Single-bolus injection of local anesthetic, with or without continuous infusion, for interscalene brachial plexus block in the setting of multimodal analgesia: a randomized controlled unblinded trial

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ABSTRACT

Introduction Previous trials favored a continuous interscalene brachial plexus block over a single injection for major shoulder surgery. However, these trials did not administer a multimodal analgesic regimen. This randomized, controlled unblinded trial tested the hypothesis that a continuous infusion of local anesthetic for an interscalene brachial plexus block still provides superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac.

Methods Sixty patients undergoing shoulder arthroplasty or arthroscopic rotator cuff repair were randomized to receive a bolus of ropivacaine 0.5%, 20 mL, with or without a continuous infusion of ropivacaine 0.2% 4–8 mL/hour, for an interscalene brachial plexus block. Patients were provided with intravenous morphine patient-controlled analgesia. The primary outcome was cumulative intravenous morphine consumption at 24 hours postoperatively. Secondary outcomes included pain scores at rest and on movement, and functional outcomes, measured over 48 hours after surgery.

Results Median (IQR) cumulative intravenous morphine consumption at 24 hours postoperatively was 10 mg (4–24) in the continuous infusion group and 14 mg (8–26) in the single injection group (p=0.74). No significant between-group differences were found for any of the secondary outcomes.

Conclusions A continuous infusion of local anesthetic for an interscalene brachial plexus block does not provide superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac. The findings of this study are limited by performance and detection biases.

Trial registration number NCT04394130.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Continuous interscalene brachial plexus block significantly reduces opioid consumption, pain scores and postoperative nausea and vomiting for 48 hours after major shoulder surgery compared with a single injection.
⇒ Perioperative multimodal analgesic regimen is an effective way to reduce postoperative pain.

WHAT THIS STUDY ADDS

⇒ A continuous infusion of local anesthetic for an interscalene brachial plexus block does not provide superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The practice of inserting a perineural catheter after an interscalene brachial plexus block for major shoulder surgery when a perioperative regimen of multimodal analgesia is administered is questionable in terms of analgesia.

INTRODUCTION

A continuous infusion of local anesthetic in a perineural catheter prolongs analgesia after peripheral nerve block.[1] More specifically, a recent meta-analysis of data from 15 trials concluded that continuous interscalene brachial plexus blocks significantly reduced opioid consumption, pain scores and postoperative nausea and vomiting for 48 hours after major shoulder surgery compared with a single injection.[2] However, inserting a perineural catheter is time-consuming and requires coordination of resources, such as an acute pain service with nurses visiting patients twice a day. Moreover, perineural catheters are prone to migration or spontaneous dislodgement, and associated with potential backflow of local anesthetic, resulting in insufficient analgesia,[3] and have a reported secondary failure rate of up to 40%.[4] For example, 45% of patients scheduled for shoulder arthroscopy reported pain scores of four or more on postoperative days 1 and 2 despite a continuous interscalene brachial plexus block.[5]

In addition, many authors advocate for a perioperative multimodal analgesic regimen[6 7] inclusive of intravenous dexamethasone,[8] intravenous magnesium,[9] acetaminophen[10] and a non-steroidal

