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Comparative study of Hijama *Bila Shart* (Dry Cupping Therapy) and Hijama Bil shart (wet Cupping) in *Wajaul Mafasil* (Arthritis) of Knee.

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ABSTRACT

Background and Objectives: *Wajaul Mafasil* is a compound Arabic term, where *Waja* literally means 'pain' and *Mafasil* means joints. Osteoarthritis is the most common form of the arthritisand is the leading cause of disability in older persons, affecting 10% of population >60 years of age, in which 80% of individual have limited mobility and 25% cannot perform major dailyactivities. The disease follows a more severe course in women with greater symptoms, more extensive involvement, and increased prevalence of knee and hand joint involvement. There are wide range of treatment options available in different system of medicines. Inspite of that patient are not fully satisfied. Unani scholars in their treatise have mentioned different formulations but their scientific validation have still not done. Hence a study was conducted to evaluate the efficacy of *Hijamah bila Shurt and Hijama Bil shart* in *Wajaul Mafasil* of knee.

Methods: The study was conducted as comparative clinical study. A total of 72 eligible patientsfitting the inclusion criteria were selected from OPD/ IPD. However, only 60 patients (30 in each group) completed the trial. Group A patients received treatment with *Hijamah bila Shart* for 30 days and Group B patient received *Hijamah bil Shart* on knee daily for period of 30 days. Patients were assessed on subjective and objective parameters at baseline and on every follow up till 30th day. Safety parameters were assessed at baseline and after the end of the trial. The results were analysed statistically using Student t test and Paired Proportiontest.

Results: Significant improvement was observed in all the subjective parameters ($p<0.01$), and all the objective parameters ($p<0.001$). No adverse effect was reported.

Interpretation and Conclusion: This study reveals that *Hijamah bil Shurt* is effective treatment for *Wajaul Mafasil* of knee as compare with *Hijamah bila Shart.* There were no clinically or statistically significant side effects after the trial. However large sample sized controlled clinical trials of longer durationare required to generalize the results.

Key Words: *Waja-ul-Mafasil; Unani Medicine; Hijamah bila Shurt; Arthritis; Hijamah bil Shurt*

I. INTRODUCTION

Wajaul Mafasil

Wajaul Mafasil is a compound Arabic term, where Waja literally means 'pain' and *Mafasi*l means joints. So, the term *Wajaul Mafasil* literally refers to joints pain[1].

The history of *Wajaul Mafasil* is as old as the history of the existence of the mankind. Some evidences also portrayed the presence of disease in the era of dinosaurs. This malady didn't even spare historical personalities like Alexander 'The Great' (356-323 BC). This disorder is well described in the old Egyptian, Greek and Roman medical classics and thoroughly elaborated in Unani classical literatures. *Wajaul Mafasil* is one of the diseases which is vividly described by almost every scholar of ancient period. Father of Medicine, *Buqra*t (Hippocrates 460-377 BC), native of Island of Cos of Aegean Sea, Greek, wrote a concise but detailed information about the disease in his treatise, named as *Kitab-ul-Mafasil*[2,3]. Numerous Unani physicians like *Dioscorides, Rufus, Jalinoos, Orebasoos, Feel Gharyoos, Serjeus, Akandarave Tawali, Ahran bin Ain, Jurjis bin Jibrael, Yuhanna ibn Masawaih, Hunain bin Ishaque, Thabit ibn Qurrah, Rabban Tabri, Razi, Mohammad Tabri, Noohul Qamri, Masihi, Ibn Sina, Ibn Zuhr, Ismail Jurjani, Ibn Rushd, Ibn Sadeedi, Moosa bin Maimoon, Najeebuddin Samarqandi, Ibn Baitar, Ibn Hubk*

Baghdadi, Rasheed Zangi, Karim Nagauri, Nafis Kirmani, Hakim Yususfi, Rustam Jurjani, Dawood Antaki, Ali Ghilani, Abul Qusim Farishta. Hakim Alvi Khan, Akbar Arzani, Hakim M Sharif Khan, Hakim Azam Khan, Hakim Ajmal Khan has described *Wajaul* mufassil extensively[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15].

