

Effectiveness of Local Anesthetic Nerve Block compared with Spinal Anesthesia in cases of Rhomboid excision and Limberg flap closure for Pilonidal Disease

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ABSTRACT

Background: Modified Limberg Flap (MLF) is regarded as the mainstay of treatment for Sacrococcygeal Pilonidal disease due to less postoperative complications as compared to other available surgical procedures. This Operative procedure can be performed under Spinal anesthesia as well as Local Anesthesia.

Aim: To compare outcome of patients undergoing Modified Limberg Flap for Sacrococcygeal pilonidal sinus under Local anesthesia with adrenaline versus Spinal anesthesia in terms of post-operative pain, Seroma formation & Hospital stay.

Methods: This was a randomized controlled clinical trial conducted at Department of Surgery, Sughra Shafi Medical Complex, Narowal. Study was conducted for a period of 06 months and 80 patients were included through non-probability consecutive sampling technique. Patients were randomly divided into 2 equal groups by computer generated method. Patients in group LA underwent MLF under Local anesthesia with adrenaline while patients in group SA underwent MLF under Spinal anesthesia. Informed written consent was obtained from all the participating patients.

Results: Mean age of all patients was 24.78±5.12 years. Minimum and maximum age of patients was 16 and 37 years respectively. Gender distribution shows that 96.25% were male while 3.75% were female. Seroma formation in Group-LA was 0% while in Group-SA, it was 7.5%. Hospital stay of patients in Group-LA and in Group-SA was 9.60±9.39 and 29.10±9.37 hours respectively. Mean operation time in Group-LA was 42±5.64 minutes whereas in Group-SA mean operation time was 46±7.53 minutes. Mean pain score in Group-LA was 2±1.04 at 12th hour of surgery and in Group-SA it was 3.83±1.06 at 12th hour of surgery.

Conclusion: It is concluded that Modified Limberg Flap can be performed under local anesthesia as a day case procedure to save time, reduce work burden and cost of surgery.

Keywords: Modified Limberg Flap, Sacrococcygeal Pilonidal Sinus Disease, Local Anesthesia, Adrenaline, Spinal Anesthesia.

INTRODUCTION

Sacroccoccygeal Pilonidal disease is one of the common surgical pathology which mostly involves young people. Incidence of Sacrococcygeal pilonidal disease is roughly 26 per 100,000 population¹. Clinical presentation ranges from asymptomatic hair-containing cysts and sinuses to large symptomatic abscesses of the sacrococcygeal region that have some tendency to recur. Obese people are prone to develop post-operative complications and recurrence of the disease. Pilonidal disease predominantly affects males². Another study showed prolonged sitting for more than four hours per day, family history, having shower less than three times per week and obesity as the risk factors for pilonidal disease³. Diagnosis of the disease remains mainly clinical.

Many surgical techniques have been used in the management of sacrococcygeal pilonidal disease namely Excision and primary closure, excision and Limberg flap, Modified Limberg flap, Cleft lift procedures, bilateral gluteus maximus fascia advancing flap, V-Y advancement flap, Elliptical rotation flap to name a few.^{4,5,6} Some non-operative therapies like use of phenol as sclerosing agent have been used in the past that were found effective in pilonidal disease and its recurrence^{7,8}.

Generally Modified Limberg Flap(MLF) is being used as mainstay of treatment in sacrococcygeal pilonidal disease because post-operative complications are more common in primary closure as compared to MLF i.e. wound infections (more frequent in primary closure P=.0254) and recurrence (3.84% in primary closure and 0% in MLF)^{9,10}. Modified Limberg Flap is superior than classical limberg flap in terms of recurrence and wound complications at the cost of high rate of seroma formation^{11,12}. Karydakias flap and MLF are comparable in terms of recurrence^{13,14}.

