TREATMENT OF HIGH TRANS-SPHINCTERIC ANAL FISTULA: COMPARISON OF ANAL FISTULA PLUG USING SURGICAL VERSUS CUTTING SETON

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ABSTRACT

Objective: To compare the anal fistula plug using surgical versus cutting seton in the treatment of high trans-sphincteric anal fistula, in terms of frequency of fistula closure.
Study Design: Randomized controlled trial.
Place and Duration of Study: Combined Military Hospital, Bahawalpur from Aug 2013 to Feb 2014.
Patients and Methods: A total of 120 patients were randomly divided into two groups of 60 patients each using lottery method. Group-A comprised patients undergoing treatment with anal fistula plug while group B included patients undergoing treatment with seton. The patients were then checked for fistula closure for three months post operatively.
Results: Fistula closure at 3 months was observed in 40 patients (66.7%) of group-A and in 27 patients (45.0%) in group-B. The difference between two groups was statistically significant (p=0.017).
Conclusion: Anal fistula plug is superior to cutting seton in terms of frequency of fistula closure in patients with high anal fistula.

Keywords: Anal fistula plug, Cutting seton, High trans-sphincteric anal fistula, Surgicel.

INTRODUCTION

Incidence of anal fistula is 5.6 per 100,000 women and 12.3 per 100,000 men. The disease occurs predominantly in the third and fourth decades of life[1]. High anal fistulas are cumbersome for both patient and the surgeon. Simple fistulotomy is not appropriate for high anal fistula because of post operative fecal incontinence and management of this clinical entity remains a surgical challenge. Current options available in surgical armamentarium for high anal fistula include Setons, anal mucosal advancements flaps and fibrin glue application with variable success rates for each option. Cutting setons slowly divide the sphincters leading to scarring with limited disruption of the muscular ring having a healing rate of 32.6%[2] and recurrence rates of 22-39%[3]. Other studies have shown good results using cutting setons with healing rate as high as 61%[3]. Recently a technique of biologic anal plug has been introduced for anal fistula. The anal fistula plug poses a lower risk of postoperative impairment of sphincter muscle function and other postoperative complications than the cutting setons and transanal mucosal advancement flap. Such results can be achieved not only with plugs made of porcine intestinal submucosa, but also those made of other biological mesh materials, such as acellular dermal matrix, and synthetic bioabsorbable material[4]. Various materials are used as plugs; most important of which is a bioabsorbable xenograft made of lyophilized porcine intestinal sub-mucosa (Surgisis)[1,3,4] showing promising results in patients with high anal fistula with healing rates of 59.3%[2]. Many studies have shown different results with anal fistula plugging with healing rates ranging from as low as 24%[5] to as high as 100%[6]. In our study, surgicel, an oxidized regenerated cellulose bio-absorbable mesh; was used as anal fistula plug keeping in consideration the ethical and religious issues as surgisis is made

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up of porcine intestinal sub-mucosa and non-availability of surgisis in Pakistan. Surgicel is readily available and cost effective but its use has not yet been reported so far.

The rationale of this study was to find out an appropriate technique in treating high anal fistula resulting in early closure by comparing anal fistula plug with cutting seton. Very few studies have been published comparing these two methods and no local data is available.

MATERIAL AND METHODS

This randomized controlled trial was carried out at Combined Military Hospital (CMH) Bahawalpur from Aug 2013 to Feb 2014. Sample size was calculated using WHO sample size calculator. A total of 120 patients were included in the study and they were randomly divided into two groups of 60 each by using random numbers table. Patients meeting the inclusion criterion, that was all patients undergoing surgery for high trans-sphincteric anal fistula older than 18 years of age of both genders were included in the study. Patients with branching fistulous tracts, multiple fistulae, malignant fistula, inflammatory bowel disease (IBD), tuberculosis, hidradenitis suppurativa, HIV, diabetes mellitus, using steroids and recurrent fistula were excluded from the study. Patients with pregnancy and history of radiotherapy were also excluded. After permission from the hospital ethical committee, informed consent was taken from all the patients. Hospital registration number, name, age, gender, address and phone number (optional) were noted. All the patients were admitted. A detailed history and physical examination was carried out. MRI of every patient included in the study was carried out to determine the exact type of fistula. Sampling was non-probability consecutive sampling. Patients were divided into two equal groups of 60 each by lottery method. Group A comprised patients undergoing treatment with anal fistula plug while group B included patients undergoing treatment with cutting seton. All the patients received rectal enema on the night before surgery and morning of surgery. One dose of intravenous third generation cephalosporin (1 gram) and metronidazole (500 milligram) was administered at the time of induction of anesthesia. Surgery was performed under spinal anesthesia. Hydrogen peroxide mixed with normal saline was injected into the fistula tract through the external opening using the 8 Fr nasogastric (NG) tube to identify internal opening. The external opening and fistula tract were gently probed using a standard 3mm blunt-tipped probe. The amount of sphincter superficial to the probe was evaluated. Granulation tissue was curetted out. In the anal fistula plug group (group A), surgicel was passed from external opening to internal opening. Excess plug material was trimmed flush with the anal mucosa at the level of internal opening and external opening. The plug was secured at the internal and external openings with single vicryl 2-0 suture. Silk 1 seton was passed from external to internal opening and tied tightly, in patients randomized to seton group (group B). Non-adherent dressing was applied over the external wound. Postoperatively, patients were shifted to the ward; two further doses of intravenous metronidazole and third generation cephalosporin were administered at specified time. Patients were discharged on the first postoperative day. Patients were advised daily hot soaks (Sitz bath). Patients in group A were followed up at two weeks, four weeks and eight weeks and at twelve weeks while those in group B underwent tightening of the seton under local anesthesia every week till the seton cut

Table: Comparison of two groups for frequency of fistula closure (p=0.017).

