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A randomized comparative clinical study on osteoarthritis knee with Unani formulations (oral and local) and Hijama Bila Shart

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Abstract

Osteoarthritis is the most common form of chronic arthritis affecting 250 million people worldwide. Obesity has been recognized as one of the strong risk factor of knee osteoarthritis. In Unani system of medicine joint diseases are treated with several regimens, therefore, it is hypothesized to evaluate comparatively the efficacies of two different treatments viz Unani formulation(s) and *Hijama Bila Shart* in osteoarthritis knee among obese.

Methods: This study was conducted as a comparative, open, randomized, active control clinical trial on 35 patients, 20 patients in test group (*Habb* with *Zimad*) and 15 patients in active control group (*Hijama bila shart*). Both groups were treated continuously for 15 days. The pre and post treatment effects were assessed with subjective and objective parameters.

Results: Subjective parameters Knee joint pain and Difficulty in movement were found highly significant in either groups (p<0.001), whereas, Morning stiffness was found insignificant (p>0.05)in both groups, WOMAC Index scores (combined, pain and physical function) were found significant (p<0.001) whilst, Stiffness subscale was observed not significant (p>0.05). The results were analyzed statistically by using Paired t test, Friedman test with posttest, one-way ANOVA with posttest and Kruskal Wallis test with Dunn's multiple compare test.

Discussion: This comparative trial revealed that interventions of both groups are effective in ameliorating the symptoms of osteoarthritis knee. Test drugs were found comparatively little more effective than control. Moreover, interventions of both groups were found to be effective without any adverse effect.

Keywords: Wajaul Mafasil, Unani formulation, Hijama Bila Shart, osteoarthritis knee, obesity

Introduction

Osteoarthritis is characterized by unbalanced degeneration and regeneration of articular cartilage and bone, where the intrinsic repair mechanisms are insufficient ^[1]. Osteoarthritis is considered to be primary if it is idiopathic and secondary due to previous injury or disease of joint ^[2]. it can occur in every synovial joint, like hip, knee, hand, foot and spine but most clinically significant site is Knee ^[3]. As per the survey and a study report about 6% of males and 12% of females suffer from Knee Osteoarthritis (KOA) in Asia ^[4]. In India alone OA is the 2nd most common rheumatologic problem and is the most frequent joint disease with prevalence of 22% to 39% ^[5], but prevalence of knee pain and OA in the Indian subcontinent is approximately 35% ^[6]. Risk factors for developing OA include advanced age, obesity, female sex, prior joint injury, positive family history ^[7] and heavy work load ^[8, 9, 10]. Obesity is one of the most important risk factor for the development of severe KOA ^[11].

In Unani medicine, diseases of joint pain was broadly used in a term Wajaul Mafasil, where "Waja" stands for pain and "Mafasil" means joint. Osteoarthritis is being literally termed as Wajaul Mafasil. As per the Unani science, Simane Mufrit is a clinical state due to increased rutoobat and buroodatbadan leading to imbalance of humours in the body and increases tendency of accumulation of Akhlatefasida particularly Maddaebalghamia in joint cavity and causes difficulty in movement [12, 13, 14].

Unani physicians were treated *Wajaul Mafasil* of different joints with various methods and regimens, out of such regimens and drugs, *Hijama Bila Shart* ^[15, 16, 17] and a combination of Unani formulations Habb ^[18] and Zimad ^[19] are being selected for testing the efficacy comparatively. So, it is hypothesized to compare the effects of compound formulations *Habb* and *Zimad* with a regimen *Hijama Bila Shart* in Osteoarthritis knee among obese patients.

