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A 3-arm randomized clinical trial comparing interscalene blockade techniques with local infiltration analgesia for total shoulder arthroplasty

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Background: The ideal analgesic modality for total shoulder arthroplasty (TSA) remains controversial. We hypothesized that a multimodal analgesic pathway incorporating continuous interscalene blockade (ISB) provides better analgesic efficacy than both single-injection ISB and local infiltration analgesia.
Methods: This single-center, parallel, unblinded, randomized clinical trial evaluated 129 adults undergoing primary TSA. Patients were allocated to single-injection ISB, continuous ISB, or local infiltration analgesia. The primary outcome was the Overall Benefit of Analgesia Score (range, 0 [best] to 28 [worst]) on postoperative day 1. Additional outcomes included pain scores, opioid consumption, quality of life, and postoperative complications in the first 24 hours, at 3 months, and at 1 year.
Results: We analyzed 125 patients (42 with single-injection ISB, 41 with continuous ISB, and 42 with local infiltration analgesia). The Overall Benefit of Analgesia Score was significantly improved in the continuous group (median [25th percentile, 75th percentile], 0 [0, 2]) compared with the single-injection group (2 [1, 4]; $P = .002$) and local infiltration analgesia group (3 [2, 4]; $P < .001$). Pain scores were significantly lower in the continuous group compared with the local infiltration analgesia group ($P < .001$ for all time points) and after 12 hours from ward arrival compared with the single-injection group (median [25th percentile, 75th percentile], 1.0 [0.0, 2.8] vs. 2.5 [0.0, 4.0]; $P = .016$). After postanesthesia recovery discharge, opioid consumption (oral morphine equivalents) was significantly lower in the continuous group (median [25th percentile, 75th percentile], 7.5 mg [0.0, 25.0 mg]) than in the local infiltration analgesia group (30 mg [15.0, 52.5 mg]; $P < .001$) and single-injection group (17.6 mg [7.5, 45.5 mg]; $P = .010$). No differences were found across groups for complications, 3-month outcomes, and 1-year outcomes.

This study was approved by our Institutional review board (No. 15-009646; Mayo Clinic, Rochester, MN, USA).
This study was registered at ClinicalTrials.gov (NCT02876055; https://clinicaltrials.gov/ct2/show/NCT02876055; August 23, 2016).

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Conclusion: Continuous ISB provides superior analgesia compared with single-injection ISB and local infiltration analgesia in the first 24 hours after TSA.
Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Interscalene nerve block; local infiltration analgesia; total shoulder arthroplasty; pain management; OBAS; SF-12 score; ASES score

Total shoulder arthroplasty (TSA) may result in severe postoperative pain, particularly in the first 48 hours after surgery.[37] While multimodal analgesia protocols incorporating interscalene blockade (ISB) are associated with a reduction in pain scores,[14,22] alternative pain-relieving techniques such as local infiltration analgesia (synonymous with periarticular injection) have recently emerged.[7,16] However, the possibility of these newer techniques replacing ISB as an integral component of a multimodal clinical pathway for TSA needs to be further investigated.[7,9,36]

Continuous ISB through an indwelling nerve catheter is considered the most effective modality to treat moderate to severe pain after major shoulder procedures given its ability to provide profound and extended analgesia.[21,37] Despite this, operator experience, increased procedure time, and infection risk are a few of the drawbacks precluding its ubiquitous use. In addition, continuous ISB is not universally accepted by orthopedic surgeons. A 2013 survey revealed that only 15% of surgeons elected for continuous ISB whereas 59% elected for single-injection ISB and 26% elected for no peripheral nerve block.[23]

The goal of this investigation was to compare the analgesic efficacy of 3 techniques (single-injection ISB, continuous ISB, and local infiltration analgesia) after TSA using the Overall Benefit of Analgesia Score (OBAS) (Table I). This unique, multidimensional pain assessment tool evaluates pain intensity, opioid-induced side effects, and patient satisfaction.[17] We hypothesized that within a multimodal analgesic pathway, continuous ISB would result in a lower OBAS, indicating greater analgesic benefit, compared with single-injection ISB and local infiltration analgesia on postoperative day (POD) 1.

Materials and methods

We conducted a 3-arm, parallel, outcome adjudicator–blinded, superiority, randomized clinical trial in adult patients (aged $\geq$ 18 years) undergoing elective, unilateral, primary TSA (anatomic or reverse TSA) between November 2016 and February 2018 at a single academic center. All patients provided written consent to participate, and this study was completed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[31]

Study patients

All adult patients with an American Society of Anesthesiologists physical classification of I to III scheduled for primary TSA and meeting the study criteria were randomized to 1 of 3 interventions (Fig. 1): (1) single-injection ISB, (2) continuous ISB, or (3) local infiltration analgesia. Patients were excluded if they had a documented history of chronic pain syndrome (eg, fibromyalgia or complex regional pain syndrome); chronic opioid use defined as greater than 30 mg of oral morphine equivalents (OMEs)/day for less than 1 month or greater than 5 mg of OMEs/day for 1 month or longer; body mass index greater than 45 kg/m^2; allergy to study medications; history of malignant hyperthermia; major systemic illness such as renal insufficiency (estimated glomerular filtration rate $<$ 50 mL/min), cardiac insufficiency (congestive heart failure with New York Heart Association class III to IV), liver disease (acute hepatic failure or cirrhosis), or moderate to severe pulmonary disease (use of home oxygen, preoperative baseline oxygen saturation $<$ 94% on room air, forced expiratory volume in 1 second $<$ 60% of predicted value); contralateral hemidiaphragm dysfunction or phrenic nerve injury; contraindication to regional anesthesia (eg, neuropathy or coagulopathy); previous contralateral TSA managed with regional anesthesia or local infiltration analgesia within the past 12 months; or impaired cognition and if they were known to be pregnant or actively breastfeeding.

Potential study subjects were identified from the operative calendar of 2 fellowship-trained orthopedic surgeons with special interest in shoulder arthroplasty surgery. During the preoperative clinic visit, a trained study coordinator reviewed the informed-consent documentation with patients and enrolled those eligible for participation. Given the potential for history and physical examination changes in the period between study enrollment and the procedure date, randomization occurred on the day of surgery after the patient's anesthesiologist performed a preoperative evaluation and verified eligibility for any of the 3 potential therapeutic options.

A computer-generated randomization schedule was prepared by a statistician (D.R.S.) using a block size of N = 6; after every sixth patient was enrolled, a 1:1:1 allocation ratio was maintained to ensure an equal representation of each treatment arm over time. The randomization was concealed from the investigators through central randomization. To avoid loss of concealment, the group to which the patient was allocated could only be accessed after the patient was deemed eligible. Patients, health care providers, and data collectors were not masked to group allocation. However, outcome adjudicators were blinded to the prospectively collected data.

