Combination of real-time needle-tip pressure sensing and minimal intensity stimulation limits unintentional intraneural injection during an ultrasound-guided peripheral nerve block procedure: A randomized, parallel group, controlled trial

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Combination of Real-Time Needle-Tip Pressure Sensing and Minimal Intensity Stimulation Limits Unintentional Intraneural Injection during an Ultrasound-Guided Peripheral Nerve Block Procedure: a Randomized, Parallel Group, Controlled Trial

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Abstract

Study objective: Ultrasound guidance does not eliminate the risk of intraneural injection, which must be avoided during PNB. Combining ultrasound guidance (USG), nerve stimulation (NS), and injection pressure monitoring is advocated to prevent nerve injury during PNB. We hypothesized that combining patient-tailored dynamic NS and real-time pressure sensing (RTPS) could reduce the incidence of intraneural injection and nerve puncture during USG PNB compared with a traditional fixed thresholds (Control) procedure.

Design: Randomized, prospective study

Setting: Operating room

Patients: One hundred ASA physical status I to III patients undergoing orthopedic surgery

Interventions: Patient anesthetized using axillary, sciatic or femoral USG PNB were randomized to the PresStim group (Dynamic RTPS and NS set at 1.5 mA then decreased; n = 50) or Control group (fixed thresholds for in-line pressure mechanical manometer and NS at 0.2 mA; n = 50).

Measurements: Procedural ultrasound images and videos were recorded, stored and reviewed in random order by two experts in ultrasound-guided PNB blinded to the group. They noted the needle-to-nerve relationship and intraneural injection for all blocked nerves.

Main Results: One hundred and twenty-three USG PNBs were performed (56 axillary brachial plexus blocks, 40 femoral nerve blocks and 27 sciatic popliteal nerve blocks); 235 blocked nerves and videos were recorded and analyzed (PresStim, 118; Control, 117). Less paresthesia was noted in the PresStim group (12.7%) compared with the Control group (18.8%). The risk of intraneural injection was significantly higher in the Control group (odds ratio [OR], 17.1; 95% confidence interval [CI], 2.2-135, $P = 0.007$). The risk of nerve puncture (OR, 22.7; 95% CI, 2.9-175, $p = 0.003$) and needle-nerve contact (OR, 4.7; 95% CI, 2.4-9.5, $p < 0.001$) was significantly higher in the Control group than the PresStim group.

Conclusions: Under the conditions of the study, dynamic triple monitoring combining RTPS, NS and USG decreases intraneural injection and unintentional needle-nerve contact and puncture during a PNB procedure.

Introduction

Postoperative nerve injury resulting in long-term damage remains a complication after peripheral nerve block (PNB). The estimated incidence of transient neuropathy after PNB is 3%,[1] and the rate of long-term injury is reported to be in the range of 2 to 4 per 10,000 PNBs in recent decades.[2] Injury may occur as a result of patient-related comorbidities, local anesthetic neurotoxicity and direct damage by the block needle. Ultrasound guidance does not eliminate the risk of intraneural injection[3–5] because adequate images of the needle-nerve interface are not obtained consistently.[6] The incidence of unintentional intraneural injection is estimated to be between 15% and 17% for ultrasound-guided interscalene and sciatic nerve blocks.[4,5] Most of these occurrences are not associated with clinical neurologic symptoms. Nonetheless, available laboratory evidence suggests that intraneural injection must be avoided during PNB.[1] Animal experiments have shown that intrafascicular injection resulting in high injection pressure might promote nerve fascicles rupture and cause nerve injury and neurological deficit.[7] In a recent clinical study, intentional intraneural sciatic nerve injection of 1% ropivacaine promoted persistent electrophysiologic changes, suggesting possible neuropathy.[8] Recent clinical guidelines from the American Society of Regional Anesthesia conclude that anesthesiologists should not purposefully seek needle-to-nerve contact or intraneural injection.[2] Although there is no evidence that peripheral nerve stimulation (NS), ultrasound, or injection pressure (IP) monitoring can prevent nerve injury, the practice advisory panel also believes it reasonable to consider using several of these modalities in combination.[2]

