Indian Journal of Traditional Knowledge
Vol 22(4), October 2023, pp 708-716
DOI: 10.56042/ijtk.v22i4.7187

Majun-e-Suranjan and *Habb-e-Azraqi* are two Unani compound drugs that are effective and safe in cases of gout - An initial study

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Received 28 October 2021; revised & accepted 18 September 2023

Present study evaluated the therapeutic efficacy and safety of two Unani compound drugs namely *Majun-e-Suranjan* and *Habb-e-Azraqi* in cases of gout on modern scientific parameters *viz.,* clinical, biochemical and haematological. This work was conducted at Regional Research Institute of Unani Medicine (RRIUM), Aligarh, during 2014-2019. 71 people were chosen from the pool of patients visiting the outpatient department (OPD). Patients received the Unani medicines *Majun-e-Suranjan* in a dose of 5.0 g and *Habb-e-Azraqi* in a dose of 1 pill (250 mg) twice daily after meals for a period of 56-days. One-way analysis of variance (ANOVA) was used for the analysis of data, and the statistical significance of the findings was determined by Dennett's test. The study reveals that the two Unani medicines are safe, non-toxic, and significantly relieve the symptoms of gouty arthritis. It is suggested to conduct more research among a large population.

Keywords: Gout, Unani compound drugs (*Majun-e-Suranjan*, *Habb-e-Azraqi*), efficacy and safety

IPC Code**:** Int Cl[23]: A61K 36/00, A61K 9/00

Most prevalent common inflammatory arthritis in both men and women is gout[1], characterised by extreme pain, redness and tenderness in joints. Gout affects 1-4% of the general population. It affects 3.6% men 3-6% and 1-2% women in western countries. Over the age of 80, the prevalence rises to 10% for males and 6% for women. Every year, 3 out of every 1000 persons develop gout. Men are 2-6 times more likely than women to have it. Gout incidence and prevalence appear to be increasing internationally because of unhealthy lifestyle such as fast food, inactivity, rising obesity rates, and metabolic syndrome[2-4]. Gout can be controlled by making lifestyle adjustments like regulating weight, consuming less alcohol[5] and cutting back on meals that contain purine rich meats and fish[6]. Drinking more coffee and higher consumption of dairy products is associated with a decreased incidence of gout, but higher consumption of meat and seafood is linked to increased risk. The first-line systemic treatment for acute attacks is suggested to be either colchicines or oral non-steroidal anti-inflammatory drugs (NSAIDs)[7]. NSAIDs are linked to unfavorable gastrointestinal, renal, and cardiovascular effects[8]. Antihyperuricemic medications including allopurinol, benzbromarone, sulfinpyrazone and probenecid can have significant adverse effects[9-13]. Because of its unfavorable side effects, benzbromarone, a preferred medication was taken off the market in Europe in 2003.

A review of Unani text[14,15] indicates that there is a treasure of herbo-mineral drugs widely used and practiced to treat and cure gouty arthritis since time immemorial. Besides, there are many specialized therapies to get rid of the disease. These are listed below:

Single Unani durgs for treatment of gout

1. Single Unani drugs (oral administration): *Withania somnifera* L. (Asgandh), *Tanacetum umbelliferum* L. (Bozidan), *Piper nigrum* L. (Filfil Siyah), *Operculina turpethum* L. (Turbud), *Zingiber officinale* Rosc. (Zanjabeel), *Cassia angustifolia* L. (Sana Maki), *Solanum nigrum* L. (Mako), *Terminalia chebula* Retz. (Haleela Siyah), *Cichorium intybus L.* (Kasni), *Foeniculum vulgare* Mill. (Badiyan), *Rosa*

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damascena Mill (Gul-e-Surkh), *Aloe barbadensis* L. (Elva/Sibr), *Atropa belladonna* L. (Lufah), *Commiphora mukul* L. (Muqil), *Centauria centaurium* L. (Qunturyoon), *Saussurea lappa* CB Clarke (Qust) *Colchicum autumnale* Linn. (Suranjan Shirin) and *Colchicum luteum* Baker (Suranjan Talkh)[16].

2. Single Unani drugs (local application): *Astragalus hamosus* L. (Nakhoona), *Matricaria chamomilla* L. (Baboona), *Brassica nigra* L. (Khardal) and *Origanum majorana* L. (Marzanjosh), *Eryngium foetidum* L. (Eryngo), *Blepharispermum subsessile* DC[17,18].

