PAIN MANAGEMENT AFTER KSHAR-SUTRA LIGATION OF HAEMORRHOIDS WITH HERBOMINERAL PREPARATION AND STANDARD NSAID: A CONTRASTIVE STUDY

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KEYWORDS: Haemorrhoids, Kshara-sutra ligation, post-operative pain, Triphala Guggulu, Gandhaka Rasayana.

ABSTRACT

The disease haemorrhoids is an Ano-rectal disorder and is as old as mankind. A large population of the world population is troubled with this disease which is due to inconsistency of the human diet and social obligations demanded by civilization. The management of 3rd degree haemorrhoids needs mainly a surgical approach. The Kshara-sutra ligation method of haemorrhoids is done by Ayurvedic surgeons but facing hardships in post ligation pain management. A complete Ayurvedic postoperative pain management is the need of every Ayurvedic surgeon. This study was carried out with an attempt to find an effective and safe Ayurvedic postoperative pain management and for this, 30 patients who were undergone Kshara-sutra ligation of haemorrhoids were selected from the IPD of Post Graduate Department Shalya Tantra, Jammu Institute Of Ayurveda And Research Hospital, Nardani, Jammu. Selected patients were randomly divided into two groups each of 15 patients. For pain relief, the patients in Group A were administered with Diclofenac sodium, which is an established NSAID, in the dose of 50mg TDS orally where as the patients in Group B were administered with Triphala Guggulu and Gandhaka Rasayana in the dose of 450 mg TDS and 250 mg TDS orally respectively. Although satisfactory result obtained on all parameters with Triphala Guggulu and Gandhaka Rasayana but Diclofenac sodium is found statistically more significant.

INTRODUCTION

Ayurvedic approach towards the disease is holistic. Numerous therapeutic modalities have been advocated by our Acharyas in the management of each and every disease. But their efficicacy needs reestablishment by means of thorough and intensive researches. Sushruta, the father of Indian surgery has scientifically classified, in a systemic manner, a wealth of clinical material and the principles of management which are valid even today. In the field of Ayurvedic surgery, management of Arshas by Kshara-sutra ligation has gained immense popularity and its efficicacy has been proved time immemorial. Pain is unavoidable in this technique too after the procedure. Hence Ayurvedic surgeons are facing the problem of post ligation pain management. Inspite of all the complications induced by modern Analgesics, Ayurvedic surgeons are forced to prescribe them. A complete and Ayurvedic Postoperative Pain management is the need of every Ayurvedic surgeon. Triphala guggulu and Gandhaka rasayana are well studied drugs in post operative pain management. So in the present study, the patients who have undergone Kshara-sutra ligation for Arsha will be subjected to oral medication of Triphala Guggulu and Gandhaka Rasayana with luke warm water sitz bath in the post ligation period for assessment of their analgesic effects. The results are compared with Diclofenac sodium, which is an established modern non-steroidal analgesic drug.

DRUG CONTRIVE

Preparation of Triphala Guggulu

Hareetaki, Vibheetaki, Aamalaki and Pippali each one Pala in quantity are taken in the dry form and powdered separately. Five Pala of Guggulu is taken in the Shodhita form and pounded along with the above prepared powder and made in to paste. Using small amount of ghee they are rolled in to pills.

Preparation of Gandhaka rasayana

Shuddha Gandhaka is taken. Three Bhavana are given out of each one of Goksheera, Chaturjata and Guduchi. Similarly eight Bhavana are given out of each one of Pathya, Dhaatri, Aksha, Bhrungaraja and Aaddraka. It is considered as Gandhaka Rasayana.
CLINICAL PARAMETERS OF STUDY

**Visual analogue scale Pain score**

1. **Inflammation**
   - No inflammation: 0
   - Mild inflammation: 1
   - Moderate inflammation: 2
   - Severe inflammation: 3

2. **Tenderness**
   - No tenderness: 0
   - Mild tenderness: 1
   - Moderate tenderness: 2
   - Severe tenderness: 3

METHODOLOGY:

1. **Source of data**
   Patients undergone Kshara sutra ligation of haemorrhoids and admitted in IPD of Post Graduate Department Shalya Tantra, Jammu Institute Of Ayurveda And Research Hospital, Nardani, Jammu were randomly selected for the trial.

