

## Clinical Outcomes of Stapler Haemorrhoidopexy versus Laser Haemorrhoidoplasty with Finger Guided Haemorrhoidal Artery Ligation in Grade II & III Internal Haemorrhoids

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Received: 25-04-2024 / Revised: 23-05-2024 / Accepted: 25-06-2024

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Conflict of interest: Nil

### Abstract:

**Objective:** The aim of this study is to compare the intra- and postoperative time and bleeding, postoperative pain and duration of hospitalisation, postoperative clinical outcomes viz. stenosis, recurrence and patient satisfaction Stapler Haemorrhoidopexy and Laser haemorrhoidoplasty in the management of second-degree and third-degree piles.

**Methods:** This randomized prospective comparative study was done in the department of General surgery at RKDF Medical College Hospital and Research Centre, Bhopal. The work started after the review and approval of protocol of study by Institutional Ethics and Research committees. All patients fulfilling the inclusion criteria were studied pertaining to disease under study. The allocation of patients to the two surgical techniques was randomized. The details of the cases was recorded as per the proforma. The patients were followed up for a duration of 6 month. Operative time, postoperative pain and complications, resolution of symptoms, and length of return to daily activity were prospectively evaluated.

**Results:** The most common presenting features were bleeding (93%), pain (89%), and prolapsed haemorrhoids (69%). Most of the patients have grade II haemorrhoids (60.7%) (Table 1). No patients suffered from spontaneous bleeding after surgery. While 112 patients (65%) experienced post-defecatory bleeding the day one after surgery, and 49 patients (28.3%) on postoperative day 3. The average VAS score 6h,12h,24h,48h and 72h after surgery were 3,2,2,1,3,0,4 and 0.1 respectively. There was no deviation in any patient from the normal postoperative course or any need for pharmacological treatment or surgical, endoscopic, and radiological interventions in this study.

**Conclusion:** Laser haemorrhoidoplasty appears to be a promising and effective non excisional surgical procedure in the treatment of symptomatic haemorrhoidal disease with high patient satisfaction, acceptable postoperative symptoms, minimal complications, and short operating times. MMH + ND-HAL was a satisfactory surgical modality for treating II/III haemorrhoids.

**Keywords:** Milligan-Morgan haemorrhoidectomy (MMH), Non-doppler hemorrhoidal artery ligation (NDHAL).

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### Introduction

Haemorrhoidal disease is the most common anorectal disease affecting millions of people around the world and representing a major medical and socioeconomic problem, severely affecting patients' quality of life [1,2]. Haemorrhoids or haemorrhoidal columns are submucosal cushions containing venules, arterioles, and smooth muscle fibres; with the internal anal sphincter, they are essential in the maintenance of anal continence by providing soft tissue support and keeping the anal canal closed tightly [2]. Despite modifications and progress in the haemorrhoidal disease, surgical

techniques, postoperative pain and discomfort, mucous discharge, daily activity limitation, and recurrence remain the major drawbacks [1]. However, the conventional haemorrhoidectomy (Milligan–Morgan) is associated with a low rate of recurrence, but postoperative pain and discomfort are still of major concern. Instead, the newly developed techniques lead to less postoperative pain and discomfort, but are associated with higher recurrence rates. The postoperative complications that a patient may experience after haemorrhoidectomy are variable: degrees of pain

vary according to the technique used, urinary retention, bleeding, incontinence, wound infection, abscess formation, fistula formation, anal fissure, stenosis, and recurrence [3-6]. Stapled haemorrhoidopexy is performed with a circular stapler device, which circumferentially disconnects the mucosa and submucosa above the dentate line. Many studies have reported less pain, short hospital stay, and early return to work in comparison with conventional haemorrhoidectomy, which accounts for the preference among patients toward haemorrhoidal disease. Laser haemorrhoidoplasty is a newly developed minimally invasive and painless 1-day surgery technique for the treatment of symptomatic haemorrhoids, influencing the shrinkage of the haemorrhoidal piles. The commonly used laser energy in medicine includes diode, carbon dioxide, argon, and Nd: YAG. The laser beam causes tissue shrinkage and degeneration at different depths according to the laser power and the duration of application of laser light [2,7].