Compound Unani drugs for treatment of gout

1. Compound Unani drugs (oral administration): Ma'jun Jograj Gugul , *Habb-e-Gul-I Akh*, *Habb-e-Asgandh*, *Habb-e-Muntan*, *Habb-e-Najah*, *Habb-e-Sheetraj*, *Habb-e-Mafasil*, *Habb-e-Kuchla*, *Iyarij Faeqra*, *Jawarish Jalinoos*, *Jawarish Safarjali*, *Ma'jun Azraqi*, *Ma'jun Chobchini*, *Ma'jun Najah*, *Ma'jun Safarjali*, *Ma'jun Ushba, Qurs Mafasil*, *Tiryaq-e-Kabir*, *Tiryaq-e-Arba*, and *Tiryaq-e-Farooque*[19-21].

2. Compound Unani drugs (local application): *Roghan-e-Malkangani*, *Roghan-e-Chahar Barg*, *Roghan-e-Haft Barg*, *Roghan-e-Surkh*, *Roghan-e-Mafasil* Hakeem Ajmal Khan, *Roghan-e-Qust*, *Roghan-e-Marzanjosh Roghan-e-Baboona, Roghan-e-Zaitun*, *Roghan-e-Chobchini*, *Roghan-e-Satawri*[22-24] and others.

Present work

According to a review of the literature, there hasn't been any systematic clinical research on the test medications *Majun-e-Suranjan* and *Habb-e-Azraqi* to support the old, time-tested assertions about their efficacy and safety. Hence the present studies.

Materials and Methods

Research plan

Gout and arthritis treatments with Unani medicines of *Majun-e-Suranjan* and *Habb-e-Azraqi* were obtained from the Central Council for Research in Unani Medicine, New Delhi. The RRIUM Aligarh, India, conducted the study between 2014 and 2019. A group of patients who have symptoms and characteristics that meet the established inclusive/exclusive criteria were examined in the outpatient department (OPD). Of these 102 patients between the ages of 18 and 60 years, of either sex, were chosen, 71 completed the study and 52 dropouts. On the basis of clinical, biochemical, and haematological characteristics, *Majun-e-Suranjan* and *Habb-e-Azraqi* were assessed for their therapeutic effectiveness and safety.

Composition of test drugs

Ethical clearance of study

Every patient who took part in this study provided written informed permission. The research project was filed to the Clinical Trial Registry-India for registration on March 5, 2015, with reference number CTRI/2005/03/005610. Furthermore, the Regional Research Institute of Unani Medicine (RRIUM), Aligarh's Institutional Ethics Committee (IEC) gave its approval to the study with reference number F. no. 8-22/2014-15/RRI-ALG/Misc./20, dated May 17, 2016.

Selection standards

Patients were enrolled in accordance with the following inclusion and exclusion standards:

Inclusion standards

1. Any patient, between the ages of 18 and 60.
2. Serum uric acid level: Within the range of 7.0-8.9 mg/dL, normal or above normal.
3. Gout sufferers who exhibit any of the following symptoms or indicators include:

- Joint discomfort, particularly in the first metatarsophalangeal (MTP) joint.
- Swelling; Tenderness; and Redness

Exclusion standards

1. Other illnesses that affect both small and major joints.
2. Breastfeeding and pregnant ladies.
3. Patients suffering from any systemic disorders, such as osteomalacia, osteoporosis, hepatic and renal disease, hypertension, diabetes mellitus, and cardiovascular/cerebrovascular diseases.
4. Obese people (BMI $\leq$ 30).
5. Patients receiving long-term treatment.
6. Patients using medications that lower serum calcium levels and raise serum uric acid levels (thiazide, diuretics, etc.).

Medication, dosage, and route of administration

5.0 g of *Majun-e-Suranjan* and 250 mg *Habb-e-Azraqi* tablet were administered orally to the patients twice daily after meals for 56 days. At the beginning of the study and 56 days later, when it was over, biochemical and haematological assays were conducted (Table 1-4)[25-30].

Table 1 — Constituents of *Majoon-e-Suranjan*[25]

Name of ingredients	Quantity
Suranjan Shireen *(Colchicum autumnale* L.)	500 g
Sana (*Cassia senna* L.)	250 g
Zanjabeel (*Zingiber officinale* Rosc.)	100 g
Zeera Siyah (*Carum carvi* L.)	100 g
Filfil Daraz (*Piper longum* L.)	100 g
Asroon **(*Valeriana wallichii* DC.)**	100 g
Asal OR Qand Safaid *(Saccharum officinarum* L.)	3.5 Kg

Table 2 — Constituents of *Habb-e-Azraqi*[26]

Name of ingredients	Quantity
Azraqi Mudabbar (*Strychnos nux-vomica* L.)	20 g
Filfil Siyah (*Piper nigrum* L.)	10 g
Filfil Daraz (*Piper longum* L.)	10 g
Araq-e-Ajwayia *(Trachyspermum ammi* (L.) Sprague)	10 g
Aab-e-Barg-e-Tambool (*Piper betle* L.)	Q.S.

