



COMPARATIVE STUDY BETWEEN EXCISION AND PRIMARY CLOSURE VERSUS LIMBERG FLAP FOR MANAGEMENT OF SACROCOCCYGEAL PILONIDAL SINUS

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ABSTRACT **Introduction:** Pilonidal sinus is a disorder of the sacrococcygeal region affecting younger individuals with a higher hair and weight distribution. Treatment involves the use of various surgical modalities, most of which are associated with a high rate of complications. Excision with primary closure and Limberg Flap (LF) are two commonly performed surgical procedures for the correction of pilonidal sinus disease in our setup. The objective of our study was to compare the treatment of pilonidal sinus disease by excision and primary closure versus Limberg Flap in terms of frequency of postoperative wound infection. **Material and Methods:** After approval from IEC, this prospective, interventional, randomized controlled was conducted on 60 patients aged >15 years who presented to the OPD at Department of Surgery, Index Medical College Hospital & Research Centre during the study duration and were diagnosed with sacrococcygeal pilonidal sinus disease based on history of intermittent pain, swelling, discharge and repeated abscess over sacrococcygeal region. Patients satisfying the inclusion criteria were enrolled after taking a written informed consent. Patients were randomly and equally divided into two groups with 30 patients each depending upon surgical procedure. Group A consisted of patients who underwent pilonidal surgery by Excision with primary closure only (Control Group) and Group B consisted of patients who underwent pilonidal sinus surgery by Limberg flap technique. Post-operative follow up was done till 6 months and complications were noted. The data was tabulated and SPSS version 22.0 was used for statistical analysis. **Results:** Pilonidal sinus disease is common in age group 20 years and above and more common in males than females. Operating time was statistically less in Limberg flap as compared to primary closure group (38.2 ± 3.64 (range 35-45) vs 27.92 ± 3.16 (range 25-35) minutes). The post-operative pain in the long term follow up is less in the Limberg flap procedure, although in the initial postoperative period it is slightly higher as compared to primary closure. In Limberg flap procedure, post-operative complications like stitch line infection, wound dehiscence are low as compared to primary closure. Limberg flap require 3-4 days hospital stay as compared to 1 day in primary closure. The study found that patients who underwent excision with a Limberg flap had less complications compared to those who underwent primary closure. Infections were reported in 13.3% of patients, wound dehiscence in 16.7%, and recurrence in 3% of patients. The duration of hospital stay was longer in the Limberg flap technique (3-4 days vs 1 day) **Conclusion:** Our results showed that both excision and primary closure versus Limberg Flap are comparable. However, Limberg flap surgery was found to be better. We recommend the Limberg flap method for primary pilonidal disease with low morbidity rates over primary closure.

KEYWORDS : Pilonidal sinus, Limberg flap, Visual analogue scale

INTRODUCTION

"Pilonidal sinus" describes a common, benign, chronic condition of the sacrococcygeal region affecting young adults with a higher hair and weight distribution. Pilonidal sinus is commonly found in the natal cleft overlying the coccyx; however, it can also affect interdigital space and umbilicus. [1]

Pilonidal sinus (PS) is characterized by weak hair accumulation within and usually consists of one or more, usually non-infected, midline openings, which communicate with a fibrous track lined by granulation tissue. [2]

It has been referred to as "jeep disease". Although the disease was defined by Herbert Mayo in 1883 for the first time, who suggested that it was of congenital origin due to remnant of an epithelial lined tract, the name "pilonidal" derived from Latin for hair (pilus) and nest (nidus), was used by Hodge in 1880 for the first time. [3]

Now, however a widely acceptable view is that, it is acquired and caused by local trauma, poor hygiene, excessive hairiness, or presence of a deep natal cleft. [4-6] Individuals, who are male, young, overweight, and hirsute or have a positive family history, have a predilection of developing this benign disease. [4-10]

A deep natal cleft is a favourable environment for sweating, maceration, bacterial contamination and penetration of hairs. Thus, for treatment and prevention, these causative factors must be eliminated. [11]

