

PHARMACEUTICAL PREPARATION & STANDARDIZATION OF ARKA-KSHEER BHAVIT KSHARSUTRA FOR ANORECTAL DISORDERS W.S.R. TO ARSHA ROGA

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ABSTRACT

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 *ksharsutra* thread is formulated, standardized and applied for the non surgical treatment of *Arsha* patients. *Arka ksheer bhavit ksharsutra* has been considered along with the analysis of the raw material used. This *ksharsutra* 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 *Arkaksheer Bhavit Ksharsutra* on *Arsha* patients.

Keywords: *Arsha* (piles), *ksharsutra* (medicated thread), *arsha chedan* (pilectomy)

INTRODUCTION

Maintaining the health in healthy and eradication of diseases are the two fundamental aims of *Ayurveda*. To fulfill these Ayurvedic principles, drugs are the most suitable media to achieve the aim. Preparation of drugs and their clinical applications requires a great attention. Success of the treatment depends upon the skillful preparation of genuine drugs and their application against the diseased conditions. *Arsha Roga* has become very common disease in modern world due to current lifestyle, sedentary habits and unwholesome diet. *Ayurveda* offers a distinct treatment modality for ano-rectal disorders. *Acharya Charaka*^[1] says *Arshas* is the *adhimamsavikara* due to vitiation of *mamsadhatu* leading to *sirashaithilya* (loss of venous tension) in

guda. *Acharya sushruta* has suggested to use *kshara sutra* as a treatment preference^[2]. *Acarya Chakradatta* has mentioned the procedure of *Kshara sutra* in detail^[3]. The Preparation of *kshara sutra* has undergone many changes and has passed through various stages before it reached the present standard of manufacturing. Thus in nutshell, it can be stated that the 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. So, addition of new drugs in preparation of *ksharsutra* is important. The Ano-rectal disorders like *Arsha* is a well recognized condition known as *Mahagada* in texts and considered as most abundant

disorder among all Anorectal disorders. Therefore present study is carried out to know the clinical efficacy of *Arka Ksheer Bhavita Kshar sutra* in comparison to other threads in cases of *Arsha* along with is standardization.

MATERIALS AND METHODS:

Arka ksheer bhavit ksharsutra was prepared in the Pharmacy of JIAR, Jammu and the study was conducted in 30 adult patients of Govt. Ayurvedic Hospital, Jammu as per International conference of Harmonization Good Clinical Practices Guidelines (ICH-GCP).

INCLUSION CRITERIA:

1. Subjects of age group between 20-60 years.
2. Subjects presenting with classical subjective and objective features of *Raktaarshas*.
3. Bleeding Hemorrhoids of grade II and grade III and grade IV.

EXCLUSION CRITERIA:

1. Subjects less than 20 years and more than 60 years of age.
2. Subjects suffering from systemic disorder like Diabetes, Tuberculosis, IHD, CHD, HIV, HbSAg etc.
3. Subjects suffering from Hemorrhoid with Ulcerative Colitis, Liver disorders and other chronic diseases and bleeding disorders.

BLOOD INVESTIGATIONS-CBC, CT, BT, RBS, ESR, HIV, Hb

Table 1.1: Showing Materials used in preparation of *Arka ksheer Bhavita ksharsutra*

S.No.	Material used	Quantity
1.	Barber linen thread	30 mts
2.	<i>Arka ksheer</i>	500 ml
3.	<i>Apamarga Kshar</i>	70 gm
4.	<i>Haridra</i>	40 gm

Preparation of Kshara sutra

With the fresh latex of *Arka ksheer* a specially prepared alkaline powder known as *Apamarg kshar* from *Achyranthes aspera*. Linni is prepared. The thread is treated manually first with the latex eleven times, followed by seven alternate coating of latex

4. Subjects suffering from Fissure, Fistula in ano and CA Rectum.
5. Bleeding Hemorrhoids of 3rd and 4th degree pile mass and Anemia with Hb<10gm%.

