

## Original Research

# Drained mucosal advancement flap versus rerouting Seton around the internal anal sphincter in treatment of high trans-sphincteric anal fistula: A randomized trial

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## ABSTRACT

**Background:** Several sphincter saving techniques have been described for complex anal fistula (CAF) with variable outcomes. The present trial aimed to compare two techniques for CAF; the drained mucosal flap technique and rerouting Seton around the internal anal sphincter (IAS).

**Methods:** Adult patients with high trans-sphincteric anal fistula were randomly assigned to one of two groups: group I underwent mucosal advancement flap with drainage Seton rerouted around the external anal sphincter, and group II underwent rerouting Seton around the IAS. The two groups were compared in terms of the incidence of postoperative fecal incontinence (FI), healing of fistula, complications, and changes in anal pressures. **Results:** 97 patients (80 male) of a mean age of 39.5 years were included. One patient developed FI in group I versus 7 in group II ( $p = 0.03$ ). Failure of healing occurred in 2 patients in group I and 4 in group II ( $p = 0.43$ ). In group II, the average time for spontaneous fall of Seton was  $14 \pm 2.8$  days whereas in group I the average time for removal of Seton was  $40 \pm 14.9$  days ( $p < 0.0001$ ). There were no significant differences between the two groups in complication rate. Postoperatively, the decrease in resting anal pressure was significant in Group II but not group I.

**Conclusion:** The drained mucosal flap technique was associated with significantly lower incidence of FI, yet longer operative time and longer time to complete healing compared to rerouting Seton around the IAS. The success rates of both techniques was comparable.

## 1. Introduction

Optimal surgery for complex anal fistula aims to eradicate anorectal sepsis without compromising the continence state. However, achieving both goals is quite challenging. Different sphincter-sparing techniques were described with variable results including Seton, advancement flap, ligation of the intersphincteric fistula tract (LIFT), fistula plug, fistula tract Laser closure (FiLaC), and video assisted anal fistula treatment (VAAFT) [1–3].

Ideal sphincter saving techniques should aim to preserve both the internal anal sphincter (IAS) and external anal sphincter (EAS) to avoid affection of continence. Nevertheless, preserving the IAS may be associated with inadequate eradication of the fistula which may result in high recurrence rates that reach up to 30% after advancement flap and up to 40% after LIFT [3–5].

Dividing the IAS during surgery for complex anal fistula could be

associated with minor degree of fecal incontinence (FI) as recorded after the classic draining Seton technique which involves staged division of the sphincter muscle [6] and modified Park's technique that was described to decrease recurrence rate but was also complicated by minor FI [7]. Even rectal advancement flap can be associated with minor FI and the rate of which essentially depends on the thickness of the IAS dissected along with the flap [8].

Recently, EAS-sparing Seton using the rerouting technique was described with satisfactory outcomes. In this technique the Seton was rerouted around the IAS to divide it slowly, thus avoid affection of the continence mechanism. However, minor FI was still recorded in 7% of patients after spontaneous falling of the Seton [9].

Given the importance of the IAS in continence, we suggest complete sparing of both IAS and EAS muscles by placing a drainage seton around the EAS only and excision and closure of the internal fistula opening with a mucosal advancement flap followed by cutting the loose

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seton upon complete healing of the fistula without allowing the Seton to cut through the EAS muscles. We hypothesized that this technique would preserve anal continence completely and would also achieve high cure rate by adequately closing the internal opening and draining all possible associated perianal sepsis. Zbar and colleagues [10] described a similar technique in 2005, yet they allowed the Seton to cut through the EAS fibers which was associated with intermittent flatus incontinence in 5.5% of patients.

The aim of the present study was to compare the drainage Seton around the EAS combined with mucosal advancement flap (drained mucosal flap technique) and rerouting Seton around the IAS in terms of postoperative FI, healing rate, healing time, recurrence of anal fistula, and complications.

## 2. Patients and methods

### 2.1. Study design and setting

This is a prospective, randomized, single-blinded controlled study on patients with high trans-sphincteric anal fistula. Patients were operated upon in a private colorectal surgery centre in Mansoura City in the period of January 2017 through May 2018. Ethical approval for the study was obtained from the Institutional Review Board (IRB) of Mansoura Faculty of Medicine. The trial was registered in the clinical trial registry and was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

### 2.2. Eligibility criteria

Adult patients of both sexes aging between 18 and 65 years with high trans-sphincteric cryptoglandular anal fistula were included. High trans-sphincteric fistula was defined as anal fistula that involves more than 30% of the EAS muscles [6].

