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TESTING THE EFFICACY OF *DRY CUPPING* AND *HABBE HUDAR* IN MANAGEMENT OF KNEE PAIN – A COMPARATIVE RCT

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ABSTRACT

Objectives: Osteoarthritis, the most prevalent type of arthritis, affects 10% of people over 60 and is the main cause of impairment in this age group, leaving 80% of affected people with reduced mobility and 25% unable to carry out important daily tasks. In women, the disease progresses more quickly, with more severe symptoms, wider-ranging involvement, and a higher rate of knee and hand joint involvement. A variety of medical systems offer a wide range of treatment possibilities. Despite this, the patient is not completely content. Different formulations were mentioned by Unani experts in their treatises, but their scientific veracity has not yet been established. The effectiveness and safety of *Habbe Hudar* and dry cupping in *Wajaul Mafasil* (Knee pain) were therefore compared and evaluated in a study. **Methods:** The trial was carried out as a clinical comparison research. From OPD/IPD, a total of 72 eligible patients who met the inclusion criteria were chosen. Only 60 patients, 30 in each group, finished the trial, though. For 30 days, Group A patients received 2 pills of *Habbe Hudar* orally twice daily, whereas Group B patients received dry cupping on their knees each day. Patients were evaluated at baseline and every follow-up visit until the 30th day based on both subjective and objective criteria. At the beginning of the experiment and after it had concluded, safety parameters were evaluated. The student t test and Paired Proportion test were used to statistically analyse the results. **Results:** All subjective parameters ($p<0.01$*) and all objective parameters ($p<0.001$**) both showed significant improvement. There was no adverse-effect noted. **Interpretation and Conclusion:** This study shows that while both *Habbe Hudar* and dry cupping are viable treatments for the knee pain, Dry cupping is considerably more successful. Neither during the trial nor after it, there were no toxicities or side effects that were clinically or statistically significant. To generalise the findings, however, larger sample size, longer duration controlled clinical trials are needed.

KEYWORDS: *Unani Medicine; Hijamah; Cupping; Knee Pain; OA; Wajaul Mafasil.*

INTRODUCTION

The term *Wajaul Mafasil* literally refers to "joints pain". It is a broad term usually denoting all types of painful joint disorders such as rheumatoid arthritis, osteoarthritis, rheumatic arthritis etc. The clinical presentation of *Wajaul Mafasil* described by the eminent Unani physicians are very similar to the symptoms of osteoarthritis. Osteoarthritis is a chronic degenerative arthropathy, which frequently leads to compromised functions and loss of independence. With the continuous growth in the population of elderly people, osteoarthritis is becoming a major health problem. Knee osteoarthritis is a condition that is much more prevalent in India than West and accounts as much disability as any of the other chronic condition.

Definition

Wajaul Mafasil was defined by various renowned Unani scholars as: *Jalinoos* (Galen) suggested that *Wajaul Mafasil*, *Niqras* and *Irqun Nisa* as the same group of the disease, and their different names identify different areas of involvement.[1]

Impact

Osteoarthritis is the most common type of arthritis. Its high prevalence, especially in elderly, and high rate of disability related to disease make it a leading cause of

disability in the elderly. Because of the aging of Western populations and because obesity, a major risk factor, is increasing in prevalence, the occurrence of OA is on the rise. In the United States, OA prevalence will increase by 66-100% by 2020.[2]

METHODOLOGY

The current study, "Comparative clinical trial of *Habbe Hudar* & dry cupping therapy in knee pain was carried out on patients from the OPD/IPD of Shameem Ahmed Saeedi Hospital in Deoband over a period of 13 months from September 2015 to September 2016, with the approval of the institutional ethical committee for biomedical research.

