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RESEARCH ARTICLE

A CLINICAL TRIAL BASED STUDY OUTCOME OF OSTEOARTHRITIS KNEE WITH LEQUESNE INDEX

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ABSTRACT

Background and Objective: Osteoarthritis knee is one of the major causes of disability among aged and relatively obese patients. The prevalence of Osteoarthritis is estimated as it is affecting 250 million people worldwide. To provide effective and safe mean of pain management associated with OA knee certain Unani regimens and formulations have been tested to validate their claims.

Methods: This study was a open label, 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 of the study were assessed with Lequesne Index.

Results: **Lequesne Index (ISK) s**ubscales of Pain and discomfort, ADL and Total scores are highly significant with p value < 0.001, Whereas, Maximum distance walk subscale is clinically significant but statistically insignificant. The results were analyzed statistically by using Paired't' test, Friedman test and Kruskal Wallis test with Dunn's multiple compare test.

Interpretation and Conclusion: The findings of the study reveals that the interventions of both groups are effective in alleviate the symptoms of osteoarthritis knee. Test drug was found comparatively more effective than control.

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INTRODUCTION

In Unani system of medicine onset of diseases are inflicted with the imbalance of *akhlath* (humours). *Waja ul mafasil* is a state of pain in joints; (Sina, YNM; Razi, 2004; Arzani, YNM; Baghdadi, 2007) Osteoarthritis is being a form of Joint disease literally termed as *Waja ul Mafasil*. As per the Unani science, *Simane Mufrit* is a clinical state due to increased *rutoobat* and *buroodat badan* leading to imbalance of humours in the body and increases tendency of accumulation of a*khlate fasida* particularly *maddae balghamia* in joint cavity and causes difficulty in movement. (Jurjani, 2010; Sina, YNM ; Ahmed, 2010)It suggest that obesity is being consider as a risk factor for osteoarthritis.

Osteoarthritis is a common degenerative disorder of the articular cartilage associated with hypertrophic changes in the bone. (Sinusas, 2012) In Osteoarthritis the primarily affected joints are the knee and hip. The presence of obesity has been shown to be associated with increased risk of knee OA and may also increase the rate of articular cartilage degeneration. (Yusuf *et al*, 2011; Firestein *et al*, 2008) OA is one of the leading causes of disability, its worldwide prevalence estimate for symptomatic OA is 9.6% among men and 18% among women. (Patil *et al*, 2012)[11]It is painful and debilitating disease of the synovial joints, affecting 12-15% of the population between 25-74 years of age. (Guilak, 2011; Gremion *et al*, 2009) Using national data, the Healthcare Cost and Utilization Project showed that osteoarthritis accounted for US$ 10.5 billion in hospital charges in 2006, making it a more expensive condition than pneumonia, stroke or complications from diabetes. Hospital admissions for arthritis are more than doubled from 1993 to 2006. (Sowers and Karvonen-Gutierrez, 2010)

Obesity is the greatest modifiable risk factor for OA. According to some reports, subjects with BMI >30 were 6.8 times more likely to develop knee OA than normal weight controls. (King *et al*, 2013) The most common symptom of knee OA is pain. Overall, higher levels of pain from knee OA are linked to lower physical function and lower quality of life.(Elbaz *et al*, 2014; Longo *et al*, 2012 ; Munjal, 2012) Currently a wide variety of treatments are available and they

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ranges from simple educational help to highly technical and skilled physical, medical or surgical procedure. (Adebajo, 2010 ; Colledge *et al*, 2010 ; Imboden *et al*, 2013) Surgical treatment is generally reserved for failed medical management with functional disability affecting patient's quality of life. (Arya and Jain, 2013 ; Kapoor *et al*, 2011) Unani physicians were treated *Waja ul Mafasil* of different joints with various methods and regimens, out of such regimens and drugs, *Hijama Bila Shart* (Sina, 2006 ; Masihi, 1986 ; Sina, 1993 ; Quamri, 2012) and a combination of formulations Habb (Majoosi, 2010) and Zimad (Razi, 2004) are selected for testing to establish their efficacy. So it is hypothesized that the drug and regimen will have certain comparative effects on osteoarthritis knee, hence, to compare the effects of compound formulations *Habb* and *Zimad* with a regimen *Hijamat Bila Shart* in Osteoarthritis knee among obese patients this study was conducted.

