



A pilot randomized controlled trial on ligation of intersphincteric fistula tract (LIFT) versus modified parks technique and two-stage seton in treatment of complex anal fistula

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Abstract

Complex anal fistula (CAF) is a challenging condition for surgeons. This randomized trial aimed to compare ligation of the intersphincteric fistula tract (LIFT), modified Parks technique, and two-stage seton in the treatment of complex anal fistula in terms of the success of treatment and complications. This was a pilot randomized trial conducted in the period of January 2019 to December 2019 on adult patients with CAF who were allocated to one of three groups: LIFT, modified Parks technique, and two-stage seton. The main outcome measures were healing rates, time to healing, complications, operation time, and quality of life. Sixty-six patients (75.7% males) of a mean age of 45.2 years were included. Mean operation time of LIFT was significantly shorter than the other two procedures ($p < 0.0001$). There was a significant difference between the three groups in terms of success rate ($p = 0.04$) but not in regard to complications ($p = 0.59$). The modified Parks technique had a significantly higher success rate than LIFT (95.2% vs 68.1%, $p = 0.045$) whereas the success rates of two-stage seton and LIFT were not significantly different (86.9% vs 68.1%, $p = 0.16$). The average time to healing after LIFT was significantly shorter than the other two procedures. The quality-of-life scores were comparable among the three groups. There was a significant difference in healing rates after the three procedures as the modified Parks technique achieved the highest success rate followed by two-stage seton and then the LIFT procedure. Time to complete healing after LIFT was significantly shorter than the other two procedures. The three procedures achieved similar quality of life and complication rates.

Keywords LIFT · Modified parks · Two stage · Seton · Complex anal fistula · Randomized

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Introduction

Anal fistula is a common surgical condition that, despite being a benign condition, represents a unique challenge to colorectal surgeons. The majority of anal fistulas are attributed to the cryptoglandular theory where a fistula is a sequel to an anorectal abscess that was spontaneously or surgically drained [1]. However, some anal fistulas are secondary to specific etiologies such as inflammatory bowel disease, particularly Crohn's disease [2].

Anal fistulas can be classified into simple and complex. Simple anal fistulas include intersphincteric and low trans-sphincteric fistulas that involve less than 30% of the external anal sphincter fibers. Complex anal fistulas comprise high trans-sphincteric fistulas, suprasphincteric, extrasphincteric fistulas, and horseshoe fistulas [3].

While the treatment of simple anal fistula is usually straightforward with fistulotomy is recommended as the gold standard treatment [4]; management of more complex

fistulas requires more sophisticated treatments aiming to preserve the anal sphincters and to eradicate the fistula pathology. Surgery for complex anal fistula includes placement of seton, rectal advancement flap, ligation of intersphincteric fistula track (LIFT), video-assisted anal fistula treatment (VAAFT), fistula laser closure, and anal fistula plug [5–7].

LIFT is a sphincter-saving procedure that is based on the concept of secure closure of the internal opening and concomitant removal of infected cryptoglandular tissue in the intersphincteric plane [8]. Modified Parks technique [9] involves adequate drainage of the intersphincteric space by extending the internal anal sphincterotomy. Placement of seton in the fistula tract has been used for decades and is still being currently used. Two-stage seton has been advocated to promote adequate drainage of infection and can be employed as a definitive treatment of anal fistula [10, 11].

The present pilot randomized trial aimed to compare LIFT, modified Parks technique, and two-stage seton in treatment of complex anal fistula in terms of success of treatment and complication rates.

Patients and methods

Study design and setting

This was a parallel-group, randomized, controlled, open-label clinical trial on patients with complex anal fistula who were treated in the General Surgery Department and Colorectal Surgery Unit of Mansoura University Hospital in the period of January 2019 to December 2019. Patients recruited were allocated to one of three procedures: LIFT, modified Parks' technique, and two-stage seton. The rationale for the selection of the three procedures for the trial was to examine the efficacy of the modified Parks technique, which was recently introduced by our unit as a promising one-stage treatment of complex anal fistula [9, 12], in comparison to two commonly performed procedures for complex anal fistulas, LIFT and two-stage seton. Ethical approval for the study was obtained from our institution. The trial was registered in www.clinicaltrials.gov with the special identifier NCT04377542 and was reported in adherence to the standards of the CONSORT guidelines.

