Outcome of Seton in the Management of Complex Fistula in Ano in a Tertiary Care Center in Bangladesh

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Abstract:

Background: The management of high and complex anal fistulas remain a therapeutic challenge as it is often associated with recurrence and anal incontinence. The oldest and theoretically the simplest technique is to use a seton. The aim of this study is to find out the outcome of seton in the treatment of complex fistula in ano.

Materials and methods: This cross-sectional study was done in surgical units of ShSMCH and colorectal surgery units of BSMMU from September 2014 to August 2015. Fifty patients with high anal fistula having internal opening above dentate line and with multiple fistulas tract were included by purposive sampling. Patients with low anal fistula, fistula in ano associated with Crohn’s disease, active abdominal tuberculosis, carcinoma of rectum, previous radiation therapy, with recurrent fistula in ano and in whom the internal opening could not be located were excluded. After initial evaluation, the fistula tract and opening were located. The skin and anoderm overlying the fistulous tract were incised. This double-strand seton was then tied over itself on the sphincter without excessive tension. The long end of each suture was tapped to the patient’s medial thigh. Postoperatively warm sitz bath after each bowel movement was advised. The patients were informed in detail about the presence of seton prosthesis and they were warned about the possible serous discharge that would continue until the seton dropped, and the wound healed. Data were recorded on the predesigned questionnaire and analyzed using SPSS version 16.

Results: Among 50 cases mean age was 41 years, M: F was 4.5:1. Discharge from perianal sinus, pain, swelling and itching were common clinical presentation. All of the patients were discharged on the third postoperative day. None required readmission or needed narcotic analgesics after discharge. The average time for the seton to cut through the sphincter was 1 to 3 months. 28% had complete healing at 1 month and 66% at 3 months postoperatively. Flatus Incontinence was noted 16% cases followed by recurrence (6%), liquid stool incontinence (4%) and postoperative anal stricture was (2%) of cases.

Conclusion: This study found that the seton is a safe and low morbidity option for the treatment of high and complex fistula-in-ano, having higher healing rates, with good quality of life. It can therefore be recommended as the standard treatment for complex fistula-in-ano.

Key Words: Complex fistula in ano, Seton therapy

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Introduction:
Fistula-in-ano is one of the commonly encountered surgical problems with the incidence for men to be 12.3 per 100000 and that for women 5.6 per 100000.¹ Anal fistula is mostly nonspecific (idiopathic, crypto-grandular) with infection of an anal gland in the intersphincteric space as the initiating pathology.² ³ ⁴ However it may be associated with several specific conditions like Crohn’s disease, tuberculosis, malignancy, lymphogranuloma venerium, presacral dermoid, rectal duplication, actinomycosis, trauma and foreign body.⁵ ⁶ ⁷ Surgical management of fistula is challenging. Fistulotomy or laying open has long been considered the standard treatment for intersphincteric and low transsphincteric fistulas.⁸ ⁹ Different types of Seton (string like material) are also used for management of fistula in ano, the cutting setons which incise through
the tissue and non-cutting setons which facilitate the drainage of the tract. It takes three weeks to one year to cut through the tissue.\textsuperscript{8, 10, 11} Other surgical options are ‘rectal advancement flap’ (RAF) The success rate for RAF varies in the literature from 29 to 95%.\textsuperscript{12} Cutaneous flaps: island flap\textsuperscript{13} or V-Y flap\textsuperscript{14}, have been described with good results. Fibrin Glue seals the fistula tract in 30-60 seconds. Success rates of this procedure ranges from 31-85%.\textsuperscript{15, 16} LIFT procedure is the ligation of the inter-sphincter fistula tract first described by Rojanasakul in Thailand and success rate of the procedure was 58%.\textsuperscript{17}

It is clinically evident that laying open a fistula tract is the most successful method of treatment and in most situations this can be done without any disturbance of continence. In case of high or complex anal fistula, where laying open method is not appropriate, another form of definitive repair will be required. In this situation seton application may be a safe and effective as well as the best option. So the aim of this study to find out the outcome of seton in the treatment of complex fistula in ano.

