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Consequence Of Roghan-E-Hina (Lawsonia Inermis L.) In Waja' Al-Rukba (Knee Osteoarthritis)-A Randomized Standard Control Trial

***Dr. Aftab M. Nadaf [1], Dr. Juned Ahmad [2], Dr. Asma khan [3], Dr. Shaik Muzeeb [4], Dr. Shaik Mohammed Hussain [5], Dr. Aslaaf Nayeem Shaikh [6]**

** [1] Assistant professor, Dept. of Amraz-e-Ain, Uzn, Anf, Halaq-wa-asnan, Inamdar Unani Medical College & Hospital, Kalaburagi, Karnataka. India.*
[2] Associate Professor, Dept. of Amraz-e-Ain, Uzn, Anf, Halaq-wa-asnan, Inamdar Unani Medical College & Hospital, Kalaburagi. Karnataka. India.
[3] Associate Professor, Dept. of Ilmul Qabalat wa Amraz-e-Niswan, Inamdar Unani Medical College & Hospital, Kalaburagi, Karnataka. India.
[4] Associate Professor & HOD, Dept. of Killiyat-e-Tibb, Inamdar Unani Medical College & Hospital, Kalaburagi, Karnataka. India.
[5] Assistant Professor, Dept. of Moalajat, National Research Institute of Unani Medicine for Skin Disorders, Hyderabad. Telangana. India.
[6] Professor, Dept. Of Moalajat, NRIUMSD, Hyderabad, Telangana. India.

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Knee osteoarthritis is a prevalent degenerative joint disorder causing pain, disability, and reduced quality of life, particularly among older adults. This randomized controlled trial compared the efficacy and safety of Roghan-e-Hina (Lawsonia inermis L.) with diclofenac diethylamine 1.16% in managing knee osteoarthritis (Waja' al-Rukba). Forty participants were randomly assigned to test and control groups, receiving topical applications for 45 days. Outcomes were measured using the Knee Injury and Osteoarthritis Outcome Score and a visual analogue scale (VAS). Both groups showed significant improvements in pain severity and joint function, with no statistically significant differences between them. No adverse events were reported during the study. The findings suggest that Roghan-e-Hina is as effective and safe as diclofenac gel for knee osteoarthritis management, offering a promising alternative with potential therapeutic benefits rooted in Unani medicine. In this article author explain that effect of Roghan-e-Hina in Waja' al-Rukba (Knee Osteoarthritis) was carried out in department of Moalajat, Luqman Unani Medical College Hospital and Research Centre, Vijayapur, Karnataka.

Keywords: Knee osteoarthritis, Waja' al-Rukba, Roghan-e-Hina, Diclofenac diethylamine, Unani medicine, randomized controlled trial, KOOS score, pain management,

I. Introduction of Knee osteoarthritis

Knee osteoarthritis is a major public health problem related to ageing marked by gradual damage of articular cartilage resulting in pain, functional impairment, disability and compromised quality of life [1]. Almost 10% of the world population above 60 years of age may complain of this condition [2]. It is estimated that the prevalence of knee osteoarthritis may increase by 40% due to the steady aging of the world population in 2025. Persons who are overweight have a high prevalence of knee osteoarthritis. For many years, it was not clear whether being overweight preceded or was a consequence of osteoarthritis, given the immobility and disability the disease can produce[3].

