

Evaluation of clinical efficacy and safety of Herbal liniment (Rumalaya liniment) in orthopedic patients

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Abstract

This study was planned to evaluate the efficacy and safety of Herbal liniment in orthopedic disorders. One hundred patients of either sex in the age group of 10 to 63 years were enrolled in the study after they fulfilled the inclusion and exclusion criteria. Patients applied Herbal liniment over the affected area, twice daily with gentle rubbing for a period of one month. Statistical analysis of changes in various parameters from baseline values was evaluated by Wilcoxon Signed Rank test. This study indicated that there was a significant reduction in pain, joint tenderness, joint swelling, mobility restriction and early morning joint stiffness. In patients with periarthritis shoulder joint, osteoarthritis knee joints, and nonspecific arthritis, there was moderate reduction of pain. There were no adverse events reported or observed during the entire period.

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INTRODUCTION

With the high speed of transportations, mechanization, industrialization and sports activities, the incidence of trauma including trivial injury and certain orthopedic joint problems are constantly increasing in the society. Simple movements such as walking, bending, and turning require the use of hip and knee joints. Normally, all parts of these joints work together and the joint moves easily and without pain. But when the joint becomes diseased or injured, the resulting pain can severely limit one's ability to move and work. The international association for the study of pain has defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". According to the World Health Organization (WHO), pain is the most common reason for which patients visit their physician (Katz, 2002). Pain can be divided into two basic categories, acute and chronic. A common definition of acute pain is "the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus associated with surgery, trauma and acute illness". Even brief intervals of acute pain can induce long-term neuronal remodeling and sensitization (plasticity), chronic pain, and lasting psychological distress (Daniel B. Carr, Leonidas C. Goudas, 1999).

Chronic pain refers to pain that persists after an injury, pain

related to a persistent or degenerative disease, and long-term pain from an unidentifiable cause. Chronic pain may be caused by the body's response to acute pain. One of the frustrating aspects of chronic pain is that the stimulus may be unknown. For example, the stimulus cannot be identified in as many as 85% of individuals suffering lower back pain.

The common causes of joint pain are osteoarthritis (OA), rheumatoid arthritis (RA), post-traumatic arthritis, and avascular necrosis. Joint pain can also be caused by deformity or direct injury to the joint. In some cases, joint pain is made worse by the fact that a person will avoid using a painful joint, weakening the muscles and making the joint even more difficult to move. To meet with these problems various methods of treatment including conservative and surgical are in practice. Conservatively, analgesics, muscle relaxant gel, and pain relieving liniments are some of the simplest external application methods for relieving pain. One of the most commonly prescribed types of drugs are the non-steroidal anti-inflammatory agents or NSAIDs, which has to be taken for long-term to reduce both the pain and swelling caused by arthritis. NSAIDs are among the most widely used medications, but the side effects of these drugs frequently include gastrointestinal (GI) ulceration, indigestion, burning, and bleeding (Wallace and Vong, 2008). A relatively new class of anti-inflammatory drugs called COX-2 inhibitors may provide significant benefits in the treatment of OA. COX-2 inhibitors were claimed to be devoid of ulcer-promoting effects; however, this promise has been

unfulfilled, and there are concerns about the cardiovascular safety of COX-2 inhibitors (Wallace and Vong, 2008; Vardeny and Solomon, 2008). In rare cases, serious stomach problems, such as bleeding, can occur without warning. NSAIDs and COX-2 inhibitors should not be taken by people who are allergic to aspirin (Bavbek et al., 2007; Palmer, 2005). Another type of medication prescribed to reduce severe pain and swelling are corticosteroids. Corticosteroid injections offer quick, effective pain relief. However, they can be used only few times a year because they weaken bone and cartilage (Silbermann, et al., 1981a; Silbermann, et al. 1981b; Silbermann, et al., 1979; Silbermann et al., 1977). Also, as corticosteroids can cause other potentially serious side effects (Benyamin et al., 2008; Kubota et al., 2008), their use must be monitored by a physician.

