

## AN INNOVATIVE MANAGEMENT OF BHAGANDARA (W.S.R TO HIGH ANAL FISTULA): KSHARA SUTRA WITH PARTIAL FISTULECTOMY

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### ABSTRACT

**Background:** In Ayurveda, Bhagandara is considered one of the grave diseases by Sushruta due to its higher recurrence rate. Ksharasutra is a para-surgical procedure that is found more effective in the management of fistula-in-ano. Ksharasutra is routinely prepared with Snuhi Ksheera (latex), Haridra powder, and Apamarga Kshara. The treatment procedure of perianal fistula aims at complete eradication of sepsis while preserving continence. Identifying better treatment procedures would benefit the treatment of complex fistula in ano in terms of reduced recurrence and reduced postoperative morbidity in source-limited settings. **Aim:** To compare the efficacy of Apamarga Ksharasutra with partial fistulectomy and Apamarga Ksharasulta alone in the management of Bhagandara. **Materials and Methods:** In this research study, 60 patients of Bhagandara (fistula-in-ano) were selected and randomly divided into two groups. In group-A (n = 30),

patients were treated only with application of Apamarga Ksharasutra and in group-B (n = 30), partial fistulectomy was done and then Apamarga Ksharasutra was applied in remaining fistulous tract. After the Ksharasutra application, patients were assessed for relief in symptoms such as pain, discharge, burning sensation, development of granulation tissue, and fistula tract length as parameters on a weekly follow-up basis, and Ksharasutra was changed by railroad technique up to complete cut through of the tract. **Results:** After 12 weeks of treatment maximum (53%) patients in group B were cured than group A (33%). Whereas 36.67% of patients in group A and 40% in group B were improved maximally after 12 weeks

of treatment. This study revealed that Gr-B is more effective in reducing pus discharge, pain, burning sensation, granulation tissue development, and fistula tract length than Gr-A.

**Conclusion:** Partial fistulectomy with Apamarga Ksharasutra is better than the Apamarga Ksharasutra application in Bhagandara (fistula-in-ano) cases.

**KEYWORDS:** Bhagandara, Fistula-in-ano, Ksharasutra, Partial fistulectomy.

## INTRODUCTION

The fistula in ano is defined as an abnormal tract lined by granulation tissue, which runs between the external openings in the perineum to an internal opening located in the anorectal canal.<sup>[1]</sup> This disease comes under Ashtamahagdas under eight grave disorders described by Sushruta in ancient documentation of surgery in India.<sup>[2]</sup> Ksharsutra has been a modality of fistula in ano treatment since ancient times in India. Ksharsutra is a type of Seton placed after cannulating and probing the fistulous tract without surgically excising the tract. Ksharsutra induces sclerosis in the fistulous tract after the tract has been drained.<sup>[3]</sup> It is a medicated thread prepared by smearing Kshar of Apamarga (*Achyranthus aspera*), Haridra (*Curcuma longa*), and Snuhi (*Euphorbia nerifolia*).<sup>[4]</sup> The Ksharsutra works as a draining and cutting seton while simultaneously promoting healing. Ksharsutra is inserted using a metallic probe passing through the external opening and thread tied to the tail end of the probe, and the probe advanced through the tract to exit through the external opening. The Ksharsutra must be changed and progressively tightened at regular intervals of one week. It helps in ischemic necrosis of the muscle complex and promotes fibrosis of the fistula tract.<sup>[5]</sup> Fistulectomy is a procedure where the entire probed tract will be tried to be excised. The treatment procedure of perianal fistula aims at complete eradication of sepsis while preserving continence. Fistulotomy, which involves the lay open of the fistula tract, has shown promising results for simple fistula in ano.<sup>[6]</sup> Identifying better treatment procedures would benefit the treatment of complex fistula in ano in terms of reduced recurrence and reduced postoperative morbidity in source-limited settings.

## MATERIALS AND METHODS

This was a prospective randomized study. After the approval from the ethical committee of the institute, patients with high anal and recurrent fistula in ano attended the outpatient department of Shalya Tantra Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India, were recruited for the study. Non-cryptogenic fistula in ano was excluded from the study. A total of 60 patients were divided into two groups, group A and group B. Each group was

enrolled with 30 patients. The simple randomization method was adopted. The primary objective of this study was to compare the effectiveness of Apamarga Ksharasutra and partial fistulectomy with Apamarga Ksharasutra in the management of fistula in ano. Patients in group A were treated with Ksharasutra application in the fistula tract, and group B was treated with partial fistulectomy and application of Ksharasutra. The assessment was based on discharge, pain, granulation tissue, burning sensation, and fistula tract length. Discharge was assessed by counting the use of a cotton pad (20 X 20 X10 mm), measurement of pain was done using the British pain measurement scale, granulation tissue was assessed by visualizing clinically, burning sensation was assessed by using objective numerical counting method (ONCM). The length of the fistula tract was measured by probing and measuring the length of Ksharasutra (0= healed, 1= < 3 cm, 2= 3-6 cm, 3= > 6cm). Follow-up was conducted in 1st week, 4th week, 8th week, and 12th week.

