

Comparative Study between Fibrin Glue and Surgical Treatment of Pilonidal Sinus

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ABSTRACT

Background: Published results have shown that fibrin glue may be effective in closure of pilonidal fistula. We report the final results of a randomized clinical trial evaluating the use of fibrin glue in treatment of pilonidal fistula.

Objectives: to determine the efficacy of a new simple with minimal tissue loss and a low recurrence rate technique that uses fibrin glue in the closure of pilonidal sinus (PS) in comparison with surgical technique.

Methods: the results of treatment of pilonidal fistula by fibrin glue in 10 patients were compared with those obtained by conventional surgery in another 30 patients, we carried out this study on 40 patients at Al-Zharaa University Hospital, Egypt between March 2017 and March 2019. The outcome was evaluated by recurrence or not.

Results: out of 40 patients, 19 patients were male and 21 were female. Fibrin glue injection was done in 25% of patients and surgery was done in 75%. Recurrence occur in 10 % in fibrin glue and 36 % by surgical treatment.

Conclusion: fibrin glue is a simple, reasonable, feasible, reproducible technique and competitive alternative to other surgical intervention. It is accompanied by a reduction in pain, reducing hospital stay, minimizing tissue assault, promoting early work resumption and with lower recurrence rate. In spite of the surgical approach is still the standard modality for pilonidal sinus treatment.

Keywords: Pilonidal fistula, Fibrin glue and Rhomboidal flap.

INTRODUCTION

Pilonidal sinus is a common and often difficult condition to treat. It most frequently affects men (male-to-female ratio is 3:1) between the ages of 18–40 years. It is a chronic inflammatory condition with hairs found in midline natal pits and associated secondary tract extensions. The presentation of the disease varies from acute abscess formation to chronic non-healing pits⁽¹⁾.

Many conservative and surgical methods have been described for the treatment of pilonidal sinus disease, but the standard and optimal surgical method remains controversial. The main principle in the treatment is to enable patients to return to their normal life at the earliest after a complication-free surgical procedure as well as to prevent recurrence⁽²⁾. Although it affects mainly the most active portion of society, creating a considerable health and economic burden, the best disease management strategy for PS remains unclear. A variety of operations have been described: from minimal surgical methods including simple excision, lying open, marsupialization, elliptical, medial or para-medial excision and primary closure, to complicated flap procedures such as rhomboid and rotation⁽³⁾.

In all techniques (primary closure or flap), a cavity is created after the excision of the pilonidal cyst accompanying healthy tissue; this should be filled or closed, or else it causes is a technical

problem, which is frequently encountered, and can result in complications such as “dead space”, hematoma, wound infection, and wound separation during the early postoperative period⁽⁴⁾.

The ideal management strategy should be simple with minimal tissue loss and a low recurrence rate. Furthermore, both shorter hospital stay and postoperative disability from active life should be minimal, with low cost and high cosmeses. Therefore, simple methods such as pit excision and the mechanical clearance of sinus, as well as chemical treatments, have gained greater acceptance in the management of PS. Fibrin glue has been used for three decades in many fistula diseases with varying success. It has been applied in enterocutaneous fistulas, repairing dura tears, bronchial fistulas and for achieving hemostasis after spleen and liver trauma⁽⁵⁾.

The use of fibrin glue in PS is relatively new and encouraging results have been reported. It is a tissue sealant, which uses the activation of fibrinogen to form a fibrin clot. It has been used as an adjunct to wound closure in excisional pilonidal surgery, its suggested benefit being in obliterating potential space underneath the wound. Now fibrin glue is used alone as a line of treatment with an excellent cosmeses and minimal tissue loss, without excision of large amounts of tissue⁽⁶⁾.

MATERIALS AND METHOD

Treatment of pilonidal sinus in this study is done either by fibrin glue injection or conventional surgery; we carried out this study on 40 patients at Al-Zahraa University Hospital, Egypt between March 2017 and March 2019.

Written informed consent:

An approval of the study was obtained from Al- Azhar University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

Technique:

Fibrin glue: The procedure was performed under local or general anesthesia with the patient lying prone. Antibiotic prophylaxis was given before the procedure. Iodine antiseptic solution was applied on the shaved skin of the buttocks and sterile drapes were used to expose the natal cleft. The sinus tracks were thoroughly curetted or brushed through the midline pits (after dilation if necessary) with a small Volkmann's spoon or dental brush to remove hair, debris and granulation tissue.

