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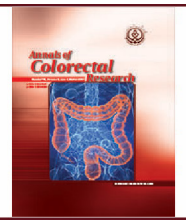

Short Term Outcomes of Laser Pile Ablation (LPA) to Treat II-III Degree Symptomatic Hemorrhoidal Disease

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Abstract

Background: This study aimed to assess the outcomes of Laser Pile Ablation (LPA) in patients affected by II-III degree symptomatic hemorrhoidal disease (HD).
Methods: Consecutive patients suffering from II-III degree symptomatic HD were enrolled to undergo LPA. The primary study endpoint was to assess postoperative pain according to both the numerical rating scale (NRS; 0-10) and the painkiller use. Secondary endpoints were intraoperative and postoperative complications and the recurrence rate (including bleeding and prolapse). Patient satisfaction was assessed at 6 and 12 months using a visual analog scale (VAS; 0-10) and by asking the patients whether they would undergo the procedure again and recommend it to a relative or friend.
Results: Twenty-five patients (7F–18M) were enrolled in the study. All the procedures were performed under spinal anesthesia and the mean amount of energy delivered was 472.6±50.7 J. The mean follow-up was 9 months (range 6-12). Mean postoperative pain (NRS) was 4.7±1.5 at 12 h, 4.4±1.3 at 24 h, and 2.2±1.0 at day 10. Pain was generally managed with paracetamol, with only 30.7 % requiring NSAIDs. The recurrence rate was 7.7% at 3 and 6 months after the procedure. The mean time interval to return to work was 2.7±2.1 days. All the patients were extremely satisfied with the procedure (VAS=9).
Conclusion: LPA is a safe, effective, and minimally invasive procedure for treating II-III degree HD with optimal management of postoperative pain and excellent patient satisfaction.

Keywords: Laser pile ablation, Laser hemorrhoidoplasty, Hemorrhoid, Laser, Stapled hemorrhoidopexy, Hemorrhoidectomy

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Introduction

Hemorrhoidal disease (HD) is defined as the symptomatic enlargement and distal displacement of the normal anal cushions caused by the distortion of the vascular channels associated with changes in the supporting connective tissue (1). HD is one of the most common anorectal benign diseases with an underestimated prevalence (2). It represents a socioeconomic problem due to its natural history and recurrent symptoms, which influence patients' quality of life (3, 4).

The most frequent symptoms are bleeding (inducing in some cases anemization), prolapse (which could be reduced manually or spontaneously after defecation), burning, and itching. The pain is frequently related to an acute hemorrhoidal crisis (5).

The treatment strategy is based on a step-up approach beginning with medical therapy. In case of persistent bothersome symptoms inadequately responsive to first-line therapy, a surgical approach is indicated. It may vary from minimally invasive and outpatient treatment to more conventional procedures performed in the operative room.

The postoperative outcomes including recurrence and patient satisfaction (due to effectiveness of the procedure and entity of post-operative discomfort) depend on the procedure performed, which should be chosen while taking into account the patients' preoperative expectations. Indeed, the negative perception of classical surgical procedures for HD may induce the patients to hesitate and delay the treatment to improve their quality of life because of the fear of the pain.

Over the last decade, efforts have been focused on finding less invasive surgical treatments for the management of HD with lower postoperative complications rates and less postoperative discomfort (5, 6). Laser Pile Ablation (LPA) is a novel technique first described in 2007 by Karahaliloglu *et al*. based on the shrinkage of the hemorrhoidal pile due to the application of the laser beam (7). This study aimed to assess the outcomes of LPA in patients affected by symptomatic II-III degree HD.

Materials and Methods

Between February 2019 to January 2020, all patients referred to the Coloproctologic Unit of Private Hospital of Forlì suffering from symptomatic II-III degree HD were enrolled to undergo LPA. The inclusion criteria were age >18 years and symptomatic II-III degree HD unresponsive to medical treatment. Exclusion criteria were recurrent HD after surgical treatment, acute thrombosis, inflammatory bowel disease, and inability to complete the study protocol.

Patients were preoperatively evaluated according to the following protocol: full clinical evaluation with medical and surgical history, physical examination with digital exploration, and anoscopy. Continence status was assessed through Cleveland Clinic Incontinence Score (8) before and after the procedure. Colonoscopy was preoperatively performed according to national guidelines for colorectal cancer screening. The follow-up was scheduled at 10 days and 1, 3, 6, and 12 months. All procedures were performed by the same surgeon (F.C.), experienced in coloproctological diseases.