Epidemiology

It is most common joint disorder in the United States and the world[16]. Radiological evidence of OA is found in 35% of people under 30 years of age, and in 85% of 80- years-olds[17]. The prevalence of OA rises progressively with age and it has been estimated that 45% of all people develop knee OA and 25% hip OA at some point during life. Although some of these patients are asymptomatic, the life time risk of having a total hip or knee replacement for OA in someone aged 50 is about 11% in women and 8% in men. Symptoms attributable to OA are more prevalence in women, except at the hip, where men are equally affected.[18]

II. METHODOLOGY

Present study was conducted in *Jamia Tibbiya Deoband* hospital, Deoband from September 2015 to September 2016. A total of 80 eligible patients fitting the inclusion criteria were selected from OPD/ IPD. However, only 60 patients completed the trial. During the selection procedure, complete history including general physical and Introduction 4 systemic examination was carried out and recorded on a particularly designed CRF and the interference were made by appropriate statistical analysis.

Method of Collection of Data

Collection of data was made directly by the investigator in a specially designed proforma i.e., Case Report Form (CRF)

Source of data: OPD/IPD of Shamim Ahmed Saeedi super speciality hospital for *Waja-ul-Mafasil* (Joint pain), under Ministry of AYUSH

Sample size: The sample size was fixed as 60 patients; 30 in each group

Duration of protocol: The treatment period was ascertained as One month

Allocation of subjects: The 60 patients along with 20% expected drop outs and withdrawal were allocated into two groups comprising 36 patients in each through randomisation by using G ad soft. Group A were subjected placebo Group B with *Hijamaht bila shurt* A total of 250 patients were screened, out of which 80 cases fulfilled the study criteria, hence they were subjected to clinical & laboratory investigations. Finally, 72 cases were enrolled and randomly allocated to two groups, viz., Group A (40 patients) and Group B to *Hijamaht Bila Shurt* (40 cases). A total of 80 Methodology 60 cases completed the study protocol (30 in each group). 20 cases lost to follow up.

Criteria for selection of drugs: The form regimen *Hiajmah Bila Shurt* indicated for alleviating pain along with diversion of *madda*. Hence, this formulation along with regimen was selected to validate their efficacies and safety on scientific parlance.

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc

III. RESULT

Table 1: Joint stiffness: Assessment at different study points in two groups of patients studiedJoint stiffness

Joint stiffness	0 day	7 day	15 day	22 day	30 day	% difference
Group A (n=30)						
• **1**	0(0%)	0(0%)	1(3.3%)	15(36.7%)	14(36.7%)	36.7%
• **2**	4(13.3%)	13(43.3%)	20(66.7%)	15(50%)	18(60%)	46.7%
• **3**	18(60%)	17(56.7%)	9(30%)	4(13.3%)	1(3.3%)	-56.7%
• **4**	8(26.7%)	0(0%)	0(0%)	0(0%)	0(0%)	-26.7%
Group B(n=30)						

• 1	0(0%)	0(0%)	2(6.7%)	15(50%)	20(66.7%)	66.7%
• 2	6(16.7%)	14(43.3%)	24(76.7%)	16(50%)	12(33.3%)	16.6%
• 3	22(70%)	18(56.7%)	6(16.7%)	0(0%)	0(0%)	-70.0%
• 4	5(13.3%)	0(0%)	0(0%)	0(0%)	0(0%)	-13.3%
p value	0.483	1.000	0.510	0.144	0.038*	-

Table 2: Joint stiffness: Assessment at different study points in two groups ofpatients studied

Joint Stiffness	Group A	Group B	Total	P value
0 day	3.13±0.63	2.97±0.56	3.05±0.59	0.281
7 day	2.57±0.50	2.57±0.50	2.57±0.50	1.000
15 day	2.27±0.52	2.10±0.48	2.18±0.50	0.203
22 day	1.77±0.68	1.50±0.51	1.63±0.61	0.090+
30 day	1.67±0.55	1.33±0.48	1.50±0.54	0.015*

Table 3: Difficulty in movement: Assessment at different study points in two groupsof patients studied

