British Journal of Anaesthesia **103 (3):** 434–9 (2009)
doi:10.1093/bja/aep195 Advance Access publication July 16, 2009

BJA

Analgesic effectiveness of ropivacaine 0.2% *vs* 0.4% via an ultrasound-guided C5–6 root/superior trunk perineural ambulatory catheter

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Background. In this prospective, randomized, triple-blinded study, we tested the hypothesis that a 48 h continuous C5–6 root/superior trunk patient-controlled infusion of ropivacaine 0.4% would provide superior analgesia after shoulder surgery compared with the same infusion of ropivacaine 0.2%.

Methods. Patients presenting for painful shoulder surgery were recruited. A perineural catheter was placed under ultrasound guidance immediately adjacent to the C5–6 roots/superior trunk. Ropivacaine 5 mg ml^{-1} (30 ml) was administered via this catheter before surgery under general anaesthesia. At the end of surgery, patients were randomized to receive ropivacaine 2 mg ml^{-1} (0.2%) (n=32) or 4 mg ml^{-1} (0.4%) (n=33) via an elastomeric pump delivering 2 ml h^{-1} with on-demand patient-controlled boluses of 5 ml as required. Acetaminophen and diclofenac were administered if any postoperative pain occurred, ropivacaine boluses for a numerical rating pain score (NRPS, 0–10) of >2, and rescue tramadol for an NRPS >3. All patients were phoned on postoperative days 1 and 2 and questioned for indices of treatment effectiveness and adverse effects.

Results. NRPS, patient ropivacaine demands, and supplemental tramadol consumption were similar in each group [median 'average daily pain' days 1/2 (0.2%=1/3, 0.4%=2/3)]. Episodes of an insensate/densely blocked arm occurred only with ropivacaine 0.4% (5 *vs* 0 episodes, P=0.05). Satisfaction (numerical rating scale, 0–10) was higher for ropivacaine 0.2% [mean difference (95% confidence interval)=1.3 (0.3–2.4), P=0.01)].

Conclusions. After major shoulder surgery, ropivacaine 0.2% at 2 ml h^{-1} with on-demand 5 ml boluses administered via an ultrasound-guided C5–6 root/superior trunk perineural catheter produces similar analgesia, but higher patient satisfaction compared with ropivacaine 0.4%.

Trial Registration: ANZCTR: ACTRN12608000591358. URL: www.anzctr.org.au/registry/trial_review.aspx?ID=83028.

Br J Anaesth 2009; **103**: 434–9

Keywords: anaesthetic techniques, regional brachial plexus; anaesthetics local, ropivacaine

Accepted for publication: June 7, 2009

Little information exists regarding the optimal combination of local anaesthetic volume and concentration for continuous interscalene nerve blocks when used for postoperative analgesia after shoulder surgery. Studies have supported the administration of relatively high volumes (>5 ml h^{-1}) of dilute local anaesthetic, consistent with the large surface area of the brachial plexus in this region.[1]

Compared with placement with traditional techniques, ultrasound guidance for interscalene catheter placement has been shown to improve the catheter effectiveness, as measured by postoperative local anaesthetic and opioid

consumption.[2] This relates to ultrasound facilitating catheter positioning adjacent to the most appropriate elements of the brachial plexus, which for shoulder surgery correspond to the C5–6 roots/superior trunk. These findings inevitably raise important issues regarding the relevance of previous dose–response studies conducted using traditional catheter placement techniques.

We commonly use a regimen of ropivacaine 0.2% (2 mg ml^{-1}) at 2 ml h^{-1}, supplemented with on-demand 5 ml hourly boluses for continuous peripheral nerve block.[3] Low background infusions are advantageous for ambulatory perineural infusions, in that they enable prolongation of the potent analgesia provided by limited volume pumps.[1] However, analysis of postoperative pain scores from a previous group of patients who had undergone rotator cuff repair, total shoulder joint replacement, or both revealed a significant proportion of patients who experienced moderate-to-severe breakthrough pain requiring ropivacaine bolus demands.[3 4] Ropivacaine 0.2% at 2 ml h^{-1} with additional 5 ml hourly boluses as required represents a relatively low total dose of administered ropivacaine. Increasing the ropivacaine concentration to 0.4% (4 mg ml^{-1}) with the aim of both improving analgesia and reducing patient bolus demands (and therefore early pump depletion) is feasible from a pharmacokinetic perspective, as the total dose is still less than the toxic range.

