the completion of the trial, at 24 months follow-up, for all participating patients.

Statistical analysis

All statistical analyses were performed using SPSS (version, IBM Corp, Armonk, NY, USA). Quantitative data were expressed as median/range and mean ± SD. Age, grade of hemorrhoids, preoperative bleeding, pain at evacuation, and constipation score were assessed as potentially predictive factors of failure by means of univariate analysis. Student's *t* test and χ^2 test were used where appropriate to analyze data. Statistically significance was reached when *p* value resulted < 0.05.

Results

Two-hundred-eighty-four patients (183 males and 101 females) with a mean age of 47.5 years were included in the trial. Ten (3.5%) had recurrent symptoms after previous surgery for hemorrhoids.

Five patients were classified as Grade I, 174 as Grade II, 101 as Grade III and four as Grade IV hemorrhoids. The frequency of acute hemorrhoid-related episodes requiring medical therapy was reported as 3–5 episodes per year in 142 patients (50%) and > 5 episodes per year in 137 patients (48%). Bleeding was the most frequent symptom (63%). Frequency of bleeding was reported as 1–2 times per week in 114 (40%) and > 3–4 times per week in 64 (23%) patients.

At 2 years postoperatively, 8 patients were lost at follow-up. The final outcome of the 276 patients (179 males) who completed the 2-year follow-up are summarized in Table 1. Statistically significant improvement of subjective evaluation of QOL (from a mean of 4.63 ± 0.62 to 8.62 ± 1.48; $p < 0.0001$), reduction of pain (from a mean of 4.8 ± 1.22 to 1.85 ± 1.38; $p < 0.0001$), bleeding (from a mean of 2.4 ± 1.07 to 0.63 ± 0.81; $p < 0.0001$), and frequency of acute symptoms (from a mean of 2.03 ± 0.16 to 0.63 ± 0.81; $p < 0.0001$) were reported. No statistically significant difference was reported between pre- and postoperative constipation and incontinence scores.

Overall resolution of symptoms at 2 years was observed in 248/276 (89.9%) patients. 256 (92.8%) reported personal satisfaction with the procedure and declared they were willing to recommend the procedure.

Of the 28 (10.1%) patients with persistent or recurrent symptoms, 12 had pain (4.35%), 10 had bleeding (3.6%) and 6 (2.2%) had bothersome prolapse at defecation; 11 of these 28 patients required additional surgery. One was treated with rubber band ligation (RBL), one with Procedure for Prolapse and Hemorrhoids (PPH) 2 with HeLPexx (HeLP + mucosopexy), 3 with redo-HeLP, and 4 with Milligan & Morgan.

At univariate analysis, constipation and high-grade hemorrhoids were associated with statistically significant higher failure rates ($p = 0.046$ and 0.012, respectively). A higher success rate was reported in patients with a higher preoperative pain score at evacuation ($p = 0.028$). Age, gender, and bleeding score were not significantly associated with failure (Table 2).

Discussion

The difference between HeLP and other techniques of hemorrhoidal dearterialization is the method of reducing blood overflow from the hemorrhoidal arterial system into the hemorrhoidal veins plexus. In the HeLP procedure, 12 terminal branches of the superior rectal artery, clearly identified

Table 1 Results at 24-month follow-up

Patients	(*n* = 276)	Overall resolution of symptoms: 248 (89.9%) Overall personal satisfaction: 256 (92.8%)	*p* value[c]
	Preoperative	Postoperative	
Bleeding score[a]	2.4 ± 1.07	0.63 ± 0.81	< 0.0001
Quality of life (VAS)	4.63 ± 0.62	8.62 ± 1.48	< 0.0001
Pain at evacuation (VAS)	4.8 ± 1.22	1.85 ± 1.38	< 0.0001
Frequency of acute symptoms requiring medication[b]	2.03 ± 0.16	0.63 ± 0.81	< 0.0001
Constipation score	2.55 ± 2.57	2.7 ± 2.94	0.84
Incontinence score	3.2 ± 1.80	3.1 ± 1.97	0.58

Values expressed as mean ± SD

VAS Visual Analog Scale

[a]Bleeding score expressed as: < 1/month = 1; 1/week = 2; > 1/week = 3; 3–4/week = 4

[b]Expressed as: 2/year = 1; 3–5/year = 2; < 5/year = 3

[c]Student's *t* test

with a 20 MHz Doppler probe, are closed by means of diode laser energy. The use of a point-shaped Doppler probe set at a frequency of 20 MHz is deemed necessary for accurate identification of the arterial branches, whose diameter varies between 0.6 and 2 mm and are approximately 2 mm deep. In the Hemorrhoidal Arterial Ligation (HAL) or Transanal Hemorrhoidal dearterialization (THD) procedures, 6–8 arteries are identified by means of a 7 MHz Doppler probe and closed approximately 4–5 cm above the dentate line using suture-ligation [1,7].

In the HeLP, the distal branches of the superior hemorrhoidal artery are sealed just prior to entering the hemorrhoidal venous plexus above the dentate line, where no interposition of capillaries between the arterial and venous systems has been found [8,9]. In doing this, complications are minimized and the reduction of blood overflow into the venous plexus is enhanced. The need for Doppler guidance for the HeLP is crucial due to the small size of the distal arterial branches and the large variation in the anatomical site of the arteries a few centimeters above the dentate line. Furthermore, accurate identification of the arteries is particularly required considerating the restricted field of action of laser energy, which is confined to a distance of 4 mm from the laser-emitting probe.

In contrast to the Laser Hemorrhoido-Plasty (LHP), which is another recently proposed laser procedure, the HeLP uses laser energy to close the hemorrhoidal arteries without treating the distal hemorrhoidal piles. LHP delivers laser energy directly into the enlarged hemorrhoidal plexus in an attempt to shrink the piles [10,11] without targeting the blood overflow, which is the potential etiopathogenetic factor of hemorrhoids. This aspect of the LHP procedure may be responsible for the higher recurrence rate at longer term follow-up [12]. In addition, the thermal effect caused by laser energy on the surrounding tissues cannot be completely controlled. This factor could explain the high morbidity rate (18%) with 3 Clavien–Dindo grade IIIb complications in patients treated with LHP in a recent study [12]. One potential advantage of the HeLP procedure is lower morbidity and better pain control, compared to the LHP. Furthermore, HeLP can be performed without anesthesia in an out-patient setting.

To date, no comparative studies between the two laser procedures have been conducted. It is noteworthy that, in most series, LHP included a suture-pexy [13,14]. In this regard, the LHP procedure should be compared with more invasive techniques such as PPH, THD, HeLpexx or Milligan and Morgan hemorrhoidectomy and, in general, with procedures requiring anesthesia rather than with almost painless, minimally invasive procedures such as HeLP.

The efficacy, safety, and high success rate of the HeLP have been reported in previous publications (Table 3) [2,15–19]. A randomized multicenter trial comparing the HeLP with RBL, which is the most common minimally invasive procedure to treat hemorrhoids, showed a statistically significant higher success rate in patients treated with laser, including better control over postoperative pain [20].

In our previous short-term analysis, an overall resolution of symptoms of 90.3% (130/144 patients) was reported at one-year follow-up [2]. The current prospective study, based on almost double the number of patients who completed the 2-year follow-up, confirmed the good initial results. A resolution of symptoms in 89.6% of patients (248/276) and a satisfaction rate of 93% was reported, showing a stable healing curve. The recurrence rate was very low at 10.1% (28/276), with only 11 patients requiring further surgery.

Surprisingly, these data are not much different than those from the majority of published studies regarding more invasive forms of dearterialization (HAL, THD) that showed failure rates varying between 3 and 24% and a reintervention rate to treat recurrent symptoms varying between 2.7 and 22% [21].

The high success and low recurrence rates with the HeLP reported in our series may be explained by the stringent patient selection. The presence of preoperative severe and symptomatic mucosal prolapse can be considered a relative contraindication for HeLP and, in general, was an exclusion criterion for our trial. In the case of high-grade prolapsing hemorrhoids, plication of the prolapse (mucopexy) is advised in order to implement the effectiveness of laser dearterialization (HeLPexx) [22]. This was confirmed in our study that showed better results in low-grade hemorrhoids.

