Multimodal nerve injection provides noninferior analgesic efficacy compared with interscalene nerve block after arthroscopic rotator cuff repair

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Abstract

Purpose: This randomized noninferiority trial aimed to evaluate whether combined suprascapular, axillary nerve, and the articular branch of lateral pectoral nerve block (3NB) is noninferior to interscalene nerve block (ISB) for pain control after arthroscopic rotator cuff repair (ASCR). Materials and Methods: Eighty-five patients undergoing ASCR were randomized to either 3NB (n = 43) or ISB (n = 42) group. We used 5 and 15 ml of 0.2% ropivacaine for each nerve in the 3NB and ISB groups, respectively. The primary outcome was the visual analog scale (VAS) pain score at 4 h postoperatively measured assessed on an 11-point scale (ranging from 0 = no pain to 10 = worst pain) that was analyzed using noninferiority testing. The secondary outcome was VAS pain scores in the recovery room and at 8, 12, 24, 36, 48, and 72 h postoperatively. Rebound pain, IV-PCA usage during 48 h, dyspnea, muscle weakness, and satisfaction were evaluated.

Results: Regarding the primary outcome, the mean difference in VAS pain scores between the 3NB (2.5 ± 1.6) and ISB (2.2 ± 2.3) groups at 4 h postoperatively was 0.3, with a 95% confidence interval (CI) of −0.56 to 1.11. The upper limit of 95% CI is lower than the noninferiority margin of 1.3 (p < 0.001). At all other time points, except in the recovery room, 3NB showed noninferior to ISB. Rebound pain, IV-PCA usage during the second 24 h, and muscle weakness were lower in the 3NB group (all p < 0.005). The satisfaction was similar in both groups (p = 0.815). Conclusion: Combined 3NB is noninferior to ISB in terms of pain control after ASCR; and is associated with low levels of rebound pain, IV-PCA usage, and muscle weakness. Level of evidence: Randomized controlled trial, Level I.

Keywords
axillary nerve block, interscalene nerve block, lateral pectoral nerve block, postoperative pain control, rotator cuff repair, suprascapular nerve block

Introduction

Pain control after shoulder surgery is important for postoperative rehabilitation and range of motion recovery and for obtaining favorable functional outcomes.1 The interscalene nerve block (ISB) is commonly used for pain control after shoulder surgery. Although ISB is well-tolerated by most patients,2 some patients may develop phrenic nerve palsy after receiving it.3 The suprascapular nerve block (SSB) can be an alternative to ISB.4 SSB is safe and can...
control postoperative pain without the risk of phrenic nerve palsy. SSBB is also used for pain control in various shoulder problems, such as rotator cuff tears, adhesive capsulitis, glenohumeral joint arthritis, and shoulder rheumatoid arthritis. Many studies have reported favorable outcomes with combined SSBB and axillary nerve block (AXB). Dhir et al. reported better pain control and fewer side effects at 24 h with combined SSBB and AXB than with ISB in an equivalence study on arthroscopic shoulder surgery. Neuts et al. reported in a noninferiority trial that pain scores obtained with combined SSBB and AXB were similar to those obtained with ISB on the first postoperative night and at 24 h postoperatively.

The posterosuperior area of the shoulder joint is innervated by the suprascapular nerve, the anteroinferior area by the axillary nerve, and the anterosuperior area by the articular branch of lateral pectoral nerve (LPN). A recent cadaveric study showed that the articular branch of LPN innervating the shoulder joint was present in 67.4% cases. Nam et al. suggested that surgeons should consider the articular branch of LPN block (LPB) to obtain maximum block coverage for pain control after shoulder surgery.

So far, no clinical study on pain control after shoulder surgery has assessed the blockade of the articular branch of LPN. Although the combined three-nerve block including SSBB, AXB, and LPB may cause discomfort to the patient because the needle requires to be punctured three times, we tried to figure out its analgesic efficacy. The purpose of this prospective, randomized noninferiority trial was to compare ISB with the combined three-nerve block (3NB) including SSBB, AXB, and LPB in patients undergoing arthroscopic rotator cuff repair (ASRCR). We hypothesized that this 3NB is noninferior to ISB for early postoperative pain control after ASRCR.

