Patient-initiated mandatory boluses for ambulatory continuous interscalene analgesia: an effective strategy for optimizing analgesia and minimizing side-effects

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Editor’s key points

- Continuous interscalene analgesia facilitates shoulder surgery being performed as an overnight or even day stay procedure.
- Following rotator cuff repair, a 2 ml h⁻¹ ropivacaine infusion combined with 6 hourly mandatory and PRN boluses provided similar analgesia to a 5 ml h⁻¹ infusion and PRN only boluses.
- The higher background infusion resulted in more patients experiencing side-effects.

Background. This prospective, randomized study tested the hypothesis that a reduced dose continuous interscalene regimen incorporating a low background infusion with mandatory boluses would provide similar shoulder surgery analgesia compared with a dose regimen incorporating a conventional higher background infusion.

Methods. After rotator cuff surgery, patients received via an interscalene catheter, one of two elastomeric pumps, each having a 5 ml per 60 min bolus function and a 2 ml h⁻¹ (n=38) or 5 ml h⁻¹ (n=43) ropivacaine 2 mg ml⁻¹ infusion. Boluses commenced from the onset of pain and continued for >48 h as required (pro re nata, PRN) up to every hour for a numerical rating pain score (NRPS, 0–10) >2. Group 2 ml h⁻¹ received mandatory 6 hourly boluses irrespective of the NRPS. Rescue tramadol was available. Patients were questioned on postoperative days 1 and 2 for treatment effectiveness and side-effects.

Results. Postoperative pain was similar between the groups [Group 2 ml h⁻¹ day 2 median (IQR) (95% confidence interval of the mean) worst movement pain = 4 (1–5) (2.8–4.7) vs 4 (2–5) (3.1–4.6), P=0.99], as were night awakenings and tramadol consumption. Numerically rated numbness and weakness were similar between the groups; however, nine patients (21%) in the 5 ml h⁻¹ group vs one (3%) in the 2 ml h⁻¹ group required a temporary infusion cessation due to side-effects (predominantly hand numbness) (P=0.02).

Conclusions. Continuous interscalene ropivacaine 0.2% 2 ml h⁻¹ with mandatory 6 hourly (and PRN) boluses provides similar analgesia after rotator cuff repair but with reduced side-effects compared with 5 ml h⁻¹ with PRN only boluses.

Trial registration. ANZCTR: ACTRN12609000740291.

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

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Significant advances have occurred in the perioperative management of pain after shoulder surgery.¹ This surgery traditionally required a two to three night hospital stay for opioid analgesia, but with steady progress over the last 5 yr in our understanding of the requirements for successful continuous interscalene analgesia in the ambulatory setting, this surgery can now be performed as an overnight or even day-stay procedure, with patients experiencing excellent analgesia and generally high satisfaction.² ³

Despite the well-demonstrated effectiveness of continuous interscalene analgesia, for rotator cuff repair, interscalene ropivacaine 0.2% 2 ml h⁻¹ with PRN (pro re nata) 5 ml h⁻¹ boluses was associated with a significant number of patients experiencing episodes of moderate-to-severe breakthrough pain.⁴ An intervention to reduce breakthrough pain involves increasing the basal infusion, but this can be problematic. First, a larger and therefore heavier reservoir is required, potentially compromising patient satisfaction. Without a larger reservoir, the infusion duration (and consequent potent analgesia) is limited.⁵ Secondly, higher basal infusions might increase unwanted motor block, which can further compromise patient satisfaction.⁶ ⁷

Compared with a continuous only infusion, an automated electronic bolus system has been recently shown to reduce local anaesthetic consumption¹ and improve the analgesic effectiveness of continuous popliteal sciatic blocks.⁸ However, this automated delivery system is not presently available in the commonly used disposable ambulatory
pumps. An analogous alternative with these pumps is to have patients ‘self automate’ through bolusing at pre-specified time intervals.

