Ligation of intersphincteric fistula tract versus fistulectomy in transsphincteric perianal fistula: a randomized, clinical trial Hazem Nour, Amr A. Bari, Mohamed I. Farid, Hany Mohamed

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Background

Management of transsphincteric perianal fistula is mainly surgical; fistulectomy, fistulotomy, or ligation of intersphincteric fistula tract LIFT technique shows diversity in their outcome. Continence status is considered the most important point in the treatment outcome followed by recurrence rate and local wound complications. The emerged LIFT technique was claimed for a better outcome. In this study, our aim is to compare between LIFT technique and fistulectomy in transsphincteric perianal fistulas.

Patients and methods

In all, 78 patients with transsphincteric perianal fistula were randomly allocated into group A: 39 patients who underwent LIFT and group B 39 patients who underwent fistulectomy. The patient follow-up and operative data were recorded and properly analyzed.

Results

The preoperative and demographic data between both groups show nonsignificant differences. Operative time was significantly shorter in the fistulectomy group. In the LIFT group recurrence and nonhealing of fistula were significantly higher (six cases) versus one in the fistulectomy group. Incontinence is significantly higher in the fistulectomy group (four cases) and zero in the LIFT group. Wound infection and dehiscence were more in the LIFT group.

Conclusion

In the treatment of transsphincteric fistula, LIFT technique led up to a lower incontinence rate than fistulectomy, but fistulectomy has proved to have a lower recurrence rate.

Keywords:

fistulectomy, ligation of intersphincteric fistula tract, perianal fistula

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Introduction

Perianal fistula is a common condition encountered by general surgeons [1]. It is considered as the chronic phase of perianal suppurations [2], characterized by the presence of internal and external openings connected together by a fistulous tract, with intermittent attacks of suppurative perianal discharge [1]. Parks *et al.* [3,4] classification is a known classification that classifies anal fistulas according to their level at which the tract traverses the anal sphincter. Parks classified anal fistulas into four major categories: extrasphincteric, suprasphincteric, transsphincteric, and intersphincteric. Subcategories emerge when the fistulous tract is complicated by side tracts [5]. Surgery is the best way for the management of anal fistulas [6]. Options of management depends on pathological conditions, as most of simple fistulae (nonbranching, transsphincteric involving less than one-third of anal sphincters and intersphincteric types) showed complete cure by fistulotomy and fistulectomy [7,8]. Complicated fistulas, high fistulas involving most of the anal sphincter, suprasphincteric and extrasphincteric types need more complicated surgeries (two stages, seton application or even stool diversion) [1,9]. Most of fistula treatment operations carries the risk of recurrence, incontinence, delayed healing, and local wound complications [10,11]. Ligation of the intersphincteric fistulous tract (LIFT) [12] as a surgical option entails secure ligation and cutting of the fistulous tract at the intersphincteric plane and curettage of the infected granulation tissue lateral to the ligatures, aiming at fistula healing without severing the anal sphincters [13]. In this study, we aim at evaluation of LIFT in comparison to fistulectomy in transsphincteric fistulas.

Patients and methods

This randomized, comparative clinical trial was carried out on 78 patients with transsphincteric anal fistulas in

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All patients were informed and signed a written consent for participation in this study. The study was approved by the local ethics committee of our university and registered in the clinical trials with the number NCT04351074. The sample size was calculated by the statistical unit of the local institutional review board.

Patient selection

Patients included in this study are those above 18 years old, suffering transsphincteric anal fistula diagnosed by clinical examination and MRI in doubtful cases.

We excluded all patients with

- (1) Anorectal malignancy.
- (2) Patients with previous radiotherapy to the region.
- (3) Those with fistula due to specific disease as Crohn's disease.
- (4) Patients with anal incontinence.
- (5) Patients with perianal collections.
- (6) Patients on cytotoxic or immunosuppressive therapy.

Randomization

According to intervention, patients were randomly allocated using computer-generated random numbers into two groups: group A included 39 patients. They underwent LIFT and group B included 39 patients), who underwent fistulectomy.

Procedures

All patients were subjected to full clinical examination including detailed history, formal digital rectal examination for assessment of anal sphincter integrity, and identification of internal and external orifices of the fistula. MRI was performed in those with doubtful clinical examination. Preoperative investigations were performed according to the American Society of Anesthesia guidelines. All patients received 1g third-generation cephalosporin with induction of anesthesia and was continued for 24 h postoperatively. Fleet enema was performed 12 and 2 h before operation.

Surgical technique

All operations were carried out by the same group of surgeons, under spinal anesthesia, in lithotomy position. The patients were prepared and draped. Rectal examination was done under anesthesia for identification of the internal and external openings and the fistulous tract course. After identification of the external opening it was probed by a 14 g cannula through which 2 ml hydrogen peroxide was injected and traced through an anoscope inside the anal canal to identify the internal opening. After that the fistulous tract was gently probed, the definitive procedure was then performed according to patient allocation.

