Zagazig University Medical Journal
www.zumj.journals.ekb.eg

https://doi.org/10.21608/zumj.2022.161814.2640 Volume 31, Issue 1.1, JAN. 2025, Supplement Issue

Manuscript ID ZUMJ-2209-2640
DOI 10.21608/zumj.2022.161814.2640

ORIGINAL ARTICLE

Posterior Proximal Sciatic Nerve Block through Franco's Midgluteal Approach versus Classic Labat-Winnie's Approach in Obese Patients: A Randomized Clinical Trial

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Submit Date 09-09-2022
Revise Date 12-10-2022
Accept Date 22-10-2022

ABSTRACT

Background: Sciatic Nerve Block (SNB) is commonly used for providing either anesthesia or analgesia for lower limb surgery.

Methods It is a comparison between Franco's midgluteal approach and the classic Labat-Winnie's approach for SNB to provide anesthesia for below knee orthopedic surgery in obese patients to find out the approach with the best outcome. It is randomized clinical study that involved eighty adult obese patients undergoing below knee surgery. These patients were randomly allocated into two equal groups: Franco's midgluteal approach and the classic Labat-Winnie's approach groups. In this study, technical characteristics [number of attempts to get the proper injection site and block performance time], anesthetic and analgesic characteristics [success rate, block onset, potency and duration, time to the first ask and the consumed amount of postoperative analgesia], discomfort level and the associated complications were recorded.

Results: The mean of number of attempts to get the proper injection site and block performance time were significantly shorter in Franco's midgluteal approach than in classic Labat-Winnie's approach group. Anesthetic and analgesic characteristics of SNB with both approaches were comparable. Discomfort level and the incidence of hematoma formation were significantly lower in Franco's midgluteal than in classic Labat-Winnie's group.

Conclusions: Although the anesthetic and analgesic characteristics of posterior proximal SNB block with both approaches were comparable, Franco's midgluteal approach has significantly lower number of attempts to get the proper injection site, shorter block performance time, lower discomfort level and lower rate of hematoma formation than classic Labat-Winnie's approach.

Keywords: Electric nerve stimulator; Regional anesthesia; Saphenous block; Sciatic block

INTRODUCTION

Sciatic Nerve Block (SNB) is commonly used especially in combination with femoral nerve block to establish either anesthesia or postoperative analgesia for lower limb surgery.

There are many approaches for SNB. Most of them depend on one or more (2 or 3) bony landmarks for determination of the point of needle insertion [1-6]. The main drawback of these approaches is difficult and inadequate identification of the buried landmarks especially in obese patients with subsequent higher failure rate [3]. To overcome this drawback, a non-bony landmark approaches for SNB were introduced by some workers. Radha et al., [7] introduced infragluteal-parabiceps approach for SNB in adults. This approach depends on two non-bony landmarks. These two non-bony landmarks are gluteal crease and the lateral border of long head of the biceps femoris and the point of needle insertion is 1cm distal to the gluteal crease alongside the biceps femoris. Gluteal crease and the lateral border of long head of the biceps femoris landmarks are easily identifiable even in obese patients. Franco [8] and Franco et al., [9]

introduced two non-bony landmark approaches for SNB in adults. These are the Franco's MG and Franco's SG approaches respectively. These two approaches have one non-bony landmark which is a fixed distance (10cm) from the midline in all adults regardless of gender and/or body weight.

According to our knowledge, there is no available literature making a comparison between proximal posterior SNB via each of Franco's MG approach and the classic Labat-Winnie's approach. For this reason, this study is considered the first one making this comparison.

We hypothesized that Franco's MG approach will be superior to the classic Labat-Winnie's approach in the technical characteristics for sciatic nerve block.

Hypothesis.

Null hypothesis: There is no difference between the technical characteristics of sciatic nerve block via Franco's MG approach and the classic Labat-Winnie's approach. Alternative hypothesis: There is a difference between the technical characteristics of sciatic nerve block via Franco's MG approach and the classic Labat-Winnie's approach.

