

Evaluation of Effectiveness and Safety of Video Assisted Anal Fistula Treatment

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ABSTRACT

Background: Although anal fistulae are common and well-studied, complex forms remain challenging to treat, requiring a careful balance between preventing recurrence and preserving continence—making minimally invasive techniques like video-assisted anal fistula treatment (VAAFT) a promising option due to their sphincter-sparing approach and ability to accurately identify internal openings and secondary tracts.

Aim: The primary goal of this prospective pilot study is to evaluate the safety and benefits of using the new device “Fistuloscope” for the treatment of anal fistula, as Video Assisted Anal Fistula Treatment (VAAFT) is a novel technique that will be used during this study to treat anal fistula.

Subjects and methods: This prospective pilot study included 20 patients with fistula in ano who were presented to the Department of General Surgery, Faculty of Medicine, Beni-Suef University Hospital, with the study conducted from March 2018 until August 2020 (two years and five months).

Result: The mean age of males was 42.4 years and the mean age of females was 38.2 years. The internal fistula opening was closed by advancement flap in 6 patients (30%) using vicryl 2/0, by stapler in 6 patients (30%) and by primary interrupted sutures using vicryl 2/0 in 8 patients (40%).

Conclusion: VAAFT is a safe and minimally invasive procedure for the treatment of complex anal fistula while preserving anal sphincter function. Neither this study nor other studies mentioned that it was damage to the anal sphincter or fecal incontinence, accordingly- we can consider VAAFT procedure as: Sphincter-Saving Fistula Surgery.

Keywords: Anal fistula; Video-Assisted Anal Fistula Treatment (VAAFT); Fistuloscope; Fistula in ano.

1. INTRODUCTION

Despite the fact that anal fistulae are very common and have been studied extensively, some complex forms still continue to pose a difficult surgical problem. The aim of treatment for an anal fistula is to permanently eliminate abscess formation and achieve healing while preserving anal function and continence. Overly aggressive fistulotomy can lead to postoperative fecal incontinence, whereas inappropriate conservative treatment could lead to fistula recurrence (1).

High success rates can only be obtained if the surgeon has in his hands a wide range of therapeutic options. Moreover, the surgical choice must be balanced between the risk of fecal incontinence and that of recurrence (2).

Anal fistulotomy, fistulectomy, and endorectal advancement flaps have long been used with good healing rates but with a non-negligible risk of continence impairment (3).

Several minimally invasive techniques have been recently introduced to avoid any sacrifice of the sphincter complex with greatly variable results (4).

The combination of a videoendoscopic approach to a minimally invasive procedure led to the proposal of the video-assisted anal fistula treatment (VAAFT) as described by Meinero (5).

Along with the accurate identification of the internal opening and the location of possible chronic abscesses or secondary tracks are universally considered the keys to successful anal fistula treatment (6).

VAAFT uses an innovative feature, a rigid fistuloscope for the correct location of the internal opening and to study the fistulous tract looking for collections or accessory paths. One of the major potential benefits of VAAFT technique is to undertake a procedure without direct trauma to the anal sphincters (7).

The primary goal of this prospective pilot study is to evaluate the safety and benefits of using the new device “Fistuloscope” for the treatment of anal fistula, as Video Assisted Anal Fistula Treatment (VAAFT) is a novel technique that will be used during this study to treat anal fistula.

Patients and Methods

This prospective pilot study included 20 patients with fistula in ano who were presented to the Department of General Surgery, Faculty of Medicine, Beni-Suef University Hospital, with the study conducted from March 2018 until August 2020 (two years and five months).

The inclusion criteria:

All types of fistula-in-ano including :

1. Simple fistulas.
2. Fistula associated with multiple tracts.
3. Horse shoe fistulas.
4. Recurrent fistulas.
5. Anterior fistula in females.
6. Fistula with long tracts (any tract length > 10 cm).

The exclusion criteria:

1. The suspicion or diagnosis of Crohn’s disease.
2. Malignancy.
3. History of pelvic radiotherapy.
4. Fistula where internal opening cannot be localized.

Fistula associated with abscess/pus collections.

2. METHODOLOGY

Records of the patients were revised and analyzed using the following data for each patient: a full history including personal history, past medical history, previous anal fistula surgery and any complications; clinical presentation such as pain, perianal swelling, discharge, and incontinence; examination findings including external fistula openings (single or multiple), anal sepsis or discharge, proctoscopy findings, identification of internal fistula openings and their number and distance from the anal verge; investigations including all laboratory and imaging tests such as MRI or ultrasound of the anal canal; preoperative preparation with complete laboratory workup; anesthesia referral and assessment with consent; and other relevant referrals such as cardiology, endocrinology, pulmonology, or nephrology if indicated prior to the procedure.