### Materials and Methods

We conducted this randomized prospective comparative study in the department of General surgery at RKDF Medical College Hospital and Research Center, Bhopal. The work was started after the review and approval of protocol of study by Institutional Ethics and Research committees. We included all patients fulfilling the inclusion criteria, who visited RKDF Medical College Hospital and Research Center, Bhopal pertaining to disease under study. The allocation of patients to the two surgical techniques was randomized. The details of the cases was recorded as per the proforma. The patients were followed up for a duration of 6 month.

**Study type:** A randomized prospective comparative study

**Study Design:** This will be a hospital based, single-centre, parallel-group, comparative, prospective study. All the cases would be operated by a single surgeon.

**Study Setting:** Department of Surgery, RKDF Medical College, and affiliated hospitals, Bhopal, Madhya Pradesh.

**Study Duration:** 18months; from Jan 2023 to 30 June 2024.

### Study Outcomes:

1. Intra- and postoperative time
2. Intra- and postoperative bleeding
3. Pain in the postoperative period

4. Duration of hospitalization
5. Stenosis and recurrence.
6. Overall patient satisfaction

An internationally accepted visual analog score would be used for pain evaluation

**Measurement of the Outcome Time Points:** The primary outcome(s) will be measured at the following prescribed time interval:

- Intraoperative period
- Postoperative period
- At the time of discharge
- At the time of last follow up visit.
  - I) Day 7
  - II) 1 month
  - III) 6 months

**Study Population:** Patients diagnosed with second-degree and third-degree haemorrhoids. These would be randomly divided in two groups and would undergo either elective stapled Haemorrhoidopexy or laser Haemorrhoidoplasty with FGHAL.

**Sample Size:** 160.

**Participants' recruitment:** The recruitment of the participants and primary data collection will be started once the protocol is approved by the ethical committee. Following are the criteria of the study:

### Inclusion Criteria:

- i) Any adult patient who presented to the general surgery outpatient clinics with symptomatic haemorrhoid grades II and III (pain, bleeding, and discomfort defecation).
- ii) Patient who give their consent for study.
- iii) Patients who agreed to continue follow-up for 1 year.

### Exclusion Criteria:

- Any patient with
  - i) Fourth-degree haemorrhoids with mucosal prolapse (only eligible for conventional haemorrhoidectomy or stapler Haemorrhoidopexy),
  - ii) Recurrent haemorrhoids after surgery,
  - iii) Patients with thrombosed haemorrhoids
  - iv) Pregnant females
  - v) Malignancy
  - vi) Patients with portal hypertension

### Observation Chart

**Table 1: Baseline characteristic of the patients**

Characteristics	Study group (n = 173)
Age (years)	27-65
Gender	Male:127 Female: 46
Preoperative symptoms	
Bleeding	161(93%)
Pain	154(89%)
Prolapsed hemorrhoids	119 (69%) Hemorrhoid grade
II	105(60.7%)
III	65(37.9%)
IV	2(1.4%)

**Table 2: Postoperative bleeding Type Number of patients (%)**

	Day 1	Day 3	Day 7	Day 14	Day 21
Spontaneous	0	0	0	0	0
Post-defecatory	112(65%)	49(28.3%)	0	0	0
No evidence of bleeding	60(35%)	124(71.7%)	0	0	0

**Table 3: Symptoms 6-months after surgery**

Symptoms	Number of patients (%)
Completely resolved	156(90.2%)
Partially resolved	16(9.2%)
Persistent	10(0.6%)

## Results

We included 173 patients in this study, with 127 males and 46 females. The age of the patients ranged from 27 to 65 years. The most common presenting features were bleeding (93%), pain (89%), and prolapsed hemorrhoids (69%). Most of the patients have grade II hemorrhoids (60.7%) (Table 1). No patients suffered from spontaneous bleeding after surgery. While 112 patients (65%) experienced post-defecatory bleeding the day one after surgery, and 49 patients (28.3%) on postoperative day 3. From the 7th postoperative day, no bleeding event occurred in our cohort (Table 2). No patients experienced seromucous discharge for the absence of open surgical wounds, and no patients reported fecal incontinence (mean Cleveland clinic incontinence score was 0) in the follow-up period. 90.2% had completely resolved symptoms 6-months after surgery (Table 3). The average VAS score 6h,12h,24h,48h and 72h after surgery were 3,2.2,1.3,0.4 and 0.1 respectively. There was no deviation in any patient from the normal postoperative course or any need for pharmacological treatment or surgical, endoscopic, and radiological interventions in this study.