Eligibility criteria

Adult patients of either sex aged less than 65 years presenting with complex anal fistula were included. Complex cryptoglandular fistulas were defined as high trans-sphincteric (involving more than 30% of the external anal sphincter), extra-sphincteric, supra-sphincteric, horse-shoe fistulas, and anterior fistulas in females that were not secondary to a specific condition such as inflammatory bowel disease,

sexually transmitted diseases, tuberculosis, malignancy, or radiation [3].

We excluded the following patients:

- Patients with simple anal fistula (intersphincteric and low trans-sphincteric anal fistula)
- Patients with associated anorectal pathology such as anal fissure, hemorrhoids, rectal prolapse, neoplasm, solitary rectal ulcer, inflammatory bowel diseases.
- Patients on long-acting steroids or immunosuppressive drugs.
- Patients with fecal incontinence (FI) defined as Wexner incontinence score ≥ 2 .
- Patients with previous anorectal operations including surgery for previous anal fistula.
- Patients with American society of anesthesiologists (ASA) score of III and higher as they may be unfit for anesthesia and thus get excluded. Moreover, even when fit for anesthesia, patients with moderate to severe systemic disease may be less compliant with follow-up and perhaps more liable to develop complications, namely infection.

Preoperative assessment

A detailed history was taken from the patients with regard to the complaint and its duration, associated medical conditions, previous surgical operations, previous treatments for the current condition, presence of anal pain, constipation and FI. The continence state was assessed with the Wexner incontinence score [13].

Thorough clinical examination was done for all patients. Local anorectal examination was performed by direct inspection, digital rectal examination, and proctoscopy to confirm the presence of the external opening(s), to identify the location of the internal opening, and to exclude associated anorectal lesions. Preoperative MRI or endoanal ultrasound (EAUS) was used to assess the pathologic anatomy of the fistula with regard to the position of the internal opening, type of fistula tract, and presence of any secondary extensions [14].

Random sequence generation

Using online randomization software (www.randomization.com), patients were randomly assigned to one of three equal groups; Group I was treated with LIFT, Group II was treated with modified Parks technique, and Group III was treated with a two-stage seton. The allocation of patients to each group was concealed using the sealed envelope method. After the patient received spinal anesthesia in the operating theatre, the circulating nurse opened the sealed envelope and the patient was assigned to its corresponding group. The study was an

open-label study since the patients and surgeons were aware of the nature of the study and group allocation.

Surgical procedures

After explaining the nature of the study and the potential benefits and complications of each procedure, written informed consents were obtained from the patients. All procedures were performed under spinal anesthesia with the patients placed in the lithotomy position. One gram of cefotaxime was administered on induction. The procedures were performed in a standardized manner by four consultants of colorectal surgery.

All procedures started with the identification of the internal opening by injection of hydrogen peroxide through the external opening followed by insertion of a malleable metallic probe through the external opening.

Group I (LIFT): as described in the original technique [8], an incision was made at the intersphincteric groove and then blunt dissection was undertaken in the intersphincteric plane to identify the intersphincteric fistula tract (Fig. 1). Then the fistula tract was ligated twice with polyglactin 2/0 sutures and the part of the tract between the two ligatures was excised using scissors. The integrity of repair was tested by injection of hydrogen peroxide and additional sutures were placed as needed until there was no more leakage from the tract. Curettage of the granulation tissue in the intersphincteric space and the external fistula opening was conducted and the skin incision was finally closed with polyglactin 2/0 sutures. No draining seton was placed before the LIFT procedure.

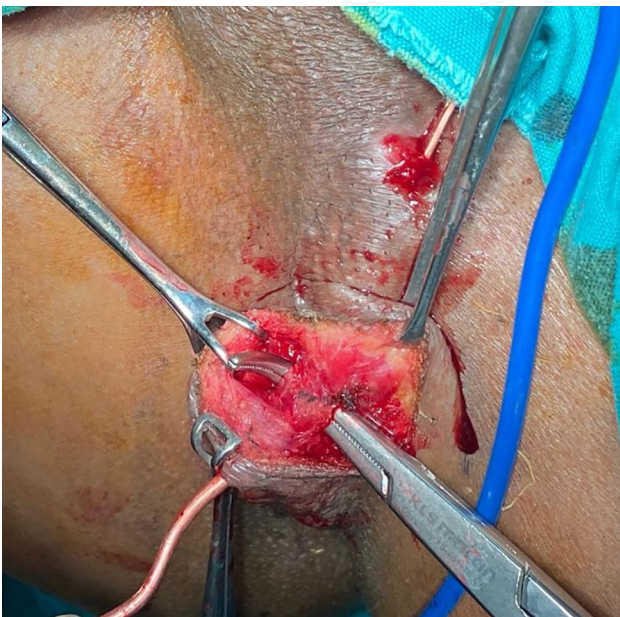


Fig. 1 Blunt dissection of the fistula tract in the intersphincteric plane before ligation and division of the tract

