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Clinical trial comparing excision and primary closure with modified Limberg flap in the treatment of uncomplicated sacrococcygeal pilonidal disease

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KEYWORDS	Abstract The aim of this study was to compare modified Limberg flap procedure with excision and
Pilonidal disease;	primary closure in the treatment of uncomplicated pilonidal disease.
Simple closure;	Methods: This study was conducted on 120 patients with uncomplicated sacrococcygeal pilonidal
Rhomboid flap	disease that were randomly allocated into two groups: group I underwent excision and primary clo- sure; group II underwent modified Limberg flap procedure. The duration of operation, postopera- tive pain, length of hospital stay, duration of incapacity for work, postoperative complications and postoperative recurrence were recorded. <i>Results</i> : Duration of operation was longer in group II than in group 1 ($P < 0.001$). However, post- operative pain was less ($P < 0.001$), duration of hospital stay shorter ($P < 0.001$), time to resump- tion of work shorter ($P < 0.001$) and postoperative complications were significantly fewer in group II. During follow-up period of 21.5 \pm 6.82 (months) for group I and 22 \pm 7.64 (months) for group II, single case of recurrence 1.67% was detected in patients in group II versus four patients (6.67% patients) in group I ($P = 0.032$). <i>Conclusion</i> : Wide excision with a modified Limberg transposition flap reconstruction is a very effec- tive operative procedure for uncomplicated pilonidal sinus, associated with a low complication rate, short hospitalization and disability, and a low recurrence rate. © 2011 Alexandria University Faculty of Medicine. Production and hosting by Elsevier B.V. All rights reserved.

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1. Introduction

Pilonidal sinus is known to be a simple condition that refers to a tract or cavity that contains loose hair and is associated with repeated infection and abscess formation. Its incidences are higher in male than in female and increase with obesity and hairy skin.¹ It is more common in people aged 15–30 years after puberty due to the effect of sex hormones on pilosebaceous glands and change in healthy body hair growth.²

Although different surgical approaches have been used to manage sacrococcygeal pilonidal sinus, none of these approaches eliminate the postoperative morbidity including delayed wound healing, discomfort and high rate of recurrence which range between 1% and 43% in different studies.³

The surgical wound may be left to heal by open healing (secondary intention). Advocates of this technique state that reduced wound tension facilitates trouble free healing without recurrence if all sinus tracts are fully excised. Alternatively, the wound may be closed to heal by primary closure (primary intention). Methods can be broadly categorized as midline closure techniques (with the wound lying within the natal cleft) or other techniques (where the wounds placed out with the midline). Advocates of primary closure perceive benefits of faster tissue healing.^{4,5}

Excision and primary closure involve excision of the entire sinus with closure of the wound. This procedure has the advantage of avoiding wound packing. One problem is that the incision tends to be situated in a deep midline cleft where there is tension and also the propensity to accumulate hair.⁴

Skin flaps have been described to cover a sacral defect after wide excision; this keeps the scar off the midline and flattens the natal cleft. The techniques available include the cleft closure, advancement flap (Karydakis procedure), local advancement flap (V-Y advancement flap), and rotational flap (Limberg flap, modified Limberg flap, gluteus maximus myocutaneous flap).^{5,6}

However, there have been few clinical studies to compare the rhomboid fasciocutaneous transposition flap procedure (modified Limberg flap) with other conventional procedures in the treatment of uncomplicated pilonidal disease. The recurrence rate in the modified Limberg flap group was lower than the recurrence rate in the other flap techniques. The modified Limberg flap technique provides a more efficient flattening of the natal cleft, including the most inferior part that is inclined to invert towards the anal region, lateralization of the inferior apex of the classic Limberg flap decrease recurrences which could occur in the inferior midline.^{6,7} The aim of this study was to perform a randomized clinical trial to compare the modified Limberg flap procedure with excision and primary closure in the treatment of uncomplicated pilonidal disease.

2. Methods

This study was conducted in Colorectal Unit, Surgery Department at the Alexandria University Hospital during the period from February 2008 to March 2011. One hundred and twenty patients who were treated for uncomplicated pilonidal disease were eligible for the study. The patients who presented with acute pilonidal abscesses were excluded from this study. Recurrent or complex pilonidal sinuses were also excluded from this study.

