Original Article

Efficacy and Safety of Laser Hemorrhoidoplasty in High-risk Patients: A Case-matched Study in a Single Center

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Key Words
Laser;
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Introduction. Hemorrhoids significantly impact one's quality of life, often necessitating surgical intervention. Laser hemorrhoidoplasty (LHP) has emerged as a relatively new minimally invasive option. However, the safety and efficacy were still not evaluated in high-risk patients.
Methods. A retrospective analysis was conducted at Taichung Veterans General Hospital, encompassing patients with symptomatic grade II-III hemorrhoids who underwent LHP between September 2020 and August 2022. Patients were categorized into high-risk (ASA score 3-4) and low-risk (ASA score 1-2) groups. Propensity score matching was employed to ensure balanced demographic and clinical characteristics between the groups. Data on patient demographics, surgical technique, postoperative outcomes, and follow-up were all collected and analyzed.
Results. Of the 182 patients who underwent LHP during the study period, 10 were categorized as high-risk, with 20 propensity-matched low-risk patients selected. The two groups exhibited similar baseline characteristics. No significant differences were observed in pain levels, complication rates, or patient satisfaction between the high-risk and low-risk groups. LHP demonstrated favorable short-term outcomes, including both reduced postoperative pain and bleeding. During telephone follow-ups, symptom recurrence rates were comparable between the two groups. However, a few patients reported dissatisfaction, primarily due to postoperative discomfort.
Conclusion. Laser hemorrhoidoplasty appears to be a safe and effective treatment for high-risk patients diagnosed with symptomatic hemorrhoids. Its minimally invasive nature and favorable short-term outcomes support its use as an alternative to traditional surgical interventions. Further research with extended follow-up is still needed in order to validate these findings.

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Hemorrhoids, composed of blood vessels and smooth muscle fibers, play a vital role in maintaining normal defecation and continence functions, as well as anal canal closure. The pathophysiology of symptomatic hemorrhoidal disease is increased blood flow and engorgement of the hemorrhoidal vascular plexus, due to the dysfunction and dilation of the hemorrhoidal vessels. Additionally, deterioration of the

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supportive tissue leads to the descent of hemorrhoids.[1] Symptoms associated with hemorrhoidal disease affect between 4.4% and 36.4% of the population,[2] and typically include bleeding, pain, anal irritation and prolapse, significantly impairing the quality of life for individuals affected.

Initial treatment usually consists of dietary adjustments, hydration and avoiding any straining during bowel movements. Topical remedies such as creams and suppositories can alleviate symptoms. Outpatient procedures such as rubber band ligation or sclerotherapy may be recommended for additional treatment. Surgical intervention is considered if conservative methods prove ineffective. Nonetheless, a hemorrhoidectomy often involves considerable postoperative pain, bleeding and urinary retention, leading to a prolonged recovery period.[3-5] Therefore, patients with moderate to severe systemic diseases, as well as the elderly, should carefully consider surgical treatment options.

Laser hemorrhoidoplasty (LHP) uses diode laser technology to target hemorrhoidal tissue, inducing vessel destruction and fibrous tissue development. This method is recommended for individuals diagnosed with grade II and III hemorrhoids. Its minimally invasive approach, offer of reduced pain, and shorter recovery period have made this non-excisional procedure increasingly popular for treating symptomatic hemorrhoids.[6] For high anesthetic risk patients, conservative treatments have usually been preferred, however the role of LHP had not yet been previously established. This study aims to assess the safety and treatment efficacy of LHP in patients with a high anesthetic risk.

Materials and Methods

This retrospective study was carried out at Taichung Veterans General Hospital from September 2020 to August 2022 and received approval from their Institutional Review Board (TCVGH-IRB No.: CE 23101C). All individuals diagnosed with symptomatic grade II to III hemorrhoids, who had undergone LHP during the above-stated period, were sequentially enrolled in this retrospective study. Patients were divided into two groups: high-risk and low-risk. The high-risk group comprised all patients with an American Society of Anesthesiologists (ASA) score of 3 or 4. The low-risk group was selected from patients with ASA scores of 1 or 2. Comparative analysis of the two groups was conducted through a case-matched design, taking into account patient demographics and clinical attributes such as gender, age and their grade of hemorrhoids. Data pertaining to patients were gathered from hospital records as an integral aspect of this study. Subsequent to the surgical procedures, follow-ups were carried out through a combination of clinic appointments and individual telephone interviews. Those patients who opted out of participating in the telephone interviews were excluded from the analysis. To ascertain the absence of any additional underlying diseases, we confirmed that all patients over the age of 45 had undergone a colonoscopy within the past three years.

