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TOPICAL 'ARQ 'AJĪB FOR PRIMARY DYSMENORRHOEA: RETROSPECTIVE ANALYSIS OF OUTPATIENT CASE RECORDS

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ABSTRACT: Objective: Primary dysmenorrhoea (PD) is a prevalent disease, which is marked by menstrual pain without pathology in the pelvis. 'Arq 'Ajīb is a classical Unani formulation traditionally used for pain relief. This retrospective study aims to evaluate the immediate change in menstrual pain following the topical application of 'Arq 'Ajīb in women with PD, based on an analysis of previously recorded clinical data. **Methods:** This retrospective analysis of outpatient records at RRIUM, New Delhi (June–August 2025) identified 33 women with PD and baseline pain scores of 6–9 on the Visual Analogue Scale (VAS) who received a single lower-abdominal topical 'Arq 'Ajīb treatment on Day 1 of menstruation. Eighteen (18) records were in the inclusion criteria. The intensity of pain was assessed using a 0–10 VAS prior to and following the intervention. Pre-post differences were analyzed by the Wilcoxon signed-rank test, whereas Pearson and Spearman coefficients were employed to study correlations. **Results:** The average VAS score was reduced to 3.06 ± 0.87 (median 3.0) out of the 7.58 ± 0.94 (median 7.5) demonstrating a reduction of 4.52 points on average (59.7%; $p < 0.001$). All participants reported improvements. **Conclusion:** In this small retrospective observational analysis of outpatient case records, a single lower-abdominal topical session of 'Arq 'Ajīb was associated with rapid reductions in PD pain on Day 1 of menstruation. These preliminary findings are exploratory and support further evaluation of topical 'Arq 'Ajīb in larger, prospective, well-designed, controlled studies.

INTRODUCTION: Dysmenorrhoea is characterized as painful uterine menstrual cramps and is one of the most frequent complaints of reproductive aged women to the gynecologic practice ¹. Estimating prevalence is 16% to 91% ^{2, 3} of which 29% of women have severe pain which impairs daily functioning ².

Dysmenorrhoea degrades the quality of life due to physical and emotional pain. It presents moderate to severe abdominal pain that may spread to the thighs or to the lower spine which is accompanied by fatigue, dizziness, bloating, nausea and occasionally diarrhoea. These symptoms drain the energy, raise stress and affect interpersonal relations and productivity negatively ^{4, 5}.

According to university students, reduced academic performance and social activity are common symptoms of the condition, which has both an educational and psychosocial effect on the students ^{5, 6}. Primary dysmenorrhoea (PD) pathophysiology

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is strongly linked to elevated levels of endometrial prostaglandins, specifically PGF₂ α and PGE₂. These intermediates heighten the uterine contractility and induce vasoconstriction, thus decreasing uterine blood flow and inducing ischemic pain, which is a typical symptom of the condition^{7, 8}. The main action of the current medications aims at the inhibition of the prostaglandin and comprises non-steroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, with the supportive measures that involve heat and exercise as the possible modalities of action^{1, 5, 6}.

Dysmenorrhoea in classical Unani is referred to by different names such as *Dard-e-Rehm* (uterine pain), *Awjā'-i-Rahim* (pains of the uterus), *Qa'idgibā Dard al-Shadīd* (menstruation accompanied by severe pain), and *'Usr al-Tamth* (difficult/painful menstruation). In the *Al-Qānūnfi al-Ṭibb*, *Ibn Sīnā* (Avicenna) explains painful menstruation as the obstruction of menstrual flow, which may be due to the *Sū'-i-Mizāj* (altered temperament). The pain is usually localized in the pelvis and extends to the back and inner thighs, and sometimes it imitates the pain of intestinal colic^{9, 10, 11}. *'Alī ibn 'Abbās Majūsī* (*Haly Abbas*) in *Kāmil al-Ṣanā'a al-Ṭibbiyya* and *Ibn Hubal Baghdādī* in *Kitāb al-Mukhtārātfī 'l-Ṭibb* cited painful menstruation in associated with *Ihtibās al-Ṭamth* (*Amenorrhoea*) and of the view that women with sparse menstrual flow often have painful menstrual periods^{12, 13, 14}.