We excluded patients with simple anal fistulas and anal fistulas secondary to specific etiology such as inflammatory bowel disease, malignancy, sexually transmitted diseases, or irradiation. Patients with acute anorectal sepsis, FI of any degree, and previous anorectal surgery for indications other than anal fistula were also excluded.

### 2.3. Random sequence generation

Patients were randomly allocated to one of two equal groups using special online randomization software ([www.randomization.com](http://www.randomization.com)) with 1:1 ratio. The first group was treated with drainage Seton around the EAS combined with mucosal advancement flap (drained mucosal flap technique) and the second group was treated with rerouting Seton around the IAS, preserving the EAS. Allocation of the patients to each group was concealed by the sealed envelope method. The study was single blinded as the patients were not aware of the technique they

underwent, however, the operating surgeons were aware of the nature of the study and group allocation.

### 2.4. Preoperative assessment

Patients were thoroughly assessed prior to surgery by taking detailed history of the current complaint, previous investigations and treatments for the condition. The continence state was evaluated using Wexner incontinence score [11].

Each patient was clinically examined in the left lateral position. Inspection of the perineum and anal verge was done to detect the number and site of the external opening of the fistula. Digital rectal examination was performed to assess the tone of the anal sphincter and exclude associated anorectal pathology. Patients were assessed with MRI fistulography to determine the anatomy of the fistula, position of internal opening, and type and number of tracts. Anal manometry was done before surgery to measure the resting and squeeze anal pressures.

### 2.5. Surgery

Informed consents to participate in the study were obtained from all patients after explaining possible benefits and complications of each technique. All procedures were done under spinal anaesthesia with the patient placed in the lithotomy position. One gram of cefotaxime was given on induction as prophylactic antibiotic. The procedures started with injection of hydrogen peroxide through the external fistula opening to localize the internal opening. Afterwards, a malleable metallic probe was inserted into the external opening and gently guided until its tip came out of the internal opening. The subcutaneous part of the fistula tract (lying outside the EAS) was excised with electrocautery and the remaining part of the tract and any secondary extensions were thoroughly curetted with surgical curette then Seton (0- silk suture) was then inserted in the fistula tract.

**Group I (Drained mucosal flap):** As adopted from Zbar et al. [7], after the Seton was introduced inside the fistula tract it was rerouted by dissection in the intersphincteric plane, and was tied loosely around the EAS, sparing the IAS fibers. The internal fistula opening was excised and was closed by advancement of an elliptical mucosal flap. The mucosal flap was meticulously dissected making sure it does not incorporate any IAS musculature (Fig. 1). Patients were examined under anaesthesia after 4–6 weeks to confirm healing of the flap and absence of internal opening and then the loose Seton was cut with scissors, without dividing any EAS fibers.

**Group II (Rerouting Seton around IAS):** After the Seton was introduced inside the fistula tract it was rerouted by dissection in the intersphincteric plane, and was tied tightly around the IAS, sparing the EAS (Fig. 2). The Seton was kept in place until it fell spontaneously after cutting through the IAS fibers.

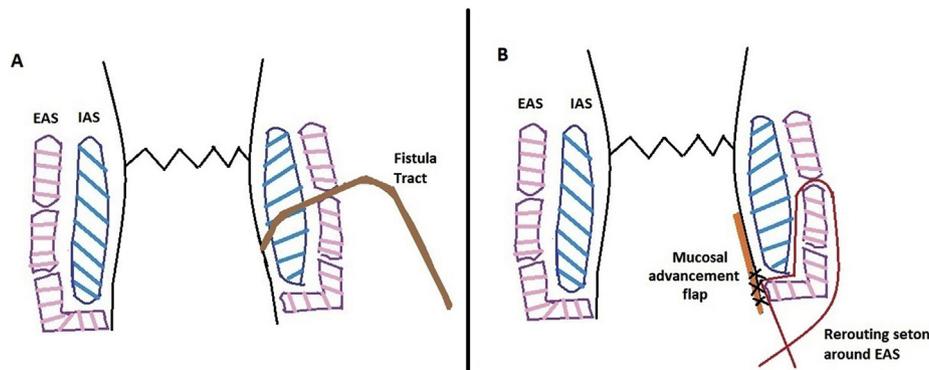


Fig. 1. Drained mucosal flap technique; drainage Seton was rerouted around the external sphincter and was tied loosely and the internal opening was closed with mucosal advancement flap.

