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A double-blind randomized controlled trial investigating the effectiveness of topical bupivacaine in reducing distress in children following extractions under general anaesthesia

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Summary. *Objective*. This study was designed to investigate the effectiveness of topical bupivacaine (0·25%) in reducing postoperative distress following extraction of teeth under general anaesthesia in children.
Design. The study was a double-blind randomized controlled trial.
Setting. The study was conducted in a dental hospital.
Sample. The sample comprised 135 children aged between 2 and 12 years of age who were undergoing outpatient general anaesthesia for simple dental extractions.
Methods. The children were randomly allocated to one of two groups: the bupivacaine group (the study group) comprised 68 children whilst the sterile water group (the control group) comprised 67. Following the extraction of their teeth, children had swabs soaked in the appropriate solution placed over the exposed teeth sockets. A five-point face scale was employed by an independent observer to evaluate the distress for each child. Evaluation of distress was made preoperatively, on recovery from the general anaesthetic, and again, 15 min following recovery from the anaesthetic.
Results. There were no statistically significant differences between the mean distress scores for the bupivacaine and sterile water groups preoperatively, postoperatively or 15 min postoperatively. For both groups, however, there were significant increases in distress scores between the preoperative and 15 min postoperative assessment scores.
Conclusion. Extraction of teeth under general anaesthesia does cause distress in children. There is no evidence that topical bupivacaine reduces this distress when compared to sterile water.

Introduction

It has been reported that fear of the dentist, as well as of dental pain, is a common and potentially distressing problem for children [1]. Pain following extraction of teeth is common in children, and management of this pain has been subject to increasing interest, but is still recognized as frequently being suboptimal [2,3]. Comments from one mother with a child who suffered distress following extractions included:

'Having a child's teeth taken out is not something as a mother I want to experience again. It was not a pleasant experience because he was distressed for some time after.'

It is apparent that parents can also suffer [4].

Morbidity associated with the extraction of teeth in children under general anaesthesia is common and has been reported as a factor causing fear of the dentist [5]. Morbidity includes bleeding, postoperative

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pain and distress, and can lead to subsequent aversion to dental care [6].

A study by Bridgeman *et al*. [7] was carried out to investigate morbidity in children requiring extractions under general anaesthesia. They reported that distress was noted in 26 (33%) patients during recovery. Continued crying was reported for 24 (39%) during the journey home and for 23 (37%) once home. Other symptoms included nausea, vomiting and prolonged bleeding. Six reported psychological trauma one month after, three had nightmares, two had continuing bad memories and one was depressed for several days.

One of the most useful practical changes related to general anaesthesia over recent years has been the introduction of Emla® (a topical anaesthetic agent applied to the skin), which permits less painful intravenous cannulation and subsequent induction for young children [8]. Infiltration local anaesthesia has been used in some surgical disciplines, with good effect, to reduce postoperative pain [9,10]. Application of topical anaesthetic for postoperative pain relief, however, has not usually been considered as a part of routine clinical practice.

A study by Smith *et al*. [11] reported that topical bupivacaine-norepinephrine is an effective alternative to lidocaine infiltration for local anaesthesia during laceration repair, especially on the face and scalp. Bupivacaine is a water soluble amide anaesthetic. It has a long duration of approximately 200 min. The addition of adrenaline increases the effectiveness and prolongs the duration of anaesthesia [12]. In 1998, a pilot study by Greengrass and his colleagues [13] demonstrated that bupivacaine-soaked dental rolls placed over the sockets in 7–15-year-old children undergoing extraction of fewer than six teeth relieved pain. The rolls were inserted after the child had woken from the anaesthetic and had reported pain.

A similar study was conducted by Andrzejowski & Lamb [14]. They also used bupivacaine, this time on swabs which were inserted immediately following the extractions, before the child had recovered from the general anaesthetic, but they found that there was no reduction in pain. Thus, the results of the two studies were contradictory.

In view of the different outcomes reached in Andrzejowski & Lamb's [14] and Greengrass *et al*.'s [13] studies, it was decided that this work should be repeated, but using a much tighter study design. The study was designed to reduce assessor variability by using only one observer. In addition, the age range was extended to include children as young as 2 years of age. It was decided to assess distress instead of pain because it can be difficult to measure pain in young children.

