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# Does topical ropivacaine reduce the post-tonsillectomy morbidity in pediatric patients?

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**KEYWORDS**
Ropivicaine;
Topical administration;
Tonsillectomy;
Pain

**Summary**

*Objectives:* To determine whether post-operative administration of topical ropivacaine hydrochloride decreases morbidity following adenotonsillectomy.
*Study Design:* Prospective, randomized, double-blind clinical trial.
*Setting:* University referral center; ENT Department.
*Participants:* Fourty one children, aged 4–16 years, undergoing tonsillectomy.
*Methods:* Patients received 1.0% ropivacaine hydrochloride soaked swabs packed in their tonsillar fossae while the control group received saline-soaked swabs. Mc Grath's face scale was used to compare the two groups in respect of pain control. Chi-square and two-tailed unpaired Student's *t*-tests or Mann–Whitney-*U*-tests were used to compare the two independent groups. As 10 we made 11 comparision between groups, for Bonferroni correction, $p < 0.005$ was accepted as statistically significant.
*Results:* Only first hour there was no significant pain-relieving effect seen in the ropivacaine group ($p > 0.05$). The other hours and days there were statistically significance between the two groups ($p < 0.001$). Also, the other post-operative parameters such as nausea, fever, vomiting, odor, bleeding, otalgia and trismus were not statistically different between the two groups. There were no complications associated with ropivacaine hydrochloride. No patients in this study suffered systemic side effects related to the use of this medication.

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*Conclusion:* Locally 1.0% ropivacaine administiration significantly relieves the pain of pediatric tonsillectomy and, it is a safe and effective method. High concentrations of ropivaciane may produce clinically significant pain relief. It is more effective to reduce of post-operative analgesic requirement after first hour.


## 1. Introduction

The new long-acting amino-amide local anesthetic, ropivacaine, combines the anesthetic potency and long duration of action of bupivacaine with a toxicity profile intermediate between bupivacaine and lidocaine. Ropivacaine is 2—3 times less lipid soluble and has a smaller volume of distribution, greater clearance, and shorter elimination half-life than bupivacaine in humans [1] Low concentrations of ropivaciane may produce clinically significant vasoconstriction, which is not increased further by the addition of epinephrine [2,3]. At low concentration, it produces sensory analgesia without profound motor blockade because of its diminished (dose-related) effect on motor fibres [4,5]. Safety and efficacy of ropivacaine in children under the age of 12 have not been established. Also, there is no specific information comparing use of ropivacaine in children with use in other age groups.

Preincisional injection of ropivacaine with clonidine prior to tonsillectomy has a preemptive analgesic effect that outlasts the local anesthetic and decreases pain, opioid use, and the time to return to normal activity [6]. In contrast that, the injection of 0.5% ropivacaine with epinephrine immediately following adenotonsillectomy results in a measurable plasma level and injection does not reduce pain post-operatively and adversely affects behavior scores, neck pain scores, and retching frequency compared with placebo. Ropivacaine with epinephrine injection for post-operative analgesia is not recommended for this patient population [7]. Furthermore, no studies have compared the effects of high dose topical ropivacaine and saline topical administiration in a randomized controlled trial. Thus, purpose of this study was to evaluate the efficacy of high dose topical ropivacaine on post-operative morbidity in pediatric patients after tonsillectomy.

## 2. Materials and methods

A protocol for a double-blind controlled prospective trial was designed and was approved by faculty ethics committee. Following informed consent from the parent, 41 children admitted for day-case tonsillectomy were randomized into two groups, Group R (ropivacaine) and S (saline). Randomization was provided by the use of a random number generator (Excel; Microsoft Corporation, Redmond, WA).

Children were enrolled between January 1, 2005, and December 15, 2005. A standard snare surgical technique was used. Group R received 2 ml topical 1.0% ropivacaine hydrochloride for each tonsilar fossae and group S received topical saline. A tonsil swab soaked with high dose ropivacaine (1.0%) was tightly packed into each of the tonsillar fossae for 5 min at the end of the procedure in group R and saline swabs were used in group S. Cautery was not used on any of the children for hemostasis and also, tightly packed swabs were sufficient.

All procedures were performed under general anesthesia by using a standardized general anaesthesia protocol; for premedication 0.5 mg/kg midazolam was applied rectally between the ages of 4 and 6 and 0.1 mg/kg midazolam was applied as intravenous between the ages of 6 and 16. Following the induction with intravenous propofol (2 mg/kg) and atracurium (0.5 mg/kg), anesthesia was maintained with propofol (2 mg/kg) IV and remifentanyl 0.1 mg/kg/min IV.

A questionnaire including age and sex provided information concerning the patient's post-operative morbidity. Post-operative information about nausea, fever, vomiting, halitosis, bleeding, otalgia, and trismus was gathered on each child by the parent during 1 week after the operation. The post-operative factors in Table 1 were analyzed by using Chi-squared test and a $p$ value of less than 0.05 was defined as statistically significant.

Pain scores at 1, 5, 13, 17 and 21 h, and first, second, third, fourth, fifth and sixth days post-operatively were recorded by the parent using Mc Grath's face scale (Table 2). A two-tailed unpaired student-$t$-test or Mann—Whitney-$U$-tests were used to compare the pain scores of the two independent groups. As 10 we made 11 comparisons between groups (e.g., 1 h, 5 h, etc.), for Bonferroni correction, a $p$ value of less than 0.005 (0.05/11) was determined as the level of statistical significance.

All patients were administered post-operatively the same oral acetaminophen pediatric suspension (10—20 ml) and antibiotic pediatric suspension (amoxicillin, 5—10 mg/kg) four times daily.