

**USE OF MUVEASE IN THE TREATMENT OF JOINT PAIN AND BACK PAIN:  
A RANDOMIZED DOUBLE-BLIND PLACEBO CONTROLLED CLINICAL TRIAL**

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**ABSTRACT**

Joint and back pain is a common problem throughout the world. Indian population were also suffering from this disorder. Aetiology of this disease is varied & therapeutic remedy in modern medicine is not enough. Not only that, the side effects of the existing medicine are causing deterioration of quality of life. A randomized double-blind placebo controlled clinical study was conducted to evaluate the efficacy, safety and tolerability of Muvease, a herbal formulation, in the management of joint pain, back pain and lumbago. Thirty patients of either sex in the age group of 55- 70 years with clinical and radiological evidence of arthritis were selected for the trial, and treated with Muvease and a placebo tablet. The study design was cross over type with intervention. Evaluation of pre and post interventional results showed significant improvement in the status of the patients treated with muvease.

**KEY WORDS:** Muvease, *Boswellia serrata*, Clinical trial, Placebo

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**INTRODUCTION**

Joint and back pain poses an enormous challenge for the physician and other health providers. The problem in developing countries is compounded by ignorance to report for early treatment and occupational compulsions in rural areas. According to Borenstein<sup>1</sup>, low back pain should be viewed as a medical disorder & the goal of the treatment is to return the patient to regular physical activity. In upto 80% patients with acute low back pain, a specific cause cannot be pinpointed. Many synthetic drugs are used to treat low back pain, joint pain and other musculoskeletal problems but all of them have serious side effects, therefore a need to develop a safe, effective and well tolerated herbal drug to treat these disorders was felt.

Muvease is a multi herbal formulation containing *Boswellia serrata*, *Commiphora wightii*, *Moringa pterygosperma* and *Vitex negundo*. *Boswellia* is a well known analgesic and anti-inflammatory<sup>2</sup>. Animal studies have found that *Boswellia* decreased polymorphonuclear leucocyte infiltration and migration, decreased primary antibody synthesis and caused almost total inhibition of

classical complement pathway<sup>3</sup>. *Boswellia* has marked sedative and anti-inflammatory activity in animal models.

*Boswellia* blocks the synthesis of pro-inflammatory 5-lipoxygenase products including 5-hydroxyeicostetraenoic acid (5-HETE) and Leukotriene B4 (LTB4). *Boswellia* is a specific inhibitor of 5-lipoxygenase<sup>3</sup>. Many non steroidal anti inflammatory analgesics (NSAID) can cause disruption of glycosaminoglycan synthesis accelerating the articular damage in arthritic condition. A recent in-vivo study<sup>4</sup> examined *Boswellia* extract and ketoprofen for their effect on glycosaminoglycan metabolism. *Boswellia* significantly reduced the degeneration of this compound as compared to control, whereas ketoprofen caused a decrease in total tissue content of this compound. *Guggulu* has been found to be a potent anti-inflammatory agent.

This study was conducted to evaluate the efficacy & safety of Muvease in the management of joint pain, back pain and lumbago.

## MATERIAL AND METHODS

Thirty patients of either sex in the age group of 55- 70 years with clinical features of arthritis and low back pain were selected for this study. Patients were selected on the basis of inclusion and exclusion criteria. Those with the clinico-radiological evidence of fracture, dislocation, tuberculosis, tumour spine, etc. were excluded from the study. Low back pain due to prolapsed intervertebral disc, lordoscoliosis, other related diseases were excluded from the trial. This was an interventional study; patients treated with placebo were taken as control. Ethical clearance of the study was taken.

Tablet Muvease (Muvease tablet composition: Each tablet contains: *Boswellia serrata*-150 mg, *Commiphora wightii*-100 mg, *Curcuma longa*-100 mg, *Moringa pterygosperma*-50 mg, *Vitex negundo*-50 mg), was used in the interventional group and identical looking tablets of placebo (Each tablet contains:450mg Glucose) was used in the control group.

The patients were randomly divided into two groups (Table 1). Group A patients received Muvease at a dose of 1 tablet twice daily, and Group B received an identical looking placebo at the same dose. All symptoms along with severity and duration were recorded prior to the drug treatment. Routine blood chemistry and radiography were done before and at the end of the treatment period.

Total duration of the study was 24 weeks. The study was conducted in the following ways-

- One week abstinence from any drugs used for pain and backache
- Eight weeks interventional study with using Tablet Muvease for Group A and placebo for Group B, then six weeks wash out period
- Eight weeks interventional study with using Tablet Muvease for Group B and placebo for Group A
- Last one week was observed for any adverse drug reactions.