Table 2 Univariate analysis of possible predictive factors ($n=276$ patients at 2-year follow-up)

Factor	Success ($n=248$)	Failure ($n=28$)	p
Age (years)	47.5 ± 9.53[a]	43.37 ± 9.53	0.09[d] ns
Gender			0.95[e] ns
Male	161	18	
Female	87	10	
Grade of hemorrhoids			0.012[e]
I ($n=2$)–II ($n=172$)	162	12	
III ($n=100$)–IV ($n=2$)	86	16	
Constipation score	2.37 ± 1.67[a]	5.3 ± 7.64	0.046[d]
Bleeding score[b]	2.27 ± 1..67[a]	2.5 ± 0.95	0.62[d] ns
Pain at evacuation[c]	4.83 ± 2.50[a]	3.11 ± 3.18	0.028[d]

[a]Values expressed as mean ± SD

[b]Bleeding score expressed as: > 1/month = 1; 1/week = 2; > 1/week = 3; > 3–4/week = 4

[c]VAS (Visual Analog Scale 1–10 where 0 = no pain and 10 = worst imaginable pain)

[d]Student's t test

[e]χ^2 test

Table 3 Published studies on the HeLP procedure

Study	Country	Design	Number of patients	Year	Follow-up (months)	Success rate (%)
Giamundo [6]	Italy	Prospective	30	2011	6	92.8
Crea [15]	Italy	Retrospective	97	2014	15	76–79
De Nardi [16]	Italy	Multicenter	51	2016	12	86.3
Boarini [18]	Brazil	Prospective	55	2017	6	84
Giamundo [17]	Italy	Prospective	268	2018	48	85
Ram [19]	Israel	Prospective	62	2018	6	NA (significant)
Giamundo [2]	Italy	Multicenter	144	2019	12	90.3
Current study	Italy	Multicenter	276	2020	24	89.9

The high patient satisfaction rate was mainly due to the minimal invasiveness of the procedure, very low intra- and postoperative pain, low overall discomfort, and rapid resumption of daily activities [2]. In addition, the possibility of undergoing HeLP without anesthesia contributed to the patients' high compliance rate. In our practice, an increasing number of patients is giving preference to this procedure in case of failure of conservative treatments.

In cases of failure in our study, pain was reported as the most commonly recurring symptom. Nevertheless, patients with preoperative high pain scores at defecation showed better postoperative outcomes in our series. Postoperative bleeding was reported in only 10 (3.6%) and increasing prolapse in 6 (2.2%) cases. These data confirm the long-lasting efficacy of dearterialization with HeLP, especially regarding bleeding which was the most frequent preoperative symptom in our series and is often responsible for patients' anxiety and discomfort.

Our long-term results confirm the absence of any alteration of the physiology and anatomy of the anal canal after laser treatment. None of the patients in our study reported any variation in continence or constipation.

At univariate analysis, constipation was a significant factor for failure. To avoid constipation, dietary adjustments and bland laxatives may be useful in the postoperative course in order to potentially reduce the incidence of recurrence.

Finally, our data confirmed that the main indication for HeLP was low-grade prolapse, not low-grade symptoms. Also, the potential benefit of this procedure in preventing the natural progression toward more severe disease cannot be ignored.

HeLP showed to be cost-effective since the procedure can be performed in an out-patient setting, thus avoiding the need for additional expensive resources. It also has organizational and health service advantages as it reduces patient waiting times and patient turn-over.

The disposable kit for HeLP costs approximately 400 Euros (US $ 470); both the laser and Doppler platforms are leased to the hospitals free of charge. The procedure is fast and is performed without anesthesia, therefore the costs related to operating rooms occupancy and anesthesiologists are significantly reduced or eliminated. In this regard an analysis of costs showed the HeLP to be cost-effective even compared with open hemorrhoidectomy or other techniques that use less expensive surgical equipments.

Study limitations include: the lack of very long-term follow-up the absence of comparative study with other procedures, the potential variation in the grading of hemorrhoids between observers in different centers and the use of non-validated QoL questionnaires.

Conclusions

Our long-term follow-up confirmed the efficacy of HeLP in curing patients with symptomatic hemorrhoids and low-grade prolapse. The minimal invasiveness, low pain, good success rate, and absence of alteration of the anatomy and physiology of the anal canal would suggest its use as 'first-line treatment' in symptomatic patients when medical therapy fails despite the absence of a comparative randomized trial.

Careful selection of patients is deemed necessary in order to maximize the success rate.

Multicenter randomized trials comparing this procedure to other minimally invasive techniques may be helpful in defining the role of the HeLP in the routine colorectal surgery practice.

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Compliance with ethical standards

Disclosures Paolo Giamundo has been hired as "surgical trainer" for live surgery demonstrations by Biolitec Italia. Andrea Braini, Giuseppe Calabrò, Nicola Crea, Paola De Nardi, Fabio Fabiano, Mauro Lippa, Alessandro Mastromarino, Andrea M. Tamburini have no conflicts of interest or financial ties to disclose.

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ORIGINAL ARTICLE

Hemorrhoid laser procedure with suture-pexy (HeLPexx): a novel effective procedure to treat hemorrhoidal disease

P. Giamundo[1] · M. De Angelis[2] · A. Mereu[2]

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Abstract

Background The hemorrhoid laser procedure with suture-pexy (HeLPexx), consisting of Doppler-guided hemorrhoidal dearterialization with laser and the addition of anal mucopexy, is a novel non-excisional procedure to treat hemorrhoids. The aim of the present study was to describe the technique and report the clinical and long-term results.

Methods A prospective study was conducted on patients with grade III hemorrhoids who had HeLPexx from January 2012 to February 2018. Pre- and postoperative assessment included a thorough clinical examination, constipation and incontinence scoring systems and a symptom questionnaire which was administered at all patients before surgery and at each follow-up visit to evaluate bleeding, prolapse, manual reduction, discomfort or pain, and impact on quality of life. Each symptom had a score between 0 and 4, (0 indicates no symptoms and 4 indicates daily symptoms). The sum of the score for each symptom constituted the Hemorrhoid Symptom Score. Resolution of symptoms, pain, morbidity, need for further medical and/or surgical therapy were also recorded.

Results One hundred and seventy consecutive patients with grade III hemorrhoids [74 females; mean age 49.5 years (range 22–79) years] were included. Median length of follow-up was 36 (range 12–72) months. Postoperative morbidity included urinary retention (7 patients, 4.1%), bleeding not requiring transfusion (1 patient, 0.6%) and thrombosis of hemorrhoidal piles (2 patients, 1.2%). The mean postoperative pain VAS score at 1 week postoperatively was 1.8 ± 1.1 (range 0–5) and 12 (7%) patients used pain medications for more than 1 week postoperatively while none of the patients reported any pain by the end of the third week postoperatively. The Hemorrhoid Symptom Score significantly improved from 15.83 ± 3.04 to 1.3 ± 2.4 ($p \leq 0.001$) and showed a statistically significant improvement in all items. Recurrent symptoms were reported in 12 patients (7%) who required further treatment. Severe chronic constipation prior to surgery was found to be a predictive factor of failure ($p = 0.04$).

Conclusions HeLPexx appears to be safe and effective for treatment of symptomatic hemorrhoids. Further studies are needed to confirm our results.

Keywords Hemorrhoids · Laser therapy · HeLP · Dearterialization · Anal mucopexy

Introduction

Postoperative pain and potential morbidity after hemorrhoidectomy has often discouraged patients from undergoing this procedure and has encouraged surgeons to develop less aggressive techniques for high grade hemorrhoids. The Hemorrhoid Laser Procedure (HeLP) is a well-established procedure to treat grade II and III hemorrhoids in patients who have failed to respond to conservative measures [1–3]. The HeLP procedure involves Doppler-guided closure of the terminal branches of the superior hemorrhoidal arteries by means of a diode laser. The primary aim of this procedure is to significantly reduce the arterial inflow to the hemorrhoidal plexus and thus achieve clinical resolution of hemorrhoid-related symptoms by preserving hemorrhoidal cushions. Although it is a good alternative to hemorrhoidectomy, hemorrhoidopexy or hemorrhoidal artery ligation (HAL) for hemorrhoids with minimal mucosal prolapse [1, 4], the presence of significant mucosal prolapse may hamper complete resolution of symptoms and clinical success.

