

**EXCISION WITH PRIMARY CLOSURE VERSUS LIMBERG
FLAP IN THE TREATMENT OF PILONIDAL SINUS DISEASE:
A RANDOMIZED CONTROLLED TRIAL**

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ABSTRACT:

The term, pilonidal sinus describes a condition found in the natal cleft overlying the coccyx. It is usually treated by excision. A randomized controlled trial was conducted among 40 patients with pilonidal sinus presenting to the surgical outpatient department of Government General Hospital, Ananthapuramu over 1 year. Patients with H/O any previous surgery in the sacrococcygeal region, abscess formation, and any immunodeficiency were excluded from the study. Patients were selected by consecutive sampling. Patients were assigned either to the study group (Limberg flap technique) or the Control group (Excision with primary closure) randomly so that each group comprised 20 patients. All patients were operated under spinal anesthesia. Informed consent was obtained from patients. Patients were followed up 6 months postoperatively. Data was presented as mean (with standard deviation), percentages, and proportions. chi-square test and unpaired t-test were used to test the difference between groups. SPSS version 25 was used for statistical analysis. The mean age of patients in the study group was 25.2 ± 5.3 years and the control group

was 24.4 ± 6.1 years. Post-operative pain on day 1 was higher among patients with the Limberg flap technique compared to excision with primary closure but on long-term follow-up, it declined gradually. The recurrence rate was 5% in the Limberg flap technique compared to 35% in excision with primary closure. Complications like seroma formation (5%), and stitch line infection (5%) were less in the Limberg flap technique as compared to primary closure (25% and 30% respectively). The Limberg flap method for the treatment of pilonidal sinus has low complication and recurrence rates compared to excision with the primary closure technique.

KEYWORDS: Excision with primary closure, Pilonidal sinus, Limberg flap, Visual Analog scale.

INTRODUCTION:

The term, pilonidal sinus describes a condition found in the natal cleft overlying the coccyx, consisting of one or more, usually non-infected, midline openings, which communicate with a fibrous track lined by granulation tissue and containing hair lying loosely within the lumen¹ It is also known as ‘jeep disease’¹. This is an acquired disease, common in hairdressers and Jeep drivers seen in the interdigital clefts¹. Hair follicles are rarely present in the walls of the sinus. The pointed hair ends are directed towards the blind end of the sinus. A deep natal cleft is a favorable environment for sweating, maceration, bacterial contamination, and penetration of hairs. So, treatment and prevention, these causative factors must be eliminated.¹ It is due to a combination of buttock friction and sheering forces that allow shed hair or broken hairs that have collected in the intergluteal cleft to drill through the midline skin or the infection in relation to a hair follicle that allows hair to enter the skin by the suction created by the movement of the buttocks so that creating a subcutaneous, chronically infected, midline tract.¹ The estimated incidence of the disease is 26 per 1 lakh people.²

It most commonly affects hirsute men, common in age groups of 20-30 years, after puberty due to the effect of sex hormones on pilosebaceous glands and change in body hair growth. Clinical features include intermittent pain, swelling, and discharge at the base of the spine. Sometimes there is a history of abscess that bursts spontaneously. The primary sinus may have one or more openings, which are all situated in the midline between the sacrococcygeal joint and the tip of the coccyx. Treatment of pilonidal sinus should be tailored to the severity of the disease; it may range from simple incision and drainage to wide excision with extensive reconstructive procedures.³

The primary excision is done without any closure and the wound left open will be healed by secondary intention, or it can be closed to heal by primary intention. Edge-to-edge approximation of the two skin margins in the midline by single or multiple-layer sutures is relatively easy to perform. The midline suture is exposed to a high risk of disunion not only because the sutures are under tension, but also because early postoperative mobilization can result in excessive traction on certain parts of the suture line and there is a chance to accumulate hair again. Skin flap techniques available include Karydakis procedure, Bascom’s procedure, V-Y advancement flap, and rotational flap (Limberg flap, gluteus maximus myocutaneous flap, modified Limberg flap).⁴ The most commonly performed is the Limberg flap technique. Irrespective of the procedure,

postoperative wound care is important and requires eliminating the hair ingrown or local hair from the wound.¹

The objective of this study is to compare the efficacy and complication rates between excision with primary closure and limber flap technique in the treatment of pilonidal sinus.

