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Diclofenac vs oxybuprocaine eyedrops for analgesia in paediatric strabismus surgery

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Summary

Forty children undergoing strabismus surgery as day patients were randomly allocated to receive oxybuprocaine 0.4% eyedrops or 0.1% diclofenac eyedrops for perioperative analgesia. A non-invasive anaesthetic technique using the reinforced laryngeal mask airway was used. The study demonstrated that both topical analgesics provided good to excellent analgesia and the anaesthetic technique was associated with a relatively low incidence of nausea and vomiting. Complications were limited to two children who were admitted with persistent postoperative nausea and vomiting.

Keywords: topical diclofenac; topical oxybuprocaine; day surgery; strabismus

Introduction

Children undergoing surgery for correction of strabismus present many challenges to the anaesthetist and surgeon. Intraoperative bradycardia, postoperative pain and emesis have proven particularly troublesome (1). However, recent developments such as the laryngeal mask airway (2) and propofol anaesthesia (3) have led to the development of high quality anaesthetic techniques and the possibility of routine day case strabismus surgery with minimal postoperative morbidity for healthy children.

Local anaesthetic drops have been employed for many years in ophthalmology in conscious adults and children for eye examinations, tonometry and minor procedures such as removal of foreign bodies (4,5). Amethocaine drops have been used for perioperative analgesia in paediatric strabismus surgery (McNicol, unpublished observations), with the added benefit of reducing opioid requirements and postoperative nausea and vomiting (6). Amethocaine, lignocaine, oxybuprocaine or proxymetacaine produce rapid topical anaesthesia of the conjunctiva within a few seconds after administration of one or two drops which lasts at least 30 min, although the effect of amethocaine may last for several hours. In the conscious patient a transient initial burning or stinging sensation is common except with oxybuprocaine and proxymetacaine. Amethocaine can produce punctate corneal keratopathy and is not recommended for repeated application.

Topical diclofenac has been shown to reduce Prostaglandin E2 (PGE2) levels in the corneas of animals undergoing laser photorefractive keratectomy (7) and evidence of a reduction in

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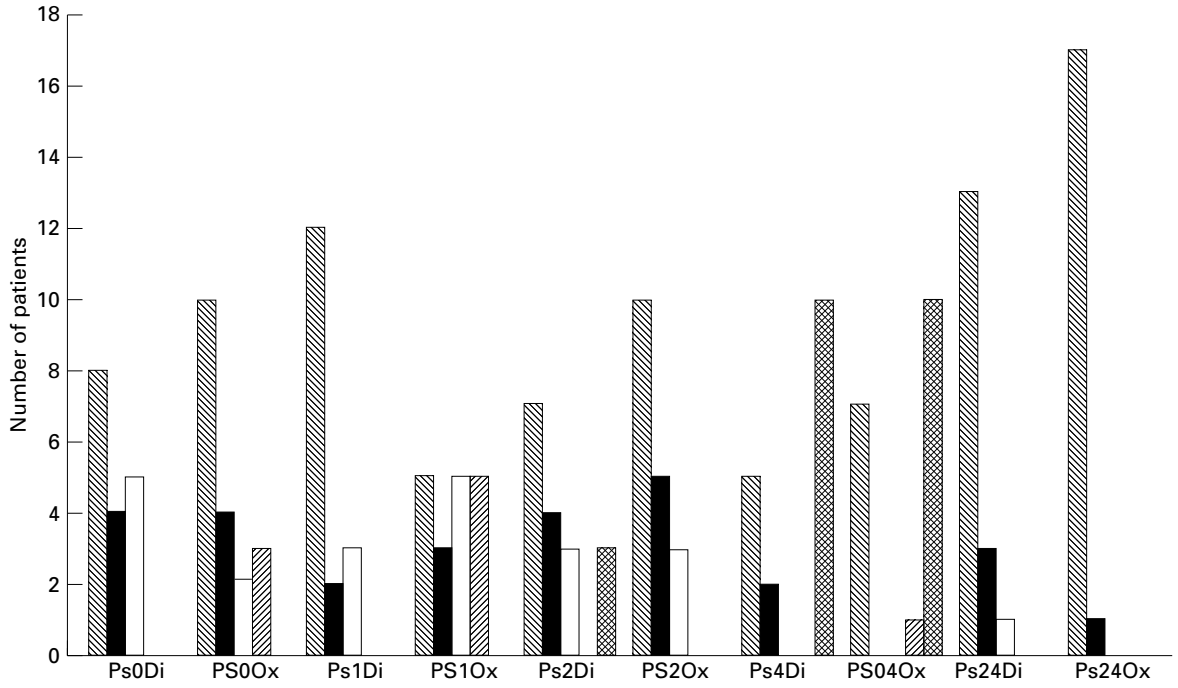

