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Original Research

Efficacy of modified rubber band ligation in the treatment of Grade III internal hemorrhoids

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Abstract
Background: Hemorrhoidal disease is a common anorectal disorder, with Grade III internal hemorrhoids often requiring procedural intervention. (MRBL) and (MMH) are two widely used techniques for treatment. While MMH is a definitive surgical option, MRBL has emerged as a minimally invasive alternative with promising outcomes. A comparative evaluation of these procedures is essential to determine their efficacy, safety, and patient satisfaction.
Aim: The purpose of this study was to compare the functional and surgical results of MMH and MRBL in patients with Grade III internal hemorrhoids, with an emphasis on postoperative discomfort, complications, recurrence rates, and overall patient satisfaction.
Methods: At the Narayan Medical College & Hospital, a prospective, single-center, double-blind randomized controlled experiment was carried out. Two groups of sixty patients with Grade III hemorrhoids were randomly assigned: MRBL (n = 30) and MMH (n = 30). Patient satisfaction, recurrence rates, postoperative complications, baseline characteristics, and intraoperative parameters were evaluated. Statistical analysis was performed using SPSS version 21.0, with a p-value < 0.05 considered significant.
Results: MRBL showed a significantly lower blood loss (15.4 ± 3.8 mL vs. 32.5 ± 7.4 mL, $p < 0.001$) and a significantly shorter operating time (18.6 ± 4.2 min vs. 34.2 ± 6.1 min, $p < 0.001$) than MMH. The MRBL group experienced a shorter hospital stay (1.2 ± 0.5 days vs. 3.5 ± 1.2 days, $p < 0.001$) and significantly lower postoperative pain scores (VAS scale) (2.8 ± 1.1 vs. 6.5 ± 1.4, $p < 0.001$). Patient satisfaction was similar in both groups ($p = 0.56$), despite the MRBL group having a significantly higher recurrence rate at 6 months (13.3% vs. 6.7%, $p = 0.39$).
Conclusion: MRBL was found to be a less intrusive, safe, and effective substitute for MMH, resulting in shorter hospital stays, quicker recovery, and less postoperative pain. The MRBL group had somewhat higher recurrence rates, but the difference was not statistically significant.
Recommendations
For Grade III hemorrhoids, MRBL can be regarded as a first-line treatment, especially in outpatient settings where less intervention and a quicker recovery are preferred. Further long-term studies are recommended to assess recurrence patterns and optimize treatment protocols.
Keywords: Hemorrhoids, Rubber Band Ligation, Milligan-Morgan Hemorrhoidectomy, Minimally Invasive Surgery, Postoperative Outcomes.

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Introduction

Hemorrhoidal disease is one of the most common anorectal disorders, affecting nearly 4% of the global population, with a higher prevalence among adults over 40 years of age [1]. It results from vascular congestion and displacement of the anal cushions, leading to symptoms such as bleeding, prolapse, pain, and discomfort. Grade III internal hemorrhoids, characterized by prolapse requiring manual reduction, are particularly challenging to manage and often necessitate procedural interventions [2].

Conventional treatment options range from conservative management (dietary changes, fiber supplementation, and topical agents) to minimally invasive procedures like Modified Rubber Band Ligation (MRBL) and surgical interventions such as

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Milligan-Morgan Hemorrhoidectomy (MMH). RBL is a widely used, minimally invasive method where a rubber band is applied at the base of the hemorrhoidal tissue, leading to ischemic necrosis and eventual sloughing. MMH, on the other hand, is a traditional open surgical technique involving excision of hemorrhoidal tissue, often reserved for severe or recurrent cases [3].

Recent studies have evaluated the comparative efficacy, safety, and patient outcomes of these two procedures. (MRBL) has emerged as an improved variation of RBL, focusing on enhanced ligation techniques to improve therapeutic efficacy and minimize complications [4]. Studies have demonstrated significantly lower postoperative pain, shorter hospital stays, and fewer complications with MRBL compared to MMH [5]. In contrast, MMH is often associated with higher postoperative pain, longer recovery time, and a greater risk of complications such as urinary retention and anal stenosis [6].

More high-quality research is required to improve recommendations for the best treatment of hemorrhoidal illness, especially in light of the increased focus on patient-centered care. With an emphasis on postoperative discomfort, recurrence rates, and overall patient satisfaction, the current study compares the surgical and functional results of MMH with MRBL [7]. With an emphasis on postoperative pain, recurrence rates, complications, and overall patient satisfaction, this study sought to compare the surgical and functional results of MRBL and MMH in patients with Grade III internal hemorrhoids. The purpose of this study was to compare the functional and surgical results of MMH and MRBL in patients with Grade III internal hemorrhoids, with an emphasis on postoperative discomfort, complications, recurrence rates, and overall patient satisfaction.

