

## Effect of Polyherbal Unani Drug in Rheumatoid Arthritis (*Waja'al-Mafāṣil*) Management: A Case Study

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### Abstract:

Rheumatoid arthritis (RA) is an autoimmune, chronic systemic inflammatory disorder characterized by symmetric polyarthritis of small joints of hands and feet, and extra-articular manifestations. Despite a wide range of treatments available in the conventional system of medicine, there is no cure for RA. An acute flare of RA occurs after cessation of medications and the disease remains incurable. In the Unani system of medicine, RA has been described under a broad term of *Waja'al-Mafāṣil*. Several systemic and topical Unani drugs are effectively used in the management of *Waja'al-Mafāṣil* (RA). The present case study was aimed to evaluate the efficacy and safety of a polyherbal Unani drug *Qurs-e-Mafāṣil* in the management of RA. A 35-year-old female patient diagnosed with RA based on the 2010 ACR/EULAR classification criteria for rheumatoid arthritis was treated with *Qurs-e-Mafāṣil* for 4 weeks. The patient showed a significant reduction in pain on the VAS score, and DAS28 was also reduced from 5.51 (high disease activity) at baseline to 2.62 (low disease activity) after treatment. The Unani drug, *Qurs-e-Mafāṣil* was found safe and effective in the treatment of RA.

**Keywords:** *Qurs-e-Mafāṣil*; Rheumatoid arthritis; Unani; *Waja'al-Mafāṣil*

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### Introduction:

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder, which usually affects small joints of hands and feet symmetrically and is characterized by deforming polyarthritis, associated with synovitis of joint and tendon sheaths, articular cartilage degradation, erosion of juxta-articular bone, osteopenia, positive IgM rheumatoid factor and anti-citrullinated protein antibodies

(ACPAs) in most of the patients along with several extra-articular manifestations. RA is present worldwide, with a prevalence of approximately 1%, and in India, its prevalence is 0.5-0.75%. It is more common in females, with a ratio of 3:1<sup>[1,2]</sup>. In classical Unani literature, rheumatoid arthritis has been described under a broad term of *Waja'al-Mafāṣil*, which is an Arabic term that consists of two words "*Waja'*" means pain and

“*Mafāṣil*” means joints and its clinical features resembles the features of RA mentioned in conventional medicine. *Waja‘al-Mafāṣil* is also known as *Hudār* and *Gathiya*<sup>[3]</sup>. According to *Ibn Sīnā* (Avicenna), *Waja‘al-Mafāṣil* is a clinical condition of pain with or without stiffness in one or more joints caused by the accumulation of *ruṭūbat ghariba* (morbid matters) in the joints. The most common morbid material is *Ṣafrā’-e-Balghamī* (phlegmatic bile), then *Balgham-e-Khām* (raw phlegm), then *Dam* (sanguine), then *Ṣafrā* (yellow bile) and rarely *Sawdā* (black bile)<sup>[4]</sup>. Conventional treatment of RA includes non-steroidal anti-inflammatory drugs (NSAIDs), disease-modifying anti-rheumatic drugs (DMARDs), TNF- $\alpha$  inhibitors, and corticosteroids which have serious adverse effects on long-term use<sup>[2]</sup>. Since RA is a chronic disease that requires long-term treatment, there is a need to search for safe and effective drugs in its treatment. In classical Unani literature, a large number of single and compound drugs have been mentioned and used by ancient physicians for the management of *Waja‘al-Mafāṣil* (RA), but they need to be validated on scientific parameters to generate data regarding their safety and efficacy. Therefore, this case study was conducted to evaluate the safety and efficacy of *Qurs-e- Mafāṣil*, a polyherbal Unani drug in the treatment of *Waja‘al-Mafāṣil* (RA).

### Methodology:

The reported patient was a case of RA diagnosed based on 2010 ACR/EULAR Rheumatoid Arthritis classification criteria. *Qurs-e-Mafāṣil* was given in the dose of 2 tablets (500 mg each) twice daily orally with water after meals. The duration of therapy was 4 weeks, from 5<sup>th</sup> November 2020 to 3<sup>rd</sup> December 2020. The patient was also advised to avoid non-vegetarian, sour, and sweet food items during the entire period of therapy. *Qurs-e-Mafāṣil* contains Zanjabeel (*Zingiber*

*officinale* Rosc.), Filfil Siyah (*Piper nigrum* Linn.), Asgand (*Withania somnifera* (Linn.) Dunal) 1 part each and Suranjan (*Colchicum luteum* Baker) 2 part<sup>[5]</sup>. The response to treatment was evaluated with patient global assessment on the visual analogue scale (VAS) for joint pain at weekly follow-up and Disease Activity Score in 28 joints (DAS28) at baseline and after completion of treatment. Therapeutic safety was evaluated by clinical adverse effects at weekly follow-up visits and laboratory investigations conducted at baseline and after 4 weeks of therapy.

