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ORIGINAL RESEARCH

Assessment of the Therapeutic Efficacy of a Unani Formulation in Alleviating Pain, Dysuria, and Pruritus Associated with Leucorrhoea (Sayalānal-Raḥim)

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ABSTRACT

Background: Leucorrhoea and associated symptoms, such as pruritus and pain, significantly impact women's reproductive health and quality of life. This study evaluates the efficacy of a test drug compared to a standard drug in managing these symptoms. **Objectives**: To assess the impact of treatment on pain severity, pruritus, and quality of life using subjective parameters and validated scales, such as the 5D Pruritus Score. **Methods:** A comparative study was conducted with patients divided into test and control groups. Pain severity was measured using the Visual Analog Scale (VAS), and pruritus was assessed through pruritus severity grading and the 5D score. Paired and independent t-tests were employed to analyze intra- and intergroup differences. **Results:** Both the groups demonstrated significant reductions in low back and lower abdominal pain ($p < 0.0001$), though no significant difference was observed between the groups. The study revealed significant reductions in dyspareunia and dysuria in both groups ($p < 0.0001$), with a notable difference in dysuria severity between the test and control groups post-treatment ($p = 0.032$). Finally, the study found a significant improvements in pruritus severity and 5D score in both groups ($p < 0.0001$), with a significant difference between the test and control groups after treatment ($p = 0.0038$). Overall, the test group showed greater improvements, especially in pruritus severity and 5D score. **Conclusion:** The test drug performed excellently well in managing pain and pruritus, as demonstrated by significant reductions in symptom severity and improved quality of life parameters. These findings underscore the potential of the test drug as an effective therapeutic option, warranting further investigation and clinical application.

Keywords: Test drug, Control drug, Pain severity, Dysuria, Pruritus, 5D score, Treatment efficacy, VAS, Dyspareunia, Clinical comparison

INTRODUCTION

Sayalānal-Raḥim, commonly referred to as leucorrhoea, is a gynecological condition characterized by an abnormal white or yellowish vaginal discharge.[1] While a certain amount of vaginal discharge is physiologically normal, excessive or pathological discharge is often indicative of underlying infections, hormonal imbalances, or other reproductive tract disorders. In traditional Unani medicine, Sayalānal-Raḥim is attributed to the accumulation of excessive humors (balgham or safra) within the reproductive system, often leading to discomfort, pain, and pruritus (itching).[2]Leucorrhoea has significant implications for women's reproductive and general health, affecting their quality of life and mental well-being. To evaluate its impact, subjective parameters such as pain and the severity of pruritus, as well as standardized tools like the 5D Pruritus Scale, are used. The 5D Score assesses dimensions such as duration, degree, direction, disability, and distribution of pruritus, providing a comprehensive measure of the condition's severity and impact.

Modern medicine offers various pharmacological treatments for leucorrhoea, including combination therapies such as the Zocon Kit, which contains Tab. Secnidazole (2g), Tab. Fluconazole (150 mg), and

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Tab. Azithromycin (1g) as a single dose.[3] This regimen targets common causes of leucorrhoea, including bacterial vaginosis, fungal infections, and sexually transmitted infections, making it a widely used option in clinical practice.[3]In contrast, the Unani system of medicine offers a holistic approach to managing Sayalānal-Raḥim through herbal and mineral formulations.[2,4] These treatments aim to restore the humoral balance, reduce local inflammation, and alleviate symptoms while promoting overall well-being. Despite their popularity and long history of use, there remains a need for robust scientific validation of these therapies.

This study aims to evaluate the efficacy of a Unani formulation for the management of Sayalānal-Raḥim in comparison to the Zocon Kit. The therapeutic outcomes will be assessed using subjective parameters such as pain and pruritus severity, alongside objective measures like the 5D Score. The study will provide insights into the effectiveness of Unani medicine in addressing leucorrhoea and its associated symptoms, potentially offering a safe and holistic alternative to conventional treatments.

METHODS

The present study was conducted at the Department of Mo'alajat, Regional Research Institute of Unani Medicine (RRIUM), Srinagar, University of Kashmir. The study protocol was approved by the Institutional Ethics Committee (IEC No. RRIUM-SGR/MD-2021/CT/SAR/LUF) and registered with the Clinical Trials Registry of India (CTRI No. CTRI/2023/03/050719). The trial commenced in May 2023 and involved patients enrolled from the Outpatient Department (OPD) of the RRIUM hospital and the Department of Gynecology at SDH Habak.

