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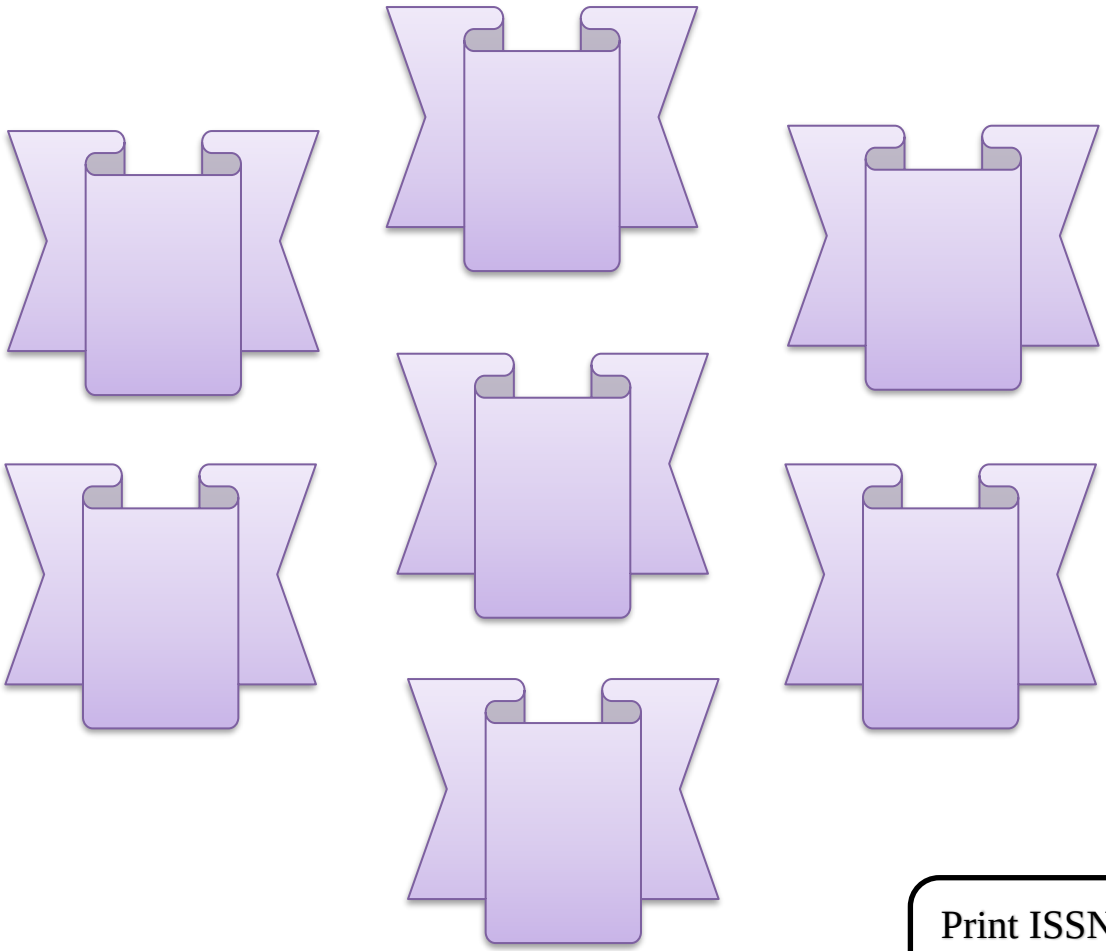

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Original Article

Role of Fibrin Glue versus Fistulotomy in Treatment of High Fistula-In-Ano

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ABSTRACT

Background: Perianal fistula is a frequent surgical condition that affect patient's daily activity, causing chronic pain and discomfort. High-type fistula-in-ano is especially hard to manage due to its position. Standard surgical methods are associated with many adverse events such as incontinence and repeated infections. Fibrin glue is a kind of biological glue which facilitates tract obliteration, with preservation of anal sphincter.

Aim of the work: This study aims at comparing the efficacy of fibrin glue versus fistulotomy in the treatment of high perianal fistulas.

