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A Comparative Study of Ayurvedic medicated seton (Kshara Sutra) and Fistulectomy in Anorectal fistulae

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Abstract

Background: Anorectal fistulae (or) Fistula in ano is a common proctological disease, resulting in recurrence, and may also result in some impairment of continence. Medicated seton (Kshara Sutra) therapy is being practiced in India with high success rate in the management of complicated anal fistula. To this purpose we evaluated the safety and effectiveness of medicated seton over standard surgical procedure fistulectomy.

Methods: This prospective study was undertaken to compare fistulectomy Vs. Medicated seton in the management of fistula-in-ano. The study has been undertaken in the period of 18 months during 2004-06. Postoperative pain was assessed at 24 hours and 48 hours postoperatively on a visual analogue scale (VAS). Primary outcome Proportion of participants developing a recurrence, defined as an abscess spontaneously discharging or requiring surgical drainage, or a recurrent fistula either at the same site or at a different site. Descriptive statistical analysis has been carried out in the present study. SPSS 15.0 Statistical software was used for the analysis of the data and Microsoft word and Excel have been used to generate tables etc.

Results: A total of 44 patients underwent surgical procedure for fistula in ano. The patient had been divided into sage groups from minimum 20 years to maximum 60 and above. The maximum number of patients was found in 31- 40 years of age group. Out of the 44 patients 32 were males 12 where women. Chronicity of the disease varied from 2 months to a maximum duration of 2 years. Patients of younger age group presented earlier than older patients comparatively female patients presented later. 25 patients had low anal variety while 10 high anal and 5 anorectal type of fistula in ano.

Conclusion: In the comparison between fistulectomy and seton offers the advantages of ease of application, minimal trauma to tissues negligible rate of recurrence and minimal post operative complications. The compliance of patients and patient satisfaction is also high. It can safely be concluded that medicated seton has a prime place as treatment option in the management of fistula-in-ano. It has to be offered as a primary option to a patient of fistula-in-ano seeking medical aid, if not before, but alongside surgical options.

Keywords: Anorectal fistulae (fistula in ano), Medicated seton, Ksharasutra, fistulectomy, visual analogue scale (VAS)

Introduction

Anorectal fistulae (or) Fistula in ano is a common proctological disease, resulting in recurrence, and may also result in some impairment of continence. The Recurrence risks range from less than 10% to as high as 57 %. [1] There are a variety of surgical options available for treatment; however the rationale for choosing each is poorly defined. But, the basic aim is treatment of fistula in ano is to internal and external anal sphincters preservation is in the interest of continence maintenance. Fistula-in-ano, usually secondary to cyptoglandular infection is a non healing chronic disease. The surgical procedure fistulectomy is the standard management. The mutilating surgery, prolonged post operative period, high recurrence rate and the complication of fecal incontinence, of this treatment, is what that had made the disease infamous. Medicated Seton (kshara sutra) is the application of a suture or rubber through the fistula and tightening it with change of seton every week for a couple of weeks. Seton as it cuts through the tissues evokes fibrous reaction that obliterates fistula, destroys residual glandular epithelium and fixes the sphincters. Ksharasutra (medicated seton) therapy is being practiced in India with high success rate (recurrence of 3.33%) in the management of complicated anal fistula. [2] We evaluated the safety and effectiveness of seton over conventional fistulectomy. Additionally, we have studied the Proportion of participants developing a recurrence, Proportion of participants developing incontinence, operative time, postoperative pain, duration of hospital stay and time taken to resume normal work.

