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A Comparative Clinical Study of *Apamarga Ksharasutra* and Seton in the Management of *Bhagandara* (Fistula –in- Ano)

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ABSTRACT

In *Ayurvedic* classics *Bhagandara* is considered as one of the *Asta mahagada* and its description is similar to *Fistula-in-Ano*. The word *Bhagandara* literary means splitting or *darana* around *guda*, *yoni* and *basti*. *Bhagandara* is one of the commonest diseases occurs in ano-rectal region. *Sushruta*, the Father of Indian Surgery has described all the details of this disease. *Fistula-in-Ano* is chronic abnormal communication, usually lined to some degree by granulation tissue which runs outward from the anorectal lumen (the internal opening) to an external opening on the skin of the perineum or buttock (or rarely, in women, to the vagina). *Fistula* surgery needs meticulous approach, otherwise complication will occur. Incontinence for flatus and often feces are the main complications. Infection, discharge, delayed healing, spread of infection are other complications. *Ksharasutra* helps in avoiding most of these complications in treating *fistula-in-Ano*.

OBJECTIVE: The study was conducted to clinically evaluate the effect of *Ksharasutra* and seton in the management of *Bhagandara*.

METHOD: This is an open clinical study conducted in the Dept. Of *Shalya Tantra*, SDM Ayurveda Hospital, Udipi, over a period of 2 years. Total 26 patients were randomly selected in the study according to the inclusion and exclusion criteria and divided into 2 groups which were designed for the study.

RESULT: Twenty six patients were registered for the study. The study showed significant result in cutting the track, discharge, pain, tenderness, itching and burning sensation within the group and there was no statistically significant result obtained between the group.

INTERPRETATION AND CONCLUSION: *Apamarga ksharasutra* is more effective in the patient with *fistula-in-ano* than the seton.



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KEYWORDS

Bhagandara; fistula-in-an, apamarga ksharasutra



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INTRODUCTION

The word fistula is derived from a Latin word a reed, pipe or flute. It implies a chronic granulating track connecting two epithelial-lined surfaces. These surfaces may be continues or mucosal. The anal fistula is a single track with an external opening in the skin of perianal region and an internal opening in the modified skin or mucosa of anal canal or rectum¹. The incidence of a fistula-in-ano developing from an anal abscess ranges from 26% to 38%. One study showed that the prevalence of fistula-in-ano is 8.6 cases per 100,000 population. In men, the prevalence is 12.3 cases per 100,000 population, and in women, it is 5.6 cases per 100,000 population². *Bhagandara* [Fistula – In – Ano] is considered under *Ashtamahagada* by *Acharya Sushruta* and *Vagbhata*^{3,4} *Bhagandara* is a disease which causes *Daarana* of *Bhaga*, *Guda* and *Basti*. When it is *Apakva* then it is called as *Pidika* and when *Pidika* gets *Pakva* and burst open then the condition is called as *Bhagandara*⁵. This condition is correlated with Fistula – in – Ano which is an inflammatory tract having external opening in perianal skin and internal opening in anal canal or rectum lined by unhealthy granulation and fibrous tissue⁶. *Bhagandara* [Fistula – in – Ano] has been categorized as a surgical condition

and almost all the Surgeons starting from *Sushruta* [800-1000 BC] to Hippocrates [400 BC] and also modern Surgeons of present time have realized the difficult course which this disease offers for its non-surgical/ surgical/ para-surgical methods of treatment. Surgical approach involving *Chedana* of *Bhagandara Naadi* was described by *Acharya Sushruta* in detail. Other treatment modalities for *Bhagandara* [Fistula – In – Ano] like *Shodhana*, *Agnikarma*, *Ksharakarma*, *Varti*, *Lepa*, *Taila* and *Ksharasutra* etc are also mentioned in classics. On other hand Hippocrates have preferred to use the application of thread which is called as *Apolinase* for the treatment of *Fistula – in – Ano*. In later period Surgeons opted to treat *Fistula – in – Ano* by laying the track open as possible. In this way modern surgeons have performed *Fistulotomy* as a first surgical operation for *Fistula – In – Ano*. *Fistulectomy* as an operation of choice was described by *Acharya Sushruta* much earlier to this. In later period *Fistulectomy* became favourite surgical treatment of choice which underwent minor technical variation from time to time. The *Ksharasutra* therapy was practiced and used since long with great success and without recurrences. The Standard *ksharasutra* is prepared by repeated coatings of *Snuhi ksheera*, *Apamarga*