During IP monitoring, high injection pressures reliably detected needle-nerve contact, and injection pressures lower than 15 psi were systematically associated with extraneural needle placements, suggesting that pressure monitoring might be a highly sensitive parameter.[9–11] When using NS as a safety sentinel tool, an evoked motor response (EMR) at

low current intensity exhibits high specificity for detecting contact of the needle tip with neural tissue.[12] A recent literature reported that combination of ultrasound and NS appears to be the preferred approach for providing PNB[13] and that the combined use of ultrasound and nerve stimulation showed lower odds of unintentional paresthesia.[14] Considering real time pressure as sensitive but not specific and NS as specific but not sensitive, the risk of nerve injury during USG PNB might be reduced by a combination of these two monitoring methods. Recent studies have investigated the utility of needle-tip real-time pressure sensing (RTPS) to identify the epidural space[15] or discriminate tissue types.[16] A combination of NS with a low minimal intensity of stimulation (MIS) and high RTPS might warn the operator of the intraneural needle-tip position during USG nerve blocks.[17] In this randomized prospective study, we hypothesized that combining NS and dynamic RTPS could reduce the incidence of intraneural injection as well as nerve puncture and needle-nerve contact during USG PNB in comparison with a Control procedure.

Materials and Methods

Study Design and Patients

After institutional ethical committee approval (Comité de Protection des Personnes Sud Méditerranée 1, Montpellier-Nimes, France, n°15129, 2015-A01850-49) and clinical trial registration (ClinicalTrials.gov ID NCT02737137), 110 patients who were American Society of Anesthesiologists physical status I to III, aged from 18 to 70 years, scheduled for elective orthopedic upper- or lower-limb surgery and anesthetized using ultrasound-guided PNB, were enrolled in this randomized, parallel group, prospective study from March 2016 to March 2017. The study method and report respect the Consolidated Standards of Reporting Trials (CONSORT) statement. Exclusion criteria were contraindications for PNB (e.g., anatomic deformity, preexisting neurologic deficit, allergy to local anesthetics), body mass index greater than 35 kg/m^2, diabetes mellitus, or inability to communicate postoperative symptoms. After written informed consent was obtained the day before or the morning of surgery, patients were brought to the preoperative holding area. Recommended French Society of Anesthesiologists monitoring and supplemental oxygen were applied, and light sedation (10 mg propofol or 1–2 mg of midazolam) was administered if needed. The patient's limb was positioned for the nerve block and the skin was disinfected with 10% alcoholic povidone-iodine. Patients were scanned with a matrix linear ultrasound transducer (6–15 MHz, Logiq S8, General Electric, Wauwatosa, WI, USA) covered with a sterile sleeve (CIV-Flex, CIVCO, Kalona, Iowa, USA) to assess whether the underlying tissues and the target nerve/plexus could be clearly identified. The best transverse view of the nerves was sought before starting the procedure, and only patients with sonoanatomy demonstrating clearly defined boundaries of nerves were included in the study. The assignment group was given to the team members at that time. Randomization was generated by our institutional biostatistics department using a

computer-generated random sequence. The randomization into two groups was stratified by type of nerve block (femoral, sciatic, axillary nerve block). For the ultrasound-guided nerve block procedures in both groups, an insulated 80-mm 22-gauge block needle (Stimuplex Ultra, BBraun Medical, Melsungen, Germany) was inserted in-plane from a lateral aspect of the transducer. The choice of local anesthetic dose (mepivacaine or ropivacaine) was selected according to desired onset, intensity, and duration of nerve blockade. The PNBs were performed by a senior anesthesiologist or a resident with previous ultrasound experience and who was qualified to perform PNB independently. Needle path and endpoints for the needle target were chosen by the operator.

The needle was directed in-plane toward the nerve until the tip of the needle was just outside the nerve's epineurium avoiding needle-nerve contact and intraneural needle placement, and to visualize a circumferential spread of solution around the nerve (the “donut” or “croissant sign”) without intraneural injection. The nerve targeted for axillary block was initially the radial nerve, then the median nerve, musculocutaneous nerve and lastly, the ulnar nerve. When femoral and sciatic popliteal block were combined to provide complete anesthesia of the lower limb and ankle, the femoral nerve block was performed after the sciatic popliteal block.

Randomized Procedural USG PNB Groups

Dynamic Real-Time Pressure Sensing and NS (PresStim Group)

The procedure was performed under ultrasound guidance, NS, with the current charge set initially at 1.5 mA, 0.1 ms (detection mode).The authors always checked that the nerve stimulator did not display a high resistance and that the electrode has been placed proximally on the same limb. Continuous IP was monitored using needle-tip RTPS (CompuFlo, Dynamic Pressure Sensor Technology, Computer Controlled Anesthesia System, Milestone Scientific,