Materials and methods

This prospective study was undertaken to compare fistulectomy Vs. medicated seton in the management of fistula-in-ano. The study has been undertaken in the period of 18 months during 2004-06. Patients were enrolled from surgery outpatient wing of hospital after careful examination. Patients with primary, simple anorectal fistula proven clinically, including intersphincteric, low and high trans-sphincteric fistulae that are cryptoglandular in origin were included. Patients were excluded if they have secondary fistula (malignancy, tuberculosis, crohns disease and hydradenitis suppurativa), complex fistula (high blind tracks and those with multiple external openings), supra sphincteric and extrasphincteric fistulae. All patients underwent a detailed clinical examination, blood investigations and pre anesthetic workup before surgery. Patients opted for either fistulectomy [3] or medicated seton depending upon their socioeconomic status. As per the standard treatment of anal fistula, complete tract should be laid open or excised. As per reference of Sushrutha samhita ancient Indian surgical text, ksharasutra treatment was mentioned.[4] Patients were operated under spinal anesthesia, in lithotomic position. Duration of surgery is calculated from the time of anoscopy to the time of completion of procedure. Duration of hospital stay is calculated from the day of surgery to the day of discharge from the hospital. Time taken to resume normal work is calculated from the day of discharge to the first day that patient had returned to their respective occupation. Postoperative pain was assessed at 24 hours and 48 hours postoperatively on a visual analogue scale (VAS)[5] ranging from 0 to 10, where 0 is no pain and 10 is the worst pain ever. Patients were then asked to come for follow up regularly once in a month for six months or as and when needed. Primary outcome Proportion of participants developing a recurrence, defined as an abscess spontaneously discharging or requiring surgical drainage, or a recurrent fistula either at the same site or at a different site (suggesting an unidentified tract at the index operation). Development of incontinence, defined by incontinence scores (its impact on quality of

life and specific problems such as use of pads, soiling, urgency, flatus, liquid stool, and solid stool). Patient global satisfaction was assessed on a 4 point scale where 0= poor, 1=good, 2=very good, 3= Excellent.

Statistical methods

Descriptive statistical analysis has been carried out in the present study. SPSS 15.0 Statistical software was used for the analysis of the data and Microsoft word and Excel have been used to generate tables etc. Results on continuous measurements were presented as Mean ± SD and categorical data as actual numbers and percentages. Unpaired t test, ANOVA and Chi-square test were used to test significance between two groups. P value is considered to be significant when it is less than 0.05 ($P<0.05$).

Results

A total of 44 patients underwent surgical procedure for fistula in ano. The patient had been divided into sage groups from minimum 20 years to maximum 60 and above. The maximum number of patients was found in 31- 40 years of age group. Out of the 44 patients 32 were males 12 where women. Chronicity of the disease varied from 2 months to a maximum duration of 2 years. Patients of younger age group presented earlier than older patients comparatively female patients presented later. 25 patients had low anal variety while 10 high anal and 5 anorectal type of fistula in ano. The clinical characteristics, type of surgery and outcomes were presented in Table-1.

Table 1: Clinical characteristics and outcomes between Seton vs. Fistulectomy.

Clinical Parameters	**Seton (n=24)**	**Fistulectomy (n=20)**	**P value**
Age in years	36±2.4	41±3.8	P<0.05
Gender (m/f)	20/4	12/8	P<0.05
Type of fistula S/L/H/A	0/15/7/2	4/10/3/3	P<0.05
Chronicity of disease (months)	12.2±5.4	18.8±3.4	P<0.05
Operation Time in min	25.87±7.67	55.8±8.8	P<0.05
Anal pain VAS (mm)24 hours	4.52±0.83	6.25±1.19	P<0.05
Anal pain VAS (mm) VAS 48 hours	1.58±0.76	3.22±0.92	P<0.05
Duration of hospital Stay in days	1.89±0.83	3.65±1.5	P<0.05
Time to normal work in days	3.5±2.25	5.1±5.4	P<0.05
Complications			
Bleeding	0	0	P>0.05
Infection	0	2	P>0.05
Recurrence	0	4	P>0.05
Incontinence	0	1	P>0.05
Patient satisfaction	Very good-20 Good-3 Not satisfied-1	Very good-12 Good-3 Not satisfied-5	P<0.05
S/L/H/A= Sub mucous/Low/High/Anorectal			

High/Anorectal fistula is inter-sphinteric, which are more prone for incontinence and recurrence.