Fistula closure at 3 month	Group A (n=60)	Group B (n=60)
Yes	40 (66.7%)	27 (45.0%)
No	20 (33.3%)	33 (55.0%)

through. Final outcome was recorded at last follow up on 12 weeks for both groups.

Data were analyzed on SPSS 17. For qualitative variables like gender and fistula closure; frequency and percentage were calculated. For quantitative variables like age, mean ± standard deviation (SD) were calculated. Chi square test was used to compare frequency of fistula closure between the two groups. To control effect modifier like age, duration of fistula, presentation of fistula and gender; stratification of patients was done. A *p* value of less than 0.05 was considered significant.

RESULTS

Out of 120 patients in the study, group A comprising of 60 patients underwent anal plug technique and group B comprising of 60 patients were treated with cutting seton. The age distribution ranged from 15-60 years in the study. Mean age was 43.13 ± 9.70 years and 41.61 ± 9.75 years in group-A and B, respectively (*p*-value 0.019). In group-A, males were 51 (85.0%) and females were 9 (15.0%) while in group-B, males were 54 (90.0%) and females were 6 (10.0%) (*p* value=0.407). Mean duration of fistula was 1.55 ± 0.95 in group-A and 1.53 ± 0.89 years in group-B (*p*-value 0.001). Fistula closure at 3 months (12 wks) was observed in 40 patients (66.7%) of group-A and in 27 patients (45.0%) in group-B. The difference between the two groups was statistically significant (*p*=0.017), and it was seen that anal fistula plug was more successful than cutting seton (table). Stratification of age, duration of fistula and gender with regard to fistula closure was carried out.

DISCUSSION

Fistula-in-ano is a difficult problem that physicians have struggled with since the time of Hippocrates[7]. Ideal surgical treatment for anal fistula should aim to eradicate sepsis and promote healing of the tract, whilst preserving the sphincters and the mechanism of continence[8]. The choice of surgical treatment of fistula- in-ano is dictated by the amount of sphincter involvement as internal and external anal sphincter preservation is in the interest of continence maintenance[7]. With the advent of more sphincter-sparing techniques, the number of patients undergoing fistulotomy should continue to decrease over time[9]. However, there are still surgeons that prefer an extensive use of complete fistulectomy and fistulotomy in both high and low anal fistulas with reported closure rates of 98 and 96% respectively, alongwith mild leakage of flatus and mucus in a third to one-quarter of patients[10,11]. For low fistulas involving less than one-third of the sphincters, primary fistulotomy can be performed safely. For high trans-sphincteric anal fistulas with abscess and local sepsis, a loose seton to act as drainage seton or a drainage tube seton should be placed aiming to eradicate sepsis[12].

The utility of cutting setons have been well-established but in some large case series have been reported to be associated with continence disorders inupto 24.1% of the cases[13]. The incidence of incontinence reported by other studies has a wide range. Guerer[14] reported no incontinence in his study whereas Isbister and Al-Sanea[15] conducted a study at King Faisal Specialist Hospital and reported incontinence in 9.1% of patients. The results of these trials worldwide, have questioned the safety of cutting seton as the treatment of choice for high anal fistulas involving the external sphincter.

Transanal mucosal advancement flap for patients with high trans-sphincteric fistulas is another surgical option and reported success rates range from 59 to 98%. However, these procedures are technically challenging and some authors report incontinence rates of up to 20%[4]. Keeping in view these varying results of different treatment options, multiple agents have been tried for plugging and sealing the fistulous tract and allow ingrowth of healthy tissue to replace it. The success of such procedures depends on the properties of biomaterial used and the environment it is placed in. Use of fibrin glue to plug the fistulous tract leads to poor long term results due to its rapid resorption. Porcine intestinal mucosa has also been tried but its

premature degradation specially in an infected environment leads to poor short term results. Moreover, its use remains controversial ethically especially in Muslim countries. However, research for a biological agent continues, so as to find an appropriate agent which has optimum short term and long term results with no ethical issues related to its use.

In our study, frequency of fistula closure was noted to be 66.7% and 45.0% in group-A (anal fistula plug with surgicel) and group-B (cutting seton), respectively. Previous studies have demonstrated different results with anal fistula plugging with healing rates ranging from as low as 24% to as high as 100%[5].

CONCLUSION

On the basis of the results obtained in the study, it can be concluded that the anal fistula plug is more successful when compared with cutting seton in terms of frequency of closure of fistula.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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