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Original Research Article

Comparison of "medicated seton versus fistulectomy" in the management of fistula-in-ano in tertiary care hospital

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ABSTRACT

Background: Fistula-in-ano is defined as communication between anal canal or rectum to external surface. The main objectives of the study are to compare management of fistula-in-ano by "Medicated seton Vs Fistulectomy" and its outcome in term of complications and the recurrences if any.
Methods: This study is a randomized controlled trial. Total 46 consecutive patients presenting to the Department of Surgery at SVNGMC Medical College Yavatmal with fistula-in-ano during the time of Sep-13 to Oct-15 were included in the study. All the patients were studied as per the proforma and treated by either medicated seton or fistulectomy.
Results: It was observed that operative time required (min) in medicated seton was significantly less than fistulectomy procedure. Hospital stay (days) required was significantly more in fistulectomy procedure as compared to medicated seton. Time required for complete healing (days) was significantly more in medicated seton as compared to fistulectomy.
Conclusions: It is concluded that treatment of fistula-in-ano by medicated seton is simple, easy, and safe. Medicated seton treatment is an outpatient procedure and can be done in a minor operation theatre or even at Primary Health Care level. Procedure not left with a large perineal wound and its associated morbidity.

Keywords: Fistulo in ano, Fistulectomy, Medicated seton

INTRODUCTION

The fistula is an opening between two organs of the body, or between an organ and the skin, that would not normally exist, caused by injury, infections, etc. Fistula-in-ano is defined as communication between anal canal or rectum to external surface.

Anal fistulae have been known as a common surgical ailment for over two and half millennia one of the earliest literature written by Hippocrates about 430 B.C. made reference to surgical therapy for fistulous disease and he was the first person to advocate fistulectomy as well as the use of a seton (from the Latin seta, ra bristle) made up of horse hair wrapped with lint of threads.[1]

It is very common to see a patient with recurrent fistula because of unsuccessful surgical attempts. The popular conventional surgical approaches leave the patient with distressful postoperative surgical problems like incontinence of anal sphincter, anal stenosis and recurrence. Prolonged hospital stay, bed occupancy, painful postoperative dressings, and loss of valuable man hours forbid us from surgical approach as the primary treatment of fistula-in-ano.[2]

Fulfilling all these goals has been a challenge to the skill, patience and reputation of surgeon. In such a situation, the revival of medicated seton technique described first by the Great Indian surgeon, Sushruta, as a primary therapeutic approach towards fistula-in-ano, can prove to

be a boon for the ailing humanity. For simple and most distal fistulae, conventional surgical options seem to be relatively safe. However, for more complex fistulae where a significant proportion of anal sphincter is involved, great concern remains about damaging the sphincter and subsequent poor functional outcome, which is common inevitable following conventional surgical treatment. For this reason, many sphincter-preserving procedures for the treatment of anal fistula have been introduced with the common goal of minimizing the injury to the anal sphincters and preserving optimal function.[3]

Seton have been used to treat anal fistulae from ancient times. In recent times, success rate over 98% have been reported. With medicated seton technique the patient can be treated on out-patient basis obviating the need of prolonged hospitalization and a proper operation theatre set-up even can be done at Primary Health Care level. The patient can remain ambulatory throughout the treatment period and continue with his work unhindered. The technique is, therefore, very fit for adopting at rural medical level.[4] The main objectives of the study are to compare management of fistula-in-ano by "Medicated seton versus Fistulectomy" and its outcome in term of complications and the recurrences if any.

METHODS

Total 46 consecutive patients presenting to the Department of Surgery at SVNGMC Medical College Yavatmal with fistula-in-ano during the time of Sep-13 to Oct-15 were included in the study. This study is a randomized controlled trial. All the patients were studied as per the proforma and treated by either medicated seton or fistulectomy. All patients from all age groups and both sex presenting with fistula-in-ano during the study period, patients were consecutively enrolled into the study after informed consent. Those with recurrence after previous fistula surgery were also included in study. Patients presenting with fistula in ano having uulcerative colitis; Crohn's disease; carcinoma of rectum; active abdominal tuberculosis; radiation therapy and patients with perianal injuries. Patients not giving consent or those who were not able to give valid consent for study were also excluded from study.

Ethics committee approval to conduct study was obtained from the joint institutional ethics committee before the commencement of the study. Detailed clinical examination of all the patients carried out and relevant and special investigations were ordered. Patient having any parasitic infestation of the gastro-intestinal track were first treated for it before starting the treatment of fistula proper. Fistulous discharge was examined for fungus and acid-fast bacilli in suspected cases and submitted for culture inoculation. Detailed pre-operative evaluation of the patient and appropriate preparation for surgery. After obtaining consent patients were randomly allocated to be treated by either medicated seton or by fistulectomy. Surgical treatment according to the merit of the case decided by the attending surgeon under suitable anaesthesia and operative findings noted. Post-operative course observed for complications and their management done. Follow up after 1 month initially, then after 3 months subsequently at 6 monthly intervals till one and half year.

