

Efficacy of Unani Formulations in *Waja-ul-Mafasil* (Rheumatoid Arthritis)- A Randomized Comparative Clinical Study

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Abstract

Arthritis is described in the Unani system of Medicine under the broad term "*Waja'al-Mafasil*," which encompasses various joint disorders, including inflammatory, non-inflammatory, infectious, metabolic, and other musculoskeletal disorders. In the conventional system of Medicine, Rheumatoid arthritis is considered a chronic inflammatory disorder that can affect more than just joints. In India, it affects 15% (180 million) of the population. According to the Unani concept, the pathological changes in the joints are mainly caused by derangement of Akhlat (humoural) temperament and accumulation of Fasid madda (morbid material) in the joint spaces. The aim of the study was to evaluate and compare the efficacy of Group-A & Group-B Medicine in the Management of *Waja-ul-Mafasil* (Rheumatoid Arthritis) and also to provide alternate safe and effective herbal medicines with maximum efficacy and minimal side effects. A randomized comparative clinical study was conducted with 40 participants recruited from the male Outpatient Department (OPD) and Inpatient Department (IPD) of Moalijat (General Medicine) at Government Nizamia Tibbi College & Hospital in Hyderabad. Verbal consent was obtained from patients before examinations and investigations. All participants provided written informed consent prior to the trial. Group A and Group B received medication for 6 months, and pre- and post-trial assessments were conducted using the Student's t-test and paired test. Pre- and post-trial drug efficacy assessment was conducted using VAS. After completion of the trial, a 90% response rate was observed in Group A, whereas Group B showed a 70% response rate (p-value 0.001*), indicating high significance. It was concluded that the response to selected Unani Medicines was better in the early stages of the disease when there are no gross structural changes in the affected joints. However, even in chronic cases, Group-A medicines proved to be more effective than Group-B."

Keywords: *Waja-ul-Mafasil*, Rheumatoid Arthritis, *Khilt Ghar tabayi*, Unani formations

Introduction

Waja-ul-Mafasil (Rheumatoid arthritis) is a chronic inflammatory, destructive, and deforming polyarthritis associated with systemic disturbances, various extra-articular lesions, and the presence of circulating antiglobulin antibodies (Rheumatoid factors). This disease affects peripheral joints, typically following a prolonged course with periods of exacerbation and remission, accompanied by general systemic disturbances. Characterized by swelling of the synovial membrane and periarticular tissue, subchondral osteoporosis, erosion of cartilage and bone, and wasting of associated muscles (1).

Unani Concept of *Waja-ul-Mafasil*

In the Unani system of medicine, it is clear that *Waja-ul-Mafasil* (Rheumatoid arthritis) occurs due to abnormal

humours or reeh. The disease is named after the dominant humor as *Waja ul Mafasil damavi*, *safravi*, *balgami*, *saudavi*, and *reehi* (2). Among these categories, *Balgami* is more dominant and widely seen in patients. The production of abnormal humours has been indicated in modern texts as one of the suspected causes of *Waja ul Mafasil*, but exact causative factors have not been definitively (2, 3).

According to conventional medicine, Rheumatoid Arthritis (RA) is a chronic systemic inflammatory disease of unknown cause that primarily affects the peripheral joints in a symmetric pattern. It is one of the most prevalent forms of chronic inflammatory joint diseases. In its typical form, RA manifests as a symmetrical, destructive, and deforming polyarthritis, impacting both small and large synovial joints.

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The disease is characterized by associated systemic disturbances, various extra-articular features, and the presence of circulating antiglobulin antibodies (rheumatoid factors). Typically, RA follows a prolonged course marked by periods of exacerbation and remission. However, atypical forms of the disease are also common, varying in their clinical presentation and disease progression. (4)

Constitutional symptoms such as fatigue, malaise, and morning stiffness are frequently observed in rheumatoid arthritis (RA). In addition to joint involvement, RA can affect organs such as the skin, heart, lungs, and eyes, posing significant health risks. Joint destruction caused by RA contributes substantially to morbidity and mortality. Treatment options for RA are evolving rapidly, with the introduction of innovative therapies enhancing management strategies (4).

