Tension-free primary closure compared with modified Limberg flap for pilonidal sinus disease: a prospective balanced randomized study

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Background
Pilonidal sinus disease (PSD) is a common disease that affects the patient's quality of life. We analyzed the outcome of the tension-free primary closure (TF 1ry) in comparison with the modified Limberg flap (MLF) technique.

Patients and methods
A total of 120 patients suffering PSD were assigned to one of two equal groups by closed envelope balanced randomization. Group I represents TF 1ry method and group II represents MLF.

Results
There were 102 (85%) male patients and 18 (15%) female patients elected for surgery. The mean follow-up period was 43.5 ± 3.4 months. There were no statistically significant differences between the two groups regarding patients' demographic data, clinical presentation, immediate postoperative complications, and disease recurrences. The operative time, blood loss, hospital stay, surgeon's performance scale, wound hypothesia, wound cosmoses score, patient satisfaction score, and patient quality of life (bodily pain and social functioning) were better in the TF 1ry group. The MLF group had better clinical results regarding frequency of seroma formation and time to drain removal.

Conclusion
Flap techniques are effective and efficient for PSD. TF 1ry closure can be tailored for female PSD patients and a junior surgeon. MLF can be tailored for male PSD patients and a senior surgeon.

Keywords:
Limberg flap, pilonidal sinus, primary closure

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Introduction

Pilonidal sinus disease (PSD) is a common and well-recognized entity. Hodge in 1880 suggested the term pilonidal disease [1]. It typically affects young male patients after puberty [2]. Absence of the exact etiology explains the diversity of treatment lines [3] and failure of treatment options [4]. Radical treatment has been wide excision of the chronic tracts with or without closure. Higher morbidity rate has been reported with primary closure due to tissue tension [5,6].

The main problem is the high rate of recurrence, which can diminish the patient's quality of life (QoL) [7]. Hence, the ideal operation should minimize PSD recurrences and financial cost (patient–community), should have short hospital stay, should cause minimal pain, should be associated with a low patient and procedure morbidity rates, and should be simple for surgeons [8].

Flap techniques reduced PSD recurrences and wound morbidity due to 'tension-free' healing site. Modified Limberg flap (MLF) technique is a simple modification of classic Limberg flap to eliminate midline maceration and reduce recurrence rate [9,10]. Tension-free primary closure (TF 1ry) has been suggested to avoid wound dehiscence, wound infection, and recurrence [4,11,12].

In this study, sufficient sample size was enrolled, and objective scoring systems were performed for procedures, patients, and surgeons.

The aim of study was to compare TF 1ry versus MLF technique regarding recurrence as a primary outcome measure. The secondary outcome measures included:

(a) Patient-related factors: postoperative pain scores (patient inconvenience), time to sit on toilet and walk pain free (patient financial cost), the QoL, and satisfaction;
(b) Procedure-related factors: operative time, blood loss, immediate postoperative complication, hospital stay (community financial cost), and wound morbidities; and
(c) Surgeon-related factor: surgeon performance.

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Patients and methods

This study was a prospective randomized single-blinded clinical trial. Local ethics committee approval was obtained. A total of 165 patients with PSD were referred to Mansoura General and Colorectal Surgery Units between March 2006 and September 2012. Forty-five patients were excluded from the study (15 patients were medically unfit and 30 had pilonidal abscess). The remainder patients (120) were enrolled in the study. They were assessed by documentation of clinical symptoms and their duration, full discussion of pain, satisfaction, and the QoL scores. Patients were prepared by overnight evacuation enema and operative site shaving on the day of surgery. Perioperative antibiotics 'ampicillin–sulbactam' were used. All patients received spinal anesthesia, except if sinus tracts were too high, general anesthesia was used. Patients were operated upon using the prone Jack knife position. Patients were randomized at operation room using sealed envelope into two equal groups.

Group I patients (tension-free primary closure)

It included 60 patients with a mean age of 27 ± 6.8 years. All of them were subjected to TF 1ry [13]. Excision of the sinus tract with elliptical skin incision was performed followed by 3 cm lateral subcutaneous tissue release. Suction drain was inserted. Flaps closure was achieved by 0 vicryl sutures including the presacral fascia and subcutaneous tissue by 3/0 vicryl sutures. Skin closure was performed with 3/0 polypropylene sutures or skin staples (Fig. 1).

