Clinical evaluation of Rumalaya forte in osteoarthrosis

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INTRODUCTION
Arthritis is one of the most common medical problem affecting joints of the knees, hips, spine and hands. The etiology of osteoarthrosis is not clear and differs according to the age, sex, genetic factors and obesity. Repeated trauma is known to be associated with a higher incidence of osteoarthrosis.

The common symptoms of osteoarthrosis include pain in the joint during or after use, discomfort in the joint before or during a change in the weather, swelling and stiffness in the joint particularly after using it and bony lumps on the middle or distal end of the joints of the fingers or base of the thumb. There may be associated loss of flexibility of a joint. The acute pain of early osteoarthrosis often tends to fade within a year of its appearance, but may revert back with overuse of the affected joint. No single test can diagnose osteoarthrosis as diagnosis is based on a combination of clinical history, physical examination, radiological examination of the joint and if required aspiration of synovial fluid for confirmatory diagnosis.

Treatment options available for osteoarthrosis include topical systemic pain relievers, NSAID’s, COX-II inhibitors and intra-articular injections of corticosteroids or hyaluronic acid. NSAIDs like aspirin, ibuprofen, ketoprofen and naproxen sodium are widely used pain relievers, but are not effective in preventing the progress of the disease. All NSAIDs have the risk of side effects that increases when used at high doses for long-term treatment.

Intra-articular injections with a corticosteroid or hyaluronic acid offer pain relief for 4–6 months but are associated with increased chances of intra-articular infections.

Rumalaya forte is a polyherbal formulation containing extracts of Boswellia serrata, Alpinia galanga, Commiphora wightii, Glycyrrhiza glabra, Tinospora cordifolia and Tribulus terrestris. These ingredients have shown to have anti-inflammatory, anti-arthritis, immunomodulatory, muscle relaxant and analgesic activities.

Hence, the present study was conducted to compare the efficacy of Rumalaya forte in terms of relieving pain, inflammation and improving free mobility of the joint and safety in patients suffering with osteoarthrosis.

METHODOLOGY
Study population
A total of 57 patients attending the orthopedics outpatient department of Grant Medical College and Sir J.J. Group of Hospitals, Mumbai, diagnosed with osteoarthrosis of the knee were enrolled after obtaining informed written consent.
Inclusion criteria
1. Ambulatory patients of both sexes in the age group of 30-65 years.
2. ARA functional Class I, II, or III.
3. Clinical diagnosis of primary OA of the knee (tibio-femoral joint) based on clinical and radiographic criteria i.e. patients at the time of enrolment in this study had moderate to severe knee pain with or without morning stiffness of <30 minutes duration and radiographic osteophytes with one or more of the following:
   a. Marginal lipping
   b. Narrowing of joint space
   c. Sharpened articular margin
   d. Sclerosis i.e. damaged thickened or eburnated subchondral bone
   e. Bone cysts
4. Clinical symptoms of OA for at least 6 months prior to study entry.

Study design
This was a double blind, placebo-controlled study where the observer and subjects were unaware of the study medication. The study was approved by the institutional ethics review committee.

All patients underwent complete general examination to rule out any gross abnormalities and were evaluated clinically and radiologically to assess the joints involved.

Subjects were divided into two groups receiving one of the following treatments:
1. Study medication: Received 1 tablet of Rumalaya forte twice daily orally for a period of 3 months.
2. Control medication: Received 1 tablet of placebo twice daily orally for a period of 3 months.

Follow-up and assessment
All subjects were evaluated when enrolled and, thereafter every month for a period of 3 months.

Efficacy was assessed by symptomatic evaluation of:
1. Joint swelling assessed on a four point rating score
2. Pain on a 0-100 Visual analogue scale
3. Joint malfunction
4. Muscle weakness
5. Difficulty in climbing steps

Safety was assessed by incidence of adverse effects and laboratory evaluation of complete hemogram with clinical biochemistry, including liver and kidney function tests.

The laboratory evaluation was carried out at enrolment and after 3 months of drug treatment.

Statistical analysis
Two groups were compared for baseline comparability of different parameters by unpaired ‘t’-test.

Changes in various parameters from baseline values after 1st, 2nd and 3rd month were evaluated by paired ‘t’-test for statistical significance.
The reduction in pain scores and swelling scores were evaluated for difference between the two treatment groups for statistical significance by unpaired ‘t’-test.