The term “complementary medicine” describes a range of preparations, including herbal medicines, homoeopathic remedies, essential oils and dietary supplements, which mainly sit outside conventional medicine. The use of complementary medicine is a popular healthcare approach in the UK, and there are signs that the use of such products is continuing to increase. Patients and the public use complementary medicines for health maintenance, for the treatment or prevention of minor ailments, and also for serious, chronic illnesses (Joanne Barnes, 2003a). Many complementary medicines, particularly herbal medicines, have a long history of traditional use (Joanne Barnes, 2003b). The use of herbs to treat illness has its roots in an ancient holistic healing tradition that originated in Asia more than 3,000 years ago. Largely discounted by 19th and 20th century practitioners of western medicine, healing practices incorporating herbal remedies, such as Traditional Chinese Medicine (TCM), Japanese Kampo, and Indian Ayurveda, are rapidly gaining acceptance in the west as we enter the 21st century. Herbal medicines are complex mixtures of minimally processed medicinal plants (e.g., plant parts that are boiled to make a tea). In conjunction with other components of traditional healing philosophies, such as acupuncture or massage, herbal medicines are used to treat a large range of symptoms and ailments. Herbal drug treatment has been known for centuries as a part of traditional medicine. Nowadays, it is still considered a useful and natural way to treat several medical conditions, including mental disturbances. The most frequently treated mental conditions include mood disorders (mainly depression), anxiety disorders, somatoform disorders, age-related cognitive decline, and sometimes psychotic disorders

(Jarema, 2008).

Herbal liniment is a polyherbal formulation and it contains extracts of proven herbs like *Psoralea corylifolia* (Haraguchi et al, 2002), *Piper nigrum* (Chopra et al., 1996b), *Pinus longifolia* (Yoganarasimhan, 2000b; Damas et al., 1986; Deflandre et al., 1983), *Gaultheria fragrantissima* (Chopra et al., 1996a), *Sesamum indicum* (Yoganarasimhan, 2000c), *Cinnamomum camphora* (Chopra et al., 1996c), *Mentha arvensis* (Yoganarasimhan, 2000a; Galeotti et al., 2002; Thomas Fleming, 2000; Ichiyama et al., 2002; Dorman et al., 2003), and *Carum copticum* (Dashti-Rahmatabadi et al., 2007). This study was planned to evaluate the efficacy and safety of Herbal liniment in orthopedic disorders.

Application of Herbal liniment as a treatment modality has been evaluated in 100 patients attending the out-patient clinic of Department of Orthopedics, Olatpur Hospital at Bairoi, Cuttack, Orissa.

METHODOLOGY

AIM OF THE STUDY

The present study was aimed to evaluate the clinical efficacy and long-term safety of Herbal liniment (Rumalaya liniment) in orthopedic problems.

STUDY DESIGN

This study was an open clinical trial conducted in the Department of Orthopedics, Olatpur Hospital at Bairoi, Cuttack, Orissa during April 2007 to July 2007.

INCLUSION CRITERIA

One hundred patients of either sex in the age group of 10-63 years were enrolled in the study. A written informed consent was obtained from all these patients. All included patients had clinical symptoms of either of the following:

- Sprain of knee, ankle, elbow, wrist, and metacarpophalangeal and interphalangeal joints of fingers.
- Muscle strain
- Periarthritis shoulder joint (frozen shoulder)
- Osteoarthritis knee joints
- Injury to joints without fracture
- Nonspecific arthritis
- Tennis elbow.

EXCLUSION CRITERIA

Patients with established hypertension, renal, hepatic or cardiac failure, on long-term steroid treatment, and patients suffering from autoimmune disorder, spastic condition or genetic disorders were excluded from the study.

