

Randomized Trial

Intermediate Cervical Plexus Block in the Management of Persistent Postoperative Pain Post Carotid Endarterectomy: A Prospective, Randomized, Controlled, Clinical Trial

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Background: The mechanisms of persistent postoperative pain (PPP) with neuropathic features after carotid endarterectomy (CEA) are multifaceted and are incompletely understood.

Objectives: The aim of this research was to assess whether the ultrasound-guided (USG) intermediate cervical plexus block (ICPB) could provide better control of PPP and neuropathic disturbances (NPDs) after CEA than the USG superficial cervical plexus block (SCPB).

Study Design: Prospective, randomized, controlled, clinical trial.

Setting: This clinical trial was conducted at the SS Filippo and Nicola Academic Hospital of Avezzano (L'Aquila, Italy).

Methods: Patients who were scheduled for primary CEA were chosen. In the experimental group, the USG-ICPB was performed unilaterally, at the level of the third cervical vertebra. The needle was inserted into the deep lamina of the deep fascia of the neck, between the posterior border of the middle scalene muscle and the anterior border of the posterior scalene muscle. Three milliliters saline solution was injected into the opening of the deep lamina, and 20 mL 0.375% levobupivacaine was injected. In the control group, the anesthetic target was located at the inferior border of the sternocleidomastoid muscle at the level of the third cervical vertebra. The needle was superficially inserted below the skin, and 2 to 3 mL saline solution was injected into the opening of the superficial lamina of the deep fascia of the neck. A total of 20 mL 0.375% isobaric levobupivacaine was subsequently injected.

The primary outcome measure was the proportion of patients with PPP on movement and at rest 3 months after surgery. The secondary outcome measures were NPD assessment scores using the von Frey hair test and the Lindblom test, opioid and pregabalin consumption. Adverse effects were also recorded.

Results: A total of 98 consecutive patients were enrolled and randomized to receive either a USG-SCPB (control group, n = 49) or a USG-ICPB (experimental group, n = 49). The sensory blockade was longer in the experimental group. Three months after surgery, the proportions of patients with PPP on movement were significantly different between the experimental and control groups (33%, 95% confidence intervals [CI], 20%-47% vs. 71%, 95% CI, 57%-83%; $P < 0.001$), whereas there were no differences in the proportions of patients with pain at rest between groups (31%, 95% CI, 18%-45% vs. 49%, 95% CI, 34%-64%; $P = 0.063$). The proportions of patients with NPDs were not different between the groups, whereas the sizes of the areas of interest (cm²) were significantly different.

Limitations: A limitation of this study is that we assessed NPDs for only 3 months using the von Frey hair test and the Lindblom test without additional instrumental techniques. Additionally, there are many risk factors for NPDs after CEA. For this reason, another limitation of this research is that we neglected to consider the relationship between the choice of anesthetic block and the presence of these risk factors.

Conclusions: The USG-ICPB provided long-lasting analgesia during the postoperative period and might mitigate the development of NPDs, thereby decreasing the analgesic drug requirement.

Key words: Carotid endarterectomy, intermediate cervical plexus block, myofascial planes of neck, neuropathic disturbances, persistent postoperative pain, superficial cervical plexus blocks, ultrasound guidance, vascular disease

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The mechanisms of persistent postoperative pain (PPP) with neuropathic features in vascular disease are multifaceted and are incompletely understood (1), especially after carotid endarterectomy (CEA) (2). CEA can be performed under regional anesthesia or general anesthesia (GA). Ultrasound-guided (USG) superficial or intermediate cervical plexus blocks (CPBs) could be considered effective methods for providing useful anesthesia for patients undergoing CEA (3-4). There is a small amount of evidence that investigates whether the superficial or intermediate CPB improves analgesia in the post-CEA period. There is no evidence regarding early and long-term pain with neuropathic features after CEA (1).

We hypothesized that USG intermediate cervical plexus blocks (ICPBs) could provide better control of PPP with neuropathic disturbances (NPDs) than USG superficial cervical plexus blocks (SCPBs). The primary outcome of our study was to compare the incidence of PPP between patients undergoing CEA who received a USG-ICPB and those who received a USG-SCPB.

