

# Clinical Study on Efficacy and Safety of *Hijāmat- bil- shart* (Wet Cupping) in the Management of *Waja-ul-mafāsīl*

Ehsan Ahmad<sup>1\*</sup>,  
S. S. Jamil<sup>2</sup>,  
A. Sultana<sup>3</sup>

<sup>1</sup>HSZH Unani Medical College & Hospital, AYUSH Campus, Nehru Nagar, Kolar Bypass Road, Behind MANIT, Bhopal-462003

<sup>2</sup>Central Council for Research in Unani Medicine, 61-65 Institutional Area, Janakpuri, New Delhi-110058

<sup>3</sup>Department of Moalajat, Faculty of Medicine (Unani), Hamdard University, New Delhi-110062

## Abstract

*laj- bil- Hijāmat* (cupping therapy) is one of the commonest classical modes of treatment in Unani System of Medicine and is widely used to manage and prevent various illnesses and ailments supposed to be caused by the predominance of humors, including *Waja-ul-mafāsīl* (arthritis and sciatica). A randomized open controlled clinical trial was conducted to evaluate the efficacy and safety of *Hijāmat- bil- shart* (wet cupping). The study was conducted on 40 human subjects equally allocated in test and control groups (20 in each). The test group was subjected to the *Hijāmat- bil- shart* along with pharmacopoeial Unani drugs over a period of 6 weeks while the control group received the drugs only over the same period. The laboratory and radiological investigations were carried out before and after the treatment. Significant improvements were observed in disease specific symptoms e.g. joint pain, joint swelling, joint stiffness, restriction of movement and muscular weakness. In test group the pain level decreased by 62.50%, stiffness by 64.16%, swelling by 52.50%, restriction of movement by 77.50% and muscular weakness by 31.16%. Control group showed decrease in pain by 28.75%, stiffness by 38.33%, swelling by 22.50%, restriction of movement by 24.16% and muscular weakness by 22.50%. No significant difference was observed in laboratory and radiological findings in different groups. The study demonstrated that *Hijāmat- bil- shart* induced significant reduction in the cardinal symptoms of *Waja-ul-mafāsīl*.

**Keywords:** Cupping therapy, Wet cupping, Arthritis, Sciatica, Unani Medicine

## Introduction

*Waja-ul-mafāsīl* is a broad and comprehensive term which encompasses most of the inflammatory disorders of joints such as osteoarthritis, rheumatoid arthritis and sciatica e.t.c. The commonest form of *Waja-ul-mafāsīl* is, however, osteoarthritis. It is a common pathophysiological condition among geriatric populations across the globe. Though having a wide distribution, it is more prevalent in temperate regions. The peak age of onset is 30 to 50 years. Females are more commonly affected with it than males. Routine complains are joint pain, morning stiffness, restriction of movement, tenderness and muscular weakness (Wall and Melzack, 1994). Constitutional symptoms like general malaise and anorexia may also be felt by patients.

Rheumatoid arthritis is a chronic systemic inflammatory disease of unknown cause, chiefly affecting synovial membrane of multiple joints. The disease has

\* Author for correspondence

wide clinical spectrum with considerable variability in joints and extra-articular manifestations. The prevalence in the general population is 1-2%; female patients outnumber males almost by 3:1. The usual age at onset is 20-40 years, although rheumatoid arthritis may begin at any age (Lawrence *et al.*, 2004). Diagnosis of RA is made with four or more of the following:

Morning stiffness (>1 hour), arthritis of three or more joints, arthritis of hand joints, symmetrical arthritis, rheumatoid nodules, rheumatoid factor, radiological changes and duration of six weeks or more (Nicholas *et al.*, 2006).

In developed countries low back pain ('lumbago') is the most common medical cause of inability to work. In the great majority of patients it is due to abnormalities of joints and ligaments in the lumbar spine. Pain in the distribution of lumbar or sacral roots ('sciatica') is often due to disc protrusion, but can be a feature of other rare but important disorders including spinal tumour, malignant disease in the pelvis and tuberculosis of the vertebral bodies (Nicholas *et al.*, 2006).

