

## TOPICAL CALCIUM CHANNEL BLOCKERS VERSUS LATERAL CLOSED INTERNAL SPHINCTEROTOMY FOR PAIN RELIEF AFTER MILLIGAN-MORGAN HAEMORRHOIDECTOMY: A PROSPECTIVE COMPARATIVE STUDY

### General Surgery

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| <b>Mukesh Patel</b>     | Associate Professor, Department of General Surgery, NAMO Medical Education & Research Institute and NAMO Hospital, Silvassa, India                |
| <b>Hridaynath Desai</b> | Associate Professor, Department of General Surgery, NAMO Medical Education & Research Institute and NAMO Hospital, Silvassa, India                |
| <b>Nisarg Patel*</b>    | FCPS Trainee, Department of General Surgery, NAMO Medical Education & Research Institute and NAMO Hospital, Silvassa, India *Corresponding Author |

### ABSTRACT

**Background:** Pain after Milligan-Morgan haemorrhoidectomy is partly attributed to internal anal sphincter spasm. Chemical sphincterotomy with topical calcium channel blockers is reversible and sphincter-preserving, whereas lateral closed internal sphincterotomy (LCIS) may provide stronger relaxation but raises continence concerns. **Methods:** This prospective comparative interventional study included 108 adults with grade III or IV haemorrhoids undergoing Milligan-Morgan haemorrhoidectomy. Group A (n=54) received topical calcium channel blocker ointment (diltiazem 2% in 43 patients; nifedipine 0.3% in 11), and Group B (n=54) underwent adjunctive LCIS. Pain was assessed using the Visual Analogue Scale (VAS) from 6 hours to day 14. Analgesic use, first-defecation pain, complications, continence symptoms, recovery and satisfaction were compared. **Results:** Groups were comparable at baseline. LCIS produced lower mean VAS scores at 6, 12, 24, 48 and 72 hours (all  $p < 0.001$ ); differences were no longer significant on days 7 and 14. First-defecation VAS was lower with LCIS ( $3.77 \pm 0.74$  vs  $4.75 \pm 0.86$ ;  $p < 0.001$ ), as were analgesic doses in the first 72 hours ( $5.59 \pm 1.45$  vs  $7.46 \pm 1.50$ ;  $p < 0.001$ ) and rescue opioid use ( $7.4\%$  vs  $24.1\%$ ;  $p = 0.035$ ). Hospital stay, wound healing and return to activity favoured LCIS. Flatus incontinence ( $9.3\%$  vs  $3.7\%$ ) and faecal soiling ( $5.6\%$  vs  $0\%$ ) were numerically more frequent after LCIS, but differences were not significant. **Conclusion:** LCIS provided superior early pain control and faster recovery after Milligan-Morgan haemorrhoidectomy, at the cost of numerically more transient continence symptoms. Topical calcium channel blockers remain a non-invasive alternative when sphincter preservation is prioritized.

### KEYWORDS

Calcium Channel Blocker, Diltiazem, Haemorrhoidectomy, Lateral Internal Sphincterotomy, Nifedipine, Postoperative Pain, Visual Analogue Scale

### INTRODUCTION

Haemorrhoidal disease represents symptomatic enlargement and distal displacement of the normal anal cushions. Current guidelines reserve excisional haemorrhoidectomy for selected patients with advanced prolapse, substantial external disease, recurrence or failure of conservative and office-based treatment.<sup>1,3</sup> Milligan-Morgan open haemorrhoidectomy remains durable and widely used, but postoperative pain is a major limitation.<sup>4</sup> Haemorrhoidectomy is among procedures associated with unexpectedly high early pain in routine practice, which may delay mobilisation, defecation, discharge and return to work.<sup>5,6</sup>

Post-haemorrhoidectomy pain is multifactorial. Exposed anoderm, local inflammation, wound trauma, stool passage and reflex internal anal sphincter spasm all contribute.<sup>6,7</sup> Targeting sphincter spasm is therefore biologically plausible. LCIS provides immediate mechanical reduction in sphincter tone, and meta-analytic evidence suggests that it can reduce pain and analgesic requirement after excisional haemorrhoidectomy.<sup>8,9</sup> However, division of the sphincter may cause transient or persistent flatus incontinence or soiling, making routine use controversial.<sup>8,10-12</sup>