Patients and Methods: In the present study, 30 patients diagnosed with a high-type perianal fistula were divided into two groups; group [1] undergone standard fistulotomy, and group [2] undergone fibrin glue. Operative outcomes, post-operative improvements and complications were compared.

Results: Patients in group [2] had significant short operative time [31.1 ± 12.5 min. in group 1 vs. 19.7 ± 1.62 min. in group 2; P, 0.004]. Group 2 had a significantly shorter hospital stay length than group 1 [1.93 ± 0.79 days for group 1 and 1.31 ± 0.35 days for group 2; P, < 0.001]. No significant difference was shown between studied groups regarding pain improvement, wound infection, wound discharge and incontinence at one week following surgery. However, group 1 patients had a significant [P, <0.001] less healing time than group 2. At six months following surgery, patients in group 1 reported higher rate of infection [four patients vs. none in group 2; P, 0.03] and higher recurrence rate [six in group 1 vs. one patient in group 2; P, 0.03].

Conclusion: The use of fibrin glue injection is a viable, valuable, and effective alternative for treating fistula-in-ano. It is associated with lower complications and less recurrence, although it had longer time for complete healing.

Keywords: Fibrin Tissue Adhesive; Rectal Fistula; Fecal Incontinence.

INTRODUCTION

Perianal fistula is a frequently encountered noncancerous anal condition in routine surgical practice. It is characterized by an abnormal tract that is lined with epithelial tissue, connecting two areas, typically the rectal mucosa and the skin around the anus [1]. The exact prevalence of fistula-in-ano remains uncertain. The occurrence of fistula-in-ano arising from an anal abscess varies between 26% and 38% [2].

Perianal fistula represents a chronic stage of infection in the anorectal region and is characterized by persistent discharge of pus or recurring pain due to abscess formation, followed by periodic spontaneous drainage [3]. Various classifications have been proposed to categorize these fistulas based on their location [low or high], complexity [simple or complex], or anatomical characteristics [inter-sphincteric, trans-sphincteric, suprasphincteric, or extra-sphincteric] [4].

Low perianal fistulas are characterized by their opening location below the anorectal ring, whereas high perianal fistulas open at or above the anorectal ring. Low-type fistulas are the most prevalent type of anal fistulas, comprising approximately 90% of cases [5].

There is currently no specific medical treatment available for this condition, although long-term use of antibiotics and anti-inflammatory medications may be considered for patients with Crohn's disease and recurring fistulas. Surgery is the preferred treatment approach, aiming to drain the infection, eliminate the fistula tract, prevent persistent or recurring disease, and preserve the functionality of the anal sphincter [6].

Different surgical interventions, such as fistulotomy, fistulectomy, seton placement, and more advanced sphincter-preserving procedures, are employed based on the type of fistula and the patient's continence status. In recent times, additional sphincter-preserving techniques like fibrin glue injection and fistula plug insertion have emerged as treatment options [7].

Treating a high anal fistula presents challenges due to its location. Seton placement is commonly used for such cases; however, this treatment approach is associated with issues like fecal incontinence, fistula recurrence, and prolonged and painful healing [8].

Fistulotomy is the established surgical procedure for treating anal fistulas. It involves a partial incision of the internal and external sphincter muscles, which is limited to less than one third of their extent. This method is known to be safe in terms of preserving continence in patients and does not lead to incontinence [9, 10].

The use of fibrin glue to treat anal fistulas is growing in popularity. Aprotonin factor 13 and calcium are two additional clotting factors that, when coupled with fibrinogen and thrombin, create the final phase of the clotting process and result in the formation of a gel-like clot [11].

Due to its ability to spare the sphincter muscles and so avoid incontinence, this adhesive offers a special form of treatment. Additionally, it lessens patient suffering and lost work hours. It is straightforward and reproducible, and failure does not preclude trying another approach. Although fibrin glue is increasingly utilized to treat anal fistulas, its long-term effectiveness and specific function in this situation have not yet been determined [12].