PATIENTS AND METHODS:

Study Design: A Randomized Controlled Trial

Study setting: Government General Hospital, Ananthapuramu

Study sample: A total of 40 patients were included in the study with each group comprising 20 patients.

Sampling technique: Consecutive sampling. Selected patients were randomly assigned to either the study group (To undergo the Limberg flap technique) or the Control group (To undergo Excision with primary closure).

Study period: 1 year

Study population: Patients presenting with pilonidal sinus to the Surgery department at GGH, Ananthapuramu.

Inclusion criteria: Patients with pilonidal sinus of both sexes.

Exclusion criteria: H/O any previous surgery in the sacrococcygeal region, abscess formation, and immunodeficiency.

Randomization: Patients selected based on inclusion and exclusion criteria were allocated into two different groups using sealed numbers envelopes that were opened sequentially. They were then subjected to undergo either Excision with primary closure or the Limberg flap technique.

Operating Procedures:

Routine investigations like CBP, RFT, LFT, and Serology were done. Magnetic Resonance Imaging (MRI) was done to eliminate anorectal fistulas and to estimate the length of the sinus tract to find any complex fistulous tract. All surgeries were performed under spinal anesthesia after a pre-anesthetic checkup was done.

Excision with primary closure:

The excision site was marked 1 cm away from the sinus. Next, a vertical incision that reached the post-sacral fascia was created. After the tissue was removed, electrocautery was used to achieve the hemostasis. The wound was then closed in layers. The deep tissue was closed with interrupted 2-0 Vicryl thread, and the superficial soft tissue was closed with 3-0 Vicryl string, The skin was closed with 2-0 nylon string. Routine dressing was done after the surgery

Excision with Limberg Flap:

The excision and flap site were mapped. A rhomboid-shaped incision was made including both the midline pits and any lateral sinus extensions with the ratio of length to width as 60%. This incision was deepened to the post sacral fascia and the tissue was excised. Then the fascia-cutaneous flap was raised including the skin, subcutaneous fat, and the fascia overlying the gluteus muscle, and rotated to cover the rhomboid defect. The deep tissue was closed with interrupted 2-0 Vicryl thread after placing a hemo-vacuum drain. The wound was closed with a 2-0 nylon string. Routine dressing was performed and removed the day after the operation. The patients were followed up for 6 months in both procedures.



(a)



(b)



(c)



(d)

Fig 1: (a) Marking of rhomboid-shaped incision including the sinus (b) Excision of the tract (c) Raising of flap (d) Closing the defect with rotation of flap.

Variables: Duration of surgery, Postoperative pain, and complications like Seroma formation, Stitch line infection, wound dehiscence, and recurrence rate were assessed. The postoperative pain was assessed using the Visual Analog Scale (VAS). It is a subjective measure of pain intensity, used to compare pain severity between patients with similar conditions or to record patients pain progression. The score ranges from 0 to 10 with 0 indicating no pain at all and 10 as excruciating severe pain.⁵

Data analysis: Data was collected and entered into MS Excel. Descriptive data was presented as mean (with standard deviation), percentages, and proportions. SPSS version 25 was used for statistical analysis. The chi-square test was used to test the difference between proportions. An unpaired t-test was used to compare the mean VAS scores post-operatively. p-value of < 0.05 was considered to be statistically significant.

Human Participation Protection: Informed consent was obtained from study participants before the study.

