International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR)

ISSN:2347-6567

IJAMSCR |Volume 7 | Issue 3 | Jul - Sep - 2019
www.ijamscr.com

Research article *Medical research*

Randomized comparative clinical trial of udumbar kshara sutra andsnuhi kshara sutra with standard apamarg kshara sutra in the patient of bhagandara (fistula in ano)

Kumari Nidhi Shree Bibhuti[1] Mrutyunjay Panda[2] Siddaram Arawatti[3]

[1]*MD, Shalya Tantra, Major SD Singh PG medical Collage, Fatehgarh, Farrukhabad*
[2]*Prof and HOD department of Shalya Tantra, Major SD Singh PG medical Collage, Fatehgarh, Farrukhabad*
[3]*Asso prof. department of Shalya Tantra, Major SD Singh PG medical Collage, Fatehgarh, Farrukhabad*
Corresponding Author: Kumari Nidhi Shree Bibhuti

ABSTRACT

Bhagandara(fistula in ano) is one of the commonest diseases occurring in ano-rectal region. The incidence of a fistula-in-ano developing from an anal abscess ranges from 26% to 38%. The surgical management of Bhagandara caries several problems and complications as severe pain for a long period during dressing. Operative raw site is the potential space for infection by faeces. Hospitalization and non-ambulatory life for a long period, Retention of urine, Incontinence. Ksharasutra is a successful novel drug delivery system in which a special thread smeared with Kshar and other herbs is applied to induce both mechanical and chemical effect which helps in cutting and healing of the Fistula tract. In this clinical study total 30 patients of Bhagandara was registeredfrom OPD and IPD of Shalya Tantra department, Major S.D. Singh P.G. Ayurvedic Medical College, Farrukhabad, and randomly divided in three groups. In this comparative clinical study all the subjective parameters like pain, itching and objective parameter like swelling, discharge, unit cutting time showed statistically significant results in all groups.It was found that Udumbar Ksharasutra was more effective than Snuhi & Apamarg Ksharasutra. It is cost effective and easy to apply & Patient treatedwith Udumbar Ksharasutra found better than Snuhi & Apamarg. Hence, it can be used as an alternative approach for management of Bhagandar.

Keywords: Bhagandara (fistula in ano), Apamarg Ksharasutra, Udumbar Ksharasutra, Snuhi Ksharasutra.

INTRODUCTION

Bhagandara (Fistula in ano) is some of the oldest diseases known to the ayurvedic medical science . History of medical literature available today very clearly speaks that the disease, Fistula in ano affects more reputations of surgeons who deals with it.The period of Acharya Sushruta was certainly golden era in the field of Ayurvedic surgery. A bird‟s eye view of the Ayurvedic medical history in general and surgical history in particular reveals that various surgical procedures performed in those days appears as miracles today.Sushruta Samhita is one of the most ancient,

classical textbook of Shalya Tantra included Bhagandara in AshtaMahagada (Eight grave diseases) which are very difficult to manage. The incidence of Bhagandara developing from anorectal abscess ranges from 26 to 38%. The true prevalence of Fistula in ano is unknown. According to a recent study conducted on prevalence rate of Fistula in ano is 8.6 cases per 1,00,000 population, in Men, the prevalence is 12.3 cases and in Women 5.6 cases per 1,00,000 population, Male: Female ratio is 1.8:1.Mean age of patient is 38.3 year. In modern science Fistula in ano treatment seems to have limited scope due to high chance of recurrence and some of them complicates as incontinence. The reported rate of recurrence is 0-18% following standard fistulotomy, and the rate of stool incontinence is 3-7%. In fistulectomy a big deeper wound is created and yet no advantage shown over fistulotomy.

The Pidaka occurring at perianal region create tear in the area of pelvic, rectum and urinary bladder is called Bhagandara. In its unsuppurated stage it is called pidaka, while it is called Bhagandara when it is in stage of suppuration. Sushruta has told the difference between a simple superficial boil and Bhagandara. Eruptions developing inside the anus, accompanied with less pain and swelling and disappearing quickly is different from Bhagandara. But eruption which develops in the area of two angulas around the anus, deep seated, associated with pain and fever is Bhagandara pidaka . According to Madhavkara a painful boil which is presented within two fingers of the anal opening, When bursts is known as Bhagandara. Bhagandara is situated about one or two fingers away from the anal margin within the rakta and mansadhatu.Acharya Sushruta while stating the pathogenesis of shatoponaka Bhagandara consist of mansa and shonita as dushya or adhishstana of Bhagandara. Besides above, sushruta has counted the seventh layer-the 'Mansadhara-kala' as the adhishthana for Bhagandara.

