A Prospective, Randomized, Controlled Trial Comparing Ultrasound Versus Nerve Stimulator Guidance for Interscalene Block for Ambulatory Shoulder Surgery for Postoperative Neurological Symptoms

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BACKGROUND: Visualization with ultrasound during regional anesthesia may reduce the risk of intraneural injection and subsequent neurological symptoms but has not been formally assessed. Thus, we performed this randomized clinical trial comparing ultrasound versus nerve stimulator-guided interscalene blocks for shoulder arthroscopy to determine whether ultrasound could reduce the incidence of postoperative neurological symptoms.
METHODS: Two hundred thirty patients were randomized to a standardized interscalene block with either ultrasound or nerve stimulator with a 5 cm, 22 g Stimuplex® insulated needle with 1.5% mepivacaine with 1:300,000 epinephrine and $NaCO_3$ (1 meq/10 mL). A standardized neurological assessment tool (questionnaire and physical examination) designed by a neurologist was administered before surgery (both components), at approximately 1 wk after surgery (questionnaire), and at approximately 4–6 weeks after surgery (both components). Diagnosis of postoperative neurological symptoms was determined by a neurologist blinded to block technique.
RESULTS: Two hundred nineteen patients were evaluated. Use of ultrasound decreased the number of needle passes for block performance (1 vs 3, median, $P < 0.001$), enhanced motor block at the 5-min assessment ($P = 0.04$) but did not decrease block performance time (5 min for both). No patient required conversion to general anesthesia for failed block, and patient satisfaction was similar in both groups (96% nerve stimulator and 92% ultrasound). The incidence of postoperative neurological symptoms was similar at 1 wk follow-up with 11% (95% CI of 5%–17%) for nerve stimulator and 8% (95% CI of 3%–13%) for ultrasound and was similar at late follow-up with 7% (95% CI of 3%–12%) for nerve stimulator and 6% (95% CI of 2%–11%) for ultrasound. The severity of postoperative neurological symptoms was similar between groups with a median patient rating of moderate. Symptoms were primarily sensory and consisted of pain, tingling, or paresthesias.
CONCLUSIONS: Ultrasound reduced the number of needle passes needed to perform interscalene block and enhanced motor block at the 5 min assessment; however, we did not observe significant differences in block failures, patient satisfaction or incidence, and severity of postoperative neurological symptoms.
(Anesth Analg 2009;109:265–71)

Ultrasound guidance for regional anesthesia has increased in popularity. A recent systematic review of randomized controlled trials (RCTs) comparing ultrasound guidance with conventional techniques[1] noted similar efficacy between ultrasound guidance versus nerve stimulator when regional anesthesia was performed by experts. However, the ability of ultrasound to dynamically visualize needle placement to avoid intraneural contact and injection of local anesthetic may offer a greater safety margin to avoid neurological injury after peripheral nerve blocks.[2] Although nerve stimulator guidance is the current technique of

This article has supplementary material on the Web site: www.anesthesia-analgesia.org.

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Accepted for publication January 8, 2009.

Supported by the Department of Anesthesiology, Hospital for Special Surgery.

Spencer S. Liu is the Section Editor of Pain Medicine for the Journal. This manuscript was handled by Terese T. Horlocer, Section Editor of Regional Anesthesia, and Dr. Liu was not involved in any way with the editorial process or decision.

Presented in part at the annual meeting of the American Society of Regional Anesthesia, Cancun, Mexico, May 2, 2008.

Reprints will not be available from the author.

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DOI: 10.1213/ane.0b013e3181a3272c

choice, it may have suboptimal ability to detect intraneural needle placement. Both laboratory and clinical studies suggest that use of a minimal nerve stimulator current threshold (e.g., mA = 0.3–0.5) as a cutoff to detect intraneural needle placement and subsequent increased risk for neurological injury may be neither sensitive nor specific.[3–5]

Interscalene blocks are commonly performed to provide anesthesia and analgesia for shoulder surgery but have a comparatively frequent incidence of postoperative neurological symptoms.[6] Incidences of postoperative neurological symptoms within the first week after interscalene block for shoulder surgery typically range from 4% to 16%.[7–9] The etiology of these postoperative neurological symptoms is unclear, and permanent nerve injury after shoulder arthroscopy appears to be rare (approximately 0.1% to 0.2% without specifications on type of anesthesia).[7,8] Nonetheless, the frequent initial incidence of this distressing complication led us to compare ultrasound versus nerve stimulator-guided interscalene blocks for shoulder arthroscopy to determine whether ultrasound could reduce the incidence of postoperative neurological symptoms at 1 wk after surgery.