In a study conducted by Kirkil et al, MLF under spinal anesthesia had 14.5% incidence of seroma formation, 3.2 days average hospitalization¹⁵ while another study by Awad et al, claims

that MLF under local anesthesia has less incidence of seroma formation and mean hospital stay as compared to spinal or general anesthesia i.e. seroma formation (0% in Local) , mean hospital stay (0 ±0 days in Local, 7±1 days in spinal)¹⁶. A study shows that Local anesthesia has incidence of lower post-operative pain with mean values of visual analogue score (VAS) of mean 1.28cm±0.41 and shorter hospital stay with 67% of the patients in LA group left the hospital on day of surgery¹⁷. Another study by Onder et al. showed that local anesthesia has higher complication rates in terms of recurrence both in primary closure as well as limberg flap surgery in pilonidal disease¹⁸. A Turkish study revealed a 30% rate of wound complications with local anesthesia¹⁹. Another study reveals that sacrococcygeal local infiltration anesthesia(LA) for pilonidal sinus resulted in lower complications in terms of shorter hospital stay with two third of the patients in the local infiltration anesthesia group (65.6%) left the hospital on the day of surgery, compared to only (34.4%) in the spinal anesthesia group leading to more post-operative patient satisfaction and post-operative pain with mean values according to VAS of 3.73 ±0.17cm in local anesthesia against 4.5±0.24cm in spinal anesthesia²⁰.

This study was conducted to ascertain which technique is better for MLF as some studies showed local anesthesia is better in terms of post-operative pain, mean hospital stay & seroma formation while others showed that there is no statistically significant difference in terms of post-operative complications in both groups. There is no local data available either favoring or discouraging the use of either local or spinal anesthesia in sacrococcygeal pilonidal surgery.

METHODOLOGY

Randomized controlled clinical trial was conducted at Department of Surgery, Sughra Shafi Medical Complex Narowal, from March 2021 to September 2021 for a period of 06 months after permission from IRB. Non-probability, consecutive sampling was done for a sample size of 80 cases (40 in each group) estimated by using 80% power of test, 5% level of significance and taking

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expected percentage of seroma formation in both groups i.e. 14.5% in group SA vs 0% in group LA in patients undergoing modified limberg flap procedure. Patients aged 13-45 years with clinical diagnosis of Pilonidal sinus/cyst only (diagnosed clinically; presence of single/multiple sinuses/cysts in sacrococcygeal area and/or evidence of hair in sinus) were included. Patients with Pilonidal abscess (diagnosed clinically i.e. had history of fever, purulent discharge, localized tenderness or erythema may be present; evidence of presence of microbial growth on culture/sensitivity). Patients with recurrent disease, pregnant ladies, allergy to drugs used in this study, alcohol addict or intravenous drug abusers, incapable of providing informed consent, not fit for surgery, with chronic medical conditions like Chronic Liver Disease, coagulation disorders etc. (having previous medical record or proved during preoperative work up) were excluded.

Data Collection / Retrieval: After taking approval from hospital ethical committee, 80 patients fulfilling inclusion criteria were enrolled in the study after admission through outpatient department. Informed written consent was obtained from all participating patients. Demographic information (name, age, gender, contact & profession) were noted. The patients were randomly divided into two equal groups by using computer generated method. Patients in Group LA underwent MLF under Local Anesthesia with Adrenaline while patients in Group SA underwent MLF under Spinal Anesthesia. Standard dose of local anesthetics according to weight were used i.e. inj. Lignocaine with adrenaline as 7mg/kg in a ratio of 1:200,000 and inj. Bupivacaine as 2mg/kg. No sedative agent was used. The technique is as follows. The sacrococcygeal block was executed with the patient in the prone position, after obtaining intravenous access. The buttocks were pulled outwards with adhesive tapes, exposing the sacral area and the pilonidal sinus. After aseptic preparation of the skin, four injection sites were marked: 4 cm above and below, and 3 cm lateral to the center of the pilonidal sinus on both sides as described by Naja MZ *et al.*¹⁷. A total of 30–40 ml of the local anesthetic mixture was used, depending on the patient's weight. All operations were performed by same surgical team. All patients received same antibiotics post operatively. Redivac suction drain number 14 Fr. was used in all patients. After surgery patients were shifted to ward and followed up there. All patients were given single analgesic dose of intramuscular diclofenac at 6th post-operative hour. Post-operative pain was assessed by using Visual Analogue Scale on 12th post-operative hour. Post-operative hospital stay and seroma formation were assessed. All the data was collected on a specifically designed proforma.

Data Analysis: Data was entered and analyzed through using SPSS 17. The Quantitative data like age, pain score & hospital stay were presented by using Mean and SD. The Qualitative data like gender and seroma formation were presented by using frequency and percentage. The mean pain score & mean hospital stay were compared between two groups using t-test. Seroma formation was compared in both groups by using chi-square test. $p\text{-value} \leq 0.05$ was considered statistically significant. Data was stratified for age, gender & single/multiple sinuses/cysts to address effect modifiers. Post stratification Chi-square test was applied to check the significance with $p\text{-value} \leq 0.05$ as significant.

