

## THE EFFECT OPENING INJECTION PRESSURE MONITORING DEVICE FOR DETECTS NEEDLE NERVE CONTACT DURING ULTRASOUND GUIDED POPLITEAL APPROACH IN DIABETIC PATIENTS FOR BELOW KNEE AMPUTATION

Dr. Ahmed Basim Qasim<sup>\*1</sup>, Prof. Iyad Abbas Salman<sup>2</sup>, Dr. Eethar Adel Ismail<sup>3</sup>

<sup>1</sup>MBChB, FICMS, Specialist of Anesthesia and Intensive Care, Medical City, Baghdad, Iraq.

<sup>2</sup>MBChB, FICMS, CABA&IC, FIPP, Chairman of the Scientific Council of Anesthesia and Intensive Care.

<sup>3</sup>MBChB, CABR, IFIPM, Specialist of Radiology and Fellowship in Pain Management, Baghdad Teaching Hospital, Medical City, Baghdad, Iraq.

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\*Corresponding Author: Dr. Ahmed Basim Qasim

MBChB, FICMS, Specialist of Anesthesia and Intensive care, Medical City, Baghdad, Iraq.

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### ABSTRACT

**Background:** Ultrasound-guided popliteal sciatic nerve blocks and femoral are useful adjuncts for below knee amputation limb also provide excellent analgesia for all major foot and ankle procedures. Using of the injection pressure monitoring device enhances the accuracy of the local anesthetic deposition in popliteal sciatic nerve blocks. Our hypothesis is that an intraneural injection is associated with higher pressures and an increase in the risk of neurologic injury as compared with perineural injection. **Aim of the study:** The injection pressure monitoring enhances accuracy of local anesthetic deposition in addition to the use of ultrasound during popliteal sciatic nerve blocks and to Prevention of an intraneural injection of a local anesthetic during peripheral nerve block is considered important to avoid neurologic injury. **Methods:** Fifty patients ASA class III\_IV, age (30\_80)years of either sex scheduled for elective surgery unilateral below knee amputation were randomly assigned to receive either sciatic nerve block using a popliteal approach In a lateral position received amount of LA (20 ml of bupivacaine (0.375%) with monitoring of the bupivacaine injection pressure by a disposable pressure manometer and the continuous ultrasound view monitoring pressure level and additional ultrasound guided femoral nerve block by 12 ml of bupivacaine (0.375%) to ensure sensory block of the medial side of the leg. Time to complete sensory and motor block, time taken to perform the block, block-related complications, block duration were recorded and intraoperatively PR, noninvasive mean BPRR, ECG, SpO2 was monitored. **Results:** Regarding to the pressure of the injections monitoring , we noticed that in this study, the highest proportion of study patients recorded needle nerve contact (44%) ,needed low pressure <15 psi (38%) , while all Intrafascular injection (18%). Sensory Block three points scale of pin brick sensation to check sensory block before and after nerve block. In this study, we noticed that all patients were normal in both pre nerve block and 5 minutes after nerve block, (74%) of patients were normal and 26% was decrease pain after 10 minutes from nerve block, at 15 minutes from nerve block, most patients were showed decreased pain (86%). The highest proportion of study patients after 20 minutes from nerve block was showed decreased pain (70%), then after 25 minutes of nerve block, the highest proportion of patients didn't show pain (88%). All patients were completely free from pain after 30 minutes of nerve block. Motor block duration lasted for  $\geq 20$  mints in (68.1%) of study patients and the mean duration of achievement of complete motor block was  $20.21 \pm 2.43$  mints. **Conclusions:** High injection pressures at the onset of injection >15psi may indicate an intraneural needle placement and lead to severe fascicular injury and persistent neurologic deficits. If these results are applicable to clinical practice, avoiding excessive injection pressure during nerve block administration may help to reduce the risk of neurologic injury. The injection pressure monitoring enhances the accuracy of local anesthetic deposition in addition to the use of ultrasound.

**KEYWORDS:** Injection pressure monitoring, ultrasound guided femoral- popliteal sciatic nerve block, Below knee amputation, Bupivacaine, pin brick sensation scale.