Material and methods:
This cross-sectional study was done in surgical units of ShSMCH and colorectal surgery units of BSMMU from September 2014 to August 2015. Fifty patients with high anal fistula having internal opening above dentate line and with multiple fistulas tract were included by purposive sampling. Patients with low anal fistula, fistula in ano associated with Crohn’s disease, active abdominal tuberculosis, carcinoma of rectum, previous radiation therapy, with recurrent fistula in ano and in whom the internal opening could not be located were excluded. Before enrollment informed consent were taken. All the procedures were performed under spinal anaesthesia in lithotomy position. The treatment method was decided during the operation based on the relationship of the fistulous tract with the sphincter muscles. After initial evaluation, the external and internal opening were located using a blunt-tipped, flexible metal probe and hydrogen peroxide injection along the tract. The portion of the tract outside the sphincters was laid open and curetted, as were any lateral secondary tracts. A non absorbable suture (e.g. prolene 0) was inserted through the external opening of fistula tract by using a buttonhole probe in a double-strand fashion. The skin and anoderm overlying the fistulous tract were incised. This double-strand seton was then tied over itself on the sphincter without excessive tension. The long end of each suture was taped to the patient’s medial thigh. Postoperatively warm sitz bath after each bowel movement was advised. The patients were informed in detail about the presence of seton prosthesis and they were warned about the possible serous discharge that would continue until the seton dropped, and the wound healed. The patients with co-morbid conditions like diabetes mellitus, hypertension, ischaemic heart disease and COPD were treated for the condition first and then reassessed for fitness for surgery.

Repeated examinations were carried out at weekly interval for 1 month and fortnightly for 3 months. At each visit, the position of seton was assessed and tightened progressively. The data of previous anal operation, history of fecal incontinence before and after seton treatment, wound healing and recurrence of anal fistula were recorded. Patients were followed up upto three months after operation. Postoperative pain was evaluated with a visual analog score (VAS) on the first and eighth postoperative days. The days required for the seton to cut through and drop were recorded, as well as complications and complete healing rates at 1 and 3 months, respectively. Preoperative and postoperative (at 3 months) anal incontinence scores were assessed. Therefore, the primary end points was fistula healing. The secondary end points were changes in baseline incontinence scores, complication rate, and time required for complete healing.

Statistical analysis:
Analysis was performed with SPSS software, versions 22.0. Continuous data that were normally distributed was summarized in mean, standard deviation, median, minimum and maximum. Skewed data was presented in the maximum, upper quartile, median, lower quartile, minimum and number of observations. Categorical or discrete data was summarized in frequency counts and percentages. For end points analysis, chi square test was used for categorical variables.

Results:
Among 50 study cases mean age was 41 ears and M: F was 4:1, majority of them were day labor and farmer [Table-1]. Purulent discharge from fistula with pain were common clinical presentation, 80% cases had history of spontaneous rupture of anal abscess. Few cases had associated comorbidities DM (8%) and COPD (8%) [Table 2]. Fistulogam was done among 48% cases [Table-3]. Postoperative pain was noted by visual analog scoring system. In 1st postoperative day majority of the 25 (50%) patient’s complaint of moderate pain (Score 4-6) followed by 18 (36%) had severe pain (score 7-10) and 7 (14%) had mild pain (score 1-3). In 8th postoperative day the majority of the patients (76%) had mild pain, 12 (24%) had moderate pain and none had severe pain (Figure-1). The average time of the seton to cut through the sphincter was 1 to 3 months, 28% had complete healing by 1 month and 66% at 3 months postoperatively. Acute retention of urine (32%), flatus
incontinence (16%), bleeding (6%), liquid stool incontinence (4%) and abscess formation (2%) were found common post-operative complication. Worsening of baseline continence was noted in 10 patients of which and was noted in 2 patients (4%). Out of 50 patient's recurrence of the fistula was noted in 3 patients (6%) and anal stricture was noted in 1 patient (2%) [Table IV].

**Table 1**

| Variables                  | Frequency (%) |
|----------------------------|---------------|
| Age (Years)                |               |
| 21-35                      | 17 (34%)      |
| 36-50                      | 27 (54%)      |
| 51-65                      | 6 (12%)       |
| Sex                        |               |
| Male                       | 41 (82%)      |
| Female                     | 9 (18%)       |
| Occupation                 |               |
| Labor                      | 16 (32%)      |
| Farmer                     | 10 (20%)      |
| Shopkeeper                 | 7 (14%)       |
| Housewife                  | 7 (14%)       |
| Service holder             | 5 (10%)       |
| Student                    | 3 (6%)        |
| Maidservant                | 2 (4%)        |

**Table-II**

| Symptoms & signs                        | Frequency (%) |
|-----------------------------------------|---------------|
| Discharge, swelling & pain              | 08 (16%)      |
| Discharge & pain                        | 12 (24%)      |
| Discharge & itching                     | 09 (18%)      |
| Discharge                               | 21 (42%)      |
| **Type of discharge**                   |               |
| Purulent                                | 33 (66%)      |
| Seropurulent                            | 11 (22%)      |
| Serosanguinous                          | 6 (12%)       |
| **Previous ano-rectal abscess**         |               |
| Spontaneous ruptured                    | 80%           |
| Incision & drainage                     | 20%           |
| **Associated co-morbid conditions**     |               |
| COPD                                     | 4 (8%)        |
| DM                                       | 4 (8%)        |
| HTN                                      | 2 (4%)        |
| Pulmonary TB                            | 1 (2%)        |

