"Study of Outcomes in the Repair of Pilonidal Sinus Using Flap Techniques in Gtmch, Theni-A Prospective Study"

Dr.K.Kannan, M.S¹, Dr.P.Ganesh,M.S²

¹Associate Professor Of Surgery, Govt Theni Medical College, Theni. ²Associate Professor Of Surgery, Govt Theni Medical College, Theni.

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I. Introduction

Pilonidal sinus is most commonly seen in the sacrococcygeal region. It can also affect many other areas of the body. In the sacrococcygeal region, the commonest site is the natal cleft located probably 4-5 cm above the anal verge. Extranatal sites affected by the pilonidal sinus disease are the fingers, ear, axilla, umbilicus, perineum, suprapubic area, amputation stump & chest wall.

AIMS AND OBJECTIVES

AIM:

To study the outcomes in the repair of pilonidal sinus using flap techniques

OBJECTIVE:

- 1. The primary objective is to evaluate and analyze the clinical effectiveness of flap surgeries in the management of pilonidal sinus disease.
- 2. The secondary objective is to estimate the difference in post surgical outcomes in terms of quality of life between the various flap techniques in the management of pilonidal disease.

II. Materials And Methods

This study was designed as a Prospective study conducted in the surgical clinic in Theni government medical college and hospital. The purpose of this study was to evaluate and compare the efficacy of various flap surgeries in pilonidal sinus disease. This study was conducted from May 2018 to Jan 2021.

ETHICAL COMMITTEE APPROVAL:

This study proposal was placed before the Institutional Ethical Committee and prior approval were procured before the commencement of the study (REFERENCE NO: 884/MEIII/19). All the patients participating in the study were explained about the nature of the disease related defects, the surgical procedure and their possible complications, following which a written informed consent was obtained before initiation of treatment.

Sample size for the study was calculated based on the study done by Dahmann S, Lebo PB et al in 2016. 66 A total of 50 patients who full-filled the inclusion criteria and exclusion criteria were allocated into the study where 31 patients underwent Limberg's flap procedures, 14 patients underwent Z plasty procedures and 5 patients underwent Karyadakis flap procedures. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) was used.

RECRUITMENT OF PATIENTS:

The recruitment of patients was done followed by the evaluations such as General examinations, systemic examinations, investigations such as complete hemogram, liver function test, renal function test, USG abdomen, MRI sacrococcygeal region with sinus mapping, ESR, CXR. Along with these evaluations, patients who satisfies the inclusion criteria were included in the study.

SUBJECT SELECTION CRITERIA: INCLUSION CRITERIA:

- 1. Patients aged between 18-60 years
- 2. Patients with Pilonidal sinus disease

EXCLUSION CRITERIA:

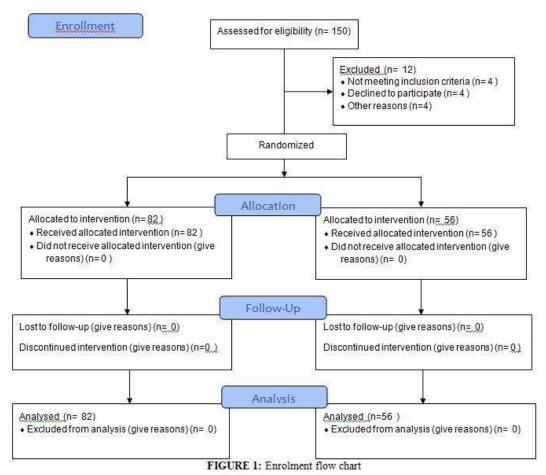
- 1. Patients aged above 60 yrs
- 2. Patients with systemic complications
- 3. Patients with poor general conditions like malignancy, renal failure, bleeding diathesis, fistula in ano, actinomycosis, tuberculosis, acute pilonidal abscess.

RANDOMISATION:

The cases were randomized into two groups as Group A and Group B

GROUP A: Patients underwent Limberg flap surgery. **GROUP B:** Patients were subjected to Z plasty procedure. **GROUP C:** Patients underwent Karyadakis flap procedure.

All the three groups were studied for incidence of hematoma, pain, wound infection, flap necrosis, and recurrence.



SURGICAL PROCEDURES:

With patient in prone position, under strict aseptic precautions, under spinal anesthesia, buttocks are parted using adhesive tapes on either side. The following procedures are done accordingly to the selected patients respectively.