Table I OBAS questionnaire*

1. Please rate your current pain at rest on a scale between 0 = minimal pain and 4 = maximum imaginable pain.
2. Please grade any distress and bother from vomiting in the past 24 h: 0 = not at all to 4 = very much.
3. Please grade any distress and bother from itching in the past 24 h: 0 = not at all to 4 = very much.
4. Please grade any distress and bother from sweating in the past 24 h: 0 = not at all to 4 = very much.
5. Please grade any distress and bother from freezing in the past 24 h: 0 = not at all to 4 = very much.
6. Please grade any distress and bother from dizziness in the past 24 h: 0 = not at all to 4 = very much.
7. How satisfied are you with your pain treatment in the past 24 h? 0 = not at all to 4 = very much.

OBAS, Overall Benefit of Analgesia Score.
The OBAS was calculated using the following equation: OBAS = (Sum of scores for question 1 through question 6) + (4 – Score for question 7). The OBAS ranges from 0 (best) to 28 (worst); a low score indicates high benefit.
* Used with written permission from Elsevier.[17]

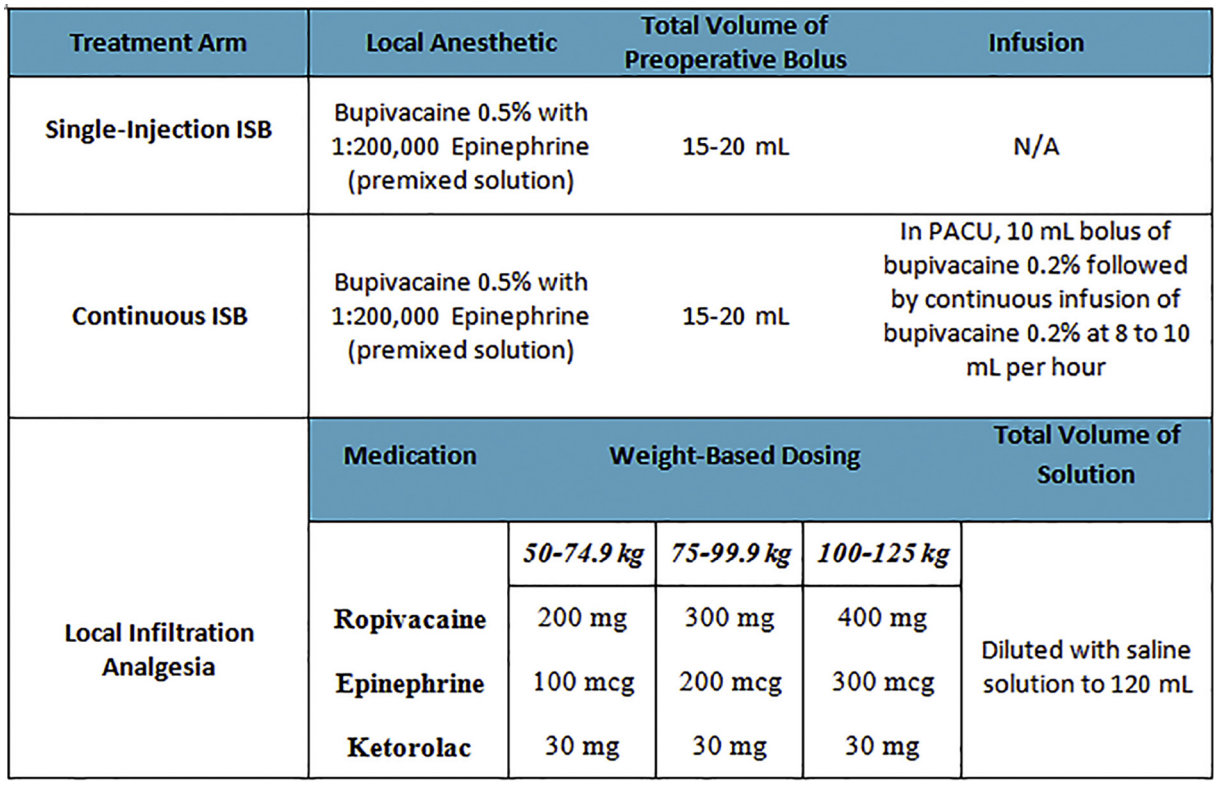

Figure 1 Total shoulder arthroplasty intervention groups. *ISB*, interscalene blockade; *N/A*, not applicable; *PACU*, postanesthesia care unit.

Anesthetic and surgical technique

All patients were administered a standardized multimodal analgesia total joint pathway (Fig. 2). Intraoperative anesthetic management involved general endotracheal anesthesia with standard American Society of Anesthesiologists monitoring, and all patients received 8 mg of intravenous (IV) dexamethasone. Intraoperative opioids, antiemetic prophylaxis, and additional intraoperative monitoring (eg, arterial line) were used at the discretion of the attending anesthesiologist.

All shoulder arthroplasties were performed through a deltopectoral approach. Deep exposure was obtained through a subscapularis tenotomy when the subscapularis tendon was still intact. Two implants were used in the study: Comprehensive (Zimmer Biomet, Warsaw, IN, USA) (91 shoulders) and ReUnion (Stryker, Mahwah, NJ, USA) (34 shoulders). All humeral components were fixed without cement. At the end of the procedure, the subscapularis tendon was repaired in all anatomic shoulder arthroplasties; it was also repaired in all reverse shoulder arthroplasties whenever possible.

Peripheral nerve block

Technique

All peripheral nerve blocks were performed prior to induction of anesthesia by anesthesiologists specialized in regional anesthesia or by residents or fellows under direct supervision of a regional

