Prospective Study

The Median Effective Volume of 0.375% Ropivacaine for Ultrasound-guided Anterior Suprascapular Nerve Block in Arthroscopic Shoulder Surgery

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Background: The suprascapular nerve (SSN) is an important nerve that contributes to shoulder joint sensation and movement. The anterior suprascapular nerve block (aSSNB) has the potential for noninferior analgesic effect compared with the interscalene block while preserving respiratory function. This study investigated the median effective volume (MEV) of 0.375% ropivacaine in aSSNB for analgesic effect among patients undergoing arthroscopic shoulder surgery.

Objectives: Our primary objective was the MEV. The secondary objectives included the 24 hour sufentanil consumption, 24 hour patient-controlled analgesia (PCA) presses, and incidences of diaphragm impairment.

Study Design: Prospective registered (ChiCTR2300070129), single-armed, volume-finding study.

Setting: This study was conducted in a tertiary, single center.

Methods: There were 23 patients who completed the study. Using an up-and-down process, patients enrolled in the study received different volumes of 0.375% ropivacaine for an aSSNB adjusted based on the success or failure of the previous patient in the study's block by increasing or decreasing the volume by 3 mL. The first patient received 15 mL of 0.375% ropivacaine. The nerve block's were evaluated by the sensory score of the C5 and C6 dermatomes.

Results: MEV50 (50% of the patients) was 6 mL (95% CI, 5.78 - 6.78 mL), and MEV95 (95% of the patients) was 13.88 mL (95% CI, 13.37 - 14.87 mL). There was no significant difference in the PCA presses, 24 hour sufentanil consumption, and incidences of diaphragm impairments between successful and unsuccessful blocks.

Limitations: Our study focused on the analgesic effect rather than hemi-diaphragmatic paralysis with 0.375% ropivacaine for an aSSNB. The study also did not test varying ropivacaine concentrations while keeping the volume constant. Further investigation with varying concentrations and a larger sample size is indicated to address the optimal volume and concentration to balance analgesia and diaphragm function.

Conclusions: To produce effective analgesic effect, the MEV50 is 6 mL, and the MEV95 is 13.88 mL in patients undergoing arthroscopic shoulder surgery who receive an aSSNB using 0.375% ropivacaine for analgesia.

Key words: anterior suprascapular nerve block, ultrasound-guided, median effective volume, dose finding, up and down procedure, postoperative analgesia, diaphragm movement, centered isotonic regression

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The analgesic gold standard for patients undergoing shoulder surgery is the interscalene block (ISB) (1). However, while the ISB provides good analgesic effect, it may cause hemi-diaphragmatic paralysis (h-DP) due to local anesthetics accidentally spreading to the phrenic nerve. The incidence of h-DP is reported to be up to 100% (2).

The suprascapular nerve (SSN) is an important nerve that contributes to shoulder joint sensation and movement. It originates from the C5 and C6 roots and then travels down the upper trunk of the brachial plexus (3). At the supraclavicular level, it branches off the upper trunk and travels under the omohyoid muscle. Before reaching the transverse scapular ligament, the articular branch separates from the SSN, innervating the coracohumeral ligament and the posterior acromioclavicular joint capsule (4). After the SSN reaches the top of the scapula, it travels under the transverse scapular ligament and through the suprascapular notch. The SSN then enters the supraspinous fossa and releases the muscular branches upwards and downwards, innervating the supraspinatus and infraspinatus muscles. The posterior shoulder joint is also innervated by this branch of the SSN (4).

The anterior suprascapular nerve block (aSSNB) was first reported by Siegenthaler et al (5). The SSN in the supraclavicular region is more superficial and easier to identify than in the supraspinous fossa, making it an easier target (6). A recent study showed that an aSSNB had a better analgesic effect than a posterior suprascapular nerve block (pSSNB) in arthroscopic surgeries (7). Another study showed that an aSSNB was noninferior to an ISB for analgesia in arthroscopic surgeries (8). However, it was reported that aSSNB had a higher incidence of h-DP than pSSNB (aSSNB 40% vs. pSSNB 2%) (6). Notably, these h-DP incidences were 76.3% in upper trunk blocks and 97.5% in ISBs (8).