STUDY PROCEDURES

The trial was conducted in 100 patients with a mean age of 41.1 ± 13.1 years with 56 male and 44 female patients. Duration of illness ranged between 2 days to 7 years. Out of 54 male patients, 16 were smokers and 7 were alcoholics. The nature of orthopedic injury was due to various factors like fall or accident, traumatic, osteoarthritis, sprain, peri-arthritis, frozen shoulder, jerk, tennis elbow, etc. The diagnosis of the concerned disease was confirmed by clinical examination. The study duration was one month. The evaluation parameters included symptomatic relief in pain intensity, swelling, tenderness, and movement. Score for pain intensity, swelling, and tenderness was done using 0-3 scale where 0: no pain, 1: mild, 2: moderate, and 3: severe. In case of movement the scoring was 0: no restriction, 1: mild restriction, 2: moderate restriction, and 3: severe restriction. All patients were advised to apply Herbal liniment over the affected area, twice daily for a period of one month.

FOLLOW-UP AND ASSESSMENT

The patients were followed-up at fortnightly interval during which evaluation of the clinical parameters was recorded. A complete clinical and orthopedic evaluation was carried out at the end of the study.

PRIMARY AND SECONDARY OUTCOME MEASURES

The predefined primary outcome measures for efficacy were relief of pain, swelling and tenderness. Secondary outcome measures were short and long-term and patient compliance to therapy.

STATISTICAL ANALYSIS

Statistical analysis was carried out using Wilcoxon Signed Rank test. The scores for symptomatic relief of various parameters were expressed as mean \pm SD. The minimum level of significance was fixed at $p < 0.05$. Statistical analysis was carried out using GraphPad Prism software, Version 4.01.

RESULTS

A total of 100 patients were enrolled and completed the

study. They were in the age group ranging between 10-63 years.

The results and the statistical significance for various parameters are shown in Tables 1 and 2.

Figure 1

Table 1: Effect of Herbal liniment on clinical parameters

Symptomatic relief	Mean score		p value
	Before	After	
Pain intensity	2.35 ± 0.54	1.05 ± 0.58	$p < 0.0001$
Swelling	2.15 ± 0.65	1.38 ± 0.64	$p < 0.0001$
Tenderness	2.34 ± 0.56	1.63 ± 0.66	$p < 0.0001$
Movement	2.45 ± 0.69	1.51 ± 0.73	$p < 0.0001$

Figure 2

Table 2: Effect of Herbal liniment on incidence (%) of symptom score before and after treatment

Symptomatic relief	Before treatment (% incidence)				After treatment (% incidence)			
	None	Mild	Moderate	Severe	None	Mild	Moderate	Severe
Pain intensity	0	3.3	58.7	38.0	14.13	66.3	19.6	0
Swelling	3.3	4.4	66.3	26.1	8.7	44.6	46.7	0
Tenderness	0	4.4	57.6	38.0	9.8	17.4	72.8	0
Movement	2.2	4.4	40.2	53.3	14.1	20.7	65.2	0

The patients with sprain, muscle sprain, injury to joints, and tennis elbow cases experienced substantial relief from pain. Swelling and tenderness also reduced considerably. Patients with osteoarthritis, nonspecific arthritis, and peri-arthritis shoulder joint had temporary relief from pain and required additional therapy.

Those patients who had received additional sample of liniment had considerable relief from pain; in fact, many of them were comfortable after using two bottles of liniment indicating the long-term safety and efficacy of Herbal liniment.

There was good compliance to the treatment and no adverse events were reported or observed in the study patients during the entire study period. None of the patients withdrew from the study.

ADVERSE EVENTS

Most patients under trial were satisfied with the use of Herbal liniment. Two patients had more pain and swelling after massaging the liniment, which was corrected within 2-3 days of continued application of the liniment.

DISCUSSION

Pain is an unpleasant feeling that is conveyed to the brain by sensory neurons. The discomfort signals actual or potential injury to the body. However, pain is more than a sensation or the physical awareness of pain; it also includes perception, the subjective interpretation of the discomfort. Perception gives information on the pain's location, intensity, and something about its nature. The various conscious and unconscious responses to both sensation and perception, including the emotional response, add further definition to the overall concept of pain. A survey conducted in approximately 26,000 patients has indicated that one adult in five suffers from chronic pain, and out of these 21.5% have experienced pain lasting for longer than 6 months. Pain is the third leading reason for absence from work in the United States, where the problem of chronic pain translates into an annual expenditure of at least \$50 billion (Katz, 2002).