Background

Credit for introducing the term "Rheumatism" is attributed to Galen in the second century A.D. He used it to describe pain caused by the discharge of peccant humours into body cavities or surfaces, with arthritis being just one manifestation. The dropping of these humours into joint cavities was termed "Gout" (from "Gutta," meaning a drop), which initially encompassed various forms of arthritis. It was not until Sydenham that distinct clinical entities were differentiated based on their unique features. Over time, "Rheumatism" evolved to encompass painful disorders affecting the locomotor system, including joints, muscles, fascia, and bones (5-7).

Sahib e Kamil argues that pinpointing the exact causative factor of 'Hadaar' is not feasible. According to Samar Khandi, the 'Madda' responsible for 'Waja ul mafasil' has a thick consistency and is white in color. On the other hand, Shaik Bu Ali Ibn Sina (980-1037) describes this substance as closely resembling pus" (5).

Orthopedics, deriving from the Greek words 'ortho' meaning "straight" or "upright" and 'pedics' meaning "child", was initially coined by Nicholas Andry, a French physician who applied it to the correction of deformities (8). During Andry's era, modern orthopedic surgery did not exist; surgical techniques were primitive compared to today, with sporadic attempts by individuals marking the extent of medical progress since Hippocrates' time (6, 7). A.E. Garrod classified chronic arthritis into two distinct diseases: Osteoarthritis and Rheumatoid arthritis. In 1904, American Goldthwait further categorized arthritis as hypertrophic and atrophic types. E.H. Nicholas and P.L. Richardson later described it as a "Systemic Inflammatory Disease" (8).

In the latter half of the 19th century, significant advancements were made in the field of orthopedics. These included the discovery of Ether Anesthesia by Crawford Long in 1842 and W.T.G. Morton in 1846, which revolutionized surgical practices. Equally pivotal was Sir Louis Pasteur's discovery in the 19th century that bacteria are the causative agents of many diseases, transforming medical understanding. Additionally, Sir Roentgen's discovery of X-rays in 1895 marked a crucial milestone in diagnostic capabilities within orthopedics (8).

Incidence

The worldwide incidence of rheumatoid arthritis (RA) is approximately 3 cases per 10,000 people, with a prevalence rate of around 1%. RA affects all populations, though some groups show higher prevalence rates, such as 5-6% in certain Native American communities, while others, like Black individuals from the Caribbean, exhibit lower rates. First-degree relatives of RA patients have an increased disease frequency of about 2-3%. Concordance in monozygotic twins is approximately 15-20%, indicating significant genetic influence. The relatively consistent global frequency suggests the potential role of a ubiquitous infectious agent in its etiology (1, 4).

Precipitating Factors

"Infection, strain, exposure to cold, surgery, and injury are frequently cited as precipitating factors. Short et al. (1957) identified strain over prolonged periods, often followed by an infection just before the onset of joint symptoms, as the most common combination. As the disease progresses, with or without intermittent remissions, there is a tendency for it to spread and involve the wrists, elbows, shoulders, knees, ankles, subtalar, and mid-tarsal joints. The hip joints become involved primarily in more severe cases, while neck pain and stiffness from cervical spine involvement are common. Occasionally, joints such as the temporomandibular, acromioclavicular, sternoclavicular, and cricoarytenoid can also be affected, as can all synovial joints" (4).

Onset of the Disease

Rheumatoid arthritis presents in various forms: Oligoarticular in 44%, Polyarticular in 35%, Monoarticular in 21%, Insidious Acute in 15%, Systemic in 10%, and Palindromic in 5% of cases. In 10-15% of patients, the disease begins as acute polyarthritis accompanied by severe systemic symptoms. A more gradual systemic onset characterized by fever, weight loss, profound fatigue, and malaise, without joint symptoms, is less common, particularly among middle-aged men. For some patients, the onset is palindromic, involving recurrent acute episodes of joint pain and stiffness in individual joints that last only a few hours or days. Rheumatoid arthritis is classified into three stages based on its onset type" (1, 8).