We therefore tested the hypothesis that doubling the concentration of an ultrasound-guided C5–6 root/superior trunk low flow perineural ropivacaine infusion from 0.2% to 0.4% would enhance postoperative analgesia after painful shoulder surgery. Secondary endpoints studied included ropivacaine bolus demands, opioid supplementation, and the adverse effects of continuous brachial plexus block: arm numbness, weakness, and episodes of an insensate arm.

Methods

After institutional review board (New Zealand Northern X Regional Ethics Committee) approval, patients undergoing elective arthroscopic or open rotator cuff repair and total shoulder joint replacement in the authors' practice in two separate institutions were recruited. Exclusion criteria included patient refusal of interscalene block, severe respiratory disease, known allergy to amide local anaesthetic drugs, and chronic opioid therapy. Written informed consent was obtained from all patients.

Oral acetaminophen 1 g, diclofenac SR 75 mg, and omeprazole 20 mg were administered 1 h before surgery. I.V. sedation to a maximum of midazolam 2 mg and alfentanil 0.5 mg was administered 5 min before the catheter placement. A superficial cervical plexus block (lidocaine 5–10 ml injected along the posterior border of the sternomastoid muscle midway between the level of C6 and the mastoid process) was administered to all patients to facilitate the catheter placement and ensure blockade of the supraclavicular nerves.

Perineural catheter

The perineural catheter was placed by one of the two investigators (M.J.F., D.J.P.) both of whom are experienced in ultrasound-guided regional anaesthesia. With the patient under conscious sedation, the scalene muscles and interscalene brachial plexus were imaged in the short axis at approximately the level of C6–7 with a 38 mm 13-6 MHz linear ultrasound probe (SonoSite HFL with MicroMaxx or M-Turbo, Bothell, WA, USA). A 3.8 cm 18 G insulated Tuohy needle (Contiplex Tuohy, B. Braun, Bethlehem, PA, USA) was inserted at the posterior border of the sternocleidomastoid muscle ~3 cm cephalad of the level of C6–7. The needle was advanced using out-of-plane needle-probe orientation superficially in a peripheral direction into the middle scalene muscle until tissue displacement was observed just lateral to the two most superficial elements of the brachial plexus. At the C6–7 level, these correspond to the C5–6 roots/superior-middle trunks.[2] The tip of the needle was then angled medially towards the two most superficial brachial plexus roots/trunks until a resultant medial movement was observed. Needle tip position was ultimately determined by the injection of dextrose 5% (5–10 ml) and observation of injectate spread immediately lateral to the target roots/trunks, or alternatively by elicitation of a sustained deltoid or biceps motor response at <0.5 mA (0.1 ms, 2 Hz) (Pajunk Vario, Tucker, GA, USA). The choice of endpoint was left to operator preference, based on the results of a recent study.[4]

In both groups, a non-stimulating multi-orificed catheter was then advanced blindly past the needle tip, but after needle removal, withdrawn such that 2 cm of the catheter remained distal to the original needle tip position.[5 6] Ropivacaine 0.5% (5 mg ml^{-1}) 30 ml was administered through the catheter after fixation and standard intravascular injection precautions.

Intraoperative management

All patients were given a standardized general anaesthetic using a laryngeal mask airway, volatile anaesthesia, and spontaneous respiration. Sensory and motor testing was not performed before surgery. No long-acting opioid was administered; however, alfentanil 0.25 mg was administered p.r.n. for a ventilatory frequency >25.

Randomization was with a computer random number generator, with group allocation to the 0.2% or 0.4% group being revealed by the anaesthesia assistant during surgery, who then filled the ambulatory elastomeric pump in an area adjacent to the operating theatre. The pump was labelled with the specified drug concentration, and this label was covered by a second blank label, thus concealing

treatment group to both the primary investigators, subjects, and care givers.