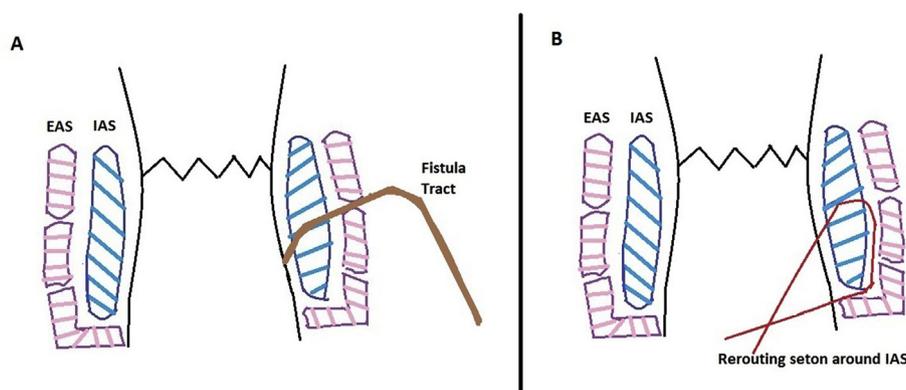


Fig. 2. Rerouting Seton around the internal anal sphincter.

### 2.6. Postoperative follow up

Patients were followed-up at one, two, and four weeks, then every month in the outpatient clinic. At 6 and 12 months postoperatively patients were clinically assessed for recurrence of anal fistula and the continence state was assessed using Wexner incontinence score. Anorectal manometry was performed at 6 months after surgery.

### 2.7. Outcomes of the study

The primary outcome of the study was the continence state after surgery as assessed with Wexner incontinence score. Secondary outcomes included complete healing of fistula, duration to healing, recurrence rates, operation time, and postoperative complications.

Complete wound healing was defined as complete epithelialization of the wound, with no evidence of external fistula opening or perianal discharge, as detected by clinical examination. Persistence was defined as failure of complete healing of the anal fistula for more than six months after surgery [12]. Recurrence was defined as the clinical re-appearance of the fistula after complete healing of the surgical wound after removal or fall of Seton, occurring within 1 year after the procedure [13].

### 2.8. Sample size calculation

The sample size for the current trial was calculated using online software (<https://clincalc.com/stats/samplesize.aspx>) based on the primary outcome of the study (the incidence of FI after each technique).

In light of previous literature [14,15] that reported minor FI to occur in up to 25.5% of patients with anal fistula after division of the IAS, and presuming that the rate of FI in first group (drained mucosal flap) will be 5%, a sample size of 94 patients, equally divided on the two groups was found necessary to achieve a study power of 80% with alpha set at 5%. In order to compensate for loss to follow-up, 97 patients were ultimately included.

### 2.9. Statistical analysis

Data were analyzed by SPSS version 23 (IBM corp; Chicago, USA). Continuous data were expressed in form of mean  $\pm$  standard deviation (SD), or median and normal range and categorical data were expressed as number and proportions. Student t-test was used for analysis of quantitative data and Fisher's exact test or Chi-square test were used to analyze categorical data. P-value less than 0.05 were considered significant.

## 3. Results

### 3.1. Patients' characteristics

A total of 153 patients were initially screened, 51 patients did not meet the inclusion criteria of the study and were excluded, and 102 patients were enrolled to the trial. Five patients were lost to follow-up, and 97 were included to the final analysis (Consort flow chart, Fig. 3). Patients were 80 (82.4%) male and 17 (17.6%) female. The mean age of patients was  $39.5 \pm 12.2$  years.

Fifty (51.5%) patients had anteriorly-located anal fistula and 47 (48.5%) had posterior anal fistula. According to preoperative MRI, 6 (6.1%) patients had horse-shoe fistula, 6 (6.1%) had supralelevator collection, and 5 (5.1%) had ischioanal collection. Nine (9.3%) patients had history of previous surgery for anal fistula. The mean preoperative resting anal pressure was  $75.1 \pm 9$  mmHg and the mean preoperative squeeze anal pressure was  $110.3 \pm 10.1$  mmHg.

Forty-nine patients were allocated to the drained mucosal flap group (Group I) and 48 were allocated to the rerouting Seton around IAS group (Group II). There were no significant differences between the two groups regarding patients' characteristics, fistula type, and history of previous fistula surgery as shown in Table 1.