These classical insights form the basis of current Unani principles for managing painful menstruation, which emphasize restoring balance, eliminating obstruction, and relieving pain. Drugs with *Mudirr-i-Hayd* (emmenagogue), *Muḥallil-i-Awrām* (anti-inflammatory), and *Musakkin* (analgesic) properties are used. *Mudirr-i-Hayd* (emmenagogue) drugs with hot temperament and vasodilator properties, are believed to fluidize the blood and enhance uterine flow, thereby improving circulation and addressing underlying functional disturbances. In addition, *Musakkin* and *Muḥallil* activities contribute to the relief of uterine spasms and inflammation, which have symptomatic and functional advantages^{12, 13, 14}. *Rāzī* (Rhazes) explained several reasons of uterine pain and focused on the treatment using local applications

and massage with medicated oils. Mint (*Mentha spicata* L.) and saffron (*Crocus sativus* L.) are used as analgesics, emmenagogues, and neuro-calming agents in Unani practice⁹.

Complementary and alternative medicine (CAM) has become a widely used practice all over the world and most women have preferred to use the CAM methods in treating menstrual pains. They are acupuncture, massage, transcutaneous electrical nerve stimulation (TENS), behavioural interventions, and herbal therapies^{15, 16}. The use of essential oils in medical systems can be traced back centuries, and its main purpose was analgesia. *'Arq 'Ajīb* is a classical Unani pharmacopoeial formulation containing *Kāfūr* (*Cinnamomum camphora* (L.) J. Presl), *Satt-i-Pudīna* (plant extract of *Mentha arvensis* L.), and *Satt-i-Ajwā'in* (seed extract of *Trachyspermum ammi* (L.) Sprague) in a 2:2:1 ratio. This formulation is effective as an analgesic, digestive, and antispasmodic medicine, used for respiratory health (coryza, catarrh) and digestive issues (gastralgia, GERD, colitis, nausea, flatulence, cholera). Its topical application is known to relieve headache, migraines, joint pain, and otalgia^{17, 18}. While the efficacy of topical *'Arq 'Ajīb* for headaches is established¹⁹, its antispasmodic and analgesic effects in PD remain undocumented. This study explores data from the topical application of *'Arq 'Ajīb* in dysmenorrhoea routine care to guide future clinical trials.

MATERIALS AND METHODS:

Study Design and Setting: This was a retrospective observational study of outpatient case records undertaken at the Regional Research Institute of Unani Medicine (RRIUM), New Delhi, India. The analysis covered routine outpatient (OPD) visits for PD between June 2025 and August 2025, during which women received a single lower-abdominal topical session of *'Arq 'Ajīb* as part of usual Unani care on Day 1 of menstruation.

Participants: The analysis focused on unmarried female patients aged 12–25 years with PD and regular menstrual cycles (21–35 days) who attended the RRIUM OPD from June 2025 to August 2025. Case records were included if they documented PD with baseline pain scores of 6–9 cm on a 10 cm Visual Analogue Scale (VAS) on the first day of menstruation (D1) and recorded

pain scores immediately before and after the topical application of 'Arq 'Ajīb. In eligible records, only topical 'Arq 'Ajīb was documented, with no concomitant use of analgesics or other medications.

Ethical Permission: The research adhered to the Declaration of Helsinki (2013 revision) and ICMR National Ethical Guidelines. Management with topical 'Arq 'Ajīb, a widely used Unani Pharmacopoeial formulation, was provided as part of standard OPD care. Only de-identified information from existing records was used; no additional interventions or patient contacts occurred for research purposes. As a minimal-risk observational study involving fully anonymized routine data, an exemption from the institutional ethical committee review was sought and obtained.

Outcome Measure: In this retrospective study, pain intensity on D1 was routinely assessed using a 10 cm VAS (0 = "no pain", 10 = "worst imaginable pain"). Analysis retained only records with baseline VAS scores of 6–9 cm immediately before topical application and a corresponding post-application score during the same visit. The primary outcome was the change in pain intensity (Δ VAS), defined as the difference between post-application and pre-application scores. A secondary objective was to explore the association between patient age and the magnitude of pain reduction.

Statistical Analysis: Continuous variables are summarized as mean \pm standard deviation (SD) and median (range), as appropriate. The Shapiro–Wilk test assessed the normality of paired differences in VAS scores. As the data were non-normally distributed, pre and post comparisons were done using the Wilcoxon signed-rank test²⁰. The effect size for the Wilcoxon signed-rank test was calculated as $r = Z/\sqrt{N}$ (where N is the number of paired observations); r values of ~0.1, 0.3, and 0.5 were considered small, moderate, and large effects, respectively. The correlation between age and pain reduction (Δ VAS) was evaluated by means of the

Spearman rank correlation coefficient. All statistical analyses were two-sided and $p < 0.05$ was regarded as statistically significant. The analyses were done with Python (version 3.9) and R (version 4.2).

