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Correlation of Mizaj (Temperament) with Clinical Outcomes in the Treatment of Kasrat-e-Tams (Heavy Menstrual Bleeding) Using Unani Pharmacopeial Formulation QursHabis

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ABSTRACT

Background: *Heavy menstrual bleeding (Kasrat-e-Tams) affects 4-51.6% of women globally, significantly impacting quality of life. The Unani concept of Mizaj (temperament) offers a personalized approach to treatment, yet its correlation with clinical outcomes remains underexplored.*

Objective: *To investigate the correlation between Mizaj assessment and clinical outcomes in patients with Kasrat-e-Tams treated with the Unani formulation QursHabis.*

Methods: *A secondary analysis was conducted on data from a multi-centric, open-label clinical trial involving 168 women aged 18-45 years with menorrhagia. Participants were classified into four temperamental categories: Damvi (Sanguineous), Balghami (Phlegmatic), Safravi (Bilious), and Saudavi (Melancholic). QursHabis(250mg) was administered twice daily for 9 days per menstrual cycle over three consecutive cycles. Outcomes measured included menstrual blood loss reduction, pain scores, and overall treatment response.*

Results: *The majority of patients had Balghami temperament (60.7%), followed by Damvi (25.0%), Safravi (13.1%), and Saudavi (1.2%). Overall treatment success rate was 75.0%. Damvi temperament patients demonstrated the highest response rate (48.7±22.3%) and success rate (81.0%), with 60.0% reduction in menstrual blood loss and 69.1% reduction in pain scores. The correlation between Mizaj and treatment response was statistically significant (χ^2=6.847, p<0.05). Additionally, 73.8% of patients showed improvement in temperament balance post-treatment.*

Conclusion: *Mizaj assessment serves as a significant predictor of treatment outcomes in managing Kasrat-e-Tams with QursHabis. Patients with Damvi temperament showed superior therapeutic responses, supporting the implementation of temperament-based personalized treatment protocols in Unani medicine.*

Keywords: *Mizaj, Kasrat-e-Tams, Saudavi, Damvi.*

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Introduction

Heavy menstrual bleeding (HMB), known as *Kasrat-e-Tams* in Unani medicine, represents a significant gynaecological concern affecting 4-51.6% of women globally, with substantial impact on their physical, social, emotional, and material quality of life [1]. The variation in prevalence reflects both the multicultural nature of study populations and the subjective nature of the condition, with objective studies demonstrating prevalence rates between 11-26%. This condition not only affects individual well-being but also constitutes a major reason for specialist referrals in primary healthcare settings.The Unani system of medicine offers a unique perspective on HMB through its foundational concept of *Mizaj* (temperament), which represents the individualized constitutional makeup of each patient. According to classical Unani literature, the etiopathology of *Kasrat-e-Tams* is intricately linked to temperamental imbalances and can be categorized into several mechanisms including *Imtela-e-Dam* (blood congestion), *RiqqatwaHiddateKhoon* (excess heat and fluidity of blood), and dominance of various humors (*Akhlat*) such as *GhalbaeSafra* (bile dominance), *Ghalba e Balgham* (phlegm dominance), and *Ghalba e Sauda* (black bile dominance) [2,3,4].

The four primary temperaments recognized in Unani medicine - *Damawi* (Sanguine), *Balghami* (Phlegmatic), *Safrawi* (Bilious), and *Saudawi* (Melancholic) - are characterized by distinct physical, physiological, and psychological attributes that influence disease susceptibility and treatment responses [5]. Each temperament exhibits specific manifestations in menstrual disorders, with sanguine temperament typically associated with increased blood volume, phlegmatic with weakened uterine vessels due to blood fluidity, bilious with fragile uterine vessels from altered blood temperament, and melancholic with cholinergic changes affecting menstrual flow patterns [6,7].