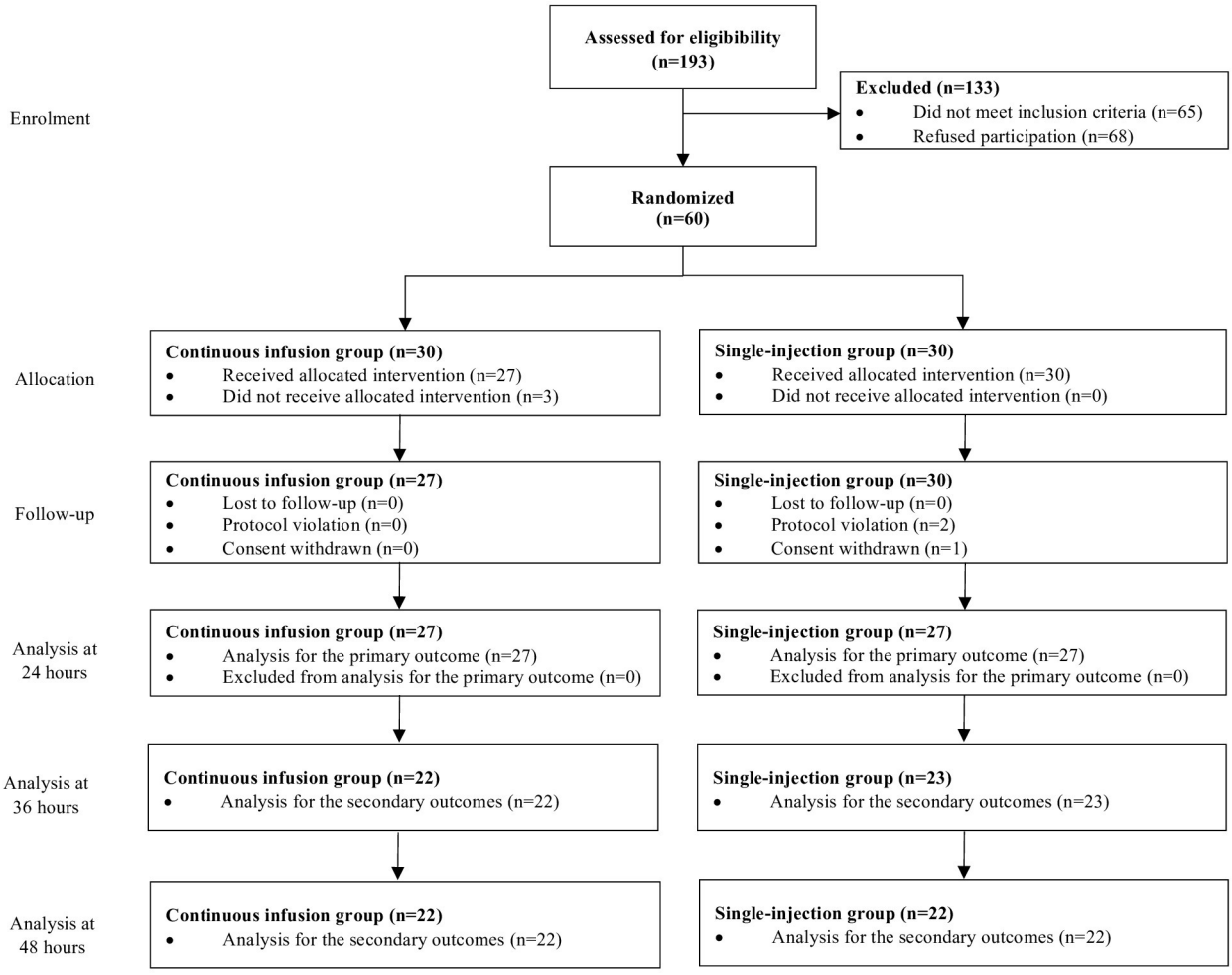

Figure 1 CONSORT study flow chart. CONSORT, Consolidated Standards of Reporting Trials.

anti-inflammatory drug such as ketorolac[11] to reduce postoperative pain. However, only 2 of the 15 trials included in the above-mentioned meta-analysis administered a non-opioid analgesic intraoperatively, and another used a combination of two non-opioid analgesics postoperatively.[2] Therefore, in contemporary practice of anesthesia, the question about the clinical efficacy of a continuous infusion of local anesthetic in a multimodal analgesic setting remains unanswered.

This randomized, controlled unblinded trial tested the hypothesis that a continuous infusion of local anesthetic for an interscalene brachial plexus block still provides superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac.

METHODS

We followed the recommended process described in the Consolidated Standards of Reporting Trials statement.[12] The study was prospectively registered on ClinicalTrials.gov (Identifier: NCT04394130; Date of registration: May 19, 2020. URL: https://clinicaltrials.gov/ct2/show/NCT04394130). The study ran from May 12, 2020 to September 30, 2022.

All patients aged 18 years or older, American Society of Anesthesiologists physical status I–III, who were scheduled to undergo elective shoulder arthroplasty or arthroscopic shoulder rotator cuff repair under general anesthesia were eligible to participate in this study. Exclusion criteria included contraindications to peripheral nerve block (eg, coagulopathy, infection in the area), known allergy to any drug used in the study protocol, pregnancy, and chronic use of opioids. After providing written informed consent, participating patients were randomly allocated on the day of surgery to one of the two study groups using a computer-generated randomization table (block size of 10). The information regarding the treatment group allocation was concealed in a sealed opaque envelope.

