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## Therapeutic Effects of Eight *Unani* (Herbal) Drugs in the Patients of *Waj-ul-Mafasil* (Rheumatoid Arthritis) in the Development of *Nuzj* (Purgation) and Maintenance of pH of Urine - A Randomized Open Controlled Study

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### Abstract

The aim of this study was to assess the clinical effects of eight *Unani* (Herbal) drugs in the form of decoction in the patients of *waj-ul-mafasil* (Rheumatoid Arthritis (RA) in the development of *nuzj* (purgation) and maintenance of pH of urine in a randomized open controlled study. The diagnosis of RA was made as per American Rheumatology Association (ARA) criteria. The patients on test group were put on test drugs and control patients on control drug. The study was carried out at Department of *Moalijat*, Faculty of Medicine (*Unani*) and *Majeedia* Hospital, *Jamia Hamdard* (*Hamdard* University), New Delhi, India on 30 patients of rheumatoid arthritis, diagnosed and selected as per American Rheumatoid Association (ARA) criteria, divided in two groups namely test and control, with 15 patients in each, were included in the study. The patients in test group received decoction twice daily of the botanically identified eight *Unani* (herbal) drugs namely Badyan (seeds of *Foeniculum vulgare* Mill), Baikhe Badyan (roots/stem of *Foeniculum vulgare* Mill), Tukhme Kasni (seeds of *Cichorium intybus* Linn), Baikhe Kasni (roots of *Cichorium intybus* Linn), 5 gm each, Suranjan (*Colchicum luteum* Baker), 3 gm, Mawiz munaqqa (*Vitis vinifera* Linn), 7 No, Turbud safed (*Operculina turpethum*), 5gm and Barge sana (leaves of *Cassia senna* Linn), 5 gm and control patients got standard *Unani* pharmacopeial drug for arthritis along with an Oil for local application for arthritis. The decoction of eight *unani* (herbal) drugs in randomized open controlled study has been found to be effective in the recovery of signs and symptoms of RA, development of *nuzj* (purgation) and maintenance of pH of urine in the patients of test group. The study was carried out during PG study in *Moalijat* at Department of *Moalijat*, Faculty of Medicine (*Unani*) and *Majeedia* Hospital, *Hamdard* University, New Delhi, India from August, 2005 to July, 2007. The details have been presented in the paper.

**Keywords:** therapeutic effects; *unani* (herbal) drugs; *waj-ul-mafasil*; maintenance; pH; urine:

### 1. Introduction

Rheumatoid arthritis (RA) is one of the commonest inflammatory diseases<sup>[1, 2]</sup> affecting joints in a balanced way, usually develops slowly between the age of 20 and 45 with 75% of patients being women. It is an extremely common disorder and affecting 0.5 to 3.8% women and 0.15 to 1.3% men<sup>[3]</sup> with worldwide incidence of 0.09% in India, 0.09% in US, 0.91% in UK and 0.09% in Canada<sup>[4]</sup>. The inflammatory process initially produces tenderness, soreness, stiffness, swelling and eventually destruction of the cartilage and bone. RA usually affects joints in a balanced way, if one knee is affected; the other knee is also affected. Rheumatoid arthritis is self-prorogated by the free radicals released by the neutrophils. This is further accentuated by decrease of "scavengers" which protect aerobic organisms against the potential and deleterious effects of free radicals in joint cavity that mop up the free radicals<sup>[5]</sup>. As per *Unani* conventional and literal explanations, arthritis is defined as the pain which occurs in different joints of the body especially in the joints of arms and legs etc<sup>[6-11]</sup> and the description of disease is based on the four-humor doctrine of *Unani* Medicine. The pathological changes in the joints are caused mainly by derangement of temperament of humors, which leads to accumulation of morbid materials into the joint spaces<sup>[6, 8, 12-15]</sup>. The pain in the joints is sometimes accompanied by with or without swelling. The morbid materials develop contractures also. Hippocrates says that the chronic illness like arthritis arises from the accumulation of toxic materials<sup>[16]</sup>.