Group II (Modified Parks technique): the fistula tract was laid open using electrocautery, starting from the external opening sparing the external anal sphincter and dividing the internal anal sphincter up to the internal opening. The mucosa of the internal opening and proximal epithelialized part of the track passing through the external anal sphincter were cauterized and then the laid-open fistula tract was curetted. Finally, the point of passage of the fistula tract through the external anal sphincter was closed with polyglactin 2/0 sutures [12]. No draining seton was placed before the modified Parks technique (Fig. 2).

Group III (Two-stage seton): the external part of the fistula tract was excised using electrocautery until the point where the tract passed through the external anal sphincter muscles. Silk 1 suture was attached to the end of the metallic probe and then withdrawn from the external opening along with the probe. The silk thread was tied around the remaining part of the fistula tract and the anal sphincter muscles (Fig. 3). The seton was left for 2 months up till the fistula tract was downstaged to intersphincteric or low trans-sphincteric position, then examination under anesthesia (the second stage) was done and the remaining part of the tract was divided by lay open fistulotomy.

Follow-up

Patients were followed up at 1 and 4 weeks after surgery and then at 3, 6, and 12 months afterwards. During follow-up, wound healing was assessed by clinical examination done by a surgical resident and an attending surgeon who were unaware of the nature of the study. Complete healing of the anal fistula was considered when complete epithelization of the surgical wound was ascertained, the external fistula opening was closed, and no discharge was experienced. During follow-up visits, the patients completed the Wexner incontinence score to assess the continence state and complications were recorded. The quality of life related to anal fistula was assessed before surgery and at 12 months after surgery using the Quality of Life in patients with Anal Fistula Questionnaire (QoLAF-Q) [15].

Outcomes of the study

The primary outcome was the success of each operation, defined as complete healing of anal fistula at 12 months after surgery. Failure of healing comprised persistence or recurrence of anal fistula. The fistula was considered persistent if healing was not achieved for 6 months after surgery whereas recurrence was defined as reappearance of the fistula within 1 year after complete healing of the surgical wound [16]. Postoperative recurrence was diagnosed by clinical examination and then MRI was performed to assess for the position of the internal opening, number and type of fistula tracts, and secondary extensions or abscess cavities. The secondary

Fig. 2 Steps of the modified Parks technique; **A** laying open of the extrasphincteric portion of the tract; **B** division of the internal anal sphincter and the intersphincteric part of the tract; **C** electrocauterization of the internal opening and the trans-sphincteric part of the tract; closure of the point of passage of the tract through the external anal sphincter with suture