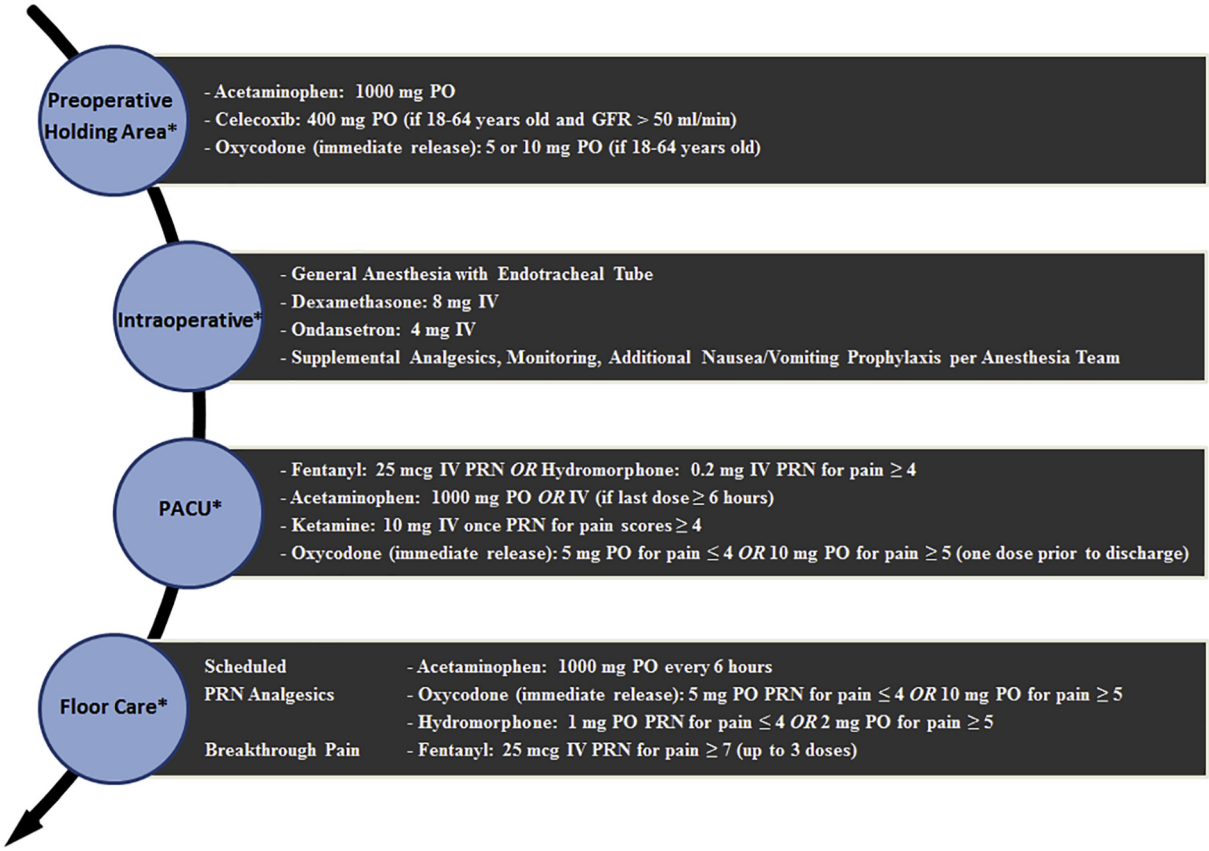

Figure 2 Multimodal analgesia total joint pathway. *Preoperative holding area, intraoperative, and postanesthesia care unit (*PACU*) medication administration is at the discretion of the anesthesiologist, whereas floor care medication administration is at the discretion of the orthopedic surgical team. The medications listed are the recommended analgesic options for each patient. Pain scores listed refer to the numeric rating scale from 0 to 10. *PO*, orally; *GFR*, glomerular filtration rate; *IV*, intravenous; *PRN*, as needed.

anesthesiologist. After an IV line was established, patients were provided oxygen and light sedation with IV midazolam (1-4 mg) and fentanyl (50-200 μg).

An ultrasound-guided ISB was performed with the patient in the supine position, the head inclined approximately 30° to 45°, and the neck turned to the nonoperative side. After aseptic skin preparation with chlorhexidine and draping, a linear HFL38, 6- to 13-MHz ultrasound transducer (X-Porte; SonoSite, Bothell, WA, USA) was placed over the interscalene region to visualize the brachial plexus between the anterior and middle scalene muscles in the short-axis view.[8] Under continuous live ultrasound guidance, an 18-gauge 50-mm (2-inch) Contiplex Tuohy needle (B. Braun, Bethlehem, PA, USA) (continuous ISB group) or 22-gauge 50-mm (2-inch) Stimuplex needle (B. Braun) (single-injection ISB group) was advanced via an in-plane or out-of-plane approach to the posterolateral border of the interscalene groove, located between the middle scalene muscle and brachial plexus fascial sheath (peri-plexus approach).[34] In cases with unclear or atypical anatomic findings under ultrasound, a combined nerve stimulator and ultrasound guidance technique was used. Appropriate needle positioning was verified by visualizing the spread of normal saline solution, 0.9%, within the interscalene groove at the level approximately between the C5 and C6 nerve roots of the brachial plexus.

In the continuous ISB group, a nonstimulating Perifix catheter (B. Braun) was advanced 1 to 2 cm beyond the needle tip within the interscalene groove, and the catheter-tip position was verified by the spread of normal saline solution, 0.9%, injected through the catheter. After successful positioning, the catheter was secured with Dermabond (Ethicon, Somerville, NJ, USA); Mastisol (Ferndale IP, Ferndale, MI, USA); and a clear, occlusive sterile dressing used to cover the catheter insertion site.

Dosing

The local anesthetic solutions used for each block are displayed in Figure 1. The initial loading dose for the continuous ISB group was administered through the nerve catheter, and the infusion rate (between 8 and 10 mL/h) was at the discretion of the operating room anesthesiologist and, subsequently, the inpatient pain service. The catheter was discontinued on the morning of POD 1.

Assessment

Patients in the single-injection and continuous ISB groups underwent sensory examination testing to determine block success. Sensation to cold over the ipsilateral deltoid muscle (where 0 indicates absent or diminished and 1 indicates at baseline) was

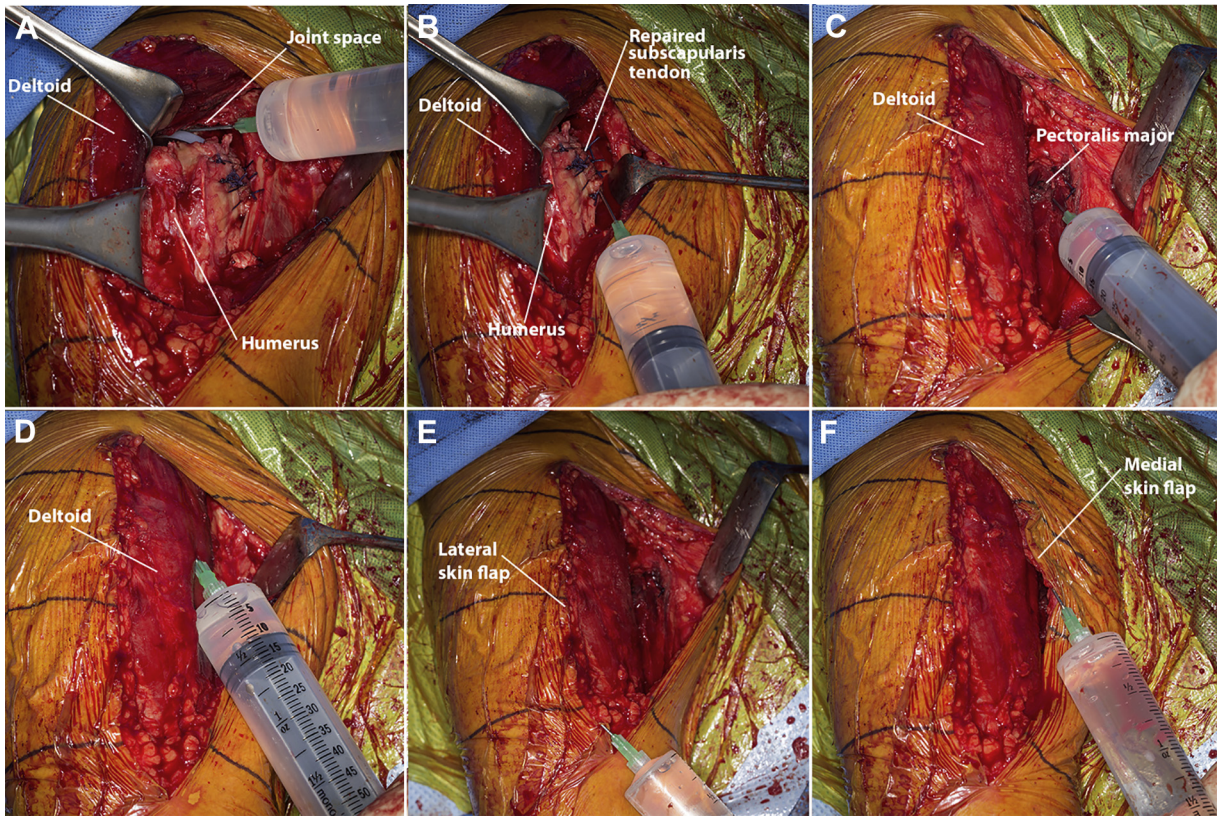

Figure 3 Local infiltration analgesia weight-based ropivacaine solution injected into posterior rotator cuff (**A**), subscapularis (**B**), pectoralis major (**C**), deltoid (**D**), and subcutaneous layers of lateral and medial skin flaps (**E**, **F**).