The estimated incidence is 26 per 100000 people affecting men twice as often as women. [12] 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. [13]

Patients present with complaints of pain over sacrococcygeal region,

swelling and discharge from the sinus. Multiple treatment modalities are available for management of pilonidal sinus. Patients can be treated conservatively with regular shaving, medically with phenol instillation or laser ablation and surgically with different procedures such as Excision and primary closure, Limberg procedure, Karyadakis procedure or Bascom flap procedure, depending on patient's condition and surgeon's choice of procedure. Whatever the line of treatment is selected for the patient, postoperative wound care forms an essential component for the management of pilonidal sinus disease. [14]

Although many treatment modalities are described, surgery remains the mainstay of treatment and is aimed at a simplified procedure with minimal post-operative pain, minimal wound care, rapid wound healing, shorter hospital stay, early return to daily activities and low recurrence rate. [14] The surgical wound after primary excision may be left to heal by open healing (secondary intention) or may be closed to heal by primary closure (primary intention). [15,16] But since the incision tends to be situated in a deep midline cleft where there is tension and also the propensity to accumulate hair. [15] Skin flaps techniques available include the advancement flap (Karyadakis procedure), local advancement flap (V-Y advancement flap) and rotational flap (Limberg flap, modified Limberg flap, gluteus maximus myocutaneous flap). [16]

While various different surgical techniques, ranging from Wide local excision to complex rotation flaps procedures have been developed, no single method is labeled as the ideal treatment. [17] A study done on outcome of pilonidal sinus reported wound infection rate of 38.4% after open procedure and another study reported wound complication rate of 7% with Limberg Flap Procedure. [18] While some reported Limberg Flap procedure has better healing as compared to open procedure.

However, there have been few clinical studies proving that the recurrence rate in the Limberg flap group was lower than the

recurrence rate in the other flap techniques and 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 recurrence which could occur in the inferior midline. [8,9]

In advent of same this prospective, interventional, randomized controlled study was planned to compare excision and primary closure versus Limberg flap for management of sacrococcygeal pilonidal sinus. Thus, the results of our study will greatly help surgeons in their future choice of surgical procedure for pilonidal sinus disease leading to a better choice of technique for this chronic disease and reduction in the economic burden and morbidity of the disease.

MATERIAL AND METHODS

After approval from IEC, this prospective, interventional, randomized controlled was conducted on 60 patients aged >15 years who presented to the OPD at Department of Surgery, Index Medical College Hospital & Research Centre during the study duration and were diagnosed with sacrococcygeal pilonidal sinus disease based on history of intermittent pain, swelling, discharge and repeated abscess over sacrococcygeal region. Patients satisfying the inclusion criteria were enrolled after taking a written informed consent.

Selection Criteria

Inclusion Criteria:

- All patients with sacrococcygeal pilonidal sinus requiring surgical intervention
- Patients previously treated by conservative management

Exclusion Criteria:

- Fistula-in-ano
- Pregnant females
- Below 15 years of age
- Patients with abscess formation, who are having immuno-deficiency, diabetes mellitus, hypertension, patients those with existing recurrent disease or previous surgery in the sacrococcygeal region, who have severe hirsutism in female patients, patients with psychiatric disease or poor hygiene and patients with contraindication to spinal anaesthesia or prone position.

Methodology

The inclusion and exclusion criteria were followed and all the patients underwent routine investigations and then preanaesthetic fitness. Patients were randomly divided into 2 groups depending upon the surgical intervention done:

- Group A (N=30): Patients who underwent pilonidal surgery by Excision with primary closure only. (Control Group)
- Group B (N=30): Patients who underwent pilonidal sinus surgery by Limberg flap technique. (Study Group)

Patients were reviewed after surgery in ward and after discharge in surgery OPD and were assessed in terms of morbidity, length of hospital stay, post-op complications and recurrence rate. Follow up of patients was done at 2weeks, 4weeks, 6weeks and 3 months. The data was collected on the pre-structured proforma especially designed for the study.