kshara and *Haridra*. But some of the problems are faced during the preparation and also in the course of *Kshara sutra* therapy. To overcome these disadvantages was of utmost importance to make the treatment widely popular and acceptable. In spite of the good rates of cutting, severe pain and burning sensation caused during the treatment withheld many patients from accepting this treatment. The similar action is also seen in case of application of Seton in Fistula-in-Ano [6]. Setons aim to achieve the high fistula eradication rates associated with fistulotomy but without the degree of functional impairment endowed by division of the sphincters at a single stage. The enclosed muscle is gradually severed such that the divided muscles do not spring apart, and the site of the fistula tract is replaced by a thin line of fibrosis as it is brought down. Considering these applications it is necessary to compare the action of Seton with that of *Ksharasutra* specifically the *Apamarga ksharasutra* prepared out of 21 coatings. Hence the present study is taken to see the comparative effect of *Ksharasutra* and Seton in the management of *Bhagandhara*.

OBJECTIVE OF THE STUDY

- Conceptual and detailed study of *Bhagandara* and Fistula-in-Ano.

- To prepare *Ksharasutra* as explained in classics.
- To evaluate the efficacy of *Ksharasutra* and Seton in the management of *Bhagandara*.
- To review the information on Seton therapy.

METHODOLOGY

Ethical Committee Approval No SDMCAU/ACA/-49/ECA80/16-17 Date-24/05/2017

The present study has been undertaken to analyze *Apamarga Ksharasutra* and to compare it with Seton in the management of *Bhagandara* (Fistula-in-ano). Sincere efforts have been carried out to evaluate the clinical efficacy of *Apamarga Ksharasutra* and Seton in *Bhagandara*. It was an open labeled clinical study in which 26 patients were selected on the basis of simple random sampling (SRS) procedure and divided in 2 equal groups, strictly confined to the treatment of low anal fistula. It was performed on the patient who attended OPD and IPD of department of *Shalya Tantra* SDM Ayurveda Hospital, Kuthpady, Udupi.

Group 1 – 13 patients were treated with *Apamarga Ksharasutra*.

Group 2 – 13 patients were treated with Seton



MATERIALS

The *Ksharasutra* care unit contained Lithotomy table, Shadowless light, *Ksharasutra* dressing trolley with sterile bin containing gauze piece, cotton balls, drapes etc. Instrument tray having various size probes, artery forceps, scissors, surgical blade, scalpel, plain forceps. Other requirements are Sterile gloves, Sterile test tubes containing *Ksharasutra*, Hand sterilizer, Local anesthesia drugs i.e Xylocaine 2% jelly, Bottle of antiseptic lotion, Disposable syringes, Inj. Xylocaine 2%.

METHODS

Total 26 patients from OPD and IPD of S.D.M. College of Ayurveda diagnosed with Fistula-in-Ano where selected after being diagnosed and screened by the inclusion and exclusion criteria. Detailed findings were recorded in a specially designed case proforma to analyze the demographic values and the efficacy of *Apamarga Ksharasutra* and Seton on each individual sign and symptom.

INCLUSION CRITERIA

- Selection of patients will be done irrespective of sex.
- Patients will be selected in the age group of 16 to 65 years.

- Patients with signs and symptoms of *Bhagandara* as explained in Ayurvedic Classics will be selected.

EXCLUSION CRITERIA

- Patients found to be positive for HbsAg and HIV will be excluded.
- Patients suffering from secondary fistula due to Carcinoma, ulcerative colitis, tuberculosis etc will be excluded.
- Patients suffering from systemic diseases like inflammatory bowel disease, Crohn's disease, ulcerative colitis, malignancy will be excluded
- High level fistula- in -ano
- Multiple fistula

STUDY DESIGN

It is a comparative clinical study with pre-test and post-test design.

INVESTIGATIONS

Blood- Hb%, TC, DC, ESR, HIV, HBsAg, X-Ray (if necessary), Fistulography (if necessary), Any other investigations (if necessary)

Duration of treatment:

- Changing of *Ksharasutra* will be done once a week until the track is healed.
- Seton will be changed once a week till the track is healed.

