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## A Comparative Study to Evaluate the Efficacy of *Kshara Sutra* Ligation and Lord's Anal Dilatation in Internal Haemorrhoids

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### ABSTRACT:

**Background-** *Sushruta samhita* is the pioneer literature of *Shalya tantra* which not only describes the prevention and management of simple diseases but also the treatment of those which are of dreadful nature, *Haemorrhoids (Arshas)* being one amongst them. *Acharya Sushruta*, (su.su.33/4) has placed *arshas* in a notorious group of diseases known as – '*MAHA AGADAS*' (Diseases cured with greater difficulties).

**Aims & Objectives:** To study the comparative effect of *kshara sutra* ligation and lord's anal dilatation in *Arshas* (Haemorrhoids)

**Materials and Methods-** The patient fulfilling the clinical criteria for diagnosis of haemorrhoids were randomly selected irrespective of their age, sex, religion, occupation etc. from OPD and IPD section of Department of Shalya tantra, JIAR Hospital and from Arogyadham Ayurveda Clinic.

**Results:** KSL' scored higher on the parameters, Bleeding 78.57%, Itching 78.125% and Discharge 83.33% as compared to LAD. It can accounted to the fact that KSL reduces or cures proctorrhagia by ligation and phytochemical cauterization of hemorrhoidal mass or vascular cushions and so treats bleeding.

**Conclusion-** It was found that both the treatments i.e. *Kshara sutra* ligation and Lord's anal dilatation gave highly significant results individually (intra group) in all the clinical features, but on (inter group) comparison statistically insignificant difference was found between two groups.

**Keywords:** Haemorrhoids (*Arshas*), *Bheshaj chikitsa*, *Agni karma*, *shastra karma*, *Kshara karma*, *Kshara Sutra* Ligation.

## INTRODUCTION

The disease *Arsha* has been described as *Durnam* in *Atharvaveda*<sup>1</sup>. *Acharya Sushruta* has narrated it in the *Astamahagadas*<sup>2</sup>. *Sushruta* has described its different types

and various surgical as well as Para surgical procedures for curing it. *Charka* has also mentioned a complete chapter for this entity explaining its medical management<sup>3</sup>. According to *Vagbhata* it is an entity in which muscular



projection troubles the patient like enemy and causes obstruction of the anus<sup>4</sup>. Haemorrhoids has plagued human civilization for centuries. The word "Haemorrhoids" is derived from Greek word **Haima (bleed) + Rhoos (flowering)**, means 'bleeding'. The 'pile' is derived from the Latin word **Pila** means 'Ball'<sup>5</sup>. Piles are associated with the symptoms of Pain, Bleeding, Mucous discharge, Prolapse and if neglected, may lead to complications such as strangulation, thrombosis, portal pyaemia, fibrosis, suppuration etc. *Madhukosh* describes *arsha* as a disease which torture the life like enemy, showing it's dreadfulness<sup>6</sup>. In India, one million new cases are reported annually at the rate of 47 per 1000 people and this rate increases with age. Current statistics suggest that nearly half of the world's population suffer haemorrhoids especially when they reach the golden age of 50yrs. In addition to it, western population statistics reported that the prevalence of haemorrhoids may be around 37% with an equal frequency in men & women. "*Kshara karma*" is most effective and acceptable of all the treatment procedures because it does the actions of both shastras and *anushtas* and pacify all the three doshas<sup>7</sup>. The effect of *kshara* is praised so much that it can replace shastra karma, so does the function of *Chedna, Bhedna, and Lekhna karma* without the help of *shastra*<sup>8</sup>. It is simple, safe, effective, ambulatory, unhazardous, with minimal or no complications.

On the other hand, as far as the modern treatment is concerned the conservative treatment of haemorrhoids emphasizes on the use of laxatives, high residual diet and operative treatment involves the procedures such as - sclerotherapy, rubber band ligation, cryosurgery, infrared photocoagulation, maximal lord's anal dilatation, laser therapy, haemorrhoidectomy etc. are in practice. But unfortunately all the procedures have their own limitations with the risk of post operative complications, and high recurrence rate.

## AIMS & OBJECTIVES

1. To study the comparative effect of *kshara sutra* ligation and lord's anal dilatation in *Arshas* (Haemorrhoids).
2. To study the various effective modalities of treatment options available for *Arshas* (Haemorrhoids).
3. To evaluate the advantages and disadvantages of one treatment modality over the other.
4. To evaluate the efficacy of *kshara* in internal haemorrhoids.

## CLINICAL STUDY: MATERIALS AND METHODS

Enrollment Number 407-Ayu-06

**Selection of Patients-** The patient fulfilling the clinical criteria as for diagnosis of haemorrhoids were randomly selected irrespective of their age, sex, religion, occupation etc. from OPD and IPD section of Department of Shalya tantra, JIAR Hospital and from *Arogyadham* Ayurveda Clinic.

