Original article

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Short- and long-term outcomes of laser haemorrhoidoplasty for grade II–III haemorrhoidal disease

S. Faes*†, M. Pratsinis*‡, S. Hasler-Gehrer*, A. Keerl* and A. Nocito*

*Department of Surgery, Cantonal Hospital Baden, Baden, Switzerland, †Department of Visceral Surgery, Lausanne University Hospital CHUV, Lausanne, Switzerland, and ‡Department of Urology, Cantonal Hospital Saint-Gall, St Gallen, Switzerland

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Abstract

Aim Laser haemorrhoidoplasty is associated with minimal postoperative pain and good symptom improvement in the short-term. However, less is known about its long-term efficacy. This study aims to determine the short- and long-term outcomes of laser haemorrhoidoplasty.

Method Between October 2010 and May 2012, 50 consecutive patients with grade II–III haemorrhoids were treated with laser haemorrhoidoplasty. Short-term follow-up was assessed on days 1, 30 and 60 and long-term follow-up was at 5 years (haemorrhoidal stage reduction, pain, patient satisfaction, symptom improvement, incapacity for work, continence, complications, recurrence).

Results Short-term follow-up was achieved for all patients and long-term follow-up for 44/50 patients (88%). At short-term follow-up, haemorrhoidal stage reduction was documented in 49 (98%) patients. Complete or good symptom improvement was reported by 36/50 (72%) and 10/50 patients (20%) at 60 days. Postoperative complications occurred in 9/50 patients (18%) with three Clavien–Dindo grade IIIb complications (two fistulas, one incontinence), one grade IIIa (perianal thrombosis) and five grade I (one perianal thrombosis, two perianal eczema, one local bleeding, one anal fissure). Postoperative pain was low (visual analogue scale 0–1) at day 1 in 37/50 (74%), at day 30 in 47/50 (94%) and at day 60 in 50/50 patients (100%). After a mean follow-up of 5.4 years (SD 5.4 months) the recurrence rate was 34% (15/44 patients) with a median time to recurrence of 21 months (range 0.2–6 years).

Conclusion Although laser haemorrhoidoplasty achieves a high short-term success rate with respect to stage reduction and symptom improvement, it is associated with a high rate of minor postoperative complications and long-term recurrence. Therefore, laser haemorrhoidoplasty should be used with caution.

Keywords Laserhaemorrhoidoplasty, haemorrhoids, laser surgery, minimal invasive haemorrhoidectomy, long-term outcome of haemorrhoidectomy

What does this paper add to the literature?
The short-term results of laser haemorrhoidoplasty are encouraging; however, the results of the study indicate that long-term recurrence is high. Laser haemorrhoidoplasty may not be appropriate for all patients with haemorrhoidal disease.

Introduction

Haemorrhoidal disease is common, affecting around 40% of the adult population and 50% of the population over 50 years of age [1,2]. In the USA almost one-third of these patients will present to a surgeon [2]. Since the first description of a haemorrhoidal operation in 460 BC by Hippocrates [3] a wide range of surgical procedures has evolved, with conflicting opinions on the most effective and least harmful technique. Whilst excisional techniques such as open or closed haemorrhoidectomy are recognized for their high short- and long-term efficacy, their drawback is severe postoperative pain and other complications [4–6]. Minimally invasive techniques maintain the integrity of the somatically innervated anoderm and are associated with less postoperative pain but higher long-term recurrence [4,7–10]. The optimal technique for the treatment of haemorrhoids would be associated with minimal pain and postoperative complications as well as a low long-term recurrence rate.

Laser haemorrhoidoplasty (LHP) was first described between 2007 and 2009 [11–13] and represents one of the most recent techniques to be described which seeks to provide optimal therapy for haemorrhoidal disease.

Correspondence to: S. Faes, Department of Surgery, Cantonal Hospital Baden, Im Ergel 1, CH-5404 Baden, Switzerland.
E-mail: seraina.faes@chuv.ch

The principle of this minimally invasive technique is the coagulation of the haemorrhoidal plexus through submucosal application of laser irradiation. A diode laser placed in the centre of a haemorrhoid cushion deploys radial energy at a wavelength of 1470 nm. This thermal energy leads to closure of the haemorrhoidal plexus and fixation of the rectal mucosa and submucosa to the muscular layer. Furthermore, fibrosis and tissue remodelling are initiated, leading to consecutive volume reduction, finally resulting in a retraction of the haemorrhoidal lobe in the ensuing weeks [11]. A further laser procedure, called the haemorrhoidal laser procedure (HeLP) [14], uses a different concept of laser surgery by achieving haemorrhoidal dearterialization. Here, a diode laser of wavelength 980 nm is used to coagulate and close the terminal branches of the superior haemorrhoidal arteries after their localization by Doppler guidance.