Materials and methods

Study design

This single-blinded, randomized noninferiority trial was performed at our hospital. The study protocol was reviewed and approved by the Ulsan University Hospital Institutional Review Board of the senior author’s (S.H.K.) institution (IRB No. UUH-2020-08-029). Written informed consent for participation was obtained from all patients included in the study.

Patient selection

The inclusion criteria were (1) persistent symptomatic shoulder pain with small-to-medium full-thickness rotator cuff tear after conservative treatment at least for 6 months, and (2) patients who consented to this study. Between January 2018 and December 2019, we recruited 90 symptomatic patients with small-to-medium full-thickness rotator cuff tears. The rotator cuff tears were diagnosed via preoperative magnetic resonance arthrography. All the patients underwent ASRCR (performed by the senior author, S.H.K.) under general anesthesia. The tear sizes were confirmed during arthroscopic surgery via measurement with a paper ruler. The exclusion criteria were (1) massive rotator cuff tear, (2) patients who had hypersensitivity reactions to local anesthetics, a history of drug abuse or lung-related disease or dysfunction, (3) patients who had a history of fracture around the shoulder, (4) patients who were evaluated an American Society of Anesthesiologists (ASA) physical status above III, or (5) patients who refused to participate this study. Computer-generated randomization was performed by a statistician from our institution who was not involved in this study (allocation ratio, 1:1). The allocation numbers were enclosed in opaque envelopes and opened only before the blockade. ISB was performed by a senior orthopedic surgeon and ISB by a senior anesthesiologist. They had no involvement in any other aspect of the study’s execution. All other medical staff, including nurse and doctors who participated in the surgery, data collector, outcome assessors, and patients were blinded to the allocation.

Nerve block and surgical techniques and postoperative care

All blocks were performed under aseptic technique with no sedation. The local anesthetic used was ropivacaine, which has low toxicity, a rapid onset, and a prolonged anesthetic effect.

ISB was performed before general anesthesia induction using the ultrasound-guided “in-plane” technique with the patient in the supine position by an experienced anesthesiologist. A 21-gauge SonoPlex Stim needle (Pajunk Medical Systems, Tucker, GA) was inserted into the interscalene groove. The tip of the needle was placed inferoposterior to the C6 root, and a single-shot injection of 15 ml of 0.2% ropivacaine was performed.

3NB was performed before general anesthesia induction by the same senior surgeon with >20 years’ experience in shoulder surgery and sports medicine.

For performing SSB, the suprascapular notch was confirmed using a transducer and the suprascapular artery confirmed using color Doppler imaging. A 21-gauge SonoPlex Stim needle tip (Pajunk Medical Systems, Tucker, GA) was placed near the suprascapular nerve under the superior transverse scapular ligament, and 5 ml of 0.2% ropivacaine was injected. For performing AXB, the transducer was placed on the posterior aspect of the humeral head in the sagittal plane, and the posterior circumflex humeral artery was confirmed using color Doppler imaging. A 21-gauge SonoPlex Stim needle tip (Pajunk Medical Systems, Tucker, GA) was placed close to the axillary nerve adjacent to the posterior circumflex humeral artery, and 5 ml of 0.2% ropivacaine was injected. LPB was performed with a blind technique using the method suggested by
Nam et al. After placing the patient in the beach chair position, at the nearest line connecting the coracoid and the clavicle, a needle was inserted 1 cm vertically into the skin at a point 1.5 cm below the clavicle; following this, 5 ml of 0.2% ropivacaine was injected (Figure 2).

To confirm a successful nerve block, we checked if the visual analog scale (VAS) pain score decreased to 0 or 1 at 30 minute after injections. After a successful nerve block, ASRCR was performed under general anesthesia. Subacromial decompression and acromioplasty was performed in all the patients. The rotator cuff was repaired using single-row repair or double-row suture bridge repair techniques according to the tear size using a 5.0-mm Bio-Corkscrew suture anchor (Arthrex, Naples, FL) and a 4.75-mm Bio-SwiveLock (Arthrex, Naples, FL).

