CLINICAL STUDY ON POST OPERATIVE PAIN MANAGEMENT WITH VEDANA STHAPAKA KASHAYA IN ARSHAS

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ABSTRACT
Background: Post-operative pain is the common outcome of the Surgery and the ability to alleviate this pain is one of the most important goals for surgery. In case of ksharasutra ligation, the patient experiences agonizing pain in the wound which may persist for long time. To manage this we have to rely on the modern analgesics which are having lots of side effects. Objective: To evaluate the efficacy of Vedana Sthapaka Kashaya in post operative pain management of patients undergone ksharasutra ligation for Arshas. Methodology: In this study, minimum 40 patients were selected and placed in two groups by simple random sampling method i.e. 20 in trial and 20 in standard groups. In trial group “Vedana sthapaka kashaya 35 ml TID” was given where as in the standard group “Tab. Diclofenac sodium 50 mg BD” was given. The therapeutic effects were analyzed by using the subjective parameter. The duration of treatment was 5 days and clinical assessment was done every day. Observation: in observation along with others the main reason found was that maximum 82.5% of patients were having constipated bowel. More straining for expelling constipated stools will leads to dilation of venous plexus. Result: At the end of clinical study all 20 patients in group A and 20 patients in group B showed maximum improvement. Conclusion: The study showed both Diclofenac sodium and Vedana sthapaka kashaya were proved to be effective in the management of post operative pain in the patients who undergone ksharasutra ligation in arshas but comparatively, Tab. Diclofenac sodium was found superior than Vedana sthapaka kashaya.

Keywords: Vedana, Postoperative pain, Ksharasutra ligation, Vedana sthapaka kashaya, Diclofenac sodium.

INTRODUCTION
Surgery gives fastest relief from various diseases but the common outcome is the post operative pain which comes under acute pain. Pain is said to be an important indicator of abnormal process going inside the body which urges the person to take required treatment¹. Early treatment of acute post operative pain may prevent the development of chronic post operative pain.

In Ayurveda, pain can be co-related with Vedana. Acharya Sushruta mentioned that Vedana can not arise in body without involvement of the Vata Dosha². So, the drug or procedure which alleviates Vata Dosha acts as a potent Vedana Sthapaka.
Nowadays *Arsha*\(^3\) is a very common disease. It mainly occurs in ano-rectal region which is a very sensitive area. *Acharya Sushruta* mentioned *Shastra Karma* or surgical procedure for the management of *Arshas*.\(^4\) When any surgical or para-surgical procedure is done in ano-rectal region it creates so much pain which can be considered as post operative pain and it needs an urgent medication. But the post operative pain management in *Ayurvedic* point of view is still a setback. So, in *Ayurvedic* field there is a need to establish an effective treatment for pain management.

In the present study the patients who had undergone *ksharasutra* ligation for *Arshas* were subjected to *Vedana Sthapaka Kashaya* for Post Operative Pain Management. An assessment of the analgesic effects was done and the results were compared with modern *Non Steroidal Anti Inflammatory Drug, Diclofenac Sodium*.\(^5\)

So, in this study an effort was made to evaluate the analgesic effect of *Vedana Sthapaka Kashaya*\(^6,7\) in post operative pain management of *Arshas*.

**MATERIALS AND METHODS:**

**Sample Source:** Patients attending OPD and IPD of Alva’s Ayurveda Medical college Hospital, Moodbidire, medical camps and other referrals were selected. Each patient was selected for the trial after voluntary consent.

**Sample size:** Minimum 40 patients who were fit for the study as per inclusion criteria were selected randomly and placed into 2 equal groups, Group A (Standard Group) and Group B (Trial Group).

**Study design:** Open Clinical Study.

**Selection Criteria:** The cases were selected strictly as per the pre-set inclusion and exclusion criteria.

**Diagnostic criteria:** Patients who have undergone *Ksharasutra* ligation for *Arshas*.

**Inclusion criteria**
1. Patients of both sexes in age group of 21-70 years were included.
2. Patients fulfilling the diagnostic criteria.

**Exclusion criteria**
1. Patients having unexplained severe pain before operation.
2. Patients who develop other complications apart from pain in post operative period.
3. Pregnant women were excluded.

**INTERVENTIONS**

A total number of 40 patients were randomly selected for the study. They were divided into 2 groups of each 20 patients.

**Group A - (Standard Group)**
- Sample size: 20 patients
- Tab. Diclofenac sodium administered orally
- Dose: 50 mg B.D. after food
- Duration: 5 days

**Group B - (Trial Group)**
- Sample size: 20 patients
- *Vedana sthapaka kashaya* administered orally
- Dose: 35 ml T.I.D. before food
- Duration: 5 days

Criteria for assessment were based on Mc Gills Pain Score Index. Review of intensity of post operative pain was done everyday up to 5 days. Findings were subjected for statistical analysis.