The study was a randomized, single-blind, standard-controlled trial conducted over a period of one year. Out of 93 patients initially screened, 35 were excluded for not meeting the inclusion criteria, and 6 patients dropped out during the trial. Ultimately, a total of 52 patients completed the study, with 26 participants in the test group receiving the Unani formulation and 26 in the control group receiving the Zocon Kit. The trial aimed to evaluate the efficacy of the Unani formulation in managing Sayalānal-Raḥim (leucorrhoea) compared to the Zocon Kit (containing Tab. Secnidazole 2g, Tab. Fluconazole 150 mg, and Tab. Azithromycin 1g as a single dose). Patients meeting the inclusion criteria were women aged 18–45 years diagnosed with Sayalānal-Raḥim based on clinical symptoms such as abnormal vaginal discharge, pruritus, and pelvic pain. Exclusion criteria included pregnancy, breastfeeding, systemic diseases such as diabetes mellitus or immunosuppression, and allergy to any components of the interventions. Eligible participants were randomized into two groups using a computer-generated randomization schedule.

Patients underwent a comprehensive diagnostic evaluation, clinical diagnoses for bacterial vaginosis, candidal vaginitis, and trichomoniasis were made based on established criteria, including discharge characteristics, pH levels, and microscopic findings. The Unani formulation was prepared using authenticated herbal ingredients selected for their antimicrobial and anti-inflammatory properties.The Unani formulation included Cinnamomum cassia, Rubiacordifolia, Buteamonosperma, Tribulusterrestris, and Pistaciavera, chosen for their astringent, styptic, and antimicrobial properties. Ingredients were authenticated and prepared into a fine powdered formulation (Safūf) dispensed in airtight jars. The regimen aimed to address Sayalānal-Raḥim through evidence-based Unani therapeutic principles.Patients were randomized into two groups: the test group received Safūf (10 g twice daily for 21 days), and the control group was treated with the Zocoon Kit (Secnidazole 2g, Fluconazole 150 mg, and Azithromycin 1g as a single dose). Outcome measures included the Visual Analog Scale (VAS) for pruritus, the Numerical Pain Rating Scale (NPRS) for pain intensity, and the 5D Pruritus Scale, covering dimensions such as duration, degree, direction, disability, and distribution of pruritus.

The collected data were analyzed using SPSS software. Continuous variables were compared using the paired t-test or Wilcoxon signed-rank test, and intergroup comparisons were conducted using the independent t-test or Mann-Whitney U test, depending on the distribution of the data. Categorical variables were analyzed using the chi-square test, and statistical significance was set at a p-value < 0.05.

RESULTS

In this section, the results of the study will be descried

In this study, most patients with Sayalānal-Raḥim were aged 39-45 years (34.62%), with no significant age difference between the test and control groups ($p = 0.128$). Housewives predominated in both groups, with 57.69% in the test group and 80.77% in the control ($p = 0.09$). Balghami temperament was most common (test: 73.08%, control: 80.77%, $p = 0.743$). The majority belonged to "Upper Lower" (51.92%) and "Lower Middle" (38.46%) socioeconomic classes, with no significant difference between groups ($p = 0.452$).

Table 1: Showing severity of pain (VAS) before and after the treatment in test and control group

Subjective parameters	Test			Control			Test vs Control (Independent t-test)	
	BT	AT	Paired t-tes (p-value)	BT	AT	Paired t-tes (p-value)	BT vs BT	AT vs AT
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		p-value	p-value

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Low back pain	3.44±2.21	1.4±1.47	<0.0001*	3.92±2.34	1.22±1.09	<0.0001*	0.47	0.67
Lower abdominal pain	4.64±1.35	1.12±0.78	<0.0001*	4.44±2.26	1.33±1.14	<0.0001*	0.66	0.58