Therefore, we sought to determine in this prospective, randomized study whether a reduced dose ‘mandatory + PRN bolus’ regimen incorporating a low background infusion with mandatory (and PRN) boluses would provide similar analgesia compared with a ‘PRN only’ regimen incorporating a conventional but higher dose, higher background infusion with boluses administered PRN only. The primary outcome endpoint was postoperative pain on postoperative days 1 and 2. The main secondary endpoints included side-effects of treatment, in particular, extremity numbness and weakness.

**Methods**

Local institutional review board (Northern X Regional Ethics Committee, Auckland, New Zealand) approval for the study was obtained and the trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12609000740291). We enrolled adult American Society of Anesthesiologists physical status I–III patients undergoing elective surgery involving arthroscopic or open rotator cuff repair at the Southern Cross Brightside and North Harbour hospitals between May 2009 and April 2010. Subjects were identified from the investigators’ regular operating lists. Initial invitation to participate was made by a research assistant but definitive enrolment was by the operating investigator. Exclusion criteria included patient refusal of interscalene block, severe respiratory disease, known amide local anaesthetic drug allergy, non-steroidal anti-inflammatory drug intolerance, and preoperative opioid therapy administered for chronic suffering.

Written informed consent for study procedures was obtained and the trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12609000740291). We enrolled adult American Society of Anesthesiologists physical status I–III patients undergoing elective shoulder surgery involving arthroscopic or open rotator cuff repair at the Southern Cross Brightside and North Harbour hospitals between May 2009 and April 2010. Subjects were identified from the investigators’ regular operating lists. Initial invitation to participate was made by a research assistant but definitive enrolment was by the operating investigator. Exclusion criteria included patient refusal of interscalene block, severe respiratory disease, known amide local anaesthetic drug allergy, non-steroidal anti-inflammatory drug intolerance, and preoperative opioid therapy administered for chronic suffering.

**Oral acetaminophen 1 g was administered 1 h before surgery. In an area immediately adjacent to the operating theatre, i.v. sedation with up to midazolam 2 mg and alfentanil 0.5 mg was administered. All blocks were administered by one of the four investigators, all of whom were experienced in ultrasound and nerve stimulation-assisted interscalene catheter placement.**

**A superficial cervical plexus block was performed using standard landmarks and lidocaine 1% (5–10 ml) with epi-nephrine 1/200 000. The patient was transferred to the operating table, a pulse oximeter was applied, and appropriate aseptic precautions were observed.**

**Interscalene catheter placement**

The patient was positioned supine with the head turned to the contralateral side and supported with one to two pillows. The scalene muscles and interscalene brachial plexus were imaged in the short axis at approximately the level of the 6th/7th cervical vertebrae with a 38 mm 13-6 MHz linear ultrasound probe (SonoSite HFL/MicroMaxx or M-Turbo, Bothell, WA, USA). A 4–5 cm 18 G insulated Tuohy needle (Contiplex Tuohy, B. Braun, Bethlehem, PA, USA) connected to a nerve stimulator (Pajunk Vario, Tucker, GA, USA) was inserted approximately at the posterior border of the sternocleidomastoid muscle ~3 cm cephalad of the level of the 6th/7th cervical vertebrae. The needle was advanced using out-of-plane needle-probe orientation superficially into the middle scalene muscle until tissue displacement was observed just lateral to the most superficial elements of the brachial plexus. At the 6th/7th cervical vertebral level, these correspond to the 5th/6th cervical roots or superior/middle trunks. The needle tip 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% (10 ml) and observation of injection spread immediately lateral to the target roots/trunks, or depending on operator preference, by elicitation of a sustained deltoid or biceps motor response at <0.5 mA. If a sustained motor response was present at <0.2 mA, the needle was manipulated until the response was eliminated.

A non-stimulating triple-orificed catheter was advanced blindly and then withdrawn such that 2–3 cm of the catheter remained past the original needle tip position. The catheter was finally fixed to the skin with a catheter-anchoring device (Lockit-plus® Portex, Hythe, UK).

**Intraoperative management**

All patients were given a standardized light general anaesthetic (end-tidal minimum alveolar concentration=0.8–1.0) using a laryngeal mask airway, desflurane anaesthesia, and spontaneous respiration. Ropivacaine 0.5% (30 ml) was administered via the catheter following the induction of general anaesthesia but before surgery. No long-acting opioid was administered; however, alfentanil 0.25 mg was administered PRN for a ventilatory frequency >25.