Methodology

Study Design: It was a prospective, parallel-arm, double-blind, randomized controlled experiment conducted at a single center.

Study Setting: The study was conducted in the Department of General Surgery at NarayanMedicalCollege & Hospital, Bihar, after obtaining clearance from the Institutional Ethics Committee (IEC).

Study Duration: The study was done during the from March 2021 to February 2022.

Participants: The study comprised 60 participants who had been diagnosed with Grade III internal hemorrhoids. All eligible participants were evaluated and randomized into two study arms: MRBL and MMH.

Inclusion Criteria

- Patients aged 18–65 years diagnosed with Grade III hemorrhoids.
- Medically cleared for general anesthesia.
- Provided informed written consent.

Exclusion Criteria

- Patients who had undergone prior hemorrhoid treatment or surgery within the last six months.
- Patients with acute infections (e.g., hepatitis B, syphilis, HIV).
- Fasting blood glucose ≥8 mmol/L.
- Anemia severe (Hb < 60 g/L).
- Coagulation issues.
- Women who are menstruation or pregnant.
- Individuals suffering from serious systemic illnesses, such as cancer or cardiovascular disease.

Randomization and Bias Control

- Randomization: Patients were randomly allocated into either the MRBL or MMH group using computer-generated block randomization.
- Allocation Concealment: Each enrolled patient was assigned a unique identity number to ensure blinding. The allocation sequence was generated separately from the execution of the study to minimize selection bias.
- Blinding: The study was double-blind, meaning both the patients and outcome assessors were unaware of the treatment allocation.

Data Collection

- Baseline demographic and clinical data, including age, gender, preoperative symptoms (constipation, incontinence), hemorrhoid size, smoking/alcohol history, comorbidities, and medication use, were collected using structured case report forms.
- Preoperative assessment included (BMI), ASA (American Society of Anesthesiologists) score, digital rectal examination, and anorectal pressure measurements.
- Sigmoidoscopy or colonoscopy was performed in selected patients.
- Operative data, including surgical time, intraoperative bleeding, and complications, were recorded.

Procedure

1. **(MRBL):**
   - Patients were positioned in the right lateral position.
   - Under anesthesia, the hemorrhoids were visualized using an anal endoscope.
   - An elastic band was placed at different points above the dentate line to induce controlled strangulation.
   - Care was taken to avoid muscle tissue involvement.

2. **(MMH):**
   - The hemorrhoid was clamped, lifted, and excised using an electric knife.

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- Ligation was performed at the base, preserving at least 1 cm of normal mucosa.
- The surgical site was examined for bleeding or anal stenosis, and hemostatic dressings were applied.

Postoperative Care and Follow-up

- All patients received oral antibiotics, pain management, dietary modifications, and sitz baths.
- Primary Outcome Measure:
- Recurrence rate at six months (defined as recurrent prolapse or rectal bleeding).
- Secondary Outcome Measures:
- Postoperative pain (VAS scale) at 24 hours, 3 days, 7 days, and 14 days.
- Bleeding severity assessment.
- Urinary retention evaluation at 24 hours, 1 day, and 3 days.
- The sensation of anal distension at various intervals following surgery.
- Prior to and one month following surgery, resting anal pressure (RAP) was recorded.
- To assess recurrence, patients were contacted by phone at one and six months.

Statistical Analysis

- SPSS version 21.0 and GraphPad Prism 5 were used to analyze the data.
- If a continuous variable was normally distributed, the independent t-test was used for analysis; if not, the Mann-Whitney U test was used.
- The Chi-square test or Fisher's exact test were used to compare categorical variables.
- Calculations of cumulative incidence were used to examine recurrence rates.
- A p-value of less than 0.05 was deemed statistically significant.

Results

1. Baseline Characteristics

A total of 60 patients diagnosed with Grade III internal hemorrhoids were enrolled and randomized into two groups: (MRBL) (n = 30) and (MMH) (n = 30).

Table 1: Baseline Characteristics of Study Participants

Variable	MRBL (n = 30)	MMH (n = 30)	p-value
Age (years) (Mean ± SD)	45.2 ± 8.3	46.5 ± 9.1	0.62
Gender (Male/Female)	20/10	18/12	0.58
BMI (kg/m²) (Mean ± SD)	26.1 ± 3.5	25.8 ± 3.9	0.77
Smokers (%)	10 (33.3%)	12 (40.0%)	0.61
Diabetes (%)	8 (26.7%)	9 (30.0%)	0.78
Hypertension (%)	6 (20.0%)	5 (16.7%)	0.72

Age, gender distribution, BMI, smoking status, and comorbidities did not differ statistically significantly between the two groups ($p > 0.05$).

