

Coring Out Fistulectomy with Closure of Internal Sphincter Opening Versus Lay Open Fistulotomy and Primary Sphincter Repair in Transsphincteric Perianal Fistula; A Prospective Randomized Comparative Study

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ABSTRACT

Background: Surgical The treatment of transsphincteric fistulas is extremely difficult, and new methods are being developed every day in an effort to find the safest and most efficient approach. Based on their post-operative results, two of the most successful procedures are compared in this study.

Objective: To compare the postoperative outcomes (such as postoperative pain, wound infection, incontinence, and recurrence at 1 year) of coring out fistulectomy with closure of the internal sphincter opening versus lay open fistulotomy with primary sphincter repair in transsphincteric per-ianal fistula.

Patients and Methods: The current study, which took place at Ain Shams University Hospitals from November 2022 to April 2023 and follow up ended at April 2024, was a prospective, randomized, controlled, single-center, single-blind trial. 60 patients presented with transsphincteric perianal fistulas, with a postoperative follow-up of one year.

Results: In our study, there were sixty patients, thirty in each group. In this sense, 2 patients in group I and 5 patients in group II presented a postoperative wound infection ($p=0.424$). In group I, no cases of incontinence, however, six cases of gas incontinence in group II received only a Wexner score of 3/20 ($p=0.026$), indicating a significant difference between the two methods. Recurrence during the 1-year follow-up occurred in 11(36.7%) patients in group (I). While in group II, recurrence occurred in 2 patients (6.7%) with high statistical significance given that the p value is ≤ 0.005 .

Conclusion: Compared with modified LIFT, fistulotomy with primary sphincteroplasty is a highly successful procedure for transsphincteric fistula repair, with a statistically significant reduced recurrence rate at 1-year follow-up. However, the incidence of gas incontinence is higher.

Key Words: Fistulotomy, Fistulectomy, High Trans-Sphincteric Fistula, Modified LIFT, Primary Repair.

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INTRODUCTION

Among gastrointestinal cancers, pancreatic cancer is kTrans-sphincteric fistulas include both sphincters since they traverse the external sphincter's oppos-ing side before emerging in the perianal region. The position of the tract with respect to the external and internal sphincters defines anorectal fistulas. As a result, trans-sphincteric fistulas are difficult to cure and frequently need for more involved or phased care ^[1].

To address the shortcomings of the conventional LIFT technique, Chen *et al.*, ^[2] presented a novel sphincter-preserving strategy for treating anal fistula in 2012. This technique entails high closure of the inter-sphincteric fistula track via lateral approach ^[3].

Still, the majority of surgeons maintain that a standard fistulotomy is the most effective treatment for perianal fistulas. Therefore, when compared to other treatment strategies for trans-sphincteric anal fistulas found in the literature, one-stage surgery—primary sphincteroplasty and fistulotomy—has been found to produce good wound healing, a manageable risk of incontinence, and a relatively low re-currence rate ^[4,5].

PATIENTS AND METHODS:

In the current study, which took place at the Colorectal Surgery Unit of Ain Shams University Hospitals from November 2022 to April 2023 and follow up end at

April 2024, a single-center randomized controlled trial was conducted. Of the 60 patients, 42(70%) were male and 18(30%) were female and presented with high trans-sphincteric perianal fistulas and had a one-year postoperative follow-up end at April 2024, we did this comparison between both techniques according to the thesis protocol.

Randomization and blinding:

Randomization was performed the day before surgery. Patients were divided into two groups using a randomly generated computer code: Group I underwent a modified LIFT operation to perform a coring out fistulectomy with closure of the internal sphincter opening, while Group II underwent fistulotomy with primary anal sphincter repair. The two groups were balanced in a 1:1 ratio. The study was conducted in a single-blinded manner.

Inclusion criteria:

Patients over 18 years of age and diagnosed with high transsphincteric fistula by clinical examination and magnetic resonance imaging (MRI).

Exclusion criteria:

Patients under the age of eighteen who refuse surgery may have intersphincteric, horseshoe, branch-ing, and suprasphincteric fistulas, inflammatory bowel diseases such as Crohn's disease, tuberculosis, and those with a history of faecal incontinence. Anal surgery previously.

Pre-operative:

The patient's history, including their comprehensive personal history, complaints, full anorectal examination, and Wexner score evaluation of their continence.

