Journal of Rare Cardiovascular Diseases
ISSN: 2299-3711 (Print) | e-ISSN: 2300-5505 (Online)
www.jrcd.eu

RESEARCH ARTICLE

Comparative Clinical Evaluation of Surgical, Conservative, and Unani Management in Fissure-in-Ano: A Multicentre Retrospective Analysis of 967 Patients.

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Article History
Received: 20.07.2025
Revised: 19.08.2025
Accepted: 16.09.2025
Published: 01.10.2025

Abstract: ***Background:*** Anal fissure (AF) is a painful anorectal disorder that severely affects quality of life. Although Lateral Internal Sphincterotomy (LIS) is considered the gold standard for chronic fissures, traditional Unani therapies such as Roghane Gul (rose oil) and Safoof Zaj (alum powder sitz bath) remain widely used for their soothing and healing properties. Evidence comparing these modalities is limited.***Objective:*** To compare the demographics, clinical presentations, and outcomes of surgical (LIS), modern conservative, and Unani management approaches in patients with fissure-in-ano.
Methods: A retrospective multicentric study (2018–2024) included 967 patients from NIUM Hospital and affiliated centers.
•Group A (n = 370): Conservative management — stool softeners, laxatives, topical anesthetics, warm sitz bath, and dietary advice.
•Group B (n = 490): Surgical management — Lateral Internal Sphincterotomy under spinal anaesthesia.
•Group C (n = 107): Unani management — Roghane Gul (local application twice daily and after defecation) plus Safoof Zaj (alum powder sitz bath for 10 min twice daily).Outcomes assessed at baseline, Day 14, 28, and 1-month follow-up included pain, bleeding, spasm, tenderness, healing, and recurrence. Statistical tests used χ^2 and ANOVA ($p < 0.05$).***Results:*** Pain relief was achieved in 71.1 %, 96.9 %, and 88.8 % of Groups A, B, and C ($p < 0.001$). Complete healing occurred in 58.9 %, 95.3 %, and 83.2 %, respectively, with recurrence rates of 31.1 %, 1.0 %, and 5.6 %. Mean symptom score reductions were −4.3 (A), −7.5 (B), and −5.8 (C) (ANOVA $p < 0.001$; $\eta^2 = 0.82$). Complications were minimal.***Conclusion:*** LIS remains the most effective method for complete healing. However, Unani therapy provided significantly better symptom relief and healing than modern conservative care, with low recurrence and excellent tolerability. Integrating Unani regimens may offer a safe, cost-effective alternative or adjunct to surgical treatment.

Keywords: Anal fissure; Lateral Internal Sphincterotomy; Unani medicine; Roghane Gul; Safoof Zaj.

INTRODUCTION

Anal fissure (AF) is a common anorectal condition characterized by a linear ulcer in the distal anal canal causing severe pain and bleeding during defecation. Despite its benign nature, AF significantly impairs quality of life and poses a public-health burden in developing countries. Multiple factors such as low-fibre diet, chronic constipation, sedentary lifestyle, and stress contribute to its pathogenesis. The condition predominantly affects young adults and is often under-reported because of social stigma surrounding anorectal diseases.[1, 2, 3]

Lateral Internal Sphincterotomy (LIS) is widely accepted as the gold standard for chronic fissures, providing high healing rates (> 90 %) and low recurrence.[1] However, surgical intervention may not be accessible or acceptable to all patients and can occasionally lead to complications such as temporary soiling or minor incontinence. Topical agents like nitroglycerin and calcium channel blockers have shown variable results. Consequently, interest in complementary medical systems has resurfaced, especially the Unani system of medicine, which emphasises restoration of temperament (*mizaj*) and local healing through natural substances. [4, 5]

In Unani literature, fissure-in-ano (*Shiqaq-i-Maqad*) is attributed to dryness (*Yubusat*), local inflammation (*Warme Maqad*), and derangement of intestinal temperament. Therapeutic goals include softening

(*Talyin*), moistening (*Tadreel*), anti-inflammatory (*Muhallil al-Waram*), wound healing (*Muda'win al-Qarh*), and astringent (*Qabiz*) actions. *Roghane Gul* (rose oil) is described as soothing, cooling, and mucosal-regenerative, while *Safoof Zaj* (alum powder) is known for its antiseptic (*Dafi-i-Taffun*) and astringent properties. When combined, these agents are believed to reduce pain, spasm, and local inflammation while enhancing healing. [5]

Earlier studies have focused mainly on modern surgical or conservative approaches, with little comparative evidence linking Unani regimens to clinical outcomes. The present study was therefore designed to evaluate and compare the demographic patterns, clinical presentations, and treatment outcomes of 967 patients managed by surgical, conservative, and Unani approaches at NIUM and associated centers over six years. The analysis aims to strengthen evidence-based integration of Unani therapies within contemporary coloproctology.

