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# A comparative evaluation of laser hemorrhoidoplasty versus open surgical hemorrhoidectomy treatment of grade III and IV hemorrhoids. A prospective observational study

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ABSTRACT

The aim of the present study was to evaluate and compare the efficacy and outcomes of laser hemorrhoidoplasty with that of open surgical hemorrhoidectomy. This prospective observational study consists of 50 subjects in each group. The open surgery group underwent a standardized Milligan-Morgan technique, and the laser group underwent laser hemorrhoidoplasty with a diode laser of 1470 nm (LASOTRONIX), 8.5 watts with a continuous pulse. Postoperative pain was considered as the primary outcome and was evaluated in both groups using the visual analog scale. There was a statistically significant difference between the two groups in VAS score at different follow-up period, with a mean score of 2.3±1.05 and 5.1±1.11 (24 hours) for the laser hemorrhoidoplasty group and open surgery group, respectively (p value < 0.008). There was an improvement in VAS score in the laser hemorrhoidoplasty group compared to the conventional open surgical group in 1, 7, 14, 21, and 30 days follow up.

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## Introduction

Hemorrhoids are typical anorectal conditions defined as the symptomatic enlargement and distal displacement of the anal cushions [1]. The international incidence varies between 50% -80%, in India the incidence being around 75% of the population [2]. The most well-known manifestations include pain, anal irritation, rectal bleeding, anal mass prolapse, and lifestyle disorders [3]. The internal anal sphincter and anorectal vascular cushions provide soft tissue support and keep the anal canal closed, thus maintaining the continence. The downward displacement of the suspensory (Treitz) muscle is considered to be the key factor causing hemorrhoids [4].

The various nonsurgical treatments include rubber band ligation (RBL), cryotherapy, injection sclerotherapy, infrared coagulation, laser therapy, and diathermy coagulation, a considerable lot of which might be proceeded as outpatient procedures without anesthesia. These nonsurgical methods are considered to be the essential procedure for grades I-III hemorrhoids [5]. Although various therapies have been recommended for this benign disease, cases of symptomatic hemorrhoids refractory to medical therapy require surgical treatment [6–8].

The choice of surgery remains debatable. Open (Milligan-Morgan) or closed (Ferguson) techniques are the commonly employed surgical methods, the Milligan-Morgan hemorrhoidectomy being the benchmark and regularly performed procedure. Although there is a low recurrence rate with this therapeutic approach, the post hemorrhoidectomy pain is the major problem associated with the surgical techniques. On the other hand, suspensive approaches are associated with a high recurrence rate. Thus, even if they have low postoperative pain and discomfort, such procedures are often associated with the onset of new symptoms. In spite of many modifications made to the hemorrhoid surgical techniques, postoperative pain and discomfort still remain the main concern. Postoperative pain is the major drawback of Milligan-Morgan hemorrhoidectomy [9]. Additional complications are represented by urinary retention (20%), bleeding (2%-

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6%) and subcutaneous abscess (0.5%), which appear in the first days. The long-term complications include anal stenosis (1%), anal fissure (1%-2%), fistula (0.5%), incontinence (0.4%), and recurrence of hemorrhoids [10-12]. For this reason, mildly symptomatic patients often decline to go through surgical treatment for this benign disease [13].

Laser hemorrhoidoplasty (LHP) is a novel, less invasive and painless procedure compared to the surgical therapy of symptomatic hemorrhoids. Diode laser is used in this technique to promote shrinkage of the hemorrhoidal outgrowths. Commonly used laser energy sources are carbon dioxide, argon, and Nd:YAG. Tissue shrinkage and degeneration at different depths are performed by the laser beam, and the result varies depending on the power of the laser and the duration of application of laser light [11,13].

The aim of the present study was to evaluate and compare the efficacy and outcomes of laser hemorrhoidoplasty with that of open surgical hemorrhoidectomy, among the symptomatic grade III and IV hemorrhoidal disease admitted for surgery. The objective of the studies was:

- To compare the VAS score after laser hemorrhoidoplasty and open surgery for grade III and IV hemorrhoidal disease.
- To compare the usage and requirement of analgesics, duration of hospital stay, and recovery time after both procedures.

## Materials and Methods

*Study population*

The study population included all patients with symptomatic hemorrhoids, grade III and IV according to the Goligher's classification [14], admitted for surgery in Dr. B. R. Ambedkar Medical College and Hospital Bangalore during the study duration.

*Inclusion criteria*

- The inclusion criteria were represented by patients with an American Society of Anesthesiologists' (ASA) physical status of grade I or II.
- Age ≥ 18 years
- Symptomatic hemorrhoidal disease of III and IV-degree with failure of conservative medical treatment.