We hypothesized that an aSSNB has the potential for a noninferior analgesic effect compared with an ISB, while preserving respiratory function. There have been cadaveric studies investigating aSSNB volume, but no volume studies in vivo (9). Our primary objective was the median effective volume (MEV) of 0.375% ropivacaine in an aSSNB in patients undergoing arthroscopic shoulder surgery. We conducted our study to explore the effective analgesic effect for MEV50 (50% of patients) and MEV95 (95% of patients). The secondary objectives were the 24 hour sufentanil consumption, 24 hour patient-controlled anesthesia (PCA) presses, and incidences of diaphragm impairment.

Methods

Our trial was prospectively registered in the Clinical Trial Registry of the People's Republic of China. Registry No. ChiCTR2300070129. The ethics committee chairperson is Jianping Gu. The trial was approved by the Ethics Committee of Nanjing First Hospital (Reference ID: KY20230116-01). The approval date was January 16, 2023.

Twenty-four patients undergoing shoulder arthroscopy were screened; one patient was excluded due to ischemic heart disease. All patients enrolled in the study had given their informed consent for participation in this research. Inclusion criteria were: scheduled for arthroscopic shoulder surgery, American Society of Anesthesiologists Physical Status Classification I-II, age between 18 - 70 years, and a body mass index (kg/m^2) between 18 - 30. Exclusion criteria were: injection site infection, sepsis, coagulation defects, local anesthetic allergy, uncontrolled hypertension, ischemic heart disease, a sequela of cerebral infarction, liver or renal failure, a history of surgery in the supraclavicular fossa, and the patient refusing to give consent.

Preoperative Preparation

Shoulder pain was assessed and recorded on an 11-point Numeric Rating Scale (NRS-11) from 0 to 10 preoperatively as the baseline. The aSSNB was conducted under standard monitor. All patients received one mg midazolam and 5 μg sufentanil for sedation. All patients were supine with a small pad underneath the shoulder and head turned toward the contralateral side in order to facilitate block site access.

Ultrasound-guided aSSNB

A single experienced anesthesiologist conducted all nerve blocks. An assistant recorded all the data in the anesthesia preparation room. These 2 were not involved in subsequent data collection in the operating room and postanesthesia care unit (PACU) evaluation. An independent observer unaware of the block volume conducted an assessment of the sensory and motor blocks. Ropivacaine 0.375% was used for all aSSNBs.

Under aseptic techniques, a linear probe (6 - 13MHz, Wisonic) was placed in parallel with the clavicle. The upper trunk of the brachial plexus was first confirmed, then the SSN branching off from the upper trunk was identified. The SSN was traced distally until it went underneath the omohyoid muscle, which was the ideal injection spot for our study. After the skin was infiltrated with 2% lidocaine, a 22G 2-inch block needle

(B. Braun Medical Inc.) was inserted in-plane from lateral to medial toward the SSN. The needle went through the omohyoid muscle and stopped at the lateral border of the SSN.

Local anesthetics were injected in divided doses after negative aspiration for blood. The first patient received a total volume of 15 mL based on previous reports (10,11). The spacing of the dosing volume change should be close to the standard deviation, which was 3.7 mL in our pilot study. We therefore applied 3 mL as our spacing volume based on the literature (12). If the block succeeded, we would decrease the volume by 3 mL for the next patient. If the block failed, we would increase the volume by 3 mL. The maximum volume was 60 mL to avoid local anesthetic toxicity; the minimum volume was 3 mL because the next staircase was 0 mL.

aSSNB Quality Assessment

An observer, blinded to the injection volume, conducted assessments on sensory and motor blocks every postinjection 5 minutes for 30 minutes.

Sensation to cold was evaluated over the C4 (top of shoulder), C5 (lateral shoulder), C6 (thumb and second finger), C7 (third finger), C8 (fourth and fifth fingers), and T1 (medial side of forearm) dermatomes, with the contralateral side as the control. Sensory testing was graded by a 3-point scale: 0 was no block, one was analgesia (patient could feel touch, but not cold), and 2 was anesthesia (patient could feel neither touch nor cold).

The motor block was evaluated over the C5 (abduction and extorsion of the shoulder), C6 (elbow flexion), C7 (elbow extension), C8 (thumb opposition), and T1 (finger adduction), compared with the contralateral side. The motor block was also evaluated by a 3-point scale: 0 was no block (normal movement), one was partial block (partial movement), and 2 was complete block (no movement). We considered a block to be successful if the sensory score of both C5 and C6 were equal to or greater than one. Otherwise, the block was considered a failure.

