EVALUATION OF SAFETY AND EFFICACY OF RUMAFLAM TABLETS & RUMAFLAM CREAM IN THE TREATMENT OF MUSCULOSKELETAL DISORDERS

Dr. K.H.H.V.S.S Narasimha Murthy¹ and Dr.S.K.Mitra²*

¹Associate Professor, Faculty of Ayurveda, Institute of Medical Sciences, B.H.U, Varanasi,  
²Head of Research and Development, Matxin Labs, Bangalore.

ABSTRACT

Musculoskeletal disorders occur due to excessive exertion and includes sprain, strain and damage to the body parts. This is one of the commonest reasons for reduced productivity at work due to sick leave and absenteeism. Therefore a need was felt to have a product that would help improve musculoskeletal disorders affecting bones, muscles, joints and cartilages. In the present clinical trial Rumaflam tablets and ointment, the two safe herbal products were found to be effective in the treatment of MSD. There were 20 males and 10 female patients in the trial and their age group varied between 35-68 years. They were asked to take Rumaflam tablets at the dose of 1 tablet twice daily and Rumaflam cream to be applied at the affected part twice daily for 8 weeks. There were 16 patients suffering from osteoarthritis, 3 patients had Arthritis of foot, 6 patients had low back pain, 5 patients had cervical spondylosis. At the end of the study 75% patients had complete relief, 24% patients had partial relief and only 1% patients did not respond well to the treatment. The product was found to be safe and no major side effect was reported during the trial.

KEYWORDS: Musculoskeletal disorders, Pain, Osteoarthritis, Sprains, Swelling, joints, Spine, Spondylosis.

INTRODUCTION

Musculoskeletal disorders are injuries or dysfunctions affecting bones, muscles tenons, ligaments, joints, cartilages and vertibral discs. MSD or the musculoskeletal disorders
represent one of the most common and important occupational health problems in working populations, being responsible for a substantial impact on quality of life and incurring a major economic burden in compensation costs and lost wages.\textsuperscript{[1,2]} They decrease productivity at work due to sick leave, absenteeism and early retirement\textsuperscript{[3,4,5]}, and are also costly in terms of treatment and individual suffering.\textsuperscript{[6]} Moreover, this disorder represent a common health-related reason for discontinuing work and for seeking health care. In many occupations, they include a wide range of inflammatory and degenerative conditions affecting the muscles, ligaments, tendons, nerves, bones and joints; and can occur from a single or cumulative trauma.\textsuperscript{[7,8]} MSD include sprains, strains, tears and connective tissue injuries.\textsuperscript{[1,2]} In the US alone, more than 600,000 workers have.

MSD resulting in days away from work each year.\textsuperscript{[9]} It was estimated that the cost of MSD in the US, in 1995, was approximately $215 billion.\textsuperscript{[10]} MSD may occur as a result of overexertion, cumulative load, contact of body parts with equipment or furniture, or as a result of falls. Activity demands can cause or aggravate MSD.\textsuperscript{[11,12]} Maintenance of static exertion for prolonged time compresses veins and capillaries inside the muscles, causing micro-lesions due to the absence of oxygenation and nutrition. All of these factors can cause imbalance, fatigue, discomfort and pain due to disruption of tissues.\textsuperscript{[13]} The risk of work-related musculoskeletal disorders is high among various healthcare professionals.\textsuperscript{[14,15]} Musculoskeletal disorders can lead to increased health care use\textsuperscript{[17]}, reduced work productivity, and lower levels of health-related quality of life.\textsuperscript{[16]} Previous studies indicated that prevalence of musculoskeletal complaints, particularly low back and neck-shoulder, were high in nurses and X-ray technologists.\textsuperscript{[18,19]} A study conducted on 1,600 employees in six hospitals in Turkey reported that nurses had the highest prevalence of low back pain. Age, female sex, smoking, occupation, perceived work stress, and heavy lifting were significant and independent risk factors for low back pain.\textsuperscript{[20]} Another cross-sectional study conducted on dentists, laboratory technicians, nurses, physicians, and physiotherapists in a tertiary care hospital in India revealed that working in the same position for long periods, working in awkward positions, and handling a large number of patients were commonly reported risk factors for work-related musculoskeletal disorders.\textsuperscript{[21]}