Livingston, NJ, USA). The CompuFlo is a computerized pressure-sensing device, which uses a proprietary algorithm to measure the exit pressure at the tip of the needle *in situ*; it is capable of providing real-time, continuous pressure monitoring and a maximum pressure can be set.[18] The injection pump was calibrated and set to zero before connection. The needle was connected to a 20 mL saline-filled DPS Bare syringe (Misawa, Shanghai, China), loaded into the injection pump by 122 cm of arterial pressure tubing (Icumedical, San Clemente, CA, USA) linked to an electronic pressure transducer (figure 1). The CompuFlo device was initially set to deliver the solution at a rate of 1.2 mL/min during the real-time IP measurements with the maximum pressure limited to 15 psi (775 mmHg). The flow was started after puncture of the skin. The operator was informed that the flow stopped automatically at 15 psi. During the procedure, the current intensity of the nerve stimulation was decreased step by step in case of EMR until muscle contractions disappeared. If paresthesia, intraneural location of the needle, or intraneural injection was noted, the procedure was immediately interrupted and the needle repositioned. When paraneural location was reached, the injection rate of the syringe containing ropivacaine 5 mg/mL or mepivacaine 10 mg/mL was increased to 12 mL/min in order to perform a subparaneural local anesthetic injection, in accordance with common clinical practice.[19] A second anesthesiologist controlled the start of injection and stopped infusion in cases of paresthesia and/or intraneural location of the needle, or intraneural injection not reaching 15 psi.

Classic Procedure (Control Group)

The procedure was performed under ultrasound guidance. A nerve stimulator, with the current charge set at 0.2 mA, 0.1 ms (fixed sentinel safety mode) throughout the procedure, was connected to the nerve block needle.[2,13] A manometer manufactured to quantify IP (BSmart, B. Braun Medical Inc, Bethlehem, PA, USA) was inserted in-line between the syringe filled with local anesthetic and the injection tubing.[2,11] In that group, NS and pressure

manometer did not help for nerve block guidance but there were used as safety tools.[2] When the physician began to inject the local anesthetic solution, if pressure in the tubing increases, a piston is pushed out of the device, showing color-coded indicators of pressure ranges (less than 15 psi, 15–20 psi, exceeding 20 psi). The operator was asked to look at the manometer (high pressure injection warning light) during injection. There's no low flow continuous injection compared to dynamic pressure sensing group. During the procedure, if paresthesia was reported, an EMR, intraneural location of the needle, intraneural injection, or a pressure peak >15 psi was observed, the operator was asked to stop the procedure and reposition the needle.

For both groups, the second anesthesiologist collected the following data: duration of the procedure, paresthesia during the procedure, IP peak >15 psi, and volume of local anesthetic.

Patient Follow-Up

At 20 min after block placement, blinded dermatomal sensory response to cold was analyzed on a three-point scale (2, normal sensation; 1, blunted sensation; and 0, absence of sensation). Patients were asked to fill out the neuropathic pain diagnostic questionnaire (DN4) on day 1 and day 7.[20] This questionnaire was completed by a research nurse who was blinded to all data other than the type of surgery and type of block. Patients' medical records were reviewed 15 and 90 days after surgery to assess postoperative signs or symptoms of residual neurologic injury. Any patient with a suspected postoperative neurologic complication underwent a complete neurological evaluation and standard diagnostic testing to define the cause and determine the prognosis of postoperative neurological symptoms.

Video Analysis

Ultrasound images were recorded on a digital recorder from skin puncture until completion of the injection for each procedure (figure 1). Three sequences were stored (radial

nerve, median nerve, ulnar nerve) during axillary nerve block and one sequence was stored during femoral and sciatic popliteal nerve blocks. After editing, video clips were uniform in appearance and contained no identifying information. They were then numbered, classified and stored for expert review. The ultrasound sequences were reviewed in random order by two experts in ultrasound-guided PNB blinded to the data being studied (videos 1 and 2). They were asked to rank the needle-to-nerve relationship (contact with displacement >1 mm, rotation around its axis, deformation of bordering, puncture, crossing). The main objective was to detect an intraneural needle position and intraneural injection of local anesthetic. If not present, the distinction between extraneural or subparaneural injections was determined. Intraneural injection was defined by visualization of nerve swelling (i.e. change in the cross-sectional area of the nerve) or halo. The experts did not report a distinction between extra, inter or intra-fascicular locations. Subparaneural injection was defined by visualization of the needle tip at the peripheral nerve margin and a circumferential spread of local anesthetic around the nerve ("donut" or "croissant" sign) without nerve swelling. Extraneural injection was defined by the spread of local anesthetic close to the nerve without circumferential spread.