3. Intraoperative and Postoperative Outcomes

Table 2: Comparison of Surgical Outcomes between MRBL and MMH

Outcome Variable	MRBL (n = 30)	MMH (n = 30)	p-value
Operating Time (min) (Mean ± SD)	18.6 ± 4.2	34.2 ± 6.1	**<0.001**
Blood Loss (mL) (Mean ± SD)	15.4 ± 3.8	32.5 ± 7.4	**<0.001**
Hospital Stay (days) (Mean ± SD)	1.2 ± 0.5	3.5 ± 1.2	**<0.001**
Postoperative Pain (VAS Score)	2.8 ± 1.1	6.5 ± 1.4	**<0.001**
Urinary Retention (%)	2 (6.7%)	7 (23.3%)	**0.045**
Incontinence (%)	0 (0%)	1 (3.3%)	0.31
Wound Infection (%)	1 (3.3%)	3 (10.0%)	0.29

- MRBL experienced a considerably reduced intraoperative blood loss (15.4 mL vs. 32.5 mL, $p < 0.001$) and a significantly shorter operating time (18.6 min vs. 34.2 min, $p < 0.001$).
- The MRBL group experienced considerably less postoperative pain (as measured by the VAS score) than the MMH group ($p < 0.001$).
- MRBL patients experienced a considerably shorter hospital stay (1.2 vs. 3.5 days, $p < 0.001$).
- The MMH group experienced urinary retention more frequently (23.3% vs. 6.7%, $p = 0.045$).
- There was no discernible difference between wound infections and incontinence ($p > 0.05$).

3. Postoperative Complications

Table 3: Incidence of Postoperative Complications

Complication	MRBL (n = 30)	MMH (n = 30)	p-value
Bleeding (%)	2 (6.7%)	6 (20.0%)	0.12

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Anal Distension (%)	3 (10.0%)	8 (26.7%)	**0.08**
Recurrence at 6 months (%)	4 (13.3%)	2 (6.7%)	0.39

- The incidence of postoperative bleeding was 20.0% in MMH patients and 6.7% in MRBL patients; however, the difference was not statistically significant (p = 0.12).
  Patients with MMH experienced anal distension more frequently (26.7% vs. 10%, p = 0.08).
- At six months, MRBL had a significantly higher recurrence rate (13.3%) than MMH (6.7%), however this difference was not statistically significant (p = 0.39).

4. Recurrence Rate and Follow-up

Table 4: Recurrence and Patient Satisfaction at 6-Month Follow-up

Outcome Measure	MRBL (n = 30)	MMH (n = 30)	p-value
Recurrence Rate (%)	4 (13.3%)	2 (6.7%)	0.39
Patient Satisfaction (Scale 1-10, Mean ± SD)	8.2 ± 1.4	7.9 ± 1.7	0.56

- At six months, the MRBL group had a marginally higher recurrence rate (13.3%) than the MMH group (6.7%), although the difference was not statistically significant (p = 0.39).
- The two groups' patient satisfaction ratings were similar (p = 0.56).

Key points

- The study demonstrated that MRBL is a safer and more effective alternative to MMH for treating Grade III internal hemorrhoids.
- MRBL had significantly lower operating time, less blood loss, and shorter hospital stays, making it a minimally invasive and cost-effective treatment.
- Patients with MRBL had considerably reduced pain scores, which suggests improved postoperative comfort.
- The MRBL group had somewhat higher recurrence rates, but the difference was not statistically significant.
- Patient satisfaction remained high for both groups.

Discussion

The findings showed that MRBL was a minimally invasive, successful, and well-tolerated surgery that offered benefits in terms of hospital stay, postoperative discomfort, and surgical time, potentially making it a better option than MMH. Comparability was ensured by the similarity of baseline characteristics between the two groups, including age, gender, BMI, smoking status, and comorbidities. The fact that there were no statistically significant differences in the demographics of the patients confirmed that any disparities in the results were caused by the surgical methods and not by the individual patients.

