Original Article

The use of fibrin glue in surgical treatment of pilonidal sinus disease: A prospective study in the limberg flap procedure

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ABSTRACT

Objective: Different surgical techniques for pilonidal disease have been described in the literature. Limberg flap has low morbidity and recurrence rates. Fibrin sealant, a two-component tissue adhesive composed of fibrinogen and thrombin, has been used in a number of surgical procedures to achieve hemostasis and to seal tissues. The purpose of this study was to investigate the effect of fibrin sealant on the Limberg flap procedure.

Methodology: 132 male patients with pilonidal sinus who underwent Limberg flap operation were evaluated prospectively. The patients were assigned randomly into two groups (group 1; with suction drain, group 2; fibrin glue).

Results: Seroma was encountered in 5 of 132 patients (3.78%); Flap oedema occurred 4(6.06%) patients in group 1. Wound infection occurred in one patient (1.5%) in group 1. Most patients in group 2 were mobilized on the first postoperative day, and the median time to first mobilization was earlier in group 2 than in group 1 (1 (1–1) *versus* 2 (1–2) days respectively; $P<0{\cdot}001$). The median duration of incapacity for work was 17 (15–20) days in group 1 and 8 (6–12) days in group 2 ($P < 0{\cdot}001$).Total wound dehiscence and flap necrosis did not occur in any patient. There has been no recurrence in any of the patients during the follow-up period. The mean time for complete healing of wound after rhomboid excision and Limberg flap plus fibrin sealant was 8.13±7.88 days (range 6-28 days). This was markedly increased in group 1 patients (mean 22.08±8.59 days, and range 15-60)($p < 0.001$).

Conclusion: We recommend the use of fibrin sealant with Limberg flap technique. Our results suggest that drains may be avoided with fibrin sealant.

KEY WORDS: Pilonidal disease, Limberg technique, Fibrin sealant, Surgical techniques.

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INTRODUCTION

Sacrococcygeal pilonidal disease may be treated by a number of surgical techniques. When primary closure, lay-open technique, and marsupialization are compared, primary closure has been shown to have the advantage of earlier wound healing and shorter hospitalization.[1] An ideal operation for pilonidal disease should be simple, necessitate a short hospital stay, and have a low recurrence rate. In the literature, different surgical methods have been described for this condition. Most commonly, marsupialization, primary midline closure and skin flaps are used as treatment.[2,3] Different rates of

morbidity and recurrence and hospitalization times have been reported for each technique.[2,4] Among skin flaps, the Limberg flap has been procedure of choice because of its relatively low morbidity and recurrence rate.[2–4] Fibrin sealant, a two component tissue adhesive composed of fibrinogen and thrombin, has been used in a number of surgical procedures to achieve hemostasis and to seal tissues.[5] Therefore, the purpose of this study was to investigate the impact of fibrin sealant on wound healing and length of hospitalization after Limberg flap procedure for pilonidal sinus.

METHODOLOGY

Between January 2007 and January 2009, 132 consecutive male patients with pilonidal disease were enrolled in the study. Patients with recurrent disease, having a very large cavity and sinuses extending lateral to the natal cleft and orifices near to the anus were excluded from the study. The patients were randomized into two groups drained and non-drained according to the admission protocol number. In the control group, patients were treated with standard Limberg flap technique. In the fibrin sealant group, patients were treated with standard Limberg flap technique plus fibrin sealant application. Skin sutures were removed on the tenth postoperative day.

The duration of operation, postoperative pain, time to first mobilization, length of hospital stay, duration of incapacity for work, postoperative complications (infection, flap oedema, wound dehiscence, seroma) and wound healing time were recorded. Duration of operation was defined as the length of time between the first incision and placement of the last suture. Postoperative pain was assessed according to a visual analogue scale (VAS) from 0 (no pain) to 10 (the worst pain imaginable) on the first postoperative day. Patients were discharged from hospital when the drain had been removed (Group 1) and intramuscular analgesia was no longer required (Group 1 and Group 2). Duration of incapacity for work was defined as the time from the date of surgery to the date on which the patient returned to normal activities including employment and leisure activities. A questionnaire was used to assess the duration of recovery. All patients are reviewed weekly until the wound had healed and there after every three months for one year.