In the post-anaesthesia care unit (PACU), patients reporting a numerical rating pain score (NRPS) of >2 (scale 0–10) were first given a bolus of lidocaine 1% (10 mg ml^{-1}) 10 ml. If the NRPS subsequently remained >2, the catheter was withdrawn 1 cm and additional lidocaine 1% (10 ml) was administered. If the NRPS still remained >2, the catheter was either replaced and ropivacaine 0.5% (20 ml) subsequently administered via the replacement catheter or the patient was excluded from the study.

Postoperative management

Postoperative management of the catheter was as previously described.[3] Specifically, the infusion was administered via an elastomeric pump delivering 2 ml h^{-1} with patient-controlled boluses of an additional 5 ml every hour (PainBuster, Surgical Synergies, Auckland, New Zealand). Patients were instructed to depress the ropivacaine bolus button, if the NRPS increased to >2. Acetaminophen (1 g 6 hourly) and diclofenac SR (75 mg 2 hourly) were continued after operation for as long as ropivacaine boluses were required. If the NRPS was >3, despite regular acetaminophen, diclofenac, and ropivacaine boluses, tramadol 100 mg SR 12 hourly was added. If after regaining sensation in the arm from postoperative day 1, patients subsequently became unable to move or feel the arm (defined as an insensate arm), they were instructed to turn the infusion off until sensation, pain returned, or both. Discharge home occurred either on the day of surgery, the morning of postoperative day 1 (rotator cuff repair), or postoperative day 2 (shoulder arthroplasty). Shoulder physiotherapy was commenced after postoperative day 3 depending on the surgeon preference.

Data collection

The operating investigator recorded the needle endpoint used (ultrasound or neurostimulation) and the number of boluses of alfentanil 250 μg administered during surgery. The patient's primary PACU nurse recorded the worst NRPS in the PACU and details of the catheter interventions. A research assistant phoned all subjects on the afternoon of postoperative days 1 and 2 and questioned for pain scores, oral analgesic consumption, sleep disturbance, arm numbness/weakness, and the requirement for a temporary cessation of the infusion because of an insensate/densely blocked arm. On postoperative day 2, subjects were also questioned for satisfaction on a numerical rating scale (0–10; 0, very unsatisfied; 10, very satisfied). On postoperative day 10, the same research assistant re-contacted all patients at home and questioned for new neurological symptoms.

New neurological symptoms that were sought at the day 10 consultation included hand weakness, numbness or altered sensation anywhere in the arm, and pain distal to the elbow. The principal investigator followed all patients who reported symptoms at this consultation until resolution of those symptoms. Referral for electrophysiological evaluation was planned, if neurological symptoms persisted beyond 3 months and showed minimal ongoing improvement.

Statistical analysis

Normal distribution of the data was first evaluated using the Kolmogorov–Smirnov test. Postoperative pain, tramadol consumption, ropivacaine boluses, night awakenings, satisfaction, and arm numbness/weakness were all compared with the Mann–Whitney *U*-test. Episodes of an insensate arm were compared using Fisher's exact test. Comparison of tramadol consumption, ropivacaine boluses, night awakenings, and the arm numbness/weakness scores was conducted after collation of the days 1 and 2 data for each variable, thus resulting in a single *P*-value. A *P*-value of <0.05 was considered significant in all cases with two-sided tests used for all comparisons. Statistical analysis was with Prism 5.0a (GraphPad Software Inc., La Jolla, CA, USA).

The sample size was based on postoperative pain. Data from a similar group of shoulder surgeries performed by the lead investigator had an SD of 2.5 points on the 11-point numerical rating pain scale. Detection of a mean shift of 2 points in NRPS would require 32 subjects in each group (unpaired *t*-test, α=0.05, two-tailed, power=90%). To allow for drop-outs, we planned to recruit 70 patients.