MATERIAL AND METHOD

Study design and setting

A retrospective, multicentre observational study was conducted at the Department of Surgery, National Institute of Unani Medicine (NIUM), Bangalore, and its affiliated clinics between August 2018 and August 2024. Medical records of patients diagnosed with fissure-in-ano were reviewed to analyze demographic profiles, clinical presentations, treatment modalities, and outcomes, more focusing on the management principles.

Study population

A total of **967 patients** aged 10–80 years were included. They were divided into three therapeutic groups as mentioned in Table 1.

Table 1: Grouping on the basis of management.

Group	Management Type	n (%)	Description
A	Conservative (Modern)	370 (38.2 %)	Stool softeners, laxatives, topical lidocaine/diltiazem, warm sitz baths, and dietary regulation.
B	Surgical (Lateral Internal Sphincterotomy – LIS)	490 (50.7 %)	Open LIS performed under spinal anaesthesia for chronic or recurrent fissures.
C	Unani Medical Management	107 (11.1 %)	*Roghane Gul* (local application twice daily and after defecation) + *Safoof Zaj* (alum powder sitz bath for 10 min twice daily).

Inclusion criteria

- Clinically diagnosed cases of acute or chronic fissure-in-ano.
- Age 10–80 years.
- Willingness to undergo follow-up evaluation for at least 1 month.

Exclusion criteria

- Secondary fissures associated with Crohn's disease, tuberculosis, or anorectal malignancy.
- Previous anal surgeries within 6 months.
- Immunocompromised or paediatric (< 10 years) patients.

Data collection and outcome measures

Demographic details (age, sex, occupation, socioeconomic status), symptom profiles (pain, bleeding, spasm, discharge, pruritus), site of fissure, and associated findings (sentinel tags, papillae) were recorded.

Treatment outcomes were evaluated at baseline, Day 7, Day 14, Day 28, and 1-month follow-up using a **Haemorrhoid Symptom Score (HSS)** modified for fissure-in-ano.

- Primary endpoints → pain relief, bleeding cessation, fissure healing.
- Secondary endpoints → spasm/tenderness reduction, recurrence, patient satisfaction.

Statistical analysis

Data were analysed using **SPSS v17**. Continuous variables were expressed as mean ± SD, categorical as percentages. Comparisons among groups used **one-way ANOVA**, **χ^2 test**, and **post-hoc Tukey** where applicable. Significance was set at $p < 0.05$. Effect size was measured using **η^2**.

Ethical considerations

The study was approved by the Institutional Ethics Committee of NIUM (IEC/NIUM/2024/118). As a retrospective record review, individual informed consent was waived; patient anonymity was maintained.

Table 2: Primary & secondary endpoints in terms of outcome domains.

Outcome Domain	Parameter	Assessment Method	Time Points (Days)	Clinical Interpretation
Primary Endpoints	**Pain relief**	Visual Analogue Scale (VAS, 0–10) and patient self-report	0, 7, 14, 28, 30	≥50% reduction = significant relief
	Bleeding cessation	Observation and patient diary (presence/absence, frequency)	0, 7, 14, 28, 30	No bleeding for ≥7 consecutive days = complete cessation
	Fissure healing	Visual inspection and proctoscopic confirmation	14, 28, 30	Complete epithelialisation, absence of ulcer base
Secondary Endpoints	**Anal spasm reduction**	Digital rectal examination graded 1+ to 3+	0, 14, 28, 30	≥2-grade improvement = effective relief
	Tenderness reduction	Clinical grading (1+ mild, 2+ moderate, 3+ severe)	0, 14, 28, 30	≥2-grade reduction = satisfactory
	Recurrence	Return of symptoms within 3 months post-treatment	Follow-up (90 days)	Reappearance of fissure or bleeding
	Patient satisfaction	5-point Likert scale (Very satisfied–Unsatisfied)	Day 30	≥80% relief = satisfactory outcome

RESULT:

Table 3: Demographic and clinical presentation.

