ANESTHESIOLOGY

Subomohyoid Anterior Suprascapular Block *versus* Interscalene Block for Arthroscopic Shoulder Surgery

A Multicenter Randomized Trial

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ANESTHESIOLOGY 2020; 132:839–53

ABSTRACT

Background: Interscalene brachial plexus block, the pain relief standard for shoulder surgery, is an invasive technique associated with important complications. The subomohyoid anterior suprascapular block is a potential alternative, but evidence of its comparative analgesic effect is sparse. The authors tested the hypothesis that anterior suprascapular block is noninferior to interscalene block for improving pain control after shoulder surgery. As a secondary objective, the authors evaluated the success of superior trunk (C5–C6 dermatomes) block with suprascapular block.

Methods: In this multicenter double-blind noninferiority randomized trial, 140 patients undergoing shoulder surgery were randomized to either interscalene or anterior suprascapular block with 15 ml of ropivacaine 0.5% and epinephrine. The primary outcome was area under the curve of postoperative visual analog scale pain scores during the first 24 h postoperatively. The 90% CI for the difference (interscalene-suprascapular) was compared against a –4.4-U noninferiority margin. Secondary outcomes included presence of superior trunk blockade, pain scores at individual time points, opioid consumption, time to first analgesic request, opioid-related side-effects, and quality of recovery.

Results: A total of 136 patients were included in the analysis. The mean difference (90% CI) in area under the curve of pain scores for the (interscalene-suprascapular) comparison was –0.3 U (–0.8 to 0.12), exceeding the noninferiority margin of –4.4 U and demonstrating noninferiority of suprascapular block. The risk ratio (95% CI) of combined superior trunk (C5–C6 dermatomes) blockade was 0.98 (0.92 to 1.01), excluding any meaningful difference in superior trunk block success rates between the two groups. When differences in other analgesic outcomes existed, they were not clinically important.

Conclusions: The suprascapular block was noninferior to interscalene block with respect to improvement of postoperative pain control, and also for blockade of the superior trunk. These findings suggest that the suprascapular block consistently blocks the superior trunk and qualify it as an effective interscalene block alternative.

(ANESTHESIOLOGY 2020; 132:839–53)

EDITOR'S PERSPECTIVE

What We Already Know about This Topic

- Interscalene brachial plexus block is a commonly used procedure for shoulder surgery, but it can be associated with important complications

What This Article Tells Us That Is New

- Subomohyoid anterior suprascapular block is noninferior to interscalene block in providing analgesia for the first 24 h after shoulder surgery
- Subomohyoid anterior suprascapular block does not appear to differ significantly from interscalene block in terms of superior trunk blockade or overall quality of recovery

The ongoing quest for effective alternatives to the interscalene block of the brachial plexus for postoperative analgesia after shoulder surgery[1] has been prompted by the interscalene block's invasiveness[2,3] and undesirable respiratory side effects related to phrenic nerve block,[4] which restrict its use in certain populations.[5] The posterior suprascapular nerve block in the suprascapular notch has been proposed as an alternative that spares the phrenic nerve,[6,7] but several randomized clinical trials[8–10] concluded that it is inferior to the interscalene block for pain control, at least in the first 4 h after shoulder surgery, which can delay discharge after outpatient shoulder surgery.

This inferiority is likely because both the axillary and subscapular nerves are major contributors to shoulder joint

This article has been selected for the Anesthesiology CME Program. Learning objectives and disclosure and ordering information can be found in the CME section at the front of this issue. This article is featured in "This Month in Anesthesiology," page 1A. This article has a visual abstract available in the online version.

Submitted for publication June 1, 2019. Accepted for publication December 17, 2019. Published online first on January 22, 2020. Corrected on April 3, 2020. From the Department of Anesthesiology and Pain Medicine, and the Ottawa Hospital Research Institute, University of Ottawa, Ottawa, Canada (F.W.A.); the Department of Anesthesia (F.W.A., D.N.W., R.B., A.M., V.W.S.C.), the Institute of Health Policy, Management, and Evaluation (D.N.W., A.L.), the Department of Medicine (A.L.), and the Dalla Lana School of Public Health (K.E.T.), University of Toronto, Toronto, Canada; the Li Ka Shing Knowledge Institute of St. Michael's Hospital, University of Toronto, Toronto, Canada (F.W.A., D.N.W., A.L.); the Department of Anesthesia (D.N.W.), and the Department of Medicine (A.L.), St. Michael's Hospital, Toronto, Canada; the Department of Anesthesia and Pain Management, University Health Network, Toronto, Canada (D.N.W., V.W.S.C.); the Department of Anesthesia, Women's College Hospital, Toronto, Canada (R.B.); the Department of Anesthesia, North York General Hospital, Toronto, Canada (A.M.); the Department of Anesthesia, Wexner Medical Center, Ohio State University, Columbus, Ohio (N.H.); and the Applied Health Research Centre, Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Canada (K.E.T.).

 Anesthesiology 2020; 132:839–53. DOI: 10.1097/ALN.0000000000003132

<zdoi;. DOI: 10.1097/ALN.0000000000003132>

innervation. Contrary to earlier belief that the suprascapular nerve innervates 70% of the shoulder joint,[11] recent anatomical studies[4,12] indicated that its contribution is modest and confined to the posterior superior quadrant of the joint. The C5 and C6 nerve roots that form the brachial plexus superior trunk (C5–C6) are major contributors to all of the axillary, subscapular, and suprascapular nerves. Hence superior trunk block *per se* may provide effective pain control for shoulder surgery. Nonetheless, the superior trunk may still be too close to the phrenic nerve, and evidence of its effect on diaphragmatic function is still awaited.[4,12]

In their description of the anterior suprascapular block, Siegenthaler *et al.*[13] and Laumonerie *et al.*[14] have uncovered an indirect approach to block the superior trunk that is relatively far from the neck and phrenic nerve. Owing to anatomical proximity and proximal spread,[15,16] performing an anterior suprascapular nerve block under the inferior belly of the omohyoid muscle in the supraclavicular fossa seems to consistently block the superior trunk and brachial plexus, even when very small local anesthetic volumes are used.[15–17] Consequently, we thought that the subomohyoid anterior suprascapular block is another approach to superior trunk block that blocks the majority of shoulder innervation, thus providing postoperative analgesia that is not worse than the interscalene block for shoulder surgery.

We therefore undertook a randomized trial to determine whether single-injection anterior suprascapular block provides noninferior analgesia compared to single-injection interscalene block in patients having outpatient arthroscopic shoulder surgery, as characterized by the area under the curve for postoperative pain scores measured during the first 24 h after surgery. As a secondary objective, we aimed to clinically investigate the mechanistic effect by evaluating the consistency of superior trunk block with suprascapular block through quantifying the frequency of sensory-motor block in the C5–C6 dermatome.

Materials and Methods

This multicenter, randomized, patient- and assessor-blind, parallel-group, placebo-controlled noninferiority clinical trial was approved by the Research Ethics Boards at the three hospitals where it was conducted: Toronto Western Hospital (Toronto, Canada; application UHN 14-8577-A), North York General Hospital (Toronto, Canada; application 15-0005), and Women's College Hospital (Toronto, Canada; application 2014-0107-B). The study was registered on www.ClinicalTrials.gov (NCT02517437, principal investigator: Faraj W. Abdallah) on August 7, 2015, and patients were randomized between September 2015 and January 2018. We adhered to the guidelines of the Consolidated Standards of Reporting Trials[18,19] and the Consolidated Standards of Reporting Trials extension for noninferiority trials in preparing this article.[20] The full protocol can be accessed by contacting the corresponding author.

