

PROSPECTIVE NON-RANDOMIZED COMPARATIVE STUDY OF LOCAL CRYOTHERAPY APPLICATION VERSUS MAGNESIUM SULFATE DRESSING IN THE EMERGENCY CONSERVATIVE MANAGEMENT OF ACUTELY PROLAPSED HEMORRHOIDS

Dr. Kotamareddi Anuhya¹, Dr. Manish Babbu², Prof. Dr. Sivarajan N³, Dr. Tarun Teja P. B⁴, Dr Balaji R⁵

¹. Final year MS General Surgery post graduate Saveetha Medical College and Hospital

². Assistant Professor, Department of General Surgery Saveetha Medical College and Hospital

³. Professor, Department of General Surgery Saveetha Medical College

⁴. Assistant Professor, Department of General Surgery Saveetha Medical College and Hospital

⁵. Senior Resident, Dr.Raghul. U, Senior Resident Department of General Surgery Saveetha Medical College

ABSTRACT

Background: Acutely prolapsed hemorrhoids can present with severe pain, edema, and difficulty in manual reduction. Conservative treatment may provide symptomatic relief and facilitate reduction in selected patients without necrosis or other indications for urgent surgery. Local Cryotherapy application and magnesium sulfate (MgSO₄) dressing are inexpensive local measures, but direct comparative evidence is limited. This study prospectively compared their short-term clinical effects in patients with acutely prolapsed irreducible Grade IV internal hemorrhoids.

Methods: This prospective non-randomized comparative study included 30 consecutive adults presenting to a tertiary-care emergency department. Fifteen patients received intermittent local Cryotherapy application and 15 received topical MgSO₄ dressing. No a priori sample-size calculation or single prespecified primary endpoint was documented; therefore, this analysis is considered exploratory, with 1-hour VAS treated as the principal efficacy endpoint for interpretation. Pain, edema, manual reduction, time to meaningful pain relief, recurrence, complications, and emergency surgery were assessed. Categorical variables were rechecked using Fisher's exact test where small expected cell counts were present; continuous between-group comparisons were checked using independent-samples methods. Effect estimates and 95% confidence intervals were added where calculable from the reported summary data.

Results: Baseline age, sex distribution, and symptom duration were similar between groups. At 1 hour, mean VAS was lower with local Cryotherapy than with MgSO₄ (4.1 ± 0.9 vs 5.9 ± 1.0 ; mean difference -1.8 points, 95% CI -2.51 to -1.09 ; $p < 0.001$). At 24 hours, mean VAS was lower with MgSO₄ (2.3 ± 0.8 vs 3.2 ± 0.9 ; mean difference -0.9 points, MgSO₄ minus ice, 95% CI -1.54 to -0.26 ; $p \approx 0.01$). Time to meaningful pain relief was shorter with local Cryotherapy (24.8 ± 7.6 vs 51.4 ± 11.2 minutes; mean difference -26.6 minutes, 95% CI -33.80 to -19.40 ; $p < 0.001$). Successful manual reduction occurred in 86.7% and 93.3% of the local Cryotherapy and MgSO₄ groups, respectively; Fisher's exact $p = 1.00$. Marked edema reduction at 1 hour occurred in 73.3% versus 40.0% (Fisher's exact $p = 0.139$), and at 24 hours in 60.0% versus 86.7% (Fisher's exact $p = 0.215$). Recurrence within 24 hours occurred in 40.0% versus 13.3% (Fisher's exact $p = 0.215$). The reported mean times to recurrence suggested a longer interval with MgSO₄, but individual time-to-event data were unavailable for independent survival analysis; therefore, this finding is considered exploratory.

Conclusion: In this small prospective non-randomized study, local Cryotherapy application was associated with more rapid early pain relief, whereas MgSO₄ was associated with lower pain scores at 24 hours. Differences in edema and early recurrence were not statistically significant using Fisher's exact test. The findings are hypothesis-generating and should not be interpreted as evidence that MgSO₄ prevents recurrence or that sequential local Cryotherapy followed by MgSO₄ is superior. Larger randomized studies with standardized interventions, prespecified outcomes, and appropriate longitudinal and time-to-event analyses are warranted.

KEYWORDS: acutely prolapsed hemorrhoids; local Cryotherapy; cryotherapy; magnesium sulfate; conservative management; emergency surgery; pain; recurrence.