METHODS

This clinical trial was approved by the local research ethics committee of the health unit of L'Aquila (Italy) (protocol number: 0174363/2017; ClinicalTrials.gov identifier: NCT03409068), and it was conducted at the SS Filippo and Nicola Academic Hospital of Avezzano (L'Aquila, Italy) in accordance with CONSORT (Consolidated Standards of Reporting Trials Statement for Reporting Trials). Written informed consent was obtained from all patients or their legal surrogates.

All patients fulfilled the following inclusion criteria: age 18 to 75 years, American Society of Anesthesiologists (ASA) physical status I to III, and scheduled for primary CEA. Patients with the following criteria were excluded: pregnancy, body mass index (BMI) > 39.99 kg/m², known allergies to local anesthetics, neurologic diseases, psychiatric diseases, history of chronic pain or neuropathic disorders, history of drug abuse, previous CEA, ASA physical status IV, neck ab-

normalities, septic state, and skin infections on the neck.

The proxies, attending physicians, nursing staff, research assistants, and surgeons were blinded to the study treatment. The patients were randomized using the sealed envelope method to receive either a USG-ICPB (experimental group) or a USG-SCPB (control group). The patient information recorded included gender, age, level of education in years, employment (yes/no), BMI (kg/m²), heart rate (in bpm), systolic blood pressure (in mm Hg), diastolic blood pressure (in mm Hg), and oxygen arterial saturation (SaO₂%). The patients were monitored with an INVOS system (5100C Cerebral/Somatic Oximeter, Medtronic, Minneapolis, MN); intraoperative assessments of consciousness, stump pressure, and invasive pressure were also monitored during surgery. Peripheral venous access was obtained in all patients.

In the experimental group, the USG-ICPB was performed unilaterally, and the patients were placed in a supine position with their heads turned to the opposite side of surgery. A 22-gauge 100-mm atraumatic Sprotte-type needle was used for the peripheral nerve blocks (SonoPlex Stim cannula; Pajunk GmbH Medizintechnologie, Geisingen, Germany). Under aseptic conditions, a linear ultrasound probe (5-12 MHz, SonoSite MicroMAXXM-Turbo, FUJIFILM Italia S.P.A., Milan, Italy) was placed perpendicular to the skin in the horizontal plane at the level of the fourth cervical vertebra (C4). The transverse process (TP) of C4 was detected, and then the probe was moved to identify the TP of C3.

The in-plane approach was used, and the needle was inserted under the inferior border of the sternocleidomastoid (SCM) muscle, and medially and deeply advanced into the deep lamina (prevertebral fascia) of the deep fascia of the neck, between the posterior border of the middle scalene muscle (MSM) and the anterior border of the posterior scalene muscle (PSM) (Fig. 1). Three milliliters saline solution was injected into the opening of the deep lamina, and 20 mL 0.375% levobupivacaine was injected (Fig. 1) (5).