Randomization to the ‘mandatory + PRN bolus’ or ‘PRN only bolus’ group was implemented with a computer-generated random number previously delivered in pre-prepared sealed opaque envelopes with randomization performed by a research assistant away from the study procedures.

**Post-anaesthesia care unit protocol**

In the post-anaesthesia care unit (PACU), patients reporting a numerical rating pain score (NRPS) of more than 2 were first given a bolus of lidocaine 1% (10 ml). If the NRPS subsequently remained more than 2, the catheter was withdrawn 1 cm and an additional lidocaine 1% (10 ml) was administered. If the NRPS still remained more than 2, the catheter was replaced. Patients receiving a replacement catheter received a repeat bolus of ropivacaine 0.5% (20 ml).

**Postoperative management**

All pumps were filled with ropivacaine 0.2%. The specific treatment protocol for each group is summarized in Table 1. Specifically, patients in each treatment group received ropivacaine boluses from the onset of operative...
site pain and these continued as required every hour if the NRPS was > 2. The ‘mandatory + PRN bolus’ group also received boluses on the clock every 6 h irrespective of the NRPS from the onset of operative site pain. However, comfort permitting, patients slept through the night period (~ 11 p.m. – 6 a.m.) without a mandatory bolus. This protocol continued for at least 48 postoperative hours. The 6 h bolus interval was an arbitrary compromise between any potential therapeutic effect from mandatory boluses, patient inconvenience from having to manually activate the bolus device while also enabling a dose reduction in the mandatory bolus group (Table 1).

Acetaminophen (1 g every 6 h) and diclofenac slow release (75 mg every 12 h) were continued if any postoperative pain occurred. If the NRPS was more than 2 despite regular acetaminophen, diclofenac, and two consecutive ropivacaine boluses, tramadol slow release (100 mg every 12 h) was added. Discharge home occurred on the morning of postoperative day 1.

Patients were instructed to clamp off the infusion if, late on the afternoon of postoperative day 1, the hand was excessively numb or weak, or if the hand became excessively numb or weak after the initial primary block had begun to resolve. The written instructions handed out on the morning of day 1 reiterated these instructions albeit with more stringent stopping criteria: to clamp off the infusion ‘if you feel that you can’t move your hand at all or you don’t have any feeling in the arm and hand’ and to ‘unclamp it when you start to be able to move or feel the hand. Unclamp it also if you start to feel any discomfort in the shoulder’.

**Data collection**

The operating investigator recorded the needle endpoint used for the catheter placement and the number of alfentanil 0.25 mg boluses administered during surgery. A research assistant phoned all subjects on the afternoon of postoperative days 1 and 2 and questioned for ropivacaine bolus demands, supplemental tramadol consumption, NRPS (at rest, on movement, and ‘average’ pain but specifically excluding pain that was present in the recovery room), arm numbness/weakness (0 – 10; 0, no pain, numbness/weakness; 10, worst imaginable pain, numbness/weakness), the number of night awakenings, and whether the infusion had to be temporarily discontinued during the previous 24 postoperative hours. At 48 h, subjects were also questioned for dissatisfaction from the cumbersome nature of the elastomeric pump and for overall satisfaction with the technique (0 – 10; 0, no dissatisfaction, very unsatisfied; 10, worst dissatisfaction, very satisfied).

**Blinding**

The research assistant who questioned patients on days 1 and 2 for the main outcome data could be considered blinded to the treatment group at the start of patient interrogation. However, treatment group allocation would have become obvious after questioning. The operating investigators and patients were not blinded to the treatment group.

**Statistical analysis**

An independent statistician not otherwise involved in the study performed all calculations. Categorical outcomes were compared using the $\chi^2$ test (tramadol requirement, day 2 night awakenings) or Fisher’s exact test (temporary infusion cessation, day 1 night awakenings). Ordinal outcomes (ropivacaine bolus consumption, numerically rated pain, numbness, weakness, dissatisfaction, and satisfaction) were compared using the Mann–Whitney U-test. $P$-values of $< 0.05$ were considered statistically significant. Two-sided tests were used for all experimental outcomes.