ASSESSMENT CRITERIA:

Patients of Govt. Ayurvedic Hospital Jammu were treated with the application of *arka ksheer bhavit ksharsutra*. Findings in each case were recorded over a follow-up of three weeks (postoperative days 1, 3, 7, 15 and 21)

SUBJECTIVE PARAMETERS:

For this study scoring grading method for improvement was used (0-3)

[**Good relief-3, Moderate relief-2, Mild relief-1, No relief-0**] and three symptoms were mainly selected for assessment,

1. Fullness of rectum,
2. Pain,
3. Bleeding per rectum

OBJECTIVE PARAMETERS:

ON PROCTOSCOPY -Number of internal hemorrhoid, Size of hemorrhoid, Position of haemorrhoidal mass.

and *Apamarg kshar*, dried at 50 degree centigrade in specially designed cabinet. In the final phase, three alternate coatings of latex & *Haridra* powder 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 a silica bag as the desiccant. In this preparation of *ksharsutra*, *Arka ksheer* is used in



Image 1 *Arka ksheera*



Image 2 *Apamarg kshara*



Image 3 *Haridra*



Image 4 *Arka ksheera bhavita kshara sutra*

STANDARDIZATION OF **KSHARA SUTRA**:-

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

Acharaya Chakrapani mentioned *kshar-sutra* application in *arsh roga* in his treatise "*Chakra dutta*". Generation of adequate data for transfer of *kshar-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 ksharsutra* are shown as per standardization done in Oasis Test House Limited, Jaipur, Rajasthan.

place of *Snuhi ksheer* respectively.

ANALYSIS OF **KSHARA SUTRA**:-

Minimum breaking load — Coated material of *ksharsutra* was removed gently 7 cm from either end. One end was tied to a hook attached to a solid support and a 250g pan was hanged on to the other end. A 2 kg 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: 5 kg (1), 2 kg (2), 1 kg (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 *ksharsutra*. Results of each *ksharsutra* breaking at or within 1 cm of either knot were discarded, Results are shown in reports.

Length — The length of each *ksharsutra* 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 *ksharsutra* and their centre was recorded as the diameter of

ksharsutra. 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 *ksharsutra*.

Weight of coated material — The material coated on the thread of each *ksharsutra* 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 *ksharsutra* is recorded in reports.

Alkalinity (pH) — Carbon-dioxide free water (10ml) was added to 0.1 g coated material of *ksharsutra*. 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 *ksharsutra* 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 (Systronice: 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 *ksharsutra* (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 *ksharsutra* calculated by interpolation from the calibration plot is shown in reports.

Curcumin Determination — Content in coated material of *ksharsutra* was determined by preparative thin layer-chromatography coupled with UV spectroscopy. The solution of coated material of *ksharsutra* (10ml) prepared for the estimation of turmeric, as described in the preceding paragraph, was allowed to evaporate at room temperature to about 0.1 ml and whole of the concentrate was applied quantitatively on one part of the chromatoplate. Second part of the chromatoplate was loaded with 50µl 1 mg/ml solution of reference curcumin in acetone, and to the third part (blank) was applied with 50ul acetone. The chromatoplate was developed in chloroform, methanol (49:1). The yellow coloured curcumin zones and the corresponding blank zone were marked, and extracted with 5 x 4 mL methanol. Volume of methanol extracts was made up to 25 ml in each case and absorbance of methanol solutions of coated material of *ksharsutra* and curcumin were recorded, after suitable dilution, against blank at 418nm. Curcumin content of coated material of *ksharsutra* is shown in report.

Turmeric determination — coated material of *ksharsutra* (0.2g) and turmeric (0.05g) were moistened separately with 0.5 ml %v/v hydrochloric acid. The mixture was extraction after 5 minutes with 4x5 ml acetone. Time for each extraction was 10 minutes with 30 seconds vortexing for 5 and 10 minutes. Volume of respective pooled extracts separated by centrifugation was made up to 25 ml using acetone. Absorbance of the extracts was determined, after suitable dilution, at 418 nm against acetone blank. Percentage of turmeric in the coated material of *ksharsutra* was calculated using the absorbance of turmeric as reference. Reports show the results.

Table 1.2: Physio-Chemical analysis (*Arka ksheer coated ksharsutra*)

Colour of Ksharsutra	Orange
Minimum breaking load(Kg)	5.36
Length(cm)	203
Diameter average(mm)	1.20
Weight of coating material in(gm/cm)	0.0244
Weight of coating material(%w/w)	28.420
Ph of 5.0%w/v solution	9.90
Loss on drying (%w/w)	8.512
Sodium content as Na(%w/w)	0.145
Potassium content as k (%w/w)	3.352
Curcumin (%w/w)	0.052
Turmeric (%w/w)	4.12

OBSERVATIONS AND ANALYSIS OF THE CLINICAL APPLICATIONS

Thirty patients between age group 20 yrs to 60 years were selected during this study, mostly fresh cases (22), and total eight chronic cases with inadequate treatment are 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 amount of exudates, reduction in pain, presence of granulation tissue, under granulation or over granulation tissue along with these the main symptoms aimed are to reduce are fullness of rectum, pain and bleeding, the results are shown below.