Topical calcium channel blockers relax smooth muscle and reduce anal resting pressure without permanently dividing the sphincter.<sup>13-15</sup> Diltiazem and nifedipine have shown analgesic benefit after haemorrhoidectomy, although results are heterogeneous and recent trial data do not demonstrate benefit for every topical regimen.<sup>13-17</sup> Direct comparative evidence between chemical and surgical sphincterotomy remains limited. This study compared topical calcium channel blockers with LCIS after Milligan-Morgan haemorrhoidectomy, focusing on pain, analgesic use, complications, continence and functional recovery.

### MATERIALS AND METHODS

A hospital-based prospective comparative interventional study was conducted over one year in the Department of General Surgery of a tertiary-care teaching hospital after Institutional Ethics Committee approval. Written informed consent was obtained from all participants.

Adults aged 18 years or older with grade III or IV haemorrhoids planned for elective Milligan-Morgan haemorrhoidectomy were eligible. Exclusion criteria included grade I-II disease, thrombosed external haemorrhoids requiring emergency treatment, associated

fissure/fistula/abscess, inflammatory bowel disease, suspected anorectal malignancy, previous anorectal surgery, pre-existing incontinence or sphincter dysfunction, uncontrolled systemic disease, unintermittible anticoagulation, contraindication to calcium channel blockers, pregnancy or lactation, and inability to complete follow-up.

The planned sample comprised 108 patients (54 per group), consistent with the directly comparable prospective trial by Chauhan et al.<sup>10</sup> The source thesis did not document the allocation sequence or allocation concealment; consequently, this manuscript does not describe the study as randomized.

All patients underwent standard Milligan-Morgan open haemorrhoidectomy with preservation of mucocutaneous bridges. Group A received topical calcium channel blocker ointment postoperatively: diltiazem 2% in 43 patients and nifedipine 0.3% in 11, according to institutional availability. Group B underwent adjunctive lateral closed internal sphincterotomy through a small lateral incision with limited division of the lower internal sphincter. Both groups received routine wound care, sitz baths, dietary advice, fluids, stool softeners and analgesia according to institutional protocol.

The primary outcome was postoperative pain measured on a 0-10 VAS at 6, 12, 24, 48 and 72 hours and on days 7 and 14. Secondary outcomes included first-defecation pain, analgesic doses in the first 72 hours, rescue opioid use, urinary retention, bleeding, wound infection, nausea/vomiting, headache, hypotension, local irritation, flatus incontinence, faecal soiling, hospital stay, wound-healing time, return to routine activity and patient satisfaction.

### Statistical Analysis

Continuous variables were summarized as mean  $\pm$  standard deviation and compared with the independent-samples t-test; categorical variables were summarized as frequency and percentage and compared with the chi-square test or Fisher exact test, as appropriate. Point-wise VAS comparisons were performed at each prespecified time point. A two-sided  $p$  value  $< 0.05$  was considered statistically significant.

### RESULTS

All 108 patients were included in the analysis, with 54 in each group. Mean age, sex, haemorrhoid grade, BMI, symptom duration and preoperative haemoglobin were comparable (Table 1). Grade III

disease accounted for 63.0% of cases. The mean number of excised columns was similar, whereas operative time was longer with LCIS (39.11±5.13 vs 33.59±6.13 minutes;  $p<0.001$ ).

Mean VAS scores fell progressively in both groups. LCIS was associated with lower VAS scores at 6, 12, 24, 48 and 72 hours (all  $p<0.001$ ), but not on day 7 or 14 (Table 2; Figure 1). First-defecation VAS was also lower after LCIS (3.77±0.74 vs 4.75±0.86;  $p<0.001$ ).

Patients undergoing LCIS required fewer analgesic doses during the first 72 hours (5.59±1.45 vs 7.46±1.50;  $p<0.001$ ) and less rescue opioid (7.4% vs 24.1%;  $p=0.035$ ) (Table 2; Figure 2). LCIS was associated with shorter hospital stay, earlier wound healing and earlier return to routine activity (Table 4; Figure 3).

