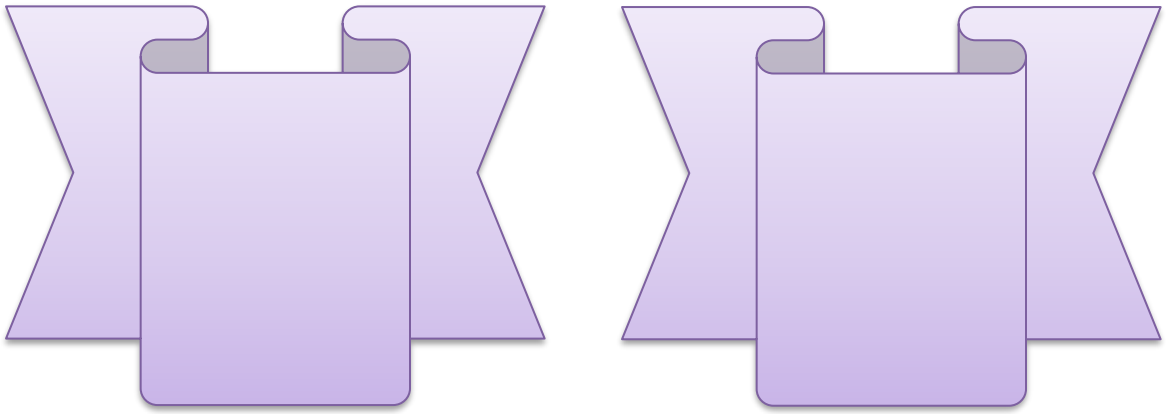
International Journal of Medical Arts

Volume 5, Issue 2, February 2023

https://ijma.journals.ekb.eg/



Print ISSN: 2636-4174

Online ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Plastic Surgery]

Original Article

Clinical Experience with Primary Closure Versus Limberg Flap for The Treatment of Sacrococcygeal Pilonidal Sinus

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Article information

Received: 26-03-2023

Accepted: 25-04-2023

DOI: 10.21608/IJMA.2023.202237.1651

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Citation: Abd-Elghany SM, Moawed MM. Clinical Experience with Primary Closure Versus Limberg Flap for The Treatment of Sacrococcygeal Pilonidal Sinus. IJMA 2023 February; 5 [2]: 3025-3032. doi: 10.21608/IJMA.2023.202237.1651.

ABSTRACT

Background: Pilonidal sinus is a common condition. Different treatment options are available with pros and cons of each method. The standard treatment is not yet determined.

Aim of the work: Comparing excision with primary closure to Limberg flap reconstruction in the treatment of sacrococcygeal pilonidal sinus.

Patients and Methods: The study included 120 patients who were divided into two equal groups [60 patients in each group]. All were assessed on the clinical basis and those who eligible were recruited. Patient demographic and other data related to the sinus characteristics were documented. Both groups were compared regarding operative data, postoperative variables [e.g., pain, duration of hospital stay, pain-free walking, return to work]. The recurrence rate in the first year is the primary outcome, while complications and other variables represent the secondary outcome.

Results: Operative time was significantly shorter in primary closure than Limberg flap [30.17 ± 3.67 vs. 52.07 ± 6.75 minutes]. Similarly, primary closure was associated with significantly shorter duration of hospital stay, days to return to work, time to walk pain-free and time to painless toilet seat. However, the recurrence rate was significantly among the primary closure than Limberg flap [20.0% vs. 1.7%]. Otherwise, both groups were comparable.

Conclusion: Although the direct postoperative outcome [early] seems to be favorable in primary closure, the recurrence rate is higher with this procedure with comparable rate of complications. Thus, Limberg flap is advocated for treatment of pilonidal sinus.

Keywords: Reconstruction; Inflammatory; Excision; Flaps; Recurrence; Cosmetic.