Observation period:

- The patients will be observed once a week during the intervention period.



- Follow up of the patient will be done once in a week for 4 weeks after the intervention period.

ASSESSMENT CRITERIA

- Pain
- Discharge
- Burning sensation
- Tenderness
- Itching
- Length of track
- Induration

STATISTICAL DESIGN

Paired 't' –test of significance : All the information based on various parameters were collected, tabulated and statistical study was carried out in terms of means (x), Standard deviation (S.D), Standard error (S.E), Paired t test(t value) and result were incorporated in terms of probability(P) as Wilcoxon Signed Rank Test

Unpaired 't' - test

Mann Whitney test

- $P > 0.05$ - no significant
- $P < 0.05$ - significant
- $P < 0.01$ and $P < 0.001$ - highly significant

RESULT

The present study has been undertaken to analyse *Apamarga Ksharasutra* and to compare it with Seton in the management of *Bhagandara*. A sincere effort has been carried out to evaluate the clinical efficacy

of *Apamarga Ksharasutra* and Seton in *Bhagandara*.

Ksharasutra group shows 91.6% in reduction of length of the track this is because of *Kshara* which has the property of cutting and healing of the track. Seton group showed 90.47% in reduction of length of the track. As Seton is a non-medicated silk thread, it takes more time to cut. On 7th day mean score of pain in *ksharasutra* group was found to be 2.15 before treatment, and on 70th day it was reduced to 0.00 after treatment. On 7th day mean score of pain in Seton group was found to be 2.15 before treatment, and on 77th day it was reduced 0.00 after treatment. Highly significant reduction of pain was due to continuous discharge of pus from track and also may be effect of internal medication. On 7th day mean score of burning sensation in *ksharasutra* group was found to be 1.15 before treatment, and on 35th day it was reduced 0.00 after treatment. On 7th day mean score of burning sensation in Seton group was found to be 0.53 before treatment, and on 35th day it was reduced 0.08 after treatment. Burning sensation was reduced probably due to gradual reduction in discharge and internal medication. On 7th day the mean score of itching in *Ksharasutra* group was found to be 0.61 before treatment, and on 42nd day it was reduced 0.00 after treatment. On 7th mean



score of itching in Seton group was found to be 0.69 before treatment, and on 49th day it was reduced 0.08 after treatment. In group A itching is reduced on 42nd day whereas in group B even after 49th day there was mild persistent itching. This may be due to the action of *Haridra* in Group A. On 7th day mean score of tenderness in *ksharasutra* was found to be 1.61 before treatment, and on 42nd day it was reduced 0.00 after treatment. On 7th day mean score of tenderness in Seton group was found to be 1.38 before treatment, and on 42nd day it was reduced 0.23 after treatment. Probably tenderness is reduced due to drainage of accumulation pus and healed of track. On 7th day mean score of discharge in *ksharasutra* group was found to be 2.23 before treatment, and on 63rd day it was reduced 0.08 after treatment. On 7th day mean score of discharge in Seton group was found to be 2.15 before treatment, and on 63rd day it was reduced 0.15 after treatment. Most of the patient with fistula has discharge as their complaint. Once the thread is applied its start drainage of the pus. Hence decreased in pus discharged was seen. On 7th mean score of induration in *Ksharasutra* group was found to be 0.46 before treatment, and on 28th day it was reduced 0.00 after treatment. On 7th day mean score of induration in Seton group was found to be 0.84 before treatment, and

on 56th day it was reduced 0.08 after treatment. Staged debridement of unhealthy granulation tissue occurs, thus reducing the induration.

Result between the Groups

Comparative effect between the groups in reduction of length of the track, before treatment to 7th day, Seton group showed statistical significant results with p value (0.004.)