High prevalence for back pain, neck, shoulder, and hand-wrist region complaints among dental professionals had also been reported.\textsuperscript{[22,23]} Results from a mail survey of 3,297 randomly selected physical and occupational therapists living in Wisconsin reported that their
annual incidence rate of work-related injuries were comparable to that among workers employed in heavy manufacturing.[24] A systematic review of 65 studies revealed that a high prevalence of upper limb musculoskeletal disorders in dental professionals, nurses, and laboratory technicians but not in physiotherapists.[25] Although a number of studies have previously examined the risk of musculoskeletal disorders among healthcare workers, many of them used a cross-sectional study design and were based on self-reporting and recall of injuries. The information collected is prone to recall bias. Osteoarthritis is one of the most devastating type of MSD affect people around the world. Although the usual population associated the condition is elderly who are mostly inactive, athletes and younger people are also affected. Obesity seems to be the most common cause of OA in young individuals.

Treatment of MSD involves physiotherapy, reducing body weight and lifestyle adjustment. Drugs that are commonly prescribed for MSD includes NSAIDS like Ibuprofen group, steroids and other anti-inflammatory drugs. But most of these drugs cannot be given for a long period of time because of many side effects and long term toxicities.[26] Many herbs are advised in the ancient system of Ayurveda for the treatment of MSDs and the most important herbs are Commiphora wightii, Rubia cordifolia, Terminalia chebula and Moringa pterygosperma. Commiphora wightii causes down-regulation of the expression of inflammatory mediators, including interleukins, transcription factors and cytokines, and hyaluronidase and collagenase enzymes.[27,28,29,30] Rubia cordifolia has been found to be effective in reducing pain and inflammation.[31] Moringa inhibits inflammation and pain[32] and Studies have shown that leaf extract poses both peripheral and central analgesic activity. The possible mechanism behind the analgesic activity of extract is through the antagonism of NMDA receptors.[33] Rumaflam Cream and Tablet contains pure extract of these herbs and was found to be effective in the treatment of various MSDs, therefore a clinical trial was planned to evaluate the safety and efficacy of Rumaflam in the treatment of MSDs.

MATERIALS AND METHODS
Thirty patients suffering from various MSDs were selected for this study. Patients were selected based on inclusion and exclusion criteria. Those patients suffering from any terminal illnesses like cancer, renal, cardiac and hepatic failure, hypertension, bronchial asthma, on steroids and any other modern medications, pregnant and lactating mothers were excluded from the trial. Patients were asked to withdraw any NSAIDs taken at least one week before participating in the clinical trial. There were 20 males and 10 female patients in the trial and
their age group varied between 35-68 years (Table-1). Informed consent was taken from each patient and they were briefed about the nature of the drug, the ingredients present and dosage to be taken. Each patient was given one bottle of Rumaflam tablet containing 60 tablets and one tube of Rumaflam Cream. They were asked to take Rumaflam tablets at the dose of 1 tablet twice daily after meals and to apply Rumaflam Cream over the affected area twice daily for 8 weeks. They were told not to apply Rumaflam Cream over any cuts or raw wounds. There were 16 patients suffering from osteoarthritis, 3 patients had Arthritis of foot, 6 patients had low back pain, 5 patients had cervical spondylosis. Total 16 patients had involvement of knee joint, 6 patients had involvement of spine, 5 patients had involvement of neck and 3 patients had involvement of foot joint(Table-2).