Other data were summarized using appropriate descriptive statistics (mean, $s_d$, and 95% confidence interval of the mean for normally distributed or symmetric variables; median and inter-quartile ranges for skewed variables; number and proportion for categorical variables). Because our primary interest was equivalence (non-inferiority) of the primary outcome (postoperative pain), 95% confidence intervals (of the mean) were presented for these data regardless of the data distribution. All statistical analyses were performed using SPSS Statistics 18.0.0 (SPSS Inc., Chicago, IL, USA).

The sample size calculation was based on the primary hypothesis that the ‘mandatory bolus/low background infusion’ technique would provide similar (not significantly inferior) analgesia to the ‘PRN only/high background infusion’ technique. Assuming an $s_d$ of 2.28 in each group based on the results from a recent study, a two-sided error protection of 0.05 and a power of 0.80, 80 patients would detect a difference in 1.65 points on the 11-point NRPS (StatMate 2.0; GraphPad Software, San Diego, CA, USA)—with a 15% adjustment for using the t-test when a subsequent non-parametric test was likely.
Results

Eighty-seven patients presenting for rotator cuff surgery were enrolled during the study period: 43 patients were randomized to the mandatory + PRN bolus group and 44 patients to the PRN only bolus group. There were no differences in patient and surgical characteristics between the groups (Table 2). Six patients were excluded after randomization (Fig. 1). Thus, 81 patients completed the study according to protocol (‘intention to treat’). Intraoperative and PACU interventions are detailed in Table 3.

Postoperative pain, night awakenings, and tramadol consumption were similar on both days 1 and 2 (Table 4) (Fig. 2): Group 2 ml h⁻¹ day 2 median (IQR) (95% CI of the mean) worst movement pain = 4 (1–5) (2.8–4.7) vs 4 (2–5) (3.1–4.6) (P = 0.99). Day 2 PRN ropivacaine bolus requirement was lower in the mandatory + PRN bolus group (median (inter-quartile range) = 0 (0–1) vs 2 (1–3), P = 0.002). Numerically rated numbness and weakness were similar between groups on each day; however, nine patients (21%) in the PRN only bolus group vs only one patient (3%) in the mandatory + PRN bolus group had to temporarily stop the infusion because of side-effects (P = 0.02) (Table 4). Of these 10 patients, eight patients stopped the infusion because of excessive hand numbness or weakness and two patients stopped the infusion because of mild dyspnoea. Neither dissatisfaction with the cumbersome nature of the device nor overall satisfaction differed between the groups (Table 4).

No patient demonstrated symptoms or signs of local anaesthetic toxicity in the recovery room, and there were no pneumothoraces evident clinically.

Discussion

In the context of continuous interscalene analgesia after rotator cuff repair, a delivery system incorporating a 2 ml h⁻¹ background infusion combined with 6 hourly mandatory (and PRN) boluses provided similar analgesia after rotator

![Fig 1](https://example.com/fig1.png)

Fig 1 Patient flow through the study. ¹Three patients had no rotator cuff tear on diagnostic arthroscopy. ²Two patients did not have catheters placed successfully. ³One patient had a prolonged catheter disconnect on postoperative day 1.

### Table 2 Patient and surgical characteristics. Values are mean (SD), median (inter-quartile range), or n (%). PRN, pro re nata

<table>
<thead>
<tr>
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<th>Mandatory + PRN bolus (n=43)</th>
<th>PRN only bolus (n=44)</th>
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</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>32 (74)</td>
<td>30 (68)</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>56 (13)</td>
<td>56 (9)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>83 (14)</td>
<td>85 (16)</td>
</tr>
<tr>
<td>Duration preoperative pain (months)</td>
<td>12 (6–18)</td>
<td>10 (5.5–18)</td>
</tr>
<tr>
<td>Surgery</td>
<td>Rotator cuff repair 43 (100)</td>
<td>44 (100)</td>
</tr>
<tr>
<td></td>
<td>+ Total shoulder arthroplasty 3 (7)</td>
<td>4 (9)</td>
</tr>
</tbody>
</table>
cuff repair compared with a regimen delivering 5 ml h⁻¹ combined with PRN only boluses. The higher background infusion regimen was associated with a significantly higher proportion of patients experiencing side-effects (predominantly hand numbness or weakness).