METHODS

It is a comparison between Franco's midgluteal approach (which depends on non-bony landmark) and the commonly used classic Labat-Winnie's approach (which depends on 3 bony landmarks) for SNB to provide anesthesia for below knee orthopedic surgery in obese patients to find out the approach with the best outcome.

This prospective randomized comparative controlled clinical trial was conducted at Zagazig University Hospitals from 1st of August 2018 to 30th of August 2021. The study protocol was approved by the local ethics committee and institutional review board (IRB) of Zagazig University Faculty of Medicine. This study was carried out in according to the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Sample size was calculated according to the findings of previous study of Franco, [8]. He reported that, the mean ± SD of the onset times of sensory block on the dorsum and on the planter side of the foot were 12.6±4.1 min. and 16.5±5.8 min. respectively, so, the estimated sample size by using Open Epi program with power 80% and C.I. 95% was 80 patients (40 patients in each group).

Inclusion criteria included both sex adult obese (BMI 30 to 39.9) patients, aged from 21to 50 years, with physical statuses (PS) according to American Society of Anesthesiologists (ASA) classification ranged from class II to class III (Obesity per se is considered a class II according to ASA PS classification) and undergoing elective below knee orthopedic surgeries.

Exclusion criteria included patients who refused to participate in the study, those having allergy to local anesthetics, peripheral neuropathy, coagulopathy, diabetes mellitus, severe hepatic and renal impairment, infection, mass, crush injury and open wound at the nerve block site and chronic analgesic therapy.

All patients have been visited at the night before the operation for complete general and the block site examination to find out any exclusive criteria for the technique. The technical procedures of SNB were explained to these patients, an informed consent was taken from them and any associated medical problem was controlled. The method of estimation of pain intensity by using Visual Analogue Scale (VAS) was explained to each patient (0 corresponding to no pain and 10 to the worst pain), instruction about the fasting period (at least 6 hours before surgery) was given and premedication (type, dose and the time of administration before operation) was prescribed. The eighty involved patients were randomly allocated via a computer-generated random numbers table into 2 equal groups (each 40 patients). These 2 groups were Franco's MG approach group and the classic Labat-Winnie's approach group. Electric nerve stimulation was the used method for sciatic nerve localization in both groups. In operating room, a wide bore 18-gauge IV cannula was inserted, and standard monitors [pulse oximetry, electrocardiogram and non-invasive arterial blood pressure] were applied to patients. All patients were pre-medicated by giving iv injection of 0.02 mg/kg midazolam (Sunny Pharmaceutical, Egypt). In this study, technical procedures for SNB include the following: 1. Equipment preparation which included: i. Disinfectant solution and swabs for skin preparation, ii. Sterile gloves and drapes, iii. Local anesthetic of choice in 20-ml syringe, iv. Marking pen, v. One 1½" 25-gauge needle and 1% lidocaine for skin infiltration, vi. Surface electrode, vii. A peripheral nerve stimulator and viii. 20 gauge, 15-cm insulated short beveled electric needle.

2. Patient positioning:

With Franco's MG approach, the patient was placed in the lateral position and both hips and knees were slightly flexed and the buttock formed a 90-degree angle with the table.

With classic Labat-Winnie's approach, the patient was placed in the lateral (Sim's position) with the side to be blocked uppermost and rotated forwards. The nondependent lower limb was flexed

90 degrees at both hip and knee joints and rests against the dependent lower extremity.

3. Surface landmarks and the point of needle insertion:

In Franco's MG approach: The surface landmark is the inter-gluteal sulcus (the posterior midline) from mid-gluteal level to the level of sub-gluteal fold. The point of needle insertion is 10 cm lateral to intergluteal sulcus and the direction of its insertion is perpendicular to the skin (Figure 1).

