Clinical Trial of Rumalaya Tablets and Rumalaya Cream in cases of Low Backache

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INTRODUCTION
Low backache is a troublesome condition afflicting mankind since time immemorial. Defective posture, minor trauma in day-to-day life and osteoarthritis of the spine with advancing age are probably the most common causes contributing towards this disease entity. In certain recognised conditions responsible for low backache, e.g. spondylolisthesis, spina bifida, prolapsed intervertebral disc (PIVD) etc., surgery has proved to be a definitive and curative treatment. But still in a large number of disease entities, e.g., lumbar spondylosis, L.S. strain (lumbo-sacral strain) and backache of obscure origin, the search for a definitive and ideal treatment is going on.

Various drugs and drug combinations with physiotherapy have been tried and advocated. Long-term therapy with these drugs is not without the hazards of side effects. Recently, there has been an increased interest in the use of indigenous drugs in the treatment of various orthopaedic problems. Rumalaya (The Himalaya Drug Co.) is one such drug. It is available in tablet and cream form (the latter for local application). This drug has been tried and found useful in various orthopaedic problems like osteoarthritis of the knee joints, rheumatoid arthritis, ankyllosing spondylitis and cervical spondylosis by various Indian authors, but was never tried in cases of low backache. Low backache incapacitates the patient for a long period of time, affecting his day-to-day life and causing physical discomfort as well as imposing a financial burden on him.

We, therefore, though it worthwhile to undertake this study and observe the therapeutic effectiveness of Rumalaya in patients with low backache.

Each Rumalaya tablet contains:
Mahayograj guggul 0.162 g
Exts. Maharasnadi quath 65 mg
   Moringa pterygosperma 16 mg
   Pristimera indica 6 mg
   Rubia cordifolia 13 mg
   Tinospora cordifolia 10 mg
   Tribulus terrestris 16 mg
Shilajeet (Purified) 16 mg
Swarnamakshik bhasma 5 mg
Shankh bhasma 65 mg
Muskdana 10 mg
Swarna (Gold) catalyst

Processed in Vitex negundo, Tinospora cordifolia, Ocimum sanctum, Eclipta alba, Withania somnifera, Zingiber officinale, Dashamoola.

MATERIAL AND METHODS
The present work was undertaken in the out-patient department of Orthopaedic Surgery, H.P. Medical College, Simla. One hundred and twenty eight cases of low backache were studied, of which sixteen cases were put on placebo. The effect of the drug, its side effects if any and results were noted. The results were classified as “excellent”, “good”, “fair”, or “poor” depending upon the criteria as shown in Table 1.

<table>
<thead>
<tr>
<th>Result</th>
<th>Sense of well-being</th>
<th>Relief of Pain</th>
<th>Degree of tenderness in grades, i.e. 0,1,2,3</th>
<th>Relief of spasm</th>
<th>S.L.R. test*</th>
<th>Spinal mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>++</td>
<td>No pain</td>
<td>0</td>
<td>No spasm</td>
<td>—ve</td>
<td>Normal</td>
</tr>
<tr>
<td>Good</td>
<td>+</td>
<td>Markedly reduced</td>
<td>1</td>
<td>Spasm ++</td>
<td>—ve at 60°</td>
<td>Almost normal</td>
</tr>
<tr>
<td>Fair</td>
<td>+</td>
<td>Appreciable relief</td>
<td>2</td>
<td>Spasm +++</td>
<td>+ve at 40°</td>
<td>Limited in final 10°</td>
</tr>
<tr>
<td>Poor</td>
<td>—</td>
<td>No relief or worsened</td>
<td>3</td>
<td>Spasm ++++</td>
<td>+ve at 20°</td>
<td>Restricted beyond 50°</td>
</tr>
</tbody>
</table>

* Straight Leg Raising Test

**TYPES OF CASES**
Low backache cases as a result of lumbar spondylosis, PIVD, LS strain, ankylosing spondylitis, old fracture of spine, contusion and cases of backache with obscure origin were studied. Details are given in Table 2.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Condition</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lumbar spondylosis</td>
<td>53</td>
</tr>
<tr>
<td>2.</td>
<td>Low backache of obscure origin</td>
<td>41</td>
</tr>
<tr>
<td>3.</td>
<td>PIVD</td>
<td>18</td>
</tr>
<tr>
<td>4.</td>
<td>LS strain</td>
<td>12</td>
</tr>
<tr>
<td>5.</td>
<td>Old fracture of lumbar spine</td>
<td>2</td>
</tr>
<tr>
<td>6.</td>
<td>Ankylosing spondylitis</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>Contusion</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>128</td>
</tr>
</tbody>
</table>

Preliminary clinical, radiological and haematological examinations were carried out. X-rays and blood examinations were helpful in diagnosing the following conditions:-

(a) Congenital, e.g. spina bifida occulta, spondylolysis and spondylolisthesis.