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Material and methods

This study conducted from March 2014 to January 2015 by enrolling 35 patients who were fulfilling American College of Rheumatology classification criteria for knee osteoarthritis (based on history, Physical examination and laboratory findings)from OPD & IPD of NIUM Hospital, Bangalore, based on the Inclusion criteria as both gender, age group of $\geq\!30$ to $\leq\!60$ years, BMI $\geq\!30$ to $\leq\!39.9$, Kellgren - Lawrence Grading Scale from 0 to 3, and patients with Pregnancy and lactation, age between <30- $>\!60$, Other than OA, BMI $\geq\!40$, Kellgren - Lawrence Grading Scale $\geq\!4$, History of systemic, endocrine and metabolic diseases were excluded.

Ethical clearance

This study is approved from Institutional Ethical Committee for Biomedical Research, vide no. NIUM/IEC/2012-13/006/Moal/06

Study Design: Openlabel randomized control study.

A total of 250 patients were screened, out of which 38 patients randomly allocated them into two groupsviz, test group (n = 21) received *Habb* and *Zimad* and active control group (n =17) received *Hijama Bila Shart*. Both groups were treated for 15 days continuously, with five follow ups. The study outcomes were assessed as subjective and objective findings from baseline to each follow up. At last 35 patients completed the study (test group 20 patients, control group 15 patients).

Interventions

Test group was administered with two tablets of each of 800 mg orally three times a day with water after meal. Ingredients of Habb: Suranjan (Colchicum autumnale), indicum), Bozidan (Pyrethrum Hanzal (Citrullus colocynthis), Garigun (Agaricus alba), Sibr (Aloe barbadensis), Muqil (Commiphora mukul), (Operculina turpethum) and Zimad (local application) 10gms/ per affected side / day, it is made up of Moam (Bees wax) Thukhmekatan (Linum usitatissimum) Luabemethi (Trigonella foenum) Roghane Babuna chamomilla).

All subjects were instructed to apply cream on the affected knee with a thin coating for three times a day. These preparations are made as per the GMP guidelines as stated in the texts.

Control Group: Active Control group was subjected to *Hijma Bila Shart* (Dry Cupping) continuously for 15 days on affected joint for 15 minutes.

Clinical Assessment and Statistical Analysis

Assessment of Efficacy was carried out through the VAS (10 cm numerical Likert scale) and Womac Index (Modified Crd Pune Version). Statistical tests were carried out to analyze the data using Instat Graph Pad. The tests which used were Paired t test, Friedman test for intra group comparison and one way anova and Kruskal- Wallis test with Dunn's multiple pair comparison for inter group comparison. Numerical variables are described by mean and

standard deviation.

Safety evaluation

Safety assessments (Haemograme, Erythrocyte Sedimentation Rate, Alanine aminotransferase, Aspartate aminotransferase, Alkaline phosphatase, Blood Urea and Serum Creatinine) were performed at baseline and last follows up. This study has shown no adverse effects in either group.

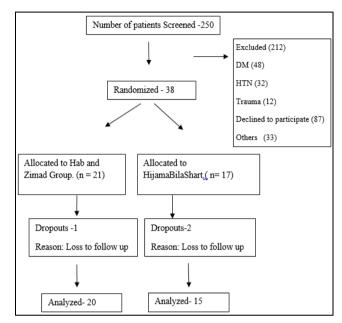


Fig 1: Consort flow diagram

Results

Out of 35 patients participated in this study, 57.2% were found in the age group of 41-50 years, 31.4 % in 30-40 years and 11.4% in 51-60 age groups, 91.4% were females and 8.6% were males, all the cases were married, according to dietary habit, 80% patients were found with mixed dietary habit and 20% pure vegetarian. Socioeconomically, 57% patients were from upper lower class (IV), 22.9% in lower middle (III), 14.3% in upper middle class (II) and 5.7% in lower class (V).