Sample Size Estimation (SSE) and Statistical Analysis

The primary endpoint in both patient groups was the incidence of unintentional intraneural injection. Intraneural injections have been shown to occur in approximately 15% of all PNBs performed, even with ultrasound guidance.[4,5] We hypothesized that combining dynamic RTPS and NS would result in less than 1% intraneural injections. For a 2-tailed $\alpha = 0.05$ and a power of 90%, a sample size of 59 procedures per group was required. We estimated that a SSE of 60 procedures per group would be sufficient for our study. Some patients received several procedures (i.e. femoral and sciatic popliteal nerve blocks), therefore a NSN of 50 patients has been recorded. Statistics are presented as means (SD) or medians

[interquartile range] for quantitative data and numbers (percentage) for qualitative parameters. For the univariate analysis, continuous variables were compared using the Mann-Whitney U test or the Student t test. Discrete variables were compared using the χ^2 test or the Fisher exact test when indicated. A multivariate analysis was performed for the stored videos analysis using a mixed model accounting for repeated measurements in the same patient. Each categorical evaluation was the dependent variable, the group was the fixed effect and the patient was random effect. The results are presented as odd ratios (95% confidence intervals) with the PresStim group as reference.

A *P* value <0.05 was considered statistically significant. Statistical analyses were performed using SAS for Windows version 8.2 (SAS Institute Inc, Cary, NC, USA).

Results

Of 110 patients considered for inclusion, 100 were enrolled in the study and randomized to the two groups (50 PresStim, 50 Control). Ten patients were excluded because of suboptimal ultrasound anatomy (figure 2). Demographic characteristics of the patients, comorbidities and surgeries are reported in table 1. There was no significant difference between the groups for age, sex, type of surgery, volume of local anesthetic, sensory blockade at 20 minutes and associated general anesthesia. A flowchart for the study and the composition of the groups are reported in figure 2. One hundred and twenty-three USG PNBs were performed (56 axillary brachial plexus blocks, 40 femoral nerve blocks and 27 sciatic popliteal nerve blocks). A total of 235 blocked nerves and videos (56 radial, 56 median, 56 ulnar, 40 femoral, 27 sciatic popliteal nerves) were recorded and analyzed (PresStim group, 118; Control group, 117). The median (quartiles) duration of the nerve block procedure was 102 s (65–140 s) in the PresStim group and 120 s (90-160 s) in the Control group. For ten nerves (8.55%), the IP exceeded the threshold of 15 psi (related to the BSmart device) in the Control group. The threshold was never exceeded in the PresStim group when injections for nerve block loading dose were done. For all procedures, paresthesia was noted in 15 of 118 nerve locations (12.7%) in the PresStim group and 22 of 117 nerve locations (18.8%) in the Control group. The results of the analysis of the 235 stored ultrasound images in both groups are reported in table 2. For the whole panel of patients, 148 injections were in the paraneural space and 71 were extraneural ($P = 0.12$ and $P = 0.7$, respectively). Sixteen (6.8%) intraneural injections were noted, 1 (0.8%) in the PresStim group and 15 (12.8%) in the Control group. The risk of intraneural injection was significantly higher in the Control group (odds ratio, 17.1; 95% confidence interval, 2.2–135; $P = 0.007$). The incidence of nerve puncture and needle-nerve contact was significantly lower in the PresStim group compared with the Control group for nerve displacement >1 mm, nerve deformation of its border, and nerve

rotation around its axis (table 2). No postoperative neurologic complication was noted in any patient at follow up. At D1 and D7, respectively 13 and 9 patients in PresStim group and 11 and 10 patients in Control group complained about pain; 7 and 6 patients in PresStim group and 3 and 7 patients in the Control group reported paresthesia; and 8 and 6 patients in the PresStim group and 6 and 4 patients in the Control group noted numbness.

Discussion

In this randomized controlled study, we compared triple monitoring combining dynamic RTPS, NS and ultrasound guidance with a control PNB procedure. Our study confirms that, despite use of NS and a pressure manometer as safety tools, unintentional intraneural injection is fairly common during USG PNB and that patient-tailored triple monitoring significantly decreases the incidence of intraneural injection. Moreover, the incidence of all types of needle-nerve contacts and nerve puncture was decreased using the triple monitoring compared with the Control nerve block procedure.

In an exploratory trial, we combined dynamic RTPS and NS and we established that high IP and low MIS characterized an intraneural location of the needle tip during USG PNB.[17] We tested the PresStim technology that uses a propriety algorithm to provide real-time continuous pressure monitoring. The outcomes of the exploratory study were sensitivity and specificity, and predictive values for each needle tip location. We reported all the associated components of the dynamic triple monitoring procedure during PNB. In the present clinical prospective randomized study, we confirmed the results of the previous trial.