### **Surgical protocol**

Preoperatively, patients were examined, necessary investigations were done, and sodium phosphate enema was given the night before the surgery. Patients were shifted to the operating room on the day of surgery, and standardized local anesthesia was given. The lithotomy position was preferred for the procedure. Parts were painted with betadine and draped. Complete aseptic techniques and precautions were followed throughout the surgery.

For patients who underwent ksharasutra ligation, anal dilatation was done, and a copper malleable probe was inserted through the external opening till the internal opening and the ksharasutra were ligated.

For patients who underwent partial fistulectomy, anal dilatation was done before surgery. A copper malleable probe was inserted from the external opening till it reached the internal opening, and coring out the tissue around the probe was done to excise the fistulous tract partially. After partial excision of the fistula tract, ksharasutra was ligated to the remaining fistula tract.

All the patients were shifted to the ward, and postoperative pain was managed using non-steroidal anti-inflammatory drugs. All the patients were advised to sitz bath, and were encouraged to ambulate, self-void urine, and oral diet as early as possible. Postoperatively, all the patients were kept under observation for urine retention and postoperative bleeding. After the discharge, patients were strictly instructed to report any postoperative complications such

as early incontinence, bleeding, wound infection, abscess formation, bleeding, and urine retention. No postoperative complications were observed in either group, and follow-up was done for in the 1st, 4th, 8th, and 12th weeks, depending on the cutting and healing of the fistula tract.

Descriptive and inferential statistics were performed. Results on continuous measurements were presented as mean  $\pm$  standard deviation, and results on categorical measurements are presented in number (n, %).

## RESULTS

The study was conducted on 60 patients, where 37 were male (group A, 21 and group B, 16) and 23 were female (group A, 09 and group B, 14), with a maximum age group (40%) between 31 to 40 years. This study revealed middle-class people (65%), mixed diet (90%), patients with a history of constipation (63%), tobacco-addicted patients (35%), literate (86%), patients with a history of prolonged sitting (71%), Vata-Pittaja Prakriti patients (48%) were commonly sufferer from this disease. The maximum patients (63%) had the normal anal sphincter tone. After 12 weeks of treatment maximum (53%) patients in group B were cured than group A (33%). Whereas 36.67% of patients in group A and 40% in group B were improved maximally after 12 week of treatment.

In case of discharge the man difference (MD) and standard deviation (SD) for group A was 0.53 & 0.51 ( $p < 0.001$ ) and for group B was 2.11 & 0.78 ( $p < 0.001$ ) respectively after 12 week of treatment.

In case of pain the MD & SD for group A was 1.30 & 0.58 ( $p < 0.001$ ) and for group B was 1.56 & 0.78 ( $p < 0.001$ ) after 12 week of treatment.

In case of development of granulation tissue the MD & SD for group A was 1.32 & 0.65 ( $p < 0.001$ ) and for group B was 1.45 & 0.79 ( $p < 0.001$ ) after 12 week of treatment.

In case of burning sensation the MD & SD for group A was 1.28 & 0.76 ( $p < 0.001$ ) and for group B was 1.95 & 0.79 ( $p < 0.001$ ) after 12 week of treatment.

In case of length of fistula tract the MD & SD for group A was 1.35 & 0.61 ( $p < 0.001$ ) and for group B was 1.55 & 0.81 ( $p < 0.001$ ) after 12 week of treatment.

## DISCUSSION

The average percentage change in Discharge after treatment of 1st week (AT1), 4th week (AT2), 8th week (AT3), 12th week (AT4) in Gr-A patients was 14.28, 25, 45, 62.5 respectively and in Gr-B patients was 17.30, 32.69 & 52, 75.6.

The average percentage change in Pain after treatment of 1st week (AT1), 4th week (AT2), 8th week (AT3), 12th week (AT4) in Gr-A patients was 18.36, 63.26, 71.32, 95.91 respectively and in Gr-B patients was 10, 57.5, 74.12, 97.5.

The average percentage change in Granulation tissue after treatment of 1st week (AT1), 4th week (AT2), 8th week (AT3), 12th week (AT4) in Gr-A patients was 21.95, 24.39, 58.67, 92.68 respectively and in Gr-B patients was 19.47, 23.8, 59.7, 95.47.

The average percentage change in Burning sensation after treatment of 1st week (AT1), 4th week (AT2), 8th week (AT3), 12th week (AT4) in Gr-A patients was 13.88, 61.11, 82.33, 94.44 respectively and in Gr-B patients was 18.18, 48.48, 68.8, 96.67.

The average percentage change in Length of tract after treatment of 1st week (AT1), 4th week (AT2), 8th week (AT3), 12th week (AT4) in Gr-A patients was 4.91, 16.39, 45, 67.54 respectively and in Gr-B patients was 8.92, 33.92, 55.33, 85.78.

### **Effect on discharge**

It was analyzed that in Gr-A after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce discharge, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce discharge & in Gr-B after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce discharge, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce discharge.

