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Clinical Efficacy and Safety of the Unani Pharmacopoeial Formulation Sailani in the Management of Sayalān al-Rahim (Excessive Abnormal Vaginal Discharge): An Open-Label Clinical Trial

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ABSTRACT

Background: *Sayalān al-Rahim, characterized by excessive abnormal vaginal discharge (EVD), is prevalent in Indian women of reproductive age (prevalence: 26.3% in rural India) and is associated with significant morbidity. The Unani formulation Sailani possesses documented astringent, antimicrobial, and uterotonic properties; however, clinical evidence validating its therapeutic use remains limited.*

Objective: *To evaluate the clinical efficacy and safety of Sailani in managing Sayalān al-Rahim over a four-week treatment period.*

Methods: *An open-label clinical study was conducted at RRIUM Mumbai, enrolling 100 women aged 18–45 years presenting with (EVD),. Participants received Sailani tablets (2 tablets twice daily post-prandially with lukewarm water) for four weeks. Clinical symptoms, laboratory parameters (CBC, LFT, KFT, urine analysis), and quality of life (WHO-BREF) were assessed at baseline, Week 2, and Week 4.*

Results: *Statistically significant reductions were observed in discharge quantity, vulval itching, low backache, and generalized weakness ($p < 0.01$). No clinically significant adverse effects or haematological/biochemical abnormalities were recorded. WHO-BREF domain scores demonstrated significant improvements across physical, psychological, and social dimensions.*

Conclusion: *Sailani demonstrated clinically meaningful efficacy and an acceptable safety profile in the management of Sayalān al-Rahim, supporting its evidence-based integration into gynaecological practice under the Unani system of medicine.*

Keywords*: Sayalān al-Rahim; Abnormal Vaginal Discharge; Unani Medicine; Sailani; Clinical Trial; WHO-BREF; Reproductive Health*

1. Introduction

Vaginal discharge represents one of the most common gynaecological complaints among women of reproductive age, encompassing a spectrum from physiological secretion to pathological discharge indicative of underlying reproductive tract infections (RTIs) or sexually transmitted diseases (STDs) [1]. Abnormal vaginal discharge (EVD), is clinically distinguished by alterations in colour, consistency, quantity, and odour, frequently accompanied by vulval pruritus, dysuria, and pelvic discomfort.

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In India, population-based surveys report (EVD), prevalence rates of up to 26.3% in rural women, highlighting it as a significant public health burden with implications for reproductive outcomes and quality of life [2]. In classical Unani medicine, the nosological equivalent of (EVD), is termed Sayalān al-Rahim (literally, uterine flux), documented extensively in canonical texts including Kāmil al-Ṣanāʿa and Firdaus al-Hikmat [3,4]. The pathophysiology is attributed to Sū' Mizāj (morbid temperamental dyscrasia) of the uterus, precipitating humoral imbalance and defective metabolic processing of nutritive fluids, culminating in the excretion of aberrant discharge. Clinical phenotype—discharge colour and consistency—is postulated to reflect the predominant dyscrasia: Damawī (sanguineous), Ṣafrāwī (bilious), Balghamī (phlegmatic), or Sawdāwī (atrabilious) [3]. The Unani Pharmacopoeial compound formulation Sailani incorporates constituents possessing Muqawwi-e-Rahim (uterine tonic), Habis (haemostatic-astringent), Qabiz (styptic), and Dāfiʿ-e-Taffun (antiseptic/detergent) pharmacological properties [5]. Preclinical studies on constituent drugs indicate antifungal and antibacterial activities against common aetiological agents of EVD [6,7]. However, robust clinical evidence substantiating the safety and efficacy of this formulation is lacking. The present study was therefore designed to generate prospective clinical data on the therapeutic utility of Sailani in women with Sayalān al-Rahim.

2. Materials and Methods

2.1 Study Design and Setting

This was a prospective, open-label, single-arm clinical trial conducted at the outpatient department (OPD) of the Regional Research Institute of Unani Medicine (RRIUM), Mumbai, India, over a two-year study period. The study protocol received institutional ethics committee approval, and written informed consent was obtained from all participants prior to enrolment (CTRI registration pending/number). The trial adhered to the principles of the Declaration of Helsinki.

2.2 Participants

Women aged 18–45 years presenting with clinical symptoms consistent with Sayalān al-Rahim were assessed for eligibility. Key inclusion and exclusion criteria are summarised below.