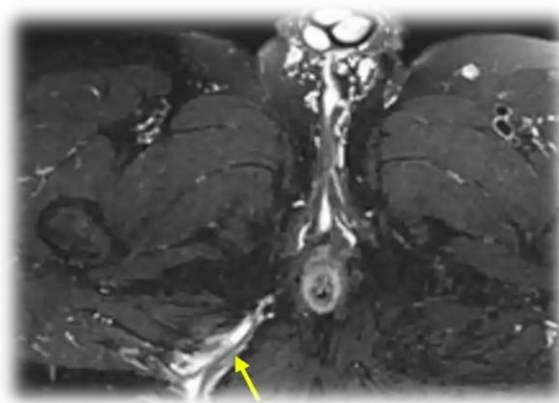


Figure (1): Pelvic MRI for Right Intersphincteric anal fistula.



Figure (2): Pelvic MRI for Left Intersphincteric anal fistula.

The operative management carried out:

Intraoperative assessment was performed using a proctoscope and fistuloscope, and patients were subjected to the full procedure including diagnostic fistuloscopy, closure of the internal ostium, and coagulation of the fistula canal, with intraoperative complications, if any, recorded during the surgery.

The post-operative course and complications such as bleeding or incontinence.

Post-operative pain assessment using visual analog scale (VAS) for pain scoring.

The Visual Analogue Scale (VAS) consists of a straight line with the endpoints defining extreme limits such as ‘no pain at all’ and ‘extreme pain (8)’.

The patient is asked to mark his pain level on the line between the two endpoints. The distance between ‘no pain at all’ and the mark then defines the subject’s pain. This tool was first used in psychology by **Freyd in 1923**, If descriptive terms like ‘mild’, ‘moderate’, ‘severe’ or a numerical scale is added to the VAS it seems to be most convenient (9).

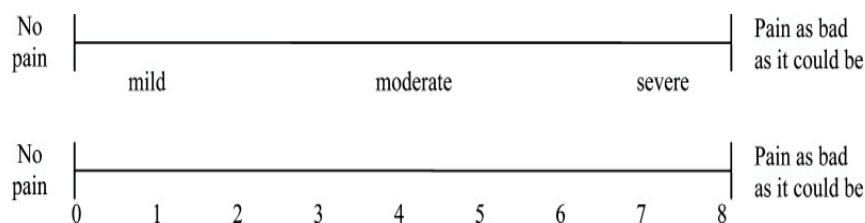


Figure (3): Visual analog scale (VAS) for pain scoring.

The patients were followed up after surgery with regard to fistula recurrence and its management, with a mean observation period of 6 months.

Statistical analysis :

The statistical analysis of the data was carried out using the statistical software program to show:

The median patients’ age, the median operating time, the median length of fistula track, the median of hospital stay, relation between male to female in our patients, recurrent to non-recurrent fistulae, percentage of complications in our patients including bleeding, infection, incontinence and recurrence.

- **VAAFT Kit:**

Karl Storz video equipment with the Meinero Fistuloscope was used, consisting of a rigid 8° angled telescope, monopolar electrode, brush, and endoscopic forceps, with irrigation via glycine-mannitol solution; the procedure was video-recorded and involved identifying the fistula tract and internal opening, fulgurating and curetting the tract, and closing the internal opening with a stapler or vicryl 2/0 suture. Patients were placed in lithotomy position under general or spinal anesthesia, given a single pre- and postoperative antibiotic dose, and managed with opioids followed by oral painkillers for 3–5 days.

- **Technique**

The Fistuloscope kit manufactured by Karl Storz (GmbH Tuttlingen, Germany) was used, with an obturator introduced into the anal canal to perform fistuloscopy for accurate identification of the internal opening, secondary tracts, and any abscess cavities; once the internal opening was located—either by direct exit of the fistuloscope, visible transillumination, or irrigation fluid—it was marked with absorbable sutures for traction, followed by removal of the obturator, fulguration of the tract using an electric diathermy probe under direct vision, removal of necrotic tissue with an endobrush and irrigation, and closure of the internal opening using absorbable sutures or a stapling device.

