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Limited fistulectomy and fibrin glue for the treatment of complex fistula-in-ano

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Abstract

Background: The study was designed to assess results of a combination of limited fistulectomy and fibrin glue instillation for the treatment of complex fistula-in-ano.

Method: All patients who fulfilled the criteria of complex cryptoglandular fistula-in-ano were included in the study. After initial assessment at surgical outpatient clinic (SOPD), patients were admitted for examination under anaesthesia (EUA). Following the assessment of the fistula and its track, fibrin glue instillation was carried out. The fistula track was partially excised and followed by instillation of glue. All the patients were followed up at the SOPD at regular intervals to determine development of recurrence and related morbidities associated with the procedure.

Results: Fourteen patients were included in the study with a mean age of 45.6 years and the mean follow up was 13 months. Ten patients (71%) had high transsphincteric fistula. One patient had extrasphincteric fistula and the remaining three patients had multiple fistula tracks. Two (14%) patients had prior seton insertion before fibrin glue instillation due to persistent infection. All patients had successful fistula closure after the initial instillation. However 2(14%) patients had recurrence after 4 and 3 months respectively after the surgery. In our study, healing time ranged from 6 to 12 weeks (mean: 8 weeks) and all patients were free from any morbidities related to surgery.

Conclusion: A combination of limited fistulectomy and fibrin glue instillation for complex fistula-in-ano appear to be safe, easy and effective.

KEYWORDS: fistula-in-ano, fibrin glue, limited fistulectomy, anal fistula

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INTRODUCTION

Fistula-in-ano is a common anorectal disorder affecting 1 in 10 000 of the general population¹. The goal of treatment is to eradicate the source of sepsis which enhances the closure of the fistula tract and preservation of sphincter function. Management strategies in managing the fistula tend to be guided by the type of fistula itself as well as its aetiology. A simple superficial fistula is adequately treated by fistulotomy with low recurrence rate and minimal risk of sphincter injury². However complex anal fistulae are relatively difficult to treat. The term complex fistula describes fistulas whose treatment poses a higher risk for impairment of continence (Table 1)^{3,4}. Several methods have been advocated for treatment of complex fistulas which include cutting seton, staged fistulotomy, fistulectomy and advancement flaps. However all of these methods have some element of morbidity in particular, faecal incontinence. For instance, cutting seton was reported to result in minor incontinent rates ranges from 0% to 63% and up to 35% in transanal advancement flaps^{5,6,7}.

The use of fibrin glue in the treatment fistula-in-ano was introduced in 1992⁸. This approach offers a simple method of promoting fistula closure with minimal sphincter disturbances particularly in patients with complex fistula. Early results were encouraging with high rates of success but as the experience grew, the overall success rate and efficacy were questionable. Several studies have reported conflicting results in terms of healing rates and efficacy. Swincoe reviewed 15 articles that were published concerning

the use of fibrin glue for the treatment of fistula-in-ano. His conclusion was that the overall healing rate was 53% with a wide variation between studies (10% to 78%)⁹.

Presently, there are few factors that have been suggested which contribute to high recurrence rates of fistula-in-ano after fibrin glue instillation, such as presence of secondary extensions which may not be filled during instillation and persistent infection of the fistula tracks. Moreover, few studies have shown that fistula track excision is an important step in fistula surgery that may dictate recurrence. Study by Lasheen showed that excision of the fistula tracks by mean of partial fistulectomy may reduce the risk of recurrence¹⁰. Unfortunately, most of the previous studies of fibrin glue for fistula-in-ano did not involve excision of the fistula track which might be the factor for the high recurrence rates. Our current study combines the method of limited fistulectomy followed by instillation of fibrin glue, in the treatment of fistula-in-ano with the aim of eliminating factors contributing to high recurrence without compromising continence.

PATIENTS AND METHODS

Patients

All patients who presented to the surgical outpatient department (SOPD), Hospital Tengku Ampuan Afzan, Kuantan, Pahang, Malaysia with fistula in ano over a 2 year period were offered treatment with fibrin glue. At the initial evaluation at the SOPD, the presence of fistula was confirmed and bowel control function was documented. All patients were then subjected to examination under anaesthesia (EUA). We selected

fistulas of cryptoglandular in origin for this study. Patients with inflammatory bowel disease related fistula and malignant fistula were excluded from the study. All patients were counseled about the use of fibrin glue as part of the treatment.