## INTRODUCTION

Diabetes mellitus (DM) is one of the most important and common metabolic disorders affecting about 2–5% of the population in Europe and about 20% of the population in various other parts of the world.<sup>[1]</sup> It is estimated that around 347 million people in the world are diagnosed with diabetes mellitus. The incidence of diabetes mellitus is increasing worldwide; by 2030, it will grow up to 415 million.<sup>[2]</sup>

Every year, more than 1 million people undergo a lower-limb amputation because of diabetes, it is estimated that every 30 second a leg is lost due to diabetes somewhere in the world.<sup>[3]</sup> Every year 5% of the patients with diabetes will develop a foot ulcers are known to carry a 25% risk of major amputation and about 85% of these lower limb amputations are precede by a foot ulcer.<sup>[4]</sup>

The popliteal nerve block is a form of regional anesthesia utilized as the sole source of anesthesia for foot, ankle surgery and Achilles tendon surgery. This can be beneficial in medically compromised patients. Profound analgesia during both the operative and post-operative time and the avoidance of systemic complications. Other advantages include earlier discharge from the post-anesthesia care unit, decreased opioid consumption perioperative and increase patient satisfaction.<sup>[5]</sup> There are several techniques to administering this form of anesthesia including a posterior approach is more classic and allows easier access to the sciatic nerve in the popliteal fossa, but it typically requires prone positioning of the patient. Alternatively a lateral approach allows for a more practical and similarly efficacious application of the popliteal nerve block. The lateral technique is an indirect approach; however, it does not require the patient to be positioned prone.<sup>[6]</sup>

The BSmart™ pressure monitor (B-Braun Medical, Melsungen, Germany) is the first disposable manometer for objective monitoring of injection pressure during administration of peripheral nerve blocks (PNB). It is an in-line mechanical pressure manometer with a graduated colored piston, which protrudes proportionately to the pressure applied to the syringe plunger. Monitoring opening injection pressure with the B-Smart monitor can help identify potentially unsafe injections before they start. When the B-Smart monitor indicates high (> 15 psi) opening injection pressure, the needle can be repositioned and the injection resumed.<sup>[7]</sup> Resistance to injection is part of the standard documentation procedure during nerve blocks. Before the B-Smart monitor, documentation of resistance was merely subjective and relied on the “learned feel” and experience of the provider. The syringe-feel method of assessing injection force is inconsistent. Different needle lengths, diameter,

and syringe types also affect the feel.<sup>[8]</sup> BSmart™ (B-Braun Medical, Melsungen, Germany) in-line pressure monitor is placed proximal to the needle and in line with the non-distensible tubing and other end of the pressure monitor is attached directly to the syringe.<sup>[9]</sup>

## AIM OF THE STUDY

The injection pressure monitoring enhances accuracy of local anesthetic deposition in addition to the use of ultrasound during popliteal sciatic nerve blocks and to Prevention of an intraneural injection of a local anesthetic during peripheral nerve block is considered important to avoid neurologic injury.

## PATIENTS AND METHODS

This study is a case control study clinical trial, was conducted at Baghdad teaching hospital, medical city, Baghdad, Iraq, which started in period 1<sup>st</sup> September 2017 to 15<sup>th</sup> August 2018.

The study was approved by the Iraqi scientific council of anesthesia and intensive care, and the consent was obtained from all patients before included them in the study. A detailed history was taken from each patient; a clinical examination was performed pre operatively.

The research includes fifty patients, ASA class III\_IV, age (30\_80)years, scheduled for elective surgery unilateral below knee amputation were assigned randomly under combined ultrasound guide and injection pressure monitoring (B\_Smart) for popliteal sciatic nerve with additional ultrasound guided femoral nerve block to ensure sensory block of the medial side of the leg.