MATERIAL AND METHODS

This study was an open label randomized control clinical trial on Osteoarthritis knee among obese with oral and local Unani formulations conducted on 35 patients at OPD & IPD of NIUM Hospital, Bangalore. This study protocol was approved by the Institutional Ethical Committee for Biomedical Research of NIUM. The selection of patients was based on the criterian of inclusion as patients of both gender, age group of ≥30 to ≤ 60 years, BMI ≥ 30 to ≤39.9, ACR criterion for OA knee, Kellgren - Lawrence Grading Scale from 0 to 3, whereas, patients were excluded with Pregnancy and lactation, age group < 30 - >60, Other than OA, BMI ≥40, Kellgren - Lawrence Grading Scale ≥ 4, History of systemic, endocrine and metabolic diseases

Patients fulfilling the American College of Rheumatology (ACR) criteria for knee osteoarthritis were selected for screening. A total of 250 patients were screened, out of which 38 patients enrolled in to the study by randomization into two groups. Test group (n = 21) received Habb and Zimad and active control group (n =17) received *Hijamat Bila Shurt.* Both groups were treated for 15 days continuously. The effect of the study was assessed objectively with Lequesne Index findings from baseline to each follow up to 14th. At last 35 patients completed the study (test group 20 patients, control group 15 patients) and all the patients provided written informed consent prior to study participation.

Table 1 Ingredients of Habb (Tablets)

S No	Name of the drug	Botanical name	Quantity used in preparation
1	Suranjan sheerin	*Colchicum autumnale*	0.75gms
2	Bozidan	*Pyrethrum indicum*	0.75gms
3	Hanzal	*Citrullus colocysthis*	0.75gms
4	Gariqun	*Agaricus alba*	1.75gms
5	Sibr	*Aloe barbadensis*	1.75gms
6	Muqil	*Commiphora mukul*	3.5gms
7	Turbud	*Operculina turpethum*	3.5gms

Table 2 Ingredients of Zimad (Cream)

S No	Name of the drug	Botanical name	Quantity used in preparation
1	Thukhme katan	*Linum usitatissimum*	20gms
2	Luabe methi	*Trigonella foenum*	20gms
3	Moam	*Bees wax*	20gms
4	Roghane Babuna	*Matricaria chamomilla*	120 ml

OBSERVATION AND RESULTS

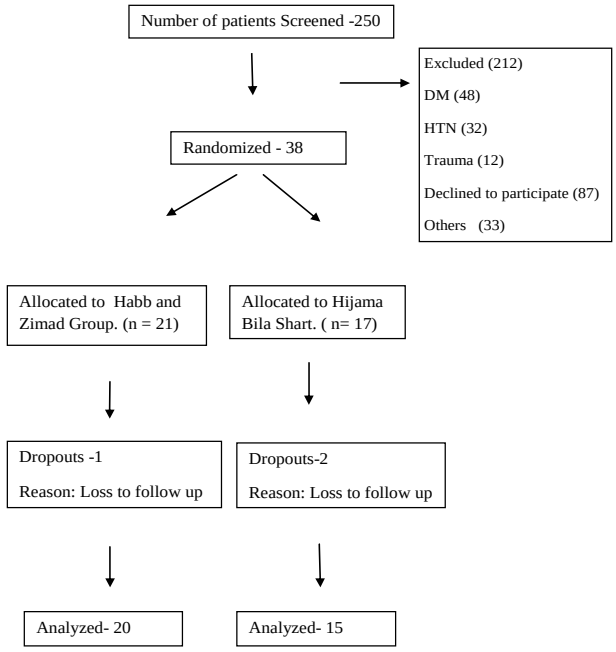


Figure 1 Consort flow diagram

Table 3 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%)

Interventions

Test group received two tablets of 800 mg each was given orally three times a day with water after meal, along with local application of Zimad (Cream) in 10 grams per affected side a day, and **Control group** was subjected to *Hijama Bila Shart*

over the affected knee, both groups received treatment for 15 days continuously.

Lequesne Index (ISK - Index for Severity of Knee Osteoarthritis) is an objective tool to assess study outcome of OA knee. ISK contains parameters like Subscales of Pain and discomfort, Maximum Distance Walked Score, Activity of Daily Life (ADL) and Lequesne Total scores.