Intraoperative outcomes favored MRBL significantly. The operating time for MRBL was much shorter (18.6 ± 4.2 min vs. 34.2 ± 6.1 min, p < 0.001), and blood loss was lower (15.4 ± 3.8 mL vs. 32.5 ± 7.4 mL, p < 0.001), suggesting that MRBL is a quicker and less invasive procedure. Furthermore, the MRBL group's postoperative hospital stay was noticeably shorter (1.2 days vs. 3.5 days, p < 0.001), suggesting a quicker recovery and less use of hospital resources.

Postoperative pain (VAS score) was lower in the MRBL group (2.8 ± 1.1 vs. 6.5 ± 1.4, p < 0.001), suggesting better patient comfort and a less painful recovery. Additionally, urinary retention was significantly less frequent in MRBL patients (6.7% vs. 23.3%, p = 0.045), reinforcing the gentler nature of the procedure. However, the rates of incontinence and wound infection did not show a significant difference between groups (p > 0.05), indicating that both procedures maintained acceptable safety profiles.

The MRBL group experienced fewer postoperative problems, including as hemorrhage and anal distension, albeit these changes were not statistically significant. Although MRBL patients had somewhat higher recurrence rates at six months (13.3% vs. 6.7%), the difference was not statistically significant (p = 0.39). There was no significant difference in patient satisfaction between the two groups (p = 0.56), suggesting that patients handled both operations well.

All things considered, the results point to MRBL as a successful and minimally invasive substitute for MMH, providing a quicker recovery, less pain following surgery, and a shorter hospital stay. MRBL had somewhat higher recurrence rates, although this difference was not statistically significant, and patient satisfaction was similar in both groups. These findings suggest that MRBL would be the best course of action for Grade III hemorrhoids, particularly in outpatient settings where a quicker recovery and fewer hospital stays are essential.

(MRBL) is being investigated more and more as a hemorrhoidectomy substitute for Grade III internal hemorrhoids. A randomized controlled experiment comparing MRBL and MMH in 120 patients was carried out by Jin et al. (2020). Comparing MRBL to MMH, the study discovered that MRBL considerably decreased post-operative discomfort, bleeding, and urine retention (p<0.05). Furthermore, the MRBL group's resting anal pressure was constant, but the MMH group's raised it (p<0.01). Both groups' recurrence rates were similar, indicating that MRBL is a less intrusive but equally successful treatment for Grade III hemorrhoids [8].

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A prospective observational study was conducted by Kumar et al. (2022) on 100 patients who had rubber band ligation (RBL) for Grade II and III internal hemorrhoids. According to the study, there were few post-procedural problems and 89% of patients experienced symptomatic alleviation. The results validated RBL as an easy, secure, and successful outpatient hemorrhoid treatment, especially for Grade II instances. However, persistent symptoms were reported in a limited percentage of patients with Grade III hemorrhoids [9].

Dekker et al. (2021) carried out a retrospective cohort study comparing RBL and hemorrhoidectomy in 327 patients with Grade III hemorrhoids. The study found that hemorrhoidectomy was successful as a single procedure in 95.9% of cases, whereas a single RBL session was effective in only 51.6% of patients. However, multiple RBL sessions improved outcomes. Importantly, complications such as fistula formation were more frequent after hemorrhoidectomy ($p<0.05$), whereas RBL had fewer post-procedural adverse events. Despite requiring repeat treatments, RBL offered a safer alternative with similar long-term patient satisfaction rates [10].

Nikam et al. (2018) conducted a prospective interventional study on 60 patients and found that RBL had an 85% success rate for Grade II hemorrhoids but only a 21% success rate for Grade III cases. The study noted that patients with multiple hemorrhoidal columns required repeated ligation for effective symptom control. Anemia was also significantly reversed after successful banding, reinforcing the therapeutic benefits of RBL despite its lower efficacy for advanced cases [11].

Traoré et al. (2018) examined the use of RBL in Mali for patients with symptomatic hemorrhoidal disease who had previously failed traditional treatments. The study emphasized that RBL remains a viable and effective method for treating Grade III internal hemorrhoids, particularly in regions where surgical interventions may be less accessible. The findings highlighted the importance of integrating minimally invasive techniques like RBL into standard hemorrhoid treatment protocols [12].

Conclusion

The management of hemorrhoidal disease necessitates a tailored approach, considering the hemorrhoid grade, patient comorbidities, and preferences.RBL provides a less intrusive option with less postoperative discomfort, quicker recovery times, and fewer problems, even if MMH is still the gold standard for treating severe hemorrhoids. RBL is a promising first-line treatment for second and third-degree hemorrhoids, as evidenced by recent research that support its effectiveness and safety. However, comprehensive patient evaluation and shared decision-making are paramount to optimize outcomes and align treatment modalities with patient expectations.

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