



## Original Research Article

## A pilot study to evaluate the efficacy of local application of unani compound formulation in geriatric knee joint oa patients

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## ABSTRACT

**Background:** OA is the single most common cause of disability in older adults. The prevalence of OA is increasing due to population aging and an increase in related factors such as obesity.

**Aims & Object:** A single centered, prospective pilot study was conducted to evaluate the efficacy of Roghan Surkh-A Unani compound formulation as local application in geriatric patients of OA. Conventional medical management of OA have its limitation due to various reasons. The aim of the study is to provide safe and effective alternate treatment of OA.

**Materials and Methods:** A pre-test and post-test pilot study was conducted at Unani OPD Majeedia Hospital, Jamia Hamdard, New Delhi. Out of 38 patients of Knee joint Osteoarthritis recruited for the study, thirty patients completed the three months duration of the study with local application of R. Surkh BID on the affected Knee joint. Clinical efficacy of test drug was measured on WOMAC Arthritis Index on three sub-scale on VAS score.

**Results:** The test drug have relief of 41.98%, 32.06% and 30% on WOMAC sub-scales of pain score, stiffness score and performing daily activities scores respectively. **Conclusion:** It may be concluded that local application of Roghan Surkh is safe and very effective in geriatric patients of Knee joint OA. Sample size and duration of the study are very short to evaluate the efficacy of test drug. So further clinical studies for longer duration and on larger sample size are required to prove the efficacy of the local application of R. Surkh on geriatric Knee joint OA patients.

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### 1. Introduction

Osteoarthritis (OA) is a long-standing chronic disease due to degeneration of the cartilage of joints which causes rubbing of cartilages together and it creates; stiffness, pain, and restricted movement of joints. The disease most commonly affects joints of the knees, hands, feet, and spine and it is relatively less common in the shoulder and hip joints.<sup>1</sup>

**Risk Factors:** While OA is related to aging, it is also associated with a variety of both adaptable and non-adaptable risk factors; obesity, lack of exercise, genetic predisposition, occupational injury, trauma, and gender. Overweight increases the risk of OA in the hip, knee, ankle, and foot joints because extra weight causes more wear and tear.<sup>2</sup> Other high risk factors of OA are; Jobs that involve kneeling or squatting for more than an hour a day. Jobs that involve lifting, climbing stairs, or walking and playing sports that involve direct impact on the joint (such as football), twisting (basketball or soccer), or throwing.<sup>3,4</sup>

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**Clinical Features:** The main symptoms are arthralgia or joint pain, swelling or tenderness in one or more joints, stiffness after periods of inactivity (sleeping or sitting), flare-ups of pain and inflammation after use of the affected joint, crunching feeling or sound of bone rubbing on bone (crepitus) when the joint is used. It also results into disability, decreased quality of life (QoL), and economic burden.<sup>5</sup>

**Treatment:** There is no cure for OA, and there is no known therapy to prevent or retard the degenerative process in articular cartilage. The treatment of arthritis is focussed on relieving symptoms and to improve the joint movements which includes non-pharmacologic measures, pharmacologic measures, surgery, and protecting cartilage. Non-pharmacological measures includes patient education, physical and occupational therapy assessment and interventions, exercise, weight loss, and dietary measures. Pharmacotherapy is mainly restricted to use of NSAIDs mostly for their analgesic effects.<sup>3,6</sup> OA is the single most common cause of disability in older adults. The prevalence of OA is increasing due to population aging and an increase in related factors such as obesity.<sup>6</sup> In 2019, about 527.81 million people worldwide were living with osteoarthritis; an increase of 113.25% since 1990. The prevalence was higher in women (317.44 million cases in 2019) than in men (210.37 million cases in 2019) of all ages. Knee OA accounted for approximately 60.6% of the total prevalent cases in 2019, followed by hand OA, and hip OA at 23.7%, 10.2%, and 5.5%, respectively.

The prevalent symptomatic OA cases in India increased 2.66-fold from 23.46 million in 1990 to 62.35 million in 2019.<sup>7</sup>

Limitations in the conventional medical management of OA indicate a real need for safe and effective treatment of OA patients. Herbal medicines may provide a solution to this problem.<sup>8</sup> Unani System of Medicine is one of the oldest traditional systems of medicine in India. It treats the imbalanced humors of the body with mainly herbal, mineral and animal origin drugs. Osteoarthritis has been described in the classical Unani literature exhaustively as Wajaul-Mafasil. This is an Arabic word consisting of two words Waja and Mafasil. Waja means pain and Mafasil means Joints. Hence Wajaul-Mafasil literally means joint pain (arthralgia) which is the main symptom of OA.<sup>9</sup>

