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The Effects of topical viscous lignocaine 2% versus per-rectal diclofenac in early post-tonsillectomy pain in children

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ABSTRACT

Introduction: Tonsillectomy is frequently associated with postoperative pain of considerable duration, which is usually accompanied by the substantial consumption of both opioid and non-opioid analgesic such as NSAIDs and local anaesthetics.
Objective: The aim of this study was to evaluate the efficacy between 2% viscous lignocaine and sodium diclofenac based upon the visual analogue scores (VASs), consumption of pethidine 0.5 mg kg^{-1} as the rescue drug postoperatively and time taken to resume feeding.
Methods: 130 patients aged between 5 and 12 years old were randomly allocated into 2 groups to be given either 2% viscous lignocaine 4 mg kg^{-1} body weight topically post-tonsillectomy or sodium diclofenac 1 mg kg^{-1} per-rectal post-induction of anaesthesia. Postoperatively visual analogues score was done for 24 h, the amount of pethidine given and time when the patient start taking oral feeding of clear fluid, soft diet and normal diet were documented.
Results: There was no significant difference in the visual analogue scores in both groups, however the requirement of pethidine as the rescue drug postoperatively was significant 2 h post-tonsillectomy ($p = 0.023$) in viscous lignocaine group compared to sodium diclofenac. The time taken to resume oral feeding and soft diet was also significant in viscous lignocaine group ($p = 0.016$ and $p = 0.007$) whereas there was no significant in taking normal diet.
Conclusion: We concluded that 2% viscous lignocaine applied topically post-tonsillectomy is comparable to sodium diclofenac per-rectal in providing analgesia and faster oral feeding.

1. Introduction

Tonsillectomy is one of the most common procedures in otorhinolaryngological practice. However the recovery period from the surgery is a painful experience [1,2]. Moreover in children, swallowing caused more pain and this will delay a return to normal activities [3–6]. That is why the provision of good analgesia is associated with less physiologic derangement and may improve morbidity. Following tonsillectomy, analgesics are required for pain-relief especially in children. The drugs that are usually prescribed include non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol and opiods.

Non-steroidal anti-inflammatory drugs such as diclofenac in relieving postoperative pain have been documented and in patient, single dose studies have shown that diclofenac is an effective analgesic in children post-tonsillectomy [1,2]. However, the use of NSAIDs for analgesia in children undergoing tonsillectomy is controversial [7–10]. Some of the side effects from the non-steroidal anti-inflammatory drugs such as their impact on hemostasis and bronchospasm in asthmatic children may hinder their usage.

Local anaesthetics have been also used either by infiltration or topical application to reduce postoperative pain, however most of the studies done commonly use infiltration at the peritonsillar tissue rather than topical application. Reported cases associated with local infiltration adverse effect include severe upper airway obstruction [11], pulmonary oedema [12] and neck abscess [13].

This study was aimed to compare the effectiveness of viscous lignocaine 4 mg kg^{-1} as post-tonsillectomy analgesic in comparison with rectal diclofenac 1 mg kg^{-1} based upon the visual analogue scale, requirement of rescue drug (pethidine) postoperatively and resumption of oral feeding.

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2. Methods

The study was approved by the University Ethics Committee and sample size was calculated comparing two mean formula with the power of study with 80% and significant level of 5. After taking into accounts of 10% drop-out rate, the total number of patients that need to be recruited was 65 per-group. There were 4 criteria that must be fulfilled before the patient was selected to engage in the study. First, the children were selected from age 5 to 12 years old with ASA 1 and 2 which were planned for elective tonsillectomy. The other criteria were the surgery must be less than 2 h and the patient's guardian were well informed regarding the procedure used and had given written consent. The patients were excluded from this study if they developed complications intra-operatively such as bleeding or bronchospasm, obese with body mass index >35, had history of asthma and allergy towards the study drugs.

The patients were randomly divided into 2 groups, Group A and Group B, Group A was to receive viscous lignocaine 2% (Astra Zeneca) 3 ml or not exceeding 4 mg kg^{-1} body weight, while Group B was to be given sodium diclofenac 1 mg kg^{-1} per-rectal. The viscous lignocaine was applied at the end of surgery by the surgeon on the raw area of tonsillar bed for 3 min and later was sucked out gently, whereas the diclofenac was given 5 min post-induction per-rectal.

All patients were pre-oxygenated and induced with intravenous fentanyl 1.5 mcg kg^{-1}, propofol 2 mg kg^{-1} and rocuronium 0.5 mg kg^{-1} as muscle relaxant. All patients will be intubated with standard endotracheal tube size according to age and the endotracheal tubes (ETT) were lubricated with lignocaine jelly. ETT cuff was inflated with air first to ensure that there was no leakage and moist throat pack was inserted by surgeon to prevent aspiration. Ventilation was controlled and anaesthesia was maintained with oxygen/nitrous oxide (30/70%), isoflurane and rocuronium until the operation was completed.