Kshara Karma (Chemical cauterization), a para surgical measures have been employed in the management of Bhagandara either alone or in combination as auxiliary to surgical procedure. Ksharasutra is a successful novel drug delivery system in which a special thread smeared with Kshar and other herbs is applied to induce both mechanical and chemical effect which helps in cutting and healing of the Fistula tract.

Ksharasutra therapy requires a minimal setup, minimal equipment's and instruments. It is minimal invasive Para surgical measure. Moreover, the best benefit to the patient is that he remains ambulatory during the whole course of treatment. It is simple, safe and comparatively sure treatment and being globally accepted. Till date many researches have been carried out in different Postgraduate institute of Ayurveda. These research works have been conducted on Snuhi Ksharasutra, Madhu Ksharasutra, Palash Ksharasutra, Guggulu Ksharasutra, Udumbar Ksheer Sutra, Papaya Ksheer Sutra, Arka Ksheer Sutra, Nimadi Ksharasutra etc. for the management of Bhagandara. The standard Apamarg Ksharasutra is prepared by repeated 21 coatings of Snuhi Ksheer, Apamarg Kshar and Haridra Churna. Although the standard Apamarg Ksharasutra is successfully used in the management of Bhagandara. Hence, this clinical trial was plannedto find out the best in Snuhi kshar and Apamarg Kshar and udumbar Ksharasutra in treatment of Bhagandara (fistula in ano).

AIMS AND OBJECTIVES

1. To compare the effect of Udumbar, Snuhi andApamarg Ksharasutra in the management of Bhagandara."
2. To observe the rate of cutting and healing.

MATERIALS AND METHODS

Total 30 patient from OPD and IPD of Shalya Tantra department, Major S.D. Singh P.G. Ayurvedic Medical College, Farrukhabad was selected. Also patients from other institutions and hospitals was included. All the patients randomly divided in three groups.

- Group A: (10 Patients): The patients of this group was treated with Snuhi Ksharsutra.
- Group B: (10 Patients): The patients of this group was treated with Udumbar Ksharsutra.
- Group C: (10 Patients): The patients of this group was treated with Apamarga Ksharsutra.

Inclusion Criteria

1. Irrespective of sex, religion, occupation, economic status and education status.
2. Patients within the age of 20-60yrs.
3. Patients with low anal fistula (bhagandara).
4. Patients who were co-operative and ready give written consent.
5. Patients who was be ready to give written informed consent.

Exclusion Criteria

1. Patient suffering from systemic diseases was excluded.
2. Patient with high rectal fistula was be excluded.
3. Patient suffering Ca. of rectum, HbsAg and HIV was alsoexcluded.
4. Patient suffering from ulcerative colitis, crohn's disease was be excluded from the study.

Diagnostic Criteria

Diagnosis was done on the basis of chief complaints of patient, past history, history of associated disease, inspection, palpation, digital examination, Proctoscopy and required investigations as per specially designed proforma.

PER RECTAL EXAMINATION

- Digital examination: This was done by introducing index finger lubricated with Xylocaine jelly into the anal canal after explaining about the examination.
- Proctoscopy:. This examination was carried out after digital examination. The proctoscope was lubricated with Xylocaine jelly and then it was slowly introduced in anus. Obturator was removed and after examination the proctoscope was withdrawn slowly. It gives complete idea about the mucosa of anus and up to the middle half of rectum and all findings was noted viz. an internal opening, like a pit or nodule. Site of internal opening was noted. If pile mass was present, it was also noted.
- Examination with dye (Methylene blue): Methylene blue was installed from external opening while doing proctoscopic examination. If the tract is complete, dye was come out from internal opening which can be seen. It is helpful to locate the other (generally internal) opening. If there are multiple openings, this test was help to locate them.

Investigations

Routine Haematological and Biochemical parameters were assessed to rule out the pathological conditions.

Informed consent

An informed written consent was obtained from all included subjects. The consent form was prepared in accordance with guideline of WHO Research Ethics Committee (ERC).This informed consent form (Annexure) has two parts: The patient information sheet (included subjects received a copy) Certificate of consent (signed by the subjects, attached with the research proforma).

Duration of study

28 days The effect of trial was assessed on the basis of improvement in sign, symptoms. During the trial drug period the patients were advised to adopt following dietary regimen regarding pathya-apthaya.