Stages of the Disease (1)

Acute stage: In the acute form, the condition closely resembles acute rheumatism, but the joints remain swollen, and later assume the typical characteristics.

Sub-acute stage: The sub-acute onset is much the commonest having a classical clinical picture.

Chronic stage: This stage lasts for years and a gradual deformity of the finger develops leading to joint and bone destruction.

Diagnosis (1, 9)

Rheumatoid arthritis is an inflammatory disease that causes Pain, Swelling, Stiffness, and Loss of function in the joints. It has several special features that make it different from other kinds of arthritis.

The American College of Rheumatology developed the following criteria for the classification of RA:

1. Morning stiffness: This occurs in and around the joints and lasts at least 1 hour before maximal improvement.
2. Arthritis of 3 or more joint areas: At least 3 joint areas simultaneously have soft tissue swelling or fluid observed by a physician. The 14 possible areas are right or left proximal interphalangeal (PIP), metacarpophalangeal (MCP), wrist, elbow, knee, ankle and metatarsophalangeal (MTP) joints.
3. Arthritis of hand joints of at least one area swollen in a wrist, MCP, or PIP joint.
4. Symmetric arthritis with simultaneous involvement of the same joint areas on both sides of the body: Bilateral involvement of PIPs, MCPs and MTPs, is acceptable without absolute symmetry.
5. Rheumatoid Nodules: Subcutaneous nodules are present over bony prominences or extensor surfaces or in juxta-articular regions.
6. Serum RF: Abnormal amounts of serum RF are demonstrated by a method for which the result has been positive in fewer than 5% of healthy control subjects.
7. Radiographic changes typical of RA on postero-anterior hand and wrist radiographs, which must include erosions or unequivocal bony decalcification localized in or most marked adjacent to the involved joint: Osteoarthritic changes alone do not qualify.

A patient can be classified as having RA if 4 of 7 criteria are present. Criteria 1-4 must be present for at least 6 weeks, and a physician must observe criteria 2-5. These criteria are intended as a guideline for classification of patients, often for research purposes. They do not absolutely confirm or exclude a diagnosis of RA in a particular patient, especially those with early arthritis. Patients often present with constitutional complaints including malaise, fever, fatigue, weight loss, and myalgias. They may report difficulty performing activities of daily living eg, dressing, standing, walking, personal hygiene, using their hands etc,

Physical examination

Morning Stiffness: Joint stiffness especially if lasting more than 1 hour in the morning after inactivity is prominent, guide to the inflammatory process, so duration of morning Stiffness is often used as a quantitative (9).

Investigations (1,8,9)

Magnetic resonance imaging (MRI) and ultrasound may help diagnose rheumatoid arthritis in the early stages of the disease.

Treatment

There is no cure for rheumatoid arthritis. But clinical studies indicate that remission of symptoms is more likely

when treatment begins early with medications known as disease-modifying antirheumatic drugs (DMARDs).

Objectives

The aim of the study is to Evaluate and compare the efficacy of Group A & Group B Medicine. To provide alternate safe and effective herbal medicines with maximum efficacy and minimal side effects.

Methods

The study of *Waja-ul-Mafasil* (Rheumatoid Arthritis) was carried out with selected Unani medicines at Govt. Nizamia Tibbi College and General Hospital, Hyderabad.

The subjects were selected on the basis of clinical examination, X-rays findings, routine & specific investigations and confirmably by RA factor.