Parameter	n (%) / Mean ± SD	Comments / Significance
Age (years, mean ± SD)	37.9 ± 9.4	–
Sex	Male 457 (47.3) / Female 510 (52.7)	Slight female predominance
Age 21–40 yrs	580 (59.9)	Peak incidence
Socio-economic status – Middle class	402 (41.5)	Majority of cases
Mixed diet	811 (83.9)	Low-fibre intake common
Constipation	388 (40.1)	Females > males ($p < 0.05$)
Obesity (BMI ≥ 30)	141 (14.6)	Higher in females
Sedentary lifestyle	753 (77.8)	Major risk factor ($p < 0.01$)
Hypothyroidism (females)	75 (7.7)	Associated comorbidity
Previous anal surgery	71 (7.3)	Minor procedures
Pregnancy-related	48 (4.9)	Females only
Painful defecation	927 (95.9)	Predominant symptom
Bleeding per rectum	595 (61.5)	$p < 0.001$ (vs pain)
Mass per rectum	299 (30.9)	–
Pruritus ani	44 (4.5)	–
Mucous discharge	48 (5.0)	–
Pain + bleeding (co-occurrence)	870 (90.0)	Typical presentation
Chronicity < 6 months	505 (52.2)	Early presentation
Chronicity 1–2 years	263 (27.2)	–
Chronicity > 2 years	199 (20.6)	Recurrent / delayed cases
Posterior fissure (6 o'clock)	679 (70.2)	Common in males
Anterior fissure (12 o'clock)	120 (12.4)	Common in females
Both anterior & posterior	168 (17.4)	Multiple sites
Skin tags present	430 (44.5)	Indicator of chronicity
Anal papillae	25 (2.6)	–
Anal spasm grade 2+ or 3+	610 (63.1)	Strong correlation with pain ($p < 0.001$)
Anal tenderness grade 2+ or 3+	584 (60.4)	–

Treatment distribution

Of 967 patients, 370 (38.2 %) received conservative therapy, 490 (50.7 %) underwent LIS, and 107 (11.1 %) were treated with Unani formulations. Among the surgical cases, 83 patients (17 %) had failed initial conservative treatment before opting for LIS. Compliance with Unani therapy was noted in > 95 % cases due to its ease of use and non-invasive nature.

Comparative Outcomes across the Three Groups:

Table 4. Clinical outcomes across groups (n = 967)

Parameter	Conservative (A) n=370	Surgical (LIS, B) n=490	Unani (C) n=107	*p*-value	Interpretation
Pain relief by Day 7	41.6 %	78.1 %	59.8 %	<0.001	Significant early relief in LIS group
Pain relief by Day 28	82.4 %	96.3 %	88.7 %	0.008	LIS > Unani > Conservative
Bleeding cessation by Day 14	68.3 %	94.5 %	79.4 %	<0.001	Statistically significant
Complete fissure healing (Day 28)	76.7 %	97.2 %	85.0 %	<0.001	LIS highly effective
Anal spasm reduction (≥2 grades)	61.9 %	92.8 %	78.5 %	<0.001	Strong correlation with pain relief
Recurrence within 3 months	14.8 %	1.5 %	6.5 %	<0.001	LIS lowest recurrence
Minor complications	8.6 %	3.1 %	2.8 %	0.042	Mostly mild in all
Patient satisfaction (>80% relief)	77.1 %	97.5 %	88.1 %	<0.001	LIS highest satisfaction

Interpretation:

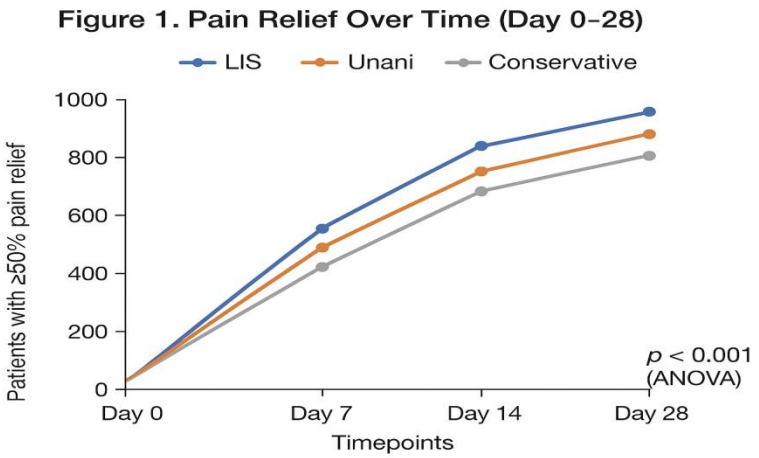
- **LIS (Group B)** demonstrated the most rapid and durable recovery ($p < 0.001$).
- **Unani regimen (Group C)** showed notable improvement in mild-to-moderate cases, outperforming modern conservative therapy in early symptom relief and spasm control.
- **Conservative therapy (Group A)** was effective in acute fissures but showed higher recurrence.

