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Randomized controlled trial of the intraligamental use of a local anaesthetic (lignocaine 2%) versus controls in paediatric tooth extraction

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Background. Children still experience pain upon waking following dental extraction under general anaesthesia. Local anaesthetic has been shown to reduce this pain, but needs to be administered via a method that causes minimum injury or distress to the child.

Aim. This study aims to evaluate the use of intraligamental injection of local anaesthetic, under general anaesthesia prior to the extraction of the tooth, for postoperative pain control in children aged 2–5 years.

Design. A randomized, single-blind, controlled trial of intraligamental lignocaine (2% lignocaine solution with adrenaline (epinephrine) 1 : 80 000) for primary teeth extraction under general anaesthesia was performed. Pain was scored by the investigators at 5-, 15-, 30-, and 60-min time points in the first hour using the Toddler-Preschooler Postoperative Pain Scale.

Results. Eighty-six children were recruited in the study: 42 randomized in the lignocaine treatment group and 44 in the control group. There was no significant difference ($P = 0.42$, Mann–Whitney U-test) in the cumulative four time point median pain score over the first hour. In the lignocaine treatment group, this was 3 (interquantile range (IQR) 0–7.5) and in the control group this was 3 (IQR: 0–10). At the 5-min time point after the child returned from recovery, the pain score in the lignocaine group (0 IQR 0–1) was statistically lower than that in the control group (0 IQR 0–5) ($P = 0.023$). There was no difference in the 15-, 30-, or 60-min time points.

Conclusions. Intraligamental lignocaine used for dental extraction under general anaesthesia in young children initially causes less pain after recovery, but this difference is not sustained over the first hour after dental extraction.

Introduction

Pain following dental extraction in children has now become better recognized and can be a cause of distress to both the child and their parents. Previous studies suggest that 33% of 5- to 12-year-old children experience moderate to severe pain, as assessed by their parents, following removal of primary teeth[1]. This rose to nearly 80% with more difficult extractions (ankylosed primary and permanent teeth). Other studies[2] argue figures as high as 80% using methods of parental observation of pain and self-reporting by children.

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Pain is problematic within the first few hours postoperatively and thought to be secondary to the trauma to hard and soft tissues during the extraction. Uncontrolled pain can delay discharge of the child from hospital. Studies investigating the use of oral preoperative analgesia[3], ibuprofen and paracetamol, suggest no significant benefit to postoperative pain in comparison to placebo administration. Observational studies in the community dental clinic highlight that local anaesthetic injections appear superior to systemic analgesia, and patients who received local anaesthetic injections seem more settled in recovery[4].

Local anaesthesia has been used in conjunction with general anaesthesia to reduce postoperative pain in a variety of other surgical procedures. Use of local anaesthesia in addition to general anaesthesia in adult patients for third molar extractions significantly reduced

the pain scores on the day following surgery[5]. Previous studies have found no improvement of postoperative pain when evaluating the intraoperative use of topical bupivacaine in children undergoing dental extraction[6,7]. Lignocaine is thought to be a safe drug for perioral anaesthesia[8]. Although reversible root-surface changes in children's teeth following intraligamentary anaesthesia have been described, there have been no long-term concerns and the technique was concluded to be safe[9].

This study evaluated the use of intraligamental injection of the local anaesthetic lignocaine administered during general anaesthesia prior to the extraction of primary teeth. Intraligamental administration does not produce anaesthesia of the lip or tongue and, therefore, eliminates the risk of self-damage in children during the postoperative period of anaesthesia. Lignocaine has a rapid onset of analgesia and duration of approximately 4 h and should prevent pain immediately after the procedure.

Materials and methods

A single-blind, randomized, controlled trial of intraligamental injection of the local anaesthetic lignocaine versus a standard treatment group of children having primary teeth removed under general anaesthesia was performed. The study received ethical approval from the Southern Derbyshire Local Research Ethics Committee.