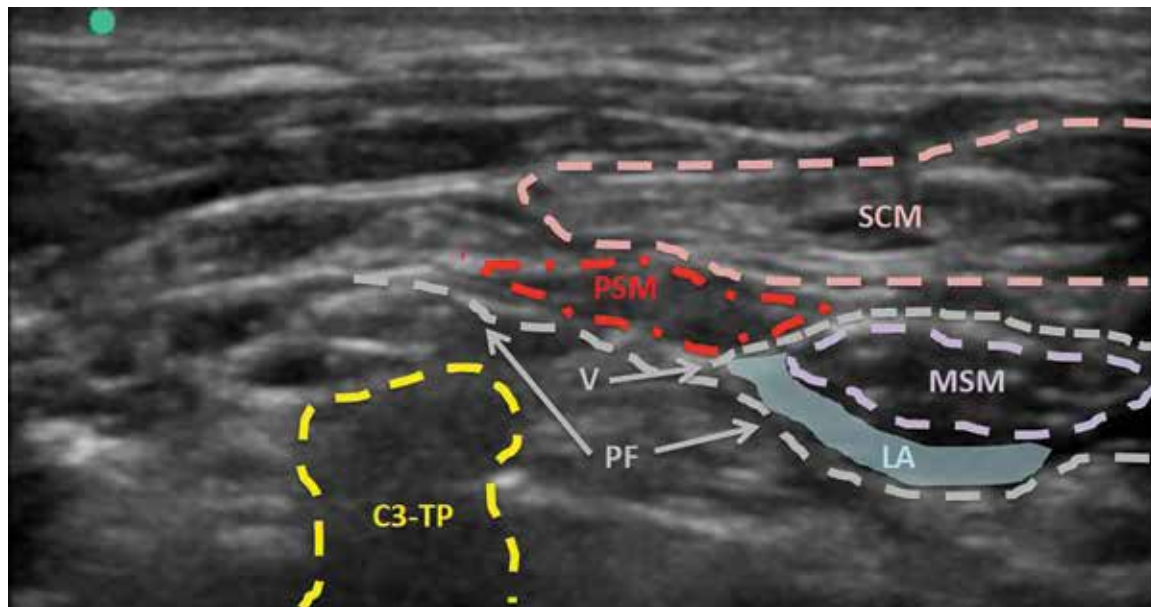


Fig. 1. *Ultrasound scan. LA: local anesthetic spread into the prevertebral fascia; SCM: sternocleidomastoid muscle, PSM: posterior scalene muscle; MSM: middle scalene muscle; PF: prevertebral fascia; V: “V sign” identifies the opening of the myofascial compartment between the posterior border of the inferior multifidus muscle (IMM) and the anterior border of the PSM; C3-TP: transverse process of third cervical vertebra.*

In the control group, the anesthetic target was located at the inferior border of the SCM muscle at the C3 level. The needle was superficially inserted below the skin, and 2 to 3 mL saline solution was injected into the opening of the superficial lamina of the deep fascia of the neck. A total of 20 mL 0.375% isobaric levobupivacaine was subsequently injected (6).

Before each injection, color Doppler echography was performed to avoid puncturing a vessel.

Bilateral cold tests and touch tests were performed every 2 minutes to confirm that dermatome levels were blocked, and the patient was considered ready for surgery when a complete loss of cold and touch sensations was observed for the C2 to C4 dermatomes. Inadequate surgical anesthesia was converted to GA and noted as an unsuccessful block. Standards for Basic Anesthetic Monitoring and Standards for Postanesthesia Care were respected (7-8).

After discharge from the postanesthesia care unit, the patient was admitted to the ward. All patients were hospitalized in the ward for 1 day because the first surgical wound evaluation was performed the day after surgery. In the ward, sensory block was assessed by cold and touch tests after exposing the surgical wound,

by respecting aseptic conditions. A neurologic clinical evaluation was performed to record symptoms related to the side effects of local anesthetics (LA). The following adverse effects were also assessed: iatrogenic hematoma, hypotension (30% decrease in blood pressure), severe hypotension (> 30% decrease in blood pressure), cardiac arrest, hoarseness, cough, difficulty swallowing, and postoperative nausea and vomiting. Before the patients were discharged from the hospital and 3 months after surgery, a blinded anesthesiologist performed the in-hospital and at-home visits to evaluate pain on movement and at rest and the presence of NPDs, in accordance with our protocol for patients with vascular disease.

The primary outcome measure was the proportion of patients with PPP on movement and at rest, based on the Numeric Rating Scale (NRS-11; an 11-point numeric rating scale from 0 [no pain] to 10 [worst pain imaginable]). The patients were considered to have PPP when the NRS-11 score was ≥ 4 . The presence of PPP on movement and at rest were recorded before the patients were discharged from the hospital and at 3 months after surgery. At-home pain management consisted of 1,000 mg acetaminophen per os every 6

hours if the pain was rated as an NRS-11 score of 3 to 5 (maximum 4,000 mg per day), 500 mg of acetaminophen with 30 mg of codeine per os every 4 hours for NRS-11 scores 5 to 7, and 100 mg of tramadol per os for NRS-11 scores ≤ 7 (maximum 400 mg per day). Pregabalin 75 mg per os every 12 hours was administered for patients with NPDs who were unresponsive to the other analgesic drugs. PPP on movement (9-10) was assessed by asking the patients to turn their head to the left and to the right and by coughing and swallowing. PPP at rest was assessed with the patients in the sitting or lying position.

