ISSN 2456-3110
Vol 3 · Issue 6
Nov-Dec 2018

Journal of Ayurveda and Integrated Medical Sciences

www.jaims.in

JAIMS

Charaka Publications

Indexed

ISSN: 2456-3110 ORIGINAL ARTICLE Nov-Dec 2018

A Clinical Study on Chronic Anal Fissure by ligating *Ksharasutra* (medicated thread) w.s.r. to Sphincterotomy

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ABSTRACT

The *Ksharasutra* is well known Ayurvedic treatment for fistula-in-ano with less chance of incontinence and recurrence. Thirty patients were selected from the OPD of Government Ayurveda College Hospital, Tripunithura, Kerala, India, satisfying the inclusion and exclusion criteria and follow up done upto 6 months. The ligating *Ksharasutra* is highly effective in relieving the subjective parameters such as Pain (≤0.001), Bleeding (≤0.001), Sphincter Spasm (≤0.001) and Straining (≤0.001).

Key words: *Ksharasutra, Anal Fissure, Sphincterotomy, Ligation, Pain.*

INTRODUCTION

Anal fissure is so innocent at a look, but is the most irritating disease that hampering the routine life. Fissure is the longitudinal ulcer (Figure 1), and when the stool is passing over the ulcer site it irritates the nerve endings causing reflex sphincter spasm and severe pain.[1] Generally in acute cases their needs no surgical intervention but when the ulcer is not healing then surgical intervention is needed. The reports suggest that chronically elevated internal anal sphincter tone is the primary initiating event in the non-healing of acute fissures.[2] The greatest pressure is measured 1 to 2cm from the anal verge.[3] (Figure-2) The hypertonic sphincter creates micro vascular hypertension and subsequently causes a relative ischemia to the lining of the anal canal.[4] In chronic cases the primary aim is to decrease sphincteric tone. So, for the treatment there is a lot of option. In chronic case sphincterotomy is the choice of option but may results risk of incontinence. The *Ksharasutra* (medicated thread) is well known in Ayurveda (The Indian indigenous system of medicine) as an alternative treatment for fistula-in-ano[5] with less chance of incontinence and recurrence. *Ksharasutra* therefore is used for the ligation in the chronic anal fissure to decrease the sphincter tone. Scientific approach with the traditional surgical system is yet to be established which is being narrated in current paper.

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Submission Date : 30/10/2018 Accepted Date: 16/11/2018

Access this article online

Quick Response Code

Website: www.jaims.in

DOI: 10.21760/jaims.3.6.4

MATERIALS AND METHODS

This was a single open controlled study conducted after getting approval of Institutional ethical committee, Government Ayurveda College, Tripunithuira, Kerala and receiving informed consent according to WHO-Helsinki consent format. The consecutive patients of either gender aged 16-60 years presenting to the out patient department of Government Ayurveda College from February 2008 to December 2010 with features of chronic anal fissure were included in the study. The anal fissure which was indurate lasting more than one month and visible fibers of sphincter muscle at base of fissure, were selected for the study. Patients with cardiovascular

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diseases, pregnant and lactating mothers and patients with anal disease that warranted surgery such as abscess or fistula, were excluded. The large sentinel tags were also excluded in the study and the patients who were not responding in the conventional medicinal treatment such as stool softeners and sitz bath.

Thirty patients who satisfied the selection criteria were treated surgically with *Ksharasutra* for partial posterior midline sphincterotomy. The *Ksharasutra* was prepared with the fine powder of the dry *Curcuma longa* Linn. (Family - Zingiberaceae, Common name - *Haridra*) and the latex of *Euphorbia nerifolia* (Family - Euphorbiaceae, Common name - Snuhi) according to the description of Rasatargani.[6] This coating should be done for 7 times. The number 20 Barbour's linen thread was used for this purpose. The diameter of the thread was 1mm. The coated material present in the 30 cm of thread was 0.22 mg. The pH of the thread was 5.8. Previously relevant medical histories were recorded. The data related to the pain, bleeding per rectum, sphincter spasm and straining were recorded in numeric rating scale (NRS) 0 - 10**.** The maximum amount of spasm during defection, intensity of pain, amount of bleeding per rectum, and the duration of strain was rated 10 and the absent of symptom was 0. (Figure 3)[7]

The rate of healing was recorded, according to the time period for final epithelization after cut through. The recurrence rate, risk of continance and other complication was also noted after cut through of the *Ksharasutra*. Wound healing closely related with inflammatory response which may be evaluated by routine hematologic examination. Haemoglobin, total erythrocyte count, differential leucocytes count and erythrocyte sedimentation rate were recorded before and after completion of the therapy. Results are analyzed statistically by using paired 't' text. All values were expressed as mean ± SE.