Common early complications did not differ significantly (Table 3). Headache and local irritation were numerically more frequent with topical calcium channel blockers. Flatus incontinence and faecal soiling were numerically more frequent after LCIS, but the differences were not statistically significant. Excellent or good satisfaction was reported by 83.3% in Group A and 85.1% in Group B ( $p=0.500$ ).

## DISCUSSION

This prospective comparative study found a clinically coherent early advantage for LCIS after Milligan-Morgan haemorrhoidectomy. Pain scores were lower from 6 to 72 hours, first-defecation pain was less intense, analgesic and rescue-opioid requirements were reduced, and recovery milestones occurred earlier. By days 7 and 14, pain was low in both groups and the intergroup difference had disappeared. Thus, the principal benefit of LCIS was concentrated in the early postoperative period rather than sustained beyond the first week.

The findings support internal sphincter spasm as a modifiable component of post-haemorrhoidectomy pain. Wang et al. reported in a meta-analysis of randomized trials that lateral internal sphincterotomy reduced pain and postoperative analgesic requirement.<sup>8</sup> Jin et al. similarly concluded that targeting sphincter spasm with lateral sphincterotomy, botulinum toxin, topical diltiazem or glyceryl trinitrate can reduce pain.<sup>9</sup> Galizia et al. reported benefit from lateral sphincterotomy after open haemorrhoidectomy, whereas Khubchandani found no pain benefit, illustrating persistent heterogeneity across technique, extent of sphincter division, background analgesia and outcome timing.<sup>11,12</sup>

The direct comparison most relevant to this study is the randomized trial by Chauhan et al., which compared internal sphincterotomy with topical 2% diltiazem in grade III-IV disease.<sup>10</sup> That trial also reported lower pain and analgesic consumption with sphincterotomy, although the separation in pain became apparent later than in the present dataset. Differences in perioperative analgesia, sphincterotomy technique, topical regimen and assessment schedule may explain variation in timing. The present finding of lower first-defecation VAS after LCIS is clinically important because bowel-movement pain influences fear of defecation, constipation and delayed recovery.<sup>20</sup>

Topical calcium channel blockers nevertheless showed meaningful pain reduction over time and offer a reversible, sphincter-preserving strategy. Randomized studies of topical diltiazem and nifedipine have shown reduced pain after haemorrhoidectomy, and systematic reviews generally report modest benefit with acceptable morbidity.<sup>13-16</sup> However, topical evidence is not uniformly positive: the recent TAPH factorial trial found no significant improvement when diltiazem was added to topical metronidazole, emphasizing that formulation, co-interventions and comparator choice matter.<sup>17</sup> In the present study, the topical arm was heterogeneous (diltiazem in 43 patients and nifedipine in 11), so the findings apply to a pragmatic local-CCB strategy rather than to one standardized drug regimen.

Safety is the central counterweight to the superior early analgesia of LCIS. Flatus incontinence occurred in 9.3% after LCIS and 3.7% with topical therapy, while faecal soiling occurred in 5.6% and 0%, respectively. Although these differences were not statistically significant and symptoms were described as transient or minor, the study was underpowered for uncommon continence outcomes. Meta-analytic evidence has similarly identified increased continence disturbance after lateral sphincterotomy despite improved pain.<sup>8,9</sup> Consequently, better early analgesia should not be interpreted as justification for routine sphincter division in every patient.

The shorter hospital stay, earlier wound healing and earlier return to activity observed with LCIS are plausible downstream consequences of lower early pain and easier defecation. Nevertheless, the absolute differences were modest: approximately 0.39 day for hospital stay, 2.40 days for wound healing and 1.72 days for return to routine activity. These effects should be weighed against the additional operative time (about 5.5 minutes), the potential continence trade-off, and patient preferences. Both groups achieved high overall satisfaction, suggesting that either approach can be acceptable when appropriately selected and counselled.

LCIS may be considered for carefully selected patients in whom rapid early pain control is a priority and baseline continence is robust. Topical calcium channel blockers are preferable when avoiding permanent sphincter division is important, including patients with pre-existing continence concerns or elevated risk of sphincter dysfunction. A standardized topical regimen and a tailored, limited sphincterotomy technique are essential for future comparative trials.