INTRODUCTION

Hemorrhoidal disease is common, and acute prolapse may be associated with severe pain, edema, venous congestion, and difficulty in reduction. In selected patients without necrosis, gangrene, or other indications for urgent operative

management, conservative measures may be used to control symptoms and facilitate reduction. Current guidance emphasizes disease-specific assessment and individualized treatment rather than assuming that every acute prolapse requires immediate surgery [1–3].

Local cooling can produce transient vasoconstriction and reduce nerve conduction and nociceptive signaling, providing rapid symptomatic relief [4,5]. Osmotic dressings have been used clinically to reduce tissue edema, although high-quality comparative evidence for MgSO₄ dressings in acute hemorrhoidal prolapse are limited. The physiological rationale for MgSO₄ does not by itself establish comparative clinical effectiveness.

The principal objectives of emergency management are prompt pain relief, reduction of edema, facilitation of manual reduction, and avoidance of emergency hemorrhoidectomy, which is technically more demanding in the presence of severe inflammation and carries increased morbidity. Emergency surgery becomes necessary when conservative treatment fails or when serious complications such as gangrene or hemorrhoidal necrosis develops. In particular, thrombosis and strangulation of prolapsed hemorrhoids can progress to portal pyaemia or frank gangrene of the hemorrhoidal tissue, demanding urgent surgical intervention—these represent true surgical emergencies where blood-borne infection or tissue death can lead to systemic sepsis and significant morbidity. Recognition of these potential complications underscores the importance of effective, timely conservative management (2,3,5).

Conservative management remains the first-line approach and includes oral analgesics, non-steroidal anti-inflammatory drugs, stool softeners, warm sitz baths, and topical interventions such as osmotic dressings and local cooling measures. Identifying an effective conservative modality that provides rapid symptom relief while minimizing recurrence and preventing progression to life-threatening complications remains an important clinical objective (3,4,6).

The present study therefore compared local Cryotherapy application with MgSO₄ dressing in adults presenting with acutely prolapsed irreducible Grade IV internal hemorrhoids. The original hypothesis was that local Cryotherapy would provide faster immediate analgesia, whereas MgSO₄ might produce a slower but more sustained response. Because the study was non-randomized and small, the objective of the revised analysis is to describe the observed between-group differences without making causal or superiority claims that are not supported by the design.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, non-randomized comparative study conducted in the Department of General Surgery at a tertiary-care teaching hospital over 12 months. Institutional Ethics Committee approval was obtained before commencement, and written informed consent was obtained from all participants. The study should be reported in accordance with the STROBE recommendations for observational comparative studies [6].

Treatment allocation was not randomized. Patients were assigned to the ice-pack or MgSO₄ protocol according to the treatment protocol followed at presentation. Consequently, the possibility of allocation bias and residual confounding cannot be excluded.

Study Population and Participant Flow

Thirty consecutive adults meeting the eligibility criteria were enrolled: 15 in the local Cryotherapy group and 15 in the MgSO₄ group. All 30 participants completed the stated follow-up and were included in the final analysis.

Inclusion Criteria

- Age 18–70 years.
- Acutely prolapsed, irreducible Grade IV internal hemorrhoids presenting within 48 hours of symptom onset.
- Severe anal pain with clinically evident prolapse and edema.
- Written informed consent.

Exclusion Criteria

- Gangrenous or necrotic hemorrhoids requiring immediate surgery.
- Associated perianal abscess or fistula-in-ano.
- Acute anal fissure as the primary pathology.
- Previous hemorrhoid surgery.
- Coagulopathy or current anticoagulant therapy.
- Pregnancy.
- Known hypersensitivity to magnesium sulfate.
- Declining participation.

Interventions

Local Cryotherapy Application

An application of local Cryotherapy by wrapping ice pack in sterile gauze was applied locally over the prolapsed hemorrhoidal tissue. Intermittent applications were performed over a total period of approximately 15–20 minutes, with individual applications lasting approximately 3 minutes and an interval of 30 seconds in between.

Magnesium Sulfate Dressing

Sterile gauze soaked with MgSO₄ and glycerin solution was applied over the prolapsed tissue for approximately 30–45 minutes and replaced according to clinical response. Preparation was performed by dissolving 20 gms of powdered MgSO₄ crystals in 100ml glycerin 1:5 ratio and warming this solution in low heat until the crystals dissolve completely. This dressing was changed every 6 hours.

