Extended duration regional analgesia for total knee arthroplasty: a randomised controlled trial comparing five days to three days of continuous adductor canal ropivacaine infusion

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Summary

There is a growing body of evidence in favour of continuous adductor canal block (CACB) for total knee arthroplasty. However, there are no studies describing the optimal duration of the infusion. At our institution the usual practice was to stop the infusion on day three. Our hypothesis was that extending the infusion to five days would improve analgesia and quality of recovery. A prospective, non-blinded, randomised trial was undertaken. Patients received a continuous infusion of 0.2% ropivacaine via an adductor canal catheter for either three or five days. Primary outcome was pain while walking during the 24-hour period up to day five (numeric rating scale from 0 to 10). The minimum clinically important difference was set at 1.5 on the numeric rating scale. Secondary outcome measures included quality of recovery, mobility, pain while walking on postoperative day six, Oxford Knee Scores, and complications. Eighty-six patients were recruited with 43 randomised to each group. Seventy-eight were analysed. Median pain scores reported on day five were significantly better in the intervention group (1 versus 3, *P*=0.003). Furthermore, quality of recovery (QOR-15) scores were significantly better in the intervention group (133.6 versus 123.4, *P*=0.017). No statistically significant difference between groups was identified for other secondary outcome measures. CACB prolonged to five days provides superior analgesia and a higher quality of recovery on postoperative days four and five compared to a three-day infusion. This benefit did not extend beyond the period of infusion.

Key Words: regional analgesia, catheter, knee arthroplasty, adductor canal

There is a growing body of evidence in favour of continuous adductor canal block (CACB) as part of a balanced multi-modal analgesic approach for total knee arthroplasty[1-7]. Most adductor canal catheter studies limit the infusion to a maximum of three days[3,4,6,8-12]. However, it is recognised that patients may experience severe pain beyond this time frame[13]. Extended duration perineural infusions for up to five days have been shown to be safe and effective in shoulder surgery[14,15]. Similarly a four-day continuous femoral nerve block for knee arthroplasty has also been shown to be feasible but there are concerns regarding the safety of this technique with regard to motor weakness and risk of falls[16]. There are no studies of extended duration adductor canal block (ACB) infusions beyond three days.

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Methods

This trial was approved by the Hollywood Private Hospital Research Ethics Committee (HPH464) and prospectively registered with the Australia and New Zealand Clinical Trials Registry (Registration number: ACTRN12616000610437). All patients provided written informed consent.

Trial design

The trial was designed as a parallel group randomised controlled trial and structured in accordance with the Consolidated Standards of Reporting Trials statement[17]. There were no changes to the protocol following trial commencement.

Participants

Patients were recruited from a single-centre private practice involving two experienced surgeons. Patients were American Society of Anesthesiologists Physical Status classification 1–3, over 18 years of age, able to give informed consent and booked for elective primary unilateral total knee arthroplasty. These patients were typical of knee arthroplasty patients in other studies involving adductor canal catheter infusions[3,4,6,9]. Exclusion criteria were previous major ipsilateral knee surgery, revision arthroplasty, pre-existing neuropathy of the operative limb, patients unable to consent, prisoners

or Worker's Compensation claimants, and patients with significant musculoskeletal or neurological impairment in mobility. Randomisation was completed immediately after recruitment by an independent researcher using a computer generated randomisation technique based on a parallel trial design with 1:1 allocation. None of the participants, treating clinicians or researchers were blinded to the intervention.

Interventions

All patients received standard monitoring in accordance with Australian and New Zealand College of Anaesthetists guidelines. Large bore intravenous (IV) access was secured and patients received anxiolysis with midazolam 1 to 2 mg IV prior to intrathecal administration of isobaric 0.5% bupivacaine 2.0 to 2.5 ml via a 24G spinal needle with full aseptic precautions. Intrathecal morphine was not administered. With full aseptic technique, an 18G infusion catheter (Pajunk® SonoLong Echo NanoLine 100 mm 18G Tuohy kit, Pajunk Medizintechnologie, Geisingen, Germany) was placed in the adductor canal prior to operation. Starting at the midpoint between the anterior superior iliac spine and the proximal border of the patella, ultrasound (Sonosite X-Porte®, FUJIFILM SonoSite, Inc., Bothell, WA, USA) was used to identify a cross sectional view of the saphenous nerve lateral to the femoral artery below the sartorius muscle. Twenty millilitres of 0.2% ropivacaine was injected and a catheter advanced 2 to 3 cm distally under ultrasound guidance. The catheter was secured using several sterile watertight dressings. Patients were then sedated with propofol using a target-controlled infusion (plasma concentration 0.5 to 1.5 µg/ml) or given a general anaesthetic with deeper-level continuous propofol infusion (plasma concentration 2.0 to 3.5 µg/ml) at the discretion of the treating anaesthetist. Fentanyl 1.0 to 1.5 µg/kg was administered to facilitate laryngeal mask insertion if a general anaesthetic was administered. Intraoperatively, patients also received dexamethasone 8 mg IV, granisetron 1 mg IV and parecoxib 40 mg IV.

