A COMPARATIVE CLINICAL STUDY OF APAMARGA KSHARA SUTRA LIGATION AND VEDANASTHAPANA MAHAKASHAYA COATED THREAD LIGATION IN THE MANAGEMENT OF ARSHA

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ABSTRACT

Arsha (hemorrhoids) is engorgement of the hemorrhoidal venous plexus, characterized by bleeding per rectum, constipation, pain in ano, prolapse and discharge per anum. In modern modalities, the conservative treatment consists use of laxative, high residual diet and prevailing treatment which are – Sclerotherapy, Rubber band ligation, Infra-red coagulation, Laser therapy, Lord’s dilatation, Cryosurgery, Haemorrhoidectomy, etc in practice. Ayurveda is well known for the treatment of Arsha with Kshara sutra for yielding negligible rate of recurrence, cost effective, less pain, no bleeding, no infection, no anal incontinence and requiring minimal hospitalization during treatment. In this present study, Vedanasthapanama Mahakashaya coated thread was ligated to overcome post Kshara Sutra discomfort like pain, irritation, bleeding, etc. The present study was conducted on 30 patients of Arsha with an objective to compare the efficacy of Apamarga Kshara Sutra ligation and Vedanasthapanama Mahakashaya coated thread ligation on Arsha patients. The patients were divided into two groups of 15 patients in each group. Patients of Group A were recommended Apamarga Kshara Sutra ligation, while patients of Group B were treated by Vedanasthapanama Mahakashaya coated thread ligation. After observing the overall effect of therapy, it was found that Vedanasthapanama Mahakashaya coated thread ligation shows better results than Apamarga Kshara Sutra ligation on all subjective(bleeding per anum & pain in ano) and objective parameters(swelling per anum & condition of anal sphincter tone). The effect of therapy of Vedanasthapanama Mahakashaya coated thread ligation was comparatively very significant on pain in ano.

KEYWORDS: Arsha, Astha Mahagada, Apamarga Kshara Sutra, Vedanasthapanama Mahakashaya.

INTRODUCTION

Arsha (Piles/Haemorrhoids) is one of the commonest disease occurring in ano rectal region. Its incidence increases with advancing age and peaks in people aged 45 to 60 and at least 50% of people over the age of 50 years have some degree of haemorrhoidal symptoms. Now a days most of the persons suffer from any one of the complaints of piles during their life time. Ayurvedic Shalya Tantra has wide scope in the management of Arsha.[11]

According to modern science, Piles are dilated veins within the anal canal in the subepithelial region formed by radicles of the superior, middle, and inferior rectal veins. In the management of ano rectal diseases there are many diseases which are difficult to manage by conservative treatment alone. Among them Arsha is one of such grave disease for which it has been included in Ashita Mahagada by Sushruta.[12] This show the gravity of this disease, piles can affect anyone.

In the midst of 20th Century introduction of Kshara-Sutra for the management of ano-rectal disease by Prof. Despande diverted the sight of surgeons towards ancient art of surgery. Kshara Sutra was initially successfully tried over the management of fistula-in-ano following other ano rectal diseases like – fissures, piles, etc. But as a principle, kshara sutra of low potency was used for the management of piles. Modern modalities are concerned, the conservative treatment consist use of laxative and high residual diet and prevailing treatment which are – Sclerotherapy, Rubber band ligation, Infra-red coagulation, Laser therapy, Lord’s dilatation, Cryosurgery, Haemorrhoidectomy, Trans haemorrhoidal...
artery ligation and Stapled haemorroidectomy in practice.

The present study is undertaken as mentioned in Chakradatt, 5th chapter of “Arshachikitsaadhyaya” and also in Bhavprakash khand 2/5/244. Acharya Charaka has mentioned Vedanasthapana Mahakashaya in the 4th chapter of Sutrasthana.

AIMS OF STUDY

- To Assess & validate the Vedanasthapana effect of Vedanasthapana Mahakashaya Coated Thread Ligation in Arsha.
- To study the comparative effect of Apamarga Kshara Sutra Ligation with Vedanasthapana Mahakashaya coated Thread Ligation in Arsha.

