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A comparison of prilocaine and lidocaine for intravenous regional anaesthesia for forearm fracture reduction in children

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Summary

Background: In this prospective blinded randomized study, we compared prilocaine and lidocaine for intravenous regional anaesthesia for forearm fracture reduction in children.

Methods: Two hundred and seventy-nine children, aged 3–16 years, were enrolled and randomly assigned to receive 3 $mg \cdot kg^{-1}$ of either prilocaine or lidocaine. The severity of fracture was classified according to the displacement of the radius (i.e., no radial fracture, angulated, partly displaced or completely displaced). Pain during the procedure was assessed as none, minimal, moderate or severe.

Results: There was no significant difference between agents in the proportion of patients with a successful reduction (prilocaine 94%, lidocaine 92%). Compared with less severe fractures, successful reduction was less common in the completely displaced fractures ($P < 0.001$) but there was no significant difference in this category between anaesthetic agents (successful reduction: prilocaine, 84%; lidocaine, 78%). Analgesia was superior in the lidocaine group with more patients having no or minimal pain (prilocaine, 78%; lidocaine, 90%, $P < 0.05$).

Conclusions: Both agents are effective for forearm fracture reduction in children with a high incidence of successful reductions, particularly in the minimally or nondisplaced fractures. Lidocaine provided superior analgesia.

Keywords: prilocaine; lidocaine; intravenous regional anaesthesia; children; forearm fractures

Introduction

Intravenous regional anaesthesia (IVRA) has been well described as a safe and effective technique for reduction of forearm fractures in both adults and

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children (1–7). Toxicity from inadvertent systemic injection due to cuff failure is a concern with IVRA. The use of bupivicaine is contraindicated due to toxicity. Prilocaine and lidocaine are both widely used (2,3). Prilocaine has a potentially lower toxicity due to a greater volume of distribution and clearance (8,9) and reports of series of large numbers of patients have shown very few complications (3). For IVRA, prilocaine has been shown to be as effective and potent as lidocaine in several small studies in adult surgical patients (10–12). The aim of this study was to compare the efficacy of prilocaine and lidocaine IVRA for the reduction of forearm fractures in children.

Methods

After parental consent and institutional ethics board approval, 279 children, aged over 3 years, presenting to the emergency department with acute forearm fractures, were entered into this trial. Children with a history of local anaesthetic allergy, developmental delay or significant other injuries were excluded. Prior to the commencement of the study, numbered ampoules were randomly assigned to contain either 0.5% lidocaine or 0.5% prilocaine. The code was not broken until completion of the study. The ampoules were used consecutively with only one ampoule used per patient. The dose given in each case was 0.6 $ml \cdot kg^{-1}$ (either 3 $mg \cdot kg^{-1}$ of lidocaine or 3 $mg \cdot kg^{-1}$ of prilocaine). The operator was blinded to the contents of the ampoule. Prior to the IVRA, all children received intramuscular hyoscine 0.008 $mg \cdot kg^{-1}$ and papaveretum 0.4 $mg \cdot kg^{-1}$. A pneumatic tourniquet of appropriate cuff size was checked for leaks and applied above the elbow; iv access was achieved on the dorsum of each hand distal to the fracture and the arm elevated for 30 s prior to inflation of the tourniquet to 200 mmHg. The arm was not exsanguinated any further because our previous experience showed that it was likely to be too uncomfortable for the children. 0.6 $mg \cdot kg^{-1}$ of the local anaesthetic was then slowly injected over 30–60 s. After 10 min, the reduction was attempted if there was no or minimal pain when the fracture was gently manipulated. If there was severe pain on gentle manipulation or on attempted reduction, or the reduction was unsuccessful, then the efficacy of the block was reassessed 5 min later. If at this time there was severe pain with gentle manipulation or on attempted reduction, then the procedure was regarded as a failure and the child booked for a general anaesthetic. After reduction a below elbow cast was applied and a radiograph taken. The tourniquet cuff was kept inflated for a minimum of 20 min. After deflation of the cuff, the cast was extended above the elbow if necessary. The child was observed for at least 1 h prior to discharge. Heart rate, blood pressure and respiratory rate were recorded until discharge. The assistant also noted any alteration in consciousness or seizures during or after deflation of the tourniquet.