Study Participants

We enrolled adults (age greater than 18 yr) with American Society of Anesthesiologists Physical Status classification I to III and body mass index 35 $kg \cdot m^{-2}$ or less scheduled to undergo unilateral ambulatory arthroscopic shoulder surgery under general anesthesia. All study subjects provided written informed consent before participating in this trial. The surgical procedures included shoulder arthroscopy, rotator cuff repair, acromioplasty, Bankart repair, and superior labrum anterior posterior repair. Patients were excluded if they had severe bronchopulmonary disease, known phrenic nerve pathology, existing chronic pain disorders (or daily opioid consumption 30 mg or greater oxycodone or equivalent), existing neurologic deficits or neuropathy involving the brachial plexus on the surgical side, contraindication to nerve blocks (infection, bleeding diathesis, allergy to local anesthetics), contraindication to any component of multimodal analgesia, or history of significant psychiatric conditions that may affect patient assessment and pregnancy. Potentially eligible patients were identified from surgeons' booking lists before the scheduled surgery. An information leaflet briefly describing the study was provided at the surgeons' clinics to study candidates. Subsequently, patients were interviewed by the study coordinators during their preadmission clinic visit before the day of surgery. The coordinator introduced the study, responded to questions, obtained informed consent, and performed a baseline assessment.

Training of Study Investigators

All study investigators completed structured training before the trial on how to perform subomohyoid anterior suprascapular block. The 2-day training included description of the suprascapular block and scanning of the relevant anatomy in live volunteer models. As well, the principal investigator observed the anesthesiologists performing both interscalene block and suprascapular block on actual patients to ensure consistency of technique. Anesthesiologists who completed the training and demonstrated competency in performing the blocks were invited to participate in this trial.

Randomization and Blinding

The Applied Health Research Center of St. Michael's Hospital (Toronto, Canada), a research methods center, coordinated this study and provided support for data collection (*via* Research Electronic Data Capture, a web-based database developed by Vanderbilt University, Nashville, Tennessee), data management, and statistical support. The randomization list was generated and stratified by center using randomly varying block sizes of 2 and 4 with a 1:1 ratio. The analyst generating the allocation sequence was not involved in any other study procedures. On the day of the scheduled procedure, after informed consent was

obtained, investigators logged into the study website to retrieve treatment allocation. The treatment allocation was not disclosed to the patient or coordinator. An electronic case report form was used to collect and enter outcome data online.

The anesthesiologist providing intraoperative care was different from the study anesthesiologist who performed the block. Both the research coordinator enrolling patients and collecting the outcome data and the anesthesiologist providing intraoperative care during surgery were not present in the block room during block performance or assessment of block success. The anesthesiologist performing the intervention and assessing block success did not have any further contact with the patient or role in the study. The success of maintaining patient blinding was evaluated at discharge by asking patients which nerve block they thought they had received.

Preoperative Management

On the day of surgery, patients received acetaminophen 1 g and celecoxib 400 mg orally. Blocks were performed in the block procedure room under standard monitoring (noninvasive blood pressure, electrocardiogram, and pulse oximetry). Before block performance, all patients received IV midazolam 1 to 2 mg and/or fentanyl 25 μg IV for anxiolysis and analgesia, as needed, while avoiding deep sedation. All blocks were performed using aseptic technique, with patients positioned supine with their shoulder in neutral position, and neck tilted away from the shoulder being blocked. All blocks were performed using 15 ml of 0.5% ropivacaine with epinephrine 1:200,000.

Suprascapular Group

The suprascapular nerve was blocked in the supraclavicular fossa, as described by Siegenthaler *et al.*[13] A linear array transducer (6 to 13 MHz, Sonosite M-Turbo, Sonosite, USA) probe protected by a 3M Tegaderm dressing or a sterile sheath was placed in the transverse plane to visualize the superior trunk in the short axis. The suprascapular nerve was identified as it branched off from the superior trunk and traced until it coursed beneath the inferior belly of the omohyoid muscle. After infiltration with 1 ml of 1% lidocaine, a 5-cm 22-gauge insulated needle (B. Braun Medical Inc., USA) was inserted in line with the probe in a lateral-to-medial orientation toward the suprascapular nerve. Local anesthetic solution was then injected in 5-ml aliquots after negative aspiration for blood to achieve circumferential spread around the neurovascular bundle. Patients also received a sham interscalene block at the designated site using a 25-gauge needle to inject 1 ml of lidocaine 1% subcutaneously. Skin sterilization, scanning with ultrasound, probe pressure on the skin, and the duration of scanning matched an actual interscalene block. Figure 1 illustrates the subomohyoid anterior suprascapular block technique.

Interscalene Group

Ultrasound scanning was performed in the transverse plane to visualize the brachial plexus between the anterior and middle scalene muscles. A 5-cm 22-gauge insulated needle (B. Braun Medical Inc.) was then inserted in line with

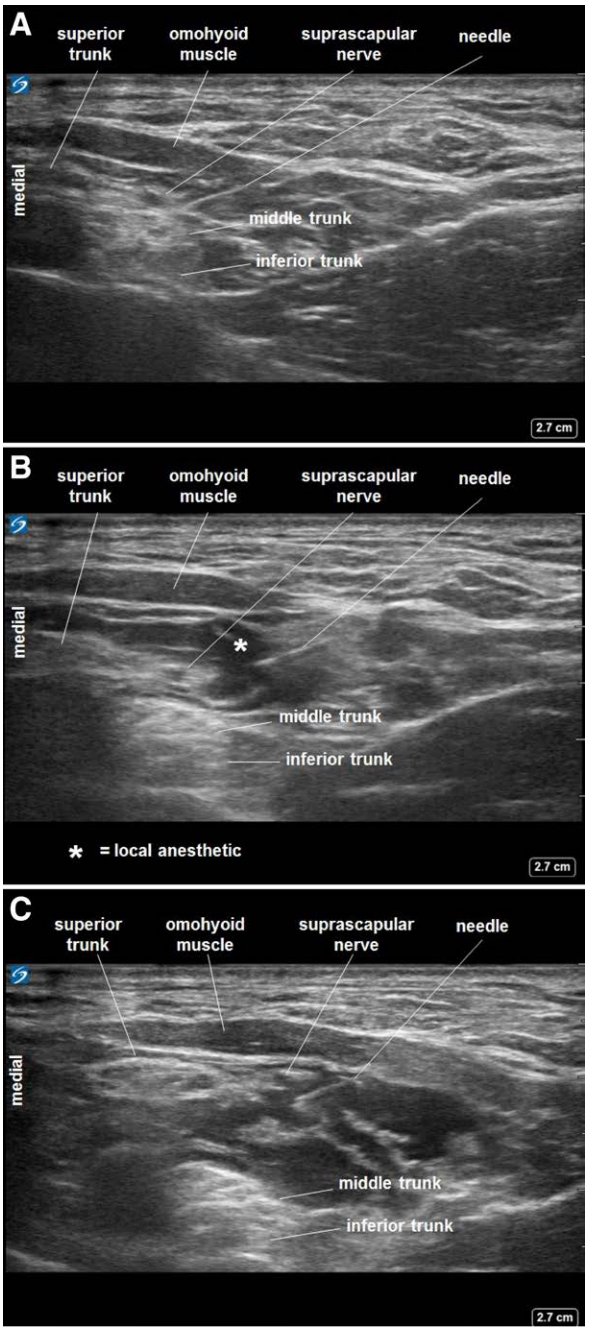

Fig. 1. Subomohyoid–suprascapular block technique. (*A*) Targeting the suprascapular nerve as it branches from the superior trunk. (*B*) Local anesthetic spread around suprascapular nerve. (*C*) Local anesthetic tracking back around the superior trunk.

the probe in a lateral-to-medial needle orientation. Local anesthetic solution was then injected in 5-ml aliquots after negative aspiration for blood to achieve spread posterior to or between the C5 and C6 nerve roots. Additional needle adjustments were made to ensure this local anesthetic spread pattern. Patients also received a sham suprascapular block at the designated site using a 25-gauge needle to inject 1 ml of lidocaine 1% subcutaneously. Skin sterilization, scanning with ultrasound, probe pressure on the skin, and the duration of scanning matched an actual suprascapular block.

