Cover page

# Ketamine versus dexmedetomidine as an adjuvant in ultrasound-guided supraclavicular brachial plexus block

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# Ketamine versus dexmedetomidine as an adjuvant in ultrasound-guided supraclavicular brachial plexus block

**Background**: peripheral nerve block has gained increased popularity due to less postoperative pain, reduced need for post-operative analgesic drugs, reduction of PACU time, and improved patient satisfaction.

**Objectives**: The aim of the study was to compare the effect of ketamine and dexmedetomidine as additives to bupivacaine on onset and duration of the block, post-operative VAS, and analgesic consumption, after ultrasound guided supraclavicular nerve block.

## Study Design

**Study type:** interventional

**Actual enrollment:** 75 patients

**Allocation:** randomized

**Intervention model:** parallel assignment

**Intervention model description:** The patients were randomly classified into three groups using computer generated table numbers each contain (25) patient.

***Ketamine group (group K):*** 20 ml 0.5%bupivacaine and 20 ml 0.9% normal saline plus 1 mg\kg ketamine,

***Dexmedetomidine group (group D):*** 20 ml 0.5% bupivacaine and 20 ml 0.9% normal saline plus 1μg\kg dexmedetomidine

***Control group (group C):*** 20 ml 0.5%bupivacaine and 20 ml 0.9% normal saline.

**Masking:** double blind (participant and investigator)

**Masking description:** The investigator's study is a prospective, randomized, double blind

**Actual study start date: April 2**1, 2019

**Primary study completion date February**. 21, 2020

**Site of study: El-Minia university hospital**

**Eligibility criteria:**

Age: 18-75 years

**Sex:** All

**ASA Physical Status:** I–II

**Inclusion Criteria:** The study included 75 patients undergoing elective and emergency forearm and hand surgeries under ultrasound guided supraclavicular brachial plexus block.

**Exclusion Criteria:**

Patient with bleeding disorders
Damage or disease of the brachial plexus
Uncontrolled diabetes mellitus
Patients with neuromuscular diseases
Patients with local skin infection at the site of injection
Patients with known hypersensitivity to studied drugs

**Outcome Measure:**

***Primary outcome:***

1. Evaluate onset and duration of sensory and motor block

***secondary outcome:***

1. Assess postoperative pain score
2. time to first analgesic request
3. total analgesic requirements
4. sedation score secondarily

**Preparation of the studied medications:** The patients were randomly classified into three groups using computer generated table numbers each contain (25) patient. Ketamine group (group K): 20 ml 0.5%bupivacaine and 20 ml 0.9% normal saline plus 1 mg\kg ketamine, Dexmedetomidine group (group D) 20 ml 0.5% bupivacaine and 20 ml 0.9% normal saline plus 1µg\kg dexmedetomidine *(precedex® Hospira,Inc.,Lake Forest USA*).
Control group (group C) 20 ml 0.5%bupivacaine and 20 ml 0.9% normal saline. All medications were prepared in similar sterile coated bottles by the supervisor who didn't included in anesthetic or operative team, 75 bottles numbered from 1 to 75 were prepared . After completion of the study, the key was opened by the supervisor

**Block technique**: On patient's arrival to the operating room, a 20 G intravenous cannula was inserted in a peripheral vein of unaffected limb and standard monitoring commenced as noninvasive blood pressure (NIBP), (ECG), and Oxygen saturation (Spo2) *(UltraviewSL2700,Spacelaps,USA*), all equipment and drugs for general anesthesia and resuscitation were prepared, the ultrasound device *(Sonosite, Nanomax ,USA* ) lubricating gel, 21guge 50 mm length, short bevel, insulated stimulating needle (*Laboratoires pharmaceutiques, Vygon,France*). Patient lie supine with head turned to the other side and ipsilateral arm adducted gently with flexed elbow. Under complete aseptic condition , the identified

area and the ultrasound probe was prepared with anti-septic (*Povidone-Iodine 10%)* solution and the skin infiltrated with 1-2 ml of lidocaine 2% solution subcutaneously, the brachial plexus was visualized by placing the transducer in the sagittal plane in the supraclavicular fossa behind the middle-third of the clavicle. Two distinct appearances of the supraclavicular brachial plexus was seen, it either appeared as a grape like cluster of 5 to 6 hypoechoic circles, located lateral and superior to the subclavian artery between the anterior and middle scalene muscles at the lower cervical region or as 3 hypoechoic circles with hyperechoic outer rings , the predetermined volume of 40 mL of the study drug solution was administered around the brachial plexus after negative aspiration to avoid accidental intravascular injection, expansion of the brachial plexus sheath was considered as an indication of correct needle placement, multiple injections was used to deposit the total amount of the study drugs, skin massage for about 3 minutes was done to facilitate drug distribution.