We therefore aimed to assess the effectiveness of fibrin glue and fistulotomy in the treatment of high perianal fistulas in this study.

PATIENTS AND METHODS

A prospective randomized comparative clinical study was carried out at the Department of General Surgery, Damietta Faculty of Medicine, Al-Azhar University Hospital during the period from August 2021 to January 2022.

After approval of local ethical committee and after given an informed written consent, a total of 30 adult patients with a clinical diagnosis of high non-complicated anal fistulae were included, subjected to surgical intervention and were followed up for 6 months duration.

Exclusion criteria: Complex anal fistulae, anterior fistulas in female patients, recurrent fistulas, fecal incontinence, inflammatory bowel disease, multiple and branching fistula and local irradiation.

The patients were separated into two groups at random**; Group A** included 15 patients who had fistulectomies, and **Group B** had 15 patients who had fibrin glue.

Preoperative assessment

All of the participants in this study underwent interviews to learn more about their clinical histories, which included the onset and duration of their symptoms as well as any past surgeries, chronic illnesses, or anorectal sepsis. Each patient's anal continence is evaluated using inquiries. All patients underwent thorough clinical evaluations to determine their overall health, the presence of systemic disease, and the pathology of their anorectal organs.

The examination includes proctoscopic evaluation, digital rectal examination, perineal inspection, and palpation. During the clinical examination, the distance between the external opening and the anal margin was measured using a plastic scale.

Fistulogram, in which the dye intensified the internal opening and manifested in the rectum, was necessary for the diagnosis of high perianal fistula [internal opening above ano rectal ring]. It aids in the discovery of any cavities and the quantity of tracts.

Routine preoperative work up included complete blood picture, liver and kidney functions tests, coagulation profile, ECG and echo when needed.

Surgical methods

After performing a normal approach for routine preoperative workup. All procedures were performed while sedated in the spine. The internal opening of the anal tract and the exterior opening of the lithotomy/prone jack knife were noted.

Group A: surgical procedures such as lay-open of the fistula tract as a complete transection of the tissue between the fistula tract and anoderm. The tract was taken out of the surrounding tissue and incised into the subcutaneous tissue (figure 1).

Group B: The fibrin glue's two components were drained into tuberculin syringes after the fistula tract had been curetted and irrigated with ordinary saline. The tips were injected into the tract opening while they were attached to a dual chamber applicator (figure 2). When the fibrin glue emerged from the internal aperture, the two components were then simultaneously injected into the external opening. After that, a petroleum jelly gauze was placed over the exterior opening, and the patients were sent home with a regular diet and five days of oral antibiotics. The operations were performed by staff surgeons using the same technique and rules.

Follow-up

Ciprofloxacin and metronidazole were given as perioperative antibiotics to patients in both groups for a total of three days. As analgesics, diclofenac sodium [50 mg twice daily] was administered for a total of 3 days. The day after their surgery, the patients were discharged.

The patients received advice on oral medication, upholding local cleanliness, using a sitz bath after urinating, dressings, and routine follow-ups. The first postoperative evaluation was carried out twenty-four hours after the procedure. The visual analogue scale [VAS] was used to rate the intensity of postoperative pain on a scale from 0 to 10. We questioned patients about their anal incontinence. The three-point Lickert scale was used to evaluate the development of incontinence based on the capacity to distinguish between feces and gas, difficulty holding gas, and soiling of underwear [0, never; 1, occasionally; 2, always].

For the first six weeks, patients were observed weekly; the following six weeks, they were observed every two weeks. The patient's postoperative discomfort, wound infection, anal incontinence, and postoperative wound discharge [defined as a non-infected sero-sanguinous secretion from the open postoperative wound] were all evaluated during each follow-up visit. Erythema, induration around the wound, or systemic symptoms like fever are considered signs of wound infection.

It was documented how long the postoperative wound needed to heal completely, which was determined as the amount of time it took for all areas to have an epithelized surface.