**Type of Study -** Randomised Clinical Trial

### Inclusion Criteria-

- Age: 20 - 60 years.
- Patients with internal haemorrhoids

### Exclusion Criteria-

The following patients were excluded from study-

1. Pregnancy
2. Ca. Rectum
3. Hepatitis, HIV patients
4. Hypertension, uncontrolled diabetes.
5. Tuberculosis
6. Leprosy
7. Rectal prolapse
8. Portal hypertension
9. Haemorrhoids associated with fistula in ano.
10. Thrombosed piles
11. Piles with Fistula in ano
12. Piles with Ulcerative Colitis
13. Chronic / Acute anal fissure

### Diagnostic Criteria.

- a. All the patients were diagnosed & assessed on the basis of following Ayurvedic & modern classical signs & symptoms of *Arsha*:<sup>11</sup>
  - *Raktasrava*(bleeding per rectum)
  - *Vedana* (pain in ano)
  - *Bibandha* (constipation)
  - *srava*(discharge)
  - Itching(*kandu*)
- b. A special proforma was designed to record all details of the patients.
- c. The routine Haematological, Urine, Stool, Biochemical & Radiological investigations were also carried out to

exclude any other pathology.

#### **Grouping -**

A total number of 40 patients of Arsha were registered for the present study.

They were randomly divided into two groups:-

#### **Group-(A) *Kshara sutra* ligation-**

The patients selected in this group (20) were subjected to *Kshara sutra* ligation procedure.

#### **Group-(B) Lord's Anal Dilatation-**

The patients selected in this group (20) were subjected to Lord's anal dilatation procedure.

#### **Procedure Of *Kshara Sutra* Ligation (Ksl) -**

##### ***Purva Karma-***

It includes preparation in relation to the patient and the procedure-

1. Written consent
2. Inj. T.T (0.5ml) IM
3. Xylocaine sensitivity test
4. Part preparation .
5. First the required instruments like Proctoscopes, Pile holding forceps, Needle holder, Round body curved needles, Artery forceps, Scissors, *Kshara Sutra* etc. are kept ready with proper sterilization.
6. The night prior to ligation, the patient is usually given light diet, afterwards nil orally.
7. Soap water enema given at prior night and also 4 hours prior to procedure.
8. N.B.M 6hr.

#### **"Method Of Preparation" :**

The ingredients used in preparation of *Kshara sutra* are-

1. Thread - Linen Barbour No-20
2. Fresh *Snuhi Ksheera*
3. *Apamarga Kshara*
4. Fine *Haridra* powder
5. *Kshar sutra* cabinet-fitted with timer, hanger, heater, U.V. light
6. Gloves
7. Swabs
8. Sealing materials

#### **Thread-**

Barbour linen thread was used because it possess good

tensile strength, with well absorption capacity and can hold the intact smearing and coatings of medicines applied.

#### **Collection of *Snuhi-Ksheera-***

*Snuhi ksheer* was collected in autumn season by giving a stab to *snuhi* plant. The latex was collected in clean container.

#### **Preparation Of *Kshara Sutra-***

The Barbour linen thread was autoclaved, after autoclaving the thread was tied on the hanger. A piece of gauze was taken and folded into a small square. It was then dipped in the fresh *Snuhi Ksheera* and the thread was coated (i.e. *Bhavana* was given) with the *Ksheera* from down to upwards. The second coating was given only when the previous coating dries. The thread is coated 11times in this manner; one after the other after the previous coating of the *Ksheera* dries completely. The threads are placed in a *Kshara sutra* cabinet for drying.

After completing the first 11 coatings of *Snuhi Ksheera*, now proceeding to coat the thread with both *Snuhi Ksheera* and *Apamarga Kshara* was done. The thread was coated with fresh *Snuhi Ksheera* in the way described above. *Apamarga Kshara* was coated on it immediately (i.e. when the thread is still wet) so that it sticks to the thread properly. This was done by sliding the thread over the heap of *Kshara* in such a way that the thread passes through the heap of *Kshara* and the *Kshara* sticks on the wet thread. The thread was coated in this way 7 times; only when the previous coat got completely dried.

The last 3 coatings were given with *Snuhi Ksheera* and *Haridra*. This was done in the same way as the previous coating mixing with substituting *Haridra* powder in place of *Apamarga Kshara*. While applying every coat, care was taken that the drug spreads evenly on all the sides of the thread and does not become thick at one spot to make knot like appearance. The thread should be smooth and even, having the same thickness throughout the length.

Care was taken to carry out the procedure in a dry atmosphere. After finishing the coating on the threads 21 times, threads were dried well in the cabinet and were then packed in sterilized glass tubes.

