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Comparative study between saddle block and local anesthesia on excision of pilonidal sinus by using ligaSure

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Abstract

Background: The excision of the pilonidal sinus starts at 1833. Local, spinal, or general anesthetic procedures for the disease are widely used. The excision of the pilonidal sinus by using ligaSure reduces blood loss, reduces procedure time, and reduces patient length of stay. Therefore, the purpose of this study is to compare between local anesthesia and saddle block on the excision of the pilonidal sinus by using ligaSure, with respect to recovery time, postoperative complications, and patient satisfaction.

Results: Forty patients were analyzed; the mean time of anesthesia, operation time, and operating room time were showing highly significantly lower in group LA when compared to group SA (*P* value < 0.01). At the postoperative period, patients in group LA experienced less intense postoperative pain with prolonged time of the first request for analgesia than patients in other groups.

Conclusion: Local anesthesia has more efficacy in early start of anesthesia, early discharge from the hospital with prolonged analgesia, strong hemostasis, more patient satisfaction, and more than saddle block .Therefore, local anesthesia is considered as an alternative to the saddle block on the excision of the pilonidal sinus by using ligaSure.

Keywords: Local anesthetic, Saddle block, ligaSure, Pilonidal sinus

Background

Rational and background

Pilonidal sinus disease is a painful condition that usually occurs in the intergluteal zone, which carries a high recurrence rate of 37% after surgery (Jones 1992).

It was first described by Mayo in 1833 (Hull and Wu 2002). Since that time, the disease has puzzled the physicians about its etiology, whether congenital or acquired. More than 78,000 troops were treated from this disease during the Second World War, which resulted in less intensive surgical treatment intended to get soldiers out of the hospital and return them to active duty. Therefore, most operations are now conducted as an ambulance (Matter et al. 1995; Ding et al. 2005; Levy and Emery 2003; Sungurtekin et al. 2003; Armstrong and Barcia 1994). Local, spinal, or general anesthetic procedures for the disease are widely used (Sungurtekin et al. 2003).

LigaSure delivers a unique combination of pressure and energy to create a consistent seal with each use. It provides a combination of pressure and energy to create vessel fusion (Ding et al. 2005). Permanently fused vessels include 7 mm in diameter and tissue bundles without dissection or isolation in which the average seal cycle is 2 to 4 s when used with the Force Triad TM energy platform. It reduces blood loss compared to sutures and clips, reduces procedure time compared to sutures, and reduces patient length of stay compared to sutures (Ding et al. 2005; Levy and Emery 2003).

Various health centers apply different techniques of anesthesia without reaching to the best technique of anesthesia (Schmittner et al. 2013). There have been few trials to equate general and local anesthesia for the

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pilonidal sinus condition in the primary midline closure, and the findings are inconsistent (Sungurtekin et al. 2003; Naja et al. 2003; Kayaalp and Aydin 2009). This study was designed to compare the effect of the local anesthetic and saddle block on the ligaSure excision of the pilonidal sinus (Fig. 1).

Aim of the study

In this context, this study aimed to evaluate and compare local anesthesia with saddle block on the excision of the pilonidal sinus by using ligaSure, with respect to recovery time, postoperative complications, and patient satisfaction.

Methods

Patient population and ethical approval

This study was carried out after approval from the hospital ethical committee and obtaining signed informed written consent from the patients between June 2019