✉ P. Giamundo
pgiamundo@gmail.com

[1] Policlinico Monza, Monza, Italy

[2] S. Spirito Hospital, Bra, Italy

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The hemorrhoid laser procedure with suture-pexy (HeLPexx) is a novel procedure developed to address symptomatic prolapse by adding mucopexy to the HeLP procedure, allowing a more accurate treatment of hemorrhoidal disease as the two major pathogenetic factors (vascular impairment and prolapse) are addressed. The aim of this prospective study was to describe this new technique and its clinical and long-term outcomes. Primary study end points were resolution of symptoms. Secondary endpoints were morbidity, need for further medical and/or surgical therapy and quality of life.

Materials and methods

We performed a prospective evaluation of patients with grade III hemorrhoids treated with HeLPexx from January 2012 to February 2018 at the Department of General Surgery of the S. Spirito Hospital in Bra, Italy. The operations were all performed by the first author. Hemorrhoids were graded according to Goligher's classification [5].

Preoperative assessment included a proctoscopy in all patients. A colonoscopy was prescribed for patients > 50 years old with a family history of colorectal cancer or with symptoms suspect for neoplasia. Indications for HeLPexx included third degree, symptomatic, prolapsing hemorrhoids resistant to conservative therapy or recurrent hemorrhoids after surgical treatment. The presence of 'significant' symptomatic, manually reducible mucosal prolapse at rest and/or straining at preoperative evaluation was an indication for HeLPexx instead of HeLP. Patients with active proctitis in ulcerative colitis were excluded from the study.

Data regarding type of symptoms, prior treatments, constipation [6] and incontinence scores [7] were recorded. In addition, operative time, number of arteries closed with laser, and number of mucopexies and associated procedures were also recorded and entered into a password-protected database.

A symptom questionnaire was administered at all patients before surgery and at each follow-up visit to evaluate baseline and recurrent symptoms such as bleeding, prolapse, manual reduction, discomfort or pain, and impact on quality of life. Each symptom had a score between 0 and 4, (0 indicates no symptoms and 4 indicates daily symptoms). The sum of the score for each symptom constituted the Hemorrhoid Symptom Score (Table 1) [8].

Constipation was assessed using the Altomare constipation score [6] and incontinence was assessed using the Cleveland Clinic Florida—Fecal Incontinence Score (CCF-FIS) [7].

Finally, after 1 year of follow-up, all patients were asked to state whether they were satisfied with the procedure or not.

All patients provided written informed consent and the study was conducted in accordance with the ethical standards reported in the Declaration of Helsinki. The HeLP procedure and hemorrhoidopexy are routinely performed in our hospital therefore this study was deemed exempt from internal institutional review board approval.

Operative technique

The HeLP procedure has been previously described [1]. In summary, all procedures were performed under spinal or general anesthesia with patients in the lithotomy position. A specially designed disposable proctoscope that is part of disposable instrument kit designed for the HeLP procedure (Biolitec Biomedical Technology, Jena, Germany) is inserted into the anal canal. A Doppler transducer is set at a frequency of 20 MHz allowing for identification of the terminal branches of the superior rectal arteries approximately 2.5 cm proximal to the dentate line. At this level, the caliber of the vessels varies between 0.6 and 2 mm and arteries are located approximately 2 mm under the mucosal lining [9, 10]. The Doppler probe is placed in a small window of the anoscope. Once the arterial pulse is located, the Doppler probe is replaced by a 1000-μm laser optic fiber connected to a diode laser platform (Fig. 1) (Leonardo, Biolitec Biomedical Technology, Jena, Germany), set at a 980 nm wavelength. Closure of the arteries is performed through a sequence of 5 laser shots delivered in pulsed mode at 13 W (Fig. 2). At this wavelength, the laser beam is selectively absorbed by chromophores of hemoglobin and causes a shrinkage of underlying tissue

Table 1 Hemorrhoid Symptom Score [17]

	Never	At least once/year	At least once/month	At least once/week	With every evacuation
Bleeding	0	1	2	3	4
Prolapse	0	1	2	3	4
Manual reduction	0	1	2	3	4
Discomfort/pain/discharge	0	1	2	3	4
Impact on QoL	None (0)	Minimal (1)	Moderate (2)	Severe (3)	Very severe (4)

QoL quality of life

Fig. 1 Diode laser platform, "Leonardo" dual, Biolitec Biomedical Technology, Germany

Fig. 2 Closure of identified arteries by means of a laser fiber

Fig. 3 Fenestrated proctoscope for suture mucopexy ("The Beak"). Sapimed, Alessandria, Italy

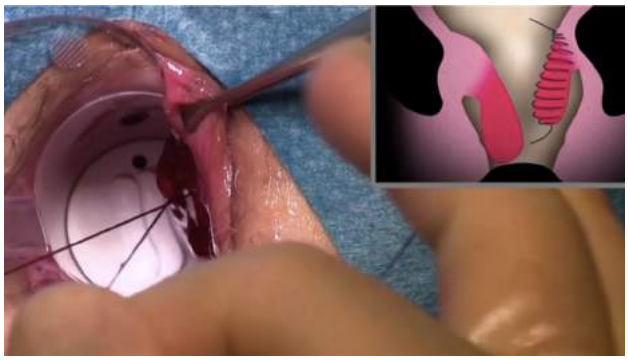

Fig. 4 Running sutures causing lift of prolapsing hemorrhoids

within a maximum depth of 4 mm. In case of persistent arterial flow, indicated by persistent Doppler sound, a second sequence of 3 laser shots is delivered over the same artery. A maximum of 12 arterial branches are identified and closed within the circumference of the anal canal.

Once laser dearterialization has been completed, the HeLP proctoscope is replaced by a disposable, fenestrated proctoscope (The Beak, SAPIMED, Alessandria, Italy) (Fig. 3). Continuous longitudinal running sutures (absorbable, 2/0 Polisorb) are applied in a proximal-to-distal fashion for a length of approximately 4 cm at approximately 0.5 cm above the dentate line. Three to six sutures are placed, depending on the severity and location of the prolapsing mucosa, usually at the odd-numbered clock positions around the anus (1, 3, 5, 7, 9 and 11). The proximal end of the suture is placed and tied approximately 4–5 cm above the dentate line. The distal end of the running suture is tied to the proximal stitch causing a lift of the prolapsing hemorrhoids (Fig. 4). No tissue is excised. Per hospital policy, all patients are discharged on postoperative day 1.

Follow-up was scheduled at 2 and 4 weeks, 3, 6 and 12 months, and annually thereafter. Postoperative evaluation included a complete clinical evaluation, proctoscopy, use of medications, constipation, incontinence, and hemorrhoid symptom scores. Follow-up at 2 years or longer was performed with telephone interview.

Statistical analysis

Qualitative data are reported as absolute numbers and percentages. Quantitative data are presented as mean ± standard deviation (SD) or median and interquartile range and are analyzed using Student's *t* test or the Fisher's exact test. A *p* value of 0.05 or less was considered significant.

Results

One hundred and seventy consecutive patients with grade III hemorrhoids [74 females; mean age 49.5 (range 22–79) years] treated with HeLPexx were included in the study.

Patients with highly symptomatic skin tags or IV degree hemorrhoids were treated with excisional hemorrhoidectomy as they were considered not suitable for a non-excisional procedure.

All patients had a long-standing history of persistent and worsening symptoms (mean 5 years; range 1–15 years) and failed attempts at medical therapy. Fourteen patients had undergone prior surgical treatment an average of 5 (range 1–25) years prior to HeLPexx. This treatment included rubber band ligation (RBL) ($n=3$; 1.8%), Milligan Morgan procedure ($n=3$; 1.8%), procedure for prolapse and hemorrhoids (PPH) ($n=3$; 31.8%), HeLP procedure ($n=4$; 2.4%), and transanal anopexy with HemorPex System (HPS) ($n=1$; 0.6%). The main symptoms reported were bleeding associated with symptomatic prolapse in 125 patients (73.5%), prolapse alone in 18 (10.6%), and pain associated with prolapse and recurrent thrombosis of single piles in 27 (15.9%). Twelve patients (7.1%) had symptomatic anal skin tags and one patient had concomitant anal fissure (0.6%). Five patients had one or more polyps in the anal canal (2.9%).