Ethical consideration

Participant recruitment was started after approving research trial by Scientific and Ethical committee of GNTC&H. CTRI was done. IEC No.16/2

Participants and setting

After obtaining IEC approval this study was conducted initially on 60 both male and female patients between 15-65 years of age. Only those cases were selected who satisfied the criteria proposed by American Rheumatism Association (ARA criteria)

Inclusion Criteria:

- Patients both gender between the age group of 15-65 years
- Patients complain of pain, tenderness, morning stiffness lasting longer than 1 hour, limitations of movement, fever.
- The patients presenting with any four of the above symptoms and signs persisting for at least three months duration were included in case study.
- Arthritis involving 3 or more joint
- Bilateral involvement of joint areas (Symmetrical Arthritis)
- Presence of Rheumatoid Nodules over bony prominences
- Positive Serum Rheumatoid factor (RA factor >1:80 titre/ >20 I.U.)
- 7. Radiological changes of Rheumatoid Arthritis.

Exclusion criteria:

The study excluded patients with uncontrolled systemic diseases, known drug allergies, complications of Rheumatoid Arthritis, other joint diseases, as well as pregnant and lactating women. Recruitment and data collection:

Participants were recruited from male OPD and IPD of Moalijat (General Medicine) in Government Nizamia Tibbi College & Hospital, Hyderabad. Final decision for eligibility and all clinical examinations of participants including X-ray,

RA factor and CRP was done before trial. The investigator completed a VAS Score to assess the severity of pain. Patient verbal consent was taken prior examination and investigations. Written informed consent was obtained from all participants before trial.

Study procedure

A special proforma for Waja-u-Mafasil (Rheumatoid Arthritis) was designed for the assessment of demographic data like Age, Sex, Socioeconomic status, temperament, chronicity, duration of complaints and response of medicines of both groups were discussed after observing the cases in details.

Randomization and intervention

This study was a Randomized Comparative Clinical study. Total 40 cases were enrolled and divided into two groups as Group-A and Group-B.

Criteria for the selection of the drugs

The drugs were selected based on their temperament, pharmacological activities, easy availability and least or no side effects. The selected drugs were identified and confirmed before the eminent and expert professors and readers of P.G, Department of Moalijat, Government Nizamia Tibbi College, Hyderabad.

Group-A Medicine consists *munzij*, *mushil*, *tabreed*. *Safoof e mafasil* (as analgesic & tonic), and *rogghan e mafasil* (locally acting analgesic). Medicine given in the form of decoction, fine powder orally and oil for massage. (10,11)

Group-B only *Safoof & Rogghan* was used to treat patient symptomatically. Considering the etiology and progress of the disease and its main symptoms in both Unani and modern medicine the therapeutic drug plan was designed. The drugs selected have the following properties.

Munzij (Coctive), *Mohallil* (Resolvent), *Musakkin Auja* (Analgesic), *Muqawwi Azae Rayeesa wa Asab* (Tonic to vital organs and nerves)) *Mulatif* (Demulcent), *Musaffi* (Blood purifier), *Mushil* (Purgative), *Mubarid* (Relaxant). (11-13)

Route of administration of trial drugs

The administration of Group-A medicines i.e., *Munzij* (*Beeq-e-Azqar*, *Beeqe-Karafs*, *Tewaaj*, *Suranjan Shereen*), *Mushil* (*Turbud*, *Barg-e-Sana*, *Magz Amaltas*), *Tabreed* (*Bahidana*, *Isapghul*), *Safoof* (*Magz-e-Gajga*, *Asgand*, *Chobchini*, *Zaraband*), *Rogghan* (*Roghan-e-Kunjad*, *Zakhum*) and Group - B medicines i.e., *Safoof* (*Magz-e-Gajga*, *Asgand*, *Chobchini*, *Zaraband*), *Rogghan* (*Roghan-e-Kunjad*, *Zakhum*) have proved that they were effective and can reverse the pathological process and stops progression of disease by its anti-Rheumatoid Property (8).

Group-A: Ingredients:

Oral Administration:

Munzij contains *Beeq-e-Azqar*, *Beeqe-Karafs*, *Tewaaj*, *Suranjan Shereen*. (14,15)

Mushil comprises of *Turbud*, *Barg-e-Sana*, *Magz Amaltas* (14)

Tabreed was given with *Bahidana*, *Isapghul*

Safoof: *Magz-e-Gajga*, *Asgand*, *Chobchini*, *Zaraband* used as *Muqavvi and musakkin wo muhallil* . (14)

Local Application:

Rogghan : *Roghan-e-Kunjad*, *Zakhum* was used to prepare oil for massage.