Comparative effect between the groups, in reduction of length of the track, before treatment to 14th day, BT-21st day, BT-28th day, BT-35th day, BT-42nd day, BT-49th day, BT-56th day, (p value 0.84, p value 0.87, p value 0.35, p value 34, p value 0.22, p value 0.16, p value 1.00) there was no statistical significant difference between the groups. Whereas *Ksharasutra* group showed better results. Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day and 77th day, (p value 1.00, p value 0.94) statistically there was no significant difference in between the group on effect on pain. Whereas better results were showed in *Ksharasutra* group. Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day, 35th day (p value 1.18, p value 0.24) statistically there was no significant difference in between the group on effect on burning sensation. Whereas better results



were showed in *ksharasutra* group .Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day and 49th day, (p value 1.00, p value 1.00) statistically there was no significant difference in between the group on effect on itching .Whereas better results were showed in *Ksharasutra* group. Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day, 42nd day (p value 0.62, p value 0.38) statistically there was no significant difference in between the group on effect on tenderness. Whereas better results were showed in *Ksharasutra* group. Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day, 63rd day (p value 1.00, p value 0.51) statistically there was no significant difference in between the group on effect on discharge .Whereas better results were showed in *Ksharasutra* group. Between the group analyses (at mean rank of subordinate level of the significant) before treatment to 7th day, 56th day, (p value 1.00, p value 0.18) statistically there was no significant difference in between the group on effect on induration. Whereas better results were showed in *Ksharasutra* group.

DISCUSSION

When comparing both groups, *Ksharasutra* procedure gave highly significant result statistically and practically in treating *Bhagandara* especially in reduction in the length of the track, tenderness, induration, burning sensation, itching, discharge, pain, when we compare the mean values before and after the treatment. Statistical insignificant result were obtained between the group. Thus it can be considered that *Ksharasutra* is more beneficial treatment in *Bhagandara* in comparison with Seton. No complication of the therapy was observed during the study in both the groups. No cases were reported with inflammation during the course of treatment with *Ksharasutra* and Seton group. One case with pyrexia was reported in *Ksharasutra* group during the treatment for about 2 days. No pyrexia was reported in Seton group.

Mechanism of action of Ksharasutra:

The surgical linen thread number 20 retains the tensile strength for a longer period comparatively and hence it is used as standard thread in *Ksharasutra* preparation. *Apamarga Ksharasutra* produces debridement by its hygroscopic nature. *Snuhi ksheera* also produced debridement by its proteolytic enzyme present in it. It has sticking property by which more powder of *Apamarga Kshara* is held and thus resultant action of debridement is excessively potentiated. *Haridra choorna* possess a



weak antiseptic, anti-histamine property. The fine coating of *Snuhi Ksheera* and *Haridra* is done to avoid the direct contact of *Apamarga Kshara* with atmosphere thus preventing *Apamarga Kshara* to catch moisture which would result it becomes useless.

Mechanism of action of Seton:

The Seton can be placed alone, combined with fistulotomy or in a staged fashion. The purpose of Seton are to drain, promote formation of granulation tissue, healing by fibrosis and track recedes downwards. Seton in situ creates ischemic necrosis, dividing the muscle slowly without allowing it to spring apart avoiding gutter deformity. Even though internal sphincter is divided in this, causing adequate laying open of entire fistula track, it will well-preserve the sphincter function and pressure. This allows the fistula to granulate and heal from above and to close track completely.

CONCLUSION

The *Ksharasutra* preparation has not been elaborately described by our *Acharya*. The word *Ksharasuta* and its application in *nadi varna* have been explained by ancient surgeon *Sushruta* in 17 chapter of *chikistasthana*. The commentator *Dalhana* has commented *kshara peetena sutram*,

means the *sutra* containing or dipped in *Kshara*. *Chakrapani datta* the authoritative commentator of *Charaka Samitha* has described the preparation of *Ksharasutra* by smearing the latex of *Euphorbia nerrifolia* and powder of *Curcuma longa* repeatedly. The 21 coating *Ksharasutra* is a unique technique developed by Shalya, Shalakyia department of IMS B H U was considered the best *Ksharasutra*. Similarly in modern surgery great emphasis is ascribed to Hippocrates for describing *Fistula-in-Ano* and its management by Seton. The aim of present study was to compare between *Apamarga Ksharasutra* and Seton in the management of *Bhagandara*. The application *Apamarga Ksharasutra* caused more cutting of track by its alkaline character than the Seton, there is continuous discharge of pus from the track, relief in pain, itching, burning sensation, induration, pain and tenderness. Both the group *Ksharasutra* and Seton have shown statistically highly significant result within the group. But between the groups statically insignificant results were obtained. There was difference seen within the group. This proves the efficacy of *Ksharasutra* against Seton.



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