Surgical technique: All the patients were operated under spinal anaesthesia. Antibiotic prophylaxis was done, using 1gm of intravenous Cefotaxime at the time of induction of anaesthesia. After anesthesia, the patients were placed in the prone, jack-knife position, with buttocks strapped apart with the use of wide adhesive tape. Methylene blue was injected in the sinus tract using 6 Fr feeding tube. The excision was carried down to the fascia overlying the sacrum and laterally to the fascia of the gluteus maximus muscle. Dissection was performed with electrocautery. A Limberg flap was prepared from the right or left gluteal region. A suction drain (B-VAK Wound Drainage System™, 10 Ch, Ref. 17110211, BiCakCilar, Istanbul, Turkey) was placed through a separate incision located 2 cm lateral from the initial incision in 66 (50 percent) patients (Group 1) and kept in place until the drainage decreased to less than 10 ml/day. In group II, 6 ml fibrin sealant (CryoSeal FS System, Thermogenesis, Rancho Cordova, USA) was sprayed on to surgical site and under the flap using a double-barrel syringe and spray tip applicator (Fig-1a). Afterward, the wound was immediately closed, allowing the fibrin sealant to seal the apposed tissues. Rapid closure permitted polymerization of the sealant while skin and underlying fascia were in direct contact, helping to eliminate any potential space. The skin was sutured with 000 polypropylene sutures (Fig-1b).

Statistical Analysis: Student's *t* test was used for comparison of age between the groups. Complications were analysed with the $\chi 2$ test. Time to first mobilization, length of hospital stay, duration of incapacity to work, follow-up period, duration of operation and VAS pain scores were analysed with the Mann–Whitney *U* test. The probabilities of less than 0.05 were accepted as significant.

RESULTS

The study enrolled 132 men with pilonidal disease, of which 66 were treated with standard Limberg flap procedure plus drainage and 66 were treated with Limberg flap plus fibrin sealant (Table-I).

There were no significant differences between the two groups in terms of age and body mass index (BMI). The mean age was 24 (range, 20–36) years. The operative time was longer in group 1 patients (45 minutes). Hospitalization time in the control group was also significantly higher than that in the fibrin sealant group (mean, 3.5vs 2.0 days; $p<0.001$). Most patients in group 2 were mobilized on the first postoperative day, and the median time to first mobilization was earlier in group 2 than in group 1 (1 (1–1) *versus* 2 (1–2) days respectively; $P<0\cdot001$). The median duration of incapacity for work was 17 (15–20) days in group 1 and 8 (6–12) days in group 2 ($P < 0\cdot001$) (Table-II). The mean follow-up in the control

Table-I: Clinical, operative characteristics and complications between groups.

	Group 1	*Group 2*	*p value*
Gender	66 male	66 male	
Mean age (yr) (range)	25 (21-33)	23.5(20–36)	0.21**
BMI, kg/m2	25,75	26	0.55**
Hospitalization time, days	3,5	2	<0.001*
Fluid collection N (%)	4 (6.06%)	1(1.5%)	0.017**
Wound infection	1((1.5%)	0	0.022**
Flap oedema	4 (6.06%)	1(1.5%)	0.017**

Group 1 = with suction drains.
Group 2 = without drains.(fibrin selant)
*Mann–Whitney U test. **χ2 test

group was six months and in the fibrin sealant group 2 months. In the control group, one patient had infection (1.5%) and four had seroma (6.06%). Total wound dehiscence and flap necrosis did not occur in any patient. Five patients (3.78%) had seroma with negative culture in all groups. Flap oedema occurred 4(6.06%) patients in group 1. Wound infection occurred one patient (1.5%) in group 1 (Table-I). The mean time for complete healing of wound after rhomboid excision and Limberg flap plus fibrin sealant was 8.13±7.88 days (range 6-28 days). This was markedly increased in group 1 patients (mean 22.08±8.59 days, and range 15-60) (p <0.001). The median VAS pain score was significantly lower in group 2 patients ($P < 0.001$). There has been no recurrence in any of the patients during the follow-up period.

DISCUSSION

Sacrococcygeal pilonidal disease may be treated by a number of surgical techniques. When primary

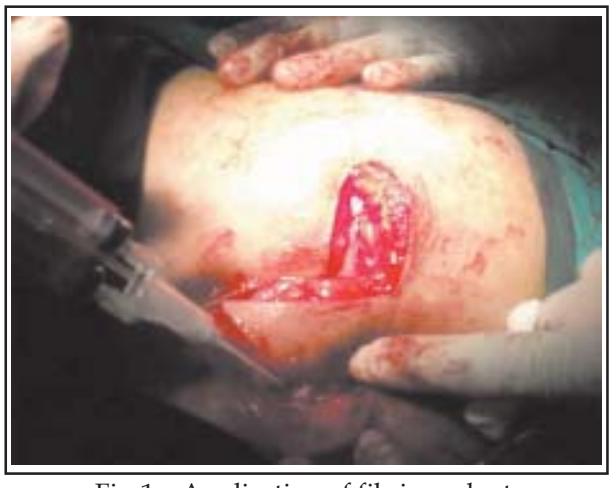

Fig-1a: Application of fibrin sealant.

Table-II: Operative and postoperative outcomes.