Informed consent was obtained from all patients included in the study which was approved by the local ethics committee. All patients were subjected to history taking, clinical examination, and laboratory test. Randomization was achieved through a computer-generated schedule and the results were sealed into envelopes. The envelopes were drawn and opened by a nurse in the operating room.*The patients were then randomized into two groups*: group I underwent excision and primary closure; group II underwent modified Limberg flap procedure.

All patients were operated under general anaesthesia. Patients were placed in prone Jack-knife position with two adhesive straps in each glutted region to pull them laterally to allow better visualization of the natal cleft, then shaving off the hairs around the sinus and cleaning the area with povidone iodine. Antibiotic prophylaxis of 1.2 g amoxicillin–clavulinic acid was given intravenously at the time of induction and continued for 48 h. Then this was changed to oral form for five days.

2.1. Group I (excision and primary closure procedure)

The procedure begins by excising the wound, with the sinuses removed en bloc with a vertical elliptical specimen of overlying skin to the level of the sacrococcygeal fascia. After placing deep approximating 0 polyglactin sutures (VicryITM; Ethicon, New Jersey, USA), the skin was approximated with 3/0 polyglactin interrupted subcutaneous sutures (VicryITM; Ethicon, New Jersey, USA) and the skin edges were closed with 2/0 polypropylene interrupted mattress sutures (Propilen; Dogsan, Trabzon, Turkey). At the end of the procedure, a suction drain was inserted from a separate incision (Figs. 1 and 2).

2.2. Group II (modified Limberg flap)

The lesion was excised with a rhomboid shaped incision with each side equal in length (Figs. 3 and 4) with lateralization of the inferior apex. The depth of the rhomboid excision was extended to the gluteal fascia. The rhomboid flap was then rotated from the gluteal fascia to the excised area without tension. Subcutaneous tissue sutured with interrupted 3/0 vicryl (VicrylTM; Ethicon, New Jersey, USA) and the skin was sutured separately with interrupted proline 2/0 sutures (Propilen; Dogsan, Trabzon, Turkey) (Fig. 5). At the end of the



Figure 1 Skin edges were closed with 3/0 polypropylene interrupted mattress sutures.



Figure 2 The wound was closed in multiple layers over a closed suction drain.



Figure 3 Rhomboid shaped incision with each side equal in length.



Figure 5 The rhomboid flap was then rotated from the gluteal fascia to the excised area without tension.

procedure, a suction drain was inserted. Methylene blue was not used to identify the tracks in either group. A single dose of antibiotic prophylaxis was used immediately before incision.

Patients were discharged when clinically free after the operation, removal of the drain 4–5 days after operation and all patients were advised to visit the outpatient clinic every week for one month and then every 3 months for at least 12 months during the follow-up period. Stitches were removed 14 days postoperatively (Figs. 6 and 7). All patients were recommended to walk freely but not to exercise until removal of stitches. All patients were advised to shave the area well around the operative site at least monthly.

The duration of operation, postoperative pain, length of hospital stay, duration of incapacity for work, postoperative complications (infection, flap oedema, wound dehiscence), and postoperative recurrence 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 (worst pain imaginable) on the first postoperative day. Duration of incapacity for work was defined as



Figure 4 Rhomboid shaped incision with each side equal in length.



Figure 6 The rhomboid flap after removal of stitches.



Figure 7 Primary closure after removal of stitches.

the time from the date of surgery to the date on which the patient returned to normal activities including employment and leisure activities. Infection was considered as leakage of purulent secretion through the surgical wound and not only peri-incisional hyperaemia.

2.3. Statistical analysis

The statistical analysis of data was done by using excel programme and SPSS program statistical package for social science version 10. The description of the data was done in the form of mean \pm SD for quantitative data, frequency and proportion for qualitative data. The analysis of the data was done to test statistical significant difference between groups. For quantitative data Student's *t*-test was used to compare between two groups. Chi square test, and Fisher's exact test was used for qualitative data.

N.B.: *P* is significant if ≤ 0.05 at confidence interval 95%.