RESULTS

Total 80 patients were enrolled in this study. Mean age of all patients was 24.78 ± 5.12 years. Minimum and maximum age of patients was 16 and 37 years respectively. Mean age of patients in Group-LA and in Group-SA was 24.93 ± 4.72 and 24.63 ± 5.55 years respectively (Table-1). Gender distribution shows that in Group-LA 39(97.5%) patients were male and 1(2.5%) were females while in Group-SA there were 38(95%) male and 2(5%) female patients respectively (Figure-1).

Overall incidence of Seroma formation remained 3.75%. In Group-LA no patient suffered from Seroma Formation i.e. 0(0%) patients had seroma formation while in Group-SA 3(7.5%) patients

had Seroma Formation. $p\text{-value}$ was statistically non-significant i.e. 0.12 (Figure-2)

Overall hospital stay of all patients was 19.35 ± 13.53 hours with minimum and maximum hospital of patients being 6 hours and 48 hours respectively. Hospital stay of patients in Group-LA and in Group-SA was 9.60 ± 9.39 and 29.10 ± 9.37 hours respectively which was statistically significant with $p\text{-value}$ 0.00 (Table-2).

Mean operation time in Group-LA was 42 ± 5.64 minutes. Minimum and maximum operative time in Group-LA was 30 and 60 minutes respectively. Whereas in Group-SA mean operation time was 46 ± 7.53 minutes. Minimum and maximum operative time in Group-SA was 35 and 70 minutes respectively. In terms of $p\text{-value}$ mean operation time was statistically different in both treatment groups. Operative time of Group-LA was less as compared to Group-SA. i.e. ($p\text{-value}=0.009$) (Table-3)

In this study, the mean pain score in Group-LA was 2 ± 1.04 with minimum and maximum score of 1 and 6 respectively at 12th hour of surgery and in Group-SA it was 3.83 ± 1.06 with minimum and maximum score of 2 and 6 respectively at 12th hour of surgery. Statistically there is significant difference found between the groups and pain score i.e. $p\text{-value}=0.000$ (Table 4).

In Group-LA mean drain output at 24th hour after surgery was 69.25 ± 21.91 ml with minimum and maximum drain output as 30ml and 110ml respectively while In Group-SA mean drain output at 24th hour after surgery was 129.63 ± 25.56 ml with minimum and maximum drain output as 80ml and 210ml respectively. $p\text{-value}$ was statistically significant among two groups i.e. $p\text{-value}=0.00$ (Table 5)

In Group-LA mean drain output at 48th hour after surgery was 84.25 ± 25.51 ml with minimum and maximum drain output as 40ml and 140ml respectively while In Group-SA mean drain output at 48th hour after surgery was 171.50 ± 32.21 ml with minimum and maximum drain output as 120ml and 270ml respectively. $p\text{-value}$ was statistically significant among two groups i.e. $p\text{-value}=0.00$ (Table 6).

In Group-LA mean drain output at 72nd hour after surgery was 92.13 ± 30.70 ml with minimum and maximum drain output as 40ml and 160ml respectively while In Group-SA mean drain output at 72nd hour after surgery was 196.00 ± 38.43 ml with minimum and maximum drain output as 130ml and 310ml respectively. $p\text{-value}$ was statistically significant among two groups i.e. $p\text{-value}=0.00$ (Table 7). When data was stratified for age, gender; there was statistically no significant difference, $p\text{-value}$ was more than 0.05.

Table 1: Age (years) of patients in treatment group

	Group-LA	Group-SA	Total
N	40	40	80
Mean	24.93	24.63	24.78
SD	± 4.72	± 5.55	± 5.12
Minimum	18	16	16
Maximum	36	37	37

Table 2: Descriptive statistics for hospital stay (hours)

	Hospital Stay (Hours)		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	9.60	29.10	19.35
SD	± 9.39	± 9.37	± 13.53
Minimum	6	24	6
Maximum	48	48	48

$P\text{-value}=0.00$ (Significant: $p\text{-value}<0.05$)

Table 3: Descriptive statistics for operation time (minutes)