All ultrasound-guided procedures were conducted prior to surgery in a dedicated block procedure room by an experienced staff regional anesthetist, or a directly supervised regional anesthesia fellow. ECG, pulse oximetry, and blood pressure monitors were routinely applied, and oxygen was provided. Peripheral intravenous access was established. Intravenous midazolam 0.05 mg/kg was given before the block procedures for anxiolysis and sedation. Patients were positioned supine with the head turned 45° to the non-operative side. The catheter insertion site was sterilized with a solution of chlorhexidine 2% in isopropyl alcohol 70%. Under sterile conditions, a high-frequency linear array transducer (18–6 MHz, HF Linear Array 8870, BK Ultrasound, Pea- body, Massachusetts) was placed over the interscalene region to visualize the carotid artery and brachial plexus in the short axis view. The C5, C6, and C7 roots were identified, and the brachial plexus sheath was recognized as the linear hyperechoic layer surrounding the roots of the brachial plexus. After infiltration of the skin with 1–3 mL of lidocaine 1%, a 19-gauge 50 mm catheter-through-needle device (SonoLong Echo

Table 1 Patient demographics and clinical characteristics

	Continuous infusion group	Single injection group
Sample size, n	27	27
Sex, n (%)		
Female	16 (59.3)	13 (48.1)
Male	11 (40.7)	14 (51.9)
Mean age (SD) in years	65 (10)	64 (13)
Mean weight (SD) in kg	71 (15)	81 (19)
Mean height (SD) in cm	167 (10)	168 (10)
Mean BMI (SD) in kg/m^2	25.5 (4.6)	28.7 (5.8)
ASA score, n (%)		
I	4 (14.8)	5 (18.5)
II	21 (77.8)	17 (63.0)
III	2 (7.4)	5 (18.5)
Type of surgery, n (%)		
Shoulder arthroplasty	11 (40.7)	11 (40.7)
Rotator cuff repair	16 (59.3)	16 (59.3)
Mean duration of surgery (SD) in min	101 (31)	106 (21)

ASA, American Society of Anesthesiologists; BMI, body mass index.

NanoLine; Pajunk, Geisingen, Germany) was inserted in-plane with the ultrasound beam on the lateral side of the transducer until the needle tip was positioned between C5 and C6. A small amount (3–5 mL) of dextrose 5% was used for tissue expansion at the discretion of the operator. The catheter was then inserted, and its tip positioned under direct ultrasound guidance between C5 and C6. A bolus of lidocaine 1% with epinephrine 5 µg/mL, 20 mL was administered.

Assessment of sensory and motor block was performed by a blinded research assistant every 5 min for up to 30 min after injection. Sensory block was tested in the C5 and C6 dermatomes using a blunt tip needle pinprick test. Motor block was tested using arm abduction (C5), and forearm flexion (C6). A successful block was defined as complete sensory and motor block in the distribution of the C5 and C6 nerve roots within 30 min of injection. In case of block failure or spontaneous catheter dislodgment prior to initiation of the local anesthetic infusion, the catheter was repositioned within the plexus as per our routine institutional practice. Data for these patients were analyzed on an intention-to-treat basis.

After application of routine monitors in the operating theater, patients received a standard general anesthetic. Anesthesia was induced using intravenous fentanyl 1–2 µg/kg and intravenous propofol 2–4 mg/kg with endotracheal intubation facilitated by intravenous rocuronium 0.6 mg/kg. Maintenance of anesthesia was via inhaled sevoflurane 1.6%–2.4% in a 40:60 mixture of oxygen and air. Positive pressure ventilation was initiated with tidal volume and rate adjusted to maintain an end-tidal carbon dioxide pressure of 35–40 mm Hg. Intravenous fentanyl 25 µg was administered as needed to treat increases in blood pressure or heart rate of more than 20% above preinduction baseline values. After surgery, muscle relaxation was antagonized with neostigmine 50 µg/kg and glycopyrrolate 5–10 µg/kg. Intraoperatively, all patients received an intravenous multimodal analgesic regimen including magnesium sulfate 40 mg/kg and intravenous dexamethasone 0.15 mg/kg at the beginning of surgery, and ketorolac 30 mg and acetaminophen 1 g at the end of surgery. All patients also received intravenous ondansetron 4 mg for antiemetic prophylaxis.