These results are consistent with previous studies involving continuous sciatic and epidural block: compared with a continuous infusion, an intermittent bolus regimen has been shown to reduce local anaesthetic consumption and improve analgesia.⁹⁻¹¹ It was postulated that boluses generate higher injection pressures than a slow infusion; in the sciatic nerve area, this might overcome anatomical distances between the catheter orifice(s) and nerve. In the epidural space, experimental studies have confirmed the intermittent bolus technique results in more uniform local anaesthetic spread.¹² In the current study, despite the lower local anaesthetic dose administered in the mandatory bolus group, analgesia was similar to the higher dose, higher infusion regimen. It is likely that similar to the sciatic area, the higher pressures generated by the intermittent boluses facilitated spread to the appropriate roots/trunks (e.g. 5th/6th or 7th cervical nerve roots) of the brachial plexus. The reduction in side-effects with this regimen is more difficult to explain, but it is possible that total local anaesthetic dose is the main determinant of extremity numbness and weakness as evidenced by the higher proportion of patients having to temporarily discontinue the infusion in the high background infusion group.

We feel that a cautious historical comparison is warranted in this instance. The current study is very similar to a recent study by our group; the only difference being the addition of two new operators and one surgeon. In the recent study, ropivacaine 0.2% and 0.4% were compared when administered via the same infusion regimen. No difference was found in analgesic effectiveness between the groups; however, a significant number of patients experienced moderate-to-severe breakthrough pain: day 2 worst pain on movement had a median (inter-quartile range) of 5 (3–8).⁴ In contrast, in the current study, the median (inter-quartile range) day 2 worst pain on movement was 4 (1–5). This suggests that mandatory boluses are effectively minimizing breakthrough pain, while the lower total local anaesthetic dose administered also optimizes the infusion duration for a given reservoir volume.

Table 3 Intraoperative and PACU interventions. Values are n (%). PRN, pro re nata; PACU, post-anaesthesia care unit

<table>
<thead>
<tr>
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<th>Mandatory + PRN bolus (n=43)</th>
<th>PRN only bolus (n=44)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound needle endpoint</td>
<td>31 (72)</td>
<td>31 (70)</td>
</tr>
<tr>
<td>Alfentanil bolus ≥ 1</td>
<td>1 (3)</td>
<td>7 (16)</td>
</tr>
<tr>
<td>PACU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACU catheter bolus only</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>PACU catheter withdrawal + bolus</td>
<td>1 (3)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>PACU catheter replacement</td>
<td>1 (3)</td>
<td>3 (7)</td>
</tr>
</tbody>
</table>

Table 4 Postoperative outcomes. Data expressed as n (%) or median (inter-quartile range). PRN, pro re nata; NRS, numerical rating score (0–10; 0, no numbness/weakness or not dissatisfied/satisfied; 10, very numb/weak or very dissatisfied/satisfied). *Total (mandatory + PRN) boluses. †PRN only boluses (mandatory boluses not included in this value)