First, by continuously injecting a low flow of fluid, we observed that the MIS to elicit an EMR was higher with saline, i.e. local anesthetic as a conductive solution, in comparison with 5% dextrose water. The infusion of a conductive solution appeared preferable to discriminate intraneural from paraneural location of the needle tip and extraneural MIS to elicit EMR associated with an RTPS. Furthermore, using saline as the conductive solution, a high current intensity was not associated with patient discomfort, likely because of current dispersion at the needle tip. In the present study, we speculate that during a nerve block with local anesthetics, a combination of RTPS and NS in detection mode, i.e. current charge initially set to 1.5 mA and decreased, would warn of vicinity of a nerve before nerve contact. We could have started the nerve stimulation at 1 mA. However, in our clinical practice with DPS

injecting a ionised solution during the approach, we noted that a motor response was not always observed during nerve contact at 1mA because of the dispersion of the current at the needle tip. Increasing the current to 1.5 mA was well tolerated by the patients if nerve contact was noted because of low voltage associated to the low resistance at the needle tip and lower current density. We can confirm the results of Perlas *et al.*[22] who reported that, with a stimulating current of 0.5 mA or less, a motor response was only 74.5% sensitive for detection of needle-to-nerve contact. On the other hand, the specificity of that parameter is high because for stimulation currents of 0.2 mA or less, no needle-tip location was observed extraneurally in any patient.[12] As a consequence, the parameter is highly specific. The occurrence of EMR to NS indicates needle-to-nerve contact. The absence of stimulation indicates that the needle is in contact with a fascia distant from the nerve. In the Control group, the sentinel current charge at 0.2 mA was not sensitive for detection of needle-to-nerve contact,[22] and the BSmart mechanical device only operates when the physician injects and not during the entire procedure of puncture.

Second, IP monitoring has been reported to detect high IPs reliably associated with needle-nerve contact and intraneural injections.[9,10,16] During a loading dose injection, IPs lower than 15 psi were systematically associated with extraneural or paraneural needle placement, suggesting that injection pressure monitoring might be a highly sensitive tool. The interstitial pressure produced at the needle tip when using dynamic RTPS results in different fluid dynamic than those obtained with a hand-driven traditional syringe[9,10]. This is the main factor that explains the difference between our concepts and former models based on opening injection pressure (OIP).[9,10] OIP is reached once the pressure inside the system overcomes the static resistance, and flow starts to occur. In contrast, dynamic injection pressure is the pressure within the system that exists once low flow is established. RTPS enables fluid pressure and flow rate at the needle tip to be precisely controlled and monitored in real-time

during all phases of the injection process. RTPS allows to accurately identify specific tissue types at the needle tip, based on tissue compliance. In the present study, we reported that OIP peaks were observed with the in-line mechanical manometer in the DG group versus none in the PresStim group. In a recent study, we observed for the first time in clinical practice during USG PNB that multiple peaks in IP are generated during manual syringe injection of the local anesthetic solution.[21] These peaks of pressure are related to the injection, and repositioning of the needle tip to optimize the spread of local anesthetic solution. In the PresStim group, the CompuFlo device was intentionally set to a maximum pressure limited to 15 psi (775 mmHg). When the upstream pressure reaches 15 psi, the flow is interrupted, preventing any further injection of fluid until the pressure is reduced, thereby preventing potentially injurious needle-tip pressures. Importantly, this computer-controlled technology is typically calibrated to precisely measure pressure at a low flow rate (1.2 mL/min) and in pressure ranges relevant to injection monitoring for nerve block (i.e. up to 1060 mmHg). The system is highly sensitive and specific to determine levels of injection pressure >15 psi in bench studies.[11] Accuracy, as measured by the F1 score, for detecting a pressure of $\geqslant$15 psi was 0.96 for the CompuFlo system and only 0.74 for the BSmart system. In addition, RTPS provides an objective audible and visual warning of a change in resistance during needle advancement. The physician is informed in real time when the needle comes in contact with a dense tissue. Under the conditions of the present trial, not only the risk of nerve puncture and intraneural injection were lower in the PresStim group but the incidence of all type of unintentional nerve contacts was also decreased in comparison with the traditional procedure.