Criteria for Selection of Cases

Based on inclusion, exclusion, subjective and objective parameters

Inclusion criteria

1. Patients of either sex in the age group of 30-65 years.
2. Patients having *Wajaul Mafasil* of the knee(s) fulfilling the following American College of Rheumatology (ACR) criteria:

a. Knee Pain
b. Osteophytes (on radiographs) and at least 1 of the following 3 criteria:

- Age ≥ 50 years
- Morning Stiffness ≤ 30 minutes
- Crepitus on active motion

Exclusion criteria

1. Secondary, RA, systemic joint disease, or any other type of arthritis.
2. Arthroscopy or any knee surgery in the previous 6 months
3. Intra-articular treatment (e.g., corticosteroids or hyaluronic acid) or treatment with medicine for Arthritis in the previous 3 months (e.g. glucosamine sulphate, chondroitin sulphate, diacerein, piascledine).
4. Treatment with anticoagulants or history of haemophilia.
5. Patients with anaemia and diabetes mellitus.
6. ESR > 40 mm/h and CRP level >10 mg/L
7. Any significant systemic diseases (cardiovascular, gastrointestinal, hepatic, renal, neurologic or psychiatric disorder) that require long-term treatment.
8. Pregnant and lactating women
9. H/O addiction (alcohol, drugs)

Study parameters

a. Subjective parameters

- Joint Stiffness
- Difficulty in movement.
- Joint pain

b. Objective parameters

- WOMAC Questionnaire
- VAS

Selection of the patients

History Taking

During the selection procedure detailed general and specific history was recorded in a predesigned proforma according to the objectives of the study, and patients were graded into different socioeconomic status by using Kuppuswamy's socioeconomic scale

Examination

After history taking each patient was subjected to comprehensive general physical and systemic examination. Likewise, careful local knee joint examinations were also performed with special emphasis on, warmth, tenderness, active and passive range motion of affected knee joint etc.

Investigations

Certain investigations were carried out in all enrolled patients before and after completion of treatment (except X-ray, RBS, CRP, Serum uric acid and RA factor), with the aim to exclude the patients if found with any pathological conditions as per the exclusion criteria, and moreover, to establish the safety of the intervention used. Hence, following investigations were carried out.

1. Heamogram (Hb%, TLC, DLC,)
2. ESR
3. Sputum for AFB
4. Urine routine & microscopic
5. Random Blood Sugar
6. KFT- (Blood urea, serum uric acid & serum creatinine)
7. LFT- S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
8. C- Reactive protein
9. RA factor
10. X-ray Knee PA view

Assessment of *Mizaj*

Determination of *Mizaj* of enrolled patients was made through the principles of *Ainase Ashra* as per the doctrine of Unani medicine

Informed Consent

Enrolled patients after fulfilling the inclusion criteria were given the informed consentsheet to refer thoroughly which possess details regarding the nature of the study, the drugs and regimens to be used, method and duration of treatment, its risk and benefits and the patient's association with the study is purely voluntary, his responsibilities andconfidentiality of records etc. Patients were given enough time to go through the contents of informed consent sheet. They were given the right to ask any query with the investigator, after acceptance to participate in the study, were requested to give written informed consent duly signed with date.

Method of Collection of Data

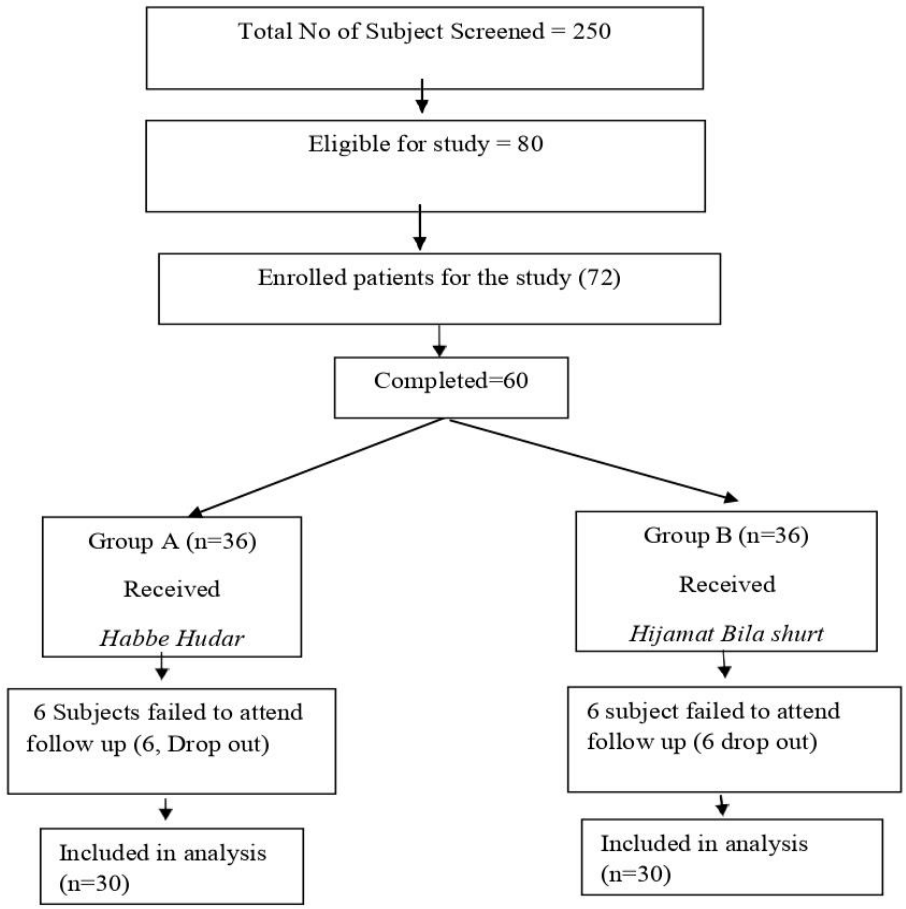
Collection of data was made directly by the investigator

