Paediatric and Perinatal Drug Therapy, 2005; 6 (4)

A clinical trial of topical application of bupivacaine to reduce post-operative pain in children following dental extractions

William Quirke[1], Kanta Bhaskar[2], Imti Choonara[2]

[1]*Senior Community Dentist, South Derbyshire Community and Mental Health Services NHS Trust, Derby, UK*

[2]*Academic Division of Child Health, University of Nottingham, Derbyshire Children's Hospital, Derby, UK*

Corresponding author

Professor Imti Choonara, Academic Division of Child Health, University of Nottingham, Derbyshire Children's Hospital, Uttoxeter Road, Derby DE22 3DT, UK. Email: imti.choonara@nottingham.ac.uk

Aims: **To study the efficacy of topical bupivacaine intra-operatively in children undergoing dental extractions.**

Methods: **A randomised double blind placebo controlled study of bupivacaine 0.25% with adrenaline 1:200,000 was performed in children undergoing dental extractions under general anaesthesia. Pain was assessed using the Toddler Pre-schooler Post-operative Pain Scale (TPPPS). Assessments were carried out on recovery from the anaesthetic and at 5, 10, 15 and 30 minutes.**

Results: **48 children were recruited, of whom 24 received bupivacaine and 24 received placebo. The ages of the children ranged from 4 to 13 years with a median age of 7 years. Seven children in the bupivacaine group and eight children in the placebo group scored 0 at all four pain assessment time points. There was no significant difference in the individual maximum pain scores between the two groups (Mann-Whitney *U* test, *P* > 0.05). The four pain scores were combined for each individual patient. The median pain scores were 1.5 and 1.0 in the bupivacaine and placebo groups respectively, which were not significantly different (*P* > 0.05, Mann-Whitney U test).**

Conclusion: **Topical bupivacaine 0.25% with adrenaline 1:200,000 does not reduce post-operative pain following dental extractions in children.**

Paed Perinatal Drug Ther 2005; 6: 197–199

Keywords: children – dental extraction – topical bupivacaine – pain

Introduction

It is well recognised that dental extractions under general anaesthesia often result in post-operative pain in children, with over 70% complaining of pain[1]. A previous study of 24 children (aged 7 – 15 years) suggested that there might be significant benefits in applying dental rolls soaked in bupivacaine 0.25% with adrenaline 1:200,000[2]. The dental roll was only applied if pain and discomfort were reported on waking.

In this pilot study we have set out to test the efficacy of topical bupivacaine intra-operatively, i.e. immediately after extractions were completed and before return to consciousness.

Methods

The study was approved by the Southern Derbyshire Ethics Committee. The parents of children who were eligible to enter the study were approached. The inclusion criteria were:

- Weight of 15 kg or over
- No complicating medical history
- Due to have dental extractions under general anaesthesia

Written informed consent was obtained from the parents. Only children attending the surgical list of a single dentist (WQ) were approached and entered into the study.

A maximum of three children were entered into the study on each day. Treatment was randomised by the use of a book of random numbers. Only the pharmacy department were aware of whether bupivacaine 0.25% with 1:200,000 adrenaline (5 mcg/ml) or placebo (0.9% sodium chloride) was being administered.

Extractions were carried out in the usual way by a single dentist only (WQ). When completed the ends of the gamgee swabs were soaked with 5 ml of the solution and placed over the sockets (gamgee is normally used in this manner to aid haemostasis). The patient was then taken through to the primary recovery area where the swabs were removed as the patient recovered. The dentist noted the time of the swab placement and the number and type of teeth. The research nurse noted the time of removal of the swab and followed the patient through until discharge. All patients in the study were asked if they had any numbness in their mouth prior to discharge.

The research nurse (KB) assessed the children for their degree of pain using a validated pain tool, the Toddler Pre-schooler Post-operative Pain Scale (TPPPS)[3]. The TPPPS is an observational scale for measuring post-operative pain that was originally devised for children aged 1–5 years but has been used in other settings i.e. accident and emergency[4]. Scores range from 0 to 8 with a high score suggesting significant pain whereas a score of 0 indicates no pain. It was felt appropriate to use it in older children immediately after surgery, as these children would be unable to carry out a self-report assessment on awakening from anaesthesia.