Recruitment and consent

Parents were informed by letter or during the pre-hospital appointment that the study was taking place and were given a parent information leaflet. Prior to theatre, on the morning of the child's operation, the parent/guardian was approached to participate and informed consent was obtained. Inclusion criteria include all children aged 2 to 5 years attending for tooth extraction at the Derbyshire Children's Hospital under the care of a single dentist. The children needed to stay for 1 h after the procedure for observation. Exclusion criteria were children with known cardiac disorders, porphyria, liver or renal impairment, children unable to understand the pain scale due to age or learning difficulties, and a parent or guardian with a poor command of English who was unable to give full informed consent.

Procedure

All children participating received single preoperative doses of ibuprofen (10 mg kg^{-1}) and paracetamol (20 mg kg^{-1}). If this was medically contraindicated, children were excluded from the study. Children were randomized to receive, following induction to general anaesthetic, either 2% lignocaine solution with adrenaline (epinephrine) 1 : 80 000 intraligamentally by a single dentist (W.Q.) prior to the operative procedure (group A) or standard treatment (group B controls). A standard general anaesthetic routine was used for the procedure. The number of teeth removed and their positions (maxillary or mandibular) were recorded. In group A, each primary tooth removed was injected with 0.15 mL: the maximum total dose used being 2 mL[8]. The intraligamental injection was not administered to an acutely inflamed site. Group B received the standard treatment for tooth extraction consisting of postoperative codeine pain relief as required. No intraoperative local anaesthetic was given to children in group B.

Pain scoring

Pain scores were recorded in hospital using the Toddler-Preschooler Postoperative Pain Scale[10], which has been validated in children aged 1–5 years. Each pain assessment is scored out of seven: 0 indicating 'no pain' and 7 suggesting 'significant pain'. Pain assessments were performed at 5, 15, 30, and 60 min upon the child's return from theatre, as soon as the child awoke. Pain assessments were performed by one of the two investigators, blinded to the child's treatment. Investigators initially consecutively scored on the first seven patients to provide a measure of variability assessor consistency. If further analgesia was required in the first hour postoperatively, codeine phosphate was administered (500 μg – 1 mg kg^{-1} per dose 4–6 hourly[11]). This was administered by the paediatric nurse caring for the child on the ward and not the investigators.

Once the child was discharged home, parents were asked to record if any further pain was reported by the child and if any analgesia was required over the next 3 days. Parents were given a diary and the Wong and Baker Faces Pain Scale for the child to use to self-report[12,13]. This pain scale has been validated for self-assessment in children aged 3–12 years. Parents were asked to score their child's pain every hour after returning home, and for the next 5 h or until their child went to bed. This was then related to the child's operation time. A guidance analgesic protocol was given for the administration of paracetamol and ibuprofen once discharged from hospital (paracetamol 15 mg kg^{-1} 4–6 hourly and ibuprofen 5 mg kg^{-1} 6–8 hourly[11]) and related to their preoperative dosing. Diaries and pain charts were returned by post for assessment.

Adverse events

Adverse events were recorded by observation during the procedure by the anaesthetist and immediately after the procedure with an hour observation of the child on the ward. There was a follow-up telephone conversation at 24 h and 7 days postoperatively with parents. Dental complications were recorded if the child returned to the dental service within the next few weeks after extraction.

Statistics

The primary outcome measure was the total pain score over the first hour after tooth extraction. It was felt that a 50% decrease in the first hour would be significant. The secondary outcome measure was the pain experienced at home and the child's analgesic requirements. It was felt that no increase in pain or analgesic use for the children at home should be present once the local anaesthetic action had worn off.

Power calculations from a previous study[7] showed that 58 children were needed in each group in order to detect a decrease of 50% in the mean pain scores in the first hour postoperatively (80% power, 5% significance level). Block randomization was done by the statistician and the randomization was placed into sealed envelopes. Results were recorded and analysed using the statistical package SPSS 14.0.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed (percentages, median, interquantile ranges (IQR)). The difference between the median scores of the treatment and control groups were analysed using the nonparametric Mann–Whitney *U*-test. Binary logistic regression was used for the presence of pain adjusting for age, sex, total teeth removed, and tooth position. Chi-squared test was constructed for testing the association between categorical variables. The level of agreement for the total pain score between the two investigators was analysed using the interclass correlation coefficient (ICC).

