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Chronic anal fissures treated with Unani formulation – A series of case reports



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ARTICLE INFO	A B S T R A C T
Keywords: Fissure-in-ano Anal pain Constipation Unani medicine	 Background: Chronic anal fissure is recognized for its profound impact on quality of life and the propensity for treatment relapse, underscoring the need to explore safe and alternative clinical interventions. Unani medicine offers a wealth of therapeutic approaches for anal fissures, yet empirical evidence remains limited. Objective: This study aimed to assess the efficacy of the Unani formulation Marham Safeda Kafoori in treating chronic anal fissures. Methods: Seven patients with chronic anal fissures underwent a 14-day treatment with Marham Safeda Kafoori. Concurrently, two Unani interventions, namely Habb-e-Bawaseer Amya and Habb-e-Muqil, were administered for the management of constipation. Therapeutic response was assessed using a 100mm Visual Analog Scale for anal pain and burning sensations, alongside evaluating non-hemorrhoidal rectal bleeding and fissure healing status. Results: Following a two-week follow-up, pain and burning decreased significantly. Similarly, all the cases were healed completely with no instances of rectal bleeding. Conclusion: The trial formulation demonstrated promising efficacy in the management of anal fissures, with no observed adverse effects. Nevertheless, it is prudent to recommend rigorous prospective clinical investigations to validate its scientific soundness.

1. Introduction

Anal fissure, frequently likened to the sensation of passing broken glass, manifests as a disruption in the integumentary structure of the distal anal canal, thereby precipitating distress upon defecation, occasionally accompanied by rectal bleeding. This condition exhibits an incidence rate of approximately one in every 350 adults.¹ Notably, it afflicts both young men and women within the age bracket of 15–40 with equal frequency, though instances may also present in older adults and children, particularly attributed to suboptimal toileting practices.^{1,2} Anal fissures may originate due to the passage of hardened fecal matter and can also manifest spontaneously or in association with episodes of loose stool. Additionally, alternative hypotheses propose ischemic events within the midline of the anal integument and insufficiencies within the

nitric oxide synthase pathway as potential contributing factors.^{3,4} An acute anal fissure initially heals within 1–2 weeks, while a chronic fissure persists for over 6 weeks, showing distinct features like indurated edges, a skin tag, and visible internal anal sphincter fibers at its base.⁵ Patients are initially managed conservatively with a regimen comprising a high-fiber diet, increased fluid intake, sitz baths, and, in severe cases, stool softeners and analgesics.⁶ Topically, nitrates or calcium-channel blockers are added. Surgical intervention may be necessary for fissures resistant to topical treatments.^{6,7} This condition, known for its substantial impact on quality of life and treatment relapse, underscores the importance of investigating safe and alternative clinical interventions.⁵

Unani physicians historically referred to anal fissures as *Shuqāq-i Miq'ad*. According to their observations, the etiology of this condition is primarily attributed to the dry and hot (*Harārat* and *Yabūsat*) state of the

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anus. This dryness and heat predispose the anus to fissures, often precipitated by the passage of hardened fecal matter or, in some instances, triggered by minor irritants. Anal fissures may also arise as a consequence of hemorrhoids or congestion of the anal blood vessels. Inflammation of the anus is another potential causative factor. Moreover, this condition can be incited by factors such as diarrhea, the expulsion of corrosive humours, and the protracted suppression of the urge to defecate. *Marham Safeda Kafoori* is recommended in the Unani system of medicine to alleviate heat and dryness while promoting wound healing.⁸ However, scientific evidence supporting its efficacy in treating anal fissures is limited. Therefore, there is a pressing need for scientific evaluation to assess the safety and effectiveness of this formulation.

The information collected from the study participants adhered to the ethical principles of the Helsinki Declaration. Furthermore, the compilation of these case reports followed the guidelines set forth in the CARE case report guidelines.⁹

2. Patients information

The study incorporated a cohort of seven male participants within the age range of 22-56 years. These individuals sought medical evaluation at the outpatient department (OPD) of the Regional Research Institute of Unani Medicine, Silchar. They presented with a history of chronic anal fissure, spanning from 1 to 3 years, and reported abstaining from any anal fissure medication in the month preceding their clinical consultation (Table 1). Notably, the exclusive enrolment of male participants in our study was incidental, driven by their demonstrated willingness to undergo comprehensive fissure examinations, adhere to the prescribed treatment duration, complete the therapeutic regimen, and provide consent for deidentified data publication. Conversely, limited interest from female patients, attributed to cultural barriers, introduced a gender bias. Moreover, this study aims to describe a series of cases encountered in clinical practice, strict inclusion criteria were not applied. This approach enables a more representative depiction of anal fissure cases observed in our clinical setting.