Results

Seventy-two patients were recruited. Seven patients were excluded after enrolment (two unsuccessful catheter placements, three normal rotator cuffs at arthroscopy, one minor pump malfunction, and one catheter displacement on day 1). Therefore, 65 subjects completed the study according to protocol and were thus retained for analysis. There were no differences in patient and surgical characteristics between the groups (Table 1). The majority of catheters were placed without concomitant neurostimulation (Table 2). There was no difference between the groups in NRPS at rest, on movement, or 'on average' (median 'average NRPS' on days 1/2, 0.2%=1/3, 0.4%=2/3). Patient ropivacaine bolus demands, supplemental tramadol consumption, and episodes of night awakenings were all similar between the groups (Fig. 1, Table 2). Numbness and weakness were similar between the groups; however, episodes of an insensate arm requiring a temporary cessation of the background infusion occurred on six occasions (in five different subjects) in the 0.4% group but not in the 0.2% group (*P*=0.05) (Table 3). Resultant overall satisfaction with the treatment was higher for ropivacaine 0.2% [95% confidence interval for

Table 1 Patient, anaesthesia, and surgical characteristics. Values are mean (range) for age, mean (SD), median (inter-quartile range), or *n*. F, female; M, male; US, ultrasound; NS, neurostimulation; PACU, post-anaesthesia care unit; RCR, rotator cuff repair; TSJR, total shoulder joint replacement

	0.2% ropivacaine (*n*=32)	0.4% ropivacaine (*n*=33)
Patient		
Gender (M/F)	20/12	18/15
Age (yr)	56 (35–78)	58 (26–78)
Weight (kg)	85 (19)	80 (18)
Duration of preoperative pain (months)	8 (5–18)	8 (4–24)
Catheter placement (*n*)		
Needle endpoint (US/NS)	22/10	25/8
Intraoperative alfentanil bolus ≥1	2	3
PACU catheter bolus only	0	1
PACU catheter withdrawal+bolus	3	1
PACU catheter replacement	1	1
Surgery (*n*)		
Arthroscopic RCR	8	6
Open RCR	20	21
TSJR	4	6

Table 2 Analgesic effectiveness. Values are median (inter-quartile range) on Days 1/2. No significant differences between the groups

	0.2% ropivacaine (*n*=32)	0.4% ropivacaine (*n*=33)
Ward/home (Days 1/2)		
Tramadol tablets	0 (0–0)/0 (0–1)	0 (0–1)/0 (0–1)
Ropivacaine boluses	1 (0–3)/4 (2–8)	2 (0–6)/4 (1–8)
Night awakenings	3 (1–5)/2 (1–3)	3 (2–5)/2 (1–4)

ropivacaine 0.2%, 8.6–9.6; ropivacaine 0.4%, 6.8–8.7 (P=0.01)].

Six patients (0.2%=3, 0.4%=3) reported new neurological symptoms at the day 10 consultation. All symptoms were relatively minor and did not fulfil the criteria for further investigation.

Discussion

This study compared low flow patient-controlled ropivacaine at 0.2% and 0.4% administered via a C5–6 root/superior trunk perineural catheter placed under ultrasound guidance, in the setting of ambulatory continuous brachial plexus block after painful shoulder surgery. Ropivacaine 0.2% and 0.4% were associated with similar levels of postoperative pain, supplemental ropivacaine bolus demands, and supplemental opioid administration. However, ropivacaine 0.2% was associated with increased patient satisfaction.

We have chosen a change in the description for the perineural catheter in this study, favouring C5–6 root/superior trunk perineural catheter over the more conventional interscalene catheter. Our observation of the needle positioning under real-time ultrasound guidance is that the needle tip and injectate spread is rarely *between* the anterior and the middle scalene muscles, but rather lateral to the nerve roots/trunks within the body of the middle scalene muscle. This is partly a result of the needle approach being from cephalad/lateral and along the long axis of the brachial plexus. This contrasts with the original Winnie's[7] description for the interscalene block, which advocated a tangential approach to the plexus which might be expected to promote a true interscalene needle position. Neurostimulation-guided anterolateral approaches for interscalene catheter placement may also result in a true interscalene catheter position as the technique often relies on directing the needle directly into the interscalene groove, and therefore the fascial space between the anterior and the middle scalene muscles.[8] A previous study showing evidence for more effective catheter performance with catheters placed using ultrasound guidance supports this new terminology,[2] as it is well accepted that for shoulder surgery, the most important element of the brachial plexus requiring blockade is the C5–6 roots/superior trunk.[9]

