# Effectiveness of additional thoracic paravertebral block in improving anesthetic effects of regional anesthesia for proximal humeral fracture surgery in elderly patients

## Study Protocol

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**Objective**

To investigate whether supplementary T2 thoracic paravertebral block (TPVB) could improve the anesthetic effect of cervical-brachial plexus block based regional block.

**Background**

Proximal humeral fractures (PHF) is a common disease occurring in the elderly population over 60 years. The deltopectoral approach is commonly used in the PHF surgery. The innervation of PHF surgical area is complicated and unclear. Ultrasound-guided brachial plexus combined with cervical plexus block is probably inadequate for the anesthesia of proximal humeral surgery. Missing blockade of T1-T2 nerves may be the reason. The primary aim of this trial is to investigate the effectiveness of additional T2 thoracic paravertebral block (TPVB) in improving the anesthetic effects of regional anesthesia for elderly patients in proximal humeral fracture surgery.

**Methods**

We have designed a two-armed, parallel, randomized controlled trial (RCT) to observe the anesthetic effects of ultrasound-guided brachial and cervical plexus block with or without additional T2 TPVB in terms of the following outcomes: success rate, sensory block and safety. The elderly patients aged 65 or older, referred for anterior approach proximal humeral fracture surgery, will be enrolled. Each participant will be randomly assigned 1:1 to receive IC block (combined interscalene brachial plexus with superficial cervical plexus block) or ICTP block (combined thoracic paravertebral block with IC block). The primary outcome is the success rate of surgical anesthesia. The secondary outcomes are as follows: sensory block at surgical area, proportion of participants who need supplementary anesthesia (intravenous remifentanil or conversion to general anesthesia), cumulative doses of intraoperative vasoactive medications and adverse events. The necessary sample size is estimated to be 80.

**Randomization and blinding**

Random allocation will be performed by a researcher (HZ) before the trial using a randomization sequence. The allocation concealment strategy is achieved with sequentially numbered, opaque, sealed envelopes to conceal the sequence until the intervention is assigned. The envelopes will be opened sequentially before the nerve block is performed. Participants will be randomly assigned in a 1:1 ratio to receive IC block or ICTP block. As the nerve block intervention cannot be blinded from participants and staff implementing the intervention, only the outcome assessor and data statistician will be kept blinded to the randomized allocation and intervention. The envelope will be resealed after confirming the allocation.

**Interventions**

All the participants will undergo preoperative fasting for 8 hours and water deprivation for 2 hours. After placement of standard ASA monitors, intravenous access for fluid infusion will be established in the forearm. No sedatives or analgesic medication will be given prior to the block. The participant will receive ultrasound-guided IC block or ICTP block according to the allocation. It will be performed following standard skin disinfection with a SonoSite S-Nerve$^{TM}$ ultrasound machine (Bothell, WA, USA). The entire nerve block procedure of all the participants will be performed by the same anesthesiologist, who is skilled in performing ultrasound-guided regional anesthesia.

In the IC group, the procedure will be performed as followed.

The participant will be placed in the lateral decubitus position with the operative side upwards. A linear array transducer (6-13 MHz) with a sterile cover and a 22G (gauge) block needle will be used. An in-plane approach, advancing the needle along the longitudinal axis of the transducer and visualizing the entire shaft, will be employed. Twenty ml of 0.375% ropivacaine will be injected between superior and middle trunk of brachial plexus at C7 level to reduce phrenic nerve palsy. The transducer will be then moved cephalad until the superficial cervical plexus emerges from the C4 intervertebral foramen. Ten ml of 0.25% ropivacaine will be injected to block the nerve.

In the ICTP group, the procedure will be performed as followed.

On the basis of IC block, T2 TPVB will then be performed. The T2-T3 intervertebral space should be determined by ultrasound image scanning and palpation counting from C7 spinous process. A curve array transducer (2-5 MHz) will be placed at the T2-T3 intercostal level with a slightly oblique scan to visualize the transverse process, costotransverse ligament, internal intercostal membrane and parietal pleura. A 10cm, 22G needle will be introduced into the thoracic paravertebral space beyond the internal intercostal membrane with its tip positioned outside the transverse process. Following negative aspiration of air, blood or cerebrospinal fluid in the needle, 10 ml of 0.25% ropivacaine will be injected into the paravertebral space.

Then the participant will be placed in the supine position. Twenty minutes later, after the sensory block assessed, the participant will be transferred to the operating room and placed in a beach-chair position. One mg midazolam will be given intravenously. Oxygen will be routinely given via a nasal catheter at the flow rate of 3L/min until the end of operation. In case of inadequate analgesia, remifentanil (50μg/ml), propofol (10mg/ml) and laryngeal mask airway (LMA) insertion will be prepared. The anesthetic effects will be assessed since the operation begin: 1) if it is successful, the operation will be continued; 2) if it is failed, the operation will be paused and remifentanil will be given intravenous at the rate of 0.25μg/kg/min. Two minutes later, the operation will be continued if the participant is satisfied with the anesthetic effect. The rate of intravenous remifentanil can be appropriately regulated (no more than 0.25μg/kg/min) in the following operation according to the $P_{ET}CO_2$ and respiratory rate of the participant. On the contrary, the intolerable participant will be induced with propofol (1.5-2 mg/kg) for converting to GA with LMA. The participant who received GA will be transferred to post-anesthesia care unit (PACU) after the operation.

**Statistical analysis plan**

Primary analyses will be undertaken on an intention-to-treat basis, including all participants as randomized, except whose who withdraw consent for the use of their

data. Data will be expressed as mean ± standard deviation (SD), median (interquartile range), or percentage. Continuous variables will be analyzed with a two-sample t test with equal/unequal variance or with a Mann and Whitney U test, if appropriate. A chi-square test or Fisher's exact test will be used for categorical variables. The statistical analysis will be performed using SPSS V.24.0 (IBM Corporation, Armonk, New York, USA) with a significance level of 0.05.