

Clinical evaluation of leech therapy in the management of knee osteoarthritis: A pilot study

Abstract

Background: Osteoarthritis (OA) is by far the most common form of arthritis and is a major cause of pain and disability in the elderly. The reported prevalence of OA from a study in rural India is 5.78%. In India, OA of knee joint is more common than of hip joint. Leech therapy has been suggested and successfully practiced by Unani physicians in the management of musculoskeletal and chronic skin disease since antiquity. **Objective:** To assess the efficacy and safety of leech therapy in the management of knee OA on scientific parameters. **Materials and Methods:** The study was conducted in National Institute of Unani Medicine Hospital; Bangalore, India, Thirty patients of OA were enrolled in the trial after obtaining their informed consents. All the patients were clinically assessed and diagnosed on the basis of thorough history, clinical and radiological examination of the affected joint. Then, four leeches were applied on the affected joint for a period of approximately 30 minutes. The severity of OA and efficacy of leech therapy was assessed by Western Ontario and McMaster University (WOMAC) Score and Visual Analogue Scale (VAS) Score. Then, the results were compared with each other, employing a Paired Student's t-test. **Results:** The results showed significant reduction in the WOMAC and VAS scores of post-treatment group ($P < 0.01$) as compared to pre-treatment scores. **Conclusion:** It is concluded that leech therapy may be used safely and effectively in the management of OA, after considering its safety and effectiveness.

Key words: Knee osteoarthritis, leech therapy, Unani medicine, Visual Analogue Scale Score, Western Ontario and McMaster University Score

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INTRODUCTION

Osteoarthritis (OA) is a major health problem in terms of its prevalence, associated disability and effect on the quality of life. It is the most common form of arthritis worldwide and the leading cause of mobility related disability in the elderly.^[1,2] Patients usually complain of joint pain, stiffness and swelling which are worse in the morning.^[3] According to the World

Health Organization, OA is the second most common musculoskeletal condition (30%) after back pain (50%). The reported prevalence of OA from a study in rural India is 5.78%.^[4] In India, OA of knee joint is more common, more prevalent and more commonly associated with symptoms in women than OA of hip joint.^[5,6]

OA, also known as degenerative joint disease, represents failure of the diarthrodial (movable, synovial lined) joint, which is characterized clinically by pain and functional limitations, radiographically by osteophytes and joint space narrowing, and histopathologically by alterations in cartilage and subchondral bone integrity.^[7]

There is no cure for OA. Symptomatic relief is obtained with analgesics and non steroidal anti-inflammatory

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Website:
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DOI: 10.4103/0000-1112.84049

drugs (NSAIDs), but the prolonged use of these drugs produce significant side effects.^[8] Therefore, patients with OA constantly seek long-term control of symptoms through non pharmacological measures such as leech therapy, thermal modalities, tidal irrigation, patient education, exercise, massage, cupping, etc.

In Unani system of medicine, the term *Wajual Muffasil* (arthritis) is collectively used for all joint diseases but the features of *Wajual Muffasil Balghami* (phlegmatic arthritis) are same as that of OA. Various renowned Unani physicians like Zakaria Razi, Ibne Abbas Majoosi, and Ibne Sina described it as the inflammation or pain of joints and considered it as a *Maddi Marz* (humoral disease) caused by the accumulation of morbid humors (phlegm) or vitiated matter in the joint or its surrounding periarticular tissues). Ibne Sina in his famous treatise, “The Canon of Medicine” has mentioned that psychological factors and emotional states play an important role in the causation of this disease along with the weakness of joint.^[9-11]

In this system of medicine, various regimes of non pharmacological or regimental therapy are used for the management of OA along with pharmacotherapy and diet therapy.^[12,13] Leech therapy is one of the treatments that has been suggested and is successfully practiced by Unani physicians in the management of musculoskeletal and chronic skin disease.^[14,15] However the safety and efficacy of this therapy has not been scientifically evaluated till date. This study was carried out to determine the efficacy and safety of leech therapy in the management of knee OA using standardized outcome measures.^[16]

MATERIALS AND METHODS

The study was conducted in the Regimental Therapy Unit, National Institute of Unani Medicine Hospital, Bangalore, from March 2009 to April 2010 and it was an open randomized uncontrolled trial. The patients were randomly selected from OPD and IPD of NIUM Hospital. A total of 35 patients with knee OA, who were eligible based on the inclusion criteria, were enrolled after obtaining their informed consents. Patients enrolled into study were given the information sheet having details about the nature of the study and the procedure of treatment. They were allowed to go through the contents of informed consent form and ask any question related to study. They were requested to sign the informed consent form. All the patients were clinically assessed and diagnosed on the basis of thorough history, clinical and radiological examination

of the affected joint. But five patients were lost to follow-up and were excluded from the study, leaving behind 30 patients who completed the study.