Assessment of Block Onset

Assessment of sensory block onset was performed to confirm block success. Sensory block onset was tested by the anesthesiologist performing the block every 5 min for the subsequent 30 min using a blunt 22-gauge needle applied to the skin, in comparison to the contralateral upper extremity. Sensory testing for the interscalene and suprascapular blocks was performed over the posterior and superior deltoid area.[21,22] Block success was scored on a 3-point scale as follows: (2) normal sensation; (1) reduced sensation; and (0) no sensation. Block success was defined as complete sensory loss to pinprick (score = 0) at 30 min. Patients in whom block success was not achieved after 30 min were considered to have failed blocks, but were still retained in the study to ensure validity of an intention-to-treat analysis.

Intraoperative Management

All patients received a standardized general anesthesia regimen. General anesthesia was induced using fentanyl 0.5 to 2 μg · kg^{-1} IV and propofol 2 to 4 mg · kg^{-1} IV. A laryngeal mask airway or an endotracheal tube was inserted, as necessary. Patients who required endotracheal intubation received rocuronium at a dose of 0.6 mg · kg^{-1}. General anesthesia was maintained using 2 to 6% of desflurane or 0.8 to 2.8% sevoflurane in a 50:50 mixture of oxygen and air. Patients were allowed to breathe spontaneously if a laryngeal mask airway was used. Supplemental analgesia as needed was provided by morphine 2.5 to 5 mg IV boluses to a maximum of 15 mg, or hydromorphone 0.2 to 0.4 mg IV boluses to a maximum of 2.4 mg, to treat hemodynamic increases (heart rate or blood pressure) of more than 15% above preinduction baseline values. Desflurane or sevoflurane was discontinued at completion of surgery, and rocuronium was antagonized with neostigmine 50 μg · kg^{-1} and glycopyrrolate 5 to 10 μg · kg^{-1}, if necessary. Patients also received ondansetron 8 mg as an antiemetic after induction of anesthesia.

Postoperative Management

During the stay in the postanesthesia care unit, postoperative pain at rest was assessed using a Numerical Rating Scale (0 = no pain, 10 = worst pain imaginable) score. Patients with a score 4 or greater or patients requesting additional analgesia received IV fentanyl in 25-μg increments every 5 min, as needed, up to a total of 100 μg, followed by IV morphine in 5-mg increments every 10 min up to a total of 20 mg or hydromorphone in 0.2-mg increments every 10 min up to a total of 3 mg. Once patients met institutional postanesthesia care unit discharge criteria, they were transferred to the same-day surgery discharge unit. In this unit, pain was treated with oral acetaminophen 300 mg plus codeine 30 mg combination tablets every 4 h, as needed, followed by oral oxycodone 5 to 10 mg every 4 h, as needed. Pain scores at time of postanesthesia care unit admission, as well as time to first analgesic request, were documented. All postoperative analgesics administered in the postanesthesia care unit and same-day surgery discharge unit were also documented. The site of nerve blocks was assessed for any block-related complications before discharge.

Postdischarge Management and Follow-up

After hospital discharge, patients received a prescription for acetaminophen 300 mg plus codeine 30 mg combination tablets, as needed, or acetaminophen 325 mg plus oxycodone 5 mg combination tablets if intolerant to codeine. They were also given a home diary that was to be completed and returned to the study team using a stamped, return-addressed envelope. In this diary, patients were asked to record their pain scores at 6, 12, 18, and 24 h after surgery, their oral analgesic consumption since hospital discharge, and their satisfaction with pain relief (reported on an numerical rating scale, 0 = least satisfied, 10 = most satisfied).

Follow-up

A research coordinator conducted a follow-up phone call 2 weeks after surgery to assess any potential block-related neurologic symptoms such as pain, paresthesia, dysesthesia, sensory loss, or motor power weakness.

Outcomes

Primary Outcome. We were interested in determining whether the suprascapular block is noninferior to interscalene block in providing postoperative analgesia after ambulatory arthroscopic shoulder surgery. Therefore, the primary outcome in this trial was the area under the curve of the postoperative pain severity scores, measured at 0, 6, 12, 18, and 24 h postoperatively.

Secondary Outcomes. For our secondary objective, evaluating the consistency of superior trunk blockade with suprascapular block, we aimed to assess local anesthetic spread to the superior trunk by quantifying the frequency of sensory-motor block in the C5–C6 dermatome at 30 min postblock. This was achieved by a dermatomal assessment of the sensory and motor functions of the brachial plexus.[23] These sensory-motor functions were scored as follows: 0 = function is absent, 1 = function is reduced, and 2 = function is intact. We considered evidence of either sensory or motor

changes (score 1 or less) indicative of a sensory-motor block. We also considered the combined sensory-motor block in both C5 and C6 dermatomes simultaneously as indicative of a successful block of the superior trunk.

For sensory testing, we evaluated the following dermatomes in their corresponding anatomical areas: C5: lateral upper arm, C6: thumb/ index finger, C7: middle finger, C8: fourth and fifth fingers, and T1: medial side of arm. For motor testing, we evaluated the following dermatomes based on their corresponding functions: C5: lateral rotation of the arm and/or abduction of upper arm, C6: flexion at the elbow, C7: extension of the forearm, C8: finger flexion (hand grip), and T1: finger abduction (spreading fingers).

The secondary analgesic outcomes included (1) individual rest pain scores at 0, 6, 12, 18, and 24 h postoperatively, (2) presence of moderate-to-severe pain, defined as pain score 4 or greater during the first 24 h postsurgery, (3) time to first reported pain and first analgesic request during postanesthesia care unit stay (in minutes), (4) recovery time, including duration of postanesthesia care unit and same-day surgery discharge unit stay, (5) time to first reported pain after discharge, (6) analgesic consumption during surgery, in postanesthesia care unit, and during the first 24 h postsurgery (converted to IV morphine equivalents),[24] (7) opioid-related side effects (postoperative nausea and vomiting), (8) patient satisfaction with analgesia (on a numerical rating scale), and (9) quality of recovery at 12 and 24 h postoperatively (using the Quality of Recovery-15 scale).[25]

Quality of Recovery-15 is a multidimensional (pain, comfort, independence, psychologic, and emotional) scale. It has a maximum score of 150 (best recovery), and good recovery has a score estimate of 118. Quality of Recovery-15 comprises five domains of testing: pain (two questions), physical comfort (five questions), physical independence (two questions), psychologic support (two questions), and emotional state (four questions). Each question uses a 10-point scale ranging from 0 = none of the time to 10 = all of the time (scoring is reversed for negative questions). The sum of the individual domains generates an aggregate (or global) score with the maximum score (best recovery) obtained being 150. The minimally clinically important difference for Quality of Recovery-15 is estimated to be 8.[25]

Block-related outcomes included (1) block procedural pain score, (2) block success rate, defined as occurrence of complete sensory block in the deltoid area within 30 min of injection, (3) block-related complications (intravascular injection, local anesthetic systemic toxicity, hematoma, pneumothorax, epidural spread, and Horner's syndrome), (4) hemodynamic complications during surgery, defined as a 30% drop in blood pressure or heart rate compared to baseline, (5) respiratory complications, defined as oxygen saturation less than 95% during postanesthesia care unit stay, and (6) transient neurologic complications (paresthesia, motor weakness, and new-onset pain) at 2 weeks postsurgery.

Before hospital discharge, we also assessed success of blinding based on the proportion of patients who correctly answered the question, "Which block do you think you received?"