Operative Procedure

Preoperative: All the patients were admitted the day before surgery and intergluteal area was shaved. The patients were placed in the prone position and the buttocks were separated with wide adhesive tapes. They received 1 g Ceftriaxone 15 min before the incision.

Surgical Procedure: Control group underwent excision with primary closure only and study group underwent primary closure by Limberg flap technique.

- Excision and primary closure: The excision site was marked 1 cm away from the sinus. Then an elliptical incision was made that extended to the post sacral fascia. The tissue was resected and hemostasis was completed applying electrocautery. Then the wound was closed in layers after hemo- vacuum drain was placed in subcutaneous plane, deep tissue was closed with interrupted 2-0 Vicryl string, superficial soft tissue was closed with 3-0 Vicryl string and the skin was closed with 2-0 nylon string. Routine dressing was performed and removed the day after operation.
- Limberg flap technique: The excision and flap site was mapped. The ratio of length to width was 60%. This rhomboid shape incision was made and continued to the post sacral fascia and the

tissue was excised. Then the fascio-cutaneous flap was divided from the underlying gluteus muscle and rotated to the defect. The wound was closed with 2-0 nylon string after hemo-vacuum drain placement. Routine dressing was performed and removed the day after operation (Figure 1).



a. Primary Excision of Sacrococcygeal Pilonidal Sinus



b. Limberg Flap Repair
Figure 1. Surgical Procedure

Postoperative: Patients were advised to lie in prone position. Drain was removed if no/minimal discharge. Oral antibiotics and analgesics were prescribed after patients were discharged.

Postoperative complications

- Postoperative pain was measured by visual analogue scale (VAS).
- Infection at stitch line.
- Seroma formation.
- Wound dehiscence.

Follow up was done at 2 weeks, 4weeks, 6weeks and 3 months

Statistical Analysis

The collected data will be entered in Microsoft excel spread sheet and analyzed statistically using SPSS version 20.0 software (Chicago, USA). The data was collected in the form of intraoperative time, post-operative complications, hospital stay and recurrence after follow up of patients was done at 2weeks, 4weeks, 6weeks and 3 months. Numerical and Categorical variables will be given as mean $\pm$ SD and percentage, respectively. Two sample T test will be used for comparing the mean values of Normal Distributed variables. One-way ANOVA will be done to compare the equality of Means for more than two groups. Correlation coefficient will be used to determine the correlation between two variables. Chi square test will be used to determine the association between two variables. A p value < 0.05 was considered significant.

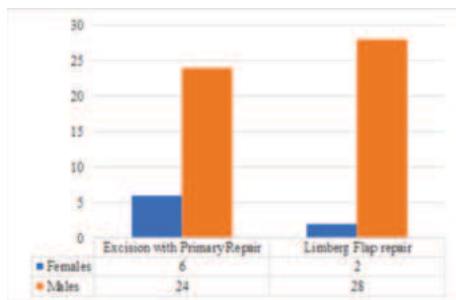
RESULTS

This study was conducted in the Department of General Surgery, Index Medical College, Indore. 60 patients were included in this study, 30 patients underwent excision with Limberg flap and 30 patients were managed by excision with primary closure on a randomized basis. Patients were followed up for a period of three months.

Demographic Profile: Patients affected with sacrococcygeal pilonidal sinus disease mostly fall into the age group of 20-30 years with a mean age of 28.55 ± 7.88 and 28.8 ± 7.25 in the Excision with primary closure and Limberg flap repair respectively. A statistically non-significant association was observed between the occurrence of pilonidal sinus disease and age (Table 1). There was higher male preponderance affected by sacrococcygeal pilonidal disease in both groups. (Graph 1)

Table 1. Age Group Distribution Of Sacrococcygeal Pilonidal Sinus Disease

Age (years)	Excision with Primary repair	Limberg Flap repair	Total	P value
15-20	3	1	4	>0.05 Non-Significant
20-25	9	11	20	
25-30	14	12	26	
30-35	3	4	7	
35-40	1	2	3	
Mean Age	28.55 ± 7.88	28.8 ± 7.25	60	