METHODS

After obtaining approval by our IRB to conduct this prospective, randomized clinical trial, 230 patients scheduled to undergo an outpatient shoulder arthroscopy under interscalene block and sedation gave written, informed consent. Exclusion criteria were age younger than 18 or older than 75 yr and typical contraindication to interscalene block including patient refusal, pregnancy, dementia, severe pulmonary disease, and known preexisting neurological disorders involving the operative limb.

Each subject underwent a standardized sensory and motor neurological evaluation and physical examination to determine baseline neurological function (Appendix 1, available at: www.anesthesia-analgesia.org). This tool was prospectively designed by our neurologist coinvestigator (TS), who subsequently trained two coinvestigators to administer this tool (VB and JN). Patients were then randomized to either ultrasound guidance or nerve stimulator guidance for interscalene block with a computer-generated random number table, using a sealed envelope sequence, and with the sequence concealed until after the enrollment of the subject.

Each subject was placed supine with the usual American Society of Anesthesiologist monitors. Midazolam up to 5 mg was used for sedation at the discretion of the anesthesiologist to allow comfort and cooperation from the patient. The "interscalene area" was prepared with an antiseptic solution. The time to complete each block (from needle insertion to final needle withdrawal) and number of needle movements (each forward movement of the needle after halting or retracting until acquisition of end point) was recorded by an investigator not performing the block.

Nerve Stimulator Group

A 5 cm, 22 g Stimuplex® insulated needle (B Braun Medical, Bethlehem, PA) was placed into the interscalene groove with the bevel oriented parallel to the groove. The initial settings for the nerve stimulating unit were a current of 0.6–1.5 mA at 2 Hz. A motor response in the distribution of the axillary, musculocutaneous, ulnar, radial, or median nerve was accepted as evidence of correct needle placement. The current was decreased to a range between 0.2 mA and 0.5 mA while maintaining a motor response. If a motor response was still evident at a current $<$0.2 mA or more than 0.5 mA, the needle placement was adjusted accordingly. This range of stimulation end points was meant to reflect common practice and has been used in several previous large surveys and RCTs of nerve stimulator-guided interscalene blocks for shoulder surgery.[9–12]

After a 1 mL test dose to exclude severe pain or resistance on injection, local anesthetic was injected in divided doses with frequent aspiration. If pain or resistance with injection was evident, the needle placement was adjusted accordingly. For patients below 50 kg, a total dose of 45–55 mL was used. For patients $\geq$50 kg, a total dose of 55–65 mL was used. The local anesthetic consisted of mepivacaine 1.5% with 1:300,000 epinephrine and $NaCO_3$ (1 meq/10 mL).

Ultrasound-Guided Group

A linear 10–13 MHz ultrasound probe was used to visualize the brachial plexus. Initial ultrasound visualization was at the interscalene area. If the brachial plexus was not well visualized, then the probe was repositioned at the supraclavicular fossa, the brachial plexus visualized, and the probe tracked cephalad to follow the brachial plexus to the interscalene area. A 5 cm, 22 g Stimuplex® insulated needle (B Braun Medical) was placed through the middle scalene muscle, into the interscalene groove, and adjacent to the brachial plexus via in-plane ultrasound guidance to visualize the entire needle with the bevel oriented parallel to the interscalene groove. After a 1 mL test dose to exclude obvious intraneural injection, local anesthetic was injected in divided doses with frequent aspiration under ultrasound visualization. If intraneural injection or resistance to injection was observed at any time, then the needle was repositioned, and this observation was recorded. Type and dose of local anesthetic was identical to the nerve stimulator group.

After block placement, the patient was positioned in the beach chair position for surgery. Sensory and motor block were evaluated by an investigator (VB or JN) who was aware of type of block. Motor block was evaluated by testing deltoid motor function and biceps motor function on a 0 (no movement), 1 (weak), and 2 (normal) scale every 5 min until a score of 0 was

reached or surgery commenced. Sensory function was evaluated at the same time in the distribution of the median nerve ("money sign")[13] using a 0 (numb), 1 (dysesthesia), and 2 (normal) scale. Upon commencement of surgery, the anesthesiologist who performed the block rated the effectiveness for surgical anesthesia on a scale of 2 (complete), 1 (adequate), and 0 (inadequate). A block was considered successful if rescue general anesthesia was not required.