The principal of treatment of arthritis is '*tanqiya*' i.e., cleansing and evacuating of morbid materials out of the body through *munzij wa mus'hil* (concoctive and purgative) drugs which help correct deranged temperament<sup>[15]</sup> by the complex process of detoxification<sup>[17]</sup>. The mode of action of concoctive and purgative drugs may be detoxification and excretion of

morbid materials out of the body. The free radicals may also be one of these morbid materials. Detoxification helps purges the digestive tract of accumulated waste and fermenting bacteria, the body systems especially the growth hormone and it stimulates the immune system [18]. For this purpose of the study, 30 patients of rheumatoid arthritis diagnosed as per ARA criteria were selected and divided into two groups, namely test and control groups with 15 patients in each group. The patients in the test group were given the decoction twice daily of botanically identified eight crude *Unani* drugs namely, Badyan (seeds of *Foeniculum vulgare* Mill), Baikhe Badyan (roots/stem of *Foeniculum vulgare* Mill), Tukhme Kasni (seeds of *Cichorium intybus* Linn), Baikhe Kasni (roots of *Cichorium intybus* Linn), 5 gm each, Suranjan (*Colchicum luteum* Baker), 3gm, Mawiz munaqqa (*Vitis vinifera* Linn), 7 No, Turbud safed (*Operculina turpethum*), 5 gm and Barge sana (leaves of *Cassia senna* Linn), 5 gm and control patients got standard *Unani* pharmacopeial drug meant for arthritis. The standard local application in the form of Oil over affected joints was given to the patients in both groups. The study was carried out during PG study in *Moalijat* at Department of *Moalijat*, Faculty of Medicine (*Unani*) and *Majeedia* Hospital, *Jamia Hamdard*, New Delhi, India from August, 2005 to July, 2007. No such research has ever been conducted in *Unani* System of Medicine in India and no any other Thesis written before on this topic, so it is very new and unique work of its kind in India.

## 2. Materials and Methods

For the randomized open controlled study, 30 patients of rheumatoid arthritis, diagnosed and selected as per American Rheumatoid Association (ARA) criteria were divided in two groups namely test group and control group, with 15 patients in each. The duration of study was one year and duration of protocol therapy was 28 days.

### 2.1. Method of Preparation of Decoction:

The patients in test group were given decoction made in 250 ml of water, twice daily of the following botanically identified eight *Unani* (herbal) drugs e.g., as under:

1. Badyan (seeds of *Foeniculum vulgare* Mill) 5 gm
2. Baikhe Badyan (roots/stem of *Foeniculum vulgare* Mill) 5 gm
3. Tukhme Kasni (seeds of *Cichorium intybus* Linn) 5 gm
4. Baikhe Kasni (roots of *Cichorium intybus* Linn) 5 gm
5. Suranjan (*Colchicum luteum* Baker) 3gm
6. Mawiz munaqqa (*Vitis vinifera* Linn) 7 No
7. Turbud safed (*Operculina turpethum*) 5 gm
8. Barge sana (leaves of *Cassia senna* Linn) 5 gm

The first six drugs of eight drugs mentioned above were soaked in 250 ml water at room temperature in evening for ten hours and boiled in the morning at 100 degree for 01 minute and decoction was filtered through 60 No. sieve, set to cool for 05 minutes and was given with 10 ml honey, in the morning empty stomach half-an-hour before breakfast and repeated in the evening at 5 pm by the same method for 28 days. The last two drugs of eight drugs mentioned above were added with the six drugs on three alternate days (i.e., 23<sup>rd</sup>, 25<sup>th</sup> and 27<sup>th</sup> day) and decoction given on 24<sup>th</sup>, 26<sup>th</sup> and 28<sup>th</sup> day in the same method. The patients in control group were given a standard compound drug meant for arthritis, 2 pills orally twice daily along with local application of above oil for 28 days. The patients were followed up on the day 0 (date of registration), 7, 14, 21 and day 28 (on day of completion of study). Before start of the study, informed consent from the patients on Prescribed