Our study had several limitations. First, the objective of this study was to compare the two strategies as two distinct entities (ie., RTPS + 1.5 mA decremental MIS was better than or safer than conventional manometer + 0.2 mA fixed sentinel safety nerve stimulation, in USG guided PNB). The maximum pressure was limited to 15 psi and the initial current charge

started at 1.5 mA; we can only conclude that, considering these settings, needle-nerve contact might be prevented. In the Control group, the sensitivity for detection of needle-to-nerve contact might have been improved by increasing the current charge to 0.5 or 1 mA. Second, only data analysts were blinded; it was not possible to blind patients and physicians who took part in trial assessment. In the PresStim group, the additional physician was operating the pump, whereas, in the Control group, he intervened only in the case of intraneural location of the needle or intraneural injection. Third, to standardize the protocol, we used one needle gauge size and one injection speed. It is possible that other needle gauges and rates of injection could have yielded different results. Fourth, we could have considered a control group with only ultrasound but this would have been contrary to current knowledge on the optimal nerve block procedure.[2,11,13,14]. Fifth, the results are limited by the sensitivity and specificity of ultrasound to detect nerve injury/intraneural placement, as ultrasound is by no means the gold standard to detect intraneural needle placement or injection. Sixth, the choice of two different LA might have added a new variable. Mepivacaine was chosen for surgical anesthesia in surgeries that did not promote high levels of postoperative pain and ropivacaine for potentially painful or long duration surgeries. Considering the methods and study's primary hypothesis, the LA type was not considered as a new variable as it did not influence the mains results (intraneural injection) that bared the consequence of the needle approach and not the injected LA. Seventh, even if the long term neurological outcome should have been considered as the ultimate goal, the study was not sufficiently powered to assess the incidence of neurologic dysfunction or nerve injury. There are sources of variability including different patients, and different nerve block targets. The importance of intraneural injection may depend on the nerve involved. Large series with short- and long-term follow-up are needed to confirm the possible impact of the real-time triple monitoring on nerve damage. Lastly, the authors do not discuss the practicality of the technique: additional cost, setup time

and cumbersome equipment to potentially reduce an already low rate of permanent nerve injury (4 per 10,000).

In conclusion, under the conditions of the study, triple monitoring combining RTPS, NS and ultrasound guidance may help in detecting intraneural injection as well as needle-nerve contact during USG PNB. RTPS gives the sensitivity of detecting dense tissue and NS the specificity that this dense tissue is a neural structure. Future large-scale studies are needed to determine whether routine real-time triple monitoring reduces the risk for neurologic injury.

Table 1. Demographic Characteristics of Patients in Both Groups, Type of Surgery and Nerve Blocks Data

	PresStim Group (n = 50)	**Control Group (n = 50)**
Age (years), mean (SD)	42 (17)	49 (19)
Weight (kg), mean (SD)	72 (12)	74 (17)
Sex ratio (m/f), n	33/17	31/19
ASA I/II/III, n	27/18/5	32/24/4
Type of surgery, n (%)		
Osteosynthesis	29 (58)	26 (52)
Wound exploration	14 (28)	13 (26)
Intramedullary nailing	1 (2)	2 (4)
Arthroscopy	0	2 (4)
Removal of osteosynthesis material	1 (2)	0
Other	5 (10)	7 (14)
Type of nerve blocks, n	62	61
Axillary	28	28
Femoral	20	20
Popliteal sciatic	14	13
General anesthesia, n (%)	2 (5)	2 (5)
Neuropathic pain (DN4 $\geqslant$ 4), n (%)		
Day1	0 (0)	2 (4)
Day 7	1 (2)	1 (2)
Scores of Sensory block at 20 min, n (%)	n=118 nerves	n=117 nerves
0	16 (13.5)	17 (14.5)
1	102 (86.5)	97 (83)
2	0 (0)	3 (2.5)

Sensory Blocks scores: 0: absence of sensation; 1: blunted sensation; 2: normal sensation

Table 2: Video Recording Analysis of Needle-Nerve Relationships According to Blocked Nerves (n) and Number of Events (%)

Blind Video Recording Classification	**PresStim Group (n = 118), n (%)**	**Control Group (n = 117), n (%)**	***P* Value (Univariate Analysis)**	**Adjusted OR [95% CI]**	***P* Value of Group Effect**
Intraneural	1 (0.85)	15 (12.82)	<0.001	17.1 [2.2–135]	0.007
Vascular puncture	2 (1.69)	0 (0)	0.5	None	None
Nerve contact with displacement	13 (11.02)	37 (31.62)	<0.001	3.7 [1.8–7.6]	0.0004
Nerve contact with deformation	14 (11.97)	46 (39.32)	<0.001	4.7 [2.4–9.5]	<0.001
Nerve contact with rotation	4 (3.39)	21 (17.95)	<0.001	6.2 [2–19]	0.0016
Needle crossing the nerve	0 (0)	4 (3.42)	0.06	None	None
Needle puncturing the nerve	1 (0.85)	19 (16.24)	<0.001	22.7 [2.9–175]	0.003

Adjusted odds ratio after mixed model analysis for repeated measurements in patients; the PresStim group was the reference. None, no convergence of the model. *P* value considered significant at 0.05.