RESULTS AND DISCUSSION
Musculoskeletal Disorders are defined as a group of disorders that affect the musculoskeletal system including the nerves, tendons, muscles, and joints and supporting structures such as inter-vertebral discs etc. Musculoskeletal Disorders could result in pain, injury, illness, poor quality of life and reduced productivity. They are the most common cause of severe long term pain and disability, and are currently reported to be affecting hundreds of millions of people around the world. In the present study 30 patients were participated in the trial. None of them were suffering from any terminal disorders of major organs. They were asked to stop taking any NSAID any other allopathic drugs at least a week before the start of the treatment. There were significant response to treatment by Rumaflam tablets and Cream. The number of joints involved came down from 25 to 2, Pain and Swelling of the joints also reduced. Joint malfunction and secondary muscle weakness also improved within 8 weeks of treatment. Most important finding was a sense of wellness was observed in all the patients and there was no dropout in the trial. None of the patients complained of any gastric irritation, vomiting which are normally seen with any allopathic drugs. Both Rumaflam tablets and Cream were found to be safe except some patients complained of mild irritation at the site of application of Rumaflam Cream but they continued the treatment. Rumaflam tablets and Cream were found to be safe and effective. Rumaflam tablets contain oleoresins from Commiphora wightii which are potent anti-inflammatory.[34,35] Moreover other ingredients like Moringa pterygosperma and Terminalia chebula also showed significant anti-inflammatory response. They are safe and till now no side effects have been reported with these ingredients even after long-term administration. Although many modern drugs are available for the treatment of MSD but most of them have severe side effects and cannot be continued for a
longer period of time. Herbal extracts present in Rumaflam tablets and Cream are safe for long time use and none of the patients participated in the trial complained of any gastric irritation.

Table-1: Showing Distribution of Patients who participated in the trial.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>AGE GROUP OF PATIENTS</th>
<th>NUMBER OF PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>40-45 YEARS</td>
<td>10</td>
</tr>
<tr>
<td>2.</td>
<td>50-60 YEARS</td>
<td>16</td>
</tr>
<tr>
<td>3.</td>
<td>61-65 YEARS</td>
<td>4</td>
</tr>
</tbody>
</table>

Table-2: Showing Number of Patients by Involvement of Joints

<table>
<thead>
<tr>
<th>S.NO</th>
<th>NAME OF THE JOINT INVOLVED</th>
<th>NUMBER OF PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>KNEE JOINT</td>
<td>16</td>
</tr>
<tr>
<td>2.</td>
<td>SPINE</td>
<td>6</td>
</tr>
<tr>
<td>3.</td>
<td>NECK</td>
<td>5</td>
</tr>
<tr>
<td>4.</td>
<td>FOOT</td>
<td>3</td>
</tr>
</tbody>
</table>

Table-3: Total Number of Patients Showing Improvement after Treatment with Rumaflam Tablets and Rumaflam Cream.

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Symptoms</th>
<th>Number of Patients Suffering before treatment</th>
<th>Number of Patients suffering after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>More than 3 No. of Joints involved</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>2.</td>
<td>Pain</td>
<td>30</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>Swelling</td>
<td>21</td>
<td>4</td>
</tr>
<tr>
<td>4.</td>
<td>Joint Malfunction</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>5.</td>
<td>Secondary Muscle Weakness</td>
<td>23</td>
<td>8</td>
</tr>
<tr>
<td>6.</td>
<td>Difficulty in Climbing Steps</td>
<td>18</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure-1: Showing Improvement of Symptoms in Patients post Rumaflam tablets and Cream Treatment.
Figure-2: Showing overall Response of Rumaflam Tablets and Cream in Patients suffering from MSD

REFERENCE


9. Musculoskeletal disorders (MSDs) and workplace factors. A critical review of epidemiologic evidence for work-related musculoskeletal disorders of the neck, upper extremity, and low back.


32. Evaluation of Hydroethanolic extract of Moringa leaves for Analgesic activity. Oyedepo T.A. & Babarinde S.O. Department of Basic Sciences Adeleke University Ede, OsunState, Nigeria , Sodamade A Department of Chemistry Emmanuel Alayande College of Education Oyo, Oyo State, Nigeria.