3. Results

This study was conducted on 120 patients with uncomplicated sacrococcygeal pilonidal disease that were randomly allocated by closed envelop technique into two groups, group I (60 patients) the mean age was 27 ± 9.4 years (46 men, and 14 women) who underwent excision and primary closure procedure and group II (60 patients) the mean age was 26 ± 8.6 years (45 men, and 15 women) that underwent modified Limberg flap procedure. There was no significant difference between both groups regarding age, sex, preoperative symptoms, and period of follow-up. Intermitted discharge and pain were the most common symptoms. Follow-up (months) was 21.5 ± 6.82 for group I and 22 ± 7.64 for group II (Table 1).

Operative data showed that the operative time (minute) for group I was 40.6 ± 6.8 which was significantly less than that for group II 55.2 \pm 7.6. However, hospital stay, pain score, period off work, and healing period were significantly higher in group I than for group II (Table 2).

Postoperative follow-up showed that incidence of complications was significantly higher among patients of group I as

Table	1 I	Demographic	and	pre-treatment	symptoms	of
patients	with	h uncomplicat	ed sad	crococcygeal pil	onidal diseas	se.

Group I $(n = 60)$	Group II $(n = 60)$	P value
46:14	45:15	0.4139 ^a
$27~\pm~9.4$	$26~\pm~8.6$	0.6648^{a}
21.5 ± 6.82	$22~\pm~7.64$	0.3955 ^a
51	49	0.3138 ^b
38	36	0.3550 ^b
16	17	0.5778^{b}
3	4	0.6542 ^b
	$\begin{array}{c} 46:14\\ 27 \pm 9.4\\ 21.5 \pm 6.82\\ 51\\ 38\\ 16 \end{array}$	$27 \pm 9.4 \qquad 26 \pm 8.6 \\ 21.5 \pm 6.82 \qquad 22 \pm 7.64$ 51 $49 \\ 38 \qquad 36 \\ 16 \qquad 17$

^b Chi square test.

Table 2 Outcome after surgical treatment.					
	Group I $(n = 60)$	Group II $(n = 60)$	P value [*]		
Operation time (minute)	$40.6~\pm~6.8$	55.2 ± 7.6	< 0.001*		
Hospitalization (days)	$3.8~\pm~1.6$	2.1 ± 1.2	$< 0.001^{*}$		
Period off work (days)	21.6 ± 3.5	16.2 ± 2.1	< 0.001*		
Pain VAS score	5.2 ± 1.4	2.1 ± 1.2	< 0.001*		
Healing Period (days)	$19.1~\pm~3.7$	$14.1~\pm~2.9$	< 0.001*		
VAC : 1 1 1					

VAS, visual analogue scale.

* Denotes a significant P value

wound infection occurs in six patients 10%, flap oedema in eight patients 13.33%, wound dehiscence in four patients 6.67% and recurrence in four patients 6.67% (Table 3).

4. Discussion

The varied surgical techniques proposed for the eradication of pilonidal sinuses are evidences of the lack of a completely satisfactory method of management of this surgical problem. Most of the procedures have some merits and are based on seemingly sound surgical principles, but regardless of the methods employed, there is recurrence in a significant proportion of cases.

Complete excision of the sinus is widely practiced, but controversy remains about what to do with the wound after excision.⁵ Excision and packing, excision and primary closure, marsupialization, and flap techniques are surgical procedures that have been developed for treatment of pilonidal sinus.⁸ Despite the controversy about the best surgical technique for the

Table 3Postoperative complications.					
Group I $(n = 60)$	Group II $(n = 60)$	P value ^a			
6 (10)	2 (3.33)	0.0295 ^a			
8 (13.33)	2 (3.33)	0.0166 ^a			
4 (6.67)	1 (1.67)	0.0322 ^a			
4 (6.67)	1 (1.67)	0.0322 ^a			
	$\begin{array}{c} Group I \\ (n = 60) \\ \hline 6 (10) \\ 8 (13.33) \\ 4 (6.67) \end{array}$	Group I Group II $(n = 60)$ $(n = 60)$ 6 (10) 2 (3.33) 8 (13.33) 2 (3.33) 4 (6.67) 1 (1.67)			

^a Fisher's exact test.