INTRODUCTION

Pilonidal sinus is a common inflammatory disease of gluteal area. Its accounts for 26/100,000 and it affects working males of ages 15 to 30 years old [1]. It was first described at 1833 by Herbert Mayo in a woman, as a sinus containing hair follicles in sacrococcygeal region [2]. It usually presented in the intergluteal region. However, it may be present elsewhere [e.g., the umbilicus and in finger webs in hairdressers] [3, 4]. Predisposing factors include extensive body hair, young male adulthood, family history, poor hygiene, local trauma, family history, shed or cut hairs, obesity and deep natal cleft [5, 6]. The quality and type of hairs are important protective factors against development of pilonidal sinus. An important factor is the site of hair growth. Specifically, hairs penetrating the skin facilitate infection development and formation of the sinus

Not only the quality and type of the hair are important, but also the place where hair grows. Whether it is located either above or under the skin does not make any difference, but hairs penetrating the skin facilitate the establishment of the infection. Clinical presentation ranges from the simple pit to the complex infected type with multiple orifices and purulent or serosanguinous discharge [7].

Clinical diagnosis is straightforward varying from acute pilonidal abscess, chronic pilonidal sinus, complicated pilonidal sinus and recurrent pilonidal disease. According to the pathogenesis of the disease, different treatments have been introduced including non-operative treatment, excisional and incisional procedure and flaps [8].

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 [9, 10].

The surgical wound may be left to heal by secondary intention. Advocates of this technique state that reduced wound tension facilitate trouble free healing without recurrence if all sinus tracts are fully excised. Alternatively, the wound may be closed to heal by 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 [11].

Excision and midline 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. 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. Available techniques include the cleft closure, Karydakis procedure, local advancement flap [V-Y advancement flap], rotational Limberg flap and gluteus maximus myocutaneous flap [12].

In a recent study, **Song *et al.*** [13] advocated the Limberg flap for pilonidal sinus disease as it has a stable therapeutic outcome. However, they did not find any statistical significance than other skin flaps, but its design is simple and is not affected by the known risk factors before operation. But the outcome is affected by postoperative squatting and premature defecations

THE AIM OF THE WORK

To compare between excision with off midline primary closure versus Limberg flap procedure in the treatment of sacrococcygeal pilonidal sinus.

PATIENTS AND METHODS

This prospective randomized clinical study was performed on 120 patients with pilonidal sinus disease who were admitted to Al-Azhar University Hospitals. The sample size was calculated based on the analysis of the primary outcome [recurrence of pilonidal sinus at 12 months of follow-up]. We estimated the recurrence rate after excision and primary closure to range from 15-25% and recurrence after Limberg flap to range from 0-5% in accordance with the published literature [14-16]. A sample size of 58 patients was estimated to be necessary at a power of 80% with alpha level set at 5%. In order to compensate for loss to follow-up and drop out, a sample size of 60 patients was finally included to the study in each group.

Adult patients of both genders with symptoms from sacrococcygeal pilonidal sinus

were included in our study. On the other side, the exclusion criteria were patients with abscess formation, immunodeficiency, patients with congenital asymptomatic pits, patient with psychiatric disease disabling surgical intervention, and pregnant females.

Patients were randomized to one of two equal groups; group [A] was treated with excision and off midline primary closure and this group included 60 patients. In addition, group [B] were treated with excision with rhomboid flap [Limberg flap] and this group included 60 patients. Randomization was achieved through a computer-generated schedule and the results were sealed into envelopes. The envelopes were drawn and opened by a nurse not included in the study.

Preoperatively, all patients were subjected to detailed preoperative evaluation, detailed history, general **&** local clinical examination and routine preoperative blood tests [complete blood cell count [CBC], renal function, liver function, prothrombin time, and random blood glucose]. The following demographic data were documented [age, sex, job and BMI were calculated]. Occupation was defined as the occupation performed during two years prior to diagnosis of pilonidal sinus [PNS]. Shower habits of patients was approximately calculated by number of baths/weeks. Family history was assessed negative or positive. Moreover, if positive whether it is first degree relatives [father, mother, sister, brother or grandmother] or not.