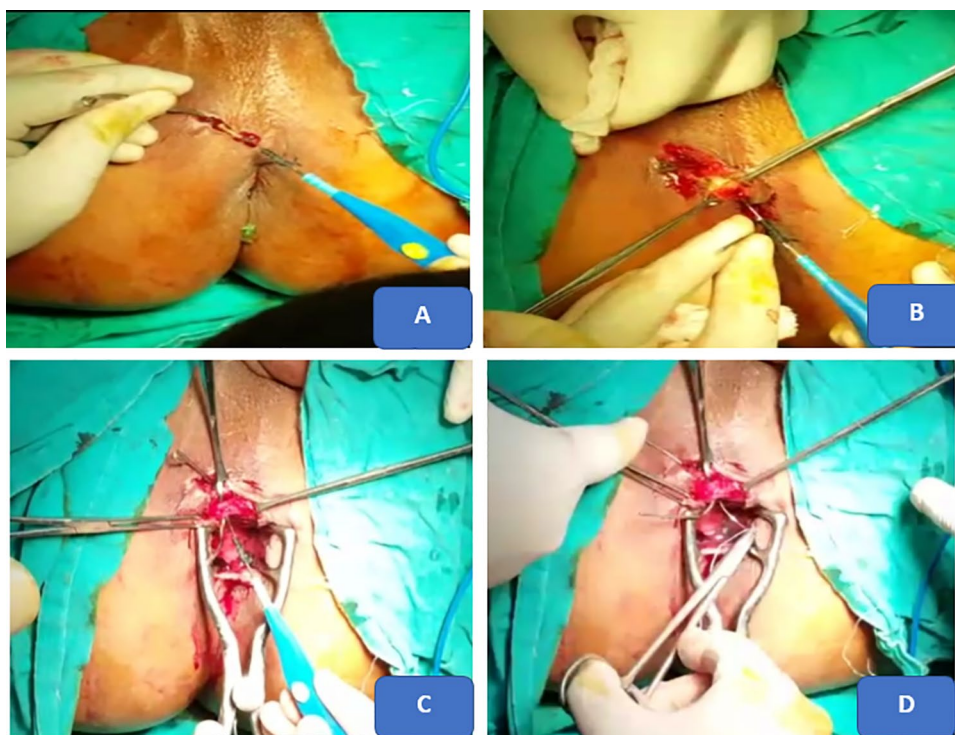


Fig. 3 Insertion of silk seton in the fistula tract

endpoints included operation time, average time to healing, complications, FI, and quality of life.

Sample size calculation

The sample size was calculated using sample size and power calculation software (G* power™). Based on previous studies [9, 10, 17] that reported the success rates of LIFT, two-stage seton, and modified Parks technique as 70%, 85%, and

95%, respectively, it was assumed that a total of 571 patients were needed to detect a difference equal to 15% in the effect size (success rate) between the groups. The study power was set at 80% and alpha was set at 5%. As a pilot randomized trial, 10% of the actual sample size for the full-scale trial was required, yielding a minimum sample size of 57 patients, equally divided into three groups.

Statistical analysis

Data were analyzed with SPSS™ (version 23, IBM Corp; Chicago, USA). Continuous data were expressed as mean \pm standard deviation (SD) or median and range. Categorical variables were expressed as numbers and proportions. Student *t* test or one-way ANOVA test was used to process continuous data and Fisher exact test or Chi-square test was used for processing categorical variables. Per protocol and intention to treat (ITT) analyses of the primary endpoint (successful healing) was conducted. *p* values less than 0.05 were considered significant.

Results

Patients' characteristics

After screening 126 patients with anal fistula who were treated in the study period, 51 patients did not meet the

inclusion criteria of the trial or declined to participate and were excluded. Seventy-five patients were recruited and were equally allocated to one of the three groups. Nine patients were lost to follow-up and were excluded; thus, 66 patients were ultimately included (Fig. 4).

Patients were 50 (75.7%) males and 16 (24.3%) females of a mean age of 45.2 ± 11.7 years. Twenty-four patients had medical comorbidities; 14 had type II diabetes mellitus, eight had hypertension, and two had chronic liver disease. Thirty-seven (56.1%) patients had a history of surgical drainage of a perianal abscess within a period ranging from 3 to 96 months before inclusion to the study. None of the patients

had preoperative FI (median Wexner score = 0 in the three groups).

The external opening of the fistula was posteriorly located in 30 patients, anteriorly located in 18 patients, and laterally located in 15 patients. Three patients had more than one external opening of the anal fistula.

All patients underwent preoperative imaging assessment. MRI was done in 48 (72.7%) patients and EAUS in 18 (27.3%) patients. All patients had high trans-sphincteric fistula, three (4.5%) had supralelevator extension of the primary tract, and six (9.1%) had a horseshoe fistula.