Difficulty in movement	0 day	7 day	15 day	22 day	30 day	% difference
Group A(n=30)						
• 1	0(0%)	0(0%)	0(0%)	6(20%)	14(46.7%)	46.7%
• 2	0(0%)	3(10%)	13(43.3%)	18(60%)	16(53.3%)	53.3%
• 3	8(26.7%)	14(46.7%)	15(50%)	6(20%)	0(0%)	-26.7%
• 4	22(73.3%)	13(43.3%)	2(6.7%)	0(0%)	0(0%)	-73.3%
Group B(n=30)						
• 1	0(0%)	0(0%)	2(6.7%)	16(53.3%)	29(96.7%)	96.7%
• 2	0(0%)	5(16.7%)	13(43.3%)	11(36.7%)	1(3.3%)	3.3%
• 3	2(6.7%)	19(63.3%)	13(43.3%)	2(6.7%)	0(0%)	-6.7%
• 4	28(93.3%)	6(20%)	2(6.7%)	1(3.3%)	0(0%)	-93.3%
P value	0.080+	0.168	0.692	0.014*	<0.001**	-

Table 4: Difficulty in movement: Assessment at different study points in two groupsof patients studied

Difficulty in movement	Group A	Group B	Total	P value
0 day	3.73±0.45	3.93±0.25	3.83±0.38	0.038*
7 day	3.33±0.66	3.03±0.61	3.18±0.65	0.074+
15 day	2.63±0.61	2.50±0.73	2.57±0.67	0.448
22 day	2.00±0.64	1.60±0.77	1.80±0.73	0.033*
30 day	1.53±0.51	1.03±0.18	1.28±0.45	<0.001**

Table 5: WOMAC score: Assessment at different study points in two groups of patients studied

WOMAC score	Group A	Group B	Total	P value
0 day	63.00±8.73	59.17±11.61	61.08±10.37	0.154
7 day	51.60±8.37	48.60±9.44	50.10±8.97	0.198
15 day	40.23±6.89	38.57±6.62	39.40±6.75	0.343
22 day	32.80±6.52	29.37±6.45	31.08±6.66	0.045*
30 day	26.53±5.04	23.33±6.52	24.93±6.00	0.038*

Table 6: VAS score: Assessment at different study points in two groups of patientsstudied

VAS score	Group A	Group B	Total	P value
0 day	8.90±0.80	8.90±1.06	8.90±0.93	1.000
7 day	7.00±0.98	6.50±1.28	6.75±1.16	0.095+
15 day	5.70±1.37	5.10±1.94	5.40±1.69	0.171
22 day	3.83±1.98	2.70±2.29	3.27±2.20	0.045*
30 day	2.40±1.22	0.90±0.88	1.65±1.30	<0.001**

IV. DISCUSSION

The study entitled as "Comparative clinical trial of *Hijamah bila Shurt* (dry cupping therapy) and in *Hijamah bil Shurt* (wet cupping therapy) *Wajaul Mafasil* (arthritis) of knee was conducted on 60 patients with 30 ineach group (Group A & Group B). The study protocol was 30 days and the patient was treated with *Hijamah Bila Shurt* (Dry cupping) *treatment* and *Hijamah Bil Shurt* (wet Cupping) was done to group A and group B respectively. The assessment was done on before and after the treatment with the help of VAS and WOMAC OA index

Joint stiffness

Joints stiffness was assessed on arbitrary scale which was graded as severe, moderate, mild andbarely perceptible and was coded as 4, 3, 2, and 1 respectively. At baseline in Group A, 0(0%) patient barely perceptible joint stiffness, 4 patients (13.3%) had mild stiffness, 18 patients (60%) had moderate stiffness and 8 patients (26.7%) had severe stiffness. At the end of of treatment in Group A, 11 patients (36.7%) had barely perceptible joint stiffness, 18 patients (60%) had mild stiffness, 1 patient (3.3%) had moderate stiffness and 0 patient (0%) had severe stiffness. At baseline in Group B, 0(0%) patient barely perceptible joint stiffness, 5 patients (16.7%) had mild stiffness, 21 patients (70 %) had moderate stiffness and 4 patients (13.3%) had severe stiffness. At the end of treatment in Group B, 20 patients (66.7%) had barely perceptible joint stiffness, 10 patients (60%) had mild stiffness, 0 patient (0%) had moderate stiffness and severe stiffness. (Table No. 1) The p value calculated by ChiSquare/Fisher Exact

Test at the end was 0.038* which is moderately significant. The data show that there was no significant difference between the groups and both were matched in characteristic of joint stiffness.