Patient Counselling and Consent:

The patient was given a thorough description of the various surgical procedures and potential problems the day before the procedure.

The specifics of the operation were described to aid in understanding the results, dangers, and advantages of the suggested technique.

The patient was asked to sign an informed consent form, and at their request, any questions, worries, or concerns were discussed with both the patient and a first-degree family. patients were kept on a soft diet and take a laxative the day before surgical intervention.

Operative Details:

Under General and spinal anesthesia, the same surgical team carried out each surgery while the patient was in the lithotomy posture. Upon inducing anesthesia, each patient was administered a single dosage of a third-generation cephalosporin antibiotic.

Group (I) underwent modified LIFT:

Under spinal or general anaesthesia, the patient was in the lithotomy posture. If it was feasible, a probe was inserted into the external entry to view the fistulous tract internal opening. A solution of diluted hydrogen peroxide was used to rinse the fistula's lumen. An incision was made around the opening of the external fistula and the dissection started from the external entrance and continued along the entire length of the fistula to the internal opening (Figure 1A). To avoid damage to the sphincter muscle, the fistulous tract is carefully dissected at the opening of the internal sphincter muscle (Figure 1B). After the fistulous tract enters the internal sphincter, Vicryl 3-0 was used to tie it (Figure 1C). Using scissors, the distal part of the fistulous tract was removed. Then, the associated proximal fistulous tract was closed by placing a purse string suture with PDS 4-0 at the borders of the internal sphincter.

Lastly, the external Sphincter borders are approximated using PDS 3-0. The usual unipolar cautery was used to achieve haemostasis. To allow for drainage, the incision was left open.

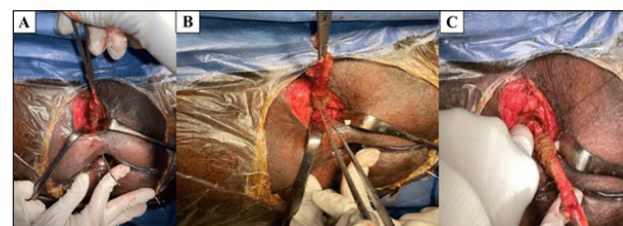


Figure 1: Patient of group A who underwent modified LIFT.

Group (II) underwent Fistulotomy with primary sphincteroplasty:

Under General and spinal anesthesia, the patient underwent lithotomy position. Using a probe inserted via the external hole toward the internal opening of the fistulous tract (Figure 2A). A marking stitch was passed through the sphincter's margins after fistula tract excising, starting from the external orifice and moving toward the lateral border of the external sphincter (Figure 2B). Sphincter dissection up to the fistula's proximal side. Granulation excision and curettage. PDS 3-0 transverse mattress sutures were used for the restoration of the sphincter (Figure 2C). Standard unipolar cautery was used to establish hemostasis. The wound was allowed to drain and heal naturally.

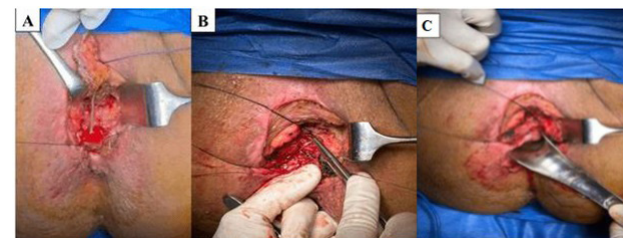


Figure 2: Patient of group (A) who underwent Fistulotomy and primary sphincteroplasty.

After surgery, patients were given oral antibiotics for one week. After the procedure, they were instructed to begin drinking liquids in the evening and to follow a soft diet for two days and take laxatives for two weeks. Patients had their wounds dressed on the moment postoperative day. Each understanding gotten instruction on self-cleaning procedures and wound dressing strategies, and any early postoperative complications were noted. Taking after one week, two weeks after release from hospital, and after that each two weeks until full recovery, all patients were checked. At that point every two months to finish the follow-up after a year. When the exterior wound healed totally without discharge, the fistula was considered healed. Recurrence was characterized as an progressing or recurring external opening that continued beyond two months following the surgery. During the follow-up stage, patients were checked for recurrence and status related to continence. During the follow-up stage, none of our patients lost their way.