Statistical Methods

The data generated in the clinical study was analysed by applying students't' test. The obtained results were interpreted as – Non-significant (NS)P > 0.05, Significant(S) P< 0.05 or P<0.01, Highly significant (HS) P<0.001

Subjective Criteria

- Pain
- Itching

Objective Criteria

- Swelling
- Discharge
- Local tenderness
- Length of tract
- Unit Cutting Time

Follow Up

Cases are followed for another one months for recurrence of the symptom if any.

Preparation of Udumabar Ksharasutra

Method of Preparation

Ksharasutra is prepared in a well-equipped Ksharasutra lab. Drugs required for Ksharasutra preparation:

- Snuhi Ksheer (Euphorbia nerifolia Linn)
- Udumbar Kshar (Ficus racemosa)
- Fine Haridra Churna (Curcuma longa Linn.)
- Apamarga Kshara (Achyranthes aspera Linn)

Processing of Ksharasutra

Table no. 1 Number and pattern of coatings:

Snuhi/Apamarg/ Udumbar Ksharasutra Coatings	Coatings
Snuhi Ksheer	11
Snuhi Ksheer+ Udumbar Kshar/ Snuhi/Apamarg	7
Snuhi Ksheer + Haridra churna	3
Total coatings	21

After every coating the hangers were kept in the Ksharasutra cabinet for drying and sterilization purpose. A total 21 coating were done. The Ksharasutra was cut into pieces of 10 inch and each piece of Ksharasutra was packed in air tight glass tube.

Ksharasutra Karma Vidhi

Pre-operative procedure

Written informed consent from each patient was taken before performing of surgery. Patients were kept nil orally from midnight. Xylocaine sensitivity test was done and injection tetanus toxoid (TT) intramuscular was given before surgery. Local perianal part preparation was done and proctolysis enema was given as per routine preoperative procedure.

- **Operative procedures:** Under low spinal anesthesia (saddle block), Ksharasutra was applied in the fistula tract in patients. first partial fistulectomy was done and then Ksharasutra was applied in remaining part of the fistulous tract. Sterile pad and 'T' bandage were applied and the patients were shifted to the ward in conscious condition.
- **Postoperative procedures:** Patients were kept in head low position and nil by mouth for about 6 h after surgery. Patients were advised to start warm water sitz bath with Panchavalkala decoction from the next day of operation.Ksharasutra was changed with a new one by rail-road technique at weekly interval. The progress of healing and length of thread was noted to assess the Unit Cutting Time (UCT) till the complete cure of fistulous tract was achieved.
- Observation and result: Total 30 patients were randomly selected and divided into three groups, in present study. The efficacy of the therapy was at adjudging on varied parameters and the results were derived after execution of statistical methodology.In symptoms like pain 87.5%,77.78% and 50% of relief was observed in group A,B, and C respectively. Relief in itching was 70% in group-A, and 80% in group-B while in group C it was 75%. Group–B was much better than group-A. The result showed that treatment was statistically highly significant at $p < 0.001$. In swelling 83.33%, 87.5%, 80.90% of relief was observed in group A, B, and C respectively. In symptoms like discharge 84.61%,87.5% and 77.78% relief was observed in group A, B, and C respectively. The result shows statistically highly significant value$p < 0.001$ in Group –B, The result for effect on Unit cutting time showed that treatment was statistically highly significant at $p < 0.001$ in all groups. It was high in group b (88%) than group A than group c.

Table no. 2 Effect on Subjective & Objective Criteria

Subjective&Objective Criteria	Mean±SD			% RELIEF		
	Group A	Group B	Group c	Gr. A	Gr.B	Gr.c
Pain	0.7778±0.441	1.1667±0.408	1±0.6325	77.77	87.5	50
Itching	1.1429±0.378	1.1667±0.408	1.2857±0.951	80	70	75
Swelling	1.6154±0.960	1.6154±0.960	1.5455±0.522	87.5	83.33	80.95

Discharge	1±0.5774	1±0.5774	0.875±0.3536	87.5	84.61	77.77
Unit Cutting Time	1.3333±0.516	1.3333±0.516	0.875±0.3536	88.88	81.81	63.63

Effect on Unit cutting time- (UCT)

1. The mean U.C.T. of overall patients in group b was 8.97 days/cm and in group a it was 9 days/cm., while in group c it was 10.1 days/cm.
2. U.C.T. (Unit cutting time)was less (4.66 days/cm.) in sub cutaneous fistulae. In this category, Mean U.C.T. was found 8.44 days/cm.
3. In relation to types of Bhagandara U.C.T. was less (4.26 days/cm.) in Shatponaka Bhagandara. Mean U.C.T. was found 6.27 days/cm in this category.
4. U.C.T. decreases as length of fistulous tract increases; U.C.T. was 7.22 days/cm. in tract having initial length within 5 cm. whereas it was 4.26 days/cm in tract of more than 10 cm. In this category, Mean U.C.T. was found 9.30 days/cm (according to length of fistulous tract) and 8.99 days/cm (according to chronicity).
5. Presence of infection and inflammation delays the Unit Cutting Time.