Surgery was performed by one of two experienced surgeons using a standard medial parapatellar approach. A thigh tourniquet was used routinely. Prior to implantation of the prosthesis, 0.2% ropivacaine 100 ml with no additives was infiltrated under direct vision by the surgeon into the posterior aspect of the joint capsule. Postoperatively, the anaesthetist connected the catheter to an Admedus ambIT® PCRA Infusion Kit (Admedus, Milton, Queensland) pump programmed to deliver a background infusion of 0.2% ropivacaine at a rate of 6 ml/hour with intermittent patient-controlled bolus (10 ml bolus, four-hour lockout). This was connected to a 400 ml bag of 0.2% ropivacaine, which was replaced once emptied. Postoperatively, all patients received a standardised multimodal oral analgesia regimen including regular paracetamol, celecoxib or meloxicam, pregabalin and slow release tapentadol (50 mg 12 hourly). Immediate release tapentadol 50 mg or oxycodone 5 to 10 mg was used for breakthrough analgesia as required. All participants received a single portable disposable pump worn in a bag over the shoulder when ambulating. The acute pain service team reviewed patients daily. The infusion was ceased and the catheter removed on the morning of postoperative day (POD) 3 and POD 5 for the control and intervention group respectively. For those patients who were discharged home with the regional infusion in place, a full bag of 0.2% ropivacaine was replaced prior to discharge. Patients received detailed advice and written guidelines on when to remove the catheter, in addition to receiving phone calls from an acute pain service nurse.

Outcomes

The primary outcome was pain experienced while walking. Patients used a numeric rating scale (NRS) with anchors of 0 (no pain) and 10 (most severe pain). The minimum clinically important difference in pain score was set at 1.5 in keeping with previously reported clinically significant differences[18]. Patients were asked to reflect on the pain experienced over the previous 24 hours and recorded their scores in a patient diary. This timepoint, being 48 hours after cessation for the control group, was selected to allow time for full offset of the regional anaesthetic and to give patients time to deal with any rebound increase in pain, which may occur in the first 24 hours after cessation of the infusion[19].

Secondary outcomes included quality of recovery (QOR-15) scores, and incidence of severe pain experienced while walking. The QOR-15 score (scale zero to 150) is a self-reported functional outcome score validated for orthopaedic surgery and reflects a broad range of recovery indices (such as sleep, pain, nausea) which are important to patients[20-22]. A difference of 8 is considered clinically important[23]. Severe pain was defined as having a NRS of 7 to 10. These patient-reported outcomes were recorded at baseline (POD 3) and following the intervention (POD 5). Walking speed was assessed by a physiotherapist via a timed ten-metre walk test on POD 4. Complication incidence was recorded by a researcher who screened the acute pain chart and medical notes, and reviewed the patient on POD 6. Pain while walking on POD 6, hospital length of stay, and improvement in Oxford Knee Score from baseline to three months postoperatively were also assessed.

Statistical methods

Sample size was calculated to achieve power (1-β) of 0.8 with a one-tailed significance level of 0.05. A standard deviation for NRS pain scores of 2.6 was derived from a large series of ambulatory pain scores for adductor canal catheter infusions from our own institution (unpublished data). We required 38 patients in each group and, allowing for 10% attrition, 43 patients in each group were recruited.