Statistical Analysis:

The gathered data were coded, tabulated, and statistically assessed using IBM SPSS (Statistical Package for Social Sciences) statistical software, version 28.0, IBM Corp., Chicago, United States of America, 2021. The normality of the quantitative data was examined using the Kolmogorov-Smirnov test. The data were displayed as the range's minimum and maximum values as well as the mean±standard deviation (SD). The findings were

compared using an independent *t* test. The Chi-square test and Fisher's exact test for the variables were used to compare the description of the quantity and percentage of qualitative data. A *p*-value was deemed significant if it was less than 0.050; otherwise, it was not.

RESULTS:

Between November 2022 to April 2023 and 1 year follow up ended at April 2024, we conducted a prospective cohort study on 60 patients with high trans-sphincteric peria-nal fistulas at Ain Shams University Hospitals. Of the sixty patients, eighteen (30%) were women and forty-two (70%) were men. They were divided into two groups of thirty patients each. Group (I) had high ligation of the intersphincteric fistula tract using the MODIFIED LIFT method, while Group (II) received primary sphincteroplasty and fis-tulotomy. With a standard deviation of ±9.1, the average age of Group I is 41.6. In contrast, the average age of Group II was 43.9 with a standard deviation of 7.5 (*p*= 0.290). One of the patients' co-morbidities was diabetes. Group I consisted of five patients, whereas Group II included six. Fifteen patients had hypertension, eight in group I and seven in group II. Seven patients had both hypertension and diabetes, with three in group I and four in group II. There were 41 individuals with no co-morbidities (Table 1). There were 20 patients in Group I and 21 in Group II (*p*= 0.781).

Table 1: Demographic characteristics between the studied groups.

Variables		Modified LIFT group (Total= 30)	FIPS group (Total= 30)	<i>p</i> -value
Age (years)	Mean±SD	41.6±9.1	43.9±7.5	^0.290
	Range	28.0–64.0	22.0–58.0	
Gender (n, %)	Male	22	20	#0.573
	Femle	8	10	
BMI (kg/m ²)	Mean±SD	28.7±3.2	28.3±2.9	^0.635
	Range	23.2–35.4	23.6–34.7	
Smoking (n, %)		9	11	#0.584
Hypertension (n, %)		8	7	#0.766
Diabetes mellitus (n, %)		5	6	#0.739
Hypertension and diabetes mellitus (n, %)		3	4	§ 0.999
No comorbidities (n, %)		20	21	#0.781
ASA (n, %)	I	17	16	#0.795
	II	13	14	

BMI: Body mass index; ASA: American Society of Anesthesiologists; ^: Independent *t*-test; #: Chi square test; §: Fisher's Exact test.

Operative time was significantly shorter in the Modified LIFT group (compared with the FIPS group). In contrast, mean intraoperative blood loss was slightly lower in the Modified LIFT group than in the FIPS group, though this difference was not statistically significant (Table 2).

Wound discharge persisted as a complaint in the early postoperative phase and was experienced by 100% of the research participants.

Postoperative wound infections occurred in two patients (6.7%) in group I and five patients (16.7%) in group II;

however, the incidence was not statistically significant ($p=0.424$). For a week following surgery, postoperative pain was measured using the visual analogue score (VAS), which has a range of 0 to 10 with 10 being the highest. The two groups' anxiety levels did not differ from one another. With a mean score of 2.6 and a standard deviation of 1.4, twelve patients (40%) and eight-teen patients (60%) in group (I) assessed their pain as moderate on a scale of 4 to 6.

13 patients (43%) in group (II) reported mild pain, with scores ranging from 1 to 3, whereas 17 patients (56.7%) experienced moderate pain, with scores ranging from 4 to 6. The average grade was 3.1, with a standard deviation of 1.3 ($p=0.186$) (Table 3). At 4.5 weeks with ± 1.2 standard deviations, ranging from 3 to 8 weeks, and at 6.7 weeks with ± 1.1 standard deviation, ranging from 5 to 9 weeks, Group I experienced no incontinence events, but Group II had a longer average healing period (p value <0.001).

Table 2: Intraoperative outcomes between the studied groups.