The block was performed by the duty orthopaedic registrar or fellow. Several fellows and registrars were involved in the study. A nurse or physician from the accident and emergency department provided assistance and monitored the patient. The orthopaedic registrar or fellow performing the block assessed the degree of pain during the procedure. Pain was categorized as being none (no sensation, child easily distracted), minimal (some pain but child consolable and not distressed), moderate (significant pain but reduction unhindered) or severe (child very distressed or unable to proceed with reduction). Pain was recorded at the 10 and 15 min times if applicable. The pain score taken for analysis was the worst pain score achieved during the procedure. The orthopaedic registrar or fellow performing the block also assessed the severity of the fracture. The severity of the forearm fracture was classified according to the angulation and displacement of the radial fracture, as used in a previous study (1). In increasing order of severity, the categories were: no radial fracture (ulnar fracture only); angulated but undisplaced fracture of the radius; incompletely displaced fracture of the radius; and completely displaced fracture of the radius.

A two-tailed Fisher's exact test was used for comparing 2×2 contingency tables. $P < 0.05$ was considered statistically significant. Confidence intervals were calculated using a comparison of two proportions. Previous trials at our hospital have shown 3 $mg \cdot kg^{-1}$ of lidocaine to be 90% effective in successfully reducing the fracture without general anaesthesia (1,4,6). The number of patients required was calculated using a two-group test of equivalence

in proportions as described by Makuch and Simon (13). Using an $\alpha = 0.05$, $\beta = 0.2$, expected proportion 0.9, equivalent limit difference 0.1 (a minimum difference detected of 10%), then 142 patients were required in each group for a two-tailed test.

Results

Two hundred and seventy-nine patients were entered in the study. Fourteen cases were excluded after failure to gain iv access. Another 16 were excluded from the analysis due to inadequate information or protocol violations (usually fractures other than forearm fractures). Of these 16 cases excluded, only one had an unsuccessful reduction requiring general anaesthesia. Excluding these 30 patients, 249 were included in the final analysis, 116 in the prilocaine group and 133 in the lidocaine group. There was no significant difference between the groups in age, weight, sex distribution or severity of fracture (Table 1). No adverse effects from the local anaesthetics were recorded in either group.

There was no significant difference between groups in the proportion requiring reduction under general anaesthesia [prilocaine 109/116 (94%) reduced successfully, lidocaine 123/133 (92.5%) reduced successfully]. The 95% confidence intervals for the difference of 1.5% were −4.7 to 7.7%. Similarly, there was no difference between anaesthetic agents in incidence of unsuccessful reduction when the fractures were classified according to severity. For prilocaine, 26/31 (84%) of completely displaced fractures were reduced successfully and 83/85 (98%) for all other fracture types. For lidocaine 21/27 (78%) of completely displaced fractures reduced successfully and 102/106 (96%) for all other fracture types. There was a significantly greater need for general anaesthesia in the completely displaced fractures compared with the non or partially displaced radial fractures ($P < 0.001$).

All fractures requiring general anaesthesia were reduced successfully in the operating theatre by closed reduction. Not all reduction failures requiring general anaesthesia were due to inadequate analgesia. Three patients in the lidocaine and two in the prilocaine groups had no or minimal pain but the surgeon was unable to achieve a satisfactory reduction with IVRA. All the other patients had significant pain on reduction.

In 12 cases, the pain was not recorded and these patients were excluded from the analysis of pain. None of these 12 patients required general anaesthesia. When assessing worst pain, there was a significant difference between the groups, with the lidocaine group having better analgesia (Table 2). Compared with prilocaine, the use of lidocaine resulted in significantly more patients with what we regarded as acceptable pain (no or only minimal pain) as opposed to unacceptable pain (moderate or severe pain) ($P < 0.05$). Patients with completely displaced fractures had significantly greater pain. For completely displaced fractures, 42% (15/36) had moderate or severe pain and for other fractures 21% (42/202) ($P = 0.01$). When patients with completely displaced fractures are excluded, a greater proportion of patients also had unacceptable pain in the prilocaine group; although this was possibly due to the smaller numbers, the difference is not significant (prilocaine 13/91, lidocaine 8/106) ($P = 0.1$). Because pain was scored at both 10 and 15 min, it was possible to examine if there was any improve-

Table 1
Patient population

	Prilocaine (n = *116*)	*Lidocaine* (n = *133*)
Age (years)	9.5 ± 2.9 (5–16)	9.6 ± 2.9 (3–16)
Weight (kg)	35 ± 15 (18–102)	36 ± 14 (13–75)
Sex		
Male	73	95
Female	43	38
Severity of radial fracture		
No radial fracture	1 (1%)	1 (1%)
Angulated/nondisplaced	56 (48%)	64 (48%)
Incompletely displaced	28 (24%)	41 (31%)
Completely displaced	31 (27%)	27 (20%)

Data for age and weight are given as mean ± SD (range).

