10.5005/jp-journals-10064-0045

RESEARCH ARTICLE

Jalaukavacharana (Leech Application) in Pain Management: A Pilot Open-Label Clinical Trial

[1]Krishna K Pandey, [2]Gyanendra D Shukla, [3]Arun K Tripathi

ABSTRACT

Introduction: In most musculoskeletal disorders, primary medicine seeking symptom is a pain, but due to "time taking the line of treatment" of Ayurveda in chronic conditions common mass adopts non-sectorial anti-inflamatory drug (NSAIDs) and other analgesics even if undesirable. This study is an attempt to provide an alternative to NSAIDs for pain management by Ayurvedic means.

Materials and Methods: Eighteen patients suffering from painful musculoskeletal disorders of varied etiology, i.e., osteo-arthritis (OA)/rheumatoid arthristis (RA)/low back pain (LBA)/ Gout, primarily having knee joint pain, were randomly divided in three groups with six patients in each group, These patients were unable to perform their routine activity without NSAIDs. Group A patients were given Etoricoxib. Group B patients were given three sittings of *Leech therapy* (*Jalaukavacharana*) within 3 days. While Group C patients were given sugar-coated tablets. The assessment was done on 1st day, 9th day and 15th day based on changes in subjective criterias and outcome was statistically analyzed.

Results: Pain was significantly reduced in the patients treated with *Leech therapy,* and the relief consistency was better than NSAID treated group. However, the results obtained in Group C patient were not significant.

Conclusion: In this pilot study, *Leech therapy* has shown promising results in pain management and can be used as a substitute for modern analgesics. However, more studies with large sample sizes are required to justify this clinical outcome so that *Leech therapy* can be implemented as a pain management module instead of NSAIDs in painful musculoskeletal conditions.

Keywords: *Jalaukavacharana*, *Leech therapy*, Musculoskeletal disorders, Pain management

How to cite this article: Pandey KK, Shukla GD, Tripathi AK. *Jalaukavacharana*

(Leech Application) in Pain Management–A Pilot Open-Label Clinical Trial. J Res Ayurvedic Sci 2018;2(2):99-107.

[1]Medical Officer, [2]Assistant Professor, [3]Director

[1]Ayurveda and Unani Services, Uttarakhand Government, Haldwani, Uttarakhand, India

[2]Department of Panchkarma, Uttarakhand Ayurved University, Haridwar, Uttarakhand, India

[3]Department of Ayurveda and Unani Services, Uttarakhand Government, Dehradun, Uttarakhand, India

Corresponding Author: Krishna Kant Pandey, Medical Officer, Ayurveda and Unani Services, Uttarakhand Government, Haldwani, Uttarakhand, India, Phone:9634465557, Email: kkpandey.dr@gmail.com

Source of support: Nil

Conflict of interest: None

INTRODUCTION

Pain is the most common medicine seeking symptom around the world. In the United States, the annual cost of pain was greater than the annual costs of heart disease ($309 billion), cancer ($243 billion), and diabetes ($188 billion) in 2010 and nearly 30% higher than the combined cost of cancer and diabetes.[1]

Rheumatic or musculoskel et al. conditions comprise over 150 diseases and syndromes, which are usually progressive and associated with pain. They can be broadly categorized as joint diseases, physical disability, spinal disorders, and conditions resulting from trauma. Musculoskel et al. conditions are leading causes of morbidity and disability, giving rise to enormous healthcare expenditures and loss of work. Symptomatic OA affects approximately 10% of men and 18% of women over 60 years of age, while RA affects between 0.3 and 1% of adults worldwide.[2]

Serious adverse effects of NSAIDs are well understood, being related largely to their underlying mechanisms of action. It has been estimated that 5 to 7% of hospital admissions are related to adverse effects of drugs, and, of these hospitalizations, those that result from gastrointestinal, nervous system, renal, or allergic effects of non-aspirin NSAIDs are responsible for approximately 11 to 12%.[3,4]

NSAIDs like indomethacin, ibuprofen, diclofenac, naproxen, aspirin, causes damaging action upon the stomach and intestine due to their acidic nature.[5] While the selective COX-2 inhibitors cause significant adverse effects in the renal and cardiovascular systems, possibly more serious than those caused by conventional NSAIDs.[6]

These payouts in the form of adverse effects can't be justified as they do not cure the disease, instead make the patient dependent on the medicine.