Body hair ratio was graded after **Harlak *et al*.** [17]. Hairless was defined as the clean intergluteal sulcus with traces of hair; Mild hairy describes those with little number of hairs in the intergluteal sulcus, and hairy described as the fullness of hair. The complaint [Pain, pruritis, bleeding and\or discharge] and it`s preoperative duration was recorded. The number of openings and clinical staging were noticed. The PNS was staged according to **Guner *et al*.** [18].

Surgical technique

All the patients were admitted one day before surgery. Operations were performed under spinal or general anesthesia. The intergluteal area was shaved. The patients were placed in the prone Jack knife position and wide adhesive taps were used to separate the buttocks. Patients received antibiotics in the form of 3rd generation cephalosporin before the incision [19].

In group A [excision with off midline primary closure group], the procedure completed as described by **Tavassoli *et al*.** [20]**.** Briefly, the sinus was probed, then the sinuses were removed en block through a vertical elliptical specimen of the overlying skin 1 cm away from the sinus reaching the sacrococcygeal fascia. After resection of the tissues, the hemostasis was achieved by electrocautery. A suction drain was inserted from a separate incision. The deep fascia was closed by polyglactin sutures, and the skin was closed by 2/0 polyprolene sutures after approximation of the skin by 3/0 polyglactin interrupted subcutaneous sutures.

In group [B], [excision with Limberg flap transposition], a rhomboid shaped incision was mapped while the patient is standing. The length to width ratio was 60.0%. Equal length of the lesion was excised on each side and the depth of excised tissues was extended to the gluteal fascia. The rhomboid flap was then rotated from the luteal fascia to the excised area without tension. A subcutaneous suction drain was inserted. The subcutaneous tissue was approximated by interrupted 2/0 Polyglactin sutures and the skin was sutured separately with interrupted mattress Polyproline 2/0 sutures

The postoperative standard care was applied. It included mobilization and return to normal diet as quickly as possible. Early and late postoperative complications [e.g., bleeding, infection, wound dehiscence, flap necrosis, flap edema, numbness, hypothesia and urine retention] were recorded. The postoperative pain was measured by the visual analogue scale at the first postoperative day and visit. The discharge was scheduled for the second postoperative day. Oral antibiotics and analgesics were individualized and continued after discharge. Drain output and seroma formation were recorded. All patients were advised to walk freely but not to exercise until stitches removal. All the patients were advised to shave the area well around the operative site at least monthly. The follow up visits were scheduled for outpatient visits twice weekly for 2 weeks, then weekly till the end of the first postoperative month. Another two visits at 3 and 6 and 12 months were scheduled to complete follow up.

Figure [1]: Excision with primary off midline closure with skin edges closed with 2/0 polyprolene interrupted mattress sutures [Group A]

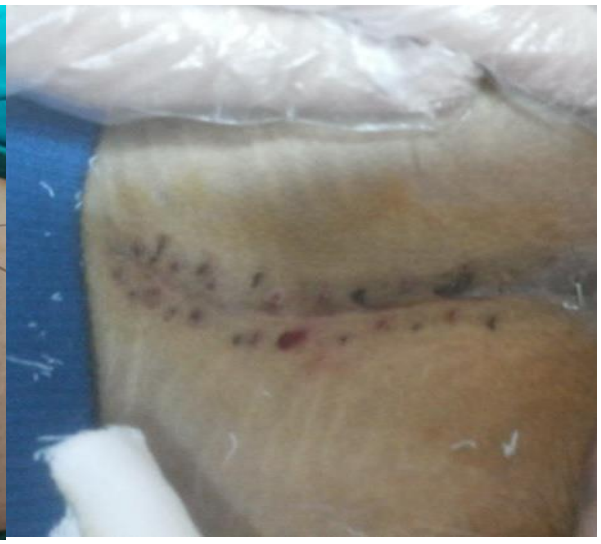

Figure [2]: Excision with off midline primary closure after removal of stitches

Figure [3]: Rhomboid shaped incision with each side equal in length

Figure [4]: The rhomboid flap at the end of follow up [6 months after surgery]