Throughout the follow-up period, the patients were monitored for the recurrence of the fistula. In order to gauge the extent of the patients' satisfaction with the medical care, interviews with them were conducted. The patients were asked to report whether their postoperative physical, social, and sexual behaviors had changed as a result of the treatment.

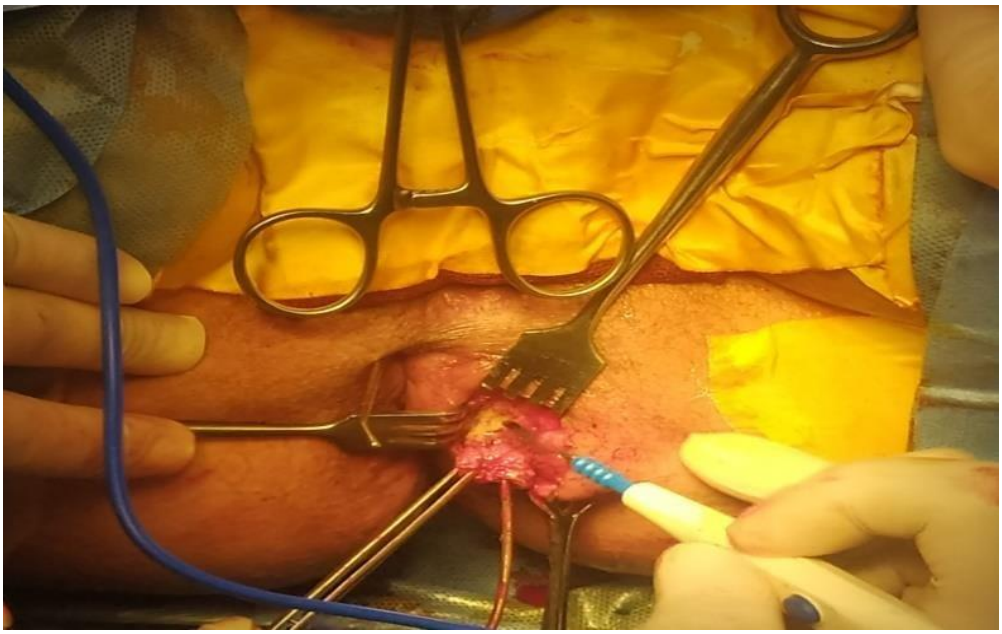

Figure (1): Field of fistulotomy

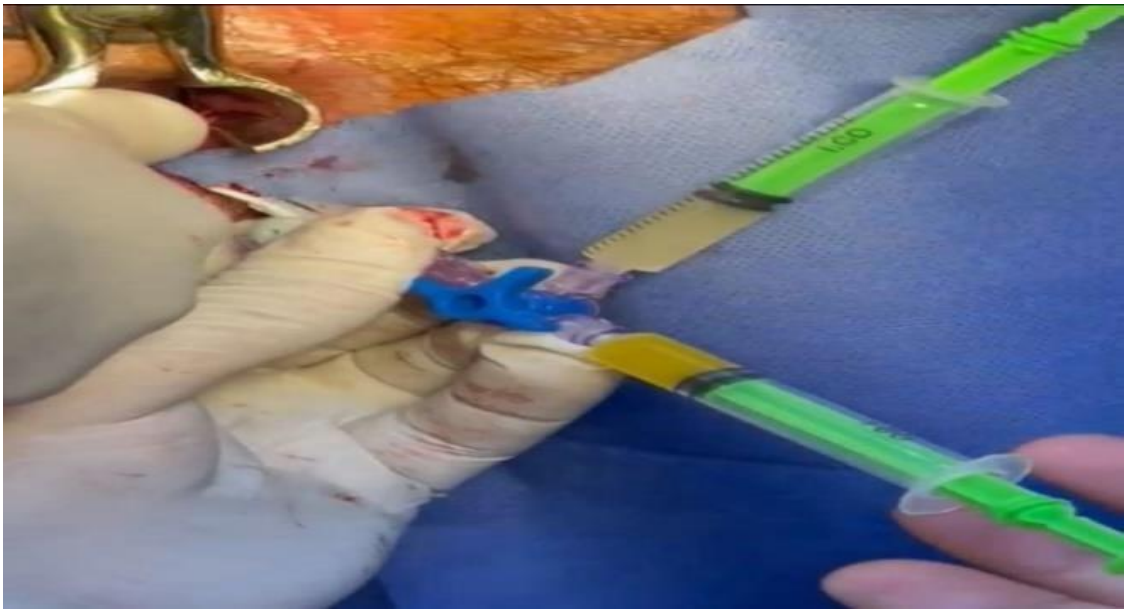

Figure (2): Fibrin glue injection

Statistical analysis: SPSS version 26 [IBM SPSS Statistics for Windows, version 26, IBM Corp., Armonk, NY, USA] was used to analyze the data. Standard deviations and the mean were used to express continuous data. Categorical data were presented as percentages and frequency. The Kolmogorov-Smirnov test was used to determine the degree of normalcy. The student t-test [for normally distributed variables] or Mann-Whitney test [for non-normally distributed variables] were applied to compare two continuous variables. Chi square test or Fisher's exact test were applied to nominal variables. Significant data was defined as P value 0.05.

RESULTS

Regarding age, sex, the length of the symptoms and presenting complaints, there was no significant difference between the study groups. In both groups, men predominated [80% in group 1 and 66.6% in group 2]. Perianal discharge was the most common complaint in both groups [table 1].

There was no significant variation in the length of the fistula tract between the two groups. In terms of operative time, there was a significant difference between the two groups [31.1 12.5

min. in group 1, and 19.7 1.62 min. in group 2; P, 0.004]. Group 2 experienced a significantly shorter hospital stay than group 1 [1.93 0.79 days for group 1 and 1.31 0.35 days for group 2; P, 0.001] [table 2].

No significant difference between studied groups were shown regarding pain improvement, wound infection, wound discharge and incontinence at one week following surgery. In group 1, two patients reported always presence of incontinence and one patient reported sometimes; while in group 2, two patients had incontinence sometimes [table 3].