In the postanesthetic care unit (PACU), after motor block recovery and normal neurological status verified, the interscalene catheter was infused with a bolus of ropivacaine 0.5%, 20 mL. Patients in the single injection group had the catheter removed, while patients allocated to the continuous infusion group had the catheter connected to an electronic pump and infused with ropivacaine 0.2% at a rate of 6 mL/hour until the morning of postoperative day 2. The infusion rate was increased to 8 mL/hour if the pain score increased to above 3 or was decreased to 4 mL/hour if there was worsening paresia on the C6 territory. All patients were provided with intravenous patient-controlled analgesia (PCA) using morphine with boluses of 2 mg available every 10 min and were instructed on the use of the PCA device; PCA was discontinued on the morning of postoperative day 2. On the ward, patients received acetaminophen 1g every 6 hours, and ibuprofen 400 mg every 8 hours. Antiemetic medications on the ward included intravenous ondansetron 4 mg and intravenous metoclopramide 10 mg, administered on request.

The primary outcome was cumulative intravenous morphine consumption at 24 hours postoperatively. Secondary outcomes were as follows: intravenous morphine consumption at 12, 36 and 48 hours; pain scores at rest and on movement measured at 2, 12, 24, 36 and 48 hours (using a Visual Analog Scale (VAS) from 0 to 10); rates of postoperative nausea and vomiting, and pruritus at 2, 24 and 48 hours; satisfaction score (VAS, 0–10);

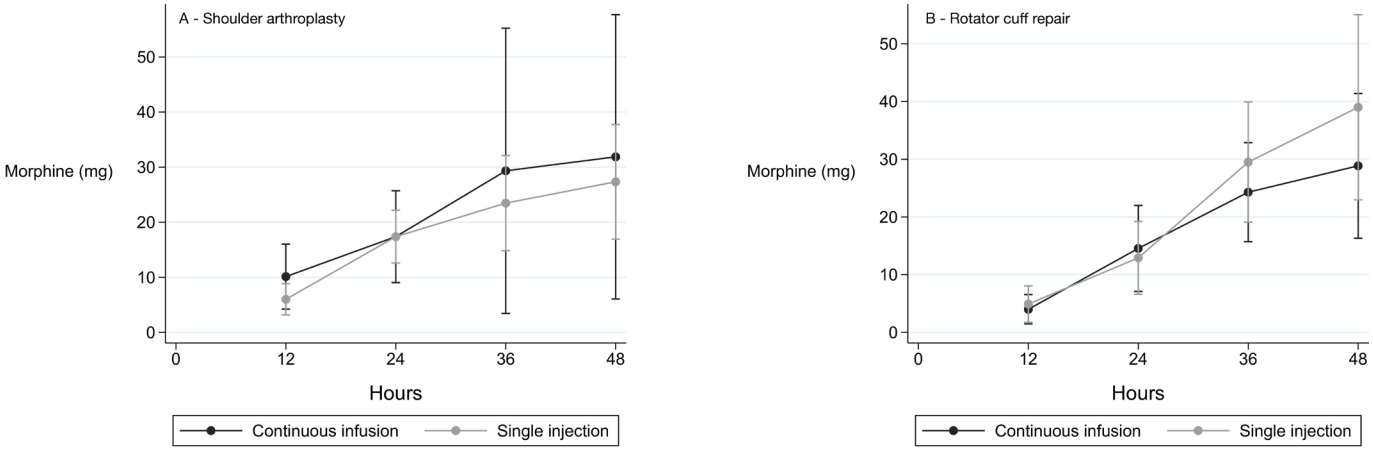

Figure 2 Cumulative intravenous morphine consumption for patients undergoing shoulder arthroplasty (A) or arthroscopic rotator cuff repair (B). Data are mean values with 95% CI.