A number of studies have demonstrated that LHP is associated with minimal postoperative pain [11,15,16]. Furthermore, laser procedures are reported to lead to successful resolution of haemorrhoidal bleeding and prolapse, resulting in symptom relief in up to 97% of the patients [16]; this is associated with an earlier return to work [15] and high patient satisfaction [17].

Although LHP was first described over 10 years ago, most of the current literature still focuses on short-term benefits. The aim of this study was to investigate the long-term outcomes of LHP and seek to establish if the short-term benefits are maintained.

Method

Study design

This single-centre prospective study evaluated the short-term outcome of LHP over 60 days and the long-term outcome over 5 years with respect to postoperative pain, improvement of symptoms, reduction of haemorrhoidal prolapse, and recurrence. Follow-up was achieved by the use of a seven-point patient questionnaire (Figure S1 in the online Supporting Information) established specifically for this study and including the Visual Analogue Scale score (VAS score) [18] for pain and the Patient's Global Impression of Improvement scale (PGI-I) [19] for improvement of symptoms, together with clinical examination by the surgeon. A sample size of 50 patients was estimated as being necessary to ensure a sufficient number of patients at 5-year follow-up considering a possible drop-out rate of 10% to 20%. The study was approved by the ethical committee of north-west and central Switzerland.

Inclusion criteria, enrolment and study period

Inclusion, enrolment and follow-up followed the CONSORT 2010 statement (Fig. 1). Inclusion criteria were: age over 18 years, presence of symptomatic second- or third-degree haemorrhoids, the ability to complete the follow-up questionnaire in German or English, the absence of any contraindication for ambulatory surgery or treatment with paracetamol, ibuprofen or bupivacaine, and the completion of informed patient consent. Inclusion criteria were confirmed in outpatient clinics with evaluation of patient history, and examination of the anal region including proctoscopy. Enrolment of patients started in October 2010 and ended in April 2012 after the predefined number of 50 consecutive patients was reached. Five-year follow-up was concluded in May 2017.

Operative technique

All patients underwent LHP. They were all operated on by the same colorectal surgeon who was experienced in LHP. All procedures were performed using spinal or general anaesthesia. A biolitec laser system with a Ceralas E 1470 nm laser was used. A small skin incision with an electrocautery needle was performed at the entry point of the laser fibre. The radial fibre was inserted into the submucosa, advanced to the haemorrhoid cushion and then activated. The procedure was executed for one or more haemorrhoidal locations as necessary. Intra-operative cooling with a cold pack was intermittently performed between laser applications. Additional anal skin tags and fissures were treated by resection and fissurectomy, respectively. A pudendal block with bupivacaine was established at the end of the operation. Operative data including the number of haemorrhoids treated, as well as details of skin tag excision and fissurectomy, were recorded. In addition, we recorded the energy delivered per patient and per haemorrhoid, and all intra-operative complications. Patients were discharged home on the same day as surgery. Postoperative analgesia was managed by a nonsteroidal anti-inflammatory drug (NSAID; ibuprofen, 400 mg three times per day) and paracetamol (1 g four times per day).

Short- and long-term follow-up

Short-term outcome was assessed at postoperative days 1, 30 and 60. Long-term outcome was evaluated 5 years postsurgery. The parameters of short- and long-term follow-up are listed in Table 1 and include reduction of haemorrhoidal volume, recurrence, complications, incontinence (assessed by the surgeon), pain, improvement of