The NPD assessment was a secondary outcome and was assessed using the von Frey hair test and the Lindblom test (11-13). The mechanical sensitivity (von Frey) test consisted of applying thin calibrated plastic filaments to the patients' skin. Our testing protocol began by pressing the filament against the skin at a 90° angle until the filament bowed. The filament was held in place for 1.5 seconds and was removed when a single patient response was obtained. The Touch-Test 20 Piece Full Kit (Stoelting Europe Ground Floor, Hilton House, Dublin, Ireland) was used, and the test began with the 2.83 filament (Operation Manual, Touch-Test Sensory Evaluators, Semmes Weinstein Von Frey Aesthesiometer; Revised Version).

During the test, the patients were asked to state which type of sensation they perceived after the elicited stimulus at each point of the surgical site; if a normal cutaneous sensation was documented, the examination was considered normal and complete. If the patient did not respond to the stimulus, the next largest monofilament was chosen, and the process was repeated with increasing sizes of monofilaments, up to the 4.31 filament. The lack of a response to the large filaments indicated a diminished light touch sensitivity that could be considered hypoesthesia (14). A painful first touch stimulus was recorded as allodynia (14). Hyperesthesia was defined as an elevated response to stimuli that was previously recognized as normal; in cases of dysesthesia, a normal touch stimulus was described as an unpleasant sensation (14).

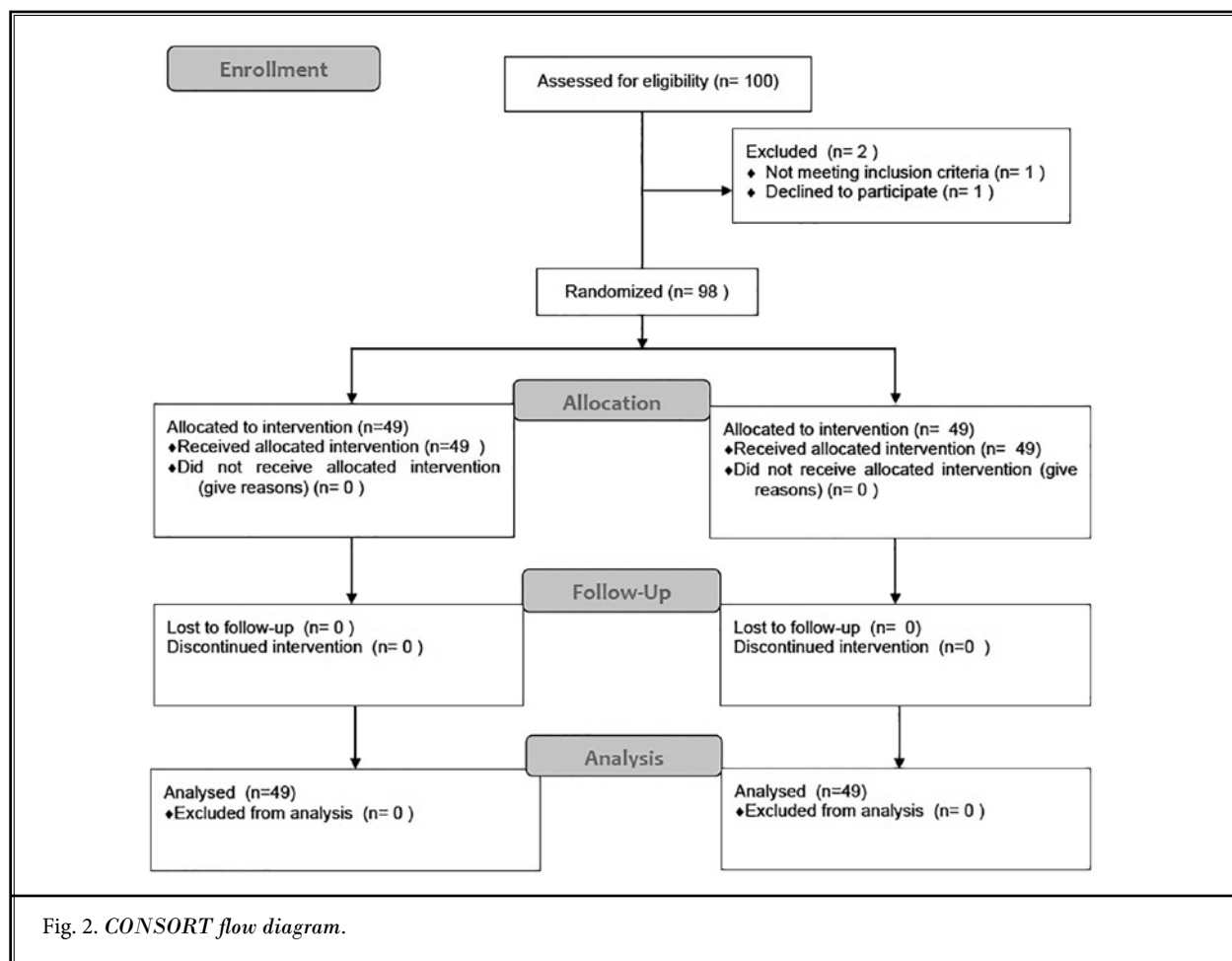
The sensory dysfunction assessment (Lindblom test) was performed using Rolltemp II (Somedic, Hörby, Sweden). Two rollers on handles were used: one roller was warm (40°C), and the other roller was cold (25°C). Before testing the skin around the surgical wound, the cold and warm rollers were rolled on opposite sides of the wound, and the patients were queried as to which way they sensed these stimuli. The skin surrounding