Procedure of *Ksharasutra* techniques

The patient was operated in lithotomy position. Local anaesthesia was given by injecting 1ml of 1% lignocaine hydrochloride beneath the fissure bed. A small incision was made just below the fissure. A curve cutting probe was introduced through this artificial opening, at right angle upto 2-3mm and there after, it curved along the fissure bed and reopen near apex of fissure, through which the *Ksharasutra* was applied. The probe was guided out by surgeon finger which was protected by adhesive plaster and finger tips. Then the *Ksharasutra* was tied firmly, not loosely or not very much tightly as shown diagrammatically in figure 4. The blue line indicating the direction of the probe during the procedure and the red line shows when the *Ksharasutra* had been tied (Figure 5). Routine gentle anal dilatation was done for 2 days. Figure 6 to figure 9 shows the application of *Ksharasutra* in a patient with an anal fissure. All the patients were given laxatives and sitz bath postoperatively. The sitz bath was done with the lukewarm (~40°C) decoction of *Triphala* (An Ayurvedic formulation comprising equal amount of fruits of three hearbs - *Terminalia chebula, Embilica officinalis* and *Terminalia belarica*). All Patients were followed upto 6 months.

Observations and Results

The mean age of the patients was 33.3yrs. The study included four females and twenty six male participants. Out of 30 patients, 13.3% were suffering from anal fissure for 1½ month to 2 months, 16.6% were suffering from anal fissure above 2 months to below 1 year, 20% were suffering from anal fissure from 1 year to 5 year and rest 63.3% were above 5 years. The mean of the chronicity of the disease was 53 months. Mean initial length of *Ksharasutra* was 1.82cm and the day for cut through of *Ksharasutra* was 7.30 days. The mean unit cutting time, that was the average time (in days) taken to cut one centimeter of the artificial track was 4.01 days.

Mean score of pain before the treatment was 7.60 and after the treatment it was reduced to 1.83. As well as sphincter spasm was 7.10 and was reduced to 2.07 after treatment. The mean gradation of Strain during defecation before treatment was 7 which decreased to 2.73 after the treatment. Out of 30 patients 73% patients complain of bleeding. Its initial

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mean score was 4.50, which reduced to 0.47 after the treatment. All these subjective parameter was statistically significant (P<0.001). (Table 1)

There was no significant change in total count, differential count, erythrocyte sedimentation rate and fasting blood sugar. The haemoglobin slightly increased which was statistically significant (p<0.02). (Table 2) The pain disappears just after the cut through, but for final epithelization, it took some weeks. The half of the patients wound healed between 2 to 4 weeks, 26.7% wound healed within 2 weeks, 16.7% wound healed between 4 to 6 weeks and the rest 6% wound healed within 6 to 8 weeks. There was no recurrence and any sort of incontinence within 6 month. In the follow-up period among 20% complain of itching on 4th week, that the last phase wound healing suggesting the epithelization process was going on.

Table 1: Effect of *Ksharasutra* on different subjective parameters before and after 1 weeks of cut through according to NRS.

Symptoms	BT (μ ± S.E)	AT (μ ± S.E)	t	p
Pain	7.60 ± 0.13	1.83 ± 0.21	22.4572	p≤0.001
Bleeding per rectum	4.50 ± 0.55	0.47 ± 0.18	8.0031	p≤0.001
Sphincter spasm	7.10 ± 0.20	2.07 ± 0.14	18.7094	p≤0.001
Strain during defecation	7.00 ± 0.20	2.70 ± 0.19	15.5766	p≤0.001

Table 2: Effect of *Ksharasutra* on biology constituents of blood before and after 1 weeks of cut through.