Perioperative Management

All patients received standard general anesthesia care during the intraoperative period, including sufentanil 0.5 μg/kg, propofol one mg/kg, and cisatracurium 0.2 mg/kg for induction and trachea intubation. Propofol 4 mg/kg/h and remifentanil 0.3 μg/kg/min were infused for maintenance, and titrated to keep heart rate and blood pressure within 20% of baseline. Flurbiprofen axetil 50 mg was injected for analgesia (flurbiprofen is not available as an injectable in the US, only an oral tablet). Dexamethasone 5 mg, tropisetron 2 mg (tropisetron is not approved for use in the US), and droperidol one mg were used to prevent postoperative nausea and vomiting. Bispectral index was maintained within 40 - 60. Oxycodone 0.6 mg/kg was injected during skin incision closure. The surgery's duration, propofol consumption, and remifentanil consumption were recorded.

Postoperative Management

Patients were transferred to the PACU after skin closure. Muscle relaxants were reversed using neostigmine 0.05 mg/kg, and atropine 0.025 mg/kg in the PACU before extubation. Postoperative pain was assessed using the NRS-11. Patients with an NRS-11 score > 4 received rescue analgesia using oxycodone one mg titrated until the NRS-11 score was 3 or lower. A PCA device with sufentanil was used for postoperative analgesia (volume 250 mL, concentration 0.6 μg/mL, continuous dose 3 mL/h, bolus 5 mL, lock time 8 minutes, maximum dose 35 mL/h). Patients could be discharged from the PACU if Aldrete's score was > 9. The NRS-11 scores at 0, 1, 2, 4, 8, 12, and 24 hours postextubation were recorded. Patients' total sufentanil consumption in 24 hours and times pressing the PCA button were also documented.

Diaphragm Function Assessment

Diaphragm function was assessed using an ultrasound technique. We placed a convex array probe (3.5-5Mhz, Wisonic) under the costal margin between the anterior axillary and the midclavicular line with patients placed supine. The liver on the right side and the spleen on the left side were used as acoustic windows to view the diaphragm. In M-mode, the craniocaudal movement of the diaphragm was documented as the patients were instructed to take deep breaths. Diaphragm movement was assessed before the aSSNB, 30 minutes post- aSSNB, 30 minutes postextubation in the PACU, 4 hours postblock, and 8 hours postblock. The h-DP was defined as a > 25% reduction in diaphragm movement measured under M-mode.

Statistical Analysis

The up-and-down procedure (UDP) as previously described by Dixon (12) was used in our study. An SD of 3.7 and standard error of the mean of 1.3 were established in our pilot test. According to the formula $n = 2(SD/SEM)^2$ for UDP design by Dixon and Massey (13), a

minimum of 17 patients were needed. We recruited 24 patients, thus meeting the stopping rules.

The stopping rules were defined as previously described, including: 3 consecutive patients at the upper bound of volume, 5 reversals occurred in any 6 consecutive patients, And 4 followed the first reversal and 2 likelihood ratios, which compare the MEV_{50} estimate with MEV_{50} values above and below, exceeding a critical value of 2.5 (14).

The MEV was calculated based on the Centered Isotonic Regression (CIR) package of R software (The R Foundation) (15). The probability of response was calculated by a pooled adjacent violators algorithm using the CIR package of R software. Data are shown as mean ± SD or median (interquartile range) for the continuous variables depending on the data distribution. The Mann-Whitney U test was used for skewed variables by R software.

Results

The Consolidated Standards of Reporting Trials (CONSORT) recruitment flow diagram is illustrated in Fig. 1. There were 24 patients enrolled in our study. Baseline characteristics are summarized in Table 1. The average age of patients were 54.21 ± 8.55 years old. There were no major clinical meaningful differences between patients who had a successful block those who had a failed block.