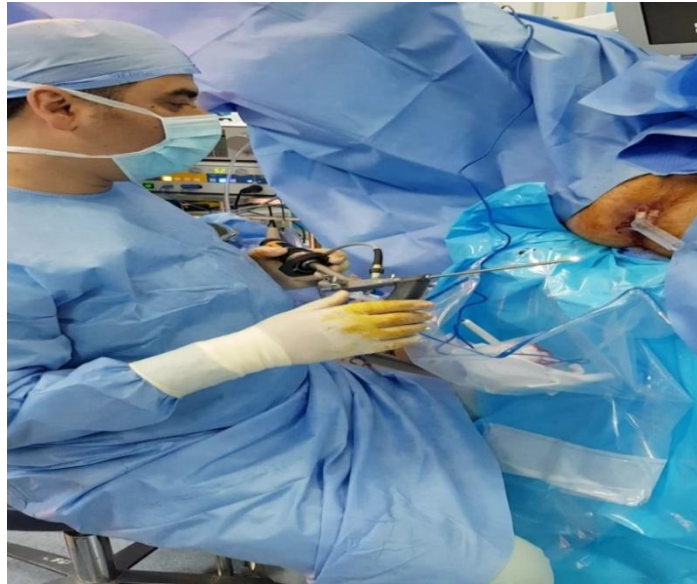


Figure (4): During VAAFT procedure.

3. RESULTS

This procedure was performed for the first time in Beni-Suef University hospital. The study started in March 2018 and ended in August 2020. During this period, 2 patients were missed from the follow up and were replaced by two new patients to complete twenty which is the total number of patients in our study. After finishing six months follow up as minimum for each patient, we started to collect the final data. All our patients tolerated the procedure- Video Assisted Anal Fistula Treatment (VAAFT).

Demographic consideration:

This study included 20 patients, 4 females (20%) and 16 males (80%), the youngest male was 28 years old, and the oldest male was 60 years old, the mean age of males was 42.4 years, the youngest female was 33 years old, and the oldest one was 42 years old, the mean age of females was 38.2 years (**Figure 5**).

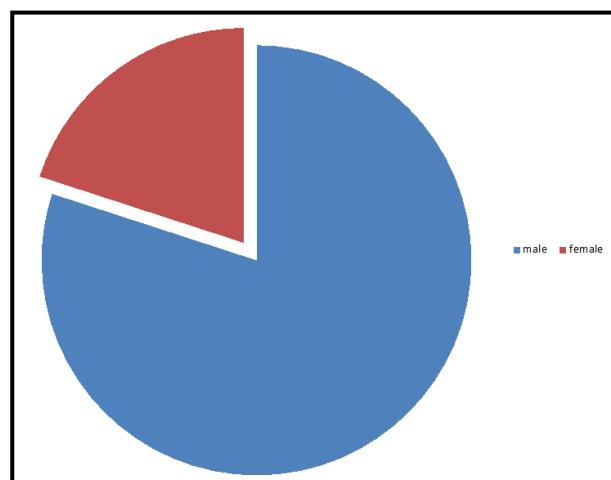


Figure (5): Percentage of females to males ratio

Concerning the clinical presentation:

All our patients were presented first with anal sepsis, complicated by anal fistula, and the period of time from presentation with anal sepsis until the VAAFT procedure was done (Evolution time) was calculated in months, where the minimum Evolution time was 2 months, the maximum was 24 months, and the mean Evolution time was 10 months (**figure 6**).

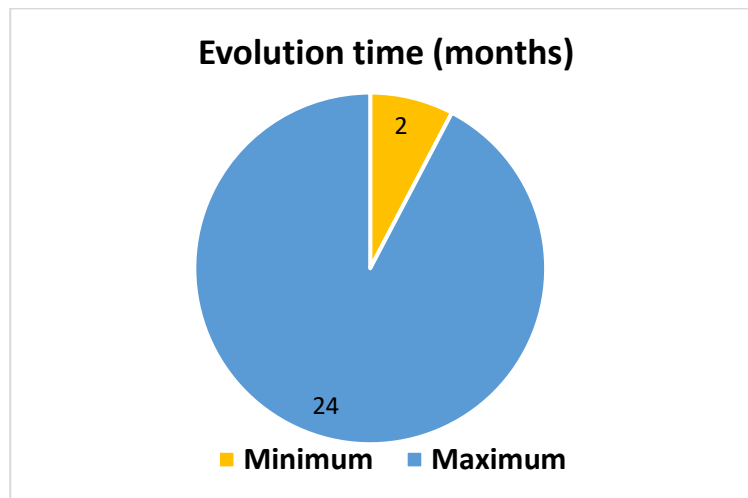


Figure (6): Evolution time in months

Sixteen patients in our study (80%) underwent incision and drainage of an anorectal abscess performed by different surgeons before presenting with anal fistula, while the remaining four patients (20%) had anorectal abscesses that ruptured spontaneously without any surgical intervention (**Figure 7**).