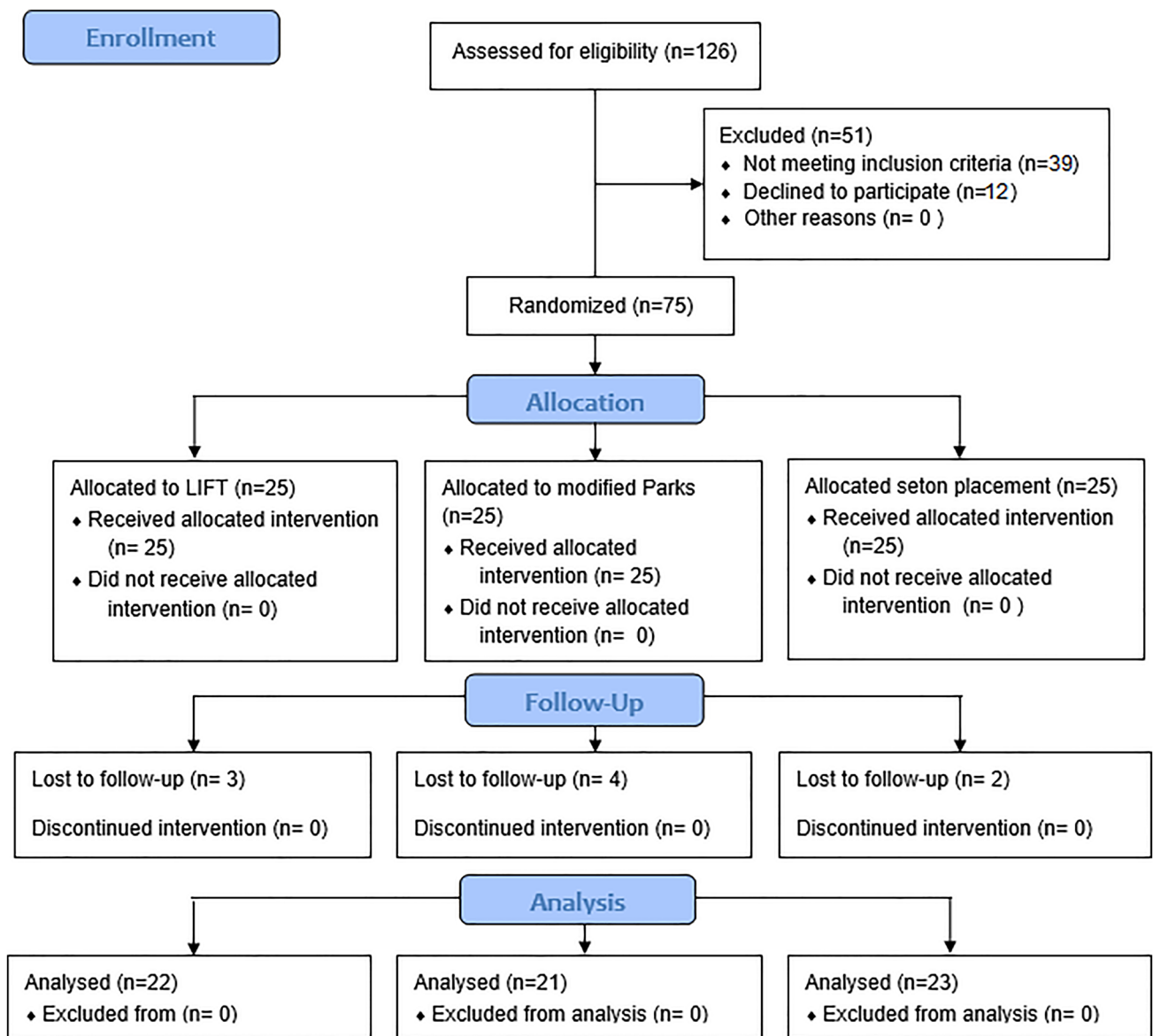


Fig. 4 Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the progress through the phases (enrollment, intervention allocation, follow-up, and data analysis) of a three parallel group ran-

domized controlled trial that compared ligation of intersphincteric fistula tract or modified Parks technique or two-stage seton

There were no significant differences between the three groups with regard to patients' age, sex, medical comorbidities, position of the fistula tract and external opening, and horseshoe fistula as shown in Table 1.

Operative details and complications

The mean operation time of LIFT, modified Parks technique, and two-stage seton was 19.6 ± 2.7 , 24.2 ± 3.1 , and 22.9 ± 3.6 min, respectively. The difference in the operation time between the three procedures was statistically significant ($p < 0.0001$).

Postoperative complications were recorded in three patients after LIFT, three after the modified Parks technique, and two after two-stage seton. Complications included FI ($n = 2$), infection ($n = 2$), bleeding ($n = 1$), and urinary retention ($n = 3$). One patient developed minor FI

after the modified Parks technique and had a Wexner score of 3 and another patient experienced flatus incontinence after two-stage seton placement and had Wexner score of 2. Overall, the median postoperative Wexner score was 0 in the three groups ($p = 0.57$). There was no significant difference between the three groups in regards to the postoperative complications ($p = 0.59$) (Table 2).

Healing and recurrence of fistula

Failure of healing was recorded in seven patients after LIFT (persistence = 3, recurrence = 4), in one patient after modified Parks technique (recurrence = 1), and in three patients after two-stage seton (persistence = 1, recurrence = 2). Among the 11 patients who experienced failure of healing, eight had residual intersphincteric fistulas and three had low