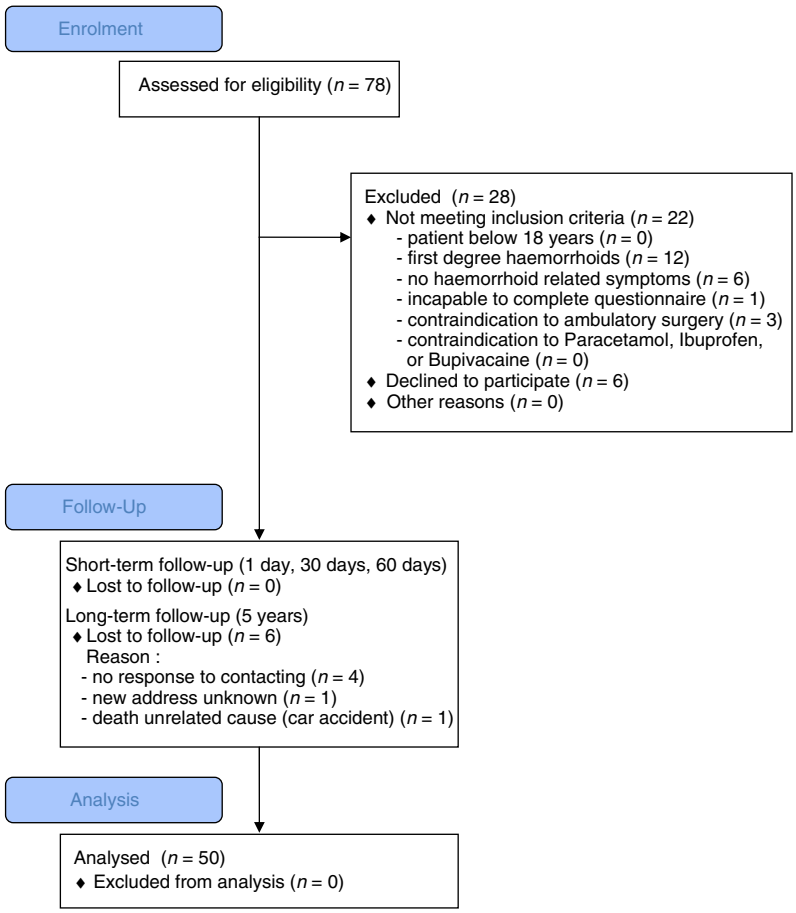

Figure 1 CONSORT flow diagram of the study showing its schematic profile.

Table 1 Short-term and long-term postoperative follow-up.

Evaluated by the surgeon	Reduction of haemorrhoidal volume: - diminution to first-degree haemorrhoids - no diminution to first-degree haemorrhoids Recurrence: - reappearance of haemorrhoidal prolapse Complications: - Clavien–Dindo score [31–33] Incontinence (Vaizey score) [20]
Evaluated by the patient (questionnaire in Figure S1)	Pain (VAS score [18]) Improvement of symptoms (PGI-I score [19]) Incapacity for work (number of days) Satisfaction (yes/no) Restraint of activity (yes/no) Benefit from operation (yes/no) Recommendation of the operation (yes/no)

symptoms, incapacity for work, satisfaction, restraint of activity, benefit from the operation and recommendation of the operation (assessed by the patient according to the questionnaire in Figure S1). Improvement of symptoms was assessed by the PGI-I scale [19] with respect to the five haemorrhoidal-related symptoms of bleeding, moistening, soiling, itching and pain.

Data analysis

Clinical findings were collected by an independent observer not present during the surgery. The age and gender of patients together with intra-operative and postoperative data (Table 1) were entered into an anonymised database. Data analysis was performed with GraphPad Prism 7.03, and figures were created with Microsoft Office Excel 2007 and GraphPad Prism 7.03. Nonparametric variables were compared with the two-tailed Mann–Whitney test. Categorical variables were analysed with contingency tests, where Fisher's exact test was used in the case of two categories and the chi-square test in the case of more than two categories. Since the two categories 'much worse' and 'very much worse' in the analysis of symptomatic improvement were zero, they could not be taken into account for the contingency test. Statistical significance was defined as $P < 0.05$.

Results

Pre- and intra-operative data

The study included 23 women and 27 men with a median age of 46 years (range 24–73). Haemorrhoidal disease was classified as grade II in 25 patients and grade III in 25 patients. A median number of three haemorrhoids per patient were treated (range one to six). Additional resection of anal skin tags was performed in 20 patients and three patients had a simultaneous fissurectomy. A mean energy of 486 J per patient and 154 J per haemorrhoid was applied. No intra-operative complications were observed.

Short-term follow-up

All 50 patients completed the short-term follow-up of 1, 30 and 60 days (Fig. 1).

Pain

Postoperative pain at day 1 was low in 37 patients with a VAS score of 0–1. VAS scores for the remaining 13 patients did not exceed 5. Pain decreased significantly from day 1 onwards [day 30 ($P = 0.04$); day 60 ($P = 0.0001$)]. The median VAS score was 0 for all time points (Fig. 2).