**Materials**
- *Vedana sthapana gana dravya*
- Tab. Diclofenac sodium 50mg

**Preparation of Kashaya**
- The drugs of *vedana sthapana gana* i.e. *shala, katphala, kadamba, padmaka, tumba, mocharasa, shirisha, vanjula, elavaluka, ashoka* were made into coarse powder form separately.
- Then the coarse powder of all the drugs was taken in equal quantity.
- One part of coarse powder was mixed with 16 parts of water and boiled.
- When one eighth of initial content was remained, it was filtered and thus the *kashaya* was prepare.

Drug presentation- It was presented in the form of *kashaya* and was administered orally 35ml TID before food.

**ASSESSMENT CRITERIA:**

**Subjective Criteria**
- Post operative Pain.
**OBSERVATION:**
AGE: Maximum of 27.50% of patients are in the age group of 41-50 years. This may be due to the reason that most of the people of this age group belong to working class. Long time sitting, strenuous work, irregular and unwholesome food in this particular age group might be the triggering factors. OCCUPATION: It was evidenced from the study that maximum i.e. (30%) were doing service, the people who are doing office works, due to prolonged sitting, avoidance of natural urges due to inevitable circumstances, faulty food habits etc. may be the reason for haemorrhoids. SOCIO-ECONOMIC CONDITION: Analysis of Socio-economic status of 40 patients revealed that majority of patients i.e. (55%) belonged to middle class, Mental stress, strain and the living standard of middle class may be the reason for GI disturbances causing the haemorrhoids. DIET: Maximum patients 60% were of mixed diet. Intake of meat, fish, more spices etc lead to Arshas as they contain more protein and less fibre and are ushna and vidahi. APPETITE: Among 40 patients, 72.50% were having poor appetite. This point toward the role of mandagni which is a causative factor in the manifestation of Arshas. NATURE OF BOWEL HABITS: In this series a maximum 82.5% of patients were having constipated bowel. More straining for expelling constipated stools will leads to dilation of venous plexus.

**RESULT:** In the present clinical study, management of post operative pain with Diclofenac Sodium and Vedana sthapaka kashaya in Arshas were studied and results of all the cases were noted on the basis of statistical data.

For Grading of pain: Mc Gills pain score index
0- No pain, 1- Mild pain, 2- Discomforting,
3- Distressing, 4- Horrible, 5- Excruciating pain

Table 1: Overall Clinical Assessment Of Results Of Both Group Based On McGill Pain Score Index

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Relief</th>
<th>Group A</th>
<th>Relief % of Group A</th>
<th>Group B</th>
<th>Relief % of Group B</th>
<th>Total</th>
<th>Total % Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Complete relief</td>
<td>5</td>
<td>25</td>
<td>2</td>
<td>10</td>
<td>7</td>
<td>17.5</td>
</tr>
<tr>
<td>2</td>
<td>Marked relief</td>
<td>9</td>
<td>45</td>
<td>8</td>
<td>40</td>
<td>17</td>
<td>42.5</td>
</tr>
<tr>
<td>3</td>
<td>Moderate relief</td>
<td>5</td>
<td>25</td>
<td>9</td>
<td>45</td>
<td>16</td>
<td>40</td>
</tr>
<tr>
<td>4</td>
<td>Mild relief</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>No relief</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
</tbody>
</table>

Based on McGill’s pain score index, the overall effect of therapy in Group A and Group B is as follows- Complete relief in 7 patients (17.50%), Marked relief in 17 patients (42.5%), Moderate relief in 16 patients (40%), Mild relief in 2 patients (5%) and 0 patient (0%) with no relief.

![Figure 1](image-url)
DISCUSSION

Effectiveness on Pain of Both Groups

<table>
<thead>
<tr>
<th></th>
<th>EFFECTIVENESS %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st day</td>
</tr>
<tr>
<td>Post op. Pain</td>
<td></td>
</tr>
<tr>
<td>Group A</td>
<td>11.76</td>
</tr>
<tr>
<td>Group B</td>
<td>6.024</td>
</tr>
</tbody>
</table>

Discussion on comparative effect of both the Groups

Pain was reduced by 74.11% in Group A & 65.06% in Group B. Both the groups showed improvements with significant p-value of < 0.001. Severity of pain in both the groups is mainly due to aggravation of vata dosha and irritation of sangyavaha srothas caused by ksharasutra ligation. According to modern science, post operative pain initiates by injury to the tissue, ultimately the nerve ending and pain receptors present in the skin and other tissue. But the quantum of pain depends upon Psychological factor, Neurological factor and Constitutional status of the individual.

Discussion on over all probable mode of action of vedanasthapaka kashaya: Vedanasthapana means that which eliminates dukhatmaka vedana i.e. painful stimuli in the body. Here, Vedanasthapana gana includes the following drugs - Shaala, Katphala, Kadamba, Padmaka, Tumba, Mocharasa, Shirisha, Vanjula, Elavaluka, Ashoka.

1. Shaala, shirisha and vetasa are having madhura rasa and madhura rasa helps in vata shaman and leads to vedana sthapan.
2. Guna like ushna, guru and snigdha of shala, kadamba and padmaka respectively alleviates vitiated vataand helps in vedanasthapana.
3. Drugs like katphala and tumba are having ushna virya which pacifies vata dosha and enhance vedana sthapana.
4. Drugs like mocharasa, katphala, tumba, shala, kadamba and tumba are having vata-pitta, vata-kapha and tridoshahara property. All these drugs are capable of vata shaman and acts as vedana sthapana.
5. Katphala having sandhaneeya property and Sirisha having vrana ropana property. Both helps in wound healing and thus helps in reducing pain.