the surgical wound was tested in the same manner, and subsequently the patients reported the corresponding sensation. Pain evoked by the moderate cold or warmth of these rollers indicated allodynia. An increased response to stimuli that were previously recognized as normal was recorded as hyperesthesia, whereas dysesthesia was defined as the patients indicating that these moderate cold or warmth stimuli elicited an unpleasant abnormal sensation (14). During the posthospital follow-up and after the von Frey hair test and the Lindblom test, a dermatographic pen was used to outline the areas of neuropathic disorder on the patient's skin; these regions were photographed with a digital camera (reference of 5 cm). The camera was placed 50 inches from the patient's skin. The AUTOCAD software package (AUTOCAD, Autodesk, Inc., San Rafael, USA) for parametric design was used to calculate the size (in cm²) of these areas. Pregabalin (mg per day) and opioid requirements (equianalgesic mg of morphine per day) were also recorded. An evaluation of the surgical wound was performed at the same time and was based on the judgment of the blinded surgeons.

Statistical Analyses

The sample size calculation was based on a 1:1 allocation and was estimated to compare proportions of patients with NRS-11 scores ≥ 4 as the primary outcome. A total of 42 patients would be needed in each group to detect a difference of 30% (15) in proportions with a power of 80% and alpha 0.05 (2-sided); we aimed to recruit 50 patients for each group to account for possible dropouts.

Descriptive statistics (mean and standard deviation for numeric variables, frequencies for categorical variables) were calculated for all variables in the study. The chi-square test or the Fisher exact test were used to test categorical variables. Continuous variables were tested for normality with the Shapiro-Wilk test, and the mean values were analyzed using the independent samples t-test or the Wilcoxon rank-sum test when appropriate. A *P* value < 0.05 was considered statistically significant. To analyze the primary outcome, a single NRS-11 cutoff score of 4 for pain was used to create a dichotomous variable (PPP: yes/no); the chi-square tests were used to examine the proportion of patients with PPP between groups, and 95% confidential intervals (CIs) were reported. Repeated measures analysis of variance (RM-ANOVA) with group (experimental vs. control) as the between-patient factor, and time (before



the patients were discharged from the hospital and at 3 months after surgery) as the within-patient factor was used to assess the presence of significant differences in the areas of hyperesthesia, allodynia, and dysesthesia disturbances between groups. Statistical analyses were performed by using STATA 14 software (StataCorp, College Station, TX).