Results

Eighty-six children were recruited in the study: 42 in the lignocaine treatment group and 44 in the control group (Fig. 1). One child in the lignocaine group did not stay for the whole hour postoperatively and was excluded from the analysis. Recruitment was terminated early by the Erewash Primary Care Trust and no reason was given to the investigators for this. Fifty-eight pain diaries (67%) were returned by parents. There were 47 boys and 38 girls with an equal sex distribution in the treatment and control groups. The median number of teeth removed was 4 (range 1–13). There was no statistically significant difference in numbers of teeth removed between the two groups ($P = 0.64$). The median number of teeth removed in the lignocaine group was 4 (IQR 2–6) and in the control group was 4 (IQR: 2–5). The level of agreement between the two investigators was 0.99 (0.98–0.99: 95% CI) for nine cases.

The scores were not normally distributed. The pain scores were analysed by adding the four time points together to given a total hour pain score, the primary outcome measure. Figure 2 shows the total pain scores in each child. The median pain score in the lignocaine treatment group was 3 (IQR 0–7.5) and the control group was 3 (IQR: 0–10) and there was no statistically significant difference ($P = 0.42$) (Mann–Whitney *U*-test). The interquantile ranges were wider in the control group and

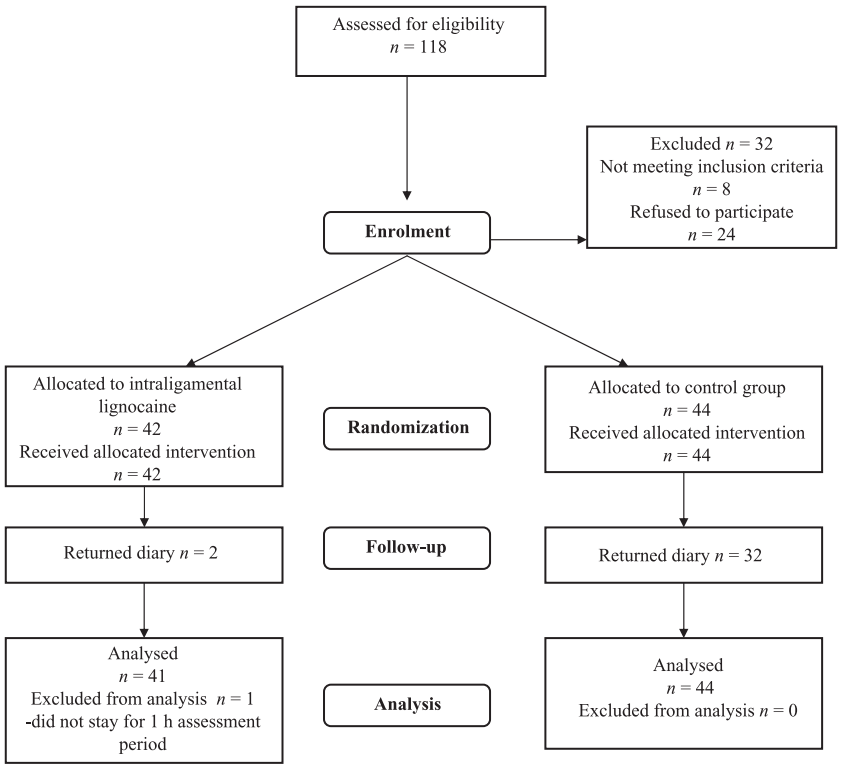

Fig. 1. CONSORT statement – participant flow though the study.