	Group 1	*Group 2*	*p value**
Duration of operation (min)	50 (40–70)	45(40–60)	0.001
Pain VAS score	4 (2–6)	2 (1–3)	<0.001
Time to first mobilization(days)	2 (1–2)	1 (1–1)	<0.001
Duration of incapacity for work (days)	17 (15–20)	8 (6–12)	<0.001
Complete healing time(days)	22.08±8.59 (15-60)	8.13±7.88 (6-28)	<0.001

*Mann–Whitney U test
Group 1 = with suction drains.
Group 2 = without drains. (fibrin selant)

closure, lay-open technique, and marsupialization are compared, primary closure has been shown to have the advantage of earlier wound healing and shorter hospitalization.[1] Routine drainage of the cavity after excision with primary closure[6], Limberg flap procedure[7], and asymmetric excision with primary closure[8] has been suggested by other investigators.[9] One recognized problem associated with flap construction is early development of seroma and haematoma formation. This predisposes to wound infection and flap failure. To prevent this, insertion of suction drainage has been advocated by many centers. However, Erdem et al[10] reported that there was no difference in early wound complications between the drained and nondrained patients treated with the Limberg flap procedure. Erdem et al. operated on 40 patients with Limberg flap. They were divided the patients into closed suction drain group (n=19) and nonclosed suction drain group (n=21). They did not find any statistical significant differences between groups in the length of hospital stay,

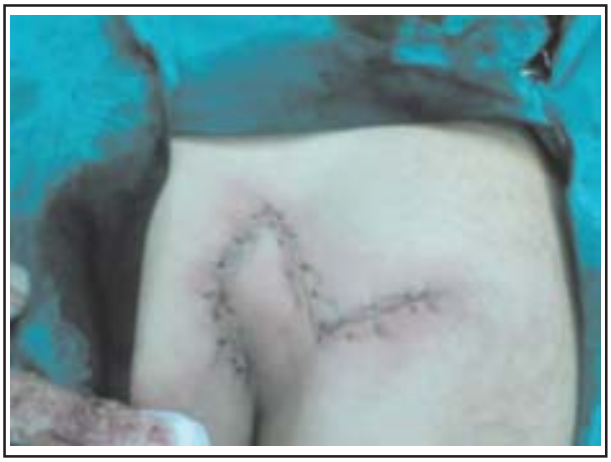

Fig-1b: Final stage of the operation. The skin was closed with interrupted mattress sutures.

infection and haematoma rate.[10] Different series have reported wound infection rates of 1.5-7%.[3,11]

Bozkurt & Tezel[2] and Urhan et al[12] had reported a mean hospital stay of 3.7 days and 4.1 days respectively. This is similar to what we have observed in our study. In contrast to that, patients who underwent simple excision of the sinus tract had to stay for a longer time in hospital due to presence of an open wound. The reported recurrence rate for Limberg flap varies from 0.8 to 2.7%, respectively[9]. Topgul et al operated on 200 patients and recurrence was noted 2.5%.[8] Daphan et al operated on 147 patients with a median follow-up time of 13.1 months, and recurrence was noted 4.8%.[13] The use of drains after Limberg flap has been challenged in a randomized trial that demonstrated that drains were not needed after Limberg flap.[10] Nonetheless, drains have continued to be used by all surgeons performing this technique.[14] Fibrin sealant is a biological adhesive that imitates the final stage of coagulation. It is composed of purified, virus-inactivated human fibrinogen and thrombin. Fibrin glue promotes wound healing by enhancing homeostasis and angiogenesis, and by stimulating macrophages, which have a role in fibroblast proliferation and collagen production in the wound site.[15,16] It stimulates the normal clotting process and is subsequently resorbed by normal tissue enzyme systems, without causing foreign-body reaction or extensive fibrosis. Fibrin sealant has also been shown to be effective in reducing seroma formation in animal models of mastectomy and in reducing drainage after axillary dissection.[17,18] Altinli E et all suggest that drains may be avoided with fibrin sealant.[19] Disadvantages of using drains include prolonged hospital stay, patient discomfort, and increased risk of infection.[9,14] Because of the drastic decrease in wound drainage observed in the patients treated with fibrin sealant, we propose that drains may be safely avoided without accumulation of serous fluid and risk of infection.[10,16] Disadvantages of using drains include prolonged hospital stay, patient discomfort, and increased risk of infection.[10,16] Postoperative pain scores were significantly lower in group 2 than in group 1, presumably because less wound tension was created.

CONCLUSION

We believe that Limberg flap is a very efficient surgical technique of flattening the natal cleft. Hospitalization time and fluid collection amount were less in the fibrin sealant group than in the control group. It is not necessary to use closed suction drain after Limberg flap procedure. We recommend the use of fibrin sealant with Limberg flap technique. Our results suggest that drains may be avoided with fibrin sealant.

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