After surgery, patients were discharged from the postanesthesia care unit using our standard discharge criteria.

The patients were contacted by telephone at 1 wk after surgery and the same neurological questionnaire (Appendix 1) was administered by VB or JB. Upon surgical follow-up (usually at 4–6 wk postoperatively), the patient was again evaluated with the same neurological questionnaire and physical examination (Appendix 1) administered by VB or JB. Results from neurological testing were recorded and compared with baseline by our neurologist coinvestigator (TS), who was blinded to interscalene block technique. Postoperative neurological symptoms were defined as neurological symptoms within the operative site brachial plexus that were related to brachial plexus irritation but were unrelated to the surgical procedure as determined by our neurologist TS. Symptoms involving the axillary or suprascapular nerves were considered to be potentially related to the surgical procedure[8,14] and were not considered to be postoperative neurological symptoms. Patients were asked to rate overall severity of postoperative neurological symptoms as mild = barely noticeable, moderate = definitely noticeable, or severe = very preoccupied. All patients with postoperative neurological symptoms were offered a complete neurological evaluation and standard diagnostic testing (e.g., nerve conduction velocities, electromyography) by TS to define the cause and determine prognosis of postoperative neurological symptoms. Any patient with postoperative neurological symptoms at each follow-up was followed monthly by phone until resolution of symptoms, until lost to follow-up or submission of this manuscript.

Statistics

Power Analysis

The largest series from Borgeat et al.[11] found an approximately 16% incidence of postoperative neurological symptoms at 1 wk after the nerve stimulator technique for interscalene block. No studies have evaluated the incidence of postoperative neurological symptoms with the use of ultrasound for interscalene block. Direct ultrasound visualization of the brachial plexus and block needle throughout the block would theoretically prevent any intraneural injection and should potentially decrease the risk of postoperative neurological symptoms. Thus, we assumed that the risk of postoperative neurological symptoms with ultrasound guidance was similar to the lowest previous rate of postoperative neurological symptoms of approximately 4% at 1 wk follow-up.[15] Power analysis indicated a sample size of 109 patients in each group was needed to detect a difference (4% vs 16%) between techniques ($\alpha = 0.05$, $\beta = 0.8$). To compensate for expected dropouts, we planned to enroll 230 patients. Analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC). χ^2 was used to compare rates of postoperative neurological symptoms between groups and for other incident data. Continuous variables were compared with t test or Wilcoxon's rank sum for nonparametric data. Because each group had a large sample size (>100), according to the central limit theorem, the sample proportion was approximately normally distributed. Thus, confidence intervals for the incidences and for the relative risks were calculated based on the normal theory tests.[16]

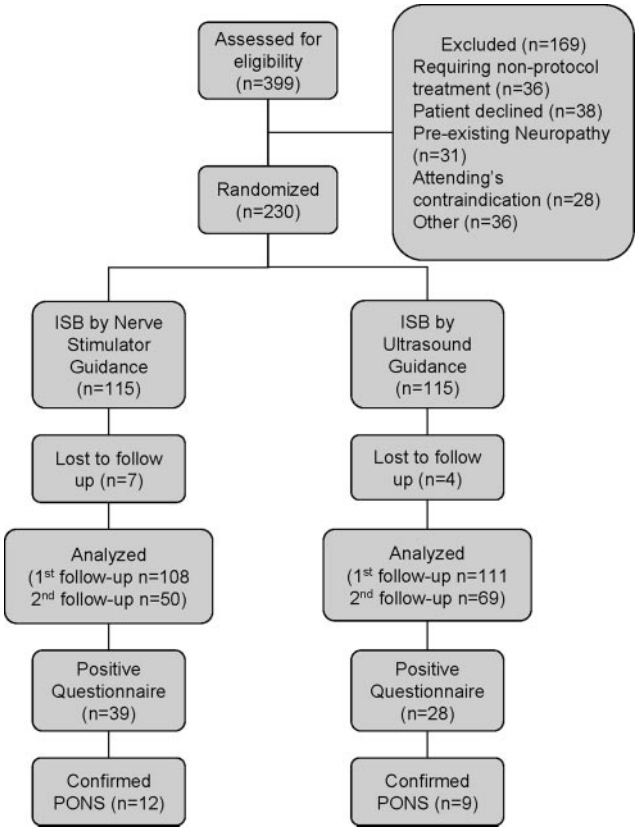

Figure 1. CONSORT diagram of patient flow through study protocol.