The primary study endpoint was to assess the postoperative pain according to both the numerical rating scale (NRS; where 0 indicates the absence of pain and 10 is the maximum imaginable pain) and the use of painkillers. Postoperative pain was assessed at 12 h, 24 h, 10 days, and 30 days. Secondary endpoints were intraoperative and postoperative complications as well as the recurrence rate (including bleeding and prolapse). Patient satisfaction was assessed at 6 and 12 months using the visual analog scale (VAS; 0-10) and also through the questions "Would you undergo this surgery again?" and "Would you recommend this procedure to a relative or friend?".

Surgical Procedure

The laser procedure was performed using a 1470 – diode laser (LASEMAR® 1500 – Eufoton S.R.L., Trieste, Italy) with optic fiber (Hemofiber® - Eufoton S.R.L., Trieste, Italy). With the patient in the lithotomy position, three perianal stab incisions at the level of the main piles were performed (left lateral, right anterior and posterior). A single-use plastic proctoscope (Gull – Sapimed S.P.A. Alessandria, Italy) was used. The fiber was then introduced and advanced inside the hemorrhoidal pedicle until the base of the pile. Laser energy was delivered at 8.0 W power in pulsed mode with 5 pulses for each pile. Each pulse lasted 3.0 seconds with a 0.06 seconds pause. After each treatment, a wet gauze was applied for a few seconds to avoid overtreatment. The skin incisions were left open.

Results

Out of 32 patients referred to our center affected by symptomatic HD, 25 (7 women; 18 men) were enrolled to undergo the LPA procedure. The mean age was 50.8±13.3 years. The patients' characteristics are presented in Table 1. All the procedures were performed under spinal anesthesia and the mean amount of energy delivered was 472.6±50.7 J. There were no intraoperative complications, and the mean operative time was 15±5 min. The mean follow-up was 9 months (range 6-12 months).

Mean postoperative pain, assessed through the NRS scale, was 4.7±1.5 at 12 h, 4.4±1.3 at 24 h, and 2.2±1.0 at day 10. The pain was managed with paracetamol 1 gr (3 times per day); only 30.7% (8 pts) required NSAIDs in addition for 3 days.

All patients were discharged within 24 hours. In terms of minor postoperative complications, 11.5% (3 pts) developed urinary retention treated with catheterization, 11.5% (3 pts) experienced acute thrombosis of the external hemorrhoid treated conservatively, and 3.8% (1 pt) had abscess with superficial anal fistula requiring surgery. In 15.4% (4 pts) of cases, there was seromucous discharge from the small incisions for a few weeks after treatment. There were no cases of postoperative bleeding or impaired anal continence (no significant difference between preoperative and postoperative Cleveland Clinic Incontinence Score).

The recurrence rate was 7.7% (2 pts) at 3 and 6 months after the procedure, with both patients

Table 1: Patient characteristics

Characteristics	Study group (n=25)
Age (years)	50.8±13.3
Gender	18 males (72%) 7 females (28%)
Preoperative symptoms	
Bleeding	68%
Pain/discomfort	20%
Prolapsed hemorrhoids	12%
Hemorrhoid degree	
II	15 (60%)
III	10 (40%)
Number of piles treated	
2	8 (32%)
3	17 (68%)
Postoperative pain (NRS; 0-10)	
12 h	4.7±1.5
24 h	4.4±1.3
10 d	2.2±1.0
Postoperative complications	
Acute urinary retention	3 (11.5%)
Acute hemorrhoidal thrombosis	3 (11.5%)
Abscess with superficial anal fistula	1 (3.8%)
Persistent seromucous discharge	4 (15.4%)

NRS: Numerical rating scale

referring due to persistent bleeding. Both patients had three piles treated. They were treated with sclerotherapy, and the symptoms resolved.

The mean time interval to return to work was 2.7±2.1 days. All the patients answered that they would undergo the operation again and that they would recommend this procedure to a relative or friend, with a mean VAS satisfaction rate of 9/10.