Reviewing scenario mentioned above, need of a pain management protocol other than conventional NSAIDs use arises as an emergent subject, which must be safe as well as economical.

In the recent years, various novel approaches have been given by Ayurveda and Yoga system of

medicine[7-10] still most of them are neither adopted by the doctors nor by the patients. The reason behind this appears to be therapy's long duration protocol as the common mass in today's lifestyle wants effective as well as a fast-acting remedy for their complaint.

Although, Ayurvedic texts are filled with various treatment modules including *Panchakarma* (five bio purificatory measures of Ayurvedic medicine) along with many herbo-mineral drugs which are also proved by various trials[8] to be effective in musculoskeletal disorders still they are not able to provide pain management in a short duration. Again this limitation diverts the patients towards the "pain relieving" NSAIDs.

Leech or *Hirudo medicinalis,* has been historically used in medicine to remove blood from patients. *Leech therapy* was practiced in ancient India and Greece, and evidence of its use is also present in 18th and 19th centuries in Europe and North America.[11]

Leech therapy or *Jalaukāvacāraṇa,* universally accepted around the globe, is an integral part of Ayurvedic medicine especially *Panchakarma.* Although not directly indicated for pain-management in Ayurveda texts, various studies have identified the presence of analgesic enzymes in leech's saliva[12] that can be effective in pain management in musculoskeletal disorders. Few studies have been done previously on the management of OA of the knee joint by leech therapy. But no comparative study with NSAIDs was found during literature review. Also, there is no study which shows its efficacy in pain management irrespective of the site and pathology involved. This trial was conducted to compare the efficacy of leech application as a substitute to the NSAIDs so that if found effective, leech therapy can be used as the pain management method along with primary treatment of that particular musculoskeletal disorder.

MATERIALS AND METHODS

The present study was a randomized controlled trial conducted at the *Panchakarma* Department of Rishikul Campus, Uttarakhand Ayurved University, Dehradun. Although, Groups A and C patients were unaware of the intervention, Group B patients were informed about the leech therapy procedure. Total 18 patients fulfilling the inclusion criteria were selected and randomly divided into three groups with six patients in each group. Ethical clearance was granted by the Institutional Ethical committee (IEC Number: RC/UAU/IEC/15-16/01 dated 27/04/2015). Trial was also registered on the Clinical Trial Registry in India (CTRI) website.(CTRI Number: CTRI/2015/07/005990 Registered on 09/07/2015) A written consent was obtained from each patient after explaining them about the study.

Inclusion Criteria

- Patient of either sex, >30 years of age.
- Patient with history of pain for >6 months.
- Pain in either of knee joint because of OA/RA/Gout or any other disease.
- Pain in any other joint along with knee joint due to OA/RA/LBA/Gout.
- Patient having difficulty in walking with increased walking time.
- Patient unable to perform a routine activity like bathing, eating, dressing due to pain.

Exclusion Criteria

- Patients <30 years of age.
- History of pain for <6 months.
- Number of painful sites/joints = 4 or more.
- Patient with bleeding disorders.
- Patients with uncontrolled diabetes.
- Patient with history of allergy to leeches.
- Patient with a history of incompliance for etoricoxib.
- Pain due to malignancy or some secondary cause.
- Pain due to acute (duration >6 month old) traumatic injury.
- Infective Joint diseases.
- Pregnant and lactating mothers.

Randomization

Patients were randomly allocated to three groups according to the randomization chart generated by GRAPHPAD online randomization tool.

METHODOLOGY

Selected patients were known cases of either OA/RA/LBP or Gouty arthritis with primary symptom as pain in knee joint. Pretreatment assessment of the patients was done as per assigned criteria. The patient was not allowed to take any other medication during the period of study.

Following intervention was provided to the patients:

- *Group A*–Etoricoxib tablet 90 mg (ETROBAX by Ranbaxy Laboratories Ltd.) once a day for nine days in the morning, after breakfast (controlled group).
- *Group B*–3 sittings of *Leech therapy* after every three-day interval.
- *Group C*–250mg sugar tablet twice daily after food (Placebo group).

Methodology for *Leech Therapy*

Source of Leeches: All the leeches used in trial were purchased from a reputed biological product supplier, India Biologicals from Agra, UP.

Procedure of *Leech Therapy*[13]

Pūrva Karma

Preparation of the leeches: Before applying on patients, Leeches were first prepared by keeping them in *Haridr Jala* (turmeric water), prepared by adding few pinches of *Haridr Carna* in a kidney tray half filled with fresh water. When the leeches became active, i.e., moves very fast in the vessel then they were taken out and transferred into a vessel containing fresh cold water. On every sitting new leeches were used for the procedure.

