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CLINICAL EVALUATION OF ARAGVADHADI SUTRA IN THE MANAGEMENT OF BHAGANDARA

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ABSTRACT

Anal fistula is a common problem that causes substantial morbidity in persons who are otherwise healthy. It is one in which a patient experiences pain, discharge and un-comfortness etc. Owing to the numerous surgical complications while treating the disease, the Ksharsutra therapy came as a breakthrough and Aragvadhadi sutra was accepted as the standardized one. This study was conducted to evaluate the effectiveness of Aragvadhadi sutra in the management of Bhagandara (Fistula-in-ano). A total of 40 patients were included in this study on inclusion criteria and divided into two equal groups. Trial group treated with Aragvadhadi sutra and control group treated with Standard Ksharsutra. Assessment was made on pain and objective (Nadi Chedan Kala) parameters. Observations were made before the treatment and on every 7th day of the therapy until complete cutting of the track. This study reveals that in group A the patients had Grade II, III and IV severity of pain and in group B the pain grade was observed as Grade I, II and III. In Group A (Standard Ksharsutra) the Nadi Chedan Kala was 0.91 cm/week and in Group B (Aragvadhadi sutra) the Nadi Chedan Kala was 0.84 cm/week. The study showed that the trial drug Aragvadhadi sutra was as good as the standard Ksharsutra in the treatment of Bhagandara.

KEYWORDS: Aragvadhadi sutra, Bhagandara, Fistula-in-ano.

INTRODUCTION

Bhagandara is considered as one of the Ashtamahagad i.e. very difficult to cure. Bhagandara is one of the commonest diseases occurring in anorectal region. The word Bhagandara is the combination of two words 'Bhaga' and 'Darana' which are derived from root Bhaj and Dri respectively. The Bhaga has different meanings as described by different authors. Bhaga is a word, which means all the structures around the guda including yoni and Basti. The second word Darana means tear of the surface associated with pain.

Bhagandara, is a pathological condition which causes tear and pain in the ano-rectal canal, vagina or urinary bladder due to vitiation of Apana Vata. All the Ayurvedic classics have described the Bhagandara in their own way. Charaka says that Bhagandara is a disease which occurs on the guda after bursting of suppurated painful Bhagandara pidika. Sushruta has described the disease in detail and says that Bhagandara starts as deep-rooted pidika (boil) within two fingers circumference of anal opening. This Bhagandara if neglected; flatus urine, faeces and semen may start coming from it. Acharya Charaka and Vagbhata have mentioned that horse riding is one of the causative factors for different types of Bhagandara and advocated Ksharsutra in the management.

Bhagandara clinically co-related to Fistula-in-ano means 'read' or 'flute' is a communicating tract lined granulation tissue opens internally deep in the anal canal or rectum and superficially on the skin around the anus, bhagandara is major disease of anorectal and characterized by persistent pus discharge associated with intermittent pain if not treated gives raises so many complications.

In 90% of the cases, the origin is from crypto glandular infection. It is said that acute crypto glandular infection leads to anorectal abscess and chronic infection causes fistula-in-ano. When an acute infection is untreated or inadequately treated, it breaks open into the peri anal skin to form a fistula-in-ano. But in 1/3rd of the cases no such history is forthcoming. In the remaining 10% of the cases a specific cause may be found. These are tubercular infection, inflammatory bowel disorders, diverticulosis, obstetric injuries rarely colloid carcinoma of the rectum and lymphogranuloma venereum infection. Sometimes a Fistula in ano can result from an infected fissure.

Despite the development of newer surgical and para-surgical techniques in the management of Fistula-in ano, there is little data on how to manage the high rate of recurrence (0.7 to 26.5 %), impaired continence (5-40%) and failure to heal (0.3 to 5.6%) 4. Operative procedures adopted are fistulectomy, fistulotomy, use of a Seton, newer methods like fibrin plug, Endo anal flap etc. Because of the lack of satisfactory results newer techniques have constantly been adopted for its management. The reasons for this are many. As the wound is located in the anal region, it is more prone to infection, thus takes a long time to heal. Also, the unhealthy granulation tissue formed further hinders the healing process. Thus, surgical treatment of fistula-in-ano requires hospitalization, regular post-operative care and the involved complications. To alleviate such miserable problems, surgeons have been craving for some alternative technique to treat these cases with minimal operative complications and failures.