All the patients prepared properly to the operation room, wide bore IV cannula inserted (18G), connecting to the monitoring (pulse rate (PR), noninvasive BP, SPO2&ECG). And receiving infusion of Ringer lactated or normal saline solution at begin of surgery, under aseptic condition. Ultrasound with linear probe, sterile gel with gloves, 20 ml syringe contain local anesthesia, 10cm long bevel needle, 22-gauge (Stimuplex, BBraun medical) connect to injection pressure monitoring devise. The popliteal sciatic nerve block was preformed after premedication consisting of midazolam (1\_2mg) IV. The premedication was adjusted for individual patient to decrease their anxiety and discomfort from the procedure, while maintaining meaningful patient contact. the patient in a lateral position and ultrasound probe (sonosite) position over popliteal fossa the ultrasound probe should be slid proximally until tibial and common peroneal nerve are visualize coming together to form sciatic nerve before its division, The skin puncture site 2\_3 cm lateral to ultrasound probe to improve the visualization of needle. The needle is inserted in plane and advance to sciatic nerve once the needle tip is adjacent to the nerve and use 20ml syringes connect to an in-line injection pressure monitoring (BSmart, concert medical), the injection of local anesthesia was an incremental fashion after careful negative aspiration every

2\_3ml and (1\_2ml) local anesthesia is injected to conform proper injection site. When the initial injection pressure was elevated will recorded or when patient experienced pain or paresthesia, the needle slightly withdrawn (1mm) from the nerve, and injection was reattempted. the injection should distribution of local anesthesia surround the sciatic nerve, the total local anesthesia injection 20 ml about (0.375%) of bupivacaine not exceeded 2mg/kg. Afterward, the patient was turned to the supine position and for femoral nerve block, under aseptic condition ultrasound probe position place transversely on the inguinal crease followed by slow movement laterally and medially to identify the femoral artery the nerve immediately lateral to artery and underneath to the fascia iliaca, which is typically hyperechoic and visualized at a dept (2\_4cm), the skin puncture site 2cm lateral to ultrasound probe. The needle is inserted in plain and advanced to femoral nerve, the passage of the needle through the fascia iliaca and the injection of local anesthesia was an incremental fashion after careful negative aspiration every 2\_3ml and(1\_2ml) local anesthesia is injected to conform proper injection site. The total local anesthesia injection 12\_15 ml (0.375%) of bupivacaine (not exceeded 2mg/kg).

Sensory block: was assessed by using the loss pin-prick sensation according the scale (normal sensation 0, decrease pain sensation 1, no pain sensation 2). Sensory test was performed for popliteal sciatic nerve block (pinprick to sole of foot) while femoral never block was defined as complete loss of pinprick sensation on the medial aspect of leg.

Motor block: was monitoring for popliteal sciatic nerve block was defined by (dorsiflexion, plantar flexion foot and toes), and for femoral never block was defined as the inability to extend the leg of the operated limb against gravity with the hip passively flexed at 90 degrees.

Readiness for surgery was defined as complete loss of pinpricks sensation with motor assessment. after readiness for surgery was achieved, the patient was continues observed for any unexpected and unwanted events. Stander monitoring was used throughout the procedure, include electrocardiogram (ECG) 5 or 3 leads, Heart rate (HR) Noninvasive Blood pressure (NIBP), Respiratory rate (RR), pulse oximetry (SpO2).

The data analyzed using Statistical Package for Social Sciences (SPSS) version 25. The data presented as mean, standard deviation and ranges Categorical data presented by frequencies and percentages.

**RESULTS**

The total number of study patients was 50. All of them were undergone amputation below knee joint operation under nerve block procedure by opening injection pressure under U/S guide.

The distribution of study patients by general characteristics is showing in figures (1, 2) and table (1). Study patient’s age was ranging from (40 to 76) years with a mean of (59.26) years and standard deviation (SD) of ( $\pm$  8.94) years. The highest proportion of study patients was aged ( $\geq$  60) years (58%).

Regarding sex, proportion of males was higher than females (52% versus 48%) with a male to female ratio of (1.08:1).

Concerning side, amputation below knee joint in the left side was (54%) of cases By American Society of Anesthesiologists (ASA) classification system, the highest proportion of study patients was classified as grade IV (56.2%).

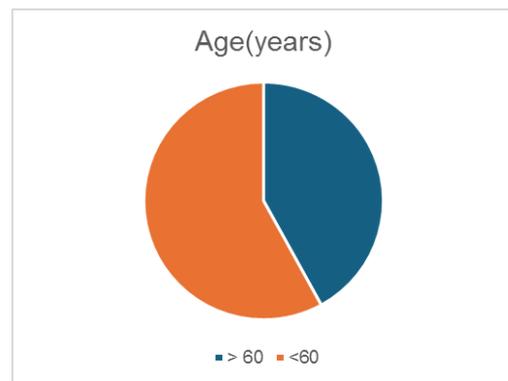


Figure 1: Distribution of study patients by age.