Fibrin Glue

In our study, Tisseel[®] (Baxter Health Corp) fibrin glue was used in all patients and was reconstituted according to the manufacturer's instruction.

Operations

All patients were admitted one day prior to the operative procedure. Sodium phosphosoda (Fleet[®]) enema was given on the morning of operation. No prophylactic antibiotics were given on induction for all patients. The operation was performed under spinal anaesthesia and patients were placed in the lithotomy position. The external opening was assessed and recorded. Eisenheimer retractor was gently inserted into the anal canal to assess the internal opening. Once both openings were delineated, the complexity of fistula was assessed. Those with superficial and low fistula underwent fistulotomy. Patients included in the study were those with complex fistula or deemed to be high fistula in which fistulotomy may compromise sphincter function. Whenever active infection or a secondary track was identified, a loose seton was inserted in order to drain the collection. Once the fistula was determined to be suitable for fibrin glue instillation, Prolene[®] suture was inserted along the track, aided by Lockhart-Mummery probe to secure the track.

Subsequently, an incision around the external opening was made by using diathermy and deepened up to the level of sphincter complex. The track were cored out and sent for histopathological examination. The residual track within the sphincter complex was curetted to remove the granulation tissue (Figure 1).

The Tissel[®] fibrin glue was prepared in the operating room by a nurse according to the manufacturer's instruction. Individual components were mixed and warmed in a Fibrinotherm[®] (Baxter AG, Vienna, Austria) and were then drawn up into two syringes (syringe 1: thrombin and calcium chloride solution; syringe 2: fibrinogen, factor XIII, fibronectin, aprotinin and plasminogen). Both syringes were subsequently placed in a Duploject[®] (Baxter AG, Vienna, Austria) two-syringe clip, where they shared a common plunger. This apparatus was then connected to a double lumen catheter and the tip of which was visualized at the internal opening. Upon injection, both components mixed at the tip of catheter to form the fibrin glue. The catheter was slowly withdrawn from the track while injecting to ensure the whole length of track was filled with the glue and a finger was placed over the internal orifice to prevent unnecessary loss of the product into the anal canal. The glue set within three minutes and light dressing was applied on the wound.

Post operatively, patients were prescribed oral Cefuroxime 250 mg BD, oral Metronidazole 400 mg TDS, stool softener and analgesia. The dressing was removed on day 1 after the surgery and the wound inspected. The patients were discharged after 24

hours and advised to have regular Sitz bath at home. All patients were reviewed again at the SOPD at 2 weeks post operation.

Follow-up

All patients were followed up at the surgical outpatient clinic regularly by the same surgeon at week 2, week 4, week 8, week 16, week 24 and every 12 weeks thereafter. During the follow up, special attention was paid to the clinical evidence of healing, presence of any associated morbidity such faecal incontinence and signs of recurrence. Recurrence is defined as reappearance and visualization of an external opening associated with persistent discharge and pain. Healing is defined as an absence of those symptoms with evidence of closure of the fistula opening.

During the follow-up, whenever patients complained of any symptoms suggestive of recurrence or abscess collection, the patients were scheduled for EUA. Those with a collection or evidence of infection, a loose seton was inserted. Once the infection had cleared, another instillation of glue was carried out in the same way as described earlier.

RESULTS

There were 14 patients treated with limited fistulectomy and fibrin glue. Twelve patients (86%) were males and the remaining were females with a mean age of 45.6 years (range 32 – 52 years). Three (21%) patients had more than one external opening and 10 (71%)

had high transsphincteric fistula in which the internal opening were above the dentate line. One patient (8%) had extrasphincteric fistula and two patients had both transsphincteric and intersphincteric fistulas. Two (14%) patients had insertion of loose seton during initial EUA session due to the presence of pus collection along the fistula track. Two patients had 2 different procedures during the initial EUA: fistulotomy for superficial fistula and limited fistulectomy and fibrin glue instillation for the other fistula track. The median follow up was 13 months (ranges from 6 to 24 months). All patients had fistula closure after the first fibrin glue instillation. Twelve (86%) patients had healed without any evidence of recurrence after one instillation of fibrin glue. Two patients (14%) had recurrence within 4 months after the first instillation. The first patient who had recurrence was one with a complex fistula. She had a previous loose seton insertion prior to fibrin glue instillation. The second patient was found to have high transsphincteric fistula. The former had a repeat fibrin glue instillation but she had a recurrence after 2 months. She subsequently underwent another EUA that revealed a collection and a loose seton was then inserted. The second patient presented to our surgical clinic with symptoms and sign of perianal abscess which was drained and had a seton inserted. In our study, the healing time was between 6 to 12 weeks with a mean of 8 weeks. There were no morbidities related to the procedure performed in our patients.