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PICTURES DETAILS

- 1- Preop picture 9- Karydakis procedure 2- Limberg rhomboid flap marking 10- Z-plasty markings
- 3- After Rhomboid excision 11- Sinus excised 4- Excised rhomboid shaped 12- Z flaps raised tissues with sinus
- 5- Limberg rhomboid flap raise 13- Flaps sutured 6- Flaps approximated 14,15,16- Followup
- 7- Flaps sutured images after 1 year 8- Post operative image

KARYDAKIS FLAP

In this procedure an ellipse of skin and underlying fat down to the deep fascia is excised. The ellipse is parallel to, but 2 cm from, the midline. It must be at least 5 cm in length as there is increased tension on closure of a short ellipse.

The medial side of the incision should just cross the midline and should encompass all the diseased midline tissue. In extensive natal cleft disease a very long ellipse may thus be required, but this does not create any problem. However, when there are bilateral sinus extensions it may not be possible to excise all diseased tissue with this technique.

The ellipse must be symmetrical, and the surgeon must resist the temptation to cut the lateral part of the ellipse less generously in an attempt to remove less tissue, as this only results in the scar failing to lie away from the midline.

The whole length of the medial side of the incision is then mobilized by undercutting a distance of 2 cm at a depth of 1 cm. In thin patients the undercutting incision is at the junction of the fat and deep fascia. Any strapping to distract the buttocks is now removed.

The first sutures are placed between the limit of the undercutting incision and the deep fascia in the midline. These draw the flap over and recreate a new shallow midline sulcus.

Pressure from an assistant to unroll the flap as the sutures are tied will reduce tension. A vacuum drain and a second layer of more superficial fat sutures are then inserted, and finally the skin is opposed with interrupted nonabsorbable sutures.

The wound lies a few centimetres from the midline, and the patient has a new shallow natal cleft with healthy unscarred skin.

Z-Plasty

In this reconstructive flap, an elliptical excision of all the sinus tracts was performed including the narrow margins of healthy surrounding skin down to presacral fascia and then the limbs of the Z- plasty should be marked according to dimensions of the wound created and the wound is then closed in two layers with suction drain. Shorter hospital stay, earlier and good wound healing, shorter time off from work, reduced recurrence rate, and lower score of postoperative pain are the main advantages this techniques.

Therefore, Z-plasty technique is recommended because it makes the natal cleft shallow and reduces sweat and hair accumulation resulting in perfect balance between conservatism and radicalism.

The disadvantage of the Z-plasty procedure is that part of the wound is in the midline, which is the main cause of recurrence. Besides the flap tip, necrosis has been reported. Z-plasty requires back cuts and incisions at specific angles and is not supplied by robust perforators like V-Y-plasty, technically demanding as geometrical planning is involved.

LIMBERG FLAP

For this operation the patient is placed prone and the buttocks are strapped apart. A rhombic area of skin and subcutaneous fat is excised which includes both the midline pits and any lateral sinus extensions. The long axis of the rhomboid is in the midline and its shape determined by angles of 60 degrees at **A** and **C** and 120 degrees at **B** and **D**. Accuracy is essential for success, and the rhomboid of tissue to be excised and the flap must be measured and marked with indelible pen at the start of surgery.

Planning with angles is difficult and the following linear measurements will always produce the correct angles to the rhomboid. First, the line A-C is drawn and its length measured. C should be adjacent to the perianal skin, and A is placed so that all diseased tissue can be included in the excision.

The line **B**–**D** transects the midpoint of **A**–**C** at right-angles and is 60 per cent of its length. It is this ratio of lengths which determines the correct shape to the rhomboid. The flap is planned so that **D**–**E** is a direct continuation of the line **B**–**D** and is of equal length to the incision **B**–**A** to which it will be sutured after rotation. **E**–**F** is parallel to **D**–**C**, and of equal length. After rotation, it will be sutured to **A**–**D**.

The skin and subcutaneous fat to be removed is excised down to, but not including, the deep fascia. Scalpel dissection is preferable to diathermy to preserve maximum vascularity, but multiple vessels piercing the fascia will have to be accurately coagulated.

The flap is raised so that it includes skin, subcutaneous fat and the fascia overlying gluteus maximus. It is then rotated to cover the midline rhomboid defect and the defect this creates can be closed in a linear fashion. Deep absorbable sutures, to include fascia and fat, are placed over a vacuum drain and then finally the skin is closed with interrupted sutures. This operation produces a tension-free flap of unscarred skin in the midline.