Table 1 Baseline characteristics of patients in the three groups

Variable	LIFT	Parks	Seton	<i>p</i> value
Number	22	21	23	–
Mean age in years	42.8 ± 12.9	47.7 ± 10.2	45.1 ± 11.8	0.39 [#]
Gender				
Male (%)	14 (63.6)	18 (85.7)	18 (78.3)	0.23***
Female (%)	8 (36.4)	3 (14.3)	5 (21.7)	
Medical comorbidities (%)	5 (22.7)	11 (52.4)	8 (34.8)	0.14**
History of surgical drainage of abscess (%)	10 (45.4)	12 (57.1)	15 (65.2)	0.43**
Location of the external opening				
Anterior (%)	5 (22.7)	6 (28.6)	7 (30.4)	0.77***
Posterior (%)	11 (50)	11 (52.4)	8 (34.8)	
Lateral (%)	6 (27.3)	4 (19)	5 (21.7)	
Multiple (%)	1 (4.5)	0	2 (8.7)	
Horseshoe fistula (%)	1 (4.5)	2 (9.5)	3 (13)	0.68***
Supralevator extension (%)	1 (4.6)	1 (4.7)	1 (4.4)	0.99***

LIFT ligation of intersphincteric fistula tract

**Chi-square test

***Fisher exact test

[#]One-way ANOVA test

Table 2 Operation time and complications in the three groups

Variable	LIFT ($n = 22$)	Parks ($n = 21$)	Seton ($n = 23$)	<i>p</i> value
Mean operation time in minutes	19.6 ± 2.7	24.2 ± 3.1	22.9 ± 3.6	< 0.0001 [#]
Fecal incontinence (%)	0	1 (4.8)	1 (4.3)	0.76***
Infection (%)	1 (4.5)	1 (4.8)	0	0.54***
Bleeding (%)	1 (4.5)	0	0	0.65***
Urine retention (%)	1 (4.5)	1 (4.8)	1 (4.3)	0.99***
Total complications (%)	3 (13.6)	3 (14.3)	2 (8.7)	0.59***
Median Wexner score	0	0	0	0.57***

LIFT ligation of intersphincteric fistula tract

***Fisher exact test

[#]One-way ANOVA test

trans-sphincteric fistulas. Failure of healing was treated with either fistulotomy ($n=9$) or placement of seton ($n=2$).

As per protocol analysis, the success rates of LIFT, modified Parks technique, and two-stage seton were 68.1% (95% CI 45.1–86.1%), 95.2% (95% CI 76.2–99.8%), and 86.9% (95% CI 66.4–97.2%), respectively, with a statistically significant difference ($p=0.04$). Longitudinal analysis of healing rates at different time points (Fig. 5) revealed that healing rates after LIFT, modified Parks technique, and seton were 86.4%, 0, and 0 ($p<0.0001$) at 1 month, 86.4%, 100%, 95.6% ($p=0.2$) at 3 months, 81.8%, 100%, and 95.6% ($p=0.07$) at 6 months, and 68.1%, 95.2%, and 86.9% ($p=0.04$) at 12 months.

The modified Parks technique had a significantly higher success rate than LIFT (95.2% vs 68.1%; $p=0.045$) whereas the success rates of two-stage seton and LIFT were not significantly different (86.9% vs 68.1%; $p=0.16$). The average time to complete healing after LIFT was

significantly shorter than after the modified Parks technique and two-stage seton (Table 3).

As per the ITT analysis of the primary endpoint (successful healing), patients who were lost to follow-up ($n=9$) were included to the final analysis. The last known outcome at the last recorded visit to the outpatient clinic was assumed as the ultimate outcome for these patients. The ITT showed that successful healing was achieved in 16/25 patients who underwent LIFT, 23/25 who had modified Parks technique, and 22/25 who had two-stage seton (64% vs 92% vs 88%; $p=0.03$).

Quality of life after surgery

There was a significant improvement in the postoperative quality of life after the three procedures ($p<0.0001$). The preoperative and postoperative quality of life scores