Evaluation of Mizaj (Temperament)

At the baseline, Mizaj (Temperament) was evaluated.

Follow-up evaluation

Clinical evaluations of the patients were performed every two weeks, *i.e.,* at days 14, 28, 42, and 56. Both the subjective and objective clinical findings were written down on the follow-up sheet.

Guideline for evaluating effectiveness

The following parameters were used to evaluate the following parameters for gout patients.

Subjective standards

- ***Joint pain***

0-Zero pain

1-Hardly noticeable

2-Mild: Capable of managing daily tasks with some difficulty.

3-Moderate: Able to perform daily tasks with ease.

4-Severe: Bed ridden.

- ***Joint sensitivity***

0-No sensitivity

1-Patients report that it feels tender when touched upon palpation.

2-When palpated, the patient complains of pain and grimaces.

3-Patients wince and pull back when it is palpated and claims it is tender.

4-The patient refuses to allow contact during palpation.

- ***Joint enlargement***

0-No swelling.

1-Hardly noticeable.

2- Mild: Able to be felt.

3-Moderate: Little swelling.

4-Extreme: Significant swelling.

- ***Redness***

0-No

1- Yes

Assessment of safety

Biochemical analysis

SGPT (EC 2.6.1.2) and SGOT (EC 2.6.1.1) are two different types of serum glutamate transaminases[31], serum alkaline phosphatase enzyme (S-ALP, EC. 3.1.3.1)[32], blood urea[33], serum creatinine[34], total bilirubin[35], uric acid[36], and C-reactive protein[37] were performed.

Haematological evaluation

The parameters of haematology were performed[38]. Haemoglobin (Hb), erythrocyte sedimentation rate (ESR), total leucocyte counts (TLC), red blood cells (RBC), and differential leucocyte counts (DLC): polymorphs, lymphocytes, and eosinophil counts were all taken into consideration in the analysis. Collection of blood serum:

Blood samples were obtained at each investigation by pricking a vein. Ethylene diamine tetraacetic acid (EDTA) was added to 1.0 mL of blood for various haematological parameters, and 2.0 to 2.5 mL of blood was allowed to coagulate before the serum was separated by centrifugation for various biochemical parameters. Investigations into biochemistry and hematology were conducted as follows.

Statistical evaluation

Dennett's test was used to statistically analyze the data using one-way analysis of variance (ANOVA). The values were considered significant when the P-value was less than 0.05.

Observations

1. There is symptomatic relief in joint pain score, joint tenderness, joint swelling but no redness in gout patients.

2. These test medications are effective against gout, as evidenced by the fact that individuals treated with them experience a considerable decrease in uric acid levels. However, there is slight increase in CRP level but this is non-significant.

3. Both liver function tests and renal function tests show no significant change. As a result, it suggests that these medications are secure.

Table3 — Biodynamic notes (relevant information on the chemical constituents and biological activities)[27-30] of the ingredients used in *Majoon-e-Suranjan* wherever available are given.

