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Comparison of Surgical Outcomes Between Video-Assisted Anal Fistula Treatment and Fistulotomy Plus Seton for High-Lying Perianal Fistula

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ABSTRACT

Introduction: This study aims to compare video-assisted anal fistula treatment with fistulotomy plus seton in the management of high perianal fistula in terms of postoperative outcomes. There is limited research on the treatments of high-lying perianal fistulae. This study will help us improve pain severity, return the patients to regular work, improve healing time, and reduce the recurrence rate, leading to better patient management. **Study Design:** Randomized controlled trial. **Study Period:** From July 20, 2024, to January 19, 2025. **Methodology:** There were 60 patients of high-lying perianal fistulae, ranging in age from 18 to 60 years. Patients having a history of prior perianal surgery, a medical record-based history of inflammatory bowel disease, uncontrolled diabetes, or a lump on a digital rectal examination that suggested malignancy were excluded. All the patients were assigned to two groups using an online randomizer, i.e., Group A were undergone video-assisted anal fistula treatment, and Group B were undergone fistulotomy plus seton. Postoperative pain was determined 6 hours after the surgery using the visual analogue score. Patients were followed up in the outpatient clinic at three months to determine healing status, anal incontinence and recurrent rate. **Findings:** Group A (VAAFT) experienced mean post-operative pain of 5.41 ± 1.89, whereas Group B (fistulotomy plus seton) experienced mean post-operative pain of 3.24 ± 1.29 (p-value = 0.0001). In Group A (VAAFT), the mean healing time was 38.40 ± 5.25 days, whereas in Group B (fistulotomy plus seton), it was 25.93 ± 4.30 days (p-value = 0.0001). 33.33% and 0.0% of patients in group A (fistulotomy plus seton) experienced post-operative pain and anal incontinence, respectively, whereas 13.33% and 0.0% of patients in group B (fistulotomy plus seton) did the same. **Conclusion:** VAAFT is a novel sphincter-saving procedure used to treat high perianal fistulas.

INTRODUCTION

Fistula is an abnormal communication between the anorectal tract and the perineal soft tissue. Its incidence varies from 2 cases per 10,000 population per year to 9 per 100,000, and it affects men more than women, with a peak incidence between the ages of 20 and 40 years.[1] Although fistula rarely has life-threatening consequences, it can be debilitating and socially embarrassing, significantly impacting patients' quality of life because of pain, discharge, recurrent abscess formation, sphincter, and perianal tissue destruction.[2] Established complex perianal fistulas are challenging to treat, with surgical intervention aiming to control sepsis and preserve continence. Commonly used techniques include a one-step fistulotomy or fistulectomy with the initial placement of a cutting or loosely fitting drainage seton, with a view to definitive management at a later date once the patient is sepsis-free.[3,4] However, a variable level of postoperative sphincter dysfunction is linked to these treatments. Many surgical techniques have been developed in an attempt to lessen sphincter complex damage. In order to prevent muscle damage, collagen plugs, fibrin glues, and more invasive treatments including intersphincteric fistula tract closure and mucosal flap advancement techniques are all used. Success rates for postoperative incontinence or recurrence, however, have varied. Complex perianal fistulas can be treated endoscopically and minimally invasively with video-assisted anal fistula treatment (VAAFT). With little harm to the anal sphincters, the surgeon can see the fistulous tract up close.[5,6]

The mean pain score was considerably greater in the video-assisted anal fistula therapy (VAAFT) group (4.22) than in the seton group (2.82), and the recurrence rate was 25% in the VAAFT group and 12.5% in the fistulotomy plus seton group, according a study by Siddique et al.[7] Compared to the seton group, which took 9.2 days to return to work, the VAAFT group took 7.4 days on average. individuals treated with VAAFT had a considerably shorter mean healing time (5.75 weeks) than individuals treated with a seton (9.7 weeks). They came to the conclusion that, while there was no discernible difference in the recurrence of fistulas, VAAFT was linked to an earlier healing period and an earlier return to work than the conventional seton procedure. VAAFT is a minimally invasive procedure that, when done when appropriate, enables patients to quickly resume their regular lives, which is best for both patients and doctors. Liu et al.[8] found that VAAFT was more effective than fistulotomy plus seton at locating internal openings (90.6% vs 100%), resulting in less intraoperative blood loss (26 ± 15 vs 12 ± 5 mL), a lower incidence of postoperative bleeding (10.9% vs 1.5%), a shorter postoperative hospital stay (6.8 ± 5.1 vs 5.0 ± 3.3 days), less postoperative pain, and decreased wound secretion (all $P < 0.05$). After VAAFT, 12 patients (17.6%) experienced fistula recurrence; logistic analysis showed that extensive postoperative wound secretion, multiple fistula tracts, and extended operating time were independent risk factors. According to Andley M., in VAAFT recurrence rate was 3.3%, the surgical site infection rate was 0%, and the incontinence rate was 0%, While in fistulotomy, the recurrence rate was 10%, the surgical site infection rate was 3.3%, and the incontinence rate was 0%.[9]