### 3.2. Outcome of the two groups

FI developed in eight patients (one patient in group I and 7 in group II). Five patients had flatus incontinence and three had minor fecal soiling. All patients showed spontaneous improvement in the continence state at 6 months of follow-up. The median Wexner incontinence score was similar in both groups (Table 2).

On follow-up, 2 (4.1%) patients in group I and 4 (8.3%) patients in group II experienced persistence or recurrence of anal fistula, the difference between the two groups was not statistically significant ( $p = 0.43$ ). In group II, the average time for spontaneous fall of Seton was  $14 \pm 2.8$  days whereas in group I the average time for removal of Seton was  $40 \pm 14.9$  days ( $p < 0.0001$ ).

Group II had significantly shorter operation time than group I ( $38.9 \pm 6.5$  Vs  $56.1 \pm 7$ ;  $p < 0.0001$ ). Seven patients developed postoperative complications, four in group I (flap disruption = 2, bleeding = 1, urine retention = 1) and three in group II (bleeding = 1, urine retention = 2). There were no significant differences between the two groups in complication rate and follow-up duration (Table 2).

### 3.3. Changes in anal pressure after surgery

Both groups had comparable preoperative resting and squeeze anal pressures with no significant differences. Postoperatively, group II showed a significant decrease in the resting anal pressure ( $75.9 \pm 8.6 \rightarrow 65.8 \pm 7.7$  mmHg,  $p = 0.0005$ ), whereas the decrease

CONSORT 2010 Flow Diagram

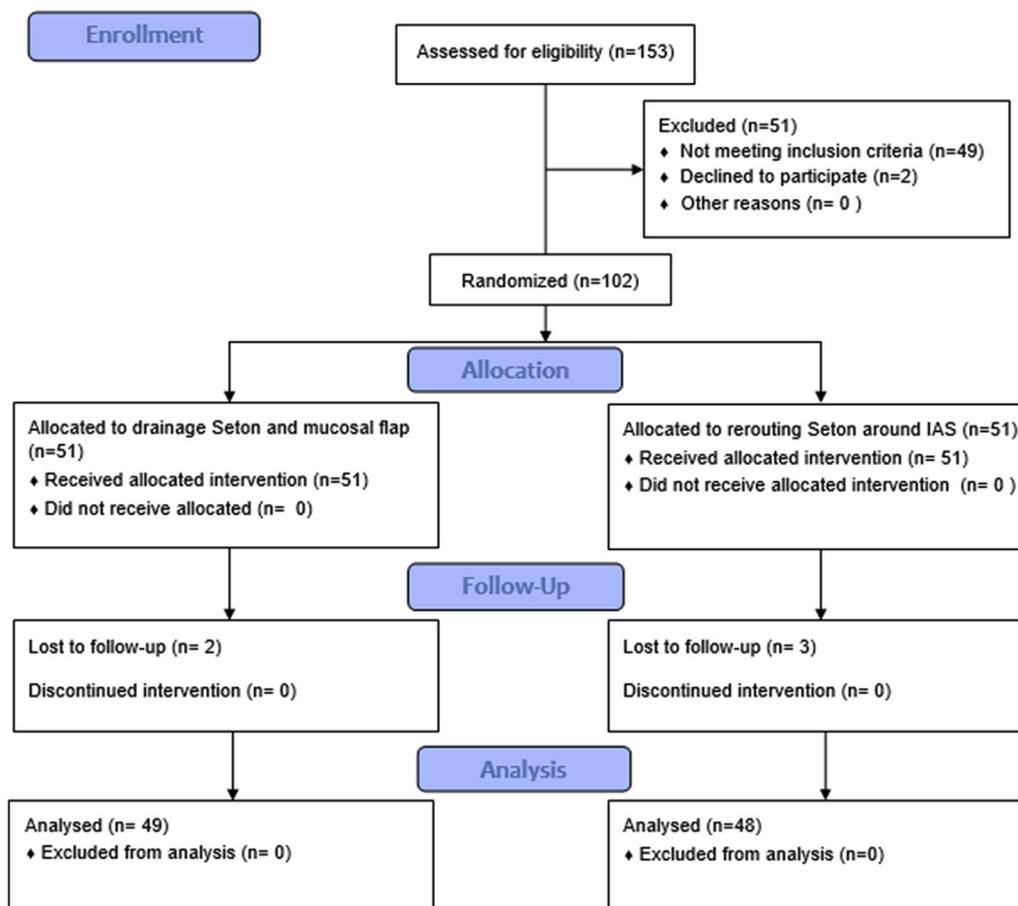


Fig. 3. Consort flow chart illustrating the process of patient recruitment and exclusion.