These inflammatory conditions and few other diseases of the joint have been discussed in Unani medicine as *Waja-ul-mafāsīl*.

Non-steroidal anti-inflammatory drugs (NSAIDs) and steroids are commonly used for treatment of *Waja-ul-mafāsīl* in modern system of medicine. The adverse effects and long-term toxicities of NSAIDs and steroids, however, motivate some of the patients to look for alternative treatment, particularly in the traditional systems of medicine. Unani system of medicine has been found at this occasion to provide effective and safe treatment of a number of diseases and therefore is being appreciated as suitable alternative for the diseases for which modern medicine does not possess effective treatment. In this system of medicine the method of treatment is divided basically into three major categories based on the therapeutic agents used. These are *Ilāj-bil-Tadbeer* (Regimenal therapy), *Ilāj bil-Dawā* (Pharmacotherapy) and *Ilāj bil-Yad* (Surgery) (Ajmal, YNM; Ibn Nafees., 1908; Ibn Sina., YNM; Nafees, 1313 A.H.). The first mode of treatment is safer than the other two modes as it interferes only with six essential factors and in a large number of regimens nothing is introduced into the body and thus, normal metabolic processes are not affected. *Hijāmat* is an important regimen, which is practiced for treating many bodily disorders since long past. In medieval period it gained much popularity during the time of Prophet Mohammad (pbuh). He opted for this therapy frequently to prevention & to treat many bodily disorders and described its utility and effectiveness to the people also (Azeemabadi, 1415 A.H.; Bukhari, 1987; Anas, YNM.; Hajar, 1996; Abdullah, YNM; Abdullah, 1985).

The word “*Hijāmat*” has been derived from the Arabic verb ‘Hajama’; literally, it means to suck something and to minimize the size of a thing or to restore its previous basic size (Husaini, 2003; Ibn Manzoor, YNM). Technically it refers to a process that is carried out by creating a partial vacuum in the cupping glasses, placed on the body surface, by mean of heat or suction, in order to evacuate the morbid materials, to divert the material from the diseased part, to return a displaced organ to its normal position or to encourage the blood flow to the site of *Hijāmat*.

### Types of Hijāmat

*Hijāmat* is classified on the two basis, first is the bloodletting and non letting, and second is the method of cup application.

On the basis of bloodletting and non letting it has two types:

1. *Hijāmat- bil-Shart* (wet cupping/cupping with scarification) and
2. *Hijāmat- bilā-Shart* (dry cupping/cupping without scarification),

On the basis of method of cup application also it is of two types:

1. *Hijāmat-e-Nāriyah* (cupping with fire)
2. *Hijāmat-e-Ghair-Nāriyah* (cupping without fire).

The *Mihjamah* (cup) used prior to the twentieth century was made of horn, bamboo and pottery (Jafar, 2005). Nowadays very sophisticated and well-modified cups of glass are available.

The equipments needed to perform the whole procedure of *Hjāmat* are as follows:

Glass cups, medical antiseptics, lamp or candle, inflammable small cones of paper, sterilized gloves, sterilized medical scalpel, pack of cotton and sterilized medical gauze, micro pore tape and razor to remove the hair of the site, if needed.

*Hijāmat* is frequently used in many countries especially in Syria, India, China, United Arab Emirates, Saudi Arabia, Egypt, Iran, England, America, Thailand, Korea, Malaysia and Singapore etc (Anonymous, 2003, 2004). Common indications for this traditional method are muscular pain, arthritis, lumbago, hypertension, cardiac infarction, cardiomyopathy, angina pectoris, arteriosclerosis, chronic bronchitis, asthma, gastrointestinal disorders, migraine, headache, diabetes, paralysis, excessive iron level in the morbid body, hemophilia, leukemia and cancer etc (Ameen, 1999).