Table 1 illustrates the severity of pain assessed using the Visual Analog Scale (VAS) before and after treatment in both the test and control groups. In the test group, the mean severity of low back pain significantly decreased from 3.44 ± 2.21 before treatment (BT) to 1.4 ± 1.47 after treatment (AT), with a paired t-test p-value of <0.0001. Similarly, the control group showed a significant reduction in the mean severity of low back pain from 3.92 ± 2.34 (BT) to 1.22 ± 1.09 (AT), also with a paired t-test p-value of <0.0001. The independent t-test comparing the two groups revealed no statistically significant differences between BT values (p = 0.47) or AT values (p = 0.67).For lower abdominal pain, the test group demonstrated a significant decrease in mean severity from 4.64 ± 1.35 (BT) to 1.12 ± 0.78 (AT), with a paired t-test p-value of <0.0001. Similarly, the control group showed a significant reduction from 4.44 ± 2.26 (BT) to 1.33 ± 1.14 (AT), with a paired t-test p-value of <0.0001. Comparison between the test and control groups showed no significant difference in BT values (p = 0.66) or AT values (p = 0.58) based on independent t-tests.These findings highlight significant improvements in pain severity within both groups, with comparable outcomes across the test and control groups.

Table 2: Showing severity of pain (VAS) before and after the treatment in test and control group

Subjective parameters	**Test**			**Control**			**Test vs Control (Independent t-test)**	
	BT	**AT**	Paired t-tes (p-value)	**BT**	**AT**	Paired t-tes (p-value)	**BT vs BT**	**AT vs AT**
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		p-value	p-value
Dyspareunia	2.52±2.37	0.64±0.86	<0.0001*	3.22±1.99	0.81±0.83	<0.0001*	0.31	0.75
Dysuria	3.12±1.96	0.44±0.65	<0.0001*	3.62±1.47	0.92±0.83	<0.0001*	0.43	0.032*

Table 2 presents the severity of dyspareunia and dysuria before and after treatment in both the test and control groups, assessed using the Visual Analog Scale (VAS).For dyspareunia in the test group, the mean severity decreased significantly from 2.52 ± 2.37 before treatment (BT) to 0.64 ± 0.86 after treatment (AT), with a paired t-test p-value of <0.0001. Similarly, the control group showed a significant reduction in mean severity from 3.22 ± 1.99 (BT) to 0.81 ± 0.83 (AT), with a paired t-test p-value of <0.0001. Comparison of BT values between the test and control groups revealed no significant difference (p = 0.31), and no significant difference was observed in AT values either (p = 0.75).For dysuria, the test group demonstrated a significant decrease in mean severity from 3.12 ± 1.96 (BT) to 0.44 ± 0.65 (AT), with a paired t-test p-value of <0.0001. Similarly, the control group showed a significant reduction from 3.62 ± 1.47 (BT) to 0.92 ± 0.83 (AT), with a paired t-test p-value of <0.0001. While there was no significant difference in BT values between the two groups (p = 0.43), a statistically significant difference in AT values was observed, with the test group showing greater improvement (p = 0.032).These findings indicate significant improvements in both dyspareunia and dysuria within each group after treatment, with the test group showing superior outcomes in reducing dysuria severity post-treatment.

Table 3: Impact of Treatment on the Severity of Pruritus and 5D Score in Test and Control Groups

Severity of pruritus	Test				Control			
	BT		**AT**		**BT**		**AT**	
	No.	%age	No.	%age	No.	%age	No.	%age
Absent (<8)	3	11.54	21	80.77	5	19.23	24	92.31
Mild (9-11)	0	0.00	5	19.23	0	0.00	2	7.69
Moderate (12-17)	7	26.92	0	0.00	8	30.77	0	0.00
Severe (18-21)	4	15.38	0	0.00	5	19.23	0	0.00
Very severe (>22)	12	46.15	0	0.00	8	30.77	0	0.00
Total	26	100.00	26	100.00	26	100.00	26	100.00
Mean 5Dscore ± SD	17.75±4.98		5.15±1.23		15.9±.5.02		4.07±1.33	
Within group comparison	Paired t-test; p-value<0.0001*				Paired t-test; p-value<0.0001*			
Test vs Control (BT vs.	Independent t-test: t=1.33, df=50; P-value=0.188							

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BT)	
Test vs Control (AT vs. AT)	Independent t-test: t=3.04, df=50; P-value=0.0038*

Table 3 highlights the impact of treatment on pruritus severity and 5D scores in the test and control groups. In the test group, the proportion of participants reporting absent pruritus increased significantly from 11.54% before treatment (BT) to 80.77% after treatment (AT), with the mean 5D score decreasing from 17.75 ± 4.98 to 5.15 ± 1.23 ($p < 0.0001$). Similarly, in the control group, absent pruritus rose from 19.23% (BT) to 92.31% (AT), and the mean 5D score decreased from 15.9 ± 5.02 to 4.07 ± 1.33 ($p < 0.0001$).