RESULTS

A total of 100 consecutive patients were enrolled and randomized. Of these patients, 49 patients were randomly selected to receive a USG-ICPB, and the remaining patients received a USG-SCPB. Two patients were excluded because one did not meet the inclusion criteria, and the other patient declined to participate, as shown in Fig. 2 (CONSORT flow diagram). The demographic and other clinical characteristics of the patients are presented in Table 1. At the time of hospital discharge, the mean score for pain on movement was

significantly different between the experimental and control groups (4.3 ± 1.5 vs. 5.1 ± 1.9 ; $P = 0.028$), whereas the score for pain at rest was not different between groups (3.0 ± 1.4 vs. 3.0 ± 2.1 ; $P = 0.957$).

As reported in Fig. 3, the proportions of patients with PPP on movement (NRS-11 ≥ 4) 3 months after CEA were significantly different between the experimental and control groups (33%, 95% CI, 20%-47% vs. 71%, 95% CI, 57%-83%; $P < 0.001$), whereas there were no differences between groups in terms of the proportions of patients with PPP at rest (31%, 95% CI, 18%-45% vs. 49%, 95% CI, 34%-64%; $P = 0.063$).

None of the patients in either group required supplemental opioids or LA during surgery. None of the patients needed GA in either group, and the blocks were generally well tolerated by the patients. The patients had sensory blockades from the C3 to C4 dermatomes, with the same proportion of positive and negative anesthetic responses to the sensory tests. None of the

patients in either group experienced adverse effects. Hoarseness, cough, and difficulty swallowing was reported in 15 patients in the control group (38.7%) and in 14 patients in the experimental group (28.6%). Wound healing was optimal in all patients. The sensory blockade was longer in the experimental group than in the control group (6.4 ± 3.2 vs. 4.6 ± 1.3 hours).

Three months after surgery, the proportions of patients with NPDs were not different between the experimental and control groups (hyperesthesia: 47% vs. 55%; $P = 0.419$; allodynia: 49% vs. 41%; $P = 0.417$; dysesthesia: 49% vs. 63%;

$P = 0.154$), whereas the sizes of the areas of interest (cm^2) were significantly different (Fig. 4). Figure 4 shows that the mean sizes of the areas affected by NPDs (at discharge and 3 months after surgery) were always lower in the experimental group than in the control group. RM-ANOVA showed that ICPB had a significant effect on the size of the hyperesthesia area ($F_{1;96} = 184.4$; $P < 0.001$), allodynia area ($F_{1;96} = 52.3$; $P < 0.001$), and dysesthesia area ($F_{1;96} = 94.0$; $P < 0.001$).

The within analysis demonstrated the main effect of time and the presence of a time by treatment interaction for the areas affected by NPDs ($P < 0.001$). Although allodynia and dysesthesia persisted in the 2 groups over time, hyperesthesia decreased in both groups over time ($F_{\text{time};96} = 130.4$; $P < 0.001$) and disappeared in the experimental group after 3 months.

Patients systematically required 2,000 mg acetaminophen per day to control pain during the postoperative follow-up. Three months after the surgery, 68 patients in the control group (29%) needed opioids to control pain; 9 mg per os per day of equianalgesic morphine was administered in this group. In the experimental group, the total opioid consumption recorded in equianalgesic mg of morphine was 3 mg per os per day. No patients requested tramadol for postoperative pain. In the control group, 150 mg per day of pregabalin was administered to the patients to treat persistent NPDs, whereas patients in the experimental group requested 75 mg per day of pregabalin to control these disturbances.

Table 1. Demographic and other baseline characteristics.