RESULTS

Figure 1 displays the CONSORT flow of patients through the study protocol. Demographics were similar between groups (Table 1). Two hundred nineteen patients were available for early follow-up (nerve stimulator = 108 and ultrasound = 111), and all analyses were based on intent to treat for these patients. Perioperative characteristics are displayed in Table 2. Use of ultrasound significantly decreased the number of needle passes (1 vs 3, median, $P < 0.001$)

Table 1. Patient Demographics

	Nerve stimulator	Ultrasound
Age	49 ± 14	48 ± 16
Height	174 ± 10	173 ± 9
Weight (kg)	85 ± 24	86 ± 34
Body mass index	28 ± 7	29 ± 11
Shoulder arthroscopy procedure types		
Diagnostic	4	1
Rotator cuff repair	40	41
Stabilization	8	9
Acromioclavicular joint resection	4	3
Debridement	7	9
Labral repair	19	23
All decompressions	23	23
Other	3	2

Table 2. Perioperative Characteristics

	Nerve stimulator	Ultrasound
Needle passes* (median/mode)	3 (1)	1 (1)
Time to perform block (min)	5 ± 3	5 ± 3
Accentuation on injection	22 (20%)	26 (23%)
History of diabetes	4 (4%)	6 (5%)
Attending/trainee	26/82	40/71
Postoperative pain at needle site	23 (21%)	16 (14%)
Satisfaction	96%	92%
Definite PONS assessment at 1 wk	12 (11%)	9 (8%)
Pons severity at 1 wk (median/mode); 1 = mild; 2 = moderate 3 = severe	2 (2)	2 (1)
Definite PONS assessment at late follow-up	8 (7%)	7 (6%)
Pons Severity at 4 wk (median/mode); 1 = mild; 2 = moderate 3 = severe	1.5 (1)	1 (1)

PONS = postoperative neurological symptoms.

* Different between groups, $P < 0.05$.

compared with the nerve stimulator, but time to perform blocks was similar (5 min for both groups). Motor block at the biceps was enhanced ($P = 0.04$) at the 5-min assessment for ultrasound (Fig. 2). No patient required conversion to general anesthesia for failed block. The number of patients who were satisfied with anesthesia was similar between groups (96% nerve stimulator and 92% ultrasound, Table 2). The incidence of postoperative neurological symptoms was similar at 1 wk follow-up with 11% (95% CI of 6%–18%) for nerve stimulator and 8% (95% CI of 4%–15%) for ultrasound and was similar at late follow-up with 7% (95% CI of 3%–13%) for nerve stimulator and 6% (95% CI of 3%–12%) for ultrasound. Tables 3 and 4 display individual characteristics of patients with postoperative neurological symptoms. The relative risk for postoperative neurological symptoms at 1-wk follow-up was not statistically significant at 1.37 (nerve stimulator versus ultrasound) with 95% CI of 0.6–3.1. The relative risk for postoperative neurological symptoms at late follow-up was not statistically significant at 1.2 (nerve stimulator versus ultrasound) with 95% CI of 0.4–3.1. The severity of postoperative neurological symptoms was similar in both groups with a median self-report of moderate (Tables 2–4). All patients declined to return to the hospital for formal diagnostic evaluation by our neurologist coinvestigator.

DISCUSSION

Our primary finding was that the use of ultrasound guidance did not significantly reduce the incidence or severity of postoperative neurological symptoms after interscalene block for outpatient shoulder arthroscopy when compared with a nerve stimulator technique. Real-time visualization with ultrasound has been proposed to improve the safety of peripheral nerve blocks due to the ability to avoid intraneural needle placement,[5,17] whereas other techniques may often result in unintentional intraneural placement.[18] Despite this theoretical advantage, ultrasound was not associated with a significant reduction in postoperative neurological symptoms within the framework of our study. A potential reason is that we used a fixed two-dimensional cross-sectional image plane on the ultrasound, thus a similar rate of neural contact may have occurred due to the inability to fully visualize all three planes in real time. In addition, common clinical steps, such as monitoring for difficult injection or complaints of pain upon injection,[19] were included for both techniques and may have narrowed a potential difference between groups.