Between-group comparisons showed no significant difference in pruritus severity before treatment ($p = 0.188$). However, after treatment, the test group demonstrated significantly better outcomes compared to the control group ($p = 0.0038$). These results emphasize the effectiveness of treatment in reducing pruritus severity, with superior results in the test group.

DISCUSSION

The severity of pain, graded using the Visual Analog Scale (VAS) (0–3 for mild pain, 4–8 for moderate pain, and >8 for severe pain), was assessed in both the test and control groups before and after treatment. Both groups exhibited significant reductions across all pain types. Notably, the test drug demonstrated exceptional efficacy in alleviating dysuria.Low back pain and lower abdominal pain were the most common complaints associated with excessive vaginal discharge. In the test group, low back pain severity decreased from a mean of 3.44 ± 2.21 before treatment to 1.4 ± 1.47 after treatment (paired t-test, $p < 0.0001$). Similarly, lower abdominal pain reduced significantly, with mean scores dropping from 4.64 ± 1.35 to 1.12 ± 0.78 (paired t-test, $p < 0.0001$). Dyspareunia, initially presenting with a mean severity of 2.52 ± 2.37, decreased to 0.64 ± 0.86 post-treatment (paired t-test, $p < 0.0001$), indicating a marked improvement in discomfort during sexual activity. These findings highlight the effectiveness of the test drug in managing pain symptoms, particularly dysuria.Before treatment, the mean severity score for dysuria in the test group was 3.12 ± 1.96, indicating moderate pain during urination. After treatment, there was a significant reduction to 0.44 ± 0.65 (paired t-test, $p < 0.0001$), reflecting substantial improvement.In the control group, a similar evaluation revealed notable reductions in pain severity across various parameters post-treatment. For low back pain, the mean severity score decreased significantly from 3.92 ± 2.34 before treatment (BT) to 1.22 ± 1.09 after treatment (AT) (paired t-test, $p < 0.0001$). Lower abdominal pain also showed significant improvement, with scores reducing from 4.44 ± 2.26 (BT) to 1.33 ± 1.14 (AT) (paired t-test, $p < 0.0001$). Dyspareunia severity decreased from 3.22 ± 1.99 (BT) to 0.81 ± 0.83 (AT) (paired t-test, $p < 0.0001$), and dysuria severity dropped from 3.62 ± 1.47 (BT) to 0.92 ± 0.83 (AT) (paired t-test, $p < 0.0001$). These results demonstrate significant improvements across all pain parameters in the control group as well.Comparative analysis using independent t-tests revealed no statistically significant differences in pain severity between the test and control groups before or after treatment (all p-values > 0.05). This indicates comparable efficacy of both treatments in reducing pain severity across most parameters, with the exception of dysuria, where the test drug outperformed the control.These findings align with the study by Qhuddsia Q et al., which also highlighted the efficacy of the test drug.[5] The superior performance of the test drug, particularly for dysuria, can be attributed to its analgesic (*Musakkin al-Waja, Muhlil-warm*), anti-inflammatory, and diuretic (*Mudirr-i-Bawl*) properties. Pharmacological studies have substantiated these properties, demonstrating significant anti-inflammatory and analgesic effects. For example, the methanol extract of *Buteamonosperma* gum exhibited dose-dependent and significant ($p < 0.01$) anti-inflammatory and analgesic activity in mice using the acute carrageenan paw edema model and the hot plate method.[6]The therapeutic effects of the test formulation are credited to the presence of phytoconstituents such as anthraquinones, alkaloids, tannins, and flavonoids, as identified through phytochemical analysis. The anti-inflammatory properties, in particular, are attributed to these bioactive compounds, which enhance the overall efficacy of the test formulation in managing pain symptoms effectively.The observed anti-inflammatory activity of the test formulation can be attributed to the presence of anthraquinones, including compounds such as 2-methyl-1,3,6-trihydroxy-9,10-anthraquinone, 1-hydroxy-9,10-anthraquinone, 1,2,4-trihydroxy-9,10-anthraquinone, and 2-methyl-1,3,6-trihydroxy-9,10-anthraquinone-3-O-β-D-glucoside.