MATERIALS AND METHODS

Drugs


Study Design – Randomized control clinical trial.

Selection of the patients

- Patients were registered from OPD/IPD of Department of Shalya Tantra, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University Hospital, Jodhpur, irrespective of sex, occupation and religion.

Inclusion criteria

- Patient willing to participate in the research trial.
- Patient aged in between 20-65 years.
- Patients of 2nd, 3rd and 4th degree internal piles were considered.
- Interno-external piles.

Exclusion criteria

- Patients associated with HBsAg and HIV was excluded from the study.
- Patient associated with prolapsed rectum, Fistula-in-ano, fissure, carcinoma of the rectum, diabetes mellitus, ulcerative colitis, crohn's disease, Hepatic disorder, cardiac disorders mentally ill and non-cooperative patients were excluded from the study.

Laboratory investigations

The routine laboratory investigations were performed in patients like – TLC, DLC, Hb%, ESR, CT, BT, Blood sugar, HIV, HBsAg, VDRL and urine examination.

Grouping

Total 30 patients of Arsha were registered and randomly divided into two groups:-

Group-(A) 15 patients were selected for Apamarga Kshara Sutra ligation.

Group-(B) 15 patients were selected for Vedanasthapana Mahakashaya Coated Thread ligation.

Assessment Criteria

Subjective parameters

- Bleeding P/R
  0- o bleeding
  1- Bleeding in the form of streak
  2- Bleeding in the form of drops
  3- Bleeding in the form of splash in the pan
  4- Bleeding in the form of stream.

- Pain in ano
  0- No pain
  1- Localised feeling of pain during movement only but no feeling during rest.
  2- Localised tolerable pain even rest but completely relived by hot sitz bath.
3. Radiating intolerable pain relieved by oral analgesics but no disturbance the sleep.
4. Intolerable radiating and continuous pain with sleep disturbance and patient seek medical help as earlier possible.

Objective Parameters
- **Swelling per anum**
  0- No swelling around the anal verge
  1- Mild swelling around the anal verge, which patient do not identifies himself
  2- Mild swelling around the anal verge, which patient himself identifies also
  3- Moderate swelling limited to pile mass position only
  4- Severe swelling affecting whole anal area.
- **Condition of anal sphincter tone**
  0- Easy DRE
  1- DRE with discomfort
  2- Painful DRE
  3- DRE is not possible.

Assessment of the efficacy of the trial drug on the Parameters mentioned above is done on 0 day, 1<sup>st</sup> week, 3<sup>rd</sup> week and 5<sup>th</sup> week and follow-up is taken every first week up to 3 months.

**Criteria for assessment for overall effect of therapy**
The overall effect of therapy was assessed as:
- Complete relief: 100% relief in presenting signs symptoms of the disease.
- Marked relief: above 75% relief of signs symptoms.
- Moderate relief: 51% to 75% relief of signs symptoms.
- Mild relief: 25% to 50% relief of signs symptoms.
- No relief: below 25% relief of sign symptoms.

**OBSERVATIONS**
The observations were as follows: Maximum numbers of patients were obtained in the age group of 31-40 Years (26.67%) followed by the age group of 20-30 Years (40%). Male patients were 93.33% and female patients were 6.67%. Most of the patients 26.67% were service class and the maximum numbers of the patients 60% middle income group. Most of the patients 60% were non-vegetarian. Most of the patients 46.67% found from sedentary life style.