Group-B: The Ingredients include

Safoof: *Magz-e-Gajga*, *Asgand*, *Chobchini*, *Zaraband* for oral use (19)

Local application

Rogghan: *Roghan-e-Kunjad*, *Zakhum* for massage (18)

Beeq-e-Azkhar, *Beeq-e-Karafs*, *Suranjan Shereen* and *Teewaj as munzij*; (16) *Turbud sufaid*, *Barg-e-Sana* and *Amaltas* was selected (11).

Comparative study has been made between the two groups. The patients were asked to fill up a diary about the use, relief of symptoms and any side effects and to inform any serious adverse event immediately by phone or in person and the inferences were observed and recorded in CRF.

Method of preparation of *munzij* of both groups:

All the medicines are grinded and powdered to use as decoction, the powder of said medicine is to be soaked in 200ml of water over night. In the next day morning water is boiled till it remains 100ml. The decoction is to be used lukewarm before breakfast daily for about 21 to 30 days.

Tabreed

The medicines are soaked in 100ml of water for 2-3hrs and advised to be taken twice daily after filtering it, *tabreed* to be taken in between two *mushils* and then after for two more days.

Preparation of Oil

The root of *zakhum* are taken in vessel containing *rogghan e kunjad* and fried till red and remove the burned roots from the oil and the *rogghan* is ready to apply. 10-15 ml of oil to be massage twice daily or as per the number of joints involved till the pain subsides.

Duration of study was 3-6 months.

Follow-up visits

The participants were asked for weekly follow up during trial to assess the severity of the sign and symptoms by VAS scales. Drug accountability was done by asking the patient to come with unused drug on each visit. After completion of trial reassessment of sign and symptoms were done by both clinical and laboratory findings to assess the response of drugs of both groups.

Sample size and statistical analysis

The sample size was calculated using normal values of variables. Mean and SD of variable obtained from previous study. Level of significance = 5%, Power = 80% and a 10% probable drop in the sample. Type of test = Double group study. Sample size was estimated for two groups study using 'z' test as basic premise. Formula of calculating sample size is: $n = [(Z\alpha/2 + Z\beta)^2 \times \{2(\sigma)^2\}] / (\mu_1 - \mu_2)^2$ Data analysis was performed by using student 't' test and paired proportion test was used to compare the response before and after trial.

Recruitment and follow up

The participants were recruited and follow up was done. All the participants were instructed to visit at every week for three weeks during the trial and one month after trial completion

Baseline characteristics

The baseline characterizes of the participants were almost similar before and after trial.

Outcome

After completion of trial 90% response was observed in Group A and in Group B 70% was observed (p value 0.001*) which was highly significant. (Table 2) Assessment of the response was done by using VAS scales before and after trial. (Table 3) The response with the selected Unani Medicines is better in the early stages of the disease when there are no gross structural changes in the affected joints. However, even in chronic cases, Group-A medicines proved to be effective

Safety

No specific side effects were noted in all the cases treated with Group A & B Medicines except mild gastric irritation in few cases, which was corrected by adding Qurs-e-Zaranbad. This again proves that our unani medicines are safe, cheap and effective in treating acute as well as chronic cases as compared to that of modern medicines which definitely produces alarming side effects.

Results

Waja-ul-Magfasil (Rheumatoid Arthritis), is a significant public health concern. The study of was carried out with Unani Medicine at Govt. Nizamia Tibbi College & General Hospital, Hyderabad. The details of observation are discussed below:

Sex distribution

Out of 40 cases observed 11 cases are males and 29 are females. This indicates that RA is 3 times more common in females as compared to males. (Table 1.)