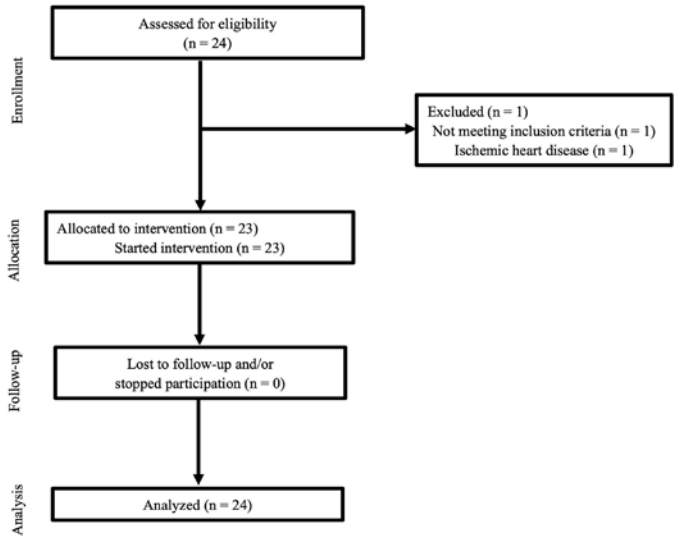

Fig. 1. *CONSORT flow diagram.*

The MEV of 0.375% Ropivacaine

The sequential block result of aSSNB is illustrated in Fig. 2. According to the isotonic regression algorithm, the MEV50 was 6 mL (95% CI, 5.78 - 6.78 mL), and MEV_{95} was 13.88 mL (95% CI, 13.37 - 14.87 mL) (Fig. 3). Response probability is shown in Table 2. The mean block duration of successful blocks was 13.54 ± 2.60 hours.

Postoperative Pain and PCA Consumption.

The NRS-11 score of successful blocks was significantly lower than failed blocks at 0, 2, 4, and 8 hours (P = 0.024, 0.048, 0.038, 0.034, respectively) (Fig. 4). There was no significant difference in the PCA presses and 24 hour sufentanil consumption between patients with successful and unsuccessful blocks (P = 0.059, 0.059, respectively) (Table 3).

Diaphragm Movement

The DM at different time points is shown in Table 4. There was no significant difference at all time points. Three out of 23 patients developed h-DP (the injection was 12 mL in 2 patients and 6 mL in one patient); DM in all 3 patients recovered within 8 hours.

Discussion

Our study on ultrasound-guided anterior suprascapular nerve block indicates that the MEV_{50} analgesic effect with 0.375% ropivacaine was only 6 mL, with a 95% CI of 5.78 - 6.78 mL. This is the first human study based on our best knowledge.

We chose 30 minutes postinjection as the time point to decide if the block was successful or not. Our study defined patients' sensory scores at both the C5 and C6 dermatomes at 30 minutes postinjection as successful analgesia because we focused on shoulder arthroscopy analgesia. Innervation of the glenohumeral joint capsule includes suprascapular, axillary, and subscapular nerves innervated by C5 and C6 (4).

In our study, we observed that several patients presented a delayed onset of C5/6 sensory block with < 6mL of volume injected. This may lead to an overestimation of the actual MEV. However, we believe that a 30 minute cutoff might provide a more clinically meaningful MEV for daily practice. Despite the different volumes (6 -15 mL) in successful blocks, 0.375% ropivacaine lasted for 13.54 ±

2.60 hours. The postoperative pain score after a successful block was significantly lower than an unsuccessful block at 0, 2, 4, and 8 hours. These data indicate that 0.375% ropivacaine provides a reliable analgesic effect for at least 8 hours. However, the 24 hour sufentanil consumption and PCA presses were not significant between the successful and unsuccessful block groups.

Previous volume studies of aSSNB have all been conducted on fresh cadavers with contrast medium dye instead of actual patients receiving local anesthetics. In accordance with other aSSNB studies, we decided to use an initial volume of 15 mL. Our study recruited 24 patients before meeting the stopping rule, which was based on a revised UDP design (14). The advantage of a UDP design over a fixed design is that the experimenter can decide