Our study examined the efficacy of anesthesia as secondary outcomes. Use of ultrasound guidance reduced the number of needle passes and provided more complete motor block at the 5 min assessment. This is in agreement with most previous RCTs comparing the two techniques. However, block success was not improved with the use of ultrasound, as no patient required conversion to general anesthesia due to failed block. This is likely explained by the already high-success rate of interscalene block with a nerve stimulator (97%–99%) in experienced hands,[10–12] thus there may be little room for improvement with the use of ultrasound. One other RCT recently compared nerve stimulator versus ultrasound specifically for interscalene block.[20] This study reported greater block success for surgical anesthesia with ultrasound (99% vs 91%). However, clinical applicability of the study technique may be limited, as multiple needle passes under real-time ultrasound visualization were performed to ensure complete spread of local anesthetic around the nerve roots of C5-T1. Such a technique may require more skill than most clinicians possess,

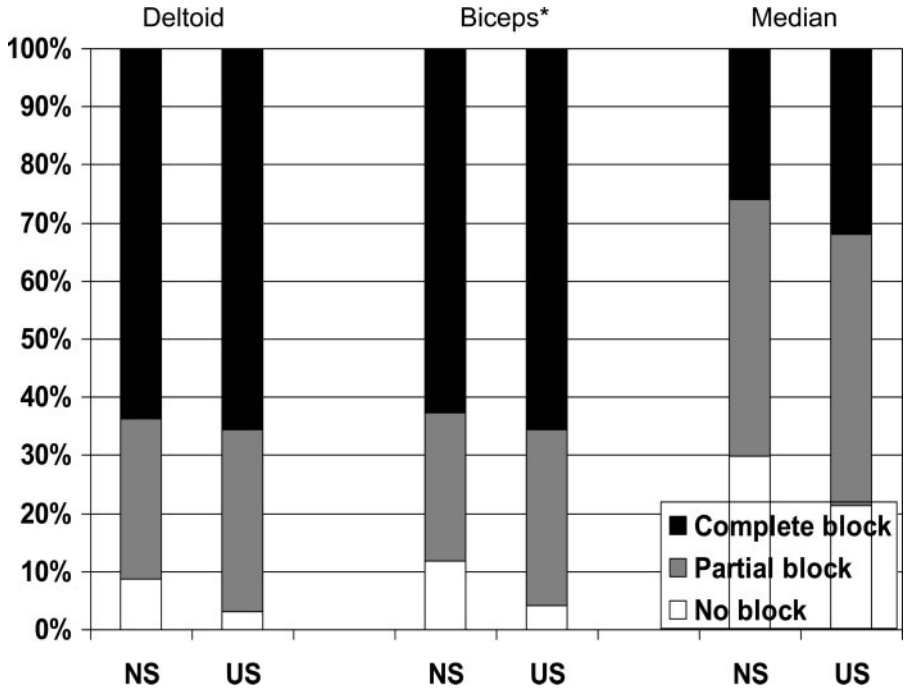

Figure 2. Evidence of sensory or motor block at 5 min. NS = nerve stimulator group. US = ultrasound group. * = different between groups, $P = 0.04$.

Table 3. Nerve Stimulator Patients with Postoperative Neurological Symptoms (PONS)

Patient no.	Location of twitch	Location of accentuation with injection	Location of PONS	Description of PONS	Procedure type	PONS severity (early/late)	Duration of PONS
1	Deltoid	Shoulder	Arm and hand	Tingling	Rotator cuff Repair	Severe/–	3 days
2	Fingers-radial	None	Tips of fingers	Parasthesias	Diagnostic	Moderate/moderate	Continues (17 mo)
11	Deltoid	None	Wrist and fingers	Pain and weakness	Decompression	Mild/mild	Continues (17 mo)
30	Trapezius, phrenic, triceps	Neck	Elbow and shoulder	Pain	Decompression	Moderate/moderate	3 mo
55	Trapezius, deltoid	Neck	Hand, upper arm	Parasthesia and pain	Decompression	Moderate/mild	4 mo
97	Deltoid	Neck, shoulder, and upper arm	Biceps and shoulder	Tightness	Stabilization	Moderate/mild	Continues (11 mo)
107	Biceps, deltoid	None	Mid-arm to shoulder and neck	Pain	Rotator cuff	Severe/–	1 wk
150	Triceps	None	Fingers and hand, biceps	Tingling fingers, pain in biceps	Rotator cuff	Mild/–	2 wk
173	Triceps	None	Triceps, deltoid, scapula	Pain	Decompression	Moderate/moderate	Continues (7 mo)
179	Trapezius, biceps	Biceps	Ring, pinky fingers	Parasthesia	Rotator cuff	Mild/–	3 days
193	Deltoid	None	Fingertips	Tingling	Labral repair	Mild/mild	Continues (6 mo)
210	Trapezius, triceps	Neck	Fingertips, neck, shoulder	Tingling fingers; pain elsewhere	Debridement	Severe/severe	Continues (5 mo)

