



## Research Article

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### CLINICAL EVALUATION AND STANDARDIZATION OF RASANJAN BHAVIT KSHARSUTRA IN ANO-RECTAL DISORDERS WITH SPECIAL REFERENCE TO ARSHA ROGA

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**ABSTRACT**

Life style related diseases are very common now a day. Ano-rectal diseases are manifested due to unhealthy eating habits and sedentary lifestyle. Piles is one such grave disease. In Ayurveda, Arsha is correlated with Piles as maximum concepts are similar. Arsha incidence increases with advancing age, at least 50% of people over the age of 50 years have some degree of hemorrhoidal symptoms. In modern medicine surgical intervention is the main line of treatment with high recurrence rates. Whereas, Ayurveda entrusts upon non invasive techniques with very low recurrence rates. Kshara sutra is one such treatment modality in ano-rectal disorders. The present paper is based on the study carried out in the Jammu Institute of Ayurveda and Research and Govt. Ayurvedic Hospital Jammu. In this research kshara sutra thread are formulated for the non surgical treatment of anorectal disorders. Rasanjana bhavita kshara sutra has been considered for the study. This kshara sutra is clinically tested, standardized and the clinical results are evaluated on the framed patients of Arsha. The paper highlights the observations and results of using Rasanjana Bhavit Ksharsutra on Arsha patients. The paper reports the difference observed in the symptoms of the patients of same complaints by using rasanjan bhavit ksharsutra.

**KEYWORDS:** arsha (piles), kshara sutra (medicated thread), arsha chedan (pilectomy).**INTRODUCTION**

Maintaining the health in healthy and eradications of diseases are the two fundamental aims of Ayurveda. To fulfill these two, Ayurvedic principles drugs are the most suitable medium. With this, it will become clear that these drugs are important components of health care. Preparation of drugs and their clinical applications require a great attention. The effort behind is to bring required results in small doses and that too by safe ayurvedic preparations. Success of the treatment depends upon the skillful preparation of genuine drugs and their application against the diseased conditions. Acarya Susruta has mentioned fourfold line of treatment for arsha roga i.e. beshaja (oral therapy), kshara (kshara patana and kshara sutra application), agni karma (cauterisation) and shastra karma (surgical removal)<sup>1</sup>. Among these four, kshara sutra has been considered a measure having less complications and Susruta has advised to apply kshara sutra in weak, feeble, fearful, difficult to treat patients<sup>2</sup>. In today's scenario these indications are very common. Therefore kshara sutra is a better intervention in treating arsha roga.

The usage and process of making of kshara sutra was firstly described by Acarya Chakrapani in his famous treatise of medicine Chakra Datta<sup>3</sup>. It is essential to know the difference between the methods of preparation of ksharsutra mentioned in Chakradatta and in other texts and other methods of preparation. So, addition of new drugs in preparation of ksharsutra is important. In Vedic period also, there is mention of number of drugs and especially. Atharaveda classified the therapies on the basis of usage of medicine. The Preparation of kshara sutra has undergone many changes and has passed through various stages before it reached the present standards of manufacturing. Thus in nutshell, it can be stated that pharmaceuticals in the field of Ayurveda especially in ksharsutra applications which have become the identity of Indian surgery has one of the supreme importance and requires continuous research. The strive is to bring more comprehensiveness in the use of kshara sutra for ano-

rectal disorders. The ano-rectal disorders like arsha a condition being well recognized as Mahagada in texts and considered as most abundant disorder among all ano-rectal disorders. Rasanjan bhavit kshara sutra acts both as cutting and healing material thread and acts differently as fast cutting than other threads.

**MATERIAL AND METHODS**

Rasanjan bhavit ksharsutra is prepared in JIAR College Pharmacy and patients of Govt. Ayurvedic Hospital, Jammu are treated with the application of Rasanjana Bhavita Kshara sutra as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP). Following the approval of the Ethical Committee of JIAR, the study was conducted in 30 adult patients with grade II and grade III hemorrhoids. Patients of OPD from Govt. Ayurvedic Hospital Jammu are treated with the application of Rasanjan bhavit ksharsutra. Findings in each case were recorded over a follow-up of four weeks (postoperative days 1,3,7, 15 and 30).