Table 1. Distribution of the patients according to Gender

Sl.No	Gender	No. of patients	Percentage
1.	Male	11	27.50%
2.	Female	29	72.50%
3.	Total	40	100%

Age

In our study regarding age maximum number of patients are recorded in the age group of 46-55 as shown in Table No. III. Out of 40 cases observed 13 belongs to this group that amounts to 32.5%. The next most susceptible group is 26-35 & 36-45 years having 22.5% and 22.5%. In age groups 15-25 and 56-65 and above only few cases are recorded. It is cleared that Waja-UL-MAFASIL (Rheumatoid Arthritis) is more common in 26 — 45 years of life span. (Table 2)

Table 2. Distribution of the patients according to Age group

Sl.No	Age group	No. of patients	Percentage
1.	15-25	6	15%
2.	26-35	9	22.5%
3.	36-45	9	22.5%
4.	46-55	13	32.5%
5.	56-65	3	7.5%
	Total	40	100%

Socio Economic Status (SES)

Maximum number of patients reported belongs to Middle income group i.e., 30(75%) cases out of 40 cases and 4 cases (10%) falls in High income group and about 6 cases (15%) belong to Low income group. The above findings shows that the Middle-income group has got more susceptibility to Waja-UL-MAFASIL (Rheumatoid Arthritis). According to Kuppaswami scale (Table 3.)

Table 3. Distribution of the patients according to Socioeconomic Status

Sl.No	SES	No. of patients	Percentage
1.	High income group	4	10%
2.	Middle income group	30	75%
3.	Low-income group	6	15%
	Total	40	100%

Mizaj (Temperament)

Certain parameters are used for the assessment of the mizaj. Out of 40 cases, 26 i.e (65%) patients belong to Balghami Mizaj As stated by Avicenna that people with Balghami Mizaj are more susceptible to Waja-ul-Mafasil (Rheumatoid Arthritis) and remaining i.e. 11 (27.5%) were found with Damvi mizaj and only 3 (7.5%) were found with Safravi 129. No patient were found with Saudavi Mizaj. (Table 4.)

Table 4. Distribution of the patients according to Mizaj (Temperament)

Sl.No	Mizaj (Temperament)	No. of patients	Percentage
1.	Damvi	11	27.5%
2.	Balghami	26	65%
3.	Safravi	3	7.5%
4.	Soudavi	-	-
	Total	40	100%

Signs and Symptoms

In this study it was found that 100% of cases i.e. 40 cases had definite Pain and Tenderness in Joints. The next

important symptom was Swelling in which about 85% (34 cases) showed swelling in affected joints. Then comes Morning stiffness which accounts for about 83% (33 cases). Besides other symptoms like limitation of Joints and fever were also seen in 50% (20 cases) and 55% (22 cases). All these were helpful in diagnosing the disease. By observing these cases is evident that Pain, Tenderness, joint swelling, and Morning Stiffness are major clinical manifestations that were helpful in diagnosing the disease. (Table 5.)

Table 5. Distribution of the patients according to sign and Symptoms

Sl.No	Sign and Symptoms	No. of patients	Percentage
1.	Pain	40	100%
2.	Tenderness	40	100%
3.	Swelling	34	85%
4.	Morning Stiffness	33	83%
5.	Limitations of movement	20	50%
6.	Fever	22	55%

Onset of the Disease:

As per the observations, out of 40 cases, 33 cases (82%) had insidious onset of signs and symptoms of the disease whereas 7 cases (18%) had sudden onset of signs and symptoms of the disease. (Table. No. 6)

Table 6. Distribution of the patients according to onset of the disease

Onset	Female	Male	No. of patients	Percentage
Sudden	5	2	11	18%
Insidious	23	10	29	82%
Total	28	12	40	100%

Family History:

Out of 40 patients selected for clinical trial, only 9 cases noted with family history This indicates that Waja-ul-Mafasil (Rheumatoid Arthritis) is not a disease which runs in families. (Table. No. 7)

Table 7. Distribution of the patients according to family history

Family History	No. of patients	Percentage
Present	9	22.5%
Absent	31	77.5%
Total	40	100%