Discussion

Fistula in ano has a simple presentation but presents a challenge to surgeons the coloproctologists in view of high recurrence rate, faecal incontinence. Fistulectomy involves excision of the tract and allowing the wound to heal by granulation. Of the six patients who underwent fistulectory, those patients who had sub-mucous fistulae, were discharged after forty eight hours with regular weekly follow up for fifteen days with advice to return to the hospital if there is recurrence of symptoms. Patients with low anal fistulae were in patients for four days, when the wound was examined daily. They were discharged with the advice of sitzbath daily till the wound heals, follows up every week at the hospital for the month. Once the wound had healed, they were adviced to return to hospital in case of recurrence of symptoms.The patients with high anal fistula with multiple external opening had a in-hospital stay of two weeks with regular daily inspection of wound and under post operative surveillance for a further period of one month every week and bi weekly for one month. These patients had not returned with complaints of recurrence or incontinence till date. But most patients, especially the employed, had to stay away from work, until such time the wound had healed. The prolonged convalescence period and loss of work days was unacceptable to these patients. The surgery especially in cases of high anal fistulae adds to the misery of the patient rather than alleviate it. Seton, though in vogue for several years is still not an accepted procedure among surgeons. But the ease of application, the changes undertaken as an office procedure, lack of discomfort to the patient and no loss of work days, without the complication of incontinence is a boon to the patient. The cutting seton allows tissues to reunite behind it. This means that when the medicated seton finally cuts through the skin, there is very little residual. The fibrosis associated with cutting seton destroys residual gland epithelium. Recent works suggest that most fistulae have few organisms and histological examination of the tracks has shown that many of them contain epithelium derived either from anal glands themselves or from anal transition zone, rectum or skin. It is well established, that epithelialisation is a common reason why tracks elsewhere in the body fail to heal and such epithelialisation may be an important reason why anal fistulae persist. Seton as it destroys epithelium prevents recurrence of fistulae. So seton must be a part of the armamentarium of coloproctologists in the management of fistula in ano. Drainage of primary intersphinteric infection in all types of fistulas as well as the primary track across the external sphincter and secondary tracks within the anorectal fossa is the key to management of fistula-in-ano. Fistulectomy or seton in the management of fistula-in-ano has to be viewed in context of patient comfort, type of fistula, the incidence of incontinence and loss of work days. Each case has to be approached individually and managed accordingly.The cryptoglandular infection which eventually leads to fistula is notorious to eradicate and hence recurrence is common in the treatment of fistula-in-ano. Any extensive surgery in this area that deals with complex fistulae is liable to disturb the sphincter mechanism and anorectal ring, ultimately leading to incontinence. Kronborg[(6)] reported that the recurrence rates following a fistulectomy and a fistulotomy were 9.52% and 12.5%, respectively, during a follow-up period of 12 months. In a retrospective study conducted to determine satisfaction following surgery, 12% of the patients expressed dissatisfaction following surgery. The majority of those patients attributed their dissatisfaction to recurrence and anal incontinence following surgery. [(7)] Seton has the advantage of ease of application as a day care surgery, no wound care, change of seton on outpatient basis, no loss of work days to patient, almost

negligible side effects. [8] As a treatment option, medicated seton has the advantage in high anal and anorectal fistulae, in that anal incontinence is not a complication as the fibrosis fixes the sphincter. The extensive fibrosis also reduces the recurrence rate to a minimum, as it destroys any residual gland epithelium.

Study limitations

We have evaluated small cohort of patients in this study with a small duration of follow-up. So we could not able to calculate relative risk of recurrence of incontinence.

Conclusion

In the comparison between fistulectomy and seton offers the advantages of ease of application, minimal trauma to tissues negligible rate of recurrence and minimal post operative complications. The compliance of patients and patient satisfaction is also high. It can safely be concluded that seton has a prime place as treatment option in the management of fistula-in-ano. It has to be offered as a primary option to a patient of fistula-in-ano seeking medical aid, if not before, but alongside surgical options.

Conflict of Interest: None

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