The blunt and snare dissection technique for tonsillectomy was performed by an otolaryngologist. The tonsils were dissected from the anterior to posterior palatoglossal fold by blunt dissection. The inferior poles of the tonsils were snared. Haemostasis was managed with suction, bipolar diathermy, suturing and packs if needed. Meticulous care was taken during the dissection and suction clearance in order to minimize trauma to the surrounding tissue. At the end of surgery, anaesthesia was discontinued and tracheal extubation will be performed when all extubation criteria were met and full reversal of neuromuscular block with return of spontaneous breathing or ability to follow verbal command like eye opening and hand grip. Post-extubation, patients were placed in the left lateral position to prevent aspiration until patient was fully conscious. The oxygen flow was maintained post-extubation when patient was nursed in the recovery room. Vital signs were then charted and pain assessment was done using VAS 0.5 hourly and before discharge to ward.

In the ward, patients were then follow-up for 24 h, another nurse blinded to the study groups will measure the degree of pain in the ward using a visual analogue scale (VAS: 0–100 mm) at 1 h, 2 h, 4 h, 12 h and 24 h postoperatively. The VAS was arranged as a 100 mm vertical line with anchors at either end (no pain and worst pain possible). If the patients complain of intolerable pain, VAS will be done by the nurse to assess the severity and rescue medication intravenous pethidine 0.5 mg kg^{-1} will be given. The time, frequency and the total dose given will be recorded. The type of diet whether clear fluid, soft diet or normal diet was recorded with the time and duration of resume feeding postoperatively based upon the information from the parents or guardian.

All data analysis and data entry will be done using social science and statistical packaged (SPSS®) version 12.0 software licensed to Universiti Sains Malaysia. The results were presented as the number of patients (%) or mean (SD) when appropriate. Statistical analysis will be performed using independent *t*-test (for the numerical data) and Chi-square's test (for categorical data). The evaluation of pain scores was compared across treatment groups using ANOVAs for repeated measures. Statistical significance is considered at p value <0.05.

3. Results

One hundred and thirty children aged 5–12 years who had underwent tonsillectomy, with ASA 1 and 2 were recruited. The Group A and Group B consist of equal number of 65 patients. The age and sex distribution of the children are as shown in Table 1.

There were no significant differences between the two groups in age distribution, weight, sex and ASA physical status (Table 1).

Pain assessment score (VAS) in the recovery room and ward 24 h postoperatively was almost similar between both the groups and were not significant (Fig. 1).

The requirement for rescue drugs, IV pethidine only showed one significant finding at 2 h postoperatively ($p = 0.023$) whereby the viscous lignocaine group required less pethidine compared to diclofenac group (Table 2).

The time taken to resume oral feeding and type of feeding is significantly reduced in viscous lignocaine group when compared to diclofenac, oral fluid ($p = 0.016$) and soft diet ($p = 0.007$) (Table 3).

4. Discussion

This study recruited 130 children aged 5–12 years who had undergone tonsillectomy with ASA 1 and 2. The main aim of our study is to determine the effectiveness of viscous lignocaine compared to rectal diclofenac as conventional medication for tonsillectomy pain. The pain assessment methods used in this study are visual analogue scale (VAS) and physiological parameters. The outcome used in this study includes the time return to oral fluid or food (behavioral outcome) and the need for rescue medication (the cumulative dose of pethidine and number of rescue analgesic). VAS is considered as one of the gold standard for pediatric pain assessment tools. It is appropriate for patients of more than 5 years old because it is simple, easy to be validated and reliable. Many literatures used VAS for assessment tools because it correlates well with pain intensity and reproducible [14,15]. However pain intensity is a subjective measure. That is why we measured the cumulative dose of pethidine as an objective

Table 1
Demographic variables for the two groups [mean (SD) and percentage].

	Viscous lignocaine 2% ($n = 65$)		Diclofenac ($n = 65$)		p value
Age	7.98 ± 1.88		8.02 ± 1.84		0.952 (Independent *t*-test)
Sex	M: 37 (56.9%)	F: 48 (43.1%)	M: 35 (53.8%)	F: 30 (46.2%)	0.76 (Fisher's Exact test)
Weight	20.92 ± 7.03		18.00 ± 4.87		0.066 (Independent *t*-test)
ASA	I: 57 (87.7%)	II: 8 (12.3%)	I: 59 (90.7%)	II: 6 (9.3%)	0.437 (Fisher's Exact test)