	Operation Time (Minutes)		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	42	46	39.13
SD	± 5.64	± 7.53	± 15.36
Minimum	30	35	20
Maximum	60	70	75

$P\text{-value}=0.009$ (Significant: $p\text{-value}<0.05$)

Fig. 1: Gender distribution of patients in treatment groups

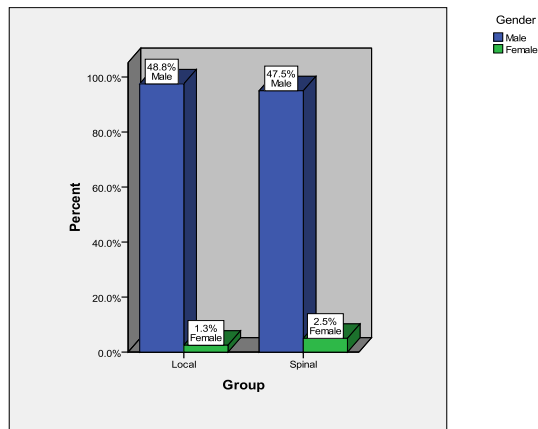


Fig. 2: Distribution of patients on seroma formation

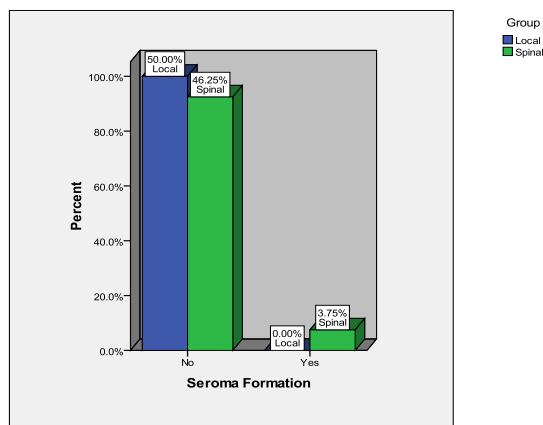


Table 4: Descriptive statistics for mean pain score (cm)

	Mean Pain Score (cm)		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	2	3.83	2.91
SD	±1.04	±1.06	±1.31
Minimum	1	2	1
Maximum	6	6	6

P value= 0.01(Significant: p-value<0.05)

Table 5: Descriptive statistics for mean drain output (ml) at 24th hour

	Mean Drain Output (ml) At 24 th Hour		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	69.25	129.63	99.44
SD	±21.91	±25.56	±38.50
Minimum	30	80	30
Maximum	120	210	210

P value= 0.00(Significant: p-value<0.05)

Table 6: Descriptive statistics for mean drain output (ml) at 48th hour

	Mean Drain Output (ml) At 48 th Hour		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	84.25	171.50	127.88
SD	±25.51	±32.21	±52.54
Minimum	40	120	40
Maximum	140	270	270

P value= 0.00(Significant: p-value<0.05)

Table 7: Descriptive statistics for mean drain output (ml) at 72nd hour

	Mean Drain Output (ml) At 72 nd Hour		Total
	Group-LA	Group-SA	
N	40	40	80
Mean	92.13	196.00	144.06
SD	±30.70	±38.43	±62.66
Minimum	40	130	40
Maximum	160	310	310

P-value= 0.00(Significant: p-value<0.05)

DISCUSSION

The operation of choice for pilonidal sinus disease had been a long debate. The best procedure for sacrococcygeal pilonidal sinus disease must be simple, require short or no hospitalization and have a low recurrence rate²². There should be least pain and wound care, rapid return to routine activity and treatment should be cost effective²³. To find answers of all these questions, a number of surgical and anesthetic techniques have been advocated to reach this goal¹⁷. Generally Modified Limberg Flap (MLF) is being used as mainstay of treatment in pilonidal disease because post-operative complications are more common in primary closure as compared to MLF i.e., wound infections (more frequent in primary closure P=.0254) and recurrence (3.84% in primary closure & 0% in MLF)^{9,10}.

Local infiltration anesthesia, spinal anesthesia and general anesthesia are frequently utilized anesthetic techniques for treatment of pilonidal sinus disease (PSD). However, the best anesthetic technique to reach our goals remains unknown²⁴. Pain is one of the most important factor which could affect the quality of patients' life after a surgery. Many attempts have been made to select an appropriate surgery and anesthesia technique to reduce patient's pain during and after surgery^{25,26}.