Concomitant Treatment

All patients received conservative care consisting of an oral analgesic (Paracetamol 650 mg every 8 hours), stool softeners, high-fiber diet, oral hydration, and warm sitz baths after successful reduction, together with advice to avoid prolonged straining. No additional topical anti-inflammatory or anesthetic preparation was administered during the observation period.

Outcome Measures

No primary endpoint was prespecified. The analysis is therefore exploratory, and 1-hour VAS was selected post hoc as the principal outcome for descriptive interpretation.

- Pain severity using a 10-point VAS at baseline, 1 hour, and 24 hours.
- Clinically assessed reduction in hemorrhoidal edema at 1 and 24 hours. Same surgeon assessed all patients.
- Successful manual reduction.
- Time to meaningful pain relief.(reduction in VAS score by 2 or more points)
- Recurrence within 24 hours.
- Time to recurrence.
- Emergency hemorrhoidectomy.
- Treatment-related complications and patient satisfaction.

Follow-up

Patients were observed in the emergency department until adequate symptom relief and then reviewed at 24 hours, 7 days, and 2 weeks. At each follow-up, recurrence of prolapse, persistence of pain or edema, complications, and need for surgical intervention were documented.

Sample Size

No formal a priori sample-size calculation was performed. The study therefore should be regarded as exploratory and potentially underpowered for uncommon outcomes such as recurrence and emergency surgery. A future definitive study should prespecify one primary endpoint, a clinically meaningful treatment difference, an expected standard deviation or event rate, alpha, power, allocation ratio, and allowance for attrition.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26. Continuous variables were summarized as mean $\pm$ SD and categorical variables as counts and percentages. Independent-samples comparisons were used for continuous variables when the assumptions of approximately normal distributions were considered reasonable. Because of the small sample size and small expected cell counts, Fisher's exact test was used for the reported 2 $\times$ 2 categorical comparisons.

Mean differences with 95% confidence intervals are reported for continuous outcomes where these can be calculated from the summary statistics. The original repeated VAS measurements are not available at the individual-patient level; therefore, a mixed-effects model or repeated-measures analysis could not be performed from the available information. Likewise, individual recurrence times and censoring information were unavailable, so a Kaplan–Meier/log-rank analysis and hazard ratio could not be independently calculated. These limitations are explicitly reflected in the interpretation.

A two-sided $p < 0.05$ was considered statistically significant.