The present study has been designed to investigate the efficacy and safety of *Hijāmat- bil-Shart* in the patients of *Waja-ul-mafāsil*.

## Methodology

This is a prospective, single-centered, randomized controlled trial. All the patients underwent a treatment period of 6 weeks. The protocol was approved by the Institutional Ethics Committee of Jamia Hamdard University, New Delhi. The trial was conducted under the Good Clinical Practice (GCP) guidelines. All the patients gave written informed consent. Patients aged between 10-60 years who visited the Unani OPD in Majeedia Hospital, New Delhi, were screened. The patients having the obvious symptoms of *Waja-ul- mafāsil*, irrespective of radiological and laboratory findings were included in the study. Out of total 40 subjects selected for the study, 28 were diagnosed as the patient of osteoarthritis of knee, 4 of rheumatoid arthritis and 8 of sciatica. The patients were randomly allocated into two groups (test and control) of 20 patients each. After randomization 15 cases of osteoarthritis, 2 cases of rheumatoid arthritis and 3 cases of sciatica were possessed by test group while 13 cases of osteoarthritis, 2 cases of rheumatoid arthritis and 5 cases of sciatica were possessed by control group. The test group was treated with *Hijāmat* and a combination of 3 pharmacopeial Unani formulations, while the control group received the pharmacopeial Unani formulations only in same dose. Since the intervention was invasive, hence it could not be blinded. On day 0 (visit 1), patients were asked to stop the use of NSAIDs and other drugs and were subjected to the regimen of *Hijāmat* (Ibn Sina, YNM; Jurjani, YNM; Kabeeruddin, YNM; Khan, YNM; Majoosi., 1889; Razi, 1962) along with the 3 Unani formulation . 6 sittings of *Hijāmat* were given with an interval of one week. Two cups were applied on and around each knee joint in case of osteoarthritis and rheumatoid arthritis as the knee joint was chiefly affected. In case of sciatica 4 cups were applied on each sides of LS spine. In single sitting around 5 ml blood was drawn in a single cup however the exact quantity was not measured. The clinical evaluation (joint pain, joint swelling, joint stiffness, restriction of movement and muscular weakness) of both groups was carried out after every 14 days. The severity of these symptoms was evaluated by using the grading system (from 0 to 4). In case of joint pain, nil, barely perceptible, mild (can carry out daily activities with some trouble), moderate (cannot carry out daily activities easily) and sever (bed ridden) were graded as 0, 1, 2, 3 & 4 respectively. In case of morning stiffness, no stiffness, up to 15 minutes, 15 to 30 minutes, 30 to 45 minutes and more than 45 minutes were graded as 0, 1, 2, 3 & 4 respectively. In case of swelling no swelling/

effusion, barely perceptible, mild, moderate, severe were graded as 0, 1, 2, 3 & 4 respectively. In case of movement, active range of motion (Full voluntary movement), active range of motion (Partial voluntary movement), passive range of motion (Full movement, when the joint is moved by the examiner), passive range of motion (Partial movement, when the joint is moved by the examiner) and no movement at all were graded as 0, 1, 2, 3 & 4 respectively. In case of muscular weakness, Full strength, strength against gravity and added resistance, strength only against gravity, not added resistance, muscular contraction occurs, but not sufficient to overcome gravity and muscular contraction with little or no movement were graded as 0, 1, 2, 3 & 4 respectively.

LFT (Bilirubin, AST, ALT, Alk. phosphatase), KFT (Blood Urea, Serum Creatinine), CBC, Arthritis Profile (RA Factor, C-RP, Uric Acid and ESR) and radiological investigations (x-ray of the affected joints) were carried out on the first day and at final visit. Test for BT, CT, Blood Sugar (F & PP) were carried out only on first visit to rule out the bleeding disorder and diabetes, as wet cupping is contra indicated in these disorders. The reading of all these investigations was recorded on case record form (CRF). The basal clinical findings (day 0) were compared with the findings recorded on days 14, 28 and 42. The basal findings of investigations were compared with that of the post treatment findings. The data of clinical findings was analyzed by Wilcoxon Signed Rank Test. The analysis of data of investigations was executed by using Paired 't' test.