Table 2 Secondary pain-related and functional-related outcomes

	Continuous infusion group	Single injection group	P value*†
2 hours postoperatively			
Median rest pain VAS (IQR)	0 (0–2)	0 (0–2)	0.65
Median dynamic pain VAS (IQR)	1 (0–3)	1 (0–3)	0.86
Postoperative nausea and vomiting, n (%)	0 (0.0)	1 (3.7)	1.00
Pruritus, n (%)	0 (0.0)	0 (0.0)	N/A
Dyspnea, n (%)	1 (3.7)	0 (0.0)	1.00
Claude-Bernard Horner syndrome, n (%)	2 (7.4)	0 (0.0)	0.49
Dysphonia, n (%)	1 (3.7)	0 (0.0)	1.00
12 hours postoperatively			
Median rest pain VAS (IQR)	0 (0–2)	0 (0–2)	0.68
Median dynamic pain VAS (IQR)	1 (0–3)	2 (0–3)	0.44
Postoperative nausea and vomiting, n (%)	2 (7.4)	1 (3.7)	1.00
Pruritus, n (%)	0 (0.0)	0 (0.0)	N/A
Dyspnea, n (%)	2 (7.4)	1 (3.7)	1.00
Claude-Bernard Horner syndrome, n (%)	6 (22.2)	0 (0.0)	0.02
Dysphonia, n (%)	2 (7.4)	1 (3.7)	1.00
24 hours postoperatively			
Median rest pain VAS (IQR)	2 (0–4)	1 (1 – 3)	0.83
Median dynamic pain VAS (IQR)	3 (2 – 5)	3 (2 – 4)	0.85
Postoperative nausea and vomiting, n (%)	2 (7.4)	4 (14.8)	0.67
Pruritus, n (%)	0 (0.0)	1 (3.7)	1.00
Dyspnea, n (%)	1 (3.7)	0 (0.0)	1.00
Claude-Bernard Horner syndrome, n (%)	2 (7.4)	0 (0.0)	0.49
Dysphonia, n (%)	3 (11.1)	2 (7.4)	1.00
Median active-assisted anterior flexion (IQR), degrees	40 (30–68)	45 (35–80)	0.09
Missing, n	3	1	
Median active-assisted abduction (IQR), degrees	35 (30–50)	40 (30–75)	0.41
Missing, n	4	5	
Median active-assisted external rotation (IQR), degrees	0 (–25 to 0)	0 (–10 to 0)	0.93
Missing, n	3	4	
36 hours postoperatively			
Median rest pain VAS (IQR)	1 (1 – 4)	1 (0–2)	0.23
Median dynamic pain VAS (IQR)	3 (2 – 6)	3 (1 – 4)	0.13
Postoperative nausea and vomiting, n (%)	4 (17.4)	1 (4.5)	0.35
Pruritus, n (%)	0 (0.0)	2 (9.1)	0.23
Dyspnea, n (%)	3 (13.0)	0 (0.0)	0.23
Claude-Bernard Horner syndrome, n (%)	0 (0.0)	0 (0.0)	N/A
Dysphonia, n (%)	1 (4.3)	1 (4.3)	1.00
48 hours postoperatively			
Median rest pain VAS (IQR)	1 (0–2)	1 (0–2)	0.30
Median dynamic pain VAS (IQR)	3 (2 – 4)	2 (2 – 4)	0.47
Postoperative nausea and vomiting, n (%)	3 (13.6)	3 (13.6)	1.00
Pruritus, n (%)	0 (0.0)	3 (13.6)	0.23
Dyspnea, n (%)	2 (9.1)	0 (0.0)	0.49
Claude-Bernard Horner syndrome, n (%)	0 (0.0)	0 (0.0)	N/A
Dysphonia, n (%)	0 (0.0)	0 (0.0)	N/A
Median satisfaction VAS (IQR)	10 (9–10)	10 (8–10)	0.58
Median active-assisted anterior flexion (IQR), degrees	40 (35–70)	55 (35–80)	0.36
Missing, n	9	7	
Median active-assisted abduction (IQR), degrees	35 (30–58)	40 (30–60)	0.60
Missing, n	11	11	
Median active-assisted external rotation (IQR), degrees	0 (–20 to 0)	0 (–10 to 0)	0.75
Missing, n	8	9	

*p value compares continuous infusion versus single injection.
†Mann-Whitney-Wilcoxon test used to compare medians and Fischer's exact test used to compare proportions.
VAS, Visual Analog Scale.