The subjects were allocated in to two groups by randomization into Group 'A' - Seton treatment and Group 'B' – Fistulectomy. After explaining the procedure and follow-up in detail, consent for treatment taken. Lithotomy position was given. Inspection and palpation of the track was done. Blunt curved fistula probe director with frenulum slit introduced through the external opening gently and its tip palpated through the anal canal by an index finger of opposite hand and the tip of the probe is gently brought out through internal opening and then through anal opening.

A medicated seton introduced into the fistula track through the slit in probe. Both the ends of seton tied at the surface outside the anal canal. The knot was tightened with such a tension to produce controlled cutting of the fistulous track. It was tied neither too tightly nor too loose. Patients were observed for one to six hour for immediate complication like severe perianal pain then patients were sent home on next morning and advised antibiotics, stool softener and analgesics. Those patients admitted to hospital post-operative pain was assessed using VAS (Visual Analogue Scale) ranging from 0 to 10 (0-3 mild, 4-7 moderate, and 8-10 severe). Patients were advised to take sitz bath twice a day at home. The previously tied seton could remain in-situ for one week and patients were called after one week for change of seton. Rail- Road technique was used for the same. The change of seton was done again as an OPD procedure without any anaesthesia.

The procedure repeated each week till the last seton fell out spontaneously by cutting through the tissue. The weekly change of seton generally maintained a diminution of thread corresponding to 1 to 1.5 cm. In case of fistula with multiple opening (multiple fistulous tracks) all the tracks were threaded in one sitting only. Patients were not restricted for any diet. When the seton fell off spontaneously i.e. cutting through the fistulous track and healing it from within completely, that treatment was terminated. After the termination of treatment patients were advised to come for follow up after 1 month initially, then after 3 months subsequently at 6 monthly intervals till one and half year.

All the patients were hospitalized and consent for operation taken one day prior to surgery. Preanasthetic fitness was obtained for all patients. Patients were kept nil per oral overnight, with enema given. Local shaving of the parts was done previous evening. Perianal region was cleaned with soap and savlon. The perianal skin was cleaned with betadine under all aseptic condition.

Procedure was done in lithotomy position under spinal anaesthesia. After the internal opening was found its level was judged in relation to the anorectal ring. There were subcutaneous and low anal fistula tracks. These were simply laid upon throughout their length by incision on the probe division of tissue completed by sliding the scalpel along the groove on probe.

In few cases the fistula was blind attempt was made to feel the inner end of the probe per rectally under the anal mucosa or skin and if it was felt deep to the internal sphincter or skin or mucosa then with little force the blind fistula was made complete. If the probe entered the anal canal below the anorectal ring, then the track was cut open. If the internal opening was not found, then the probe point was directed forwards and made to project against and slightly in front of it; an incision was then made on the probe releasing and exposing part of the fistula. For the high going blind extension the treatment performed was curettage of upper extensions while the peripheral tracts were excised.

The wound was dressed Vaseline gauze in the rectum and covering the raw area with Vaseline gauze, one corner of gauze entering the anal canal to cover the raw area there. Cotton pads were kept over this and a 'T' bandage was applied. Postoperative pain assessed using VAS (Visual Analogue Scale) ranging from 0 to 10 (0-3 mild, 4-7 moderate, and 8-10 severe). For first two days liquid diet and from third day onward normal diet with syrup lactulose 15 ml at bed time.

Patients were advised sitz bath followed by dressing with sterile Vaseline gauze covering the whole raw area. Thereafter the dressing of the wound was done once a day in the morning after sitz bath and bowel action. Patients were advised perineal exercise after operation.

Oral or injectable analgesia was given as per complaint of patients. When the wounds of patient healed adequate so that they did not need supervised dressing any more those patients were discharged. At discharge patient was advised sitz bath daily for 20-30 minutes followed by dressing of wound. Patient was called at weekly intervals till complete healing. Thereafter patient was called at 1 month, 3 month and subsequently at 6 monthly intervals for follow-up. An excised track from fistulectomy was sent for histopathological examination and reports followed.

The data has been collected, compile, and analysed by continuous variables by unpaired 't' test. Categorical variables were analysed by chi square test/Fischer's exact test.