Ayurvedic line of treatment includes medical management, Para-surgical management and surgical management. Para-surgical management includes Kshara Karma, Agni karma and Varti. The Ksharsutra treatment was in fact first mentioned in the Nadivrana Adhikara and the same treatment was said to be followed in Bhagandara. The preparation of this was mentioned much later by Chakrapanidatta. This technique has been accepted as superior to all the surgical and parasurgical techniques available today in the field of proctology. The advantages of this procedure are, it is cost effective, needs minimal hospitalization and has least adverse effects. This can be employed efficiently in both high and low anal fistulas. The recurrence rate of Ksharsutra ligation is negligible (3-5%) with a success rate of 95%. This type of therapy is considered as a minimal invasive para-surgical measure at global level.

The standard Ksharsutra is prepared by repeated coatings of Snuhi Ksheera, Apamarga Kshara and Haridra churna which is very effective and being widely used. Yet patients still complain of severe burning sensation and pain during the procedure of Ksharsutra application. Also, some of the problems are faced during the preparation and in the course of Ksharsutra therapy, like collection and preservation of Snuhi Ksheer, Apamarga Kshar successive changes, local irritant skin reactions during course of therapy. Considering all these factors an attempt is made in this study to substitute Aragvadhadi Sutra for the preparation of sutra used in the management of Bhagandara. Similarly, in modern surgery the use of ligation and some irritant chemicals like urethane and silver nitrate has been advised but most of the modern surgeons depend on operative treatment for this disease. Where they follow the radical excision of the track along with the removal of a major portion of surrounding tissue. The present study aims at establishing the efficacy of Aragvadhadi sutra in the management of Bhagandara.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of Aragvadhadi sutra in the management of Bhagandara.
2. To evaluate the efficacy of Aragvadhadi sutra in the management of Bhagandara by comparing the same with the efficacy of standard Ksharsutra.

METHODS

A total of 40 patients of Bhagandara especially diagnosed as complete fistula were selected after being diagnosed and screened by the inclusion & exclusion criteria. All the patients were examined for different signs and symptoms, local examination along with detailed history. Detailed findings were recorded in a specially designed case report form to analyze the demographic values and the efficacy of Aragvadhadi sutra on each individual.

Source of Data: Patients with Bhagandara attending the OPD of Shri Ayurved Mahavidyalaya and All India Ayurved Research Institute, Hanuman Nagar, Nagpur were selected for the study.

Inclusion criteria

1. Patients within the age of 20-60 years
2. Irrespective of sex, religion, occupation, economic status and education status.
3. Patients with complete fistula.
4. Patients with classical features of Fistula-in-ano confirmed by probing, presenting with seropurulent discharge from the tract, presence or absence of pain, pruritis ani and induration.
5. Patients with the external opening within 6 cm from the anal verge.

Exclusion Criteria

1. Fistula-in-ano caused as secondary due to other diseases like- Tuberculosis, Crohn's disease, Ulcerative colitis, Osteomyelitis, Veneral diseases, HIV, Appendicitis, Regional Ileitis and Intestinal & Pelvic Malignancies and patients suffering from external blind fistula.
2. Associated with other anorectal disorders which may come in the way of the treatment (Carcinoma rectum and anal canal, 3rd degree Hemorrhoids or bleeding hemorrhoids, acute fissure in ano, thrombosed sentinel pile)
3. Pregnancy
4. Patients suffering with systemic disorders which may come in the way of Ksharsutra treatment.

Materials Required: The Shalya tantra care unit contains following equipments-

1) Lithotomy table
2) Shadow less light
3) Dressing trolley with following:

a. Drums containing sterile cotton, pad, gauze piece etc.

b. Instruments tray having - Various sizes of probes, Artery forceps, Scissors, Surgical blade, Scalpel, Plain forceps

4) Sterile gloves
5) Surgical tray containing Aragvadhadi sutra and Standard Ksharsutra tubes
6) Sterilizer
7) Local anesthetic drugs i.e. Xylocaine 2% Jelly
8) Bottles of antiseptic lotion etc
9) Disposable syringes
10) Inj. Xylocaine 2%
11) Betadine Q.S.
12) Probe- curved, malleable, metallic 3 different sizes

Study Design: A total number of 40 patients of Bhagandara after considering the above-mentioned criteria were included for the study. The patients included were randomly allocated into two groups namely Group-A (Control group) and Group-B (Trial group) with 20 patients in each group.