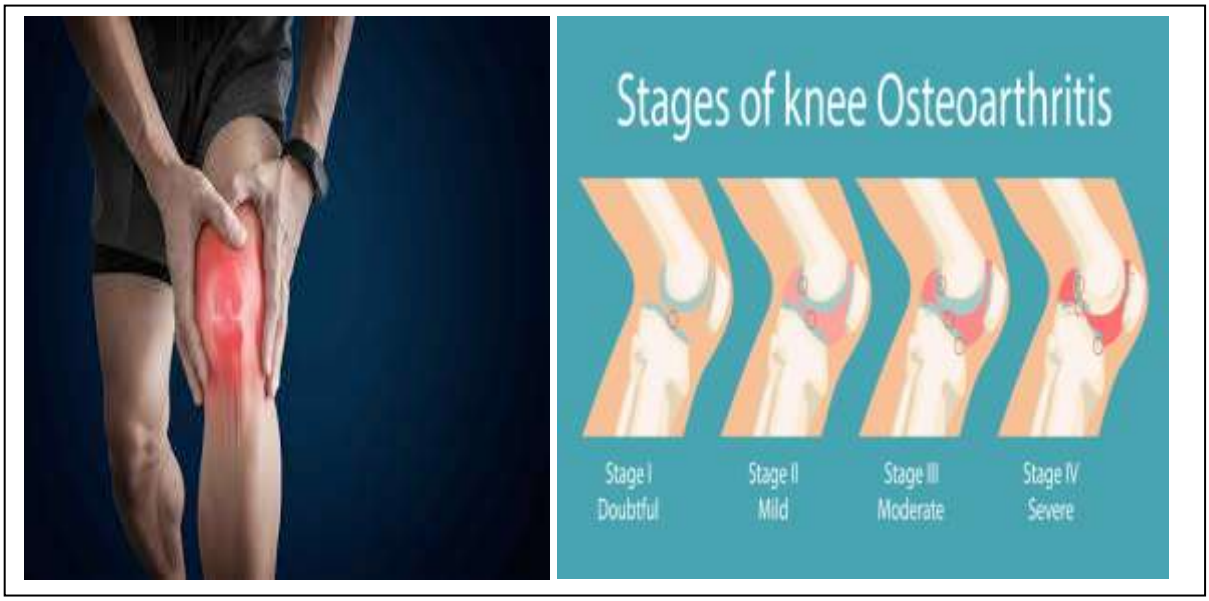

Fig. 01 stages of Knee Osteoarthritis

Waja al-Mafasil which strongly simulates with osteoarthritis has been extensively discussed by Unani scholars. Rabban Tabri has defined it as the pain of legs which occurs due to Buroodat, insensitivity, and Balghami matter [4]. Razi defined it as joint pain except Niqris and Irq al Nasa isWaja al-Mafasil[5]. The symptoms of Waja,, al-Mafasil have been mentioned based on the types recognized. The clinical features can be evaluated for site of pain, color of Waram, heaviness, discomfort, hotness and coldness of the affected joint.

As per Unani doctrines, Waja al-Mafasil occurs due to weakness of the joint followed by accumulation of morbid material into the same. The morbid matter is accumulated in the affected joint; tendons become tense, and ligaments attached to the bones also get tout with ensuing pain[5]. Acute joint pain may be caused by two reasons: ligaments and nerves of joint serve the function of sensory organs, and secondly, joint has a very least space and accumulation of morbid matter results in development of pain [6,7]. The pathologic picture consists of two components:

(1) Sabab-e-Munfa'il: the affected joint which accepts the disease, is characterized by dilatation of Majariy-e-Tabiyiya due to congenital or acquired processes, and is strongly associated with previous history of Excess joint movements, and
(2) Sabab-e-Faili: it produces pain due to deposition of morbid matter into the joints. The disease is caused by weakness of joint and Su-e-Mizaj Mustakam due to increased Hararat from increased movements. The morbid matter may be Dam, Balgham, Safra, and Sawda, mixed humours of Balgham with Sauda or Riyah. Balgham mixed with Safra is the commonest cause of Waja al-Mafasil followed by Balgham-e- Khaam; Dam, and Safra, and rarely Sawda Nazla and Zukam may also contribute to its pathogenesis, as Nazlawi Ma'adda consistently flows into joints from the brain in case of Waja al-Mafasil [6] The morbid humours are produced from second and third digestion. Occasionally, the morbid humour becomes stony and solid like lime, especially Balgham-e-Khaam, and gets deeply penetrated into the joint, and makes it hard [6]. The deposition of morbid humours in the joints results from two important causes: Asli and Aarzi. Asli Asbab is three in number: joints are provided with least gap and Rutubat (fluid) to perform the movements easily in order to ensure the non-collision and non-friction of opposing bones and prevent the joint structures from drying. Thats why excess movement of joints leads to increased Hararat in joints, and resultantly dry up of the joint fluid occurs Aarzi Asbab (temporary causes) are seven in number and basically constitute predisposing factors, such as decreased physical activity[7] stomach debility, meal intake at odd times in unorganized fashion and less nutritious diet, excess indulgence, alcohol intake at breakfast, coitus and exercise just after meal, and flow of catarrhal secretion into joints [4], Thus, Waja,, al-Mafasil is an established entity in Unani medicine with extensive details on definition, classification, signs and symptoms, pathogenesis and treatment. In recent years, various clinical trials have been conducted on Waja al-Mafasil in Unani medicine with promising results in disease activity as well as quality of life of the patients. Contrary to this, conventional medicine is largely dependent on use of NSAIDs with wide range is of side effects including GI bleed, gastric irritation etc [8]. Thus, the situation warrants that the search for safer drug may be led by Unani medicine which is equipped with wide range of therapeutic modalities and treatment options The trial drug was selected from makhzan-ul-mufridat of Kabeeruddin who has recommended its use in Waja,, al-Mafasil [9] Thus, the present study was designed to compare the safety and efficacy of Roghan-e-Hina with diclofenac diethylamine 1.16% in the management of knee osteoarthritis.
(3)