#### Inclusion criteria

Patients aged between 10-60 years, of either sex with clinical and/or radiographic evidence of *Waja-ul-mafāsīl* (arthritis, sciatica), were included in the study.

#### Exclusion Criteria

Patients having anemia (Hb % < 12 g % in male <10 % in female), diabetes mellitus, obesity and past history of blood disorders were excluded from the trial.

#### Unani formulation

The pharmacopeial Unani formulations given to both groups in same dose are as follows:

Capsule *Aujai* (2 cap. once a day at morning) (Anonymous, 1968), *Majoon-e-Sooranjan* (7 gm once a day at bed time) (Kabeeruddin, Y.N.M.) and *Roghhan-e-Sooranjan* (applied/massaged locally twice a day) (Anonymous, 1968).

#### Procedure adopted for Hijāmat

To perform the *Hijāmat*, the patient was allowed to be in comfortable and correct position for *Hijāmat*. The area to be cupped was exposed (and the hairs were removed) and sponged with warm water so as to increase the blood flow to the site and *Hijāmat-bilā-Shart* (dry cupping) was applied to further increase the circulation of the blood. The area was cleaned with antiseptic lotions (e.g. Betadine lotion and Savlon), skin was lacerated with the help of surgical blade and the cups were applied for five to ten minutes to withdraw the blood. After removing the cups, the area was again cleaned with Betadine lotion and sterile dressing was applied.

#### Results

In joint pain, the improvement was statistically significant in both groups on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days ( $P < 0.01$ ) (Table 3). In morning stiffness improvement was not significant in control group on 14<sup>th</sup> and 28<sup>th</sup> days, it however improved significantly towards the end of therapy ( $P < 0.05$ ). In test group on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days a significant improvement was observed ( $P < 0.01$ ) (Table 4). In joint swelling, no significant improvement was found in control group on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days ( $P \geq 0.05$ ), whereas in test group a significant reduction in swelling was observed on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days ( $P < 0.01$ ) (Table 5). In the movement of joint no significant improvement was found in control group on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days, whereas in test group significant improvement was found on 14<sup>th</sup>, 28<sup>th</sup> and 42<sup>nd</sup> days ( $P \geq 0.01$ ) (Table 6). No changes in muscular weakness was recorded in control group, whereas a significant improvement was recorded on 28<sup>th</sup> and 42<sup>nd</sup> days ( $P < 0.01$ ) in test group (Table 7). Change in laboratory parameters were assessed by using Paired 't' test, however no significant change was observed in any group.

**Table 1:** Distribution of the patients according to type of arthritis

Arthritis	Frequency	Percentage
Osteoarthritis	28	70%
Rheumatoid Arthritis	4	10%
Sciatica	8	20%
Total	40	100%

**Table 2:** Baseline characteristics of study patients

Variable	Test Group (n = 20)	Control Group (n = 20)
Joint Pain	3.20±0.09	3.00±0.07
Morning Stiffness	2.10±0.19	1.65±0.18
Joint Swelling	1.55±0.26	1.50±0.25
Restriction of Movement	1.50±0.15	1.10±0.16
Muscular Weakness	1.10±0.17	0.95±0.11

**Table 3:** Effect on joint pain

Joint pain	Control Group (N = 20)				Test Group (N = 20)			
	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT
Mean	3.00	2.40	2.05	2.15	3.20	1.50	1.05	1.20
±	±	±	±	±	±	±	±	±
S.E.M.	0.07	0.13**	0.11**	0.13**	0.09	0.13**	0.8**	0.11**
% of variation		20.41%	31.66%	28.75%		53.33%	67.08%	62.50%

