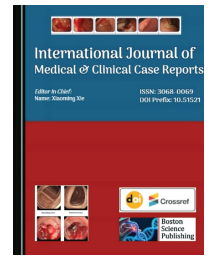


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Therapeutic Evaluation of Compound Unani Formulation for Chronic Fissure-In-Ano: A Case Series

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ABSTRACT

Anal fissure is a painful linear tear in the distal anal canal, often described as a sharp or cutting sensation during defecation. It affects approximately one in 350 adults and is most common between the ages of 15 and 40 years. In the Unani system of medicine, *Shuqaq-i-Miqad* is associated with *Shadeed qabz*, *Sue mizaj har yabis*, *warm-e-har*, *warm-e-barid wa reehi*, the passage of acrid (irritant) humors, and local trauma. Management typically emphasizes a high-fiber diet, gentle laxatives, avoidance of *tursh*, *qabiz*, and *khushk foods*, and the use of drugs that promote healing, reduce inflammation, and provide lubrication. In the present study, a Unani treatment regimen consisting of *Shahtra* Decoction (*Khisanda Shahtra*) (comprising *Chirayta*, *Sandal Safed*, *Unnab*, *Barg-e-Sana Makki*, and *Barg-e-Henna*) along with *Luab-e-Aspaghhol* (mucilage of *Plantago ovata*) was administered to three male patients with clinically diagnosed chronic fissure-in-ano. All patients presented with posterior midline fissures associated with sentinel piles, and proctoscopic examination was deferred because of severe pain. The treatment resulted in significant improvements in pain, bleeding, and local inflammation, along with improved bowel habits and progressive fissure healing over a three-week follow-up period. No adverse effects were observed during treatment. These findings suggest that the Unani regimen may offer an effective and safe conservative approach for the management of chronic fissure-in-ano; however, further studies with larger sample sizes are required to validate these results.

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Introduction

Anal fissure, often described as feeling like passing broken glass, is a tear in the lining of the distal anal canal that causes pain during defecation and may be associated with rectal bleeding. The condition affects approximately one in every 350 adults.¹ It affects both young men and women aged 15-40 with similar frequency, and it can also occur in older adults and children, often due to poor toileting habits [1,2]. Anal fissures may result from the passage of hard stool and can also appear spontaneously or during episodes of loose stool. Other proposed explanations include reduced blood flow in the midline of the anal lining and deficiencies in the nitric oxide synthase pathway [3,4]. An acute anal fissure usually heals within 1-2 weeks, whereas a chronic fissure lasts for more than 6 weeks and typically shows signs such as thickened edges, a skin tag, and exposed internal anal sphincter fibers at its base [5]. Patients are first treated conservatively with measures such as a high-fiber diet, adequate fluid intake, sitz baths, and, when needed, stool softeners and pain relief [6]. Topical nitrates or calcium channel blockers may be used, and surgery may be required for fissures that do not respond to these treatments [6,7]. This condition, which significantly affects quality of life and is prone to recurrence, highlights the need to explore safe and alternative treatment options [5].

Unani scholars have described anal fissures as *Shuqaq-i-Miqad*. They noted that the main cause of this condition was the dry and hot (*Hararat and Yabusat*) temperament of the anal region. This heat and dryness make the area prone to tearing, usually after the passage of hard stool or, at times, due to minor irritants. Fissures may also develop secondary to hemorrhoids or congestion of the anal vessels. Anal inflammation is another contributing factor. Additionally, diarrhea, the passage of corrosive humors, and prolonged suppression of the urge to defecate can lead to this condition. Thus, it is essential to assess the efficacy of Unani formulations in the treatment of anal fissures. For this purpose, *Khisanda Shahtra* and *Luab-e-Aspaghhol*, well-known Unani pharmacopeial compounds, were used for treatment, as described in classical texts. However, evidence supporting their effectiveness in treating anal fissures is limited, highlighting the need for scientific studies to evaluate the safety and efficacy of this formulation [9-12].