The aim of this study was to investigate whether the general anaesthesia extraction experience could be improved for children by reducing the postoperative distress experienced. The hypothesis was that applying a topical anaesthetic solution to the extraction socket areas whilst the child was still under general anaesthetic would reduce postoperative pain, and hence, the child would be less distressed on recovery. The null hypothesis was that there would be no difference in distress levels when using topical bupivacaine compared with sterile water.

Methods

Ethical approval was sought and granted by the Central Manchester Local Research Ethics Committee.

Prior to the study, a statistician randomly allocated the sequence of patient identity numbers to either a test or control group using computer-generated random numbers. Slips of paper with either 'bupivacaine' or 'sterile water' printed on them were placed in opaque envelopes and sealed. This was carried out by a secretary who was not associated with the study. These envelopes had been numbered sequentially on their outside with the patient identity number. Following the screening, as a child was accepted into the study, she or he was given their patient identity number. The correspondingly numbered opaque envelope was attached to the patient's dental hospital treatment record.

Children who attended the Unit of Paediatric Dentistry in the University Dental Hospital, Manchester, UK, and who were scheduled for extraction of teeth under general anaesthesia were considered for inclusion in the study.

Patients who fulfilled the following criteria were eligible for inclusion in the study:

1 those who were male or female and aged from 2 to 12 years of age;

2 those who were scheduled for extraction of between one and 10 teeth;

3 those who were ASA I or II patients [15];

4 those who had a parent/guardian who was able to understand and cooperate with the requirements of the protocol, and was able and willing to exercise an appropriate written informed consent.

Patients who met any of the following criteria were excluded from participating in the study:
1 patients with a known hypersensitivity or allergy to local anaesthetic;
2 patients with a known hypersensitivity or allergy to paracetamol;
3 patients who refused the preoperative dose of oral paracetamol; and
4 patients and/or parents who were too distressed or upset to be approached.

All patients received preoperative paracetamol 15 mg/kg elixir (Calpol) and topical anaesthetic Emla® paste was applied to both hands at least an hour before induction. This is the usual clinical practice at the dental hospital. General anaesthesia was administered in an outpatient theatre with an associated recovery room. Intravenous induction with proprofol, and inhalational maintenance with nitrous oxide, oxygen and a volatile agent such as enflurane was the usual anaesthetic method. On rare occasions when intravenous access was difficult, inhalational induction with sevoflorane was used. The airway was maintained using laryngeal mask airways. Standard extraction techniques using elevators and dental forceps were employed. In theatre, once the extractions had been completed and whilst the child was still anaesthetized, one long swab, with the appropriate solution, was pressed into the sockets in the child's mouth. If the slip in the envelope indicated that the child was in the bupivacaine group, swabs were impregnated with a cold solution of bupivacaine 0·25% with 1:4000 adrenaline. If the slip in the envelope indicated sterile water, the swab impregnated with cold sterile water was applied to the sockets. The slip was put back in the envelope, which was replaced in the patients records in turn. This ensured that the patient and the dentist carrying out the assessment were blind as to which group the child had been allocated.

The patient was then wheeled through into the adjacent recovery room. As the child began to recover from the anaesthetic, the swab was removed from the child's mouth, together with the laryngeal mask airway. The children were cared for in the recovery area by nurses and accompanied by their parents until they were assessed as being fit enough to be discharged home by the anaesthetist.

Each child was observed for signs of distress and these observations were recorded using the smiling faces scale (Fig. 1). The scores given were: (0) no sign of distress; (1) mild distress; (2) moderate distress; (3) severe distress; or (4) very severe distress. Evaluation of distress was made preoperatively, on waking from the anaesthetic and again just before discharge at 15 min. The researcher (G.G.) who made all the distress assessments was completely independent of the whole process.

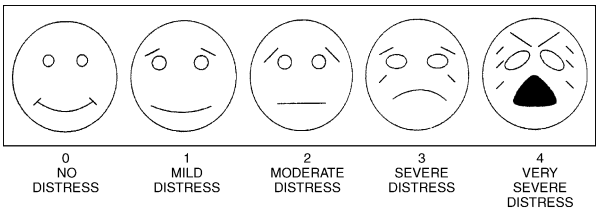

Fig. 1. Five-face scale.

Statistical analysis

A pilot study was carried out in order to calculate the sample size. From the results of the pilot study, it was calculated that a sample size of 57 in each group would have 80% power to detect a difference in means of 0·80 (the difference between a control group mean of 1·80 and a test group mean of 1·00), assuming that the common standard deviation was 1·50, using a two group *t*-test with a 0·05 two-sided significance level. The power level selected was based on the results of the study by Andrzejowski & Lamb [14]. Comparisons between the test and control group distress scores would be made using an independent-sample *t*-test at the 0·05 level of significance.