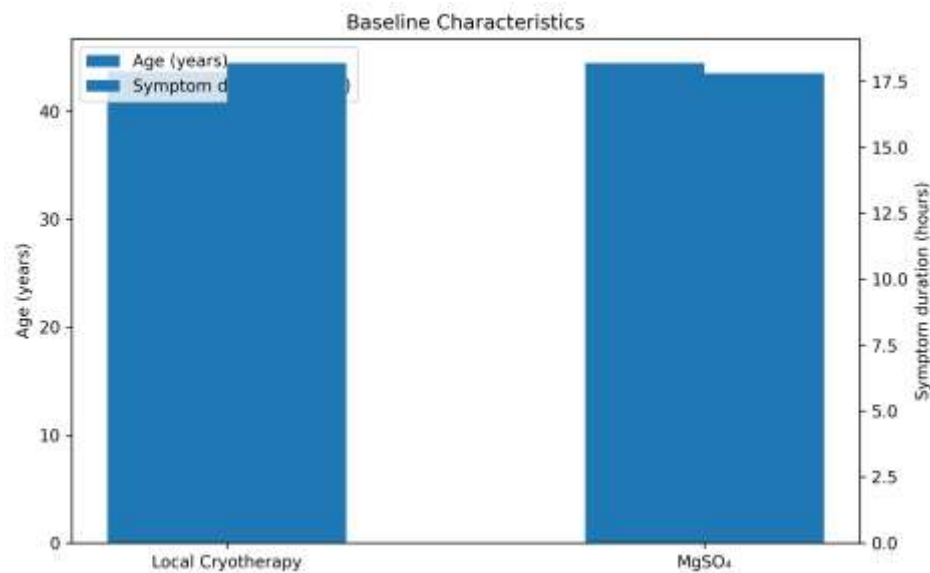
RESULTS

Patient Characteristics

Thirty patients were analyzed, with 15 receiving local Cryotherapy application and 15 receiving MgSO₄ dressing. All participants reportedly completed follow-up. Mean age was 43.7 ± 10.5 years in the local Cryotherapy group and 44.5 ± 9.8 years in the MgSO₄ group. Male sex was present in 10/15 (66.7%) and 9/15 (60.0%), respectively. Mean symptom duration was 18.2 ± 6.3 and 17.8 ± 5.9 hours. No clinically important baseline difference is apparent from the reported summary data; however, the small sample size limits the ability of baseline statistical tests to exclude imbalance.

Variable	Local Cryotherapy (n=15)	MgSO ₄ (n=15)	P value
Age (years), mean $\pm$ SD	43.7 ± 10.5	44.5 ± 9.8	0.82
Male, n (%)	10 (66.7)	9 (60.0)	1.00*
Female, n (%)	5 (33.3)	6 (40.0)	—

Duration of symptoms (hours), mean $\pm$ SD	18.2 $\pm$ 6.3	17.8 $\pm$ 5.9	0.85
---	----------------	----------------	------

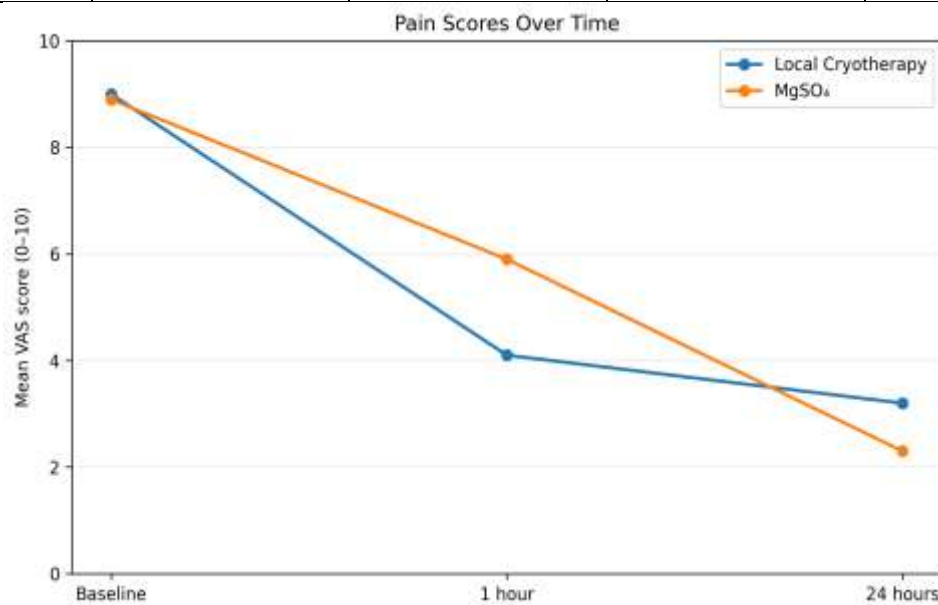


*Fisher's exact test; p values are reported using the small-sample approach for categorical variables.

Pain

Baseline VAS was similar between groups (9.0 ± 0.8 vs 8.9 ± 0.7 ; mean difference 0.10, 95% CI -0.46 to 0.66 ; $p \approx 0.74$). At 1 hour, VAS was lower in the local Cryotherapy group (4.1 ± 0.9 vs 5.9 ± 1.0 ; mean difference -1.8 , 95% CI -2.51 to -1.09 ; $p < 0.001$). At 24 hours, VAS was lower in the MgSO₄ group (2.3 ± 0.8 vs 3.2 ± 0.9 ; MgSO₄ minus local Cryotherapy -0.9 , 95% CI -1.54 to -0.26 ; $p \approx 0.01$).