Parameters	BT (μ ± S.E)	AT (μ ± S.E)	t	p
Hb.	10.90 ± 0.18	11.53 ± 0.17	4.8287	P>0.05
TC	7056.7 ± 200.7	7068.3 ± 187.1		P>0.05
Neutrophil	59.67 ± 1.06	60.47 ± 1.01		P>0.05
Lymphocyte	34.47 ± 0.81	34.13 ± 0.98		P>0.05
Eosinophil	5.87 ± 0.37	5.40 ± 0.33		P>0.05
ESR	15.67 ± 0.71	14.73 ± 0.38		P>0.05

Figure 1: Diagrammatic representation of anal fissure

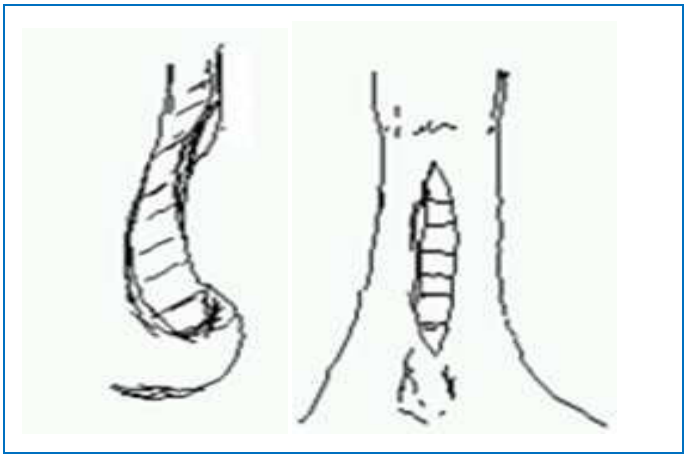

Figure 2: The sphincter muscle in dorsal projection

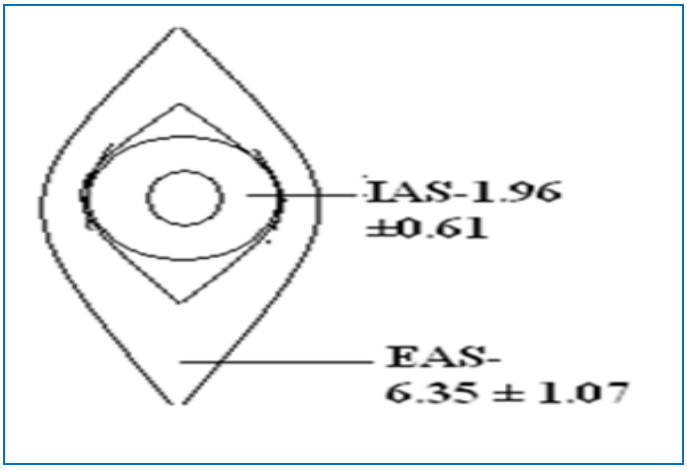

Figure 3: Numeric Rating Scale

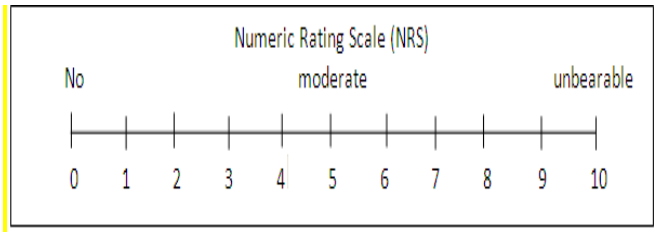

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Figure 4: Diagrammatic representation of the *Ksharasutra* application in anal fissure in horizontal section.