Name of ingredient	Biodynamic notes
1. Suranjan Shireen (*Colchicum autumnale* L.)	*Chemical constituents*: The main alkaloid found in *Colchicum autumnale* L. (Liliaceae) is colchicines which is made up of three chemical components: colchicine, colchicoside, and 3-demethylcolchicine[2,3] *Biological activity*: It is effective in treating acute attacks gout. [1]
2. Sana (*Cassia senna* L.)	*Chemical constituents*: Pinnitol, sucrose, glucose, and fructose are all present in leaves. Galactose, arabinose, rhamnose, and galacturonic acid make up mucilage. Sennoside-C (8, 8'-diglucoside of rhein-aloe-emodin-dianthrone) is also present in the leaves. Sennosides A and B, glycosides of the anthraquinones rhein and chrysophanic acid, are found in pods. Sitosterol is present in seeds. *Biological activity*: Leaf and pod –laxative, especially useful in habitual constipation.
3. Zanjabeel (*Zingiber officinale* Rosc.)	*Chemical constituents*: d-camphene is an essential oil's primary component. Along with these, there was β-phellandrene, cineole, citral, borneol, gingerol, α-pinene, limonene, methylheptenone, and linalool. Asparagines and pipecolic acid are two free amino acids found in rhizomes. *Biological activity*: Rhizome-antirheumatic, carminative, rubefacient, antidropsical, bechic, stimulant, stomachic, aphrodisiac, laxative, in affections of throat, head and chest, haemorrhoids, urticaria, colic, antioxidant.
4. Zeera Siyah (*Carum carvi* L.)	*Chemical constituents*: Essential oil contains mainly carvone and limonene along with α and β-pinene, camphene, myrcene, Δ3-careen, γ-terpinene, p-cymene, cadinene, myristicin, carveyl acetate, dihydrocarveyl acetate, dihydrocarvone, terpinen-4-ol, dihydrocarveol, perillyl alcohol, carveols, cadinene and germacrene D. *Biological activity*: Fruit- stomachic, carminative, adjuvant, lactogogue. Essential oil- antispasmodic.
5. Filfil Siyah (*Piper nigrum* L.)	*Chemical constituents*: The fruit contain piperylin, piperoleins A and B, and N-iso-butylcicosa-trans-2-trans-4-dien-amide, as well as piperine, piperidine, and amides. Piperine, hentriacontanone, hentriacontane, and β-sitosterol were present in the stems. Pinene, Sabinene, Myrcene, Limonene, Terpinene, P-Cymene, Bergamotene, Caryophyllene, α-Humulene, and its Oxides, as well as Selinene. Other essential oils camphene, linalool, terpincoland nerolidol were present in the fruit's essential oil. Monoterpines were present in trace amounts in leaf oil, whereas sesquiterpene content was high. Fruit produced phenolic amides as well N-5-(4-hydroxy-3-methoxyphenyl) piperidine Pentadienoyl piperidine, 2E, 4E-pentadienoyl, N-5-(4-hydroxy-3-methoxyphenyl) N-trans-feruloyltyramine, -2E-pentenoyl piperidine, and N-5-(4-hydroxyphenyl)-2E-4E pentadienoyl piperidine (coumaperine). *Biological activity*: Fruit-diuretic, carminative, stimulant, stomachic, anticholerin, sialagogue, tonic, bechic, antiasthmatic, in malerial fever, alterative, in paraplegia and arthritic diseases, A gargle made of an infusion that is externally rubefacient and stimulating to the skin is used to treat sore throat and hoarseness. Fruit extract's antibacterial and antifungal properties, fruit's taenicidal and larvicidal properties, leaf's hypertensive properties, and ability to enhance pentobarbitone-induced hypnosis in mice.
6. Asroon (*Valeriana wallichii* DC.)	*Chemical constituents*: The *Valeriana wallichii* DC.'s pharmacological activity is caused by the existence of several types of secondary metabolites, along with valerianic acid, valerosidatum glycoside, valepotriates, dihydrovaltrate, 6-methylapigenin, hesperidin, sesquiterpenoids, bornylisovalerianate, isovalerenic acid, 1-camphene, 1-pinene, terpineol, valerianine, bornylisovalerianate, valerianine and so on. *Biological activity*: The Indian traditional medical system has long employed the plant *Valeriana wallichii* DC. as a sleep cure. Additionally, it is employed as a diuretic, spasmolytic, and analgesic. It has been claimed to have cytotoxic potential and is used to treat epilepsy, dyspeptic symptoms, failing reflexes, persistent constipation, insanity, nerve debility, obesity, spastic disorders, and snake poisoning.
7. Asal OR Qand Safaid (*Saccharum officinarum* L.)	*Chemical constituents*: *Saccharum officinarum* the principal constituents of sugarcane juice were reported to be L-apigenin, tricin, and luteoline glycosides including orientin, vitexin, schaftoside, and swertisin. Numerious policosanols and steroids were also recognized in different portions of *S. officinarum*. *Biological activity*: Numerous bioactivities of *Saccharum officinarum* L. include hepatoprotective, analgesic, antihyperglycemic, anti-inflammatory, and analgesic properties.

4. Gout has more incidences in males (66.20%) than female (33.80%).

5. The disease gout has less incidence in vegetarian (15.49 %) than non-vegetarian (84.51%).

6. According to the temperament of gout patients, the incidences was found more in phlegmatic patients (39.44%) followed by sanguine (26.76%) and bilious (33.80 %).

Results and Discussions

Demographic evaluation

Out of 71 gout patients, 47 (66.20%) were male (mean age 47.32 years) and 24 (33.80%) were female (mean age 47.29 years) according to demographic data. This is brought on by estrogen's uricosuric action, which lowers urate levels in premenopausal women[39]. Gout is more common in individuals

Table 4 — Biodynamic notes (relevant information on the chemical constituents and biological activities)[30] of the ingredients used in *Habb-e-Azraqi* wherever available are given.