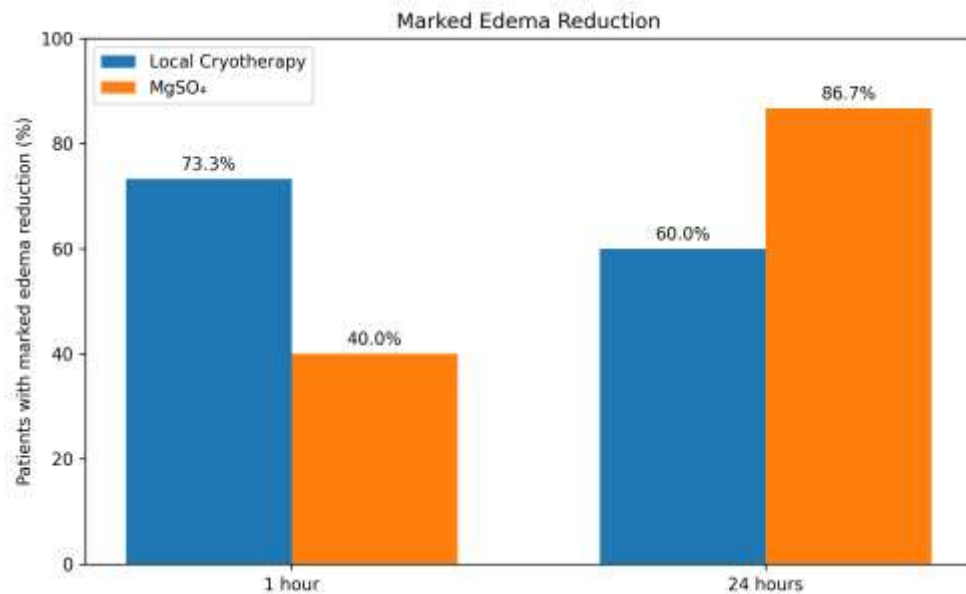
Time	Local Cryotherapy	MgSO ₄	P value	Between-group difference (95% CI)
Baseline	9.0 ± 0.8	8.9 ± 0.7	0.74	0.10 (-0.46 to 0.66)
1 hour	4.1 ± 0.9	5.9 ± 1.0	<0.001	-1.80 (-2.51 to -1.09)
24 hours	3.2 ± 0.9	2.3 ± 0.8	0.01	0.90 (0.26 to 1.54), ice-MgSO ₄



Edema Reduction

At 1 hour, marked edema reduction was observed in 11/15 (73.3%) patients in the local Cryotherapy group and 6/15 (40.0%) in the MgSO₄ group. Fisher's exact test gave p=0.139. At 24 hours, marked edema reduction occurred in 9/15 (60.0%) and 13/15 (86.7%), respectively, with Fisher's exact p=0.215. The originally reported p=0.04 for both comparisons could not be reproduced from the displayed 2×2 tables and has therefore been corrected.

Outcome	Local Cryotherapy	MgSO ₄	Corrected P value	Risk ratio (95% CI)
Marked reduction at 1 hour	11 (73.3%)	6 (40.0%)	0.139	1.83 (0.92–3.66)
Marked reduction at 24 hours	9 (60.0%)	13 (86.7%)	0.215	0.69 (0.44–1.09), local Cryotherapy vs MgSO ₄