Aim of the Study:

This study aimed to evaluate the clinical efficacy and safety of a Unani formulation consisting of *Khisanda Shahtra* and *Luab-e-Aspaghhol* in the management of chronic anal fissures.

OBJECTIVES OF THE STUDY:

Primary Objective: To assess the effectiveness of the Unani formulation

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in reducing pain, bleeding, and constipation and promoting healing of chronic fissure-in-ano.

Secondary Objectives: To evaluate improvement in bowel habits and reduction in straining during defecation and to assess the safety and tolerability of the treatment regimen. To observe changes in local inflammatory signs and fissure characteristics over the treatment period.

Case 1:

A 34-year-old man presented to the Moalajat OPD of Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh, with complaints of severe pain during defecation and intermittent rectal bleeding for the past three months. The pain was sharp and cutting in nature, occurring during and persisting after defecation. He also reported a burning sensation in the anal region and fear of passing stool because of pain. The symptoms began following an episode of severe constipation associated with the passage of hard stools. The patient had no history of diarrhea, weight loss, or mucus discharge. The patient had a similar episode one year earlier that resolved with medication. There was no history of diabetes mellitus, hypertension, or any other chronic systemic diseases. The patient was a non-smoker and did not consume alcohol. His dietary history revealed a low fiber intake and inadequate hydration. On general examination, the patient was stable, and the vital parameters were within normal limits. Local examination revealed a posterior midline fissure at the 6 o'clock position with a small sentinel pile. The fissure appeared deep and tender on palpation and was surrounded by mild inflammation. Digital rectal examination and proctoscopy were deferred due to severe pain and sphincter spasm. Based on the clinical findings and duration of symptoms, the patient was diagnosed with a chronic anal fissure (*Shuqq al-Maqad*).

Case 2:

A 39-year-old man presented to the Moalajat OPD of Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh, with complaints of painful defecation and rectal bleeding for the past two months. Bleeding was noted as streaks over the stool and occasionally as drops following defecation. The patient also reported a sensation of incomplete evacuation and discomfort that persisted after bowel movements. He had a history of recurrent episodes of similar complaints over the past three years, with only temporary relief

from previous medications. The patient also reported chronic constipation with the frequent passage of hard stools and habitual straining. There was no history of diabetes mellitus, hypertension, inflammatory bowel disease, or previous anorectal surgery. The patient was a non-smoker and did not consume alcohol. The dietary history revealed irregular eating habits with low fiber intake. On general examination, the patient was stable, and the vital parameters were within normal limits. Local examination revealed a posterior midline fissure at the 6 o'clock position with indurated margins and a prominent sentinel pile. The surrounding skin was edematous and inflamed, and the fissure was markedly tender upon palpation. Digital rectal examination and proctoscopy were deferred because of severe pain and sphincter spasm. Based on the history, recurrence, and local findings, the patient was diagnosed with a chronic anal fissure (*Shuqq al-Maqad*).

Case 3:

A 35-year-old male, a laborer by occupation, presented to the Moalajat OPD of Ajmal Khan Tibbiya College & Hospital, AMU, Aligarh, with complaints of pain during defecation and bleeding per rectum for approximately two and a half months. The pain was burning in nature and was associated with difficulty passing stool and excessive straining. Bleeding was noted as streaks over hard stools and occasionally as drops following defecation. The dietary history revealed a mixed diet with irregular meal timings and low fiber intake. The patient had a history of chewing tobacco for the past 8-10 years. His occupation involved prolonged physical exertion and inadequate hydration. There was no history of diabetes mellitus, hypertension, tuberculosis, or previous anorectal procedures. The family history was not significant. On general examination, the patient was moderately built, and the vital parameters were within normal limits. Local examination revealed a posterior midline fissure at the 6 o'clock position with moderately indurated edges and a small sentinel pile. The surrounding skin showed mild edema and inflammation, and the fissure was tender upon palpation. Digital rectal examination and proctoscopy were deferred because of severe pain and sphincter spasm. Based on the clinical history, lifestyle factors, chronicity of symptoms, and local examination findings, the patient was diagnosed with chronic anal fissure (*Shuqq al-Maqad*).