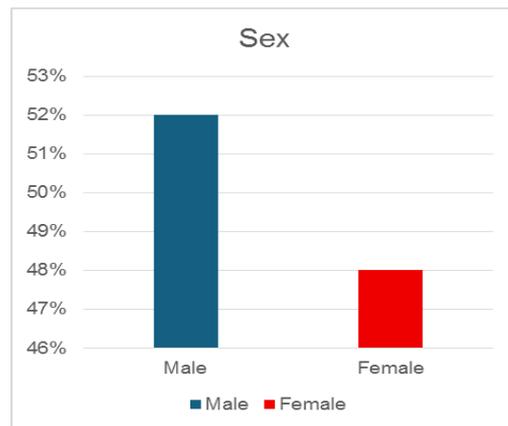


Figure 2: Distribution of study patients by sex.

Table 1: Distribution of study patients by side, ASA and duration.

Variable	No. (n= 50)	Percentage (%)
<b>Side</b>		
Right	23	46.0
Left	27	54.0
<b>ASA classification</b>		
Grade III	22	44.0
Grade IV	28	56.0
<b>Duration of Motor Block n= 50</b>		
< 20 Min	15	30.0
$\geq$ 20 Min	35	70.0

Motor block duration lasted for  $\geq 20$  mints in (70 %) of study patients.

The mean duration of achievement complete motor block was  $(20.21 \pm 2.43)$  mints.

Table 2 shows the distribution of study patients by three point's scale of pin brick sensation to check sensory block before and after nerve block. In this study, we noticed that all patients were normal in both pre nerve block and 5 minutes after nerve block, (74%) of patients were normal and (26%) was decrease pain after 10 minutes from nerve block, at 15 minutes from nerve block, most patients were showing decreased pain (86%).

The highest proportion of study patients after 20 minutes from nerve block were showing decreased pain (70%), then after 25 minutes of nerve block, the highest proportion of patients did not show pain (88%). All patients were completely free from pain after 30 minutes of nerve block (100%).

**Table 2: Assessment of sensory block before and after nerve block.**

Three points scale	No. (n= 50)	Percentage (%)
<b>Pre Nerve Block</b>		
Normal	50	100.0
<b>5 Mints after Nerve Block</b>		
Normal	50	100.0
<b>10 Mints after Nerve Block</b>		
Normal	37	74.0
Decrease Pain	13	26.0
<b>15 Mints after Nerve Block</b>		
Normal	7	14.0
Decrease Pain	43	86.0
<b>20 Mints after Nerve Block</b>		
Normal	1	2.0
Decrease Pain	35	70.0
No Pain	14	28.0
<b>25 Mints after Nerve Block</b>		
Decrease Pain	6	12.0
No Pain	44	88.0
<b>30 Mints after Nerve Block</b>		
No Pain	50	100.0

The distribution of study patients by pressure monitoring record is show in table (3). In this study, the highest proportion of study patients recorded needle nerve contact (44%).

**Table 3: Distribution of study patients by pressure monitoring record.**

	No. (n=50)	Percentage (%)
<b>Pressure Monitoring Record</b>		
Low Pressure	19	38.0
Needle Nerve Contact	22	44.0
Intrafascular injection	9	18.0

Table 4 shows the means of mean arterial pressure pre and after nerve block. In this study, mean of MAP pre nerve block was  $113.67 \pm 12.98$ , 10 minutes after nerve block was  $115.08 \pm 14.76$ . 30 minutes after nerve block was  $108.81 \pm 11.78$ , and 60 minutes after nerve block was  $108.49 \pm 10.3$ .