In this study mean Hospital stay of patients in Group-LA and in Group-SA was 9.60±9.39 and 29.10±9.37 hours respectively which was statistically significant with p-value 0.00.

Awad *et al*¹⁶ reported shorter hospital stay of patients who underwent modified limberg flap (MLF) under local anesthesia which was 0±0 days & longer hospital stay under spinal anesthesia which was 7±1 days. p=0.001

Kirkil C *et al*¹⁵ also documented longer hospital stay (3.2 days) in modified limberg flap under spinal anesthesia in their study. This agrees too with Sungurtekin *et al*²⁴, who studied regional and spinal anesthesia in pilonidal sinus surgery and found that patients with local infiltration anesthesia had shorter hospital stay, and lower overall costs with no side effects. Another study reveals that sacrococcygeal local infiltration anesthesia (L.A) for pilonidal sinus resulted in lower complications in terms of shorter hospital stay with two third of the patients in the local infiltration anesthesia group (65.6%) left the hospital on the day of surgery, compared to only (34.4%) in the spinal anesthesia group²⁰. A study shows that mean hospital stay of patients who underwent limberg flap under spinal anesthesia was 2.45 days (1-5)²⁹.

A local study by Aslam MN *et al*²⁷ shows a longer hospital stay i.e. 3.0 days in patients who underwent limberg flap under spinal anesthesia. Another local study by Khan JS *et al*²⁸ conducted at Holy family hospital shows relatively longer hospital stay i.e. 1.75 days in spinal anesthesia group.

In this study in Group-LA no patient suffered from Seroma Formation i.e. 0(0%) patients had seroma formation probably due to vasoconstriction caused by adrenaline while in Group-SA 3(7.5%) patients had Seroma Formation. Although there is a gross difference between seroma formation in both groups, but p-value was statistically non-significant i.e. 0.12

Awad *et al*¹⁶ reported 0% seroma formation in Local anesthesia group while 6% in spinal anesthesia group. Kirkil C *et al*¹⁵ showed high incidence of seroma formation i.e. 14.5% in spinal anesthesia group. Another study shows that there was 3.5% incidence of seroma formation in spinal anesthesia group²⁹.

In this study, the mean pain score in Group-LA was 2 ± 1.04 at 12th hour of surgery and in Group-SA it was 3.83 ± 1.06 at 12th hour of surgery. Statistically there is significant difference between the groups in terms of pain score i.e. p -value=0.000.

A study shows that Local anesthesia has incidence of lower post-operative pain with mean values of visual analogue score (VAS) of mean 1.28 ± 0.41 .¹⁷ Khasawneh MA et al reported lesser post-operative pain with mean values according to VAS of 3.73 ± 0.17 cm in local anesthesia as compared to 4.5 ± 0.24 cm in spinal anesthesia group.²⁰

A local study by Khan JS et al²⁸ VAS of 3.65 (range 3-5) in spinal anesthesia group which is consistent with this study.

Mean operation time in Group-LA was 42 ± 5.64 minutes due to less blood loss caused by topical adrenaline. Whereas in Group-SA mean operation time was 46 ± 7.53 minutes. In terms of p -value mean operation time was statistically different in both treatment groups. Operative time of Group-LA was less as compared to Group-SA. i.e. (p -value=0.009)

There was no significant difference in operation time between group LA and group SA which was 20 minutes in patients who underwent excision and primary closure.²⁰

Khan JS et al²⁸ showed that mean operative time was 44.4 minutes (range 40-50) in patients who underwent limberg flap under spinal anesthesia.

CONCLUSION

Modified Limberg Flap (MLF) under local anesthesia shows better results in terms of mean hospital stay, postoperative mean VAS scores, mean operative time and postoperative drain output when compared with modified limberg flap under spinal anesthesia. Modified Limberg Flap can be performed under local anesthesia as a day case procedure and in this way we can save time, burden of work and cost of surgery.

Author's Contributions: All the authors mentioned have significantly contributed to each of the mentioned below:

- Concept and design of study, data collection, analysis and interpretation of data.
- Drafting the manuscript/ critical revision for important intellectual content.
- Final approval of the manuscript to be published.

Conflict of Interest: Authors declare no conflict of interest

Ethical Approval: The ethical approval of study was obtained through Institutional Review Board (IRB) of SKMCH & RC.

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