RESULTS:

The mean age of patients in the study group was 25.2 ± 5.3 years and the control group was 24.4 ± 6.1 years. Table 1 presents the age and gender distribution of patients in both study and control groups. As the p-value is more than 0.05 it implies that there is no significant difference present between the two groups in terms of age and sex.

Table 1: Age and gender distribution of study participants (n=40)

	Study (n=20)	Control (n=20)	Total (n=40)	p-value
Age in years				
<20	2(50%)	2(50%)	4(100%)	0.92
21-30	13(48.2%)	14(51.8%)	27(100%)	
>30	5(55.6%)	4(44.4%)	9(100%)	
Gender				
Males	14(48.2%)	15(51.8%)	29(100%)	0.72
Females	6(54.5%)	5(45.5%)	11(100%)	

Operating time in both groups was noted from skin incision to the closure of the wound and the results were presented in table 2.

Table 2: Distribution of study subjects based on duration of surgery(n=40)

Duration of surgery in minutes	Study (n=20)	Control (n=20)	Total (n=40)
≤25	0(0%)	12(100%)	12(100%)
26-35	6(42.86%)	8(57.14%)	14(100%)
>35	14(100%)	0(100%)	14(100%)

Seroma occurred in 6 patients and 5 of them belonged to the control group while one was from the study group. No statistical significance was found as the p-value was >0.05 . Stitch line infection occurred in 7 patients, out of which 85.7% were from the study group and 14.3% were from the control group with a p-value of 0.04 indicating statistical significance in the difference between the groups. Wound dehiscence occurred in a total of 8 patients out of which 7 patients belonged to the Control group and 1 patient was from the study group. The difference was statistically significant($p=0.02$). 7 out of 20 patients who were operated on with excision with primary closure developed recurrence compared to 1 out of 20 patients operated with Limberg flap technique developing recurrence during 6-month follow-up. p-value of 0.02 indicates the statistical significance of the difference between the two groups. The results are presented in Table 3.

Table 3: Comparison of Postoperative complications in study and control groups (n=40)

Postoperative complications	Study (n=20)	Control (n=20)	Total (n=40)	p value
Seroma	1	5	6	0.07
Stitch line infection	1	6	7	0.04*
Wound dehiscence	1	7	8	0.02*
Recurrence	1	7	8	0.02*

*Significant at p-value < 0.05

Pain on Postoperative day (POD) - 1

Most of the patients (12) experienced pain of 7 on the VAS scale on POD-1 with 8(40%) of them belonging to the study group and 4(20%) of them belonging to the study group out of 20 patients in each group. The mean VAS score in the study group was 6.35 ± 1.03 and in the control group was 5.55 ± 1.19 with a p-value of 0.03. This indicates a statistical significance is present in the difference between the mean VAS score in the two groups. (Figure 2)

Pain on POD-2

The majority i.e., 14 patients recorded a score of 3 on the VAS scale on POD-2, out of which 10 (50%) were from the control group and 4(20%) were from the study group. The mean VAS score of study group patients was 4.2 ± 1.24 and for control group patients was 3.6 ± 0.94 with a p-value of 0.09. It implies that there is no statistical significance between the pain scores on POD-2 (Figure 3)