\*\*P<0.01 (Basal vs 14<sup>th</sup> day, 28<sup>th</sup> day and 42<sup>nd</sup> day in both groups)  
(Wilcoxon Signed Rank Test)

**Table 4:** Effect on morning stiffness

Morning Stiffness	Control Group (N = 20)				Test Group (N = 20)			
	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT
Mean	1.65	1.40	1.10	1.00	2.10	0.70	0.35	0.60
±	±	±	±	±	±	±	±	±
S.E.M.	0.18	0.8NS	0.9NS	0.17 *	0.19	0.12 **	0.10**	0.11 **
% of variation		14.16%	33.33%	38.33%		63.33%	78.33%	64.16%

NS P≥0.05 (Basal vs. 14<sup>th</sup> day and 28<sup>th</sup> day in control group)

\* P<0.05 (Basal vs. 42<sup>nd</sup> day in control group)

\*\*P<0.01 (Basal vs 14<sup>th</sup> day, 28<sup>th</sup> day and 42<sup>nd</sup> day in test group)  
(Wilcoxon Signed Rank Test)

**Table 5:** Effect on joint swelling

Joint Swelling	Control Group (N = 20)				Test Group (N = 20)			
	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT
Mean	1.50	1.30	1.15	1.05	1.55	0.60	0.30	0.35
±	±	±	±	±	±	±	±	±
S.E.M.	0.25	0.23 NS	0.22 NS	0.22 NS	0.26	0.13**	0.10**	0.10**
% of variation		8.33%	15.00%	22.50%		41.66%	55.83%	52.50%

NS  $P \geq 0.05$  (Basal vs 14<sup>th</sup> day, 28<sup>th</sup>, and 42<sup>nd</sup> day in control group)

\*\* $P < 0.01$  (Basal vs 14<sup>th</sup> day, 28<sup>th</sup> day and 42<sup>nd</sup> day in test group)

(Wilcoxon Signed Rank Test)

**Table 6:** Effect on restriction of movements

Restriction of Movement	Control Group (N = 20)				Test Group (N = 20)			
	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT
Mean	1.10	0.90	0.75	0.75	1.50	0.50	0.40	0.45
±	±	±	±	±	±	±	±	±
S.E.M.	0.16	0.16 NS	0.12 NS	0.12 NS	0.15	0.15 **	0.13 **	0.13**
% of variation		15.00%	24.16%	24.16%		75.83%	80.00%	77.50%

NS  $P \geq 0.05$  (Basal vs 14<sup>th</sup>, 28<sup>th</sup>, and 42<sup>nd</sup> day in control group)

\*\* $P < 0.01$  (Basal vs 14<sup>th</sup> day, 28<sup>th</sup> day and 42<sup>nd</sup> day in test group)

(Wilcoxon Signed Rank Test)

**Table 7:** Effect on muscular weakness

Muscular weakness	Control Group (N = 20)				Test Group (N = 20)			
	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT	BT	14 <sup>th</sup> Day	28 <sup>th</sup> Day	AT
Mean	0.95	0.85	0.75	0.70	1.10	0.85	0.60	0.60
±	±	±	±	±	±	±	±	±
S.E.M.	0.11	0.10 NS	0.12 NS	0.12 NS	0.17	0.13 NS	0.13*	0.13*
% of variation		7.50%	17.50%	22.50%		14.16%	34.16%	31.16%

NS  $P \geq 0.05$  (Basal vs 14<sup>th</sup> day, 28<sup>th</sup> day, and 42<sup>nd</sup> day in control group and Basal vs. 14<sup>th</sup> day in test group)

\* $P < 0.01$  (Basal vs 28<sup>th</sup> day and 42<sup>nd</sup> day in test group)

(Wilcoxon Signed Rank Test)

## Discussion

The finding of the study demonstrated that the wet Cupping significantly improved pain, stiffness, swelling, restriction of movement and muscular weakness over 6 weeks. Although it is a preliminary study but provides a significant evidence in favour of the efficacy and safety of Hijāmat and indicates its wide therapeutic potential.