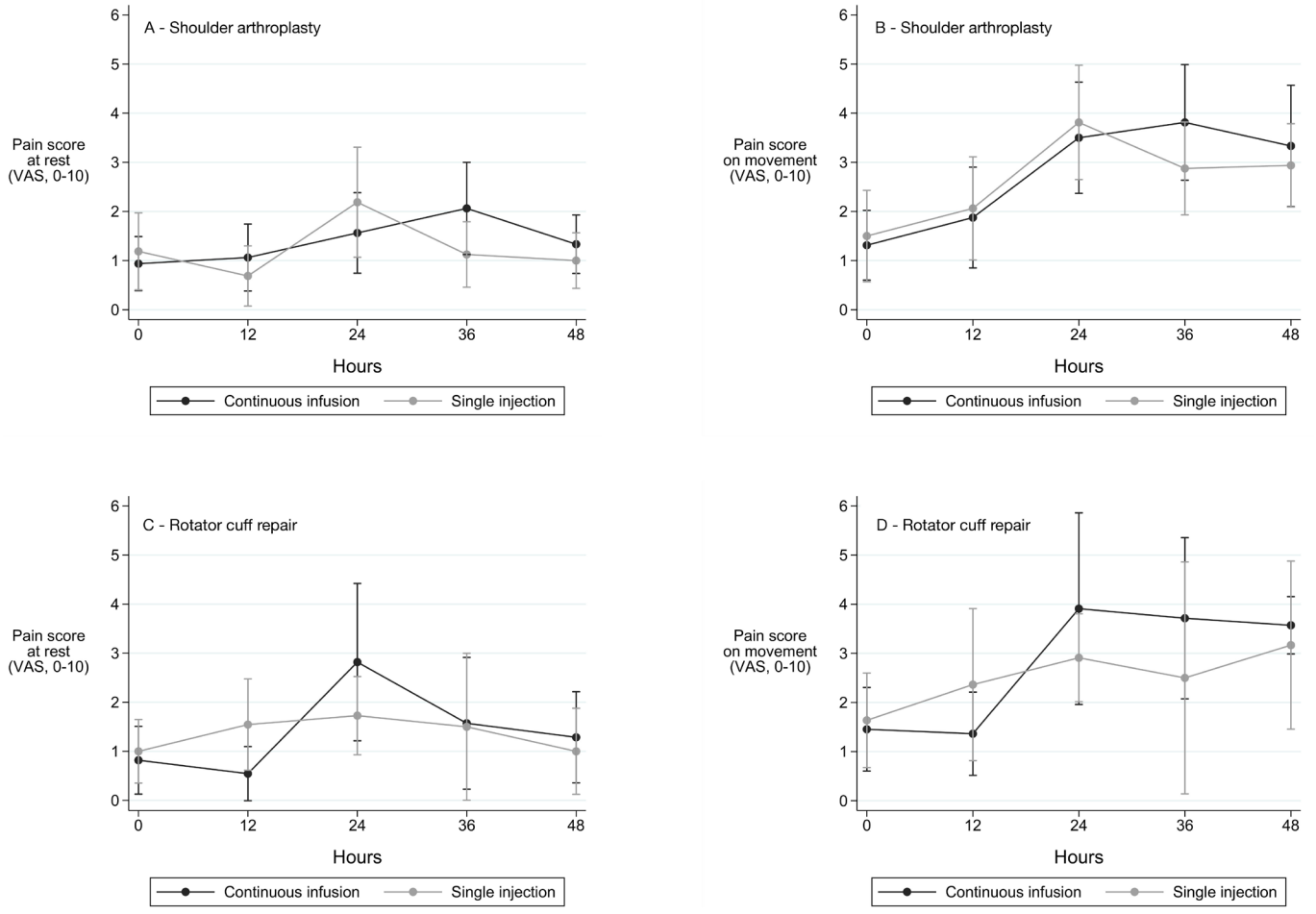

Figure 3 Pain scores at rest and on movement for patients undergoing shoulder arthroplasty (A, B) or arthroscopic rotator cuff repair (C, D). Data are mean values with 95% CI. VAS, Visual Analog Scale.