The Mizaj (temperament) of the patients was found to be, 74.3% were Balghami mizai, 22.9% Damavi and 2.8% Safravi mizai, occupationally 74.3% were housewives, 11.4% government service, 8.6% businessmen and 5.7% laborers, according to BMI, 62.8% were found with BMI of 30 -34, 17.2% in each with 34.01-36 and 36.01-38 ranges and 2.8% with 38.01-40, the chronicity of the disease was observed as, 42.9% in between 1-20 months, followed by 25.7% with 21-40 months, 14.3% with 41-60 month, 11.4% with 81-100 months and 5.7% with 61-80 months, according to the site of the knee joint involvement, bilateral knee joint was observed in 85.7% and unilaterally observation was found as 8.6% in left knee and 5.7% in right side of the knee, based on KL grading of X -ray findings 40% cases were found with KL grade-3, 25.8% with grade - 0 and 17.1% in each grade 1 and 2.

Table 1: Demographic data

S. No	Variables	Statistical unit	Test group	Control group		
1	Age	30-40	7(35%)	4(26.7%)		
		41-50	12(60%)	8(53.3%)		
		51-60	1(5%)	3(20%)		
2	Gender	Male	2(10%)	1(6.7%)		
		Female	18(90%)	14(93.3%)		
3	Marital Status	Married	20(100%)	15(100%)		
		Unmarried	0(0%)	0(0%)		
4	Mizaj	Damavi	4(20%)	4(26.7%)		
		Balghami	15(75%)	11(73.3%)		
		Safravi	1(5%)	0(0%)		
5	Occupation	Service	2(10%)	2(13.3%)		
	-	Business	1(5%)	2(13.3%)		
		Laborer	2(10%)	0(0%)		
		House wife	15(75%)	11(73.4%)		
6	BMI	30-32	4(20%)	7(46.66%)		
		32.01-34	5(25%)	6(40%)		
		34.01-36	6(30%)	0(0%)		
		36.01-38	5(25%)	1(6.67%)		
		38.01-40	0(0%)	1(6.67%)		
7	Duration of illness(Months)	1-20	8(40%)	7(46.67%)		
		21-40	5(25%)	7(26.66%)		
		41-60	3(15%)	2(13.33%)		
		61-80	1(5%)	1(6.67%)		
		81-100	3(15%)	1(6.67%)		
8	Knee joint involvement	Right	1(5%)	1(6.7%)		
		Left	2(10%)	1(6.7%)		
		Both	17(85)	13(86.6%)		
9	KL Grade	0	6(30%)	3(20%)		
		1	4(20%)	2(13.3%)		
		2	3(15%)	3(20%)		
		3	7(35%)	7(46.7%)		

Table 2: Effect of the study on subjective parameters in Test Groups (mean $\pm SD$)

Subjective Denometer	Test Group							
Subjective Parameter	BL	F1	F2	F3	F4	F5	p value	
Knee Joint Pain	5.9 ± 0.91	5.5±0.83	4.75±1.07	4.35±1.31	3.45±1.15	3.25±1.07	< 0.001	
Morning Stiffness	1.45±1.05	1.35±0.93	1.3±0.92	1.15±0.81	1.05±0.82	1±0.72	>0.05	
Difficulty in Movement	2.45±0.51	2.35±0.489	2.05 ±0.83	1.8±0.62	1.7±0.66	1.5±0.61	< 0.001	

Table 3: Effect of study on Subjective parameters in Active Control Group (mean ±SD)

Subjective Parameter	Active Control Group (Hijama Bila Shart)								
Subjective Farameter	BL	F1	F2	F3	F4	F5	p value		
Knee Joint Pain	5.93±0.88	5.8±0.86	4.93±1.16	4.6±1.24	4.07±1.39	3.73±1.22	< 0.001		
Morning Stiffness	1.27±0.88	1.2±0.86	1.13±o.74	1.07±0.79	1±0.84	0.93±0.96	>0.05		
Difficulty in Movement	2.33±0.49	2.27±0.46	1.93±0.80	1.87±0.64	1.47±0.74	1.33±0.62	< 0.001		

Table 4: Effect of study on Objective parameters in Test Group (mean $\pm SD$)