II. Historical Background of Waja al-Mafasil

Waja,, al-Mafasil is the term used in Unani literature for Arthritis, which encompasses all types of joint pain such as Niqris (gout), Waja,, al-Warik (ischial Pain), Irq al-Nasa (sciatica), Waja al Rukba (knee pain), etc.[10] Osteoarthritis is a non-inflammatory degenerative joint disease Knee joint which is the most common type of arthritis. It is also referred to as osteoarthrosis.[11]After 1986 definition of OA is existed most of the authors describe about OA.[12] Disorder of unknown aetiology primarily it affects articular cartilage and chondrocyte as compared to rheumatoid arthritis which affects the synovial membrane.[11] the Subcommittee on Osteoarthritis of the American College of Rheumatology Diagnostic and Therapeutic Criteria Committee, proposed the following definition of OA. As the disorder is characterised

by a diverse set of joint symptoms and indications that are linked to articular cartilage defects, in addition to related changes in the underlying bone at the joint margins. Osteoarthritis (OA) is a common cause of disability and pain in the geriatric age group representing a significant burden for society and elderly people.[13] Waja al-Mafasil , which is characterised as a kind of arthralgia in the Unani medical terminological anthology, denotes joint pain.6which involves several joints like the knee, hip, wrists, hand etc "Waja al-Mafasil" according to Unani physician Allama Najeebuddin samarqandi, is pain and inflammation that develops in the joints of the organs.6This illness, which extends back 100 million years, is claimed to have afflicted even dinosaurs. Great historical figures such as Alexander the Great (356-323 BC), Charlemagne (742-814), Henry VI (1165-1197), and Goethe (1749-1832) also suffered from this illness. In ancient Egyptian, Unani, and Roman medical texts, this illness is well-documented. [7] AZIM HUSAIN **8**

Hippocrates' Kitab-ul-Mafasil was the first compendium on the ailment, while Dioscorides (70 AD) detailed the disease in depth in his work Kita-ul-Hashaish. Rufus (117 AD) wrote the second compendium on the ailment, Kitab Auja-ul-Mafasil, while Galen (129-217 AD) wrote Kitab-ul-Elal-wal-Amraz, which discussed the disorder. .4According to Ibne Sena, Waja al-Mafasil is the pain of joints which includes Niqris (Gout), Irq al-Nasa (Sciatica) and other types of joint pains .[4]

III. Introduction of Barg E Hina (Lawsonia Inermis L.)

Fig. 02 Hina Leaf (*Lawsonia Inermis L.*)

Lawsonia inermis Linn, commonly known as henna, is a member of the Lythraceae family and has been found to contain a variety of compounds with both industrial and medicinal applications in its stem, bark, roots, flowers, and seeds. This report provides a comprehensive review of the bioactive components, pharmacological activities,

pharmacokinetics, and pharmacological side effects of Lawsonia inermis. Lawsonia inermis contains a variety of bioactive compounds, including flavonoids, coumarins, triterpenoids, steroids, xanthones, polyphenols, fatty acids, alkaloids, quinones, tannins, leucocyandin, epicatechin, catechin, and quercetin. The plant is been traditionally used to treat numerous conditions, including ulcers, bronchitis, lumbago, hemicrania, leukoderma, scabies, boils, ophthalmic disorders, hair loss, and jaundice. It has also been found to possess a range of pharmacological activities, including antioxidant, anti-inflammatory, analgesic, antiparasitic, hepatoprotective, antifungal, antitumor, wound healing, and hypoglycemic effects.

The potential of Lawsonia inermis for various biological applications is promising, and further studies are needed to fully explore its therapeutic benefits for various diseases of public health. Concern advances in drug development could enable the characterization of various bioactive constituents and facilitate their development and application for the benefit of humanity.

A. **Action of Hina Leaf:** Balgami o Rihi Amraz, Muhalil e Aworam, Musakin e Alam, Daf e Tashannuj, Talayeen e mufassil Mukhaddir, Mujaffif
B. **Important Compound Formulation**
   Roghan Amla Sada, Habb-e-musaffi –khoon
C. **Scientific reports:**

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Fig. 03 Roghan-e-Kunjad (Sesame oil) *Sesamum indicum*

Ali Esmail Al Snafi reported that Lawsonia inermis L has antimicrobial effect, Antiparasitic effect, Molluscicidal effect, antioxidant activity, Hepatoprotective activity, Central nervous effect, anti-Inflammatory effect and antipyretic effects.

IV. Introduction of Roghan-e-Kunjad (Sesame oil) Sesamum indicum

The drug consists of dried seeds of Sesamum indicum L. It is an erect annual plant more or

less foetid and glandular in shape. The plant is indigenous to tropical Africa and is cultivated India. The oil is extracted from cold compression technique from Sesamum indicum L. seeds. The oil is light yellowish in color and thin in consistency.

Sesame oil has a long history of usage as a food and medicine. It is the most used oil as a medicine or as a base oil for preparations of many compound drugs in the Unani system of medicine. It has a wide range of biological activities as mentioned in Unani classical text; this review highlights its pharmacological activities and their possible mode of action. Searched many Unani classical literature online and offline and simultaneously did parallel search on databases like PubMed, and Science Direct, and extraction of data related to sesame oil, sesame seeds with its pharmacological activities, mode of action, then interpretation and summarization of all related data. Sesame oil possesses many biological activities like anti-inflammatory, antihyperlipidemic, antiatherosclerotic, hepatoprotective, antiasthmatic, analgesic, emollient, antipruritic, and wound healing effects, which were scientifically demonstrated as mentioned in Unani literature. Sesame oil has a hopeful effect on modulating diseases with no significant toxic effect; so, there is a need to identify its safety and efficacy on human subjects to develop a new potential drug.