All the patients were administered postoperative adjuvant analgesics; they received 325 mg acetaminophen (three times a day) and 37.5 mg tramadol (three times a day). Intravenous patient-controlled analgesia (IV-PCA) was applied as routine protocol in all patients. IV-PCA was provided in a fixed-dose combination as follows: continuous infusion rate, 1 mL/h; total volume, 100 ml (normal saline + fentanyl 700 μg + neupam 40 mg + Nasea [0.6 mg; PT Astellas Pharma Indonesia, Jakarta, Indonesia]); loading dose, 0.5 mL; and lockout time, 15 min. The PCA usage count for 48 h was measured twice, every 24 h. Nausea, vomiting and other complications were recorded. The patient with persistent pain 5 or higher in VAS score even on this pain manage protocol received rescue analgesia with IV pethidine hydrochloride 25 mg.

**Outcome measurements**

All data were prospectively collected by a shoulder fellowship-trained surgeon who did not participate in the ASRCR, and was blinded to the present study. The primary noninferiority outcome was the VAS pain score at 4 h postoperatively. The VAS pain score was assessed on an 11-point scale (ranging from 0 = no pain to 10 = worst pain). After arthroscopic surgery, the affected arm was immobilized using an abduction brace; motion pain was not assessed. The secondary noninferiority outcomes were VAS pain scores at various time points, including the scores in the recovery room and at 8, 12, 24, 36, 48, and 72 h postoperatively. Rebound pain, IV-PCA usage count during 48 h, dyspnea, and muscle weakness as nerve block complications and satisfaction scores were evaluated as the secondary outcomes. Rebound pain was confirmed when the VAS pain score increased between 12 and 24 h postoperatively. The satisfaction score was rated from 0 (unsatisfactory) to 10 (very satisfactory). The time between the nerve block and completion of general anesthesia was analyzed.

**Statistical analysis**

The sample size was calculated to eliminate the inferiority of 3NB to ISB. The noninferiority margin was considered as 1.3 points of the VAS pain score based on a previous study. We have previously reported a standard deviation (SD) of 1.4–1.6 for VAS pain scores at 4 h postoperatively. We selected an SD of 1.5 in the present study. The upper limit of the mean difference in VAS score in the two-sided 95% confidence interval (CI) is equivalent to the upper limit of the one-sided 97.5% CI. Values. The sample size in this study was calculated using an alpha 0.025 for one-sided test, and a power of 90%. A minimum sample size of 31 patients in each group was required at a power of 90%, an alpha level of 0.025 for one-sided test, and a dropout rate of 10%. All primary and secondary endpoints were evaluated according to a noninferiority design. The noninferiority hypothesis (primary endpoint) was evaluated using a one-sided t-test. The null hypothesis for the noninferiority trial was that the difference in VAS pain scores was $\geq 1.3$ points. The alternative hypothesis was that the difference in VAS pain scores was $<1.3$ points. Noninferiority is considered when the lower limit of the 95% CI does not exceed the noninferiority margin, whereas the comparison is considered inconclusive if the lower limit of the 95% CI crosses the noninferiority margin. The secondary endpoints were compared between the groups using a $\chi^2$ test for categorical variables and an independent t-test or Mann–Whitney U test for numeric variables, as appropriate. All statistical analyses were performed using SPSS software version 25.0 (IBM Corp., Armonk, NY, USA). Values of $p < 0.05$ were considered significant.
Results

Of the 90 patients, 5 were excluded because of a history of fracture around the shoulder (n = 2), ASA physical status >III (n = 1), and patient refusal to participate (n = 2). The remaining 85 patients were randomly allocated to either the 3NB (n = 43) or ISB (n = 42) group using a computerized random sequence generator (Figure 1). None of the remained 85 patients failed the nerve block. There were no significant between-group differences in the overall demographic data, including age, sex, body mass index, rotator cuff tear size, repair technique, ASA physical status classification, and preoperative VAS pain score (Table 1).

Primary outcome: VAS pain score at 4 h postoperatively

The mean VAS pain score at 4 h postoperatively, the primary outcome, was $2.5 \pm 1.6$ (95% CI, 2.0–2.9) for the 3NB group and $2.2 \pm 2.3$ (95% CI, 1.5–2.9) for the ISB group. The between-group difference in the mean VAS pain scores at 4 h postoperatively was 0.3 (95% CI, −0.56 to 1.11). The upper limit of the 95% CI (1.11) for the mean difference was less than the prespecified noninferiority margin of 1.3; thus, this result was conclusive for noninferiority at 4 h postoperatively ($p < 0.001$; Figure 3).