The mean operative time was 26.4 ± 6.4 (range 15–55) min. One hundred and sixty (94.1%) patients had spinal and 10 (5.9%) had general anesthesia. Twelve terminal branches of the superior hemorrhoidal artery were identified in 169 cases (99.4%). Only 11 arteries were identified in 1 case (0.6%). The mean number of mucopexies performed per patient was 4.0 ± 1.1 (range 1–6 mucopexies). Twenty-three patients underwent an associated procedure: excision of anal polyps in 5 (2.9%), excision of skin tags in 12 (7.1%), excision of one thrombosed pile in 5 (2.9%), and biopsy of a chronic anal fissure in 1 (0.6%). Intraoperative bleeding requiring hemostatic suture was reported in 7 (4.1%) patients. Seven patients (6 males, 4%) developed urinary retention within the first 24 h postoperatively.

The median duration of follow-up was 37 (range 12–76) months. None of the patients was lost to follow-up. The mean postoperative pain VAS score (based on a score of 0 to 10; 0 = no pain and 10 worst imaginable pain) at 1 week postoperatively was 1.8 ± 1.1 (range 0–5). Twelve patients (7%) used paracetamol and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for pain for more than 1 week postoperatively. None of patients reported any pain by the end of the third week postoperatively. Bleeding was reported in 3 patients (1.7%), between 5 and 12 days postoperatively. Of these, 1 patient was readmitted to the hospital on postoperative day 6. Dyschezia was reported by 12 patients (7%) for a maximum of 2 weeks postoperatively. Four of these patients (2.3%) were managed with medications (flavonoids, rectal ointments) and 8 (4.6%) did not require treatment. Postoperative thrombosis of single piles was noted in 2 (1.2%) patients. All cases were treated conservatively with no further complaints.

Ten (5.9%) patients complained of urgency and fractioned or incomplete evacuation for the first 10 days postoperatively. Of these, only 2 complained of altered evacuation for more than 1 year. All postoperative complications were treated conservatively and none of the patients required surgery or blood transfusion. The Symptom Score showed a statistically significant improvement, postoperatively, in all items (bleeding, manual reduction, pain/discomfort, impact on quality of life). No significant changes in constipation and fecal incontinence were reported. A summary of clinical results is reported in Table 2.

Twelve patients (7%) required further treatment and these 12 were considered failures. Eight of them required a single session of RBL, 3 were treated with hemorrhoidectomy (1 for recurrent bleeding and prolapse and 2 for recurrent bleeding in patients with hemophilia) and 1 wasted with excision of a skin tag together with a prolapsing residual pile.

The overall patient satisfaction rate was 96.5% (164/170 patients). The overall success rate was 93% (158/170 patients). Univariate analysis showed severe chronic constipation as a possible predictive factor for recurrence of prolapse at long-term follow-up (Table 3).

Table 2 Clinical results of HeLPexx

	Preoperative	Postoperative	p^a
Symptom Score			
(Total)	15.83 ± 3.04	1.3 ± 2.4	< 0.001
Bleeding	3.52 ± 0.62	0.11 ± 0.3	< 0.001
Prolapse	2.94 ± 0.6	0.21 ± 0.4	< 0.001
Manual reduction	2.73 ± 0.57	0.22 ± 0.4	< 0.001
Pain/discomfort	3.29 ± 0.70	0.16 ± 0.37	< 0.001
Impact on QoL	3.35 ± 0.6	0.6 ± 0.49	< 0.001
Constipation Score	3.7 ± 5.2	2.47 ± 3.59	0.29
CCF-FIS	1.9 ± 1.5	2.1 ± 1.7	0.89

Values expressed as mean + SD

HeLPexx hemorrhoid laser procedure with suture-pexy, *CCF-FIS* Cleveland Clinic Florida—Fecal Incontinence Score, *QoL* quality of life

[a]Student's *t* test

Table 3 Univariate analysis of possible predictive factors for recurrence

Factor	Success ($n=158$)	Failure ($n=12$)	p
Age (years)	49 (22–78)[a]	50 (23–79)[a]	0.92[b]
Bleeding	3.48 ± 0.5	3.37 ± 0.5	0.76[c]
Pain	3.5 ± 2.84	3.3 ± 2.68	0.72[c]
Quality of life	3.45 ± 2.24	3.28 ± 2.82	0.78[c]
Constipation score	3.7 ± 0.95	7.5 ± 5.6	**0.0487**[c]

Bold indicates the statistical significance value compared to the other values

[a]Values expressed as median (range)

[b]Fisher's exact test

[c]Student's *t* test

Discussion

Several treatment options can be offered to patients with symptomatic third degree hemorrhoids.

Hemorrhoidectomy is still considered by many to be the gold standard [11], especially in patients with fourth degree hemorrhoids. However, the potential morbidity including iatrogenic incontinence and anal canal stenosis, should not be underestimated. Furthermore, postoperative pain, although it may be reduced using newly developed devices [12, 13], is undoubtedly invalidating in the vast majority of patients. A recent systematic review and network meta-analysis comparing clinical outcomes and effectiveness of surgical treatments for hemorrhoids including 98 trials with 7827 patients and 11 surgical treatments concluded that, despite the lower recurrence rate, both open and closed hemorrhoidectomy resulted in more postoperative complications and slower recovery when compared with non-excisional procedures [14].

Non-excisional procedures are a revolutionary approach to treating hemorrhoids. The majority of these therapies cure symptoms, while leaving hemorrhoidal piles and their physiological function in the anus intact, with no changes to the anatomy of the anal canal. The idea of curing hemorrhoids by reducing arterial overflow into the hemorrhoidal plexus was introduced by Morinaga in 1995 [15] who described the Doppler-guided transanal hemorrhoidal artery ligation (HAL). The HAL was recently modified by the addition of suture mucopexy for a more specific treatment of prolapse associated with high degree hemorrhoids (transanal hemorrhoidal dearterialization; THD) [16].

Since then, several publications have reported the effectiveness and safety of hemorrhoidal artery ligation for second, third, and even fourth degree hemorrhoids [17, 18]. A systematic review including 17 studies and 1996 patients reported a satisfactory overall success rate with a mean recurrence rates of 11% for prolapse, 10% for bleeding, and 9% for pain at defecation at 1-year follow-up [19]. In another meta-analysis including 2904 patients from 28 studies, the overall mean recurrence rate was 17.5% with a reintervention rate of 6.4% [20]. A recent multicenter trial including 803 patients who underwent THD reported a success rate of 90.7% with recurrence of prolapse, bleeding or both in 6.3%, 2.4% and 0.6% of patients, respectively [21].

Dearterialization as a safe and effective alternative to conventional treatments as has also been recognized by the National Institute for Health and Care Excellence (NICE) [22].

Several prospective randomized trials comparing dearterialization procedures with other techniques showed good overall resolution of symptoms in all procedures with better results concerning postoperative pain in the dearterialization group [23, 24]. One exception to these findings are the results reported by the HuBble trial, which questioned the cost effectiveness of Doppler-guided dearterialization and reported more pain after HAL compared to RBL [25].

When compared to other non-excisional procedures for hemorrhoids such as the PPH, dearterialization may have the advantage of reducing the potential incidence of life-threatening complications [26]. Due to concerns regarding the need for Doppler guidance to locate and close the arterial hemorrhoidal branches [27], a simple mucopexy without clear Doppler-guided dearterialization may also be effective for prolapsing hemorrhoids [28]. However, based on findings in anatomical studies [9, 10] that showed great variability in the location of arterial branches above the dentate line, we feel that Doppler-guidance is crucial in identifying and treating the arteries, especially when dearterialization is performed by laser, given the limited field of action with each laser shot.

Although, historically, using laser to treat hemorrhoids is not a novel idea [29], the HeLP procedure uses laser for its selective shrinking and coagulating effects on vessels rather than for excisional purposes. The HeLP procedure is based on the same principles as the HAL. The terminal branches of the superior hemorrhoidal arteries are closed by means of diode laser. Twelve arteries are sealed close to the dentate line where arterial branches meet the hemorrhoidal piles without interposition of capillaries [1]. Consequently, a reduction of blood inflow to the hemorrhoidal cushions is assured. Potential advantages of this procedure compared with HAL include higher accuracy in detecting arteries, a larger number of vessels closed, and minimal invasiveness.