Graph 1. Sex Distribution Of Sacrococcygeal Pilonidal Sinus Disease

Operative time period for two procedures: Operating time in both the groups was noted from skin incision to the closure of wound. A mean of 38.2 ± 3.64 (range 35-45) minute for Limberg flap procedure against a mean of 27.92 ± 3.16 (range 25-35) minutes for primary midline closure. Although near similar value of these parameters for two procedures should render them a less important factor in determining the superiority of one procedure over the other. A statistically significant difference was seen in the operative time and Type of surgical procedure ($P < 0.05$; Chi-square test)

Table 2: Distribution Of Patients According To Duration Of Surgery In Excision With Primary Repair And Limberg Flap Group

Duration of Surgery (in min)	Excision with Primary repair	Limberg Flap repair	Total	P value
<25	5	0	5	<0.05 Significant
25-35	22	6	28	
35-45	3	16	19	
>45	0	8	8	
<25	5	0	5	
Mean Age	27.92 ± 3.16	38.2 ± 3.64	60	

Post-operative pain: Measurement of the post-operative pain as per VAS for patients of both groups on post-operative day 1 was done. On VAS, maximum number of patients recorded a score of 5 in Excision with primary closure group, compared to score of 7 in Limberg flap repair group.



Graph 2. Percentage Of Patients In Excision With Primary Repair And Limberg Flap Group With Different VAS Score On POD-1.

Post-operative pain on post-operative day 1 (POD-1): On VAS, maximum number of patients recorded a score of 7 i.e., 19 in which 13 patients (43.33%) in study group and 6 patients (20.00%) in control group out of 30 patients in each group. Mean VAS score in study= 6.57 ± 0.9 and control= 5.63 ± 1.33 . P value of postoperative pain on POD-1 is 0.004 (Graph 2)

Post-operative pain on POD-2: Majority of patients recorded a score of 3 on VAS scale i.e., totally 20 patients out of which 6 (20.00%) patients are from study group and 14 (46.67%) patients are from control group. Mean VAS score in study group is 4.4 ± 1.1 and control group is 7 ± 0.95 . P value of post-operative pain on POD-2 is 0.01 (< 0.05). Means the comparison of pain in study and control group was statistically significant on POD-2.

Post-operative pain on PO- 1 week: Majority number of patients recorded a score of 3 on VAS i.e., totally 25 patients out of which 12 patients (40.00%) are from study group and 13 (43.33%) patients from control group. Mean VAS score in study group= 3.13 ± 1.01 and control group= 2.97 ± 0.89 . P value for post-operative pain on PO week 1 is 0.449 (> 0.05). Means post-operative pain comparison was not statistically significant on post-operative week 1.

Post-operative pain on PO 1 month: Majority of patients recorded a score of 2 on VAS i.e., 31 patients out of which 15 (50%) patients are from study group and 16 (53.33%) patients are from control group. Mean VAS score of Study group is 1.9 ± 0.71 and Control Group is 2.1 ± 0.76 . P-value for post-operative pain on post-operative 1 month is 0.332 (> 0.05). Means post-operative pain comparison was not statistically significant at post-operatively 1 month.

Post-operative pain on PO 3 month: Majority of patients recorded a score of 1 on VAS i.e., totally 35 patients out of which 20 (66.67%) patients are from study group and 15 (50%) patients are from control group. Mean VAS score of study group is 0.87 ± 0.57 and control group is 1.23 ± 0.68 . P value for post-operative pain on post-operative 3 month is 0.027 (< 0.05). Means post-operative pain comparison was statistically significant post-operatively at 3 months.

Post-operative pain on PO 6 month: Majority of patients recorded a score of 0 on VAS i.e., totally 41 patients out of which 28 (93.33%) patients are from study group and 1 (43.33%) patients are from control group. Mean VAS score in study group is 0.07 ± 0.25 and control group is 0.77 ± 0.77 . P value for post-operative pain on post-operative 6 month is < 0.0001 (< 0.05). Means postoperative pain comparison was statistically significant post-operatively at 6 months.

Table 3: Post-operative Complications And Their Significance.