Assessments were carried out on recovery from the anaesthetic and at 5, 10, 15 and 30 minutes. All children were offered oral paracetamol suspension post-operatively. Given the exploratory nature of this pilot investigation, formal power calculations were not applied to determine subject number. Rather, a convenience sample of 48 children was used with the goal of doubling the number of evaluable study subjects over that previously reported by Greengrass[2].

Results

48 children entered the study, of whom 24 received bupivacaine and 24 received placebo. The ages of the children ranged from 4 to 12 years with a median age of 7 years in the bupivacaine group and 4 to 13 years with a median age of 6 years in the placebo group. The swabs were kept in place for a median of 16 minutes (range 3–30 minutes) in the bupivacaine group and for a median of 15 minutes (range 8–41 minutes) in the placebo group. All children had multiple dental extractions (range 2–12). The median number of dental extractions (4) was the same in both groups.

Seven children in the bupivacaine group scored 0 at all four time points following surgery. The remaining 17 children had at least one positive pain score, which ranged from 1 to a maximum of 8. Eight children in the placebo group scored 0 at all four time points and the remaining 16 children had scores ranging from 1 to a maximum of 7. The mean and median scores for each group are shown in Table 1. There was a downward trend in the mean scores from the assessment at 10 minutes. There was, however, significant inter-individual variation in the pain assessment scores in both groups at all time points.

There was no significant difference in the individual maximum pain scores between the two groups (Mann-Whitney U test, $P > 0.05$). The four scores were combined for each individual patient. The combined scores for the two groups were bupivacaine (median 1.5, range 0–29) and

Table 1 Individual scores at each time point

Time (min)	Bupivacaine			Placebo		
	Mean ± SD	Median	Range	Mean ± SD	Median	Range
5	2.0 ± 2.7	0	0–7	1.3 ± 2.3	0	0–7
10	2.7 ± 3.0	1	0–8	1.4 ± 2.4	0	0–7
15	2.4 ± 3.1	0	0–7	1.1 ± 1.9	0	0–7
30	2.2 ± 2.8	1	0–7	0.5 ± 1.4	0	0–5

placebo (median 1.0, range 0–25). Statistical analysis was carried out by the Mann-Whitney *U* test, which showed no significant difference between the two groups ($P > 0.05$).

Discussion

Previous studies in children have shown that post-operative pain is a significant problem following dental extractions[1]. A previous study in children aged 7 years and over seemed to show that the application of 0.25% bupivacaine with adrenaline 1:200,000 offered significant benefits to those children reporting pain after dental extractions under general anaesthesia[2]. A subsequent study in children aged 5–12 years, however, failed to show any benefit[5]. Neither of these studies, however, used a validated pain score.

Since the method appeared to be simple and safe, it was decided to carry out a study applying the solution intra-operatively as suggested by the authors. Unfortunately, no benefit could be observed in this study using this method. A weakness of our study was the large number of children who did not experience pain following dental extraction. There was also significant inter-individual variation in the pain scores. Further studies are required to determine which analgesic intervention is effective in reducing post-operative pain following dental extractions in children.

Conclusion

This study fails to show any benefit in the intra-operative topical application of bupivacaine 0.25% with adrenaline 1:200,000 in the reduction of post-operative pain in children undergoing dental extractions under general anaesthesia.

Acknowledgements

KB was funded by South Derbyshire Community and Mental Health Services NHS Trust.

References

1 Atan S, Ashley P, Gilthorpe M S et al. Morbidity following dental treatment of children under intubation general anaesthesia in a day-stay unit. Int J Paediatr Dent 2004;14:9–16
2 Greengrass SR, Andrzejowski J, Ruiz K. Topical bupivacaine for pain control following simple dental extractions. British Dental Journal 1998;184: 354–355
3 Tarbell SE, Cohen I, Marsh JL. The Toddler PreSchooler Postoperative Pain Scale: an observational scale for measuring postoperative pain in children aged 1–5. Preliminary report. Pain 1992;50:273–280
4 McCarthy C, Hewitt S, Choonara I. Pain in young children attending an A & E department. J Accid Emerg Med 2000;17:265–267
5 Andrzejowski J, Lamb L. The effect of swabs soaked in bupivacaine and epinephrine for pain relief following simple dental extractions in children. Anaesthesia 2002; 57: 266–283

PPDT – 0137, *Accepted for publication:* 21 September 2005
Published Online: 27 October 2005
doi:10.1185/146300905X65678