Continuous interscalene infusion and single injection using levobupivacaine for analgesia after surgery of the shoulder

A DOUBLE-BLIND, RANDOMISED CONTROLLED TRIAL

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We performed a double-blind, randomised controlled trial to assess the effectiveness of a continuous-infusion brachial plexus block with levobupivacaine compared with that of a standard single injection for the management of post-operative pain after surgery on the shoulder.

Eight patients were randomised to receive a pre-operative brachial plexus block using 30 ml of levobupivacaine 0.5% with adrenaline 1:200 000 followed by insertion of a 20-gauge polyamide catheter. This was connected to a disposable elastometric pump, set immediately after surgery to administer a continuous flow of levobupivacaine 0.25% at a rate of 5 ml per hour. The other eight patients were randomised to receive only the initial injection of 30 ml. The study was double-blinded with the aid of sham catheters and clamped pumps.

All patients were given regular paracetamol and were prescribed morphine through a patient-controlled analgesia pump. Motor and sensory block assessments, visual analogue scale pain scores and consumption of morphine were recorded after the operation and then at 6, 12 and 24 hours after administration of the block.

Satisfactory motor and sensory block was achieved in all patients. The mean visual analogue scale pain score at 12 hours and consumption of morphine at 24 hours after injection were significantly lower (p < 0.05) in the continuous-infusion group. This group also took longer to request their first additional analgesia and reported a significantly higher overall level of satisfaction.

Our study has shown that continuous interscalene infusion of levobupivacaine is an effective method of post-operative analgesia after major surgery of the shoulder.

The use of local and regional anaesthetic techniques is becoming more popular because they offer the advantages of excellent post-operative relief from pain, and the ability to eat, drink and mobilise soon after surgery while avoiding the risks and side-effects of general anaesthesia. In a meta-analysis Rodgers et al suggested that mortality associated with major surgery was reduced by 30% when regional anaesthesia was used, with or without general anaesthesia. This may be related to the many multisystem pathophysiological benefits outlined by Herrick and Van Rooyen, such as better maintenance of respiratory function, improved coronary blood flow and reduced myocardial oxygen demand. Local and regional techniques offer faster mobilisation of patients undergoing surgery to the upper limb, who may be fully ambulant on return to the ward and able to go home later that day. The quicker recovery of individual patients and minimised admission for post-operative pain, nausea or prolonged sedation allow an increased throughput of patients, thereby reducing costs.

Regional anaesthetic techniques may be used on their own, or combined with general anaesthesia, to provide post-operative relief from pain. The current practice in shoulder surgery is to achieve a brachial plexus block with a long-acting local anaesthetic agent given in one dose immediately before surgery. This offers a period of analgesia post-operatively until the local anaesthetic wears off. However, brachial plexus block with a continuous infusion of local anaesthetic through a catheter and elastometric pump is now used in some centres in the United Kingdom and USA to provide effective and longer-lasting analgesia. There is also the possibility of delivering a later bolus of local anaesthetic through a catheter, or to set up a patient-controlled pump to deliver local anaesthetic as required.

Our aim was to assess the effectiveness of a continuous-infusion brachial plexus block with
levobupivacaine in the management of post-operative pain (group 1) and to compare it with a single-shot brachial plexus block begun immediately before surgery (group 2). A double-blind, randomised controlled trial was used to assess the completeness of the motor and sensory block, the extent of post-operative pain, the requirement for additional analgesia, the incidence of nausea, and patient satisfaction.

**Patients and Methods**

At first we carried out a power analysis to determine sample size. This predicted that detection of a 25-point difference in 100 mm visual analogue pain scores at 24 hours, with an SD of 10 points, would confer 99.6% power with a sample size of eight patients in each of the two groups. This is a very high power, exceeding that sought in most designs of trials, and allowed a safe margin for dropout or failure to recruit subjects.

Between December 2003 and March 2004, 16 patients undergoing open shoulder surgery were therefore enrolled. Patients were excluded if they were less than 18 years old or greater than 80 years, if they had a known sensitivity (allergy) to a local anaesthetic agent, if they suffered from severe respiratory disease or an unstable neurological condition, or if they were unable to give informed consent. A letter and information sheet outlining the study were sent to the patients one week before admission. The study had ethical approval and informed consent was obtained from all the patients.