POST OPERATIVE FOLLOWUP AND INSTRUCTIONS:

In post operative ward, after anesthesia effect weaned, all patients were scored by pain scale. Followed by analgesics were given. Wound opened after 48 hours and checked for collection, infection and bleeding. Daily cleaning and dressing done. Patients were discharged based on individual patients' condition. Sutures were removed on 10th day. Patients were kept under regular follow-up.

SCREENING PROCEDURES AND FOLLOWUPS:

- O Patients were reviewed immediately 1 week after surgery and the surreal parameters such as collection under flap & wound infection were recorded.
- O Patients were reviewed at 4weeks, 12 weeks, 6 months & 1 year, assessed for wound infection, wound dehiscence, flap necrosis & recurrence.

III. Results:

The purpose of the study is to evaluate and analyze the clinical effectiveness of flap surgeries in the management of pilonidal sinus disease. A total of 50 patients who full-filled the inclusion criteria and exclusion criteria were allocated into the study where 31 patients underwent Limberg's flap procedures, 14 patients underwent Z plasty procedures and 5 patients underwent Karyadakis flap procedures. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) was used.

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal that some variables like

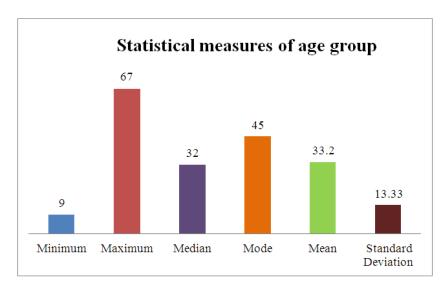
Age follow Normal distribution and some variables at different time points do not follow Normal distribution. Therefore, to analyse the data both parametric and non-parametric methods were applied. For parameters which follow Normal distribution, to compare the mean values between treatment groups independent samples t-test was applied. For non-Normal variates (pain scores) to compare pain scores between treatment groups Mann Whitney test was applied. To compare proportions between treatment groups Chi-Square test was applied, if any expected cell frequency is less than five then Fisher's exact test was used.

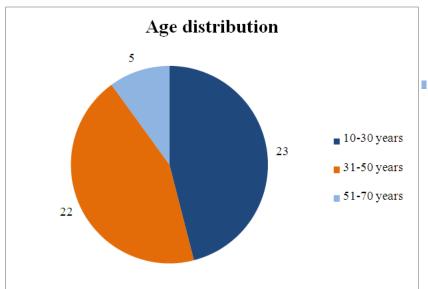
TABLE 1: AGE DISTRIBUTION

Age (in years)	Values
Minimum	9
Maximum	67
Median	32
Mode	45
Mean	33.2
Standard Deviation	13.33

TABLE 2: AGE GROUP DISTRIBUTION

Age Group	No.of patients	Percentage
10-30 years	23	46%
31-50 years	22	44%
51-70 years	5	10%
Total	50	





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TABLE 3: SEX DISTRIBUTION

Sex	No.of patients	Percentage
Male	32	64%
Female	18	36%

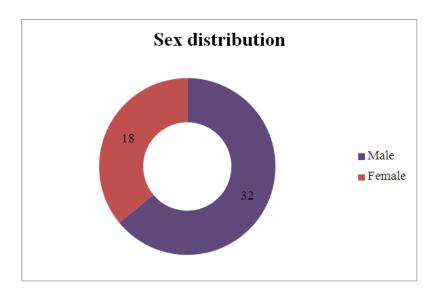


TABLE 4 : SURGICAL PROCEDURES ALLOCATED

Procdure	No.of patients	Percentage
Limberg's flap	31	62%
Z plasty	14	28%
Karydakis'flap	5	10%