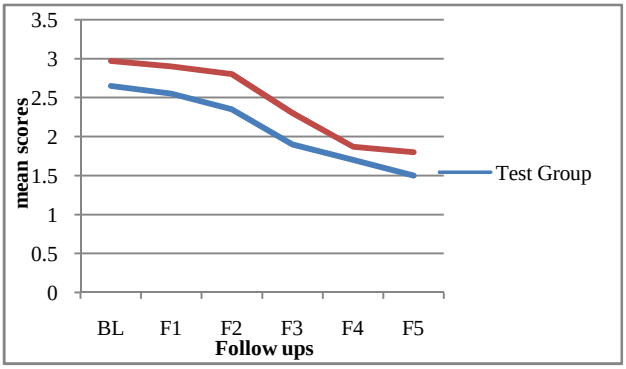
This study based findings of Lequesne parameters viz subscales of Pain and discomfort, Activity of Daily Life (ADL) and Lequesne Total scores outcomes are highly significant with p value < 0.001, Whereas, Maximum distance walk subscale is clinically significant but statistically insignificant

Table 4 Effect of study on Lequesne Index (ISK) as Objective parameters in Test Group (mean ±SD)

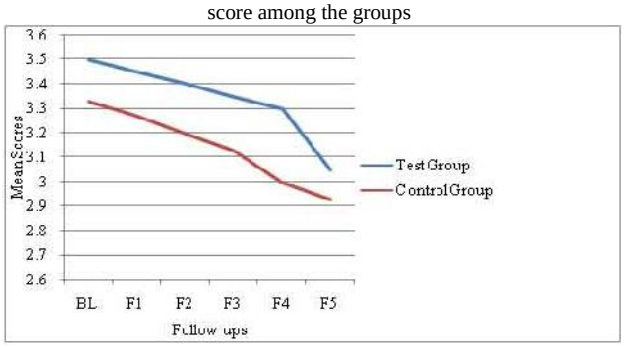
Objective Parameter	Test Group						
	BL	F1	F2	F3	F4	F5	p value
Pain and Discomfort	2.65±1.42	2.55±1.4	2.35±1.46	1.9±1.65	1.7±1.56	1.5±1.43	<0.001
Maximum Distance walked score	3.5±0.76	3.45±0.69	3.4±0.68	3.35±0.87	3.3±0.92	3.05±0.83	>0.05
ADL score	4±0.97	3.95±0.9987	3.72±1.13	3.42±0..98	2.9±0.87	2.75±0.91	<0.001
Lequesne total score	10.25±2.78	9.95±2.66	9.47±2.75	8.72±3.05	7.9±2.98	7.3±2.84	<0.001

Table 5 Effect of study on Lequesne Index (ISK) Objective parameters in Active Control Group (mean ±SD)

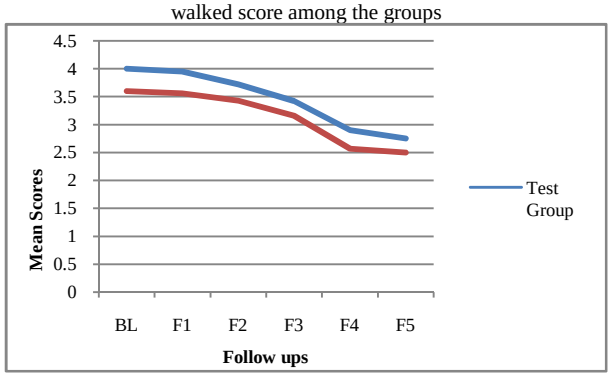
Objective Parameter	Active Control Group						
	BL	F1	F2	F3	F4	F5	p value
Pain and Discomfort	2.97±1.49	2.9±1.47	2.8±1.52	2.3±1.60	1.87±1.59	1.8±1.47	<0.001
Maximum Distance walked score	3.33±0.49	3.27±0.46	3.2±0.56	3.13±0.64	3±0.75	2.93±0.70	>0.05
ADL score	3.6±0.83	3.56±0.84	3.43±1.02	3.16±0.82	2.57±0.70	2.5±0.71	<0.001
Lequesne total score	9.9±2.65	9.73±2.46	9.43±2.86	8.53±2.47	7.43±2.51	7.16±2.32	<0.001



