

Topical bupivacaine in paediatric day-case tonsillectomy: a prospective randomized controlled trial

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Abstract

Post-operative pain and delayed oral intake are common reasons for failure of discharge in day-case tonsillectomy. A double blind prospective randomized study was devised to investigate the effectiveness of topical bupivacaine in reducing post-operative pain in paediatric day-case tonsillectomy. Ninety-nine patients aged between three and 16 years were recruited into the study. One group received bupivacaine soaked swabs tightly packed in their tonsillar fossae while the control group received saline-soaked swabs. The bupivacaine group was found to drink ($p < 0.001$) and eat ($p = 0.006$) earlier than the control group. The pain scores at one ($p < 0.001$), three ($p < 0.001$) and six ($p < 0.001$) hours post-operatively were also found to be lower in the bupivacaine group than the control group. We conclude that topical bupivacaine has a role in facilitating recovery in day-case tonsillectomy in children.

Key words: Tonsillectomy; Pain; Postoperative Period; Bupivacaine

Introduction

Tonsillectomy is one of the most commonly performed operations in the United Kingdom. The majority of tonsillectomies are performed on an in-patient basis. There is now, however, increasing willingness to undertake day-case tonsillectomy, even in children, when the relevant pre-operative criteria are fulfilled.¹ St George's Hospital in London was one of the first centres in the UK to undertake paediatric day-case tonsillectomy, and how has considerable experience in this field. We still find that occasionally discharge from our day surgery unit is not possible. The factors responsible for this include, post-tonsillectomy pain, inadequate oral intake, nausea and vomiting and reactionary haemorrhage. It has been estimated that up to 15 per cent of day-case tonsillectomy discharges are delayed as a result of such complications.²

Post-tonsillectomy pain is regarded as the primary cause of discharge failure. Poor pain control can lead to reluctance to swallow and inadequate oral intake. Pain begins with local tissue damage during surgery, that causes the release of inflammatory substances. This leads to the generation of electrical impulses at peripheral nociceptors. The electrical impulses are conducted by A delta fibres and C fibres to the spinal cord (transmission). Local anaesthetics can block the transmission of the electrical impulses when applied to the wound. It is hypothesized that surgical trauma produces a barrage of pain signals to the spinal cord,

that act as a priming mechanism in sensitizing the central nervous system. The rationale behind several studies is that by providing analgesia using local anaesthesia, these sensitizing neuroplastic changes can be reduced within the spinal cord, leading to diminished post-operative pain.³

There are numerous studies in which a local anaesthetic has been applied to the tonsillar fossae in tonsillectomy. The local anaesthetic is usually applied by infiltration or by topical spray. The effect of such treatment on post-operative pain control and related morbidity is inconsistent. The infiltration technique carries the risk of accidental intravascular injection, which can lead to cardiac arrhythmias and convulsions. Indeed life-threatening upper airway obstruction after bupivacaine infiltration has been reported in children.⁴ Cervical osteomyelitis⁵ and visual loss⁶ can be associated with infiltration. In this study, bupivacaine-soaked swabs are tightly packed into the tonsillar fossae after the removal of tonsils. We believe that this is a safe and reliable method of administering bupivacaine to the tonsillar fossae.

Materials and methods

Between October 1998 and July 1999, 99 patients (53 male and 46 female) between the ages of three and 16 years were recruited into the study. Following informed consent from the parent or guardian, patients admitted for day-case tonsillectomy were randomized into two groups using sealed envelopes.

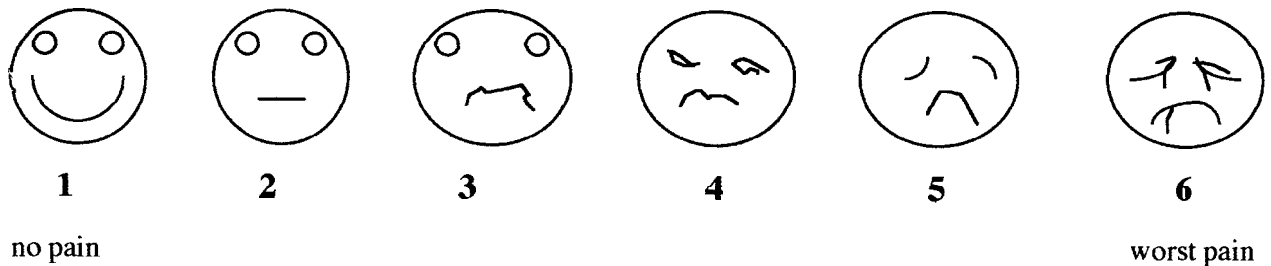


FIG. 1

Visual analogue pain scores.