(b) Infective, e.g. tuberculosis etc. and

(c) Neoplastic, e.g. primary or secondary conditions. These were not included in this trial.

**DOSAGE**
One hundred and twenty eight cases were studied. Out of these, one hundred and twelve cases were put on Rumalaya tablets and Rumalaya cream. The remaining sixteen were administered placebo to compare the results. We followed the following dosage schedule.

**Rumalaya Group**

1st week
- Rumalaya tablet: 2 tablets, t.i.d.
- Aspirin gr. X: 1 tablet, t.i.d.
- Rumalaya cream for local application

2nd week
- Rumalaya tablet: 2 tablets, t.i.d.
Rumalaya cream for local application

3rd & 4th weeks
Rumalaya tablet
Rumalaya cream for local application

Placebo Group

1st week
Placebo tablet
Placebo tablet Aspirin gr. X

2nd week
Placebo tablet
Placebo tablet Aspirin gr. X

We added aspirin to the therapeutic trial during the first week only because Rumalaya tablet is slow-acting initially as it takes about one week to reach appreciable blood levels to exert its effect. However aspirin was not given in three cases with a known history of peptic ulcer.

Patients were then called for weekly or, if coming from remote places, fortnightly intervals for review. The response to these drugs or side effects if any were recorded.

**OBSERVATIONS**

The maximum number of cases were between the third to the fifth decades of life in both the sexes, as shown in Table 3. More females (58.5%) were accepted than males (41.5%).

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-20 years</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21-30 years</td>
<td>17</td>
<td>23</td>
<td>40</td>
</tr>
<tr>
<td>31-40 years</td>
<td>14</td>
<td>19</td>
<td>33</td>
</tr>
<tr>
<td>41-50 years</td>
<td>15</td>
<td>22</td>
<td>37</td>
</tr>
<tr>
<td>51-60 years</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>61-70 years</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>53(41.5%)</td>
<td>75(58.5%)</td>
<td>128</td>
</tr>
</tbody>
</table>

The occupation of most of the patients (both sexes) was agriculture. They are prone to repeated stresses and strains to their spine, due to the strenuous nature of their work.

**RESULTS**

In the Rumalaya group we recorded 29.4% “excellent” results, 37.5% “good” results and 25.08% “fair” results, whereas only 7.93% cases showed “poor” response as shown in Table 4.

<table>
<thead>
<tr>
<th>Groups &amp; No. of cases</th>
<th>“Excellent”</th>
<th>“Good”</th>
<th>“Fair”</th>
<th>“Poor”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rumalaya group 112 cases</td>
<td>29.4%</td>
<td>37.5%</td>
<td>25.08%</td>
<td>7.93%</td>
</tr>
<tr>
<td>Placebo group 16 cases</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>100%</td>
</tr>
</tbody>
</table>

All the 16 placebo group patients (100%) showed “poor” response.

We did not observe any untoward reaction or side effect of this drug.

The drug was found safe even in patients with a known peptic ulcer history (three cases).

**DISCUSSION**

Most of the low backache problems (excluding congenital, infective and neoplastic conditions as already mentioned) have a great tendency towards chronicity. This is a common orthopaedic problem to be tackled between the third to fifth decades of life in both the sexes. Because of the chronicity of its nature, it requires a prolonged, safe and economical treatment.
The drugs used so far like salicylates, phenylbutazone, indomethacin, dextropropoxyphen, corticosteroids etc., if administered for long periods produce side effects like gastroenteritis, bone marrow depression, glycosuria, renal damage, hypertension etc. These can cause in some patients a lot of harm rather than relief from a comparatively less alarming disease like low backache. So, safety of the drug used is one important factor in the treatment of low backache. As we did not observe any side effect on using Rumalaya even in a single patient and also due to the fact that it was well tolerated in there cases with peptic ulcer, the safety of this drug is established.

As all patients cannot afford the costly drugs used in this chronic disorder, the cost aspect is another important factor to be taken into consideration. Moreover, to detect the side effects of the toxic drugs in long-term treatment, the patient is required to attend hospital and undergo various laboratory tests again and again thus increasing the cost of the regimen with such toxic drugs.

Therefore, we should have a drug which
1) can be prescribed to the patients without fear of untoward side-effects on prolonged treatment,
2) does not require too frequent hospital visits and too frequent laboratory investigations,
3) is not very costly and
4) can be prescribed without reservations to patients of all socio-economic strata of life.

In lumbar spondylosis, L.S. strain, PIVD, ankylosing spondylitis and backache of obscure origin after administering Rumalaya tablet and cream for a period of four weeks in reasonable amounts, combined with time honoured conventional adjuvants like physiotherapy, hot fomentation and hard bed rest where required, we could achieve overall “excellent” to “fair” results in 92% of cases. This trial has established that Rumalaya tablets and cream are valuable in the management of low backache. Rumalaya tablets and Rumalaya cream are safe, devoid of any side effects and can be administered to any age group without any apprehension.