Figure 1
Pain scores (PS) for the diclofenac (Di) and oxybuprocaine (Ox) treated patients at times 0, 1 h, 2 h, 4 h and 24 h.
Self report pain scores
▧ 0 = not sore at all
■ 1 = not really sore
□ 2 = quite sore
▨ 3 = very sore
▩ not recorded

leucocyte accumulation in the anterior chamber in response to either surgery or leucotactic factor has been demonstrated in animals (7,8). It has been used in a variety of ocular inflammatory conditions (9,10). In surgical patients undergoing laser photorefractive keratectomy and cataract surgery topical diclofenac reduces intraoperative miosis and also produces analgesia (11,12).

There are no published studies of the use of topical diclofenac in strabismus surgery and the present study was designed to test the analgesic efficacy of topical diclofenac compared with topical anaesthesia in children undergoing day case strabismus correction under general anaesthesia.

Methods

Following ethics committee approval, informed consent was obtained from parents of 40 children aged three to eight years scheduled to undergo unilateral or bilateral correction of strabismus on a day case basis. Children with mental handicap, asthma, eczema, renal disorders, known allergy to nonsteroidal antiinflammatory drugs (NSAIDs) or local anaesthetics and those unsuitable for day case surgery were excluded (13). No sedative premedication was used and parental presence during induction was routine. Topical EMLA cream was applied to the dorsum of each hand one hour prior to surgery. Propofol, $4\,mg{\cdot}kg^{-1}$ with added lignocaine, $0.2\,mg{\cdot}kg^{-1}$ was used for induction, a reinforced laryngeal mask airway was inserted and maintenance of anaesthesia was by spontaneous ventilation of 67% nitrous oxide, 33% oxygen and isoflurane 1.0-1.5 MAC. After induction children were allocated at random to receive two drops of either oxybuprocaine 0.4% or diclofenac 0.1% applied to the eye/eyes to be operated upon. The drops

Table 1
Demographics

		Diclofenac	*Oxybuprocaine*	P *value*
Age (y)	Mean + SD	6.35 ± 2.5	5.6 ± 1.6	0.143
	Range	3–12	3.5–8.5	
Weight (kg)	Mean + SD	23.4 ± 7.5	20.8 ± 7.1	0.147
	Range	14–43	15–47	
Time (mins)	Mean + SD	38 ± 10.5	31.4 ± 9.6	0.02*
	Range	25–59	15–45	

* Statistically significant.

were given after induction of general anaesthesia but before surgery and were repeated at the end of surgery prior to awakening. Anticholinergics were not routinely used. Each child was allowed to recover in a quiet environment and time 0 was recorded when the child was awake enough to answer simple questions. The child was assessed at this time and again 1, 2, 4 and 24 h later by an observer who was unaware which type of drops had been used. Pain was assessed by a simple self report interval scheme (0 = 'not sore at all'; 1 = 'not really sore'; 2 = 'quite sore'; 3 = 'very sore'). Further eye drops were offered to each child if pain recurred, or was present once awake. Oral paracetamol, 15 $mg \cdot kg^{-1}$, was administered by nursing staff or parents if pain persisted after the eye drops or if the child refused eye drops but was still in pain. If pain was still not controlled, supplementary analgesia was offered and recorded while the child was in hospital and if at home the parent was advised to call their family doctor. At each time interval, a visual assessment was made of conjunctival inflammation by scoring oedema, redness and bleeding as nil, mild, moderate or severe. Nausea and vomiting was assessed on a four point scale (0 = no nausea or vomiting; 1 = nausea only; 2 = vomiting $\times 1$; 3 = vomiting $> \times 1$). Any complications were recorded. The groups were compared using the *t*-test or Chi-squared test as appropriate.