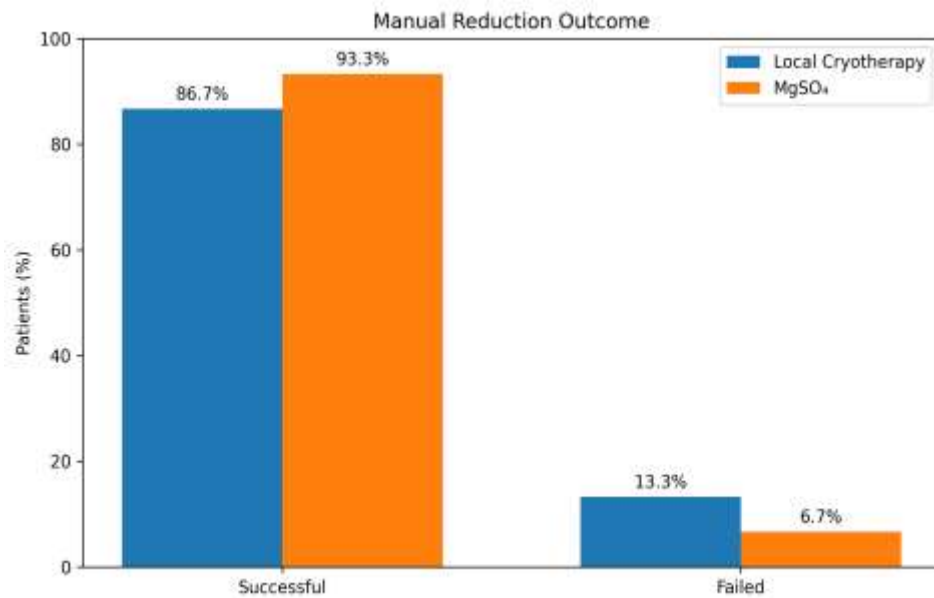


Manual Reduction

Successful manual reduction occurred in 13/15 (86.7%) patients in the local Cryotherapy group and 14/15 (93.3%) in the MgSO₄ group. Fisher's exact p=1.00. The observed absolute difference was small and does not provide evidence of a between-group difference in overall reduction success.

Outcome	Local Cryotherapy	MgSO ₄	P value
Successful	13 (86.7%)	14 (93.3%)	1.00*
Failed	2 (13.3%)	1 (6.7%)	—

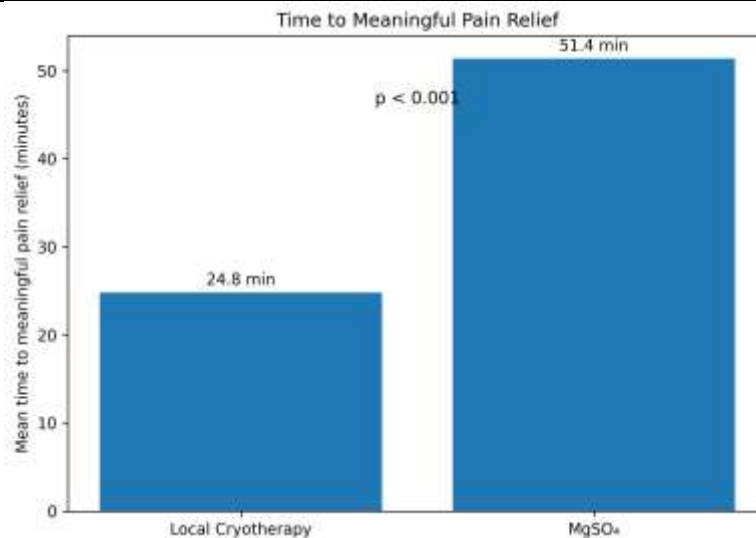
*Fisher's exact test.



Time to Clinical Improvement

Mean time to meaningful pain relief was 24.8 ± 7.6 minutes in the local Cryotherapy group and 51.4 ± 11.2 minutes in the MgSO₄ group. The mean difference was -26.6 minutes (95% CI -33.80 to -19.40 ; $p < 0.001$). This finding supports a faster onset of symptomatic pain relief with local Cryotherapy in this small study, although the operational definition of meaningful pain relief was not documented in the original protocol.

Outcome	Local Cryotherapy	MgSO ₄	P value	Mean difference (95% CI)
Time to meaningful pain relief (min)	24.8 ± 7.6	51.4 ± 11.2	<0.001	-26.6 (-33.80 to -19.40)