Primary and secondary outcomes were assessed for

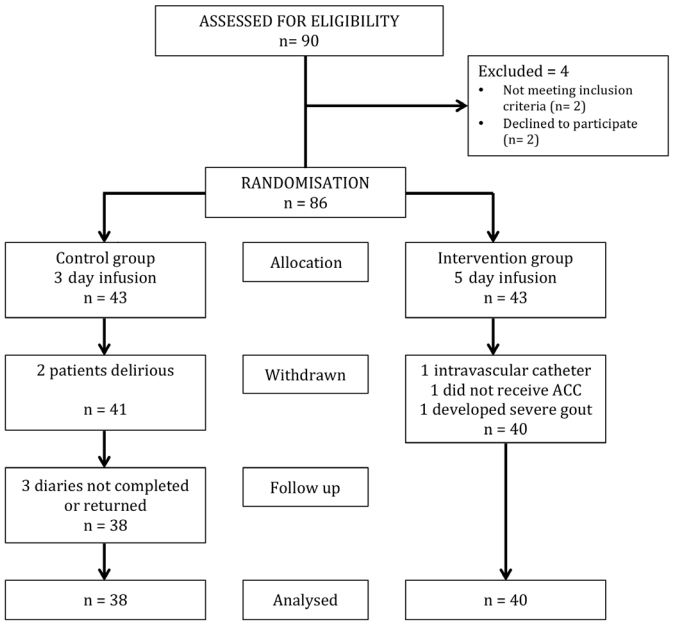

Figure 1: Patient flow diagram. Intention to Treat Analysis: Intervention group—three patients withdrawn—one did not receive the adductor canal block at the time of operation, one developed severe polyarticular gout preoperatively and one patient had an intravascular placement of the adductor canal block catheter detected on day one. Control group—five patients withdrawn—three diaries were not completed or returned for analysis and two patients became significantly confused postoperatively and were unable to continue in the study. ACC, adductor canal catheter

superiority (Mann–Whitney U test [one-tailed], Student's t-test). All statistical analyses were performed using an SPSS software package (Version 22). All data were screened for outliers (three standard deviations from the mean). Analysis was based on intention to treat.

Results

In total, 86 patients were recruited between September 2016 and March 2017 with 43 randomised to each group (Figure 1). Eight patients were withdrawn and the remaining 78 were analysed. Three patients were withdrawn from the intervention group. One did not receive the ACB at the time of operation, one developed severe polyarticular gout requiring additional steroid medication and one patient had an intravascular placement of the ACB catheter detected on day one and requested withdrawal from the study. Five patients were withdrawn from the control group. Three diaries were not completed or returned for analysis. Two patients became significantly confused postoperatively and were unable to continue in the study. There was no data available on those patients who were withdrawn from the study and therefore could not be included in the analysis. Randomisation was successful, with similar baseline demographic and clinical characteristics shown in Tables 1 and 2.

Table 1

Demographic data

	Control (3 day infusion) n=38	Intervention (5 day infusion) n=40
Age, years, mean (SD)	65.7 (9.1)	66.7 (8.5)
BMI, kg/m^2, mean (SD)	30.5 (8.0)	29.8 (6.0)
Gender		
Male, n	16	13
Female, n	22	27

BMI, body mass index; SD, standard deviation.

Table 2

Baseline postoperative data

	Control (3 day infusion) n=38	Intervention (5 day infusion) n=40		
Pain score POD 3, mean (SD)	3.4 (2.7)	2.9 (2.4)	U = 630.5, z =-0.94, P=0.35	No sig diff
QOR-15 score POD 3, mean (SD)	124.5 (21.6)	128.0 (15.6)	t < 1	No sig diff
Pre op OKS, mean (SD)	23.8 (9.2)	26.2 (7.6)	t(78)=1.64, P=0.10	No sig diff

POD, postoperative day; OKS, Oxford knee score; SD, standard deviation.

Outcomes

Pain scores

The intervention group had significantly lower pain scores than the control group, U = 486.0, z =-2.78, P=0.003 (Figure 2).

Ancillary analysis also showed a significant difference in the percentage of patients in each group who reported severe pain while walking (NRS 7 to 10). This was identical in both groups at baseline on POD 3 (12.8%). It increased to 18% in the control group by POD 5 while it fell to 5% in the intervention group. Beyond the intervention period (POD 6), the number of patients reporting severe pain was similar (10.5% in the control group versus 7.5% in the intervention group) (Figure 3).