Here, Group-B is highly effective than Group-A to reduce discharge after 12th week of treatment (As  $t\text{-value}$  is highest in Gr-B). In a study in comparing Fistulectomy and fistulotomy with marsupialization and noted that persistent wound discharge was documented up to period of 4 weeks in the fistulectomy group and up to about 2 weeks in group of Fistulectomy with marsupialization.<sup>[7]</sup>

**Effect on pain**

It was analyzed that in Gr-A after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce pain, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce pain & in Gr-B after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce pain, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce pain.

Here, Group-B is highly effective than Group-A to reduce pain after 12th week of treatment (As  $t\text{-value}$  is highest in Gr-B). In previous study it was noted that the mean pain VAS score after 24 h among Fistulectomy (7.89 SD 0.76) versus Ksharsutra (5.38 SD 0.69) ( $p < 0.05$ ) was statistically significant also after 48 h mean VAS score between Fistulectomy (4.18 SD 0.42) versus Ksharsutra (2.48 SD 0.5) ( $p < 0.05$ ).<sup>[8]</sup>

**Effect on granulation tissue**

It was analyzed that in Gr-A after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce granulation tissue, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce granulation tissue & in Gr-B after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce granulation tissue, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce granulation tissue.

Here, Group-B is highly effective than Group-A to reduce granulation tissue after 12th week of treatment (As  $t\text{-value}$  is highest in Gr-B).

**Effect on burning sensation**

It was analyzed that in Gr-A after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce burning sensation, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce burning sensation & in Gr-B after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce burning sensation, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce burning sensation.

Here, Group-B is highly effective than Group-A to reduce burning sensation after 12th week of treatment (As  $t\text{-value}$  is highest in Gr-B).

**Effect on length of tract**

It was analyzed that in Gr-A after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce length of tract, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce length of tract & in Gr-B after 1st week  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce length of tract, after 4th, 8th and 12th week,  $p\text{-value} < 0.001$  which is highly significant at 0.1% level to reduce length of tract.

Here, Group-B is highly effective than Group-A to reduce length of tract after 12th week of treatment (As t-value is highest in Gr-B).

Therefore, here Null Hypothesis ( $H_0$ ) is rejected and also Alternate Hypothesis-1 ( $H_1$ ) is rejected as Apamarga ksharasutra is not highly effective than Apamarga ksharasutra with Partial fistulectomy.

Thus, Alternate Hypothesis – 2 ( $H_2$ ) is accepted because Apamarga ksharasutra with Partial fistulectomy is highly effective than Apamarga ksharasutra because of proper drainage of abscess and disappearance of complications.

Comparing the effectiveness of Gr-A and Gr-B, in reducing discharge, it was observed that, after 1st week, 4th week, 8th week & 12th week of treatment the  $p\text{-value} < 0.001$ , which was highly significant. Here, mean difference in Gr-B is higher than Gr-A. It shows that Gr-B is more effective to reduce discharge than Gr-A.

In case of Pain, after 1st week, 4th week, 8th week & 12th week of treatment the  $p\text{-value} < 0.001$ , which was highly significant. Here, mean difference in Gr-B is higher than Gr-A. It shows that Gr-B is more effective to reduce pain than Gr-A.

In case of Granulation Tissue, after 1st week, 4th week, 8th week & 12th week of treatment the  $p\text{-value} < 0.001$ , which was highly significant. Here, mean difference in Gr-B is higher than Gr-A. It shows that Gr-B is more effective to reduce granulation tissue than Gr-A.

In case of Burning Sensation, after 1st week, 4th week, 8th week & 12th week of treatment the  $p\text{-value} < 0.001$ , which was highly significant. Here, mean difference in Gr-B is higher than Gr-A. It shows that Gr-B is more effective to reduce burning sensation than Gr-A.



In case of Length of tract after 1st week, 4th week, 8th week & 12th week of treatment the p-value  $<0.001$ , which was highly significant. Here, mean difference in Gr-B is higher than Gr-A. It shows that Gr-B is more effective to reduce length of tract than Gr-A.

## CONCLUSION

The present study aimed to determine the efficacy and applicability of Apamarga Ksharasutra with Partial Fistulectomy in managing Bhagandara. Based on the above clinical evaluation & statistical data, it may be concluded that there was a marked reduction of signs & symptoms like discharge, pain, burning sensation, and other post-operative and fistulectomy complications. Proper drainage of abscess occurred when Apamarga Ksharasutra with Partial Fistulectomy was applied in patients suffering from High Anal Fistula. Length of tract was mostly reduced in a quick manner in the case of Apamarga Ksharasutra with Partial Fistulectomy in comparison to the application of only Apamarga Ksharasutra as a result of which the patient has been cured in a shorter time period. No recurrences of cases were reported during the last 3 months of follow-up. Thus, Apamarga Ksharasutra with Partial Fistulectomy can be considered a better alternative modality because this innovative procedure proved mostly effective than only the Apamarga Ksharasutra application.

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## Conflicts of interest

There are no conflicts of interest.

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