

Treatment of perianal fistulae with fibrin sealant

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Abstract

Background: The surgical management of high perianal fistula is associated with the risk of sphincter injury. Injection of fibrin sealant in the fistula tract is a simple procedure in an attempt to avoid more radical surgical intervention .

Objective: The purpose of this study was to evaluate the effects of fibrin sealant in treatment of high perianal fistula.

Method: Between October 2006 to December 2009, only patients with high perianal fistulae were included in this study. Injection of fibrin sealant into the fistulous tract under anesthesia was done. Patients were actively followed up at two weeks, one, two, six months and one year.

Results: The study included a total of 16 patients, 12 males (74.5%) and 4 females (25.5%), the age ranging from 32 to 55 years, the mean age 43.2 years. The type of fistulae as delineated by ultrasound were 10 intersphincteric (62.5%) and 6 transsphincteric (37.5%). The success rate was 50%, the success rate among intersphincteric type of fistula was 60% and the transsphincteric type was 34%. No complications were reported in our study.

Conclusion: Fibrin sealant injection was a useful treatment alternative in the treatment of perianal fistula. It may potentially preclude more extensive surgery in more than one half of patients. Further study should be designed to define predictors of success for better patient selection.

Key words: Fibrin sealant, treatment, perianal fistula.

Introduction:

Surgical management of complex perianal fistulae is challenging and may be associated with the risk of sphincteric injury.¹

Complications from the repair of fistulae in ano can be devastating. While it is common practice to treat individuals with intersphincteric or low transsphincteric fistulae with fistulotomy, fecal incontinence in these patients has been reported. Even more common, but often under reported, is permanent flatus incontinence. Another postoperative complication after surgical treatment of anal fistula is recurrence.^{2,3}

Fibrin sealant has been used in many surgical conditions. Several trials of using fibrin sealant in the treatment of fistula in ano have been performed.^{2,3} By using fibrin sealant in treating high perianal fistula, patients can avoid the risks of staged seton procedure and the risk of fecal incontinence.

In addition the prolonged discomfort associated with wound dressing after operation can be avoided.^{2,4}

Fibrin sealant is a tissue sealant that uses the activation of thrombin to form a fibrin clot, which mechanically seals the fistula tract. The clot undergoes gradual fibrinolysis while promoting tissue healing processes to permanently obliterate the fistula tract. The use of fibrin sealant has recently emerged as a simple and repeatable procedure for the treatment of high perianal fistulae. This procedure, done as a day case surgery, does not interfere or compromise subsequent surgical options. Moreover the prolonged discomfort associated with wound dressing after surgery may be avoided.^{3,5-7}

The objective of this study was to assess the use of fibrin sealant in the treatment of high perianal fistulae.

Methods:

Between October 2006 to December 2009, sixteen patients suffering from high perianal fistulae participated in our study; twelve of

them were males (74.5%) and four were females (25.5%). Their ages ranged from 32 to 55 years, the mean age was 43.2 years.

The inclusion and exclusion criteria are listed in this table.

Inclusion criteria:
1- Age: above 18 years of age
2- High perianal fistula encompassing at least one third of external anal sphincter muscle
3- Patient understanding the study and signs an informed consent.
Exclusion criteria:
1- Perianal abscess or undrained collection noted on preoperative clinical assessment.
2- Perianal abscess or undrain collection as assessed by preoperative imaging studies defined as local enlargement at least twice the width of the fistula tract
3- Body temperature > 38
4- White blood cell count > 12,000
5- Known allergy to fibrin sealant
6- Immunodeficiency condition
7- Pregnancy

Preoperative investigations:

All patients were preoperatively examined by a surgeon for eligibility to participate in this study. Determination for inclusion was undertaken by clinical examination, endorectal ultrasound and fistulographic examination. Imaging of the fistula tract with ultrasound and fistulography was aimed at detecting any associated cavities and secondary tracts.

Surgical procedure:

Two days prior to surgery, patients were placed on a liquid diet and cleansing enema was done prior to injection. The procedure took place as a day case surgery under general or spinal anaesthesia with the patient placed in the lithotomy position. The fistula tract was curetted using a blunt curette. Gauze was packed in the rectum of the patient before injection to prevent spillage of fibrin sealant into the rectum or anal canal. A commercially made fibrin sealant was used. Before

application, the fibrin sealant was prepared and kept at room temperature, as recommended by the manufacturer. Two components were prepared (the first component: fibrinogen concentrate, human plasma protein fraction with factor XIII activity and aprotinin; the second component: Thrombin and calcium chloride solution). They were then siphoned into two syringes and connected to a dual chamber applicator. The dual-chamber applicator syringe was put inside the fistula tract through the external opening and fibrin sealant was injected until the whole tract was filled with sealant. This normally required a total of 1ml, the patient was then instructed to have a half-hour period of rest to avoid back flow of fibrin sealant and to allow fixation of the fibrin plug. After that the gauze pack was removed and a one week course of oral antibiotics prescribed (cefuroxime 250 mg twice daily and metronidazol 500mg three times daily).