Characteristics	Groups	
	Experimental n = 49	Control n = 49
Gender (M/F)	26/23	19/30
Age, years	72 ± 10.7	72.9 ± 9.2
BMI, kg/m^2	26.8 ± 3.3	28.2 ± 4.1
ASA (n (%))		
II	16 (33)	19 (39)
III	33 (64)	30 (61)
Systolic blood pressure	154.3 ± 17.6	153.1 ± 16.6
Diastolic blood pressure	81.7 ± 7.3	80.4 ± 8.1
Heart rate	73.5 ± 12.3	72.7 ± 16.7
Oxygen arterial saturation (SaO_2 , %)	94.2 ± 3.1	94.1 ± 3.3
Time to perform experimental procedure (minutes)	11.6 ± 4.7	12.6 ± 4.1
Time to perform standard procedure (minutes)	12.0 ± 5.2	11.8 ± 5.9

Plus-minus values are means and standard deviations

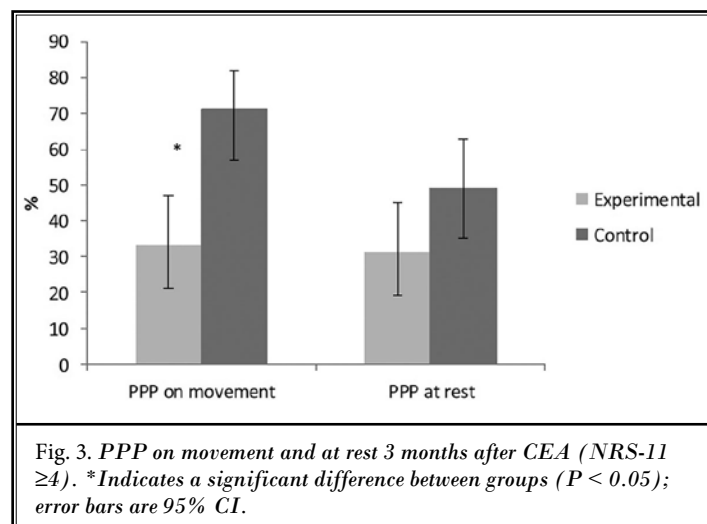


Fig. 3. PPP on movement and at rest 3 months after CEA (NRS-11 ≥ 4). *Indicates a significant difference between groups ($P < 0.05$); error bars are 95% CI.

DISCUSSION

The objective of this study was to investigate whether USG-ICPBs could provide better control for PPP than USG-SCPBs. Our findings revealed that after carotid surgery, the proportions of patients with PPP were different between the group treated with ICPBs and the group treated with SCPBs, (33% vs. 71% for PPP on movement, and 31% vs. 49% for PPP at rest). The USG-ICPB provided a longer sensory blockade and longer-lasting analgesia during the early postoperative period than the USG-SCPB.