Postoperative complications

The 60-day complication rate was 18% (9/50). Minor complications classified as Clavien–Dindo I–IIIa amounted to 12% (6/50): two perianal vein thrombosis, two perianal eczema, one minor local bleeding and one anal fissure. Except for one patient with perianal vein thrombosis who received a thrombectomy under local anaesthesia, all patients were managed conservatively. Three (6%) major complications classified as Clavien–Dindo IIIb and higher occurred: two subcutaneous fistulas treated by fistulotomy under general anaesthesia and one patient with postoperative incontinence (Vaizey score of 18 [20]) treated by biofeedback and sacral nerve modulation. No systemic complications were observed.

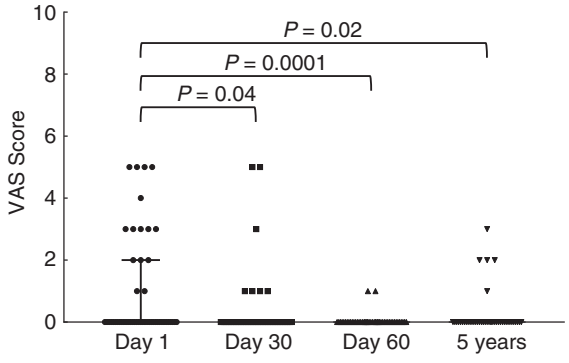

Figure 2 Postoperative pain scores.

Improvement of symptoms

At 30 days, 80% of patients (40/50) indicated a considerable improvement in their symptoms [very much improved in 56% of patients (28/50) and much improved in 24% of patients (12/50)] (Fig. 3). Little or no improvement was seen in 20% (10/50). At 60 days, 92% of the patients indicated that their symptoms had significantly improved [very much in 72% (36/50); much in 20% (10/50)]. Little or no improvement was found in 8% of the patients (3/50 little improvement; 1/50 no improvement). No patient indicated a deterioration of symptoms at 30 or 60 days. The two time points of 30 and 60 days did not differ significantly when considering all categories of improvement ($P = 0.29$). However, results suggest a tendency of improvement between 30 and 60 days which might be due to the prolonged time necessary for remodelling of initial pathological changes in the extracellular matrix in varicose veins [21].

Reduction of haemorrhoidal prolapse and recurrence

Reduction of haemorrhoidal prolapse to grade I was seen in all patients at 30 days and in 49 patients at 60 days, with a recurrence of grade III haemorrhoidal prolapse in one patient, resulting in a recurrence rate of 2% (1/50) at 60 days.

Incapacity for work and restriction of daily activity

The median postoperative incapacity for work was 2 days (range 0–20 days). One patient reported a restriction of daily activity, this patient being the one with faecal incontinence.

Benefit, satisfaction and recommendation

Out of 50 patients, 49 (98%) reported that they had benefited from the operation, were satisfied with the outcome and would recommend it to other patients or relatives. The one patient that reported no benefit or satisfaction from the operation and would not recommend the operation to others was the abovementioned patient with postoperative incontinence.

Long-term follow-up

Long-term outcome was assessed 5 years after LHP [mean follow-up of 5.4 years (SD 5.4 months)]. The 5-year follow-up rate amounted to 88% (44/50). Four patients did not respond to contact, one patient had

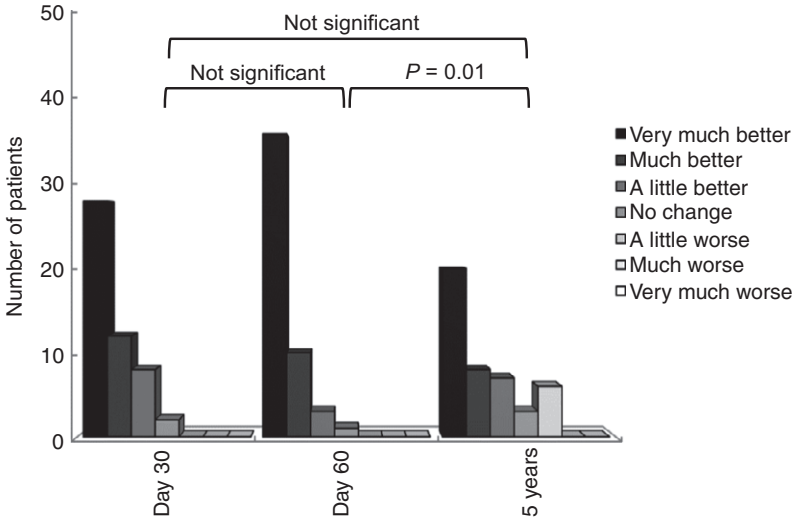

Figure 3 Symptom improvement using the Patient's Global Impression of Improvement scale (PGI-I) [19].

moved to an unknown new address and one patient had died in a car accident (Fig. 1).