A. Unani description

There are famous seeds of the plant Sesamum indicum L. It is of two varieties: black and white. Sesame seeds are rich in oil content. The oil becomes rancid quickly. According to some physicians, it is of no use except for causing and moistening effect in the people having malanotic temperament. Arsimin is a variety of sesame which is unpleasant in taste.

B. Action of Sesame oil

- Musakin e alam, Musamin e badan, Murattib, Mulayeen e jild

V. Diclofenac Gel

It is well established that topical diclofenac penetrates the skin, through pores and enter in to dermal layer then underlying tissues, and enters the synovium. diclofenac inhibits the cyclooxygenase2 enzyme (COX2) and reduces the pain

Method: Direct application over the pain site. **Doses:** 1.5 % diclofenac gel in 1.5ml qid

Methodology: The present study was carried out in department of Moalajat, Luqman Unani Medical College Hospital and Research Centre, Vijayapur, Karnataka. Before starting study, the protocol was submitted for ethical clearance. Accordingly, the Institutional Ethical Committee approved the protocol BJP/LUMC/PG/IEC/04/201920/MOALIJ AT/04 as well as CTRI number was attained CTRI/2021/01/03026 The study was conducted 40 eligible participants of (Knee Osteoarthritis). The trial data was recorded in the Case Report Form (CRF).

A.Selection of subjects

- Participants fulfilling the inclusion and exclusion criteria& ready to sign written informed consent and diagnosed of primary osteoarthritis knee were randomly allocated either to test (n=20) or control group (n=20) The test group was given Roghan-e-Hina for local application in the form of oil to be applied lukewarm twice daily on the affected knee joint/s in sufficient quantity for 45 days. The control group received diclofenac diethylamine gel 1.16%for local application to be applied twice daily on the affected knee joint/s in sufficient quantity for 45 days

B. Informed consent

- The voluntary written informed consent was sought from the trial participants before administering the trial intervention. The trial subjects were provided ample time to go through the aims and objectives, nature of the study, the intervention to be given, method of treatment etc. in local language. Besides, the same was explained verbally to them. They were given the opportunity to ask any question or doubt about the trial

C. Method of collection of data

- The data were collected from patients visiting Moalajat OPD/IPD of Luqman Unani Medical College, Hospital and Research Centre, Vijayapur, Karnataka
- Patients of Waja' al-Rukba (Knee Osteo arthritis)
  Enrolled from OPD/IPD of LUMC and diagnosis made on the basis of laboratory investigation, history taking and physical examination. The selected patients included in the study after taking their voluntary written consent.
- **Secondary outcome:**

- **100 mm VAS for Knee Joint Pain**
  Patient pain assessment will be evaluated using 100mm visual analogue scale
  Sample: "Please indicate the amount of pain recently experienced by marking an (X) through the line:"
- **Sample size:** The sample size was 40

D. Duration of the study: 18months

E. Duration of protocol: 45 days

Follow-up: Day0, 15th, 30th, 45thday, all patients were screened and randomized at baseline on day 0

Followed-up every 15th day of trial for 45 days.

F. Details of interventions:

- **Test drug: Rogan-e-Hina applied topically in sufficient quantity.**
- **Ingredients:**
- Barg-e Hina (Lawsonia inermis L.)1000gm
- Rogan-e-Kunjad (sesame oil)1liter 125ml as base

- **Route of administration:** Local application
- **Dosage:** Quantity sufficient, **Form**: oil
- **Method of preparation**: the extract will be obtained after crushing Hina (Lawsonia inermis L.) leaves. Sesame oil will be heated up in a pan and extract will be added in the oil pan and heated on slow flame till water content is evaporated and oil is left. The pan will be taken off the flame; the supernatant oil will be collected and stored in glass bottles when oil cools down.
- **Standard drug:** Diclofenac diethylamine 1.16%

- **Route of administration:** Local application,
- **Dosage:** Quantity sufficient
- **Form**: Gel

G. Withdrawal criteria

- Failure to follow the protocol therapy
- Any adverse drug reaction or adverse event

VI. Results

Participant flow:

A total of 56 participants were screened for eligibility in which 11 were excluded due to not meeting inclusion criteria. However, 45 participants were randomised to test(n=22) & control (n=23) group & received allocated intervention. During the course of the trial 5 participants were dropped out (2 from test group & 3 from control group). Statistical analysis was done o 40 participants, 20 in test group and 20 in control group, who completed the protocol therapy.