in a specially designed proforma i.e. Case Report Form (CRF)

Source of data: OPD/IPD of Shamim Ahmed Saeedi super speciality hospital for Joint pain under Ministry of AYUSH
Study design: Comparative RCT
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 were randomly divided into two groups, each with 36 patients, using G ad soft, along with the 20% projected dropouts and withdrawals. Group A received *Habbe Hudar* treatment, whereas Group B received dry cupping.

A total of 250 patients were screened; 80 met the criteria for the study, therefore they underwent clinical and laboratory tests. At last, 72 cases were enrolled, and two groups—Group A, *Habbe Hudar* (36 patients), and Group B, dry cupping—were randomly assigned (36 cases). The study procedure was completed by 60 cases in total (30 in each group). The specifics of 12 cases that were lost to follow-up are shown in the flowchart.



Criteria for selection of drugs
The formulation *Habbe Hudar* is indicated in several types of arthritis as they possess anti-inflammatory and analgesic property, and they have been promoted by different physicians by reporting their efficacy, whereas the regimen *dry cupping* 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. The formula of *Habbe Hudar* is taken from *NFUM, Bayaze Kabeer and Kitabul Murakkabat.*

Test Formulation: *Habbe Hudar*.

Procedure of study
Patients fulfilling criterion of selection before enrolling into the study were kept on wash out period of one weak, and advised no concomitant therapy during the clinical trial, later obtained written informed consent and randomly allocated into three groups viz Group A and B.

Group A: Group A patients were administered orally two pills (250 mg) twice i.e., 500 mg a day with water after meal for 30 days.

Group B: Group B patients received *dry cupping* with the site (Knee joint) was cleaned with an antiseptic

solution, thereafter 2-3 manual suction cups of different calibers (65 mm / 55 mm / 45 mm) (central, medial and lateral) for 10-15 minutes based on the area of knee are applied.

Follow up

All the groups were received treatment for 30 days of duration with 4 follow ups for assessment on 7th, 15th, 21st day and at the end of treatment. The observations in each follow up subjective and objective were recorded in case report form.

Efficacy Assessment

Assessment of efficacy was made subjective and objectively at each follow up with reference to baseline findings. Accordingly, patients were assessed at every visit by using Visual Analogue Scale (VAS) and *WOMAC OA* Index.