Objective Denometer	Test Group							
Objective Parameter	BL	F1	F2	F3	F4	F5	p value	
WOMAC pain	7.05±2.44	6.8±2.04	6.15±2.41	5±3.09	4±2.25	3.9±2.29 [,]	< 0.001	
WOMAC stiffness	2.75±1.92	2.7±1.87	2.6±1.85	2.45±1.8	1.85±1.53	1.8±1.47	>0.05	
WOMAC function	33.5±11.51	33.45±11.48	31.8±11.09	29.8±12.19	27.9±11.23	27.1±10.61	< 0.001	
WOMAC total	43.3±15.06	42.95±14.69	40.55±14.36	37.25±16.12	33.8±14.15	32.85±13.59	< 0.001	

 $\textbf{Table 5:} \ Effect \ of \ study \ on \ Objective \ parameters \ in \ Active \ Control \ Group \ (mean \ \pm SD)$

Objective Parameter	Active Control Group (Hijama Bila Shart)							
Objective Farameter	BL	F1	F2	F3	F4	F5	p value	
WOMAC pain	6.67±1.79	6.6±1.88	5.33±2.58	4.87±1.68	4.46±2.23	4.2±1.94	< 0.001	
WOMAC stiffness	2.33±1.59	2.27±1.49	2.2±1.42	2.13±1.59	1.67±1.49	1.6±1.40	>0.05	
WOMAC function	31.06±9.88	30.87±9.66	30.6±9.87	29.93±9.66	29.07±9.62	26.2±9.96	< 0.001	
WOMAC total	40.07±12.6	39.73±12.46	38.2±13.31	36.93±12.23	35.26±12.88	32±12.92	< 0.001	

BL-baseline, F1-followup 1, F2- follow up 2, F3- follow up 3, F4- follow up 4, F5- follow up 5.

Womac: Western Ontario and McMaster Universities Osteoarthritis Index Statistical test used is Friedman Test for intra-group comparison and Kruskal-Wallis Test with Dunn's Multiple Comparisons test for inter-group comparison.

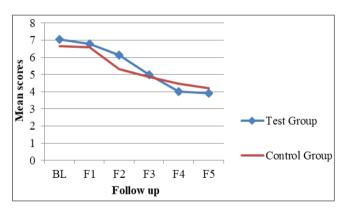
The study outcomes on subjective parameters viz Knee joint pain, Morning stiffness, Difficulty in movements were assessed. The Effect of the study on knee joint Pain was found progressively relief and it was observed as highly significant with p value <0.001 in both groups, but clinically test group was found little more effective in comparison to active control group. Similarly the effect of the study on morning stiffness in both groups shows clinically significant but statistically not significant (p>0.05), whereas, Difficulty in movements was found highly significant in both the groups with p value <0.001, whilst, inter group comparison was found not significant. However, active control group shows superiority in responses over test group.

Objective parameters assessed with WOMAC index (Modified CRD Pune Version). There was significant improvement in the WOMAC Total score, and the WOMAC subscales scores of Pain and Physical function with p value < 0.001 in either group, whereas, Stiffness subscale was found clinically significant but statistically insignificant with p value > 0.05 in both groups.

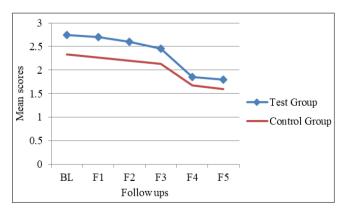
Assessment of safety

The studied methods were found safe without any adverse effects.

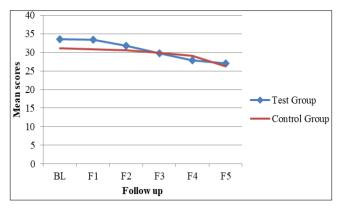
WMAC scores over time in the studied patient.