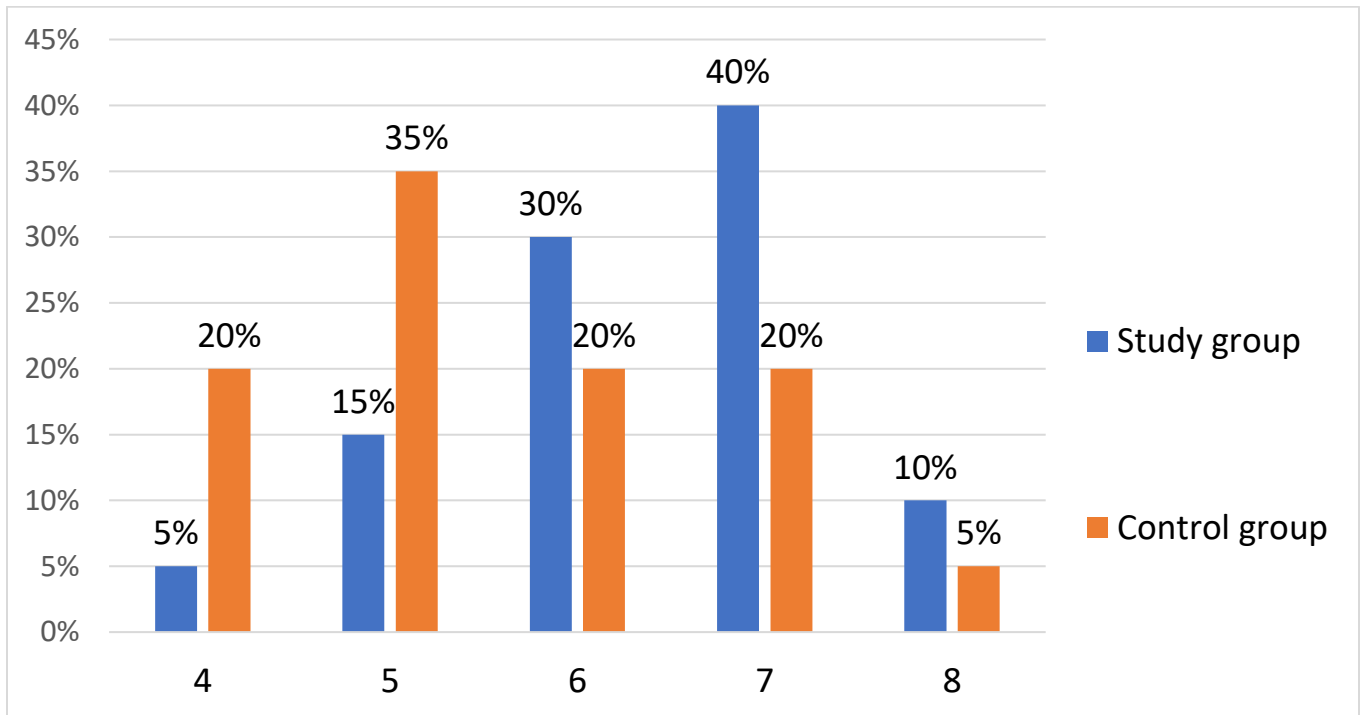


Fig 2 : Pain on POD 1 Using VAS Scale

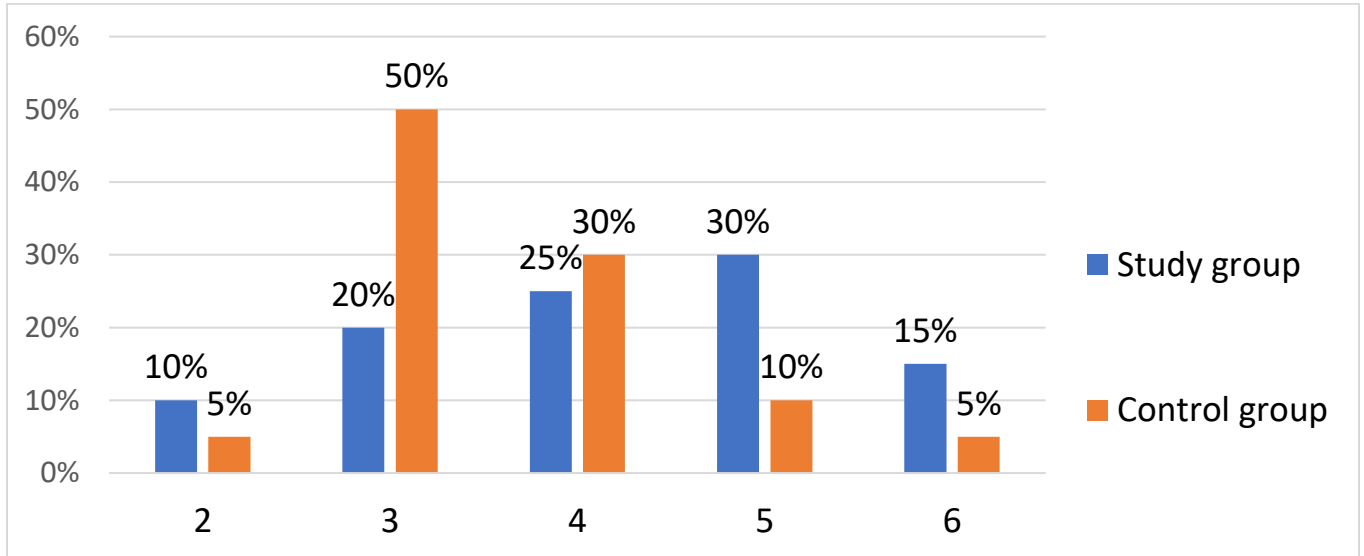


Fig 3 : Pain on POD 2 Using VAS Scale

Mean VAS scores post-operatively on day 7, 1 month, 3 months, and 6 months are presented in Table 4. Patients in the control group showed a higher mean VAS score of 0.70 (SD 0.73) after 6 months of surgery compared to patients in the Study group who recorded a mean VAS score of 0.15 (SD 0.48) with a p-value of 0.07 indicating a statistically significant difference between the two groups.

Table 4: Comparison of mean VAS scores postoperatively in study and control groups (n=40)

Mean VAS score	Study Group (n=20)	Control Group (n=20)	p-value
POD 7	3.20 ± 1.10	2.90 ± 0.85	0.35
Postoperative -1 Month	1.90 ± 0.72	2.10 ± 0.78	0.40
Post operative-3 months	0.90 ± 0.64	1.3 ± 0.65	0.05
Postoperative -6 months	0.15 ± 0.48	0.70 ± 0.73	0.007*

*Significant at p-value < 0.05

DISCUSSION:

The age and gender difference between the study and control groups was insignificant in the present study (p-value of 0.92 and 0.72 for age and gender respectively), indicating that the study and control groups are comparable.

In our present study recurrence rates of pilonidal sinus were higher in patients operated with excision with primary closure (35%) compared to patients operated with Limberg flap procedure (5%), with a statistical significance (p -value: 0.02). These findings are comparable to findings reported by other studies, namely Sondenaa et al⁷ and Mentés et al⁶ where the recurrence rates reported were 3.33% for the Limberg flap group and 26.67% recurrence in the primary closure group. In a study conducted by Meena OK,⁸ recurrence rates were 5% and 40% in the Limberg flap group