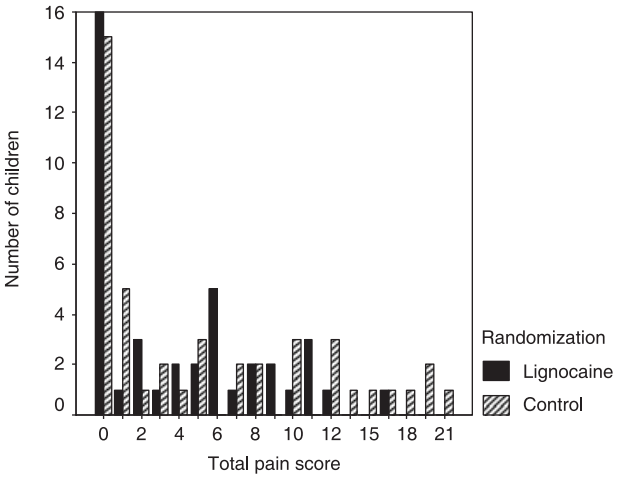

Fig. 2. Total cumulative pain scores for lignocaine and control groups.

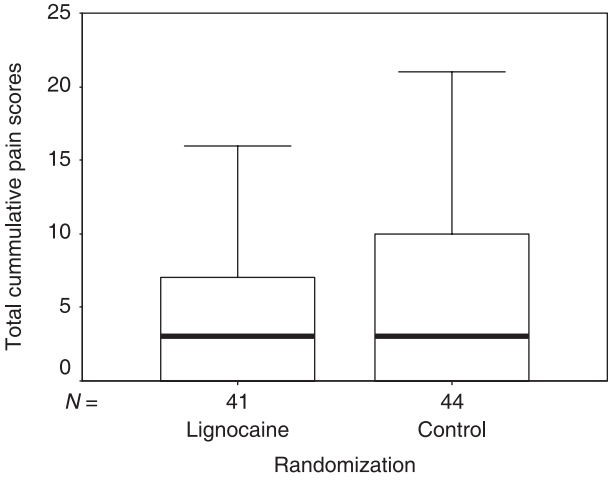

Fig. 3. Total cumulative pain scores in each group showing median (thick black line) and IQR (block area).

those with higher scores were more likely to be within the control group (Fig. 3). Sixteen children (39%) in the lignocaine group and 15 (34%) in the control group had total hour pain scores of zero. Codeine was given to 22 (51%) in the lignocaine group and 23 (52%) in the control group. There was no statistically significant difference between the two groups ($P = 0.89$) (χ^2-test).

The pain score at 5 min after the child returned from recovery in the lignocaine group was statistically lower than that in the control group ($P = 0.023$) (Mann–Whitney *U*-test). The median pain score in the lignocaine group was 0 (IQR 0–1) and in the control group was 0 (IQR 0–5) (Table 1). The median pain scores were the same in the two groups but the IQRs were significantly wider in the

Table 1. Median pain scores (interquantile ranges) in the treatment and control groups for the first hour.

Randomization	5 min score	15 min score	30 min score	1 h score
Lignocaine	0 (0–1)	1 (0–4)	0 (0–2)	0 (0–0)
Control	0 (0–5)	1 (0–4)	0 (0–3)	0 (0–0)
P-value	0.023	0.904	0.797	0.763

control group leading to the statistical significance. There were no statistically significant differences in the pain scores at 15 min, 30 min and 1 h.

The effect of total number of teeth removed, position of teeth removed (mandibular or maxillary), sex and age were tested using binary logistic regression for the presence or absence of pain. For the whole group the only variable that was a significant predictor of pain was the number of maxillary primary teeth removed: odds ratio (OR) 1.66 (95% CI, 1.18–2.34). Looking at the groups separately, in the lignocaine group none of the variables significantly predicted the presence of pain, whereas in the control group only the number of mandibular teeth removed was significant OR 1.8 (95% CI, 1.08–3).

Upon returning home from hospital there was no statistically significant difference between the groups in the amount of paracetamol ($P = 0.72$) and ibuprofen ($P = 0.38$) (χ^2-test) administered by parents. Seventy-two per cent of parents who returned the diaries gave paracetamol at home and 54% gave ibuprofen. There was no difference in the timing of analgesic use between the two groups and no difference in the pain scores in the first 4 h after returning home or on the 2 days following the extraction. This demonstrates that lignocaine does not influence pain or analgesic use when its effect finishes. There were no adverse events reported in this study.