and the incidence of any adverse events such as dyspnea, Claude-Bernard-Horner syndrome, dysphonia, hematoma, and infection at 2, 24 and 48 hours postoperatively. The following functional outcomes were also measured: active-assisted range of motion (in degrees) at 24 and 48 hours for shoulder anterior flexion, shoulder abduction, and shoulder external rotation. At 3 months postoperatively, patients were contacted by telephone to assess any persistent paresthesia or paresia and neuropathic pain. The trial was monitored by an independent person and 50% of patients had their data verified for accuracy.

A previous meta-analysis reported mean consumption of intravenous morphine of 15 mg and 32 mg in patients with a continuous infusion or single injection of local anesthetics, respectively (SD 12 mg).[2] However, in the setting of a multimodal analgesic treatment, we estimated that morphine consumption after a single injection of local anesthetic would be reduced to 25 mg. We hypothesized that patients in the continuous infusion group would have a 10 mg reduction in intravenous morphine consumption at 24 hours compared with patients in the single injection group. A 10 mg difference in intravenous morphine consumption represents 20 mg of oral oxycodone, which we deemed clinically relevant. To obtain a minimum power of 80% with an alpha of 5%, we calculated that 23 patients per group needed to be included. To correct for an anticipated drop-out and protocol violation rate of 25%, the plan was to recruit a total of 60 patients (30 per group).

Data were analyzed on an intention to treat basis. Categorical variables are presented as frequencies, and continuous variables are summarized as mean with SD, 95% CI or median with IQR, as appropriate. Distributions of the continuous data (Gaussian, not Gaussian) were determined with a Shapiro-Wilk test. Between-group comparison of continuous data was performed using a Student's t-test or a Mann-Whitney-Wilcoxon test depending on their distribution. Categorical and dichotomous data were compared by using the χ^2 test or the Fisher's exact test, as appropriate. A Bonferroni correction was applied for repeated measures. Statistical significance was defined as $p<0.05$ based on a two-tailed probability. Statistical analysis was performed by using the Stata software (Stata V.16.1, StataCorp).

RESULTS

Of 193 patients evaluated for eligibility, 60 were included and randomized, and 54 completed the protocol to measurement of the primary outcome; 9 patients left the hospital on postoperative day 1 and one early in the morning of postoperative day 2 (figure 1). Baseline patient characteristics are presented in table 1. Two patients in the single injection group initially had an arthroscopic rotator cuff repair planned but the surgery was finally performed with an open access. Four patients in the continuous infusion group had a spontaneous removal of the catheter and one was reinserted; data for these four patients were included in the analysis, as per the intention-to-treat approach.

Median (IQR) cumulative intravenous morphine consumption at 24 hours postoperatively was 10 mg (4–24) in the continuous infusion group and 14 mg (8–26) in the single injection group (p=0.74). Morphine consumption was also similar in the continuous infusion and single injection groups at postoperative hour 12 (6 mg (0–12) and 4 mg (2–10); p=0.77), 36 (18 mg (12–28) and 22 mg (10–38); p=0.45), and 48 (21 mg (12–36) and 24 mg (10–52); p=0.41). Cumulative intravenous morphine consumption in the two treatment groups after shoulder arthroplasty and rotator cuff repair are shown in figure 2. Pain scores at rest and on movement (table 2) and the trajectory of pain scores at rest and on movement for patients having a shoulder arthroplasty and a rotator cuff repair (figure 3) were similar in the continuous infusion and single injection groups. There were no significant between-group differences in other secondary pain-related outcomes and functional-related outcomes (table 2). No patients developed hematoma, infection, persistent paresthesia, paresia or neuropathic pain.

DISCUSSION

In this randomized controlled unblinded trial, a continuous infusion of local anesthetic for an interscalene brachial plexus block does not provide superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac. Indeed, the absence of statistically significant differences between the two treatment groups in morphine consumption, pain scores at rest and on movement, and functional outcomes question the practice of inserting a perineural catheter for major shoulder surgery when a perioperative regimen of multimodal analgesia is administered.