**Parameters assessed**:

-*Hemodynamic data*: The hemodynamic variables as HR, MAP and Spo2 were assessed. The parameters were recorded preoperatively just before the block as a baseline value, at 5,10,20,30,60, 90 minutes during the operative time and at 1,2,4,6,9 and 12 hours after the end of operation.

-*Sensory block* was assessed by pin prick test using a 3-point scale [16] Grade 0 = normal sensation, Grade 1 = loss of sensation of pin prick (analgesia), and Grade 2 = loss of sensation of touch (anesthesia).

- *Motor block* was determined by thumb abduction (radial nerve), thumb adduction (ulnar nerve), thumb opposition (median nerve), and flexion of elbow (musculocutaneous nerve) according to the modified Bromage 3 point scale :Grade 0: Normal motor function with full flexion and extension of elbow, wrist, and fingers. Grade 1: Decreased motor strength with ability to move the fingers only. Grade 2: Complete motor block with inability to move the fingers [16].

- *Onset time* for sensory and motor block: the time interval between the end of local anesthetic administration and complete sensory and motor block by min.

- *Sensory block duration*: the time interval between the complete sensory block and complete resolution of anesthesia on all the nerves (score 0)

-*Motor block duration*: the time interval from complete motor block to complete recovery of motor function of hand and forearm (grade 0) by hours.

-*Visual analogue scale* (VAS): postoperative, the patients were familiarized with a 10-point visual analog scale (VAS) ranged from 0 = no pain, up to 10 = the worse imaginable pain. VAS was measured at 1, 2, 3, 6, 9, 12 hour. When it is equals or >4 we give IM diclofenac sodium (75 mg amp) *(voltaren , Novartis Pharmaceuticals Corporation, Switzerland*).

-*Time of first analgesic request:* The time passed from supraclavicular brachial plexus block to the patient's first request for analgesic medication by hours

-*Total analgesic requirements* in 24 hours (diclofenac consumption)

-*Sedation score*: was assessed according to the modified Ramsay Sedation Scale 1987(RSS) from 1-6 as follows: 1 = anxious, agitated, restless; 2 = cooperative, oriented, tranquil; 3 = responds to commands only; 4 = brisk response to light glabeller tap or loud noise; 5 = sluggish response to light glabellar tap or loud noise; 6 = no response [17].

-*Adverse effects*: any adverse effects such as hypotension (i.e. 20% decrease relative to baseline), bradycardia (HR <60 beats/min), nausea, vomiting, hypoxemia (SpO2 <90%),local hematoma, hemothorax ,pneumothorax ,recurrent laryngeal nerve block ,intravascular injection ,Horner's syndrome and signs of local anesthetic toxicity were recorded during the operation and for 12 hours postoperative.

**Statistical analysis**

Results were calculated as mean ± standard deviation (SD) and Mann-Whitney test for quantitative variables, categorical variables were calculated using Chi- square test or Fisher's exact test Statistical significance was determined when $P \leq 0.05$. All statistical analysis was done using SPSS software (version 13.0, SPSS Inc., Chicago, Illinois). To determine the sample size, we used sample size calculator for comparing two independent means [18]. It was calculated regarding the onset of analgesia using local anesthetics for supraclavicular nerve block, which was determined in previous studies [19]. Assuming a pooled standard deviation of 12 minutes and expected mean difference of 10 minutes between test and reference groups, the study would require a sample size of 23 patients for each group, with a power of 80% and two sided level of significance of 5%, at a confidence interval (CI) of 95%. Therefore, a

sample of 25 patients in each group could be enough to achieve the targeted onset of analgesia.