Pain of inflammatory origin is produced in a variety of ways. Change in local pH and concentration of certain ions play a role in stimulation of nerve endings. The release of chemicals like Histamine, 5-HT, K<sup>+</sup> ions and plasma kinins can stimulate the local sensory nerves. In addition, the physical effect of inflammatory swelling causes an increased pressure resulting in mechanical pain. The effectiveness of wet cupping in reducing joint pain is likely to involve the inhibitory interference in the above mentioned inflammatory process. The technique of wet cupping has been quoted in literature to involve the sucking out of morbid materials (*Istifrāgh*) (Kabeeruddin, Y.N.M.) and reducing the local plethora which contribute to the swelling. It appears that wet cupping relieves pain by eliminating the morbid materials and by draining excessive blood along with the pro-inflammatory chemical mediators. Many a times, wet cupping diverts morbid materials from an area of high vitality or depth towards periphery and surface from where they are removed easily (like in the depth of the joints) (*Imālah*) (Kabeeruddin, Y.N.M.). The diversion also dislodges morbid materials from the site of actual pathology and also contributes to reduce physical cause of pain i.e. swelling. Morning stiffness originates from spasm of the synovial membrane and related tendons due to lack of oxygen and tissue nourishment. Immobilization of the joint for over night makes the area deficient of blood and relatively cool. Swelling also contributes in ischemia by exerting mechanical pressure over microvasculature. It is this coolness in turn causes spasm in synovial membrane. As the movement of a particular area is restored, circulation automatically gets improved and making the area warmer. It explains why *Waja-ul- mafāsil* gets aggravated in winter and it is why common in the subject of cold. Once the local temperature is maintained the spastic condition gets rectified and pain is relieved gradually. Thus in case of morning stiffness, wet cupping does what is expected from massage or physiotherapy.

Local swelling and effusion take place due to the extravasations of fluid and cells from the blood stream to the intercellular spaces. This abnormal accumulation of fluid in joint is responsible for the visible swelling, pain and also for the restriction of movement. Two main principles i.e. evacuation (*Istifrāgh*) and diversion (*Imālah*) on which wet cupping is based have direct

effect on joint swelling by allowing fluids to come out and thereby reducing the swelling. Restriction of movement is directly related with pain and swelling. Anything that relieves the pain and swelling will reduce the restriction of movement. Muscular weakness is basically caused by poor vascularity of the area and immobilization of joint. The reason for immobilization is pain and swelling. By *Hijāmat* pain and swelling get reduced which in turn helps improve the mobility of the joint. Once the mobilization is restored, the affected part gets some strength and this strength increases gradually with frequent movement. As far as the question of poor vascularity is concerned, wet cupping helps in increasing the vascularity by vasodilatation as well as by elimination of morbid materials providing space for fresh blood.

There was no change in RA Factor, C -reactive protein, Uric Acid, ESR, Hemoglobin, TLC, DLC, LFT & KFT and in the radiological findings indicating that the normal physiological and biological process of the body have not been affected. Therefore the changes of inducing any side effect are minimal.

There was no change in C-reactive protein in both groups, suggesting that Unani formulations and wet cupping had no effect on these acute phase proteins. Further the apprehension that wet cupping leads to anemia due to blood loss was removed as the therapy was not found to alter the hemoglobin level.

In view of the above observation and discussion it can be concluded that *Hijāmat- bil- shart* is able to induce significant improvement in physiopathology and the sign & symptoms of *Waja- ul- mafāsil* specially the commonly prevalent condition such as osteoarthritis, Rheumatoid arthritis and Sciatica. The regimen can be used effectively and safely in the management of joint diseases.

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