The two groups were well matched with regard to age, gender, general health and body mass index (BMI). The mean age of group 1 was 57.5 years (39 to 72) and of group 2 was 51.4 years (31 to 71). There were four men and four women in each group. The modal American Society of Anesthesiologists (ASA) physical status score was II in group 1 and III in group 2. The mean BMI in group 1 was 28.6 (23.2 to 33.8) and 27.0 in group 2 (17.4 to 34.3).

The surgical procedures were all open and consisted of hemiarthroplasty, subacromial decompression, shoulder stabilisation and repair of the rotator cuff.

Randomisation was achieved by placing eight cards with the words ‘continuous infusion’ and eight with the words ‘single shot’ into 16 unmarked envelopes. The envelopes were mixed together at random and then numbered from 1 to 16. Each successive patient in the study received the treatment in the corresponding numbered envelope. This randomisation was organised by the anaesthetist (DMC), since the researcher remained blinded until the completion of the study.

Thus, eight of the patients were randomised to receive a pre-operative interscalene brachial plexus block using 30 ml of levobupivacaine 0.5% with adrenaline 1:200 000 followed by insertion of a 20-gauge polyamide catheter (group 1). This catheter was connected to a disposable elastometric pump, set immediately after surgery to administer a continuous flow of levobupivacaine 0.25% at a rate of 5 ml per hour. The other eight patients were randomised to receive only the initial injection of 30 ml (group 2). They were equipped with a sham catheter and pump for blinding purposes.

On arrival in the anaesthetic room, the patients were attached to standard monitoring equipment, namely an electrocardiograph, non-invasive blood pressure monitor and pulse oximeter. Intravenous access was established in the non-operated upper limb using a 16-gauge intravenous cannula and between 1 mg and 4 mg of intravenous midazolam was administered to provide sedation for the block procedure.

The brachial plexus block was achieved by means of an interscalene approach and on each occasion this was performed by the same anaesthetist (DMC). Using an aseptic technique, a skin weal was raised with 1 ml of 1% plain lidocaine over the interscalene groove at the level of the cricoid cartilage (C6). An 18-gauge insulated Tuohy needle (Pajunk Medizintechnologie, Geisingen, Germany) connected to a peripheral-nerve stimulator was then inserted through the skin weal. The brachial plexus was localised by eliciting a motor response distal to the acromion with optimisation of muscle contraction at 0.5 mAmp, and 30 ml of levobupivacaine 0.5% with 1:200 000 adrenaline were injected through the needle after careful aspiration.

In the continuous-infusion group, a 20-gauge polyamide catheter was threaded through the needle for a distance of 2 cm. The needle was then removed leaving the catheter in situ. It was secured to the skin with a Tegaderm dressing (3M Corporation, St Paul, Minnesota). In the single-shot group, the needle was removed and a sham catheter was attached to the skin using an identical Tegaderm dressing.

Sensory and motor block assessments were made at ten and 20 minutes after injection. General anaesthesia was then induced with intravenous propofol, and maintained with isoflurane in N₂O₂ gas, using a laryngeal mask.

At the end of surgery, the continuous-infusion group had an infusion of levobupivacaine 0.25% begun through the brachial plexus catheter, at a rate of 5 ml/hour for 24 hours from a disposable elastometric pump (Homepump Eclipse, Sheffield, United Kingdom; C-Series 270 ml volume, 5 ml/hr) (Fig. 1). The single-shot group had a sham infusion pump containing normal saline attached to the sham catheter, but the administration set remained clamped.

For blinding purposes, the catheter tips were covered with Mepore dressings (Mölnlycke Health Care, Goteburg, Sweden) and the pump and clamp were placed inside a cloth bag. Patients were not informed whether they had been given a real or sham catheter and pump.