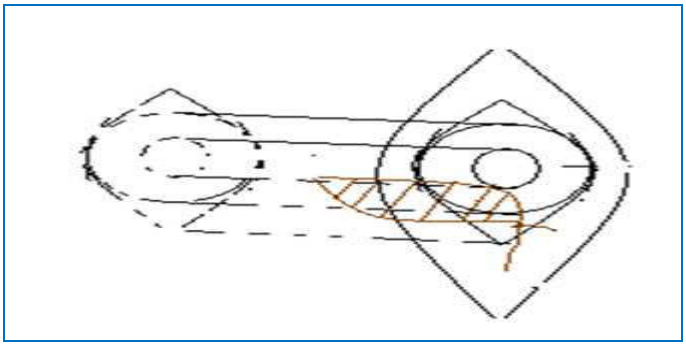


Figure 5: Diagrammatic representation of the *Ksharasutra* application in anal fissure in ano in longitudinal section.

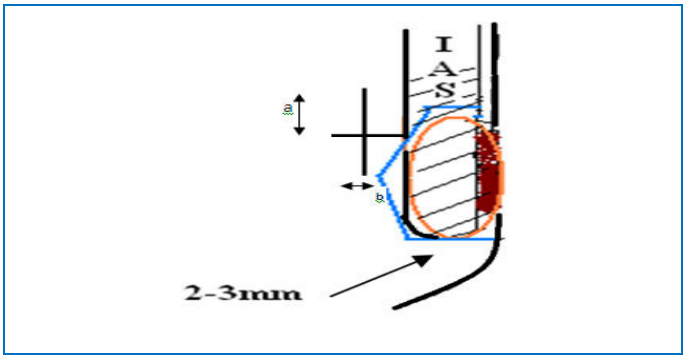


Figure 6: A small incision is made for inserting the probe.

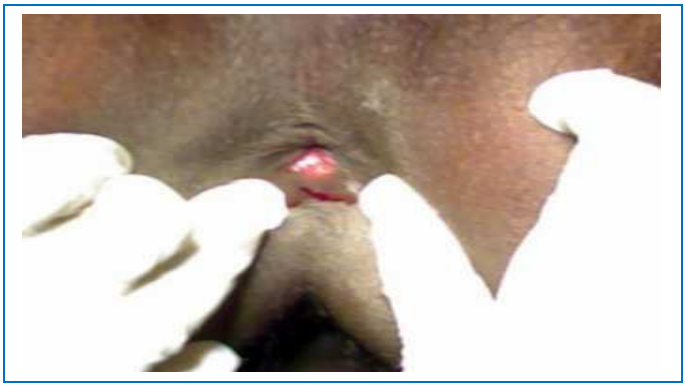
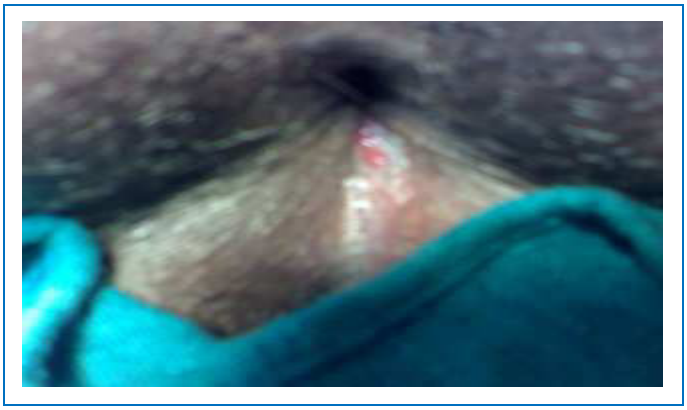


Figure 7: The probe introduced.

Figure 8: The *Ksharasutra* had pass through the artificial tract.

Figure 9: The photograph shows before, after and the application of *Ksharasutra* in Anal fissure.



DISCUSSION

Ksharasutra type of surgical operation is a popular treatment for fistula-in-ano in India and is well recognised by many contemporary medical books.[8] This study is postulated after proper understanding of surgical anatomy of anal canal. Fissure bed lies in between anal verge to dentate line i.e., within 2cm. Internal anal sphincter lies just beneath to the fissure. It was studied that internal anal sphincter 50 to 55 percent, external anal sphincter is 25 to 30 percent, and anal cushions 15 to 20 percent, contributions toward resting basal tone. Complete internal anal sphincter myotomy produce 55% pressure reduction in patients with anal fissure.[9] The maximum pressure founds near the anal verge. The fissure bed lies in these areas. The aim of our study was to cut the internal sphincter muscle of these areas.