Criteria	Excision with primary closure	Limberg flap procedure	P value
Infection at suture site	4 (13.3%)	1 (3.3%)	0.005*
Wound dehiscence	7 (23.3%)	5 (16.7%)	0.024*
Postoperative Hospital stay	3.45 ± 1.23	2.26 ± 0.51	0.012*
Recurrence	3 (10%)	1 (3.3%)	

Postoperative complications: Lesser complications were observed in patients who underwent patients underwent excision with Limberg flap as compared excision with primary closure with infection observed in 1(3.3%) and 4(13.3%) patients respectively, wound dehiscence observed in 5 (16.7%) and 7(23.3%) patients respectively and recurrence observed in 1(3.3%) and 3 (10%) patients respectively. A statistically significant difference was observed in occurrence of complications between the groups.

For duration of Hospital stay, minimum number of days hospitalization required is 2 days in total 32 (53.33%) patients out of which 23 (76.67%) patients are from study group and 9 (30.00%) patients are from control group. The mean of a total hospital stay of 2.26 ± 0.51 days for Limberg flap group and 3.45 ± 1.23 days for primary closure group and the difference was statistically significant with p value of < 0.05 . (Table 3)

DISCUSSION

After examining the hospitalisation period from this standpoint, no statistically significant difference was observed between the groups in the present study. However, the Limberg flap method resulted in a significantly shorter time required to resume daily activities, including pain-free walking, toilet training, and work. However, the efficacy of a procedure in preventing sinus recurrence is likely to be predicated

primarily on its capacity to completely eliminate the profundity of the natal fissure. Given this, one might anticipate that flap procedures would be more effective than excision with straightforward closure in preventing disease recurrence. Sondenaa et al. have documented a high recurrence rate of 7-42% for primary closure, whereas Menten et al. have documented a recurrence rate of 0-3% for Limberg flap. [19,20]

In our study mean age of Limberg flap group was 28.8 ± 7.25 years and in primary closure group it was 28.55 ± 7.88 years and the difference was statistically insignificant with p-value of >0.05 . This was similar to study done by Meena Ok et al. who reported the mean age as 28.33 ± 7.55 and 28.8 ± 7.3 for Limberg flap and Excision with primary closure group. [1]

A higher preponderance was seen for occurrence of pilonidal sinus in male patients as compared to females in our study with M:F ratio of 6.5:1. This was similar to results reported by Meena OK et al. who reported a M:F ratio of 2:1. [1]

In our study, the mean operative time was 38.2 ± 3.64 (range 35-45) minute for Limberg flap procedure against a mean of 27.92 ± 3.16 (range 25-35) minutes for primary midline closure. A statistically significant difference was seen in the operative time and Type of surgical procedure ($P < 0.05$; Chi-square test). This was similar to results reported by Akca et al, and Meena OK et al. [1,21] Akca et al have published a median operative time 60 min for Limberg flap group against 45 min for the primary midline closure group and the difference has been found to have p value of 0.001. [21] Meena OK et al. reported mean time for Limberg flap group is 36.3 ± 3.24 minutes as compared to 24.93 ± 3.06 minutes for primary closure procedure. P value of this comparison is <0.0001 (<0.05) which is statistically significant. [1] However, contrasting results were reported by Galala et al have found an insignificant difference in the operative time periods of the two techniques. [22]

For Postoperative pain on day 1 (POD-1) recorded by VAS scores, maximum number of patients recorded a score of 7 i.e., 19 in which 13 patients (43.33%) in study group and 6 patients (20.00%) in control group out of 30 patients in each group. Mean VAS score in study = 6.57 ± 0.9 and control = 5.63 ± 1.33 . P value of postoperative pain on POD-1 is 0.004. Post-operative pain in patients with Limberg flaps was significantly higher on both POD 1 and POD 2 compared to the control group ($P < 0.05$). All 30 patients in the study group experienced pain on VAS with a mean score of 6.57, while in the control group, it was 5.63. The study found that post-operative pain on POD 1 and POD 2 was statistically significant, with the Limberg flap causing higher pain compared to primary closure. ($P < 0.05$) This suggests that injectable opioids may be necessary for managing post-operative pain. This was in concordance with results reported by Meena Ok et al. who reported that on POD 1, all 30 patients (100%) in study group reflected pain on VAS with mean pain score of 6.57. In the control group, all 30 patients (100%) expressed pain on VAS with a mean pain score of 5.63 with a p value of 0.004 which was statistically significant. [1]