**RESULTS**
All the enrolled patients completed the study as per the study protocol. The two groups were similar with regard to the demographic data and baseline parameters including pain score.

Pain scores significantly reduced in the study group at the end of 1\(^{st}\), 2\(^{nd}\) and 3\(^{rd}\) month (Table 1). Pain scores reduced from 73.33 ± 18.25 to 56.19 ± 16.57 at the end of 1\(^{st}\) month in the control group, which was significant. At the end of 2\(^{nd}\) and 3\(^{rd}\) month the pain scores increased to 60.00 ± 16.12 and 79.04 ± 18.41 respectively in the control group (Table 1).

Swelling scores reduced in the study group at the end of 1\(^{st}\), 2\(^{nd}\) and 3\(^{rd}\) month, the reduction being significant only at 2\(^{nd}\) and 3\(^{rd}\) month period ($p<0.05$). Swelling scores reduced at the end of 1\(^{st}\) month in the control group, which was not significant statistically. At the end of 2\(^{nd}\) and 3\(^{rd}\) month the swelling scores increased to 1.09 ± 0.76 and 1.14 ± 0.79 respectively in the control group, which is not significant (Table 2).

Joint malfunction was present in 13 patients in the control group at enrolment and improvement was seen only in 1 patient at the end of 3 months.

In the study group, joint malfunction was present in 28 patients at enrolment. After 1\(^{st}\) month 3 patients had improved joint malfunction whereas at the end of 2\(^{nd}\) and 3\(^{rd}\) month improvement was seen in 13 and 23 patients respectively in the study group.

Muscle weakness was present in 2 patients in the control group at enrolment and there was an improvement in 1 patient at the end of 3\(^{rd}\) month.

In the study group, muscle weakness was present in 4 patients at enrolment out of which 3 patients had improvement in muscle weakness at the end of therapy.

At enrolment, 17 patients in control group had difficulty in climbing stairs. Improvement was seen in only 4 patients at the end of therapy.

In the study group, 35 patients in the study group had difficulty in climbing stairs. Improvement was seen in 6 and 29 patients at the end of 1\(^{st}\) and 2\(^{nd}\) month respectively. All the patients having difficulty in climbing stairs at enrollment had no difficulty in climbing stairs after 3 months of therapy in the study group.

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**Table 1: Pain scores on VAS in the two treatment groups (Mean ± SD)**

<table>
<thead>
<tr>
<th></th>
<th>Study group (n=36)</th>
<th>Control group (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>75.13 ± 19.02</td>
<td>73.33 ± 18.25*</td>
</tr>
<tr>
<td>After 1 month</td>
<td>51.25 ± 16.70$^a$</td>
<td>56.19 ± 16.57$^a$</td>
</tr>
<tr>
<td>After 2 month</td>
<td>35.27 ± 12.64$^a$</td>
<td>60.00 ± 16.12$^a$</td>
</tr>
<tr>
<td>After 3 month</td>
<td>15.69 ± 10.89$^a$</td>
<td>79.04 ± 18.41$^a$</td>
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* $p>0.05$ compared with study group; $^a$p$<0.05$ compared with baseline value.

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**Table 2: Swelling scores in the two treatment groups (All values in Mean ± SD)**

<table>
<thead>
<tr>
<th></th>
<th>Study group (n=36)</th>
<th>Control group (n=21)</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>1.05 ± 0.47</td>
<td>1.04 ± 0.38*</td>
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<tr>
<td>After 1 month</td>
<td>0.97 ± 0.50</td>
<td>1.00 ± 0.54</td>
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<tr>
<td>After 2 month</td>
<td>0.33 ± 0.58$^a$</td>
<td>1.09 ± 0.76</td>
</tr>
<tr>
<td>After 3 month</td>
<td>0.13 ± 0.42$^a$</td>
<td>1.14 ± 0.79</td>
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* $p>0.05$ compared with study group; $^a$p$<0.05$ compared with baseline value.
All the patients had radiologically evident signs of osteoarthrosis in the form of sub-chondral sclerosis.

At end of the study period, no radiological deteriorations occurred in the study group, 2 patients had newly developed osteophytes, 1 patient developed subchondral cyst and 1 patient had chondral collapse in the control group.