Table 01: Distribution of participants according to socio Economical status

H. E. S	TEST	CONTROL	TOTAL
LOWER	5 (23.8%)	1 (5.3%)	6 (15.3%)
LOWER MIDDILE	4 (19.0%)	9 (47.4%)	13 (32.5%)
UPPER	1(4.8%)	0(0.0%)	1 (2.5%)
UPPER LOWER	7 (33.3%)	3 (15.8%)	10 (25.0%)
UPPER MIDDLE	4 (19.0%)	6 (31.6%)	10 (25.0%)
TOTAL	21 (100.0%)	19 (100.0%)	40 (100.0%)

P=0.105 (Fisher's Exact Test)

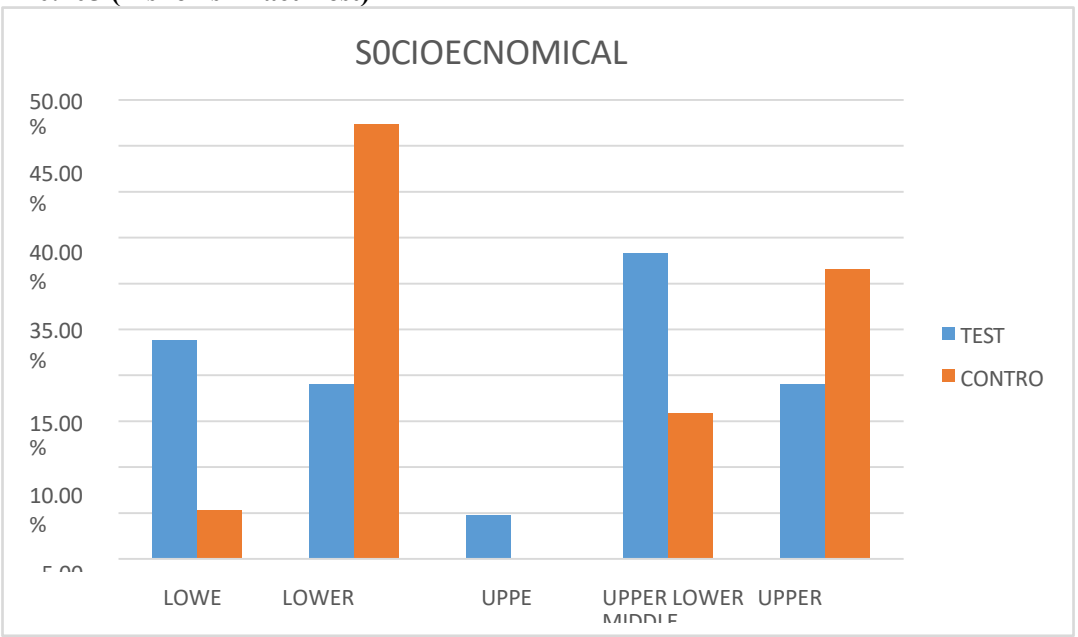


Figure 04: Distribution of participants according to socio Economical status

Table 02: Distribution of participants according to Habitat

HABITAT	TEST	CONTROL	TOTAL
RURAL	7(33.3%)	5(26.3%)	12(30.0%)
URBAN	14(66.7%)	14(73.7%)	28(70.0%)
TOTAL	21(100.0%)	19(100.0%)	40(100.0%)

P=0.446(Fisher's Exact Test)