The primary outcome was the recurrence rate while the secondary outcome included other parameters [e.g., extended postoperative hospital stay, time consumed to restore normal activity, time for stitch removal, time of drain removal, cosmetic satisfaction and final scar]. Recurrence was defined as reappearance of pilonidal sinus at the site of surgery during the follow up period [one year]. The cosmetic outcome and patient satisfaction were designed by a scale described in **Ertan *et al*.** [21]

Data analysis: the analysis was performed by the statistical package for social science [SPSS] version 16 [SPSS Inc., Chicago, Illinois, USA]. Mean and standard deviation were computed for continuous normally distributed data. However, relative the description of the data was done in the form of mean ± standard deviation [SD] for quantitative data, frequency and proportion for qualitative data. For quantitative data, Student's t-test was used to compare between two groups. Chi square test or Fisher's exact test was used for qualitative data. P value of < 0.05 was considered statistically significant.

RESULTS

The demographic data of study populations were presented in table [1]. This revealed that, both groups were comparable regarding patient gender, age and body mass index [BMI]. In addition, no significant difference was observed regarding sinus characteristics [e.g., clinical presentation, sinus type, hair distribution, baths/week, associated comorbid conditions, duration before surgery and sinus stage.

Regarding operative data, primary closure was associated with significant decrease of operative time, duration of hospital stay, days to return to work, total amount of drained fluid, time to stitch removal, time to walk pain-free and time to painless toilet seat. However, primary closure was associated with significant increase cosmetic satisfaction score and recurrence within the first year after surgery. Otherwise both groups were comparable regarding compilation rate and type, time to drain removal, and the final scar [Table 2].

The recurrence of PNS was significantly associated only with increased body hair and presence of diabetes mellitus [Table 3].

Table [1]: Patient and PNS characteristics among study groups

Variable		Group A	Group B	Test	P
Sex [n, %]	Male Female	53 [88.3%] 7 [11.7%]	55 [91.7%] 5 [8.3%]	0.37	0.54
Age [years]	Mean ± SD	27.68±7.03	26.95±6.59	0.59	0.34
BMI [kg/m^2]	Mean ± SD	26.53±1.91	26.23±2.20	0.65	0.42
The most distressing symptom [s] [n, %]	Pain	30 [50.0%]	33 [55.0%]	0.30	0.58
	Discharge	45 [75.0%]	42 [70.0%]	0.37	0.54
	Pruritus	29 [48.3%]	28 [46.7%]	0.03	0.85
	Bleeding	1 [1.7%]	2 [3.3%]	0.34	0.55
Type of the sinus	First presentation Recurrent	47[78.3%] 13[21.7%]	49[81.7%] 11[18.3%]	0.20	0.64
Hair Distribution	Hairless Mild hairy Hairy	18[30.0%] 28[46.7%] 14 [23.3%]	14 [23.3%] 28 [46.7%] 18 [30.0%]	0.21	0.64
Baths / week	<3 ≥ 3	42 [70.0%] 18 [30.0%]	41 [68.3%] 19 [31.7%]	0.04	0.84
Comorbidities	DM	9 [15.0%]	5 [8.3%]	1.29	0.26
	Smoking	16 [26.7%]	18 [30.0%]	0.16	0.68
PNS duration [months]	Mean ± SD	15.52±5.60	14.73±4.59	0.83	0.40
No of pits	Mean ± SD	1.47±0.60	1.62±0.74	1.22	0.22
PNS stage	S1	5 [8.3%]	6 [10.0%]	2.37	0.67
	S2	27 [45.0%]	21 [35.0%]		
	S3	12 [20.0%]	17 [28.3%]		
	S4	3 [5.0%]	5 [8.3%]		
	SR	13 [21.7%]	11 [18.3%]		

BMI: Body Mass Index; SD: Standard Deviation; DM: Diabetes Mellitus; PNS: Pilonidal Sinus