In classic Labat-Winni's approach: The surface landmarks are three bony landmarks [Greater trochanter (GT), Posterior-superior iliac spine (PSIS) and Sacral hiatus (SH)]. These were outlined by a marking pen. A first, line was drawn between the GT and PSIS. Then, a second line was drawn between the GT and sacral hiatus (SH). After that, a perpendicular line was dropped from the midpoint the first line till it intersects the second line. The point of needle insertion is the point of intersection of the two lines and the direction of its insertion is perpendicular to the skin (Figure 2).

4. Sterilization of the blocked site:

In both approaches, the skin of the blocked site had been sterilized with an antiseptic solution and draped before needle insertion. Also, all aseptic measures were performed to avoid infection.

5. Local anesthetic skin infiltration:

In both approaches, 2ml of 1% lidocaine was infiltrated subcutaneously and deep intramuscularly at the predetermined point of needle insertion to prevent pain during advancement of nerve block needle.

6. Sciatic nerve localization (SNL):

In both approaches, a 15cm, 20 gauge insulated nerve block needle (Stimuplexw A, B. Braun Melsungen AG, Germany) was inserted perpendicularly through the predetermined point of needle insertion. The needle was connected to a nerve stimulator (Stimuplexw A, B. Braun Melsungen AG, Germany) with a starting output of 1.5 mA and 2 Hz. The needle was slowly advanced perpendicularly to the skin till elicitation of ipsilateral foot dorsi-flexion, plantar flexion, eversion, or inversion. Then the nerve stimulator current was gradually lowered to 0.4 mA. The needle was considered to be close enough to the nerve when the stimulating current was 0.4 mA.

In both approaches, if SNL was failed to get after the first attempt, another free number of attempts were allowed to get SNL. Each attempt included re-adjustment of one or more of the following: patient position, point of needle insertion and/or needle withdrawal to the subcutaneous tissue then redirected with an approximate 10° correction angle, first laterally and then, if necessary, medially using the same original insertion point.

7. Local anesthetic injection:

In both approaches, after SNL and epinephrine-containing test dose, the needle had been held immobile and 20ml of 0.5% of bupivacaine with 1:200.000 of adrenaline was injected incrementally, with attention paid to the presence of paresthesia, reflex movement and resistance to injection.

8. Immediately after LA injection and removal of the nerve block needle, the site of needle insertion had been covered with sterile dressing, and then all patients were placed in supine position.

9. Supplementary saphenous nerve block was performed if the surgical field extends to the area supplied by this nerve. Saphenous nerve block was performed by subcutaneous infiltration of 5ml of 0.25% bupivacaine on the medial side of the tibia below the knee level.

In all patients, following establishment of anesthesia, a double cuff pneumatic tourniquet was applied on the mid-thigh of the blocked side after its exsanguination by using Esmark rubber band. The proximal cuff was inflated to 100mmHg above the systolic blood pressure of the patient. Alternating inflation of the proximal with the distal cuff was used to maintain bloodless surgical field and to minimize tourniquet pain during surgery.

At the end of the operation, all patients were shifted from OR to Post Anesthesia Care Unite (PACU) for continuous monitoring and assessment of pain severity. At the end of the 1st hour after tourniquet deflation, all patients were transferred to their wards. Postoperatively, when pain severity score became >3 according to VAS, a rescue analgesia was given by intramuscular injection of 75 mg of Diclofenac Sodium and repeated after 6 hours if necessary.

In this work the following data were recorded in each group:

I. The primary outcomes were the technical characteristics: These are the number of attempts to get sciatic nerve and the total SNB performance time (the time from the moment of patient positioning to the moment of removal of needle after LA injection).