Surgical technique

In this study, the Laser Hemorrhoidoplasty (LHP) procedure employed the LHP kit provided by Biolitec® biomedical technology. Patients were placed in the jack-knife prone position before receiving an intravenous general anesthesia. Local anesthesia, consisting of bupivacaine 0.5% (20 ml), lidocaine 2% (20 ml), and distilled water (10 ml), was peripherally injected into the external sphincter of each quadrant as a pudendal nerve block.[7] A Ferguson retractor was introduced, followed by the insertion of the diode laser probe through the perianal skin, advancing it submucosally. Intermittent laser shots were delivered using a 980 nm wavelength with a power output of 2 watts, combined with a 1,470 nm wavelength at a power output of 6 watts (Fig. 1). After the conclusion of each laser devascularization, an ice column was introduced into the anal canal and maintained for 2 minutes in order to facilitate both cooling and compression (Fig. 2). The post-surgery photos are as shown in Fig. 3. Upon discharge, analgesics (Flurbiprofen 100 mg, Acetaminophen 500 mg) were prescribed for use as needed (PRN).

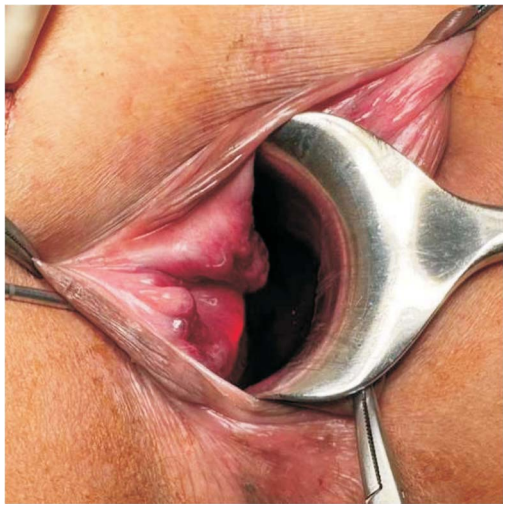

Fig. 1. The laser probe reached deep into the site where the suture ligation was performed.

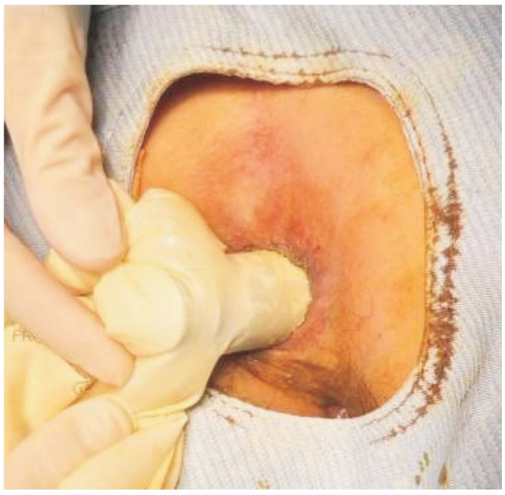

Fig. 2. Cooling compression.

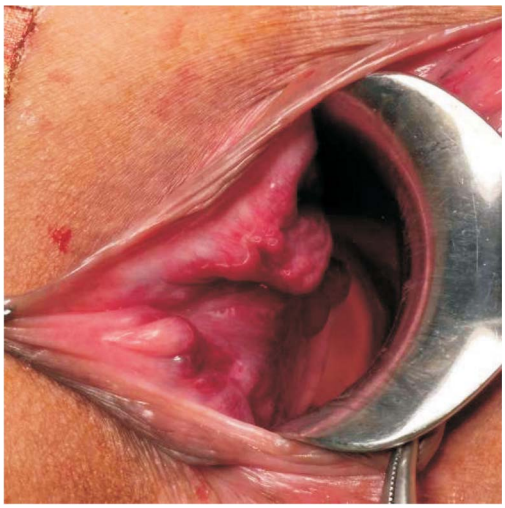

Fig. 3. After the whole procedure.

