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A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF GHONTAPHALADI SUTRA WITH APAMARGA KSHARASUTRA IN BHAGANDARA (FISTULA-IN-ANO)

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ABSTRACT

Fistula in ano is a chronic abnormal communication lined by granulation tissue that runs outwards from the ano rectal lumen to an external opening on the perianal skin. In Ayurvedic classics, it is mentioned as *Bhagandara* literally meaning "*Darana*" around *Bhag, Guda*, and *Vasti Pradesha*. Ayurvedic classics have mentioned *Ksharasutra* as effective management for *Bhagandara. Ksharasutra* is classically mentioned in the management of *Bhagandara* as per *Nadeevrana Adhikara*. Recently many research studies are carrying out to find an alternative to standard *Apamarga Ksharasutra* developed by the Salya Shalakya department, BHU in view of easy processing and also for achieving better results. So *Ghontaphaladi Varti* explained by Acharya Susruta in *Visarpanadistanaroga Cikitsa Adhyaya* is modified to form *Sutra* and used in the present study for the management of *Bhagandara*. The objective of the study was to assess the efficacy and also evaluate the cutting and healing rate of *Ghontaphaladi Sutra* in comparison with *Apamarga Ksharasutra*. A randomized clinical study with 32 participants of age group 18-60 years having fistula-in-ano from OP, Department of Shalyatantra, satisfying inclusion and exclusion criteria was carried out. The participants were randomly selected and divided into two groups. Trial Group A is managed with *Ghontaphaladi Sutra* and Control Group B with *Apamarga Ksharasutra*. The present study is to

provide safe, effective, and alternative management for *Bhagandar*a which is more or equally effective to *Apamarga Ksharasutra* and thereby validates *Ghontaphaladi Sutra*.

Keywords: *Bhagandara, Ghontaphaladi Sutra, Apamarga Ksharasutra*, Fistula-in-ano

INTRODUCTION

Anorectal disorders are progressively increasing in society. Anorectal disorders are daily encountered by general practitioners, gastroenterologists, and general surgeons. A correct diagnosis is basic to prevent benign conditions from becoming invalid or affecting the quality of life[1]. A sedentary lifestyle, irregular and inappropriate diet, prolonged sitting, and psychological disturbances like anxiety, and depression are a few important causes out of a number of them. All causes result in derangement of *Jatharagni* which leads to constipation and other associated symptoms.

The incidence of the anorectal disease is increasing day by day. The prevalence rate is 8.6 cases per 100,000 population. The prevalence in men is 12.3 cases per 100,000 population and in women its 5.6 cases per 100,000 population. The mean age of the patient is 38.3 years.[2]

Bhagandara (Fistula-in-ano) ranks first among the common ailments of the anorectal region. Due to its complexities and high recurrence rate, it is known as an enemy of a surgeon and is noted as a difficult surgical disease in all ancient and modern medical kinds of literature. This condition is described as one among the *Ashtamahagada* by Acharya Susruta.[3] The disease is named *Bhagandara*, as it creates a tear in the *Bhaga*, *Guda*, and *Basti Pradesha*. At first, it presents as *Pidaka* around *Guda* and when it burst out, it is called *Bhagandara*.[4]

In modern medical science, the disease can be correlated to a fistula in ano. An anal fistula is a chronic abnormal communication, usually lined by some degree of granulation tissue, which runs outwards from the anorectal lumen to an external opening on the skin of the perineum or buttock.[5] Pain, discharge, bleeding, or a history of an abscess that was drained either surgically or spontaneously are common, as fistulas represent the chronic phase of the disease.[6] It is the recurrent nature of this disease that makes it more and more difficult to treatment. However initial drainage of the sepsis and seton placement as a temporary or permanent remedy still has a role. Setons are usually inserted following drainage of abscess, to relieve residual sepsis and prevent collections, and facilitate controlled transection of the sphincter muscles to heal the fistula.[7]