Table 1 Patients' characteristics in both groups.

Variable	Group I (n = 49)	Group II (n = 48)	P value
Mean age in years	40.6 ± 12.8	38.4 ± 11.6	0.37
Male/female	44/5	36/12	0.09
Location of fistula	Anterior 24 (48.9%) Posterior 25 (51.1%)	Anterior 26 (54.2%) Posterior 22 (45.8%)	0.76
Horse-shoe fistula	5 (10.2%)	1 (2.1%)	0.2
Supralevator collection	2 (4.1%)	4 (8.3%)	0.43
Ischeoanal collection	4 (8.2%)	1 (2.1%)	0.36
History of previous fistula surgery	6 (12.2%)	3 (6.2%)	0.48

Table 2 Outcome of both groups.

Variable	Group I (n = 49)	Group II (n = 48)	P value
Mean operation time in minutes	56.1 ± 7	38.9 ± 6.5	< 0.00001
Fecal incontinence	1 (2%)	7 (14.5%)	0.03
Median postoperative Wexner score	0 (0–2)	0 (0–4)	0.99
Mean time to removal or spontaneous fall of seton in days	40 ± 14.9	14 ± 2.8	< 0.0001
Persistence/Recurrence	2 (4.1%)	4 (8.3%)	0.43
Complications	4 (8.2%)	3 (6.25)	1
Mean follow-up in months	20.7 ± 4.3	20.5 ± 4.4	0.82

in the resting anal pressure in group I was not statistically significant (74.3 ± 9.4 → 71.5 ± 8 mmHg, p = 0.11). Changes in the squeeze anal pressure postoperatively were not statistically significant in both groups (Table 3).

4. Discussion

Complex anal fistula is a challenging problem in which radical treatment of anorectal sepsis may be associated with some disturbance of the continence state. It is evident from the literature that the procedures which aim to preserve both anal sphincters completely such as LIFT, VAAFT, and fistula plug can be associated with high recurrence rates [2,16&17]. It can be assumed that failure after these procedures is probably due to improper drainage of abscess cavities and secondary

**Table 3**  
Changes in anal pressures in both groups.

Variable	Group I (n = 49)	Group II (n = 48)	P value
Mean preoperative resting anal pressure	74.3 ± 9.4	75.9 ± 8.6	0.37
Mean postoperative resting anal pressure	71.5 ± 8	65.8 ± 7.7	<b>0.0005</b>
P value	0.11	< <b>0.0001</b>	–
Mean preoperative squeeze anal pressure	108.5 ± 9.2	112.1 ± 10.7	0.07
Mean postoperative squeeze anal pressure	106.6 ± 9.8	108.9 ± 11.9	0.3
P value	0.32	0.17	–

extensions of the primary fistula track, including supra-levator collection, which is considered to be responsible for anal fistula persistence or recurrence after surgery [6].

The placement of drainage Seton has been advocated as a preliminary step in treatment of complex anal fistula before undertaking the definitive surgical treatment. However, drainage Seton has been also used as a definitive treatment of complex fistulas with good results [6,18,19]. Despite the high rate of fistula healing after placement of drainage Seton, the duration to complete healing is often prolonged and the continence state may be compromised in some patients as the Seton cuts through the anal sphincter muscles. Rerouting of Seton around either the IAS or the EAS has been described with low recurrence rates and shorter time to complete healing [9,10].

We modified the technique described by Zbar et al. [9] in which a mucosal advancement flap was constructed and drainage Seton was inserted and was rerouted around the EAS, allowing which to cut through the sphincter muscles by the progressive migration technique. We thought that it is better to cut the Seton once healing was clinically confirmed before it divides its way through the sphincter muscles which may result in some degree of FI.

Mucosal advancement flap was chosen since it does not incorporate any IAS fibers, thus may not be associated with the risk of continence disturbance, unlike partial or full-thickness advancement flaps in which part of the IAS fibers is dissected with the flap and up to 20% of patients develop minor FI postoperatively [8]. Although failure rates after mucosal advancement flap have been reported to be up to 30% [20], combining the mucosal advancement flap with drainage Seton managed to reduce the failure rate in our study to less than 5%. This observation can be explained that failure of flap is mostly attributed to ischemia or inadequate drainage of anorectal sepsis. The drainage Seton served to achieve sufficient and constant drainage of the intersphincteric space, reducing the inflammatory activity within the tract and resolving secondary tracts which helped reduce failure of the flap as has been previously reported [21–23].