Interventions

Group	Diagnosis	Treatment	Duration
A (Control group)	Fistula-in-ano (Complete fistula)	Standard Ksharsutra (Snuhi, Apamarga, Haridra)	Complete cutting of tract
B (Trial group)	Fistula-in-ano (Complete fistula)	Aragvadhadi sutra	Complete cutting of tract

Preparation of Aragvadhadi sutra
This was prepared in the hospital using linen thread number 20. One coating of paste of Aragvadha fruit pulp was applied each day and later kept for drying in the Ksharsutra cabinet. The dried thread was again smeared with the Snuhi Ksheer and kept for drying. The same procedure was repeated alternately with Aragvadha fruit pulp and Snuhi Ksheer. In this way a thread had a total of 21 coatings of paste of Aragvadha fruit pulp and Snuhi Ksheer. A total of 21 days was needed to complete the preparation of the thread. After this the threads were cut in 2 sizes; Medium length- 25cm, small length- 16cm and packed in a sterile sealed pack after placing in the UV cabinet with a small pack of silica inside to absorb moisture. All of these were then packed in a plastic box and stored keeping it away from contact with any moisture.

Preparation of Standard Ksharsutra
This was prepared in the hospital using Barbour's thread number 20. One coating of Snuhi Ksheer (11 coatings), Snuhi ksheer & Apamarga kshar (7 coatings) and Snuhi Ksheer & haridra chura (3 coatings) was applied each day and later kept for drying in the Ksharsutra cabinet. A total of 21 days was needed to complete the preparation of the thread.

Procedure
- For both the groups required materials were kept ready. The method was explained to the patient and consent was received.
- As a laxative, Panchasakar churna were advised to the patients on the day prior to probing of the fistulous tract.
- Advised to come on the 7th day for Ksharsutra threading.

Procedure of Ksharsutra application: The patient was anesthetized prior to primary probing. Patient was placed in lithotomy position. Part prepared and painted with betadine and draped. The patency of the track was confirmed by infiltration of betadine using a 10 ml syringe through the external opening. A suitable malleable probe was passed through the external opening by lubricating it with lignocaine jelly. The tip of the probe was forwarded along the path of least resistance and was guided by the finger lubricated in lignocaine jelly in the anal canal to reach into its lumen. Then the tip was finally directed to come out of anal orifice through the internal opening in the anal canal. A suitable length of plain thread was taken and threaded into the eye of the probe. The probe was then pulled out through the anal orifice, to leave the thread in the fistulous track behind. The two ends of the Plain thread were then tied together with a moderate tightness outside the anal canal. This procedure is called primary threading and on the seventh day Aragvadhadi sutra/standard Ksharsutra application was done. Patient was advised to attend to his normal duty during the treatment period.

Change of Aragvadhadi Sutra/Standard Ksharsutra: The thread is tied to the previously applied primary thread/sutra in position towards the outer end of the knot. Then an artery forceps is applied to the inner end of the same knot. And the old thread between the forceps of the artery and the knot is cut. Pulling of the artery forceps along with the thread ultimately replaced the old thread by Aragvadhadi Sutra/Standard Ksharsutra. Then the two ends are tied snugly and a sterile pad dressing is done. This procedure is done by Railroad technique.

Follow up: Successive changes were done at weekly intervals.

Observation: The observations made before the treatment and on fresh application of procedure was recorded in the case report form prepared for the study.

Duration: Till complete cutting of the tract.

Post Aragvadhadi Sutra/Standard Ksharsutra/ Primary threading

- Patient was advised Sitz bath with lukewarm water twice daily for 20 minutes except on the day of Aragvadhadi Sutra/Standard Ksharsutra threading.
- Bland diet

Duration fixed for observing recurrence

Duration of 60 days from the day of total cutting and healing of the fistulous tract was fixed to observe the possibility of recurrence and the same was recorded in the proforma of the case sheet prepared for the study.