II. The secondary outcomes: These were the anesthetic and analgesic characteristics of SNB via both approaches, patients' discomfort level during performing SNB and the associated complications.

a. The anesthetic and analgesic characteristics of SNB via both approaches included the following:

i. Success rate i.e. number of patients with complete block of both divisions of the sciatic nerve within 45 min after LA injection. No or partial block of either one or two divisions of the

sciatic nerve within 45 min after LA injection was considered failed block. Patients with failed SNB block were excluded from the study and subjected to either neuraxial or general anesthesia to carry out their operations.

ii. Onset of complete sensory block: It is the time from the moment of local anesthetic mixture injection to the moment of complete sensory block in the distribution of the common peroneal and tibial nerves.

iii. Onset of complete motor block: It is the time from the moment of local anesthetic mixture injection to the moment at which the patient is unable to perform plantar or dorsal flexion of either ankle joint or toes of the anesthetized leg.

iv. Potency for suppression of muscle traction and tourniquet pain: The potency level of the produced intra-operative analgesia was evaluated by scoring of either surgical or tourniquet pain severity levels via visual analogue scale (VAS). VAS is a 10 cm horizontal line labeled “no pain” at one end and “worst pain” imaginable on the other end. The patient was asked to mark on this line where the intensity of the patient lies. The distance from score 0 is the score of pain severity. Intra-operatively, if the pain severity score was more than 3 according to VAS due to the effect of either marked muscles and tendons traction or tourniquet deep pressure so, the produced anesthesia was considered inadequate to solve these problems and intravenous fentanyl (1ug/kg incrementally) was used as supplementary analgesia.

v. Offset (duration) of sensory block i.e. the time from the moment of onset of sensory block to the moment of full return of sensation of the anesthetized leg (assessed by pinprick).

vi. Offset (duration) of motor block i.e. the time from the moment of onset of motor block to the moment at which the patient is able to perform plantar or dorsal flexion of either ankle joint or toes of the anesthetized leg.

vii. Time to 1st ask of postoperative rescue analgesia and total amount of diclofenac in the 1st postoperative day.

b. Patients' discomfort level during performing sciatic nerve block:

Patients' discomfort level during performing SNB, was evaluated according to Di-Benedetto et al. [5] by using a three-point scale:1 = not painful; 2 = moderately painful; 3 = extremely painful.

c. The associated complications as sciatic nerve injury, vascular puncture, hematoma formation at the site of needle insertion, local anesthetic toxicity, cardiovascular and respiratory depressions, and nausea and vomiting.

STATISTICAL ANALYSIS:

Data collected were coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. Quantitative data were represented by mean±SD, while qualitative data were represented as number and percentage. For quantitative and qualitative date, Student *t* and Chi square tests were used respectively to compare between two groups. P value at <0.05 was considered significant difference at confidence interval 95%.

RESULTS

The patients' demographic data (age, weight, height, BMI, sex ratio and ASA ps classes' ratio), type of surgery, the need for supplementary saphenous nerve block, tourniquet and surgery times were statistically comparable in the two studied groups (Tab. 1).

The mean of the numbers of the attempts to get sciatic nerve localization in Franco's MG approach group was highly significant statistically lower than that in the classic Labat-Winnie's approach group (Tab. 2).

The mean sciatic nerve block's performance time in Franco's MG approach group was statistically significantly shorter than that in the classic Labat-Winnie's approach group (Tab. 2).

The anesthetic and analgesic characteristics (Success rate, onset, potency, the duration, time to ask for the 1st postoperative analgesia and total amount of diclofenac required for pain relief during the 1st postoperative day) of SNB in Franco's MG approach and the classic Labat-Winnie's approach groups were statistically comparable (Tab. 3).

The mean patients' discomfort score during performing sciatic nerve block in Franco's MG approach group was statistically significantly lower than that in the classic Labat-Winnie's approach group (Tab. 4).

The only detected complication on the second postoperative day was small hematoma formation at the site of needle insertion in 2 out of patients 38 (5.26%) in Franco's MG approach group and 8 out of 37 patients (21.62%) in the classic Labat-Winnie's approach group. Statistically, the incidence of the associated hematoma formation at the site of needle insertion in Franco's MG approach group was significantly lower than that in the classic Labat-Winnie's approach group.

Table 1:. Patients' demographic data, type of surgery, the need for supplementary saphenous nerve block, tourniquet and surgery times in the two studied groups.