Rescue analgesia of boluses of 1 mg of morphine were prescribed for use in the recovery room if necessary. All patients had pain and motor and sensory block assessments carried out immediately after the operation in the recovery room and then on the ward at 6, 12 and 24 hours after administration of the block. All assessments were carried out by the blinded researcher (JK). Pain was assessed using
VOL. 88-B, No. 9, SEPTEMBER 2006

a 100 mm visual analogue scale (VAS) pain score (0, no pain; 100, worst pain imaginable). Feeling was assessed by awareness of pinprick from C3 to T1 using a short-bevelled, 27-gauge needle. It was graded as follows: 0, normal feeling; 1, loss of pinprick feeling; and 2, no feeling. Motor assessments were made by clinical examination of power in specific muscle groups. The axillary nerve was tested by arm abduction, the musculocutaneous nerve by elbow flexion, the radial nerve by wrist extension, the median nerve by finger flexion and the ulnar nerve by thumb adduction. These were graded as follows: 0, normal power; 1, weakness; and 2, paralysis.

All patients were given 1000 mg paracetamol every six hours and were prescribed morphine through a patient-controlled analgesia pump, to be administered when requested. The number of patient-controlled analgesia administration attempts and total morphine dose were recorded at each assessment, with a specific note of the time of the first analgesic request. The researcher also recorded the incidence of nausea and vomiting and the use of antiemetic drugs at each visit. At 24 hours after administration of the block the patients were asked to score their satisfaction using a 100 mm VAS ruler with a sliding cursor (Abbott Pharmaceuticals, Maidenhead, United Kingdom) (0, not satisfied at all; 100, could not be more satisfied).

The catheters, both real and sham, were removed by nursing staff 24 hours after administration of the block.

Statistical analysis. The main outcomes of the VAS pain scores, consumption of morphine and time until first additional analgesic request were compared between the two groups using the Mann-Whitney U test for two independent samples. Nausea and patient satisfaction were compared using the chi-squared test. The motor and sensory blocks were plotted in a graphical form to show effectiveness over time and the 24-hour sensory block was compared in the two groups, again using the chi-squared test. These tests were carried out using the statistical package SPSS 11.0 (SPSS Inc., Chicago, Illinois). Statistical significance was set at \( p \leq 0.05 \).

Results

Figure 2 shows the patients’ progress through the phases of the trial. One of the patients in the continuous-infusion group was excluded because of failure of the catheter and, therefore, a further patient was recruited. This failure was due to the patient removing the catheter accidentally while sleeping. Another continuous-infusion card was therefore placed in an unmarked envelope and mixed with the remaining envelopes which were then reshuffled and renumbered.

There was a trend for the mean effectiveness of the motor and sensory blocks in group 2, the single-shot group, to decrease before that in group 1. This is in keeping with the expectation that continuous infusion would result in blockade of longer duration than that of the single-shot technique. At 24 hours after injection, the continuous-infusion group (group 1) had five patients with a grade-2 sensory block compared with none in group 2, the single-shot group. This was statistically significant (\( p = 0.013 \)). Also, at this time, six of the group 1 patients had some sensory block in more than one dermatome compared with only one in group 2. Again this was statistically significant (\( p = 0.02 \)).
Table I. Mean (range) visual analogue scale pain scores in mm

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<tr>
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<th>Post-operative</th>
<th>6 hours</th>
<th>12 hours</th>
<th>24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>5.0 (0 to 40)</td>
<td>1.25</td>
<td>0.13</td>
<td>18.88</td>
</tr>
<tr>
<td>Group 2</td>
<td>10 (0 to 80)</td>
<td>9</td>
<td>26.88</td>
<td>41.25</td>
</tr>
<tr>
<td>p value</td>
<td>0.927</td>
<td>0.241</td>
<td>0.026</td>
<td>0.073</td>
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Table II. Mean (range) patient-controlled dose of morphine in mg

<table>
<thead>
<tr>
<th></th>
<th>Post-operative</th>
<th>6 hours</th>
<th>12 hours</th>
<th>24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>0.0 (0 to 0)</td>
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<td>0.13</td>
<td>3.38</td>
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<tr>
<td>Group 2</td>
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<tr>
<td>p value</td>
<td>1.0</td>
<td>0.317</td>
<td>0.096</td>
<td>0.011</td>
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</table>

Table I shows the mean VAS pain scores recorded at each assessment. The continuous-infusion group (group 1) had a lower mean pain score at each assessment than group 2. This was significant only at 12 hours after injection when there was a difference of 26.75 mm (p = 0.026) between the two groups. Table II shows the mean cumulative dose of morphine also recorded at each assessment. Morphine consumption was also lower in the continuous-infusion group (group 1). This was significant only at 24 hours after injection when group 2 had a mean cumulative dose of 27.63 mg compared with 3.38 mg in group 1 (p = 0.011).