In group A, a curvilinear incision was taken in the groove between the internal and external anal sphincters over the tract course, by sharp and blunt dissection using bipolar diathermy when needed. The wound was deepened between both sphincters till reaching the propped fistulous tract. The tract was dissected all around at this point. We used vicryl 3/0 sutures to ligate the fistulous track at two points: the medial one as near as possible to the internal sphincter; the lateral one is close as possible to the external sphincter. The tract was cut in between both ligatures (Figs 1 and 2). Hemostasis was achieved





Fistula tract after probing and dissection around.

Figure 2



Fistula tract after ligation and division.

and the wound was closed in two layers. The lateral part of the tract was curetted and the skin around the external opening was trimmed out.

In group B, after identification and probing of the tract as mentioned before, fistulectomy was carried out by doing elliptical incision including internal and external openings. The fistulous tract was excised severing the related part of the anal sphincters. Hemostasis was achieved as needed, wound was dressed using nonadherent dressing. Patients received nonsteroidal analgesia as required; They were discharged after tolerating oral intake.

Follow-up

It was achieved via the outpatient clinics by the attending surgeon. The patients were instructed to attend the clinic every week till complete wound healing and 3 and 6 months after wound healing. Later on the patients were contacted by phone after 1 year of the procedure. The data to be collected throughout follow up included postoperative pain measured by the visual analog scale. State of wound healing and state of continence were measured by the Vaizey score patient's questionnaire [14] as shown in Table 1. Recurrence or persistence of the fistula were measured by patient history and clinical examination.

Statistical analysis

Operative and hospital stay time together with followup data were collected and statistically analyzed using paired t test and Z test in SPSS program package 22 (IBM, Chicago, USA).

Table 1 Vaizey score

Incontinence	Never	Rarely	Sometimes	Weekly	Daily
Solid stool	0	1	2	3	4
Soft stool	0	1	2	3	4
Flatus	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4
				No	Yes
Need to wear a pad or plug				0	2
Taking constipating medicines				0	2
Lack of ability to defer defecation for 15 min				0	4

Daily, 1 or more episodes a day; weekly, 1 or more episodes a week but less than 1 a day; sometimes, more than 1 episode in the past 4 weeks but less than 1 a week; rarely, 1 episode in the past 4 weeks; never, no episodes in the past 4 weeks. Minimum score=0, perfect continence; maximum score=24, totally incontinent.

Results

In the period between March 2018 and February 2020, 78 patients underwent surgical treatment of their transsphincteric anal fistula, 39 patients underwent LIFT technique (group A) and the other 39 underwent fistulectomy (group B). Three of group A and four of group B had recurrent fistula,. Statistical analysis of demographic and preoperative data led to nonstatistically significant differences regarding sex, age, BMI, duration of illness, distance between anal margin, and external opening of the fistula. Demographic and preoperative data are presented in Table 2.

Statistically, fistulectomy took shorter operative time (28.9±5.27) than LIFT technique (32.07±6.65). Visual analog scale for pain assessment showed nonsignificant difference between both groups. All patients completed the follow-up time. On average, it was 53 weeks in group A and 56 weeks in group B. The follow-up in the outpatient clinic revealed complete healing in a mean time of 26.9 weeks in group A and 47.7 weeks in group B with high significant difference. The main outcome of this study was recurrence rate and incontinence. Recurrence was significantly higher in group A (six cases, 15.4%) than in group B (one case, 2.56%). The pattern of recurrence in the six cases led to a shorter fistula tract (downstaging of the fistula) but incontinence was significantly higher in group B (four cases, 10.23%) than group A (0). Incontinence was for flatus and occasionally for soft stool; All incontinent cases were women with previous normal vaginal delivery. The condition improved in 5-7 months. Perineal wound dehiscence occurred in six (15.4%) cases of group A but no cases of group B as wound was not closed. Wound infection occurred in six (15.4%) cases in group A and two (5.13%) cases of group B. As a complication of perineal wounds we had

Table 2 Demographic and preoperative d	Jata
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	Group A (<i>N</i> =39)	Group B (<i>N</i> =39)	P value
Sex			
Μ	23 (59)	36 (64.1 ⁾	0.62
F	16 (41)	13 (35.9 ⁾	
Age in years	30.28±7.5	31.5±8.14	0.33
BMI	28.01±3.8	28.6±4	0.27
Duration of symptoms in months	13.03±5.49	12.7±5.17	0.43
M-O distance	3.9±0.97	3.8±0.96	0.29
Recurrent fistula	3 (7.69)	4 (10.3)	0.39
Nonrecurrent fistula	36 (92.31)	35(92.31)	

Data are presented as n (%) and mean±SD. P value less than 0.05, significant difference.