Table 9. Response of Group-A Medicine

Sl.No	Sign and Symptoms	No. of Patients	Duration of relief	Recurrence	Percentage
1.	Pain	20	25-30 days	3	85%
2.	Tenderness	20	25-30 days	2	90%
3.	Swelling	16	40-45 days	2	87.5%
4.	Morning Stiffness	18	30 days	Nil	100%
5.	Limitations of movement	10	50-60 days	2	80%
6.	Fever	8	20 days	Nil	100%

CRP protein and RA Factor:

Out of 40 cases, 28 cases (70%) were found to be RA positive and 24 cases (60%) were found to be CRP positive patients. As per the observation out of 28 cases of RA Positive, 5 were Males and 23 were females and out of 24 cases of CRP Positive, 4 were Males and 20 were Females. (Table. No.8)

Table 8. Distribution of the patients according to RA and CRP+ve

Investigation	Female	Male	Percentage
CRP	20	4	60%
RA +ve	23	5	70%
Total	28	12	100%

Group-A. Response:

All the 20 cases that were treated under Group A Medicine presented "with complaint of pain, tenderness, swelling, morning stiffness and limitation of Movements, for a period of 30-60 days. After treatment it was found that pain, Morning stiffness and tenderness were subsided by 25-30 days. Swelling in joints subsided with in 40-45 days. Limitation of movements in joints subsided with in 50-60 days and low grade fever subsided with in 20 days of treatment. (Table. No. 9).

All the 20 cases treated under Group B Medicines were presented with a complaint of pain (20 cases), tenderness (20 cases), swelling (16 cases), morning stiffness (18 cases) and limitation of movements (10 cases). After treatment it was found that swelling in joints subsided by 45 days of treatment. Pain, tenderness and morning stiffness in joints disappeared by 40-50 days. Limitation of movements subsided with in 60 days of treatment and low grade fever (7 cases) subsided with in 20 days. (Table. No.10).

Therapeutic outcome:

Assessment of the response was done before and after trial in both groups. Results were analyzed based on subjective and objective parameters. In this study before trial the overall response of the Group-A and Group-B drug was assessed in terms of subjective and Objective parameters. It was inferred that Group A drug effect was found 90%, whereas Group-B Medicine has 70% effect. Overall the response of both groups Medicine was found effective and the p value is 0.005. (Table. No. 11)

Table 10. Response of Group-B Medicine

Sl.No	Sign and Symptoms	No. of Patients	Duration of relief	Recurrence	Percentage
1.	Pain	20	40-50 days	6	70%
2.	Tenderness	20	40-50 days	6	70%
3.	Swelling	16	45 days	5	75%
4.	Morning Stiffness	18	40-50 days	6	100%
5.	Limitations of movement	10	60 days	4	80%
6.	Fever	5	20 days	2	60%

Table 11. Response of Group-A and Group-B medicines

Groups	No of Patients treated	Total relief in Sign and Symptoms	No relief in Sign and Symptoms	Percentage
Group-A	20	18	2	90%
Group-B	20	14	6	70%

Efficacy of the test drugs:

The results are encouraging with both preparations. The cases have been followed up to note, any recurrence or relapse of the disease. It is observed on followup that the Group-A medicines got more encouraging result when compared to Group-B medicines.

In *Waja-ul-Mafasil* (Rheumatoid Arthritis) due to disturbance of Humours, swelling, pain, morning stiffness, tenderness appears in succession which either appears suddenly or most commonly the course of this disease is insidious in onset.

Group- A: All the 20 cases that were treated under Group-A Medicine presented with complaint of pain, tenderness, swelling, morning stiffness and limitation of movements, for a period of 30-60 days. After treatment it was found that pain, morning stiffness and tenderness were subsided by 25-30 days. Swelling in joints subsided with in 40-45 days. Limitation of movements in joints subsided with in 50 60 days and low grade fever subsided with in 20 days of treatment.