Kshara is superior to surgical or para-surgical techniques.[8] It is highly caustic and de-fibrotises tissues. *Teekshna Guna* of *Kshara* helps in *Vrana Sodhana* and promotes faster granulation. The concept of management through Ksharasutra was mentioned long back by Acharya Susruta[9] and Chakradatta.[10] Acharyas have mentioned this method, especially for *Krisa, Durbala, Bheeru*, and for those who have *Nadi* (sinus) in *Marmasthana*.[11]The treatment of fistula-in-ano was revolutionized after the availability of *Ksharasutra.* The classical method of *Ksharasutra* preparation was mentioned in Chakradatta. Nowadays a standard technique has been developed in Salya- Shalakya Department of BHU and approved by ICMR and the drug used was *Apamarga,* a seasonal plant mostly available in winter and rainy seasons. Although *Apamarga Ksharasutra* is used successfully in the management of Bhagandara, the problem in preparation, availability of raw drugs, and pain felt by the patient during the application of *Ksharasutra* have to be corrected. Some patients have reported mild allergic reactions too. Also, the preparation of *Ksharasutra* is a time-consuming process. To overcome all these, several research been carried out to find drugs have better action and acceptability than this. So here an attempt was made to find an alternative technique that will be more or equally effective to that of *Ksharasutra.*

Ayurvedic classics described various *Varthis* in the context of *Nadivrana* and one among them is *Ghontaphaladi Varthi*, which is mentioned by Acharya

Susrutha in *Nadivranachikitsa* as "*Hanthi achirena nadi".* Even though the use of Varthis is indicated in *Nadivrana Chikitsa;* they are not widely in practice. In this scenario, an attempt was done to find the efficacy of this Varti in the management of *Bhagandara*, when used as a Sutra in comparison to *Apamarga Ksharasutra.*

The present study was carried out on 32 participants diagnosed with Bhagandara following inclusion criteria. The subjects were randomly allocated to two groups with 16 participants in each group. Assessment criteria were analyzed statistically, and conclusions were drawn. The study has been carried out under a strict clinical research methodology.

AIMS AND OBJECTIVES

- To evaluate the cutting and healing effect of *Ghontaphaladi Sutra* in the management of Bhagandara in comparison with *Apamarga Ksharasutra*
- To assess the efficacy of *Ghontaphaladi Sutra* in the management of Bhagandara in comparison with *Apamarga Ksharasutra*.

MATERIALS AND METHODS

A randomized clinical study with 32 participants of age group 18-60 years having fistula-in-ano from OP, Department of Salya Tantra in my institution satisfying inclusion and exclusion criteria was carried out. The participants were randomly selected and divided into two groups using the lottery method. Trial Group A is managed with *Ghontaphaladi Sutra* and Control Group B with *Apamarga Ksharasutra.* Initial threading was done on 1st day under the sterile condition with *Ghontaphaladi Sutra* in Group A and using *Apamarga Ksharasutra* in Group B. On every subsequent 7th day Sutras were changed till attaining complete cut-through of the tract. The patient was assessed on every 7th day by assessment criteria and after a complete cut-through, follow-up was done weekly once for one month and later monthly once for 2 months. After completion of the study, all the data were analyzed with SPSS version software.

Inclusion criteria

Subjects having clinical features of *Bhagandara* (Fistula-in- ano) within the age of 18-60 years .irrespective of gender, religion, caste, and economic status were selected for the study.

Exclusion criteria

Patients who were known cases of Hepatitis B, Hepatitis C, HIV, uncontrolled Diabetes Mellitus, uncontrolled Hypertension, and bleeding disorders were excluded. Fistula secondary to known cases of Crohn's disease, Ulcerative colitis, TB, and Malignancy was also excluded.

Study parameters

- Pain
- Burning sensation
- Discharge
- Itching
- Unit Cutting Time
- Unit Healing time

Preparation of Ghontaphaladi Sutra

Table 1: Contents of Ghontaphaladi Sutra

Drug	Botanical name	Part used
Ghontaphaladi	Ziziphus jujuba	P*hala twak*
Saindhava Lavana	--	
Laksha	Laccifera lacca	Resin
Pughaphala	Areca catechu	*Phala*
Alavanapatra	Celestrus paniculatus	*Patra*
Snuhiksheera	Euphorbia neriifolia	*Ksheera*
Arkksheera	Celestrus paniculatus	*Ksheera*

Drugs for Ghontaphaladi Sutra were collected washed and dried well in the sunlight. Fresh latex of Snuhi and Arka was collected freshly. All dried drugs were taken in equal parts and made into fine powder. A sufficient amount of latex of Snuhi and Arka is taken and mixed with the powdered drug and made into a fine paste. Then this paste is coated 21times over Barbour's linen thread No.20. Each coating is applied after complete drying of the previous application. After the 21 coatings, the Sutra is kept for drying and sterilization with UV rays, inside the Ksharasutra cabinet. Each thread was kept sealed in a sterilized glass tube. The tube is opened only at the time of use.

