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ORIGINAL ARTICLE

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

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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

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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

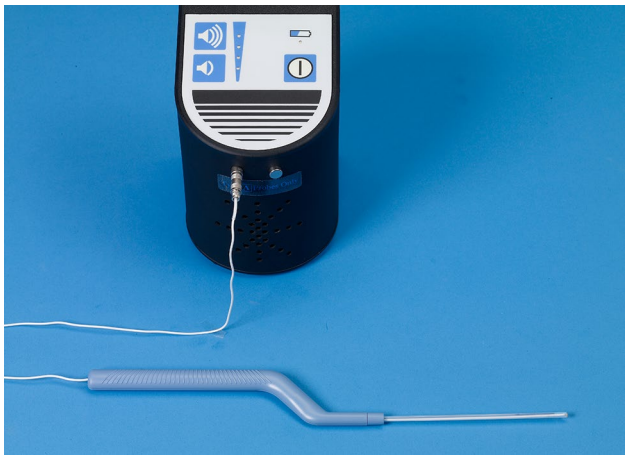

Fig. 2 Doppler platform and probe

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.

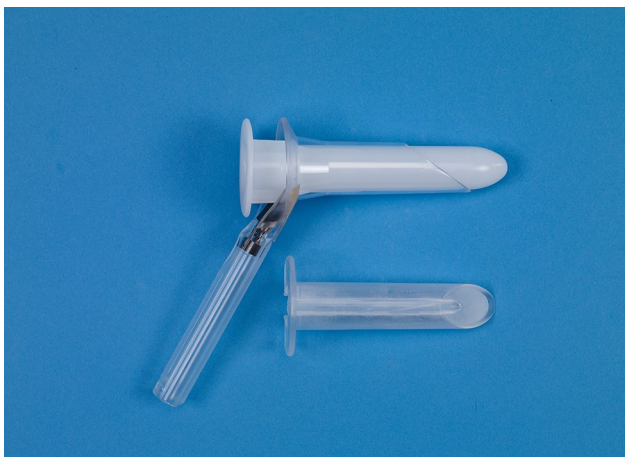

Fig. 1 Disposable anoscope (kit for HeLP)

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

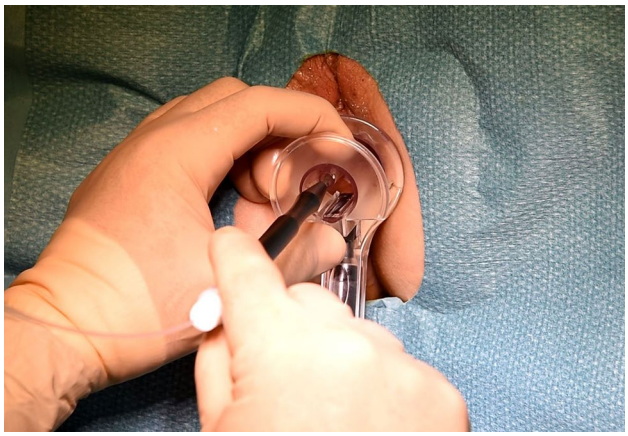

Fig. 4 Closure of arterial branches with the laser fiber

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

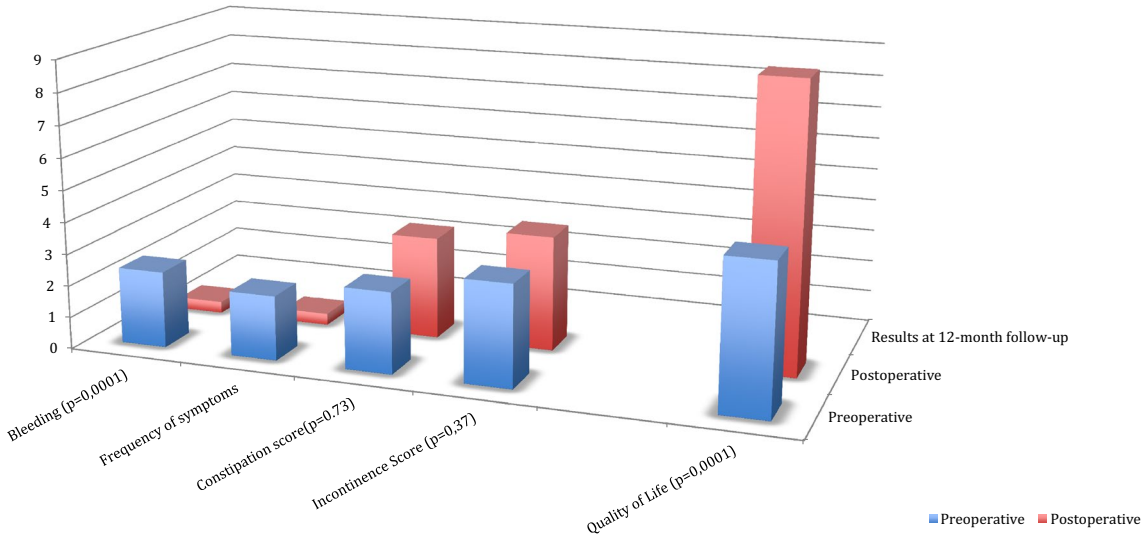

Fig. 5 Diagram showing clinical results at 12-month follow-up (144 patients)

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.

Funding No funding was obtained for this study.
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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