Follow-up

At the outset, our follow-up protocol included two consecutive outpatient visits. The initial visit was scheduled to take place within 1 to 2 weeks following discharge, while the second visit was planned for 4 to 6 weeks after discharge. A digital rectal examination was to be performed during the second outpatient visit. Subsequently, we implemented further postoperative follow-up through telephone interviews.

Outcome measures

Pain levels were assessed using a visual analogue scale (VAS) scoring system, both 4 hours after the procedure and on the postoperative day prior to discharge. During the two outpatient follow-up visits, we recorded whether patients required additional analgesics as part of the pain assessment. Postoperative complications were evaluated according to the Clavien-Dindo classification. During phone interviews, a structured questionnaire was used to inquire about any short-term post-surgical discomfort, including its duration and whether any interventions were required. Furthermore, we investigated the recurrence of symptoms prior to surgery, such as bleeding and prolapse, and assessed the timing of these recurrences. Patient satisfaction with the surgical outcome was also assessed, and in cases of dissatisfaction, the reasons for each patient's discontent were meticulously documented. We analyzed postoperative pain, complications, recurrence and satisfaction in both the high-risk and low-risk groups.

Statistical analysis

The data were analyzed using statistical software for biomedical research (SPSS software version 23). Patient characteristics were assessed using analysis of variance (ANOVA), the Fisher's exact test was utilized for two categories, and nonparametric variables were compared using the Mann-Whitney test. Statisti-

cal significance was set at $p < 0.05$.

Results

Between September 2020 and August 2022, a total of 182 patients underwent laser hemorrhoidoplasty (LHP) at Taichung Veterans General Hospital. Amongst them, 10 patients were categorized as high-risk. Propensity score matching based on gender, age, BMI and hemorrhoid grading was utilized to select a total of 20 patients in a 1:2 ratio as the low-risk group. In February 2023, telephone interviews were successfully conducted with all 30 patients, with a median follow-up period of 13 months. The study cohort consisted of 17 males and 13 females, aged between 42 and 85 years (median: 63.5 years). There were 17 patients with grade 2 and 13 patients with grade 3 hemorrhoids. BMI ranged from 15.35 to 42.52, with a median of 24.92. The follow-up period varied from 7 to 24 months, with a median of 12.5 months. The range of laser energy output per site ranged from 213.5 to 386.2 joules, with a median of 326 joules. Detailed group information is provided in Table 1.

In the high-risk group, each patient had between 1 to 3 underlying diseases. Specifically, there were a total of five patients with coronary artery disease, four with hypertension, three with cerebrovascular accidents, three with diabetes, two with arrhythmia, two with end-stage renal disease, one with morbid obesity, and one with liver cirrhosis.

Regarding pain expression, there were no statistically significant differences observed between the two groups across various time points, including four hours postoperatively ($p = 0.198$), and postoperative Day 1 ($p = 0.559$). During the first outpatient visits, 15% of low-risk patients required additional analgesics, compared to 10% of high-risk patients ($p = 0.593$). During the second visits, the proportion remained at 15% for low-risk patients, with none in the high-risk group requiring additional analgesics ($p = 0.281$). Detailed data are presented in Table 2.

Regarding complications, three patients experienced grade one urinary retention (two from the high-risk group), which was treated with catheterization. One patient in each group experienced grade two postoperative bleeding, which was managed through compression and blood transfusion. Additionally, one patient in the low-risk group required surgical hemostasis for grade three postoperative bleeding, and another developed an anal fistula, necessitating surgical intervention. However, there were no statistically significant differences in the occurrence rates of complications between the two groups. Detailed data are presented in Table 3.