RESULTS

In present study mean age; sex of study participants; Number of external opening; situation of external opening; Internal opening relation to anal axis and types of fistula were found to be non-significant (Table 1).

Table 1: Baseline characteristics among both groups.

Variables	Medicated seton (n:26)	Fistulectomy (n:20)	Significance
Age group (yrs.) Mean±SD	38.19±4.5	37.60±5.2	P>0.05; NS
Male: female	23:3	17:3	P>0.05; NS
Number of external opening (s)			
Single	24 (92.3%)	18 (90%)	P>0.05; NS
Multiple	02 (7.7%)	02 (10%)	
Situation of external opening (s)			
Anterior	7 (26.9%)	5 (25.0%)	P>0.05; NS
Posterior	4 (15.3%)	3 (15.0%)	
Anterolateral	2 (7.6%)	1 (5%)	
Posterolateral	12 (46.1%)	10 (50%)	
On both lateral sides	1 (3.8%)	1(5%)	
Internal opening relation to anal axis			
Anterior	6 (23.0%)	4 (20%)	P>0.05; NS
Posterior	17 (65.3%)	13 (65%)	
Lateral	3 (11.5%)	3 (15%)	
Types of fistula			
Subcutaneous	3 (11.5%)	1 (5%)	P>0.05; NS
Submucus	1 (3.8%)	0	
Low anal	16 (61.5%)	13 (65%)	
High anal	3 (11.5%)	3 (15%)	
Ischiorectal	2 (7.6%)	1 (5%)	
Horse- shoe	1 (3.8%)	2 (10%)	

Table 2: Comparison of intraoperative and postoperative parameters.

Variables	Medicated Seton (n:26)	Fistulectomy (n:20)	Significance
Operative time (min) Mean±SD	23.19±6.8	46± 9.2	P value < 0.05 Sign.
Hospital stay (days) Mean±SD	1.35±0.9	4.1±2.2	P value < 0.05 Sign.
Time to Normal Work in Days Mean±SD	2.8±1.1	7.5±3.2	P value < 0.05 Sign.
Time required to complete healing(days) Mean±SD	67.35±21.2	24.9±10.2	P value < 0.05 Sign.
Temporary incontinence			
For liquids and flatus	0	0	P value > 0.05 Non-Sign.
For faeces, liquids and flatus	0	2(10%)	
Recurrence of fistula	0	2(10%)	
VAS pain score at 6 hr			
0-3	04	02	P value > 0.05 Non-Sign.
4-7	20	04	
8-10	02	14	
VAS pain score at 24 hr			
0-3	09 (35%)	0	P value > 0.05 Non-Sign.
4-7	17 (65%)	16 (80%)	
8-10	0	04 (20%)	

In Table 2 operative time required (min) in medicated seton was significantly less than fistulectomy procedure. Hospital stay (days) required was significantly more in fistulectomy procedure as compared to medicated seton. Time required for complete healing (days) was significantly more in medicated seton as compared to fistulectomy. As medicated seton is a multistage procedure, patients need to come hospital every week for new seton placement Temporary incontinence and VAS pain score at 6 hr and 24 hr was not found statistically significant in both group.

DISCUSSION

Use of "chemical" Seton for treatment of fistula-in-ano is reported in ancient Indian texts. Such stenos are made from plant extracts impregnated in layers onto a cotton thread using latex. Seton may be either inserted loosely to enable track marking, stimulate fibrosis and facilitate short or long-term drainage of sepsis, or tied lightly to allow slow, controlled division of the enclosed tissue mechanism with minimal separation of the transacted end. Several modifications of this procedure are also reported. In our study, majority of the patients were in the fourth decade and there was male predominance which is consistent with other studies in India and worldwide. The distribution of number of external opening; situation of external opening (s); internal opening relation to anal axis and types of fistula is also consistent with previous studies. In present study, duration of hospital stay in medicated seton group was significantly less required for fistulectomy group patients. Other studies done by Reddy VM et al, Gouranga D et al, Shukla N et al also observed similar results.[4-6] Studies Reddy VM et al studied 44 patients of fistula-in-ano. They observed in medicated seton group, maximum time duration needed for operation was 33.54 minutes and minimum time duration was 18.2 min.[5] While, in fistulectomy group maximum and minimum time required was 64.6 and 47 minutes respectively (p <0.05). In present study Patients in medicated seton group experienced significantly (p value <0.001) less operative time than fistulectomy patients. In present study, despite this the number of days, "off work" was less in case of seton because the pain was less and there was no open wound in contrast to fistulectomy. Hence, patients following seton procedure could join their work from the next day of the procedure and it didn't affect their normal activities. Medicated seton group had significantly (p value <0.001) few days "off-work" compared to fistulectomy group. Reddy VM et al and Gouranga D et al has similar results as compared to our studies.[2,5] In present study the duration of treatment in the seton group was significantly longer than fistulectomy group. The mean duration of healing was 67.35 days in medicated seton group. In fistulectomy group, the mean duration of healing was 24.9 days. As medicated seton is a multistage procedure, patients need to come hospital every week for new seton placement. Hence, medicated seton group required significantly more number of days for healing (p value =0.181). Gouranga D et al; Gupta Shyam K et al and Shukla N et al had similar results.[2,4,6] In present study, no patient from seton treatment group developed incontinence for liquid/flatus/faeces. While 2 (10%) patients from fistulectomy group developed incontinence, one for flatus/liquids and one for faeces. Both patients with incontinence had high anal fistula. Hence, present study is comparable with other Indian studies. In present study of 46 patients the no recurrence after medicated seton treatment was observed and fistulectomy group had 10% recurrence of fistula-in-ano. As follow up ranged from 6 months to 18 months, the exact recurrence rate cannot be commented upon. Reddy VM et al studied 44 cases of fistula-in-ano observed that recurrence rate with medicated seton and fistulectomy 0% and 20%