assessed at least 25 minutes after block placement if time permitted or in the postanesthesia care unit (PACU). A successful block placement was defined as having a rating of 0 on sensory testing.

Local infiltration analgesia group

The local infiltration analgesia group received a weight-based ropivacaine injection solution (Fig. 1). The injection technique was standardized and systematically performed by layers. Half of the volume was injected into the posterior shoulder capsule and posterior rotator cuff, subscapularis, conjoined tendon, and pectoralis major (Fig. 3). The second half of the volume was injected into the deltoid and subcutaneous tissues of the medial and lateral skin flaps. Care was taken to inject along the whole length of these structures by puncturing them in multiple locations a few centimeters apart.

Postoperative management

Postoperatively, all study patients were managed similarly (Fig. 2). Per institutional policy, continuous ISB group patients underwent continuous pulse oximetry monitoring and were co-managed by both the orthopedic surgery team and an anesthesia acute pain service team, which comprised a regional anesthesiologist, anesthesia resident, and trained nursing staff. This service provides 24-hour in-hospital coverage with daily patient rounding to act on potential concerns associated with continuous local anesthetic infusion.

Primary and secondary outcomes

The primary outcome was the OBAS on POD 1. This score was collected by a trained research assistant (N.T.V.N.) who interviewed the participants on POD 1 between 9 AM and noon; to account for variation in patient surgical times, patients with earlier surgical times were seen closer to 9 am whereas patients with later surgical times were seen closer to noon. The OBAS is a validated tool measuring a patient's experience with his or her postoperative pain regimen (Table I).[17] In brief, this simple 7-question scoring system (question 1 to question 7) entails a combination of pain intensity, adverse opioid events, and patient satisfaction. The total OBAS is calculated as follows: (Sum of scores for question 1 through question 6) + (4 – Score for question 7).[17] This score consists of a 29-point scale ranging from 0 (best) to 28 (worst); therefore, a lower OBAS indicates greater analgesic benefit. During this evaluation, the aforementioned research assistant (N.T.V.N.) also obtained the pain score at rest and patient recall of worst pain since surgery using a numeric rating scale (NRS) from 0 (no pain) to 10 (worst possible pain).

Secondary outcome measures were collected from routine clinical documentation by nursing, anesthesia, and surgical care teams. These outcomes consisted of NRS pain scores (0-10 scale) every 4 hours from the PACU to POD 1 at noon, opioid consumption (measured in OMEs) during the perioperative period until POD 1 at noon, length of hospital stay, and reason for

hospital length of stay greater than 1 night (ie, social work, inadequate pain control, nausea and/or vomiting, or other). Additional outcome measures included complications associated with the regional anesthesia block or local infiltration analgesia (eg, local anesthetic systemic toxicity), as well as catheter-related complications (eg, infection or catheter dislodgment).

At 12 to 16 weeks postoperatively, a follow-up encounter evaluating chronic pain and health-related quality of life was conducted by our study coordinators via a telephone call or office visit. Patients reporting an NRS pain score greater than 3 were asked to complete the validated Leeds Assessment of Neuropathic Symptoms and Signs (LANSS); an LANSS score of 12 or greater indicates pain of neuropathic origin.[6] Health-related quality of life was assessed with the Medical Outcomes Study 12-Item Short Form (SF-12), a standardized and validated questionnaire, collected preoperatively and at the 12- to 16-week postoperative mark.[38] The American Shoulder and Elbow Surgeons (ASES) score was collected preoperatively and at the 1-year postoperative follow-up,[30] and reoperations and readmissions were evaluated during the 1-year postoperative period.

Sample size

The sample size for this study was calculated for the primary endpoint of the OBAS on POD 1. On the basis of a previous study that used the OBAS as the primary endpoint,[24] a difference of 3 or greater was considered clinically relevant and the standard deviation was assumed to be 3.0. On the basis of this assumption, an effective sample size of n = 39 per group provides statistical power of greater than 90% to detect a difference between groups of 3 units using a 2-sided test with $P < .017$ (multiple comparison adjusted for 3 pair-wise group comparisons) used to denote statistical significance. To accommodate attrition of approximately 10% (due to canceled surgery, patient dropout, and other reasons), a total sample size of N = 129 (43 patients per group) was chosen.

Statistical analysis

Data are presented as mean ± standard deviation or median (25th percentile, 75th percentile) for continuous variables and as frequency counts and percentages for categorical variables. For the primary endpoint of the OBAS on POD 1, pair-wise treatment group comparisons were performed using the Wilcoxon rank sum test with $P < .017$ (Bonferroni adjusted) used to denote statistical significance. Primary analysis was based on an intention-to-treat principle. Similar analyses were performed for secondary endpoints of NRS pain scores and opioid consumption at predefined intervals until POD 1 at noon.

Postoperative complications were compared across all 3 groups simultaneously using the Fisher exact test. Hospital length of stay was compared across treatment groups using the Kruskal-Wallis test. The SF-12 was completed at baseline and 3-month follow-up. For each treatment group, the physical and mental composite scale score change from baseline was compared with 0 using the paired t test, and scores were compared across groups using analysis of variance. NRS pain scores at 3 months were compared across groups using the Kruskal-Wallis test. Current opioid use at 3 months and problems since surgery were compared across groups using the Fisher exact test. The ASES functional assessment was completed at baseline and 1 year and scored using published guidelines.[30] For each treatment group, the visual analog scale (VAS) pain score and the ASES total score change from baseline to 1 year were compared with 0 using the paired t test and the scores were compared across groups using analysis of variance. Because baseline scores differed significantly across groups, a supplemental analysis of the change from baseline was performed using analysis of covariance with the baseline value included as a covariate. All calculated P values were 2-sided. For analyses comparing across all 3 treatment groups simultaneously, $P < .05$ was considered statistically significant. For pair-wise treatment group comparisons, $P < .017$ (Bonferroni adjusted) was considered statistically significant. The statistical analysis was performed using SAS software (version 9.4; SAS Institute, Cary, NC, USA).