Table 1. *Demographic data of patients (n = 23).*

	Total (Mean ± SD)	Successful Blocks (Mean ± SD)	Failed Blocks (Mean ± SD)
Gender	10M/13W	5M/8W	5M/5W
Age	54.21 ± 8.55	53.3 ± 10.19	55.3 ± 6.18
Height (m)	1.64 ± 0.07	1.63 ± 0.07	1.65 ± 0.07
Weight (kg)	63.72 ± 8.65	63.15 ± 8.55	64.45 ± 9.19
BMI (kg/m^2)	23.61 ± 2.53	23.86 ± 2.46	23.54 ± 2.74
ASA Physical Status	I (10)/II (13)	I (5)/II (8)	I (5)/II (5)
Surgery time (min)	80.17 ± 26.51	78 ± 28.40	83 ± 25.03
HR (bpm)	69.00 ± 9.12	69.85 ± 11.03	67.9 ± 6.23
SPO_2 (%)	99.82 ± 0.49	99.77 ± 0.60	99.9 ± 0.32
Basic systolic pressure (mm Hg)	133.17 ± 21.31	127 ± 16.15	141.2 ± 25.23
Basic diastolic pressure (mm Hg)	72.56 ± 10.11	68.23 ± 7.37	78.2 ± 10.73
Type of surgery			
Rotator cuff repair	19	10	9
Acromioplasty	2	1	1
Subacromial decompression	2	2	0
Propofol consumption during surgery (mg)	420.61 ± 124.56	392.92 ± 102.16	456.6 ± 146.52
Remifentanil consumption during surgery (μg)	1665.22 ± 413.55	1643.85 ± 388.94	1693 ± 463.51
Time to extubate in PACU (min)	21.69 ± 5.12	21.69 ± 5.71	21.7 ± 4.55
Distance from SSN to BP (mm)	5.85 ± 2.18	6.42 ± 2.44	5.08 ± 1.41

ASA, American Society of Anesthesiologists; PACU, postanesthesia care unit; SSN, suprascapular nerve; BP, brachial plexus; data shown are mean ± SD, * represents $P < 0.05$ between successful and unsuccessful blocks

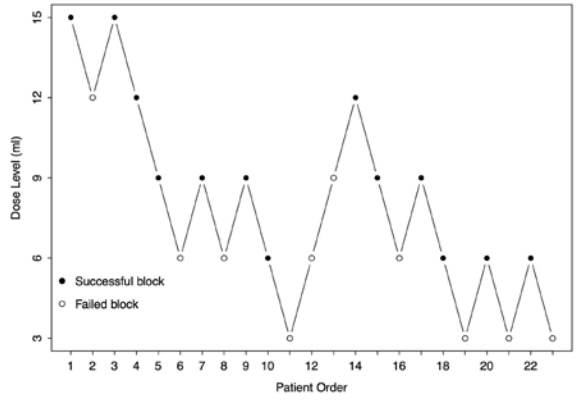

Fig. 2. *Sequential block results of anterior suprascapular nerve blocks with 0.375% ropivacaine using the up-and-down procedure*

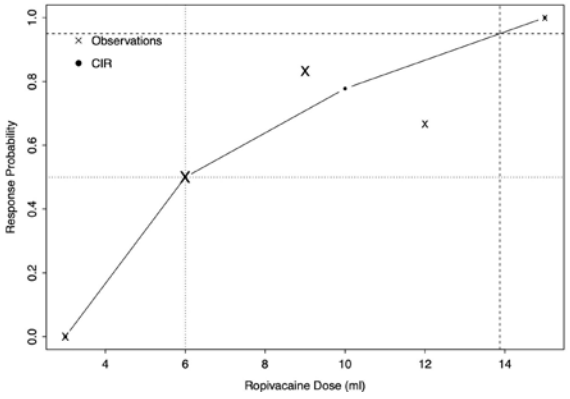

Fig. 3. *The dose-response curve of 0.375% ropivacaine was plotted by the Centered Isotonic Regression (CIR) algorithm in anterior suprascapular nerve blocks. "X" represents different doses of 0.375% ropivacaine injected. The size of the "X" gets bigger if more patients are injected with that dose. Dots and lines are calculated results of the CIR algorithm.*

Table 2. *Probability of response calculated by pooled adjacent violators algorithm.*

Dose (mL)	Probability of Response	Lower 95% CI	Upper 95% CI
3	0	0	0.49
6	0.5	0.21	0.78
9	0.7	0.39	0.89
12	0.87	0.48	0.96
15	1	0.53	1