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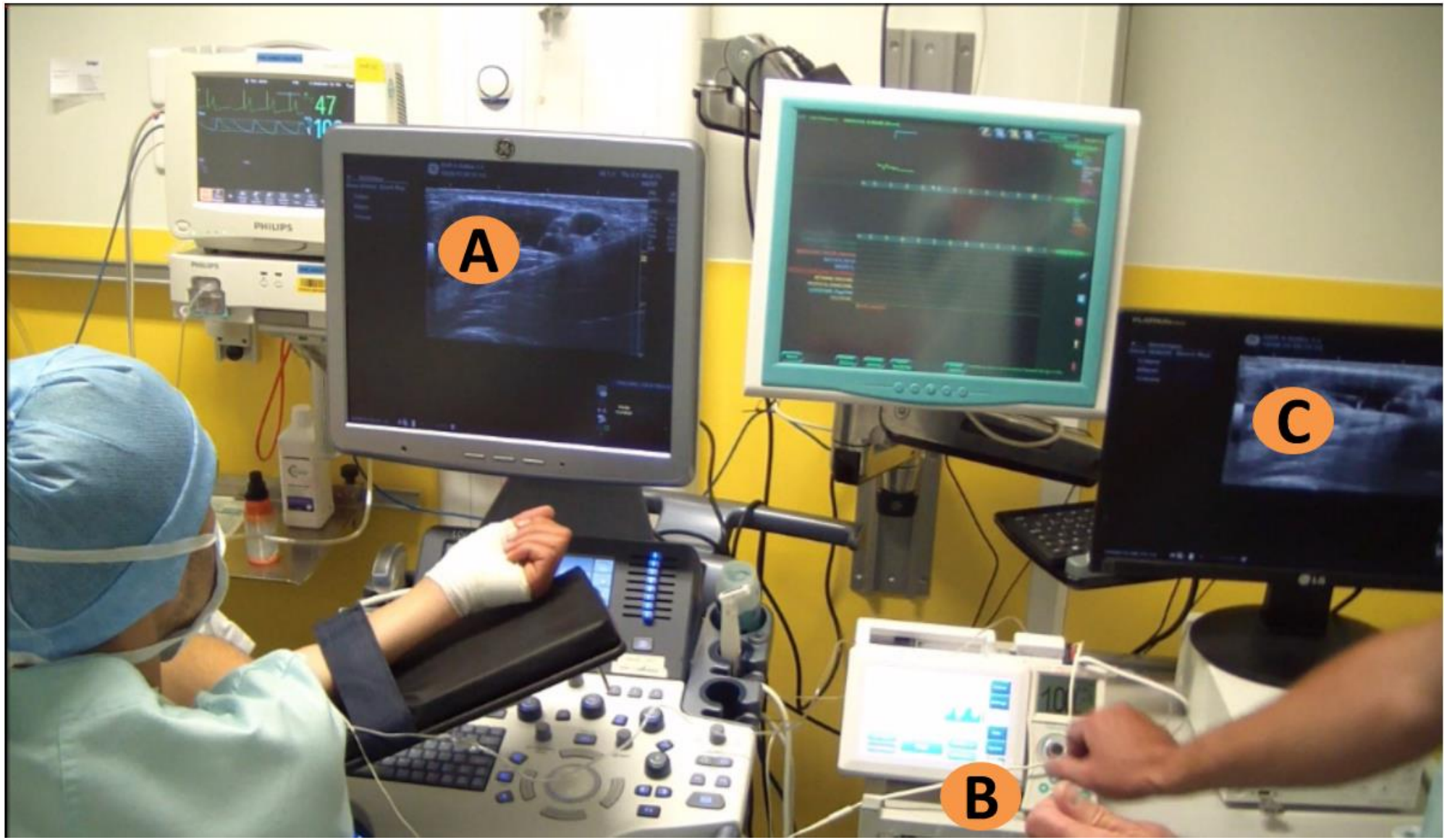
Figure Legends

Fig. 1. Devices used to perform real-time needle-tip pressure sensing (RTPS) and nerve stimulation (NS) during an ultrasound-guided peripheral nerve block: (A) Ultrasound machine (the anesthesiologist used a matrix linear ultrasound transducer (6–15 MHz)), (B) Combination of a Dynamic RTPS system (CompuFlo®) and a NS device , (C) Computer and digital recorder for secondary blinded analysis by two experts.

Fig. 2. CONSORT flowchart of patient inclusion in the study, nerve blocks procedures and video analysis of blocked nerves.

Video 1. Femoral nerve block procedure in a patient in the PresStim group: evoked motor response at 12 s. The hydrodissection obtained by the low flow of fluid is observed below the fascia iliaca and above the iliopsoas muscle and the femoral nerve.