The median 4 mg difference in cumulative intravenous morphine consumption between groups at 24 hours after surgery was substantially smaller than the 17 mg difference recently reported in a meta-analysis of data from 15 trials that included 793 patients undergoing major (shoulder arthroplasty, rotator cuff repair) or minor (subacromial decompression, clavicle resection) shoulder surgery.[2] This might be explained by the comprehensive perioperative multimodal analgesic regimen prescribed for all patients in the current study. In contrast, none of the studies included in the meta-analysis administered dexamethasone or magnesium intraoperatively, two injected ketorolac intraoperatively and only one prescribed a combination of acetaminophen and non-steroidal anti-inflammatory drug in the postoperative period. Of note, a recent prospective trial (n=559) reported that the combination of acetaminophen and ibuprofen significantly reduced intravenous morphine consumption at 24 hours in patients undergoing hip arthroplasty from 36 mg with acetaminophen alone to 20 mg in the acetaminophen+ibuprofen group.[13] Our intraoperative and postoperative multimodal analgesic regimen probably attenuates the potential benefit of a continuous infusion. A post hoc analysis on the results of our study using mean values of morphine consumption at 24 postoperative hours of 16 mg and 15 mg and an SD of 10 mg revealed that a total of 1570 patients per group would be needed to reject the null hypothesis, with alpha and beta values of 0.05 and 0.2, respectively. This highlights the potential futility of inserting a catheter in the interscalene region. However, our results cannot be generalized to all patients, as a perineural catheter with a continuous infusion of local anesthetics can still be useful in patients suffering from chronic pain conditions or opioid tolerance.

In the absence of the superiority of a continuous infusion regimen with or without intermittent boluses for continuous peripheral nerve blocks in general,[1] or continuous interscalene brachial plexus block specifically,[14] we chose a regimen of continuous infusion without boluses because it would have been difficult for patients to understand which button to activate in case of worsening pain. For example, in the meta-analysis mentioned above, 6 out of 15 trials did not prescribe boluses on top of the continuous infusion.[2]

Regarding the functional outcomes, our results can be used as pilot data for further research. Indeed, and surprisingly, we were not able to find any previous prospective trials that compared functional outcomes between patients receiving a single injection or a single injection plus continuous infusion for major shoulder surgery, while the literature contains publications reporting no improvement in shoulder function with use of a continuous interscalene brachial plexus block compared with intravenous PCA morphine.[15]

Several limitations deserve to be mentioned. First, we understand that many centers perform these surgical procedures on an ambulatory basis whereas at our institution these patients are hospitalized for a minimum of 24 hours. Nevertheless, we believe that the question of a continuous infusion is worth exploring in the setting of multimodal analgesia, especially in a program of ambulatory continuous peripheral nerve block. Another limitation might be the choice of our primary outcome, which is not considered to be a patient-oriented outcome by some physicians. However, we are convinced that this is an outcome of paramount importance because any reduction in opioid consumption is associated with reduced postoperative nausea and vomiting, among other side effects, contributing to better postoperative patient comfort. Then, we admit the injection of lidocaine 1% after catheter insertion followed by a bolus of ropivacaine 0.5% in the PACU is not common practice. We adopted this procedure in our institution to comply with orthopedic surgeons request to run an continuous infusion of ropivacaine only after normal neurological status of the upper limb has been checked. Finally, patients, physicians and research assistants were not blinded to group allocation as we elected not to run an infusion of normal saline in the single-injection group, and therefore, we cannot exclude performance and detection biases.

CONCLUSION

A continuous infusion of local anesthetic for an interscalene brachial plexus block does not provide superior analgesia after major shoulder surgery when compared with a single injection in the setting of multimodal analgesia, inclusive of intravenous dexamethasone, magnesium, acetaminophen and ketorolac. The findings of this study are limited by performance and detection biases.

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Contributors PR: study registration, data collection, manuscript editing; MC: block procedure, manuscript editing; PG: surgical procedure, manuscript editing; J-BR: statistical analysis; MB: patient recruitment, data collection; AF: surgical procedure, manuscript editing; EA: study design, block procedure, data interpretation, manuscript writing. EA is also responsible for the overall content as guarantor.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Commission d'Ethique Romande protocol number: 2019-00957. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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