This study aims to compare video-assisted anal fistula treatment with fistulotomy plus seton in the management of high perianal fistula in terms of postoperative outcomes. There is limited research on the treatments of high-lying perianal fistulae. This study will help us improve pain severity, return the patients to regular work, improve healing time, and reduce the recurrence rate, leading to better patient management.

MATERIALS AND METHODS

This randomized clinical trial was conducted at the National Hospital and Medical Center Lahore's Department of General Surgery from July 20, 2024, until January 19, 2025. Sixty patients were selected using a successive non-probability selection technique. With 80% study power and a 95% confidence interval, the sample size of 60 (30 in each group) was determined, with mean healing times of 5.7 ± 1.1 weeks in the video-assisted anal fistula treatment group and 9.7 ± 1.8 weeks in the fistulotomy with seton group.[7] The WHO sample size calculator was used to determine the sample size. Patients between the ages of 18 and 60, regardless of gender, who have high-lying perianal fistulae (intersphincteric fistulas with more than 50% involvement of the internal anal sphincter, transsphincteric fistulas with more than 50% involvement of the sphincter complex). Both before the treatment and three months after it is finished, a consultant radiologist with at least five years of expertise will evaluate these classifications using a 3D rectal ultrasound. Patients with uncontrolled diabetes, inflammatory bowel illness documented in medical records, a history of previous perianal surgery, or a mass on a digital rectal examination that seemed to be malignant were not included. Prior to obtaining the patients' consent, the Institutional Ethical Review Committee granted its approval.

The basic demographic data of the patients, i.e. age, gender, disease duration, type of high-lying perianal fistulae, i.e., intersphincteric, transsphincteric were noted. All the patients were assigned to two groups using an online randomizer, i.e., Group A were undergone video-assisted anal fistula treatment (a minimally invasive approach involving specialized video guidance to address the fistula), and Group B were undergone fistulotomy plus seton (a surgical procedure involving an incision to drain the fistula tract, followed by the placement of a seton to assist in healing). All the patients were undergone procedures under standard operating techniques under general anaesthesia by a single surgical team, including consultant surgeons having at least five years of experience. Postoperative pain was determined 6 hours after the surgery using the visual analogue score. Patients were followed up in the outpatient clinic at three months to determine healing status, anal incontinence and recurrent rate.

All the data was entered and analyzed using SPSS ver. 26.0. The categorical variables, i.e., gender, type of high-lying perianal fistulae, recurrence, and anal incontinence, were presented as frequency and percentages. The numerical variables, i.e., age, disease duration, postoperative pain score at 6 hours after surgery, mean duration of surgery and mean duration of healing were presented as mean and standard deviation. The chi-square test was applied for the association of recurrence, and anal incontinence among both groups. The Independent Sample T Test was applied for an association of postoperative pain score at 6 hours after surgery, duration of surgery and healing time among both groups. A p-value of <0.05 will be considered significant.

RESULTS

The study's participants ranged in age from 18 to 60, with a mean age of 46.37 ± 17.84 years. Patients in groups A and B had mean ages of 48.43 ± 16.29 and 46.07 ± 18.61 years, respectively. The majority of the 31 patients (51.67%) were in the 40–60 age range. With a male to

female ratio of 2:1, 40 (66.67%) of the 60 patients were male and 20 (33.33%) were female. The illness lasted an average of 4.97 ± 1.51 weeks. Table I displays the patient distribution by kind of fistula.