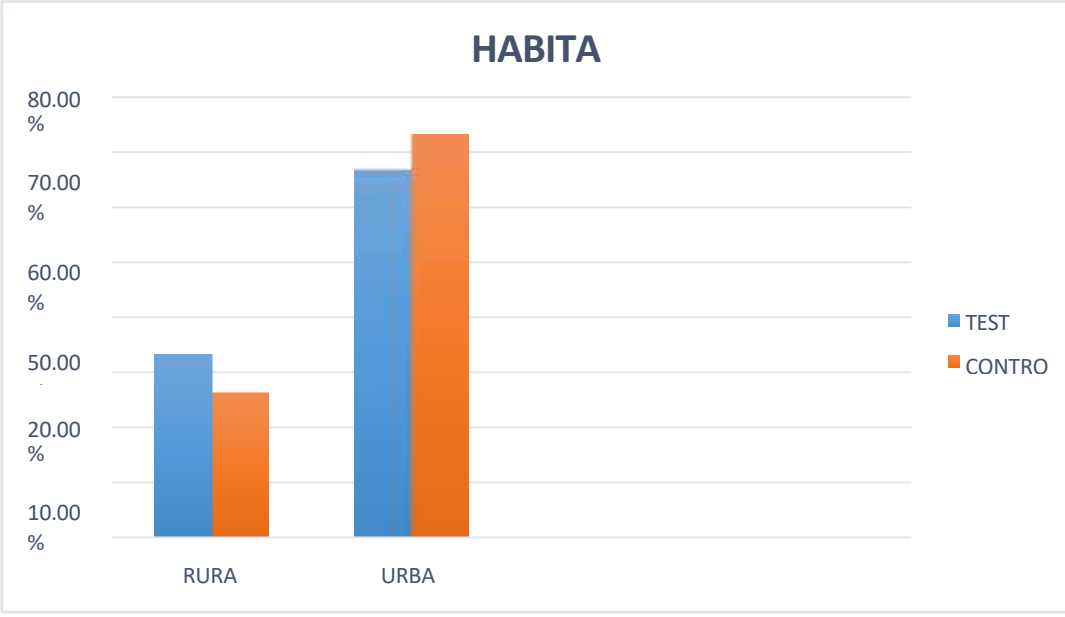


Figure 05: Distribution of participants according to Habitat

Table 03: Change in physician global assessment overall disease severity

	Test	Control	Total	p-Value* (between group)
Baseline				
Nil	0.0%	0.0%	0.0%	1.000
Mild	0.0%	0.0%	0.0%	
Moderate	1(4.8%)	0(0.0%)	1(2.5%)	
Severe	20(95.2%)	19(100.0%)	39(97.5%)	
1st follow-up				
Nil	0	0.0%	0.0%	0.721
Mild	0	0.0%	0.0%	
Moderate	6(28.6%)	4(21.1%)	10(25.0%)	
Severe	15(71.4%)	15(78.9%)	30(75.0%)	
2nd Follow-up				
Nil	0	0.0%	0.0%	0.731
Mild	1(4.8%)	0(0.0%)	1(2.5%)	
Moderate	20(95.2%)	18(94.7%)	38(95.0%)	
Severe	0(0.0%)	1(5.3%)	1(2.5%)	
3rd Follow-up				
Nil	0	0.0%	0.0%	0.870
Mild	10(47.6%)	9(47.4%)	19(47.5%)	
Moderate	11(52.4%)	9(47.4%)	20(50.0)	

Severe	0(0.0%)	1(5.3%)	1(2.5%)	

p-Value** (within group)				
Baseline vs 1st Follow-up	0.004	0.004		-
Baseline vs 2nd Follow-up	<0.001	<0.001		
Baseline vs 3rd Follow-up	<0.001	<0.001		

Figure 06: Change in physician global assessment overall disease severity

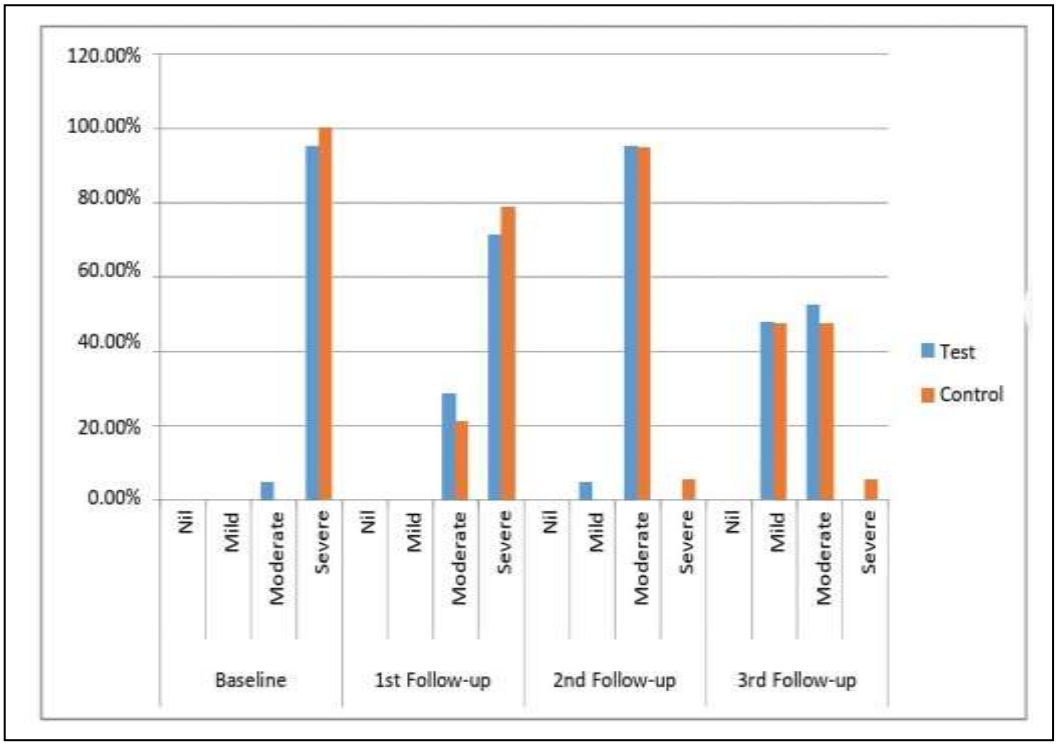
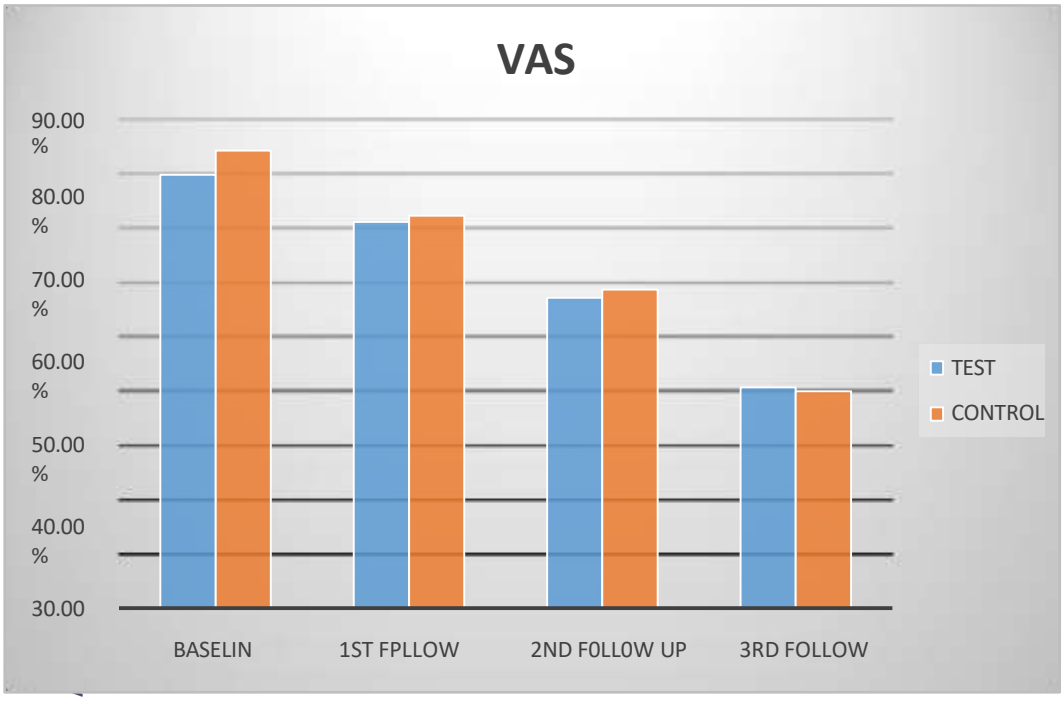