**Table 1.1: Materials used in preparation of Rasanjan bhavit ksharsutra**

| S.No. | Material used       | Quantity |
|-------|---------------------|----------|
| 1.    | Barber linen thread | 30 meter |
| 2.    | Arka ksheer         | 500 ml   |
| 3.    | Apamarga Kshar      | 70 gm    |
| 4.    | Rasanjana           | 40 gm    |

With the fresh latex of Arka ksheer (*calotropis gigantea*) a specially prepared alkaline powder known as Apamarg kshar from *Achyranthes aspera* Linn. The thread is created manually first with the latex eleven times, followed by seven alternate coating of latex and apamarg kshar, dried at 50 degree centigrade in specially designed cabinet. In the final phase, three alternate coating of latex & rasanjan powder (prepared from berberis aristata) are given and thread is dried. The threads thus prepared

are given a single fold enveloped in a polythene sachet which is sealed and packed in a glass tube along with silica bag as the desiccant.

**STANDARDIZATION OF KSHARASUTRA**

Hemorrhoids are considered first in importance among all ano-rectal abnormalities. Kshara sutra described by ancient Indian surgeon Sushruta in his famous treatise Sushruta Samhita. In Ayurvedic practice for treatment of arsha, fistula-in-ano, tumor etc. kshara sutra is employed. The technique for arsha patient involves ligation of arsha by specially prepared alkaline medicated thread (Kshara sutra) coated with herbal products.

Acharaya Chakrapani mentioned kshara sutra application in arsh roga in his treatise Chakra datta. Generation of adequate data for transfer of kshara sutra manufacturing technology to pharmaceutical industry was considered necessary and therefore detailed protocols with simple methods of analyses were evolved and employed for standardization of the ksharsutra and the raw material used for the preparation of the thread. The various reports of standardization of arka ksheer bhavit rasanjana kshara sutra are shown as per standardization done in Oasis Test House Limited, Jaipur, Rajasthan.

**ANALYSIS OF KSHARA SUTRA**

**Minimum breaking load** — Coated material of kshar-sutra was removed gently 7cm from either end. One end was tied to a hook attached to a solid support and a 250 g pan was hanged on to the other end. A 2kg weight was added to the pan. Using the following set of standard weight, 50 g increments were added to the pan each time by replacement with next higher weight: 5kg (1), 2 kg (2), 1kg (1), 500 g (1) 200g (2), 100g (1) and 50g (1): numbers in the set. Each weight was allowed to remain in the pan for a period of 2-5 seconds. The weights in the pan, including weight of the pan, at breaking point were recorded as the minimum breaking load of kshara sutra. Results of each kshara sutra breaking at or within 1 cm of either knot were discarded. Results are shown in reports.

**Length** — The length each kshara sutra was measured applying just sufficient tension to keep it straight during measurement. Results are shown in reports.

**Diameter** — Mean of 6 measurement – one each on either ends of two half-segments of kshara sutra and their centre was recorded as the diameter of kshara sutra. It was measured using a micrometer screw-gauge. Reports show the record of the results.

**Total weight** — Reports show the mean total weight of each kshara sutra.

**Weight of coated material** — The material coated on the thread of each kshara sutra was removed gently using a stainless steel spatula and weight was recorded.

**Loss on drying** — Following the method of Indian pharmacopoeia, 1985 loss on drying of coated material of each kshar-sutra is recorded in reports.

**Alkalinity (pH)** — Carbon-dioxide free water (10ml) was added to 0.1 g coated material of kshar-sutra. The mixture was vortexed for 1 minute, set aside for 15 minutes, vortexed again for 1 minute and centrifuged. Reports show the pH of clear supernatant determined using pH meter (control) Dynamics APX 175.