2. **Inclusion criteria**
   a. Patients who were undergone Kshara sutra ligation.
   b. Patients of both sexes in age group of 20-60 years.

3. **Exclusion Criteria**
   a. Patients having unexplained severe pain before Kshara sutra ligation.
   b. Patients who have developed other complication apart from pain in post ligation period.

OBSERVATION AND RESULTS

**A. GROUP A – DICLOFENAC**

<table>
<thead>
<tr>
<th>Paired Differences</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>95% Confidence Interval of the Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pair 1 DICLO_PAIN_DAY_1 - DICLO_PAIN_DAY_7</td>
<td>4.73333</td>
<td>.96115</td>
<td>.24817</td>
<td>4.20107 - 5.26560</td>
</tr>
</tbody>
</table>
Table 2: Comparison of Inflammation on 1\textsuperscript{st} and 7\textsuperscript{th} Post-Operative Day
Paired Samples Test

<table>
<thead>
<tr>
<th>Pair</th>
<th>Paired Differences</th>
<th>Mean</th>
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<th>Std. Error Mean</th>
<th>95% Confidence Interval of the Difference</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DICLO_INFLM_DAY_1 - DICLO_INFLM_DAY_7</td>
<td>1.53333</td>
<td>.51640</td>
<td>.13333</td>
<td>1.24736 - 1.81930</td>
<td>11.500</td>
<td>14</td>
<td>.000</td>
</tr>
</tbody>
</table>

Table 3: Comparison of Tenderness on 1\textsuperscript{st} and 7\textsuperscript{th} Post-Operative Day
Paired Samples Test

<table>
<thead>
<tr>
<th>Pair</th>
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<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DICLO_TNDRNS_DAY_1 - DICLO_TNDRNS_DAY_7</td>
<td>1.26667</td>
<td>.45774</td>
<td>.11819</td>
<td>1.01318 - 1.52015</td>
<td>10.717</td>
<td>14</td>
<td>.000</td>
</tr>
</tbody>
</table>

B. GROUP B – TG & GR

Table 4: Comparison of Pain on 1\textsuperscript{st} And 7\textsuperscript{th} Post-Operative Day
Paired Samples Test

<table>
<thead>
<tr>
<th>Pair</th>
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<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>95% Confidence Interval of the Difference</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TGGR_PAIN_DAY_1 - TGGR_PAIN_DAY_7</td>
<td>4.46667</td>
<td>1.06010</td>
<td>.27372</td>
<td>3.87960 - 5.05373</td>
<td>16.319</td>
<td>14</td>
<td>.000</td>
</tr>
</tbody>
</table>

Table 5: Comparison of Inflammation on 1\textsuperscript{st} And 7\textsuperscript{th} Post-Operative Day
Paired Samples Test

<table>
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<tr>
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<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TGGR_INFLM_DAY_1 - TGGR_INFLM_DAY_7</td>
<td>1.46667</td>
<td>.51640</td>
<td>.13333</td>
<td>1.18070 - 1.75264</td>
<td>11.000</td>
<td>14</td>
<td>.000</td>
</tr>
</tbody>
</table>

Table 6: Comparison of Tenderness on 1\textsuperscript{st} and 7\textsuperscript{th} Post-Operative Day
Paired Samples Test

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<tr>
<th>Pair</th>
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<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TGGR_TNDRNS_DAY_1 - TGGR_TNDRNS_DAY_7</td>
<td>1.20000</td>
<td>.41404</td>
<td>.10690</td>
<td>.97071 - 1.42929</td>
<td>11.225</td>
<td>14</td>
<td>.000</td>
</tr>
</tbody>
</table>

C. OVERALL RELIEF

Table 7: Relief of Pain at the End of 7\textsuperscript{th} Day in Both the Groups

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>MEAN B.T.</th>
<th>MEAN A.T.</th>
<th>PERCENTAGE RELIEF OF PAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>6.53</td>
<td>1.8</td>
<td>72.43%</td>
</tr>
<tr>
<td>Group B</td>
<td>6.2</td>
<td>1.73</td>
<td>72.09%</td>
</tr>
</tbody>
</table>
Table 8: Relief of Inflammation at the End of 7th Day in Both the Groups