Group II patients (modified Limberg flap)

It included 60 patients with a mean age of 28 ± 7.6 years. All of them were subjected to excision of the sinus tract and reconstruction with MLF technique [14]. A rhombus-shaped area of excision was mapped with a skin marker; its lower angle is not in the midline but 2 cm lateral to the anal canal to avoid any midline remnants below the flap. All sinus tracts were excised en-block deep until the presacral fascia in the midline and the gluteal muscles laterally. Rhomboid flap was then fashioned from the other buttock incorporating skin, subcutaneous fat, and gluteal fascia and stitched in place over a suction drain (Fig. 2). Drains were removed when outcoming serous fluid volume was below 20 ml/day. Sutures were removed on 10th postoperative day.

Follow-up visits were performed every week for 1 month, monthly for the first year then every 3 months. Operative time, blood loss, hospital stay, immediate postoperative complications, wound morbidities in the form of maceration (soft, white, and wet skin), infection (cellulitis or purulent discharge from wound edge or drain), gaping (separation of all wound layers), seroma, time of drain removal, sit on toilet, and walk pain free (walk comfortably without pain or tension) were documented. The visual analog scale (VAS), which is a measurement instrument for subjective characteristics, was used to measure postoperative pain [15], patient satisfaction [16], surgeon performance [17], and wound cosmoses [18]. Patients completed two VASs; the first evaluated postoperative pain on first and seventh days and at second and fourth weeks postoperatively, and the second measured patient satisfaction at the third postoperative month. Surgeons similarly recorded two VASs; the first was for surgeon performance at the end of surgery in terms of anatomy, tissue planes, and patient characters, and the second was for wound cosmoses at third postoperative month.

Figure 1

Tension-free primary closure (immediately postoperative).

Figure 2

Modified Limberg flap technique after sutures removal.

At the third month, the QoL assessment was performed [19] using 'SF-36 short form' in which 36 items are coded, summed, and scored on to a scale from 0 to 100 [20]. It is a generic form for QoL study; all entity and usage rules are available at *http://www.qualitymetric.com* home page. Subsequent follow-up was performed to detect disease recurrence.

The statistical analysis of the data in this study was performed using the SPSS version 10 under Windows XP (SPSS incorporation, Chicago, USA). The tests used were the arithmetic mean value (average) and SD, frequency (percentage), Student's t-test (a $P < 0.05$ was considered significant), and the χ^2-test.

Results

There were 102 (85%) male patients and 18 (15%) female patients suffering from PSD elected for surgery. All patients were followed up longer than 12 months with a mean follow-up period of 43.5 ± 3.4 months (range 12–60 months). There were no statistically significant differences between the two groups regarding patients' demographic data and clinical presentation (Table 1). Operative data study revealed significant shorter operation time, less operative blood loss, and easier surgeon performance (Fig. 3) for group I patients. There were no significant differences between the two groups regarding immediate postoperative complications (Table 2). Pain scores (Table 3) were significantly higher in group II patients on first postoperative day, but later on the differences were insignificant. Study of the first month wound morbidities revealed significant advantage regarding time until drain removal and frequency of seroma formation in group II patients but with a significant longer hospital stay (Table 4). In addition, pairwise comparison of wound complications declared significantly higher frequency of hypothesia in group II patients (Table 5). At third month, the TF 1ry technique had a significant advantage regarding patient satisfaction and wound cosmoses (Fig. 4).

Study of third month postoperative QoL revealed a significant reduction in bodily pain and better social functioning in group I patients (Table 6). The recurrence rate in group I patients [two (3.33%) patients detected at the fifth and 10th postoperative month] was not found to differ significantly from that of group II patients [one (1.6%) patient detected at sixth postoperative month].

Discussion

PSD and its recurrence are caused by forces focused on the midline (tension = force/surface area) mainly

Table 1 Patients' demographic data and clinical presentation

Patients	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Age (mean ± SD) (years)	27 ± 6.8	28 ± 7.6	NS
Preoperative duration of PSD (mean ± SD) (months)	1.8 ± 1.1	1.6 ± 1.2	NS
Clinical presentation			
Discharge	52 (86.6)	50 (83.3)	NS
Pain	30 (50)	32 (53.3)	
Pruritus	20 (33.3)	19 (31.6)	
Bleeding	4 (6.6)	3 (5)	

PSD, pilonidal sinus disease.