QOR-15 scores

Mean QOR-15 scores on POD 5 were significantly better in the intervention group. The difference between the groups of 9.7 is considered clinically important[23]. Control (mean 123.4, standard deviation [SD] 23.6), intervention (mean 133.1, SD 15.3) [t(76) = 2.17, P=0.017] (Table 3).

Timed ten-metre walk test

There was no significant difference found between the two groups. Control (mean = 28.9s, SD = 24.4s), intervention (mean = 26.0s, SD = 29.6s) [t < 1].

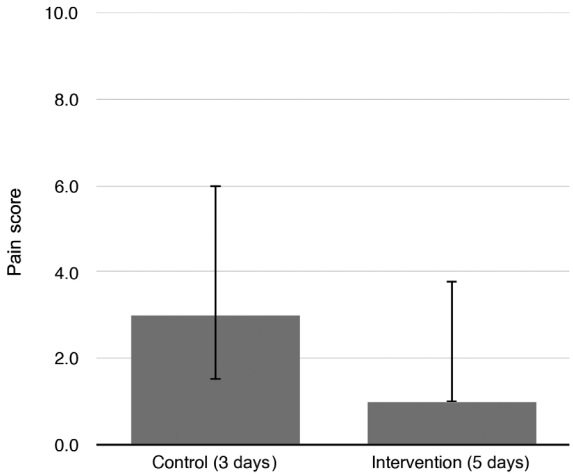

Figure 2: Pain on walking postoperative day five. Results are median numeric rating scale scores with error bars representing the interquartile range. *U = 479.5, z =-2.84, P=0.003.

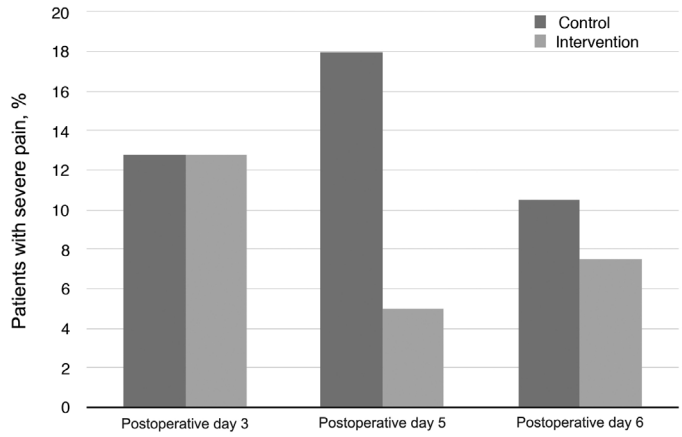

Figure 3: Frequency of severe pain on postoperative days 3, 5 and 6. Results are the percentage of patients in each group who reported pain on walking between the range 7 to 10 on the numeric rating scale.

Length of stay

One outlier who had a 19-day admission related to wound issues was removed from the control group. There was no significant difference in the length of stay between the groups. Control (mean 4.49 days, SD 1.37 days), intervention (mean 4.90 days, SD 1.37 days) [t(75) = 1.32, P=0.10].

Pain on walking on POD 6

The median pain score was not significantly different between groups (U = 591.0, z =-1.19, P=0.12).

Knee function improvement at three months

There was no significant difference in improvement between the groups as assessed by the Oxford Knee Score. Control (mean 8.38, SD 8.68), intervention (mean 9.93, SD 7.37) [t < 1].

Complications

No patient suffered a fall or a catheter-site infection. However, one patient had an intravascular placement of the regional catheter, a potentially serious complication which was not detected until day one. Other than inadequate analgesia, there were no adverse clinical effects resulting from this. Of the patients who were withdrawn, two patients suffered acute delirium, which was not attributed to the regional anaesthetic technique. One patient was re-admitted for treatment of a superficial wound infection at the distal end of the operative site. No signs of infection were present at the catheter insertion site of this patient.

Table 3

Quality of recovery scores (QOR-15) on day 5, scale 0–150

	Control n=38	Intervention n=40	
Mean	123.4	133.1	t(76)=2.17
SD	23.6	15.3	P=0.017

SD, standard deviation.