Results

Between November 2016 and February 2018, 129 patients undergoing elective, unilateral, primary TSA (anatomic or reverse TSA) were randomized to 1 of the 3 interventions (n = 43 per group) (Fig. 4). Of the 129 patients randomized, 4 did not receive the allocated treatment. A blinded, 3-person adjudication committee, unbiased from treatment or outcome, was created.[11] The committee unanimously determined that these 4 patients did not fulfill the protocol's initial inclusion criteria (Fig. 4). The final sample size of 125 patients (42 in the single-injection ISB group, 41 in the continuous ISB group, and 42 in the local infiltration analgesia group) was used for intention-to-treat analysis. There were no significant differences in baseline patient characteristics (Table II). The indications for surgery included primary osteoarthritis in 59 shoulders, rotator cuff tear arthropathy or massive irreparable cuff tear in 58, sequelae of trauma in 5, capsulorrhaphy arthropathy in 2, and rheumatoid arthritis in 1. All patients in the single-injection ISB and continuous ISB groups reported loss of sensation to cold over the deltoid muscle after the peripheral nerve block procedure. In the continuous ISB group, the use of 1 catheter was intentionally discontinued because of shortness of breath and 1 catheter was inadvertently dislodged.

Primary outcome: OBAS on POD 1

OBAS values on POD 1 are summarized in Table III. The continuous ISB group demonstrated significantly lower OBAS values than the single-injection ISB group (median [25th percentile, 75th percentile], 0 [0, 2] vs. 2 [1, 4]; $P = .002$) and local infiltration analgesia group (0 [0, 2] vs. 3 [2, 4]; $P < .001$).

Postoperative pain scores

NRS pain scores were significantly lower in the continuous ISB and single-injection ISB groups than in the local

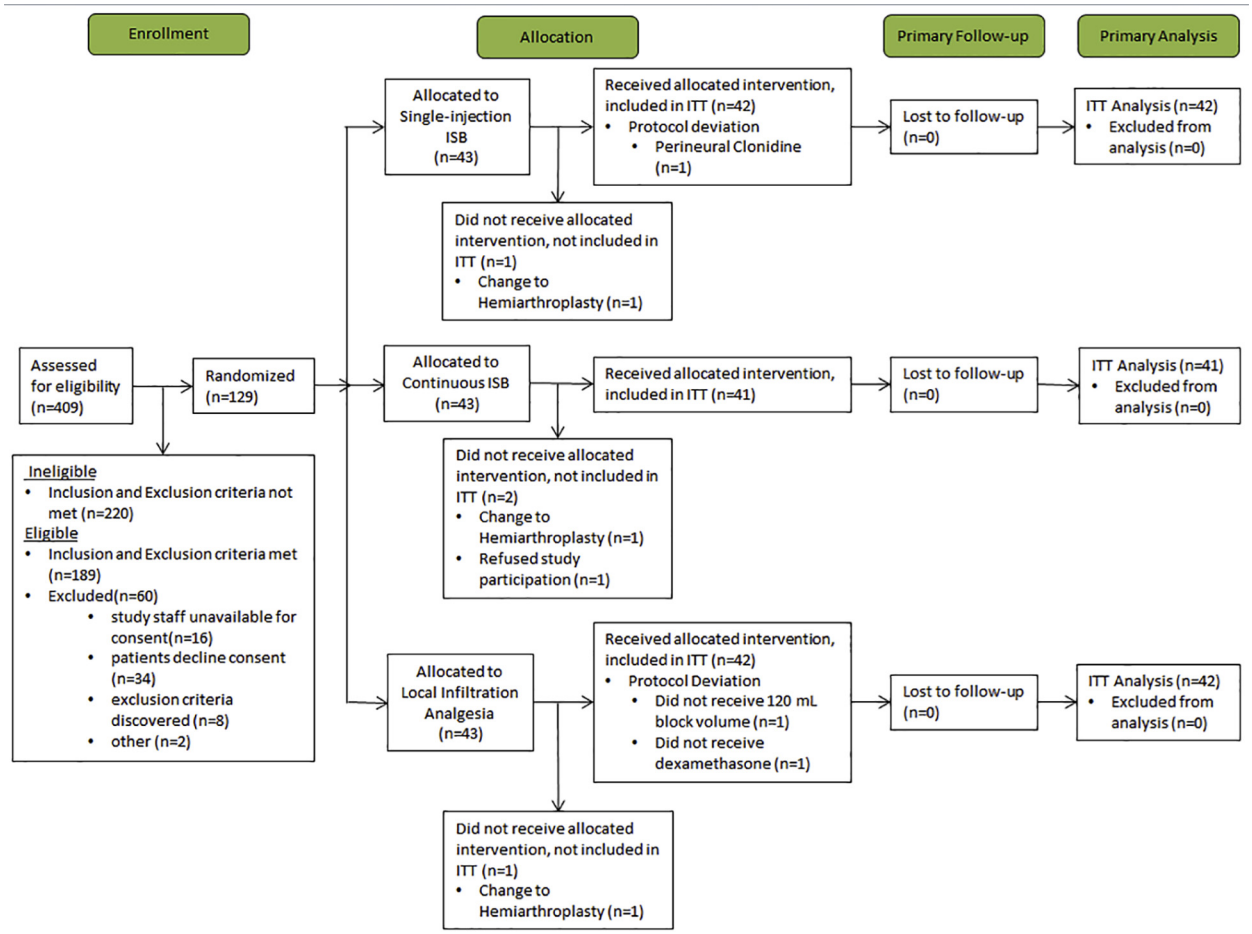

Figure 4 Consolidated Standards of Reporting Trials flow diagram. *ISB*, interscalene blockade; *ITT*, intention to treat.

Table II Patient and procedural characteristics

Characteristic	Local infiltration analgesia (n = 42)	Single-injection ISB (n = 42)	Continuous ISB (n = 41)	*P* value*
Age, mean ± SD, yr	69.5 ± 8.9	67.8 ± 13.1	68.1 ± 10.1	.750
Sex, n (%)				.413
Male	25 (60)	20 (48)	19 (46)	
Female	17 (40)	22 (52)	22 (54)	
BMI, mean ± SD, kg/m^2	30.9 ± 5.0	30.3 ± 5.2	30.2 ± 5.7	.830
ASA status, n (%)				.950
I or II	27 (64)	28 (67)	26 (63)	
III	15 (36)	14 (33)	15 (37)	
Operative shoulder				.199
Right	19 (45)	20 (48)	26 (63)	
Left	23 (55)	22 (52)	15 (37)	
Technique				.072
Anatomic	12 (29)	22 (52)	19 (46)	
Reverse	30 (71)	20 (48)	22 (54)	
Duration of surgery, mean ± SD, min	75.0 ± 15.6	71.6 ± 15.9	68.9 ± 13.5	.175

ISB, interscalene blockade; *SD*, standard deviation; *BMI*, body mass index; *ASA*, American Society of Anesthesiologists.
* Groups were compared using analysis of variance for continuous variables and the χ^2 test for categorical variables.