Variables		Modified LIFT group (Total= 30)	FIPS group (Total= 30)	<i>p</i> -value
Operative time (minutes)	Mean \pm SD	71.7 \pm 8.5	91.8 \pm 10.2	$\wedge<0.001^*$
	Range	53.0–89.0	74.0–118.0	
Blood loss (mL)	Mean \pm SD	75.3 \pm 13.0	81.1 \pm 10.6	$\wedge 0.063$
	Range	51.0–101.0	64.0–112.0	

\wedge : Independent *t*-test; *: Significant.

Table 3: Early postoperative outcomes among the studied groups.

Variables		Modified LIFT group (Total=30)	FFIPS group (Total=30)	<i>p</i> -value
Pain score (VAS-10)	Mean \pm SD	2.6 \pm 1.4	3.1 \pm 1.3	$\wedge 0.186$
	Range	1.0–5.0	1.0–5.0	
	Mild	18	13	#0.196
	Moderate	12	17	
Bleeding		2	4	\$0.671
Discharge		1	4	\$0.353
Wound infection		2	5	\$0.424
Urinary retention		5	8	#0.347
Urgency		3	7	#0.166
Hospital stay (days)	Mean \pm SD	1.2 \pm 0.4	2.5 \pm 0.5	$\wedge<0.001^*$
	Range	1.0–2.0	2.0–3.0	

\wedge : Independent *t*-test; #: Chi square test; \$: Fisher's Exact test; *: Significant.

Nonetheless, group II experienced six (20%) episodes of gas incontinence, resulting in a statistically significant Wexner score of 3/20 ($p=0.024$).

Eleven patients (36.7%) in group (I) experienced recurrence at the one-year follow-up; about seven patients

experienced inter-sphincteric fistula recurrence, and four patients experienced trans-sphincteric fistula recurrence. In contrast, two patients (6.7%) in group II experienced a recurrence as a subcutaneous fistula, which was highly statistically significant (p -value <0.005) (Table 4).

Table 4: Late postoperative outcomes among the studied groups.

Variables		Modified LIFT group (Total= 30)	FIPS group (Total= 30)	<i>p</i> -value
Healing duration (weeks)	Mean \pm SD	4.5 \pm 1.2	6.7 \pm 1.1	$\wedge<0.001^*$
	Range	3.0–8.0	5.0–9.0	
Incontinence		0	6	\$0.024*
Recurrence		11	2	#0.005*

\wedge : Independent *t*-test; #: Chi square test; \$: Fisher's Exact test; *: Significant.

DISCUSSION

For both patients and colorectal surgeons, anal fistulas are a recurring problem. After surgical therapy, recurrence is a long-term concern and continence status may be jeopardised. Depending on the condition's

location and intricacy, different treatment options are available. The ideal approach is for less recurrence rates and little influence on continence status [5].

Chen *et al.*,^[2] initially proposed altered LIFT as adjustment for LIFT method to manage high trans-sphincteric fistulas. The current study is a prospective comparison of fistulotomy with primary sphincteroplasty and ligation of the opening on internal sphincter. Restoring the structural structure of the sphincter muscles and eliminating infection are the simple goals of the second treatment, fistulotomy with primary sphincteroplasty^[6]. The majority of surgeons hate the latter treatment despite its relatively high success rates due to its complicated technicality and possible adverse effects, including faecal incontinence^[7, 8].

Group (I) has a mean age of 41.6 and a standard deviation of 9.1. In contrast, the mean age in group (II) is 43.9 with a standard deviation of 7.5 ($p=0.290$). Of the 60 patients who were included, 42 (or 70%) were men and 18(30%) were women ($p=0.573$). We also did not find any differences in co-morbidities between the two groups. These data might rule out the existence of any additional co-factor that would affect our findings about the effectiveness and drawbacks of both techniques.

When group (I) had modified LIFT management, wound healing proceeded more quickly than when group (II) underwent fistulotomy with primary sphincter reconstruction. Group I's average wound recuperating time was 4.5 weeks with a standard deviation of 1.2, ranging from 3 to 8 weeks, whereas group II's mean wound healing time was 6.7 weeks with a standard deviation of 1.1, ranging from 5 to 9 weeks. These results had strong statistical significance, since the p -value was <0.001 . This discrepancy makes sense given that group II had a wider exposed wound than group I and that group II had muscle regeneration along with the wound's extension into the anal canal.