Video 2. Radial nerve block procedure in a patient in the Control group; an intraneural injection is observed at 60 s.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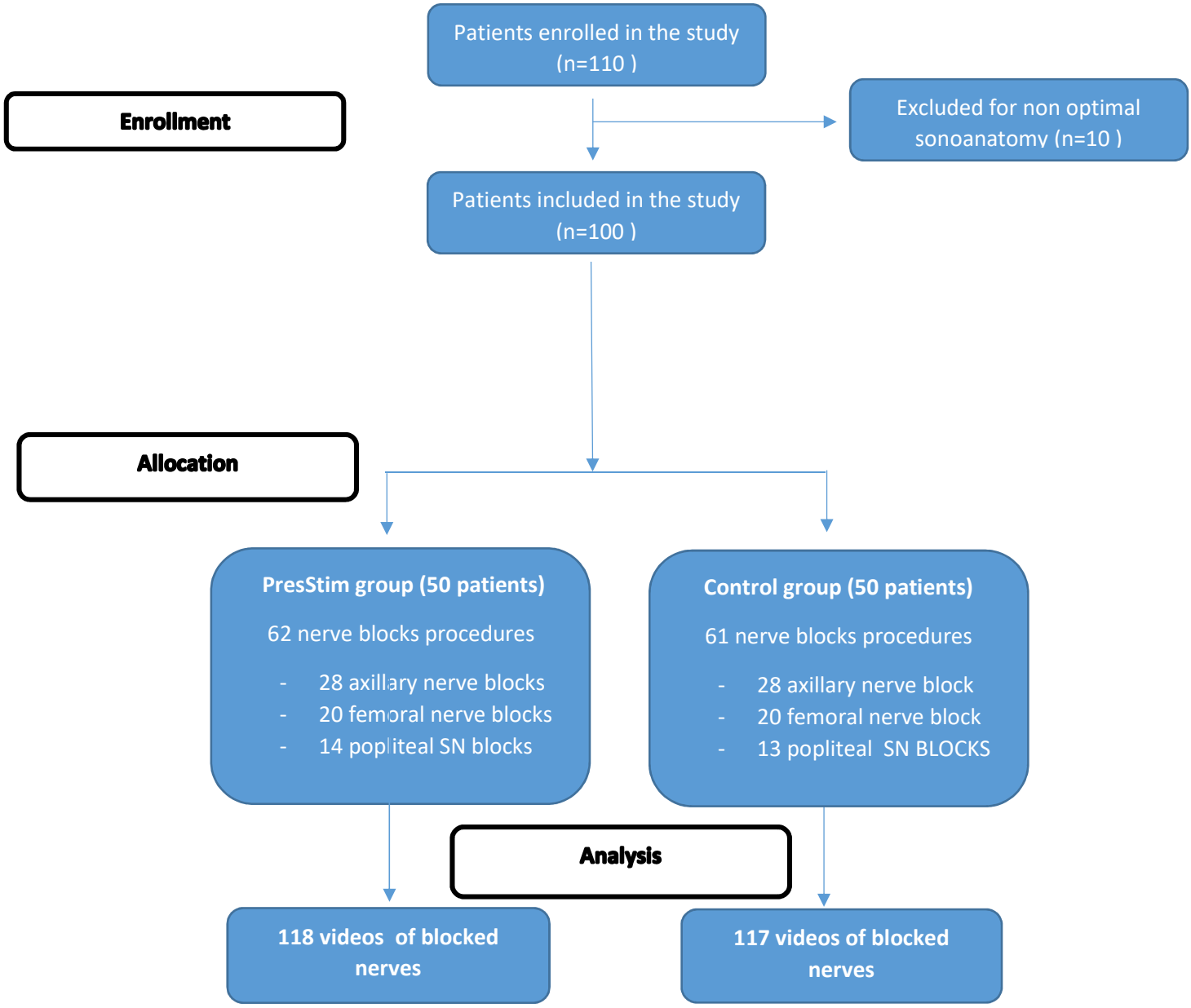
Enrollment
Patients enrolled in the study (n=110)
Excluded for non optimal sonoanatomy (n=10)
Patients included in the study (n=100)
Allocation
PresStim group (50 patients)
62 nerve blocks procedures
- 28 axillary nerve blocks
- 20 femoral nerve blocks
- 14 popliteal SN blocks
Control group (50 patients)
61 nerve blocks procedures
- 28 axillary nerve block
- 20 femoral nerve block
- 13 popliteal SN BLOCKS
Analysis
118 videos of blocked nerves
117 videos of blocked nerves