Inclusion criteria:

Age 18–45 years with clinically confirmed (EVD),

Presence of ≥1 associated symptom: vulval pruritus, low backache, generalised weakness, dysuria, or abnormal odour

Provision of written informed consent

Exclusion criteria:

Menopausal, pregnant, or lactating women

Systemic illness (hypertension, diabetes mellitus, malignancy, HIV, syphilis, gonorrhoea)

Pelvic structural pathology (fibroids, ovarian cysts, uterine prolapse, acute pelvic inflammatory disease)

Current use of oral contraceptives or intrauterine devices

2.3 Investigational Product

Participants received standardised Sailani tablets procured from the Central Research Institute of Unani Medicine (CRIUM), Hyderabad, following rigorous quality control and pharmacopoeial standardisation. The prescribed regimen was 2 tablets (500 mg each) administered twice daily post-prandially with lukewarm water for a continuous period of four weeks.

2.4 Outcome Measures

Clinical symptoms were assessed using a standardised four-point severity scale (0 = absent; 1 = mild; 2 = moderate; 3 = severe) at three time points: baseline (T0), Week 2 (T1), and Week 4 (T2). Parameters included: type and quantity of vaginal discharge, vulval pruritus, low backache, generalised weakness, dysuria, and abnormal odour.

Laboratory safety assessments included: complete blood count (CBC), liver function tests (serum bilirubin, AST, ALT, alkaline phosphatase), kidney function tests (serum creatinine, blood urea), and urine routine and microscopy. Baseline VDRL and random blood glucose were performed to fulfil exclusion criteria. Health-related quality of life (HRQoL) was evaluated using the World Health Organization Quality of Life–BREF (WHO-BREF) instrument, which captures four domains: physical health, psychological well-being, social relationships, and environmental factors [8].

2.5 Statistical Analysis

Data are expressed as mean ± standard deviation (SD) for continuous variables and as frequency (percentage) for categorical variables. Within-group comparisons across time points were performed using the Wilcoxon signed-rank test for non-parametric data. A p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY).

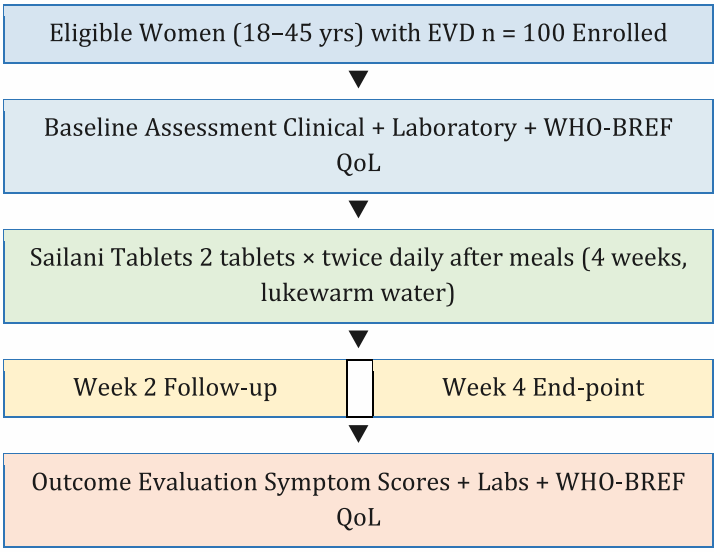

Figure 1: Schematic overview of the open-label clinical trial design for evaluation of Sailani in Sayalān al-Rahim

3. Results

3.1 Participant Characteristics

A total of 100 women were enrolled and completed the four-week treatment protocol. The mean age of participants was 32.4 ± 7.8 years (range: 18–45 years). The majority presented with mucoid (43%) or purulent (29%) discharge at baseline. Duration of symptoms ranged from 3 months to 5 years (median: 14 months).

3.2 Clinical Symptom Response

Clinically and statistically significant reductions in symptom severity scores were observed across all parameters at Week 4 compared with baseline (all $p < 0.01$). The proportion of participants reporting moderate-to-severe symptom burden at each time point is presented in Figure 2. Notably, the frequency of moderate-to-severe abnormal discharge declined from 87% at baseline to 18% at Week 4, with parallel reductions in vulval pruritus (74% → 12%), low backache (68% → 14%), and generalised weakness (62% → 10%).

Table 2: Percentage of participants reporting moderate-to-severe symptoms at baseline, Week 2, and Week 4 of Sailani treatment. Data analysed by Wilcoxon signed-rank test

Symptom	Baseline (%)	Week 2 (%)	Week 4 (%)	p-value
Abnormal Discharge (mod–severe)	87	52	18	< 0.001
Vulval Itching (mod–severe)	74	41	12	< 0.001
Low Backache	68	38	14	< 0.001
Generalized Weakness	62	35	10	< 0.001
Burning Micturition	45	22	8	< 0.01
Abnormal Odour	58	30	9	< 0.001

3.3 Laboratory Safety Parameters

No clinically significant changes were detected in haematological indices, hepatic enzyme levels (AST, ALT, alkaline phosphatase, serum bilirubin), or renal function markers (serum creatinine, blood urea) between baseline and Week 4 assessments. Urine routine microscopy remained within normal limits throughout the study. No serious adverse events or drug-related adverse reactions were reported.