**Table 4: Means of MAP pre and after nerve block.**

Mean Arterial Pressure	Mean	Std. Dev.
<b>Pre Nerve Block</b>	113.67	12.98
<b>10 Mints After Nerve Block</b>	115.08	14.76
<b>30 Mints After Nerve Block</b>	108.81	11.78
<b>60 Mints After Nerve Block</b>	108.49	10.3

Table 5 shows the means of pulse rate pre and after nerve block. In this study, mean of pre nerve block was  $108.62 \pm 16.22$ , 10 minutes after nerve block was  $106.70 \pm 12.21$ . 30 minutes after nerve block was  $94.06 \pm 8.03$ , and 60 minutes after nerve block was  $92.16 \pm 8.53$ .

**Table 5: Means of pulse rate pre and after nerve block.**

Pulse Rate (Beat/mints)	Mean	Std. Dev.
<b>Pre Nerve Block</b>	108.62	16.22
<b>10 Mints After Nerve Block</b>	106.7	12.21
<b>30 Mints After Nerve Block</b>	94.06	8.03
<b>60 Mints After Nerve Block</b>	92.16	8.53

Table 6 shows the means of respiratory rate pre and after nerve block. In this study, mean of pre nerve block was  $22.68 \pm 11.12$ , 10 minutes after nerve block was  $22.0 \pm 8.41$ . 30 minutes after nerve block was  $20.54 \pm 2.58$ , and 60 minutes after nerve block was  $20.1 \pm 2.71$ .

**Table 6: Means of respiratory rate pre and after nerve block.**

Respiratory Rate	Mean	Std. Dev
<b>Pre Nerve Block</b>	22.68	11.12
<b>10 Mints After Nerve Block</b>	22.0	8.41
<b>30 Mints After Nerve Block</b>	20.54	2.58
<b>60 Mints After Nerve Block</b>	20.1	2.71

Table 7 shows the means of SPO2 pre and after nerve block. In this study, mean of pre nerve block was  $97.00 \pm 17.80$ , 10 minutes after nerve block was  $96.82 \pm 1.02$ . 30 minutes after nerve block was  $97.26 \pm 0.87$ , and 60 minutes after nerve block was  $97.72 \pm 0.8$ .

**Table 7: Means SPO<sub>2</sub> pre and after nerve block.**

SpO <sub>2</sub> %	Mean	Std. Dev.
<b>Pre Nerve Block</b>	97.0	17.8
<b>10 Mints After Nerve Block</b>	96.82	1.02
<b>30 Mints After Nerve Block</b>	97.26	0.87
<b>60 Mints After Nerve Block</b>	97.72	0.8

**DISCUSSION**

Ultrasound-guided popliteal sciatic nerve blocks are most used as an adjunct to femoral nerve block are a form of regional anesthesia most commonly used as a

form of below knee surgery and managing post amputation limb pain. It can also be used for various foot and ankle pathologies including fracture and dislocation reduction, exploration of foreign bodies, and bedside incision and drainage. The popliteal sciatic nerve block has an additional benefit in that it decreases amount of postoperative opioid consumption limiting the complications of these medications. Recently, ultrasound imaging has gained popularity in regional anesthesia due to enhanced visibility of peripheral nerves during nerve block, reduced duration of the procedure, faster complete sensory block, reduced volume of needed drugs for successful block, decreased incidence of complications or side effects. It provides stable hemodynamic, and prolonged postoperative analgesia.

In this study, popliteal sciatic nerve blocks have been applied, and it is performed under ultrasound guided technique with close monitoring of injection pressure while the passage of the needle toward the plane. That has implemented with the viewing of the ultrasound and watching pressure of the injection.

The outcomes show the highest proportion of studied patients were needle nerve contact (44%) injected may result in intraneural, then injected Perineural injection (38%), while (18%) of them injected Intrafascicular. Also, regarding pressure of device used in injections, we noticed that all were needed Perineural injection low pressure <15psi, and needle nerve contact injected may result in intraneural intermediate 15-20psi, while all Intrafascicular injections > 20psi pressure.

In our study, needle–nerve contact was associated with high opening injection pressure (>15 psi). In contrast, extraneural (1-mm distant) needle placements were associated with low opening injection pressure (<15 psi). Moreover, opening injection pressure and pressure throughout the injection procedure remained below 15 psi during administration of the 20-ml local anesthetic used for the surgical blockade for popliteal sciatic nerve blocks. So, we need low pressure <15psi in a target (Perineural injection) site of the block.