WOMAC is a tri-dimensional, disease-specific, self-reported health status measure for hip and knee OA. It consists of 24 questions addressing severity of symptoms: 5 questions for joint pain, 2 questions for joint stiffness, and 17 questions for limitation of physical function. The Likert version of the WOMAC questionnaire will be used in which each question is assessed by using a 5-point Likert scale ranging from 0 to 4, and the aggregate WOMAC score is represented by the sum of the 24-component item scores. The WOMAC is scored on a best to worst scale, so that lowest subscale scores represent less pain, less stiffness, or better physical function

Visual Analogue Scale (VAS): The patients will be asked to mark pain severity on a VAS which is a vertically marked 0 to 10-points linear scale. The scoring for gradation of pain by using VAS ranging from 0 to 10 will be done as follows:

0-1 No pain
2-3 Mild
4-5 Uncomfortable
6-7 Distressing
8-9 Intense
10 Worst possible

Withdrawal criteria

1. Failure to follow the protocol
2. Any adverse reaction or adverse event
3. Non-compliance to the therapy

Adverse drug reaction: Any adverse effect or reaction was reported to Department of Moalajat, Jamia Tibbiya Deoband and documented in CRF.

Documentation: The Case Report Form (CRF) along with written Informed Consent form /document of participants of this trial was submitted to the department after completion of the study.

Data analyses: The data was analysed statistically to measure the study outcome, based on the pre- and post-trial subjective and objective observations. Descriptive and inferential statistical analysis has been carried out with results on continuous measurements are presented on Mean ± SD (Min-Max), whereas, the results on categorical measurements are presented in number (%). Student "t" test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Student "t" test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within the group (Intra Group analysis). Fisher Exact test has been used to find the significance of study parameters on categorical scale between three groups. Significance is assessed at 5 % level of significance.

The following assumptions on data are made

1. Dependent variables are normally distributed,
2. Samples are drawn randomly from the population
3. Samples are independent

Significance figures

+ Suggestive significance (P value: $0.05<P<0.10$)
* Moderately significant (P value: $0.01<P \leq 0.05$)
** Strongly significant (P value: $P \leq 0.01$)

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**.**

RESULT

Table 1: Knee Pain (VAS score): Assessment at different study points in two groups of patients studied.

VAS Score	0 day	7th day	15th day	22nd day	30th day	% difference
Group A(n=30)						
0	0(0%)	0(0%)	0(0%)	1(3.3%)	1(3.3%)	3.3%
1-3	0(0%)	0(0%)	2(6.7%)	12(40%)	25(83.3%)	83.3%
4-6	0(0%)	7(23.3%)	21(70%)	15(50%)	4(13.3%)	13.3%
7-10	30(100%)	23(76.7%)	7(23.3%)	2(6.7%)	0(0%)	-100.0%
Group B(n=30)						
0	0(0%)	0(0%)	1(3.3%)	6(20%)	11(36.7%)	36.7%
1-3	0(0%)	0(0%)	5(16.7%)	16(53.3%)	19(63.3%)	63.3%

4-6	1(3.3%)	15(50%)	18(60%)	5(16.7%)	0(0%)	-3.3%
7-10	29(96.7%)	15(50%)	6(20%)	3(10%)	0(0%)	-96.7%
P value	1.000	0.060+	0.498	0.021*	<0.001**	-

Table 2: Comparison of Blood parameters in two groups of patients studied beforeand after treatment.

	Group A	Group B	Total	P value
Blood Urea mg/dl				
Before Treatment	30.83±8.20	24.60±4.75	27.72±7.35	0.001**
After Treatment	27.27±8.57	22.67±3.96	24.97±7.01	0.010**
Serum Creatininemg/dl				
Before Treatment	0.90±0.18	0.77±0.13	0.83±0.17	0.003**
After Treatment	0.90±0.17	0.70±0.11	0.80±0.17	<0.001**
SGOT IU/L				
Before Treatment	24.93±7.94	16.43±3.7	20.68±7.49	<0.001**
After Treatment	24.63±7.06	15.33±3.02	19.98±7.14	<0.001**
SGPT IU/L				
Before Treatment	21.80±5.45	20.57±4.55	21.18±5.02	0.345
After Treatment	20.30±5.23	18.77±4.09	19.53±4.72	0.211
Alkaline Phosphatase				
Before Treatment	114.77±13.49	111.57±15.43	113.17±14.46	0.396
After Treatment	114.53±11.14	110.67±14.61	112.60±13.03	0.254
Total Bilirubin.mg/dl				
Before Treatment	0.75±0.29	0.81±0.19	0.78±0.24	0.331
After Treatment	0.71±0.14	0.82±0.14	0.76±0.15	0.004**

