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Evaluation of efficacy of topical herbal analgesic Arthrella Ointment in Osteoarthritic Patients

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ABSTRACT

Osteoarthritis (OA) is a chronic condition involving degradation of cartilage within the joints mostly found in Elderly population causing immense pain and disability in Patients, NSAIDs are the first line of drug in conventional medicine to manage pain. But it leads to Gastrointestinal, Cardiovascular, Renal and other systemic AEs. Arthrella Ointment being a Topical-Herbal ointment has no reported side effects and AEs. Thus, a safe treatment option to alleviate pain in OA Patients. In this Clinical study 87 Subjects with OA were divided in two groups, one was treated with Arthrella Ointment for 4 weeks and results were compared with Placebo Control Group. The result showed better WOMAC and VAS scores after 4 weeks along with statistically significant difference in the relief of pain in the two groups. This effect increased regularly over the whole study period. There were no adverse reactions attributed to the Arthrella ointment. Thus, it was concluded that Arthrella Ointment is effective in pain management Associated with OA without any AEs and Side Effects.

Key words: Arthrella Ointment, Osteoarthritis (OA), WOMAC, VAS scores

INTRODUCTION

Osteoarthritis (OA) is a chronic condition involving degradation of cartilage within the joints. It is the most common form of arthritis and is prevalent in elderly people. It is associated with pain, substantial disability and quality of life is hampered due to mobility limitations.^[1,2]

Oral therapies for patients with mild to moderate OA pain include paracetamol (acetaminophen) and NSAIDs which are associated with dose, duration and age-dependent risks of gastrointestinal, cardiovascular, renal, hematological and hepatic adverse events (AEs),

as well as clinically meaningful drug interactions.^[3,9] Topical therapies present a valuable therapeutic option for OA pain management. They provide an alternative to oral medications for patients trying to get relief from arthritis pain.^[10] Topical medications target the site of application and ideally produce effective drug concentrations locally with minimal systemic absorption and help in periarticular pain associated with OA.^[11]

Drug description

Arthrella Ointment is a Topical Herbal analgesic ointment designed for the treatment of pain associated with Osteoarthritis, rheumatoid arthritis, cervical spondylosis, frozen shoulder, sprains, sport injuries and myalgia. It has analgesic, anti-inflammatory, antioxidant, counterirritant properties.^[12] Active Herbal Ingredients in Arthrella ointment induce vasodilation, increases blood circulation and a feeling of warmth.^[12] *Gaultheria fragrantissima*, *Eucalyptus globulus* and *Cinnamomum camphora* work synergistically to reduce muscular pain, joint swelling, joint tenderness and joint stiffness and help improve range of movement of the affected joints.^[13,15]

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In the present study, the efficacy and safety of Arthrella Ointment supplied by M/S Charak Pharma Pvt. Ltd., in the symptomatic alleviation of acute and chronic inflammatory Osteoarthritis pain was evaluated.

MATERIALS AND METHODS

Study design

A placebo-controlled randomized double-blind single center clinical trial was conducted for one month. All patients gave written informed consent before randomization between Arthrella Ointment and placebo ointment groups.

Patients were recruited with the following inclusion and exclusion criteria

Inclusion criteria

- Age 40 - 80yrs of either gender
- Osteoarthritis diagnosis according to clinical history and X-ray
- Maximum visual analog score for pain on movement, between 40 - 80yrs.
- Successful completion of treadmill walking test

Exclusion criteria

- Patients with history of alcohol or drug abuse concomitant skin disease or abrasions at the application site
- Usages of any other topical product at the application site were excluded from the study.
- Pregnant and lactating women were also excluded from the study.

Study procedure

A total of 87 Osteoarthritis human subjects, suffering from acute and chronic inflammatory pain, were included in the study. 8 patients dropped out of the study. After screening, the subjects were randomly assigned to two groups (n = 38 for placebo ointment and n= 41 for Arthrella Ointment).

All the patients were advised to apply a small quantity of Arthrella Ointment topically to the affected region, with gentle massage, twice daily for one month. All the

patients were assessed for the muscular pain, joint swelling, joint tenderness, early morning joint stiffness and joint pain.

The primary efficacy variable was total WOMAC score that was modified for the target population. The index consists of 24 questions (5 pains, 2 stiffness, and 17 physical functions). Visual analog score (VAS) was used to assess pain and 6 minute walking test was performed. Patient diaries and consultations with physicians were used to determine progress at baseline, and then 2nd and 4th week. At the baseline visit, vital signs were assessed and tests were performed. All the patients were assessed for local adverse reactions like irritation, burning/stinging sensation and erythema.

Follow up was taken weekly and the WOMAC and VAS score evaluation was done during each week follow-up visit. All the adverse events either reported or observed by the patients were recorded with information about severity.

Subject demographics enrolled in the clinical trial are summarized in table 1. Randomization was effective with characteristics being indistinguishable between the two groups. Baseline Pain efficacy measures in the two groups are summarized in table 2. There was no statistical difference between groups.

Table 1: Subject demographic characteristics

Demographic Characteristics	Arthrella Ointment (n=41)	Placebo ointment (n=38)
Age (years)	53.1 ± 8.9	54.1 ± 7.7
Gender (F:M)	22:19	26:12
BMI	26.5 ± 3.3	26.5 ± 3.1

Results expressed as mean ± SD. There was no statistical difference between groups.