This was a single-centre study with limited follow-up. The source thesis did not specify random sequence generation, allocation concealment or blinding, creating risk of selection and performance bias. The topical group combined two drugs and did not document a uniform application dose, frequency or adherence. Repeated VAS measurements were analysed point-wise rather than with a longitudinal model. Objective anorectal manometry and validated continence scoring were not performed, and the sample was insufficient to exclude uncommon or persistent continence impairment. These limitations require cautious interpretation and favour confirmation in a randomized, adequately powered trial with standardized interventions and longer follow-up.

## CONCLUSION

LCIS provided superior early pain relief, reduced analgesic and rescue-opioid use, and accelerated short-term recovery after Milligan-Morgan haemorrhoidectomy. Its benefit was concentrated within the first 72 hours and accompanied by numerically more transient continence symptoms. Topical calcium channel blockers offered a non-invasive, sphincter-preserving alternative with acceptable improvement over time. Treatment should therefore be individualized according to the need for rapid analgesia, continence risk and patient preference.

**Table 1. Baseline and Perioperative Characteristics**

| Variable                  | Local CCB (n=54) | LCIS (n=54)  | p value |
|---------------------------|------------------|--------------|---------|
| Age (years)               | 42.56 ± 10.53    | 44.48 ± 9.60 | 0.323   |
| Male sex                  | 29 (53.7)        | 33 (61.1)    | 0.559   |
| Grade III haemorrhoids    | 36 (66.7)        | 32 (59.3)    | 0.550   |
| BMI (kg/m <sup>2</sup> )  | 24.57 ± 2.53     | 24.84 ± 3.49 | 0.642   |
| Symptom duration (months) | 12.61 ± 6.31     | 12.91 ± 7.09 | 0.819   |
| Preoperative Hb (g/dL)    | 12.39 ± 1.73     | 12.35 ± 1.53 | 0.911   |
| Spinal anaesthesia        | 51 (94.4)        | 48 (88.9)    | 0.489   |
| Columns excised           | 2.72 ± 0.45      | 2.85 ± 0.36  | 0.102   |
| Operative time (minutes)  | 33.59 ± 6.13     | 39.11 ± 5.13 | <0.001  |

Data are mean ± SD or n (%)

**Table 2. Postoperative Pain and Analgesic Outcomes**

| Outcome                     | Local CCB (n=54) | LCIS (n=54) | p value |
|-----------------------------|------------------|-------------|---------|
| VAS at 6 h                  | 5.90 ± 0.85      | 5.15 ± 0.81 | <0.001  |
| VAS at 12 h                 | 5.58 ± 0.94      | 4.57 ± 0.89 | <0.001  |
| VAS at 24 h                 | 4.65 ± 0.86      | 3.71 ± 0.76 | <0.001  |
| VAS at 48 h                 | 3.68 ± 0.92      | 2.90 ± 0.72 | <0.001  |
| VAS at 72 h                 | 3.01 ± 0.71      | 2.08 ± 0.48 | <0.001  |
| VAS on day 7                | 1.72 ± 0.79      | 1.56 ± 0.69 | 0.251   |
| VAS on day 14               | 0.62 ± 0.46      | 0.59 ± 0.36 | 0.780   |
| VAS at first defecation     | 4.75 ± 0.86      | 3.77 ± 0.74 | <0.001  |
| Analgesic doses, first 72 h | 7.46 ± 1.50      | 5.59 ± 1.45 | <0.001  |
| Rescue opioid required      | 13 (24.1)        | 4 (7.4)     | 0.035   |

Data are mean ± SD or n (%). VAS, Visual Analogue Scale.