Results

The forty children studied were comparable in terms of age and weight. The average length of the operative procedure was significantly longer in the diclofenac group (Table 1). Five children were excluded from the study because the standard anaesthetic technique was not used which left 35 evaluable patients, 18 in the oxybuprocaine group and 17 in the diclofenac group.

Pain scores were similar for both treatment groups (Figure 1) except at the 1 h assessment, where 71% of the diclofenac group had no pain compared with 28% of the oxybuprocaine group ($P = 0.011$). The majority of children in both study groups experienced no pain or only mild discomfort over the 24 h study period (Figure 1). No patients who received diclofenac drops reported severe pain at any of the assessments whereas in the oxybuprocaine group three children reported severe pain on awakening (NS), five did so at the one hour assessment ($P = 0.019$) and one at four h (NS; Figure 1).

Additional analgesic consumption over the 24 h study period in the form of further eye drops and paracetamol is detailed in Figures 2 and 3. No eyedrops were given to 18/35 children, with similar proportions in each treatment group. Of the 17 who received further eyedrops, six received two doses, four with oxybuprocaine. 10/35 did not receive paracetamol while in 11/14 oxybuprocaine treated children who received paracetamol, only one dose was given. In the diclofenac treated group, of the 11 who received paracetamol, six received more than one dose. However, there were no statistically significant differences between the study groups in the proportions of children receiving 0, 1, 2 or 3 doses of paracetamol. No child in the study required stronger analgesia and no call outs were made to family doctors.

Postoperative nausea and vomiting was not evident in the vast majority of cases in each study group at each assessment and there were no significant differences between the study groups in the proportion of children with no PONV at each time point (Figure 4). Data were missing at the 4 h assessment as these children were on their way home at that time. One child in each study group vomited on awakening. At 1 h one child in the diclofenac group had vomited, whereas four in the oxybuprocaine group had and this rose to three and five respectively in the subsequent hour. Two of these children had by now vomited more than once and both of these patients were in the oxybuprocaine group. By the 4 h assessment the incidence of vomiting was the same but by now one of the

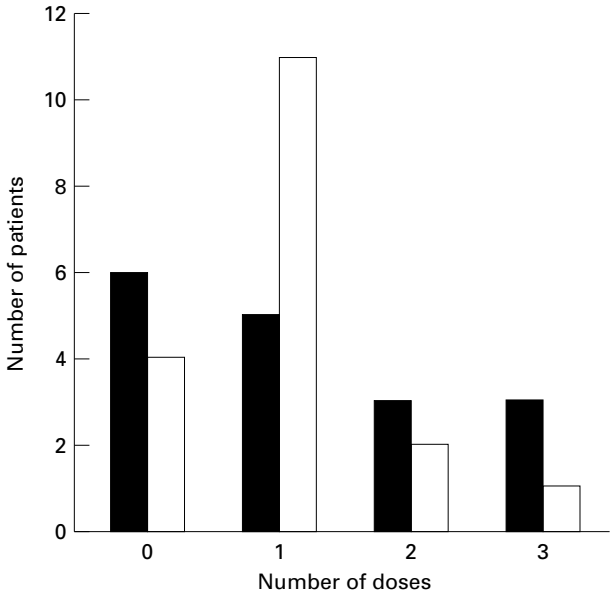

Figure 2
Paracetamol doses given in 24 h.
■ Paracetamol given over 24 h. Diclofenac.
□ Paracetamol given over 24 h. Oxybuprocaine.