Previous investigators have highlighted the urgency for dose–response studies in this area.[10] Ilfeld and colleagues[1] showed that ropivacaine 0.2% at 8 ml h^{-1} provided superior analgesia to the same drug administered at 4 ml h^{-1}. This high infusion rate is difficult to administer in the ambulatory setting as even a 400 ml pump reservoir would be exhausted within 50 h—sooner if boluses are administered or a lower volume reservoir is used. Providing potent analgesia after shoulder surgery by way of continuous nerve blocks is, in many patients, required beyond 72 h.[11] The use of higher volume pumps might seem, on the surface, to represent a simple solution; however, when specifically questioned, the most commonly reported reason for dissatisfaction with ambulatory continuous interscalene block has been shown to be the cumbersome nature of the ambulatory pump.[3] The pump used in that survey had a relatively low reservoir volume of 270 ml (total weight ~350 g). Others have reported increased patient dissatisfaction when using higher volume reservoirs.[1] Thus, prolonging the effective duration is not simply a matter of increasing the volume of the reservoir, as the increased weight of the device may compromise overall patient satisfaction. In addition to enhancing analgesia, reducing the local anaesthetic volume requirement for this treatment was our motivation for increasing the concentration of pump local anaesthetic.

Relatively high 'worst pain' scores were reported on postoperative day 2, thus reinforcing our impression from previous studies that breakthrough pain after resolution of the primary block is relatively frequent for this subgroup of surgeries (rotator cuff repair/total shoulder arthroplasty). Reassuringly, 'average' pain scores were low, as was the requirement for supplemental tramadol, suggesting that satisfactory relief was obtained via patient-initiated boluses. Caution should be exercised in comparing these pain scores with similar previous studies that have included less painful shoulder surgeries or where the collection and presentation of data has been different from