1. Azraqi Mudabbar (*Strychnos nuxvomica* L.)	*Chemical constituents*: Plant is abundant with alkaloids, such as brucine, strychnine, pseudobrucine, 3-hydroxybrucine, pseudostrychnine, 3-hydroxystrychnine, α-colubrine, 3-hydroxy-α-colubrine (vomicine), and iso-strychnine (novacine) are found in the roots, bark, and seeds. Root-bark also contains 4-hydroxy-3-methoxystrychnine, 4-hydroxy-strychnine, normacusine, protostrychnine, methoxystrychnine, (+) α-mavacurine, normacusine B, O-methylmacusine B, 16-epi-O-methylmacusine B, nor-melinonine-B, Strychnines that have been hydroxylated include 10-, 12-, and 11-hydroxy strychnines. Additionally, seeds include 3-hydroxy- α- colubrine (icajine), 15-hydroxystrychnine, and -colubrine. Additionally reported from seeds are cycloartenylpalmitate, 16-hydroxy- α-colubrine, 16-hydroxy-β-colubrine, and 3-methoxyicajine have also been reported from seeds. Leaves contain normacusine B, isostrychnine, 19, 20-dihydrostrychnine, 12-hydroxystrychnine, 12-hydroxy-11-methoxystrychnine, strychnine Nb oxide, 12-hydroxy-11-methoxystrychnine Nb oxide, 10, 11-dimethoxystrychnine Nb oxide, 3-hydroxystrychnine, 3, 12- dihydroxystrychnine, 3,12- dihydroxy-11-methoxystrychnine, 3, 12-hydroxy-11-methoxystrychnine, 3-hydroxy-10,11-dimethoxystrychnine and vomicine. The stem, bark and leaves also contain brucine and strychnine.
2. Filfil Siyah (*Piper nigrum* L.)	*Biological activity:* Leaf as poultice, in sloughing wounds and ulcers; root and root-bark-febrifuge, anticholerin; seed-stimulant, febrifuge, emetic, insecticidal, for scalp, in colic; stem-bark and wood-antiepileptic, antidysenteric, anticholerin, febrifuge, in dyspepsia; fruit-diuretic, emmenagogue, antipyretic, antirheumatic, diuretic, in jaundice, leucoderma, diseases of blood, piles, ulcers, anaemia, lumbago, ringworm. Leaf and fruit-spasmolytic. Quarternary alkaloid extract of root-bark possesses muscle relaxant activity.
3. Filfil Daraz (*Piper longum* L.)	*Chemical constituents*: Stems contained piperine, hentriacontanone, hentriacontane, hentriacontanol and β-sitosterol; fruit yielded piperine, piperidine and amides- piperylin, piperoleins A and B and N-iso-butylcicosa-trans-2-trans-4-dien-amide. Essential oil from fruit contained α and β pinene, sabinene, myrcene, limonene, terpinene, p-cymene, bergamotene, caryophyllene, α-humulene, its oxides, selinene, camphene, linalool, terpincoland nerolidol. Leaf oil contained insignificant amount of monoterpinesbut rich in sesquiterpenes. Fruit also gave phenolic amides-N-trans-ferulyl piperidine, N-5-(4-hydroxy-3-methoxy-phenyl)-2E, 4E-pentadienoyl piperidine, N-5-(4-hydroxy-3-methoxy-phenyl) -2E-pentenoyl piperidine, N-trans-feruloyltyramine and N-5-(4-hydroxyphenyl)-2E-4E pentadienoyl piperidine (coumaperine). *Biological activity*: Fruit-diuretic, carminative, stimulant, stomachic, anticholerin, sialagogue, tonic, bechic, antiasthmatic, in malerial fever, alterative, in paraplegia and arthritic diseases, a gargle made of an infusion that is externally rubefacient and stimulating to the skin is used to treat sore throat and hoarseness. Fruit extract with antibacterial and antifungal properties. fruit- taenicidal, larvicidal; leaf-hypertensive and potentiated pentobarbitone-induced hypnosis in mice.
4. Araq-e-Ajwayia *(Trachyspermum ammi* L. Sprague)	*Chemical constituents*: Roots produced the alkaloids piperine, piperinelongumine (piplartine), and piperinelonguminine as well as sesamin, methyl-3, 4,5-trimethoxycinnamate; stem produced triacotane and 22,23-dihydrostigmasterol; fruit produced N-isobutyldeca-trans-2-trans-4-dienamide; essential oil from fruit contains n-hexadecane, n-heptadecane, n-octadecane, n-nonadecane, n-cicosane, n-heneicosane, α-thujene, terpinolene, zingiberene, p-cymene, p-methoxyacetophenone, dihydrocarveol, phenylethylalcohol and caryophyllene; fruit also gave L-tyrosine, L-cysteine hydrochloride, DL-serine and L-aspartic acid; leaves yielded hentriacontane, hentriacontan-16-one, hentriacontanol and β-sitosterol. Seeds gave sylvatin, sesamin and dieudesmin. *Biological activity*: Fruit-alterative, tonic, fruit-carminative, As liniment for rheumatic pains and paralysis; root-diuretic, stimulant,sudorific; unripe fruit and root- stomachic; fruit and root-analgesic, antiepileptic, anti-inflammatory, sedative, antidyssenteric, antileprotic, antidotefor snake-bite, haematic, cholagogue, emmenagogue, abortifacient, antihelmintic, in diseases of the respiratory tract. *Chemical constituents*: Thymol serves as the primary component of the essential oil. Others are include α-and β-pinene, camphene, myrcene, Δ-3-carene, limonene, γ-terpinene, p-cymene and carvacrol. 2-methyl-3-glucosoxy-5-isopropylphenol, a phenolic glucoside, is present in seeds. *Biological activity*: Fruit-antispasmodic, antidiarrhoeal, stimulant, anticholerin, carminative, in sore throat, bronchitis, atonic dyspepsia, colic; root- carminative, diuretic; essential oil of fruit- carminative, antseptic, expectorant, in emphysema, bronchial pneumonia and other respiratory troubles. Essential oil-antifungal.