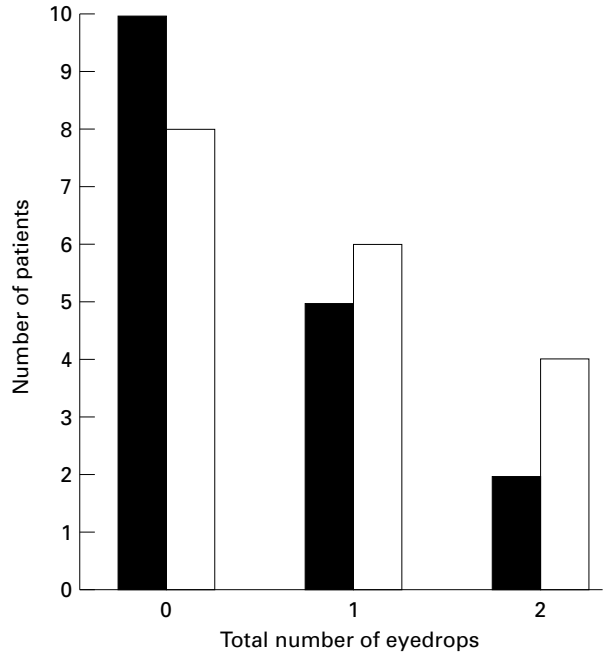

Figure 3
Number of eyedrops given in 24 h.
■ Eyedrops given over 24 h. Diclofenac.
□ Eyedrops given over 24 h. Oxybuprocaine.

diclofenac treated children had vomited more than once. One child in each study group required inpatient admission for persisting nausea and vomiting. By the 24 h assessment one further child in the diclofenac group had vomited once.

No episodes of oculocardiac reflex bradycardia occurred in this study and no patients required intravenous atropine. Mild erythema consistent with the surgeon's expectations was found in all patients but no oedema or bleeding was seen in either study group and no other complications were noted.

Discussion

With the introduction of propofol and the laryngeal mask airway, our anaesthetic technique for strabismus surgery in healthy children has evolved from an invasive technique (using muscle relaxants, tracheal intubation, controlled ventilation, anticholinergics, antiemetics and opioids) to a relatively noninvasive method (using propofol, laryngeal mask airway, spontaneous respiration, local anaesthetic eye drops and paracetamol or NSAIDs). We have found that this latter technique produces excellent intraoperative conditions, a low incidence of oculocardiac reflexes and low postoperative morbidity which allows surgery on a day care basis. This impression is confirmed by the results of this study which demonstrates that topical local anaesthesia or NSAID supplemented by paracetamol gives good to excellent analgesia in most children after day case strabismus correction. The fact that pain is well controlled by such simple measures suggests that opioids are not necessary for this type of surgery, contrary to common practice elsewhere. Diclofenac does appear to produce analgesia for strabismus surgery when applied topically to the eye which is as effective as oxybuprocaine and may be longer lasting in its effects, as indicated by the higher early pain scores found in the local anaesthetic group. The use of a longer acting local anaesthetic such as amethocaine may therefore be more logical but there are concerns amongst many ophthalmologists about inadvertent trauma to the anaesthetised cornea by children. This is a potential drawback also of repeated application of short acting local anaesthetic drops. The pattern of use of supplementary analgesia in the first 24 h suggests oxybuprocaine treated children tended to receive repeated drop administrations with