### Case Report:

A 35-year-old female patient reported to the Out-Patient Department (OPD) of the National Research Institute of Unani Medicine for Skin Disorders, Hyderabad on 2<sup>nd</sup> November 2020 for Unani treatment, with complaints of pain, tenderness, and stiffness in bilateral proximal interphalangeal, wrist, elbow, knee and ankle joints and swelling in the right knee joint for the past 7 months. She was quite well 7 months back, then she gradually developed pain in both ankle joints, knee joints, pain and stiffness in bilateral proximal interphalangeal, wrist & elbow joints, difficulty in walking, and swelling in the right knee joint. She reported morning stiffness, which gets relieved within 15-30 minutes. She took allopathic treatment from a local general physician for joint pain and got temporary relief, but on stopping medications, she developed severe joint pain. There was no past medical history of trauma, joint pain, infections, fever, hypertension, diabetes mellitus, thyroid disorders, etc. There was no family history of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, childhood arthritis, SLE, etc. She was a non-vegetarian with a good appetite, sound sleep, regular bowel habits, and a moderate hard-working lifestyle. Her age of menarche was 16 years; her menstrual cycle was regular with normal flow. There was no history of pain or per vaginal discharge. The last menstrual

period date was 3<sup>rd</sup> October 2020; she was a multi-gravida and multi-para had three children with full-term normal delivery and last children delivered in 2014. There was no history of abortion and oral contraceptive pills intake.

On physical examination, she appeared unwell with a lean body built (Height: 158cm, Weight: 50kg, BMI: 20 Kg/m<sup>2</sup>), whitish complexion, and her gait was slow, stiff, and painful. Pallor was present. There were no palpable lymph nodes, cyanosis, clubbing, jaundice, or edema. Her vitals were stable. The position of all joints was normal with painful movement restriction on the affected joints.

### Observations and Results:

The patient showed a significant reduction in signs and symptoms of RA after 4 weeks of treatment with *Qurs-e-Mafāṣil*. VAS score for joint pain was 60 (severe pain) at baseline, which reduced significantly to 20 (mild pain) after treatment, swelling in the right knee joint

was completely relieved, and joint tenderness present in 10 joints at baseline was relived in 4 joints after treatment (Table 1).

ESR was high at baseline and significantly reduced to the normal range after 4 weeks of treatment. DAS28 was 5.51 at baseline, indicating high disease activity, which reduced significantly to 2.62 after treatment, indicating low disease activity and very close to remission (Table 2).

The patient had mild anaemia with haemoglobin 10.2 gm/dL at baseline, which was maintained at the same level and no further reduction in haemoglobin was noted after treatment. No clinical adverse effects were reported, and values of all haematological and biochemical safety parameters conducted at baseline and after 4 weeks of treatment were within the normal range (Table 3). The patient did not develop severe joint pain after treatment and had improved quality of life and no further clinical changes were noted during the post-treatment follow-up of 4 weeks.

**Table 1: Reduction in Subjective Parameters**

	Baseline	1 <sup>st</sup> FU	2 <sup>nd</sup> FU	3 <sup>rd</sup> FU	4 <sup>th</sup> FU
VAS Score	60	55	40	30	20
SJC	1	1	1	1	0
TJC	10	10	9	8	6

SJC= Swollen Joint Count; TJC= Tender Joint Count; FU= Follow-up

**Table 2: Reduction in Objective Parameters:**

		Before Treatment	After Treatment
ESR	1 <sup>st</sup> Hour	42	04
	2 <sup>nd</sup> Hour	95	08
DAS28		5.51	2.62
Stage of Disease		High Disease Activity	Low Disease Activity

**Table 3: Effect on Haematological & Biochemical Parameters:**

Parameters	Baseline (0 week)	After Treatment (4 <sup>th</sup> week)
Hb (gm/dL)	10.2	10.2
RBC Count (million/cumm)	4.5	4.7
TLC (Cells/Cumm)	5400	6800