respectively.[5] Mohite JD et al studied 114 patients of fistula-in-ano treated with medicated seton.[7] They observed 0% recurrence over a follow up of 6 month to 2 ½ years. Gupta Shyam K et al studied 60 patients of fistula-in-ano and reported recurrence of 3.33% with medicated seton and 10% recurrence with fistulectomy.[6] Shukla N et al in their study reported recurrence of 4% with medicated seton and 11% recurrence with fistulectomy.[4] Post-operative pain was assessed at 6hr, 24 hr and 48 hr on a visual analogue scale. In present study, the postoperative pain was assessed at 6 hours; 24 hours and 48 hours based on a visual analogue scale. After 6 hour medicated seton group had significantly (p value <0.022) less pain compared to fistulectomy group. Gupta Shyam K et al studied 60 patients with fistula-in-ano and assessed the postoperative pain at 6 hr based on a visual analogue scale medicated seton group had moderate pain in 100% of patients.[6] Fistulectomy patients had moderate pain in 77% of patients and severe pain in 23% of patients. P = <0.001 present study is comparable with other Indian study. In present study, the postoperative pain was assessed at 24 hr using a visual analogue scale medicated seton group had medicated seton group had significantly (p value <0.001) less pain compared to fistulectomy group. Hence, present study is comparable with other Indian study.

CONCLUSION

It is concluded that treatment of fistula-in-ano by medicated seton is simple, easy, and safe. Medicated seton treatment is an outpatient procedure and can be done in a minor operation theatre or even at Primary Health Care level. Procedure not left with a large perineal wound and its associated morbidity. It does not require hospitalisation, whereas the average hospital stay following medicated seton varies from 1 to 2 days. The hospital stay is significantly less in medicated seton treatment as compare with fistulectomy. Hence, the application of medicated seton is a better option not only because it is cost effective but also due to lesser postoperative complications and less "off-work" days. The technique is, therefore, very fit for adopting at rural medical level.

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REFERENCES

1. Malik AI, Nelson RL. Surgical management of anal fistula: a systemic review. Colorect Dis. 2008;10:420-30.
2. Datta G, Bain J, Ray A, Dey S, Das N, Das B. Comparing Ksharasutra (Ayurvedic Seton) and open fistulotomy in the management of fistula-in -ano. Journal of Natural Sci, Biol Med. 2015;6(2):406-10.
3. Limura E, Giordano P. Modern management of anal fistula. World J Gastroenterol. 2015;21(1):12-20.
4. Shukla NK, Narang R, Bapat RD, Hande A, Nair NGK, Radhakrishnas, et al. Multicentric randomised controlled clinical trial of Ksharsootra in the management of fistula-in-ano. Indian J Med Res. 1991;94:177-85.
5. Reddy VM, Reddy MM, Sreeram S. A comparative study of Ayurvedic medicated seton (Kshara Sutra) and fistulectomy in Anorectal Fistule. Int J Sci Appl Res. 2015;2(8):64-8.
6. Gupta S, Khanna V, Gupta G, Bhardwaj A. A Compatative study to evaluate the efficacy of standard fistulectomy procedure and kshar-sutra ligation in the management of fistula-in-ano. Int J Res Ayurveda Pharma. 2014;5(4):470-3.
7. Mohite JD, Gawai RS, Rohondia OS, Bapat RD. Ksharsootra (medicated seton) treatment for fistula-in-ano. Indian J Gastroenterol. 1997;16(3):96-7.

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