Results

One hundred and fifty-three children were recruited into the study, but 14 children were excluded because they fell into the exclusion criteria. One hundred and thirty-nine children were randomly allocated to one of the two groups. At the end of the study, however, there was missing data for four children (three in the sterile water and one in the bupivacaine group), giving 68 children in the bupivacaine group (study) and 67 in the sterile water group (control). Therefore, the final sample size comprised 135 children. It was considered appropriate to use parametric tests to analyse the data because of the distribution of the data and the large numbers in each group. The patients in the two groups were similar in terms of gender, age, weight, number of extractions and

Table 1. Distribution of males and females according to group.

Gender	Number of patients
Bupivacaine	
Female	32
Male	36
Total	68
Sterile water	
Female	34
Male	33
Total	67

Table 2. Age, weight and number of teeth extracted for the 135 children in the study.

Variable	Minimum	Maximum	Mean ± SD
Age (years)	2	12	5·9 ± 2·16
Weight (kg)	13·5	58·5	22·1 ± 7·70
Number of teeth extracted	1	13	7 ± 2·76

time from preoperative Calpol to having their teeth extracted (see Tables 1–3). The overall outcome of the distress scores of the 135 children who participated in the study is summarized in Table 4. There were no statistically significant differences between the mean distress scores for the bupivacaine and sterile water groups preoperatively, postoperatively and 15 min postoperatively: *P*-values from independent-sample *t*-tests (0·51, 0·19, 0·81, respectively) are given in Table 5). For both the bupivacaine and sterile water groups, changes in distress scores from the preoperative score to the postoperative score and to the 15 min postoperative score were made using the paired-sample *t*-test. There was no difference for either group when comparing the preoperative score with the postoperative score (*P*-values: 0·45 and 0·21; Table 6). For both groups, however, there were significant increases in distress scores between the preoperative and 15 min postoperative scores (*P*-values: < 0·001 and 0·005).

Postoperatively, it was also found that children aged between 2 and 6 years recorded higher distress scores than children aged between 7 and 12 years (mean = 1·7 and 1·0, respectively). This was the same 15 min postoperatively (mean = 2·2 and 1·4, respectively). These results are illustrated in Table 7.

Reliability

In the pilot study, there were 30 children who were having teeth extracted under general anaesthesia. These were observed by one of the authors (G.G.) and another examiner in order to examine the inter-examiner agreement. Weighted kappa statistics were calculated for the three distress scores measured

Table 3. Comparison between the children in the bupivacaine and sterile water groups in terms of mean age, weight and number of teeth extracted.

Variable	Number of children	Mean ± SD	*t*-value (d.f. = 133)	*P*-value
Age (years):				
bupivacaine	68	5·9 ± 2·08	−0·03	0·97
sterile water	67	5·9 ± 2·24		
Weight (kg):				
bupivacaine	68	22·2 ± 8·00	−0·04	0·97
sterile water	67	22·1 ± 7·47		
Number of teeth extracted:				
bupivacaine	68	7 ± 2·58	1·77	0·80
sterile water	67	6 ± 2·89		

Table 4. Summary of the outcomes of distress scores for the children in bupivacaine and sterile water groups.

Distress score	Assessment group					
	Preoperative (n = 135)		Postoperative (n = 135)		15 min postoperative (n = 135)	
	Bupivacaine	Sterile water	Bupivacaine	Sterile water	Bupivacaine	Sterile water
0	35	29	29	17	20	13
1	11	15	11	15	6	12
2	6	6	10	17	15	16
3	9	7	16	16	15	17
4	7	10	2	2	12	9
Total	68	67	68	67	68	67

Table 5. Comparisons between mean distress scores for the bupivacaine and sterile water groups preoperatively, postoperatively and 15 min postoperatively.

Group	Number of children	Mean ± SD	*t*-value (d.f. = 133)	*P*-value
Preoperative:				
bupivacaine	68	1·15 ± 1·43	0·66	0·51
sterile water	67	1·31 ± 1·49		
Postoperative:				
bupivacaine	68	1·28 ± 1·31	−1·33	0·19
sterile water	67	1·56 ± 1·20		
15 min postoperative:				
bupivacaine	68	1·90 ± 1·49	−0·24	0·8
sterile water	67	1·96 ± 1·33		

Table 6. Comparisons between mean preoperative distress scores, and postoperative or 15 min postoperative scores for children in the bupivacaine and sterile water groups.