**Table 3. Early Complications, Treatment-related Adverse Effects and Continence Outcomes**

| Outcome | Local CCB (n=54) | LCIS (n=54) | p value |
|---------|------------------|-------------|---------|
|---------|------------------|-------------|---------|

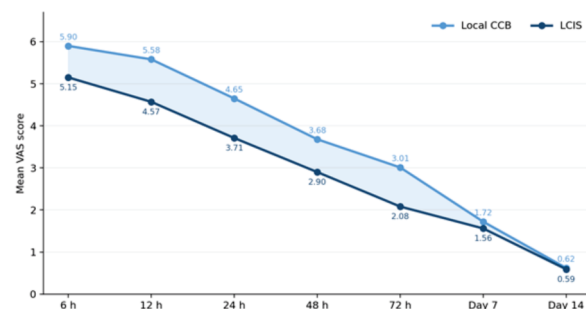
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|-----------------------------|----------|----------|-------|
| Urinary retention           | 5 (9.3)  | 2 (3.7)  | 0.437 |
| Postoperative bleeding      | 5 (9.3)  | 4 (7.4)  | 1.000 |
| Wound infection             | 7 (13.0) | 1 (1.9)  | 0.060 |
| Nausea/vomiting             | 8 (14.8) | 9 (16.7) | 1.000 |
| Headache                    | 8 (14.8) | 2 (3.7)  | 0.097 |
| Hypotension                 | 3 (5.6)  | 0 (0.0)  | 0.243 |
| Perianal irritation/burning | 7 (13.0) | 1 (1.9)  | 0.060 |
| Flatus incontinence         | 2 (3.7)  | 5 (9.3)  | 0.437 |
| Faecal soiling              | 0 (0.0)  | 3 (5.6)  | 0.243 |

Data are n (%). Fisher exact test was used where cell counts were small.

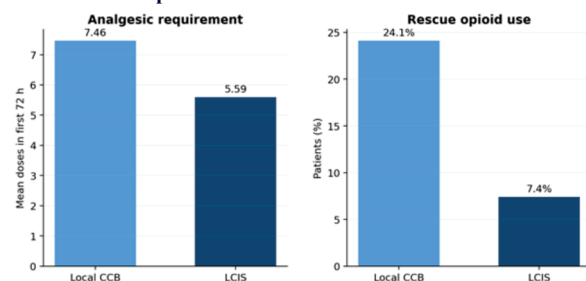
**Table 4. Recovery Outcomes and Patient Satisfaction**

| Outcome                           | Local CCB (n=54) | LCIS (n=54)  | p value |
|-----------------------------------|------------------|--------------|---------|
| Hospital stay (days)              | 2.35 ± 0.48      | 1.96 ± 0.39  | <0.001  |
| Wound healing (days)              | 24.33 ± 4.46     | 21.93 ± 3.90 | 0.004   |
| Return to routine activity (days) | 10.87 ± 2.13     | 9.15 ± 2.41  | <0.001  |
| Satisfaction: excellent           | 18 (33.3)        | 24 (44.4)    | 0.500*  |
| Satisfaction: good                | 27 (50.0)        | 22 (40.7)    |         |
| Satisfaction: fair                | 8 (14.8)         | 8 (14.8)     |         |
| Satisfaction: poor                | 1 (1.9)          | 0 (0.0)      |         |

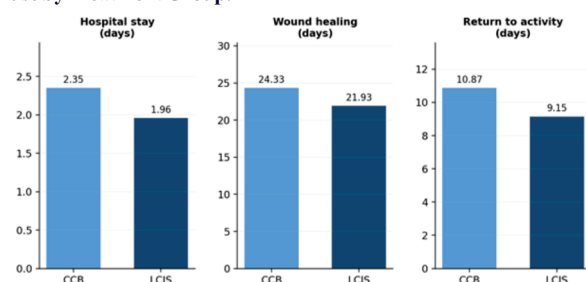
Data are mean ± SD or n (%). \*Overall distribution of satisfaction categories.



**Figure 1. Mean Postoperative Visual Analogue Scale Scores by Treatment Group.**



**Figure 2. Analgesic Doses in the first 72 Hours and Rescue Opioid use by Treatment Group.**



**Figure 3. Postoperative Recovery Outcomes by Treatment Group.**

## DECLARATIONS

- Ethics Approval and Consent to Participate:** Institutional Ethics Committee approval was obtained before enrolment; written informed consent was obtained from all participants.
- Funding:** No external funding was reported.
- Conflict of Interest:** None declared.
- Acknowledgement:** The authors acknowledge the patients and the clinical and nursing teams involved in perioperative care.

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