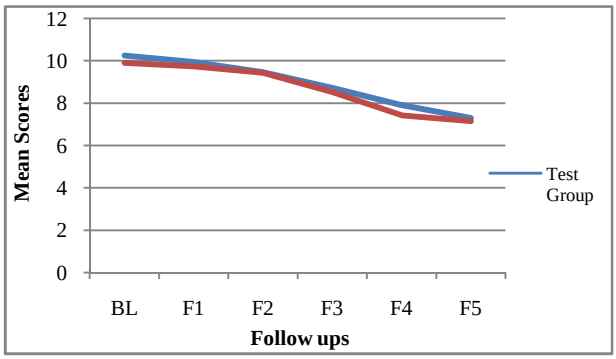
Graph 1 Effect of study on Lequesne (ISK) index pain and discomfort score among the groups



Graph 2 Effect of study on Lequesne (ISK) index Maximum Distance walked score among the groups



Graph 3 Effect of study on Lequesne (ISK) index ADL score among the groups



Graph 4 Effect of study on Lequesne (ISK) Index total score among the groups

Clinical assessment and statistical analysis

Clinical assessment of study outcome was carried out by using Lequesne Index (ISK -Index of Severity for Knee Osteoarthritis). 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 Kruskal-Wallis test with Dunn's multiple pair comparison for inter group comparison. Numerical variables are described by mean and standard deviation

The data of the study revealed that the disease is more prevalent in 4th and 5th decade of life. This finding supports the observations of Shakoor *et al* (Shakoor *et al*, 2009) According to the gender, the disease is higher in females than males which coincide the description made by Firestein *et al* and Colledge NR. In this study the Mizaj (temperamental) observed as 26 (74.3%) were *Balghami*, (22.9%) *Damavi* and 1(2.8%) *Safravi mizaj*, This mizaj correlation of patients supports the concept of Zakariya Razi and Ibn Sina that *Balghami mizaj* individuals are more liable to develop *Waja ul Mafasil* in comparison of other humours.

In this study, occupationally majority of the patients were found to be housewives, this correlates with the findings of Shakoor *et al* that the disease is highest among housewives

Based on the Radiological findings of the study participant (Kellgren & Lawrence classification of OA knee grading system) maximum of 14 (40%) of patients found with KL grade-3, followed by 9(25.8%) grade-0, 6 (17.1%) each in grade 1and 2. This finding support the description of Hassan M *et al* (Hassan and Shuckett, 2010) 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.

Objective parameters assessed with **LequesneIndex (ISK).** Subscales of Pain and discomfort, ADL and Total scores are highly significant with p value < 0.001, Whereas, Maximum distance walk subscale is clinically significant but statistically insignificant

Safety evaluation

Safety assessments of study were carried out with (Haemograme, Erythrocyte Sedimentation Rate, Alanine aminotransferase, Aspartate aminotransferase, alkaline phosphatase, Blood Urea and Serum Creatinine) and all safety parameters were found within normal range. It suggests that the studied methods were found safe without any adverse effects.

CONCLUSION

Based on the results of the study 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.

However, future studies may be required with different methodology and parameters on larger sample size to evaluate comparatively the effects of these treatments in not only symptoms modification associated with the diseases but also in disease modification too.