**Table III**

| Radiological Examination | Frequency (%) |
|--------------------------|---------------|
| Fistulogram              | 24 (48%)      |
| MRI                      | 07 (14%)      |
| EUS                      | not done      |
| X-ray chest              | 50 (100%)     |

**Visual analog scale**

| Mild (1-3) | Moderate (4-6) | Severe (7-10) |
|------------|----------------|---------------|
| 7          | 25             | 18            |

**Figure 1:** Shows visual analog scale score of the patients

**Table-IV**

| Outcome                                      | Frequency (%) |
|----------------------------------------------|---------------|
| **During of healing**                        |               |
| <1 month                                     | 14 (28%)      |
| < 3 months                                   | 33 (66%)      |
| No healing                                   | 3 (6%)        |
| **Early complications**                      |               |
| Urinary retention (catheterization not needed)| 12 (48%)      |
| Urinary retention (Catheterization required) | 4 (8%)        |
| Bleeding                                     | 3 (6%)        |
| Flatus incontinence                          | 8 (16%)       |
| Liquid stool incontinence                    | 2 (4%)        |
| Abscess formation                            | 1 (2%)        |
| **Late complication**                        |               |
| Recurrence                                   | 3 (6%)        |
| Stricture                                    | 1 (2%)        |
Discussion:
Management of complex fistula in ano is a surgical challenge. It is notorious for its chronicity, recurrence and frequent acute exacerbations. Complex and high anal fistula disease is not uncommon in adults and has its maximum incidence between third and fourth decades of life. The age distribution (mean 41 year ) and male predominance (82%) seen in this study is in agreement with the other studies. In this study most of the patients were from low socioeconomic group which indicate poor personal hygiene and ignorance. All of the patients have previous anorectal abscess and it seems to be the most common cause of complex fistula in ano. The main presenting complaints of the patients (Discharge, pain, swelling and itching) in this study are also in agreement with other study.

Prolene-0 has been used in this study as cutting seton. This is durable, non-toxic/non-allergic and is easily available in sterile packing at a reasonable price. There are several other materials used as seton as mentioned in introduction, but whatever the material is, recurrence and incontinence rate is mainly dependent on expertise and judgement of the surgeon.

Usually the healing after a seton procedure is uneventful, though minor control problems may occur in a variable number of patients. This study found 16% of flatus incontinence and 4% of liquid stool incontinence in early postoperative period. All the patients were recovered fully within one month of operation. The incidence of incontinence following seton insertion reported by other studies ranged from 0% to 47%. On the other hand, Isbister conducted a study at King Faisal Specialist hospital, reported incontinence in 47% of patients. Similarly, in 2008, Chaung et al, conducted a study on 112 patients with complex anal fistula. They reported incontinence of 24.1 %. Incontinence rate of this study can be attributed to meticulous surgical technique whereby sphincter remains intact. Low recurrence rate may due to proper identification of internal opening and the extensions of fistula tract. The use of seton was not associated with significant pain. The postoperative VAS score were low and none of the patients were needed narcotic analgesics after discharge.

This study has found 6% recurrence rate in 50 patients treated with cutting seton for high and complex anal fistulas. Different studies have shown different results with recurrence rate ranging from 0 to 18%. Mac Courty in his study reported only 4% recurrence after treating complex high fistula-in-ano, with cutting seton without preliminary internal sphincterotomy. Guere conducted a study over nine patients with high fistula-in-ano, reported no recurrence. Thus the result of this study correlates with the result of other studies.

The preliminary results of this series have shown that the seton is a promising tool for the treatment of high and complex anal fistulas. The follow-up period is short only three months and the success rate appears to be high. This method is apparently free from significant complications. Anal contour is largely preserved, and baseline continence is not significantly disturbed. Moreover, 94% healing was achieved within three months. The remaining 6% was not healed within follow up period. The study is a single-arm study with no comparison group.

Conclusion:
This study concluded that the seton is a safe and low morbidity option for the treatment of high and complex fistula-in-ano. As compared to other modalities of treatment, seton therapy is cheaper, easier to perform, and follow-up, having reasonably higher healing rates, with good quality of life. It can therefore be recommended as the standard treatment for complex fistula-in-ano.

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