Group A (mean age = 7.96 years, SD = 3.54) received topical bupivacaine (0.5 per cent, 3 mg/kg). Group B (mean age = 9.20 years SD = 3.15) received topical 0.9 per cent saline (10 ml). Fifty patients were given topical bupivacaine and 49 were given saline.

All patients underwent tonsillectomy with bipolar forceps dissection using a standardized general anaesthesia protocol. Patients received diclofenac per rectum (1.5 mg/kg) before the start of the procedure. A tonsil swab soaked with bupivacaine was tightly packed into each of the two tonsillar fossae for five minutes at the end of the procedure in Group A and saline swabs were used in Group B. The surgeon was blinded to the medication on the tonsil swabs, as the opening of the sealed envelope and the mixing of the swab with active or placebo agent, was performed by a second doctor. The anaesthetist was informed whether bupivacaine or placebo was being used prior to application.

Outcome measures included the time when each patient first ate and drank after the procedure, and also pain scores at one, three and six hours post-operatively. The latter were recorded using a visual analogue scale (Figure 1). This data was recorded by the day-care nurses, who were blinded to the intra-operative topical analgesia regimen. Patients were administered post-operative paracetamol (10 mg/kg) and codeine phosphate (3 mg/kg) according to a standard post-operative protocol. The number of successful discharges, re-admissions and post-operative haemorrhages were also recorded.

Results

There were 50 patients in the bupivacaine group and 49 in the saline group respectively. A two-tailed unpaired Student *t* test was used to compare these two independent groups with the null hypothesis that

there would be no difference in time of the first oral intake and pain scores.

The mean (standard deviation SD) of the time of first drink for the bupivacaine group was 104.3 mm (SD = 61.8 minutes) and for the control group was 159.5 minutes (SD = 48.8 minutes). The mean of the time of first eating for the bupivacaine group was 166.9 (SD = 62.7 minutes) and for the control group was 194.4 (SD = 41.9 minutes). There was a significant reduction in mean time to first drink ($p < 0.001$) and first eating ($p = 0.006$) between the bupivacaine group and the control group (Table I).

The mean (SD) post-operative pain scores were 1.88 (SD = 0.718) at one hour, 2.28 (SD = 0.858) at three hours and 2.1 (SD = 0.789) at six hours post-operatively for the bupivacaine group. The mean pain scores were 3.12 (SD = 1.130) at one hour, 3.39 (SD = 0.931) at three hours and 3.31 (SD = 0.962) at six hours post-operatively for the control group. There was a significant reduction in mean pain scores at one hour ($p < 0.001$), three hours ($p < 0.001$) and six hours ($p < 0.001$) post-operatively in the bupivacaine group (Table I). No significant difference is shown in the post-operative analgesic requirement between the two groups.

All 50 patients in the bupivacaine group were discharged the same day. Two out of the 49 patients in the control group (4.1 per cent) were admitted overnight due to inadequate oral intake, but were discharged uneventfully the following day. One out of the 49 patients in the control group (2.0 per cent) was re-admitted, after discharge, with a secondary haemorrhage. None of the 50 patients from the bupivacaine group reported any complications.