**RESULTS**

Table No. 1: Showing Effect of Therapy in Subjective and Objective Parameters in 15 patients of Group A.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean decrease</th>
<th>% relief</th>
<th>SD</th>
<th>SE</th>
<th>P Value</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding per anum</td>
<td>2.2667</td>
<td>0.3333</td>
<td>1.9333</td>
<td>85.29</td>
<td>0.7073</td>
<td>0.1817</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Pain in ano</td>
<td>1.6667</td>
<td>0.2667</td>
<td>1.4</td>
<td>84.00</td>
<td>0.6324</td>
<td>0.1633</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Swelling per anum</td>
<td>1.8667</td>
<td>0.2667</td>
<td>1.6</td>
<td>85.71</td>
<td>0.7367</td>
<td>0.1902</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Condition of anal sphincter tone</td>
<td>1.7333</td>
<td>0.2</td>
<td>1.5333</td>
<td>88.46</td>
<td>0.7432</td>
<td>0.1918</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
</tbody>
</table>

(BT–Before treatment, AT–After treatment, SD–Standard deviation, SE–Standard error, P–Probability, S–Significance)

Table No. 2: Showing Effect of Therapy in Subjective and Objective Parameters in 15 patients of Group B.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Mean decrease</th>
<th>% relief</th>
<th>SD</th>
<th>SE</th>
<th>P Value</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding per anum</td>
<td>2.4467</td>
<td>0.2</td>
<td>2.2667</td>
<td>91.89</td>
<td>0.7988</td>
<td>0.2062</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Pain in ano</td>
<td>2.4467</td>
<td>0.0667</td>
<td>2.4</td>
<td>97.29</td>
<td>1.0559</td>
<td>0.2725</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Swelling per anum</td>
<td>1.9333</td>
<td>0.1333</td>
<td>1.8</td>
<td>93.10</td>
<td>0.7746</td>
<td>0.2</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Condition of anal sphincter tone</td>
<td>2.0667</td>
<td>0.2</td>
<td>1.8667</td>
<td>90.32</td>
<td>0.8338</td>
<td>0.2152</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
</tbody>
</table>

(BT–Before treatment, AT–After treatment, SD–Standard deviation, SE–Standard error, P–Probability, S–Significance)

Table No. 3: Comparative effect of both the therapy in Subjective and Objective Parameters in group A and B.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group</th>
<th>Sum of rank</th>
<th>Diff.</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>U value</th>
<th>P value</th>
<th>Res</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding per anum</td>
<td>A</td>
<td>208.0</td>
<td>1.93</td>
<td>85.29</td>
<td>0.7073</td>
<td>0.1817</td>
<td>88.0</td>
<td>0.3128</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>257.0</td>
<td>2.27</td>
<td>91.89</td>
<td>0.7988</td>
<td>0.2063</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in ano</td>
<td>A</td>
<td>169.5</td>
<td>1.4</td>
<td>84.00</td>
<td>0.6325</td>
<td>0.1633</td>
<td>49.5</td>
<td>0.0090</td>
<td>VS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>295.5</td>
<td>2.4</td>
<td>97.29</td>
<td>1.056</td>
<td>0.2726</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling per anum</td>
<td>A</td>
<td>215.0</td>
<td>1.6</td>
<td>85.91</td>
<td>0.7368</td>
<td>0.1902</td>
<td>95.0</td>
<td>0.4735</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>250.0</td>
<td>1.8</td>
<td>93.1</td>
<td>0.7746</td>
<td>0.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition of anal sphincter tone</td>
<td>A</td>
<td>207.0</td>
<td>1.53</td>
<td>88.46</td>
<td>0.7432</td>
<td>0.1919</td>
<td>87.0</td>
<td>0.2942</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>258.0</td>
<td>1.867</td>
<td>90.32</td>
<td>0.8338</td>
<td>0.2153</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table No. 4: Overall effect of therapy in group A.

<table>
<thead>
<tr>
<th>Effect of therapy</th>
<th>No. of patients</th>
<th>% Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete relief (100%)</td>
<td>3</td>
<td>20.00</td>
</tr>
<tr>
<td>Marked relief (76-99%)</td>
<td>9</td>
<td>60.00</td>
</tr>
<tr>
<td>Moderate relief (51-75%)</td>
<td>3</td>
<td>20.00</td>
</tr>
<tr>
<td>Mild relief (25-50%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No relief (&lt;25%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table No. 5: Overall effect of therapy in group B.