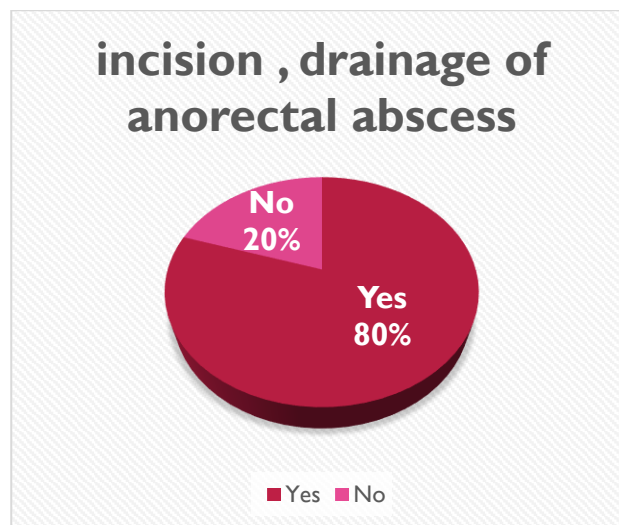


Figure (7): Drainage of anorectal abscess prior to fistula formation

Concerning the previous surgery (recurrence of anal fistula):

Three patients in our study (15%) had previous fistula surgery before VAAFT, 2 of them (10%) underwent Fistulotomy, the remaining one (5%) underwent Seton placement.

Concerning the length of fistula track:

Fifteen patients (75%) presented with high anal fistula and five patients (25%) with low anal fistula, and the minimum length of the fistula tract measured by MRI was 2 cm while the maximum length was 12 cm (**Figure 8**).

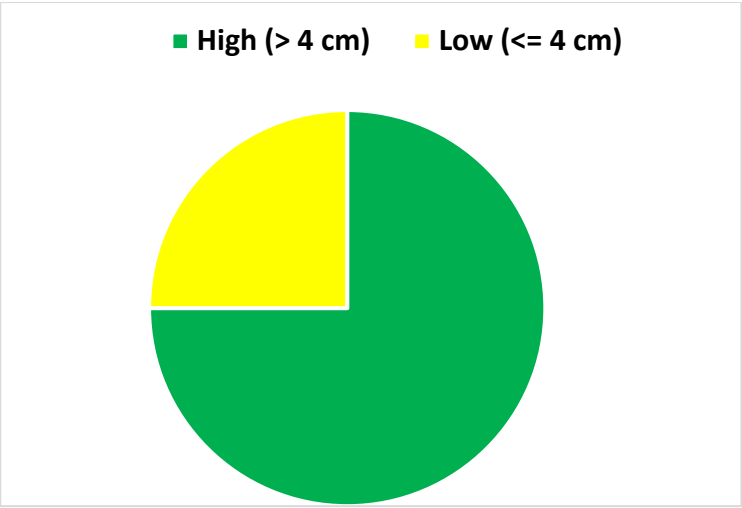


Figure (8): Length of fistula track

Concerning the position of internal and external opening:

External opening

Nine patients (45%) in our study had anterior anal fistula, eight patients (40%) had posterior anal fistula, two patients had lateral anal fistula, and three patients (15%) had transverse anal line fistula (Table 1, Figure 9).