DISCUSSION

Major concerns in the management of fistula in ano are preservation of the anal sphincter function and fistula recurrence. Surgical treatment of fistula can be classified as open

method, in which the sphincter may be damaged or cut (for example: fistulectomy and fistulotomy) and those in which the sphincter muscle is not damaged or cut¹¹. Sphincter preservation fistula surgery method includes fibrin glue instillation. Fistulotomy has been proven to be the best option for low or simple fistula with minimal risk of faecal incontinence¹². However for high fistula, open method may disfigure the sphincter complexes which expose the patients to fecal incontinence. There are few methods of sphincter preservation surgery that have been described to treat those complex or high fistula with an impressive outcome. Lasheen described partial fistulectomy and fistula wall flap by using a special fistulectomy tube for the treatment of high perianal fistulas with a good healing rates and minimal recurrence rate¹⁰. Hidaka et al also described a complicated method for sphincter preserving operations for treating a variety of high fistula¹¹.

It is generally accepted that procedures that divide the tissue encircled by the fistulous track are the most effective in treating fistula and reduce the recurrence rate but usually are associated with high rates of fecal incontinence¹³. Our study showed that all perianal fistulas closed after fibrin glue instillation with a recurrence rate of 14% at a mean follow up of 13 months. The finding was comparable to the result of a study done by Sentovich in which his recurrence rate was 13% but in his study, the type and complexity of fistula were not documented¹⁴. On the other hand, the study by Buchanan et al found that 86% of his patient had recurrence after 16 months of fibrin glue instillation¹⁵. Another similar study of fibrin glue instillation by Cintron also found a high recurrence rate following glue instillation. One common factor in those studies was that, the fistula track was not

excised. This may have been the factor for the high recurrence rate. Buchanan et al claimed that one of the reasons for high recurrence rate is due to fact that the fistula track was not adequately curetted before instillation of fibrin glue thereby jeopardizing the success rate¹⁵. In addition, the natural process of re-epithelialization of the track may also contribute to early recurrence¹⁷. Another possibility is due to the presence of a hidden secondary track which was not detected during the initial operation. Therefore from our series, we concluded that limited excision of fistula track play a major factor in reducing the recurrence rate in cryptogenic complex fistula.

In our series, 2 recurrences developed within 4 months after the procedure. This observation was also consistent with other previous studies which used fibrin glue as a mode of treatment. The earliest study by Hjortrup found that all of the recurrences occurred within 3 months after fibrin glue instillation⁸. Another study by Cintron et al found that their recurrences occur as early as 2 months¹⁶. A pilot study by Aitola et al noted that 90% of recurrences occurred in the first month after operation¹⁸. Furthermore Sentovich found that a late fistula recurrence, which he defined as a recurrence that occurs after 6 months following successful closure with fibrin glue, was uncommon¹⁹. However other studies have found slightly delayed recurrences. Mazier in his follow up of 1000 patients of fistula in ano, found that most of recurrences developed at one year but can be as long as 7 years after surgery²⁰. Another study of the outcome of fistula-in-ano after surgery by Vasilevsky et al also found that the average period of recurrences was 12 months (range from 5 to 25 months)²¹. This observation shows that those who underwent fibrin glue instillation, if they do recur, they tend to recur at an early stage of

post-operative period. The finding shows that there are also other technical factors in which the fibrin glue may be dislodged prematurely apart from the reason stated earlier.