<table>
<thead>
<tr>
<th>Effect of therapy</th>
<th>No. of patients</th>
<th>% Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete relief (100%)</td>
<td>8</td>
<td>53.33</td>
</tr>
<tr>
<td>Marked relief (76-99%)</td>
<td>6</td>
<td>40.00</td>
</tr>
<tr>
<td>Moderate relief (51-75%)</td>
<td>1</td>
<td>6.67</td>
</tr>
<tr>
<td>Mild relief (25-50%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No relief (&lt;25%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

DISCUSSION

Discussion of the present study has been systematically presented under the following headings as-

1. Discussion on overall effect of therapy

- The effect of therapy that in the parameter of Bleeding per anus reveals 85.29% relief in group A and 91.89% relief in group B.
- The effect of therapy in the parameter of Pain in ano reveals 84.0% relief in group A and 97.29% relief in group B.
- The effect of therapy in the parameter of Swelling per anum reveals 85.71% relief in group A and 93.10% relief in group B.
- The effect of therapy in the parameter of Condition of anal sphincter tone reveals 88.46% relief in group A and 93.32% relief in group B.
- Comparison of both the ligation therapy of parasurgical procedure:- Vedanasthapana Mahakashayha Coated Thread ligation shows better results on all symptoms. It was statistically very significant on pain in ano and not significant on rest all the subjective and objective parameters.
- In Group – A : Out of 15 patients complete relief was seen in the 3 patients, marked relief in 9 patients, moderate relief in 3 patients, no patient was seen with mild relief and no relief.
- In Group – B : Out of 15 patients complete relief was seen in the 8 patients, marked relief in 6 patients, moderate relief in 1 patients, no patient was seen with mild relief and no relief.

2. Probable mode of action of trial drugs

Probable mode of action of Apamarga Kshara Sutra

As per analytical study thread supports the strength of ligation while the Snahi latex being the binding agent having almost all the Apamarga kshara properties. Which in fact liberates many fold of surgical medicament actions like incision, excision debridation, scrapping, dissolution etc. simultaneously to cures the disease.

According to research work it is viewed that kshara which contains 7 coatings of Apamarga kshara on kshara sutra, cauterize the tissue of mass indirectly by its ksharana guna(Corrosive properties). The action of turmeric powder provides the effect of bacteriocidal action with healing properties. All these three drugs do not contradict each other in their actions rather supports by equal effects.

Hence kshara sutra may be termed as surgicomedicement thread rather than simple medicated thread. Kshara sutra is having the ability to perform incision with excision slowly by virtue of its control chemical cauterizing action, while this Apamarga kshara sutra is used for the ligation of Haemorrhoids, there it excises slowly with the pressure effect of ligation on the piles mass. It is having controlled chemical cauterizing action on living tissue for destruction of pile mass without disturbing any other massive injury if ligated by skilled methods.

The mode of action starts immediately after contact with the tissue level. Kshara penetrates into the invaded cells of lesion till the engorged tissue of the mass destruction or up to the removal state. During the cutting effect there must be oozing of blood which is ceased by the sclerosing effect of the therapy. Kshara coagulates the protein of tissue. Due to the coagulation during cutting of the mass there was no chance of bleeding. After the haemostatic action, no collection of debridating material is allowed to deposited by there the debriding effect of therapy. The chance of infection does not occur due to sustaining action of kshara. The pressure effect made by the Kshara sutra ligation makes mechanical strangulation of blood vessels, which in fact causes the local necrosis of pile mass and ultimately forced to falling out the pile mass. After removal of piles mass, the anal wound is supposed to be oozing during stool passing, but it does not happen so due to post effect of kshara. However the majestic, simultaneous action of kshara rules over the disease to contribute maximum benefit to the patients.

Probable mode of action of Vedanasthapana Mahakashayha Coated Thread Shaala

Shaala pacifies pitta vitiated due to Shalya karma by its Madhura rasa and Sheeta veerya. Due to its Madhura anarasa, it does the anulomana of Vata. It also has shothanashaka (Anti-inflammatory), jantughna (bactericidal), vedana-shamaka (analgesic) actions, due to its chemical composition like nor-triterpenes, tannic acid, tri-terpenic acid it possess antibacterial, analgesic, anti-inflammatory and wound healing effect.

