

A COMPARATIVE CLINICAL STUDY OF APAMARGA KSHARA SUTRA LIGATION AND VEDANASTHAPANA MAHAKASHAYA COATED THREAD LIGATION IN THE MANAGEMENT OF ARSHA**Dr. Narendra Singh Shekhawat*¹, Dr. Meenakshi², Dr. Rajesh Gupta³ and Dr. O. P. Dave⁴**^{1,2}PG Scholar, PG Dept. of *Shalya Tantra*, University College of Ayurved, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan.³Associate Professor, PG Dept. of *Shalya Tantra*, University College of Ayurved, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan.⁴HOD and Professor, PG Dept. of *Shalya Tantra*, University College of Ayurved, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan.***Corresponding Author: Dr. Narendra Singh Shekhawat**PG Scholar, PG Dept. of *Shalya Tantra*, University College of Ayurved, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan.

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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, *Vedanasthapana 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 *Vedanasthapana 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 *Vedanasthapana Mahakashaya* coated thread ligation. After observing the overall effect of therapy, it was found that *Vedanasthapana 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 *Vedanasthapana Mahakashaya* coated thread ligation was comparatively very significant on pain in ano.

KEYWORDS: *Arsha, Astha Mahagada, Apamarga Kshara Sutra, Vedanasthapana 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*.^[1]

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 *Ashta Mahagada* by *Sushruta*.^[2] 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. Deshpande 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 haemorrhoidectomy in practice.

The present study is undertaken as mentioned in *Chakradatt*, 5th chapter of "*Arshachikitsaadhyaya*"^[3] and also in *Bhavprakash khand* 2/5/244.^[4] *Acharya Charaka* has mentioned *Vedanasthapana Mahakashaya* in the 4th chapter of *Sutrasthana*.^[5]

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

1. *Apamarga Kshara Sutra*: *Apamarga*, *Haridra*, *Snuhi ksheer*.
2. *Vedanasthapana Mahakashaya* Coated Thread: *Shaala*, *Katphala*, *Kadamba*, *Padmaka*, *Tumba*, *Mocharasa*, *Shirisha*, *Vanjula*, *Elavaluka*, *Ashoka*.



Fig. 1: *Apamarga Kshara Sutra*.



Fig. 2: *Vedanasthapana Mahakashaya* Coated Thread.

Apamarga Kshara Sutra: pH – 9.99, Thickness – 1.79 mm, Tensile Strength – Stable at 5 kg load.

Vedanasthapana Mahakashaya Coated Thread: pH – 6.65, Thickness – 1.8 mm, Tensile Strength – Stable at 5.5 kg Load.

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 relieved by hot sitz bath.

- 3- Radiating intolerable pain relived by oral analgesic but no disturbed 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, 1st week,

3rd week and 5th 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 signs 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% were found from sedentary life style.

RESULTS

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

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

(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.

Parameters	Mean BT	Mean AT	Mean decrease	% relief	SD	SE	P Value	S
Bleeding per anum	2.4467	0.2	2.2667	91.89	0.7988	0.2062	<0.001	HS
Pain in ano	2.4466	0.0667	2.4	97.29	1.0559	0.2725	<0.001	HS
Swelling per anum	1.9333	0.1333	1.8	93.10	0.7746	0.2	<0.001	HS
Condition of anal sphincter tone	2.0667	0.2	1.8667	90.32	0.8338	0.2152	<0.001	HS

(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.

Parameters	Group	Sum of rank	Diff.	% Relief	SD	SE	U value	P value	Res
Bleeding per anum	A	208.0	1.93	85.29	0.7073	0.1817	88.0	0.3128 (>0.05)	NS
	B	257.0	2.27	91.89	0.7988	0.2063			
Pain in ano	A	169.5	1.4	84.0	0.6325	0.1633	49.5	0.0090 (<0.01)	VS
	B	295.5	2.4	97.29	1.056	0.2726			
Swelling per anum	A	215.0	1.6	85.91	0.7368	0.1902	95.0	0.4735 (>0.05)	NS
	B	250.0	1.8	93.1	0.7746	0.2			
Condition of anal sphincter	A	207.0	1.53	88.46	0.7432	0.1919	87.0	0.2942 (>0.05)	NS
	B	258.0	1.867	90.32	0.8338	0.2153			

(SD–Standard deviation, SE–Standard error, P–Probability, Res–Result)

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

Effect of therapy	No. of patients	% Score
Complete relief (100%)	3	20.00
Marked relief (76-99%)	9	60.00
Moderate relief (51-75%)	3	20.00
Mild relief (25-50%)	0	0
No relief (<25%)	0	0

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

Effect of therapy	No. of patients	% Score
Complete relief (100%)	8	53.33
Marked relief (76-99%)	6	40.00
Moderate relief (51-75%)	1	6.67
Mild relief (25-50%)	0	0
No relief (<25%)	0	0

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 90.32% relief in group B.
- Comparison of both the ligation therapy of parasurgical procedure:- *Vedanasthapana Mahakashaya* 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 *Snuhi* 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 surgicomedicament 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 debriding 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 Mahakashaya* Coated Thread

Shaala

Shaala pacifies pitta vitiated due to *Shalya karma* by its *Madhura rasa* and *Sheeta veerya*. Due to its *Madhura anurasa*, it does the *anulomana* of *Vata*. It also has *shothanashaka* (Anti-inflammatory), *jantughna* (bacteriocidal), *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 destructing 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 *Raktaja* 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 *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 *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.

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