Is Pericapsular nerve group (PENG) block superior to interscalene nerve block regarding motor power affection in shoulder scope surgeries? A randomised comparative study.

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Study Title

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Introduction:

Advances in arthroscopic techniques have led to more reliance on shoulder arthroscope for several surgeries instead of using more conventional open techniques (1). Shoulder scope is used either for diagnostic procedures or interventional ones; most commonly rotator cuff muscles repair, labrum repair or repair for recurrent shoulder dislocation (2).

As shoulder scope procedures are usually done as day case surgeries, patients are often concerned about postoperative pain which is usually more intense during the first few hours after the procedure and mainly due to stretch of

the capsule by irrigation in addition to the manipulation of intracapsular structures (3,4). It has been established that multimodal analgesia yields best pain control as different pain pathways are targeted with different drugs and techniques with regional anesthesia being one of the most prominent modalities (5). For a long time interscalene block (ISB) has been used for shoulder scope surgeries. Although it is an effective block, the procedure is not devoid of complications which include phrenic nerve affection and diaphragmatic paralysis which could affect respiration. Also, dural spread and brachial plexus injury are among the recorded complications (6,7). Even when these complications do not occur, interscalene block affects motor power of the arm while PENG block spares motor power affection which is a key factor regarding that shoulder scopes are usually day case surgeries.

Interscalene block produces an intense motor block of the upper limb muscles which may extend to the hand muscles leading to the discomfort of patients and predisposing them to injuries (8), patients are always advised to carry the numb limb in an immobilizer and to protect it till complete sensory and motor function returns.

Therefore, alternatives for interscalene block as suprascapular nerve blocks or supraclavicular nerve blocks are being researched. Pericapsular nerve group (PENG) block is one of the novel techniques that are being studied currently, its main advantage over interscalene is that the target is the peripheral nerve endings around the joint capsule rather than tackling large nerves as the brachial plexus trunks (9). It has been first introduced in hip arthroplasty and other hip surgeries and showed promising results; thus, it is being applied to shoulder scope surgeries (10).

Papers have been published investigating the efficacy of PENG block in hip surgery with different control and comparison groups, as was done by Mosaffa F et al when comparing PENG with fascia iliaca compartment block (11). Other studies were done on PENG block efficacy in shoulder surgery, but with comparison against suprascapular nerve block, and with the main focus on postoperative pain relief as a primary outcome rather than recovery of motor power. To our knowledge, this is the first study to compare between the effect of PENG block and interscalene block on muscle power of the hand in shoulder arthroscopic surgery.

Aim of the work

The aim of the study is to compare the effect of PENG block and interscalene block on the motor power of the hand and time to full recovery of motor affection if any.

Objectives:

- To assess effectiveness of PENG block in recovery of hand motor power compared with ISB
- To compare between PENG and ISB in controlling postoperative pain
- To assess effectiveness of PENG block in reducing postoperative opioid consumption compared with ISB

Hypothesis

We hypothesize that PENG block will be superior to interscalene nerve block regarding motor power sparing.

Ethical Considerations

This study will be conducted after taking approval of the research ethical committee. Written informed consent will be obtained from study participants or their legally authorized representative.

Methodology

I. Study design

Randomised comparative single blinded superiority study.

II. Study setting and location

This study will be conducted at the theatre for orthopedic surgeries at The Cairo University Teaching Hospital.

III. Study population

Patients scheduled for arthroscopic shoulder surgery

IV. Eligibility Criteria

1. Inclusion criteria

- Adult patients (age 22-60) scheduled for arthroscopic shoulder surgery under general anesthesia
- Both genders
- ASA grade I-II
- BMI less than 35
- Duration of surgery 90-120 minutes

2. Exclusion criteria

- ASA grade III-IV
- Allergy to local anesthetics
- Coagulation disorder (INR >1.2, Platelets <100,000), or recent intake of clopidogrel or warfarin within 1 week.
- Active infection at site of injection

V. Study Procedures

1. Randomisation

This is a single centre randomised comparative trial. Patients undergoing arthroscopic shoulder surgery will be randomised to receive either PENG block, which is the intervention group, or to receive interscalene block.