3. Clinical findings

One participant had a familial predisposition to anal fissure. None of the participant had a presence or history of Crohn's disease, tuberculosis, sarcoidosis, syphilis, HIV, or anal cancer. The average disease duration among all participants was 2.29 ± 0.76 years, with a range spanning from 1 to 3 years. In all seven patients, the fissures were localized in the posterior midline. It is noteworthy that each patient had previously undergone unsuccessful treatments, having received one to three different

Table 1

Clinico-demographic profile of the participants studied.

medications from both allopathic and homeopathic modalities prior to the initiation of Unani therapeutic intervention (Table 1).

4. Timeline

The initial patient commenced treatment on September 05, 2023, and the final participant concluded a 14-day treatment regimen on October 24, 2023.

5. Diagnostics and assessment

Chronic anal fissure diagnosis relied upon clinical assessment. Initially, patients were reassured about the non-painful nature of the examination. Subsequently, gentle separation of the patient's buttocks exposed pronounced anal sphincter spasm, enabling visualization of the lower extremity of the fissure, which presented as a linear skin disruption or a tear-shaped ulcer situated in the posterior midline, consistently observed in all seven participants. The response to the therapeutic intervention was evaluated using a 100mm Visual Analog Scale (VAS) for pain and burning sensations in anus.¹⁰ Furthermore, the evaluation encompassed the assessment of non-hemorrhoidal rectal bleeding from fissures and the healing status of the fissures. These assessments were performed both during the initial evaluation and after a 14-day treatment period.

6. Therapeutic measure

The trial formulation, Marham Safeda Kafoori, was employed in accordance with the description outlined in the book Iksīr-i A'zam, authored by Hakeem A'zam Khan. This 10-g formulation consisted of various constituents, including 1.82g of Mom Safaid (white wax), 5.5 mL of Roghan Gul (Rosa × damascena Herrm. oil, prepared in adherence to Unani principles), 0.91g of Kushta Qalai (calcined tin), 0.91g of Murdar Sang (lead oxide), and 0.91g of Kafur [Cinnamomum camphora (L.) J. Presl dried bark extract].¹¹ Concurrently, potent Unani pharmacological interventions, namely Habb-e-Bawaseer Amya and Habb-e-Muqil, were administered for the management of constipation with two pills from each, twice daily after meals. Each Habb-e-Bawaseer consisted of equal quantities (125 mg) of Halyla Kabuli (Terminalia chebula Retz. ripe fruit) and Rasawt (Berberis aristata DC.), that had been subjected to roasting in Roghan Zard (cow ghee). On the other hand, each Habb-e-Muqil composed of Muqil [Commiphora wightii (Arn.) Bhandari] 44.68 mg, Post Halyla Zard (Terminalia chebula Retz. half-ripe fruit) Post Halyla Kabuli (Terminalia chebula Retz. ripe fruit), Halyla Siyah (Terminalia chebula Retz. unripe fruit), Amla Khushk (Phyllanthus emblica L.) each 31.91 mg, Sakbeenaj

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Patient no.	Age (years)	Sex	Profession	Family history	Disease duration (years)	Past interventions	Outcome of past interventions	Other clinical findings	Timeline of trial therapy (dd/mm/yy)
Case-1	52	Male	Driver	Not present	1	Allopathic and homeopathic	Got temporary relief in the symptoms	Not significant	05/09/2023 to 19/09/2023
Case-2	30	Male	Office- worker	Not present	3	Allopathic	Experienced relief from pain and burning, but there was the presence of oozing serous fluid, sometimes with blood, which subsequently led to a relapse.	Not significant	05/09/2023 to 19/09/2023
Case-3	56	Male	Tailor	Not present	3	Homeopathic	Initially experienced relief, but it increased afterwards	Not significant	15/09/2023 to 29/09/2023
Case-4	22	Male	Drvier	Not present	3	Homeopathic	Did not experience any satisfactory relief	Not significant	22/09/2023 to 06/10/2023
Case-5	34	Male	Mason	Not present	2	Allopathic and homeopathic	Did not experience satisfactory relief.	Not significant	30/09/2023 to 14/10/2023
Case-6	48	Male	Tailor	Not present	2	Allopathic and homeopathic	Experienced temporary relief from the symptoms	Not significant	03/10/2023 to 17/10/2023
Case-7	30	Male	Shopkeeper	Mother with anal fissure history	2	Allopathic treatment	Experienced temporary relief	Not significant	10/10/2023 to 24/10/2023

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(Ferula persica Willd.) 10.63 mg, Khardal (Brassica nigra W.D.J.Koch) 5.31 mg, Roghan-e-Badam (Prunus anygdalus Batsch oil) 10.63 mL, Aab-e-Gandana (Allium ascalonicum L. juice) 52.6 mL. For this study, the formulations provided by the Indian Medicine Pharmaceutical Corporation Limited, a government-supplied source, were utilized.