Post-operative pain on 1 week was not of any statistical significance on post-operative week 1. On 1 month pain was more in primary closure group as compared to Limberg flap group. At 3 months follow up, Pain was more in primary closure as compared to Limberg flap. On post-operative 6-month maximum patients from Limberg flap were pain free as compared to primary closure who experienced pain. The results were comparable to study done by Meena OK et al., Mahdy and Akca et al. [1, 21, 23]

For Postoperative complications; Lesser complications were observed in patients who underwent patients underwent excision with Limberg flap as compared excision with primary closure with infection. Outcome of our study in terms of recurrence of the pilonidal sinus as reported in our study was 1(3.3%) and 3 (10%) patients for Limberg flap surgery and excision with primary closure. This was in concurrence with study done by Sondenaa et al and Menten et al, 3.33% recurrence for Limberg flap group and 26.67% recurrence in primary closure group which was statistically significant with p value of 0.026 (<0.05). [19,20] Meena OK et al. found that recurrence of Pilonidal sinus occurred in 9(15%) of patients, with a statistically significant p value of 0.026, with 1(3.33%) patient from the Limberg Flap Surgery and 8(26.7%) from the excision with primary closure group. [1]

Menten et al published a hospital stay of 2-3 days for the Limberg flap

and 2-4 days for primary closure. In our study, we observed a total hospital stay of 3 to 4 days for Limberg flap group and 1 day for primary closure group. This was in contrast to results reported by Meena OK et al. Meena OK et al. reported a total hospital stay of 2.27 ± 0.52 days for Limberg flap group and 3.57 ± 1.43 days for primary closure group and the difference was statistically significant with p value of <0.0001 (<0.05). [19]

In our study, a stitch line infection was observed in 1(3.3%) in Limberg flap group and 4(13.3%) patients in excision with primary closure group. This was similar to results reported by Meena OK et al. who reported that stitch line infection 3.33% for Limberg flap group and 33.33% for primary closure group with p-value 0.006 (<0.05) which is statistically significant. [1] Akca et al. also reported that Stitch line infection is low for Limberg flap group as compared to primary closure group. [21] Petersen et al documented a stitch line infection 12.4% for primary closure and 1.5-6.5% for Limberg flap procedure. [24]

In our study we observed wound dehiscence in 5 (16.7%) of in Limberg flap group as compared to 7(23.3%) in primary closure group. This was in concurrence with study done by Meena OK et al. who observed wound dehiscence in 3.33% of in Limberg flap group as compared to 30% in primary closure group with p value of 0.012 (<0.05) showing statistical significance i.e., wound dehiscence is very high in primary closure as compared to Limberg flap procedure. [1] Lee et al reported post-operative wound dehiscence is 5-10% in primary closure [4] as compared to Daphan et al and Bascom who reported the incidence of 0.9-3.9% for wound dehiscence in Limberg flap. [25,26]

From above data, it is evident that a less morbid immediate post-operative complications has been encountered in the Limberg flap group than with the primary closure group.

Main technical problem of pilonidal surgery is not the removal of the cyst along with all of the sinuses, but rather reconstruction of the remaining defect area. 13 The reasons for the negative results of the primary closure method are the incision scar in the midline, the inability to flatten the natal cleft, and the tissue tension.

CONCLUSION

The present study was designed to analyze the outcomes of the two different techniques of pilonidal sinus surgery- excision with primary closure and Limberg flap with reference to operating time, post-operative complications, hospital stay and recurrence. Limberg flap method for primary pilonidal disease is recommended as less complications (such as infection, wound dehiscence) were observed less compared to excision with primary closure procedure, however further studies are necessary with a larger volume sample and longer follow up period.

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