The efficacy of the HeLP procedure in treating symptomatic hemorrhoids has been reported in several studies [1, 4, 30, 31]. However, one potential pitfall was poor resolution of mucosal prolapse accompanying hemorrhoidal symptoms. As a result, HeLPexx was developed to address symptomatic mucosal prolapse, which may hamper the complete and long-lasting clinical resolution of symptoms with higher degree

hemorrhoids. The addition of suture mucopexy allows for cure of the different pathogenetic aspects of hemorrhoidal syndrome. Vascular impairment caused by arterial overflow is cured by sealing the terminal branches of the superior hemorrhoidal arteries, whereas the mucosal prolapse due to the impairment of connective tissue underlying the hemorrhoidal piles is cured with running sutures.

Similar to THD, the advantage of HeLPexx compared to excisional procedures is less postoperative pain, faster recovery with faster return to daily activities, and the procedure can be tailored to each patient as the number of mucopexies depends on the type of prolapse. Another advantage of using a non-excisional therapy is preservation of the anal anatomy. In our study, no statistically significant changes in constipation and incontinence scores were noted.

The use of a 20 MHz (HeLP) instead of a 7–8 MHz Doppler-transducer (HAL procedures) and the closure of 12 arteries (HeLP) instead of 6 (THD/HAL) has the theoretical advantage of better accuracy in detecting the terminal branches of the superior hemorrhoidal artery and in reducing the overflow to hemorrhoidal piles circumferentially, although this concept has yet to be proven in comparative studies. A few publications have stressed the potential for higher recurrence [14, 32] after non-excisional procedures when compared to traditional hemorrhoidectomy, however, this was not reported in another recent study [24].

In our study, HeLPexx had an overall success rate of 92.9% (158/170) at long-term follow-up with a highly significant reduction of hemorrhoid symptoms and a high patient satisfaction rate. Of the 12 patients who required additional treatment, 8 underwent 1–2 sessions of RBL that was sufficient to cure recurrent symptoms. The intra- and postoperative morbidity rates were low and impairment or change in evacuation habits was reported only occasionally. One interesting finding in our study was that severe chronic constipation prior to surgery had a significant impact on clinical results and recurrence after HeLPexx. This finding suggests that thorough preoperative examination of patients for specific and tailored treatment for constipation may be necessary to reduce postoperative recurrence after HeLPexx.

Limitations of this study include its single center nature, the absence of very long-term follow-up, non-validated measurement of symptom and quality of life scores, and the absence of comparison with existing procedures. Although the scientific robustness of the trial would have been improved if it had been multicenter, the strengths of our study include the homogeneity of patients and standardization of the surgical procedure that was performed by a single surgeon.

Finally, as far as costs are concerned, the laser equipment was offered in free lease to our hospital. The disposable kit which included the proctoscopes, the fiber, the Doppler probe and the sutures had a total cost of approximately 350 euros per procedure. This makes the procedure less expensive than most non-excisional procedures.

Conclusions

The main advantages with this non-excisional procedure are little postoperative pain, morbidity, or recurrence, with no impairment of sphincter function. Although prospective randomized studies are required to confirm our findings, HeLPexx should be considered as a safe and effective treatment option for symptomatic hemorrhoids.

Compliance with ethical standards

Conflict of interest PG: Surgical Trainer for Biolitec, Biomedical Technology (no financial interests); MDA: no conflict of interest; AM: No conflict of interest.

Ethical approval The study was conducted in accordance with the ethical standards reported in the Declaration of Helsinki.

Informed consent All patients provided written informed consent.

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ORIGINAL ARTICLE

Doppler-guided hemorrhoidal dearterialization with laser (HeLP): a prospective analysis of data from a multicenter trial

P. Giamundo[1] · A. Braini[2] · G. Calabro'[3] · N. Crea[4] · P. De Nardi[5] · F. Fabiano[6] · M. Lippa[4] · A. Mastromarino[7] · A. M. Tamburini[5]

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Abstract

Background Doppler-guided hemorrhoidal laser procedure (HeLP) is a new minimally invasive technique to treat symptomatic hemorrhoids. The aim of this multicenter study was to prospectively assess clinical results and patients' satisfaction in patients treated with HeLP.

Methods Indications for HeLP included patients with symptomatic hemorrhoids resistant to medical therapy, with low-grade prolapse. Clinical efficacy was evaluated assessing resolution of symptoms and patient satisfaction. Frequency of bleeding and frequency of acute hemorrhoid-related symptoms were given a score of 0 to 4 (where 4 = more than 3 episodes/week) and 0 to 3 (where 3 = more than 5 episodes/year), respectively. Quality of life, pain at rest, and pain with evacuation were scored using a visual analogue scale (VAS) of 0 to 10. Intra- and postoperative complications were recorded. Potential predictive factors for failure were assessed.

Results Two hundred and eighty-four patients (183 males, 101 females) with a mean age of 47.5 years were included in the study. At 6-month follow-up, symptoms had completely resolved in 257/284 (90.5%) and 275/284 (96.8%) patients were satisfied with the results. An analysis of a subgroup of 144 patients followed up for a minimum of 12 months revealed a resolution of symptoms in 130/144 (90.3%) and satisfaction in 139/144 (96.5%). There was a statistically significant improvement of the bleeding score (from 2.4 ± 1.07 to 0.36 ± 0.49; $p < 0.0001$), acute symptoms score (from 2.03 ± 0.16 to 0.61 ± 0.59; $p < 0.0001$), quality of life (from 4.63 ± 1.32 to 8.96 ± 1.35; $p < 0.0001$), pain at rest (from 3.0 ± 2.05 to 1.1 ± 0.99; $p < 0.0006$), and pain with evacuation (from 4.8 ± 1.22 to 1.7 ± 1.15; $p < 0.0001$). No significant changes in continence and constipation were observed. Univariate analysis failed to show factors significantly associated with failure.

Conclusions The HeLP procedure seems to be safe and effective in patients with symptomatic hemorrhoids. It is simple, minimally invasive, and relatively pain free. It can be performed in an ambulatory setting without anesthesia, and it achieves high patient satisfaction. It may, therefore, be considered a "first-line treatment" in all patients without significant hemorrhoidal prolapse in whom medical therapy has failed.

Keywords Hemorrhoids · Dearterialization · HeLP · Lasers · Doppler

✉ P. Giamundo
pgiamundo@gmail.com

[1] Department of General Surgery, Santo Spirito Hospital, Bra, Italy

[2] Department of General Surgery, AAS 5 Friuli Occidentale, Pordenone, Italy

[3] Department of Surgery, Humanitas Gavazzeni Institute, Bergamo, Italy

[4] Department of General Surgery, Sant'Anna Clinic, Brescia, Italy

[5] Department. of Gastrointestinal Surgery, Scientific Institute San Raffaele, Milan, Italy

[6] Department of General Surgery, Evangelic International Hospital, Genoa, Italy

[7] Vascular Surgery San Salvatore Hospital, L'aquila, Italy

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Introduction

In the last few decades, several new surgical procedures have been proposed in the treatment of symptomatic hemorrhoids, with the main goal of reducing pain and postoperative morbidity. Dearterialization of terminal branches of superior hemorrhoidal arteries meets the goal of reducing blood inflow into the hemorrhoidal venous plexus and has the advantage of controlling symptoms and being less invasive than many previously described techniques [1]. It is associated with less postoperative pain and preservation of anal anatomy. The results of distal dearterialization are enhanced due to general absence of capillary interposition between the arterial and venous systems in the anal canal, as reported by anatomical studies [2, 3].

Doppler-guided hemorrhoidal dearterialization with laser (the hemorrhoidal laser procedure; HeLP) has recently been described and reported as an effective approach to the treatment of symptomatic second- and third-degree hemorrhoids, particularly in cases in which bleeding is the most frequent symptom and mucosal prolapse is low or moderate [4]. The operation has the real advantage of being almost painless and is performed as an office procedure in most cases without anesthesia.

In 2016, a group of surgeons in Italy formed the 'Gruppo Italiano Laser in Proctologia (Italian Group, Lasers in Proctology:GILP)' with the aim of exchanging professional experience and sharing expertise in the laser treatment of several proctological diseases.

This association of surgeons regularly meets to discuss results and complications related to the different laser procedures and to organize and conduct research protocols for clinical studies. All data derived from single centers belonging to GILP are prospectively introduced into a common registry and are shared within the group.

The aim of the current study was to evaluate the clinical results of HeLP performed in 7 different centers, all affiliated with GILP.