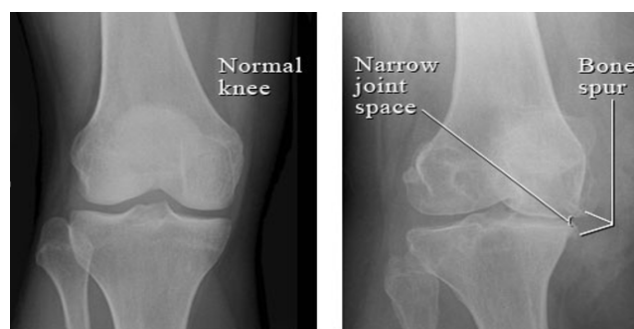
Unani medical scholars like Hippocrates, Dioscorides (70 A.D), Rufus (117 AD) and Galen (130 AD) has described Wajaul Mafasil in their classical books. Ibn-e-Sina (980-1037) used the term of Wajaul-Mafasil for pain, inflammation with accumulations and depositions of Morbid matter in the joint in his famous book *Alqanoon fi al Tibb* (Canon of Medicine).

According to Unani system of medicine, the pathological changes in joints are caused mainly by derangement of temperament of Humors which leads to accumulation of

Maddae-Fasida (Morbid Matters) in the joint spaces. The derangement of temperament of Humors may be simple which is called as Wajaul-Mafasil Sada causing only functional disturbance of the articular tissues. When organic disturbance and quantitative changes take place in the joints than it is called as Wajaul-Mafasil Maddi/Murakkab.<sup>10</sup>

Mohallile Auram (Anti-inflammatory) and Musakkin Alam (Analgesics) drugs have been recommended for the treatment of Wajaul Mafasil for local use as well as for systemic use. Roghan Surkh is an age old classical polyherbal Formulation described by many Unani authors in classical literature. It acts as Mohallile Auram, Musakkin Alam and is in use from centuries for the treatment of Wajaul Mafasil.

Keeping in view the above facts the present pilot study was designed and conducted to evaluate the efficacy of Local application of Roghan Surkh in geriatric Knee joint OA patients.



**Figure 1:** Showing x-ray of normal knee joint and knee joint osteoarthritis

## 2. Materials and Methods

### 2.1. Study design

A single centered, prospective pre-test and post-test pilot study was carried out at Unani OPD Majeedia Hospital, Jamia Hamdard, New Delhi in July 2022-June 2023. After clinical history and X-ray examination, thirty eight diagnosed patients of Osteoarthritis of either sex between 60-85 years of age were recruited for the study. Roghan Surkh of M/S Hamdard Lab Delhi was given to the patients for local application twice daily with instruction to come for follow up after one month (Three follow ups). The therapy period with local application of R. Surkh was of three months.

### 2.2. Outcome measures

WOMAC™ 3.1 Likert Index was used to measure the efficacy of test drug in OA geriatric patients which is a standard measure for clinical trial of osteoarthritis globally. It consists of three sub-scales; pain, stiffness and physical

function or difficulty in performing daily activity. The scores for each subscale are summed up on VAS scale, with a possible score range of 0-20 for pain, 0-8 for stiffness, and 0-68 for physical function or difficulty in performing daily activity before and after three months of local application of test drug.<sup>11,12</sup>

After completion of the study period of three months; X-ray of the affected joint was taken, data was collected and analyzed clinically.

### 3. Observation and Results

Out of 38 recruited patients of Knee joint OA for study, 30 patients completed the study period of three months.

#### 3.1. Demographic data

*Distribution of patients according to age:* Out of thirty patients who completed the study period of three months; 17 (56.6%) patients were in the age group of 60-70 years, 08 (26.6%) were in the age group of 71-80 years and 5 (16%) were in the age group of 81-85 years. (See Table 1)

**Table 1:** Showing number of OA patients in different age groups

| S.No. | Age Group | No. of Patients | Percentage |
|-------|-----------|-----------------|------------|
| 1.    | 60-70     | 17              | 56.6%      |
| 2.    | 71-80     | 08              | 26.6%      |
| 3.    | 81-85     | 05              | 16.6%      |

#### 4. Distribution of patients according to sex:

Out of 30 patients who completed the study period of three months; 23 (76.6%) were female and 7 (23.3%) were male. (See Table 2)

**Table 2:** Showing sex wise distribution of OA patients:

| Sex          | No. of Patients | %    |
|--------------|-----------------|------|
| Male         | 07              | 23.3 |
| Female       | 23              | 76.6 |
| <b>Total</b> | <b>30</b>       |      |

