AYURPUB.com
INTERNATIONAL AYURVEDA PUBLICATIONS

RESEARCH ARTICLE *ISSN 2456-0170*

EFFICACY OF HARTALA BHAVITA KSHARASUTRA ON 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 are 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. Chronic constipation is a most common cause of bleeding haemorrhoids. 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. Ayurvedic physician are treating this disease successfully with indigenous formulations and surgery. 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 Hartal bhavita kshara sutra thread is formulated for the non-surgical treatment of anorectal disorders. This kshara sutra is clinically tested, standardized and the clinical results are evaluated on the framed patients of Arsha. The paper report shows the difference observed in the symptoms of the patients of same complaints by using Hartal bhavit ksharsutra.

KEYWORDS: *Arsha (piles), ksharsutra (medicated thread), arsha*

INTRODUCTION

The incidence of Arsharoga has become more amongst the people of modern India due to sedentary life style, alcoholism, constipating diet. Acharya Charaka[1]. says Arshas is the adhimamsavikara due to vitiation of mamsadhatu leading to sirashaithilya (loss of venous tension) in guda. Maintaining the health in healthy and eradications of diseases are the two fundamental aims of Ayurveda. To fulfill this aim, drugs are the most suitable medium. Preparation of drugs and their clinical applications requires 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 (sugerical removal)[2]. Among these four, kshara sutra has been considered as a measure having less complications and Sushruta has advised to apply kshara sutra in weak, feeble, fearful, difficult to treat patients [3]. 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[4]. 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. 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 pharmaceutics in the field of Ayurveda especially in ksharsutra applications which have become the identity of Indian surgery is 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 is a well-recognized condition known as Mahagada in texts and considered as most abundant disorder among all ano-rectal disorders.

According to Ayurved parkash[5], Hartal have teeshna, ushna guna and vrana nashak properties ,so the Hartal bhavit kshara sutra acts both in cutting of piles mass and in healing of wound and acts differently as fast cutting due to it's teeshna ,usna guna than other threads records .

AIM AND OBJECTIVES

1. Analytical study of hartal bhavit ksharsutra.
2. clinical study of hartal bhavit ksharsutra on Arsha roga.

MATERIALS AND METHODS

Hartal 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, 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.
4. Subjects suffering from Fissure, Fistula in ano and CA Rectum.

Assessment Criteria

Patients of Govt. Ayurvedic Hospital Jammu were treated with the application of Hartal

bhavit ksharsutra. Findings in each case were recorded over a follow-up of three weeks (postoperative days1,3,7,15 and21)

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.

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

Method Used For Hartal Bhavit Kshar Sutra Preparation

Table 1.1 Showing Materials used in preparation of Hartal Bhavita ksharasutra

S.No.	Material used	Quantity
1.	Barber linen thread	30 mts
2.	*Arka ksheer*	500 ml
3.	*Apamarga Kshar*	70 gm
4.	*Hartal*	40 gm

With the fresh latex of Arka ksheer a specially prepared alkaline powder known as Apamarga 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 and Apamarg kshar, dried at 50 degree centigrade in specially designed cabinet. In the final phase, three alternate coatings of latex & Hartal 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, Hartal is used in place of Haridra respectively.

Standardization of Ksharsutra

The term standardization implies application of suitable methods and process by which optimal conditions are ensured for obtaining predictable results and products which confirm a certain set of standards in term of quality, purity, stability, safety and shelf-life. Standardization has a great role in knowing the genuineness/efficacious character of a drug. So standardization of Ayurvedic formulation is the need of hour. 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 Hartal Bhavita Ksharsutra are shown as per standardization done in Oasis Test House Limited, Jaipur, Rajasthan.

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 I 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 vortexes for 1 minute, set aside for 15 minutes, vortexes 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.

Estimation of Arsenic ─ 1 gram sample is taken into a distillation flask with a solution of FeCl3, HCl, and CaCl2 (FeCl3-300 gram, CaCl2 - 400 gram, HCl 600ml per litre of solution). The distillation is carried out 110^{o}c -112^{o}c and the distillate is absorbed into a conical flask is distilled water from the solution obtained 50ml of HCl is added to the distillate and a rapid stream of H_2S is passed through it for 10 minutes. The precipitate is allowed to stand for 1 hour and filtered through a dried and weight filtered crucible. The precipitate is washed with 8N HCl saturated with H_2S. It is followed by successive washing with ethanol, CS_2 (To remove any free sulphur which may be present) and again with ethanol. The precipitate is dried at 105^{o}c to constant

weight and weighed as AS2S3 from which arsenic content can be calculated.