Care was taken to extract all debris from the sinus to avoid remaining hair and granulation tissue after the glue is injected, which could potentially lead to further acute infection. Fibrin glue (2-4 ml, as fibro glue) was then injected through the PS opening to the sinus bed to obliterate the dead space. The product is supplied in two separate syringes, one containing human fibrinogen and the second human thrombin prepared from single donor plasma in sterile disposables under aseptic precautions. Slowly withdrawing the catheter. The skin was then pressed gently onto the sacrococcygeal fascia and pressure was maintained for 2 min, until the glue was dry. A compressive dressing was applied to the area for 24 h, and thereafter small gauze was used to keep the wound covered. The patients were kept in observation for 1 to 2 hours of procedure before being discharged with oral analgesics that were prescribed for the first few postoperative days. Hygienic advices for the gluteal region were given to all patients at the discharge time.

Open method: Probing of the pilonidal sinuses were done to detect the extent of the sinuses. An elliptical incision is done using a scalpel including all the pits and is deepened vertically until all diseased tissue has been detected. Wide clearance down to sacrococcygeal fascia is not necessary, provided all the sinus tracks have been excised. The excised dimensions should be of sufficient width at both the mouth and base of the wound to allow

packing with ease. After homeostasis is obtained, gauze was lightly packed into the wound.

Closed method: The pilonidal sinus together with all secondary orifices was encircled by an elliptical incision. The caudal end of the wound was 2-3 cm from the anus and the cranial end placed at 2 cm above the origin of the natal cleft. The incision was carried vertically down to the fascia overlying the sacrum. Careful hemostasis with diathermy was fulfilled. Full thickness deep tension sutures were placed 1.5 cm from the wound margin at 2 cm interval and left united. A suction drain 18 French was inserted. The skin edges were loosed with interrupted proline (2/0) suture. A roll of dressing gauze was placed over the length of the wound with tie-over of deep tension suture over it.

Rhomboidal flap: The pathological area to be excised was mapped on the skin. The rhombus containing the pilonidal sinus was excised down to the sacral periosteum in the midline and to the gluteal fascia laterally. The wound was temporarily packed, gloves and instruments changed and meticulous hemostasis was attained by diathermy. Both flaps were mobilized deep, at the level of gluteal fascia including the subcutaneous fat with the flaps, in order to prevent dead space and to ensure flattening and obliteration of the natal cleft after transposition. The flaps were transposed and as all sides were of equal length they fit each other exactly with no tension. The wounds were sutured by deep full thickness mattress sutures with 2-0 proline. A suction drain was inserted, the wound was dressed and the patient was nursed on his side for 10 days.

Statistical methods

Data management and statistical analysis were done using SPSS v.25. (IBM, Armonk, New York, United states). Numerical data were summarized as means and standard deviations or medians and ranges. Categorical data was summarized as numbers and percentages.

Comparisons between four groups were done using Kruskal Wallis test for numerical data. Pairwise comparisons were done in case of significant overall effect and were Bonferroni adjusted. Categorical data was compared using Fisher's exact test.

All P values were two sided. P values less than 0.05 were considered significant.

RESULTS

19 patients were male and 21 were female. There were no significant differences between study group as regard age and gender. Overall P values were 0.391 and 1.0 respectively (Table 1).

Table (1): Demographic characteristics in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Age (years)	Mean±SD	36 ±9	29 ±10	32 ±12	31 ±10	0.391
Gender	Males n (%)	4 (40.0)	5 (50.0)	5 (50.0)	5 (50.0)	<0.96
	Females n (%)	6 (60.0)	5 (50.0)	5 (50.0)	5 (50.0)	

Length of stay showed overall significant difference between study groups, overall P value was <0.001. Pairwise analysis revealed that median length of stay in group I was shorter (2 hours) than that of group II, III and IV. It was 6 hours in each group. There were no significant differences between group II, III and IV (Table 2).

Table (2): Length of stay in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Length of stay (hours)	Median (range)	2 (1 - 5)	6 (4 - 6)*	6 (5 - 7)*	6 (5 - 8)*	<0.001

*= Significantly different from group I

Postoperative pain score showed overall statistical significant difference between study groups, overall P value was <0.001. Pairwise analysis revealed that median postoperative pain in group I was lower (2) than that of group II, III and IV. It was 5 in each group. There were no statistical significant difference between group II, III and IV (Table 3).

Table (3) Postoperative pain score in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Postoperative pain	Median (range)	2 (1 - 3)	5 (4 - 6)*	5 (3 - 6)*	5 (3 - 6)*	<0.001

*= Significantly different from group I

Operative duration showed overall statistical significant difference between study groups, overall P value was <0.001. Pairwise analysis revealed that median operative duration in group I was significantly shorter (19 minutes) than that of group II (39 minutes), group III (40 minutes) and group IV (49 minutes). There were no statistical significant differences between group II, III and IV (Table 4).