Table (1): Position of external opening

Anterior	45%
Posterior	40%
Transverse anal line	15%

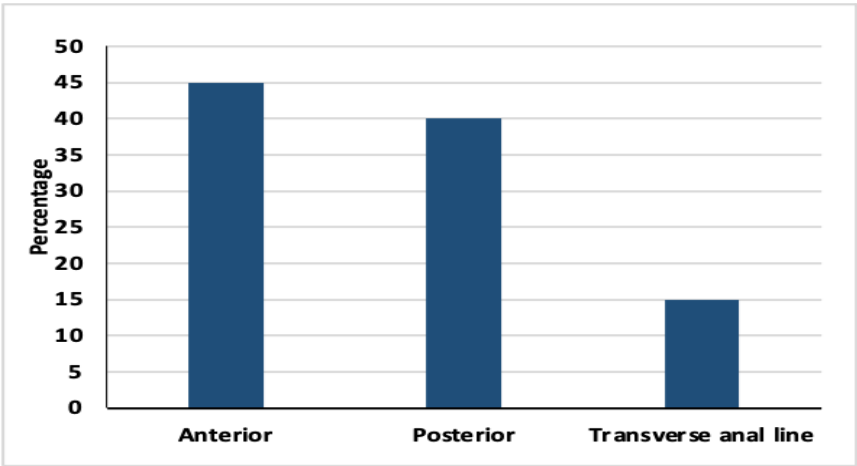


Figure (9): Position of external opening

Internal opening

Eight patients (40%) in our study had the internal anal fistula opening on the right side of the anal verge, six patients (30%) had the opening on the left side, and the remaining six patients (30%) had the opening in the midline (Figure 10).

LOCATION OF INTERNAL OPENING

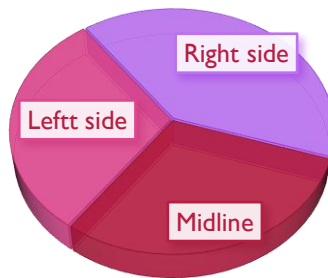


Figure (10): Location of internal opening

Concerning the perioperative details:

Eight patients (40%) received spinal anaesthesia (or saddle block), while the remaining twelve patients (60%) received general anaesthesia, and the internal fistula opening was closed by advancement flap in 6 patients (30%) using vicryl 2/0, by stapler in another 6 patients (30%), and by primary interrupted sutures using vicryl 2/0 in 8 patients (40%) (Figure 11).

Methods of closure of internal opening



Figure (11): Methods of closure of internal fistula opening.

The median time of the procedure was 45 minutes, with a minimum of 30 minutes and a maximum of 72 minutes; the average hospital stay was 24 hours, with no major blood loss during the procedure and an estimated loss of 5 to 10 ml per patient; post-operative pain was managed with ordinary painkillers like paracetamol and NSAIDs, with occasional use of a single dose of narcotic analgesics, and the average pain score on the visual analog scale (VAS) was 5; the mean post-operative follow-up period was six months, during which fifteen patients (75%) experienced fistula healing after the VAAFT procedure, while five patients (25%) had recurrence—one after two months, one after three months, and two after four months (Figure 12).

Healing after VAAFT

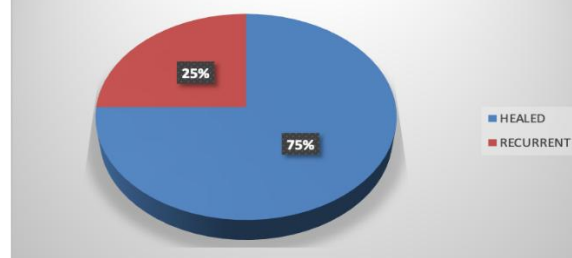


Figure (12): Fistula status after VAAFT procedure

We noticed that there was no recurrence in patients where a stapler was used for closure of the internal opening, and no major complications occurred in the post-operative period.

Table (2): Patients criteria.

Characteristics		Number n = 20	%
Sex	Male	16	80.0
	Female	4	20.0
Previous fistula treatment	No	17	85.0
	Fistulotomy	2	10.0
	SETON	1	5.0
Location of internal opening	Anterior	9	45.0
	Posterior	8	40.0
	Transverse anal line	3	15.0
Length of fistula track (cm)	High (> 4 cm)	15	75.0
	Low (<= 4 cm)	5	25.0
Complications	Healed	15	75.0
	Relapse	5	25.0

4. DISCUSSION

A fistula-in-ano is an epithelial-lined tract connecting the anal canal to the perianal skin, anal fistulas can have many causes but are most commonly the result of an anorectal abscess, although benign, the condition can cause significant distress and embarrassment to the patient.

Fistula-in-ano is one of the most common anorectal diseases, the prevalence is greater in men than women, with a rate of 1.2 to 2.8 cases per 10,000 (10).

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 (4).

Parks Classification is the most widely used classification for fistula in ano which distinguishes four kinds of fistula: intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric (11).

Fistulotomy and fistulectomy are the most widely accepted procedures performed for the management of simple anal fistulae with minimal involvement of the anal sphincter (12).

The treatment of complex fistulas is a challenge because of the high risk of postoperative complications such as incontinence, the risk of potential damage to the anal sphincters and subsequent poor functional outcome remains in a large proportion of patients with high fistulae when the tract crosses more than 30%-50% of the external sphincter, and with recurrent or complex fistulae with multiple extensions or separate tracts (4).