Discussion

Our results suggest that intraligamental lignocaine does not cause a significant decrease in pain, upon examination of four cumulative time points over an hour period. It does, however, highlight at 5 min after recovery from anaesthetic that the children in the lignocaine group had significantly less pain and were more likely to have lower pain scores. A previous study[14] of local infiltration in each quadrant requiring extraction, 0.5% lignocaine 2% with 1 : 80 000 epinephrine, had shown that in this age group (3–5 years) local anaesthetic was shown to cause distress upon recovery from general anaesthetic. This was thought to be due to the sensation from the local anaesthetic. This was not confirmed in our study using the intraligamental technique; in fact the opposite was seen at the 5-min time point after general anaesthetic recovery. Other studies in older children (5–13 years) have shown that articaine 4% had a longer duration of numbness in soft tissues than lignocaine 2%, but this was when used as a regional block[15].

The study had a pragmatic design so that it could be used on a working dental list. We did not standardize between investigational and control groups for age, sex, number, or position of teeth removed. There has been concern that the intraligamental injections could cause postoperative infection within the adult population. This was not reported in the young children who participated in this study. Previous studies have shown a difference in efficacy of intraligamental injection between jaws. Cowan[16] showed a 55% success rate in the mandible and 83.3% in the maxilla, whereas other studies[17] have shown good anaesthesia rates for both. We noted that the only significant predictor of pain was the number of maxillary teeth removed which contradicts the previous study mentioned.

The accurate assessment of pain in young child can be difficult, especially after anaesthesia. Distress can be related to pain, post-anaesthetic affects, and parental or child anxiety. Pain assessment can be performed via observational, self-reporting, or physiological measures. Both observational assessment and self-reporting (through a validated postoperative pain scale) were used as we hoped to standardize the pain assessments by doing this. It can, however, be difficult to establish what degree of the distress

is caused directly by the postoperative pain in this age group.

Because of the nature of the age of the children participating in the study and the single-blind nature of the trial, children were not asked about any sensations of numbness within the sockets. A previous study[18] reported intraligamental local anaesthetic (bupivacaine 0.5% with 1 : 200 000 adrenaline) use for postoperative pain control under general anaesthesia of permanent molars in older children. A half mouth study design was used to establish if they felt numbness and which side they preferred. Results showed that no patients had self-inflicted soft-tissue trauma and around two-thirds found pain control better on the local anaesthetic side. A majority commented upon numbness on the experimental side and the technique was found to be more effective in boys than in girls.

Unfortunately, the study was not completed to the numbers planned by the power calculation. On analysis of the results, it would have been unlikely to have led to a significant difference over the four cumulative time points. Our power calculation was based on a control group from a previous study using topical bupivacaine for postoperative pain[8]. In this group, the median cumulative pain score over the four time points was 13. In our control group the median cumulative pain score was 3. The difference between the two studies was that no preoperative paracetamol and ibuprofen was given in the first study. This was felt not to be ethical for the second study as preoperative analgesia was now the standard practice at the hospital. This may therefore have affected our original power calculation. However, previous studies have suggested that preoperative ibuprofen and paracetamol do not give significantly greater pain control postoperatively[2,19]. Further research may be needed to examine this.

This study shows that intraligamental lignocaine used intraoperatively in the infant population can decrease pain in the immediate postoperative period. It did not seem to lead to increased distress or any dental complications. It is a cheap procedural measure that could be implemented without any detrimental effect to general anaesthetic operative lists. It is unclear why the analgesic effect was not sustained for a longer time period and further research is necessary to address this question.

What this paper adds

- Intraligamental lignocaine used intraoperatively in young children (2–5 years) can decrease pain in the immediate postoperative period.
- Intraligamental lignocaine appears to be safe.

Why this paper is important to paediatric dentists

- An easily implemented measure of intraligamental lignocaine intraoperatively decreases pain following dental extraction under general anaesthetic in the immediate postoperative period, although its effect is not sustained over an hour period.

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