Assessment Criteria

Pain Scale

- Mild pain lasting for 2 hours. Patients can bear and tolerate the pain and perform their duties.
- Mild pain persisting for 2-6 hrs. patient slightly uncomfortable
- Moderate pain, persisting 6-12 hrs. difficulty in walking and sitting
- Severe pain, unbearable, dryness of throat, sweating, giddiness, change in pulse and blood pressure
- Stage of vasovagal shock

Length of the track: measured at every sitting in cm.

Nadi Chedan Kala - The Nadi Chedan kala represents the number of days/weeks required to cut the track. This is calculated by dividing the total number of days/weeks taken by a fistula to heal by the initial length of the tract.

OBSERVATIONS AND RESULTS

In the clinical study, incidence of fistula-in-ano according to age, sex, religion, chronicity, length of fistulous track, type of Bhagandara, clinical findings etc., have been calculated. The incidence of Fistula-in-ano is more common between 20-40 years of age group with peak incidence i.e. 42.5% in 31-40 years of age. Males i.e. 62.5% were more prone to this disease in comparison to females. In relation to nature of work, 75% patients were having a sedentary lifestyle and 25% patients were doing an active job. 60% of patients were having a mixed type diet. 67.5% of patients had pain during defecation. Chronicity of disease was 6 months to 1 year was present in 32.5% followed by 22.5% patients suffering for more than 3 years. 42.5% patients were addicted to tobacco followed by alcohol addiction in 27.5% and smoking in 22.5% patients. History of Gudavidhradi was present in 67.5% and other complications in 27.5% patients. Vartulakar Nadigati was present in 52.5% patients and Riju nadigati was present in 47.5% patients. Total number of sinus, 82.5% patients had one opening and 17.5% patients had two or more than 2 openings. Other disorders like Parikartika were present in 45.5% and Arsha in 27.5% patients. In relation to type of Bhagandhar, 52.5% patients were suffering from Parisravi, 30% patients were Ushtragreeva, 15% patients were Shatponak, 2.5% patients were Shambukavarta and no patient was found from Agantuj type.

Distribution of patients by Grading of Pain

Pain Grade	Number of Patients	
	Group A	Group B
I	0	6
II	5	8
III	9	5
IV	5	1
V	1	0

This study reveals that the patients of Bhagandara were observed according to grading of severity of pain after the treatment. In Group A maximum patients were having Grade II, III and Grade IV pain and in Group B, the pain grade was observed as Grade I, II and Grade III.

Nadi Chedan Kala - In Group A (Standard Ksharsutra) the Nadi Chedan Kala was 0.91 cm/week and in Group B (Aragvadhadi sutra) the Nadi Chedan Kala was 0.84 cm/week.

DISCUSSION

Kshara Sutra therapy is the most accepted and scientifically validated procedure worldwide for the treatment of fistula-in-ano. The existing data on Ksharsutra reveals very negligible chances of recurrence by this modality of treatment.

Sushruta and Vagbhata have described different types of Bhagandara and it is very essential to discuss and understand Sushruta and Vagbhata classification of Bhagandara with present modern knowledge. Shataponaka Bhagandara has multiple small openings like that in a sieve, can be compared ato anal fistulae with multiple openings which resembles ‘watering can perineum’. In Ushtragreeva Bhagandara, Sushruta has mentioned that colour of Pidika is red, small and raised with inflamed swelling like the shape of a camel’s neck. After bursting of Pidika leads to formation of long linear track which again looks like camel’s neck. It can be compared to trans-sphincteric fistula. Goligher has also recognized similar type of fistula and has described as follows - In many long-standing cases however the opening is situated on the summit of little pink or red nodule due to exuberant granulation tissue. Parisravi Bhagandara, the word itself denotes continuous mucoid discharging nature of the wound. It may be classified under fistula with big cavities associated with complaints of itching and a continuous discharge. Usually their track takes long horizontal or high rectal course and seems to be inter-sphincteric type of fistula/Tubercular fistula. Shambukavarta, Sushruta has mentioned swelling which is the size of the tip of the great toe of the foot and its specific pains (deep seated and directed inwards) like whirlpools in purna Nadi Shambukavarta or revolutions in a conch shell. Madhavakara has described that the shape of Pidika resembles like Goshtanakara i.e. a huge Indurated abscess resembling a big convex protruding surface. This seems to be the high rectal external sinus with horse-shoe type of course and thus taking an