Preparation of patient: Patients were given mild *Abhyanga* (external oleation) followed by *Vapa Svedana* (steam fomentation) over the painful sites for few minutes to increase the superficial circulation and facilitate the blood-letting. The sites were then then cleaned with dry cotton to remove all the greasiness over the area. After that, patients were made to lie in a comfortable position.

Pradhāna Karma

Pricks by lancet were done near the most tender point for application of leeches at the particular sites. Prepared active leeches were then kept over the oozing blood. When leech started sucking blood, the wet cotton pad was placed over it.

On an average, 2–3 leeches of 3–4 inches were used at each painful joint, that used to suck 30–50ml of blood individually. The leeches were applied over/nearby most tender points on the joint/site.

Paścāta Karma

Leech Management: Generally after 30-45 minutes, leech automatically detaches from the site. *Haridr Carna* was then sprinkled over the leech's anterior sucker (mouth) for inducing vomiting. Sometimes gentle squeezing of the leech was required (from its posterior sucker toward anterior sucker) to expel out the sucked blood. After expelling all the blood from its gut, leech becomes active again and stored in fresh water.

Patient Management

When the leech detaches itself from the site, there occurs a secondary bleeding from the site of bite for 2–4 hours or more. *Aatdhauta Ghrita* (purified fat) of *Vaidyaratnam Oushadhsala, Ollur*) was applied over the areas where leaches were applied. A few minutes later, cotton gauze pieces were kept over the bleeding sites with firm pressure to absorb the secondary bleeding. When the cotton gauze piece got attached to the site forming a clot, the patient was advised not to unplug it before next day morning to avoid any bleeding.

In a few patients, tight compression bandages were also used to check the bleeding.

Assessment Criteria

Assessment of the patients was done based on the difference in symptomatic score and functional improvement

(a) *Symptomatic Score*:

- Pain assessment was done based on visual analog score (VAS) ranging from 1–10 graded by the patient only.
- Tenderness was graded on the basis of ritchie articular index:[14]

Grade 0–Normal-absent or non-tender
Grade 1–Mild-tender
Grade 2–Moderate-tenderness and wincing
Grade 3–Severe-tenderness, wincing and withdrawal

(b) Functional assessment was done based on walking time. Patients were asked to walk a distance of 20 meters on a flat surface and walking time was measured pre and post intervention.

Other than this, western ontario and McMaster universities osteoarthritis index (WOMAC)–modified–Crd Pune version[15] scoring was also done in patients with knee osteoarthritis. WOMAC (modified–Crd Pune version) is a scale calculated based on questions related to pain, stiffness, and difficulty in performing routine physical activities. WOMAC (modified–Crd Pune version) scoring was done in all the patients before and after treatment.

Evaluation was done on Day 0 (before the initiation of intervention), on 9th day (completion of intervention) and on 15th day.

Statistical Analysis

The obtained results were subjected to various tests. On all subjective parameters, a paired t-test was applied within groups, and intergroup comparison was done using ANOVA. A p-value less than 0.05 is considered as statistically significant in this study.

Observations

As per demographic data obtained in 18 patients (Table 1), the mean age was 53.89 ± 7.15 years. Average height was 165.11 cms with an SD of ± 5.06 cms while average weight was 69.5 ± 6.81 kg.

Out of 18, 55.56% were females. 50% were of *Vata-Kapha Prakruti* while remaining 27.78% and 22.22% were of *Vata-Pitta* and *Pitta-Kapha Prakruti* respectively (Table 2).

About 44.44% were having three joints involved. In 38.89%, two joints were involved while in 16.67% only one knee joint was involved. In 27.78% patients, bilateral knee joints were involved while in 22.22%, vertebral joints were involved (Table 3).

About 44.44% of patients were having chronicity of the pain for more than 5 years while 38.89% were having the pain from last 2–5 years. Sixty one point eleven percent were taking analgesics once daily while 33.33% were taking twice a day (Table 4).