Secondary outcomes

Regarding the secondary outcomes, between-group differences in VAS pain scores at the selected time points were evaluated for noninferiority with 95% CI. In the recovery room, the between-group difference was inconclusive for noninferiority. At 8, 12, 24, 36, 48, and 72 h postoperatively, between-group differences in VAS pain scores were conclusive for noninferiority (Figure 3).

The mean VAS pain score in the recovery room was significantly higher in the 3NB group than in the ISB group (3.3 ± 2.6 vs. 2.2 ± 2.4; $p = 0.043$). However, the mean VAS pain scores at 12 and 24 h postoperatively were significantly lower in the 3NB group than in the ISB group (2.9 ± 2.0 vs. 4.2 ± 2.1; $p = 0.004$ and 3.2 ± 1.9 vs. 4.1 ± 2.0; $p = 0.012$, respectively). There were no between-

Table 1. Demographic data.

| Variables                  | 3NB (n = 43) | ISB (n = 42) | p Value |
|----------------------------|--------------|--------------|---------|
| Sex (M:F)                  | 17:26        | 20:22        | 0.452   |
| Dominant hand              | 27           | 26           | 0.933   |
| BMI (kg/m²)                | 24.9 ± 4.1   | 25.8 ± 2.8   | 0.288   |
| Tear size (small:medium)  | 17:26        | 18:24        | 0.756   |
| Repair technique (SR:DRSB) | 20:23        | 22:20        | 0.588   |
| ASA physical status        | 1:38:4       | 2:34:6       | 0.624   |
| classification (I:II:III)  |              |              |         |
| Preoperative VAS pain score| 6.5 ± 1.9    | 6.8 ± 2.3    | 0.204   |

M: male; F: female; BMI: body mass index; SR: single row; DRSB: double-row suture bridge; ASA: American Society of Anesthesiologists; VAS: visual analog scale.
Figure 3. Results of the noninferiority of the analgesic efficacy of 3NB to that of ISB. A between-group difference of <1.3 points in the mean VAS pain scores indicates noninferiority. The blue line designates the noninferiority margin of 1.3. The black opposing arrows designate the 95% confidence interval of the between-group difference in the mean VAS pain scores. 3NB: three-nerve block; ISB: interscalene nerve block.

Figure 4. Comparison of the postoperative VAS pain scores between the groups. VAS: visual analog scale.
group differences in the mean VAS pain scores at 4, 8, 36, 48, and 72 h postoperatively (Figure 4). The time between Rebound pain between 12 and 24 h postoperatively was significantly lower in the 3NB group (9/43, 20.9%) than in the ISB group (18/42, 42.9%; p = 0.03). The IV-PCA usage count during the first 24 h was similar between the two groups (3NB group, 7.0 ± 4.6; ISB group, 6.6 ± 4.5; p = 0.754); however, a significant between-group difference was observed during the second 24 h (3NB group, 8.1 ± 3.6; ISB group, 11.6 ± 4.4; p < 0.001). Dyspnea tended to be less common in the 3NB group (1/43, 2.3%) than in the ISB group (4/42, 9.5%; p = 0.202). Patients with dyspnea received nasal O2 supplementation until dyspnea disappeared. All cases of subjective dyspnea disappeared in both two groups at 4 to 24 hours postoperatively. Additionally, the frequency of muscle weakness was lower in the 3NB group (0/43, 0%) than in the ISB group (5/42, 11.9%; p = 0.026). The satisfaction score was similar between the groups (3NB group, 8.1 ± 2.3; ISB group, 8.3 ± 1.9; p = 0.815) (Table 2). No difference of the time between the nerve block and completion of general anesthesia was found (3NB group, 73.7 ± 14.3 minutes; ISB group, 68.2 ± 10.3, p = 0.150).

Discussion

The following were the major findings of the present study: (1) simultaneous blockade of the suprascapular and axillary nerves and the articular branch of LPN has efficacy noninferior to that of ISB at 4 h postoperatively in patients who undergo ASRCR; (2) ISB can provide better analgesia in the recovery room, whereas 3NB can be more effective 12 and 24 h postoperatively; and (3) rebound pain between 12 and 24 h as well as complications such as dyspnea and muscle weakness are more common with ISB compared with 3NB.