After the first intervention of Muvease in Group A & placebo in Group B, washout was given to all study subjects in both the groups and then groups were crossed over to receive the opposite intervention for next 8 weeks. Patients were followed up every week for a period of 8 weeks. At the end of 8 weeks symptomatic assessment was carried out to determine the clinical efficacy of the trial drug. Parameters were evaluated for efficacy of the drugs was- number of joints involved, gradation of pain, swelling of the joint, joint mobility and walking distance (Table 2)

## RESULTS

The result demonstrated the efficacy of Muvease in the treatment of joint and back pains. The patients in the Muvease treated groups responded better as compared to

placebo. The results of Muvease treated groups were significantly better as compared to the placebo treated groups. There was significant improvement in pain, swelling and flexibility of joints. Patients could walk longer distance without any difficulty. The symptom score was  $20.2 \pm 6.2$  before the treatment which was reduced to  $4.3 \pm 0.9$  in the Muvease treated group (Table 3), while placebo showed some mild reduction in group B patients. When group B patients were treated with Muvease, there was also reduction in scoring (Table 4). But there was increase in symptom scoring of the placebo treated group B patients at the end of 8 weeks of treatment.

## DISCUSSION

Joint and Back Pain are one of the most common medical problems faced by the world today<sup>5</sup>. The causes vary from lifestyle disorders to genetic predisposition. Although, most of the back pains are not life threatening, so neglected by most of the patients, but their consequences can be extremely distressing, affecting the patient's everyday life and overall health. So, diagnosis of pain and its immediate treatment is very important.

The Muvease contains standardized extracts of *Boswellia*, *Curcuma longa*, *Commiphora wightii* and *Moringa pterygosperma*. All the plants present in Muvease have significant anti-inflammatory activity<sup>6,7</sup>. In the above clinical study, the patients in group A responded well to treatment (Table 3). Group B patients showed improvement to a lesser extent to Muvease (Table 4). There was reduction of most the symptoms, patients could walk longer in this group treated with interventional drug as compared to the group treated with placebo. None of the patients complained of any side effects throughout the study period.

While there are many non steroidal anti inflammatory analgesics (NSAID) available with potent anti-inflammatory properties, but most of them produce serious side effects like gastric irritation, nausea, vomiting and sometimes long term administration of these drug could lead to hepatic and renal failure<sup>8,9</sup> etc. As a result most of the patients discontinue the treatment and the disease aggravated. Muvease<sup>10</sup>, a multi herbal product is safe and effective and could be an ideal drug for the treatment of joint and back pain. This present study again confirms the efficacy of Muvease, a herbal preparation in the treatment of pain and backache.

## CONCLUSION

Limitation of treatment regimen with modern drugs was well known. Ayurvedic and herbal drugs are time tested in the community for even thousand years, and of good efficacy and safety. In modern days, uses of these drugs are increasing tremendously. Muvease is one such drug.

Though the present study confirms the efficacy and safety of this drug in pain and backache, a clinical trial with large number of study population with control of drugs used commonly will be the future plan. Only through comprehensive approach of useful drugs of different scientific knowledge diseases like joint pain and backache can be solved easily.

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**Table 1: Distribution of patients in both the groups**

Patients	Group A	Group B
Male	7	9
Female	8	6

**Table 2: Criteria for evaluation of patients as per severity of symptoms**

<b>Number of joints involved</b>	One	1
	Two	2
	Three or more	3
<b>Pain</b>	Mild	1
	Moderate	2
	Severe	3
<b>Swelling</b>	Mild	1
	Moderate	2
	Severe	3
<b>Joint Mobility and walking distance</b>	Mild	3
	Moderate	2
	Good	1

**Table 3: Improvement of symptom scoring in Muvease treated patients of group A in comparison with placebo treated patients of group B.**

Treatment group	Before treatment	After treatment
<b>Muvease treated patients(Group A)</b>	20.2±6.2	4.3±0.9
<b>Placebo treated patients (Group B)</b>	21.3±±5.9	17.5±2.4

**Table 4: Improvement of symptom scoring in Muvease treated patients of group B in comparison with placebo treated patients of group A**

Treatment group	Before treatment	After treatment
<b>Muvease treated patients (Group B)</b>	21.4±8.2	15.21±7.6
<b>Placebo treated patients (Group A)</b>	19.7±1.6	20.2±5.2

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