Materials and methods

This was a multicenter, longitudinal study of a cohort of patients suffering from symptomatic hemorrhoids treated with the HeLP procedure from January 2016 to November 2017.

All data were prospectively registered as consecutive cases in an electronic database.

A questionnaire was administered preoperatively to all patients to collect past and current medical history, and scores on anal symptoms, fecal incontinence [5], and constipation [6]. Bleeding was assessed on a scale of 0–4, where 0 was no bleeding, 1 was < 1 episodes per month, 2 was < 1 episode per week, 3 was 1–3 episodes per week and 4 was 4 more episodes per week. Similarly, the presence of acute symptoms requiring any medications (oral or topical) was scored from 0 to 3, where 0 was none, 1 was 2 or less per year, 2 was 3–5 episodes per year, and 3 was more than 5 episodes per year. Subjective evaluation of personal quality of life (QOL) was assessed using a visual analogue scale (VAS) of 0–10 (0 = the worst possible QOL, 10 = the best possible QOL). Similarly, pain was assessed using a VAS of 0–10 (0 = no pain, 10 = the worst possible pain).

A thorough clinical examination, including anoproctoscopy, was performed in all patients. Hemorrhoids were graded according to Goligher's classification [7].

Symptomatic patients in whom conservative treatment had failed, with low or moderate prolapse at straining at time of preoperative clinical and anoscopic evaluation, were considered candidates for the HeLP procedure. Patients with recurrent bleeding and acute symptoms after failure of previous surgical treatments for hemorrhoids were also included in the study (Table 1).

The HeLP procedure is currently used in the routine surgical treatment of patients with symptomatic hemorrhoids in all centers affiliated with GILP. All patients provided written informed consent and the study was conducted in accordance with the ethical standards reported in the Declaration

Table 1 Characteristics of patients having HeLP

Features	*n* (Patients)	%
Patients	284 (183M,101F)	
(Patients previously treated with surgery: 10 (2 PPH, 3 THD, 4 RBL, 1 HPS))		
Age[a]	47.5 (range 17–77)	
Hemorrhoid grade		
Grade I	5	1.7%
Grade II	174	63%
Grade III	101	34%
Grade IV	4	1.3%
Symptoms:		
Bleeding	178	63%
Acute symptoms requiring medications		
	142	50% 3–5/year
	137	48% > 5/year
	– 5	0.7% 2/year
Pain at rest (VAS 0–10)[a]	3 (range 0–9)	
Pain at evacuation[a]	4.8 (range 0–9)	
Quality of Life (VAS 0–10)[a]	4.45 (range 2–8)	

[a]Value expressed as mean

of Helsinki. This type of study is exempt from IRB approval in all of the participating institutions.

A total of 284 patients were included in the study, as shown in Table 1. Preoperative hemorrhoidal grading was: grade 1 in 5 patients (1.7%); grade 2 in 174 patients (63%); grade 3 in 101 patients (34%); and grade 4 in four patients (1.3%). Although these last four patients did not meet the usual indications for HeLP, their general poor medical conditions contraindicated more aggressive approaches and the main symptom was bleeding. The five patients with grade 1 were complaining of recurrent bleeding and pain due internal hemorrhoid thrombosis.

All colorectal surgeons participating to the study were trained in the procedure, had attended a live-surgery laser dearterialization course at the coordinating center, and were proctored prior to participating in the study. As a result, potential bias due to differences in the surgical procedure was minimized. Since the procedure is easy to perform, the minimum number of procedures to achieve proficiency and be admitted to participate to the study for the surgeons was 10.

Preoperatively, 2 enemas were administered to all patients as rectal preparation. If patients were on anticoagulant therapy, this was substituted with low-molecular-weight heparin (LMWH) for 2 weeks according to the protocol of national guidelines for surgical procedures.

Surgical technique

The HeLP procedure has been extensively described in a previous paper [4]. Patients are treated in the lithotomy position. A specially designed disposable proctoscope, which is part of a complete kit of disposable instruments designed for the HeLP procedure (Biolitec AG, Jena, Germany) (Fig. 1), is inserted into the anal canal. A Doppler transducer (Fig. 2) set at the frequency of 20 MHz allows

Fig. 2 Doppler platform and probe

identification of the terminal branches of the superior rectal arteries approximately 2.5 cm proximal to the dentate line. At this level, the caliber of the vessels varies between 0.6 and 2 mm and arteries are located approximately 2 mm under the mucosal lining [3]. The Doppler probe is placed in a small window in the anoscope. Once the arterial pulse is located, the Doppler probe is replaced by a 1000-micron laser optic fiber connected to a diode laser platform (Fig. 3) (Leonardo, Biolitec AG, Jena, Germany) set at the wavelength of 980 nm. Closure of the arteries is performed through a sequence of five laser shots delivered in pulsed mode at 13W (Fig. 4). In case of persisting arterial flow indicated by persisting Doppler sound, a second sequence of three laser shots is delivered over the same artery.

A maximum of 12 arterial branches are identified and closed within the circumference of the anal canal.

Fig. 1 Disposable anoscope (kit for HeLP)

Fig. 3 Leonardo® laser platform (Biolitec Medical Technology)

Fig. 4 Closure of arterial branches with the laser fiber

Follow-up

Postoperative follow-up was scheduled at 4 weeks, 3 months, 6 months, and 12 months. In general, patients were asked to call the referral center in case of surgery-related complications or symptoms of possible hemorrhoidal recurrence, regardless of scheduled follow-up visits. Need for medical and/or further surgical treatment for persisting or recurring symptoms during follow-up were recorded. At each follow-up visit, a thorough physical examination and anoscopy were performed. In addition, the same type of questionnaire administered preoperatively was readministered at each follow-up visit and compared with preoperative data.

Statistical analysis

Quantitative data were expressed as median/range and mean/standard deviation (SD). Age, preoperative symptoms, QOL, grade of hemorrhoids, and number of operative laser shots were assessed as potentially predictive factors of failure by means of univariate analysis. Student's *t* test was used to compare continuous qualitative data expressed as means with SD. Fisher's exact test was used to analyze data expressed as median/range. A p value < 0.05 was considered statistically significant.

Results

Of the 284 patients who had the HeLP procedure in seven different centers affiliated with the GILP group, 183 were males and 101 were females, with a mean age of 47.5 years (range 17–77 years). Clinical data were prospectively collected from January 2016 to November 2017. Two hundred and sixty-nine patients (95%) had a history of long-term use of medications for hemorrhoids (oral intake of flavonoids and topical use of ointments) prior to surgery.

Five patients (2%) reported two episodes per year of acute pain, internal hemorrhoidal thrombosis, bleeding, and other hemorrhoid–related symptoms lasting approximately 1 week; 142 (50%) reported 3–5 episodes per year; and 137 (48%) reported more than 5 episodes per year. Preoperative pain at rest (evaluated with VAS 0–10) was 3 (range 0–9). Preoperative pain at evacuation was 4.8 (range 0–10). Bleeding was the most frequent preoperative symptom, with 114 patients (40%) reporting bleeding occurring 1–2 times per week and 64 patients (23%) reporting bleeding occurring greater than 3–4 times per week. Other preoperative symptoms included anal itching, anal "burning," sensation of permanent anal discomfort, and sensation of a "humid anus." Thirty-nine patients (13.7%) reported a sensation of incomplete rectal emptying at evacuation, showing a low grade of obstructed defecation syndrome (ODS). Median preoperative QOL was 4.45 (range 2–8) using VAS.

The procedure required no anesthesia (just lubricant or topical anesthetic cream such as lidocaine/pilocarpine 5% cream) in 246 cases (86.7%). Light sedation (intravenous [IV] midazolam, 2 mg) was induced in 34 patients (12%). Local or spinal anesthesia was used for four patients (1.3%). This kind of anesthesia was administered according to patient preference following preoperative counselling. All procedures were performed in the operating room, but the presence of an anesthesiologist was not routinely required unless the patient had preoperatively requested to undergo spinal anesthesia or because of specific hospital regulations. Preoperatively, all the patients were informed about the possible need for sutures/rubber band ligation in case of bleeding and the risk of intraoperative mild pain. The vast majority of them agreed and signed the consent form to undergo the procedure without anesthesia.

Antibiotic prophylaxis was administered in only 75 cases (26%) at the discretion of the surgeon, although it was not deemed mandatory except in patients with immunodeficiency or those with congenital heart defects or heart valve implants (endocarditis prophylaxis). The median duration of the operation was 15.5 min (range 7–31 min).