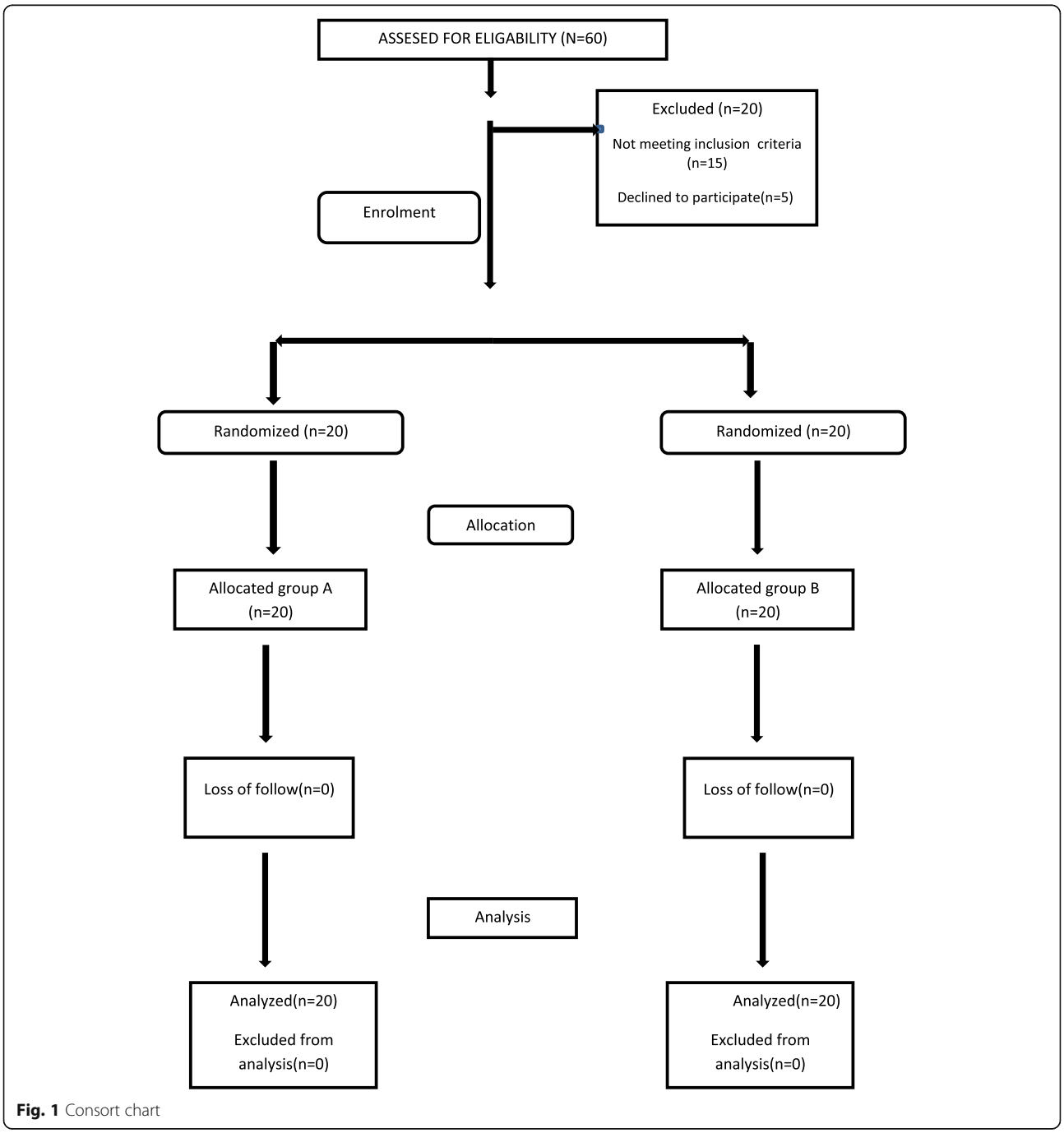

Fig. 1 Consort chart

and February 2020. This clinical trial was registered in Clinical Trial Registry as a prospective trial.

Anesthetic procedure

Forty patients of both sex, their ages ranged from 20 to 40 years, ASA physical status I and II, scheduled for elective ligaSure excision surgery of the pilonidal sinus were included in this study. They randomized into two groups using a computer-generated randomization table into two groups (LA and SA); each of them included 20 patients:

The local anesthesia group(LA) (n = 20) received 20 ml 0.5% bupivacaine plus 10 ml 2% lidocaine infiltrated around the pilonidal sinus in the sacrococcygeal area.

The saddle anesthesia group(SA) (n = 20) received 0.5 % hyperbaric bupivacaine 7.5 mg (1.5 ml) combined with 25ug fentanyl into the subarachnoid space as sacral saddle block where patients were allowed to sit for15 min.

Exclusion criteria included

The exclusion criteria were acute and recurrent pilonidal sinus disease, drug sensitivity, overweight (BMI > 35), diabetes mellitus, heart disease, bleeding, and other underlying diseases.

Pre-operative assessment of the patients included history, clinical examination, and basic investigation. The patient was transferred to the operating room; continued monitoring of HR was performed with ECG and non-invasive monitoring of systolic, diastolic, and MAP using Drager monitor vista 120 Germany, Drager Infinity monitor or vista XL-USA monitor. Oxygen was administrated through a nasal oxygen catheter connected to an anesthetic machine (Drager Primus Germany or Drager Fabius plus, USA). Then the induction of anesthesia was started according to the technique of each group.

Demographic data such as age, sex, height, and weight were reported. The ice cubes were used for the sensory block evaluation (onset, offset) (Table 1). Patient satisfaction was assessed by excellent, good, reasonable, or inadequate (Table 2) and 10 (0 = none, 1–3 = mild, 4–7 = moderate, 8–10 = severe) at the following times: 1st, 4th, and 24th postoperative hour. This scale was explained to the patients preoperatively. The time for the first dose requested of analgesia postoperatively was recorded

The primary outcome

The primary outcome of the experiment was block onset with respect to sensory and motor blockade (start and duration).