Group- B: All the 20 cases treated under Group-B Medicines were presented with a complaint of pain (20 cases), tenderness (20 cases), swelling (16 cases), morning stiffness (18 cases) and limitation of movements (10 cases). After treatment it was found that swelling in joints subsided by 45 days of treatment. Pain, tenderness and morning stiffness in joints disappeared by 40-50 days. Limitation of movements subsided with in 60 days of treatment and low grade fever (7 cases) subsides with in 20 days. After detailed observation of 20 cases Under Group-A, 18 cases i.e., 90% showed total symptomatic relief after treatment. Out of 20 cases Under Group-B, 14 cases i.e., 70% showed total symptomatic relief after treatment.

After detailed study of clinical observation and discussion it is concluded that according to sex distribution *waja-ul-mafasil* (Rheumatoid Arthritis) is more common in females than in males. Maximum number of cases reported belongs to middle class group. According to age, it is clear that *Waja-ul-mafasil* affects all ages but patients in 2" to 4" decades suffers more. According to temperament, peoples with *Balghami Mizaj* are more susceptible to *Waja-ul-Mafasil*. Cases according to symptoms showed pain, tenderness, swelling of joints and morning stiffness as major

clinical manifestation which were helpful in diagnosing the disease.

Discussion

The study of *Waja-ul-Mafasil* (Rheumatoid Arthritis) was carried out with selected Unani medicines from the OPD of Department of Moalejat, Govt. Nizamia Tibbi College and General Hospital, Hyderabad.

The clinical study and review of literature presented in this thesis provide certain important and fruitful information for understanding the disease and its management with the help of unani medicines (16).

After detailed study of clinical observation and discussion it is concluded that according to sex distribution *Waja-ul-mafasil* (Rheumatoid Arthritis) is more common in females than in males.

Maximum number of cases reported belongs to middle class group.

According to age, it is clear that *waja-ul-mafasil* affects all ages but patients in 2nd to 4th decades suffers more.

According to temperament, peoples with *Balghami Mizaj* are more susceptible to *Waja-ul-Mafasil*.

Cases according to symptoms showed pain, tenderness, swelling of joints and morning stiffness as major clinical manifestation which were helpful in diagnosing the disease.

According to chronicity, *waja-ul-mafasil* is regarded as chronic disease.

During the clinical trial, it was observed that ESR was found to be raised in all 40 Cases. RA Factor was positive in 30 patients from both group patients.

After treatment only 10 were found negative values for RA Factor most of them from those patients who are on Group-A medicines. RA Factor was positive in 30 patients from both group patients and after treatment it is concluded that 10 cases gave negative values for RA Factor most of them from those patients who are on Group A medicines.

C-Reactive Protein was found to be positive in 26 patients. After treatment 6 from Group-A and 3 from Group-B were found negative. It is concluded that clinical findings disappeared but pathologically reports showed abnormality after treatment in majority of cases.

The results are encouraging with both preparations. The cases have been followed up to note, any recurrence or relapse of the disease. It is observed on followup that the Group-A medicines got more encouraging result when compared to Group B medicines (16, 17, 19).

The study on the efficacy of drug in waja-ul-mafasil was divided into two groups ie Group-A and Group-B. 20 cases were studies from each group with different aged patients (20, 21).

The response with the selected Unani Medicines is better in the early stages of the disease when there are no gross structural changes in the affected joints. However, even in chronic cases, Group-A medicines proved to be efficient.

Conclusion

This study concluded that during clinical trial on *Waja-ul-Mafasil* explores knowledge regarding the diisease pathology, its progress, complications, changes on other system involved secondary to Rheumatoid Arthritis and effect of selected unani medicines as advised by ancient physicians in different classical texts regarding the line of treatment in chronic cases as per the dominance of *akhlat* was proved clinically.

It also concluded that the response of Group-A unani medicines was excellent compared to that of Group-B medicines. Recurrence was less in cases treated with group-A medicines.

It was also observed that drugs were more effective in early stages of disease when

Conflict of interest statement

We declare that we have no conflict of interest

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