Patients were asked after 6 months about pain improvement; 93% of the patients in group 1 had good pain improvement and all the patients in group 2 had pain improvement. After six months, four patients in group 1 had wound infections but none of the patients in group 2 did [P = 0.03]. Four patients in group 1 and two patients in group 2 had anal incontinence at the end of six months [P, 0.37]. When the patients were re-interviewed six months later, 86% of those in group 1 reported being extremely content, whereas 93% of those in group 2 reported being satisfied. There was no discernible distinction between the two groups. The patients were asked to report whether their postoperative physical, social, and sexual behaviors had changed as a result of the treatment. 60% of the patients in group 1 and 93% of the patients in group 2 reported significant improvements in their way of life, respectively [P = 0.03] as shown in table [4].

Patients in group 1 had a significant [P, <0.001] less healing time than group 2. The mean time needed to healing completely in group 1 was 8.60 ± 1.80 days, while in group 2 the mean time needed to heal was 25.4 ± 7.52 days. The recurrence in group 1 was 40%, while in group 2 the recurrence occurred only in one patient [P, 0.03] as shown in table [5].

Table [1]: Baseline characteristic of the studied cases

Variables		Group 1 [n = 15]	Group 2 [n = 15]	P value
Age [years]	Mean ± SD	39.5 ± 14.1	41.7 ± 14.7	**0.67**
Sex, n [%]	Males Females	12 [80%] 3 [20%]	10 [67%] 5 [33%]	**0.41**
Symptoms' duration [months]	Mean ± SD	16.8 ± 14.5	23.0 ± 10.9	**0.195**
Presenting symptom	Perianal discharge	12 [80%]	10 [66%]	**0.41**
	Perianal abbesses	7 [46%]	9 [60%]	**0.45**
	Pain	3 [20%]	4 [26%]	**0.70**
	PR bleeding	1 [6%]	3 [20%]	**0.26**
	Itching sensation	2 [13%]	3 [20%]	**0.61**
	Urgency	2 [13%]	0 [0%]	**0.15**