Preparation of Apamarga Ksharasutra

The Apamarga Ksharasutra is prepared by repeated coatings of Snuhi Ksheera, Apamarga Kshara, and Haridra Choorna over surgical Barbour's linen thread No.20. First eleven coatings with Snuhi latex alone should be done. The next seven coatings are done by smearing Snuhi latex first followed by Apamarga Kshara, thus permitting the particles of Kshara also to stick over the wet thread and afterwards allowed to dry. In the final phase of preparation of the thread, the remaining three coatings are done with Snuhi latex and fine turmeric powder. Thus, twenty-one coatings over the thread are completed. When dried, they are put in a sealed sterile glass tube marking the date of preparation and the length of the thread on it.

PROCEDURE:-

Preoperative procedure

The procedure is explained to the patient in detail and prior consent was obtained. A soap-water enema was given 2 hours prior to the procedure. Under the aseptic condition, the perianal and perineal region was prepared. Injection of tetanus toxoid and local anaesthetic test dose was also given before the procedure. The subject was lied comfortably in the lithotomy position.

Operative procedure

The perianal region was cleaned with an antiseptic solution and draped. Local anaesthetic (2% lignocaine) was injected around the anal orifice. The gloved finger lubricated with local anaesthetic gel is gently introduced into the anal canal. Then a probe is passed through the external opening and taken out through the internal opening and directed to come out through the anal orifice. Patients in Group A are applied with Ghontaphaladi Sutra and in Group B with Apamarga Ksharasutra is threaded into the eye of the probe and the probe is pulled out completely through the anal orifice leaving the thread behind in the fistulous tract. The two ends of the thread were tied together. Later on, on every subsequent 7th day rethreading is done with the thread till the complete cut-through of the tract. The dressing was done with Jathyadi Ghrita Varti.

Post-operative procedure

The participant was kept under observation for 4 hours and vitals were monitored. After that subject was shifted to the ward and advised to sitz a bath with Triphala Kashaya on the next day morning and evening for 15 minutes. Advised semisolid diet on the day of initial threading. Change of thread was done on weekly intervals in both groups with respective threads. The railroad technique is used for thread change in this group also.

RESULTS AND ANALYSIS

Collected data were subjected to statistical analysis using appropriate statistical techniques. Frequency, percentage, mean and standard deviation were used as descriptive statistics to summarize the data. Since the data distribution does not obey the normality assumption (Kolmogorov- Smirnov test) Mann- Whitney test was used for intergroup comparison of Group A and Group B, while Wilcoxon's signed-rank test was used for intragroup comparisons based on various study parameters. A calculated P value less than 0.05 is considered statistically significant. All the analyses were carried out with the help of software SPSS version 23 for WINDOWS.

The mean age of the patients in Group A was 44.5625, with a standard deviation of 15.5605. Group B had a mean age of 37.1250 and a standard deviation of 12.3173. The majority of patients in Group A (62.4%) are non-vegetarians, while 18.8% have a mixed or vegetarian diet. Non-vegetarians make up the majority of patients in Group B (62.4%), followed

by people who eat a mixed diet (25%) and vegetarians (12.6%). Group A had a mean position of 5 o'clock and a standard deviation of 3.0957. The mean position of Group B was 6 o'clock, with a standard deviation of 3.2016.

In Group A (93.7%) majority had an Intersphincteric fistula, whereas the remaining 6.3% had an Extra-sphincteric fistula. The majority of patients in Group B (75%) had an Intersphincteric fistula, 18.8% had an Extra-sphincteric fistula, and the remaining 6.3% had a Suprasphincteric fistula.