The difference in the mean VAS pain scores at all time points after 4 h postoperatively showed that 3NB was noninferior to ISB. The mean VAS pain score was higher in the 3NB group than in the ISB group in the recovery room, whereas it was lower in the 3NB group than in the ISB group at 12 and 24 h postoperatively. In a recent systematic review, ISB showed a superior analgesic effect over SSB in the recovery room. Neuts et al. reported the results of a noninferiority trial, wherein they compared ISB to a combination of SSB and AXB. In their study, SSB combined with AXB showed inferior results in terms of immediate postoperative pain control compared to ISB but noninferior results in the first night and after 24 h. These results are similar to those of the present study. In our study, ISB was found to be better at pain control in the recovery room, although AXB and LPB were performed in addition to SSB. The main sensory nerves innervating the shoulder joint are the suprascapular and axillary nerves; LPN, the lower subscapularis nerve, and the musculocutaneous nerve may also provide sensory innervation to the shoulder. Nonblockade of the lower subscapularis and musculocutaneous nerves and possibility of an incomplete 3NB could explain why 3NB provided inferior analgesia in the recovery room. We believe that ISB is better for initial pain control as it blocks all the sensory nerves innervating the shoulder joints. Both groups were given the same dose of 15 ml of ropivacaine, which has a relatively short sensory nerve block duration. However, the analgesic effect was different between the two groups. In this study, different administration methods (single shot for ISB versus three-times shot for 3NB) were performed on different nerves, and it is considered difficult to compare the duration of drug action directly. Further research for the duration of drug action of these different administration methods will be needed.

Nam et al. presented, for the first time, the possibility that LPB can be used for postoperative pain control after shoulder surgery through their anatomic study. They found that the articular branch of LPN enters the shoulder through the coracohumeral ligament, with the entry point being 4.6 ± 1.1 cm from the lateral end of the acromion. The appropriate nerve block point for LPB is 1.5 ± 0.6 cm vertically below the clavicle from the line connecting the nearest points between the clavicle and the coracoid process. In the present study, LPB was performed using a blinded technique at the point between the coracoid and clavicle. Because LPN innervates the acromioclavicular joint, subacromial bursa, and clavicular periosteum, LPB can also be used for postoperative pain control after distal clavicle resection.

Pectoral nerve block has been reported to control postoperative pain or reduce muscle spasm after mastectomy or shoulder dislocation. Dellon reported a good analgesic effect of LPB on anterior shoulder pain after shoulder surgery. Eckmann et al. showed in a case report that thermal radiofrequency ablation of the articular branch of LPN could induce anterior shoulder analgesia. However, to the authors’ knowledge, there has been no study on combined SSB, AXB, and LPB for analgesia after shoulder surgery. Therefore, the findings of the present prospective, randomized noninferiority trial comparing combined SSB, AXB, and LPB with ISB after ASRCR are noteworthy.

Table 2. Comparison of secondary outcomes between the groups.

| Variable          | 3NB (n = 43) | ISB (n = 42) | p Value   |
|-------------------|--------------|--------------|-----------|
| Rebound pain, n (%) | 9 (20.9)     | 18 (42.9)    | 0.030*    |
| Opioid consumption | 0.9 ± 4.2    | 2.2 ± 3.8    | 0.030*    |
| First 24 h (mg)   | 3.3 ± 2.1    | 3.9 ± 2.5    | 0.557     |
| Second 24 h (mg)  | 1.5 ± 1.2    | 2.3 ± 1.5    | 0.042*    |
| Dyspnea, n (%)    | 1 (2.3)      | 4 (9.5)      | 0.202     |
| Muscle weakness, n (%) | 0 (0)       | 5 (11.9)     | 0.026*    |
| Satisfaction score | 8.1 ± 2.3    | 8.3 ± 1.9    | 0.815     |