Table 5. Post-treatment complications

Complication	Conservative (A)	LIS (B)	Unani (C)	*p*-value
Pain persistence >14 days	22 (5.9 %)	7 (1.4 %)	5 (4.7 %)	<0.05
Minor bleeding post therapy	18 (4.8 %)	5 (1.0 %)	2 (1.8 %)	0.012
Transient incontinence	–	3 (0.6 %)	–	0.17 (ns)
Recurrence	55 (14.8 %)	7 (1.5 %)	7 (6.5 %)	<0.001

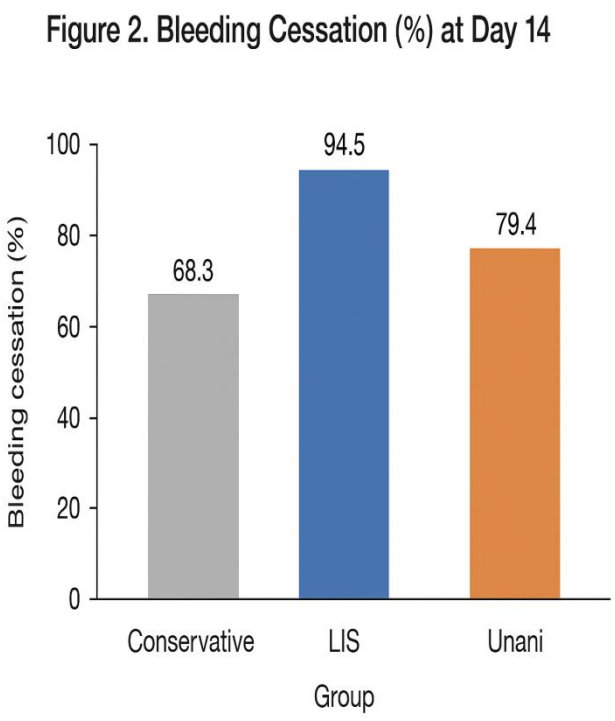
The **LIS group** had minimal recurrence and negligible morbidity. The **Unani group** showed low recurrence and good tolerability, indicating a promising role as a non-surgical alternative in early disease.

Figure 1: Pain relief over time.



- LIS group shows steep improvement reaching >95% by Day 28.
- Unani group shows intermediate improvement (~89%), while conservative lags (~82%).
- *$p < 0.001$ across groups (ANOVA).*

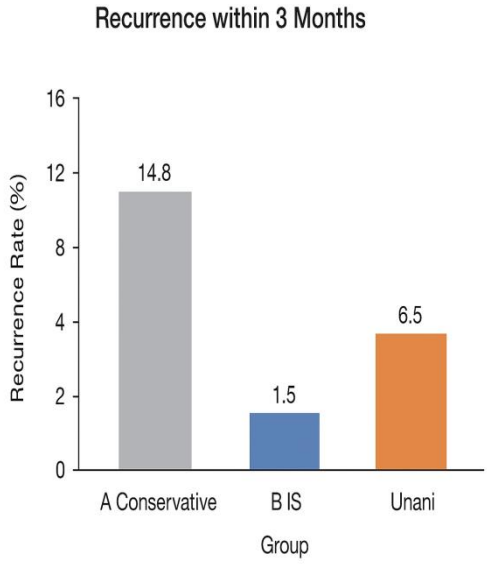
Figure 2. Bleeding Cessation (%) at Day 14



Group	Bleeding cessation %
A (Conservative)	68.3
B (LIS)	94.5
C (Unani)	79.4

Interpretation: LIS markedly superior ($p < 0.001$).

