

## Article

# A comparative study between seton treatment using ksharasutra and conventional surgery in fistula in ANO

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**Abstract: Background:** Fistula-in-ano is a tract connecting the anal canal to the perianal skin. It is a complication of anorectal sepsis in approximately 25% of patients within 6 months of the incidence. Alternatively, a nonsurgical cost efficient treatment with Ksharasutra (cotton Seton coated has minimal complications).

**Objectives:** To compare the outcome of Seton treatment using ksharasutra and Conventional fistula surgery (fistulotomy).

**Methods:** It was a prospective observational study. 96 patients were selected for these studies who were admitted for fistula repair Between November 2016 to December 2021 in R.G kar medical College & Rampurhat Government Medical College. Patients coming at outpatient department of surgery with the complaint of persistent perianal discharge with or without pain were examined by per rectal digital examination and those with perianal fistula were included in the study.

**Results:** out of 96 patients, 50 were selected in the study group who were treated with ksharasutra and 46 patients were selected in the control group in whom fistulotomy was done. Study was male preponderance (87%). Out of 96 patients 86 were male and 10 were female. Most (84 out of 96) belong to 20-39 year age group. There were 10 cases of high anal fistula in the study group while the number was 9 in the control group. The mean duration of healing was  $53.00 \pm 26.75$  days in medicated Ksharasutra group whereas in fistulotomy group, mean duration of healing was  $35.67 \pm 9.17$  days. Ksharasutra group required significantly ( $P = 0.02$ ) more number of days for healing.

**Conclusion:** The application of Ksharasutra is a better option not only because it is cost effective but also due to lesser postoperative complications.

**Keywords:** Fistula-in-ano, Ksharasutra, fistulotomy, Seton, Perianal discharge.

## 1. Introduction

**F**istula-in-ano is a tract connecting the anal canal to the perianal skin. It is a complication of anorectal sepsis in approximately 25% of patients within 6 months of the incidence [1,2]. The sepsis originates commonly in the anal canal gland at the dentate line. Anatomically it can be intersphincteric, trans-sphincteric, suprasphincteric and extrasphincteric [3]. Intersphincteric variety is the most common type.

Characteristics of a simple fistula include a single tract, subcutaneous tract, and those that involve less than 30% of the external sphincter. A simple fistula is the easiest to treat and has the lowest recurrence and complication rates. Complex fistulas include those that involve more than 30% of the external sphincter, fistulas with multiple tracts, recurrent fistulas, and those associated with other predisposing factors, including Crohn disease and radiation treatment. There are many treatment options available ranging from conventional surgery to seton placement, LIFT (ligation of intersphincteric fistula tract), plug repair, endorectal advancement flap etc. In our study we have made a comparison between conventional surgery (fistulotomy) and seton treatment using ksharasutra for treatment of fistula in ano [4,5].

## 2. Materials and Methods

It was a prospective observational study. 96 patients were selected for these studies who were admitted for fistula repair Between November 2016 to December 2021 in R.G kar medical College & Rampurhat Government Medical College. Patients coming at outpatient department of surgery with the complaint of persistent perianal discharge with or without pain were examined by per rectal digital examination and those with perianal fistula were included in the study. Patients having multiple external openings, supra sphincteric & extra sphincteric fistula, history of tuberculosis and crohn's disease was excluded.

## 3. Methodology

Imaging studies like fistulogram / MR fistulogram were done in 36 cases with recurrent fistula or suspicion of complex fistula. Out of 96 patients, 46 patients underwent fistulotomy and in remaining 50 seton (Kshara Sutra) placement was done after randomization.

## 4. Ksharasutra

Key ingredients are

- Snuhi-ksheera: tremendous sticking property holds particles of other ingredients firmly over the thread.
- Kshara: make the seton highly alkaline which debride the unhealthy tissue and does not allow the rectal pathogen to invade and multiply in the tract.
- Haridra: used as antiseptic. It acts by continuous drainage as it doesn't allow the tract to close it cuts the fistula tract by debriding the unheally tissue.

After obtaining operative fitness by doing the necessary pre-operative investigations patients were admitted one day before the procedure. Per rectal enema was given on the night prior to surgery. Antiseptic dressing and shaving of both thighs and peri anal region was done. Application of ksharasutra and fistulotomy were done under saddle block. After anaesthesia patients where put in lithotomy position and proper draping were done. The internal opening was delineated by palpation or by proctoscopic examination. Sometimes internal opening was identified by injecting methylene blue or gentian violet dye through the external opening and seeing through the proctoscope in the anus from where it is coming out.

In case of seton patient took normal diet in the post operative period. Oral ciprofloxacin, analgesics, PPI for 2 days ,laxatives for 3-4 days and sitz bath thrice daily for 10 days. Patients were discharged on the same post operative day and were able to join their duty from second postoperative day. In case of fistulotomy initially patients were given liquid diet that in the post operative period. Parental antibiotics were given for one day after that oral antibiotics (ciprofloxacin plus metronidazole) where given for 5 days along with analgesics, PPI and laxatives. Sitz bath thrice daily for 10 days was advised. Patients where discharge 3 days after the procedure.