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Reference

1. Adebajo A.(2010) ABC of Rheumatology. 4th ed. Malaysia: Wiley Blackwell Publishing Ltd : 55-58
2. Ahmed KR. Tarjuma Sharahe Asbab ma'a hashiya Sharif Khan wa Mamoolate Matab. Vol-4th New Delhi: CCRUM, Ministry of Health and Family welfare, Govt. of India :322,323.(2010)
3. Arya R and Jain V.(2013) osteoarthritis of the Knee joint: An Overview. *Journal, Indian Academy of clinical medicine*; 14(2): p. 154-62
4. Arzani A. Tibbe Akbar (Urdu Translated By HK M Hussain) Deoband: Faisal Publications: 616-626.(YNM)
5. Baghdadi IH. Al mukhtarat Fit- tibb. Part-4th, New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt. of India : 79-90.(2007)
6. Colledge NR, Walker BR and Ralston SH. (2010) Davidson's Priciples and Practice of Medicine. 21st ed. Edinburgh: Churchill Livingstone; p.1083-1087.
7. Elbaz A *et al*.(2014) Patients with Knee Osteoarthritis demonstrate improved gait pattern and reduced pain following a non-invasive biomechanical therapy: A Prospective multi-centre study on Singaporean population. *Journal of orthopaedic Surgery and Research*.; 9(1): p. 1-8.
8. Firestein GS *et al*. Kelly's Text Book of Rheumatology. Vol -2nd. 8th ed: Library of Congress Cataloging in Publication Data; Ch 89.(2008)
9. Gremion G *et al*. (.2009) Effect of Biomagnetic Therapy Versus Physiotherapy for treatment of Knee Osteoarthritis. *Journal of Rehabilitation Medicine* .41: p. 1090-1095.
10. Guilak F. (2011) Biomechanical Factors in Osteoarthritis. Best Prac Res Clin Rheumatol. Dec; 25(6): p. 815-823.
11. Hassan M and Shuckett R. (2010) Clinical features and pathogenetic mechanisms of Osteoarthritis of the hip and knee. *BC Medical Journal*. October; 52(8): p. 393-398.
12. Imboden JB, Hellmann DB and Stone JH.(2013) Current Diagsnosis and Treatment Rheumatology. 3rd ed. Newyork: MC Graw Hill Education: P-327
13. Jurjani AH. Zakheerae Khuwarsam Shahi, Vol- 6th (Urdu Translated By HK Hadi Hussain) New Delhi: Idara Kitabus Shifa : 637-645.(2010)
14. Kapoor M *et al*.(2011) Role of Proinflammatory Cytokines in the Pathophysiology of Osteoarthritis. Nat. Rev. Rheumatol. Nov; 7: p. 33-42
15. King LK, March L and Anandacoomarasamy A.(2013) Obesity and Osteoarthritis. Indian J Med Res. August;: p. 185-193.
16. Longo DL *et al*. Harrison's principles of Internal Medicine. 18th ed. New york: Mc Graw-Hill Companies; Ch-332. (2012.)
17. Majoosi AHAIAM. (2010) Kaamilus sana'a, Vol- 2nd (Urdu Translated by GH Kantoori) New Delhi: Idara Kitabus Shifa; 510-514.
18. Masihi AAFIAQ. (1986) Kitabul Umda Fil Jarahat, New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt of India : 194-200
19. Munjal YP. API Textbook of Medicine. 9th ed Mumbai: The Association of Physician of India;: 1818-1821. (2012)
20. Patil PS, Dixit UR and Shettar CM.(2008) Risk factors of Osteoarthritis Knee- A Cross-Sectional Study. *Journal of Dental and medical Sciences*. 2(5): p. 8-10.
21. Quamri MA. (2012) Unani Pain Management. Heritage Amruth. October; 8(5): p. 36-39
22. Razi ABMBZ. Kitab al Hawi Vol-11th New Delhi: CCRUM, Ministry of Health and Famly welfare, Govt. of India : 72-75,162,163.(2004)
23. Shakoor MA *et al*. (2009) Clinical Profile of Patients with Osteoarthritis of the Knee. IJPMR; 20(2): p. 44-47.

24. Sina I. Al qanoon Fit tib Vol-3rd (Urdu Translation By GH Kantoori) New Delhi: Idara Kitabus Shifa : 1119-1124.(YNM)
25. Sina I. Al qanoon Fit Tib. Vol 4th (Urdu translation By GH Kantoori) New Delhi: Idarae Kitabus Shifa:1445.(YNM)
26. Sina I.(2006) Kulliyate Qanoon (Urdu translation by Mohammad Kabeeruddin) New Delhi: Ejaz publishing House : 344-350.
27. Sina I. (1993) Al qanoon Fit tib (English Translation),Vol-1 New Delhi: Jamia Hamdard; p.364-367.
28. Sinusas K. (2012) Osteoarthritis: Diagnosis and Treatment, American Family Physician; 85(1):49-56
29. Sowers MR and Karvonen-Gutierrez CA.(2010) The evolving role of Obesity in Knee Osteoarthritis. curr Opin Rheumatol. September; 25(5): p. 533-537
30. Yusuf E *et al* (2011). Body mass index and alignment and their interaction as risk factors for progression of knees with radiographic signs of osteoarthritis, Osteoarthritis and Cartilage 19 ; 1117-1122

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