Group	Number	Mean ± SD	Paired *t*-value	d.f.	*P*-value
Bupivacaine:					
preoperative	68	1·15 ± 1·44	−0·77	67	0·45
postoperative		1·28 ± 1·31			
preoperative	68	1·15 ± 1·44	−3·92	67	< 0·001
15 min postoperative		1·90 ± 1·49			
Sterile water:					
preoperative	67	1·31 ± 1·49	1·26	66	0·21
postoperative		1·56 ± 1·20			
preoperative	67	1·31 ± 1·49	−2·94	66	0·005
15 min postoperative		1·96 ± 1·33			

Table 7. Comparisons between mean distress scores for the patients aged 2–6 years and 7–12 years, preoperatively, postoperatively and 15 min postoperatively.

Group	Number of patients	Mean ± SD	*t*-test (d.f. = 133)	*P*-value
Preoperatively:				
2–6 years	87	1·4 ± 1·5	1·87	0·05
7–12 years	48	0·9 ± 1·3		
Postoperatively:				
2–6 years	87	1·7 ± 1·3	3·13	0·001
7–12 years	48	1·0 ± 1·1		
15 min postoperatively:				
2–6 years	87	2·2 ± 1·4	3·23	0·002
7–12 years	48	1·4 ± 1·3		

preoperatively, postoperatively and 15 min postoperatively. These values all indicated substantial agreement between the two examiners (kappa = 0·87, 0·77, 0·79, respectively).

Discussion

Extraction of teeth under general anaesthesia can be distressing for children. Al-Bahlani *et al*. [6] compared the morbidity (bleeding and distress) following general anaesthesia of a group of children under 10 years of age who were given one-quarter of a cartridge (0·5 mL) of local anaesthetic containing epinephrine (1:80 000) in each quadrant before tooth extraction with a group of control children who had no local anaesthesia. It was found that the use of local analgesia with a vasoconstrictor produced a notable reduction in blood loss in the children in the study group, but there was a significant increase in postoperative distress. This increase in distress could be attributed to the feeling of numbness associated with the injected anaesthetic solution. A topical anaesthetic agent would not have this side-effect. Topical bupivacaine has been used, but in view of

the different outcomes reached in Andrzejowski & Lamb's [14] and Greengrass *et al.*'s [13] studies, it was decided that this work should be repeated.

The results of this study revealed that there was no statistically significant difference in the mean distress scores between the children in the bupivacaine group and those in the sterile water group. Thus, there was no evidence that topical anaesthetic solution was effective in reducing distress. During the course of the study, many children were seen to be upset. Two important factors can contribute to producing emotional distress: the surgical experience and the pain [16]. Pain is considered to be a major factor for promoting distress in children. This distress can lead to behaviour disorders on returning home and a negative attitude to future dental procedures [17]. In this study, the only factor that was significantly related to distress was age. The group of children who were younger than 6 years showed higher levels of distress scores on recovery compared to those who were older than 6 years in both the bupivacaine and sterile water groups. It was felt necessary to conclude that the high distress scores recorded in younger children may be based on their immaturity and lesser cognitive development. It was observed by one of the authors (G.G.) that there was a delay in some cases of calling parents to come and look after their children. In some cases, the children were completely conscious in the recovery room before their parents came to them. In addition, parents who came quickly and demonstrated a good range of coping behaviours had children who were considerably less distressed. Young children tend to depend upon their parents for support in order to cope with a fearful situation rather than have their own methods of coping. This is an area which requires further investigation.

Conclusion

This investigation has demonstrated that the postoperative distress associated with dental extractions under general anaesthesia cannot be reduced by the application of topical anaesthetic (25% bupivacaine) at the surgical site.