Table 2 Immediate postoperative complications

Variables	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Urine retention	3 (5)	4 (6.6)	NS
Bleeding	0 (0)	1 (1.6)	NS
Constipation	3 (5)	2 (3.3)	NS

Table 3 Postoperative pain scores

Timing	Group I (mean ± SD)	Group II (mean ± SD)	*P* value
Postoperative first day	2.8 ± 1.2	4.2 ± 1.4	<0.001
Postoperative seventh day	2.1 ± 1.05	2.5 ± 1.01	NS
Postoperative second week	1.0 ± 0.4	0.9 ± 0.47	NS
Postoperative fourth week	0.10 ± 0.307	0.00 ± 0.00	NS

Table 4 Postoperative wound morbidities and hospital stay

Variables	Group I (mean ± SD)	Group II (mean ± SD)	*P* value
Time to drain removal (days)	10.2 ± 2.1	4.5 ± 2.4	<0.01
Seroma formation (*n*)	5 ± 8.4	1 ± 1.6	0.05
Time to sit on toilet (days)	8.1 ± 0.17	7.8 ± 0.3	NS
Time to walk pain free (days)	6.9 ± 0.016	5.9 ± 0.21	NS
Hospital stay (days)	1.85 ± 0.7	3.8 ± 1.6	<0.05

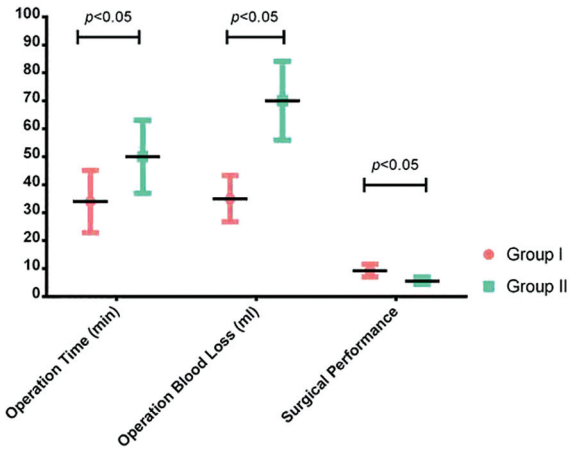
Table 5 Postoperative wound complications

Variables	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Infection	3 (5)	2 (3.3)	NS
Dehiscence	1 (1.6)	1 (1.6)	NS
Edema	2 (3.3)	1 (1.6)	NS
Maceration	1 (1.6)	0 (0)	NS
Hypothesia	2 (3.3)	6 (10)	<0.05

Table 6 Quality of life estimation

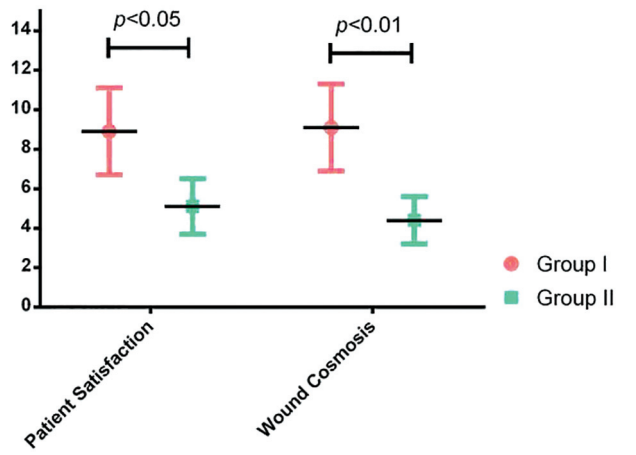
Variables	Group I (mean ± SD)	Group II (mean ± SD)	*P* value
Physical function	71.1 ± 11.7	73.4 ± 12.5	NS
Role of limitation of physical function	43.5 ± 15.1	41.9 ± 14.2	NS
Bodily pain	54.3 ± 6.3	61 ± 4.6	<0.001
Vitality and energy	74.5 ± 16.4	73.1 ± 17.4	NS
General health	73.1 ± 10.7	75.3 ± 14.3	NS
Emotional function	63.4 ± 5.3	66.2 ± 4.3	NS
Social functioning	59.6 ± 5.4	72 ± 8.7	<0.001
Role of limitation of emotional function	56.5 ± 13.7	55.4 ± 14.6	NS
Physical health perception	75.6 ± 11.7	77.3 ± 12.6	NS
Mental health perception	69.5 ± 6.4	57.5 ± 7.31	NS

Figure 3



Comparison between studied groups regarding operative time, operative blood loss, and surgeon performance.