**Statistical Analysis:** The collected data was summarized by using frequency, percentage, mean & S.D. To compare the qualitative outcome measures Chi-square test or Fisher's exact test was used. To compare the quantitative outcome measures independent t test was used. If data was not following normal distribution, Mann Whitney U

test was used. SPSS version 22 software was used to analyse the collected data. p value of <0.05 was statistically significant.

## Discussion

Gupta K et al did a retrospective cohort study on clinical outcomes in patients with haemorrhoids treated by finger-guided hemorrhoidal artery ligation with laser Haemorrhoidoplasty. Retrospectively collected and analysed the data from hospital records of patients treated with FGHAL with LHP for their haemorrhoid disease to understand the impact on pain, bleeding, and resolution of symptoms. FGHAL is a cost-effective alternative to DGHAL. FGHAL, followed by the LHP technique, provides a very low pain and discomfort with minimal need for analgesics and wound care, electing it among the procedures suitable for HD. The method is a cost-effective alternative to DGHAL.

Maloku H did a trial comparing 2 treatments for haemorrhoids of third and fourth degree Laser haemorrhoidoplasty procedure vs open surgical haemorrhoidectomy. Haemorrhoid laser procedure (LHP) is a new laser procedure for outpatient treatment of haemorrhoids in which hemorrhoidal arterial flow feeding the hemorrhoidal plexus is stopped by laser coagulation. Significant differences between laser Haemorrhoidoplasty and open surgical procedure were observed in operative time and early postoperative pain. The laser Haemorrhoidoplasty procedure was more effective than open surgical haemorrhoidectomy.

Postoperative pain and duration time are only two indicators for this difference between these procedures.

Knight JS, Senapati A et al assessed the safety and short term outcomes of the procedure for prolapsing haemorrhoids (PPH), a relatively new procedure for the treatment of symptomatic haemorrhoids. Procedure for PPH is a safe and effective procedure for symptomatic haemorrhoids with good short-term outcomes. Long-term follow-up is required perhaps through a compulsory national register. Pescatori M et al studied postoperative complications after procedure for prolapsed haemorrhoids (PPH) and stapled trans anal rectal resection (STARR) procedures. In conclusion, complications after PPH and STARR are not infrequent and may be difficult to manage. However, if performed in selected cases by skilled specialists aware of the risks and associated diseases, some complications may be prevented.

Naderan M et al did a randomized controlled trial comparing laser intra haemorrhoidal coagulation and Milligan-Morgan haemorrhoidectomy. Operative time, postoperative pain and complications, and recovery or resolution of symptoms were measured. Patients were followed up for at least one year for evaluating healing, resolution of symptoms, and late complications. One-year follow-up showed comparable results in terms of the resolution of symptoms and sustainable cure. Intra-hemorrhoidal coagulation with 980-nm diode laser reduces postoperative pain, intra-operative bleeding, and administered analgesics with a comparable resolution rate of haemorrhoid symptoms. However, for the patients who experience complications, such as hemorrhoidal thrombosis, the overall pain may be equivalent to or even worse than conventional haemorrhoidectomy.