FISSURE PROFILE:

Table 1: Inspection Findings of Fissure-in-Ano.

Parameter	Case 1	Case 2	Case 3
Site	Posterior midline (6 o'clock)	Posterior midline (6 o'clock)	Posterior midline (6 o'clock)
Number	Single	Single	Single
Shape	Regular, elliptical	Regular, elliptical	Linear with mild irregularity
Colour	Red	Red	Reddish
Size	3 × 0.5 × 0.5 cm	2 × 0.4 × 0.5 cm	2.5 × 0.5 × 0.5 cm
Edge	Sharp	Indurated and sharp	Moderately indurated
Floor	Red granulation tissue	Red granulation tissue	Covered with granulation tissue
Discharge	Blood	Blood	Blood
Surroundings	Mildly oedematous	Oedematous and inflamed	Mild oedema
Skin Tag (Sentinel Pile)	Small	Large	Small to moderate

All cases showed posterior midline fissures, which are the most common anatomical locations because of their relatively poor vascularity.

Table 2: Palpation Findings of Fissure-in-Ano.

Parameter	Case 1	Case 2	Case 3
Local Temperature	Not raised	Not raised	Not raised
Tenderness	Severe	Moderate to severe	Moderate
Sphincter Spasm	Marked	Marked	Moderate
Base of Fissure	Fixed to the underlying tissue	Indurated and fixed	Moderately indurated
Bleeding on Stretch	Present	Present	Present
Skin Tag (Sentinel Pile)	Soft and tender	Soft, large, tender	Soft, moderately tender

INVESTIGATIONS:

The following investigations were performed in all three patients to assess their general health status and rule out associated systemic conditions:

- **Complete Blood Count (CBC)** - to evaluate hemoglobin levels and detect any infection
- **Erythrocyte Sedimentation Rate (ESR)** - to assess inflammatory status
- **Blood Sugar (Fasting and Postprandial)** - to rule out diabetes mellitus
- **Liver Function Tests (LFT)** - within normal limits
- **Kidney Function Tests (KFT)** - within normal limits
- **HBsAg and HIV screening** - non-reactive

All investigation results were within normal limits in all three cases.

*Diagnosis was primarily clinical, and no invasive investigations were performed due to the characteristic presentation and patient discomfort

FOLLOW-UP AND CLINICAL OUTCOME:

All three patients were followed for three weeks, with assessments conducted on days 0 (baseline), 7, 14, and 21. Clinical evaluation was based on pain intensity (VAS score), bleeding per rectum, stool consistency, degree of straining, and local healing of the fissure.

Case 1: The patient showed early improvement within the first week of treatment, with reduced pain and bleeding. By the second week, the pain was minimal, and the bleeding had almost resolved. At the end of three weeks, the patient reported complete relief from pain, normal bowel habits, and no bleeding. Local examination revealed near-complete healing of the anal fissure.

Case 2: The patient demonstrated gradual improvement during the follow-up period. Pain and bleeding decreased significantly on day 14. By Day 21, pain was minimal, bleeding had stopped, and bowel habits had improved. Local examination revealed significant healing, although mild induration persisted.

Case 3: The patient showed moderate improvement during the first week, with reduced pain and soft stools. By the second week, the symptoms improved further, with minimal bleeding. At the end of three weeks, the patient reported marked relief, minimal residual discomfort, and improved bowel habits. Local examination showed substantial healing of the fissure

TREATMENT:

All three patients were managed with a Unani therapeutic regimen aimed at relieving constipation, reducing inflammation, and promoting healing of the anal fissure.