Table [2]: Operative and postoperative data among study groups

Variable		Group A	Group B	Test	P
Operative time [min.]	Mean ± SD	30.17±3.67	52.07±6.75	**22.04**	**<0.001***
PO hospital stay [days]	Mean ± SD	1.67±0.66	2.47±0.57	**7.15**	**<0.001***
Days to return to work	Mean ± SD	22.55±5.72	27.30±5.57	**4.60**	**<0.001***
Complications	Urine retention	1 [1.7%]	0 [0.0%]	1.01	0.32
	Wound infection	5 [8.3%]	1 [1.7%]	2.80	0.09
	Wound dehiscence	2 [3.3%]	1 [1.7%]	0.34	0.56
	Numbness, hypothesia	4 [6.7%]	6 [10.0%]	0.43	0.51
	Total complications	12 [20.0%]	6 [10.0%]	2.35	0.20
PO pain [VAS]	First PO day	4.53±1.17	4.33±1.09	0.97	0.34
Drain	Total amount [cc]	664±122.82	809.2±145.1	**5.91**	**<0.001***
	Time to removal [days]	16.18±2.34	15.78±2.43	0.92	0.36
Time for stitch removal [days]	Mean ± SD	12.57±1.8	13.97±1.35	6.03	**<0.001***
Time to walk pain-free	Mean ± SD	4.45±1.65	6.80±1.69	7.69	**<0.001***
Time to painless toilet seat	Mean ± SD	7.13±1.70	9.01±1.59	6.24	**<0.001***
Final scar [n, %]	Fine linear Bad	54 [90.0%] 6 [10.0%]	56[93.3%] 4 [6.7%]	0.43	0.51
Cosmetic satisfaction score	Mean ± SD	7.26±2.14	6.17±1.27	3.41	**0.001***
Recurrence within one year [n, %]		12 [20.0%]	1 [1.7%]	1043	**0.001***

PO: Postoperative; SD: Standard Deviation; VAS: Visual Analogue Scale; CC: Cubic Centimeter; * indicate Statistical Significance

Table [3]: Association between recurrence of PNS and other studied variables

Variable		Recurrence [n=13]	No recurrence [n = 107]	Test	P
Body hair	Clean	0 [0.0%]	32 [29.9%]	**25.30**	**<0.001***
	Mild hairy	2 [15.4%]	54 [50.5%]		
	Hairy	11 [84.6%]	21 [19.6%]		
Bathes/week	<3	10 [76.9%]	73 [68.2%]	0.41	0.52
	≥ 3	3 [23.1%]	34 [31.8%]		
Medical comorbidities	DM	6 [46.2%]	8 [7.5%]	**16.82**	**<0.001***
	Smoking	6 [46.2%]	28 [26.2%]	2.28	0.13
BMI	Normal	1 [7.7%]	26 [24.3%]	1.83	0.18
	Overweight or Obese	12 [92.3%]	81 [75.7%]		
	Mean ± SD	26.71±1.80	26.34±2.09	060	054
PNS duration [months]	Mean ± SD	16.53±4.44	14.95±5.18	105	0.29
Number of pits	Mean ± SD	1.62±0.77	1.53±0.66	0.42	0.67

DM: Diabetes mellitus; BMI: Body mass index; PNS: Pilonidal Sinus; SD: Standard Deviation; * indicate Statistical Significance.

DISCUSSION

The current work revealed that, midline excision with primary closure of sacrococcygeal pilonidal sinus is superior to Limberg flap remonstration in terms of operative time, hospital stay, return to work, stitch removal, walking pain-free and painless toilet seat. In all these domains, primary closure had significant shorter duration than the flap reconstruction. In addition, the cosmetic score is higher with primary closure than with the flap. However, the main drawback of primary closure is the higher recurrence rate in the first postoperative year [20.0% versus 1.7%]. The recurrence of PNS was significantly associated with increased body hair and presence of diabetes mellitus. Otherwise, both procedures were comparable regarding other variables mainly postoperative complications.

Tavassoli *et al.* [20] compared primary closure to Limberg flap in 100 patients, randomly divided into two groups [50 patients each]. They reported that, mean age was 24 years, with male sex predominance [male: female ratio 4:1]. However, they did not find significant difference regarding demographic data, operative time, early complications and recurrence rate characteristics. However, they reported a significant difference in return to work, first pain-free toilet sitting, pain score and patient satisfaction. These results are partially agreeing with the current work. This could be explained by differences in inclusion criteria and number of patients.