Randomisation will be done via computer generated random numbers which will be enclosed in envelopes with 60 envelopes in total, 30 for each group. This is a single blinded study so an anesthesiologist who will not partake in this study will open the envelopes and proceed with the allocated block. After the procedure, the anesthesiologist who will assess motor power recovery and collect postoperative data will also be blinded to the type of block given. Therefore, to reduce bias only the anesthesiologist and main researchers will be aware of the allocation, while the outcome data collector will be blinded.

2. Study Protocol

Patients in this study will be randomly assigned to one of two groups; Group A will receive PENG block and Group B will receive interscalene block. All patients will be evaluated preoperatively by routine lab investigations (full blood picture, serum electrolytes, liver and kidney function tests and coagulation profile).

Patients will be educated concerning the nature of the procedure and its possible complications, and all patients will sign a written informed consent. Short term fasting will be encouraged (6 hours for solid food, 2 hours for clear fluids). A 3rd generation cephalosporin will be given 30 min prior to the procedure as prophylaxis. Before admittance to the operation

theatre, a 22G cannula will be inserted and anxiolysis will be achieved by giving the patients midazolam 2 mg IV.

Upon arrival to the operation room, all patients will receive standard monitoring (Pulse oximeter, ECG, NIBP, Capnography), and baseline hemodynamic measurements of heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial blood pressure (MAP) will be recorded. Also baseline muscle power of the hand on the same side of surgery will be measured using a digital dynamometer (Handeful Digital Hand Dynamometer, Handeful, CA, United States). The dynamometer we are using is a digital one that measures grip strength in kilograms.

Group P (PENG Block group):

Patients in this group will receive PENG block prior to induction of general anesthesia. Patient will be placed in supine position with arm abducted and externally rotated. Skin will be disinfected then under ultrasonic guidance (ACUSON X300™ ultrasound system, Siemens Medical Solutions, Inc, Germany) a high frequency linear ultrasound probe (12MHz) will be applied longitudinally between the head of humerus and coracoid process then local infiltration will be done using 29 G needle to apply 3 mL lidocaine 2%. After identification of deltoid muscle and subscapularis muscle tendon which should be immediately superficial to humeral head, a 22-gauge needle (SonoPlex® STIM, PAJUNK® Medical System L.P., Germany) will be advanced to pierce the deltoid and target the tip to be just touching the subscapularis tendon. A test dose of 3 ml saline solution will be injected to visualise the separation of deltoid from subscapularis and confirm and the

needle is in the correct position. Afterwards 15 ml of 0.25% bupivacaine will be injected to complete the block. A wait time of 30 minutes will be allowed before induction of general anesthesia to ensure the full activation of the block.

Group I (Interscalene block):

Patients in this group will also receive ISB prior to general anesthesia. With patient placed in supine position and head facing away from the side being blocked, the skin is disinfected first then the linear ultrasound probe is placed transversely on the neck to identify the carotid artery. Then the transducer is moved slightly laterally until middle and anterior scalene muscles are identified with the brachial plexus between them then local infiltration will be done using 29 G needle to apply 3 mL lidocaine 2%. A 22-gauge needle will be introduced in plane in a lateral-medial direction aiming towards the space between the roots. After a 3 ml saline injection for confirmation of proper position, 15 ml of 0.25% bupivacaine will be injected with advancement of the needle as the roots are displaced by the injectate. Adequate injection will be confirmed by visualizing the roots being surrounded by the local anesthesia infiltrate.

Patients receiving either block will wait 30 minutes before induction of general anesthesia. Interscalene block will be tested using pin prick test on shoulder and upper arm area, by loss of shoulder abduction, and finally by passively moving the arm to check for loss of previously present pain on movement. PENG block will be tested using pin prick test and loss of pain on passive movement as well. A block not fulfilling these examinations will be

deemed unsuccessful, and the patients will be given additional opioids in the form of morphine 5 mg IV with induction of general anesthesia. These patients will be excluded from the study. Before induction of general anesthesia another dynamometer measurement will be recorded.

In both groups patients will receive general anaesthesia using the standard centre preferences; IV induction via propofol 2 mg/kg and fentanyl 1 mic/kg for induction, then atracurium 0.5 mg/kg for intubation followed by 0.1 mg/kg every 20 minutes for maintenance. An additional dose of fentanyl 1 mic/kg will be administered on skin incision.