which was noted in an accompanying editorial.[21] In contrast, our methodology probably more closely resembles common clinical practice. Similar to previous RCTs,[1] we noted no difference inpatient satisfaction between the two techniques despite the reduced needle passes with ultrasound guidance. This somewhat surprising finding may be related to the lack of validated tools to assess perioperative satisfaction,[22] use of amnestics before block performance or the relatively high-skill levels of operators for both techniques in the published RCTs.

There are several limitations to our study. The incidence of postoperative neurological symptoms in our control group was within the range of those previously reported by Borgeat et al.[11,12] (8%–14% at 10 days postoperative), which adds external validity to our findings. However, there is no standard definition for postoperative neurological symptoms and

Table 4. Ultrasound Patients with Postoperative Neurological Symptoms (PONS)

Patient no.	Location of accentuation with injection	Location of PONS	Description of PONS	Procedure type	PONS severity (early/late)	Duration of PONS
5	None	Up and down arm	Pain and weakness	Labral repair	Severe/severe	Continues (17 mo)
17	Neck and shoulder	Arm and hand	Pins and needles	Rotator cuff repair	Mild/mild	3 mo
66	None	Scapula, biceps	Scapula pain, weak Bicep	Rotator cuff repair	Moderate/mild	3 mo
82	None	Biceps	Pain	Labral repair	Moderate/mild	Continues (12 mo)
83	None	Armpit, upper bicep	Tingling several minutes at a time	Rotator cuff repair	Mild/mild	12 mo
118	None	Shoulder to elbow	Pain	Labral repair	Moderate/–	1 wk
135	Between elbow and shoulder	Wrist to elbow	Pain	Labral repair	Mild/mild	3 mo
155	None	Fingers, arm	Tingling and pain postoperative diagnosis of CRPS	Labral repair	Moderate/moderate	Continues (7 mo)
168	None	Wrist, fingertips, thumb	Tingling	Labral repair	Mild/–	3 days

CRPS = Complex regional pain syndrome.

incidences vary depending on measurement tool and time of assessment (incidences decrease with time). Our incidences of postoperative neurological symptoms were similar, but not identical, for the nerve stimulator and ultrasound. We note that our 95% confidence intervals do not suggest a significant clinical difference between groups and that a power analysis based on our results indicates that a follow-up RCT would require approximately 3000 subjects.*

Finally, we used postoperative neurological symptoms as a surrogate measure for neurological injury after interscalene block for shoulder arthroscopy. We considered postoperative neurological symptoms to be a reasonable primary end point, as symptoms are clinically neurological in nature, relatively frequent, distressing to the patient, and have been well established as an outcome for clinical studies.[9–11] However, the exact pathophysiology of postoperative neurological symptoms is unclear. We cannot exclude a non-regional anesthesia etiology for postoperative neurological symptoms, as we did not include a general anesthesia only group in our study. Other proposed etiologies for postoperative nerve injury after shoulder arthroscopy include patient position,[23] compression due to fluid extravasation,[8] amount of traction,[7] selection of arthroscopy ports,[14] or toxic effects of local anesthetics.[24]

In conclusion, we observed that ultrasound guidance for interscalene block does not appear to offer major advantages over nerve stimulator guidance. The use of ultrasound reduced the number of needle passes needed to perform the block; however, we did not observe significant differences in block failures, patient satisfaction or incidence, and severity of postoperative neurological symptoms.

*The power analysis was conducted with Power Analysis and Sample Size (PASS) software (NCSS, Kayesville, UT) with a target alpha 0.05. With 80% power, 1499 subjects per group are needed to detect a 3% difference. The sample size calculation is based on the normal theory tests.[19]

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