Table 1: Demographic data

Factor	*Number of patients*	*Mean ± SD*
Age	18	53.89 ± 7.15 years
Height	18	165.11± 5.06 cms.
Weight	18	69.5 ± 6.81 kgs

Table 2: Sex and *Prakruti* of patients

Factor		*No. of patients*	*Percentage*
Sex	Male	8	44.44
	Female	10	55.56
Prakruti	*Vāta-Pittaja*	5	27.78
	Pitta-Kaphaja	4	22.22
	Vāta-Kaphaja	9	50

Table 3: Joints involved/painful sites

Factor		*No. of patients*	*Percentage*
No. of Joints/ Sites Involved	1	3	16.67
	2	7	38.89
	3	8	44.44
	B/L Knee joints	5	27.78
	Vertebrae	4	22.22
Pain sites	Toe	3	16.67
	Elbow	1	5.56
	Phalangeal joint	4	22.22

Table 4: Duration of pain and frequency of analgesics

Factor		*No. of patients*	*Percentage*
Duration of pain	Upto 2 years	3	16.67
	More than 2 to 5 years	7	38.89
	More than 5 years	8	44.44
Use of analgesics per day	Once	11	61.11
	Twice	6	33.33
	More	1	5.56

RESULTS

Interventions were given in all three groups from Day 1 to Day 9. An assessment was done before initiation of trial (Day 0) and on completion of the trial (Day 9). While another assessment was done on Day 15 (follow-up assessment) to assess the residual effects of intervention and relapse of symptoms.

Pain, assessed according to VAS, was significantly reduced in both groups A and B on the 9th day, i.e., completion of the intervention. Group A showed 79.17% decrease in VAS score while Group B showed a reduction of 66.67%. Group C showed an insignificant drop of 13.2%. The difference between the Group A and Group B was not significant while the difference between the Group B and C, and Group A and C was extremely significant ($p < 0.001$) (Tables 5 and 6). Six days after intervention completion, i.e., on 15th day, Group A VAS score showed only a 6.25% reduction from the baseline (before treatment) score while group C only a 3.77% reduction from baseline score but both were insignificant statistically. On the other hand, Group B showed an extremely significant ($p < 0.001$) decrease in pain i.e. of 62.5% from baseline score before the intervention (Tables 7 and 8).

After 9th day of treatment, tenderness was significantly reduced to 88.89% in both Groups A and B. While in Group C there was in insignificant reduction of 16.67%. The difference in the results of Groups A and B was an insignificant while the percentage difference between Groups B and C, and Groups A and C were highly significant ($p < 0.01$) (Tables 5 and 6).

On 15th assessment, only Group B showed the consistent result with a significant reduction of 66.67% ($p < 0.05$) from the baseline score. Groups A, C showed insignificant minor changes of 11.11% and 8.33% respectively in tenderness when compared with baseline tenderness grading. (Tables 7 and 8) These results when compared to each other showed that the differences were significant in between Groups A, B and Groups B and C.

On 9th day assessment, both Groups A and B showed a significant reduction of 61.64 and 51.92% in WOMAC score, respectively. But the WOMAC score reduction of 5.78% in Group C was not significant.

Although the results obtained in Group A were marginally better than Group B but were not found to be significant when tested statistically. However, the result of both Group A and B, when compared with Group C, were found to be extremely significant ($p < 0.001$) (Tables 5 and 6).

In 15th day assessment also, mean WOMAC score of Group A showed a steep increase, i.e., only 2.4% drop when compared with baseline score which was insignifi-

Table 5: Nineth day assessment

Parameter	*Group*	*N*	*Mean Score (±S.D.)* *B.T.*	*A.T. (9th Day)*	*Mean diff. (B.T.-A.T.)*	*% Change*	*p-value (paired t-test)*
Pain VAS score	Group A	6	8±1.26	1.67± 0.82	6.33±0.52	79.17	<0.001
	Group B	6	8±0.89	2.67±1.21	5.33±0.82	66.67	<0.001
	Group C	6	8.83±1.17	7.67±1.51	1.17±0.75	13.2	<0.05
Tenderness	Group A	6	1.5±0.55	0.17±0.40	1.33±0.52	88.89	<0.01
	Group B	6	1.5±0.55	0.17±0.41	1.33± 0.52	88.89	<0.01
	Group C	6	2±0.89	1.67±0.52	0.33±0.52	16.7	>0.05
WOMAC score	Group A	6	36.5±4.23	14±3.46	22.5±4.76	61.64	<0.001
	Group B	6	34.7±2.34	16.7±5.35	18±4	51.92	<0.001
	Group C	6	37.5±4.28	35.3±4.5	2.17±3.6	5.78	>0.05
Walking time	Group A	6	36.17±4.07	20.5±1.52	15.67±3.39	43.32	<0.001
	Group B	6	36.5±2.43	21±1.79	15.5±1.05	42.47	<0.001
	Group C	6	37.67±4.08	36±5.21	1.66±1.86	4.24	>0.05

cant statistically. A similar pattern was seen in Group C, where the mean WOMAC score was reduced by 4.44% only which may have occurred due to chance. But, Group B WOMAC score remained almost consistent with a drop of 50.97% in comparison to baseline score, even after withdrawal of medicine and this result was found to be significantly better than group A and C when tested statistically ($p < 0.001$) (Tables 7 and 8).