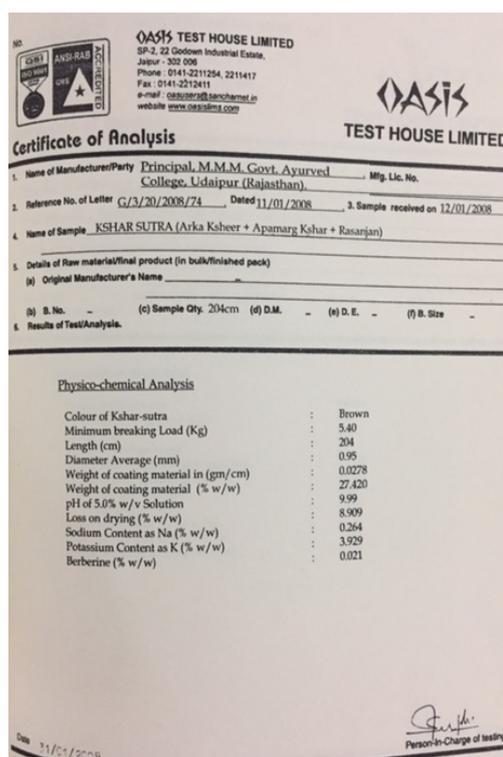
**Sodium and potassium determination** — Sodium and potassium were determined in the coated material of kshar-sutra by flame-photometry. Separate stock solution of sodium/potassium

(500mEq) was prepared by dissolving 2.9230 g sodium chloride/3.7280g potassium chloride in 100 ml triple distilled water. Separate working standard solutions containing 0.5, 1.0, 2.0, 4.0 and 5.0mEq of sodium/potassium were prepared from the respective standard stock solutions and flame-photometer (Systronic : FPM Compressor Unit 122, Flame-photometer Burner Unit 121, Digital FPM121), readings were recorded for these solutions choosing appropriate filters. Separate calibration plots for sodium/potassium were prepared. Coated material of kshar-sutra (0.10g) was shaken vigorously with 15ml triple distilled water in 50ml volumetric flask and volume was made up to the mark. The solution was filtered and the filtrate was subjected to flame photometry choosing either sodium or potassium filters. Sodium/potassium content in coated material of each kshar-sutra calculated by interpolation from the c

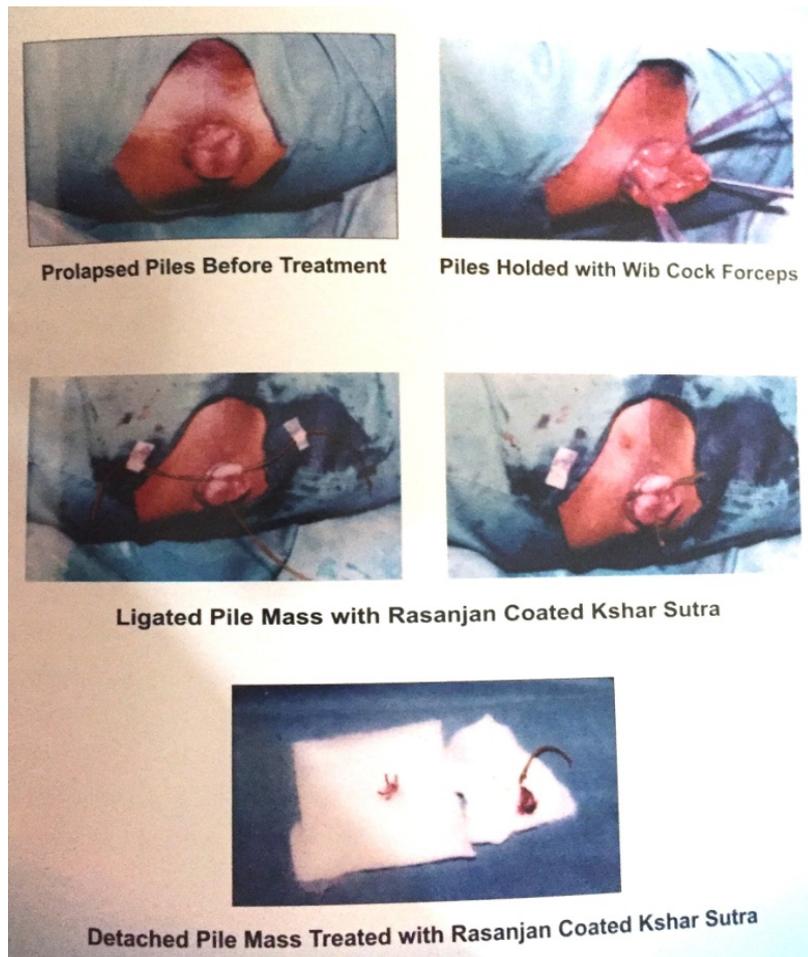
**Estimation of Berberine** — Berberine is extracted as its hydrochloride by the cold percolation method. The powdered stem bark or root is percolated successively with 2.5% acetic acid for 12 hours. It is then filtered and hydrochloride acid is added and kept at a temperature of 2-5 degree. The golden yellow precipitate of berberine-hydrochloride is separated and dried in vacuum. The yield of berberine hydrochloride was 1.9 percent from the root and 1.3% from the stem bark in *Berberis-aristata* similarly berberine-sulphate is extracted using 20% sulphuric acid. calibration plot is shown in reports.