In general, musculoskeletal pain, often in the form of arthritis, non-articular rheumatism, peripheral neuropathies and low back disorders, represents the most common cause of chronic non-malignant pain (CNMP). Exposure to low social support, low social anchorage or low social participation significantly increases the odds of a high level of pain. Most patients do not attribute chronic musculoskeletal pain to injury, but those who do report significantly higher levels of emotional distress (Katz, 2002).

For the last few decades, orthopedic treatment modalities like analgesics and external application of muscle relaxant ointments, gels and liniments have been used to relieve pain of minor injury and certain orthopedic problems. Use of analgesic, either oral or parenteral, has many associated complications like gastritis, abdominal distension, constipation, and loose motions. Moreover, analgesics cannot be used for prolonged period considering the risk of above complications.

Therefore, the ideal method for relieving pain in minor trivial injury to muscles and ligaments is a simple method of external application of gel or liniment. There is no time limitation regarding the duration of treatment by external applications. This can be used for prolonged period. In this study, it was observed that at the end of the study there was much relief of pain from muscle sprain, injury to joints, and tennis elbow. Swelling and tenderness also reduced considerably. These findings suggest the synergistic action of the ingredients of Herbal liniment.

Mentha arvensis provides potent analgesic action, and thus, is used externally in rheumatism, neuralgia, headaches, etc, (Yoganarasimhan, 2000a; Galeotti et al., 2002). *Gaultheria fragrantissima* contains 98% methyl salicylate, a known analgesic. It is applied externally in rheumatism, sciatica, and neuralgia due to its analgesic properties (Chopra et al., 1996a). *Piper nigrum* (Chopra et al., 1996b), *Sesamum indicum* (Yoganarasimhan, 2000c), and *Carum copticum* (Dashti-Rahmatabadi et al., 2007), are well-known for their analgesic activity. *Mentha arvensis* (Thomas Fleming, 2000) and *Pinus longifolia* (Yoganarasimhan, 2000b; Damas et al., 1986; Deflandre et al., 1983), have potent anti-inflammatory action that penetrates superficial inflamed tissues, increases blood flow to the affected area, and inhibits the release of pro-inflammatory chemomediators. As a result, it reduces swelling associated with inflammatory conditions, shortens recovery time, and increases mobility of the joints. *Mentha arvensis* (Ichiyama et al., 2002), *Pinus longifolia* (Damas et al., 1986), and *Cinnamomum camphora* (Chopra et al., 1996c) are used as rubefacients for external application. They produce redness of the skin by causing dilation of the capillaries and increasing blood circulation, thus distracting from the deep-seated pain and providing relief in various rheumatic conditions such as lumbago, arthritis, and neuralgia. *Psoralea corylifolia* (haraguchi et al., 2002) and *Mentha arvensis* (Dorman et al., 2003) are potent antioxidants, and act synergistically with the anti-inflammatory property of Herbal liniment.

CONCLUSION

A total of 100 patients with various types of muscle injury and some orthopedics diseases having pain, swelling, and muscle spasms were treated by Herbal liniment (*Rumalaya liniment*). The experience after using Herbal liniment has confirmed that the main clinical benefits are relief from pain, and reduction in swelling and muscle spasms. However, in chronic diseases like osteoarthritis and frozen shoulder, the symptoms are not relieved completely. The liniment was found most effective in ligament or muscle injury like sprain, strain, muscle spasm, tennis elbow, and injury to joint. The liniment was found less effective in osteoarthritis of joints, peri-arthritis of shoulder, etc. Oral or parenteral analgesic should be given for effective treatment and for synergetic action to relieve pain. No adverse reactions were reported by any of the patients.

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