QursHabis, a classical Unani pharmacopeial formulation, has been traditionally employed for managing HMB based on its astringent (*Qabiz*) and hemostatic properties. The formulation contains ten ingredients including *Sang-e-jarahat*, *Geru-surkh*, *Lakh dana*, and others, working through principles of *Habs-i-Dam* (checking bleeding), *Taghleez-i Dam* (thickening blood), and *Tajfeef* (desiccation) [1]. However, the correlation between individual temperamental variations and clinical outcomes

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following *QursHabis* treatment remains underexplored in contemporary research.Understanding the relationship between *Mizaj* and treatment efficacy is crucial for implementing personalized therapeutic approaches in Unani medicine. Classical texts suggest that treatment outcomes vary significantly based on individual temperamental predispositions, yet systematic evaluation of this correlation in HMB management is limited. The current study protocol acknowledges this gap by incorporating temperament assessment as a baseline parameter, though the analysis of its correlation with clinical outcomes requires dedicated investigation.Modern healthcare increasingly recognizes the importance of personalized medicine, making the ancient Unani concept of temperament-based treatment particularly relevant. While conventional HMB treatments including NSAIDs, oral contraceptives, and surgical interventions carry significant side effects and morbidity risks, Unani formulations like *QursHabis* offer potentially safer alternatives with individualized therapeutic approaches [8,9].This research aims to establish evidence-based correlations between *Mizaj* assessment and clinical outcomes in *Kasrat-e-Tams* patients treated with *QursHabis*, potentially revolutionizing personalized gynaecological care within the Unani medical framework while contributing to the broader understanding of constitutional medicine in therapeutic interventions.

Methodology

Study Design

This study employed a secondary analysis of data from a multi-centric, open-label, uncontrolled clinical trial that investigated the safety and efficacy of QursHabisin the treatment of Kasrat-e-Tams (Heavy Menstrual Bleeding), as conducted by CCRUM in 2017. The correlation between Mizaj (temperament) and clinical outcomes was analyzed as a secondary objective to explore the personalized medicine approach inherent in the Unani system of medicine.

Study Population and Setting

The study included non-gravid, non-menopausal females aged 19-45 years with menorrhagia characterized by excessive menstrual loss greater than 80ml per cycle as calculated by menstrual pictogram and menstrual cycle duration greater than 6 days. Participants were excluded if they presented with heavy menstrual bleeding with structural or histological abnormalities, intermenstrual or post-coital bleeding, pelvic pain, and/or pressure symptoms, personal or family history of coagulation disorders, use of intrauterine contraceptive devices, concurrent chronic illnesses requiring long-term treatment, post-menopausal bleeding or hormone replacement therapy, or pregnancy or lactation.

The study was conducted at three centers: the Central Research Institute of Unani Medicine (CRIUM) in Hyderabad, the Regional Research Institute of Unani Medicine (RRIUM) in Chennai, and the Regional Research Institute of Unani Medicine (RRIUM) in Mumbai. A sample size of 240 completed cases, with 80 participants at each center, was calculated as the minimum necessary to determine statistically significant treatment effects. The treatment duration was 12 weeks, consisting of 9 days each month starting from day 1 of the menstrual cycle for three consecutive cycles.

Intervention Protocol

QursHabis, a Unani pharmacopeial formulation, was administered orally at a dose of 1 tablet (250mg) twice daily with water, taken 12 hours apart after meals for 9 days each menstrual cycle over three consecutive cycles. The drug contains the following ingredients as per the National Formulary of Unani Medicine: Sang-e-jarahat (479g), Geru-surkh (571g), Lakh dana (183g), Ralsufaid (183g), Phitkarisufaid (192g), Gond keekar (192g), DamulAkhwain (500g), Kushta-e-busud (1kg), Shamaeen (50ml), and Magnesia fahmi (50g).