For functional assessment, walking time was recorded. On the last day of intervention, Groups A and Groups B showed a significant ($p < 0.05$) reduction of 43.32 and 42.46% respectively, in 20 m walking time. However, the results of both groups differ insignificantly. Group C showed an insignificant reduction of 4.42% and the results were significantly (<0.001) less when compared with the other two groups (Tables 5 and 6).

Table 6: Intergroup comparison of results after 9th day assessment (n = 6)

Parameter	*Group*	*Mean Diff. (BT-AT)*	*% Change*	*p-value (one way ANOVA)*
Pain VAS score	Group A	6.33±0.52	79.17	>0.05
	Group B	5.33±0.82	66.67	
	Group B	5.33±0.82	66.67	<0.001
	Group C	1.17±0.75	13.2	
	Group C	1.17±0.75	13.2	<0.001
	Group A	6.33±0.52	79.17	
Tenderness	Group A	1.33±0.52	88.89	>0.05
	Group B	1.33±0.52	88.89	
	Group B	1.33±0.52	88.89	<0.05
	Group C	0.33±0.52	16.7	
	Group C	0.33±0.52	16.7	<0.05
	Group A	1.33±0.52	88.89	
WOMAC score	Group A	22.5±4.76	61.64	>0.05
	Group B	18±4	51.92	
	Group B	18±4	51.92	<0.001
	Group C	2.17±3.6	5.78	
	Group C	2.17±3.6	5.78	<0.001
	Group A	22.5±4.76	61.64	
Walking time	Group A	15.67±3.39	43.32	>0.05
	Group B	15.5±1.05	42.47	
	Group B	15.5±1.05	42.47	<0.001
	Group C	1.66±1.86	4.24	
	Group C	1.66±1.86	4.24	<0.001
	Group A	15.67±3.39	43.32	

Table 7: 15th Day assessment

Parameter	Group	n	Mean Score (±SD) BT	Mean Score (±SD) AT (15th Day)	Mean diff. (BT-AT)	% Change	p-value (paired t test)
Pain VAS score	Group A	6	8±1.26	7.5±1.05	0.5±1.38	6.25	>0.05
	Group B	6	8±0.89	3±1.41	5±1.41	62.5	<0.001
	Group C	6	8.83±1.17	8.5±1.05	0.33±1.03	3.77	>0.05
Tenderness	Group A	6	1.5±0.55	1.33±0.52	0.17±0.41	11.11	>0.05
	Group B	6	1.5±0.55	0.5±0.55	1±0	66.67	>0.05-
	Group C	6	2±0.89	1.83±0.41	0.17±0.75	8.33	>0.05
WOMAC score	Group A	6	36.5±4.23	35.5±3.94	1±1.26	2.74	>0.05
	Group B	6	34.7±2.34	17±5.1	17.7±3.50	50.96	<0.001
	Group C	6	37.5±4.28	35.8±4.67	1.67±2.34	4.44	>0.05
Walking time	Group A	6	36.17±4.07	35.67±3.44	0.5±1.38	1.38	>0.05
	Group B	6	36.5±2.43	22.67±1.75	13.83±1.47	37.90	<0.001
	Group C	6	37.67±4.08	37.33±4.50	0.33±1.21	0.89	>0.05

Even the 15th day, Group B showed a significant ($p < 0.05$) improvement of 37.90% in walking time. While Groups A, C showed a fall in improvement after withdrawal of intervention, as the improvement in walking time reduced to 1.38 and 0.88% respectively, which was statistically insignificant when compared with baseline score and in-between. When results obtained in Group B was compared to Groups A, C it was found to be extremely significant ($p < 0.001$) (Tables 7 and 8).

Adverse Drug Reaction

Despite normal BT/CT, in two-three patients oozing didn't check even on the next day after *Leech therapy.* However tight compression bandage along with *Sphatik*ā *Carna* application was done on the next day which checked the bleeding after a few hours. No other adverse drug reaction (ADR) was found during the course of treatment in both the groups.