During telephone interviews, three patients in the low-risk group reported recurring symptoms, with recurrence developing 8, 10 and 18 months after the procedure, respectively. A total of 25 patients across both groups expressed satisfaction, while three in the low-risk group and two in the high-risk group reported dissatisfaction with their surgical outcome. Reasons for dissatisfaction included outcomes not meeting expectations, changes in defecation habits, and postoperative bleeding or infection. However, there were no statistically significant differences between the low-

Table 1. Patient characteristics

	Group		*p* value
	Low risk (n = 20)	High risk (n = 10)	
Male	10 (50%)	7 (70%)	0.314
Grade 3 hemorrhoid	9 (45%)	4 (40%)	0.803
Age*	63 (52, 77)	65 (42, 85)	0.946
BMI*	24.9 (20.0, 31.6)	24.1 (15.4, 42.5)	0.815
Follow up period (Months)*	12.5 (7, 24)	12.5 (7, 18)	0.336
Laser energy (Joule)*	325.4 (215.4, 386.2)	326.5 (213.5, 344.8)	0.655

n: number; BMI: body mass index.

* Continuous variables are expressed as median and range.

Table 2. Pain presentation

	Group		*p* value
	Low risk (n = 20)	High risk (N = 10)	
VAS (4 hours after OP)*	3 (8, 1)	2 (5, 1)	0.198
VAS (POD1)*	1 (3, 0)	1 (2, 0)	0.559
Additional analgesic at 1st OPV	3 (15%)	1 (10%)	0.593
Additional analgesic at 2nd OPV	3 (15%)	0 (0%)	0.281

VAS: Visual Analogue Scale; OP: operation; POD1: postoperative day 1; OPV: outpatient visiting; n: number.
* Continuous variables are expressed as median and range.

Table 3. Complications (Clavien-Dindo classification)

	Group		*p* value
	Low risk (n = 20)	High risk (n = 10)	
All complications	4 (20%)	3 (30%)	0.657
Urine retention, Grade 2	1 (5%)	2 (20%)	0.251
Hemorrhage, Grade 2	1 (5%)	1 (10%)	0.563
Hemorrhage, Grade 3	1 (5%)	0 (0%)	0.667
Fistula, Grade 3	1 (5%)	0 (0%)	0.667

n: number.

Table 4. Telephone interview about recurrence and satisfaction

	Group		*p* value
	Low risk (n = 20)	High risk (n = 10)	
Recurrence	3 (15%)	0 (0%)	0.281
Satisfaction	17 (85%)	8 (80%)	0.551

n: number.

risk and high-risk groups in terms of symptom recurrence (15% vs. 0%, $p = 0.281$) and satisfaction (85% vs. 80%, $p = 0.551$). Detailed data are presented in Table 4.

Discussion

Patients diagnosed with symptomatic hemorrhoids have multiple treatment options. Apart from conservative treatment, office-based procedures are also an option, with rubber band ligation (RBL) being the most commonly used.[8] However, studies have indicated that the recurrence rate after one year of RBL treatmentis 49%, with 32% of patients requiring additional treatment.[9]

In recent decades, non-excisional techniques have emerged as alternatives for treating hemorrhoidal disease. One such technique is LHP. In a systematic review,[10] compared to traditional procedures, LHP was found to reduce postoperative VAS scores (24 hours after operation: MD, -2.09; 95% CI, -3.44 to -0.75; $p = 0.002$) and decrease oral analgesic consumption (RR, 0.59; 95% CI, 0.42-0.81; $p = 0.001$). The postoperative complication rate was lower in the LHP group, including both bleeding (6 studies, n= 520; RR, 0.18; 95% CI, 0.12-0.28; $p < 0.001$) and urinary retention (5 studies, n = 316; RR, 0.30; 95% CI, 0.10-0.95; $p = 0.040$). Due to the decreased postoperative pain and fewer complications associated with LHP, patients can resume their normal daily activities more quickly. These benefits make it safer for patients with one or more moderate to severe systemic diseases to undergo this surgery. Our study found no significant differences in pain, complication rates, recurrence rates or satisfaction levels between patients with ASA scores of 1-2 and those with an ASA score of 3. This finding further reinforces the efficacy and safety of LHP as a viable treatment option for patients with hemorrhoids.