Table III OBAS and postoperative pain*

	Local infiltration analgesia (n = 42)	Single-injection ISB (n = 42)	Continuous ISB (n = 41)	Pair-wise comparison		
				Local infiltration analgesia vs. single-injection ISB	Local infiltration analgesia vs. continuous ISB	Single-injection ISB vs. continuous ISB
Primary outcome						
OBAS (total score)†	3 (2, 4)	2 (1, 4)	0 (0, 2)	.542	<.001	.002
Secondary outcome‡	‡	‡	‡			
Postoperative pain in PACU						
Average	4.3 (1.9, 6.0)	0.0 (0.0, 1.0)	0.0 (0.0, 2.5)	<.001	<.001	.689
Maximum	6 (2, 8)	0 (0, 2)	0 (0, 4)	<.001	<.001	.482
Last pain score	3 (1, 4)	0 (0, 2)	0 (0, 2)	<.001	<.001	.884
Pain after arrival to ward						
0-4 h	3.1 (2.0, 5.0)	0.4 (0.0, 2.0)	0.0 (0.0, 2.3)	<.001	<.001	.686
4-8 h	3.7 (3.0, 4.5)	0.5 (0.0, 3.0)	0.0 (0.0, 2.3)	<.001	<.001	.626
8-12 h	3.5 (2.0, 5.5)	1.0 (0.0, 3.0)	0.0 (0.0, 2.0)	<.001	<.001	.132
12-16 h	4.0 (2.0, 5.0)	2.5 (0.0, 4.0)	1.0 (0.0, 2.8)	.017	<.001	.016
Pain assessment at noon on POD 1						
Current pain at rest	3 (2, 5)	3 (1, 4)	0 (0, 3)	.280	<.001	.003
Worst pain since surgery	7 (5, 9)	4 (2, 6)	1 (0, 4)	<.001	<.001	<.001

OBAS, Overall Benefit of Analgesia Score; *ISB*, interscalene blockade; *PACU*, postanesthesia care unit; *POD*, postoperative day.

* Data are presented as median (25th percentile, 75th percentile) with pair-wise treatment group comparisons performed using the rank sum test.

† The total OBAS is calculated as follows: (Sum of scores for question 1 through question 6) + (4 – Score for question 7).

‡ For postoperative pain assessment, the number of patients with data available at the given time points varies from 39 to 42 for local infiltration analgesia, from 38 to 42 for single-injection ISB, and from 37 to 41 for continuous ISB.

infiltration analgesia group from the PACU up to 16 hours after arrival to the ward ($P \leq .017$ for all time points) (Table III). NRS pain scores were significantly lower for the continuous ISB group (median [25th percentile, 75th percentile], 1.0 [0.0, 2.8]) compared with the single-injection ISB group (2.5 [0.0, 4.0]; $P = .016$) during the 12- to 16-hour period after arrival to the ward. Furthermore, the continuous ISB group reported significantly lower NRS pain scores at rest and lower recall of worst NRS pain scores on POD 1 compared with the single-injection ISB and local infiltration analgesia groups.

Opioid consumption

During the intraoperative period, opioid administration was significantly greater in the local infiltration analgesia group (median [25th percentile, 75th percentile], 75 mg [65.0 mg, 90.0 mg] of OMEs) than in the single-injection ISB and continuous ISB groups (45 mg [30.0 mg, 60.0 mg] of OMEs; $P < .001$ for single-injection ISB and continuous ISB) (Table IV). Similarly, opioid administration was significantly greater in the PACU for the local infiltration analgesia group (30 mg [0.0 mg, 52.5 mg] of OMEs) compared with the single-injection ISB and continuous ISB groups (0 mg [0.0 mg, 0.0 mg] of OMEs and 0 mg [0.0 mg, 8.0 mg] of OMEs, respectively; $P < .001$ for single-injection ISB and continuous ISB). After PACU discharge until POD 1 at noon, the continuous ISB group consumed significantly fewer opioids (7.5 mg [0.0 mg, 25.0 mg] of OMEs) than the single-injection ISB group (17.6 mg [7.5 mg, 45.5 mg] of OMEs; $P = .010$) and local infiltration analgesia group (30 mg [15.0 mg, 52.5 mg] of OMEs; $P < .001$). Rescue IV opioid administration during hospitalization was not different across groups.

Hospital outcomes

No statistically significant differences in the length of hospital stay and adverse events were found between the 3 groups (Table V). A total of 15 patients (7 with single-

Table IV Opioid use (OMEs)*

Period	Local infiltration analgesia (n = 42), mg in OMEs	Single-injection ISB (n = 42), mg in OMEs	Continuous ISB (n = 41), mg in OMEs	Pair-wise comparison		
				Local infiltration analgesia vs. single-injection ISB	Local infiltration analgesia vs. continuous ISB	Single-injection ISB vs. continuous ISB
Preoperative	7.5 (7.5, 15.0)	7.5 (7.5, 7.5)	7.5 (0.0, 7.5)	.404	.018	.085
Intraoperative	75.0 (65.0, 90.0)	45.0 (30.0, 60.0)	45.0 (30.0, 60.0)	<.001	<.001	.810
PACU	30.0 (0.0, 52.5)	0.0 (0.0, 0.0)	0.0 (0.0, 8.0)	<.001	<.001	.280
After PACU to noon on POD 1	30.0 (15.0, 52.5)	17.6 (7.5, 45.5)	7.5 (0.0, 25.0)	.066	<.001	.010

OME, oral morphine equivalent; *ISB*, interscalene blockade; *PACU*, postanesthesia care unit; *POD*, postoperative day.
* Doses of each opioid-containing medication were converted to equivalent milligram doses of oral morphine. Data are presented as median (25th percentile, 75th percentile) with pair-wise treatment group comparisons performed using the rank sum test.

injection ISB, 3 with continuous ISB, and 5 with local infiltration analgesia) were hospitalized for greater than 1 night: 13 patients stayed because of social work issues, 1 patient (continuous ISB) requested to stay an extra night despite meeting the discharge criteria, 1 patient (single-injection ISB) stayed because of pain, and no patients required an extended stay for block-related issues. In 2 patients (1 with single-injection ISB and 1 with continuous ISB), subjective dyspnea occurred after regional anesthetic block placement; however, in the patient in the continuous ISB group, the use of the catheter was discontinued early to prevent further exacerbation. Transient neurapraxia occurred in 2 patients in the continuous ISB group: 1 patient complained of numbness and pain in the median and radial nerve distribution of the hand on POD 1, which improved on removal of the arm sling, and another patient complained of wrist drop shortly after discharge from the hospital, with full recovery after 6 weeks. No formal neurologic testing was performed in either case. In the local infiltration analgesia group, atrial fibrillation developed in 1 patient requiring intensive care unit admission, and another patient experienced a witnessed fall.

Three-month outcomes

All 3 groups displayed significant improvement in the SF-12 physical composite scale score from baseline to 3 months postoperatively, but there was no statistically significant difference across groups (Table VI). The continuous ISB group demonstrated a statistically significant improvement in the SF-12 mental composite scale score from baseline to the 3-month follow-up; however, there was no statistically significant difference across groups. NRS pain scores at rest and with movement, infection, persistent pain, continued opioid use, and neurologic changes of the operative extremity were not different across groups. At the 3-month follow-up, no patient scored 12 or greater on the LANSS examination assessing for neuropathic pain.