*Exclusion criteria*

- Patients who did not agree with the protocol and patients under 18 years of age
- Coexisting anorectal disease (perianal fistula, anal fissure, or abscess).
- Previous history of anorectal surgery.
- Regular use of immunosuppressants or analgesics.
- Neurologic deficit, chronic pain syndrome, and patients who are unfit for either surgery or anesthesia.

*Study design*

A prospective observational study

*Sample size*

The sample size was calculated assuming the expected mean and standard deviation of the VAS at six hours in the laser group as, σ1 (5.2,0.7) and in the open surgical as, σ0 (5.7,1), according to the previous study by Mohammad Naderan et al. [13]. The other parameters considered for sample size calculation were represented by 80% power of the study and 5% two-sided alpha error.

The required sample size as per the calculation was 48 in each group. To account for a non-participation rate/loss to follow up rate of about 5%, another 2 subjects will be added to the sample size in each group. Hence, the final required sample size would be 50 subjects in each group.

*Sampling technique*

All the eligible subjects were recruited by convenient sampling until the sample size was obtained (50 in each group).

*Study duration*

A duration of 18 months, from January 2019 to June 2020.

*Operative procedure*

The operations were performed for both groups under standardized spinal anesthesia with the patient in the lithotomy position. All surgical procedures were performed by surgeons experienced in proctologic surgery, assisted by an appropriate collaborative team. The open surgery group underwent a standardized Milligan-Morgan technique [7]. In the laser group, a diode laser 1470 nm (LASOTRONIX) (Figure 1) of 8.5 watts with a continuous pulse was used. The bare fiber of 0.6 mm thickness with a dose of 150-350 joule/segment was used, depending on the size of hemorrhoids (Figure 2). The energy was delivered at the apex of the hemorrhoidal mass in the submucosal plane, inside the venous plexus (Figures 3a and 3b). Fibrotic shrinkage and hemorrhoid reduction occurs due to the destruction of hemorrhoidal vessels as a result of energy absorbed by the tissues (Figures 4a and 4b).


**Figure 1**. Diode laser 1470nm (LASOTRONIX 8.5 watt)


**Figures 2** (a-b). Preoperative pictures of hemorrhoids


**Figure 3**. Laser hemorrhoidoplasty procedure. Figure 3a - delivering laser energy on mucosal side. Figure 3b- delivering laser energy to hemorrhoidal mass in submucosal plane.


**Figure 4**. Postoperative pictures performed after laser hemorrhoidoplasty; Figure 4a - external appearance, Figure 4b - showing shrinkage of hemorrhoidal mass

*Outcome measures*

Postoperative pain was considered as the primary outcome and was evaluated using the visual analog scale (VAS 0-10) [15], with 0 corresponding to 'no pain' and 10 representing 'maximum pain.' The intensity of pain using the VAS scale after discharge was evaluated at days 1, 7, 14, 21, and 30. The study group (laser/open surgery group) was considered as the primary explanatory variable.

The data obtained for the analysis include the following: the basic characteristics of the patients (including the age, gender), grade of hemorrhoids, preoperative symptomatology (bleeding, pain, itching), operative characteristics (including blood loss and operative time), and postoperative data. The usage and requirement of analgesics, duration of hospital stay, recovery time, and postoperative VAS scales were included for analysis. Early postoperative complications like secondary bleeding, urinary retention, and late postoperative complications like acute thrombosis, anal discharge, and anal stenosis were assessed.

All quantitative variables were checked for normal distribution within each category of the explanatory variable, by using visual inspection of histograms and normality Q-Q plots. Shapiro-Wilk test was also conducted to assess normal distribution. Shapiro-Wilk test p value of >0.05 was considered as the normal distribution. For normally distributed quantitative parameters, the mean values were compared between study groups using an independent sample t-test (2 groups). Categorical outcomes were compared between study groups using the chi-square test/ Fisher's Exact test (if the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.). P value < 0.05 was considered statistically significant. coGuide version V.1.0 was used for statistical analysis [16].

## Results

A total of 100 subjects were included in the final analysis. The mean time taken for the procedure was statistically significant, with less time taken for the laser group (p value <0.001). The blood loss in the laser group was minimal and this was statistically significant (p value <0.001).

The usage of analgesics was found to be less in the laser group compared to the open surgery group (p value <0.001). The mean difference in length of hospitalization (in days) was not statistically significant between the two groups (p value 0.098), while the mean difference in duration of recovery was statistically significant between two groups (p value <0.001) (Table 1).