Drug Therapy

- *Khisanda Shahtra (Decoction Shahtra):* 100 ml orally, twice daily
- *Luab-e-Aspaghool* (mucilage of *Plantago ovata*): 6 g orally at bedtime with lukewarm water

Mode of Action

- *Khisanda Shahtra*, a polyherbal Unani formulation, possesses anti-inflammatory, mild laxative, antimicrobial, and wound-healing properties, which help reduce local inflammation and promote fissure healing.
- *Luab-e-Aspaghool* (mucilage of *Plantago ovata*) acts as a bulk-forming laxative, softening the stool and reducing straining during defecation, thereby preventing further trauma to the anal mucosa.

Dietary and Lifestyle Advice

All patients were advised of the following:

- To consume a high-fiber diet (green vegetables, fruits)
- To maintain adequate hydration
- To avoid straining during defecation
- To follow regular bowel habits

Duration of Treatment

The treatment was continued for 3 weeks, with regular follow-ups on days 7, 14, and 21.

*No additional topical or surgical interventions were performed during the treatment period.

Table 3: Follow-Up and Clinical Outcome of Patients.

Parameter	Day	Case 1	Case 2	Case 3
Pain (VAS Score)	Day 0	9	9	8
	Day 7	5	6	5
	Day 14	2	3	2
	Day 21	0	1	1
Bleeding	Day 0	Fresh bleeding	Streaks/drops	Streaks
	Day 7	Reduced	Reduced	Reduced
	Day 14	Minimal	Minimal	Minimal
	Day 21	Absent	Absent	Absent
Stool Consistency & Straining	Day 0	Hard, severe strain	Hard, severe strain	Hard, severe strain
	Day 7	Soft, less strain	Soft, less strain	Soft, less strain
	Day 14	Soft, minimal strain	Soft, minimal strain	Soft, minimal strain
	Day 21	Normal, no strain	Normal, minimal strain	Normal, minimal strain
Healing Status	Day 0	Active fissure	Chronic fissure	Chronic fissure
	Day 7	Reduced inflammation	Reduced inflammation	Reduced inflammation
	Day 14	Healing with granulation	Partial healing	Healing progressing
	Day 21	Healed	Significant healing	Healed

Table 4: Ingredients of *Khisanda Shahtra*.

Unani name	Scientific Name	QTY
<i>Barg-e-Sana Makki</i>	(<i>Cassia angustifolia</i>)	6 g
<i>Chirayta</i>	(<i>Swertia chirata</i>)	6 g
<i>Sandal safed</i>	(<i>Santalum album L.</i>)	6 g
<i>Unnab</i>	(<i>Ziziphus jujuba</i>)	5 fruits
<i>Berg-e-Henna</i>	(<i>Lawsonia inermis L.</i>)	6 g

Drug Preparation and Administration:

Khisanda Shahtra (Decoction Shahtra)

All crude drugs were cleaned thoroughly and coarsely powdered, where required. The ingredients were soaked in an adequate quantity of water overnight. The following day, the soaked material was gently heated to prepare a hot infusion (*Joshanda*). The preparation was subsequently filtered through a clean muslin cloth to obtain a clear solution. The filtrate was allowed to cool to a lukewarm temperature before it was administered. A 100 ml dose of the freshly prepared infusion was administered twice daily. The formulation was freshly prepared each day to ensure optimal efficacy and stability.

Luab-e-Aspaghhol (Mucilage of Plantago ovata)

The required quantity of *Plantago ovata* was soaked in sufficient lukewarm water for a few minutes to allow swelling and mucilage (*Luab*) formation. The mucilage was administered orally at bedtime with lukewarm water. A dose of 6 g once daily at bedtime was prescribed to facilitate bowel movements and reduce straining during defecation. The preparation was freshly prepared before each administration to maintain its efficacy.

RESULTS

All three patients were followed for a period of three weeks, with clinical assessments performed on days 0, 7, 14, and 21. The evaluation parameters included pain intensity (VAS score), bleeding per rectum, stool consistency, degree of straining, and local healing of the fissure.