Janjua *et al.* [22] compared primary closure to Limberg flap and concluded that, Limberg flap is better than the primary closure in terms of post-operative pain and mean length of hospital stay at the expense of relatively increased mean operative time. However, they did not report on the recurrence rate or follow up for longer durations as in the current work. They only reported on direct operative outcome and this is partially agreeing with the current work. The small number of patients in each group [30 patients in each group] in their study when compared to the higher [60 patients in each group] in the current work could explain the differences. However, and in line with the current work, **Kartal *et al.*** [23] reported a median operative time of 54.31 ± 6.41 minutes for the Limberg flap compared to 26.94 ± 5.79 minutes for the primary closure [P < 0.05]. In addition, **Karaca *et al.*** [24] reported a mean operative time of 27.26 ± 6.41 minutes for primary closure compared to 59.64 ± 7.76 minutes for Limberg flap [P<0.05]

Pain in the postoperative day showed non-significant difference. However, primary closure showed early achievement of walking pain-free and painless toilet seat than the Limberg flap. Postoperative pain is an important factor in the determination of the surgical procedure [22]. Our results are comparable to that of **Alam El-Dein *et al.*** [25] who showed non-significant difference between primary closure and Limber flap, regarding first postoperative day pain score [4.2 ± 0.77 versus 3.8 ± 0.94 in primary closure and Limberg flap re-construction, respectively].

The duration of hospital stay reflected the economic burden of the surgical procedure on the health system. Thus, shorter duration of postoperative hospital-stay favors one procedure over the other provided that, other outcome

measurements are superior in the procedure with shorter duration of postoperative stay. The current work yielded significant shorter duration with primary closure technique. **Karaca *et al*.** [24] reported a longer duration of hospital stay in the midline than Limberg flap [3.05 ± 3.42 versus 2.69 ± 2.32 days for primary closure and Limberg flap respectively]. However, the difference was statistically not significant. 17. These results are not in line with the current work and could be attributed to the differences in sample size. **Janjua *et al*.** [22] also showed a significantly shorter duration of hospital stay with Limberg flap than the primary closure [2.43 ± 0.568 versus 5.83 ± 1.05 days, $p < 0.05$].

There was significant increase of males than females in the current work and in previous literature, as males usually affected three times more than females. This could be attributed to conservative sociocultural habits, that leads to affection of small number of women [26].

Mohamed and Alfy [27] reported higher rate of complications and recurrence after primary closure than Limber flap [20.0%, 13.3% vs 3.3%, 0.0% successively]. These results are partially in line with the current work, where rate of complications did not differ significantly between both groups in the current work. However, the recurrence rate was significantly higher in primary closure than Limber flap reconstruction.

More recently, **Ghaffar *et al*.** [28] reported that, several procedures were used for the treatment of chronic PNS but the standard procedure is not yet determined. However, the primary concern after the procedure are the recurrence and complications' rate. They reported a higher satisfaction rate with Limberg flap with lower pain and swelling. They concluded that, the flap is preferred for PNS surgery. However, patients face more discomfort due to aesthetical reasons as reported by **Tokac *et al*.** [29]**. Erkent *et al*.** also reported a higher recurrence rate after primary closure than Limberg flap reconstruction. These results are in line with the current work.

Finally, in line with the current work, **Eldsoky *et al*.** [30] reported on 60 patients with pilonidal sinus [30 in each group of primary closure and Limberg flap groups] and reported a recurrence rate of 20% in the primary midline closure group compared to none in the flap group. They also reported better direct postoperative outcome in terms of short duration of hospital stay and shorter duration to return to normal daily activities.

In short, the direct outcome after surgery is in favor of primary closure. However, the Limberg flap reconstruction is associated with better outcome through the first year after surgery, specifically regarding recurrence rate. Thus, we recommend the Limberg flap as a standard treatment option for pilonidal sinus.

Conflict of Interest and Financial Disclosure: None.

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Print ISSN: 2636-4174
Online ISSN: 2682-3780