7. Follow up and outcomes

The investigation encompassed a two-week follow-up of the study participants. Notably, the mean \pm SD of the VAS scores exhibited a highly significant reduction (p < 0.001), decreasing from 51.43 ± 10.69 at the outset to 8.57 ± 6.90 for pain, and from 74.28 ± 14.28 to 9.75 ± 5.35 for burning after 14 days of treatment. Similarly, fissures exhibited complete healing in all cases, with no instances of rectal bleeding observed after the 14-day treatment period. It is noteworthy that no adverse clinical effects were discerned throughout the course of the treatment.

8. Discussion

This study investigates the efficacy of Marham Safeda Kafoori in managing chronic anal fissure. The reduction in disease activity can be attributed to its multifaceted properties, including wound healing (Mudammil-i Quruh), anti-inflammatory (Dafi'-i Waram), disinfectant (Dafi'-i 'Ufunat), emollient (Mumallis), and local sedative (Musakkin-i *Maqāmi*), as elucidated in classical Unani literature.⁸ These attributes are further substantiated by pharmacological studies of the constituent ingredients. Kāfūr (Cinnamomum camphora) possesses antipruritic, antimicrobial, and wound healing properties and acts as a skin penetration enhancer, facilitating topical drug delivery to the affected area.^{12,13} Linalool, the bioactive compound of C. camphora, demonstrated pain reduction in mouse models, potentially through the regulation of NMDA receptors and suppression of pro-inflammatory cytokines. Borneol, another bioactive compound, in clinical investigations, significantly reduces pain compared to a placebo, possibly targeting TRPM8 channels in mice. Menthol, a natural bioactive molecule found in C. camphora, activates TRPA1, a highly sensitive menthol receptor, suggesting its involvement in counterirritants and analgesic activities.¹⁴ In addition, an RCT focusing on anal fissures, the efficacy of Rosa damascena oil and wallflower demonstrated comparability with diltiazem 2 % gel.¹⁵ The prominent bioactive compounds found in R. damascena, such as citronellol, 2-phenyl ethyl alcohol, and geraniol, may contribute to wound healing by preventing infections and reducing inflammation.¹⁶ However, additional research is necessary to establish their direct involvement in therapeutic applications for wound treatment. Moreover, an in vitro study revealed that nanoparticulate Kushta-i Qalai exhibits potent bactericidal activity against a majority of gram-positive strains and select gram-negative strains.¹⁷ Additionally, Murdar Sang serves as a potent local astringent and cooling agent, with applications in external ointments for conditions such as itching, ulcers, acne, eczematous eruptions, and various skin diseases.¹⁸

To summarise, the combined wound healing, anti-inflammatory, antipruritic, emollient, and antimicrobial properties of the constituents of *Marham Safeda Kafoori* collectively contribute to the healing process of anal fissures. Nonetheless, further studies are imperative to substantiate the individual efficacy of each component of *Marham Safeda Kafoori* in the context of chronic anal fissure.

9. Strengths and limitations of the study

While the dataset in this investigation is notably restricted in scope, the substantial magnitude of the observed alterations cannot be disregarded. These changes are presumed to be attributable to the experimental formulation, thereby fostering the resolution of anal fissures. Nonetheless, further assessment of the efficacy of *Marham Safeda Kafoori* in chronic anal fissure should be pursued through a meticulously structured retrospective controlled study or a prospective study with a larger sample size and longer duration before advancing to additional randomized controlled trials.

10. Patients perspective

From the patient's perspective, they experienced complete resolution of symptoms, including anal pain and burning sensations.

11. Informed consent

Patients were apprised of the study procedure and the potential publication of their de-identified data in a language that they could comprehend, following which written informed consent was procured from all participants.

Ethical statement

This study, which involved human subjects, adhered to all pertinent national regulations and adhered to the principles of the Helsinki Declaration (revised in 2013).

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None declared.

CRediT authorship contribution statement

Nazim Husain: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Md Akhter Hussain Jamali: Writing – review & editing, Validation, Supervision, Resources. Abdullah: Writing – review & editing, Visualization, Validation, Resources. Shakeeb Ahmad Khan: Writing – review & editing, Project administration, Investigation, Formal analysis, Data curation, Conceptualization.

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