All patients showed progressive and consistent improvements during the follow-up period. Pain intensity decreased markedly in all cases, with VAS scores reducing from severe levels at baseline to minimal or no pain by day 21. Bleeding per rectum, initially present in all patients, gradually reduced and was completely absent by the end of the treatment period. There was a significant improvement in bowel habits, with stool consistency changing from hard to soft and normal, accompanied by a marked reduction in straining during defecation. Local examination revealed progressive healing of the fissure in all patients, with a reduction in inflammation and induration, and near-complete to complete healing by day 21. Overall, all patients demonstrated significant clinical improvement in symptoms and healing parameters, without any reported adverse effects during the treatment period.

DISCUSSION

Fissure-in-ano is a common anorectal disorder that primarily results from trauma to the anal mucosa, most often due to the passage of hard stool. Persistent sphincter spasm, reduced blood flow to the anoderm, and repeated injury contribute to chronicity, leading to features such as induration, sentinel pile formation, and delayed wound healing.

In the present case series, all three patients exhibited the classical features of chronic fissure-in-ano, including pain during defecation, bleeding per rectum, and posterior midline location. Chronic constipation and straining were common factors across all cases. Additionally, lifestyle factors such as low fiber intake, inadequate hydration, and tobacco use (Case 3) further aggravated this condition. The Unani formulation used in this study, consisting of *Khisanda Shahtra* and *Luab-e-Aspaghhol*, appears to act through a multi-targeted mechanism that addresses both the causative and pathological factors.

Luab-e-Aspaghhol (Mucilage of *Plantago ovata*) plays a pivotal role as a bulk-forming laxative. Psyllium increases stool bulk, softens fecal matter, and reduces straining during defecation, thereby minimizing further trauma to the anal mucosa. This helps break the pain-spasm-ischemia cycle, which is central to the persistence of anal fissures.

Khisanda Shahtra, composed of ingredients such as *Cassia angustifolia*, *Swertia chirata*, *Santalum album*, *Ziziphus jujuba*, and *Lawsonia inermis*, contributes through its anti-inflammatory, mild laxative, antimicrobial, and wound-healing properties. These actions help reduce local inflammation, promote tissue regeneration, and prevent secondary infections.

The clinical outcomes observed in the present study support these mechanisms. All patients showed a marked reduction in pain, as evidenced by the decrease in VAS scores over the follow-up period. The bleeding resolved completely, and the bowel habits improved significantly. Progressive healing of the fissure was observed in all patients within three weeks.

Compared to conventional treatments, such as topical nitrates and calcium channel blockers, which primarily act by reducing internal anal sphincter tone, the Unani regimen offers a broader therapeutic approach. It not only reduces sphincter spasms indirectly by relieving constipation but also promotes mucosal healing and addresses the underlying etiological factors. However, the present study had certain limitations. The sample size was small, and objective diagnostic tools such as anal manometry were not used. Additionally, a long-term follow-up to assess recurrence was not conducted [3-7].

CONCLUSION

The present case series suggests that the Unani formulation consisting of *Khisanda Shahtra* and *Luab-e-Aspaghhol* may be effective in the management of chronic fissure-in-ano. The treatment demonstrated beneficial effects in reducing pain, bleeding, and constipation, and promoting fissure healing. This therapeutic effect may be attributed to its combined laxative, anti-inflammatory, and wound-healing properties. Further studies with larger sample sizes, controlled designs, and long-term follow-ups are required to establish its efficacy and safety.

Justification for Per Rectal Examination

A per-rectal examination was performed whenever clinically indicated to assess local pathology and associated complications. Surgical opinions were sought from time to time during the study period, whenever required.

Ethical Statement:

Written informed consent was obtained from all the patients. Patient confidentiality was maintained.

Institutional Review Board Statement: Not applicable.

Data Availability Statement: No new data were created or analyzed in this study. Data sharing is not applicable to this article.

Conflicts of Interest: The authors declare no conflict of interest.

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