Discussion

The efficacy of bupivacaine infiltration in post-tonsillectomy pain has been extensively studied.⁷⁻²³

TABLE I
TIME OF FIRST ORAL INTAKE AND PAIN SCORES FOR TREATMENT AND CONTROL GROUPS

Time (min)	Bupivacaine	Control	Difference	<i>t</i> -value	<i>p</i> -value
	Mean ± SD	Mean ± SD			
First drank	104.3 ± 61.8	159.5 ± 48.8	55.19	4.93	<0.001
First ate	166.9 ± 62.7	194.4 ± 41.9	27.45	2.56	0.006
Pain score at					
First hr	1.88 ± 0.718	3.12 ± 1.130	1.24	6.51	<0.001
Third hr	2.28 ± 0.858	3.39 ± 0.931	1.11	6.15	<0.001
Sixth hr	2.1 ± 0.789	3.31 ± 0.962	1.21	6.18	<0.001

Degree of freedom = 97

TABLE II
PREVIOUS STUDIES OF TOPICAL BUPIVACAINE IN TONSILLECTOMY

Reference	Authors	Country	Bupivacaine concentration	Application Technique (infiltration (i) spray (s))	Age groups	Sample size	Post-operative analgesic effects (positive (+), no effect (n) & negative (-))
7	Alvarez Garcia <i>et al.</i>	Spain	0.5	i	Paediatric children	28	+
8	Wong <i>et al.</i>	Canada	0.5	i and s	children	43	+
9	Melchor <i>et al.</i>	Spain	0.25	i	2–13	50	+
10	Jebeles <i>et al.</i>	US	0.25	i	6–18	14	+
11	Broadman <i>et al.</i>	US	0.25	i	children	42	too small a sample to evaluate
12	Strub <i>et al.</i>	Switzerland	0.25	i	children	103	n
13	Stuart <i>et al.</i>	Scotland	0.25	i	children	42	n
14	Warnock and Lander	Canada	0.25	i	5–16	129	-
					Mixed		
15	Molliex <i>et al.</i>	France	0.25	i	8–65	68	+
16	Nordahl <i>et al.</i>	Norway	0.25	i	6–42	126	n
17	Orntoft <i>et al.</i>	Denmark	0.25	i	5–36	35	n
					Adult		
18	Costas-Gastiaburo <i>et al.</i>	South Africa	0.5	i	adult	100	+
19	Johansen <i>et al.</i>	Denmark	0.25	i	18–40	26	+
20	Schoem <i>et al.</i>	US	0.5	i	adult	51	n
21	Violaris and Tuffin	England	0.5	i	>16	15	n
22	El-Hakim <i>et al.</i>	Scotland	0.5	i	>16	92	n

The post-operative analgesic effect appears to be inconsistent in different studies. The design of the studies is heterogenous in terms of sample size, age range, bupivacaine concentration and control groups (Table II). In general, it seems that bupivacaine infiltration has little or no benefit in adult and mixed age groups. In paediatric patients, bupivacaine has been shown to have some benefit (half of the paediatric studies showed in Table II reported significant benefit).

This topic has been the subject of a systematic review by the Cochrane Library.²³ The authors felt that the use of currently available peri-operative local anaesthetics in tonsillectomy for improved pain relief cannot be supported unless it is in the context of a large randomized, double blind trial.

Our study uses swabs soaked with bupivacaine to pack the tonsillar fossae. We believe this to be a safe alternative to topical infiltration. We found that the pain score was significantly lower in the bupivacaine group compared to the control group during paediatric day-case tonsillectomy. Patients are more likely to swallow when they are in less discomfort. Once post-operative swallowing is commenced, patients are more likely to eat and drink. This study has shown that both eating and drinking occur earlier following topical application of bupivacaine. Because the rate of unforeseen post-operative admission was low (4.1 per cent in the control group), this study is not large enough to assess whether topical bupivacaine would have an effect on post-operative admission rates. In addition, the post-tonsillectomy haemorrhage rate was low (2.0 per cent in the control group) so no conclusions regarding post-operative haemorrhage rates in active

and placebo groups can be made. However, admission and post-tonsillectomy haemorrhage rates were not the primary outcome measures in this study.

Conclusion

Topical application of bupivacaine to the tonsillar fossae can reduce post-operative pain and facilitate eating and drinking during the early post-operative period following tonsillectomy in the paediatric age group. A larger prospective study of a similar design is required to assess whether this could make an impact on day-case tonsillectomy admission rates.

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