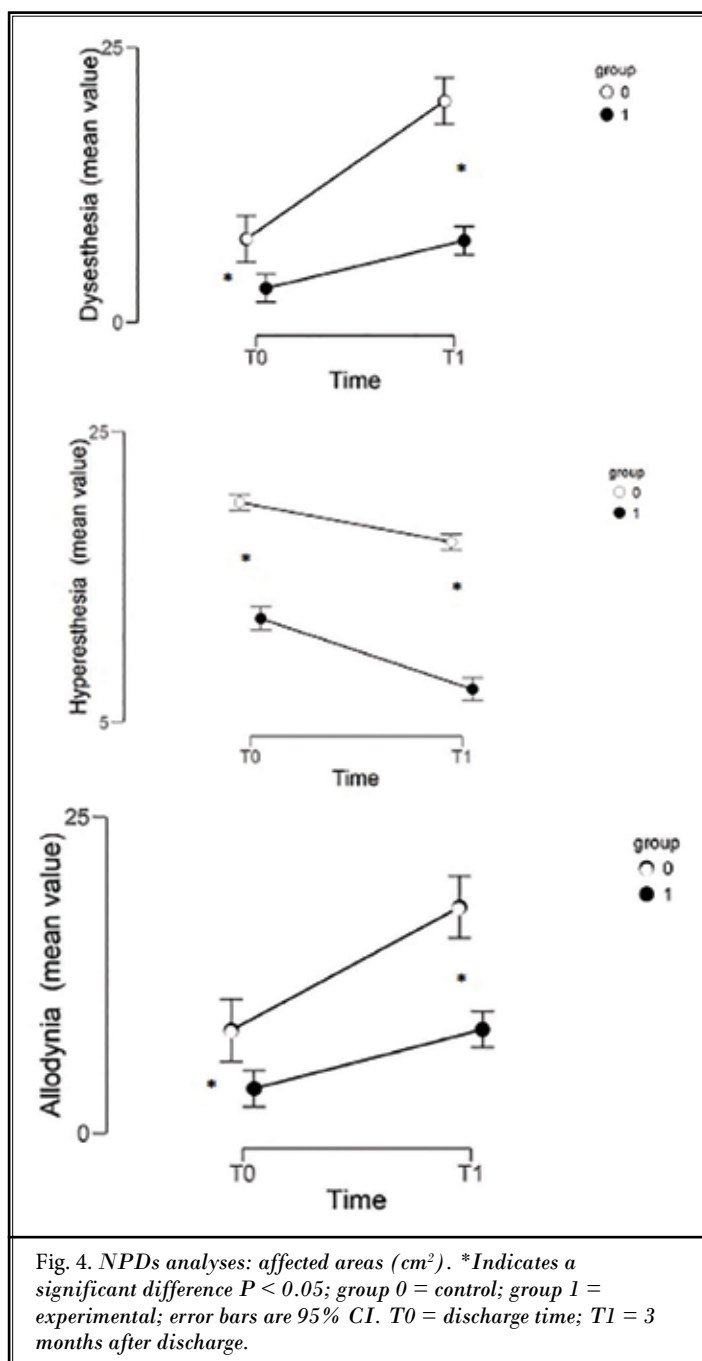
The deep fasciae of the neck have been a controversial subject since its first description by Burns in 1824. The fasciae of the neck are often involved in acute and chronic neck pain (16), especially after vascular surgery. Various techniques for ICPB have been evaluated; there is still controversy over the identification and description of a clear injection point for LA, probably because of the anatomic variations in the cervical fascial layers that can significantly influence the effects of each ICPB method.

In this study, we presented an alternative posterior approach for the ICPB; our anesthetic target is the deep lamina of the deep fascia of the neck. We speculated that our point of injection could promote LA spread into deep tissues through the prevertebral fascia, thereby obtaining deep CPB effects, which is in accordance with Pandit's hypothesis (17). We are confident that our injection site could be considered a deep topographic representation of "Erb's point" (18). In this research, the injection needle for the USG-ICPB was inserted into the myofascial space enclosed by the PSM and MSM, under the SCM muscles, and involved with the prevertebral fascia of the neck. The LA could reach the posterior cervical space (between the SCM muscle and prevertebral fascia) at the C3 level, targeting both the superficial branches of the cervical plexus, and presumably the sensory branches of the cervical plexus that supply the SCM muscle.

Acetaminophen (2,000 mg) was systematically administered to control postoperative pain in the 2 groups, but patients in the control group needed higher doses of codeine and pregabalin. This finding supports the theory that longer-lasting analgesia from ICPBs could mitigate the development of "pain vulnerability" (19,20), which is responsible for postoperative pain syndromes with NPDs.

Although NPDs were described for both groups, the sizes of the affected areas were smaller for the patients in the experimental group. In particular, USG-ICPBs appear to be more protective for hyperesthesia than USG-SPCPBs. The ICPB could also mitigate the development of allodynia and dysesthesia.

A limitation of this study is that we assessed NPDs for only 3 months using the von Frey hair



test and the Lindblom test without additional instrumental techniques. Additionally, there are many risk factors for NPDs after CEA (1). For this reason, another limitation of this research is that we neglected to consider the relationship between the choice of anesthetic block and the presence of these risk factors. After performing the USG-ICPB, our surgeons identified and evaluated the anatomic tissues that were less affected and less swollen; this

assessment could be essential for respecting the neural network of the neck. Finally, further studies are needed to describe a standard point of injection for ICPBs, and to understand which CPB variant could represent the right choice to obtain long-lasting analgesia to inhibit "pain vulnerability" and prevent the development of PPP with NPDs.

CONCLUSIONS

We believe that our ICPB variation should be considered a viable alternative to other approaches performed for CEA. The USG-ICPB provided good management of PPP and mitigated NPDs during the early postsurgery period.

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