Pain - Patients in Group A and Group B do not differ significantly based on pain (P> 0.05) before treatment. Therefore, the initial condition of the patients in Group A and Group B were similar, and hence it is possible to compare the two groups after interventions. Mann-Whitney test showed that Group A and Group B differ significantly in pain level during the 7th day, 14th day, 21st day, and 28th day (P <0.01). Group A reported speedy relief in pain as compared to group B.

Effect Of Treatment on Study Parameters

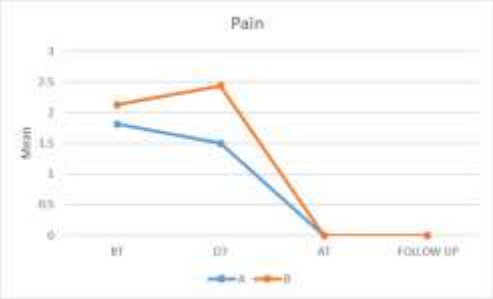

Figure 1: Line diagram on pain assessment

Discharge -Patients in Group A and Group B do not differ significantly based on discharge (P> 0.05) before treatment. Therefore, the initial condition of the patients in Group A and Group B were similar, and hence it is possible to compare the two groups after interventions. Mann-Whitney test showed that there is no significant difference in the discharge level of Group A and Group B.

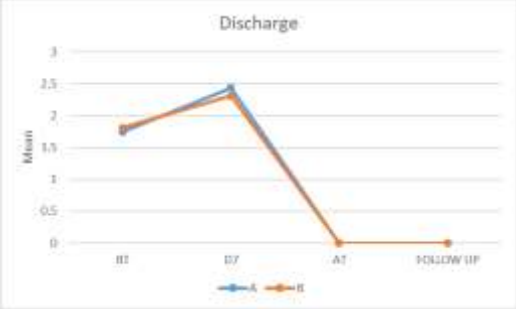

Figure 2: Line diagram on discharge

Burning sensation – Initial conditions of the patients in Group A and Group B were similar and hence it is possible to compare the two groups after interventions. Mann-Whitney test showed that there is no significant difference in the burning sensation level of Group A and Group B.

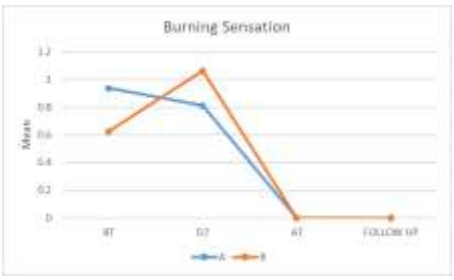

Figure 3: Line diagram on the burning sensation

Itching – Initial conditions of the patients in Group A and Group B were similar and hence it is possible to compare the two groups after interventions. Mann-Whitney test showed that Group A and Group B differ significantly in itching levels before treatment(P<0.05), 14th day(P<0.01), and on the 21st day (P<0.01). Group A reported speedy relief in itching as compared to Group B.

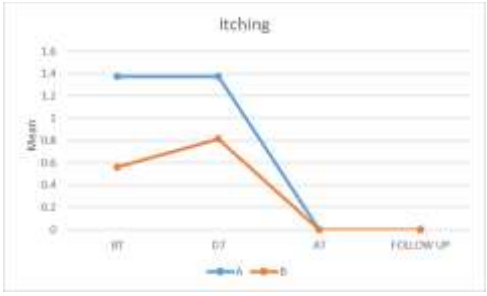

Figure 4: Line diagram on itching

Unit Cutting time - Mann-Whitney U test showed that there is no significant difference between Group A and Group B in Unit cutting time. The mean of the trial group is 9.064 and the mean of the control group is 7.72. The calculated p Value is 0.169 which is not significant (P>0.05).

Unit Healing Time(U.H.T) - No significant difference in Unit healing time between Group A and Group B in the table above. That is, the mean Unit healing time of Group A and Group B does not differ significantly (P>0.05).