Brusciano L et al studied postoperative discomfort and pain in the management of haemorrhoidal disease and evaluated laser haemorrhoidoplasty as a minimal invasive treatment of symptomatic haemorrhoids. Laser Haemorrhoidoplasty (LHP) is a minimal invasive procedure for HD treatment determining the shrinkage of the hemorrhoidal piles by diode laser. The aim of the current study is to analyse the feasibility and efficacy of LHP in patients with II–III degrees haemorrhoids. Consecutive patients with II–III degree haemorrhoids were enrolled in the study and underwent an LHP treatment using a 1470-nm diode laser. Operative time, postoperative pain and complications, resolution of symptoms, and length of return to daily activity were prospectively evaluated. Recurrence of prolapsed haemorrhoid or symptoms at a minimum follow-up of 6 months was evaluated. The greatest strength points were low postoperative pain, the presence of slightly

significant peri-anal wounds, no special anal hygienic measures and low surgical time. No postoperative spontaneous bleeding occurred. The 100% of our population came back to daily activity 2 days after surgery. At a mean follow-up period of 8.6 months, we reported a recurrence rate of 0%. LHP demonstrated a large efficacy in selected patients. The greatest strength points were low postoperative pain, the presence of slightly significant peri-anal wounds, no special anal hygienic measures and low surgical time. Thus, resulting in a negligible postoperative discomfort, LHP could be considered a painless and minimal invasive technique in the treatment of HD.

This study by Faes S et al aims to determine the short- and long-term outcomes of laser haemorrhoidoplasty. 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. 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). 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). 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.

Milligan-Morgan haemorrhoidectomy (MMH) is the most widely used surgical procedure because of its precise curative effect, but it has the disadvantages such as obvious postoperative pain and bleeding. Long Q et al did a single centre retrospective study on Milligan-Morgan haemorrhoidectomy combined with non-doppler hemorrhoidal artery ligation for the treatment of grade III/IV haemorrhoids. Authors compared demographic and clinical characteristics of both groups, including intraoperative blood loss, postoperative visual analogue scale (VAS) for pain, analgesic consumption, postoperative bleeding,

perianal incision edema, urinary retention, anal stenosis, anal incontinence incidence, recurrence rate (prolapse or bleeding), and patient satisfaction. MMH+ND-HAL was a satisfactory surgical modality for treating III/IV haemorrhoids.

Laser haemorrhoidoplasty (LHP) is an emerging nonexcisional surgical procedure in which the arteriovenous flow of the haemorrhoidal plexus is interrupted through laser coagulation. Boerhave NH et al did an observational cohort study on the efficacy of laser haemorrhoidoplasty (LHP) in the treatment of symptomatic haemorrhoidal disease. The aim of this cohort study was to assess efficacy of LHP in treating symptomatic haemorrhoidal disease through patient satisfaction, remission of symptoms (blood loss, pain, itching, soiling, mucosal prolapse) and recurrence of haemorrhoids. Patient satisfaction regarding LHP treatment was reached in 155 (84,7%) patients. Postoperative blood loss was reported by 44 (24,0%) patients during time of evaluation. Twenty-four (13,1%) patients reported postoperative pain after 6–7 weeks. Postoperative complications occurred in seven patients (3 anal fissures, 2 perianal abscess, 1 perianal fistula, 1 postoperative anaemia). Room turnover time (patient in to patient out) was 21 min with an average operating time of 7 min. Recurrence of haemorrhoids within 1 year occurred in 50 (27,3%) patients. Laser haemorrhoidoplasty appears to be a promising and effective nonexcisional surgical procedure in the treatment of symptomatic haemorrhoidal disease with high patient satisfaction, acceptable postoperative symptoms, minimal complications and short operating times.

### Conclusion

LHP surgery can be the most effective and affordable treatment option for grade II and III hemorrhoids patients. LHP technique provides a very low pain and discomfort period with minimal need of analgesics and wound care, electing it among the procedures suitable for HD. However, a longer follow-up period needs to verify long-term outcomes of this treatment for HD and compare this technique to the current conventional ones

### Declarations:

**Funding:** None **Conflicts of interest/Competing interests:** None **Availability of data and material:** Department of Surgery, RKDF Medical College, and affiliated hospitals, Bhopal, Madhya Pradesh. **Code availability:** Not applicable **Consent to participate:** Consent taken **Ethical Consideration:** There are no ethical conflicts related to this study. **Consent for publication:** Consent taken

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