There was a statistically significant difference between the two groups in VAS score at different follow-up periods (p value 0.008) (Table 2). Early and late complications were less in the laser hemorrhoidoplasty group but were not statistically significant, except for urinary retention (p value 0.009) and anal stenosis (p value 0.033) (Table 3).

**Table 1.** Comparison of baseline parameter between study group (N=100)

| **Parameter** | **Study group** | | **P-value** |
|---|---|---|---|
| | **Laser group (N=50)** | **Open surgery group (N=50)** | |
| Age (in years) **(mean ± SD)** | 42.7±10.1 | 41.6±10.3 | 0.578 |
| **Gender** | | | |
| Male | 32 (64%) | 29 (58%) | 0.681 |
| Female | 18 (36%) | 21 (42%) | |

| | | | |
|---|---|---|---|
| **Grade of hemorrhoids** | | | |
| III | 27 (54%) | 30 (60%) | 0.544 |
| IV | 23 (46%) | 20 (40%) | |
| **Preoperative symptoms** | | | |
| Bleeding | 46 (92%) | 45 (90%) | 0.738 |
| Pain | 22 (44%) | 26 (52%) | 0.548 |
| Itching | 12 (24%) | 17 (34%) | 0.378 |
| **Outcomes** | | | |
| Duration of surgery (min) **(mean ± SD)** | 23.2±1.9 | 34.3 ±5.5 | <0.001 |
| Blood loss **(mean ± SD)** | 14.0 ±5.5 | 38.5 ±8.8 | <0.001 |
| Morphine dose **(mean ± SD)** mg | 2.9 ±1.4 | 7.8 ±2.5 | <0.001 |
| Duration of hospital stay **(mean ± SD)** | 1.1 ±0.3 | 1.2 ±0.3 | 0.098 |
| Duration of recovery **(mean ± SD)** | 14.3 ±4.9 | 18.2 ±3.1 | <0.001 |

**Table 2.** Comparison of VAS score between different follow-up periods (N=100)

| Vas score | Study group | | P value |
|---|---|---|---|
| | Laser group (N=50) | Open surgery group (N=50) | |
| 1 day | 2.3±1.05 | 5.1±1.11 | 0.008 |
| 7 days | 1.6±0.08 | 3.8±1.23 | |
| 14 days | 1.1±0.04 | 1.8±0.12 | |
| 21 days | 0.6±0.03 | 1.5±0.09 | |
| 30 days | 0.2±0.01 | 0.8±0.03 | |

**Table 3.** Comparison of complications between study groups (N=100)

| Complications | Laser group (N=50) | Open surgery group (N=50) | P-value |
|---|---|---|---|
| **Early** | | | |
| Secondary bleeding | 0 (0%) | 2 (4%) | 0.475 |
| Urinary retention | 0 (0%) | 8 (16%) | 0.009 |
| **Late** | | | |
| Acute thrombosis | 2 (4%) | 0 (0%) | 0.475 |
| Anal discharge | 0 (0%) | 4 (8%) | 0.125 |
| Anal stenosis | 0 (0%) | 5 (10%) | 0.033 |

## Discussions

The results of the study showed an improvement in VAS score over a period in the laser group. Other clinical parameters like usage and requirement of analgesics, duration of hospital stay, and recovery time also improved postoperatively in the laser group compared to the open surgical group.

Postoperative discomfort and pain are the most commonly reported complications after surgical hemorrhoidectomy. An expansive range of non-excisional and less intrusive procedures, including the stapled hemorrhoidopexy, transanal hemorrhoidal dearterialization (THD), and hemorrhoidal artery ligation (HAL) was endeavored to decrease the postoperative pain [17–19]. The need for treatment for hemorrhoids is mainly based on the individual perception of the severity of symptoms, and the treatment plan is decided according to the traditional classification of hemorrhoids, which is not associated with the severity of symptoms [20]. The variety of treatment modalities further added debates regarding the choice of treatment strategy. The topic of the best treatment method stays one-sided, despite exposure to randomized assessment.

Laser hemorrhoidoplasty was presented in 2006 as an alternative minimal-invasive treatment option for hemorrhoidal disease [21]. The wavelength of the diode laser used was 1470 nm. The laser beam penetrates up to 2 mm, which causes submucosal denaturation and results in precise shrinkage of the hemorrhoidal tissue. It causes less damage to the surrounding tissue and also prevents the formation of any sphincteric lesions as compared to Nd:YAG laser due to selective and better adsorption by the hemoglobin [17]. In addition, the new connective tissue is

generated by fibrosis and thus ensures complete adherence of mucosa to the underlying tissue. In the proctologic literature reviewed, the laser ablation method had a short engagement time, low postoperative pain, and a fairly good efficiency in the treatment of hemorrhoidal disease, compared to relatively similar but more invasive techniques [13].