Table (4) Operative procedure duration in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Operative duration (min)	Median (range)	19 (10 - 25)	39 (30 - 45)*	40 (30 - 45)*	49 (40 - 60)*	<0.001

*= Significantly different from group I

Healing time showed overall statistical significant difference between study groups, overall P value was <0.001. Pairwise analysis revealed that median healing time in group I was significantly shorter (11 days) than that of group II (60 days), group III (30 days) and group IV (29 days). There was no significant difference between group III and group IV (Table 5).

Table (5) Healing time in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Healing time (days)	Median (range)	11 (7 - 14)	60 (45 - 80)*	30 (20 - 45)*#	29 (20 - 42)*#	<0.001

*= Significantly different from group I, #= Significantly different from group II

There were no statistical significant differences between study groups as regard recurrence. Overall P value was 0.443 (Table 6).

Table (6) Frequency distribution of recurrence in different study groups

		Group I (n = 10)	Group II (n = 10)	Group III (n = 10)	Group IV (n = 10)	P value
Recurrence	Yes n (%)	1 (10.0)	3 (30.0)	4 (40.0)	4 (40.0)	0.443

DISCUSSION

In this comparable study a total of 40 cases were operated upon for pilonidal sinus disease. We compared fibrin glue injection to surgical excision techniques (open and closed) and rhomboidal flap to assess the role of fibrin glue in the treatment of pilonidal sinus. There were no significant differences among the four groups with respect to age and sex.

Shabir et al. ⁽⁷⁾ have worked on 57 patients received fibrin glue injection as a monotherapy for pilonidal sinus disease, median (range) age of them was 26 (17–70) years. Forty-two (42) patients were male and fifteen (15) patients were female. In contrary to our study we worked on 40 patients divided into four groups each 10 patients, median (range) age of them was 31 (19–45) years. 19 patients were male and 21 patients were female.

We think that the main reason why PS is widely seen among males is probably because male population has more hair follicles than females and the less referral of women to health centers due to sociocultural bothers. Besides, a sex hormone activity levels are higher in young population. This could be the reason why it is usually seen in younger people. So this disease affects the young people who are between 20 and 40 and affect the most active portion of society, creating a considerable health and economic burden which gives this disease a great consideration.

Isik et al. ⁽⁸⁾ reported that fibrin glue procedure had the least score of postoperative pain, which was 2 according to VAS scale, which is similar to our study as median scale was 2 while it was 5 in other techniques. Simply; fibrin glue technique had the lowest score because it is simple non invasive technique with no excision of tissues. Open excision had the highest score (5) because the invasive excision, tissue damage of the pilonidal sinus disease (PSD), open wound management and the complications of spinal anesthesia, which are post spinal headache and low back pain⁽⁸⁾.

In our study the mean operative time was 10-25 minutes for fibrin glue injection and was 30-45 minutes for open surgical excision and was 30-45 minutes for closed surgical excision and it was 40-60 minutes in rhomboidal flap. There was a significant difference between the studied groups as regards the operative time in favour of fibrin glue injection. This may be due to longer time needed for surgical excision of the PSD. On the other hand

it was short time for fibrin glue injection due to simple curettage of the PSD and the once injection of the glue then light compression for 2 minutes until the glue formed. Throughout this study, the longest operative time was in the first cases 25 minutes for fibrin glue injection. This was because the learning curve and the time needed to prepare fibrin glue.

So, the operative time was significantly decreased in the last cases and became 10 min. The mean operative time in the present study correlate with the results of **Isik et al.** ⁽⁸⁾, who recorded 15 min for fibrin glue injection. In patients treated with open surgical excision, time ranged between 30-45 minutes which is similar to that reported by **Lin et al.** ⁽⁹⁾ which was 40–60 minutes and longer than results reported by **Sahsamanis et al.** ⁽¹⁰⁾ in which the mean operative time was 20-58 minutes.

The mean postoperative hospital stay in this study was 1-5 hours in group I and 4-6 hours in group II and 5-7 hours in group III and 5-8 in group IV. There was a significant difference in favour of group I (fibrin glue injection).

The results in this study correlated with that of **Dorman and Bass** ⁽¹¹⁾ who recorded 5.4 hours for fibrin glue injection. Also **Enshaei and Motearefi** ⁽¹²⁾ recorded that the mean postoperative stay was 6–10 hours and **Greenberg et al.** ⁽¹³⁾ recorded 8–18 hours.