**Table 1.2: Physio-Chemical analysis of Rasanjan coated kshara sutra**

|                                      |        |
|--------------------------------------|--------|
| Colour of Ksharsutra                 | Brown  |
| Minimum breaking load(Kg)            | 5.40   |
| Length(cm)                           | 204    |
| Diameter average(mm)                 | 0.95   |
| Weight of coating material in(gm/cm) | 0.0278 |
| Weight of coating material(%w/w)     | 27.420 |
| Ph of 5.0%w/v solution               | 9.99   |
| Loss on drying (%w/w)                | 8.909  |
| Sodium content as Na(%w/w)           | 0.264  |
| Potassium content as k (%w/w)        | 3.929  |
| Berberine (%w/w)                     | 0.021  |



**Image 1: Certificate of analysis**



**Image 2: application of rasanjana bhavita kshara sutra**

**OBSERVATIONS AND ANALYSIS OF THE CLINICAL APPLICATIONS**

Thirty patients between age group 20 years to 65 years were selected during this study. Mostly fresh cases (22), and total eight chronic cases with inadequate treatment were treated during this study. To assess the progress of the *Arsha* cutting and healing

process of wound which comprises of a number of factors like reduction in the number of exudates, reduction in pain, presence of granulation tissue, under granulation or over granulation tissue along with these the main symptoms aimed to reduce are fullness of rectum, pain and bleeding, the results are shown below

**Table 1.3: Improvement of s/s of *Arsha* patients between 2<sup>nd</sup> to 10<sup>th</sup> days**

| S. No | Sign/symptom           | Before Op. pts No. | After op. pts No. | Improvement% |
|-------|------------------------|--------------------|-------------------|--------------|
| 1     | Bleeding P/R           | 27                 | 3                 | 88.90        |
| 2     | Pain During Defecation | 30                 | 3                 | 90.00        |
| 3     | Anal irritation        | 18                 | 3                 | 83.40        |
| 4     | Constipation           | 24                 | 6                 | 75.00        |
| 5     | Prolapsed Hemorrhoids  | 30                 | -                 | 100          |

**Table 1.4: Improvement in cutting time of ligated piles**

| DAYS                 | NO. OF PATIENTS | PERCENTAGE | RANGE OF CUTTINGS                       |
|----------------------|-----------------|------------|---|
| 1 <sup>st</sup> Day  | -               | -          | -                                       |
| 2 <sup>nd</sup> Day  | -               | -          | -                                       |
| 3 <sup>rd</sup> Day  | -               | -          | -                                       |
| 4 <sup>th</sup> Day  | 3               | 10         | -                                       |
| 5 <sup>th</sup> Day  | 9               | 30         | 4 <sup>th</sup> to 7 <sup>th</sup> Days |
| 6 <sup>th</sup> Day  | 12              | 40         | -                                       |
| 7 <sup>th</sup> Day  | 6               | 20         | -                                       |
| 8 <sup>th</sup> Day  | -               | -          | -                                       |
| 9 <sup>th</sup> Day  | -               | -          | -                                       |
| 10 <sup>th</sup> Day | -               | -          | -                                       |