One-year outcomes

Shoulder arthroplasty resulted in substantial improvements in pain and function in all 3 groups (Table VII). After adjustment for baseline score differences, the change from baseline to the 1-year follow-up for VAS pain and ASES scores did not demonstrate statistically significant differences across groups ($P = .903$ and $P = .196$ for VAS pain score and ASES total score, respectively). At the 1-year follow-up, no patient required a reoperation or readmission.

Discussion

This study provides evidence that continuous ISB in combination with multimodal analgesia provides greater analgesic benefit in the first 24 hours after TSA compared with both single-injection ISB and local infiltration analgesia. In addition, patients in the continuous ISB group used significantly fewer opioids and reported lower pain intensity scores throughout the perioperative period compared with the other 2 groups. Although continuous ISB achieved modestly better results among the analgesic outcomes, the benefits we found in the immediate perioperative period did not persist during the 3-month and 1-year follow-up periods. Importantly, all 3 techniques were considered safe options, with no group displaying a greater risk of any adverse events.

Prior studies have shown local infiltration analgesia techniques to provide equally effective postoperative analgesia compared with peripheral nerve blocks after lower-extremity joint arthroplasty.[3,15,33] Less convincingly for upper-extremity joint arthroplasty,[2,7,28] our findings suggest local infiltration analgesia may be considered an alternative when ISB is contraindicated or not an option for patients. Our study showed that a multimodal clinical pathway including local infiltration analgesia provided clinically acceptable analgesia and recovery but did result in higher opioid consumption and mild to moderate pain intensity

Table V Hospital outcomes

Characteristic	Local infiltration analgesia (n = 42)	Single-injection ISB (n = 42)	Continuous ISB (n = 41)	*P* value*
Hospital LOS, d				.308
Median (25th percentile, 75th percentile)	1 (1, 1)	1 (1, 1)	1 (1, 1)	
Range	1-5	1-4	1-3	
Any rescue IV opioid, n (%)	6 (14)	6 (14)	3 (7)	.581
Any adverse event, n (%)	2 (5)	1 (2)	3 (7)	.325
Infection	0	0	0	
Neurapraxia	0	0	2	
Fall	1	0	0	
Dyspnea	0	1	1	
ICU admission	1	0	0	

ISB, interscalene blockade; *LOS*, length of stay; *IV*, intravenous; *ICU*, intensive care unit.
* Hospital LOS is compared across groups using the Kruskal-Wallis test. Any rescue IV opioid and any adverse event are compared across groups using the Fisher exact test.

scores throughout the perioperative period. Several theories may contribute to these results: (1) Because the surgical infiltration technique occurs toward the end of the procedure, there remains an analgesic gap in which more pain medications are required before the onset of the surgical infiltration block. This is evident by the significantly higher opioid consumption in the local infiltration group during the intraoperative and PACU phases of care. (2) Early washout of the local anesthetic solution is possible because of the lack of a tourniquet and the highly vascular territory of the shoulder joint. (3) There may be inaccessibility to apply compression to the shoulder joint, which has been shown to improve local infiltration analgesia in total knee arthroplasty patients.[4] (4) There is a paucity of data regarding the optimal adjuvants within the local infiltration analgesia solution, as well as the dose and volume of local anesthetic to be administered.[16] Our findings are consistent with those of several previous studies reporting inferior analgesia in patients receiving local infiltration analgesia, especially in the first 8 hours after surgery.[2,7,26] Despite this, the length of hospital stay, use of rescue IV opioids, and adverse events were not different between groups.

Although single-injection ISB is a popular method of postoperative analgesia for TSA,[13] 2 associated downsides are its limited duration of action and risk of rebound pain. A recent meta-analysis reported that single-injection ISB without local anesthetic adjuvants displayed a duration of analgesia under 8 hours and showed opioid-sparing effects up to 12 hours.[1] In contrast, our study showed that the single-injection ISB group had extended analgesia with lower opioid consumption in the first 24 hours (considering that time 0 hours in our investigation began on arrival to the ward as opposed to beginning on arrival to the PACU). Researchers have indicated that single-injection ISB–associated rebound pain begins at 16 hours and can last up to 24 hours postoperatively with pain intensity scores averaging greater than 3, exceeding local infiltration analgesia[26,28] and no–nerve block groups.[1] In comparison, our investigation provides evidence that the rebound pain was not as clinically significant as previous studies have claimed because (1) pain scores in the single-injection ISB group did not surpass those of the local infiltration analgesia group as seen in previous studies and (2) single-injection ISB median pain scores did not reach greater than 3 throughout the perioperative period, which is considered acceptable for most surgical patients.[25] We postulate that our observed differences are likely a result of the use of a perioperative multimodal analgesic regimen that includes IV dexamethasone, a well-established regional anesthetic adjuvant used to prolong the duration of analgesia.[29]

Although the risk profile for ISB is cited as a potential concern for its use,[2,7,26] we observed no serious complications and an overall low incidence of adverse events during the perioperative period for both groups receiving ISB. Our outcomes are comparable to those of previous studies in which operator experience has been attributed to lower complication rates after ISB procedures,[18] fewer adverse events with continuous catheter insertion,[12] and lower catheter dislodgment rates.[12,20] In addition, a small percentage of patients in each group experienced residual sensory and/or motor changes in the operative extremity. Postoperative neurologic symptoms after peripheral nerve blockade[27] or as a direct result of the surgical procedure itself (eg, excessive traction during surgical exposure or retractor placement)[5,10,19] are not uncommon and typically resolve within 6 months.[5,27]

Unique to our study was the ability to capture outcome measures at the 3-month and 1-year follow-up for a majority of our study patients. General health-related quality-of-life tools are important to assess the patient's perception of the impact of treatment on his or her overall health. All 3 groups demonstrated a significant improvement in the SF-12 physical composite scale score after surgery, achieving a

Table VI Three-month outcomes

Characteristic	Local infiltration analgesia (n = 42*)	Single-injection ISB (n = 42*)	Continuous ISB (n = 41)	*P* value†
SF-12 physical composite scale score				
Baseline, mean ± SD	35.0 ± 9.6	36.4 ± 8.0	35.9 ± 8.7	.753
Follow-up, mean ± SD	42.0 ± 9.6	43.7 ± 8.6	42.1 ± 9.3	.652
Change from baseline to follow-up, mean ± SD	7.0 ± 7.7	7.3 ± 8.2	6.2 ± 9.2	.821
P value (baseline vs. 3 mo)	<.001	<.001	<.001	
SF-12 mental composite scale score				
Baseline, mean ± SD	54.0 ± 9.6	55.3 ± 9.6	55.4 ± 8.6	.754
Follow-up, mean ± SD	56.3 ± 7.6	55.5 ± 8.1	59.1 ± 5.1	.053
Change from baseline to follow-up, mean ± SD	2.5 ± 10.5	0.2 ± 9.1	3.7 ± 9.1	.258
P value (baseline vs. 3 mo)	.138	.875	.013	
NRS pain score (0-10)				
Pain at rest				
Median (25th percentile, 75th percentile)	0 (0, 0)	0 (0, 1)	0 (0, 0)	
>3, n (%)	1 (0)	1 (2)	3 (7)	.444
Pain with movement				
Median (25th percentile, 75th percentile)	2 (0, 3)	2 (0, 3)	2 (0, 4)	.646
>3, n (%)	7 (17)	9 (21)	11 (27)	
Current opioid use, n (%)	5 (13)	6 (14)	2 (5)	.430
Problems since surgery, n (%)				
Operative extremity neurologic changes	4 (10)	6 (14)	4 (10)	.824
Wound infection	0 (0)	0 (0)	0 (0)	>.999
Persistent pain	1 (2)	4 (10)	4 (10)	.424

ISB, interscalene blockade; *SF-12*, Medical Outcomes Study 12-Item Short-Form; *SD*, standard deviation; *NRS*, numeric rating scale.