between the ages of 44 and 60 (mean age, 54.07 years) for men and 52.56 years for women (Table-5). Vegetarians had 11 (15.49%) fewer incidents than non-vegetarians (60, 84.51%)[40] (Table-5). Other authors had made comparable observations. According to socio-economic status, lower income group 41 (57.75%) had more incidences than middle income group 30 (42.25%) (Table 5). The incidences was found more in phlegmatic patients 28 (39.44%) followed by sanguine 19 (26.76%) and bilious 24 (33.80%)[41,42] (Table 5).

Table 5 — Demographic information illustrating the distribution of gout patients by age and sex, dietary habit, socio-economic status and temperament.

Name of variable ↓		Total number Mean age (Years) of patients (n=71) & % age
1. Sex	Male	47 (66.20%) 47.32 ±10.98
	Female	24 (33.80%) 47.29 ± 9.43
2. Age in years i. 18-30	Male	05 (7.04%) 26.20 ± 1.56
	Female	02 (2.82%) 25.00 ± 5.00
ii. 31-43	Male	12 (16.90%) 37.33 ± 0.95
	Female	06 (8.45%) 38.67 ± 0.87
iii. 44-60	Male	30 (42.25%) 54.07 ± 1.01
	Female	16 (22.54%) 52.56 ± 1.61
3. Dietary Habits i. Non-vegetarian		60 (84.51%)
ii. Vegetarian		11(15.49%)
4. Socio-economic Status: i. L.I.G.		41(57.75%)
ii. M.I.G.		30 (42.25%)
iii. H.I.G.		Nil
5. Type of temperament: i. Phlegmatic		28 (39.44%)
ii. Sanguine		19 (26.76%)
iii. Bilious		24 (33.80%)
iv. Melancholic		Nil

L.I.G.: Lower income group, M.I.G.: Middle income group, H.I.G. Higher income group

Table 6 — Impact of Unani medications *Majun-e- Suranjan* and *Habb-e-Azraqi* in the concentration of SGPT, SGOT and serum alkaline phosphatase, blood urea, serum creatinine, uric acid and C-reactive protein in gout patients. [ˆP is not significant]

Parameter → Group ↓	SGPT (IU/L)	SGOT (IU/L)	Serum Alkaline Phosphatase (IU/L)	Blood Urea (mg %)	Serum Creatinine (mg %)	Biliruibin (mg %)	Uric Acid (mg %)	C- Reactive Protein (mg/L)
(Baseline-Treatment) (1st -Day)	32.29±23.19	29.66±22.38	87.18±39.52	25.29±10.8	1.06±0.22	0.79±0.23	7.49±0.53	12.15±7.40
1st Follow-Up (14-Days)	29.74±19.26ˆ	27.28±15.47ˆ	78.49±23.44ˆ	25.41±8.84ˆ	1.04±0.25ˆ	0.72±0.20ˆ	6.70±1.28***	13.55±8.24ˆ
Post-treatment (56-Days)	30.98±23.71ˆ	28.19±18.10ˆ	80.04±21.02ˆ	24.23±8.30ˆ	1.05±0.21ˆ	0.78±0.24ˆ	6.59±1.25 ***	13.37±8.13ˆ