RESULTS:

Record Flow, Baseline Characteristics, and Pain Scores: Thirty-three (33) outpatient PD case records were identified during the study period. Ten (10) were left out because of the age or marital status inconsistency, and five (5) were left out because their VAS data was not complete. The final analysis included eighteen (18) records. Although the sample size was small, limiting the study, all 18 women (mean age 18.6 ± 3.4 years; range 12.5–25) presented with severe menstrual cramps on Day 1. The baseline VAS score was 7.58 ± 0.94 (median 7.5; range 6–9), indicating a high pain burden. Following the application of 'Arq 'Ajīb, mean VAS scores decreased to 3.06 ± 0.87 , shifting from severe to mild-moderate levels (Fig. 1).

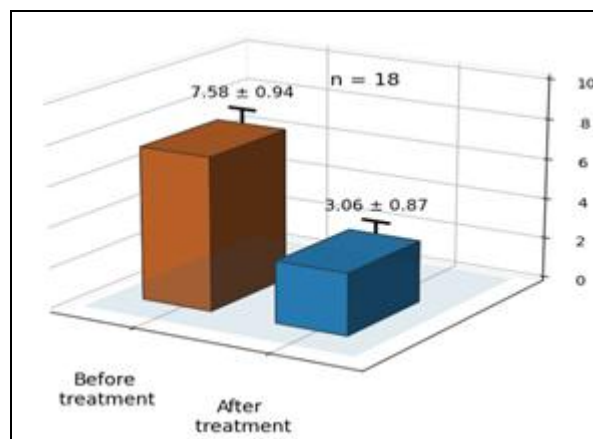


FIG. 1: MEAN VAS PAIN SCORES (0–10) ON DAY 1 OF MENSTRUATION BEFORE AND AFTER TOPICAL APPLICATION OF 'ARQ 'AJĪB

The mean absolute reduction in pain was 4.52 VAS points, a 59.7% decrease from baseline, indicating a large analgesic effect. Descriptive statistics are summarized in (Table 1).

TABLE 1: PAIN VAS SCORES (0–10) ON DAY 1 OF MENSTRUATION, BEFORE AND AFTER 'ARQ 'AJĪB TREATMENT

VAS pain (0–10)	N	Mean \pm SD	Median	Range
Before treatment (Day 1)	18	7.58 ± 0.94	7.5	6–9
After treatment (Day 1)	18	3.06 ± 0.87	3.0	2–5

Note: Values represent immediate post-application scores on the same day.

Statistical tests: The Shapiro-Wilk test indicated non-normal distribution of paired differences. VAS scores decreased significantly after application (Wilcoxon signed-rank test, $W = 0$, $p \approx 7.6 \times 10^{-6}$, effect size $r = 0.88$), with the median VAS decreasing from 7.5 to 3.0. The median change in VAS (Δ VAS) was 4.5 points.

Exploratory Correlation Analyses: We examined whether the age of the patient affected the analgesic response. The relationships between age and absolute pain reduction (pre–post Δ VAS) were non-significant (Pearson's $r \approx 0.14$, $p = 0.59$; Spearman's $\rho \approx 0.24$, $p = 0.33$). This shows that the younger and older women in this age bracket had an equal advantage. The baseline VAS and absolute pain reduction had a borderline positive correlation (Pearson's $r \approx 0.47$, $p \approx 0.051$) indicating that women who experienced higher levels of pain on the initial level could obtain greater drops in VAS though this did not reach statistical significance.

Treatment Completion and Adverse Effects: All 18 patients completed the session with documented pre- and post-treatment scores. No adverse reactions, such as skin irritation, erythema, or systemic complaints, were recorded. Within the limitations of retrospective documentation, topical '*Arq 'Ajīb* appeared well-tolerated and safe.

DISCUSSION: The analysis indicates that topical '*Arq 'Ajīb* produced substantial analgesic effects in PD, with a statistically significant 4.52-point mean reduction on a 0–10 VAS ($p < 0.001$). Our baseline scores were comparable to those reported in endometriosis studies (7.6)²¹. The 59.7% reduction exceeded minimal clinically important differences for analgesia. Although the study lacked a placebo arm, the magnitude of relief across all 18 participants suggests potential analgesic activity beyond chance.

This aligns with the Unani tradition that '*Arq 'Ajīb* relieves menstrual obstruction and spasms. Several active constituents may contribute to these effects. To our knowledge, few studies have utilized routine outpatient records to quantitatively examine the immediate analgesic effects of topical '*Arq 'Ajīb* for primary dysmenorrhoea. While '*Arq 'Ajīb* is established in Unani practice for headaches and musculoskeletal pain, structured clinical

documentation regarding its efficacy in dysmenorrhoea remains sparse, contributing to the novelty of this work. This analysis attempts to bridge this gap by providing preliminary clinical data. By revisiting OPD files and comparing pain scores shortly after a single session, we captured real-world outcomes on the first day of menstruation. The consistently large reductions in pain suggest that this simple, non-oral, clinic-based application may offer potential same-day relief and warrants confirmation in prospective trials.