Statistical Analysis

A noninferiority design is appropriate when there is no biologic rationale to suggest that the treatment being studied could be superior to the comparator arm. In the case of patients having shoulder surgery, suprascapular block may provide postoperative analgesia that is comparable to interscalene block, but it is highly unlikely to provide superior analgesia.[26] Therefore, to determine whether suprascapular block is noninferior to interscalene block, a noninferiority trial was undertaken,[27] and the area under the curve for rest pain severity scores during the first 24 h postoperatively was designated as the primary outcome. This trial design tested the null hypothesis that interscalene-suprascapular was Δ or greater, where Δ is a nonclinically important difference (noninferiority margin). The value of Δ in this case would be negative, as we examined the hypothesis that suprascapular block was noninferior (but not superior) to interscalene block using postoperative pain scores, where higher scores are indicative of worse pain. To corroborate our hypothesis, the two blocks were also compared for noninferiority over superior trunk sensory-motor block success rate, a secondary outcome. To declare that suprascapular block was noninferior, the lower margin of 90% CI for the difference should not cross Δ.[28]

We analyzed data using R statistical package version 3.4.2 (R Foundation for Statistical Computing, Austria). An intention-to-treat analysis is not conservative when performing a noninferiority comparison because it is biased toward the alternative.[29] Therefore, the primary noninferiority analysis used a per-protocol analysis. For all analyses that were not in the noninferiority framework, an intention-to-treat analysis was used. The level of significance (α) for the one-sided test of noninferiority was set at 0.05. Analysis of secondary outcomes was primarily exploratory, and we only corrected for repeated measurements of the same outcome (*e.g.*, quality of recovery). The normality of data was confirmed by the quantile-quantile (QQ) plot of residuals and by the Kolmogorov–Smirnov test with the assumptions of homogeneity of variance.

We report continuous data as mean (95% CI), categorical data as number or percentage, and ordinal data (*e.g.*, postoperative pain scores and quality of recovery) graphically as median (range) and numerically as mean (SD). The results of statistical tests were interpreted in the context of strength of evidence (*e.g.*, very weak, weak, strong, very strong) of difference rather than the conventional binary significance (*i.e.*, $P < 0.05$ or $P \geq 0.05$).[30]

For noninferiority testing of the primary outcome, we were willing to accept a type I error margin equivalent to 5% for the one-sided test of noninferiority of

suprascapular block compared to interscalene block. This error margin corresponds to using a 90% two-sided CI, as an additional 5% error margin corresponds to testing the complimentary hypothesis, or noninferiority in the opposite direction (*i.e.*, interscalene block noninferior to suprascapular block). We therefore performed noninferiority testing for the primary outcome by comparing the 90% CI of the difference between the two study groups (interscalene-suprascapular) to the predetermined noninferiority margin (Δ) for this outcome using a one-sided independent sample *t* test at a significance criterion of 0.05. If noninferiority of suprascapular block was concluded, superiority was subsequently tested using a one-sided independent sample *t* test. For area under the curve of rest pain scores, we calculated area using the weighted mean over a fixed time (trapezoid rule).

For noninferiority testing of the success of the superior trunk block (combined C5–C6 blockade), the risk ratio (90% CI) was used, and we sought to demonstrate that the comparison excludes any meaningful difference, *i.e.*, a risk ratio of 0.90 or greater. All other secondary outcomes were compared for superiority. For rest pain severity scores at the individual time points examined, we compared scores using linear mixed-effect modeling, including a predetermined analysis of time-by-treatment interaction, and calculated the mean difference (95% CI). This was the only adjusted analysis performed, and no additional stratified or subgroup analysis was conducted. We analyzed time-to-event outcomes using the Kaplan–Meier method and compared groups by the log-rank test, after verifying the assumptions of (1) proportional hazards, (2) linear covariate relationships, and independence. Missing data were right-censored at the last confirmed assessment time point. For block-related complications, we calculated the relative risk (95% CI). For repeated measures (proportion of patients having moderate to severe pain, Quality of Recovery-15 scores), we used the Bonferroni–Holm correction.[31]

Sample Size

We based the sample size calculation on our ability to test the one-sided suprascapular block noninferiority hypothesis on the mean area under the curve of rest pain severity scores during the first 24 h after surgery. The minimum clinically important difference in acute pain severity scores after shoulder and elbow surgery has been suggested to be 1.4 U.[32,33] We select a Δ of 1.1 U as a noninferiority margin for each of the five measurements (0, 6, 12, 18, and 24 h). The analgesic effect of interscalene block (and other peripheral blocks) is expected to wear off within the first 12 h after this block.[34] Assuming that acute pain at different time points during the first 24 h postoperatively holds the same clinical importance, we used the trapezoidal rule[35] to estimate the partial areas corresponding to the time intervals between the pain severity measurements. To estimate Δ for the noninferiority comparison, we assumed that both interventions have similar analgesic duration patterns (onset/offset), and postulated ideal conditions where noninferiority of area under the curve of pain scores over 24 h entails noninferiority during each of the four time intervals between the five measurements. A Δ of 1.1 units for each measurement corresponds to a Δ of area under the curve of 4.4 units during a 24-h interval, or −4.4 U for the mean difference (interscalene-suprascapular). Our meta-analysis of interscalene block in shoulder surgery[34] estimated the mean and SD of the area under the curve to be 13.0 ± 9.9 U for the 0- to 24-h interval. Assuming that the true difference in area under the curve of pain severity score between the interscalene and suprascapular groups is 0, a one-sided type I error estimate of 5% ($\alpha = 0.05$), and a power ($1 - ß$) of 80%, a sample of 63 patients per group was required. We expected a maximum of 10% incomplete follow-up or dropout of recruited patients. Therefore, we planned to enroll 70 patients per group.

Confirmatory Testing

Although area under the curve is a patient-relevant outcome, data regarding its minimum clinically important difference are scarce. Therefore, if noninferiority was concluded, we planned to further verify this conclusion by comparing the interventions at a single time point during their peak effect. As the analgesic duration of peripheral nerve blocks is generally around 8 h,[34] we decided to conduct a confirmatory test by checking whether the 90% CI of the difference in pain scores at 6 h postoperatively excluded the noninferiority margin (Δ).

Results

Three hundred twenty-three patients were assessed for study eligibility. Of these, 68 patients were not eligible because of high body mass index (37 patients), planned open surgical procedures (19 patients), high baseline opioid consumption (five patients), severe chronic obstructive pulmonary disease (three patients), preexisting brachial plexus neuropathy (two patients), and pregnancy (two patients). The remaining 255 patients were approached for study participation. Of these, 115 declined and 140 (62%) patients accepted and provided informed consent. Figure 2 depicts the Consolidated Standards of Reporting Trials participant diagram for the study. All 140 enrolled patients were randomized (interscalene: 70 patients; suprascapular: 70 patients). Four patients (interscalene: 1; suprascapular: 3) did not return their diaries and were excluded from the analysis. Missing data for secondary outcomes occurred in less than 5% of participants. The suprascapular nerve was sonographically identified in all patients who received this intervention, and block success was confirmed in all study participants; thus, all outcomes underwent a per-protocol analysis. All patients met the postanesthesia care unit and hospital discharge criteria