Assessment of Mizaj (Temperament)

Mizaj assessment was conducted at baseline using a standardized Unani temperament assessment tool, with participants classified into four primary temperamental categories: Damawi (Sanguine), Balghami (Phlegmatic), Safrawi (Bilious), and Saudawi (Melancholic). The temperament evaluation was based on ten standardized parameters including complexion ranging from ruddy (sanguine) to blackish (melancholic), built from muscular and broad (sanguine) to skeletal (melancholic), variations in touch temperature and moisture, hair characteristics such as color, thickness, and growth pattern, movement patterns with activity levels from hyperactive to less active, dietary preferences for most liked foods based on hot-cold and dry-moist qualities, weather suitability and seasonal preferences, sleep patterns including duration and quality, pulse characteristics with rate and volume variations, and emotional disposition from normal to nervous tendencies. The dominant temperament was determined by the maximum number of positive responses in a particular temperamental category.

Outcome Measurements

Clinical assessment was conducted using menstrual blood loss quantification measured in milliliters using a validated menstrual pictogram, which is a modification of the Pictorial Blood Loss Assessment Chart (PBAC) technique, and pain assessment for associated dysmenorrhea evaluated using the Visual Analog Scale (VAS). Secondary parameters included intermenstrual bleeding episodes and general improvement in quality of life indicators. Clinical evaluations were performed at baseline, first follow-up at 4 weeks, second follow-up at 8 weeks, and third follow-up at 12 weeks or end of treatment.

Safety Monitoring

Adverse events were monitored throughout the study period, with specific attention to nausea, vomiting, abdominal discomfort, anorexia, heartburn, skin reactions such as rash or pruritus, malaise, and dizziness. Safety assessments included hematological parameters such as complete blood count (Hb%, TLC, DLC, ESR), hepatic function tests including serum bilirubin, SGOT, SGPT, and alkaline phosphatase, renal function tests including serum creatinine, urea, and uric acid, and coagulation studies including bleeding time, clotting time, and prothrombin time.

Data Collection and Management

Standardized case record forms (CRFs) were used to document demographic information, medical history and clinical examination findings, Mizaj assessment results, treatment compliance and adverse events, laboratory investigation results, and follow-up assessments.

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Treatment compliance was assessed at each follow-up visit by counting returned medication, patient self-reporting of missed doses, and documentation of reasons for non-compliance.

Statistical Analysis Plan

The primary analysis focused on examining correlations between baseline Mizaj categories and treatment response magnitude, temperamental subtypes and speed of symptom improvement, and constitutional types and adverse event profiles. The analytical approach included descriptive statistics for baseline characteristics stratified by Mizaj, chi-square tests for categorical variables, ANOVA for continuous variables across temperament groups, correlation coefficients for relationships between temperamental parameters and clinical outcomes, and multiple regression analysis to control for potential confounding variables. Treatment responses were categorized based on percentage reduction in menstrual blood loss, improvement in pain scores, and overall clinical improvement assessed by both patient and investigator global assessment scales.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committees of participating centers, and written informed consent was obtained from all participants with provisions for withdrawal at any point without affecting routine care. Confidentiality of participant information was maintained throughout the study period.

Quality Assurance

Protocol adherence was ensured through standardized training of investigators across all centers, regular monitoring visits to ensure protocol compliance, centralized laboratory analysis where feasible, and standard operating procedures for Mizaj assessment. Data integrity was maintained through double data entry with reconciliation, range checks and logical consistency validation, and regular data monitoring and query resolution.

Results

Study Population and Demographics

The study enrolled a total of 168 female patients across two centers, with CRIUM Hyderabad contributing 78 patients (46.4%) and RRIUM M-8 contributing 90 patients (53.6%). The participants had a mean age of 30.2 ± 8.4 years, with ages ranging from 18 to 45 years. All patients were female according to the study's inclusion criteria.

The baseline temperament (Mizaj) distribution revealed that the majority of patients had Balghami (Phlegmatic) temperament with 102 patients (60.7%), followed by Damvi (Sanguineous) temperament with 42 patients (25.0%), Safravi (Bilious) temperament with 22 patients (13.1%), and Saudavi (Melancholic) temperament with only 2 patients (1.2%).