DISCUSSION

Pain

Knee pain was assessed on arbitrary scale which was graded as severe, moderate, mild and barely perceptible and was coded as 7-10, 4-6,1-3, and 0 respectively. At baseline in Group A, most of the patients 30 (100%.) had severe pain. At the end of treatment in Group A, 1 patient (3.3%) had barely perceptible knee pain, 25 patients (83.3%) had mild pain, 4 patients (13.3%) had moderate pain and 0 patient (0%) had severe pain. At baseline in Group B, 29(96.7%) patient severe knee pain, 1 patient (.3%) had moderate pain. At the end of treatment in Group B, 11 patients (36.7.7%) had joint pain, 19 patients (63.3%) had mild pain, 0 patient (0%) had moderate pain and severe pain. (Table No. 1)) The p value calculated by ChiSquare/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 knee pain.

Knee pain may originate in different ways. It may be inflammatory in nature and may also develop due to the change in local pH or may arise because some ions can stimulate nerve endings. Similarly, release of certain chemicals like Histamine, 5 HT, K^+ and plasma kinin can stimulate the local sensory nerves.

In addition, synovial fluid can indirectly cause pain by serving as a transport medium, distending the joint capsule and limiting the joint functions. The synovial fluid shuttles inflammatory mediators back and forth between the cartilage and synovium. Synovial fluid also serves as a reservoir for inflammatory products, cells and crystals. Furthermore, synovial fluid distends the joint, potentially compressing blood vessels, leading to the stimulation of pressure receptors in the capsule. Joint distention also compromises the transport of nutrition and oxygen from the synovium to the cartilage and waste products from cartilage to synovium.[3,4,5]

Dry cupping can reduce joint pain in different ways. Removal of excess synovial fluid volume with its inflammatory mediators is often an effective therapeutic modality, even in the absence of other intervention.[6]

It has already been mentioned in literature that the technique of *Hijamah/cupping* involves mainly two lines of treatments – Diversion (*Imala*) and Evacuation (*Istifragh*) of stagnant *Akhlat-e-Fasida* (Morbid Humours). Here in this case dry cupping diverts the morbid humours from the diseased tissues relieving the pressure symptoms, so it is beneficial for the management of the pain. This effect of *Cupping* is coinciding with finding of Razi, Akbar Arzani,[7] Ibne Sena,[8] Majoosi,[9] Carlose J, *et al*.[6]

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. The intergroup comparison at the end of treatment between Group A and Group B was found 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 significant difference exist between the group. So, it is concluded that a greater improvement was found Group B than Group A in decrease in WOMAC score.

Safety profile
Safety and tolerability of the study medication was monitored by adverse events and clinical laboratory investigations LFT and RFT before and after trial. The difference of means for SGOT, SGPT, Alkaline Phosphatase, serum creatinine and blood urea were found insignificant. (Table No.2). However, it was within normal range at baseline as well as after treatment. It indicates that the research drugs are found to be safe. No adverse effects were reported during study which showed safety of these drugs.

Strength
Dry cupping was effective for improvement in subjective and objective parameters of Knee pain as it has noticeable effect together without any side effects. Strengths of this study include its appearance, palatability, clinical and biochemically safety. Compliance of the participants was also good. This study also included widely used validated instruments for the evaluation (VAS and WOMAC).

Limitations of the study
The main limitation of this study was small sample size, short duration of intervention and loss of long term for efficacy and recurrence of symptoms. Long term follows up were not used to ascertain the microbiological and histological effect of test drugs.

Further recommendation
For better results higher dose over long duration with larger sample size may be tested. There should be longer follow up to assess recurrence and long-term reproductive outcome. Hence further wide range studies are recommended.

SUMMARY

The overall effect of the Dry cupping in the treatment of Knee pain is marked improvement in subjective parameters like pain, difficulty in movement and stiffness and reduction was seen in objective parameter VAS score and WOMAC OA index. No side effects were observed in enrolled subjects. Compliance to the treatment was found good. These results concluded that the both Dry cupping and *Habbe Hudar* are effective and safe in the management of Knee pain, but there was a better improvement in patients on which dry cupping was performed. However large sample sized controlled clinical trials of longer duration are needed for the generalization of the results.

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Conflict of Intrest
Nil.

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