and primary closure groups respectively which is comparable to the present study. The effectiveness of a procedure on the recurrence of a sinus primarily depends on its capacity to obliterate the depth of the natal cleft. Given this, one might anticipate that flap procedures will prevent the disease from returning more effectively than simple closure or excision.

Wound dehiscence was the most common complication observed in 8(20%) patients. 35% of patients operated with excision with primary closure developed wound dehiscence compared to only 5% of patients operated with the Limberg flap technique and a significant association was found ($p = 0.02$). In a study by Arnous M et al⁹ 6.6% of patients with primary closure developed wound dehiscence compared to 3.3% of patients with Limberg flap. A study by Meena OK⁸ reported similar findings of 30% in the primary closure group and 3.33% in Limberg flap-operated patients. According to Lee et al., postoperative wound dehiscence is 5–10% in primary closure versus 0.9–3.9% in the Limberg flap procedure used by Bascom and Daphan et al.^{10,11,12}

In our study stitch line infection was 5% for the Limberg flap group and 30% for the primary closure group. Meena OK et al⁸ reported stitch line infection to be 3.33% in the Limberg flap group and 33.3% in excision with the primary closure group. Arnous M et al⁹ reported wound infection to be 20% in the primary closure group and 3.3% in the Limberg flap procedure. Seroma formation was seen in 5% of the patients with Limberg flap and 25% of the patients with primary closure. Daphan et al¹¹ reported 2% seroma formation with the Limberg flap procedure. Meena OK et al⁸ reported 3.3% seroma formation in Limberg flap and 26.67% in primary closure.