6. Sirisha and vetasaare having shothahara property. Reducing the shotha or inflammation will also helps in reducing pain.
7. The pradhana karma of shala, katphala, kadamba, padmaka, elabaluka, shirisha is Vedana sthapana, so these drugs acts as vedana sthapaka by reducing pain.
8. Drugs like katphala, kadamba, padmaka, ashoka etc are having chemical compositions like myricitrin, myricetin, pentosan, genistein etc. which shows analgesic and anti inflammatory effect and therefore gives relief from pain.

Hence, Pain is always due to aggravation of Vata and Guru, Ushna, Picchila and Snigdha substances eliminates pain by carrying out vatamulomana.

So the combination of all the above said drugs is vedana sthapaka kashaya which had done the vedana sthapana effectively.

CONCLUSIONS

The review of literature and clinical study provides certain useful conclusions. Ksharasutra ligation in Arsha will cause lot of pain in post operative period and this pain has to be managed for better acceptance of the procedure.

The pain was well tolerated by the patients of both the groups from 3rd post operative day. There were no adverse effects observed due to drug in both the groups during the study. In ksharasutra ligation, post operative pain management using Diclofenac sodium tablets has been effective so far. Vedanasthapaka kashaya was also found effective in relieving pain. Although there were complain of mild pain by the patients of Group B (vedanasthapaka kashaya) even before completion of 8th hour which was speculated time for re-administration of kashaya in post operative period. But pain was well tolerated.
by the patients. There were no such complaints observed in Group A (Tab. Diclofenac sodium) patients. There is no evidence of any secondary infection seen, in both the groups. *Vedanasthapaka kashaya* also found to be useful in healing of the wound far earlier when compared to Diclofenac sodium tablets. From first assessment day onwards got statistically significant changes in both the groups. Group A got 74.11% result in relieving the post operative pain. Group B got 65.06% result in relieving the post operative pain. Though the Trial group is showing less result than the standard group but statistically showing significant result i.e. P value <0.001.

**REFERENCES**


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**Table 2:** Effect Of The Treatment In Group A

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>MEAN SCORE</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
<td>Mean AT</td>
<td>BT-AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on McGill pain score</td>
<td>4.25</td>
<td>AT1 3.75 0.50</td>
<td>11.76%</td>
<td>0.550</td>
<td>0.123</td>
<td>4.359</td>
</tr>
<tr>
<td></td>
<td>AT2 3.15 1.10</td>
<td>25.88%</td>
<td>0.587</td>
<td>0.131</td>
<td>6.850</td>
<td>&lt;0.001</td>
</tr>
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<td></td>
<td>AT3 2.75 1.50</td>
<td>35.29%</td>
<td>0.550</td>
<td>0.123</td>
<td>13.077</td>
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<tr>
<td></td>
<td>AT4 2.00 2.25</td>
<td>52.94%</td>
<td>0.562</td>
<td>0.126</td>
<td>18.291</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>AT5 1.10 3.15</td>
<td>74.11%</td>
<td>0.852</td>
<td>0.191</td>
<td>18.905</td>
<td>&lt;0.001</td>
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</tbody>
</table>

**Table 3:** Effect Of The Treatment In Group B

<table>
<thead>
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<th>Symptoms</th>
<th>MEAN SCORE</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BT</td>
<td>Mean AT</td>
<td>BT-AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on McGill pain score</td>
<td>4.15</td>
<td>AT1 3.90 0.25</td>
<td>6.024</td>
<td>0.553</td>
<td>0.124</td>
<td>2.517</td>
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<tr>
<td></td>
<td>AT2 3.50 0.65</td>
<td>15.662</td>
<td>0.513</td>
<td>0.115</td>
<td>5.940</td>
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<td>AT3 2.85 1.30</td>
<td>31.325</td>
<td>0.489</td>
<td>0.109</td>
<td>12.365</td>
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<td>AT4 2.10 2.05</td>
<td>49.397</td>
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<td>0.100</td>
<td>23.267</td>
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<td>AT5 1.45 2.70</td>
<td>65.060</td>
<td>0.759</td>
<td>0.170</td>
<td>16.480</td>
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Table 4: Effectiveness Comparison Between The Groups

<table>
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<th></th>
<th>Post op. Pain</th>
<th>1st day</th>
<th>2nd day</th>
<th>3rd day</th>
<th>4th day</th>
<th>5th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>11.76</td>
<td>25.88</td>
<td>35.29</td>
<td>52.94</td>
<td>74.11</td>
<td></td>
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<tr>
<td>Group B</td>
<td>6.024</td>
<td>15.662</td>
<td>31.325</td>
<td>49.327</td>
<td>65.06</td>
<td></td>
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</tbody>
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Effectiveness Comparison between The Groups

Figure 2: Effectiveness Comparison Between The Groups

Source of Support: Nil
Conflict Of Interest: None Declared