There was no statistically significant postoperative wound infection ($p=0.424$) in 2(6.7%) of the patients in the first group and 5(16.7%) of the patients in the second group. We increased the frequency of dressing changes and wound washing for all patients in both groups who did not require debridement or any surgical intervention. We also added an oral combination of 500mg of ciprofloxacin and 500mg of metronidazole twice daily for a week, during which time no additional management was required beyond wound care.

40 percent of patients in group I reported moderate to severe pain (mean 2.6 and standard deviation ± 1.4), while 56.6% of patients in group II reported moderate to severe pain (mean 3.1 and standard deviation ± 1.3). Despite this, there is no statistically significant difference in pain between the two groups ($p=0.196$).

The bigger wounds in group II patients, along with the anal verge and anoderm's enlargement to the wound volume, might account for this discrepancy.

Following up for a year ended at April 2024, we observed that group (II) experienced fewer recurrences than group (I). We believe that this discrepancy makes sense. The diseased tract is eliminated from the exterior to the internal opening by the fistulotomy procedure with primary sphincter repair. In contrast, the inner opening is still present in the modified LIFT. The Group (I) method, initially proposed by Chen *et al.*,^[2] had a 20% recurrence rate, which was almost the same as the one found by Kang *et al.*,^[3]. However, the altered LIFT method used in our work showed a recurrence rate of 36.7%. We chose a troublesome fistula sort than the authors who were previously cited, which is the only reason for the higher hazard of recurrence we experienced using the adjusted LIFT approach. Additionally, some reported higher recurrence rates. Galan *et al.*,^[9] discovered that the LIFT technique had a recurrence rate of 37.8%.

The acceptable range of recurrence rates after primary sphincteroplasty and fistulotomy, contingent on the kind and degree of fistula complexity, has been documented in the literature. Ratto *et al.*,^[10] included 203 patients with perianal fistulas in their analysis, and the recurrence rate was 7% over a cruel follow-up period of 56 months. In a different trial, Arroyo *et al.*,^[11] shown that, after an 81-month follow-up period, the rate recurrence in 70 patients was 8.6%. The rate of recurrence following fistulotomy with initial repair was 6.7% in our study, which is lower than those of other studies. We hypothesise that this could be because the follow-up period was brief or because the sphincter reconstruction strategy, which employs delayed absorbable sutures in conjunction with appropriate anal sphincter mobilisation to prevent tension on the stitches we used to repair the anal sphincter, was employed. Four of them had trans-sphincteric fistulas, and about seven of them acquired inter-sphincteric fistulas. Two patients in group II, on the other hand, developed a subcutaneous fistula at the healing site as a result of recurrence.

However, there was a significant difference between the two methods in group II, since there were six (20%) occurrences of gas incontinence (Wexner score of 1–3/20).

Regarding incontinence, there was a significant difference between the two groups: group I had no cases of incontinence, but group II had six mild episodes that were statistically significant, however neither patient in group II experienced severe incontinence.

As stated before, we think the results about the differences in continence between the two groups make sense. When the internal sphincter's outer fibres were visible, we stopped dissecting group 1 after dissecting and coring through the exterior sphincter muscles towards the interior orifice [3]. The operator might not have severed the anal sphincter for this reason.

There is a lot of diversity in the literature. The kind and complexity degree of the fistula treatment determine this heterogeneity. Ratto *et al.*, [10] discovered that the overall postoperative deteriorating continence rate for patients treated for complicated anal fistulas with fistulotomy or fistulectomy with primary sphincter restoration was 12.4% (mostly post-defecation soiling).

One of the study's shortcomings is the sample size. Additionally, there aren't many studies that compare the two approaches to in vivo management of high trans-sphincteric fistulas. Consequently, additional research is required to affirm the long-term impacts of these two strategies.

CONCLUSION

In comparison to the modified LIFT approach, fistulotomy with primary sphincteroplasty is a more successful procedure for the repair of trans-sphincteric fistulas, with a higher and statistically significant reduced recurrence frequency improved results in sphincter affection and a one-year follow-up. Determining the reasons behind the failure of both approaches would also be useful in figuring out their distinct functions in the surgical management of all anal fistulas.

Furthermore, we think that fistulotomy with primary sphincter restoration might be a safe and successful treatment once sphincter-preserving techniques fail and patients are properly selected (without comorbidities that negatively impact the healing process).

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CONFLICT OF INTEREST

There are no conflicts of interest.

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