Format on each CRF of the Protocol and also Ethical Clearance from the Institutional Ethical Committee, *Jamia Hamdard*, New Delhi, India was obtained. Each patient was provided Computer Generated Patient ID from Registration Department, *Majeedia* Hospital, *Jamia Hamdard*, New Delhi in order to maintain privacy and confidentiality of each patient in both test and control groups. The patients in test group were admitted in *Majeedia* Hospital, *Jamia Hamdard*, New Delhi for the purpose of *Mus'hil* Therapy on 03 alternate days in order to see the onset and appearance of *nuzj* in these patients. The pH level of patients was measured in the Pathology Laboratory of this Hospital on weekly bases with the help of standard pH paper and was the readings were recorded in the Chart in the CRFs

### 3. Observations

Out of total 30 patients of rheumatoid arthritis in both test and control groups, the maximum, 09(30.00 %) cases were found in the age group of 21-30 followed by 08 (26.66 %) in the age group of 41-50, then 06(20.00%) in the age group of 31-40, 03(10.00%) in the age group of 51-60 and 02 (06.66%) in each in age group of up to 20, and >60 years (Table 1).

#### 3.1. Distribution of the patients according to the Age in both groups

Table 1

		Groups		Total
		Test	Control	
Age in groups	Up to 20		2	2(06.66%)
	21-30	4	5	9(30.00%)
	31-40	3	3	6(20.00%)
	41-50	5	3	8(26.66%)
	51-60	3		3(10.00%)
	>60		2	2(06.66%)
Total		15	15	30

The mean age range was found to be 40.33±12.05 years in test group and 36.07±15.38 years in control group with  $p=0.405$ (Table 2).

#### 3.2. Mean Age in both groups (Group Statistics)

Table 2

	Group	Mean	Std. Deviation	
Age	Test	40.33	12.05	P=0.405 (t-test, unpaired)
	Control	36.07	15.38	

Out of 30 patients of rheumatoid arthritis, 10(33.33%) were male and 20(66.66%) were female and male to female ratio was 1:1.5. Out of 15 patients in test group, 03(20.00%) were male and 12(80.00%) were female and similarly out of 15 patients in control group, 07(46.66%) were male and 08(53.33%) were female with  $p=0.12$ (Table 3).

#### 3.3. Distribution of the patient according to the Sex

Table 3

		Group		Total
		Test	Control	
Sex	Male	3	7	10(33.33%)
	Female	12	8	20(66.66%)
Total		15	15	30
$p=0.12$				

#### 4. Results

The weekly pH level of 15 patients in test group has variable pattern and at the end of therapy, it remained between the ranges of 5 to 6.5, which is towards less acidic in nature, i.e., nearly normal maintainable pH level.

#### 5. Discussion

Rheumatoid arthritis (RA) is one of the commonest inflammatory diseases and usually develops slowly between the ages of 20 and 45. More than 75% of patients are women [1, 2]. This occurs in about 1% of the population [3]. RA is an auto-immune disorder of unknown etiology. As per *Unani* conventional and literal explanations, arthritis is defined as the pain which occurs in different joints of the body especially in the joints of arms and legs, etc [6-11]. The description of disease is based on the four-humor doctrine of *Unani* Medicine. The pathological changes in the joints are caused mainly by derangement of temperament of humors, which leads to accumulation of morbid materials into the joint spaces [6, 8, 12-15].