DISCUSSION

Acharya Sushruta has described five types of Bhagandara. According to him, vitiated Doshas gets localizedin the vicinity of two Angula of Guda Pradesha, vitiates the Rakta and Mamsa Dhatu and causes Bhagandara. The vitiation of Dosha is secondary in the Agantuja variety of Bhagandara. Acharya Sushruta has mentioned Kshar Karma, but not Ksharasutra in the chapter of Bhagandara Chikitsita Adhyaya. The use of Ksharasutra in Bhagandara are mentioned in Visarpa Nadi Stanaroga Chikitsita Adhyaaya of Chikitsa Sthana of Sushruta Samhita. The method of preparation of Ksharasutra is described in Chakradatta, Kshara Sutra is one of the important Para surgical techniques in the armamentarium of Ayurveda. The introduction of Kshara Sutra into the fistulous tract is capable of dissolving the tough fibrous tissue, unhealthy granulation tissue and ultimately draining it out, and create a healthy base for healing. This is a big revolution in the treatment of Fistula in ano. Its gradual and sustained release chemical action not only removes the debris from the tract of Fistula but also helps in encouraging fresh healthy granulation tissue, thereby accomplishing healing pattern in the depth of tissues.In this comparative clinical study all the subjective parameters like pain, itching and objective parameter like, swelling, discharge, unit cutting time showed statistically significant results in all groups.

Relief in pain is probably due to improvement in microcirculation by the active substances emitted by Snuhi & Udumbar, which reduces tissue hypoxia. Most of the contents (Kshar) have Usna Veerya. The constituents of Snuhi Ksharasutra having analgesic property which cause relief in pain of Bhagandara patient.The anaesthetic substance suppress the irritation of nerve fibers hence stop the itching. This is probably due to Tikta, Kashaya Rasa; Ushna Veerya aand Kandughna as well as antibacterial properties of most of the contents of Haridra. kshara is well known for its Kandughna Karma. The antibacterial action of Haridra stop infection. Haridra show Vrana Shodhana and Ropana property due to Tikta Rasa.Udumbar, haridra shows Vrana Shodhana by Tikta Rasa.Kshar shows Sandhana Karma due to Ropan karma. Besides above said properties, chemical constituents of trail drug which were found effective to cure discharge Haridra shows antibacterial action due to oil present in it. Kshara shows Anti-inflammatory action, Anti- bacterial action . Due to anti-microbial and anti-bacterial action of Flavonoids and Tannins of Udumbar, discharge was eliminated significantly.Kshar applied on wound improve the circulation and then enhances the healing. Kashaya Rasa was present in maximum contents, with its sandhaniya Properties. Antibacterial action of haridra prevents infection and helped to reduce the wound size by promoting healing and the rate of contraction.

CONCLUSION

Sushruta has described application of Kshara (Ash of a plant, highly alkaline) in Bhagandara and Charaka has mentioned of Ksharasutra whereas Chakrapani have described detailed preparation and

application of Ksharasutra in Bhagandara. In this study, three different type of Kshara Sutra Snuhi Kshara Sutra, Apamarga Kshara Sutra and Udumber Latex Kshara Sutra) were usedtoassesstheirefficacyinatotal30patientsof Bhagandara. In this clinical trial it isproved that Udumbar Ksharasutra was more effective than Snuhi & Apamarg Ksharasutra. It is cost effective and easy to apply & Patient compliane with udumbar Ksharasutra found better than Snuhi & Apamarg. Hence, it can be used as an alternative approach for management of Bhagandar.

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How to cite this article: Kumari Nidhi Shree Bibhuti, Mrutyunjay Panda, Siddaram Arawatti. Randomized comparative clinical trial of udumbar kshara sutra andsnuhi kshara sutra with standard apamarg kshara sutra in the patient of bhagandara (fistula in ano). Int J of Allied Med Sci and Clin Res 2019; 7(3): 1045-1050.
Source of Support: Nil. **Conflict of Interest:** None declared.