Pain

Pain re-emerged in five patients with a VAS score between 1 and 3 (Fig. 2). Overall, VAS scores at 5 years were significantly better than on postoperative day 1 ($P = 0.02$), but not significantly different from postoperative day 30 ($P = 0.67$) or postoperative day 60 ($P = 0.14$).

Improvement of symptoms and recommendation

After 5 years, 64% of the patients still reported a significant improvement of symptoms [very much improved, 20/44 patients (45%); much improved, 8/44 patients (18%)]. Seven patients (16%) had only small improvements in their symptoms. No improvement or even a deterioration was found in 20% of the patients [no improvement, 3/44 patients (7%); deterioration, 6/44 patients (14%)] (Fig. 3). Compared with 60 days postsurgery, this deterioration was statistically significant (all categories $P = 0.01$; 'very much' and 'much' versus less improvement $P = 0.001$).

Persisting symptoms at 5 years (independent of their improvement) were bleeding in 14 patients, itching in 14 patients, moistening in 8 patients and pain in 3 patients; no patients reported soiling.

At the 5-year follow-up, 64% of patients (28/44) would still recommend LHP; this was significantly less than at the short-term follow-up (98%, 49/50) ($P = 0.00001$).

Recurrence

The recurrence rate of second- or third-degree haemorrhoids 5 years after LHP amounted to 36% (16/44 patients). Out of 16 patients with long-term recurrence, 9 had an initial haemorrhoidal grade of II and 7 grade III. The recurrence rate for grade II haemorrhoidal disease was 39% (9/23 patients) and for grade III haemorrhoidal disease it was 33% (7/21 patients). These two rates were not statistically significantly different ($P = 0.761$). Median time to recurrence was 21 months (range 2 months to 6 years). While a re-intervention was necessary in 20% of the patients (9/44) (stapled haemorrhoidopexy in five, rubber band ligation in four patients), seven patients were treated conservatively.

Discussion

The aim of this study was to determine whether or not the short-term benefits of LHP persist in the long-term. It is the first study to report on long-term results after LHP. The results of this study suggest that in the short-term LHP was highly effective in terms of symptom relief and reduction of haemorrhoidal prolapse, resulting in high patient satisfaction, but in the long-term, LHP was associated with a high recurrence and reoperation rate.

The application of lasers for the treatment of haemorrhoids was first proposed in the 1970s and 1980s [22–24]. Initially, CO_2, helium/neon or Nd-YAG (neodymium-doped yttrium aluminium garnet) lasers were employed. Diode lasers were first applied in 2005 [25]. By deploying thermal energy either at the base of branches of the superior haemorrhoidal arteries guided by Doppler sonography (the HeLP-technique [14]) or directly into the centres of haemorrhoidal cushions (the LHP-technique [11]), the diode laser induces photocoagulation and thus retraction of the haemorrhoidal cushion. Due to its precision and short application field, the risk of damage to deeper anatomical structures is less than with other lasers [12–14].

Laser coagulation was reported to induce less postoperative pain and perioperative bleeding than conventional haemorrhoidectomy [26,27]. Furthermore, both HeLP and LHP have achieved a high short-term success rate and symptomatic relief in 88%–97% of patients [11,13–15,17,25,28–30]. Our results are in agreement with these published results: we also found low postoperative pain scores as well as a significant improvement of symptoms in 92% of our patients. We recognize that the low postoperative pain at day 1 might have been due to the use of a pudendal block with bupivacaine performed at the end of the procedure as well as to the prescribed postoperative analgesic treatment by NSAID and paracetamol rather than to the low pain caused by LHP. In addition, in our study incapacity for work after LHP was short and patient satisfaction high.