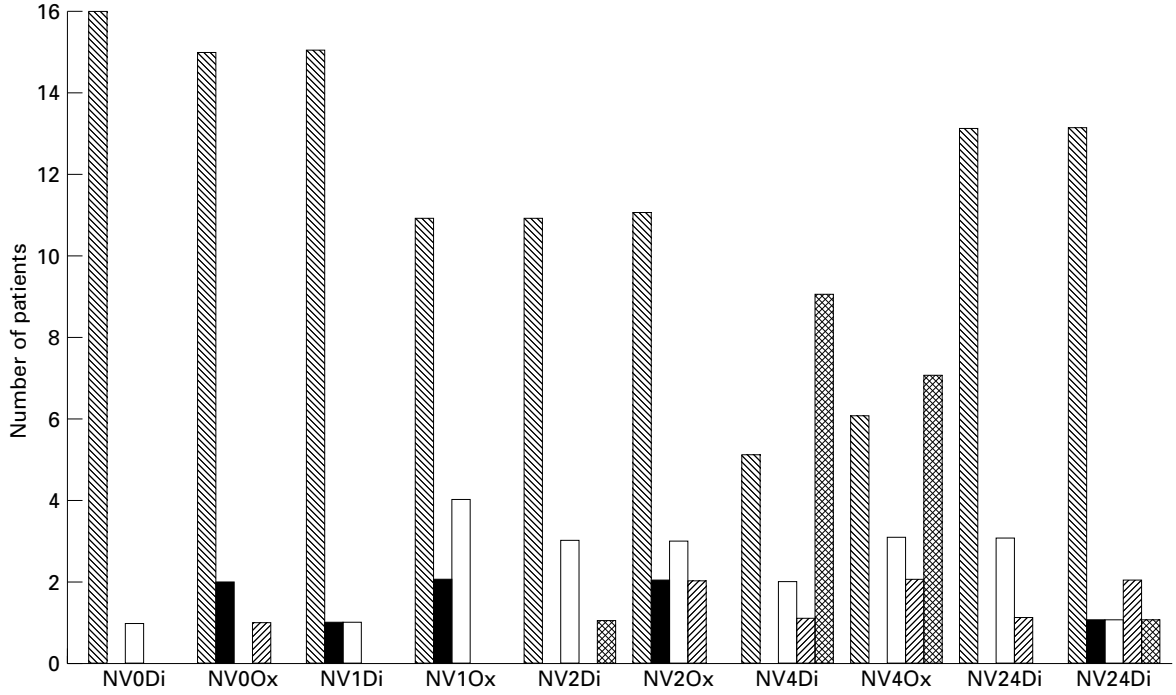

Figure 4
Nausea and vomiting (NV) scores. For diclofenac (Di) and oxybuprocaine (Ox) treated patients at times 0, 1 h, 2 h, 4 h and 24 h.
Nausea and vomiting
▧ 0 = nil
■ 1 = nausea only
□ 2 = vomiting ×1
▨ 3 = vomiting > ×1
▩ not recorded.

fewer paracetamol repeat doses while diclofenac treated children received fewer repeated drop administrations and more paracetamol repeat doses. This may be because the pain was relatively mild and easily controlled by paracetamol or that some children did not like receiving eye drops when awake. We did not specifically study whether the eye drops used in the study produce stinging in the eye of the awake child. Further studies are currently underway to investigate whether route of administration of NSAID influences analgesia.

Although we found that use of a non-invasive general anaesthetic technique where opioids are avoided is associated with a lower incidence of nausea and vomiting than previously described when no antiemetics are used (14), two children (6%) experienced persisting vomiting necessitating admission which is ten times our overall day case surgery admission rate. There was a trend towards a higher incidence and severity of nausea and vomiting in the oxybuprocaine group compared with diclofenac but patient numbers and the overall incidence of emesis are too small to draw firm conclusions. A wide range of antiemetic measures have been described for this patient group (15–18) but often these studies are conducted using what we would call emetic anaesthetic techniques and few have achieved the low rate of emesis noted in our study.

Conclusion

This study demonstrates that topical local anaesthesia or NSAID supplemented by paracetamol provides good to excellent analgesia in most children after day case strabismus correction. We found that the use of a noninvasive general anaesthetic technique where opioids are avoided is associated with a low incidence of nausea and vomiting. Further evaluation of the role of antiemetics in paediatric strabismus

surgery using a noninvasive general anaesthetic technique is needed.

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