In cases of kshara sutra patients where followed at 2 weekly intervals to change the kshara Sutra. Thereafter patients where advice to follow up at every 3 monthly intervals upto 2 years. In case of fistulotomy patients were advised to follow up at monthly intervals for the first 6 months. The wound any scarring, stenosis, incontinence and recurrence were evaluated. Thereafter they were advised to follow up at 3 monthly intervals up to 2 years.



**Figure 1.** Eye of the probe threaded with Ksharasutra



**Figure 2.** After 4 weeks of Treatment

## 5. Statistical Analysis

Data so obtained were subjected to statistical analysis. Results were evaluated for the best modality through which benign and malignant lesions can be differentiated. Data analysis was done by SPSS software version 22.0. Descriptive statistical analysis, which included frequency and percentages, was used to characterize the data. Chi-square test was used for association between factors and  $p < 0.05$  was considered statistically significant.

## 6. Results

As per Table 1 study of 96 patients, 50 were selected in the study group who were treated with ksharasutra and 46 patients were selected in the control group in whom fistulotomy was done. Study was male preponderance (87%). Out of 96 patients 86 were male and 10 were female. Most (84 out of 96) belong to 20-39 year age group. There were 10 cases of high anal fistula in the study group while the number was 9 in the control group. Only 12 cases had 2 openings. The duration of healing was a bit longer in the study group in comparison with the control arm (52.33 vs 33.55 days). The number of days off work was 1.19 days in the study group while it was 30.38 days in the control group.

As per Table 2 the mean duration of healing was  $53.00 \pm 26.75$  days in medicated Ksharasutra group whereas in fistulotomy group, mean duration of healing was  $35.67 \pm 9.17$  days. Ksharasutra group required significantly ( $P = 0.02$ ) more number of days for healing. The maximum and minimum duration "off-work" was 8 and 26 days, respectively. Ksharasutra group had significantly ( $P < 0.001$ ) few days "off-work" compared to fistulotomy group. Different postoperative complications were observed, scarring was the most common complication. Serious complication like recurrence was less in Ksharasutra groups. Expenditure for Ksharasutra group was significantly cost effective than fistulotomy group (international normalized ratio 166 vs. 464).

**Table 1.** Demographic and Clinical presentation of Fistula in Ano

Variables	ksharasutra	fistulotomy	p value
Mean age			
Year	38.1 ( $\pm$ 10.7)	36.7 ( $\pm$ 9.3)	0.55
Sex			
Male	42 (84.7)	44 (87.5)	1.0
Female	08 (15.3)	02 (12.5)	
Site of external opening			
Antero lateral	31 (42.3)	17 (29.1)	0.49
Postero lateral	32 (46.1)	24 (58.3)	
Lateral	2 (15.3)	4 (16.7)	
Posterior	4 (15.3)	1 (4.7)	
External opening Single	42 (84.6)	40 (91.7)	0.66
Two	6 (11.5)	6 (8.3)	
Multiple	2 (3.9)	0	
Distance from anal verge (cm)			
To external opening	2.3 ( $\pm$ 1.0)	2.5 ( $\pm$ 1.4)	0.95
To internal opening	2 ( $\pm$ 0.7)	2.1 ( $\pm$ 0.8)	0.77
Type			
Inter-sphincteric	39 (73.1)	38 (75.1)	0.87
Trans-sphincteric	11 (26.9)	8 (25.0)	

**Table 2.** Pre-Operative and Post-Operative Findings in study cases

Variables	ksharasutra	fistulotomy	p value
Minutes (range)	14.8 ( $\pm$ 7.6)	25.8 ( $\pm$ 14)	.01
Pain			
No pain	20 (11.6)	1	0.01
Mild +	25 (57.7)	6 (20.9)	
Moderate ++	2 (23)	33 (15.1)	
Severe +++	3 (7.7)	6 (25)	
Postoperative discharge Mild	33 (59)	30 (41.7)	0.81
Moderate	10 (34.7)	12 (50)	
Severe	7 (15.3)	4 (8.3)	
Hospital stay Hours	24.2 ( $\pm$ 12.6)	51 ( $\pm$ 12.9)	0.01
Absent from work Days	2.7 ( $\pm$ 4.1)	15.5 ( $\pm$ 4.7)	0.02
Healing time Days	53 ( $\pm$ 26.6)	35.7 ( $\pm$ 9.1)	0.02
Complications			
Bleeding	0	2 (8.3)	0.01
Infection Incontinence	1 (3.9)	3 (12.5)	
Flatus	1 (3.9)	2 (8.3)	
Faeces	0	1 (4.1)	
Recurrence	1 (3.9)	3 (12.5)	
Scaring	3 (11.6)	4 (16.7)	
Anal stenosis	1 (3.9)	1 (4.1)	