Table 7 — Impact of Unani medicines *Majun-e-Suranjan* and *Habb-e-Azraqi* on symptoms in gout patients. [*p<0.05 is significant, ***p<0.001 is highly significant and ˆP is not significant]

Group → Parameter ↓	Baseline (1st-Day)	1st F/up (14-Days)	2nd F/up (28-Days)	3rd F/up (42-Days)	4rth F/up (56-Days)
Joint Pain Score	3.17±0.53	3.01±3.41ˆ	2.32±3.49*	1.65±2.41***	0.90±2.54***
Joint Tenderness	1.45±1.16	1.77±3.77ˆ	1.04±2.20ˆ	0.42±0.97***	0.15±0.40***
Joint Swelling	2.73±0.65	2.17±0.65***	1.54±0.61***	0.97±0.65***	0.44±0.79***
Redness	Nil	Nil	Nil	Nil	Nil

Safety assessment

Liver function tests and Kidney function tests

Regarding safety assessment, no discernible changes in liver function tests or renal function tests had been seen (Table 6). This suggests that these Unani formulations did not elicit any adverse or unfavourable reactions. As a result, the medication's safety is consistent. Other authors had made comparable observations[41-42].

Clinical assessment

The change in respect of clinical assessment of various signs and symptoms were noted.

Subjective standards

i-Joint pain rating

Significantly less joint discomfort was reported at the second follow-up (28th days), with a score of 26.81% ($p<0.05$), 47.95% ($p<0.0001$) 3rd follow-up (42th days) and 71.61% ($p<0.0001$) 4th follow-up (56th days), when compared to the baseline (1st day) values to various treatment follow-up (Table 7 and Fig. 1). The other authors had made comparable observations[41-45].

ii- Joint tenderness

There was a substantial decrease in joint tenderness 71.04% ($p<0.0001$) on 3rd follow-up (42th days) and

89.66% ($p<0.0001$) 4th follow-up (56th days) had been observed, When compared to the values of baseline (1st day) to different follow-ups of therapy, no significant changes had been seen on (1st to 2nd follow-up) (Table 7 and Fig. 1). Other authors had reported similar interventions[41-45].

iii-Joint swelling

A substantial decrease in joint inflammation 20.51% ($p<0.0001$) on 1st follow-up (14th days), 43.59% ($p<0.0001$) on 2nd follow-up (28th days), 64.47% ($p<0.0001$) on 3rd follow-up (42th days), and 83.88% ($p<0.0001$) 4th follow-up (56th days), when compared to the baseline (1st-day) values to various treatment follow-ups, had been seen (Table 7 and Fig. 1). Previous researchers had reported similar results[41-45].

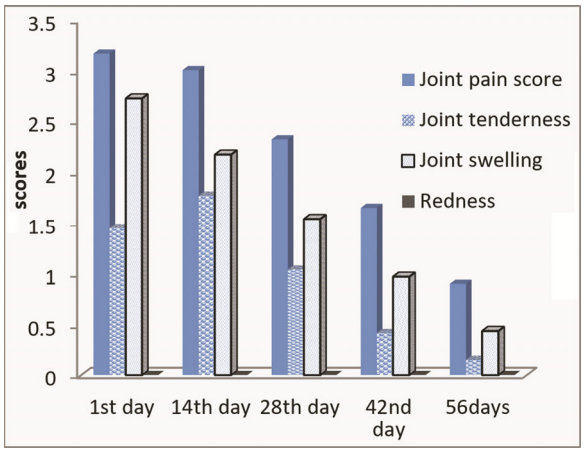

Fig. 1 — Impact of the Unani compound medicines *Majun-e-Suranjan* and *Habb-e-Azraqi* on gout patients' symptoms

iv-Redness

No redness in skin of gout patients had been observed (Table 7 and Fig. 1).

b-Objective parameters

i. Biochemical studies

Uric acid and C-reactive protein:

A substantial decrease in the concentration of uric acid (10.55%) and (12.02%) (1st Follow-up (14th-days) and 4th Follow-up (56-days)) ($p<0.001$) whereas slight increased in the level of C-reactive protein (10.02%) however no appreciable modifications have been seen as compared to baseline (1st-day), 1st – follow-up (14-days) and post-treatment follow-up (56-days) (Table 6 and Fig. 2). Previous writers had reported similar results[41-45].

ii. Haematological studies

The levels of haemoglobin, red blood cells, total leucocyte counts, erythrocyte sedimentation rate, total leukocytes and differential leucocyte counts (DLC) had not changed noticeably (Table 8).