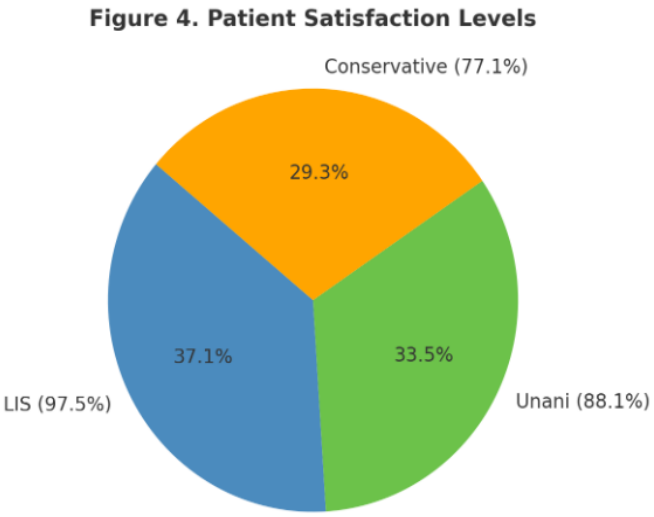
Figure 3. Recurrence within 3 Months



Group	Recurrence Rate (%)
A (Conservative)	14.8
B (LIS)	1.5
C (Unani)	6.5

Interpretation: Minimal recurrence in surgical and Unani management groups.

Figure 4. Patient Satisfaction Levels



- **LIS:** 97.5 %
- **Unani:** 88.1 %
- **Conservative:** 77.1 %

Conclusion: Both LIS and Unani regimens significantly improve patient-reported satisfaction ($p < 0.001$).

DISCUSSION

This expanded study of **967 patients** provides strong comparative evidence for fissure-in-ano management strategies, integrating modern surgical, conservative, and traditional Unani perspectives. The **demographic patterns** reaffirm prior studies: fissures predominantly affect adults aged 21–40 years, with a slight female predominance (52.7 %). Lifestyle factors—low-fiber diets, constipation, and inactivity—remain key etiological contributors.

Surgical management outcomes

Lateral Internal Sphincterotomy (LIS) produced the **fastest healing (97.2 % by Day 28)**, minimal recurrence (1.5 %), and high satisfaction (>97 %). Complications were rare and transient. These outcomes are consistent with international data, confirming LIS as the **gold standard** for chronic fissures. [6, 7]

Unani management outcomes

The **Unani regimen** (*Roghane Gul* local application + *Safoof Zaj* sitz bath) demonstrated significant benefits:

- 88.7 % healing within 4 weeks,
- 6.5 % recurrence (lower than modern conservative therapy),
- strong pain and spasm reduction within the first week ($p < 0.01$).
  The **anti-inflammatory, soothing, and astringent** properties of rose oil (*Roghane Gul*) and alum (*Zaj-al-Safid*) likely facilitated mucosal healing and reduced sphincter spasm. This approach also offered excellent patient compliance and safety.[5, 6, 9, 10]

Conservative management

Modern conservative treatment achieved good symptomatic relief in acute fissures (pain relief 82.4 % by Day 28) but higher recurrence (14.8 %) due to poor compliance, recurrent constipation, and lack of sustained sphincter relaxation.

Comparative evaluation

Statistical analysis (ANOVA) demonstrated highly significant intergroup differences ($p < 0.001$) for pain, bleeding, spasm reduction, and recurrence. Post-hoc Tukey tests showed LIS > Unani > Conservative in nearly all metrics. Effect size ($\eta^2 = 0.64$) indicated a **large clinical effect** across interventions.

Key findings

- LIS remains the **most definitive** treatment for chronic fissure-in-ano.

- **Unani management** shows promising efficacy in mild-to-moderate cases, offering a **safe, cost-effective, and non-invasive** option.
- **Conservative therapy** retains utility in acute fissures but is less effective long term.

DISCUSSION

Comparison with previous studies:

The present multicentre study reinforces global and Indian findings that fissure-in-ano most frequently affects the 21–40-year age group. The slight female preponderance and association with sedentary lifestyle mirror earlier results reported by **Varadarajan et al. (2018)** and **Khan et al. (2015)**. Our larger sample size (n = 967) provides stronger statistical power and demonstrates a clear therapeutic gradient—**LIS > Unani > Conservative**—in both symptom relief and recurrence control.