* SF-12 data are missing for 1 subject in the local infiltration analgesia group at 3 months and 1 subject in the single-injection ISB group at both baseline and 3 months. Data regarding pain at 3 months and problems since surgery are missing for 1 subject in the local infiltration analgesia group. Data regarding current opioid use at 3 months are missing for 2 subjects in the local infiltration analgesia group and 1 subject in the continuous ISB group.

† SF-12 composite scale scores are summarized using mean ± SD, with within-group comparisons of baseline and 3 months performed using the paired *t* test and between-group comparisons performed using analysis of variance. Pain scores at 3 months are compared across groups using the Kruskal-Wallis test, and the percentages of patients using opioids and reporting problems since surgery are compared across groups using the Fisher exact test.

difference greater than 5.4, which is considered the minimal clinically important difference (MCID).[39] Although there was a trivial change in the SF-12 mental composite scale score, this is consistent with a previous study failing to show a change in mental health.[39] Similarly, patients in all 3 groups displayed substantial improvements in VAS pain and ASES scores at the 1-year follow-up, surpassing the MCIDs previously reported (1.4-point change for VAS pain score and 20.9-point change for ASES score) for patients with comparable shoulder pathologies undergoing primary anatomic and reverse TSA.[35] None of the 3 intervention arms displayed superiority in functional outcomes at 3 months and 1 year.

Regarding the results of shoulder arthroplasty for these 125 shoulders, as expected, shoulder arthroplasty was associated with improvements in pain and function. No readmissions and no reoperations occurred in this study cohort, which is partly explained by the short follow-up time required to assess the effectiveness of pain management modalities in shoulder arthroplasty. All procedures were primary or reverse shoulder arthroplasties performed through a deltopectoral approach and a subscapularis tenotomy. The majority of the procedures were performed for primary osteoarthritis or cuff tear arthropathy. As such, the results of this study cannot be extrapolated to alternative exposures (superior approach for reverse arthroplasty), all diagnoses, or revision surgery.

We applied the OBAS system as our primary outcome because its multidimensional assessment provides better insight into the analgesic experience that patients encounter with therapeutic interventions as opposed to relying strictly on pain intensity tools. Because the OBAS tool was developed relatively recently and is perhaps unfamiliar to clinicians, we supplemented our study with common outcome measures such as postoperative pain scores and opioid consumption, which appear to support OBAS values (eg, the continuous ISB group had low pain scores, low opioid consumption, and low OBAS values). Furthermore, the OBAS tool has been previously validated when evaluating the total calculative score[17] and is simple to administer and practical to implement in daily practice. Although an MCID has not been formally investigated for the OBAS metric, we deemed a difference of 3 points (10% difference on a 29-point scale) to be clinically important and provide

Table VII One-year outcomes

Characteristic	Local infiltration analgesia		Single-injection ISB		Continuous ISB		*P* value*
	n†	Mean ± SD	n†	Mean ± SD	n†	Mean ± SD	
VAS pain score (0-10)							
Baseline	41	5.2 ± 2.7	42	3.9 ± 2.4	41	4.9 ± 2.2	.034
Follow-up	40	0.5 ± 1.1	42	0.6 ± 1.4	40	0.6 ± 1.4	.893
Change from baseline to follow-up	39	−4.9 ± 2.8	42	−3.3 ± 3.0	40	−4.3 ± 2.4	.024
P value (baseline vs. follow-up)*		<.001		<.001		<.001	
ASES total score (0-100)							
Baseline	38	44.0 ± 19.7	42	52.8 ± 17.7	36	42.0 ± 15.4	.018
Follow-up	40	89.7 ± 12.0	40	88.4 ± 12.9	38	89.8 ± 12.5	.853
Change from baseline to follow-up	37	+45.7 ± 20.1	40	+34.4 ± 21.0	33	+46.4 ± 19.0	.016
P value (baseline vs. follow-up)*		<.001		<.001		<.001	

ISB, interscalene blockade; *SD*, standard deviation; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons.

* Within-group comparisons of baseline vs. follow-up are performed using the paired *t* test. The *P* values presented for the comparison across groups is from analysis of variance. To adjust for baseline differences, the change from baseline was also compared across groups using analysis of covariance with the baseline value included as a covariate, and no treatment effects were detected ($P = .903$ and $P = .196$ for VAS pain score and ASES total score, respectively).

† Number of subjects with data available for given assessment.

us a reasonable sample size with high power, similarly to Mungroop et al.[24]

There are several limitations to this study. Participants and providers were not blinded to the study intervention, which increases the risk of bias.[32] We considered performing sham catheter placement; however, we concluded that the local infiltration analgesia group could still be distinguished from an ISB because of the lack of associated motor and/or sensory blockade. Next, our results may not extrapolate to patients with chronic pain syndrome or with higher preoperative opioid requirements. We encountered 3 protocol deviations in our investigation (1 patient received perineural clonidine, 1 patient did not receive IV dexamethasone, and 1 patient did not receive a 120-mL local infiltration analgesia volume); however, given the magnitude of differences observed for our primary outcome (OBAS), it is unlikely that our intention-to-treat analysis was substantially influenced by the small number of protocol violations. Although the number of complications was low overall across groups, our investigation does not have adequate statistical power to rule out the potential for meaningful differences in complication rates. We did not perform a formal cost analysis because this would require complete time-driven activity-based costing for each arm, which our study was not designed to evaluate accurately. Finally, this investigation did not evaluate newer extended-release local anesthetics such as liposomal bupivacaine, which was not approved for use in ISB within the United States until recently. Future considerations for improving pain management in the immediate postoperative period for single-injection ISB and local infiltration analgesia include optimizing local anesthetic adjuvant combinations to enhance the duration of analgesia and standardizing the local infiltration analgesia injection technique.

Conclusion

Continuous ISB provides superior analgesia compared with single-injection ISB and local infiltration analgesia as part of a multimodal analgesic regimen in the first 24 hours postoperatively for patients undergoing primary TSA. When continuous ISB is not feasible, single-injection ISB and local infiltration analgesia techniques may provide acceptable analgesia; however, a limited duration of action and pain control prior to onset of the surgical infiltration block are important areas that need further refinement and research.

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