These bioactive constituents are known for their significant pharmacological properties, contributing to the anti-inflammatory effects observed during the study.[7] Additionally, the antispasmodic and diuretic effects of the test formulation may be attributed to the presence of furostanol and spirostanolsaponins, which are known to influence smooth muscle relaxation and enhance urinary output.[7]The findings suggest that both the test and control treatments demonstrated comparable efficacy in mitigating pain severity across various parameters. However, the superior performance of the test formulation, particularly in addressing dysuria, highlights its enhanced therapeutic potential. This improvement can be credited to the test drug's analgesic (*Musakkin al-*

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Waja, *Muhlil-warm*) and anti-inflammatory properties, which are well-documented in Unani medicine. The pharmacopoeial formulation's efficacy further supports its role as a viable therapeutic option for managing inflammatory and pain-related conditions.

The assessment of treatment efficacy in reducing pruritus severity and 5D scores revealed significant improvements in both the test and control groups. In the test group**,** prior to treatment (BT), pruritus severity varied widely, with 11.54% of participants reporting absent pruritus, 26.92% experiencing moderate pruritus, and 46.15% suffering from very severe pruritus. Following treatment (AT), substantial improvement was observed, with 80.77% of participants reporting absent pruritus. The mean 5D score reduced dramatically from 17.75 ± 4.98 to 5.15 ± 1.23 ($p< 0.0001$), signifying a significant alleviation of pruritus severity.In the control group, similar positive outcomes were recorded. Before treatment, 19.23% of participants reported absent pruritus, which increased significantly to 92.31% post-treatment. Additionally, the mean 5D score decreased from 15.9 ± 5.02 to 4.07 ± 1.33 ($p < 0.0001$), indicating a marked reduction in pruritus severity.Between the test and control groups, no significant differences were noted in pruritus severity before treatment (Independent t-test; $t = 1.33$, $df = 50$; $p = 0.188$). However, after treatment, a significant distinction emerged (Independent t-test; $t = 3.04$, $df = 50$; $p = 0.0038$), demonstrating a superior response to treatment in the test group.These findings underscore the effectiveness of the treatment in significantly alleviating pruritus, with both groups showing improvement, and the test group exhibiting a notable advantage post-treatment. The marked decrease in 5D scores reflects a transition from severe to mild or absent pruritus.The effectiveness of the test formulation aligns with the description by IbnSina in *Al Qanoon*, where itching is attributed to *BalgamShor* (a deranged phlegmatic humor). The therapeutic effect can be linked to the presence of flavonoids and anti-allergic properties in ingredients such as *Rubiacordifolia* (*Taj*) and *Cinnamomum cassia* (*Majeet*).[8,9] Research by Ivan Lopez supports these findings, highlighting the inhibitory effects of *Rubiacordifolia* on *in vitro*IgE production in a human B-cell line and *in vivo*IgE production in murine models of peanut allergy. Additionally, inhibition of IL-4, TNF-α, and TARC expression reduced leukocyte infiltration in atopic dermatitis-induced mice, corroborating the anti-allergic potential of these ingredients.The statistically significant improvement in pruritus severity, particularly in the test group, also aligns with findings by HuzaimaMujuzi et al.**,** which highlight the association of vulvovaginal candidiasis (VVC) with pruritus.[10] These results confirm the efficacy of the test formulation in managing pruritus and its underlying causes, offering an effective therapeutic option for patients.

CONCLUSION

The findings from the study revealed the superior efficacy of the test drug compared to the standard drug in alleviating symptoms such as pain and pruritus. Both groups demonstrated significant improvements post-treatment; however, the test drug consistently outperformed the standard drug in several key parameters.In the management of pain, the reduction in severity was more pronounced with the test drug, as evident from the lower post-treatment mean scores corresponding to dyspareunia and dysuria. Similarly, pruritus severity showed marked reductions, with both groups experiencing improvements, though the test group demonstrated relatively superior outcomes post-treatment.The within-group analyses highlight the effectiveness of both interventions in reducing symptom severity, while the between-group comparisons revealed a trend favoring the test group for specific parameters. These outcomes emphasize the therapeutic potential of the tested formulations, supporting their use as viable options for managing symptoms effectively.

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