Apart from short-term outcome, the complication and long-term success rates of any particular procedure are critical factors in determining the overall efficacy of a surgical technique. Although we observed good short-term results with respect to pain, symptom relief, incapacity for work and early recurrence, our complication rate of 18% was considerable. This observation concurs with the findings from other studies, reporting complication rates of 10%-42% [13,15–17]. Only one publication, including 341 patients, found a remarkably low complication rate of 3.5% [30], which could be due to differences in the recording and classification of minor complications [31–33]. In line with our findings, perianal vein thrombosis and subcutaneous fistula accounted for the most frequent postoperative problems the required re-intervention [15,16]. Further complications needing surgery were bleeding, abscess, tissue necrosis and development of a fibroma at the laser entry point [13,15–17,30]. Although unpleasant, all these complications can be managed expectantly and are not associated with adverse long-term sequelae. Unfortunately, one of our patients developed postoperative incontinence. This patient had no preoperative symptoms but did have a history of perineal damage postpartum. Possible explanations for this postoperative incontinence might be the effect of pile shrinkage with an underlying incontinence reaching manifestation or incidental damage to the internal or external sphincter due to thermally induced tissue necrosis and imprecise laser application. After an initial, brief improvement through biofeedback therapy, incontinence deteriorated again, finally necessitating implantation of a sacral nerve modulator. To our knowledge, no other case of incontinence post-LHP has yet been documented in the literature.

There are many possible explanations for the high complication rates associated with LHP, including the following. The diode laser deposits a large amount of energy into the haemorrhoidal cushion. Although the high absorption coefficient in blood and water leads to a specific energy being deposited into the tissue of first contact, imprecise laser application could lead to tissue necrosis and damage to deeper anatomical structures such as the internal anal sphincter. A further reason for the higher rate of complications and potentially for clinical failure of LHP compared with HeLP might be the different concept of surgery with minimally invasive dearterialization under Doppler guidance in HeLP [14, 34–36] as opposed to a direct application of thermal energy to the haemorrhoidal piles in LHP. Finally, simultaneous treatment of additional pathologies such as skin tags and anal fissures might further increase the risk of complications.

Our main findings were that LHP was associated with significant deterioration of symptoms and a high recurrence rate in the long-term. After 5 years only 63% of our patients still reported a significant improvement of symptoms, and 36% had a recurrence of second- or third-degree haemorrhoids. Twenty per cent of these cases necessitated reoperation. Not surprisingly, patient satisfaction was significantly lower at the long-term follow-up.

There is a paucity of information in the literature about the long-term results of LHP or HeLP. A cohort study which included 497 patients [17] treated by LHP reported a recurrence rate of 8.8% at 6 months, which is not incompatible with the high recurrence rate at 5 years as observed in our study. A study which included 97 patients [37] treated by HeLP with a median follow-up of 15 months reported residual bleeding in 12%, pain in 6%, itching in 6%, acute haemorrhoidal syndrome in 6% and haemorrhoidal recurrence in 5%. Since long-term data on LHP is still lacking, our results must be compared with the long-term outcomes of other minimally invasive and nonexcisional techniques. A recent multi-centre randomized controlled trial comparing haemorrhoidal artery ligation (HAL) with rubber band ligation (RBL), found a recurrence rate of 30% for HAL and 49% for RBL at 1 year postprocedure [38]. Accordingly, long-term single-centre studies and systematic reviews reported a recurrence rate of 11%–30% for HAL and 16%–37% for RBL [8,39–46]. The latest multi-centre randomized controlled trial showed that stapled haemorrhoidopexy, another nonexcisional technique, has a recurrence rate of 42% at 24 months in [47]. After a 10-year follow-up, the rate of recurrence after stapled haemorrhoidopexy was 39% in a recent single-centre study [48]. Taken together, all these studies suggest high long-term recurrence rates for minimally invasive procedures, similar to our own results. In

addition, in our hands, LHP was associated with a high complication rate, including a serious adverse event and high procedural costs, mainly related to the cost of the laser diode probe (486 Swiss Francs per intervention).

In conclusion, LHP offers a high short-term success rate in terms of postoperative pain, symptom relief and reduction of haemorrhoidal stage. However, LHP is associated with a high complication and recurrence rate in the long-term which precludes its routine use for the management of second- and third-degree haemorrhoids.

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Conflicts of interest

The authors disclose no potential conflicts of interest, no use of off-label or unapproved drugs or products, and no use of previously copyrighted material. This work was not supported by any funding, grant or financial relationships.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Questionnaire (English version) for follow-up at days 1, 30 and 60 and at 5 years.