Table 2
Pain and incidence of successful reduction

Pain	*Prilocaine* (n = *116*)	*Lidocaine* (n = *133*)
No pain	68 (59%)	86 (65%)
Minimal pain	19 (16%)	28 (21%)
Moderate pain	18 (16%)	7 (5%)
Severe pain	6 (5%)	5 (4%)
Not recorded	5 (4%)	7 (5%)

Percentages refer to percentage in each pain category in either prilocaine or lidocaine groups.

ment in analgesia. Of those patients who scored moderate or severe pain at 10 min and the reduction was attempted again at 15 min, more patients in the prilocaine group had improved analgesia at 15 min (prilocaine 14/18 (78%), lidocaine 5/12 (42%) ($P = 0.06$)).

Discussion

This study demonstrates that at 3 $mg \cdot kg^{-1}$, prilocaine and lidocaine are both very effective agents for IVRA for reducing nondisplaced or incompletely displaced radial fractures in children; achieving successful reduction in 98% and 96% of cases, respectively. Completely displaced fractures had a higher failure rate with both prilocaine and lidocaine but successful reduction was still achieved in 84% and 78% of cases. There was significantly more unacceptable pain with prilocaine. The lack of any adverse effects is consistent with previous reports of the very low incidence of complications with either anaesthetic (2,3,5). A higher than expected number of patients were excluded from the study due to protocol violations and inability to gain iv access. The 95% confidence interval for the difference in successful reduction was −4.7% to 7.7%. This demonstrates that despite the loss of numbers we can still be more than 95% sure that the difference between agents is less than 10%. Thus the power of the study was not compromized.

The difference in analgesia may be due to differing potencies. Studies on isolated sciatic nerve show a 50% increased potency of lidocaine compared with prilocaine (14). However *in vitro* potency analysis may not correlate with *in vivo* analysis. To date, no *in vivo* trials have demonstrated any difference in potency (10–12,15) and, clinically, the two are usually regarded as being equipotent.

Failure to successfully reduce a fracture using IVRA can be due to several factors. Inadequate analgesia is one factor. We have demonstrated that the severity of fracture is another important factor associated with failure. Success may also be operator dependent. This, or the greater muscle relaxation associated with general anaesthesia, would explain the small number of patients in each group who had successful reductions under general anaesthesia, despite failed attempts with good analgesia under IVRA. Conversely, several reductions were completed despite a moderate and, in two cases, a severe amount of pain. For the above reasons, success in reduction was not a sensitive indicator of difference in analgesia.

With time, analgesia improved in more patients in the prilocaine group. This would suggest that with a longer delay before reduction the results might have been different. This study, however, was not designed specifically to test onset of analgesia.

Other techniques have been used to provide anaesthesia for reduction of forearm fractures in children. No other technique, apart from general anaesthesia, has been demonstrated to be superior to IVRA. A recent study reported axillary block to have an overall success rate of 105 out of 111 children (91%) (16). A large series evaluating nitrous oxide found 46% of children reporting significant pain and a 91% success rate (17). More recently, a small, prospective, randomized study comparing nitrous oxide with IVRA demonstrated an equal and high success rate (only one of the 28 patients enrolled had a failed reduction) and equal analgesia with low pain scores (18). Another small study comparing intramuscular pethidine and promethazine with nitrous oxide showed similarly high success rates but higher pain scores in both groups (19). Haematoma block has been widely used in adults but provides inferior analgesia and quality of reduction (20). Intravenous sedation has also been advocated with a reported success rate of 92% (21). The safety of intravenous sedation and when intravenous sedation becomes intravenous anaesthesia is a contentious subject. There are as yet no trials large enough to demonstrate the superior safety of sedation over general anaesthesia. Compared with nitrous oxide and IVRA, the use of intravenous or intramuscular sedation results in significantly longer times in the department (19,21). Techniques for increasing the efficacy of

IVRA have been proposed, including the addition of pethidine to the local anaesthetic (22).

In conclusion, when choosing an agent for IVRA in forearm fractures in children, the possibly superior analgesia with lidocaine has to be weighed against the reduced toxicity of prilocaine. For completely displaced fractures, IVRA is less effective than in minimally or nondisplaced fractures.

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