Group A (VAAFT) in my study had an average surgery time of 67.43 ± 12.38 minutes, while Group B (fistulotomy plus seton) had an average surgery time of 39.87 ± 6.52 minutes (p-value = 0.0001). Group A (VAAFT) experienced mean post-operative pain of 5.41 ± 1.89, whereas Group B (fistulotomy plus seton) experienced mean post-operative pain of 3.24 ± 1.29 (p-value = 0.0001). In Group A (VAAFT), the mean healing time was 38.40 ± 5.25 days, whereas in Group B (fistulotomy plus seton), it was 25.93 ± 4.30 days (p-value = 0.0001). 33.33% and 0.0% of patients in group A (fistulotomy plus seton) experienced post-operative pain and anal incontinence, respectively, whereas 13.33% and 0.0% of patients in group B (fistulotomy plus seton) did the same (Table III).

Table I

Distribution of Patients According to Type of Fistula

Type	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
Intersphincteric	20	66.67	19	63.33	39	65.0
Transpshincteric	10	33.33	11	36.67	21	35.0

Figure 1

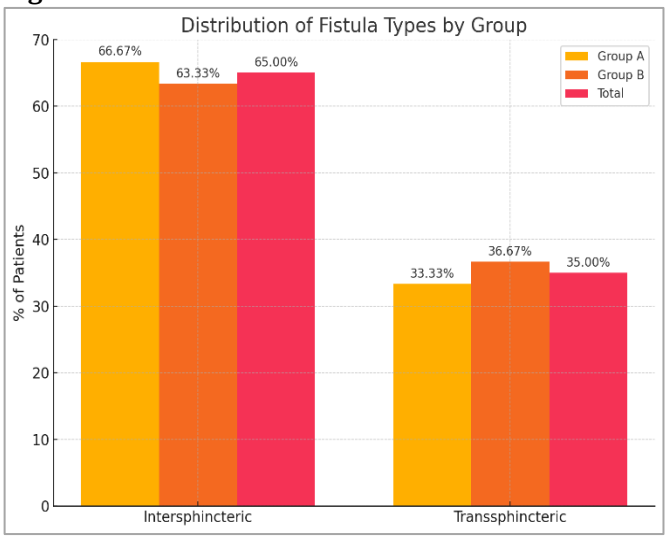

Figure 2

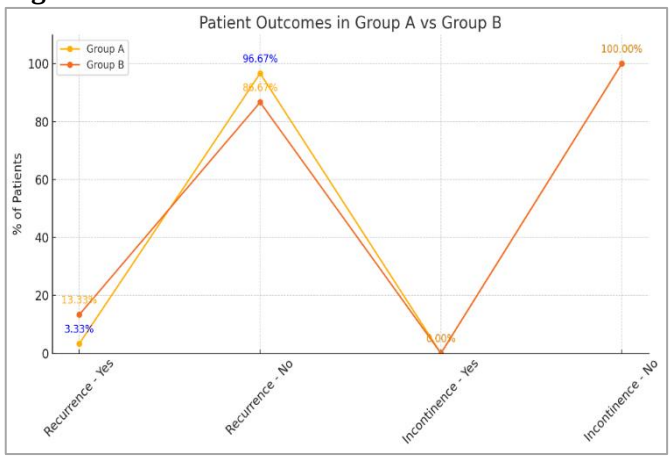

Table II

Comparison of the Post-operative Pain, Duration of Surgery and Healing time between both Groups

	Group A (n=30)	Group B (n=30)	p-value
	Mean ± SD	Mean ± SD	
Duration of surgery (minutes)	67.43 ± 12.38	39.87 ± 6.52	0.0001
Post-operative pain	5.41 ± 1.89	3.24 ± 1.29	0.0001
Healing time (days)	38.40 ± 5.25	25.93 ± 4.30	0.0001

Table III

Comparison of Complications in both Groups

Outcome	Group A (n=30)		Group B (n=30)		p-value
	Yes	No	Yes	No	
Recurrence	01 (3.33%)	29 (96.67%)	04 (13.33%)	26 (86.67%)	0.161
Anal incontinence	00 (0.0%)	30 (100.0%)	00 (0.0%)	30 (100.0%)	----