oblique curve, like ridges of a screw around the rectum. Unmargi Bhagandara caused by Abhigata and there is no doshic involvement. It is an internal sinus caused by tearing of the mucous membrane of anal canal whether by bone piece or hard scabaloids of stool and contact of infectious substance promotes the suppuration and formation of sinus and fistula. In Parikshepi Bhagandara, track surrounds the Guda as the pit around the fort. This can be compared to a posterior horse-shoe ischiorectal fistula. In Riju Bhagandara, fistulae arise from the anterior half of the anal canal with straight track in nature. Arsho Bhagandara is one of the most common types of fistula arises from the chronic fissure, by formation of a large laborious fleshy mass from the anal papilla on the dentate line at the upper end of the fissure in later stages. Infection of the sentinel pile which develops at the lower end of the fissure at the anal verge may lead to the formation of a superficial fistula. This type of fistula can be compared as Arsho Bhagandara.

In the present clinical study 40 patients had been treated with Aragvadhadi sutra and Standard Ksharsutra after being diagnosed as sub-cutaneous anal fistula. The observations were made on the different parameters including clinical findings and healing index. The incidental study like age group, sex, occupation, position and length of fistula were carried out.

The peak incidence of Fistula-in-ano is observed in 31-40 years of age. It is probably because the person is very active in this age group because of which the person is exposed to most of the etiological factors related to both diet and lifestyle. Male are more prone for this disease due to irregular lifestyle and more exposed to etiological factors of Bhagandara in comparison to females. It is most common in people doing sedentary nature of work as their occupation has them sitting for a long duration. Fistula-in-ano is a disease which often presents with pain, discharge in the perianal region associated with pruritus ani, sometimes with constitutional symptoms. It is a disease of gradual onset, more seen in constipated persons, usually with high recurrence rate. According to the Ayurvedic classics Asthishalya is one of the etiological factors for Bhagandara and the residual diet with more protein content delays digestion causing constipation. Hence indirectly caused by Bhagandara.

The kshara helps in cleaning debris from the tract as well as sterilization of the tract and thus facilitates proliferation of healthy granulation tissue. Pain is usually not a dominant feature in fistula-in-ano. It is present in the stage of Bhagandara Pidika rather than the stage of Bhagandara itself. Pain is definitely seen after the application of Ksharsutra due to the mechanical trauma and irritation by kshara. But the pain is not so severe and maybe managed with suitable medications when required. Since the duration of the study was fixed up to complete cutting of the track, all the cases were followed up till it was cured. The length of the track was noted at every sitting and graph plotted to see the weekly decrease in length. The decrease in length was based on the amount of fibrotic tissue and amount of discharge, the more fibrosed tissue and discharge the slower was the decrease in the length. The Kshara will take some time to be absorbed and produce the ksharana effect. It takes seven days to be absorbed layer by layer into each of the tissues. If it is kept for more than 7 days the thread will become loose thus the tensile strength is reduced due to which it will no longer have cutting effect.

The cutting of the tract is due to the pressure necrosis of the tissue. This is the same principle that we observe in the cutting stones today. Aragvadhadi Sutra helps in cleaning the debris from the tract, sterilizes the tract thus resulting in a healthy granulation tissue facilitating better healing of the fistula. Since the process is slow there is enough time for healthy granulation tissue to develop as well. During application of Aragvadhadi sutra the buring pain and irritation during the primary application and successive changes is quite less as compare to standard Ksharsutra. Aragvadhadi Sutra are having Chedana, Bhedana, Lekhana properties; even though it is Soumya it still has the property of Dahana, Pachana and Daarana. All these actions are seen in the Ksharsutra also which causes the excision of debris (Chedana), cutting of the track (Bhedana, Daarana) and scraping of the unhealthy granulation tissue.

CONCLUSION

The application of Aragvadhadi sutra causes debridement with local asepsis of Fistula tract promoting formation of healthy granulation tissue causes healing. Patient compliance regarding pain discharge is better, less irritations with Aragvadhadi sutra than the standard Ksharsutra group of patients. It also helps in less and smooth scar formation. The average cutting time of Aragvadhadi sutra was 0.84 cm/week and of standard Ksharsutra was 0.91 cm/week. No recurrence cases were reported during the last 2 months of follow up. The trial drug Aragvadhadi sutra showed promising results almost as good as Standard Ksharsutra, and hence may be used as a substitute in case of old age, female, children, thin patients.

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