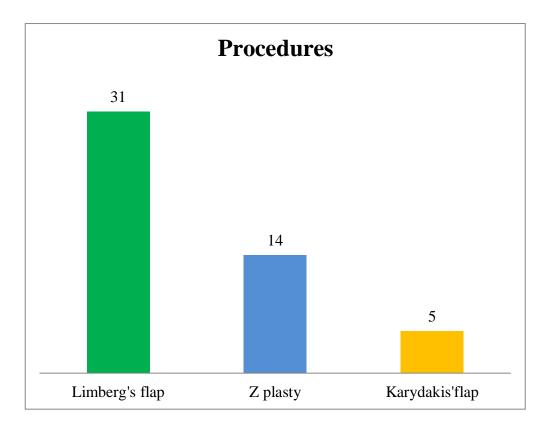


TABLE 5: COMORBIDITIES DISTRIBUTION

Comorbidities	No.of patients	Percentage	
DM	3	6%	
CKD	2	4%	
COPD	1	2%	
CAD	1	2%	

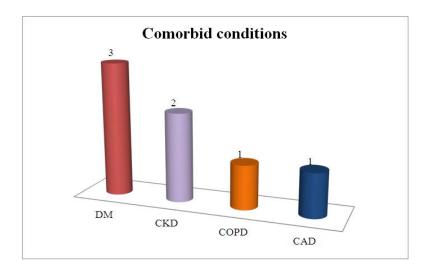
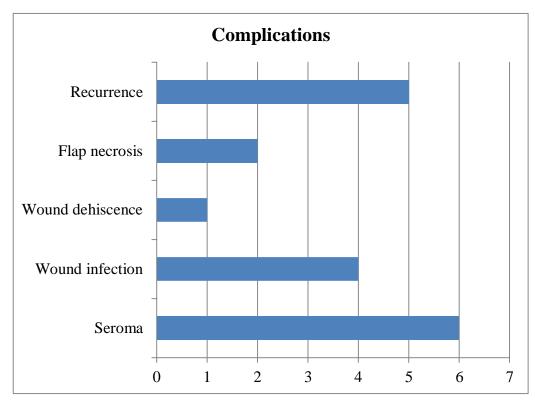


TABLE 6: COMPLICATIONS EVALUATION

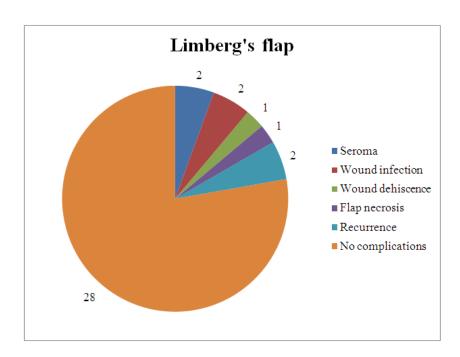
Complications	No.of patients	Percentage	
Seroma	6	12%	
Wound infection	4	8%	
Wound dehiscence	1	2%	
Flap necrosis	2	4%	
Recurrence	5	10%	

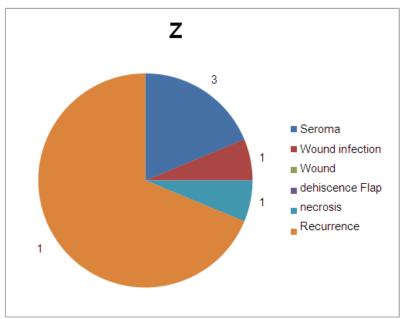


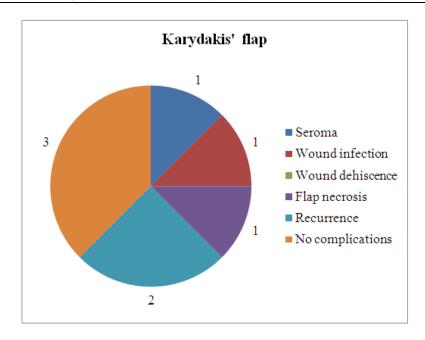
The chi-square statistic is 3.3719. The *p*-value is .185271. There is no statistically significant complications between procedures at p < .05.

TABLE 7: COMPLICATIONS EVALUATION IN THE THREE SURGERIES

		Wound infection	Wound dehiscence	Flap necrosis	Re currence	No complications
Procedure	Seroma					
Limberg's flap						
	2	2	1	1	2	28
Z plasty	3	1	0	0	1	11
Karydakis' flap						
	1	1	0	1	2	3







IV. Discussion:

The present study was designed as a prospective study in which we compared the clinical effectiveness among the three flap procedures, Limberg, Z plasty & Karyadakis procedure.

In the present study, multiple surrogate markers were analysed with the time duration of immediate, 1month, 3months, 6months and 1 year post surgery in order to compare the clinical effectiveness more appropriately.

In relevance with the allocation of subjects, age factor plays a predominant role. In our study, there was statistical significance in the age distribution among the three flap procedures, which pays a way of quite more appropriate outcome of the study.

In accordance with the gender distribution, 64% males and 36% females were included in the study.

The important surrogate markers in the analyzation of clinical effectiveness of surgical procedures between groups are seroma, wound infection, wound dehiscence, flap necrosis & recurrence.