Complications like stitch line infection, wound dehiscence, and seroma formation were low for the Limberg flap group as compared to the primary closure group in the present study and the difference was statistically significant. The data from the present study demonstrates that the Limberg flap group has seen fewer morbid acute post-operative problems than the main closure group.

Immediate postoperative pain measured by the VAS scale was higher in the study group compared to the control group on POD -1 and was statistically significant. Pain decreased in subsequent days in both the study and control groups on POD 2, POD 7, PO 1 month and 3 months and 6 months. A study by Meena OK et al⁸ reported a higher postoperative pain in patients operated with Limberg flap on POD 1 and 2. A study done by Arnous M et al⁹ reported almost similar pain scores on POD 1,4 in both groups.

CONCLUSION AND RECOMMENDATIONS:

The purpose of the current study was to compare and contrast the two methods of pilonidal sinus surgery—excision with primary closure and Limberg flap—with particular attention to the length of the procedure, postoperative complications, and recurrence.

With lower morbidity rates than primary closure, we advise the Limberg flap approach for primary pilonidal illness; Irrespective of the procedure, postoperative wound care is important and requires eliminating the hair ingrown or local hair from the wound. Nevertheless, more research with a bigger volume sample and a longer follow-up time is required.

REFERENCES:

1. Bailey & Love's Short Practice of Surgery. 28th edition. United states; CRC Press;2022 pg: 1423-25
2. McCallum I, King PM. Healing by primary versus secondary intention after surgical treatment for pilonidal sinus. Cochrane Database Syst Rev. 2007:CD006213
3. Courtney M. Townsend.. Sabiston Textbook of Surgery. 21st edition. North America: Elsevier-Health Sciences Division;2021 pg:1411
4. Galal Elshazly W, Said K. . Clinical trial comparing excision and primary closure with modified Limberg flap in the treatment of uncomplicated sacrococcygeal pilonidal disease. Alexandria J Med 2012; (1): 13–18.
5. Visual Analog scale available from https://www.physio-pedia.com/Visual_Analogue_Scale accessed on 20.02.2024.
6. Montes BB, Leventoglu S. Modified Limberg transposition flap for sacrococcygeal pilonidal sinus. Surg Today. 2004; 34:419-23.
7. Sondena K, Andersen E. Patient characteristics and symptoms in chronic pilonidal sinus disease. Int J Colorectal Dis. 1995; 10:39-42
8. Meena OK, Kalwaniya DS, Arya SV, Kuppuswami M, Bajwa JS, Pradhan RS, et al. A comparative study of excision with primary closure versus Limberg flap in pilonidal sinus. Int Surg J 2019; 6:4282-9ail
9. Arnous M, Elgendy H, Thabet W, Emile SH, Elbaz SA, Khafagy W. Excision with primary midline closure compared with Limberg flap in the treatment of sacrococcygeal pilonidal disease: a randomised clinical trial. Ann R Coll Surg Engl. 2019 Jan;101(1):21-29. doi: 10.1308/rcsann.2018.0144. Epub 2018 Oct 5. PMID: 30286636; PMCID: PMC6303836
10. Lee HC, Ho YH. Pilonidal disease in Singapore: clinical features and management. Aust N Z J Surg. 2000;70:196-8.
11. Daphan C, Tekelioglu MH. Limberg flap repair for pilonidal sinus disease. Dis Colon Rectum. 2004;47:233-7
12. Bascom JU. Pilonidal disease: correcting overtreatment and under treatment. Contemporary Surg. 1981; 18:13-28