Discussion

To our knowledge there are no other studies published which have assessed an extended duration ACB infusion. This study demonstrated that extending the duration of an ACB infusion from three to five days significantly improves analgesia and overall quality of recovery. When the regional infusion was discontinued in the control group, severe pain while walking increased, despite liberal access to opioids. In contrast to 18% of the control group, only 5% reported severe pain in the intervention group. These findings are most likely due to the superior efficacy of regional anaesthetic–based analgesia over other techniques. A reduction in severe pain is important in the early postoperative period, as pain can impair rehabilitation and is a risk factor for developing persistent postoperative pain[24].

In line with improved pain relief, extending the duration of the infusion significantly improved patients' overall recovery in the acute period as reflected in the higher QOR-15 scores. Opioid consumption and opioid-related side-effects were not separately analysed. We had previously conducted a pilot study in 20 patients having extended CACB infusions (unpublished data) and found relatively low opioid consumption (mean oral morphine equivalents 60 to 70 mg daily) and low opioid-related symptom distress scale scores (0.3, scale 0 to 4). Given these outcomes were difficult to collect reliably following discharge and had limited clinical relevance, we chose not to include them. The QOR-15 scores compared favourably to other studies of arthroplasty patients where QOR-15 scores were recorded in the first 24 hours after surgery, however we were unable to find any studies

capturing later QOR-15 scores[25]. Patient satisfaction was not separately analysed. We previously found near-universal patient satisfaction with this technique and believe that the quality of recovery score is a more objective and sensitive discriminator of patient satisfaction.

Although extending the ACB infusion improved pain relief, this did not significantly impact walking speed over a ten-metre distance. Furthermore, pain scores of the two groups converged following the intervention period on day six, which suggests that the analgesic benefit did not extend beyond the duration of the infusion. There was no impact on length of hospital stay, nor the recovery of knee function at three months. These secondary outcomes are known to be influenced by many factors, other than analgesia and motor strength, and thus may lack sensitivity when evaluating analgesic effectiveness.

No patients experienced a major complication as a result of the increased duration of the regional anaesthetic infusion, however our study was not adequately powered to draw conclusions regarding the absolute safety of the technique. Particular caution must be exercised with regard to potential intravascular placement. Catheter failure, including leak and dislodgement, is a potential limitation of prolonged infusions. However, only two patients in the intervention group failed to receive the full duration of the infusion, resulting in a 95% technical success rate. This is similar to the technical success experienced in upper limb extended duration regional infusions[15].

The cost implications warrant mention. Both groups received a disposable ambulatory infusion pump which would be an additional cost for institutions not already using this technique. The cost difference between the groups included the additional local anaesthetic volume required to continue the infusion for an extra 48 hours (one 400 ml bag), or approximately A$70. Personnel resources required to monitor and attend the infusions were also negligible. Institutions not currently using continuous regional infusion techniques would need to consider the cost implications of providing improved analgesia and quality of recovery in the absence of demonstrated reduced length of stay or improved longer-term surgical outcomes.

A limitation of our study was that patients, researchers, and treating clinicians were not blinded. Whilst the authors recognise this may have introduced bias, we felt it would be difficult to truly blind a placebo group given the return of normal sensation in the saphenous distribution. In addition to the extra inconvenience and invasive nature of the infusion, we anticipated that some patients would be discharged home before day three resulting in logistical problems with changing over to a placebo infusion.

Lastly, patients were treated by a small number of experienced anaesthetists well practised in the techniques applied and these findings may not be readily translatable to less experienced anaesthetists given the technical challenges of gaining proficiency with catheter insertion. This however has not been our experience. Since introducing the CACB technique to a core group in 2015, the group then successfully conducted teaching workshops for less experienced colleagues who adopted the technique in a short space of time. CACB is now the default primary analgesic technique for all knee arthroplasties at our hospital.

Conclusion

Our study demonstrated that extending the duration of CACB regional infusions in knee arthroplasty provided better analgesia and a higher quality recovery while the infusion was in progress. The study added some useful information on important recovery indices in the early postoperative period but an impact on functional outcomes has not been demonstrated.

This technique may be applied to all patients, or targeted to those with potentially difficult-to-manage pain. The CACB can be selectively applied, whereby the infusion is paused whilst the transition to oral analgesics is evaluated. The infusion can be easily restarted if adverse effects or poor pain control is experienced or anticipated.

We conclude that five-day CACB is feasible in both an inpatient and ambulatory setting. It provides superior analgesia and a higher quality of recovery on POD 4 and POD 5 compared to oral analgesia alone.

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Declaration of interest

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