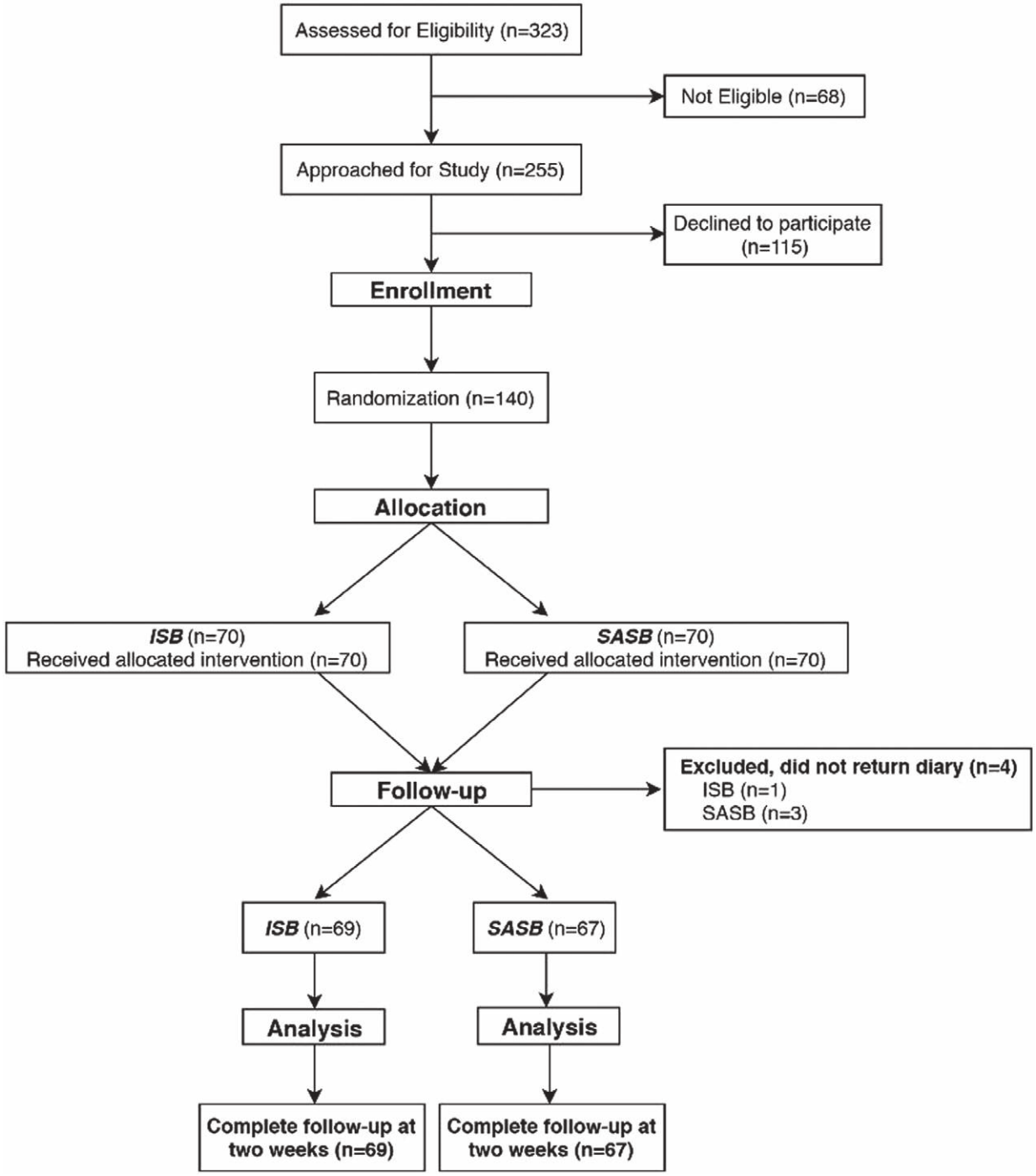

Fig. 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing patient progress through the study phases. ISB, innterscalene block; SASB, subomohyoid-suprascapular superior trunk block.

for ambulatory surgery of each institution, and none of the patients had an unplanned admission.

The baseline and demographic characteristics of study participants are shown in table 1. Apart from age, where the mean age in the interscalene group was 6.1 yr younger than the suprascapular block group, patients in both groups had similar baseline and demographic characteristics. All study participants had arthroscopic shoulder surgery, and a few had an additional open procedure (biceps tenodesis, distal clavicular excision).

Table 1. Baseline Demographic Characteristics

Parameter	Interscalene Block (N = 69)	Subomohyoid Anterior Suprascapular Block (N = 67)
Age, yr	40 ± 15	46 ± 15
Sex, female	16 ± 23.2	21 ± 31.3
Body mass index, kg · m^{-2}	26.2 ± 3.2	26.1 ± 3.6
American Society of Anesthesiologists Physical Status (I/II/III)	35 (50.7)/31 (44.9)/3 (4.3)	31 (46.3)/31 (46.3)/5 (7.4)
Surgical side, left	29 ± 42.0	28 ± 41.8
Duration of surgery, min	105 ± 47	103 ± 38
Arthroscopic procedure*		
Shoulder arthroscopy	28 (40.6)	28 (41.8)
Bankart repair	4 (5.8)	3 (4.5)
Acromioplasty	19 (27.5)	20 (29.9)
Rotator cuff repair	16 (23.2)	14 (20.9)
SLAP	9 (13.0)	5 (7.5)
Biceps tenodesis	5 (7.2)	10 (14.9)
Distal clavicle excision	1 (1.5)	3 (4.5)
Other	20 (29.0)	21 (31.3)

Results reported as mean ± SD for continuous outcomes; and as number (percentage) for categorical outcomes.
*Patients can have more than one procedure during the same surgery.
SLAP, superior labrum anterior posterior repair.

Area under the Curve for Postoperative Pain (Primary Outcome)

The areas under the curve for rest pain scores measured at 0, 6, 12, 18, and 24 h postoperatively were 13.18 and 12.84 U over 24 h for the interscalene and suprascapular block groups, respectively (table 2). The mean difference (90% CI) of −0.3 (−0.8 to 0.2) was well above the noninferiority margin of −4.4 U, providing strong statistical evidence ($P < 0.0001$) of noninferiority (fig. 3). Since the CI included a difference in area under the curves of 0, formal superiority testing was not warranted.

Confirmatory Testing

The rest pain scores at the 6-h time point postoperatively were 1.2 cm (0.8 to 1.6) for the interscalene block and 1.7 cm (1.3 to 2.1) for the suprascapular block (table 2). The mean difference (90% CI) of −0.5 cm (−1.0, 0.0) was well above the noninferiority margin of −1.1 cm, providing strong statistical evidence ($P = 0.019$) of noninferiority of suprascapular block, thus corroborating the results of the area under the curve comparison.

Superior Trunk Block

The proportions of patients experiencing sensory-motor block in any of the brachial plexus dermatomes (C5–T1) were similar between the two groups (table 2). For the superior trunk in particular (C5–C6), sensory-motor block was demonstrated in 69 of 69 and 65 of 67 patients having interscalene and suprascapular blocks, respectively. The risk ratio of superior trunk block (90% CI) of 0.97 (0.93 to 1.01) was well above the noninferiority margin of 0.9, providing strong statistical evidence ($P = 0.0006$) of noninferiority, and suggesting that any differences between suprascapular and interscalene blocks were not clinically meaningful.

Analgesic Outcomes

The suprascapular block was similar to the interscalene block for pain control at all time points examined during the first 24 h after shoulder surgery. Evaluating acute pain using linear mixed-effect modeling including time-by-treatment interaction yielded very weak statistical evidence that the two study groups were different for rest pain scores at 0 ($P = 0.052$), 6 ($P = 0.071$), 12 ($P = 0.593$), 18 ($P = 0.270$), and 24 h ($P = 0.121$), *i.e.*, all time points examined (table 2, fig. 4).

Similarly, there was very weak evidence of differences in the proportion of patients experiencing moderate to severe acute pain between the two groups at 0 ($P = 0.055$), 6 ($P = 0.362$), 12 ($P = 0.164$), 18 ($P = 0.633$), and 24 ($P = 0.303$) h, *i.e.*, during the first 24 h after shoulder surgery.

The suprascapular block was similar to interscalene block with respect to the majority of the analgesic outcomes assessed. The two groups had similar time to first pain in postanesthesia care unit, duration of postanesthesia care unit, and same-day surgery discharge unit stay, time to first pain after hospital discharge, intraoperative analgesic consumption, cumulative 24-h postoperative IV morphine equivalent consumption, incidence of postoperative nausea and vomiting, and patient satisfaction with pain relief (table 2).