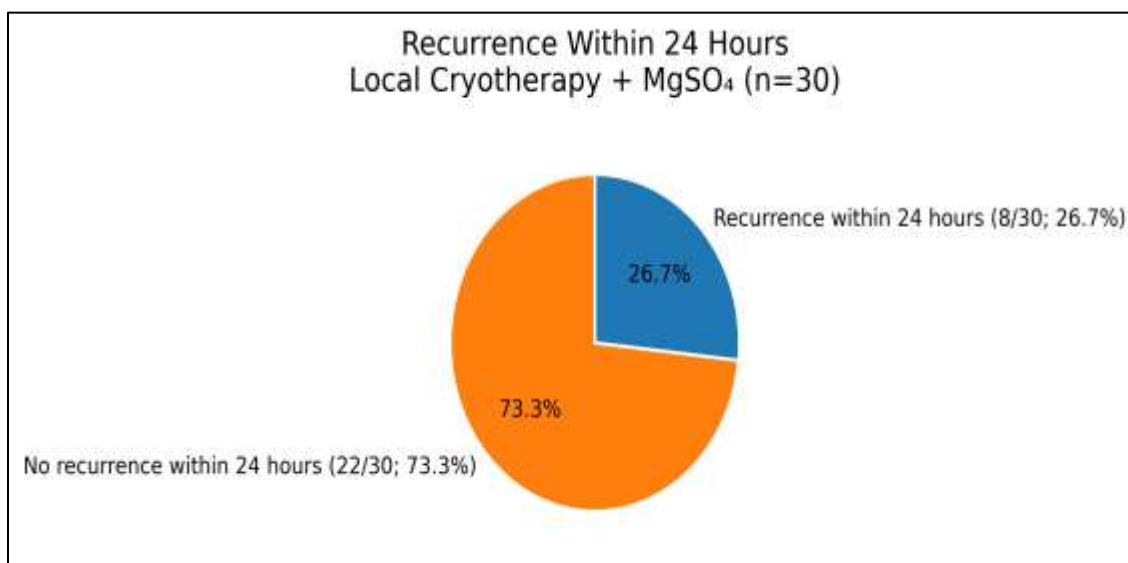


Recurrence

Recurrence within 24 hours occurred in 6/15 (40.0%) patients in the local Cryotherapy group and 2/15 (13.3%) in the MgSO₄ group. Fisher's exact $p=0.215$; the risk ratio for recurrence with local Cryotherapy versus MgSO₄ was 3.00 (95% CI 0.72–12.55). Thus, although the point estimate suggests more early recurrence after ice, the confidence interval is wide and includes no difference. .

Outcome	Local Cryotherapy	MgSO ₄	P value / effect estimate
Recurrence within 24 hours	6 (40.0%)	2 (13.3%)	Fisher $p=0.215$; RR 3.00 (0.72–12.55)

Reported time to recurrence (days)	2.3 ± 0.8	6.7 ± 1.9	-
------------------------------------	-----------	-----------	---



DISCUSSION

It is clear from this revision that the two procedures had different temporal effects. It is evident that the application of Local Cryotherapy had quicker pain relief compared to MgSO₄, which showed reduced VAS score at 24 hours. However, it must be noted that the sample size used was too small and there was no randomization, and more importantly, the original hypothesis did not identify any primary outcome measure.

Immediate Pain Relief

The biggest and most consistent difference was seen at the one-hour mark, where there was an average VAS difference of 1.8 points. This is a reasonable physiological explanation since cooling could lead to a temporary reduction in tissue temperature and nerve conduction. However, the significance of this difference should be taken with caution due to the lack of randomization in the treatment and insufficient details of the analgesics.

Pain at 24 Hours

The VAS score for the MgSO₄ group was found to be lower by about 0.9 at the 24-hour mark. While this may be due to the prolonged effect on edema, we are unable to conclude whether or not this was due to the magnesium sulfate. The next step would be to conduct a mixed-model analysis of all repeat measures of the VAS score.

Edema

The direction of the effect observed varied over time, whereby there were more cases of significant edema reduction in the local cryotherapy group after one hour while there were more cases of significant edema reduction in the MgSO₄ group after 24 hours. However, none of the comparisons made in each category achieved statistical significance through Fisher's exact test. Furthermore, 'significant reduction' had no operational definition. The data therefore do not establish superiority of either modality for edema reduction.

Manual Reduction

The overall success rate for manual reduction in patients receiving local Cryotherapy and MgSO₄ was 86.7% and 93.3%, respectively, without any statistical difference found between the two groups. The theory that local Cryotherapy allowed early manual reduction can be accepted, although not quantified by an endpoint of time to reduction.

Recurrence

The point estimate for recurrence within 24 hours favored MgSO₄, but the difference was not statistically significant and the 95% confidence interval around the risk ratio was wide. The reported mean time to recurrence cannot be adequately evaluated without patient-level event and censoring data. The data does not conclude that MgSO₄ delays or prevents recurrence.

Clinical Implications

The results suggest that local Cryotherapy may be useful when rapid pain relief is the immediate priority. MgSO₄ may need to be explored further as a way to provide continuous relief from the symptoms; however, the findings of this study do not confirm the superiority of MgSO₄ for treating edema and preventing its recurrences. The suggested sequential therapy of Cryotherapy locally followed by MgSO₄ has not been studied in this research and is to be regarded as a hypothesis.