Table 04: Change in visual analogue scale over all disease severity

VAS	TEST Mean ±SD	CONTROL Mean ±SD	P-Value (Between group)
Baseline	79.90±9.208	84.33±4.887	0.075

1st follow up	71.19±7.033	72.33±8.066	0.639
2nd follow up	57.19±7.607	58.72±9.048	0.569
3rd f0llow up	40.71±12.614	39.94±12.698	0.851
P-Value (Within group)	<0.001	<0.001	

Table 05: Change in VAS overall disease severity



DISCUSSION

The present study was carried out at department of Moalajat, Luqman Unani Medical College Hospital, Bijapur, from 28/07/2021to 05/03/2022. The observations and results inferred from the study are being discussed as under. The discussion of data demonstrating treatment efficacy based on changes in subjective and objective parameters, as well as demographic data, is interpreted below in order to draw inferences and reach a conclusion. The following sections discuss the trial's observations and results.

A. Socio economic status

Majority of participants were from lower middle class 13 (32.5%) in test and control group followed by 10(25.0%) cases each in upper lower and upper middle class of test and control

groups. Our findings are consistent with Yahaya I et al. who reported higher rate of Knee osteoarthritis in lower middle socioeconomic strata due Multifactorial reasons. They also reported rising trend in the burden of disease due to OA may reflect increasing life expectancy, and prolonged exposure to arthritis risk factors such as obesity, occupational factors, joint overuse, mechanical injury, genetics and gender.

B. Habitat

Out of 40 cases studied maximum number of cases 28 (70.0%) were from Urban area with 14 (66.7%) cases in test group and 14 (73.7%) cases in control group respectively. There were totally 12 (30.0%) cases from rural areas including 7(33.3%) cases from test group and 5(26.3%) cases from control group. This study is in confirmation with Tilaki K O H who found maximum cases were from urban areas due to multifactorial reasons. [61]

C. Effect of trial interventions on efficacy parameters

Change in VAS on Osteoarthritis: The mean ± SD of pain severity in the test group was 79.90±9.208 at baseline, which significantly reduced to 71.19±7.033 on the first follow-up, 57.19±7.607 on the 2nd follow-up, 40.71±12.614 on the 3rd follow-up ($p<0.001$). In the control group also, the mean ± SD of pain severity was 84.33±4.887 at baseline, which significantly reduced to 72.33±8.066 on the first follow-up, 58.72±9.048 on the second follow-up, 39.94±12.698on the third follow-up ($p<0.001$). However, the intergroup difference at each follow-up was statistically insignificant ($p>0.05$), which implies that both drugs are equally effective in the reduction of pain severity.

Change in physician global assessment for overall disease severity:

In test group1(4.8%) case had moderate disease and 20 (95.2%) cases had severe disease severity at baseline. The severity of disease was significantly reduced at each follow-up ($p<0.001$) Thus 6(28.6%) cases had moderate & 15(71.4%) cases had severe disease severity at first follow-up. On second follow-up1(4.8%) cases had mild, and 20 (95.2%) cases had moderate disease severity ($p<0.001$). At third follow-up 10(47.6%) cases had mild and 11(52.4%) had moderate disease severity ($p<0.001$). In control group 19(100.0%) cases had severe disease severity at baseline. The severity of disease was significantly reduced at each follow-up($p<0.001$). Thus 4 (21.1%) cases had moderate & 15 (78.9%) cases had severe disease severity at first follow-up. On second follow-up)18(94.7%) cases had moderate & 1(5.3%) case were severe ($p<0.001$). At third follow-up9(47.4%) moderate cases & 1(5.3%) case were severe in severity ($p<0.001$).