Acknowledgements

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Résumé. *Objectifs.* Cette étude a eu pour objectifs d'étudier l'efficacité de la bupivacaïne topique (0,25%) à réduire la détresse post-opératoire après extraction dentaire sous anesthésie générale chez l'enfant.
Protocole. Essai en double aveugle avec randomisation.
Mise en place. Hôpital dentaire.
Echantillon. L'échantillon a compris cent trente cinq enfants, âgés de 2 à 12 ans, devant subir une anesthésie générale pour de simples extractions dentaires.
Méthodes. Les enfants ont été répartis au hasard dans l'un des deux groupes. Le groupe bupivacaïne (groupe d'étude) a compris soixante-huit enfants contre soixante-sept dans le groupe eau stérile (groupe témoin). Après extraction des dents, une solution appropriée a été déposée sur les alvéoles. Une échelle en cinq points a été utilisée par un observateur indépendant pour évaluer l'inconfort de chaque enfant. L'évaluation a été faite en pré-opératoire, lors du réveil et 15 minutes après recouvrance post-anesthésie.
Résultats. Il n'y avait pas de différence significative entre les scores moyens d'inconfort des deux groupes aux trios temps d'observation. Cependant, pour les deux groupes, il y a eu une augmentation significative des scores entre la mesure pré-opératoire et celle 15 minutes post-anesthésie.
Conclusion. L'extraction des dents sous anesthésie générale cause de l'inconfort aux patients. Il n'y a pas de preuve que la bupivacaïne topique réduise cet inconfort, par rapport à de l'eau stérile.

Zusammenfassung. *Ziele.* Diese Studie wurde geplant, um die Wirkung von lokal appliziertem Bupivacain (0.25%) zur Reduktion von postoperativem Stress bei Kindern nach Zahnextraktionen unter Vollnarkose zu untersuchen.
Studiendesign. Kontrollierte Studie.
Untersuchungsumgebung. Zahnmedizinisches Krankenhaus.
Stichprobe. Die Stichprobe bestand aus 135 Kindern im Alter von 2–12 Jahren, bei welchen ambulant unter Vollnarkose einfache Zahnextraktionen vorgenommen wurden.
Methoden. Die Kinder wurden zufällig einer von zwei Gruppen zugeordnet. Die Bupivacain-Gruppe (Studiengruppe) bestand aus 68 Kindern, die Gruppe mit sterilem Wasser (Kontrollgruppe) bestand aus 67. Nach der Extraktion wurde den Kinder ein in der jeweiligen Flüssigkeit getränkter Tupfer auf der Extraktionsalveole platziert. Die Bestimmung des Stresses erfolgte durch einen unabhängigen

Beobachter für beide Gruppen präoperativ, unmittelbar postoperativ und 15 min postoperativ anhand einer 5-Punkte Gesichtsausdrucksskala.
Ergebnisse. Es zeigte sich kein statistisch signifikanter Unterschied der Stress-Scorewerte zwischen den beiden Gruppen für die drei unterschiedlichen Untersuchungszeitpunkte. In beiden Gruppen nahm aber der Stress-Scorewert signifikant zu von dem präoperativen Wert bis zum 15-min postoperativen Wert.
Schlussfolgerung. Eine Zahnextraktion unter Vollnarkose verursacht postoperativen Stress bei Kindern. Ein Effekt zur Reduktion durch Bupivacain (als Oberflächenanästhetikum appliziert) im Vergleich zu sterilem Wasser konnte nicht gezeigt werden.

Resumen. *Objetivos*. Este estudio se diseñó para investigar la efectividad de la bupivacaina tópica (0,25%) en reducir las molestias postoperatorias tras la extracción de dientes bajo anestesia general en niños.
Diseño. Ensayo clínico aleatorio controlado a doble ciego.
Lugar. Hospital Dental.
Muestra. La muestra comprendía ciento treinta y cinco niños de edades entre 2–12 años que fueron sometidos a anestesia general para extracciones dentales simples.
Métodos. Los niños se asignaron aleatoriamente a uno de los dos grupos. El grupo Bupivacaina (grupo estudio) comprendió 68 niños; mientras que el grupo de agua estéril (grupo control) comprendió 67. Tras la extracción de los dientes, los niños recibieron esponjas impregnadas en la solución apropiada colocada sobre los alveolos dentarios expuestos. Para evaluar las molestias de cada niño un observador independiente empleó una escala facial de cinco puntos. La evaluación de las molestias se hizo preoperatoriamente, en el momento de la recuperación de la anestesia general y de nuevo a los 15 minutos de la recuperación del anestésico.
Resultados. No hubo diferencias significativas entre los índices medios de molestia para los grupos de bupivacaína y de agua estéril preoperatoriamente, postoperatoriamente y a los 15 minutos del postoperatorio. Sin embargo para ambos grupos hubo aumentos significativos en los índices de molestia entre los índices de valoración preoperatorios y a los 15 minutos del postoperatorio.
Conclusión. La extracción de dientes bajo anesthesia general causa molestias en niños. No hay evidencia de que la bupivacaína tópica reduzca estas molestias cuando se compara con agua estéril.

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