There was a statistical significance noted between the three groups. 6% of the patients had diabetes mellitus, 4% had CKD, 2% had COPD & 2% had CAD. Of the selected 31 patients for Limberg procedure, 2 developed seroma, 2 developed wound infections, 1 developed wound dehiscence, 1 developed flap necrosis & 28 patients were free from complications.

Among the 14 patients who underwent Z plasty, 3 got seroma, 1 developed wound infection & 11 patients were developed no complications.

Among the 5 patients of Karydakis procedure, 1 patient developed seroma, 1 got wound infection, 1 developed flap necrosis & 3 patients got no complications.

The most crucial parameter in the management of pilonidal sinus is the recurrence rate.

There was 6.5% recurrence reported in the Limberg group, 7.1 % recurrence reported in the Z plasty surgery group & 40 % reported with Karyadakis group at 12 months post-surgery.

There are various options for handling the sacral defect resulting from pilonidal sinus excision ranging from conservative treatment to surgical interventions mentioned above.

Judging from the current literature, it becomes evident that there is no single technique that outperforms all others. According to meta- analysis, primary wound closure should be avoided due to an increased recurrence and complication rate ⁶⁷.

Secondary wound healing only showed improved recurrence rates compared to primary wound closure, while there was no advantage compared to off-midline procedures ⁶⁷.

A systematic review showed an improved healing time and duration of hospitalisation in secondary wound healing after minimally invasive lay open technique compared to the wide excision ⁶⁸.

Minimal invasive procedures provide a shorter stay in hospital and an earlier return to work, but appear to have a higher rate of therapy failure, even though no exact data of treatment comparison is available yet ⁶⁸.

Meta-analyses have shown a clear benefit of off-midline procedures compared to primary wound closure concerning infection rate and dehiscence, recurrences, and time to healing ⁶⁷.

In comparison to secondary wound healing, Limberg flap showed significant reductions in time to healing, in recurrence rate, as well as in postoperative pain 69,70 .

Within plastic surgical procedures only a few studies compare different flaps directly to each other. Yet, there is

no consensus in the results of this literature on whether Limberg or Karydakis flap is preferable ^{71, 72}.

Z flap results in a significantly higher recurrence rate than Limberg flap. A modification of the Limberg flap with an asymmetrical design shifting the lower pole by 1–2 cm lateral off the midline leads to a significant improvement concerning recurrence rate ⁷³, maceration, surgical site infections, and time to return to work, compared to the classical Limberg flap ⁷⁴.

Possible reasons for the improved outcome are a larger distance between the caudal end of the suture and the anus, and the prevention of a suture in the midline.

Our own studies supplement ongoing research with regard to scar quality.

We could proof a better scar elasticity after Limberg flap compared to secondary wound healing.

This result met our expectations based on the tension through distinct wound contraction of nearly 90% in pilonidal sinus wounds after secondary wound healing in combination with a lack of elastic fibres in the forming scar tissue ⁷⁵.

It remains to be analysed whether other flaps like Karydakis or Z flap reveal a higher elasticity as well, compared to secondary wound healing. In contrast to wound contraction after secondary wound healing, flap procedures provide healthy tissue to cover the defect.

We would, therefore, expect findings similar to the Limberg flap with better elasticity values for all flaps in comparison to secondary wound healing.

Whether elasticity results differ between flaps should be investigated in further studies.

Another approach to evaluate therapies is a comparison of the incurred costs.

We aimed to compare secondary wound healing with Limberg flap but face the most difficult challenge in considering conflicting perspectives. From the patient's view, a Limberg flap is less costly with shorter work absence.

The patient does not suffer from losses through sickness benefits that are paid. It becomes evident that the question of cost-effectiveness cannot be answered generally but needs to be considered individually depending on the perspective.

V. Conclusions

An infected pilonidal sinus needs surgical excision. However, there is no clear recommendation about handling the resulting tissue defect. In sum, the literature and current research propose two appropriate ways, namely secondary wound healing and local flaps. Primary closure is discouraged due to poorer outcomes concerning complications and recurrence rate. Local flaps provide an immediate wound closure by covering the defect with healthy tissue. Thus, a higher tissue quality, elasticity, and shorter time to recovery result after plastic surgical reconstruction in contrast to secondary wound healing. This is contrasted with the surgery-associated risks. Since both methods ultimately lead to wound healing, the decision on the treatment can be left to the patient's desires. In case of flap closure, the modified Limberg flap or Z plasty flap would certainly be good choices as in several studies they have proven to be successful methods.

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