Katphala

Due to its teekshna, laghu guna and ushna veerya, it pacifies vitiated kapha or any other doshas. Due to its ushna veerya, it reduces the vedana (Pain) by pacifying vata obstructed due to kapha and any other doshas.
Kadamba
Due to tikta, kashaya rasa, sheeta veerya and shothanashaka (anti-inflammatory) property, it pacifies provoked pitta and in turns it relieves pain. By virtue of its cincho-tannic acid, it has anti-inflammatory and analgesic property.

Padmaka
Due to kashaya, tikta rasa, sheeta virya and laghu guna, it especially pacifies provoked Pitta but it is also vatahara, kapha shamaka and rakta dosha shamaka. Due to these properties, it reduces the vedana (Pain). The chemical constituents present in its bark like prunetin, padmakastein, sacchuranin, taxifolin etc show activity on C.N.S. and acts like analgesic.

Tumba
It reduces the pain by destroying the obstructed vata due to kapha prokopaka by its katu, teekshana and ushna properties.

Mocharasa
It reduces the pain by pacifying vitiated pitta and rakta due to its kashaya rasa, sheeta veerya and snigdha guna. It also possess antipyretic action due to berberine, dictamine, xanthoplaninetc.

Shirisha
It pacifies Pitta and Rakta dosha by its Kashaya, Madhura and Tikta rasa, it pacifies Vata, and by pacifying Vata, Pitta and Rakta dosha it reduces the pain.

Vanjul (Jalvetas)
This drug reduces the vedana (Pain) by pacifying Rakta and Pittaja disorders like burning sensation and inflammation by virtue of its Kashaya, Tikta rasa and Sheeta veerya, also due to salicylic acid, it acts as analgesic, antipyretic and anti-inflammatory.

Elavaluka
By virtue of its Kashaya rasa and Sheeta virya, it pacifies the provoked Rakta dosha which in turn reduces the vedana. It has antipyretic action and is nervine tonic also.

Ashoka
Due to its Tikta, Kashaya rasa and Sheeta virya, pittaja disorders are reduced and by pacification of pitta, it reduces the vedana. It Possess analgesic, anti-coagulant effect due to tonnic acid, gallic acid etc.

Out of the above described ten drugs- Initially some of the drugs reduce the vedana by pacifying Vata dosha due to their snigdha guna and ushna veerya. Then due to snigdha guna it increases the Kapha dosha and induces sleep and also by its sedative action vedana is reduced.

Shaala, Mocharasa, and Jalvetas act as vedana-sthapaka by pacifying vata dosha due to their guru and pichchhila property and Ashoka, Mocharasa, Shirisha, Kadamba reduces the haemorrhagic pain by virtue of their rakta-stambhana and rakta-pitta shamana properties.

As per the modern point of view, some of the drugs have gallic acid, salicylic acid, hydrocyanic acid, and cincho-tannic acid act as analgesic, anti-inflammatory and mild sedative, and due to sedative property it also reduces the pain by acting on the nervous system.

CONCLUSION
After observing the overall effect of therapy, it was found that Vedanasthapana Mahakashaya coated thread ligation shows better results than Apanarma Kshara Sutra ligation on all subjective(bleeding per anum & pain in ano) and objective parameters(swelling per anum & condition of anal sphincter tone). The effect of therapy of Vedanasthapana Mahakashaya coated thread ligation was comparatively very significant on pain in ano. Vedanasthapana Mahakashaya coated thread has overcome post Kshara Sutra discomfort like pain, irritation, bleeding as occurs.

ACKNOWLEDGEMENT
At this moment I pay my obeisance to my parents Shri Narpat Singh Shekhawat & Smt. Pushp Kanwar whose blessing driven me to achieve the goal of success. I wish to express heartly thanks to my guide Dr. Rajesh Gupta (Associate Professor) and my fiancé Dr. Meenakshi, M.S. Scholar for their unforgettable support and encouragement.

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