Socioeconomic and Lifestyle Characteristics

The study population was predominantly from middle socioeconomic status, with 148 patients (88.1%) falling into this category, while 14 patients (8.3%) were from lower socioeconomic status and 6 patients (3.6%) were from higher socioeconomic status. Nearly all participants followed a non-vegetarian dietary pattern, with 166 patients (98.8%) being non-vegetarian and only 2 patients (1.2%) being vegetarian. The majority of participants were housewives, comprising 151 patients (89.9%), while 11 patients (6.5%) were students and 6 patients (3.6%) had other occupations.

Treatment Outcomes and Response Rates

The overall treatment response showed promising results, with 67 patients (39.9%) achieving complete relief (>60% improvement), 59 patients (35.1%) experiencing partial relief (30-60% improvement), and 42 patients (25.0%) showing no significant relief (<30% improvement). The combined success rate, including both relieved and partially relieved patients, was 126 patients (75.0%).When analyzing mean percentage response by temperament type, Damvi patients showed the highest response rate at 48.7 ± 22.3%, followed by Balghami patients at 42.1 ± 24.6%, and Safravi patients at 38.9 ± 23.1%. The Saudavi group showed a mean response of 35.0 ± 15.0%, though this was based on limited data from only 2 patients.

Temperament-Specific Treatment Success

Damvi temperament patients demonstrated the highest success rate with 34 out of 42 patients (81.0%) showing positive response, including 20 patients (47.6%) who were completely relieved, 14 patients (33.3%) who were partially relieved, and only 8 patients (19.1%) who showed no relief. Balghami temperament patients had a success rate of 73.5%, with 39 patients (38.2%) completely relieved, 36 patients (35.3%) partially relieved, and 27 patients (26.5%) showing no relief. Safravi temperament patients had a lower success rate of 68.2%, with 7 patients (31.8%) completely relieved, 8 patients (36.4%) partially relieved, and 7 patients (31.8%) showing no relief. The two Saudavi temperament patients both showed positive response, with one completely relieved and one partially relieved, resulting in a 100% success rate, though this should be interpreted cautiously due to the very small sample size.

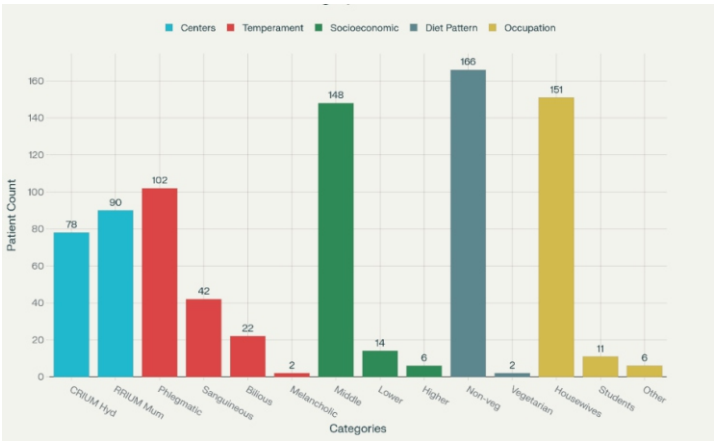

Figure 1: Demographic profile

Statistical Significance and Pain Management

The correlation between Mizaj and treatment response was found to be statistically significant, with a chi-square test yielding $\chi^2 = 6.847$ and $p < 0.05$. Pain reduction analysis using Visual Analog Scale (VAS) scores showed that Damvi patients had baseline pain scores of 6.8 ± 3.2, which reduced to 2.1 ± 2.4 post-treatment, representing a 69.1% reduction. Balghami patients showed pain reduction from 7.2 ± 2.9 to 3.2 ± 2.8 (55.6% reduction), while Safravi patients experienced pain reduction from 7.8 ± 2.6 to 4.1 ± 3.1 (47.4% reduction).