DISCUSSION

Compared to the VAAFT group, the seton group in this experiment had a significantly shorter mean surgical duration and a significantly lower mean pain score. However, recurrence rates did not differ significantly between groups, and VAAFT patients had much shorter mean recovery and return to work periods than seton patients. The use of VAAFT and seton in the treatment of perianal fistulas was compared in only one other study. In contrast to what we found, Zheng et al.10 demonstrated that VAAFT had a lower mean pain score and a shorter mean operation duration than seton-use. The discrepancy in these results may result from different levels of experience with the VAAFT procedure, which was developed in our clinic several years ago. Furthermore, we used silk 1/0 suture for the seton in our study. The Zheng study, which also showed no difference in recurrence rates between the two operations, is in agreement with our findings.

The three-year recurrence rate for patients who underwent seton repair in our study was 12.5%, higher than in a number of prior trials. Only one case of

recurrence (8%) occurred in the loose seton used for high perianal fistula repair in Choi et al.'s 2010 prospective trial.[11] In 2008, Chuang-Wei et al. reported that one patient (0.9%) experienced a recurrence of perianal fistula following an elastic band seton fistula repair.[12] According to Ege et al., 100% of patients treated with a seton experienced full healing at three months, although two patients (1.5%; one at six months, one at twelve months) experienced recurrence.[13] For high perianal fistulas, Munir et al. reported a 3.3% recurrence rate following seton insertion.[14] The increased recurrence in our study may be explained by the fact that our patients were followed up with for up to three months, whereas the follow-up duration in each of these trials was no more than six to twelve months. The absence of anal incontinence in the seton groups was another noteworthy finding of this investigation, which was consistent with a study by Andreou et al.[15] Anal incontinence rates in other research ranged from 9% to 20%, which was far higher than what we found. The material used as seton (in our case, silk 1/0) or the seton installation technique may be the cause.

After three months, the recurrence rate in VAAFT was 3.33%. Meinero reports that at the 12-month follow-up, recurrence was observed in 26 out of 136 patients (26.5%) in VAAFT.[16] Compared to Meinero's claimed recurrence rate, ours is far lower. Other research, however, revealed a recurrence incidence that was significantly lower than ours. For example, Mendes et al. found that just one patient (12.5%) experienced a recurrence during a five-month follow-up of eight patients with perianal fistula.[17] 18 patients who had surgery with VAAFT experienced a 17% recurrence of perianal fistula, according to Walega et al.[18] During a six-month follow-up, Kochhar et al. found that the recurrence rate with VAAFT was 15.85%.[19]

A single-center study precludes extrapolating our findings to a larger population, which is one of our study's limitations. Additionally, as recommended by the procedure's creator, our method did not inject adhesive into the residual tract after VAAFT; we are unsure if this change will have an impact on the rates of fistula recurrence. Because VAAFT is a relatively new method with which we have little knowledge, and we have over ten years of experience inserting setons in fistula repair, our study was not free from bias. Whether more VAAFT experience may impact fistula recurrence rates in comparison to seton use is still unknown. Lastly, we used a subjective method to quantify anal incontinence: the patient had to declare whether they had involuntary passed feces or flatus and knew which group they were in. This could be an additional source of bias in this trial. An objective assessment of anal incontinence using a score system or tests like magnetic resonance imaging, endoanal ultrasonography, or anorectal manometry would have been preferable.

There aren't enough studies comparing VAAFT with seton usage, and more study could have a beneficial and long-lasting effect on the treatment of complex fistulas, possibly changing it completely. Our research delves deeper into intricate fistula care and offers guidance to other surgeons on how to appropriately treat their patients. We highly recommend more investigation into this novel modality in light of the encouraging nature of our findings.

CONCLUSION

To summarize, VAAFT is a novel sphincter-saving procedure used to treat high perianal fistulas. Regardless of cost, VAAFT is linked to a quicker recovery period and a return to work than regular seton use, and over a three-year period, the two procedures have comparable recurrence rates. Hospital patient load, patient quality of life, and eventually the national economy could all benefit from VAAFT's shortened recovery period and quicker return to work. To investigate this possible advantage for the larger community, larger multi-center trials are necessary.

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