CLINICAL STUDY COVER PAGE

Official Study Title: Can Ultrasound-Guided Bilateral Cervical Plexus Block Combined With Translaryngeal Block For Tracheostomy Be An Alternative To General Anesthesia?

Namık Kemal University ethics committee with the protocol number: 2020.240.10.08

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Background Information

Study eligibility required that patients were 18-65 years of age, with American Society of Anesthesiology (ASA) classification I-III and scheduled for elective or emergency tracheostomy. Exclusion criteria were inability to cooperate, dementia, allergy to local anesthetics and opioids, regular daily opioid requirements, abuse of alcohol or medication, local infection at the site of injection or systemic infection, and pregnancy.

After written informed consent, 29 subjects were enrolled at Namık Kemal University Hospital, Turkey.

After a computer-generated randomization list with a 1:1 intergroup ratio, ensuring equal distribution in the two groups, 30 opaque sealed envelopes numbered 1–30 were prepared. The patients were randomly divided into the Group with bilateral CPB with 15 ml 0.5% bupivacaine or the patients with translaryngeal block with 5 ml 2% lidocaine in addition to bilateral CPB.

Following inclusion, two research assistants, with no further involvement in the study, prepared 15mL syringes and 5 ml syringes according to the envelope's specifications. The syringes were marked with the patient's randomization number. All other investigators, staff,

and patients were blinded to group allocations. Before surgery, the patients were transferred to the specified block room area monitored with 3-lead electrocardiography, pulse oximetry, and non-invasive blood pressure. All patients had two intravenous cannula lines, and then bilateral CPB block procedures were performed in awake non-sedated patients.

All patients fasted for at least six hours before the surgery. Multichannel physiologic monitors were applied, and baseline hemodynamic variables (heart rate, systolic BP, diastolic BP, mean arterial pressure, SpO2, and ECG) were recorded. An intravenous line was established, and each patient received lactated Ringer's infusion. All patients were premedicated with midazolam 0,03 mg/kg just before the incision. All patients were kept monitored in the block room for at least 15 minutes after the block.

No additional sedation or additional local anesthetic was applied to the incision area during the operation. In the postoperative period, no additional analgesia was required in both the recovery unit and clinical follow-ups.

Trial Purpose

This study aims to assess the procedural comfort of the translaryngeal block combined with the cervical plexus block. According to our hypothesis, we thought that we would provide clinically significant comfort in tracheostomy cases with a cervical plexus block combined with a translaryngeal block.

We have very well experienced in tracheostomy cases that the superficial cervical block provides sufficient anesthesia for the incision as it consists of sensitive branches of the cervical plexus. However, it does not affect the cough and the gag reflex in the patient while placing the tracheostomy cannula. Since otolaryngologists are often cautious about the incision in the trachea, inserting the cannula does not happen all at once. This almost always affects the comfort of the operation negatively.

In tracheostomy patients, moving away from the general anesthesia option increases airway safety, and avoiding the local anesthesia option in the incision area increases patient comfort.

Selection of Subjects

Forty-two subjects were screened for eligibility from June 2020 to December 2020. Eleven patients did not meet inclusion criteria and two patients declined to participate. After informed consent 29 patients were enrolled and randomized. There were no differences in subject characteristics between groups.