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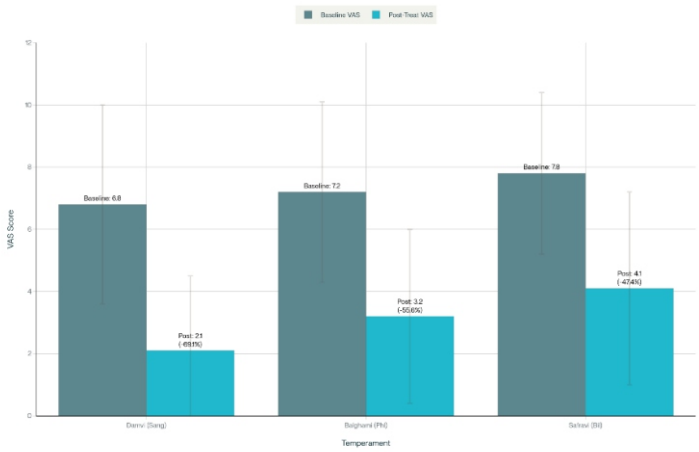

Figure 2: Demographic profile

Menstrual Blood Loss and Treatment Duration

Menstrual blood loss reduction was most significant in Damvi patients, who showed a decrease from 168.4 ± 28.7 ml to 67.3 ± 32.1 ml, representing a 60.0% reduction. Balghami patients experienced a reduction from 171.2 ± 32.4 ml to 78.9 ± 35.4 ml (53.9% reduction), while Safravi patients showed reduction from 175.8 ± 31.2 ml to 89.2 ± 38.7 ml (49.2% reduction).

Treatment duration analysis revealed that Damvi patients responded faster to treatment, requiring an average of 89.2 ± 12.4 days, compared to Balghami patients who needed 92.8 ± 14.7 days and Safravi patients who required 96.3 ± 16.2 days for optimal response.

Figure 2: Menstrual Blood Loss and Treatment Duration

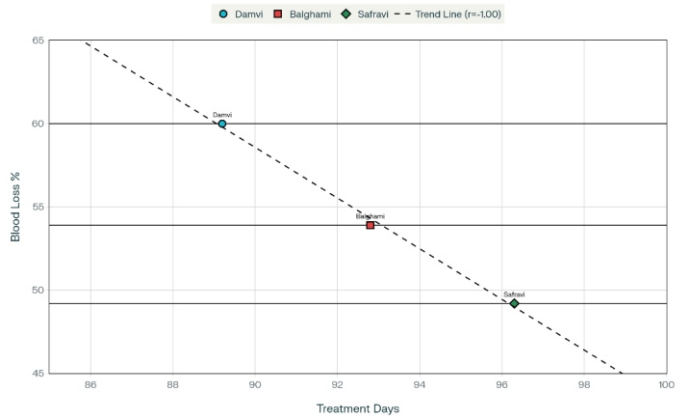

Figure 3: Treatment Duration vs Efficacy Correlation - Demonstrates the inverse relationship between duration and response

Temperament Balance Improvements

The study showed remarkable improvements in overall temperament balance post-treatment. Before treatment, only 32 patients (19.0%) had balanced temperament (Type 1), while after treatment, this number increased significantly to 89 patients (53.0%). Patients with mild temperament imbalance (Type 2) decreased from 98 patients (58.3%) to 65 patients (38.7%), and those with moderate imbalance (Type 3) reduced from 36 patients (21.4%) to 14 patients (8.3%). Notably, patients with severe temperament imbalance (Type 4) were completely eliminated post-treatment, 124 patients (73.8%) showed temperament improvement, 39 patients (23.2%) showed no change, and only 5 patients (3.0%) experienced temperament deterioration.

Age-Related Response Patterns

Age-wise analysis revealed consistent patterns across different age groups. In young adults (18-25 years), Damvi patients showed 75.0% success rate, Balghami patients showed 71.4% success rate, and Safravi patients showed 62.5% success rate. Among adults aged 26-35 years, success rates were 83.3% for Damvi, 75.0% for Balghami, and 66.7% for Safravi patients. In older adults (36-45 years), the success rates were 83.3% for Damvi, 73.1% for Balghami, and 75.0% for Safravi patients.