Pharmacological Mechanisms: While this study did not investigate molecular pathways, an effort has been made to understand the possible mechanism of action. The observed analgesic efficacy may theoretically stem from the synergistic actions of thymol, menthol, and camphor. These phytochemicals align with classical descriptions as *musakkin* (analgesic), *muħallil-i-waram* (anti-inflammatory), and *dāfi 'i-tashannuj* (antispasmodic). The literature suggests that *Satt-i-Ajwā'in* (thymol) inhibits pro-inflammatory pathways and cytokines^{22, 23} while clinical studies report antispasmodic effects in dysmenorrhoea²⁴.

Orally *Ajwā'in* capsules were found effective in reducing menstrual cramps in Fatmea Zali *et al.*'s study. Thymol, an active ingredient in *ajwā'in*, has antioxidant and anti-inflammatory properties, and reduces C-reactive protein (CRP). This plant also contains isomerism of thymol, carvacrol, which is known to reduce activation of the cyclooxygenase enzyme, the catalyst responsible for the productions of prostaglandins in smooth muscles²⁴⁻²⁵.

Satt-i-Pudīna (menthol) acts as a topical analgesic by activating TRPM8 channels, causing cooling and nociceptor desensitization^{26, 27} with proven efficacy in PD trials²⁸⁻³⁰. Mint, particularly peppermint has shown potential in reducing menstrual pain when used in the form of lotions, pastes locally as well as oral capsules. A crossover study showed the effectiveness of peppermint extract (in the form of oral capsules) in reducing pain severity and improving the associated symptoms of uterine cramps. *Mentha piperita* leaves extracts inhibit uterine smooth muscle contractions by reducing the effects of

prostaglandins (PGF₂α) and oxytocin, both of which play a key role in uterine spasms²⁸⁻³⁰.

Similarly, *Kāfūr* (camphor) functions as a rubefacient and local anaesthetic³¹ potentially inhibiting TRPA1 channels to dampen nociceptive signaling³². Eutectic combinations of these monoterpenoids may further enhance topical delivery and therapeutic potency³³.

Integrative Role of 'Arq 'Ajīb in 'Usr al-Tamth Management: Using a bedside Unani approach with *Ṭilā'* (liniment), we observed a decrease in Day-1 menstrual pain, suggesting potential short-term relief in PD. This aligns with current care patterns, where women often use complementary measures like heat and herbal oils³⁴.

Given the small sample size and limited scope, rigorous randomised, blinded trials with placebo controls are needed to monitor menstrual flow and systemic symptoms simultaneously.

Classical Unani Resonance with Contemporary Findings: The implemented Unani management principles including dietary lightness, local warmth, and aromatics align with classical guidance and modern mechanistic data³⁵.

The traditional rationale for topical oils improving comfort and circulation matches findings from clinical reviews. Our results suggest a convergence between Unani wisdom and current practice, justifying the advancement of *'Arq 'Ajīb* into confirmatory trials. Other aromatic oils, such as *Nigella sativa*³⁶ and rose essential oil³⁷ have also shown therapeutic promise in PD.

Study Limitations: This retrospective review has inherent limitations. First, the absence of a control group precludes distinguishing pharmacological effects from the placebo response, which is notably high in pain studies. Second, the open-label nature introduces potential observer bias and patient expectancy effects. Third, reliance on routine clinical records makes the study susceptible to documentation bias; inconsistencies in recording led to the exclusion of incomplete files, potentially introducing selection bias. Finally, the small sample size from a single centre limits generalizability, and the lack of long-term follow-up prevents assessment of sustained efficacy.

Future Directions: Future research should involve randomized controlled trials with varied patient groups, dose-finding studies, and broader outcomes, including menstrual characteristics and quality of life. Only then can safety and efficacy be properly evaluated. Based on these promising exploratory results, the authors have prepared a prospective placebo-controlled trial with a larger sample size to evaluate the potential of *'Arq 'Ajīb* for menstrual pain relief.

CONCLUSION: The results of this retrospective analysis indicate an association between the topical application of *'Arq 'Ajīb* and a reduction in pain scores on the first day of menstruation. While these observations are consistent with traditional Unani indications and the pharmacological properties of the formulation's constituents, definitive conclusions regarding efficacy cannot be drawn from this uncontrolled data. These findings serve as preliminary evidence to justify further investigation. Rigorous, prospective, randomized controlled trials are essential to validate these observations, account for placebo effects, and determine the true therapeutic value of *'Arq 'Ajīb* in the management of primary dysmenorrhoea.

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