<table>
<thead>
<tr>
<th></th>
<th>Mandatory + PRN bolus (n=38)</th>
<th>PRN only bolus (n=43)</th>
<th>P-value</th>
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<tr>
<td>Tramadol required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>7 (18)</td>
<td>11 (28)</td>
<td>0.31</td>
</tr>
<tr>
<td>Day 2</td>
<td>16 (44)</td>
<td>19 (44)</td>
<td>0.99</td>
</tr>
<tr>
<td>Ropivacaine boluses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>1 (0–2)*</td>
<td>0 (0–1.5)</td>
<td>0.35</td>
</tr>
<tr>
<td>Day 2</td>
<td>0 (0–1)†</td>
<td>2 (1–3)</td>
<td>0.002</td>
</tr>
<tr>
<td>Numbness NRS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>9 (6–10)</td>
<td>9 (7–10)</td>
<td>0.99</td>
</tr>
<tr>
<td>Day 2</td>
<td>2 (0–5)</td>
<td>3 (1–6)</td>
<td>0.53</td>
</tr>
<tr>
<td>Weakness NRS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>8 (6–10)</td>
<td>9 (6–10)</td>
<td>0.63</td>
</tr>
<tr>
<td>Day 2</td>
<td>5 (2–6)</td>
<td>5 (3–7)</td>
<td>0.38</td>
</tr>
<tr>
<td>Cessation of infusion required</td>
<td>1 (3)</td>
<td>9 (21)</td>
<td>0.02</td>
</tr>
<tr>
<td>Night awakenings &gt;0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>3 (8)</td>
<td>5 (12)</td>
<td>0.72</td>
</tr>
<tr>
<td>Day 2</td>
<td>16 (41)</td>
<td>19 (44)</td>
<td>0.71</td>
</tr>
<tr>
<td>Pump dissatisfaction (cumbersome NRS)</td>
<td>2 (0–4)</td>
<td>2 (0–4)</td>
<td>0.76</td>
</tr>
<tr>
<td>Satisfaction NRS</td>
<td>10 (8–10)</td>
<td>10 (8–10)</td>
<td>0.40</td>
</tr>
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</table>
For a more in-depth account of the pharmacology relevant to this treatment, readers are referred to a recent review.¹

A major strength of this study is the relative surgical procedure homogeneity: all included patients having had a rotator cuff repair; this is a unique attribute for dose-finding studies of this kind. A second strength was the insertion of all catheters by four anaesthesiologists experienced in this procedure, thus further minimizing variability between the groups; although the inclusion of four operators should allow reasonable study generalizability.

A limitation arising from the use of two structurally different infusion devices and two different protocols for bolusing was that the study could not be blinded to either investigators or subjects. The pumps in this investigation are commonly used for ambulatory continuous peripheral nerve blocks; this was the primary reason for the choice of infusion rate. Consequently, investigator bias may have manifested at the time the verbal instructions were provided on the morning of postoperative day 1. In an attempt to minimize this bias, pre-prepared explicit written instructions were given to the patient detailing criteria for bolusing and temporarily suspending the infusion. Nevertheless, ideally, the results of this study should be confirmed with a blinded study using an electronic pump.¹³ ¹⁴ Finally, we cannot be sure that the instructions given to patients by the investigators on the morning of postoperative day 1 were appropriately followed.

Despite the demonstrated advantages of the mandatory bolus group (reduced extremity numbness/weakness, prolonged infusion duration), the regimen is not without inconvenience. Anaesthesiologists/providers have to provide additional education on the bolusing regimen. Patients themselves also have to remember to activate the bolus button.

The primary bolus dose of ropivacaine warrants comment. Ropivacaine 0.5% (30 ml) has been shown to be more than that required to prevent recovery room pain in ≏ 95% of patients: a more appropriate dose for an ultrasound-guided anterolateral technique being approximately 20 ml 0.375%.⁶ There was a suggestion that this dose was associated with reduced motor block which may have accounted for the increase in patient satisfaction.⁶ However, for rotator cuff repair, where on emergence from general anaesthesia it can be clinically advantageous to have the entire upper extremity immobile in order to protect the surgical repair, our current preference is to administer ropivacaine 0.75% (10 ml) diluted with lidocaine 1% (10 ml).

In summary, an ambulatory interscalene infusion at 2 ml h⁻¹ combined with 6 hourly mandatory (and PRN) boluses provides similar analgesia after rotator cuff repair compared with a regimen delivering 5 ml h⁻¹ with PRN only boluses. The lower background infusion regimen was associated with fewer patients experiencing side-effects and has the additional advantage of enabling a longer infusion duration for a given reservoir volume.

Acknowledgement

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Conflict of interest
None declared.

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