Fistulotomy has recently been advocated as a good technique for complex fistulae, with a success rate of about 96% and acceptable objective anal parameters; but still have a risk of sphincter injury specially with high anal fistula (13).

The treatment of anal fistula requires identification of the fistulous tract and internal opening, excision of the fistulous tract, and preservation of the continence mechanism (14).

The core of VAAFT is the visualization of the fistulous tract and its internal opening. It allows real-time visualization of the tract, precise identification of the anatomy by fistuloscopy, and fulguration of the tract under direct vision. The branching tracts and abscess cavities, which diminish the successful treatment of fistula in ano, can also be identified and dealt with appropriately (15).

Moreover, the internal opening can be adequately managed either by suturing or using a stapling device. Adoption of fistuloscopy along with closure of the internal opening either by suturing or stapling device allows an effective treatment of complex anal fistulas with preservation of the anal sphincters (4).

Meinero and Mori included 98 patients with complex anal fistula in their study, 71 males and 27 females, with a median age of 42 years (range 21–77 years) (5).

Mendes et al published their study in 2014 that included 8 patients only, one (12.5 %) patient was female and seven males

(87.5 %) the mean age was 43 (29-66) year **(16)**.

The mean age in our study was 42 years which is near to that in these studies mentioned before but number of patients (20) is less than Meinero and Mori study but more than Mendes et al study.

Three patients in our study (15%) had previous fistula surgery before VAAFT, 2 of them (10%) underwent Fistulotomy, the remaining one (5%) underwent Seton placement

In some cases, with narrow external opening, it was difficult to pass the fistuloscope through it, also, posterior anal fistulas take more efforts to introduce the scope through fistula track- perhaps spinal anaesthesia will facilitate this process.

Mendes et al used simple suturing for closure of the internal opening in all cases (8 cases), fistula recurrence in one case (12.5%) **(16)**.

In our study, internal fistula opening was closed by advancement flap in 6 patients (30%) using vicryl 2/0, by stapler in 6 patients (30%) and by primary interrupted sutures using vicryl 2/0 in 8 patients (40%).

It was no recurrence in the patients where stapler was used for closure of the internal opening, this notice should be taken in consideration in further studies.

Meinero and Mori mentioned that the operative time was progressively reduced (from 2 h to 30 min) following improvement in the learning curve **(5)**.

For us, the mean procedure time was 45 minutes, the minimum time was 30 minutes while the maximum time needed to finish VAAFT procedure was 72 minutes which is not far away from the other studies.

Meinero and Mori did Pain assessment based on the visual analogue scale (VAS) score with a mean value of 4.5 (on a scale of 1–10) during the first 48 h. **(5)**.

In our study, the average post-operative pain score in visual analog scale (VAS) for pain scoring was 5, that means post-operative pain for this procedure is tolerable.

Giarratano et al found that Eight (11%) patients had postoperative complications: bleeding in four (5.5%), urinary tract infection in two (2.7%) and perianal oedema in two (2.7%) **(17)**.

In our study, the morbidity associated with the procedure was minimal. There was minimal discharge and pain at the surgical site, no raw area, and an early return to work, which led to a high level of patient satisfaction.

Giarratano et al published their study which included 72 patients with anal fistula, the follow up period after surgery was 18 months and the recurrence rate was 21% **(17)**.

In our study, the recurrence rate was 20% after 6 months follow up, which is near to the results published by Giarratano, and less than that published by Meinero and Mori.

The main advantage of VAAFT is that it is associated with minimal morbidity. Although it is associated with recurrence, it can be repeated many times with no risks of sphincter injury or incontinence.

As regards costs, there is the initial cost of the fistuloscope and kit, but they are reusable. The cost increases if a stapler is used, but not if a flap is fashioned. The adoption of expensive technology and devices does increase the cost of the procedure, but on the other hand, the short hospital stay, early recovery after surgery and early back to work result in relative cost effectiveness of the VAAFT procedure.

This procedure should be more acceptable to the patients as the treatment modality because of its low morbidity.

By time, the learning curve will improve, the procedure time will be less, scope manipulation and orientation will be better and the results will be better as well.

In conclusion, VAAFT is a safe and minimally invasive procedure for the treatment of complex anal fistula while preserving anal sphincter function. Neither this study nor other studies mentioned that it was a damage to the anal sphincter or fecal incontinence, accordingly- we can consider VAAFT procedure as: Sphincter-Saving Fistula Surgery.

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