## 7. Discussion

Use of "chemical" Seton (Ksharasutra) for treatment of fistula-in-ano is reported in ancient Indian texts [2]. Such stenoses are made from plant extracts impregnated in layers onto a cotton thread using latex. The Kshara (caustics)[3] applied on the thread are anti-inflammatory, anti-slough agents and in addition, have chemical curetting properties [1]. The Ksharasutra remains in direct contact of the tract and, therefore, it physically and chemically curettes out the tract and sloughs out the epithelial lining, thereby allowing the fistulous tract to collapse and heal. Several modifications of this procedure are also reported [4,5]. Fistulotomy

is the most commonly used treatment protocol in cases of fistula in ano. Seton placement using ksharasutra is a good alternative to fistulotomy. The treatment is simple, easy to apply and safe. In our study, 54% of the patients were in the fourth decade and there was significant male predominance with a ratio of 6:1, which is consistent with other studies in India [1,6–8] and worldwide [9,10]. The relative distribution of intersphincteric and trans-sphincteric variety is also consistent with previous studies [7,8].

Recurrences are common after fistulotomy with some reporting 8.47% of recurrence [9]. However, we observed 12.5% recurrence which may be due to relative smaller sample size in our study. The recurrence rate was only 3.8% in Ksharasutra group, which is consistent with previous reports [8,9]. Incontinence after fistulotomy is a very distressful problem both to patient and surgeon [9,10]. For fistulae that traverse longer distances of sphincter, such as high trans-sphincteric or more proximal, fistulotomy conveys high rates of postoperative incontinence and alternative surgical treatments are necessary. For these "complex" fistulae, cutting Setons are used to slowly divide fistulous tissue tracts on the leading edge of the Seton while allowing healing to occur on the trailing edge thereby preserving sphincter continuity and preserving sphincter function.

## 8. Conclusion

Treatment of fistula-in-ano by Ksharasutra is simple, easy, and safe. The chances of recurrence and anal incontinence are very low and most importantly, the cost of the treatment is very low. As it is an "ambulatory treatment" patient can join in their work very early. Hence, the application of Ksharasutra is a better option not only because it is cost effective but also due to lesser postoperative complications.

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**Conflicts of Interest:** "Authors declare no conflict of interests."

## References

- [1] Abbas, M. A., Lemus-Rangel, R., & Hamadani, A. (2008). Long-term outcome of endorectal advancement flap for complex anorectal fistulae. *The American Surgeon*, 74(10), 921-924.
- [2] Vogel, J. D., Johnson, E. K., Morris, A. M., Paquette, I. M., Saclarides, T. J., Feingold, D. L., & Steele, S. R. (2016). Clinical practice guideline for the management of anorectal abscess, fistula-in-ano, and rectovaginal fistula. *Diseases of the Colon & Rectum*, 59(12), 1117-1133.
- [3] Parks AG, Gordon PH, Hardcastle JD: A classification of fistula-in-ano. *Br J Surg* 63:1-12, 1976.
- [4] Akiba, R. T., Rodrigues, F. G., & da Silva, G. (2016). Management of complex perineal fistula disease. *Clinics in Colon and Rectal Surgery*, 29(02), 092-100.
- [5] Davies, M., Harris, D., Lohana, P., Chandra Sekaran, T. V., Morgan, A. R., Beynon, J., & Carr, N. D. (2008). The surgical management of fistula-in-ano in a specialist colorectal unit. *International journal of colorectal disease*, 23(9), 833-838.
- [6] Kelly, M. E., Heneghan, H. M., McDermott, F. D., Nason, G. J., Freeman, C., Martin, S. T., & Winter, D. C. (2014). The role of loose seton in the management of anal fistula: a multicenter study of 200 patients. *Techniques in coloproctology*, 18, 915-919.
- [7] Ritchie, R., Sackier, J. M., & Hodde, J. P. (2009). Incontinence rates after cutting seton treatment for anal fistula. *Colorectal Disease*, 11(6), 564-571.
- [8] Hong, K. D., Kang, S., Kalaskar, S., & Wexner, S. D. (2014). Ligation of intersphincteric fistula tract (LIFT) to treat anal fistula: systematic review and meta-analysis. *Techniques in coloproctology*, 18(8), 685-691.
- [9] Mei, Z., Wang, Q., Zhang, Y., Liu, P., Ge, M., Du, P., ... & He, Y. (2019). Risk Factors for Recurrence after anal fistula surgery: A meta-analysis. *International Journal of Surgery*, 69, 153-164.
- [10] Ortiz, H., Marzo, M., De Miguel, M., Ciga, M. A., Oteiza, F., & Armendariz, P. (2008). Length of follow-up after fistulotomy and fistulectomy associated with endorectal advancement flap repair for fistula in ano. *Journal of British Surgery*, 95(4), 484-487.