#### 4.1. Distribution of patients according to occupation

Out of 30 patients who completed the study period of three months; 63.3% were housewives and 3.3% were farmers, shopkeepers and laborers. (See Table 3)

#### 4.2. Evaluation of the Clinical Efficacy of Test drug based on WOMAC TM 3 1 Likert Index:

##### 4.2.1. Effect of Roghan Surkh on WOMAC Osteoarthritic Pain Score:

Before Treatment (BT) Mean of the patients WOMAC Osteoarthritic Pain score was 13.1 and AT of three months

**Table 3:** showing distribution of OA patients according to occupation

| Occupation       | No. of Patients | %    |
|------------------|-----------------|------|
| House Wife       | 19              | 63.3 |
| Teacher          | 02              | 6.6  |
| Office Attendant | 02              | 6.6  |
| Tailor           | 01              | 3.3  |
| Retired Clerk    | 03              | 10   |
| Farmer           | 01              | 3.3  |
| Shopkeeper       | 01              | 3.3  |
| laborer          | 01              | 3.3  |

with Roghan Surkh it was 7.6 with a change of 41.98%. (See Table 4)

**Table 4:** showing effect of R. Surkh on WOMAC Osteoarthritic Pain Score

| Mean BT | Mean AT | Change Percentage |
|---------|---------|-------------------|
| 13.1    | 7.6     | 41.98%            |

##### 4.2.2. Effect of Roghan Surkh on WOMAC osteoarthritic stiffness score:

BT Mean of patients WOMAC Osteoarthritic Stiffness Index was 5.2 and AT of three months with Roghan Surkh it was 3.5 with a change of 32.69%. (See Table 5)

**Table 5:** Showing effect of R. Surkh on WOMAC osteoarthritic stiffness score

| Mean BT | Mean AT | Change Percentage |
|---------|---------|-------------------|
| 5.2     | 3.5     | 32.06%            |

##### 4.2.3. Effect of Roghan Surkh on WOMAC osteoarthritic difficulty in performing daily activity score:

BT Mean of the patients WOMAC Osteoarthritic performing daily activity score was 43 and AT of three months with Roghan Surkh it was 30.1 with a change of 30.0%. (See Table 6)

**Table 6:** showing effect of R. Surkh on WOMAC Osteoarthritic difficulty in performing daily activity score

| Mean BT | Mean AT | Change Percentage |
|---------|---------|-------------------|
| 43.0 ±  | 30.1 ±  | 30.00%            |

The result shows that local application of Roghan Surkh has significant beneficial clinical effects on Mean of WOMAC Pain, Stiffness and difficulty in performing daily activity scores.

## 5. Discussion

Demographic data shows that maximum number of Knee joint OA patients were in 60-70 years age group. Female dominating with maximum number of OA patients (76.6 %.) Occupation wise maximum patient are house wives (63.3%) and minimum number are laborer, retired clerk, farmers and tailors (3.3%) and person squatting on ground for more than one hour. These findings support the general picture of Knee joint OA most commonly prevalent in females.

Joint pain is the first and foremost symptom of osteoarthritis for which patients usually visit a doctor. In this study percentage decreases with pain score is 41.89% with local application of R. Surkh. The improvement in other outcome measures like morning stiffness is 32.06% and difficulty in performing daily activity is 30% which are attributed mainly due to pain; the main symptom.

There was no difference in radiological parameter before and after treatment. No adverse effects/side effects on local application of R. Surkh were reported during study period.

The improvement in symptoms of RA patients may be due to Mohallile Auram (Anti-inflammatory) and Musakkine Alam (Analgesics) properties of R. Surkh and it acts by resolving the inflammation and swelling of cartilage and synovial membrane of the affected joint with ultimate relief in the joint pain.

## 6. Conclusion

It may be concluded that local application of Roghan Surkh is very effective in the geriatric patients of Knee joint OA. Local medication of R. Surkh is safe as no side effects/adverse effects were reported during the study period. The study proves the age-old claim of Unani scholars for effectiveness of R. Surkh in Wajaul Mafasil (OA). Sample size of the study and duration of study period are very short. So further studies for longer duration on larger sample size are required to prove the efficacy of the local application of R. Surkh on Knee joint OA in geriatric population.

## 7. Contributions

Dr. Zehra Khatoon Zaidi conceptualized and write the article with analysis of the data, Dr. Uzma Bano, and Dr. Abdul Nasir prepared the tables and charts. Dr. Shafia Mushtaq Allaqaband and Dr. Shah Alam review and finalized the article.

## 8. Source of Funding

None.

## 9. Conflict of Interest

None.

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