In present study, values of Joint stiffness (Mean ± SD) in Group A at baseline and end of treatment were 3.13±0.63 and 1.67±0.55 respectively. The values of joint stiffness (Mean ± SD) in Group B at baseline and end of treatment were 2.97±0.56and 1.33±0.48, respectively. (Table No. 2) The intergroup comparison at the end of treatment between Group A and GroupB was found highly significant (p<0.001). As the greater reduction in joint stiffness score wasfound in Group B than Group A and the inter group comparison also shows that a highly significant difference exist between the group. So, it is concluded that a greater improvement was found Group B than Group A in decrease in joint stiffness. treatment was statistically significant at p<.05 and p<.01, respectively.

The reason behind the morning stiffness is spasm of the synovial membrane and related tendons due to the lack of oxygen and tissue nourishment. Immobilization of the joint for over the night span leaves the area deficient of blood and ultimately relatively cold. Swelling of the part alsocontributes in ischaemia by exerting the mechanical pressure over microvasculature. It is the coldness of the part that actually causes spasm in synovial membrane. That is why when the movement of the particular area is restored; circulation becomes automatically improved making the area relatively warm. This is also the answer as to why the condition gets aggravated in winter and why it is common in *Barid Mizaj* subjects and in elderly people.

When there is application of cups at the diseased parts, blood circulation increases at that site and kinetic energy gets change into thermal energy improving the local temperature. Once the local temperature is maintained the spastic condition gets rectified and the stiffness goes away or comes down. The therapeutic value of applying heat includes decreasing joint stiffness, alleviating pain, relieving muscle spasm and preventing contractures.121

Hijamah decreases the morning stiffness by raising the local temperature at site and the effect is coinciding with the findings of Lehman and DeLateur.121

Difficulty in movement:

Difficulty in movement was assessed on arbitrary scale which was graded as severe, moderate, mild and barely perceptible and was coded as 4, 3, 2, and 1 respectively. At baseline in GroupA, 0(0%) patient barely perceptible as well as mild difficulty of movement, 8 patients (26.7%)had moderate stiffness and 22 patients (73.3%) had severe stiffness. At the end of treatment inGroup A, 14 patients (36.7%) had barely perceptible difficulty in movement, 16 patients (53.3%) had mild difficulty of movement, 0 patient (0%) had moderate and severe difficulty of movement. At baseline in Group B, 0(0%) patient barely perceptible difficulty in movement mild difficulty of movement, 2 patients (6.7%) moderate difficulty in movement and 28 patients (93.3%) had difficulty of movement. At the end of treatment in Group B, 29 patients (96.7%) had barely perceptible difficulty of movement, 1 patient (3.3 %) had mild difficulty of movement, 0 patient (0%) had moderate and severe difficulty of movement. (Table No. 3) The p value calculated by Chi-Square/Fisher Exact Test at the end was <0.001 which is highly significant. The data show that there was no significant difference between the groups and both were matched in characteristic of difficulty of movement.

In present study, values of difficulty in movement (Mean ± SD) in Group A at baseline and end of treatment were 3.73±0.45and 1.53±0.51respectively. The values of difficulty of movement(Mean ± SD) in Group B at baseline and end of treatment were 3.83±0.38 and 1.28±0.45, respectively. (Table No. 4) As the greater reduction in difficulty of movement score was foundin Group B than Group A and the inter group comparison also shows that a highly significant difference exist between the group. So, it is concluded that a greater improvement was found Group B than Group A in decrease in difficulty of movement.

Difficulty in the movement is directly related with pain and swelling. Swelling in the joint is due to the accumulation of the *Akhlat-e-Fasida* (Morbid Humours). Hijamah reduces the swelling by *Imala-e-Akhlat-e-Fasida* (Diversion of Morbid Humours) and this may be the reason of reducing difficulty in movement. This finding is coinciding with the statements of *Ibne Sina*.

WOMAC Index:

In present study, values of WOMAC index (Mean ± SD) in Group A at baseline and end of treatment were 63.00±8.73and 26.53±5.04 respectively. The values of WOMAC index (Mean 59.17±11.61and 23.33±6.52, respectively. (Table No. 5) The intergroup comparison at the end of treatment between Group A and Group B was found

moderately significant ($p<0.038$). As the greater reduction in WOMAC score was found in Group B than Group A and the inter group comparison also shows that a moderate significant difference exist between the group. So, it isconcluded that a greater improvement was found Group B than Group A in decrease in WOMAC score.