#### ***Pradhan Karma-***

After low spinal anesthesia, patient was kept in lithotomy position. Part was cleaned with anti septic solutions and draping was done. Position of pile masses was assessed

with *arsho yantra*.

**Catch hold:** pile mass was held with the pile mass holding forceps, slight pull was exerted over the pile mass so that its base was clearly demarcated along with the blood vessels.

**Trans fixation:** Pile mass was transfixed by passing the curved round body needle with *Kshara sutra* at its base. The trans fixation was made horizontally or vertically according to the suitable position of pile mass, preferably horizontal.

**Ligation:** After trans fixation, pile mass was ligated with *Kshara sutra*. Later the ligated pile mass was replaced inside the rectum. Then warm water irrigation was done following to T bandaging. Patient was shifted to the recovery room, adjacent to O.T.

#### ***Pashchat Karma:***

Patient was allowed orally with sips of liquids and liquid diet after 6 hours of procedure. Later patients were advised for warm sitz bath with tankan up to 10 minutes at one sitting, It relieved the pain and swelling. Also 5gm of *haritiki churna* with warm water was also given to every patient at bedtime to facilitate easy evacuation of stool. This procedure was continued up to 28 days. No effort should be made to pull out the *Kshara Sutra* ligated mass, as the immature state of removal of mass might cause pain, bleeding etc.

#### **Procedure Of Lord's Anal Dilatation-**

##### **Pre-Operative**

Same as in *Kshara sutra* ligation.

Anesthesia- Under Low spinal anesthesia

##### **Procedure**

It consists of following steps.

After the position of pile masses were assessed with proctoscope, it was followed by lubrication of index finger of both hand with xylocaine jelly and was inserted in anal canal, constricting bands were palpated then four fingers i.e. two fingers of both hand, followed by six and finally eight fingers i.e. four fingers of both hand were inserted in anal canal and dilatation was done gently by stretching at 3°clock and 9°clock positions, gentle and control stretch will be applied for 4-5 min (max). 6°clock and 9°clock positions are avoided due to less muscular support.

#### **POST OPERATIVE PROCEDURE:**

Lubricating pack was applied in anal canal to prevent oozing from small tears caused during dilatation. Patient was allowed to take sips of liquid after the procedure. Patient was given 5gm of *haritiki churna* with warm water at bedtime to facilitate easy evacuation of stool. In addition

This procedure was continued up to 28 days. patients were advised for warm sitz bath with tankan up to 10 minutes at one sitting, as relieved the pain and swelling.

#### **Duration of study :**

4 weeks

#### **Follow Up Study-**

2 Weeks.

#### **Criteria For Assessment**

The improvement provided by the therapy was assessed on the basis of classical signs & symptoms of *Arsha*. All the signs & symptoms were assigned score depending upon their severity, to assess the effect of the procedure objectively.

Effect of *kshara sutra* ligation on clinical features in 20 patients of group a (table 1) wilcoxon paired test was used for intergroup comparison effect of lord's anal dilatation on clinical features in 20 patients of group b : (table 2)

Using Mann- Whitney Test for evaluating the statistical difference between the two groups it was found that ; ( U= 156.000, T=366.000, P= .127, for constipation), (U=148.500, T=358.500, P=.120, for Pain), (U=167.500, T=377.500, P=.332 for Bleeding), (U=148.000, T=358.000, p=.126, for Itching) ,(U= 175.000 , T=385.000, p=.439 for Discharge) .

The statistical analysis showed highly significant results in all the clinical features of *Arshas* with the P <0.001 in intra group findings. But on the inter group comparison (p>0.001) statistically insignificant results were found. (Table 3)

#### **Effect Of Therapy On Clinical Features:**

In the present study 40 cases were selected and divided into two groups with 20 patients each.

#### **Bleeding per Rectum**

According to the results of study ,Group A (KSL) showed better effect on bleeding per rectum with 78.57 % relief .

In group B (LAD) relief was lesser with 72.54 % as compared to group A.

#### **Pain in Ano-**

In regard to pain in ano this study showed highly significant outcome. Group B (LAD) scored higher on this part with 90% relief, whereas 88.23% patients were clinically relieved in Group A (KSL).

#### **Constipation-**

Regarding the results of constipation, it showed highly significant response in both the groups. Constipation in Group B (LAD) with 79.59% patients was relieved whereas in group A (KSL) the relief in constipation was 77.27%.

#### **Discharge:**

The results in this symptom were better in Group A (KSL) with 83.33% relief than in group B (LAD) with 80.48%.

#### **Itching :**

The results in case of itching were good in group A (KSL) with 78.125% results as compared to group B (LAD) with 76.74% effect.