DISCUSSION

As the pain was the primary inclusion criteria for this study, the majority of the patients who got registered in the study were suffering from either osteoarthritis or Rheumatoid arthritis involving at least one knee joint.

Results obtained during the period of intervention were only marginally better in the patients who got treated with Etoricoxib in comparison to the patients who were given leech therapy as an intervention.

But the difference was not significant when tested statistically.

On the 15th day of assessment, Pain reduction was consistent in patients treated with leech therapy while on intervention withdrawal, the pain worsened again in the patients who were given Etoricoxib.

As said by Ayurveda stalwarts, pain doesn't occur without vitiation of *Vata*. For *Vata* vitiation, there must be either *Dhatu Kahaya* or *Margavarodha,* and due to a modern lifestyle in the majority of patients, *Vata* vitiation mostly occurs due to *Srotavarodha* or *Margavarodha*. This *Srotavarodha* or blockage of channels primarily occurs due to the stagnation of *Kapha/Rakta* or *Pitta*. *Leech therapy* removes vitiated *Rakta* and/or other *doshas,* which in turn leads to *Srotoaodhana* (clearance of blocked channels) at that particular site and nearby area. *Sroto odhana* causes *Anulomana* (proper movement) of stuck or vitiated *Vata* locally. Due to the *Anulomana* of *Vata*, its primary symptom, pain gets relieved. This can be a reason behind this analgesic action of *Leech therapy.*

Also according to the modern science, leech application not only remove blood from that site but also injects biologically active substances which help to manage various ailments. It injects anti-inflammatory, analgesic, and bacteriostatic substances like hirudin, hyaluronidase, histamine like vasodilators, Inhibitors of kallikrein, superoxide production and poorly characterized anesthetics and analgesic compounds with its saliva which can be helpful in subsiding inflammation and pain.[16] These substances might reach deeper tissue zones and possibly the joint spaces. Various bioactive substances in leech saliva may also be as pharmacologically potent as hirudin and thus exert substantial effects in peri-articular tissue and adjacent structure.[17] A study has proven that leech application causes a significant increase in superficial skin perfusion, especially 16 mm around the biting zone.[18] Therefore, it can be assumed that reason for the improvement in pain and inflammation might be a regional analgesic and antiphlogistic effect by these substances enforced by hyaluronidase. Also the antinociceptive effect may also be assumed responsible

Table 8: Intergroup comparison of results after 15th day assessment (n = 6)

Parameter	*Group*	*Mean diff. (BT-AT)*	*% Change*	*p-value (One way ANOVA)*
Pain VAS score	Group A	0.5 ± 1.38	6.25	< 0.001
	Group B	5 ± 1.41	62.5	
	Group B	5 ± 1.41	62.5	< 0.001
	Group C	0.33 ± 1.03	3.77	
	Group C	0.33 ± 1.03	3.77	> 0.05
	Group A	0.5 ± 1.38	6.25	
Tenderness	Group A	0.17 ± 0.41	11.11	< 0.05
	Group B	1 ± 0	66.67	
	Group B	1 ± 0	66.67	< 0.05
	Group C	0.17 ± 0.75	8.33	
	Group C	0.17 ± 0.75	8.33	> 0.05
	Group A	0.17 ± 0.41	11.11	
WOMAC score	Group A	1 ± 1.26	2.74	< 0.001
	Group B	17.7 ± 3.50	50.96	
	Group B	17.7 ± 3.50	50.96	< 0.001
	Group C	1.67 ± 2.34	4.44	
	Group C	1.67 ± 2.34	4.44	> 0.05
	Group A	1 ± 1.26	2.74	
Walking time	Group A	0.5 ± 1.38	1.38	< 0.001
	Group B	13.83 ± 1.47	37.90	
	Group B	13.83 ± 1.47	37.90	< 0.001
	Group C	0.33 ± 1.21	0.89	
	Group C	0.33 ± 1.21	0.89	> 0.05
	Group A	0.5 ± 1.38	1.38	

for pain relief, although no proven justification is available till now. As after bite, biologically active substances present in leech saliva enters the superficial blood, further reaching deep tissues and joint spaces. Hyaluronidase present in leech saliva further facilitates the penetration and diffusion of these substances into the tissues. Due to this enzyme, it is highly probable that the antiphlogistic substances in leech saliva can penetrate deep enough to exert significant effects on periarticular myofascial structures and perhaps even on intra-articular structures.[19]