Subjective parameters

1. Pain in joints
2. Tenderness on the joint area
3. Morning stiffness
4. Swelling over the affected joint
5. Restriction of movement

Objective parameters

1. Radiological (X-ray knee joint, AP and Lat. view) changes
2. Western Ontario and McMaster University (WOMAC) Scale
3. Visual Analogue Scale (VAS) score

Inclusion criteria

1. Clinically and radiologically diagnosed patients of knee joint OA
2. Patients of either sex
3. Patients in the age group 30–70 years
4. Patients who agreed to sign the informed consent form and follow up the protocol.

Exclusion criteria

1. Patients below the age of 30 years and above 70 years
2. Patients with any systemic illness (hepatic failure, renal failure, ischemic heart disease and malignancy)
3. Patients with anemia and diabetes mellitus
4. Patient suffering from other concomitant diseases such as rheumatoid arthritis, tubercular arthritis, infective arthritis, gout, syphilitic arthritis, traumatic arthritis, gonorrhoeal arthritis
5. Pregnant and lactating mothers
6. Mentally retarded person
7. Patients who failed to give consent and who failed to follow-up

PROCEDURE OF TRIAL

In classical Unani literature, two types are described (useful and poisonous leeches) along with their characteristics, indications and contraindications. The features of therapeutically useful or nonpoisonous leeches are leeches with thin tiny head, emerald green color, tiny and rounded like rats tail and leeches found in moisture rich places where frogs are in abundance. Leeches with long head, black, gray or green color should be avoided as these leeches are poisonous.^[9, 17]

Leeches were procured from a local supplier and identified as medicinal leeches (*Hirudinaria granulosa*)^[18] used for the study, at Department of Zoology, Bangalore University. Prior to the procedure, the following investigations were done to rule out the exclusion criteria. Random blood sugar (RBS), hemogram (Hb%), total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), bleeding time (BT), clotting time (CT), serum uric acid, *c-reactive protein* (CRP), rheumatoid arthritis (RA) factor, Liver Function Tests (LFTs), Renal Function Tests (RFTs), Electrocardiography (ECG), X-ray knee joint, hepatitis B surface antigen (HbsAg) and Elisa test for Human immunodeficiency virus (HIV).

First of all, the method of leech therapy was explained to the patients. The whole area of affected knee joint was thoroughly cleaned with soap and distal water. The area was gently rubbed till redness appeared. Then, four leeches were applied on the affected joint for a period of approximately 30 minutes according to the procedure as described by Ibne Sina.^[9] After detachment of leeches, the site was cleaned with betadine and covered by a loose pad and bandage. The area around leech bite was routinely observed for any local reaction. The schedule of therapy was 0, 3rd, 9th, 15th, 21st and 27th days. The duration of the trial was 30 days and the assessment of subjective and objective parameters was done fortnightly (0 day, 15th day and 30th day). All the findings were recorded in the case record proforma, designed for the trial. The assessment was done with the help of WOMAC OA Scale^[6,8,19] and VAS Score^[2,3,20] in which decrease in scores suggests improvement. The severity of various clinical parameters was graded on 4 points as (0= nil, 1= mild, 2= moderate and 3= severe). The pre- and post-treatment data (scores) were tabulated and statistically analyzed by applying paired Student's *t*-test to finally evaluate the efficacy of leech therapy. After the completion of trial, patients were again subjected to laboratory tests (Hb%, LFT, RFT) to explore the side effects or toxicity.

RESULTS AND DISCUSSION

Demographic data

Out of 30 patients included in the trial, the highest incidence (50%) was observed in the age group of 51-60 years while the least incidence (10%) was seen in the age group of 30-40 years. Besides, 19 (63.33%) patients were females and 11 (36.67%) patients were males. As far as the dietary habits are concerned 20(66.67%) patients were non-vegetarians and 10 (33.33%) were

vegetarians. Similarly, 18(60%) patients had bilateral OA, while 5(16.67%) patients complained of right-sided and 7(23.335%) patients complained of left-sided OA [Table 1].

Regarding clinical features, out of 30 patients, only 18 (60%) had tenderness, 20 (66.6%) had restricted movements, 22 (73.3%) had stiffness, 24 (80%) had swelling and all 30 (100%) patients complained of pain [Table 2].