Follow-up:

All patients were actively followed up at two weeks and one, two, six months and one year after the procedure. Each visit included physical examination to assess for recurrence and any adverse effects. Success of the procedure was defined as the clinical absence of any discharge through the external or internal opening per history, clinical examination and transanal ultrasound. Patients with fistula recurrence were offered additional injection of fibrin sealant.

Results:

Sixteen patients participated in our study, twelve of them males and four females. Their age ranged from 30 years to 55 years, the mean age was 43.2 years. The fistulae types (as delineated by ultrasound) were summarized in **Table(1)**.

Table (1): Fistula type by ultrasound and its success rate.

Fistula type	Number (%)	Success rate (%)
Intersphincteric	10 (62.5%)	6/10 (60%)
Transphincteric	6 (37.5%)	2/6 (34%)

The results were categorized as failure (persistent discharge) and success (no discharge), on follow up by clinical assessment (history, physical examination and transanal

ultrasound). No patients defaulted follow up at the end of the study period. The results are summarized in **Table(2)**.

Table (2): Age, sex, previous operation, fistula type and clinical results.

No.	Sex	Age	Previous operation	Fistula type	Rresults
1	Male	50	No	Intersphencteric	Success
2	Female	55	No	Intersphencteric	Failure
3	Male	43	No	Transphincteric	Failure
4	Male	35	Yes	Intersphencteric	Success
5	Male	37	No	Transphincteric	Failure
6	Female	32	No	Intersphencteric	Failure
7	Male	40	No	Transphincteric	Failure
8	Male	48	No	Intersphencteric	Failure
9	Male	39	No	Intersphencteric	Success
10	Male	53	No	Intersphencteric	Success
11	Female	51	Yes	Transphincteric	Success
12	Male	42	No	Transphincteric	Failure
13	Female	31	Yes	Intersphencteric	Success
14	Male	30	No	Transphincteric	Success
15	Male	46	Yes	Intersphencteric	Failure
16	Male	39	No	Intersphencteric	Success

All patients completed a six month and one year follow up from the last injection of fibrin sealant. The fistula completely healed and remained closed during the follow up period in 8 patients (50%) and in 8 patients (50%) a recurrent fistula was detected during the follow up period and the procedure was considered a failure, these patients refused the second injection and chose the surgical treatment. Only one patient did not respond after the first injection, chose a second injection one month after the first injection, and showed no response.

Four of sixteen patients had previous surgical attempts. The success rate for these patients was 50%(2/4).

The success rate with intersphincteric type of fistula was higher 60% (6/10) compared with the transphincteric 34% (2/6). All patients tolerated the injection procedure very well. There were no adverse effects.

Discussion:

Fibrin sealant is a treatment option for anal fistulae and possesses many advantages in the treatment of difficult high fistulae. Fibrin sealant treatment is simple and repeatable, failure does not compromise further treatment option and sphincter function is preserved.⁹

In our study, the procedure was done under general or regional anesthesia in all patients. This agrees with Zmora et al,¹ Loungnarath et al¹⁰ and Hammand et al.¹¹ But the procedure was performed without general or regional anesthesia by Chan et al² and Singer and Cintron.¹²

As regards the success rate, in our study 8 patients (50%) showed success, this was nearly the same as reported by Fuks et al,¹³ Maralcan et al,¹⁴ Zmora et al¹ and Jose et al¹⁵ (60%, 62.8%,11% and 54% respectively). But Jurczak et al¹⁶ and Vitton et al⁵ reported higher success rate (83.9% and 81.6 respectively). On the other hand Linsey et al, Loungnarath et al¹⁰ and Hammand et al¹¹ found lower success rate (30% 12% and 10% respectively). This may be due to the difference in types of fistulae included and the difference in follow up periods.

As regards the adverse effects of fibrin sealant injection, in our study no adverse effects

were reported in all patients. This goes hand by hand with, Hammand et al¹¹ and Chan et al.² But Zmora et al¹ reported many adverse effects in 47% of patients, the majority were mild and self limited such as minor pain, pruritus and perianal abscess which needed drainage.

Only one patient in this study selected to undergo repeated injection. The success rate after the second injection was lower than the initial attempt. This pass hand by hand with Zmora et al¹ and Chan et al.² But only one patient preferred a second injection in our study and this is not enough to compare with other results. But Roberto et al³ found higher success rate at repeated injection 70%.

In this study intersphincteric type of fistula have better success rate as shown in our results: 6 patients from 10 patients (60%) success rate per fistula type. While the transphincteric type of fistula has a lower success rate to the fibrin sealant injection, 2 patients from 6 patients (34%) showed success rate per fistula type. The possible explanation is that the activity of the sphincter muscle squeezed out the fibrin sealant from the fistula tract. This result is the same as reported by Chan et al² and Zmora et al.¹

As regards the successful rate of fibrin sealant injection in patients with recurrent perianal fistula, in our study the success rate was 50%. This is the same as reported by Chan et al.² But Vitton et al⁵ reported that only 14% of recurrent fistulae healed.

In conclusion, fibrin sealant injection is a useful treatment alternative in the management of high perianal fistula, it may potentially preclude more extensive surgery in half of the patients. Further study should be designed to define predictors of success for better patient selection.

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