Table 2: Baseline Pain efficacy measures

Baseline measures	Arthrella Ointment (n=41)	Placebo ointment(n=38)
WOMAC-Pain	7.3 ± 3.3	6.6 ± 3.4

WOMAC-Stiffness	2.8 ± 1.5	2.8 ± 1.8
WOMAC-Physical Function	29.5 ± 12.4	25.4 ± 11.4
WOMAC Total	39.6 ± 13.4	34.8 ± 15.8
VAS Pain	59.5 ± 10.0	63.2 ± 10.0

RESULTS

Efficacy in total WOMAC score

In this trial a steady reduction in total WOMAC with placebo treatment over the 4 weeks trial period was evident. However, reductions in total WOMAC were significantly greater with Arthrella ointment treatment (Table 3). This was noted from 2nd week of treatment with Arthrella ointment.

Table 3: Efficacy in total WOMAC score

WOMAC Total	Baseline value	After Treatment	
		2 nd week	4 th week
Arthrella ointment (n=41)	39.6 ± 13.4	28.5 ± 10.1	18.2 ± 8.9
Placebo ointment (n=38)	34.8 ± 15.8	34.3 ± 15.2	32.6 ± 11.2

Similar to total WOMAC, assessments for pain, stiffness and physical function indicated that Arthrella ointment was significantly more effective than placebo. Arthrella ointment resulted in significantly greater improvements than placebo ointment for all measures (Table 4).

Table 4: Assessments for pain, stiffness and physical function

WOMAC-Pain	Baseline value	After Treatment	
		2 nd week	4 th week
Arthrella ointment (n=41)	7.3 ± 3.3	6.2 ± 4.3	4.5 ± 1.2

Placebo (n=38)	6.6 ± 3.4	6.4 ± 1.6	5.9 ± 4.5
WOMAC-Stiffness			
Arthrella ointment (n=41)	2.8 ± 1.5	2.1 ± 0.5	1.4 ± 0.2
Placebo (n=38)	2.8 ± 1.8	2.6 ± 0.7	2.4 ± 0.2
WOMAC-Physical Function			
Arthrella ointment (n=41)	29.5 ± 12.4	20.2 ± 10.9	12.3 ± 9.8
Placebo (n=38)	25.4 ± 11.4	25.3 ± 12.3	24.3 ± 11.2

Efficacy in VAS Pain

Pain, assessed with a visual analog scale, was indistinguishable at baseline between groups: placebo ointment 63.2 ± 10.0; Arthrella ointment 59.5 ± 10.0. VAS pain was reduced with Arthrella ointment treatment over the 4th week study period (Table 5). The benefits were significantly greater with Arthrella ointment.

Table 5: Efficacy in VAS Pain

VAS Pain	Baseline value	After Treatment	
		2 nd Week	4 th week
Arthrella ointment (n=41)	59.5 ± 10.0	41.2 ± 4.3	32.5 ± 1.2
Placebo (n=38)	63.2 ± 10.0	60.4 ± 1.6	59.9 ± 4.5

There were no clinically significant adverse reactions (either reported by the patients, or observed by the investigators), and the overall compliance to the treatment was excellent.

DISCUSSION

Osteoarthritis is the leading cause of disability with about 240 million people affected worldwide.^[16] Age is a major risk factor and the limitations on physical

performance and concomitant pain results in osteoarthritis being a major social burden.^[1,3] Despite this burden and the high incidence of osteoarthritis there has been little in the way of treatments that modify the disease course and alleviate symptoms.

Topical administration of anesthetics and analgesics can allow for the efficient, painless delivery of medications that may reduce systemic side effects associated with the medication while providing clinical advantages over injected or oral administration for the same clinical situation.^[12]

The present clinical study was planned to study the efficacy and safety of Arthrella ointment in the symptomatic alleviation of acute and chronic inflammatory Osteoarthritis pain. The result showed better WOMAC and VAS scores after 4 weeks along with statistically significant difference in the relief of pain in the two groups. This effect increased regularly over the whole study period. There were no adverse reactions attributed to the Arthrella ointment.

These excellent beneficial actions of Arthrella ointment are because of its potent topical anti-inflammatory, analgesic and counter-irritant properties. *Cinnamomum camphora*, Oils of *Gaultheria fragrantissima* & *Capsicum annum* are counter-irritants and helps to relieve pain immediately. *Eucalyptus globulus*,^[13,15] *Vitex negundo* are analgesic, anti-inflammatory medicines.^[17] Arthrella ointment targets the peripheral nerves and soft tissue at pain site. The counter-irritants in Arthrella ointment also help the absorption of the anti-inflammatory ingredients through the skin. Thus, Arthrella ointment relieves pain immediately, reduces inflammation rapidly and restores mobility instantly.

CONCLUSION

In conclusion, this trial demonstrates the potential efficacy and safety of Arthrella ointment in the symptomatic treatment of OA pain over 4 weeks of therapy. The Arthrella ointment demonstrated better results with acute and chronic inflammatory pain experienced in chronic degenerative condition like osteoarthritis.

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