Removal of venous congestion can be another assumption regarding mode of action of *Leech therapy*. As after leech bite following primary suction of blood by a leech, secondary oozing occurs of a few minutes to hours. This primary sucking and passive-oozing phase of leech therapy decreases venous congestion in the joints. In addition to this, a broad number of anticoagulant agents decrease venous congestion such as the thrombin inhibitor hirudin, apyrase, collagenase, hyaluronidase, Factor Xa inhibitor and fibrinase one and two.[20, 21] This theory also justifies the process of *Srotoāvadhana* by *Leech therapy* as discussed earlier.

Secondary bleeding for a few minutes to hours, due to hirudin, causes the removal of toxins along with increased circulation to that particular area. A healthy cell gets sick when it is deprived of needed oxygen and nutrition and is unable to remove toxins accumulated during metabolism. Biologically active substances in leech saliva help the cells to absorb necessary nutrition and eliminate toxins.

CONCLUSION

Present work was a pilot study conducted with very small sample size. Still, it suggests that leech application reduces the pain to a significant level and improves quality of life of the patient without any ill effect. More large sampled trials are required to justify these results. Although, based on this study it can't be concluded that leech therapy can replace the primary treatment of RA or OA as per modern or ayurvedic texts because clinician should aim for the

treatment of the main pathology instead of treating a particular symptom. But leech therapy can be a substitute for overused NSAIDs, and it can be accompanied either with herbal/herbo-mineral drugs and *Panchakarma* therapy or with modern medicines.

REFERENCES

1. Gaskin DJ, Richard P. The Economic Costs of Pain in the United States. In: Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011. Appendix C.
2. Chronic diseases and health promotion. Retrieved January 17, 2015, from http://www.who.int/chp/topics/rheumatic/en/
3. Pirmohamed Munir, James Sally, Meakin Shaun, Green Chris, Scott Andrew K, Walley Thomas J. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004; 329:15.
4. Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol. 2007;63(2):136-147.
5. Cena C, Lolli ML, Lazzarato L, Guaita E, Morini G, Coruzzi G, et al. Antiinflammatory, gastrosparing, and antiplatelet properties of new NO-donor esters of aspirin. J Med Chem. 2003;46(5): 747-754.
6. Dubois RW, Melmed GY, Laine L, Henning JM. Guidelines for the appropriate use of non-steroidal anti-inflammatory drugs, COX- 2 Specific inhibitors and proton pump inhibitors in patients requiring Chronic anti-inflammatory therapy. Ailment Pharmacol. Ther. 2004; 19:197.
7. Raut A, Bichile L, Chopra A, Patwardhan B, Vaidya A. Comparative study of amrutbhallataka and glucosamine sulphate in osteoarthritis: Six months open label randomized controlled clinical trial. J Ayurveda Integr Med. 2013;4(4):229-236.
8. Chopra A, Saluja M, Tillu G. Ayurveda -modern medicine interface: A critical appraisal of studies of Ayurvedic medicines to treat osteoarthritis and rheumatoid arthritis. J Ayurveda Integr Med. 2010;1(3);190-208.
9. Vallath N. Perspectives on *Yoga* Inputs in the Management of Chronic Pain. Indian Journal of Palliative Care. 2010;16(1):1-7.
10. Pain management and *Yoga*. Retrieved on January 17, 2015, from http://www.drnespor.eu/PaYo3.pdf
11. Leech Retreieved March 17,2015, from http://en.wikipedia.org/wiki/Leech
12. Koeppen D1, Aurich M, Rampp T, Medicinal leech therapy in pain syndromes: a narrative review. Wien Med Wochenschr. 2014 Mar;164(5-6):95-102
13. Shastri Kaviraj Ambika Dutt. Chapter 13th Sutra Sthana. Sushrut Samhita, "Ayurveda Tatwa Sandeepika" Hindi Commentary Part I. Varanasi, Chaukhmbha Sanskrit Sansthan; Edition 11th
14. Ritchie DM, Boyle JA, McInnes JM, Jasani MK, Dalakos TG, Grieveson P, Buchanan WW. Clinical studies with an articular index for the assessment of joint tenderness in patients with rheumatoid arthritis. Q J Med. 1968 Jul;37(147):393-406
15. Chopra A. Rheumatology: Made in India. J Indian Rheumatol Assoc. 2004;12:43-53.
16. I.P. Baskova, G.I. Nikonov, Destabilase " An enzyme of medicinal leech salivary gland secretion that hydrolyses isopeptide bonds in stabilized fibrin" Biokhimia (USSR) 50(1985) 363-375.
17. Michalsen A, Lüdtke R, Cesur O, Afra D, Musial F, Baecker M, Fink M, Dobos GJ. Effectiveness of leech therapy in women with symptomatic arthrosis of the first carpometacarpal joint: a randomized controlled trial. Pain. 2008 Jul 15;137(2):452-9. doi: 10.1016/j.pain.2008.03.012. Epub 2008 Apr 14.
18. Knobloch K, Gohritz A, Busch K, Spies M, Vogt PM. Hirudo medicinalis-leech applications in plastic and reconstructive microsurgery-a literature review (Article in German). Handchir Mikrochir Plast Chir. 2007;39(2):103-7.
19. Singh AK, Singh OP. Analgesic and anti-inflammatory activity of leech therapy in the management of arthritis. International Research Journal of Pharmacy 2011;2(12):172-4.
20. Sviridkina LP, Borovaia EP, Makhneva AV. Hirudotherapy in combined sanatorium-spa treatment of patients with coronary heart disease (Article in Russian). Vopr Kurortol Fizioter Lech Fiz Kult. 2008;3:12-5.
21. Baskova IP, Zavalova LL, Kostrjukova ES, Titova GA, Lazarev VN, Zgoda VG. Proteomic analysis methods for characterization of proteins from the salivary gland secretions of the medicinal leech during different seasons. Biochemistry (Moscow) 2007;72(2):219-25.