In contrast, there was weak evidence that patents in the suprascapular group had slightly shorter time to first analgesic request ($P = 0.04$) in postanesthesia care unit, with

Table 2. Results

Outcome	Interscalene Block (N = 69)	Subomohyoid Anterior Suprascapular Block (N = 67)	Mean Difference (95% CI) or Risk Ratio (95% CI) or Relative Risk	*P* Value
Primary outcome				
Area under the curve for rest pain scores during first 24 h (0, 6, 12, 18, 24 h), units during 24-h interval	13.2 ± 2.0	12.8 ± 1.4	–0.3 (–0.8 to 0.2)*	< 0.0001† (noninferiority)
Secondary outcomes				
Confirmatory comparison of rest pain NRS at 6 h	1.2 ± 1.6	1.7 ± 1.6	–0.5 (–1.0 to 0.0)*	0.019‡ (noninferiority)
Proportion of patients with evidence of superior trunk sensory-motor block	69	65	0.97 (0.93 to 1.01)*	0.0006§ (noninferiority)
Proportion of patients with evidence of dermatomal sensory-motor block				
C5—superior trunk block (superior trunk)	69 (100)	65 (97.0)	0.97 (0.92 to 1.02)	0.240
C6—superior trunk block (superior trunk)	69 (100)	65 (97.0)	0.97 (0.92 to 1.02)	0.240
C7	60 (87.0)	51 (76.1)	0.86 (0.74 to 1.03)	0.112
C8	54 (78.3)	47 (70.1)	0.90 (0.73 to 1.09)	0.282
T1	7 (10.1)	0 (0)	0.07 (0.01 to 1.18)	0.060
Analgesic outcomes				
Rest pain severity NRS score analysis using linear mixed-effect modeling including time by treatment interaction				
0 h	0.6 ± 2.2	1.3 ± 2.2	–0.7 (–1.5 to 0.0)	0.052
6 h	1.2 ± 1.6	1.7 ± 1.6	–0.5 (–1.0 to 0.0)	0.071
12 h	3.7 ± 3.0	3.4 ± 3.0	0.3 (–0.8 to 1.3)	0.593
18 h	5.4 ± 2.9	4.8 ± 2.9	0.6 (–0.5 to 1.6)	0.270
24 h	5.1 ± 2.5	4.5 ± 2.5	0.7 (–0.2 to 1.5)	0.121
Proportion of patients with moderate-to-severe pain (NRS ≥ 4) during the 24 h				
0 h	6 (8.7)	14 (20.7)	2.4 (0.98 to 5.88)	0.055
6 h	8 (11.6)	5 (7.5)	1.65 (0.57 to 4.78)	0.362
12 h	34 (49.3)	25 (37.3)	0.76 (0.51 to 1.12)	0.164
18 h	51 (73.9)	47 (74.6)	0.95 (0.77 to 1.17)	0.633
24 h	50 (72.5)	43 (64.2)	0.89 (0.70 to 1.12)	0.303
Time to first pain sensation in PACU, min	129 ± 57	113 ± 68	17 (–5 to 38)	0.134
Time to first analgesic request in PACU, min	139 ± 48	128 ± 47	12 (0 to 23)	0.042
Duration of PACU stay, min	59 ± 23	67 ± 45	–8 (–20 to 4)	0.183
Duration of same-day surgery discharge unit stay, min	124 ± 46	125 ± 73	–1 (–22 to 20)	0.923
Time to first pain sensation after discharge, min	673 ± 442	783 ± 477	–110 (–265 to 45)	0.172
Intraoperative IV morphine equivalent consumption, mg	16.1 ± 6.8	17.0 ± 6.7	–0.9 (–3.2 to 1.4)	0.441
Postoperative cumulative PACU IV morphine equivalent consumption, mg	3.2 ± 6.3	5.7 ± 7.3	–2.5 (–4.8 to –0.2)	0.042
Postoperative cumulative 24-h IV morphine equivalent consumption, mg	13.4 ± 12.6	13.5 ± 15.3	–0.1 (–4.8 to 4.6)	0.961
Nausea and vomiting in the PACU	18 (26.1)	26 (38.8)	1.49 (0.90 to 2.45)	0.122
Patient satisfaction with pain relief at 24 h (NRS)	7.1 ± 2.5	7.3 ± 2.5	–0.1 (–1.0 to 0.7)	0.760
QoR-15 score at discharge	106 ± 21	102 ± 24	4 (–4 to 11)	0.300
QoR-15 score at 24 h	106 ± 25	103 ± 21	3 (–5 to 11)	0.462
Block characteristics				
Block procedural pain (NRS)	0.6 ± 1.6	0.7 ± 1.5	–0.1 (–0.6 to 0.5)	0.822
Successful block confirmed by sensory onset	69 (100)	67 (100)	N/A	1.00
Safety and complications				
Intraoperative bradycardia	11 (15.9)	7 (10.4)	0.66 (0.27 to 1.59)	0.353
Intraoperative hypotension	31 (44.9)	23 (34.3)	0.76 (0.50 to 1.17)	0.211
Block complications	0 (0)	0 (0)	N/A	1.00
Respiratory complications in PACU (hypoxemia)	6 (8.70)	10 (14.90)	1.72 (0.66 to 4.46)	0.273
Postoperative block complication at 2 weeks				
Paresthesia	1 (1.4)	0 (0)	0.34 (0.014 to 8.28)	0.510
Motor weakness	2 (2.8)	1 (1.5)	0.51 (0.05 to 5.55)	0.552
New-onset pain	0 (0)	5 (7.5)	11.32 (0.64 to 200.88)	0.104
Success of blinding: Correctly answered the question, "Which block do you think you received?"	32 (46.4)	19 (28.4)	2.18 (1.07 to 4.45)	0.030

Data presented as mean ± SD, count (percentage), mean difference (95% CI), or relative risk (95% CI).

*90% CI. †*P* value for the one-sided test of noninferiority against –4.4 U, the noninferiority margin. ‡*P* value for the one-sided test of noninferiority against –1.1 U, the noninferiority margin. §*P* value for the one-sided test of noninferiority against 0.9, the noninferiority margin.

IV, intravenous; N/A, not applicable; NRS, numerical rating scale (0–10, 0, least; 10, highest); PACU, postanesthesia care unit; QoR, Quality of Recovery.

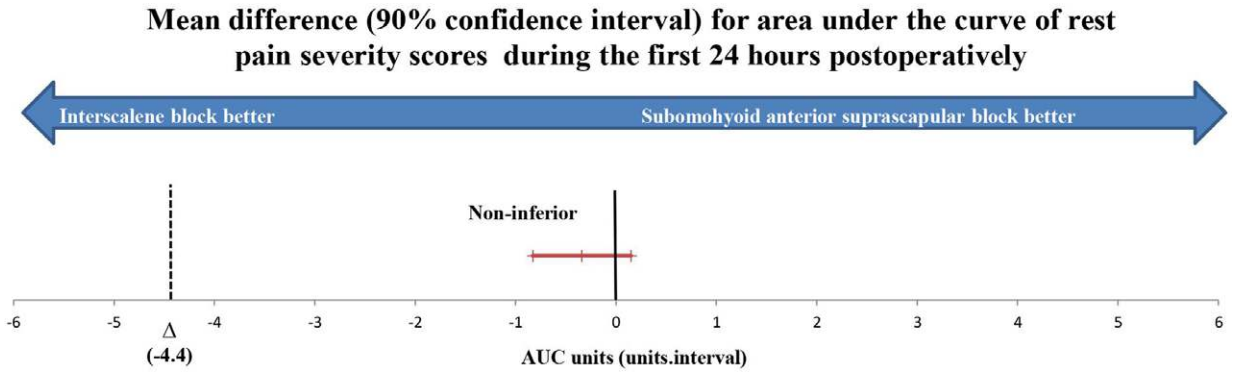

Fig. 3. Noninferiority comparison. Subomohyoid-suprascapular superior trunk block is noninferior to interscalene block for the area under the curve (AUC) for postoperative pain during the first 24 h postoperatively.