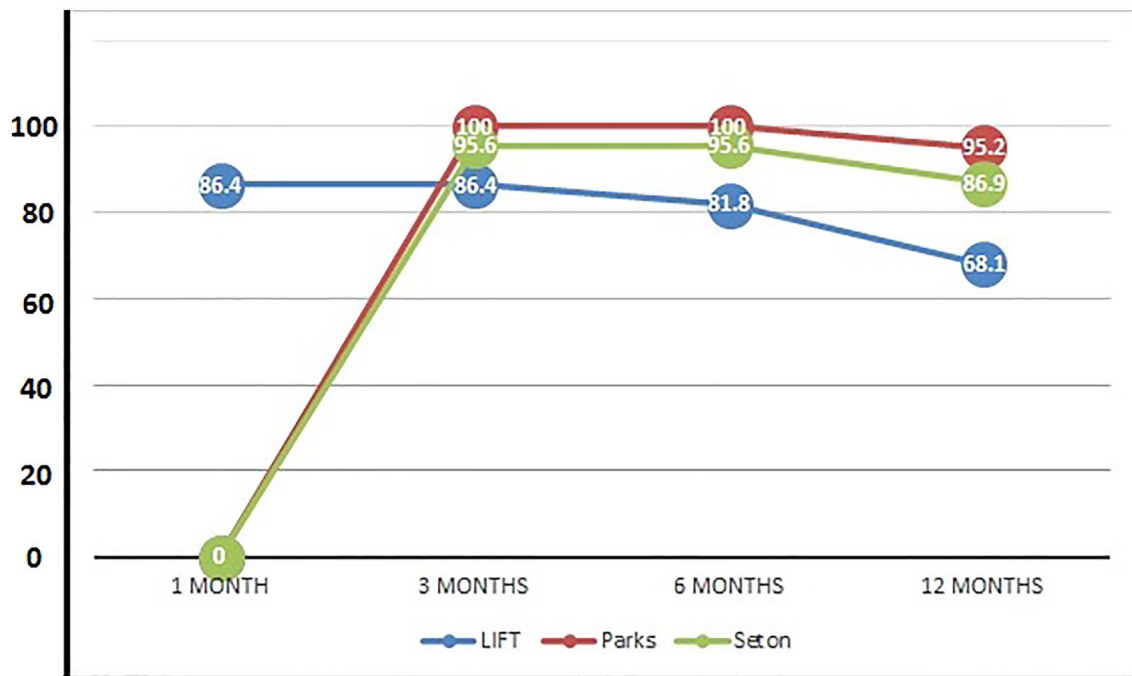


Fig. 5 Longitudinal analysis of healing rates after LIFT, modified Parks technique and seton at different time points

Table 3 Healing of anal fistula after the three procedures

Variable	LIFT ($n=22$)	Parks ($n=21$)	Seton ($n=23$)	p value
Persistence (%)	3 (13.6)	0	1 (4.3)	0.21***
Recurrence (%)	4 (18.2)	1 (4.7)	2 (8.7)	0.38***
Successful healing (%)	15 (68.1)	20 (95.2)	20 (86.9)	0.04***
Average time to healing in days	27.9 ± 10.1	45.9 ± 11.7	80.9 ± 17.7	<0.0001#

LIFT ligation of intersphincteric fistula tract

***Fisher exact test

#One-way ANOVA test

were comparable among the three groups. Modified Parks technique was followed by better improvement in quality of life than LIFT (15.8 ± 6.9 vs 24.5 ± 15.3 , $p=0.02$), yet had similar improvement to two-stage seton (15.8 ± 6.9 vs 18.8 ± 11.7 , $p=0.31$) (Table 4).

Discussion

The present trial was conducted to compare the efficacy of LIFT, modified Parks technique, and two-stage seton in treatment of complex anal fistula in terms of success of healing and complications. We chose to compare the original LIFT procedure to seton and modified Parks technique since it is considered the standard procedure as first described [8]. However; it is worthy to note that there are other variants of LIFT that include excision of the external fistula opening, division of the internal anal sphincter, addition of mucosal advancement flap, insertion of prosthetic plug (LIFT-plug), and injection of platelet-rich plasma along the divided fistula tract [18–21].

Around three-quarters of our cohort of patients were men, in line with the male predominance of anal fistula in general and in our society [13]. Anal fistula is known to be more common in males than female as shown in previous studies [22, 23] that reported male to female ratio varying between 1.8:1 and 9:1. High trans-sphincteric anal fistula accounted for 94% of total cases. This was in line with the observation that the most common type of complex anal fistula is high trans-sphincteric fistula, whereas supra- and extra-sphincteric types represent a minority of cases [24]. This reinforces what has been reported in the first published study on the LIFT procedure in which 95% of patients had trans-sphincteric anal fistulas [8].

LIFT procedure had the shortest operation time which was close to that reported in the original report on the procedure [8]. Seton placement had a longer time and the modified Parks technique entailed the longest operation time owing to the technical nature of the procedure that may consume more time. However, although the difference in the operation time

was statistically significant; it may not be clinically relevant as the difference was approximately five minutes.

There was a statistically significant difference in healing rates between the three procedures which was further confirmed by the intention to treat analysis performed. On further analysis, the modified Parks technique had a higher healing rate than LIFT (95% vs 68%), yet was comparable to the two-stage seton. The healing rate after LIFT in our study (68%) falls within the range of success after LIFT reported by other investigators (65–68%) [25, 26]. The healing rate after the modified Parks technique in our study was about 95%, close to that reported in the original study on the technique in which healing was successfully achieved in 93.7% of patients after a median follow-up of 12 months [9]. Two-stage seton was followed by complete healing in 87% of patients, similar to our own published experience (90%) [9] and to what other investigators [11] have reported (93%).