Twelve arteries were identified and treated in all cases. The median number of double sequence of laser shots per procedure was 5.1 (range 0–12 shots). Moderate intraoperative bleeding occurred in 25 patients (8.8%). Bleeding stopped spontaneously or was successfully treated by laser in 7 of them. In the remaining 18 patients (6.3%), a rubber band ligation or suture was placed for hemostatic purposes. In those patients treated without anesthesia, the intraoperative subjective evaluation of pain score was 3.1 (range 3–8) (VAS 0–10, 0 = minimal pain and 10 = maximum pain). Early postoperative morbidity (first 2 weeks) included bleeding

Table 2 Morbidity

	Patients (*n*)	%
Intraoperative bleeding requiring suture/RBL	18	6.3
Bleeding requiring medical treatment (flavonoids)	10	3.5
Anismus	4	1.4
Mild sensation of incomplete evacuation (no therapy)	9	3.1
Partial internal hemorrhoid thrombosis	4	1.4
Postoperative pain requiring paracetamol	27	9.5

RBL rubber band ligation

requiring medical treatment in 10 patients (3.5%), sensation of incomplete evacuation in 9 cases (3.1%), and anismus in 44. Early postoperative pain score (VAS) was 1.1 (range 0–5). Postoperative need for pain medications (paracetamol or similar) was reported in 27 cases (9.5%) and for a maximum of 3 days postoperatively (Table 2).

No patients were lost to follow-up. At the time of the data collection, all the 284 patients had completed the 6-month follow-up (Table 3). Of these 284, 144 patients had also completed the 12-month follow-up (51%). The results in this subgroup of 144 patients with longer follow-up are reported in Table 4.

No statistically significant difference was observed between preoperative and postoperative constipation scores which were of 2.55 ± 2.57 and 2.26 ± 3.02, respectively. No statistically significant difference was observed between preoperative and postoperative incontinence scores which were 3.2 ± 1.80 and 3.6 ± 1.56, respectively. Overall resolution of symptoms in terms of bleeding, pain, and need for medications for hemorrhoid-related symptoms was observed in 130 patients (90.3%). Of the 14 patients (9.7%) with persisting symptoms, 7 (4.8%) had persisting pain and prolapse at defecation and reported frequent use of medications, and 7 (4.8%) had bleeding at evacuation, although less frequent than preoperatively. Four of these patients required further surgery an average of 6 months after the HeLP procedure. One was treated with procedure for prolapse and hemorrhoids (PPH), 1 with transanal hemorrhoidal dearterialization (THD), 1 with Milligan & Morgan, and in 1 case a redo HeLP was performed. One hundred and thirty-nine out of 144 patients (96.5%) were satisfied with the treatment received. They declared they would recommend it to other patients with hemorrhoidal disease and they declared themselves willing to undergo a redo HeLP in case of recurrence. Clinical results at 12-month follow-up are summarized in Fig. 5.

At univariate analysis, age, preoperative symptoms, QOL, grade of hemorrhoids, and number of laser shots delivered during the single treatment were not significantly associated with failure (Table 5).

Table 3 Results at 6-month follow-up

Patients (*n* 284)	Overall resolution of symptoms: 257/284 (90.5%)	
	Overall personal satisfaction: 275/284 (96.8%)	
	Preoperative	Postoperative
Bleeding score[a]	2.4 ± 1.07	0.32 ± 0.45
Quality of life (VAS)	4.63 ± 1.32	8.99 ± 1.33
Pain at rest (VAS)	3.0 ± 2.05	0.9 + 0.79
Pain at evacuation (VAS)	4.8 + 1.22	1.8 + 1.18
Constipation score	2.55 ± 2.57	2.18 ± 2.92
Incontinence score	3.2 ± 1.80	3.5 ± 1.48

Values expressed as mean ± SD

VAS visual analogue scale

[a]Bleeding score expressed as: <1/month = 1; 1/week = 2; > 1/week; =3; >3–4/week = 4

Table 4 Results at 12-month follow-up

Patients (*n* 144)	Overall resolution of symptoms: 130/144 (90.3%)		
	Overall personal satisfaction: 139/144 (96.5%)		
	Preoperative	Postoperative	*p* value[d]
Bleeding score[a]	2.4 ± 1.07	0.36 ± 0.49	< **0.0001**
Frequency of acute symptoms requiring medications[b]	2.03 ± 0.16	0.61 ± 0.59	< **0.0001**
Quality of life (VAS)	4.63 ± 1.32	8.96 ± 1.35	< **0.0001**
Pain at rest (VAS)	3.0 ± 2.05	1.1 + 0.99	< **0.0006**
Pain at evacuation (VAS)	4.8 + 1.22	1.7 + 1.15	< **0.0001**
Constipation score	2.55 ± 2.57	2.26 ± 3.02	0.73
Incontinence score	3.2 ± 1.80	3.6 ± 1.56	0.37
Anal itching/burning[c]	35	5	

Values expressed as mean ± SD

VAS visual analogue scale

[a]Bleeding score expressed as: < 1/month = 1; 1/week = 2; > 1/week; = 3; >3–4/week = 4

[b]Expressed as: 2/year = 1; 3–5/year = 2; >5/year = 3

[c]Expressed as number of patients

[d]Student's *t* test

Discussion

The major goal of a colorectal surgeon when treating patients suffering from symptomatic hemorrhoids should be to cure symptoms and improve patients' QOL. Generally speaking, this goal should be accomplished by

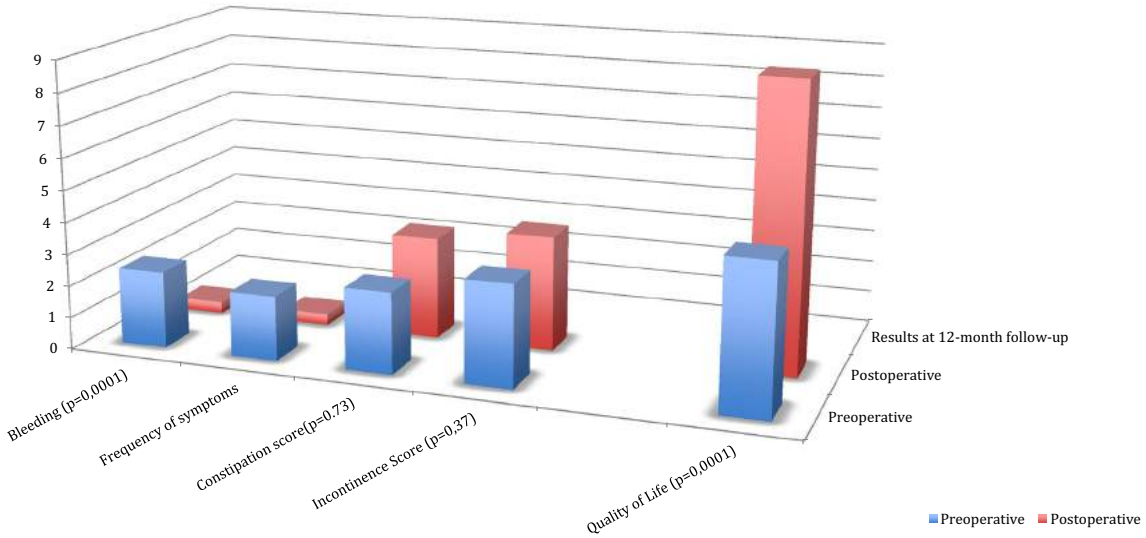

Fig. 5 Diagram showing clinical results at 12-month follow-up (144 patients)

Table 5 Univariate analysis of possible predictive factors for failure (144 patients)

Factor	Success ($n=130$)	Failure ($n=14$)	p
Age (years)	48 (19–77)[d]	47 (17–73)	0.65[e]
Pain[a]	3 ± 2.58[c]	3.66 ± 2	0.5109[f]
Bleeding[b]	2.56 ± 0.89[c]	2.77 ± 1.3	0.6283[f]
Quality of life[a]	4.45 ± 1.68[c]	5.33 ± 1.32	0.1625[f]
Grade of hemorrhoids	2.46 ± 0.63[c]	2.33 ± 0.70	0.6392[f]

[a]VAS (Visual Analogic Scale 1–10)

[b]Bleeding score expressed as: < 1/month = 1; 1/week = 2; > 1/week; =3; >3–4/week = 4

[c]Values expressed as mean ± SD

[d]Values expressed as median (range)

[e]Fisher's exact test

[f]Student's *t* test

offering surgical procedures associated with low levels of pain, low morbidity, and preservation of the anatomy of the anal canal. The choice of the right procedure to adopt can vary according to hemorrhoid grade, type of symptoms, severity of prolapse, and patients' expectations. Grading of hemorrhoids according to Goligher does not always reflect the severity of symptoms [8]. This means that a significant alteration of QOL can be reported even in patients with low-grade hemorrhoids. Indications for surgery in patients suffering from the second-degree hemorrhoids can be confusing and debatable. However, there are cases, where medical treatment or office treatment such as rubber band ligation and sclerotherapy fail [9].