The single-injection group (group 2) required additional analgesia sooner than group 1. The mean time to the first requirement for morphine was 13.39 hours (2.67 to 20.58) in group 2 and 20.03 hours (14.83 to 23.15) in group 1. This difference of 6.64 hours was statistically significant (p = 0.04). This analysis involved five of the group 1 patients and seven of the group 2 patients, since the others had no doses of morphine in the 24-hour period.

No complications were experienced as a result of the technique in either group. Group 1 had a significantly greater incidence of nausea (p = 0.047) with a mean incidence of 0.88 (0 to 2) compared with 0.25 (0 to 2) in group 2. However, group 1 also had a significantly higher overall satisfaction (p = 0.027) with a mean score of 87 mm (50 to 100) compared with 78 mm (50 to 100) in group 2. The patients were reviewed in the standard orthopaedic clinic at six weeks and no neurological complications were reported.

Discussion
We found interscalene nerve block with levobupivacaine to be an effective method of post-operative analgesia in major surgery of the shoulder. All patients received an effective block without any complications attributed to either technique. This suggests that adequate peripheral nerve blockade for surgery of the shoulder can be achieved consistently with an interscalene approach to the brachial plexus. As expected, the blocks tended to take longer to regress in the continuous-infusion patients.

We have shown that the additional use of an interscalene catheter to provide continuous infusion of levobupivacaine for 24 hours after the initial injection resulted in significantly lower pain scores and reduced morphine consumption in the post-operative period. At each visit the mean pain scores in group 1 were lower than in group 2 (Table I), with this difference being significant only at 12 hours after injection. The difference in the mean administered dose of morphine was found to be significant only at 24 hours after injection.

A further indication of the quality of regional analgesia is the length of time until the first requirement of additional analgesia through the patient-controlled morphine pump. Five of the eight patients in group 1 required the use of patient-controlled analgesia, as did seven of the patients in group 2. The mean time to the first patient-controlled morphine dose in group 1 (continuous infusion) was significantly longer than that in group 2.

The use of subjective pain scores and objective assessments of the dose of morphine and time until the first additional analgesic requirement strengthens the argument that continuous infusion provides better relief from pain. These are consistent with studies involving the use of continuous-infusion of ropivacaine.2-4

The incidence of nausea was compared in the two groups and the mean number of visits at which patients reported nausea was found to be significantly greater in group 1. This higher incidence in group 1 was surprising since less nausea was expected because of the lower consumption of morphine. It may be that this result was spurious since the study was not powered to examine this outcome. Only four patients required single-dose anti-emetic medication, three in group 1 and one in group 2.

Despite the higher incidence of nausea, group 1 also had a significantly higher mean satisfaction score. This was most likely to be because of the significantly better quality of analgesia experienced in group 1. This higher score for satisfaction may be another important factor in recommending continuous-infusion interscalene block.

Continuous levobupivacaine interscalene block may now be used without the provision of patient-controlled morphine since it has been shown to be an effective method of post-operative analgesia, with minimal need for additional opioid analgesia. With the optimal analgesia provided, and
without connection to a patient-controlled analgesia pump, patients can become ambulant more quickly. The cost of disposables represents a minimal cost addition (£20), probably balanced by a lack of need for patient-controlled analgesia. Significant savings will only be made if patients can be discharged sooner as a result of improved analgesia. The quality of analgesia is, however, significantly better and there may be implications for quicker rehabilitation and perhaps improved surgical outcome, a factor which we did not investigate.

There may also be future scope for early discharge from hospital with an interscalene catheter in situ, although this remains controversial. Other types of surgery may also benefit from this technique and the use of catheters with other types of peripheral nerve block may be beneficial. From our findings we recommend that a continuous-infusion block be used when appropriate for post-operative analgesia in patients having major surgery of the shoulder.

Supplementary Material

A further opinion by Mr Graham Tytherleigh-Strong is available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References