हिन्दी सारांश

वेदनाशामक औषधियों के विकल्प के रूप में वेदना प्रबंधन में जलौकावचारण की भूमिकाः एक प्रारम्भिक अध्ययन

[1]कृष्ण कान्त पाण्डेय, [2]ज्ञानेंद्र दत्ता शुक्ल, [3]अरुण के त्रिपाठी

परिचयः अधिकांश अस्थि–माँसपेशीगत विकारों में वेदना ही औषधि लेने का मुख्य कारण है, किन्तु जीर्ण रोगों में सामान्यजन द्वारा, आयुर्वेद की चिकित्सा द्वारा अधिक समय लेने के कारण, न चाहते हुए भी विभिन्न वेदनाशामक औषधियों का प्रयोग किया जाता है. यह अध्ययन वेदना प्रबंधन हेतु आधुनिक वेदनाशामक औषधियों का विकल्प, आयुर्वेद के माध्यम से देने का प्रयास है.

विधिः इस अध्ययन में 18 रोगियों को 3 समूहों में यादृच्छिक रूप से विभजित किया गया, जिसके प्रत्येक समूह में 6 रोगी रखे गए, ये सभी रोगी अत्याधिक वेदना में थे व आधुनिक वेदनाशामक औषधियों के बिना अपने दैनिक क्रियाकलापों में असमर्थ थे. समूह 'ए' के मरीजों को इटोरिकौक्सिब (आधुनिक दर्द निवारक) दिया गया, जबकि समूह 'बी' के मरीजों पर तीन बार 3–3 दिन के अंतराल पर जलौकावचारण (आयुर्वेदिक चिकित्साविधि) का प्रयोग किया गया, एक अन्य समूह 'सी' के रोगियों को शक्कर की गोलियां दी गईं. उक्त रोगियों की दशा/वेदना का आकलन प्रथम दिवस, 9वें और 15वें दिवस पर किया गया.

परिणामः जलौकावचारण के द्वारा उपचारित रोगियों की वेदना में अत्यंत कमी पायी गयी और यह वेदनाशमन आधुनिक वेदनाशामक औषधियों से उपचारित रोगियों वाले समूह से अधिक समय तक स्थिर पाया गया.

निष्कर्षः जलौकावचारण, जो कि पंचकर्म का एक अंग है, आधुनिक वेदनाशामक औषधियों का एक विकल्प हो सकता है. इसके परिणाम को पुष्ट करने हेतु और अधिक रोगियों में इसका अध्ययन आवश्यक है, जिससे जलौकावचारण को वेदनायुक्त अस्थि–माँसपेशीगत रोगों आधुनिक वेदनाशामक औषधियों के विकल्प के रूप में वेदना प्रबंधन हेतु प्राथमिक रूप से लागू किया जा सके.