For maintenance of anaesthesia, isoflurane will be administered at a concentration of 1.2-2%, and the patient will be mechanically ventilated using parameters that will achieve normal end-tidal CO2 (35-45 mmHg) and oxygen saturation (> 95%). To maintain relaxation atracurium will be given as 0.1 mg/kg every 20 minutes.

Intraoperative hemodynamics will be measured at 10 min intervals, both heart rate and blood pressure values (SBP, DBP and MAP) will be recorded. Bradycardia defined as heart rate below 60 beats per minute, and bradycardia will be managed if heart rate drops below 55 bpm by giving atropine 0.04 mg/kg IV bolus to be repeated after 5 minutes if needed. Hypotension also described as SBP below 90 mmHg will be managed by giving ephedrine 5-10 mg IV bolus.

At the end of surgery, patients will be given 1 g acetaminophen IV, and NSAID will be given in the recovery room in the form of ketorolac 30 mg IV.

For recovery, neuromuscular blockade will be reversed using neostigmine 0.04 mg/kg and atropine 0.02 mg/kg, and the patient will be extubated fully awake and when adequately reversed which is clinically assessed as the patient achieves tidal volumes > 5ml/kg.

Patients will be transferred to the post anesthesia care unit (PACU), and same intraoperative hemodynamics will be measured every 10 min through their PACU stay duration. With regards to postoperative management, Visual analog scale (VAS), which is a scale from 0 to 10 where 0 represents no pain at all and 10 represents the most severe pain, will be used to assess pain. VAS assessment will be carried out during the 1st hour at the PACU then at 2, 4, 6, 12, and 24 hours postoperative during day 1, and If VAS is >4, opioids will be administered in the form nalbuphine 5mg IV, and the time to first dose and total number of doses given will be noted not to exceed 60 mg per day. Also, hand grip power will be assessed at the PACU then at 2, 4, 6, 12, and 24 hours postoperatively, and this will be done using the digital dynamometer. The readings will be compared with a measurement of the patient's baseline grip power of the same hand taken before surgery and with readings taken after block administration.

3. Measurement tools

- Hand grip power will be measured using digital dynamometer at these intervals: immediately postoperative at PACU and then at 2, 4, 6, 12, and 24 hours postoperative, and results compared with baseline measurement.

- Time for full recovery of hand grip power.

- Intraoperative hemodynamics in the form of heart rate and mean blood pressure every 10 minutes.
- Postoperative pain will be measured using VAS score at theses intervals: immediately postoperative at PACU and then at 2, 4, 6, 12, and 24 hours postoperative.
- Postoperative hemodynamics in the form of heart rate and mean blood pressure in PACU every 10 minutes until discharge
- Time to first opioid dose
- Total amount of opioid administered.
- Patient satisfaction will be measured at 24 hours postoperative using self reported satisfaction scale (1= very dissatisfied and 5=very satisfied)

VI. Study outcomes

1. Primary outcome

- Time for full recovery of hand power, defined as time from start of block activation till time of achieving grip strength similar to patient's baseline

2. Secondary outcome(s)

- Hand grip power after surgery at PACU, then at 2, 4, 6, 12, and 24 hours.
- Time to first analgesia request
- VAS score after surgery at rest and during movement at PACU then at 2, 4, 6, 12, and 24 hours

- Patient satisfaction score at 24 hours postoperative
- Intraoperative hemodynamics

Statistical Analysis

I. Sample size

Based on a previous study (12) the duration of motor block in patients receiving ISB was 711± 151 min (REF). A minimum sample of 50 patients is needed to detect a 20% reduction in duration of motor block. The study power was set at 90% and alpha error was set at 0.05. Sample size was calculated using the MedCalc Software V14. The number of envelopes will be increased to 60 (30 in each group) to compensate for dropouts.

II. Statistical analysis

Statistical package for social science (SPSS) software, version 26 for Microsoft Windows (SPSS inc., Chicago, IL, USA) will be used for data analysis. Categorical data will be presented as frequency (%) and will be analyzed by the chi square test. Continuous data will be checked for normality using the Shapiro-Wilk test and will be presented as mean (standard deviation) or median (interquartile range) as appropriate. Continuous data will be analyzed using unpaired the t test or the Mann Whitney test according to normality of the data. Repeated measures will be analyzed using the analysis of variance (ANOVA) for repeated measures with post-hoc pairwise comparisons using the Boneferroni tests. A P-value less than 0.05 will be considered statistically significant.

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