Figure 4



Comparison between studied groups regarding patient satisfaction and wound cosmoses.

where the coccyx turns anteriorly [21]; vacuum effect created between the buttocks that attracts the anerobic bacteria, hair, and debris [22]; and friction movement of buttocks [23] in the presence of other risk factors such as adiposity, hirsuteness, and bad hygiene [24–27]. Thus, effective procedure will eliminate shearing forces, vacuum effect, and friction movement [26]. Both procedures had low recurrence rates with insignificant difference, in agreement with the study by Tavassoli *et al*. [27]. However, TF 1ry had shorter operative time and less blood loss, as reported by Muzi *et al.* [28], due to small defect and minimal dissection. Flap techniques achieved lower pain scores compared with direct primary closure due to tension-free construction as reported by Quinodoz *et al*. [29]. The relatively higher pain score on first day postoperatively in the MLF group is related mostly to more dissection and tension with net force. As pain (mild to moderate in this study) is the most critical point that exacerbates postoperative urine retention and constipation, their frequencies were infrequent in this study with minimal patient inconvenience. The less postoperative pain in TF 1ry closure patients and the infrequent immediate postoperative complications facilitated their early discharge, thus minimizing the financial cost to the community. This finding was similarly confirmed by the study by Muzi *et al.* [28]. Thus, regarding operative time, patient inconvenience (immediate postoperative pain, immediate postoperative complications), and financial cost to the community (hospital stay), TF 1ry closure is more advantageous than MLF. The case difficulty scale of surgeon was higher in MLF technique, being reserved for a senior surgeon, but the performance was better for TF1ry closure technique as it is simple to design and construct being reserved for junior surgeons. The MLF procedure keeps system under net force, as the recipient side is heavier (more dangling) than donor side [30]; meanwhile, the TF 1ry closure creates a TF midline healing site and keeps system in equilibrium as summation of force is zero [12]. Consequently, TF 1ry closure achieved less wound morbidity rate, which did not reach statistical significance.

Nearly, the flat natal cleft for the TF 1ry closure group and lateralized midline for the MLF group resulted in significant decrease in maceration rate, in agreement with the study by Akca *et al.* [11]. A high incidence of wound maceration (45.7%) was reported with the classic Limberg flap technique [4]; hence, both TF 1ry closure and MLF are efficient to reduce maceration.

The reduced maceration rate resulted in less wound infection as Akin *et al.* [10] and Muzi *et al.* [28] reported, compared with the higher incidence of wound infection for direct primary closure (21.8%) recorded by Zimmerman [31]. Generally, flap procedures achieve proper wound healing with less wound dehiscence, in agreement with the study by Mahdy [32]; hence, both TF 1ry closure and MLF techniques were equivalent regarding wound healing but MLF technique changed the anatomy of the gluteal region. The MLF had significantly shorter time until drain removal and less incidence of seroma formation, in agreement with the study by Erderm *et al.* [33]; this is related to more muscle exposure that deserves good absorptive power, and hence use of drains for MLF is controversial. The more dissection in MLF patients resulted in a significant higher rate of hypothesia (10%); this is comparable with the studies conducted by Akin *et al.* [10] and Soendenna *et al.* [34] who reported hypothesia in 8.9 and 9.5% of their patients, respectively. Patients after PSD surgery suffer wound

tenderness (sitting on hard chairs and time off work) that negatively affects the patient financial cost [35]. Holm and Hultén [36] found that 18% of their patients suffered pain during sitting on hard chairs. Moreover, time off work reported by Cihan *et al.* [4] was 28.6 ± 3.11 days for direct primary closure. The current study confirmed significantly shorter times to walk pain free and to sit on toilet for flap surgery. Thus, both techniques improve financial cost.

The patient satisfaction score was significantly higher for the TF 1ry closure group, which is similar to that reported by Akin *et al.* [10] and Tavassoli *et al.* [27], with positive community and patient costs, less disturbed anatomy, and minimal patient inconvenience being associated with better satisfaction. In PSD, the main problem is the high rate of morbidity and recurrence, which can greatly diminish the patient's QoL [3]. This study found TF 1ry closure advantageous in terms of bodily pain and social functioning, in agreement with the study by Ertan *et al.* [35]. The QoL drive is an important factor in decision making regarding PSD surgery modality.

Conclusion

Flap techniques are effective and efficient for PSD. TF 1ry closure can be tailored for female PSD patients and a junior surgeon. MLF can be tailored for male PSD patients and a senior surgeon.

Acknowledgements

Conflicts of interest

None declared.

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