Table 1.3: Showing improvement of s/s of *Arsha* patients between 2nd to 10th days

S. No	Sign/symptom	Before Op. pts No.	After op. pts No.	Improvement%
1	Bleeding P/R	24	6	75
2	Pain During Defecation	24	6	75
3	Anal irritation	21	0	100
4	Constipation	30	9	70
5	Prolapsed Hemorrhoids	30	-	100

Table 1.4: Showing improvement in cutting time of ligated piles

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

Table 1.5: Showing complete healing time of wound after healing of piles.

DAYS	NO. OF PATIENTS	PERCENTAGE	RANGE OF HEALING
1 ST DAY	-	-	-
2 ND DAY	-	-	-
3 RD DAY	-	-	-
4 TH DAY	-	-	-
5 TH DAY	-	-	-
6 TH DAY	-	-	-
7 TH DAY	-	-	-
8 TH DAY	-	-	-
9 TH DAY	-	-	-
10 TH DAY	-	-	12 TH -16 TH DAYS
11 TH DAY	-	-	-
12 TH DAY	3	10	-
13 TH DAY	3	10	-
14 TH DAY	9	30	-
15 TH DAY	6	20	-
16 TH DAY	9	30	-
17 TH DAY	-	-	-
18 TH DAY	-	-	-
19 TH DAY	-	-	-
20 TH DAY	-	-	-

RESULTS: The results observed are shown with the p value, t value and percentage of relief in the complaints of the *arsha* patients.

Table 1.6: Showing summarized results of *arka ksheera bhavita kshar sutra*.

S.No.	Symptoms	't' value	P value	% Relief
1	Fullness of rectum	17.67	<0.001	90
2	Relief in Bleeding	5.07	<0.001	89.47
3	Relief in pain	4.31	<0.01	61.50

DISCUSSION

The patients are treated with *Arkaksheer bhavit kshar-sutra* under all aseptic conditions with necessary precautions and patients show fast cutting and remarkable recovery from the ailing symptoms. The whole procedure of *ksharsutra* ligation is simple, safe technique with minimum discomfort and requires no prolonged hospitalization. The results observed indicate that *Arka ksheer bhavit ksharsutra* is better in curing bleeding per rectum, pain during defaecation, 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 *ksharasutra*. The *Arkaksheer Bhavit Ksharasutra* has shown a sustained and consistent improvement in *arsha* patients. *Arkaksheer bhavit kshar-sutra* acts as a curette for the *arsha* due to its proteolytic and irritant action of the caustics. The chances of recurrence are almost nil and the cutting and healing of the *arsha* (haemorrhoid) treated with *arkaksheer bhavit ksharsutra* is simultaneous.

CONCLUSION

The study suggests several opportunities as this procedure is not having major surgical interference, no contra indications to hypertensive, diabetic and cardiac patients. *Arkaksheer Bhavita Ksharsutra* is safe, cost effective, and free from any side effects. The work shows the new unexplored special features of *ksharsutra* therapy. *Arka ksheer bhavit ksharsutra* acts both as cutting and healing material thread and acts differently as fast cutting than other threads records.

REFERENCES

1. Vaidya Jadavaji Trikamji Acharya (editor). Commentary: Ayurveda Deepika of Chakrapanidatta on Charaka Samhita of Charaka, Chikitsa sthana chapter 14, verse no.5-6, Varanasi: Chowkhambha Surbharti Prakashan;Reprint2005;501
 2. Vaidya Jadavaji Trikamji Acharya, Narayanram Acharya Kavyatirtha (editor). Commentary: Nibandhsangraha of Dalhanacharya on Sushrut Samhita of Sushruta, Chikitsa sthana chapter 17, verse no.29 Varanasi: Chowkhambha Surbharti Prakashan;Reprint2003, 468
 3. Tripathi J. P. Hindi commentary on Chakradatta of Chakradatta, Chapter 5, verse no. 148. Varanasi: Chowkhamba Sanskrit Series, 66
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