We compared the drained mucosal flap technique with another technique in which Seton was rerouted and tightened around the IAS only and was allowed to cut through the sphincter fibers until it fell spontaneously. In both techniques the Seton was rerouted around either the EAS or the IAS. However; in the latter technique Seton was allowed to cut through and divide the IAS muscles. The objective was to determine which technique conferred the best outcome in regards preserved continence and complete healing of anal fistula, the perfect balance for every optimal fistula surgery.

Our results showed that both techniques achieved high cure rates with no significant difference in fistula persistence/recurrence. Persistence/recurrence of the fistula was non-significantly higher after rerouting Seton around the IAS which can be explained by the inadequate drainage of sepsis in the high inter-sphincteric and the supra-levator spaces as the Seton was placed around the lower part of the IAS. In contrast, in the drained mucosal flap technique Seton was rerouted around the EAS which allowed better drainage of sepsis in fistula-related spaces, eliminating the risk of persistence or recurrence that was attributed to the detrimental effect of ongoing disease in the remaining fistula tract [23].

The primary outcome of the trial was the incidence of FI after each

technique. Rerouting Seton around the IAS was associated with a significantly higher rate of FI which highlights the observation that even staged, slow division of the IAS may result in continence disturbance in some patients, akin to that recorded after surgical internal anal sphincterotomy [15]. On the other hand, FI was recorded in only 2% of patients who underwent the drained mucosal flap technique in which the anal sphincter muscles were completely preserved.

The significant difference between both techniques regarding anal function was paralleled by a significant reduction in the resting anal pressure after rerouting Seton around the IAS, but not in the drained mucosal flap group. Minor FI in both groups improved spontaneously with time in accordance with the literature [15].

In light of these results, the drained mucosal flap technique seems a better option for patients at higher risk of postoperative FI such as female patients with previous vaginal delivery. On another hand, rerouting Seton around the IAS conferred significantly shorter time to spontaneous fall of the Seton and healing of fistula, dispensing the need for a second stage procedure. Moreover, Rerouting Seton around the IAS had significantly shorter operative time than the drained mucosal flap technique which is reasonable as the dissection and fixation of the mucosal flap required additional minutes.

The techniques described in this paper may not be suitable for all complex anal fistulas. In recurrent anal fistulas the IAS may have been divided in previous surgery or the inter-sphincteric space may have been obliterated by fibrosis and scarring. Also the mucosa can be tough and not suitable for flap mobilization and construction in recurrent fistulas or fistulas with significant intersphincteric sepsis. Although the results of the two techniques described in this study are preliminary and these techniques may not be suitable for all fistulas, these techniques can expand the tool box of the surgeon treating complex anal fistula.

Limitations of the study include being a single institution study with relatively small number of patients in each group. Larger, multicentre trial with longer follow-up are needed to ascertain the results of the current trial.

## 5. Conclusion

The drained mucosal flap technique was associated with significantly lower incidence of FI, yet longer operative time and longer time to complete healing compared to rerouting Seton around the IAS. The success rates of both techniques was comparable and was less than 10% which is considered lower than other sphincter-sparing techniques for complex anal fistula.

## Data statement

Research data used in the study will be available on request.

## Provenance and peer review

Not commissioned, externally peer-reviewed.

## Ethical approval

Institutional review board of Mansoura Faculty of Medicine Code:

R/17.01.35.

#### Please state any sources of funding for your research

None.

#### Trial registration

NCT03983174.

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#### Author contribution

Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, writing. Others, who have contributed in other ways should be listed as contributors.

*Mahmoud Abdelnaby* designed the study, performed the procedures, followed the patients, shared in data analysis, and critical revision of the manuscript.

*Sameh Emile* shared in data collection and analysis and writing the manuscript.

*Mohamed El-Said* contributed to, data acquisition and analysis, writing and revising the manuscript.

*Emad Abdallah* contributed to data interpretation and analysis, writing and revision of the manuscript.

*Ahmed Abdelmawla* Followed the patients, shared in writing parts of the manuscript and critical revision of the final version.

#### Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Sameh Emile, M.D.

#### Declaration of competing interest

None to be declared by the authors.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijvsu.2019.11.008>.

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