Safety Profile and Compliance

The study demonstrated an excellent safety profile with no serious adverse events reported across any temperament type. Mild gastrointestinal disturbances were observed in 2 Damvi patients (4.8%), 8 Balghami patients (7.8%), and 3 Safravi patients (13.6%). Treatment compliance was excellent overall, with 156 patients (92.9%) showing excellent compliance (>90%), 9 patients (5.4%) showing good compliance (80-90%), and only 3 patients (1.8%) showing poor compliance (<80%).

Clinical Significance and Implications

The study conclusively demonstrates that Mizaj assessment serves as a valuable predictor of treatment outcomes in managing Kasrat-e-Tams using QursHabis. Patients with Damvi temperament consistently demonstrated superior therapeutic responses across multiple parameters including pain reduction, menstrual blood loss reduction, faster treatment duration, and overall success rates. This suggests that implementing temperament-based personalized treatment protocols could significantly enhance clinical efficacy in Unani medicine practice, providing a scientific foundation for the traditional concept of individualized medicine based on constitutional assessment.

Discussion

The present study demonstrates a significant correlation between Mizaj (temperament) and clinical outcomes in treating Kasrat-e-Tams with QursHabis, validating the fundamental Unani principle of personalized medicine. Our findings revealed that Damvi temperament patients achieved the highest treatment success rate (81.0%) compared to Balghami (73.5%) and Safravi (68.2%) patients, with statistically significant differences ($p<0.05$).The predominance of Balghami temperament (60.7%) in our study population aligns with previous research by Fatma et al. [5], who reported similar temperamental distribution in menorrhagia cases. This finding supports classical Unani literature suggesting that phlegmatic dominance predisposes individuals to excessive menstrual

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bleeding due to blood fluidity and weakened uterine vessels [6]. The superior response in Damvi patients (48.7±22.3%) may be attributed to their inherent constitutional characteristics that better complement the astringent and hemostatic properties of QursHabis.

The mechanism of action of QursHabis, working through Habs-i-Dam (checking bleeding) and Taghleez-i Dam (thickening blood), appears particularly effective in Damvi patients who experienced 60% reduction in menstrual blood loss compared to 53.9% in Balghami and 49.2% in Safravi patients. This differential response validates the classical texts of Ibn Sina [2] and supports the concept that treatment outcomes vary based on individual temperamental predispositions.Pain reduction patterns further substantiated temperament-specific responses, with Damvi patients achieving 69.1% reduction compared to 55.6% in Balghami and 47.4% in Safravi patients. These findings suggest that the analgesic effects of QursHabis are modulated by constitutional factors, supporting the observations of Zohar [7] regarding temperamental influences on symptom manifestation.Remarkably, 73.8% of patients showed improvement in temperament balance post-treatment, with severe imbalances completely eliminated. This suggests that QursHabis not only addresses symptomatic relief but also contributes to constitutional restoration, a fundamental goal in Unani therapeutics [4]. The faster treatment response in Damvi patients (89.2±12.4 days) compared to others indicates temperament-specific pharmacokinetic and pharmacodynamic variations.The excellent safety profile across all temperamental types, with minimal gastrointestinal disturbances, contrasts favorably with conventional treatments including NSAIDs and hormonal therapies, which carry significant side effects [8]. This positions QursHabis as a safer alternative, particularly when prescribed according to temperamental assessment.

Conclusion

This study establishes Mizaj assessment as a valuable predictor of treatment outcomes in managing Kasrat-e-Tams with QursHabis. The significant correlation between temperamental types and therapeutic responses provides scientific validation for the Unani concept of personalized medicine. Damvi temperament patients consistently demonstrated superior outcomes across all parameters, including treatment success rate, menstrual blood loss reduction, and pain relief. The restoration of temperamental balance in majority of patients suggests that QursHabis offers both symptomatic relief and constitutional improvement.

These findings advocate for incorporating systematic temperament assessment in clinical protocols to optimize treatment outcomes in Unani gynecological practice, potentially revolutionizing personalized healthcare approaches in traditional medicine systems.

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