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>MEAN B.T.</th>
<th>MEAN A.T.</th>
<th>PERCENTAGE RELIEF OF INFLAMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>2.66</td>
<td>1.13</td>
<td>57.51%</td>
</tr>
<tr>
<td>Group B</td>
<td>2.6</td>
<td>1.13</td>
<td>56.53%</td>
</tr>
</tbody>
</table>

Table 9: Relief of Tenderness at the End of 7th Day in Both the Groups

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>MEAN B.T.</th>
<th>MEAN A.T.</th>
<th>PERCENTAGE RELIEF OF TENDERNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>2.8</td>
<td>1.53</td>
<td>45.35%</td>
</tr>
<tr>
<td>Group B</td>
<td>2.73</td>
<td>1.53</td>
<td>43.95%</td>
</tr>
</tbody>
</table>

**DISCUSSION**

At the end of 7th day, VAS Pain scale in Group-A showed a relief of pain at 72.43% whereas in Group-B, VAS Pain scale had relief of pain at 72.09% in patients post-operatively who had undergone Kshara sutra ligation.

**Group A:** In the VAS pain scale index for parameter of pain, 't' values on 3rd, 5th and 7th days were 10.458 (P<0.001), 14.938 (P<0.001) and 19.073 (P<0.001) respectively. In case of inflammation, 't' values on 3rd, 5th and 7th days were 2.256 (P<0.05), 5.292 (P<0.001) and 11.500 (P<0.001) respectively. In case of tenderness, 't' value on 3rd day is 1.000 (P>0.001) which is insignificant where as on 5th and 7th days, 't' value were 4.000 (P<0.001) and 10.717 (P<0.001) respectively which
imply treatment in Group- A was highly significant statistically.

**Group B:** In the VAS pain scale index for parameter of pain, ‘t’ values on 3rd, 5th and 7th days were 8.573 (P<0.001), 13.252 (P<0.001) and 16.319 (P<0.001) respectively. In case of inflammation, ‘t’ values on 3rd day was 0.807 (P>0.01) which is statistically insignificant where as on 5th and 7th days, ‘t’ values were 4.583 (P<0.001) and 11.000 (P<0.001) respectively which implies treatment in Group- B was highly significant statistically but after 3 days. In case of tenderness, ‘t’ value on 3rd day is 1.000 (P>0.01) which is insignificant where as on 5th and 7th days, ‘t’ value were 3.500 (P<0.05) and 11.225 (P<0.001) respectively which means the treatment in Group- B was significant statistically but only after 3 days. The above data from both the groups implies that Group A and Group B treatment are not equal and by observing mean difference of Group A and Group B, Group A treatment is slightly more significant.

**PROBABLE MODE OF ACTION**

Chakradatta while explaining the properties of *Triphala Guggulu* denotes that, it reduces *Kleda, Paaka, Putigandha, Shotha* along with remarkable reduction of pain in *Vranas. Katu, Tikta rasa* present in *Gandhaka Rasayana* helps in Vranavasadana, thus helping in early wound healing and significant reduction in the pain and it is also a *Rasayana*. Sitz bath is advised with Luke warm water. Heating the tissues increases metabolic activity, increases blood flow and stimulates neural receptors. Heat appears to produce definite sedative effects. Due to *Ushna guna* induced by the sitz bath there will be muscle relaxation which intern reduces the pain. Because of these factors *Avaghaha sweda* relieves Vedana. As all these properties are antagonistic to *Vata dosha*, this drug acts as *Vata shamaka* and reduces *Vedana*.

**CONCLUSION**

The pain management after *Kshar sutra* ligation of haemorrhoids in an effective manner has always been a challenge to the Ayurvedic surgeons. The conventional treatment includes NSAIDs and Diclofenac sodium is a known potent anti-inflammatory drug. *Triphala Guggulu* and *Gandhak rasayan* are having *Vrana Shodhana, Vrana Ropana* and *Vranavasadana* properties which results in relieving inflammation and hence pain and tenderness.

After the detailed evaluation of both the groups, it was noted that both groups provided statistically significant results in relieving pain post *Kshar-sutra* ligation for haemorrhoids. The statistical data shows Group A and Group B treatment are not equal, by observing mean difference of Group A and Group B, Group A treatment is slightly more significant. However for the confirmation of the above results, large scale systematic study is required. The present study may form the base for further research in the field of post operative pain management with various Ayurvedic formulations.

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