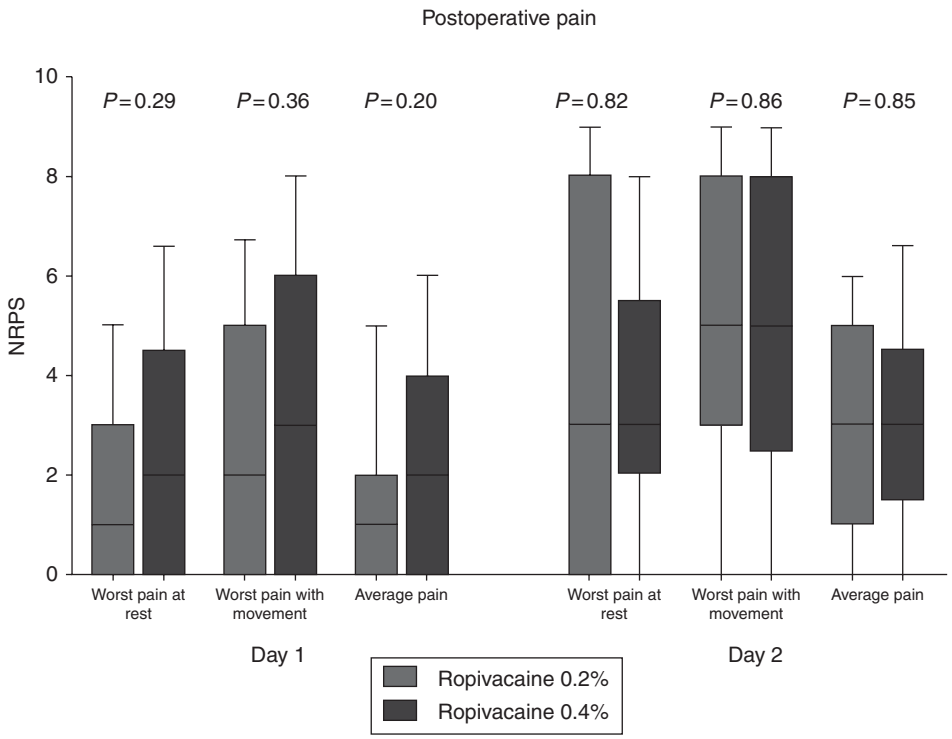

Fig 1 Analgesic effectiveness: postoperative NRPS. Values are medians (horizontal bars), quartiles (vertical columns), 10–90th centiles (whiskers). 'Worst Pain' represented the worst pain experienced at any time during the previous 24 h. NRPS, numerical rating pain score (0, no pain; 10, worst pain imaginable).

the current study.[1 8 10–12] Nevertheless, there exists substantial room for improvement in the effectiveness of the current technique.

Only one previous study has examined the effect of varying continuous interscalene ropivacaine concentration at a constant patient-controlled volume regimen. Compared with 0.25%, ropivacaine 0.4% was associated with both reduced ropivacaine bolus demands and reduced supplemental ketoprofen administration.[12] However, as the motor response sought was not mentioned, it is possible that the catheters were not placed as intimately to the C5–6 roots/superior trunk as in the current study. It is possible that the catheter placement (as might be afforded through ultrasound guidance) in a more intimate relationship to the C5–6 roots/superior trunk requires a lower concentration of local anaesthetic for effective blockade compared with a catheter placed more posteriorly within the interscalene interface. Le and colleagues[10] using a neurostimulation catheter placement technique that necessitated a biceps or deltoid motor response compared ropivacaine 0.2% and 0.4% administered at a constant total dose (8 ml infusion/4 ml bolus *vs* 4 ml infusion/2 ml bolus). The secondary outcome of postoperative pain was reduced in the high volume/low concentration group. Our results could be consistent with Le and colleagues' findings, in that at concentrations around 0.2%, further increases in local anaesthetic concentration may have little or no beneficial effect. In this area, it may be that local anaesthetic volume (particularly the bolus dose)[13–15] is the main determinant of the catheter effectiveness.

Table 3 Ropivacaine-related adverse effects. Values are medians on Days 1/2 or *n*. NRS, numerical rating score (0, no numbness/weakness; 10, very numb/weak). **P*=0.05

	0.2% ropivacaine (*n*=32)	**0.4% ropivacaine (*n*=33)**
Total episodes of an insensate arm (*n*)	0	5*
NRS for arm numbness (Days 1/2)	8/3	9/4
NRS for arm weakness (Days 1/2)	7.5/4	9.5/5

Strengths of this study include the homogeneous nature of the included surgical procedures and the insertion of all catheters by two operators experienced in ultrasound-guided regional anaesthesia. These would reduce the variability of postoperative pain and thereby maximize the likelihood of detecting a true difference between treatment groups, which is particularly relevant for studies with essentially negative outcome findings. A limitation of this study was the ambulatory nature of the treatment such that regular assessment of patient outcomes (e.g. motor block) was not possible. This analgesic treatment is, however, increasingly being used on an ambulatory basis, thus the conditions of the study replicate its increasing use in the community.[3 11 16]

In conclusion, this study demonstrates that after major shoulder surgery, ropivacaine 0.2% at 2 ml h^{-1} with on-demand 5 ml hourly boluses administered via an

ultrasound-guided C5–6 root/superior trunk perineural catheter produces similar analgesia to the same infusion of ropivacaine 0.4%. Both concentrations were associated with a significant number of patients experiencing moderate-to-severe breakthrough pain. Further study of this treatment is required to determine the optimal volume for both the basal infusion and supplementary boluses.

Funding

This work was supported by a grant from the Accident Compensation Corporation (ACC), 186 Willis St., Wellington (ACC contestable grants #07/20). This organization administers a government funded accident insurance scheme. M.J.F. has received research support from the I-Flow Corporation. This company had no involvement in any aspect of this study including but not limited to study funding, concept, design, data collection, analysis, or preparation of the manuscript.

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