#### **Comparative Study Of Both Procedures:**

Group A i.e. *Kshara sutra* ligation (KSL) and Group B (LAD) showed better results in all clinical features independently. It was statistically highly significant. But on comparing the two therapies statistically insignificant difference was found.

## **DISCUSSION**

#### **Probable Mode Of Action Of *Kshara Sutra*:**

*Kshara sutra* is a medicated thread. It contains Barbour surgical linen thread 20No., *Snuhi Latex*, *Apamarga Kshara* and turmeric powder. 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, debridement, scraping, dissolution etc, simultaneously to cure the disease. According to research work it is viewed that 7 coatings of *Apamarga kshara on kshara sutra*, cauterize the tissue of mass indirectly by its *ksharana guna* (Corrosive properties).

The action of *Haridra* powder is to provide the effect of anti-inflammatory action as well as having bactericidal properties, so is capable to make the wound clean, healthy,

and promote early healing.

The *Snuhi Ksheera* is slightly acidic in nature but also has antibacterial property which helped to check secondary infection.

All these three drugs do not contradict each other in their actions rather supports by equal effects. Hence *kshara sutra* may be termed as surgical medicament 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.

## **CONCLUSION**

Hence from the clinical study, it was found that both the treatments i.e. *Kshara sutra* ligation and Lord's anal dilatation gave highly significant results individually (intra group) in all the clinical features, but on (inter group) comparison statistically insignificant difference was found between two groups. 'KSL' scored higher on the parameters, Bleeding 78.57%, Itching 78.125% and Discharge 83.33% as compared to LAD. It can be accounted to the fact that KSL reduces or cures proctorrhagia by ligation and phytochemical cauterization of haemorrhoidal mass or vascular cushions and so treats bleeding. In ayurvedic texts *kapha* is considered to be the main culprit responsible for itching and *apamarga* by its '*kapha vata shamaka*' *guna* decreases itching and discharge respectively. Also *kshara* has *shodana* property by virtue of which it sloughs away the debridement of necrosed tissue thus, thereby reducing the discharge.

On the other hand in case of parameters like constipation and pain in ano, in internal haemorrhoids 'LAD' gave better treatment outcome than KSL with 79.59% and 90% respectively. Anal dilatation induces relaxation of the hypertrophic and hypercontracted anal sphincter through a negative central feedback mechanism thereby relieving the pressure and providing immediate relief from pain. Constipation was relieved by the combined use of *haritaki churna* 5gm with hot water at bedtime along with the anal dilatation. *Haritaki* acts as *anulomaka* to evacuate faeces easy and smoothly and dilatation enlarges the anal passage there by reducing the stretch and pressure during passage of stool.

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**Table 1 Effect Of *Kshara Sutra* Ligation On Clinical Features In 20 Patients Of Group A :**

	N	Mean	Std. Deviation	Minimum	Maximum
Constipation _BT	20	2.20	.768	1	3
Pain _BT	20	.85	.745	0	2
Bleeding _BT	20	2.10	.788	1	3
Itching _BT	20	1.60	1.046	0	3
Discharge _BT	20	1.80	.696	1	3
Constipation _AT	20	.50	.607	0	2
Pain _AT	20	.10	.308	0	1
Bleeding _AT	20	.45	.605	0	2
Itching _AT	20	.35	.489	0	1
Discharge _AT	20	.30	.470	0	1

**Table 2 Effect Of Lord's Anal Dilatation On Clinical Features In 20 Patients Of Group B :**

	N	Mean	Std. Deviation	Minimum	Maximum
Constipation _BT	20	2.45	.605	1	3
Pain _BT	20	.50	.688	0	2
Bleeding _BT	20	2.55	.510	2	3
Itching _BT	20	2.15	.745	1	3
Discharge _BT	20	2.05	.686	1	3
Constipation _AT	20	.50	.513	0	1
Pain _AT	20	.05	.224	0	1
Bleeding _AT	20	.70	.657	0	2
Itching _AT	20	.50	.513	0	1
Discharge _AT	20	.40	.503	0	1

**Table 3 Status of Relief of Clinical features in Both the Groups**

SYMPTOMS		BT	AT	M.D.	%RELIEF
CONSTIPATION	Grp A	2.20	0.50	1.70	77.27%
	Grp B	2.45	0.50	1.95	79.59%
PAIN	Grp A	0.85	0.10	0.75	88.23%
	Grp B	0.50	0.05	0.45	90%
BLEEDING	Grp A	2.10	0.45	1.65	78.57%
	Grp B	2.55	0.70	1.85	72.54%
ITCHING	Grp A	1.60	0.35	1.25	78.12%
	Grp B	2.15	0.50	1.65	76.74%
DISCHARGE	Grp A	1.80	0.30	1.50	83.33%
	Grp B	2.05	0.40	1.65	80.48%