treatment of pilonidal sinus, an ideal operation should minimize financial cost, allow patients to return earlier to work, be simple to perform, not require a prolonged hospital stay, inflict minimal pain, and have a low disease recurrence rate.⁹

Wide excision and healing by secondary intention enjoys considerable popularity, the advantage of this method is that all inflamed tissues are removed and the chance of recurrence is low, but need long hospitalization and daily dressing, moreover time to healing is long and may exceed one year in the most unfortunate patient.¹⁰ Compared with open packing and marsupialization, excision and primary closure are known to provide quicker healing and quicker return to work. Most patients return to work in 3–4 weeks¹¹ but recurrence rates of 7–42% have been reported following excision and primary closure, ^{12,13} while a number of studies have reported a recurrence rate of 0–3% after rhomboid excision and Limberg flap repair outweigh the disadvantages related to an unfavourable cosmetic appearance following rhomboid excision and Limberg flap closure.^{14–16,6}

The higher morbidity of surgical techniques was naturally reflected by hospital stay and time off work. In our study, the hospital stay for patients treated with modified Limberg flap was 2.1 \pm 1.2 days, which was shorter than 5.5 days as reported by Rossi et al.¹⁷ for Limberg flap and 5.7 days as reported by Singh et al.¹⁸ for adipo-fasciocutaneous flap. In our study, the mean hospital stay was 3.8 ± 1.6 in primary closure group, and the difference between the groups was significant. Time off work was significantly shorter for patients treated with modified Limberg flap as compared with patients treated with primary closure $(16.2 \pm 2.1 \text{ versus } 21.6 \pm$ 3.5 days), and this shorter duration in the flaps group was similar to that reported by Abu Galala et al.¹⁹ and Eryilmaz et al.¹⁵, while Gilani et al.²⁰ found that the mean time to return to work after primary closure was 25.5 days, while Lieto et al.²¹ found that the mean time to return to work was 7 days in patients with rhomboid flap while Muzi et al.²² found that there was no significant difference found in time to return to work and wound disruption.

In the current study postoperative pain scores (VAS scores) were significantly lower in group II than in group I (2.1 \pm 1.2 versus 5.2 \pm 1.4), presumably because less wound tension was created with the Limberg flap procedure, similar results were achieved by Mahdy²³ and Akca et al.²⁴ Healing period was significantly shorter in group II than in group I (14.1 \pm 2.9 days versus 19.1 \pm 3.7 days) this is also achieved by Eryilmaz et al.¹⁵ Akca et al.²⁴ and Muzi et al.²²

In the current study the rate of infection in group II was 3.33% which is significantly lower than group I with six cases of infection ie 10%, similar results were reported in literature with an infection rate range of 1.5-6% with Limberg flap,^{15,24,25} and infection rate around 10% with excision and primary closure^{24,26} which could be explained by tension on the suture line and the formation of a serosanguineous collection in the subcutaneous layer leads to infection and breakdown of the wound with excision and primary closure.

Preventing recurrence is a major concern in the surgical treatment of pilonidal sinus. Postoperative complications and recurrences, like the original sinus, develop in the midline and as the natal cleft becomes deeper, an anaerobic medium is created, resulting in an increased anaerobic bacterial content.²⁷ Furthermore, the vacuum effect created between the

heavy buttocks sucks the anaerobic bacteria, hair, and debris into the subcutaneous fat tissue.²⁸ We believe that our successful results after flap reconstructions stem from the fact that the deep midline is eliminated. When the midline is lateralized or flattened, recurrences are less likely to occur than after primary closure. In the current series recurrence observed in only one patient 1.67% with modified Limberg flap procedure which was significantly lower than recurrence with excision and primary closure which was observed in four patients ie 6.67%. Other authors have reported recurrence rates of 0–3% with Limberg flap repair.^{14–16,6} Foss²⁹ reported on a collective series of 1129 patients treated with excision and closure of their pilonidal disease. Failure of primary healing was 16% and recurrence rate was 16%.

In conclusion, the results of this series provided further evidence that wide excision with a modified Limberg transposition flap reconstruction is a very effective operative procedure for uncomplicated pilonidal sinus, associated with a low complication rate, short hospitalization and disability, and a low recurrence rate.

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