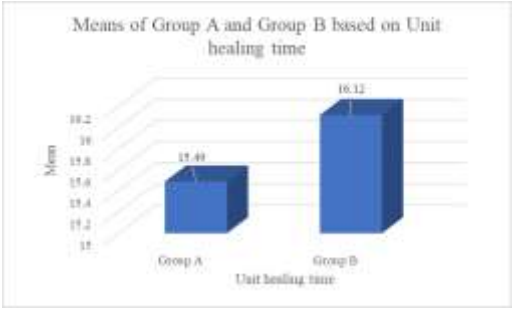

Figure 5: Bar diagram showing UHT

DISCUSSION

In this present study, the efficacy of *Ghontaphaladi Sutra* prepared from herbal compounds is compared with standardised *Apamarga Ksharasutra* in the management of Bhagandara.

Probable mode of action of *Ghontaphaladi Sutra*

Ghontaphala helps in reducing inflammation and also promotes wound healing through its *Vrana Sho-*

dhaka, Vrana Ropaka, Krimighna, and *Vata- Pittahara* properties. In *Ghontaphal*a the phytochemicals like flavonoids and tannins are known to promote the wound healing process by their astringent and antimicrobial properties which are responsible for wound contraction and increased rate of epithelialization. Saponin present in its seed also has sedative and antiallergic properties. By the *Kshara* nature and *Tikshna Guna, Saindhava Lavana* will help in scraping the fibrous tissue and its *Ropana Guna* helps in wound healing. *Laksha* by its virtue of *Kashaya Rasa* and *Seeta Veerya* helps in *Vrana Ropana*. It is *Krimighna* and *Twak Raktha Doshahara* and *Vrana Shodhaka*. The chemical constituents of *Laksha* have antiulcerogenic effects which will promote wound healing. *Pugaphala* due to its *Kashaya Rasa* helps in *Vrana Ropana*. By *Ruksha* and *Vikasi Guna* it penetrates deeper into the tissues and will do fibrolysis of unhealthy tissues. Its *Kapha- Pitta Nashaka* and *Krimighna* (anti-microbial) properties help in reducing discharge. The alkaloids and polyphenols of areca enhance collagen production and hence wound healing. *Teekshna Ushna Guna* of *Alavanapatra (Jyotishmati*) helps in the deeper penetration of tissues and do removal of fibrous tissues. The alkaloids and tannin in this promote wound healing as well as it has sedative effects. *Snuhi* by its *Katu Rasa, Laghu, Ruksha, and Tikshna Gunas* helps in deeper penetration and does debridement of fibrosed tissues in Bhagandara. It has the special property of *Dhathusodhana*. *Snuhi Ksheera* is well known for its wound healing property. The major chemical constituents Euphol and Nerifolin possess proteolytic action. Euphol has anti-inflammatory, anti-microbial, and anti-fungal action. *Arkaksheera* is *Kapha Vata Shamaka*, *Sara, Krimighna, Vishaghna, Sodhana*, and *Ropana*. The fibrinolytic action helps in the fibrolysis of unhealthy tissues. It contains tannins which help in promoting wound healing through its astringent and antimicrobial properties and thereby help in wound contraction and increased rate of epithelialization. It also possesses anti-inflammatory properties.

CONCLUSION

The disease fistula in ano mainly affects the middle age group. Male patients are mostly affected. As per socio-economic status, it is more common among middle-class individuals. Poor hygiene is also a major causative factor. Persons on irregular diets and non-vegetarian foods are more prone to this disease. The time for preparation of *Ghontaphaladi Sutra* is less compared to *Apamarga Ksharasutra*. The effect of *Ghontaphaladi Varti* which is of the same components as that of *Ghontaphaladi Sutra* is result oriented. It is cost-effective and safe. Post-operative pain and itching experienced after consecutive follow-up was less with *Ghontaphaladi Sutra.* Associated symptoms on initial threading are less in *Ghontaphaladi Sutra* than in *Apamarga Ksharasutra*. Burning sensation and discharge experienced during and after consecutive follow-ups were equal in both *Apamarga Ksharasutra* and *Ghontaphaladi Sutra*. Unit cutting time is less in *Apamarga Ksharasutra* compared to *Ghontaphaladi Sutra*. The relatively slow cutting rate of *Ghontaphaladi Sutra* might have provided better and proper drainage allowing it to heal without causing bridging of the skin edges. Unit healing time was equal in both groups with cosmetically sound scars. *Ghontaphaladi Sutra* provides proper drainage allowing it to heal without causing bridging of skin edges.

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