D. Change in KOOS on osteoarthritis

The mean ± SD of KOOS in the test group was 35.10±3.9 at baseline, which significantly improved to 57.52±2.5 after treatment ($p=0.0001$). In the control group also, the mean ± SD of KOOS was34.21±2.37 at baseline, which significantly improved to 57.21±2.3 after treatment ($p=0.0001$). The between-group analysis, however, showed statistically insignificant ($p>0.05$) difference between both the groups which implies that both drugs are equally effective in the improvement of KOOS.

E. Safety parameters

The safety of both interventions was determined using a record of adverse events and changes in Serum calcium, CRP, Xray knee & RBS levels. During the course of the trial, no adverse event was observed. However, statistically significant changes in some laboratory parameters were observed that are clinically within normal limits.

F. Overall evidence

The study was conducted to compare the safety and efficacy of Roghan-e-Hina versus diclofenac gel in management of knee osteoarthritis. On the basis of preliminary findings, it is reasonable to conclude that the test intervention is not inferior to the control drug diclofenac gel in terms of overall disease severity and clinical features amelioration.

The test intervention's effect may be attributed to the pharmacological actions described in Unani system of medicine and confirmed by recent scientific studies. The test drug Roghan-e-Hina is a multi-potency drug with hot and moist 2nd degree Mizaj and Muhallil-e-Awram (anti-inflammatory), Musakin-e-Alam (Analgesic), Talayeen-e-Mafasil (softening of joints) Mukhaddir (anesthetic), Mujaffif (desiccant) properties that may be attributed to the response of test drug and regression of knee osteoarthritis severity. Pharmacologically, Lawsonia inermis as well as its biochemical constituents such as Alkaloids, tannins, flavonoids, saponins, cardiac glycoside and steroids play an analgesic role in decreasing knee pain. Snafi et al reported analgesic, anti-inflammatory and anesthetic effects of Lawsonia inermis in reduction of knee pain.[44]

CONCLUSION

The present study was carried out at department of Moalajat, Luqman Unani Medical College Hospital, Bijapur, from 28/07/2021to 05/03/2022. The important conclusions, limitation, and recommendations are given as under.

- Knee Osteoarthritis was more common in female as compared to males.
- Knee Osteoarthritis was common in the age group of 45-50 years followed by age above 65 years.
- Occupations especially farmers, businessmen & teachers, were more affected with knee osteoarthritis due to excessive knee movements.
- The trial interventions in both groups were equally effective in reduction of Knee pain.
- Trial interventions were found safe and compliant to the participants.

VII. SUMMARY

The present study was carried out at department of Moalajat, Luqman Unani Medical College Hospital, Bijapur, from 28/07/2021to 05/03/2022.The observations and results inferred from the study are given concisely as under.

A. Socio-economic status

Majority of participants were from lower middle class 13(32.5%) in test and control group followed by 10(25.0%) cases each in upper lower and upper middle class of test and control groups.

B. Habitat

Out of 40 cases studied maximum number of cases 28(70.0%) were from Urban area with 14 (66.7%) cases in test group and 14(73.7%) cases in control group respectively. There were totally 12(30.0%) cases from rural areas including 7 (33.3%) cases from test group and 5(26.3%) cases from control group.

C. Religion

This study shows predominance of Muslims 31 (77.5%) cases among the cases of Knee Osteoarthritis. There is no persuasive data available to demonstrate the existence of this disease among different religious communities in the society.

D. Effect of trial Interventions on efficacy parameters

Change in VAS: The mean ± SD of pain severity in the test group was 79.90±9.208 at baseline, which significantly reduced to40.71±12.614 on the 3rd follow-up ($p<0.001$). In the control group also, the mean ± SD of pain severity was 84.33±4.887 at baseline, which significantly reduced to 39.94±12.698on the third follow-up ($p<0.001$)

E. Change in KOOS

The mean ± SD of KOOS in the test group was 35.10±3.9 at baseline, which significantly improved to 57.52±2.5 after treatment ($p=0.0001$). In the control group also, the mean ± SD of KOOS was34.21±2.37 at baseline, which significantly improved to 57.21±2.3 after treatment ($p=0.0001$).

Conclusion:

The results of this study demonstrate that Roghan-e-Hina (Lawsonia inermis L.) is an effective and safe alternative to diclofenac diethylamine 1.16% in the management of knee osteoarthritis (Waja' al-Rukba). Both treatments significantly improved pain severity, joint function, and overall quality of life, with no significant differences between the two groups. Moreover, Roghan-e-Hina was well tolerated and associated with no adverse effects, highlighting its potential as a complementary or alternative therapy rooted in Unani medicine. These findings support the integration of herbal formulations in the management of osteoarthritis, particularly for patients seeking natural treatment options. Further large-scale studies are recommended to validate these results and explore the long-term benefits of Roghan-e-Hina in osteoarthritis care.

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