Strengths

- Prospective data collection.
- Sequential inclusion of patients meeting criteria.
- Balanced allocation into groups.
- Clinically meaningful outcomes such as pain, swelling, reduction, and recurrence.
- Complete follow-up for all 30 enrolled subjects.

Limitations

- Small number of subjects (n=30) without any mention of an a priori power analysis.
- Non-random allocation of patients to different therapies with inherent biases and uncontrolled confounders.
- Lack of concealment of allocation process.
- Absence of blinding of patients and outcome assessors.
- Lack of a clearly identified primary outcome measure.
- Subjective and inadequately defined edema variable.
- One center study with limited follow-up.
- There was no information on number screened or reasons for exclusion before enrollment in the available report.

CONCLUSION

In this small prospective non-randomized comparative study in adult patients with acute irreducible Grade IV internal hemorrhoidal prolapse, local Cryotherapy was found to be significantly associated with faster onset of pain relief and quicker attainment of clinically significant pain relief. MgSO₄ dressings were associated with decreased pain scores at 24 hours. While there were suggestive differences between the proportions in edema and recurrence, they were not statistically confirmed after appropriate small-sample statistical tests. The apparent time-to-recurrence difference needs survival analysis at patient level to interpret.

Therefore, the study findings lend support to the hypothesis that local Cryotherapy could be effective in providing faster initial relief from symptoms, while MgSO₄ requires further research on its effectiveness in providing sustained symptom relief. They do not show any evidence of recurrence prevention or efficacy superiority of either modality or optimal sequence of ice and MgSO₄ treatment. A large prospective randomized multicenter trial with appropriate sample size determination and rigorous methodology is needed.

Reporting and Publication Declarations

Funding

This research received no specific grant from any public, commercial, or not-for-profit funding agency.

Conflict of Interest

The authors declare no conflicts of interest.

Reporting Guideline

The revised manuscript is structured with reference to the STROBE reporting recommendations for observational comparative studies [6]. A completed STROBE checklist should accompany submission where required.

REFERENCES

1. Hawkins AT, Davis BR, Bhama AR, Fang SH, Dawes AJ, Feingold DL, et al; Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Hemorrhoids. *Dis Colon Rectum*. 2024;67(5):614-623. doi:10.1097/DCR.0000000000003276.
2. Brown SR, Tiernan JP, Biggs K, et al. Haemorrhoidal disease: diagnosis and management. *BMJ*. 2021;373:n1438.
3. Lohsiriwat V. Hemorrhoids: from basic pathophysiology to clinical management. *World J Gastroenterol*. 2012;18:2009-2017.
4. Bleakley CM, Costello JT. Do thermal agents affect range of movement and mechanical properties? A systematic review. *Arch Phys Med Rehabil*. 2013;94:149-163.
5. Hubbard TJ, Denegar CR. Does cryotherapy improve outcomes with soft tissue injury? *J Athl Train*. 2004;39:278-279.

6. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol.* 2008;61:344-349.
7. Riss S, Weiser FA, Schwameis K, et al. The prevalence of hemorrhoids in adults. *Int J Colorectal Dis.* 2012;27:215-220.
8. Mott T, Latimer K, Edwards C. Hemorrhoids: diagnosis and treatment options. *Am Fam Physician.* 2018;97:172-179.
9. Ganz RA. The evaluation and treatment of hemorrhoids: a guide for the gastroenterologist. *Clin Colon Rectal Surg.* 2013;26:5-11.
10. Sun Z, Migaly J. Review of hemorrhoid disease: presentation and management. *Clin Colon Rectal Surg.* 2016;29:22-29.
11. Alonso-Coello P, Guyatt G, Heels-Ansdell D, Johanson JF, Lopez-Yarto M, Mills E, et al. Laxatives for the treatment of hemorrhoids. *Cochrane Database Syst Rev.* 2005;(4):CD004649.
12. Perera N, Liolitsa D, Iype S, Croxford A, Yassin M, Lang P, Ukaegbu O. Phlebotonics for haemorrhoids. *Cochrane Database Syst Rev.* 2012;(8):CD004322.
13. Beck DE, Roberts PL, Saclarides TJ, Senagore AJ, Stamos MJ, Wexner SD. *The ASCRS Textbook of Colon and Rectal Surgery.* 4th ed. Cham: Springer; 2022.