	Franco's MG Approach group (n=38)	**Labat-Winnie's approach group (n=37)**	**P value**
Age (year).	44.20 ± 12.41	45.63 ±11.94	P> 0.05 NS
Weight (kg).	91.77 ± 11.30	92.33 ± 12.45	P> 0.05 NS
Height (cm).	170 ± 5.5	171 ± 6.5	P> 0.05 NS
BMI (kg/m^2)	34.72 ± 2.26	34.58 ± 2.43	P> 0.05 NS
Sex ratio (Males: Females).	23:15	25:12	P> 0.05 NS
ASA ps classes (II:III).	32:6	34:5	P> 0.05 NS
Types of surgery [N(%)]: - Hallux valgus correction. - Foot/heel debridement. - Open reduction, internal fixation. - Tendon repair.	 6 (15.78%) 10 (26.31%) 12 (31.57%) 10 (26.31%)	 7(18.91%) 9 (24.32%) 11 (29.72%) 10 (27.02%)	P> 0.05 NS
The need for supplementary saphenous nerve block [N(%)].	16 (42.10%)	17 (45.94%)	P> 0.05 NS
Tourniquet time (min).	67.65 ± 7.65	66.58 ± 9.50	P> 0.05 NS
Duration of surgery (min)	90.55 ± 15.65	95.27 ± 15.3	P> 0.05 NS

Data are expressed as Mean ± Standard Deviation (SD) and numbers (%).
n = Number of patients after exclusion of the failed cases.
N (%) = Number and percent of the variable in the corresponding group.
P> 0.05= statistically non-significant difference (NS).

Table 2:. Technical characteristics of the two approaches.

	Franco's MG approach group (n=40)	**Labat-Winnie's approach group (n=40)**	**P value**
The number of attempts to get sciatic nerve localization: 1st attempt [N(%)]. 2nd attempt [N(%)]. 3rd attempt [N(%)]. 4th attempt [N(%)]. 5th attempt [N(%)].	 20 (50%) 15 (37.5%) 5 (12.5%) 0 (0%) 0 (0%)	 4 (10%) 6 (15%) 15 (37.5%) 11 (27.5%) 4 (10%)	P<0.001**
Mean of the numbers of attempts to get sciatic nerve localization.	1.625±0.10	3.125 ± 0.15	P<0.001**
Total sciatic nerve block's performance time (min).	4.05 ± 1.39	10.64 ± 3.43	P<0.001**

Data are presented as mean ± standard deviation (SD) or number and percent.
n = Number of patients before exclusion of the failed cases.
N (%)= Number and percent of the variable in the corresponding group.
P<0.001= statistically highly significant difference.

Table 3: Anesthetic and analgesic characteristics of the two approaches

	Franco's MG approach group (n=40)	**Labat - Winnie's approach group (n=40)**	**p value**
Success rate [N(%)]. Failure rate [N(%)].	38 (95%) 2 (5%)	37 (92.5%) 3 (7.5%)	P>0.05 NS
	(*n*=38)	**(*n*=37)**	
Onset of complete motor block (min.).	14. 75 ±3.55	15.13± 3.20	P>0.05 NS
Onset of complete motor block (min).	20.58± 5.31	21.63± 5.93	P>0.05 NS
Potency level of the produced intra-operative analgesia: Adequate [N(%)]. Inadequate [N(%)].	 35 (92.10%) 3 (7.90%)	 33 (89.20%) 4 (10.80 %)	P>0.05 NS
Surgical pain severity score.	1.8± 1.42	1.95± 1.38	P>0.05 NS
Tourniquet pain severity score	2.05±1.48	2.28± 1.55	P>0.05 NS
The amount of supplementary iv fentanyl to relieve muscle traction and tourniquet pain (µcg).	74.0 ± 27.6	78.4 ± 25.07	P>0.05 NS
Duration of sensory block (h).	12.74 ± 1.87	12.48 ± 1.24	P>0.05 NS
Duration of motor block (h).	8.9 ± 1. 68	8.8 ± 1.35	P>0.05 NS
Time to ask for the 1st postoperative analgesia (h)	14.45 ± 1.05	14.35 ± 1.1	P>0.05 NS
Total amount of Diclofenac required for pain relief during the 1st postoperative day (mg).	105.7 ± 25.5	110.5 ± 23.5	P>0.05 NS