VAS score:

In present study, values of VAS score (Mean ± SD) in Group A at baseline and end of treatment were 8.90±0.80 and 2.40±1.22 respectively. The values of WOMAC index (Mean ± SD) in Group B at baseline and end of treatment were 8.90±1.06 and 0.90±0.88, respectively. (Table No. 6) The intergroup comparison at the end of treatment between Group A and Group B wasfound moderately significant ($p<0.001$). As the greater reduction in pain score was found in Group B than Group A and the inter group comparison also shows that a moderate significantdifference exist between the group. So, it is concluded that a greater improvement was found Group B than Group A in decrease in WOMAC score.

Hijamah Bila shart (Dry Cupping) & *Hijamah Bil shart* (Wet Cupping) are one of the oldest and most effective methods of treatment practiced in Unani system of medicine. As it is clearly described in Unani text that the main cause of the disease is the imbalance of Humour, when it accumulates in a particular organ it causes the abnormal functioning. In case of *Hijamah bila Shart* (Dry cupping) which works on the principle of *Imalae Mawad* causes the diversion of morbid matter from one site to another, when these morbid matters are gets away from the diseased part the *Tabiyat Mudabbarae Badan* takes in the part and helps the body to restores the normal condition. *Hijamah Bil shart* (Wet Cupping) iais very effective method to evacuate the imbalance & toxic humour from the body According to the modern concept so many theories are given to describe the mechanism of action of *Hijamah* (cupping), Hong et al.[87] described that *Hijamah* (Cupping) therapy works via creating specific changes in local tissue structures as a result of local negative pressure in the cups used which stretches the nerve and muscle causing an increase in blood circulation and causing auto- hemolysis. Gao et al.88 suggested that putting cups on selected part on the skin produces hyperemia or hemostasis which results in a therapeutic effect. Taibah theory suggested that when negative pressure (suction force) is applied to the skin it results decrease in pressure (Boyle's law) around capillaries. This causes increased capillary filtration, local collection of filtered fluids, lymph and interstitial fluids and their retention inside skin up lift part. This dilutes chemical substances, inflammatory mediators, and nociceptive substances, bathes nerve endings in collected fluids and breaks tissue adhesions causing decreased pain.89

V. CONCLUSION

The present study entitled "Comparative study of *Hijamah bila Shurt*(Dry cupping therapy) & *Hijamah bil Shurt* (Wet cupping therapy) in *Wajaul Mafasil* (arthritis) of knee" was conducted on patients from OPD/ IPD of Shameem Ahmed Saeedi Hospital, Deoband, after the approval of institutional ethical committee for biomedical research over a period of 13 months from july 2015 to July 2016. The 60 patients along with 20% expected drop outs and withdrawal were allocated into two groups comprising 36 patients in each through randomisation by using G adsoft. Group A were subjected to *Hijamah bila Shart* (Dry cupping therapy) *treatment* , Group B with *Hijamah bil shurt*.

A total of 200 patients were screened, out of which 80 cases fulfilled the study criteria, hence they were subjected to clinical & laboratory investigations. Finally, 80 cases were enrolled and randomly allocated to three groups, viz., Group A *received Hijamah bila Shart treatment* (40 patients) and Group B to *Hijamah Bila Shurt* (40 cases). A total of 60 cases completed the study protocol (30 in each group). 20 cases lost to follow up

During the selection procedure, complete history including general physical and systemic examination was carried out and recorded on a prescribed proforma which was designed according to the objectives of the study.

Laboratory investigations were carried out before and after treatment for exclusion and inclusion parameters, and for safety assessment. Clinical assessment was also recorded in every follow up fortnightly.

The overall effect of the *Hijamah Bil Shurt* in the treatment of *Wajaul Mafasil compared with Hijamah bila Shurt* of Knee Markedimprovement in subjective parameters like joints pain, difficulty in movement and joint stiffness and reduction was seen in objective parameter VAS score and Womac OA index. Noside effects were observed in enrolled subjects.

Compliance to the treatment was found good. These results concluded that the *Hijamah Bila Shurt* are effective and safe in the management of *Wajaul Mafasil* of Knee, but there was a better improvement in patients on which *Hijamah* was

performed. However large sample sized controlled clinical trials of longer duration are needed for the generalization of the results.

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