Effect of leech therapy on WOMAC score

WOMAC OA Scale is an internationally accepted scale, which consists of questions based on three symptoms viz., pain, stiffness and difficulty in performing physical activities. WOMAC scores were calculated in all patients before and after treatment

Table 1: Distribution of patients according to age, gender, dietary habits and affected joint

Contents	No. of patients	Percentage
Age (years)		
30-40	3	10
41-50	8	26.6
51-60	15	50
61-70	4	13.3
Gender		
Male	11	36.6
Female	19	63.3
Dietary habits		
Vegetarian	10	33.3
Non-vegetarian	20	66.6
Affected joint		
Right knee	5	16.67
Left knee	7	23.33
Both	18	60

Table 2: Distribution of patients according to symptoms

Symptom	No. of patients	Percentage
Pain	30	100
Tenderness	18	60
Stiffness	22	73.3
Restricted movements	20	66.6
Swelling	24	80

Table 3: Effect of leech therapy on WOMAC score

Symptom	Before treatment	After treatment
Pain	14.24	4.22
Stiffness	8.68	3.34
Daily activity	36.4	10.4

Table 4: Effect of leech therapy on VAS score

Symptom	Before treatment	After treatment
Pain	4	1
Stiffness	2	0
Tenderness	3	0
Swelling	1	0
Restricted movements	2	0

according to the method described by S.Sontakke *et al.*^[9] The mean WOMAC scores for pain, stiffness and difficulty in performing physical activities were 14.24, 8.68 and 36.4, respectively, before treatment. At the end of study (after treatment) these scores were reduced [Table 3]. Then, the scores of both pre-treatment and post-treatment groups were compared and statistically analyzed by applying paired Student's *t*-test. The mean WOMAC scores of post-treatment groups were found to be significantly lowered ($P < 0.001$) when compared with mean WOMAC scores of pre-treatment group. Thus, statistically, leech therapy is an effective regimen in the management of OA.

Effect of leech therapy on VAS score

VAS scores were calculated in all the patients before and after treatment. The mean VAS scores for pain, stiffness, tenderness, swelling and restriction of movements were 4, 2, 3, 1 and 2, respectively, before treatment. At the end of study, these scores were reduced [Table 4]. Then, the scores of both pre-treatment and post-treatment groups were statistically analyzed by applying paired Student's *t*-test. The mean VAS scores of post-treatment groups were found to be significantly lowered ($P < 0.001$) when compared with mean VAS scores of pre-treatment group. Thus, statistically, leech therapy is an effective regimen in the management of OA.

The overall improvement in various clinical parameters might be due to elimination or evacuation of morbid humors present locally around the joints by leech

therapy. This is in consonance with the properties of leeches described by Raban Tabri, Razi, Majoosi and Ibne Sina.^[9,10] The effectiveness may also be attributed to the analgesic and anti-inflammatory (resolvent) activities of leech therapy^[9]. More over the saliva of leech contains about 100 pharmacologically active biological substances like hirudin, hyaluronidase, vasidiltors, inhibitors of kallikerine, anesthetics, antibacterial, fibrinases, collagenase etc as proved by various modern scientific researches. These substances are injected into human body while sucking the blood and are responsible for the analgesic, anti inflammatory and anesthetic effects of leech therapy.^[18, 21, 22]

CONCLUSIONS

It is amply clear that leech therapy produced significant improvement on various symptoms and signs including pain, tenderness, stiffness, swelling, WOMAC and VAS Scores. But there was no effect on the degenerative changes of joints as observed in the X-rays of pre and post-treatment groups. Besides, the therapy was found to be safe and well tolerated as the safety parameters (Hb%, TLC, DLC, RFT, and LFT) remained within normal limits after the treatment. No obnoxious side effects were observed except mild local itching in some patients (30%) and overall compliance to the therapy was good. Thus it may be concluded that the leech therapy is an effective and safe regimen in the symptomatic management of management of knee OA. Although the study showed remarkable response, its limitations are lack of blinding, small population, less duration of study and no control group studied. Therefore, studies with randomized standard controlled designs on large population need to be carried out for further exploration of efficacy and safety of leech therapy. Further studies of long duration and long follow-up period are recommended to determine the effect of therapy on the radiological changes of affected joint.

ACKNOWLEDGMENTS

Authors are highly grateful to the Director, NIUM, Bangalore, for necessary facilities required for the research and academic work. Authors are thankful to the staff of RTU NIUM Hospital, Bangalore, for their kind guidance and continuous moral support throughout the study.

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How to cite this article: Lone AH, Ahmad T, Anwar M, Naiyar AH. Clinical evaluation of leech therapy in the management of knee osteoarthritis: A pilot study. *ASL Musculoskel Dis* 2013;1:4-8.

Source of Support: Nil, **Conflict of Interest:** None declared.

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