Table 1.5: Complete healing time of wound after healing of piles

| DAYS                 | NO. OF PATIENTS | PERCENTAGE | RANGE OF HEALING                         |
|----------------------|-----------------|------------|--|
| 1 <sup>ST</sup> DAY  | -               | -          | -  |
| 2 <sup>ND</sup> DAY  | -               | -          | -  |
| 3 <sup>RD</sup> DAY  | -               | -          | -  |
| 4 <sup>TH</sup> DAY  | -               | -          | -  |
| 5 <sup>TH</sup> DAY  | -               | -          | -  |
| 6 <sup>TH</sup> DAY  | -               | -          | -  |
| 7 <sup>TH</sup> DAY  | -               | -          | -  |
| 8 <sup>TH</sup> DAY  | -               | -          | -  |
| 9 <sup>TH</sup> DAY  | -               | -          | -  |
| 10 <sup>TH</sup> DAY | 3               | 10         | 10 <sup>th</sup> - 14 <sup>th</sup> Days |
| 11 <sup>TH</sup> DAY | 3               | 10         | -  |
| 12 <sup>TH</sup> DAY | 12              | 40         | -  |
| 13 <sup>TH</sup> DAY | 6               | 20         | -  |
| 14 <sup>TH</sup> DAY | 6               | 20         | -  |
| 15 <sup>TH</sup> DAY | -               | -          | -  |
| 16 <sup>TH</sup> DAY | -               | -          | -  |
| 17 <sup>TH</sup> DAY | -               | -          | -  |
| 18 <sup>TH</sup> DAY | -               | -          | -  |
| 19 <sup>TH</sup> DAY | -               | -          | -  |
| 20 <sup>TH</sup> DAY | -               | -          | -  |

Table 1.6: Summarized results of Rasanjana bhavita kshar sutra

| S.No. | Symptoms           | 't' value | P value | % Relief |
|-------|--------------------|-----------|---------|----------|
| 1     | Fullness of rectum | 8.81      | <0.001  | 81.48    |
| 2     | Relief in Bleeding | 5.45      | <0.001  | 95       |
| 3     | Relief in pain     | 7.95      | <0.001  | 77.27    |

## RESULTS AND DISCUSSION

In the study incidence of Arsha had less prevalence in younger age. The service holder patients were more prone due to long sitting & irregular regime. Vata pittaja prakriti patients and patients with history of hereditary cases were found more due to congenital weakness in vein wall. It might be as per description of Charaka in Sahaja arsha<sup>4</sup>. Patient of arsha at 7 o'clock position and of first degree were more in number.

The patients were treated with rasanjana bhavita kshara sutra under all aseptic conditions and necessary precautions. Patients showed fast cutting and remarkable recovery from symptoms. The results observed indicate that rasanjana bhavita kshara sutra is better in curing bleeding per rectum, pain during defecation, anal irritation and fullness of rectum. An important aspect observed during this application is cutting and healing is fast in the cases of arsha treated with this ksharsutra. The whole procedure of ksharsutra ligation is simple, safe technique with minimum discomfort and requires no prolonged hospitalization.

## CONCLUSION

Rasanjana bhavita kshara sutra assures great prospects in the ayurvedic management of arsha roga. It showed great effect both in cutting as well as in healing time. Complications are negligible. As arsha roga is the result of mandagni<sup>5</sup> (slow digestion) therefore patients should be advised pathya ahara and vihara along with the treatment to avoid recurrence of the disease. Rasanjana has many properties. It helps in reducing bleeding in piles and enhances healing after cutting of ligated pile mass. Therefore Rasanjan

bhavita kshar sutra promises a breakthrough in the ayurvedic treatment of arsha roga. Further researches should be carried out in this direction to promote this very treatment modality.

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