During the procedure, finger inside the anus provides additional tension to the internal sphincter, by which

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one can ligate maximum number of fibers without going to the deep to external anal sphincter. Fissure bed, when it is short i.e. below 6mm, initially there is chance to cut in a half circle pattern but in maximum cases when it is slight longer in length there is great chance to cut in an ellipse pattern.

In this study mean cutting time of the artificial tract was 7.8 days and thereafter for sound healing it takes 2-4weeks. Thickness of the internal sphincter muscles in dorsal area was 1.96 ± 0.61 mm by using ultrasound and 1.72 ± 0.13 mm by using MRI.[10] *Ksharasutra* was applied to cut through the lower sphincter muscle, just beneath to the fissure bed. Initial length of thread suggests the perimeter which had been cut. So the depth of the cut through can be calculated approximately by Ramajuna formula $\rho \approx \pi\left[3(a+b) - \sqrt{(3a+b)(a+3b)}\right]$ for ellipse perimeter. The depth was near about 2 to 3.5mm which was neither so superficial nor so deep.

In this study maximum middle age group of person were more suffering from chronic fissure, may be due to hectic lifestyle and male patient are more than female. Ligating *Ksarasutra* has highly significant relief on the subjective parameter such as pain (≤0.001), bleeding per rectum (≤0.001), sphincter spasm (≤0.001) and straining (≤0.001). The consistency of stool also kept in between grade 3 and 4 according to the Bristol stool scale.[11] Bleeding per rectum was also completely stopped. Pain disappeared after cut through of the *Ksharasutra* and it was statically highly significant (≤0.001). It was the fact that due to the presence of the *Ksharasutra* the slight spasm of internal sphincter still persists. Following cut through of the lower part of the internal sphincter the spasm disappeared, and also relief from the pain. The patients who had bleeding due to disease itself or due to the association with 1st degree haemorrhoids (20% patient), significantly reduced bleeding after the *Ksharasutra* application. The resting anal pressure is slight higher in haemorrhoids patients than normal.[9] In fact it suggests that cut through of the lower part of the internal sphincter had some role for relieving symptoms of haemorrhoids. In the study there was no incontinence and recurrence.

In a nut shell the advantages of *Ksharasutra* on the anal fissure were as followed. Wound created in *Ksharasutra* therapy was very small. There was no postoperative incontinence. There was also neither any history of recurrence within 6 months. There was no key-hole deformity and being very economical.

The gradual cutting was obtained from pressure effect of the thread as well as by the irritatiting properity of latex of *Euphorbia Neripholia*. This latex[12] and the powder of *Curcuma longa*[13] had the additional wound healing properity. Latex of *Euphorbia Neripholia* has the corrosive property and also plays role in healing process as evidence increase in tensile strength, DNA content, epithelization and angiogenesis in surgically produce coetaneous wound.[14] *Curcuma Longa* also helps in earlier re-epithelialization, improved neovascularization, and increased migration of various cells including dermal myofibroblasts, fibroblasts, and macrophages into the wound bed.[15]

These advantages are due to following properties of the *Ksharasutra* mainly due to cutting and healing going simultaneously and it causes cauterization of the infected origin of the fissure and lysis of unhealthy granulation tissue.

Conclusion

Every surgeon or physician always has zeal of providing the best treatment to his patients. There were lots of options available for anal fissure. The choosing of the best treatment for a particular condition is essential. In this aspect this treatment was much more acceptable for chronic cases of anal fissure. The treatment can also be applicable after removing the sentinal tag surgically. Even it can be a best option of choice, after failure of sphincterotomy.

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How to cite this article: Dr. Suman Sarkar, Dr. K. B. Sudhikumar, Dr. P. V. Jayasree, Dr. Tuhin Kanti Biswas. A Clinical Study on Chronic Anal Fissure by ligating Ksharasutra (medicated thread) w.s.r. to Sphincterotomy. J Ayurveda Integr Med Sci 2018;6:23-28.
http://dx.doi.org/10.21760/jaims.3.6.4

Source of Support: Nil, **Conflict of Interest:** None declared.

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