Data are expressed as Mean ± Standard Deviation (SD) and numbers (%).
n= Number of patients before exclusion of the failed cases
n = Number of patients after exclusion of the failed cases
N (%) = Number and percent of the variable in the corresponding group.
P> 0.05 = statistically non-significant difference (NS).

Table 4:. Patients' discomfort levels during performing sciatic nerve block in the two studied groups.

	Franco's MG approach group (n=40)	**Labat-Winnie's approach group (n=40)**	**P value**
Distribution of patients on the various discomfort score [N (%)]: 1 (not painful). 2 (moderately painful). 3 (extremely painful).	 26 (65%) 10 (25%) 4 (10%)	 12 (30%) 18 (45 %) 10 (25%)	 P<0.05*
Mean discomfort score.	1.45±0.68	1.95±0.75	P<0.05*

Data are expressed as number and percent and Mean ± Standard Deviation (SD).
n = Number of patients before exclusion of the failed cases.
N (%) = Number and percent of the variable in the corresponding group.
P<0.05= statistically significant difference.

Figure (1): A photo showing a right nerve stimulator-guided proximal posterior sciatic nerve block in one of the patients of the Franco's mid-gluteal approach group. Note the left lateral position of patient, the surface landmark (intergluteal sulcus), the point of needle insertion (10 cm lateral to intergluteal sulcus in the lower half of gluteal region) and the needle direction (perpendicular to the skin).

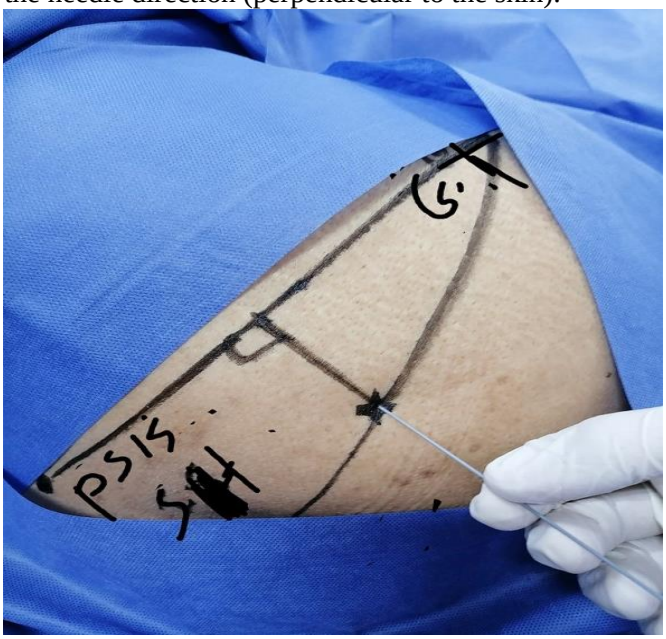

Figure (2): A photo showing right nerve stimulator-guided proximal posterior sciatic nerve block in one of the patients of the Labat-Winnie's approach group. Note the left sim's position of patient, the three bonny landmarks (GT, PSIS and SH), the point of needle insertion and the needle direction (perpendicular to the skin). GT= Greater trochanter , PSIS = Posterior superior iliac spine, SH= Sacral hiatus.

DISCUSSION

In the present study, it was found that, the number of attempts to get adequate sciatic nerve stimulation at 0.4mA and the mean of the total SNB performance time in Franco's MG approach group were statistically significant lower and shorter respectively than those in the classic Labat-Winnie's approach group.