*Statistical significance
In this study, the rebound pain between 12 and 24 h postoperatively was lower in the 3NB group than in the ISB group. ISB is more analgesic efficacy of immediate postoperative pain at the recovery room. After the block effect disappear, the patients seem to feel relatively more severe pain as the rebound pain. Rebound pain is defined as the difference in pain scores when the block is not working compared to when it is working, and its incidence is reported to be as high as 40%. Nociceptor hyper-excitability and abnormal C-fiber hyperactivity have been reported as pathophysiologic mechanisms of rebound pain. In addition, it is known that rebound pain occurs well in young patients under the age of 60, female, and patients with depression or severe preoperative pain. Patients undergoing shoulder surgery who received a single-shot injection for ISB were shown to experience more rebound pain compared with those not receiving any nerve block. A continuous peripheral nerve block or combined nerve block is recommended to reduce rebound pain. Kim et al. reported that it was better to use a continuous catheter block than a single-shot injection of ISB to reduce rebound pain. Lee et al. reported that combined AXB and SSB were associated with less rebound pain after ASRCR. Similar to this previous study, in the present study, the 3NB group, which received the combined nerve block, experienced less rebound pain between 12 and 24 h postoperatively. It is unclear why ISB, which blocks all sensory nerves around the shoulder, had less rebound pain than 3NB. ISB was injected with 15 ml of local anesthesia, which was more than the dose administered to each nerve of 3NB (5 ml). Prolonged exposure, high volume, and increased concentration of local anesthesia can reduce blood flow and cause nerve ischemia. We thought that this does difference may be one of the causes of the difference in rebound pain. Rebound pain results in a sharp increase in pain scores after the effect of nerve block has worn off, and opioid consumption increases during this period. Opioid consumption of the IV-PCA in this study was also higher in the ISB group than in the 3NB group during the second 24 h; we believe that this may be because the ISB group experienced more rebound pain.

Performing an ISB can cause a risk of respiratory complications such as phrenic nerve palsy and unilateral diaphragmatic paralysis. Blockade of a nerve root in the cervical region is associated with a higher risk of nerve damage than the blockade of a peripheral nerve. The reported incidence of transient complications after ISB is as high as 16%, which is three times higher than that after a peripheral nerve block. In the present study, there was one case (2.3%) of dyspnea in the 3NB group and four cases (9.5%) in the ISB group. One patient in the 3NB group recovered with O2 supplementation for 4 h after surgery, and we could not determine the cause of dyspnea. The ISB group had an 11.9% incidence of motor weakness, which was caused by an extensive motor block. Combined SSB, AXB, and LPB is worth recommending to orthopedic surgeons because these peripheral nerve blocks are safer, technically easier to perform than ISB, and associated with few complications such as phrenic nerve palsy and motor weakness. Performing 3NB is believed to reduce additional concerns for shoulder surgeons to manage respiratory dysfunction that may occur after ISB. Although three-times needle puncture of 3NB may cause discomfort to the patient more than a single shot of ISB, 3NB would like to be useful for the shoulder surgeons who are more familiar with the anatomy of three nerves around the shoulder.

This study is clinically significant because it is the first to compare 3NB (including LPB) with ISB for pain control after shoulder surgery. In addition, the prospective, randomized noninferiority trial design is a strength of this study. However, there are several limitations to the present study. First, we did not include a real control group. This is because all the patients wanted to receive a nerve block for postoperative pain control. A three-arm noninferiority trial including a placebo group to evaluate the sensitivity and internal validation of the new treatment is required. Second, the VAS pain score, the primary outcome measure of this study, is a subjective measurement. However, our results can be trusted because of standardized reporting of measurements performed by a single researcher who was blinded to the study. Third, IV-PCA was used for adjuvant pain control in all the patients. The combined regimen for analgesia can provide an addictive pain relief effect, however, withholding adjuvant pain control for severe pain after ASRCR could be an ethical problem. Finally, ISB was performed by an anesthesiologist and 3NB by a shoulder surgeon. However, orthopedic surgeons are not familiar with ISB, and as the two doctors and outcome evaluators were blinded to the study, we believe our results are reliable.

In conclusion, combined 3NB including SSB, AXB, and LPB is noninferior to ISB in terms of pain control after ASRCR; and is associated with lower levels of rebound pain, opioid consumption, and muscle weakness; therefore, it can be used as an alternative method of pain control after shoulder surgery.

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