All laboratory parameters by and large remained unaltered in both the treatment groups.

None of the patients in any of the treatment groups reported any serious adverse effects during the study period. Eighteen (85.71%) patients in the control group and 19 (52.77%) in the study group reported mild to moderate abdominal discomfort after starting medication. Drug discontinuation was not required in any of the patients and abdominal discomfort subsided gradually in all the patients after 1 week.

**DISCUSSION**

Rumalaya forte is a polyherbal formulation containing extracts of *Boswellia serrata*, *Alpinia galanga*, *Commiphora wightii*, *Glycyrrhiza glabra*, *Tinospora cordifolia* and *Tribulus terrestris*, which are shown to have anti-inflammatory, anti-arthritis, immunomodulatory, muscle relaxant and analgesic activities.

The primary constituent of Rumalaya forte is *Boswellia serrata*, which has been historically used in the treatment of osteoarthritis. It yields an exudative gum resin known as salai guggul. Although salai guggul has been used for centuries, newer preparations concentrated for the active components (boswellic acids) are giving better results. Boswellic acid extracts have demonstrated anti-arthritis effects in a variety of animal models. There are several mechanisms of action including inhibition of inflammatory mediators, prevention of decreased glycosaminoglycan synthesis, and improved blood supply to joint tissues\(^1,2\). Clinical studies using herbal formulas with *Boswellia* have yielded good results in both osteoarthritis and rheumatoid arthritis\(^3\). *Boswellia serrata* was found to possess marked anti-inflammatory and anti-arthritis activity against adjuvant arthritis in experimental animals and was free from toxicity or any other side effects. It was also shown to possess marked cholesterol and triglyceride lowering activity.

*Commiphora wightii* is known to possess significant anti-arthritis and anti-inflammatory activities. Experimental studies have shown that the crude aqueous extract of the oleo gum resin suppresses the secondary lesions in adjuvant arthritis very effectively without having any significant action on the primary phase. Side effects such as gastric ulceration, loss of weight and mortality were negligible in the animals treated with the extract as compared to those treated with betamethasone.

The water-soluble fraction of *Alpinia galanga* the alcoholic extract of the air-dried plant is reported to exhibit a significant anti-inflammatory activity in albino rats similar to that of \(\beta\)-methasone.

*Glycyrrhiza glabra* modulates the immune system and has shown remarkable immuno-stimulant properties. It has an antioxidant activity. It is a mild anti-inflammatory for arthritis and rheumatism\(^4\).
In the present study, Rumalaya forte has shown significant reduction in pain scores at the end of 3rd month. The earliest pain relief was observed in the 1st month. The reduction in pain scores was also seen in the control group after 1 month, which could be attributed to the placebo effect. After 2nd and 3rd month the pain scores significantly increased in the control group thus suggesting that placebo medication was not effective in controlling pain. Swelling scores also reduced in the study group at 1st, 2nd and 3rd month. Improvement in the joint malfunction, muscle weakness and difficulty in climbing stairs was significantly greater with Rumalaya forte at the end of 3 months therapy.

Patients on placebo treatment developed osteophytes, sub-chondral cysts and sub-chondral collapse over a period of time. These signs were not observed in patients receiving Rumalaya forte. Deterioration was not found in the study group suggesting that Rumalaya forte also retards the progressive degeneration of the osteoarthritic joints.

The study confirms the antiarthritic activity of Rumalaya forte, where *Boswellia serrata*, *Commiphora wightii* and *Glycyrrhiza glabra* act synergistically to reduce inflammation and pain. None of the patients on Rumalaya forte reported any serious adverse effects during the study period of 3 months. There was no alteration in the laboratory parameters in patients on Rumalaya forte.

**CONCLUSION**
Rumalaya forte shows significant improvement of symptoms like pain, swelling, joint malfunction and mobility in patients of osteoarthrosis and does not produce any serious side effects. However, since the patients of osteoarthrosis have frequent acute exacerbations of chronic osteoarthrosis at frequent intervals, it requires symptomatic treatment from time-time. Hence, the long-term studies may be conducted to evaluate the maintenance of prolonged remission of symptoms along with safety on long-term use of Rumalaya forte.

**REFERENCES**