The lower number of attempts to get adequate SN stimulation with Franco's MG approach than with the classic Labat-Winnie's approach was attributed to the adequate identification of needle insertion point in the first than in the later. In Franco's MG approach, needle insertion point can be adequately determined because it is easy to identify one non-bony landmark (10 cm lateral to midgluteal sulcus) only. In contrast, in the classic Labat-Winnie's approach, needle insertion point cannot be adequately determined because it is difficult to identify adequately the 3 burred bonny landmarks (Greater trochanter, Posterior-superior iliac spine and Sacral hiatus) especially in obese patients [3].

The shorter total block performance time with Franco's MG approach than with the classic Labat-Winnie's approach was attributed to the shorter time for patient positioning till determining the surface landmark and the point of needle insertion and the shorter time from needle insertion till adequate stimulation of sciatic at 0.4 mA due to

lower number of attempts to get adequate SN stimulation [8].

In the present study, the anesthetic and analgesic characteristics (Success rate, onset, potency, the duration, time to ask for the 1st postoperative analgesia and total amount of Diclofenac required for pain relief during the 1st postoperative day) of SNB in Franco's MG approach and the classic Labat-Winnie's approach groups were statistically comparable.

There are various factors that affect the anesthetic and analgesic characteristics of peripheral nerve blocks. These include the use of additives [10]; the type of evoked motor response [11,12]; the intensity of the current at which peripheral nerve stimulation is achieved [13,14]; the type, concentration, and volume of the injected anesthetic solution [15-16]; and the type of the used injection technique i.e. single injection or double-injection technique [17-20].

In the present study we utilized 20ml of 0.5% bupivacaine with 1:200.000 adrenaline for SNB and we considered the needle tip in close enough position to the nerve when the stimulating current was 0.4mA in both groups.

In the present study, it was found that, mean discomfort scores during sciatic nerve block in Franco's MG approach group was significantly less than that in classic Labat-Winnie's approach group. This was attributed to the significant lower number of attempts to get sciatic nerve localization with Franco's MG approach than with classic Labat-Winnie's approach [21,22].

The degree of discomfort that associate any nerve block procedure depends on the size of the used needle, the thickness of the tissue through which the needle passes when seeking the nerve and the numbers of the attempts to get nerve localization. For this, trans-gluteal approaches for sciatic nerve block are associated with more discomfort than subgluteal approaches as the result to the thick layer of muscles through which the stimulating needle passes when seeking the sciatic nerve [21,22].

In the present study, it was found that, the only detected complication that associated SNB on the second postoperative day was small hematoma formation at the site of needle insertion in 2 out of 38 patients (5.26%) of Franco's MG approach group and 8 out of 37 patients (21,62%) of the classic Labat-Winnie's approach group. The statistically lower incidence of hematoma formation in Franco's MG approach group than in the classic Labat-Winnie's approach group was attributed to the significant lower attempt number to get adequate stimulation of sciatic nerve at 0.4mA in Franco's MG approach group than in the classic Labat-Winnie's approach group [21,22].

LIMITATIONS OF THE STUDY

were single center study, a relatively small number of enrolled patients; the independent observer evaluating the evolution of sensory and motor blocks; as well as its intra-operative efficacy was not blinded to the approach used for SNB.

CONCLUSIONS:

Although the anesthetic and analgesic characteristics of posterior proximal SNB block with both approaches were comparable, Franco's MG approach has significantly lower number of attempts to get the proper injection site, shorter block performance time, lower discomfort level and lower rate of hematoma formation than the classic Labat-Winnie's approach.

CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest with this work.

FINANCIAL DISCLOSURE

No funding was provided for this research

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Citation

Attia, A., Nasr, M., Rizk, A. Posterior proximal sciatic nerve block through Franco's midgluteal approach versus classic Labat-Winnie's approach in obese patients: a randomized clinical trial. *Zagazig University Medical Journal*, 2025; (297-305): -. doi: 10.21608/zumj.2022.161814.2640