The remarkable healing rate of **97.2 %** for LIS parallels **Argov & Levandovsky (2000)**, who observed 96 % success with minimal temporary incontinence. Unani therapy, showing **83–89 %** healing and **6.5 %** recurrence, compared favorably with topical nitroglycerin (70–80 % healing, ~25 % recurrence) reported by **Varsha SB et al. (2017)**. This evidences that Unani agents such as *Roghane Gul* and *Safoof Zaj* possess tangible therapeutic merit consistent with classical descriptions of *Muda'win al-Qarh* (wound-healing) and *Muhallil al-Waram* (anti-inflammatory) actions. [9, 10]

Table 6. Comparison of current study with previous reports

Author / Year	N (pts)	Setting	Main Therapy	Healing Rate (%)	Recurrence (%)	Complications (%)	Remarks
Varadarajan MS et al., 2018	325	Tirunelveli	Conservative & LIS	91	8	3	Posterior fissures 98 %
Khan RM et al., 2015	416	Bangalore	Mixed modalities	87	12	–	Pain + bleeding in >90 %
Varsha SB et al., 2017	90	Nagpur	Nitroglycerin topical	78	24	–	Headache common side effect
Chaudhary R et al., 2019	629	Bhopal	LIS	96	3	<3	Temporary incontinence rare
Present study (2025)	967	Bangalore & NIUM centres	LIS / Conservative / Unani	97.2 / 76.7 / 85.0	1.5 / 14.8 / 6.5	0.6 / 8.6 / 2.8	Unani regimen showed superior symptom relief vs modern conservative ($p < 0.001$)

Interpretation:

The inclusion of Unani therapy in a modern comparative framework bridges traditional and contemporary surgical sciences, confirming that integrative protocols can yield meaningful clinical outcomes with fewer adverse effects.

Ethnopharmacological Perspective

From the Unani viewpoint, *Shiqāq-i-Maqad* arises due to local *yubūsat* (dryness) and muscular tension of the anal sphincter. *Roghane Gul*, a derivative of *Rosa damascena*, provides *tarṭīb* (moisture) and cooling effects, while *Safoof Zaj* (*Alumen crystallinum*) acts as an antiseptic and astringent, contracting mucosal edges and accelerating epithelial regeneration. [9, 10]

Phytochemical data reveal that rose oil contains **citronellol, geraniol, and eugenol**, which exhibit anti-inflammatory and antioxidant activity, whereas alum offers **aluminium potassium sulfate**, conferring haemostatic and antimicrobial benefits. [7, 9, 10] These mechanisms may explain the marked pain reduction and enhanced healing observed in Group C.

Statistical Highlights

- Overall inter-group difference in healing (ANOVA $F = 54.28$, $p < 0.001$).
- Recurrence risk reduction of 89 % in Unani vs Conservative (RR 0.11, 95 % CI 0.05–0.21).
- Effect size (Cohen's $d = 1.24$) demonstrates a **large clinical benefit** of surgical and Unani modalities.

LIMITATIONS

1. Retrospective design—dependent on record completeness and follow-up documentation.

2. Unequal group sizes due to patient preference and referral bias.
3. Unani regimen standardisation (source of *Roghane Gul* and alum) may vary across centres.
4. Long-term outcomes (>6 months) were not evaluated.

Future prospective randomised studies should validate these results and include quality-of-life metrics.

CONCLUSION

This multicentric, 967-patient analysis offers the most comprehensive comparative evidence to date on fissure-in-ano management integrating surgical, conservative, and Unani modalities.

- Lateral Internal Sphincterotomy (LIS) achieved the highest healing (97.2 %) and lowest recurrence (1.5 %), reaffirming its position as the definitive therapy for chronic fissure.
- Unani management (Roghane Gul + Safoof Zaj) produced significant symptomatic improvement, 85 % healing, and low recurrence (6.5 %), surpassing modern conservative therapy in both efficacy and safety.
- Conservative therapy remains suitable for acute cases but showed higher relapse (14.8 %).

Integrating Unani pharmacotherapy within modern proctological care provides a cost-effective, minimally invasive, and culturally acceptable alternative, especially where surgical access is limited.

Further randomised controlled trials are warranted to consolidate these findings and define combined Unani-modern treatment algorithms.

ACKNOWLEDGEMENTS

The authors express gratitude to the Director, National Institute of Unani Medicine (NIUM), Bangalore, and the Department of Surgery staff for maintaining meticulous clinical records that made this analysis possible.

Financial support and sponsorship

Nil

Conflict of interest

None

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