Discussion

The treatment of HD remains one of the scariest surgical procedures for a benign disease because of the postoperative pain and discomfort (9). To overcome this limit, new surgical procedures were proposed using different devices (e.g., stapled hemorrhoidopexy [SH] and transanal hemorrhoidal dearterialization [THD]) (10, 11), which share the same basic concept of repositioning the hemorrhoidal tissues inside the anal canal and avoiding local excision (12).

Since its first description in 2007, LPA represents a minimally invasive alternative to conventional treatment. It is based on diode laser application inducing shrinkage of hemorrhoidal cushions while promoting adhesion to the underlying tissues (13). Although LPA can be performed under general anesthesia or spinal anesthesia, an advantage is the availability to use only bilateral pudendal nerve block with or without sedation. This allows to perform it also in those patients with comorbidities and high risks related to anesthesia (13).

Several studies have shown as this procedure is particularly effective in reducing postoperative pain and discomfort, while having fewer intra- and peri-operative complications when compared to open surgical procedures (13-15).

In the literature, there are few papers exploring the outcomes of LPA for treating HD. The largest series by Jahanshahi *et al.* on 368 patients reported no recurrences at 1 year and only a 3.5% complication rate (16). LPA was also compared by Naderan *et al.* to excisional surgery and the authors concluded that LPA resulted in less postoperative pain and fewer complications (14).

The results of the present series confirm the promising outcomes reported in the literature. Postoperative pain was easily managed with paracetamol and only a third of patients used NSAIDs for 3 days maximum. This is notably different from the common use of analgesics after excisional surgery (9), where opioids at high doses are typically necessary for several days. Although SH and THD were revealed to be less painful than excisional surgery (5), LPA seems to offer the greatest comfort as tenesmus and urgency were not reported after surgery.

Regarding the recurrences, we reported only 2 cases (7.7%) of persistent postoperative bleeding that were effectively managed with outpatient sclerotherapy. This rate is slightly higher than those reported in other series, but no cases of prolapse recurrence were recorded. Moreover, both cases were among the first cases of the series, meaning that these recurrences may be explained by the learning curve of the procedure and the incomplete shrinkage of minimal residual hemorrhoidal tissues. In fact, a fundamental step is to move the probe tip along the three directions of the pile (central and lateral right and left) involving the whole tissues that otherwise would not be anchored and fixed (14).

The overall complication rate was 42.3%, though most complications were only minor and were managed with medical therapy, excluding the fistulizing abscess that was surgically treated. It should be noted that 11.5% experienced acute urinary retention, which was probably related to the spinal anesthesia instead of the surgical procedure itself.

In contrast to previously published papers, 15.4% of the patients experienced seromucous discharge from the small incisions, which was easily managed by the patients without any nursing support. It lasted only a few weeks, meaning that it may be tolerated better than discharge following excisional surgery, which is more abundant and usually lasts over a month.

All the patients were extremely satisfied with the procedure, and this a parameter that should always be taken into account during preoperative counseling. Surgeons should ask the patient about their expectations and requirements (social or work limitations), before proposing a treatment tailored to the anatomo-functional (17) conditions while trying to meet the patient's needs.

An issue still debated is the cost of laser use. Although it is more expensive than a classical

diathermy Milligan-Morgan procedure, the costs reach a balance with the use of disposable devices (e.g., radiofrequency or ultrasound). Moreover, a faster return to normal activity and lower analgesic use certainly compensate for the slightly higher expense of treatment.

The present study had some limitations. Firstly, the small sample size precluded a more detailed statistical analysis and the likelihood to identify rare complications. Secondly, the short-term follow-up, which did however fit with the primary endpoint of assessing perioperative discomfort and pain.

Overall, our experience indicated that LPA is a safe, effective, and minimally invasive procedure for treating II-III degree HD, with excellent outcomes in terms of postoperative pain and patient satisfaction. However, even if these preliminary results are encouraging and promising, further studies are needed to assess long-term outcomes and to draw final conclusions.

Originality

The article is an original work, has not been published before, and is not being considered for publication elsewhere in its final form, in either printed or electronic media. The authors declare that any republication of the data (e.g., in secondary analysis or translation) will not constitute redundant publication, will not breach copyright, and will reference the original publication.

Availability of Data and Materials

The data that support the findings of this study are available from the first author, [F.C.], upon reasonable request.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards

Conflicts of interests: None declared.

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