Platelet Count (Lakh/cumm)		3.0	3.2
DLC (%)	Neutrophils	60	61
	Lymphocytes	36	34
	Monocytes	02	03
	Eosinophils	02	02
	Basophils	0	0
Peripheral Blood Smear Examination	Erythrocytes	Normocytic/Hypochromic	Normocytic/Hypochromic
	Leucocytes	WNL	WNL
	Platelets	WNL	WNL
Rheumatoid Factor (Qualitative)		Positive	Positive
CRP(Qualitative)		Negative	Negative
Serum Bilirubin (mg/dL)		0.62	0.37
SGPT (IU/L)		10	11
SGOT (IU/L)		14	16
S. Alkaline Phosphatase (IU/L)		62	71
Blood Urea (mg/dL)		16	22
Serum Creatinine (mg/dL)		0.7	0.8
Urine Examination		NAD	NAD
Serum Uric Acid (mg/dL)		3.8	--
Fasting Plasma Glucose (mg/dL)		89	--

NAD=No Abnormality Detected; WNL=Within Normal Limit

### Discussion:

In Unani system of medicine, the management of *Waja'al-Mafāṣil* (RA) is based on a multi-dimensional approach, including '*Ilāj bi'l Ghidhā*' (Dietotherapy), '*Ilāj bi'l Dawā*' (Pharmacotherapy) and '*Ilāj bi'l Tadbīr*' (Regimenal therapy). The goal of treatment is to reduce morbidity and prevent disability, subsequently improving the quality of life [3,4].

In this case study, treatment with *Qurs-e-Mafāṣil* exhibited a significant reduction in signs and symptoms of *Waja'al-Mafāṣil* (RA) as indicated by the improvement in subjective and objective parameters. There was a significant reduction in joint pain on VAS, ESR, and DAS28 after 4 weeks of treatment. The results showing the efficacy of *Qurs-e-Mafāṣil* in the current study may be credited to the pharmacological activity of the individual ingredients of *Qurs-e-Mafāṣil*. *Asgand* (*Withania somnifera*) possesses immunomodulatory, antioxidant, strength promoting, and adaptogenic properties.

Aqueous extract of *Withania somnifera* roots have ameliorated arthritis in rats by regulating immune mediators of inflammation such as TNF- $\alpha$ , IL-1 $\beta$ , IL-6, transcription factor NF- $\kappa$ B, IL-10 [6,7,8,9]. *Filfil Siyah* (*Piper nigrum*) has analgesic, anti-inflammatory, anti-arthritic, and alterative effects. The active phenolic component in black pepper extract, the Piperine has potent anti-inflammatory, antinociceptive, and antiarthritic effects in an arthritis animal model [6,7,10]. *Suranjan* (*Colchicum luteum*) has shown anti-inflammatory, analgesic, and disease-modifying activity by reducing serum TNF- $\alpha$  levels and expression of pro-inflammatory mediators such as TNF-R1, IL-6, and IL-1 $\beta$  in an animal model of arthritis [11,12]. *Zanjabeel* (*Zingiber officinale*) has proven anti-inflammatory and anti-arthritic potential in pre-clinical studies [13]. Furthermore, *Qurs-e-Mafāṣil* was found safe and well-tolerated by the patient during the 4 weeks of the treatment period, as no hematological and biochemical

derangements were noted and no clinical adverse effects were reported during the entire duration of therapy. The overall results of the present case study suggest that the polyherbal Unani drug, *Qurs-e-Mafāṣil* may provide a safe and effective alternative treatment for rheumatoid arthritis.

### **Conclusion:**

In conclusion, the results of the present case study suggest that *Qurs-e-Mafāṣil* may be a safe and effective Unani drug for the treatment of rheumatoid arthritis, as it significantly reduced the signs and symptoms and lowered the DAS28 from high disease activity at baseline to low disease activity in 4 weeks duration. The potential therapeutic outcome may be attributed to anti-inflammatory, analgesic, anti-arthritis, immunomodulatory, antioxidant, and adaptogenic properties of *Qurs-e-Mafāṣil*.

### **Limitation of Study:**

It was a single case study; a randomized controlled clinical trial on a large sample size with a long duration of treatment needs to be conducted in the future to generate more valid scientific evidence about the therapeutic efficacy and safety of *Qurs-e-Mafāṣil*, so that it could be a potential remedy to treat such a chronic, painful and disabling disorder.

### **Patients consent:**

The written informed consent was obtained from the patient for the treatment and publication of this case report.

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