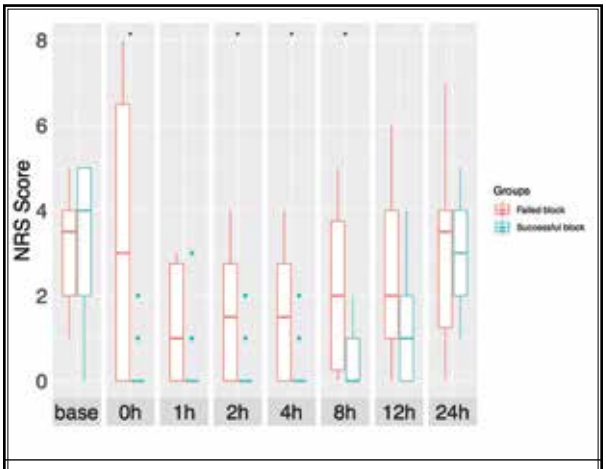

Fig. 4. *The boxplot of the Numeric Rating Scale (NRS) score in successful and failed blocks.*
Shoulder pain was assessed presurgery (baseline), and at 0, 1, 2, 4, 8, 12, and 24 hours postextubation. "*" represents $P < 0.05$

Table 3. *24 hour patient-controlled anesthesia presses and 24 hour sufentanil consumption.*

	Total	Successful Blocks	Failed Blocks
24 h PCA presses	3 (1.5 to 11)	2 (1.3 to 3)	11 (3 to 31)
24 h Sufentanil consumption (μg)	52.2 (47.7 to 76.2)	49.2 (47.0 to 56.7)	76.2 (52.2 to 136.2)

Data shown are median (interquartile range)

whether there are sufficient data points to perform the required analysis. The biased-coin design is also widely used to determine MEV in the anesthesia volume studies. We chose UDP because it is easier to perform and then easier to process by bootstrapping. We used CIR to calculate MEV_{50} rather than the method described by Dixon (13) because Dixon's formula can only calculate MEV_{50} while bootstrapping can plot a dose-response curve of a certain object.

Shoulder joint innervation knowledge keeps progressing. It was thought the suprascapular nerve consisted of 70% of a shoulder's sensation (16). A study comparing aSSNB, pSSNB, and ISB showed that p-SSNB only provided partial analgesia (7). Anatomy studies have shown that not only suprascapular, but axillary, subscapular, and lateral pectoral nerves are also involved in the innervation of shoulder joints (4,17,18). A recent study showed that the analgesic effect of an aSSNB is noninferior to an ISB because an aSSNB can block the suprascapular nerve and the upper trunk of the brachial plexus (8). Cadaveric studies have supported this idea since 3 mL of contrast medium dye can spread to the upper trunk (19). As the volume increases, solutions may spread to the middle and lower trunk and even the phrenic nerve, causing unwanted effects.

A cadaveric study used methylene blue for an aSSNB and reported that MEV90 without affecting the phrenic nerve is 4.2 mL (19). However, 4.2 mL in our study was not enough to reach even MEV_{50} for analgesia. In our research, MEV_{90} of 0.375% Ropivacaine for analgesia is 12.75 mL. It is likely that more patients in our study were actually experiencing local anesthetics diffused around the phrenic nerve without having a clinically meaningful reaction. Another cadaveric study also reported a 20% chance of the specimen having blue dye around the phrenic nerve with a 10 mL ropivacaine and methylene blue mixture (9). Their follow-up study showed that 10 mL of 0.375% ropivacaine had a 40% chance of developing h-DP (6). In our study, h-DP was observed in 2 patients who received 12 mL, and even if we reduced the volume to 6 mL, one patient still experienced h-DP. A decrease in the volume could reduce the risk of h-DP while an increase risks a failed block, based on our study and additional literature. Nonetheless, a smaller volume of 0.375% ropivacaine should be considered when conducting an aSSNB.

Our study focused on the analgesic effect rather than h-DP with 0.375% ropivacaine for an aSSNB. Further investigation with a larger sample size is indicated to address the optimal volume to balance analgesia and diaphragm function. Another limitation is that our study lacked varying ropivacaine concentrations while keeping the volume constant. The calculated MEV in our study applies only for 0.375% ropivacaine. Ropivacaine concentration may also affect the MEV and diaphragm function, which deserves further study to validate.

Conclusions

In summary, our study shows an analgesia MEV_{50}

of 6 mL and MEV_{95} of 13.88 mL for ultrasound-guided aSSNB in patients undergoing arthroscopic shoulder surgery using 0.375% ropivacaine. A high incidence of h-DP can be expected when injecting 13.88 mL.

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