Although the overall healing rate after the LIFT procedure was lower than the other two procedures; the average healing time after LIFT was significantly shorter than the modified Parks technique and seton placement. The time to complete healing after LIFT was approximately 4 weeks, whereas it was around 6 weeks after the modified Parks technique and 8 weeks after seton placement. This observation is quite reasonable since no large perianal wounds are left after the LIFT technique, unlike the other two procedures in which the extra-sphincteric portion of the fistula tract is laid open or excised, leaving a sizable perianal wound to heal.

Fecal incontinence was recorded in around 5% of patients after seton placement or modified Parks technique whereas none of the patients who underwent LIFT experienced any continence impairment in agreement with the published literature [17, 27]. The FI recorded in our study was of minor grade and transient since all patients recovered full continence state at 3 months postoperatively.

Although the nature of the modified Parks technique and two-stage seton may increase the risk of FI, the actual incidence of incontinence was quite low as only two of more than 40 patients developed minor incontinence. The low rate of FI after the modified Parks technique and two-stage seton was in line with previous studies on the two techniques

Table 4 Anal fistula-related quality of life after the three procedures

Variable	LIFT ($n=22$)	Parks ($n=21$)	Seton ($n=23$)	p value
Preoperative QoLAF-Q	47.5 ± 2.4	47.6 ± 2.3	47.4 ± 2.9	0.98 [#]
Postoperative (QoLAF-Q)	24.5 ± 15.3	15.8 ± 6.9	18.8 ± 11.7	0.057 [#]
p value	< 0.0001[#]	< 0.0001[#]	< 0.0001[#]	–

Bold indicates significant p value less than 0.05

QoLAF-Q Quality of Life in patients with Anal Fistula Questionnaire (higher scores indicate worse quality of life), LIFT ligation of intersphincteric fistula tract

[#]One-way ANOVA test

[9–11, 28, 29]. The minimal alteration in continence can be explained that in the modified Parks technique only the internal anal sphincter is divided but not the external sphincter. It is worthy to note that the recommended treatment of simple intersphincteric anal fistula is fistulotomy which also entails division of the internal anal sphincter [30]. The division of the internal sphincter may be associated with a minor degree of incontinence in 5–14% of cases which is usually transient and resolves spontaneously [31]. On the other hand, in two-stage seton the seton is allowed to divide through the anal sphincter muscles gradually and slowly to downstage the fistula tract while permitting fibrosis to develop and prevent gapping of the sphincter muscles and thus avoiding incontinence. This is different from the tight cutting seton that cuts through the sphincter fibers more quickly, omitting the need for a second stage, yet increasing patients' discomfort and the risk of FI substantially [32].

This study was conducted as a pilot study because it included only 10% of the sample size required for the full-scale study which exceeded 500 patients and thus requires a larger multicenter study. The present study included 10% of patients to examine the feasibility of conducting the trial and to assess the preliminary outcomes of the three procedures that need to be reproduced and ascertained in a larger trial.

Limitations of the present trial include being a single-center pilot study that entailed a small number of patients. Given the pilot nature of this trial, the interpretation of its results should be made with caution. Follow-up was rather short and thus longer follow-up is needed to ascertain the long-term results of each procedure. The assessment of the continence state postoperatively was based on clinical symptoms score only without objective assessment of the anal sphincter tone with anal manometry. The preliminary conclusions of the current trial may warrant conducting larger multicenter studies, comparing the outcome of the modified Parks procedure with other established operations for anal fistula with longer follow-up.

Conclusions

There was a significant difference in healing rates after the three procedures as the modified Parks technique achieved the highest success rate followed by two-stage seton and then the LIFT procedure. Time to complete healing after LIFT was significantly shorter than modified Parks technique and two-stage seton. The three procedures achieved similar quality of life, and complications on follow-up.

Author contributions ME and SE designed the study. ME, SE, MA, and SE performed the surgical procedures, and followed the patients. SE and ME shared in data analysis and writing of the manuscript. SE,

MA, and WK contributed to collection and interpretation of data, and revising the manuscript. WK contributed to the final revision of the manuscript.

Declarations

Conflict of interest None to be disclosed by the authors.

Research involving Human Participants and/or Animals The study was approved by the Institutional review board of Mansoura Faculty of Medicine.

Informed consent Informed consents were obtained from the patients enrolled in the study.

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