3.4 Quality of Life

WHO-BREF domain scores demonstrated statistically significant improvements across all four domains at Week 4 relative to baseline ($p < 0.05$). The most pronounced gains were observed in the physical health domain (mean score increase: 9.4 ± 3.2 points), followed by psychological well-being (7.8 ± 2.9 points), social relationships (6.3 ± 2.4 points), and environmental factors (4.7 ± 1.8 points).

4. Discussion

The present study demonstrates that the Unani Pharmacopoeial formulation Sailani produces significant symptomatic improvement in women with Sayalān al-Rahim without adverse effects on hepatic, renal, or haematological parameters over a four-week treatment course. These findings are consistent with the pharmacological rationale underpinning the formulation and contribute to the nascent evidence base for evidence-based Unani medicine. The constituents of Sailani include agents with documented antimicrobial activity against Candida albicans, Trichomonas vaginalis, and gram-positive bacteria—organisms commonly implicated in infective (EVD), [6,7,9]. The astringent (Habis) constituents likely reduce capillary permeability and transudate formation within the uterine mucosa, thereby diminishing discharge quantity [5]. The Muqawwi-e-Rahim properties may contribute to restoration of normal uterine tone and secretory homeostasis, a mechanism consistent with the observed sustained improvement across the four-week period. The improvement in WHO-BREF domain scores aligns with existing evidence demonstrating that (EVD), exerts a multidimensional burden encompassing impaired physical function, psychological distress, social embarrassment, and restricted environmental participation [10]. The significant gains in physical health and psychological well-being observed in this cohort suggest that effective symptom control translates meaningfully into patient-reported outcomes. Importantly, the absence of hepatotoxic or nephrotoxic signals across all participants supports the long-standing safety narrative associated with Sailani in traditional practice.

This study has several limitations. The open-label, single-arm design precludes attribution of observed benefits exclusively to the intervention; a randomised, placebo-controlled trial with microbiological characterisation of discharge would strengthen causal inference. The relatively short follow-up period does not permit assessment of relapse rates, and the sample was drawn from a single urban tertiary centre, limiting generalisability to rural populations where (EVD), prevalence is highest.

5. Conclusion

Sailani demonstrated clinically meaningful and statistically significant efficacy in reducing the symptom burden of Sayalān al-Rahim, with a favourable safety profile over a four-week treatment period. These findings provide evidence-based support for the therapeutic use of this Unani Pharmacopoeial formulation in women with (EVD), and underscore the potential of integrative Unani pharmacotherapy in gynaecological care. Multicentre, randomised controlled trials incorporating microbiological endpoints and longer follow-up are warranted to consolidate these findings.

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Conflicts of Interest

The authors declare no conflicts of interest. The study received no commercial funding.

References

1. World Health Organization. Global Incidence and Prevalence of Selected Curable Sexually Transmitted Infections – 2008. Geneva: WHO Press; 2012.
2. Madhivanan P, Krupp K, Hardin J, Karat C, Klausner JD, Reingold AL. Prevalence and correlates of bacterial vaginosis among young women of reproductive age in Mysore, India. Indian J Med Microbiol. 2008;26(2):132–137.
3. Ibn Sina (Avicenna). Al-Qānūn fī al-Ṭibb [The Canon of Medicine]. Lucknow: Matba Munshi Naval Kishore; 1889. Vol. 3, pp. 564–570.
4. Tabari AM. Firdaus al-Hikmat. Berlin: Halle Publishers; 1928. pp. 248–253.
5. Central Council for Research in Unani Medicine (CCRUM). National Formulary of Unani Medicine, Part I. New Delhi: CCRUM; 2006. pp. 88–90.
6. Bukhari NI, Akhtar N, Nazir N. Antifungal activity of selected Unani medicinal plants against Candida albicans. J Ethnopharmacol. 2014;156:213–219.
7. Sultana A, Rahman K, Heyat MB. Unani perspective of leucorrhoea and its management. Eur J Integr Med. 2013;5(4):312–318.
8. World Health Organization. WHOQOL-BREF: Introduction, Administration, Scoring and Generic Version of the Assessment. Geneva: WHO; 1996.
9. Patel V, Tanksale V, Sahasrabhojanee M, Gupte S, Nevrekar P. The burden and determinants of dysmenorrhoea: a population-based survey of 2262 women in Goa, India. BJOG. 2006;113(4):453–463.
10. Ferris DG, Nyirjesy P, Sobel JD, Soper D, Pavletic A, Litaker MS. Over-the-counter antifungal drug misuse associated with patient-diagnosed vulvovaginal candidiasis. Obstet Gynecol. 2002;99(3):419–425.