In this study, we combined the method of limited fistulectomy and instillation of fibrin glue to improve the outcome in term of better sphincter preservation and low recurrences. The fistula track was excised up to the level just proximal to the sphincter complex and the residual track within the sphincter complex was curetted and occluded by using fibrin glue. We believed that this method will not interfere with sphincter mechanism thereby avoiding the risk of incontinence. Garcia-Aguilar found that the rate of incontinence increased steadily with estimated amount of external sphincter division during fistula surgery and complexity of the fistula itself². As expected, from our observation, none of our patients in the study had symptoms of fecal incontinence during follow up period. Study by Lasheen which used fistulectomy tube to partially excise fistula track also had found that none of his patients suffered from any incontinence following the partial fistulectomy¹⁰.

In our technique, we excise the tissue surrounding the external opening and the fistula track. The duration for the wound to heal is comparable with other surgical method, such as fistulotomy. In our series, healing time ranged between 6 to 12 weeks (mean=8). An analysis by Vasilevsky et al in 1984 showed that most fistulas healed within 12 weeks following the operation and they claimed that healing time increased in parallel to the complexity of the fistula itself rather than the surgical procedure²¹. The presence of fibrin

glue within the track and the wound promotes fibroblasts migration and facilitates the process of wound healing.

We selected only patients with cryptoglandular fistulae to be included in our study to minimize factors of fistula healing rates and recurrences. Patients with perianal Crohn's or other chronic inflammatory condition and traumatic fistula were excluded as their aetiological factors are different and rather uncommon in our population. Several studies in the past demonstrated that surgery for perianal Crohn's fistula should be less aggressive as any surgical intervention may result in severe morbidities particularly fecal incontinence²²⁻²⁵. Cintron et al found that cryptoglandular fistula had a healing rate of 63% compared to 36% for fistulae of other aetiology¹⁶. This trend was also observed in a study by Venkatesh and Ramanujam who achieved healing rates of 80% in cryptoglandular fistula compared to a complete absence of healing in patients with Crohn's disease or HIV infection²⁶.

CONCLUSION

In conclusion, the present study demonstrates that partial fistulectomy and fibrin glue instillation of the remaining fistula tract appear to be safe, easy and effective for the treatment of a complex cryptoglandular fistula-in-ano. However a longer follow up with a bigger sample is required to confirm our findings.

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CONFLICT OF INTEREST

The study did not receive any kind of financial assistance either directly or indirectly with any pharmaceutical company.

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Table 1: Complex fistula-in-ano

- Track crosses more than 30 to 50 percent of external sphincter
(high transsphincteric, suprasphincteric and extrasphincteric)
- Located anteriorly in female
- Multiple tracks
- Recurrence
- Patient has pre-existing incontinence
- Local irradiation
- Associated with Crohn's disease

Table 2: Types of fistula, Level of External opening, Healing, Procedure and Follow up

Patient	Gender /Age	Primary track	External opening ((clock position)	Healing (weeks)	Procedure	Follow up (months)
1.	M/32	Transsphincteric with horseshoe extension	11 and 12	12	L.F and seton then fibrin glue	20
2.	M/33	Transsphincteric	7	8	L.F and seton then fibrin glue	14
3.	F/50	Extrasphincteric	7	12	L.F and fibrin glue	20
4.	F/48	Transsphincteric & Intersphincteric	8 and 6	8 and 12	L.F and fibrin glue for 8 o'clock. L.F and seton followed by fibrin glue for 6 o'clock. Repeated instillation. Loose seton	18 but recur after 4 months
5.	M/44	Transsphincteric	10	6	L.F and fibrin glue	24
6.	M/46	Intersphincteric and Transsphincteric	9 and 2	4 and 8	Fistulotomy for 9 and P.F with fibrin glue for 2 o'clock	20
7.	M/42	Transsphincteric	3	6	L.F and fibrin glue	12
8.	M/33	Transsphincteric	2	6	L.F and fibrin glue	12
9.	M/37	Transsphincteric	7	8	L.F and fibrin glue	6
10.	M/52	Transsphincteric	5	8	L.F and fibrin glue	6
11.	M/41	Transsphincteric	6	8	L.F and fibrin glue	6
12.	M/32	Transsphincteric	7	8	L.F and fibrin glue. Loose seton	8 but recur after 3 months
13.	M/45	Transsphincteric	7	6	L.F and fibrin glue	8
14.	M/39	Transsphincteric	5	8	L.F and fibrin glue	8

N.B: L.F: Limited fistulectomy; M: male, F: Female

Figure 1: Limited fistulectomy: up to sphincter complex, (arrow). (Dotted line: residual fistula track)