In our study, postoperative pain was significantly lower in the laser hemorrhoidoplasty group when compared with conventional open surgical hemorrhoidectomy ($p < 0.001$). Similar results were reported in the studies performed by Plapler H. et al. [17], Crea N. et al. [22], Majeed S. et al. [23], and Mohammed AF. et al. [24]. A study done by Jahanshahi et al. analyzed the feasibility of laser hemorrhoidoplasty using a 1470-nm diode laser in fifty patients, which is the largest reported series. The postoperative pain score (at 12, 18, and 24 h postoperatively) was extremely low in their study (mean value 2), which was evaluated using a visual analog scale [25]. The level of postoperative pain or VAS on day one of our studies was on average $2.3 \pm 1.05$ for the laser group, compared to $5.1 \pm 1.11$ for the open surgical group. On day 30, in the laser group, the average level of pain or VAS was $0.2 \pm 0.01$, while in the open surgery group it was $0.8 \pm 0.03$. Similar results were obtained in a study performed by Maloku H. et al. in 2019 (day one LH group VAS $2.2 \pm 0.3$ v/s MM group VAS $4.5 \pm 0.8$) [26].

Our study showed that laser hemorrhoidoplasty is a safe procedure associated with less postoperative pain. A low complication rate of 3.51% and zero recurrences at 1-year follow-up was also reported in a previous study [25]. The efficacy of laser hemorrhoidoplasty with 980 nm diode laser was compared with the conventional Milligan-Morgan resection in 60 patients by Naderan et al. The authors reported identical outcomes and effectiveness with both the techniques, emphasizing better results with laser hemorrhoidoplasty method in reducing postoperative pain and complications [13]. Conversely, laser hemorrhoidoplasty was reported to be associated with higher pain and bleeding compared to the doppler-assisted hemorrhoidal laser procedure (HeLP) by Giamundo et al. However, there are not yet relevant published data able to support this conclusion [27].

In the present study, lesser duration time and lower blood loss were observed in the laser hemorrhoidoplasty group compared with open surgical hemorrhoidectomy, which was well perceived by patients with symptomatic hemorrhoidal disease of stage III or IV (23.2 minutes versus 34.3 minutes; $p < 0.001$). Similar results were reported in a study done by Maloku H et al. (15.94 minutes for LH versus 26.76 minutes) [11].

Postoperative complications like secondary bleeding, urinary retention, anal stenosis, and anal discharge were nil in the laser hemorrhoidoplasty group in the present study. Similar results were observed in the study done by Mohammed AF. et al. [24]. These points can be viewed as persuading factors for patients with hemorrhoids to decide to follow treatment.

*Limitations*

The current study has some limitations that need to be presented. First, the sample size is small, which precluded any analysis of the effect of covariates and the evidence of rare complications. In addition, the long-term follow-up data after the procedure is not available.

## Conclusions

The laser hemorrhoidoplasty is a minimally invasive and safe procedure, being more preferred in comparison with conventional open surgical hemorrhoidectomy. Postoperative pain is significantly lower in laser procedures compared with the open surgical hemorrhoidectomy. Intraoperative and postoperative symptoms like blood loss, analgesic dose, duration of recovery, and duration of surgery showed a positive outcome in the study group. There were fewer postoperative complications and negligible need for analgesics and wound care after laser hemorrhoidoplasty. As a consequence, the laser hemorrhoidoplasty is a good and safe procedures for surgical management of hemorrhoids.

## Conflict of interest disclosure

There are no known conflicts of interest in the publication of this article. The manuscript was read and approved by all authors.

## Compliance with ethical standards

Any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript. The study was approved by the institutional review board and the ethics committee of the hospital, data confidentiality is maintained, and informed written consent was obtained from all the study participants.

## Abbreviations

ASA-American Society of Anesthesiologists', HAL-Hemorrhoidal Artery Ligation, HeLP-Doppler Assisted Hemorrhoidal Laser Procedure, LHP-Lase Hemorrhoidoplasty, MM- Milligan-Morgan, Nd: YAG-Neodymium-doped: Yttrium Aluminium Garnet, RBL-Rubber Band Ligation, THD - Trans anal Hemorrhoidal Dearterialization, VAS-Visual Analog Scale.

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