Table 3	Operative	and	follow-up	data
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	Group A	Group B	P value
Operative time (min)	32.07±6.65	28.9±5.27	0.012
VAS pain score			
After 24 h	5.38±0.96	5.56±0.88	0.2
Follow-up (weeks)	53.7±8.06	56.5±9.6	0.08
Complications			
Wound infection	4 (10.23)	2 (5.13)	0.8
Wound dehiscence	6 (15.4)	0	0.01
Recurrence	6 (15.4)	1 (2.56)	0.047
Urine retention	2 (5.13)	1 (2.56)	0.56
Incontinence	0	4 (10.23)	0.04
Healing time in days	26.9±5.68	47.7±6.8	0.001

Data are presented as n (%) and mean±SD. VAS, visual analog cale. *P* value less than or equal to 0.05, significant difference.

two (5.13%) cases of urine retention in group A and one patient in group B with nonsignificant difference. Operative and postoperative data are presented in Table 3.

Discussion

of perianal fistula is mainly surgical especially if not caused by a specific disease, that is Crohn's disease; for decades many surgical procedures were used for fistula management with varying outcomes, such as fistulectomy and fistulotomy with or without marsupialization for simple anal fistulas, and partial fistulectomy with the use of seton and/or bowel diversion in selected cases for high fistula. LIFT technique was described for the first time in 2007 [15] by its principle was ligation of the fistula tract in the intersphincteric space with curettage and drainage of the lateral part of the tract; thus, the internal sphincter was preserved, many variations of the original technique emerged as the use of interposition bioprosthesis or use of fistula plug [16]. Most of the studies proved to have excellent outcome regarding the continence status as the internal sphincter was left intact, but results vary when considering healing and fistula recurrence. In this study, we excluded cases of high perianal fistula from the comparison as the fistulectomy was not applicable. We operated upon three recurrent cases in group A and four recurrent cases in group B. Our operative time was 32.07±6.65 min in group A, significantly shorter)28.9±5.27 min) in group B. We meet many studies in this point, the mean follow-up time in our study was 53.7 weeks (12.53 months) in group A and 56.5 weeks (13.2 months) in group B. Healing time was significantly shorter in group A (26.9±5.68) than in group B (47.7±6.8) as wound healing in group A was hastened by sutures. The main outcome of this study was continence status measured by the Vaizey score, and fistula recurrence or nonresolved fistula. Emile et al. [1] in his systematic review included 26 studies on LIFT technique and reported a follow-up time range of 12-32 months. He reported an overall recurrence rate of 12.4% after a 12-month follow-up and nonhealing fistula in 9.6%. In the current study, we recorded an overall nonhealing and recurrence rate of 15.4% in the LIFT group and 2.56% in the fistulectomy group. Sun et al. [17] reported a failure rate of 34.3%. Sutharat et al. [18], Chen et al. [7], and Wen et al. [5] reported around 21% failure rate; The highest failure rate was around 60% failure reported by Wallin et al. [19] as he performed LIFT for 93 patients with transsphincteric fistula, 16 of them with horseshoe fistula. Continent status was excellent in our study in the LIFT group; all patients were continent but we recorded four (10.23%) cases in the fistulectomy group. In LIFT procedures, theoretically, incontinence should be zero as in the studies of Sutharat et al. [18], Alhaddad et al. [20] and Wen et al. [5], but Sun et al. [17] reported 2.9%. Wallin et al. [19] reported 8.6% incontinence while Chen et al. [7] reported 9.3% in a study of more than 43 patients with transsphincteric fistula; four of them had multiple tracts; incontinence in those studies was attributed to tracts multiplicity or inadvertent injury of the internal sphincter. In our study, the increased incidence of incontinence in the fistulectomy group may be attributed to the previously weakened sphincter by obstetric trauma as all cases were women who had vaginal delivery. We recorded wound dehiscence in six (15.4%) cases in group A. This was not applicable for group B as the wound was left open. Wen et al. [5], Chen et al. [7], Sun et al. [17] reported 15.5, 18.6, and 24.3% dehiscence rates while Sutharat et al. [18], Alhaddad et al. [20] and Wallin et al. [19] reported zero dehiscence rate. Wound dehiscence may be attributed to shearing movement of the perineum if the patient moved vigorously in early postoperative period or due to infection or fluid collection. In regard to wound infection we reported four (10.23%) cases in the LIFT group and two (5.13%) cases in the fistulectomy group; this incidence lies among different study findings. Study limitations: the study may be limited by the small number of patients and the lack of manometric studies of the anal sphincter before and after operations.

Conclusion

In the treatment of transsphincteric fistula, LIFT technique led up to a lower incontinence rate than

fistulectomy but fistulectomy has proved to have a lower recurrence rate.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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