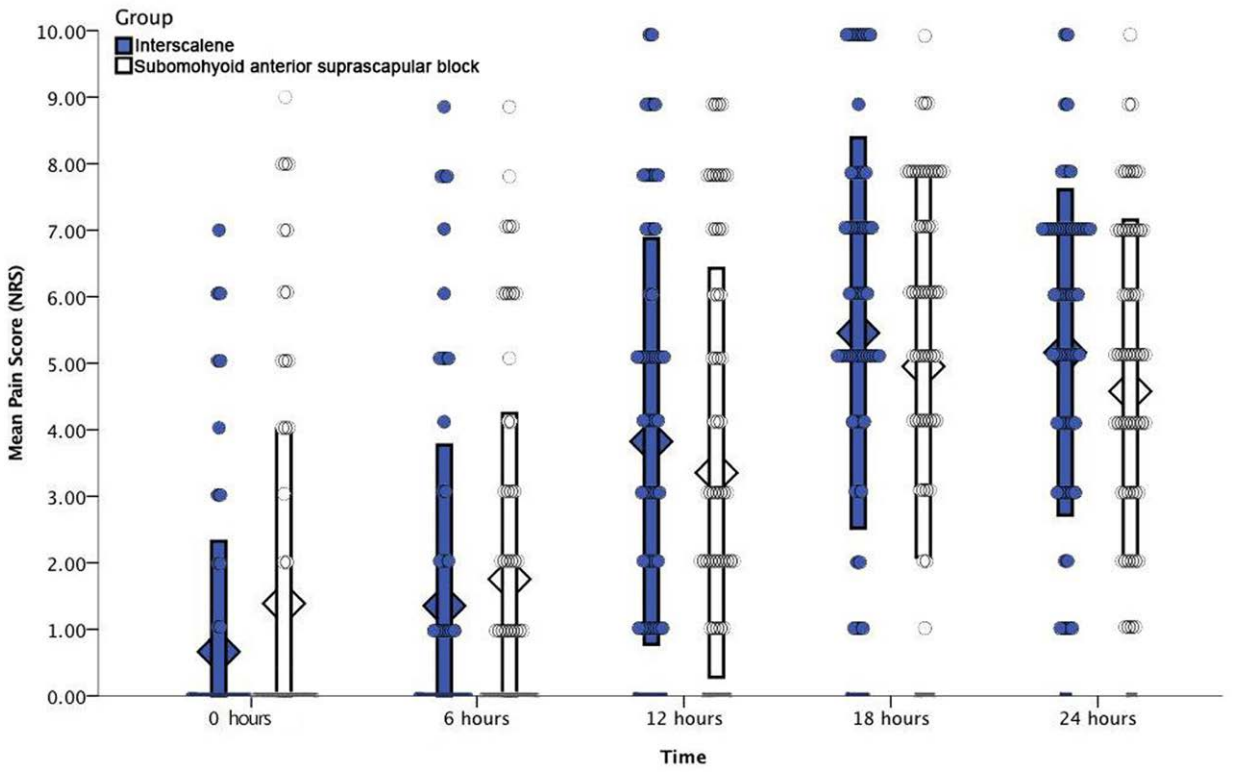

Fig. 4. Box-and-whiskers plot of postoperative rest pain scores during the first 24 h for the two study groups. No statistically significant differences were detected at any of the time points. *Boxes* correspond to 95% CI, *circles* correspond to individual measurements, and *diamonds* correspond to medians. NRS, numerical rating scale.

a mean difference (95% CI) of 12 min (0 to 23; table 2). Additionally, there was weak evidence that patients in the suprascapular group had a slightly higher IV morphine consumption ($P = 0.042$) during their postanesthesia care unit stay, with a mean difference (95% CI) equivalent to –2.5 mg (–4.8 to –0.2). The clinical importance of both these differences is questionable.

The suprascapular block was similar to the interscalene block with respect to Quality of Recovery. The mean difference (95% CI) in the overall Quality of Recovery-15

scores for the two groups was not significant at hospital discharge 4 U (–4 to 11) and 24 h postoperatively 3 U (–5 to 11; table 2). Additionally, no clinically meaningful differences were detected when the scores for the five individual domains of the Quality of Recovery-15 scale were compared for the two groups (fig. 5).

Block Characteristics

Patient-reported pain during administration of the block was consistently mild, with absence of meaningful differences between the two groups ($P = 0.822$; table 2). All patients in both groups had successful blocks, as assessed by sensory testing.

Safety Outcomes

The suprascapular block was similar to interscalene block with respect to all safety outcomes, specifically the risks of intraoperative hemodynamic complications (bradycardia, hypotension); block procedural complications; postoperative respiratory complications (hypoxemia); and postoperative neurologic complications at 2 weeks (paresthesia, motor weakness, or new-onset pain; table 2).

Success of Blinding

Thirty-two patients (46.4%) in the interscalene block groups and 19 patients (28.4%) in the suprascapular group correctly identified the type of block they received (table 2).

Discussion

This multicenter randomized clinical trial in patients undergoing ambulatory arthroscopic shoulder surgery found that single-injection suprascapular block is noninferior to the interscalene block for providing postoperative pain control for the first 24 h after surgery, and also for blocking the superior trunk of the brachial plexus. These findings are corroborated by the consistent absence of statistical evidence of differences between the two blocks for other important analgesic outcomes such as the pain scores at all time points, presence of moderate to severe pain, 24-h postoperative analgesic consumption, opioid-related side effects, and overall patient satisfaction with pain relief. Similarly, the two blocks were not different for safety outcomes and Quality of Recovery scores. Any differences between the two techniques (time to first analgesic request in postanesthesia care unit and cumulative postanesthesia care unit opioid consumption) were clinically unimportant.

Our findings present consistent evidence of superior trunk blockade when a suprascapular block is performed, indicating that blockade of the superior trunk is a major underlying mechanism to the observed efficacy of suprascapular block. These results provide the clinical correlation of the earlier anatomic studies of Sehmbi *et al.*[17] (who reported 90% staining of the brachial plexus), Laumonerie *et al.*[14] (who reported 100% staining of the superior trunk), and Siegenthaler *et al.*[13] (who reported brachial plexus block even when a 0.1 ml volume of injectate is used). The

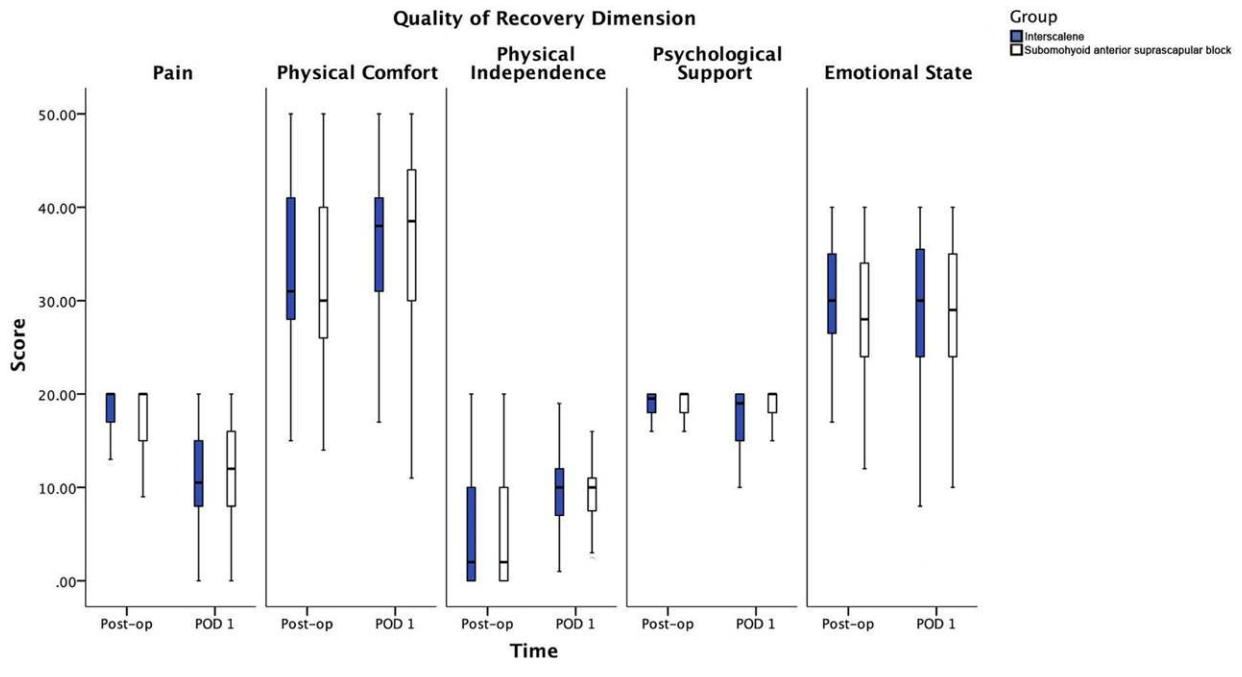

Fig. 5. Box-and-whiskers plot of the quality of recovery (QoR-15) domains for the two study groups at discharge and 24 h postoperatively. No statistically significant difference was detected in any of the domains. POD, postoperative day; Post-op, postoperatively.