Table [2]: Operative outcomes of the studied cases

Variables		Group 1 [n = 15]	Group 2 [n = 15]	P value
Fistula tract length [cm]	mean ± SD	7.41 ± 2.55	7.18 ± 2.41	**0.799**
Operative time [min.]	mean ± SD	31.1 ± 12.5	19.7 ± 1.62	**0.004***
Hospital length stay [days]	mean ± SD	1.93 ± 0.79	1.31 ± 0.35	**<0.001***

Table [3]: Early Post-operative assessments of the studied cases

Variables		Group 1 [n = 15]	Group 2 [n = 15]	P value
Pain improvement, n [%]	Improved No change Worsened	13 [87%] 2 [13%] 0 [0%]	14 [93%] 1 [7%] 0 [0%]	0.3
Wound infection, n [%]	Yes No	1 [7%] 14 [93%]	0 [0%] 15 [100%]	0.34
Wound discharge, n [%]	Yes No	3 [20%] 12 [80%]	1 [7%] 14 [93%]	0.26
Incontinence, n [%]	Yes No	3 [20%] 12 [80%]	2 [13%] 13 [87%]	0.61

Table [4]: Post-operative evaluation of studied cases at six months

Variables	Group 1 [n = 15]	Group 2 [n = 15]	P value
Pain improvement, n [%]	14 [93%]	15 [100%]	**0.31**
Wound infection, n [%]	4 [26.6%]	0 [0%]	**0.03***
Anal Incontinence, n [%]	4 [26.6%]	2 [13%]	**0.37**
Patients' satisfaction, n [%]	13 [86%]	14 [93%]	**0.54**
Return to normal life, n [%]	8 [60%]	14 [93%]	**0.03***

Table [5]: Healing time and recurrence rate of studied cases

Variables	Group 1 [n = 15]	Group 2 [n = 15]	P value
Time needed to heal [days], mean ± SD	8.60 ± 1.80	25.4 ± 7.52	**<0.001***
Recurrence rate, n [%]	6 [40%]	1 [7%]	**0.03***

DISCUSSION

In addition to examining the outcome measures in terms of pain, swelling, discharge, faecal or gas incontinence, and recurrence, this study aims to investigate the role of biological fibrin glue in the treatment of high noncomplex non branching fistulas in ano. Fistulotomy can result in a high risk of incontinence even though recovery rates are often extremely good, especially in cases of large fistulas. To lessen the danger of incontinence and postoperative scarring, sphincter-saving and scar-minimizing techniques have been utilized increasingly frequently in recent years under the right circumstances [13].

In this study, men were the predominate sex in both groups, perianal discharge was the primary symptom, and symptoms might last anywhere from three months to four years. The baseline features between the two groups did not significantly differ from one another.

The fistula tract length ranged from 4.0 cm to 13.2 cm. The operative time was a significantly shorter in group [2] [19.7 ± 1.62] min than group [1] [31.1 ± 12.5] min. Also, group [2] has significant short hospital stay length [1.31 ± 0.35] min than group [1] [1.93 ± 0.79] days.

In order to compare the surgical management of uncomplicated anal fistulas using traditional versus sphincter-sparing procedures, **Litta *et al.*** [14] conducted a comprehensive study. According to his study report, sphincter sparing surgeries often took 34.5 [19.0-52.5] minutes to complete on average, with an average postoperative hospital stay of 0.8 [0-1.5] days.

Our findings were in line with a study by **Maralcan *et al.*** [15] that examined the long-term effects of fibrin glue in patients with fistula in ano; the average operation time was 16 minutes, with a 14 to 29-minute range. A day on average was spent in the hospital.

The main advantage of fibrin glue in the recurrent study is the very low of recurrence [one patient] compared to six patients in fistulotomy group. The overall sphincter-sparing procedures in the studies cited in **Litta *et al.*** [14]'s systematic review achieved a weighted average success rate of 77.7% [25.0-100%] after a weighted average follow-up of 13.2 [2.3-71.0] months. A retrospective study that found modest incontinence in 1 out of 9 patients [11.1%] with a simple anal fistula and treatment with a sphincter-saving method was the only study to report any postoperative continence impairment.