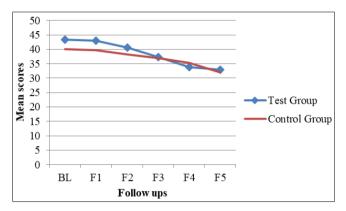
Graph 1: Effect of study on WOMAC (Modified CRD Pune Version) pain score among the groups



Graph 2: Effects of study on WOMAC (CRD Pune Version)
Stiffness score among the groups



Graph: 3: Effect of study on WOMAC (CRD Pune Version) Physical function score among the groups



Graph 4: Effect of study on WOMAC (Modified CRD Pune Version) Total scoreamong the groups.

Discussion

The data of the present study reveals that the disease is more prevalent in 4th and 5th decade of life. This finding supports the observations of Nayab M [20], Manoj Kumar et al. [21] and Longo D et al. [22] Prevalence of the disease is higher in females than males which coincide with the finding of Patil PS [23], Ratzlaff et al. [24] Rautetal [25] and also supports the description made by Humira et al. [26] and College NR. [27] Moreover, it strongly supports Ehsan S [28] findings that they found 95% of obese female developed symptomatic KOA. All cases in the study were married, this finding supports the description of cause and relationship of OA associated with active marital life according to Attiba Unani like Ibn Sina [29] and Jurjani Mizaj wise observation reveals that Balghamimizai individuals more prone to get OA knee, this mizaj (temperamental) correlation of patients supports the concept of Zakariya Razi [19] and Ibn Sinathat people with Balghamimizaj are more likely to develop Wajaul Mafasil in comparison of other humours.

In this study, occupationally majority of the patients were found to be housewives, this findings support with Shakoor $et\ al.\ ^{[8]}$ observation that the disease is highest among housewives and it may also be due to sedentary lifestyle, as described by Ibn sina, Ismail jurjani and majoosis statement. Observation of chronicity of disease was supports the claims made by College $et\ al.\ ^{[27]}$ as OA is a chronic disease.

Regarding the sides affected by OA knee, it was found in this study that most of the study subjects were suffering from both knees OA, this findings supports the Chopra A *et al.* [30] Based on the Radiological findings of the study participant, according Kellgren & Lawrence classification of OA knee grading system, this study evidence that a

maximum of 14 (40%) of patients found with KL grade-3, followed by 9(25.8%) grade-0, 6 (17.1%) each in grade 1 and 2. This finding coincides with the description of Heidari B [11] Hassan M *et al.* [31] that many individuals with radiographic knee OA are asymptomatic and in contrary in many patients with knee pain suggestive of OA radiologic findings are absent.

Assessment of Effect of the interventions on subjective parameters like "knee joint Pain" was found progressively relief and it was observed as highly significant with p value <0.001 in both groups but clinically test group was found little more effective in comparison to active control group, on morning stiffness both groups show clinically significant but statistically not significant (p>0.05), on "Difficulty in movements" both the groups found highly significant with p value <0.001, whilst, inter group comparison was found not significant. However, active control group shows superiority in responses over test group.

The effect of the study WOMAC index (Modified CRD Pune Version) total score, and the WOMAC subscales scores of Pain and Physical function with p value < 0.001 in either group, whereas, stiffness subscale was found clinically significant but statistically insignificant with p value > 0.05 in both groups. In the present study both the interventions Habb with Zimad and *Hijama Bila Shart* were observed effective in ameliorating the symptoms of knee osteoarthritis $^{[32,33]}$.

Conclusion

On the basis of the results it can be concluded that, both interventions *Habb* with *Zimad* and *Hijama Bila Shart* were found effective in ameliorating the symptoms (symptoms modification) of knee osteoarthritis without any adverse effects. Based on the observations of this study, it can be concluded that the compound formulations *Habb* with *Zimad* and a regimen *Hijama Bila Shart* can be used in the management of *Wajaul Mafasil* (Osteoarthritis Knee). However, it is suggested to have further studies with different methodology and parameters on larger sample size to evaluate the effects of these treatments in not only symptoms modification associated with the diseases but also in disease modification too.

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