consistent spread to the superior trunk observed also offers a plausible explanation for the historical discrepancy in analgesic effects relative to interscalene block observed between the posterior suprascapular block (inferior to interscalene block)[8–10] and the suprascapular block (noninferior to interscalene block). Notwithstanding, the anterior suprascapular block approach may offer a more reliable and accurate way to image and block this nerve, compared to the posterior approach, which may explain the discrepancy in analgesic efficacy. However, trials comparing the two approaches are needed to test this hypothesis. Besides elucidating the mechanism, this study has also established suprascapular block as an effective treatment for postoperative pain in patients undergoing shoulder surgery. This option is particularly attractive in patients in whom the risk of respiratory and other complications precludes the use of interscalene block. This clinical problem has received considerable attention recently, with several calls to seek alternatives to interscalene block.[1,6,36,37] Among the diaphragmatic-sparing alternatives, the modified interscalene block technique performed at the C7 nerve root level using very small volumes may be a viable and effective option.[38] However, this modified technique still lacks support from clinical trials, involves needling near the vertebral artery, causes undesirable block in the hand, and is associated with delayed respiratory dysfunction when catheter-based infusions are used,[39] unlike continuous suprascapular block.[40,41] Low-volume interscalene block *per se* is another phrenic-sparing strategy that has been shown to decrease, but not abolish, the risk of phrenic nerve block.[36,42]

The scope of phrenic-sparing interscalene block alternatives is determined by the anatomy of innervation of the shoulder joint. The peripheral nerves relevant to shoulder surgery include the suprascapular, axillary, subscapular, and lateral pectoral nerves,[43] which are all distal branches of the C5 and C6 roots.[26,44] Our understanding of shoulder innervation has recently evolved[4,12] to downplay the original predominant role of the isolated suprascapular nerve that was depicted in the historical work of Gardner in 1948.[26] Indeed, we have come to realize that the posterior suprascapular block alone blocks only the posterior superior quadrant[26] of the shoulder joint, thus providing partial pain relief only. In fact, Cho *et al.*[45] recently pooled the results of 10 trials comparing posterior suprascapular nerve block to placebo. Their meta-analysis revealed this block is only marginally better than placebo; and its analgesic effects on 24-h pain scores and opioid consumption were not clinically important. In contrast, the subscapular nerve is now recognized as a major contributor to the anterior superior quadrant of the shoulder joint, while the axillary nerve innervates the inferior half of the joint.[12] This realization of the limited analgesic role of the posterior suprascapular block has prompted researchers to investigate supplementary blocks, such as supraclavicular[46] and infraclavicular[47] blocks, to combine with the posterior suprascapular block to match the analgesic effect of interscalene block. A superior trunk block *per se* may also be an option, but its proximity to the phrenic nerve and lack of knowledge of its respiratory effects favor more distal alternatives. In contrast, the suprascapular block, by virtue of its vicinity to the superior trunk,[15,16] is purported to be more effective than posterior suprascapular block.[13] Indeed, proximal spread involving the superior trunk was frequently observed when performing suprascapular block (fig. 1). Nonetheless, the clinical demonstration of this anatomical fact has been lacking until now. Arguably, the suprascapular block may exert its effect by spread of local anesthetics confined to the supraclavicular level of the brachial plexus, rather than proximal spread along the superior trunk. However, the supraclavicular block *per se* has already been shown to be inferior to interscalene block for postoperative analgesia after shoulder surgery.[41]

Our findings serve establishing the clinical benefits of single-injection suprascapular block in ambulatory arthroscopic shoulder surgery, and in clinically ascertaining the underlying analgesic mechanism by showing that suprascapular block consistently blocks the superior trunk innervating the shoulder. Several studies comparing suprascapular block techniques to interscalene block have been published;[48] but the vast majority of these trials examined the posterior suprascapular block, which has been shown to be inferior to interscalene block.[8–10] Of the three trials that examined anterior suprascapular block *per se*,[40,41,49] two[40,41] compared continuous (catheter-based) interscalene block to continuous anterior suprascapular block. The use of catheters in this comparison limits its generalizability to single-injection blocks. For technical, logistic, and financial reasons,[50] single-injection blocks are still used at numerous centers worldwide for arthroscopic shoulder surgery.[51–53] Furthermore, the first study examined patients having shoulder arthroplasty, a population with different severity of acute pain and analgesic requirements, and because it was focused on respiratory changes associated with these blocks, it was not powered to evaluate the block's analgesic effects.[40] The second trial primarily examined pain at 60 min (during postanesthesia care unit stay), but the use of catheters may explain the lower success rate of blocking the superior trunk (C6 dermatome).[41] The third study examined anterior suprascapular block in patients having shoulder arthroscopy and concluded noninferiority to interscalene block for pain control.[49] However, it used small local anesthetic volumes (10 ml), and had important methodologic limitations,[54] most notably including preoperative pain and block procedural pain scores in the area under the curve measurement of the block's analgesic effect, as well as the use of very scant postoperative time points (6 and 24 h) to construct this curve. Hence the analgesic effects of single-injection suprascapular block had yet to be elucidated.

Our trial has several strengths including its methodologic rigor, which included standardized training of anesthesiologists performing the blocks, central web-based

randomization method, allocation concealment, use of noninvasive sham blocks,[55,56] and the blinding of patients, anesthesiologists providing clinical care, and assessors. Our assessment of the success of patient blinding indicated that it was successfully maintained. Additionally, the multicentered and multiinvestigator nature of the study suggests that the results are generalizable across both academic and community hospitals. Finally, generalizability is enhanced by the use of multimodal analgesia for management of acute pain, reflecting mainstream contemporary practices.

Our trial also has some limitations. Our results may not be generalizable to shoulder arthroplasty, catheter-based blocks, or settings where blocks are used to provide surgical anesthesia. Moreover, while further work is needed to more definitively determine the minimum clinically important difference for the area under the curve of pain scores during the first 24 h after arthroscopic shoulder surgery, comparisons of the 6-h pain scores (where minimum clinically important difference has been better determined) also confirmed that the differences did not exceed the noninferiority margin. Thus, using area under the curve of pain scores served providing a comprehensive assessment of the patients' pain experience during the first 24 h after surgery. Additionally, our study did not include an assessment of respiratory function, but previous studies have already demonstrated the preservation of respiratory function with suprascapular block.[40,41] Finally, this study was not large enough to detect rare complications, and we did not assess respiratory function. However, the phrenic-sparing effect of suprascapular block has already been demonstrated.[40]

In conclusion, this trial demonstrated that single-injection suprascapular block is noninferior to interscalene block for providing effective postoperative analgesia and blocking shoulder joint innervation in patients undergoing arthroscopic shoulder surgery. These findings suggest that suprascapular block consistently blocks the superior trunk and establish it as a clinically attractive alternative to interscalene block.

Research Support

Supported by grant No. AHSC–AFP 11–2015 from the Alternate Funding Plan Innovation Fund, Ontario Ministry of Health and Long-Term Care (Toronto, Canada). Dr. Abdallah receives research time support from the Department of Anesthesiology and Pain Medicine and the Ottawa Hospital Research Institute, University of Ottawa (Ottawa, Canada). Dr. Wijeysundera is supported in part by a New Investigator Award from the Canadian Institutes of Health Research, an Excellence in Research Award from the Department of Anesthesia at the University of Toronto, and the Endowed Chair in Translational Anesthesiology Research at St. Michael's Hospital and University of Toronto (Toronto, Canada). Dr. Brull receives research time support from the Evelyn Bateman Cara Operations Endowed Chair in Ambulatory Anesthesia and Women's Health, Women's College Hospital (Toronto, Canada).

Competing Interests

Dr. Laupacis is a member of a Data Safety Monitoring Board of Novartis (Basel, Switzerland). Dr. Chan received an honorarium from Philips Healthcare (Amsterdam, The Netherlands). The other authors declare no competing interests.

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