According to **Van der Hagen *et al.*** [16], the recurrence rate for low AFs following fistulotomy rose over time and was 7%, 16%, and 39% after 12, 24, and 72 months of follow-up, respectively. The same study highlighted the fact that the recurrence took place away from the original fistula tract in more than half of the instances. As a result, the authors proposed that the recurrence in people with a simple AF was "more likely a matter of patient disease than a failure of the treatment".

Two articles over the past 20 years have examined the effects of glue. 20 patients were the subject of the experience report by **Jain *et al.*** [17]. After the initial injection, the fistula healed in 17 cases, and two additional patients saw success with the second injection. 24 individuals were included in the report by **Barillari *et al.*** [18], 14 of them had high fistulas and 10 had low ones. With no continence issues, their healing rate was five out of seven [71.4%] for low fistulas and ten out of 101 for high fistulas. Four more patients had success with a second injection.

However, in **Cirocchi *et al.*** [19]**'s** study, who had carried out a systematic review looking for published randomized and controlled clinical trials compare the application of fibrin glue to surgery alone, considering the healing and complication rates, they reported the poor long-term results in the patients who underwent fibrin glue treatment instead of surgery, considering both healing and not-healing after an adequate 6-month follow-up, regardless of the fact that the not-healing was not as severe as the healing.

The overall healing rate with fibrin glues is 53%, ranging from 10 to 78% in a series that comprised a significant number of high fistulas reporting less favorable rates, and the rate continues over time, according to the meta-analysis published by **Swinscoe *et al.*** [20]**.**

However, these variations may be accounted for by their patient selection, exclusive use of autologous fibrin glue with a lower fibrinogen concentration, and variations in the standardization of these products, which may not have formed as strong of a plug as the commercial fibrin sealant may have, as well as their lower success rate.

Although the overall healing rate was significantly better with fibrin glue, the time needed to heal was significantly longer with the fibrin glue. The reasons for this long duration are not fully addressed. Possible explanations include that the glue takes time to adhere to the surrounding tissue and obliterate all pockets within the fistula tract [21].

Patients in both groups were satisfied about the results in general and patients in fibrin glue group were more satisfied about the quality of their lifestyles postoperatively. Our findings concurred with those of **Maralcan *et al.*** [15] who had found that the use of fibrin glue was superior to traditional surgery in terms of patient comfort, preserved sphincteric function, shorter stays in the hospital overall, less need for postoperative analgesia, and a quicker return to normal activities with minimal operative trauma and no complications.

A new alternative for treating the various varieties of fistulas-in-ano is fibrin glue. It has recently been successful in a number of chosen patients. There have also been reports of cryptoglandular healing rates as high as 80% [often early results]. Fistulas can be treated with it without endangering anal continence, and if it doesn't work, it can be tried again multiple times if necessary. Additionally, it does not restrict or change potential follow-up treatments [15]. Our methods and outcomes mirror those mentioned in the literature as well.

Limitations: Our study's results are constrained by a relatively brief follow-up period of only six months, as opposed to previous studies that used follow-up periods of up to eleven months. Currently, longer-term follow-up is advised. A small sample size is another major limitation that can affect our validity. To ascertain the more efficient course of therapy for outcomes of healing, morbidity, and cost, a larger randomized, multicenter prospective trial of fibrin glue repair is recommended.

Conclusion: As a result, fibrin glue injection is a practical, worthwhile, and efficient therapy option for the management of fistula-in-ano. The main benefit is reducing the possibility of fistulotomy-related problems such recurrence, incontinence, and wound infection. For the majority of patients, it is minimally invasive and allows them to resume their daily activities quickly. Future research will be required to identify the best fibrin glue type and application method in order to enhance these outcomes.

Conflict of Interest and Financial Disclosure: None.

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