Table 1.2 Physio-Chemical anaylsis (Hatala coated ksharsutra)

Colour of Ksharsutra	yellow
Minimum breaking load(Kg)	5.43
Length(cm)	204
Diameter average(mm)	1.10
Weight of coating material in(gm/cm)	0.0285
Weight of coating material(%w/w)	38.129
Ph of 5.0%w/v solution	9.80
Loss on drying (%w/w)	7.103
Sodium content as Na(%w/w)	0.135
Potassium content as K (%w/w)	3.164
Arsenic sulphide (%w/w)	60.05

Observations and Analysis of the Clinical Applications

After obtaining consent, thirty patients between age group 20 yrs to 60 yrs 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	21	12	42.86
2	Pain During Defecation	27	15	44.45
3	Anal irritation	21	6	71.43
4	Constipation	27	3	88.89
5	Prolapsed Haemorrhoids	30	–	100

Figure 1 showing % improvement of S/S of treated patients

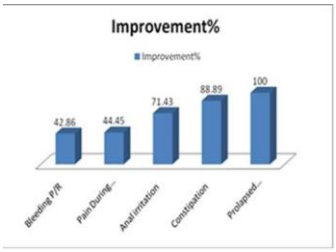

Table 1.4 Showing improvement in cutting time of ligated piles

DAYS	NO. OF PATIENTS	PERCENTAGE	RANGE OF CUTTINGS
1st Day	-	-	-
2nd Day	-	-	-
3rd Day	3	10	-
4th Day	6	20	-
5th Day	15	50	3rd to 6th Days
6th Day	6	20	-
7th Day	-	-	-
8th Day	-	-	-
9th Day	-	-	-

10th Day	-	-	

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

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

RESULTS: The Statistically calculated 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 statistically calculated results of Hartal bhavita kshar sutra

S.No.	Symptoms	't' value	' P' value	% Relief
1	Fullness of rectum	8.99	<0.001	75
2	Relief in Bleeding	3.34	<0.01	75
3	Relief in pain	13.53	<0.001	75

DISCUSSION

As per the study, linen thread used strengthens the process of ligation while the arkaksheer latex acts as a binding agent, having almost all the apamarga kshara properties intact, The arkaksheer has laghu,tikshna,lekhan,vishagna,vranavishoda na guna (virtues) and due to these properties it treats arsha with its chedana, lekhana, vranavishodhana karma which in fact have surgical actions like incision, excision debridation, scrapping and shows action like hemostatic, antiseptic, healing, etc., which acts simultaneously to cure the arsha. According to study, it is viewed that coatings of apamarga kshara on kshara sutra

cauterize the tissue of the ligated masses indirectly by its ksharana guna (corrosive properties). The action of hartal powder provides the effect of antiseptic(vishagna) action with healing(vranaropaka) properties. All these three drugs do not contradict each other in their actions infact strerngthen each other in giving the required results. Apamarga kshara sutra has the ability to perform incision and excision gradually by virtue of its cauterizing action.The mode of action of kshara sutra starts immediately after contact with the tissue. Kshara invades into the cells of the lesion till the destruction of the mass occurs or up to the removal of the pile mass.while cutting of mass,the loss of blood is ceased by the sclerosing effect of the kshara by its coagulating property of protein. The probability of infection is least due to the anti-infective action of kshara. The mechanical strangulation of the blood vessels occurs due to pressure effect made by the kshara sutra ligation, which in fact causes the local necrosis of pile mass and then forces falling out of the pile mass during defecation. The patients are treated with Hartal bhavit kshar-sutra under all aseptic conditions with necessary precautions and patients show fast cutting and remarkable recovery from the ailing symptoms.

CONCLUSION

The study suggests several opportunities as this procedure is not having major surgical interference, no contra indications to hypertensive, diabetic and cardiac patients. The whole procedure of ksharsutra ligation is simple, safe technique with minimum discomfort and requires no prolonged hospitalization. The results observed indicate that Hartal bhavit ksharsutra is better in curing bleeding per rectum, pain during defaecation, anal irritation and fullness of rectum. An important aspect during this application observed is that cutting in comparison to other ksharsutra is fast and healing is delayed in the cases of arsha treated with this kshar-sutra. Hartal bhavita kshar-sutra acts as a curette for the arsha due to its proteolytic and irritant action of the caustics. The chance of recurrence is almost nil and the cutting and healing of the arsha (haemorrhoid) treated with Hartal bhaviat ksharsutra is simultaneous. Hartal Bhavita Ksharsutra is safe, cost effective, and free from any side effects. The work shows the new unexplored special features of ksharsutra therapy. Hartal bhavita ksharsutra showed great effect both in cutting as well as in healing.

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Source of support: Nil,
Conflict of interest: None Declared

Cite this article as
Shaily Jalan : Efficacy of Hartala Bhavita Ksharsutra on Arsha Roga; ayurpub; III(4): 1006-1013

Apamarga kshara

Hartala bhavita Ksharasutra

Snuhi ksheera