In *Unani* literature, much emphasis has been given for the usage of *munzij wa mu'hil* (concoctive and purgative) drugs in the treatment of various disorders including arthritis with certain specific conditions to produce *tanqiya* or detoxification of the body from ill effects or morbid humor/s. *Tanqiya* is a complex process in the body by which the morbid and diseased materials are taken out of the body by way of evacuation, a complex phenomenon under certain environmental conditions under vigil of a physician with the help of various simple *unani* drugs having *munzij* and *mus'hil* (concoctive and purgative) effects under a very specific set of *unani* guidelines (*unani* principles for this complex process) for a certain period of time depending upon the chronicity, nature of the disease and type of *khilt*(humor) involved therein. Therefore, a specific formulation (regimen) was prepared using eight drugs namely, *Baikhe kasni* (root of *Cichorium intybus* Linn), *Kasni* (seeds of *Cichorium intybus* Linn), *Baikhe badiyan* (root of *Foeniculum vulgare* Mill), *Badiyan* (seeds of *Foeniculum vulgare* Mill), *Mawiz munaqqa* (*Vitis vinifera* Linn), *Suranjan* (*Colchicum luteum* Baker) --- - concoctive drugs and *Turbud* (*Operculum turpethum*) and *Barge senna* (*Cassia senna* Linn --- purgative drugs for oral use in the form of decoction as test drug in 15 patients in test group of RA. The beneficial effects of test formulation in the signs and symptoms of RA observed were due to analgesic and anti-inflammatory effects of *Colchicum luteum* [19-21] and *Operculina turpethum* [22] widely used as anti-rheumatic drug. It could also be due to the anti-oxidant and energizing effects of the drugs like *Colchicum luteum*, *Foeniculum vulgare*, *Operculina turpethum*, *Cichorium intybus*, *Vitis vinifera*, *Cassia senna* [19, 22-27] which maintain a balance between the formation of free radicals and their utilization in the body or elimination from the body by the complex mechanism of concoction and purgation since free radicals are responsible for the development of RA.

During the intervention of test formulation, it was found that besides recovery in the signs and symptoms of RA, it had played a role in the development of *nuzj* (purgation) and maintenance of pH of urine. *Nuzj* had started in the urine in the second week in 01(06.66%) patient and 03(20%) patients in third week. The sign of *nuzj* in second week was incomplete with appearance of mild turbidity shown as N(T) in the brackets. Similarly it was again incomplete *nuzj* on third week in three patients with no full turbidity in their urine. However, in forth week, out of 15 patients, 12(80%) patients had developed complete sign of *nuzj* with full turbidity in their urine which has been shown as N(TT) in the brackets which stand for full and complete turbidity in the urine and N-outside brackets represent the presence of *nuzj* in the urine (Table 4).

#### 5.1. Therapeutic Effects on the Sign of *Nuzj* in the Urine in Test Group on Day 0, Day 7, Day 14, Day 21, and Day 28

Table 4:

S. No.	Sign of <i>Nuzj</i> in Urine in Test Group				
	Day 0	Day 7	Day 14	Day 21	Day 28
1.	...	...	...	N(T)*	N(TT) **
2.	...	...	...	N(T)	N(TT)
3.	...	...	...	...	...
4.	...	...	...	...	N(TT)
5.	...	...	...	...	N(TT)
6.	...	...	N(T)	...	N(TT)
7.	...	...	...	...	...
8.	...	...	...	...	N(TT)
9.	...	...	...	...	N(TT)
10.	...	...	...	...	N(TT)
11.	...	...	...	...	N(TT)
12.	...	...	...	N(T)	N(TT)
13.	...	...	...	...	N(TT)
14.	...	...	...	...	N(TT)
15.	...	...	...	...	...

N (T)\*- indicates the appearance of *nuzj*. Bracketed-T shows slight turbidity.

N (TT) \*\* - indicates complete sign of *nuzj*. Bracketed-TT shows full turbidity in the urine.

It could be because test formulation had helped in keeping a correct balance between the formation of free radicals and their utilization within the body. The test formulation had its effect in bringing pH level of urine from 4(higher acidic) to 6.5(nearly alkaline) which is indicative of the fact that it had facilitated the morbid materials to be excreted out of the body thus providing a near balance of pH inside the body because a balance of pH is must for the maintenance of health (Table 5).