In a study published by **Schneider et al.** ⁽¹⁴⁾ an average healing time of 7 to 9 weeks was reported for excision with healing by second intention. The average period of healing of 6 weeks observed in their patients can be readily compared to that obtained with the standard procedures mentioned. Only excision with primary closure, a treatment considered for not acutely inflamed pilonidal sinus, results in a clearly shorter healing time of 2 weeks⁽¹⁴⁾.

This study regarding healing after surgical excision of PS is correlated to our study, which ranged from 20-45 and also is closely similar to that reported by **Enshaei and Motearefi** ⁽¹²⁾ of 25-60 days and longer than results reported by **Dorman and Bass** ⁽¹¹⁾ of 11 days and longer than that reported by **Peterson et al.** ⁽¹⁵⁾ of 13 days and also longer than results reported by **Encabo** ⁽¹⁶⁾ which was 17–31 days. As regards to the wound healing for fibrin glue injection patients in our study, it ranged from 7-14 days which is closely similar to that reported by **Sozen et al.** ⁽¹⁷⁾ of 7-25 days and

shorter than results reported by **Yalcin *et al.*** ⁽¹⁸⁾ of 30 days.

In our study regarding the postoperative complications (wound dehiscence and wound infection) of treatment of pilonidal sinus by fibrin glue injection there were 2 cases of wound dehiscence and 8 patients with complete healing without complications, which is similar to the result reported by **Enshaei and Motearefi** ⁽¹²⁾, which was (95%), and 3 developed wound infections (11%). But In comparison to **Sozen *et al.*** ⁽¹⁷⁾ and **Demircan** ⁽¹⁹⁾ the postoperative complications of their work were 0%. In our study regarding the postoperative complications (wound dehiscence-wound infection) of treatment of pilonidal sinus by surgical excision; 7 patients were with complete healing without complications (70%), and 3 developed wound infections (30%). This is disagreed by **Encabo** ⁽¹⁶⁾ whose results were 4 patients (20%) and by **Qayyum *et al.*** ⁽²⁰⁾ who found 3 patients without complications (12%) and 6 patients developed wound infections (24%). But **Lund and Leveson** ⁽²¹⁾ had especially low participant numbers making it difficult to gauge actual complication and recurrence rates with their method of curettage.

In our study regarding the recurrence rate after fibrin glue injection group at a follow up period of 36 months, 1 patients developed postoperative recurrence (10%). This result is closely similar to results reported by **Demircan** ⁽¹⁹⁾ which was (12.5%) and relatively similar to the results reported by **Lund and Leveson** ⁽²¹⁾ which was (17%), and also (5%) reported by **Isik *et al.*** ⁽⁸⁾, but it disagrees with **Dorman and Bass** ⁽¹¹⁾, **Enshaei and Motearefi** ⁽¹²⁾ and **Sozen *et al.*** ⁽¹⁷⁾, who all reported (0%) recurrence rate. In the present study regarding recurrence after open surgical excision it was 30% which agreed with a study made by **Zahid *et al.*** ⁽²²⁾ using lay open technique on 20 patients with a follow up for 6-12 month; the results showed recurrence in 25%. In our study we offered a novel technique for treatment of pilonidal sinus disease compared to other conventional surgical methods, this novel procedure tended to close the dead space of PS after the curettage by the help of fibrin glue.

Our results using autologous fibrin glue go parallel to those mentioned above. The overall success rate measured by pilonidal sinus sealant was 90%. Fibrin glue also offered a significant advantage between the three other procedures in terms of postoperative complications, hospital stay, wound healing, postoperative pain and recurrences.

Considering the limitation of this study, it was imposed by the relatively small number of patients. The 10% recurrence rate occurring among

fibrin glue patients was better than the 30-40% recurrences in other groups. Fibrin glue was successful in sealing the pilonidal sinus in 90% in our study. But in comparison to other results which were reported by **Sozen *et al.*** ⁽¹⁷⁾ and **Yalcin *et al.*** ⁽¹⁸⁾ and were 100% successful sealing, we found that fibrin glue failed to seal the PNS and this is due to learning curve in preparing the fibrin glue or may be due to its concentration.

Conclusion

Fibrin glue is a simple, reasonable, feasible, reproducible technique and competitive alternative to other surgical intervention. It is accompanied by a reduction in pain, reducing hospital stay, minimizing tissue assault, promoting early work resumption and with lower recurrence rate. In spite of the surgical approach is still the standard modality for pilonidal sinus treatment, this study suggested fibrin glue procedure as the first-line treatment of PS patients who have no history of infection and have only 1-3 sinuses. We welcome larger, preferably randomized and controlled trials to confirm the results of this study in the future.

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