The secondary outcome

Hemodynamic improvements, postoperative analgesia, and readiness for discharge were the secondary outcomes of the study. Total operating time is from the beginning of anesthetic administration to the completion of operation and discharge from the operating room of the patient (Table 3). Operating room time starts from the admission of the patient to the operating room and ends by discharge to recovery (Table 3).Time-to-readiness for discharge (TRD) recoded was defined as the time starting at the end of the surgery and ends when the condition of the patient was confirmed with stable vital signs and oral medication could regulate nausea and pain (Table 2). The required time-to-first analgesia and patient satisfaction is excellent, good, reasonable, or

Table 1 Comparison between SA group and LA group according to demographic data

Demographic data	SA group (n = 20)	LA group (n = 20)	$t/x^{2\#}$	P value
Age (years)				
Range	20–38	20–35	0.996	0.326
Mean ± SD	28.95 ± 4.79	27.55 ± 4.07		
Sex				
Male	16 (80%)	15 (75%)	0.156#	0.692
Female	4 (20%)	5 (25%)		
Weight (kg)				
Range	45-78	55-70	1.420	0.164
Mean ± SD	68.05 ± 8.09	65.26 ± 3.43		
ASA				
I	10 (50%)	8 (40%)	0.101#	0.751
II	10 (50%)	12 (60%)		
Patient satisfaction	18 (90.0%)	19 (95.0%)	0.066#	0.798

P value > 0.05 NS
t Independent sample t test
#x^2: Chi-square test

Table 2 Comparison between the SA group and the LA group according to time of 1st analgesic and time of readiness to discharge (min)

	SA group (n = 20)	LA group (n = 20)	Test	P value
Time of 1st analgesic (min)				
Range	150-220	340-485	t = 23.368	0.000008
Mean ± SD	187.89 ± 18.52	419.02 ± 40.17		
Time of readiness to discharge (min)				
Range	240-273	185-206	t = 21.928	0.000002
Mean ± SD	254.17 ± 10.02	199.63 ± 4.83		
Effect of hemostasis	18 (90.0%)	19 (95.0%)	x^2 = 0.066	0.798

t Independent sample t test; x^2 chi-square test
P value > 0.05 NS; P value < 0.05 S; P value < 0.001 HS
Group LA (local anesthesia), group SA (saddle block)

inadequate (Table 2). Pain severity by visual analog scale (VAS) as in Table 4 was reported as postoperative at 1st, 4th, and 24th hours. Postoperative pain was managed by paracetamol infusion and diclofenac infusion that they were enough (Table 2).

Methods of randomization

Computer-generated randomization and sealed opaque envelopes, aside from the researchers performing the anesthesia, all other investigators, anesthetist, surgeons, nurses were blinded to the randomization of each subject

Sample size justification

MedCalc® version 12.3.0.0 program "Ostend, Belgium" was used for calculations of sample size, statistical calculator based on 95% confidence interval, and power of the study 80% with α error 5%. According to a previous study, Al-Ghazawi (2004) showed that the mean time on the operating room (min) the in LA group (25 min) compared to the SA group (40 min), with P value < 0.001, is highly significant. So it can be relied upon in this study that based on this assumption, the sample size was calculated according to these values produced by a minimal sample size of 40 cases were enough to find such a difference, subdivide into two groups.

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent sample t test of significance was used when comparing between two means.
- Mann-Whitney U test: for two-group comparisons in non-parametric data.

Table 3 Comparison between the SA group and the LA group according to time of anesthesia, operation time, and operating room time (min)

	SA group (n = 20)	LA group (n = 20)	t test	P value
Time of anesthesia (min)				
Range	60–100	45–75	5.671	0.0003
Mean ± SD	82.65 ± 14.12	60.20 ± 10.68		
Operation time (min)				
Range	4-20	4-14	2.839	0.021
Mean ± SD	13.89 ± 5.17	9.50 ± 3.58		
Operating room time (min)				
Range	10–40	7–20	3.800	0.0006
Mean ± SD	25.35 ± 8.96	16.95 ± 4.18		

t Independent sample t test
P value > 0.05 NS; P value < 0.05 S; P value < 0.001 HS. This table shows a statistically significant higher mean in the SA group compared to the LA group according to time of anesthesia, operation time, and operating room time (min)

Table 4 Comparison between SA group and LA group according to visual analog scale

Visual analog scale	SA group (n = 20)	LA group (n = 20)	z test	P value
After 1 h	1.03 ± 0.52	0.82 ± 0.52	1.277	0.209
After 4 h.	4.12 ± 0.82	1.55 ± 0.53	11.772	0.0013
After 24 h	4.33 ± 0.83	2.58 ± 0.82	6.708	0.007

z Mann-Whitney test
P value > 0.05 NS; *P* value < 0.05 S; *P* value < 0.001 HS

- Chi-square (x^2) test of significance was used in order to compare proportions between qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the P value was considered significant as the following:
- Probability (P value)
- P value ≤ 0.05 was considered significant.
- P value ≤ 0.001 was considered as highly significant.
- P value > 0.05 was considered insignificant.