The study findings have important clinical implications, most importantly monitoring the opening injection pressure prevented the initiation of injection in all. On halting the injection process when opening injection pressure reached less than 15 psi, commencement of injection was possible only when the needle tip was withdrawn from the nerve root. Therefore, limiting opening injection pressure to 15 psi reliably detected needle–nerve contact and prevented injection when the needle tip was positioned too close to vulnerable neural structures. This is particularly to clinical practice because the ultrasound guidance alone does not appear to be a fail-safe monitor to prevent neurologic injury. Ultrasonography requires technical skill, adequate sonography anatomy, high-quality ultrasonography equipment and ultrasound technology lack the resolution to differentiate

epineurium from perineurium. For these reasons, inadvertent placement of the needle tip against the nerve before injection can occur undetected by ultrasound, particularly with multiple injection techniques that are common in clinical practice. Subsequent forceful injection, especially with a beveled needle tip that may be partially lodged in the epineurium may result in nerve inflammation or structural nerve damage.

Results of several studies suggest that high-pressure injection into the intraneural space (15-20) psi, even with small volumes, can be a major contributor to mechanical injury of neurological tissue during peripheral nerve blocks. While high injection pressure >20psi can result in persistent neurological damage indicative of intrafascicular injection.

recent study demonstrated that high opening injection pressure >15psi the pressure that must be overcome before injection can commence may be indicative of intraneural needle placement, it is important to monitor injection pressure carefully during local anesthetic injection.<sup>[10]</sup>

Several authors have reported that intraneural injections may not always lead to nerve injury and some even advocate injecting intraneurally, the safety of intraneural injections is highly controversial, with many experts that intraneural injections are associated with unacceptable risk.<sup>[11]</sup>

Jeff C. Gadsden et al<sup>[12]</sup>, demonstrates High OIP ( $\geq 15$  psi) consistently detected NNC, suggesting that injection pressure monitoring may be useful in preventing injection against nerve roots during interscalene block.

Orebaugh et al<sup>[13]</sup>, have reported that injections within the root of the human brachial plexus in fresh cadavers resulted in injection pressures > 15 psi, fascicular injury, and risk for the injectate into the epidural space.

Andrzej Krol et al<sup>[14]</sup>, Demonstrate significant differences between intraneural and perineural injection pressures in the median, ulnar, and radial nerves. Intraneural injection pressures show low specificity but high sensitivity suggesting that pressure monitoring might be a valuable tool in improving the safety and efficacy of peripheral nerve blockade in regional anesthesia.

Steinfeldt et al<sup>[15]</sup>, have established that forceful needle–nerve contact alone in porcine models of axillary brachial plexus block results in significant neural inflammation, even without injection. Therefore, it is possible that a forceful injection during needle nerve contact in patients could cause or exacerbate nerve inflammation and neurologic symptoms. In addition, forceful injection at the point of needle–nerve contact may carry an increased risk for intraneural or partial intrafascicular injection.

By comparing with the 4 above listed studies, the conducted study is a first study that use the injection pressure monitoring in popliteal sciatic nerve block, and this study shows that the required low injection pressure <15psi to inject the local anesthetic drug into a target site of popliteal sciatic nerve block, while the other 4 listed studies and through the peripheral nerves block we should avoid the pressure > 15 psi to prevent the intraneural injection.

In summary, all extraneural injections were possible with opening injection pressure less than 15 psi. In contrast, at needle–nerve contact, limiting injection pressure to 15 psi prevented injections from occurring in all except one instance.

### CONCLUSION

High injection pressures at the onset of injection >15psi consistently detected NNC may indicate an intraneural needle placement and lead to severe fascicular injury and persistent neurologic deficits. Avoiding excessive injection pressure during nerve block administration to Prevention of an intraneural injection of a local anesthetic during peripheral nerve block is considered important to reduce the risk and avoid neurologic injury. The injection pressure monitoring enhances the accuracy of local anesthetic deposition in addition to the use of ultrasound during popliteal sciatic nerve blocks. Combined femoral- popliteal sciatic nerve block using for lower limb surgeries without any major complications and with no drug toxicity.

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