The presence of severe mucosal prolapse requiring manual reduction of hemorrhoidal piles after evacuation is usually an indication for surgical procedures that eliminate or plicate the prolapse. However, if the prolapse is moderate at preoperative evaluation and manual reduction is only occasionally required, surgical techniques such as Milligan & Morgan, PPH, THD, and hemorrhoidopexy without Doppler may be too aggressive and may be replaced by less invasive procedures.

HeLP consists of Doppler-guided dearterialization of terminal branches of the superior hemorrhoidal artery by means of a diode laser. The rationale of this procedure is mainly a reappraisal of the hemorrhoidal artery ligation (HAL) technique, originally proposed by Morinaga [1]. The symptoms are cured by reducing the blood inflow coming from the hemorrhoidal arterial system into the hemorrhoidal venous plexus. The HAL procedure and its more recent evolution, THD [10], has proven to be safe and effective in several series as reported in a systematic review that included 1996 patients in 17 case series [11] or in a more recent systematic review of 2904 patients from 28 studies [12]. The efficacy of dearterialization has also been recognized by the National Institute for Health and Care Excellence (NICE) as a safe and effective alternative to conventional treatments [13]. Several comparative studies or prospective randomized trials comparing dearterialization techniques with conventional hemorrhoidectomy or with stapler hemorrhoidopexy showed similar results in terms of resolution of symptoms and better results concerning postoperative pain [14–17]. However,

the HuBble trial seems to question the cost–effectiveness of Doppler-guided dearterialization (HAL) and, although at 1-year follow-up dearterialization seemed to show fewer recurrence, this procedure was more painful than RBL [18].

The HeLP procedure has some potential advantages over the other hemorrhoidal ligation procedures. It can be performed without anesthesia in an outpatient setting, and it is painless because the laser shots are delivered approximately 2.5 cm above the dentate line, where the anal mucosa is relatively insensitive. The mild discomfort reported intraoperatively, mostly caused by the anoscope, is usually well tolerated by patients. The laser shots generate minimal damage to the mucosa and submucosa. The effect is confined to a maximal depth of 4 mm. Therefore, in our experience, the vast majority of patients were suitable candidates for HeLP without anesthesia. However, performing this procedure without anesthesia may not be a realistic expectation in other countries with different medical cultures and health systems.

Twelve arterial branches are hit and sealed with a laser. This means that a larger number of arteries than in the THD/HAL procedures can be treated and sealed in the same procedure. When ligation is performed, in general, only 6 to 8 arteries are ligated. Furthermore, the HeLP kit includes a 20 MHz Doppler probe that is very accurate in locating the terminal branches of the superior rectal artery. In fact, at the distance of 2.5 cm from the dentate line, the arteries are very superficial and thin [3]. As a consequence, the 6–8 MHz Doppler probe associated with other procedures may be inadequate to detect the arterial flow of these arteries.

A debate concerning the actual need for Doppler guidance for hemorrhoidal dearterialization continues as reported in several published papers. Gupta et al. published a study in which 48 patients were randomized into two different groups, one with and one without Doppler guidance, and found no statistically significant difference in terms of success rate between the two groups, with increased total operative time and postoperative pain in the Doppler-guided group [19]. Simple mucopexy and without a clear Doppler-guided dearterialization turned out to be effective in curing prolapsing hemorrhoids [20]. However, it is reasonable to suspect that mucopexy in general is an empiric form of dearterialization, as the sutures include submucosal hemorrhoidal arterial branches.

In the current multicenter, prospective analysis of clinical data, the HeLP confirmed the promising results reported in the previous series in the short and medium terms [4, 21, 22]. In particular, at 12-month follow-up, 96.5% of patients were satisfied with the clinical results of the procedure.

Strengths of this study are its multicenter and prospective nature. A limitation of the study is that it is non-comparative, subject to selection bias and has a relatively short overall length of follow-up. However, the final analysis of results was mainly focused on a subset of patients with a minimum of 12-month follow-up. This group of patients had an overall success rate of 90.3% with only 2.8% requiring another treatment. Another limitation of the current study is the scoring system adopted for evaluating bleeding, and acute symptoms and non-validated and that evaluation quality of life and pain is solely based on VAS scores. Patients complaining of symptomatic significant mucosal prolapse were excluded from the study. In fact, in this kind of patient, the addition of a mucopexy or a prolapsing mucosa excision is deemed advisable to reasonably improve the effectiveness of dearterialization [23]. Therefore, the main indications for HeLP included all patients with symptomatic hemorrhoids, in whom medical therapy failed and where prolapse, if present, was not a significant complaint.

Intraoperative procedure-related complications consisted of bleeding in 8.8% of cases with 6.3% of cases needing some hemostatic procedure. This may seem a rather high complication rate; however, sutures or rubber band ligation, where necessary, was well tolerated and did not interfere with postoperative healing and the final success of the procedure. Postoperative morbidity was negligible and easily treated with medical therapy. The vast majority of patients did not need any pain medication postoperatively. This may explain The high level of satisfaction among patients who, generally speaking, are fearful of postoperative pain after surgery for hemorrhoids. Another aspect of the HeLP that cannot be underestimated is the minimally invasive nature of the procedure: no alteration of the anatomy of the anal canal was reported in any patient, with minimal or no scars in the mucosa detectable at 1- and 3-month follow-up.

In the literature, there is only one case report of a major complication following HeLP. This was a patient with recurring hemorrhoids treated with laser dearterialization a few years after PPH who many years later developed a hematoma causing intestinal obstruction. However, in this particular case, the origin of the rectal hematoma was not clear and the description of the laser technique performed was not provided [24, 25].

Although recurrence and/or failure are the most worrisome issue after dearterialization procedures in the literature, in our study on the HeLP procedure, it was not an issue, with only 9.7% of patients complaining of some persisting and/or recurring symptom at 12-month follow-up. This may be due to either the shortness of follow-up or more likely to careful patient selection.

Finally, a univariate analysis performed in this study failed to show any statistically significant predictive factor of failure. For this reason and in consideration of the minimally invasive nature of the procedure, HeLP can be indicated, with almost no limitations, for patients with symptomatic hemorrhoids altering QOL.

HeLP is cost effective, since the operation can be performed as an outpatients' procedure without the need for

anesthesia in most cases. The disposable kit for HeLP costs approximately 400 euros per patient and the laser and Doppler platforms are leased to the hospitals free of charge.

Conclusions

HeLP is a valid therapeutic option regardless of hemorrhoidal grade, although its main indication does not include patients with large symptomatic prolapse. In addition, it does not hamper further surgical procedures in case of failure. In the treatment of symptomatic hemorrhoids with moderate prolapse, other minimally invasive procedures such as rubber band ligation or infrared may be less effective (undertreatment), whereas more invasive procedures such as PPH, THD, hemorrhoidopexy without doppler, or hemorrhoidectomy may be unnecessary (overtreatment). As a consequence, although randomized multicenter trials and larger studies with longer follow-ups are certainly needed, the HeLP procedure should be considered as part of the armamentarium of any colorectal surgeon for a more tailored treatment of selected patients with hemorrhoids. It could also be considered a first-line treatment in all symptomatic patients when conservative treatment fails.

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Compliance with ethical standards

Conflict of interest The first author declares that he is a "Surgical Trainer" for Biolitec Biomedical Technology with no financial interests; the other authors declare that they have no conflict of interest.

Ethical approval This type of study is exempt from IRB approval in all of the participating institutions.

Informed consent Informed consent was obtained from all individual participants in the study.

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