Results

There was no statistically significant difference between both groups(P value > 0.05) as regarded age, sex, weight, and patient satisfaction. Twenty patients (15 men and 5 women) were randomly assigned to the LA group, the mean age was 30 (ranged 20–40) years, and the mean weight was 70 (range 45–75) kg, while in the SA group, there are twenty patients (16 men and 4 females), the mean age was 26(ranged 20–35) years, and the mean weight was 65 (ranged 50–70) kg. The patients in the group LA showed highly significantly lower in the operating room time and time of anesthesia than the group SA (P < 0.001). VAS was not significantly different between both groups in the 1st hour postoperative (P value > 0.05), but at 4th and 24th hours postoperative, the patients in the group LA were highly significantly lower compared with group SA (P value < 0.01). Over the first 24 h after surgery, there was high significance prolonged in group LA as compared to group SA (P value < 0.01) as regarding the first request time for analgesia postoperative where there was a decrease in analgesic needs and mean time of discharge in group LA than group SA (P < 0.001).

Disscusion

The optimal treatment for pilonidal sinus disease should be simple, involves short or no hospitalization, and has a low rate of recurrence (Johnson and Villanueva 2001).

Effective pain and wound care should be given, a quick return to normal activity and cost-effective treatment (Jones 1992).

In order to achieve this aim, several surgical and anesthetic procedures are recommended (Naja et al. 2003).

In this analysis, we compare the saddle block with local anesthesia for the use of ligaSure. Local anesthesia and midazolam versus spinal anesthesia are studied in outpatient pilonidal surgery with ligaSure output (Sungurtekin et al. 2003).

In this analysis, the ligaSure procedure makes the local anesthesia more daring than the saddle.

Few studies have been conducted to compare general and local anesthesia for pilonidal sinus disease in primary midline closure, and the results are contradictory (Sungurtekin et al. 2003; Naja et al. 2003; Kayaalp and Aydin 2009).

Many pilonidal sinus disease surgical approaches are available (Ghnnam and Hafez 2011; Bascom and Bascom 2002; Mentes et al. 2006; Cihan et al. 2006).

But in this study, the new method is ligaSure excision of the pilonidal sinus. In many operations, such as hemorrhoidectomy (Tverskoy et al. 1990), ligasure is used successfully. Using ligaSure reduces blood loss compared to sutures and clips (Ding et al. 2005; Levy and Emery 2003), reduces operating time compared to sutures (Ding et al. 2005; Levy and Emery 2003), and decreases patient length compared to sutures (Ding et al. 2005; Levy and Emery 2003).

Another important advantage of using local anesthesia by using ligaSure is less postoperative pain as measured on VAS scale and less postoperative complications including hemorrhage, urinary retention, and wound breakdown, which is close to using ligaSure as in (Tverskoy et al. 1990).

Conclusion

We concluded that local anesthesia can be used as a good alternative to the saddle anesthesia block on the excision of the pilonidal sinus by using ligaSure for its efficacy in early start of anesthesia, early discharge from the hospital with prolonged analgesia, strong hemostasis, and more patient satisfaction.

Limitations and recommendations

Limitations of this study include the use of various functional measures, a limited long-term follow-up, and limited publications about pilonidal excision by using ligaSure to compare with them. Further studies on pilonidal excision by ligaSure are required.

Abbreviations

ECG: Electrocardiogram; SPO2: Oxygen saturation; TRD: Time-to-readiness for discharge; VAS: Visual analog score; ASA: American Society of Anesthesia

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Authors' contributions
AEH and AIF conceived the study and shared in its design. AEH undertook data collection, data capturing, and handling. AIF coordinated data analysis. AEH and AIF drafted the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials
The data of this article is available from the corresponding author. The email address of the corresponding author is aymanicu22@gmail.com.

Ethics approval and consent to participate
This was a prospective study and was granted permission by the ethics committee of Al-Azhar University for girls between June 2019 and February 2020 and obtaining informed written consent approval to participate in the study. This prospective randomized trial was registered at Al-Azhar University for girls as a prospective trial with the identification number (202007314).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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