#### 5.2. Therapeutic Effects of Test Formulation on maintenance of pH of Urine in Test Group on day 0, day 7, day 14, day 21 and day 28

Table 5:

S. No.	pH on Day 0	pH on Day 7	pH on Day 14	pH on Day 21	pH on Day 28
1.	6.5	7.2	4	6	6.4
2.	7	6.7	6.5	7.4	6
3.	6.5	5	6	5.5	6
4.	4	5.8	5.5	5.5	6
5.	6	6	6	6.2	5
6.	6	6.4	6.2	6	6

7.	6	5.5	6.2	6	6.5
8.	5	4	5	5.6	6
9.	6	6	6.8	6.8	6.2
10.	6	6.2	4	4.6	6
11.	6	6	6.5	6.6	6.5
12.	5.5	6	6.2	6.4	6
13.	5.3	6	5.5	5.5	5
14.	5.5	6	5.5	5.5	6
15.	5.5	6	6	5.5	5.5

(Note: pH level in Urine had been maintained between 5 to 6.5 at the completion of Test Formulation (Day 28))

Because if the pH inside the body is maintained towards lower acidic (pH 6.5) to weak alkalinity (pH 7), then usually diseases do not occur. The test formulation acting as anti-oxidant must be reducing the level of oxidative stress and acting as scavengers to mop out the free radicals from the body leading to the stress free state to the already loaded damaged tissues and muscles of the joints in RA thus maintaining near balance pH in the body and of course in the urine. A number of gut induced toxins including endo-toxins (cell wall compounds of bacteria, byproducts of bacteria, candida albicans, and yeast compounds) are also evacuated out due to purgation<sup>(28)</sup> thus bringing a balance of pH inside the body free of diseases. In other words, the pH in many biological experiments often needs to be kept constant in the range of pH 6-8. The kidneys also play an important role in the maintenance of acid-base balance by adjusting the excretion of acid or base in the urine, so that the pH of urine can normally vary from 4.8 to 7.5.

The extracellular fluid is usually slightly alkaline at pH 7.4 while the average cytoplasmic pH of many animal cells is about pH 6.8 that at 37° C is neutral. It is almost certain that the pH in the organelles will differ from 6.8 and the pH at most membrane surfaces will be lower than this due to the absorption of H<sup>+</sup> on the negatively charged surface. The importance of pH control is nicely illustrated in human blood, which must be kept within narrow limits for life and even narrower limits for health. Since the test formulation had maintained pH level from 5 to 6.5 within the body and also of urine, thus it had provided better effect among the patients in test group. The test formulation acting as anti-oxidants must be reducing the level of oxidative stress and acting as scavengers to mop out the free radicals from the body leading to the stress free state in the body including urine and it is here that free radicals are acting as morbid materials which disturb the pH of the body also of urine. It is also possible that the test formulation had helped in keeping a correct balance between the formation of free radicals and their utilization within the body that is why a considerable balance of pH inside the body had been maintained. It had also tried to maintain the pH of the digestive system thus clearing the body of free radicals.

## 6. Inference

**6.1.** The decoction of eight *unani* (herbal) drugs in randomized open controlled study has been found to be effective in the recovery of signs and symptoms of RA, development of *nuzj* (purgation) and maintenance of pH of urine in the patients of test group.

**6.2.** The test formulation had been able to set in *nuzj* and turbidity in urine thus making patients of RA detoxified and disease free. The test formulation will be more effective if given in optimum dosage by weight. In future studies, the dosage may be increased than the usual for prompt and optimum results.

## 7. Conclusion

**7.1.** The test formulation has been found to be effective in setting in *nuzj* in the urine and maintenance of pH balance of urine in the patients of test group.

**7.2.** The formulation is also safe and well tolerated.

**7.3.** The mechanism of action of test formulation could be elimination and detoxification of morbid materials or free radicals causing pathology in RA and it can be tried as an alternate and toxic free therapy.

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