In our study, the range of laser energy output per site ranged from 213.5 to 386.2 joules, which did not exceed the amount recommended by the manufacturer. A previous study in 2023[11] mentioned that their total laser energy applied ranged from 450 to 1242 joules, but it did not compare the treatment effectiveness or associated complications with different energy levels.

While LHP is generally considered safe, our study revealed that some complications and postoperative discomfort still affected patient satisfaction. Postoperative bleeding emerged as the most common issue. A previous study[12] reported that 60% of patients experienced post-defecatory bleeding on the day after their operation, with all cases resolving by the 7th postoperative day. In our study, one patient experienced postoperative bleeding and required a second operation. Reviewing his medical record, we found that during the first surgery, the laser energy applied at the 11 o'clock position was 172 joules. In the second surgery, a bleeding point was found at the same 11 o'clock position, and the mucosa in that area showed signs of probe penetration. Hemostasis was achieved by ligat-

ing the area with a 3-0 Vicryl suture. We hypothesize that the initial energy application was insufficient and the probe depth was too shallow, resulting in ineffective hemostasis with subsequent pressure. Additionally, since this patient was among the first treated with the newly introduced equipment, the lack of experience likely led to an inability to accurately control the probe depth. Additionally, another complication, which required surgical intervention, was the development of fistulas at the laser entry point. In our study, one patient who developed a fistula experienced mucosal layer injuries during the operation. The patient successfully recovered following a fistulotomy. Therefore, avoiding puncturing the mucosa with the laser probe could potentially reduce such complications. During phone interviews, two patients expressed dissatisfaction due to changes in defecation habits after surgery. One patient experienced a tenesmus sensation, while the other reported increased flatulence. Fortunately, these symptoms gradually ameliorated over time. In a prior study performed by Faes et al.,[13] one patient developed postoperative incontinence, which may have been attributed to unintended thermal damage to either the internal or external sphincter and imprecise laser application. Although no patients in our study experienced fecal incontinence as a complication, it still remains important to carefully control the depth of the laser probe and the duration of cauterization.

This study has several limitations that need to be acknowledged. Firstly, it is a retrospective study conducted at a single institution, with surgical procedures initiated as early as September 2020. Consequently, obtaining long-term follow-up results is unfeasible due to the relatively short duration of the study period. While short-term outcomes and satisfaction have shown to be favorable, long-term follow-up results are still necessary. Secondly, the lack of significant differences in the statistical analysis may also be attributed to the limited sample size, which could affect the generalizability of the findings.

Conclusion

In this study, LHP has been shown to be a safe procedural option for both elderly patients and those with one or more moderate to severe diseases, as there was no significant difference in postoperative complications, recurrence rate, and satisfaction. This minimally invasive procedure reduces postoperative pain and bleeding, thus facilitating a faster recovery and an earlier resumption of daily activities. Additional studies involving a long-term follow-up and a larger sample size will still be necessary in the future in order to further substantiate our findings.

Conflict of Interest Statement

The authors declare no conflicts of interest in the study.

Role of Any Funding Source

The authors declare no role of funding source in the study.

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原　著

雷射痔瘤整形術運用於高風險病患之安全性以及效果：單一中心病例對照研究

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雷射痔瘤整形術為一新的微創手術選擇，且適用於高風險患者。本研究評估了 LHP 在這群病患中的安全性和有效性。在台中榮民總醫院進行了一項回顧性分析，自 2020 年 9 月至 20229 年 8 月期間接受治療的患者。患者被分為高風險 (ASA 分數 3-4) 和低風險 (ASA 分數 1-2) 兩組。採用傾向性分數匹配並收集和分析了患者的人口統計學資料、手術技術、術後結果和隨訪資料。研究共包含 10 名高風險以及配對的 20 名低風險病患，兩組之間的術後疼痛、併發症、滿意度以及復發率皆無顯著差異。此術式是一種安全有效的治療方法，且適用於高風險患者。但仍然需要更大量之樣本數、進一步的研究以及長期追蹤以驗證此結果。

關鍵詞　雷射、痔瘡、高風險。