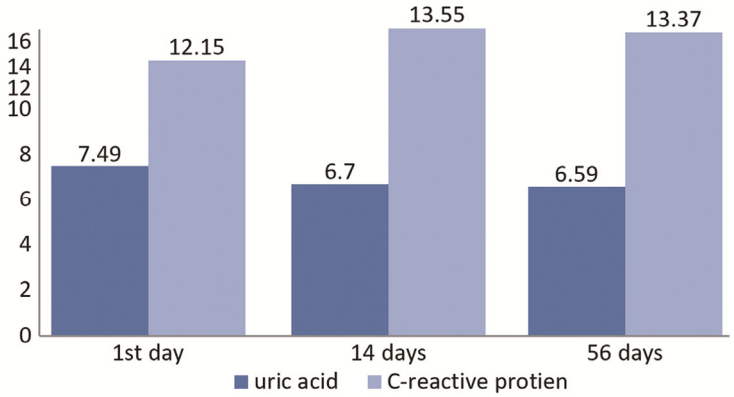

Fig. 2 — Impact of Unani medicines *Majun-e- Suranjan and Habb-e-Azraqi* in the concentration of uric acid and C- reactive protein in gout patients

Table 8 — Impact of Unani medications *Majun-e- Suranjan* and *Habb-e-Azraqi* in the level of haemoglobin, R.B.C. counts, total leucocyte counts (T.L.C.), erythrocyte sedimentation rate (E.S.R.), polymorph, lymphocyte and eosinophil counts in Gout patients. [P is not significant]

Parameter → / Group ▼	Haemoglobin (g %)	R.B.C. (10^6 /mm^3)	T.L.C. (10^3/mm^3)	E.S.R.(mm /h) 1 H	E.S.R.(mm /h) 2 H	Differential Leucocytes Counts (DLC) Polymorph (%)	Lymphocyte (%)	Eosinophil (%)
(Baseline (1st-Days)	13.12±1.56	4.43±0.55	7.70±1.98	33.00±14.87	43.00±12.45	65.00±9.56	30.00±9.79	5.00±2.32
1st Follow-Up (14-Days)	13.05±1.47•	4.44±0.53•	7.30±1.91•	33.00±15.99•	41.0±14.70•	65.00±8.86•	30.00±8.78•	5.00±2.45•
Post-treatment (56-Days)	13.08±1.65•	4.42±0.55•	7.38±1.96•	36.00±14.72•	43.0±12.45•	66.00±9.63•	29.00±9.40•	5.00±2.33•

Conclusion

The majority of people will experience gout at some point in their lives. Unani compound formulations can be utilized as a successful alternative to allopathic medications for the treatment of gout due to the recognised negligible or no adverse effects of these drugs. Based on this study, it can be concluded that the *Majun-e-Suranjan* and *Habb-e-Azraqi* (test meds) do have anti-inflammatory, analgesic and anti-rheumatic properties, as results of this preliminary study have shown significant improvement in signs and symptoms of disease *viz.,* joint pain, tenderness, swelling and also significant reduction in the uric acid level in gout patients. The findings are statistically significant.

Both Unani medicines are non-toxic and safe for humans, according to the study.

In an effort to scientifically correlate the medicinal properties of ingredients used in two drugs namely.

Chemical constituents and biological activities of *Majun-e-Suranjan* and *Habb-e-Azraqi*, have been reviewed in the literature to support or conflict the claims. This review indicates that ingredients namely, *Colchicum autumnale* L., *Zingiber officinale* Rosc., *Carum carvi* L., *Valeriana wallichii* DC., *Saccharum officinarum* L., *Strychnos nux-vomica* L., *Piper nigrum* L., *Trachysperm ammi* L., *Piper longum* L. and *Piper betel* L. do possess anti-gout properties, thereby making the drugs effective to combat gout.

Acknowledgement

The authors are indebted to Central Council for Research in Unani Medicine, New Delhi, for financial support. For completing normal laboratory investigations, we also acknowledge the staff of Mr. Kushal Pal Singh, Mr. Javed Akhtar, Mr. Mohd. Akbar Rais, Mr. Tariq Ali Beg, and Mr. Shish Mohammad from the Biochemistry and Pathology Laboratory at RRIUM, Aligarh.

Conflict of Interest

Authors declare that they do not have any conflict of interest.

Authors' Contributions

All the authors contributed equally.

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