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Pre-emptive peritonsillar dexamethasone vs. levobupivacaine infiltration for relief of post-adenotonsillectomy pain in children: A controlled clinical study

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ABSTRACT

Objectives: To investigate the effects of the pre-emptive local infiltration of dexamethasone vs. levobupivacaine on postoperative pain and morbidity in pediatric adenotonsillectomy patients.
Methods: A total of 60 patients (32 males and 28 females), aged 3–14 years, were included in this double-blind prospective randomized controlled clinical study from September of 2011 until May of 2012. Patients admitted for adenotonsillectomies after informed consent was obtained from the parents, and randomized into three groups receiving either dexamethasone sodium phosphate (Group 1, mean age 5.9 ± 1.6), levobupivacaine with epinephrine (Group 2, mean age 6.1 ± 2.6), or saline (Group 3, mean age 6.0 ± 3.4). Pain scores at the 1st, 4th, 8th, 12th, 16th, and 20th hours, and first, second, third and seventh days post-operatively were recorded by the parents using McGrath's face scale. The operation type, operation time and anesthesia time, the time of the first request for postoperative analgesia, and the total number of analgesic interventions were recorded.
Results: Pain scores were revealed in this order: Group 1 (steroid) < Group 2 (levobupivacaine) < Group 3 (saline) at all times ($p = 0.000$). The anesthesia times for Group 1 and Group 2 were different (steroid vs. levobupivacaine), and the time to first analgesic was longer in Groups 1 (steroid) and 2 (levobupivacaine) than in Group 3 (saline) ($p < 0.000$). The total number of analgesic interventions was lower in Group 1 (steroid) than in Group 2 (levobupivacaine) and Group 3 (saline) (steroid vs. saline, $p = 0.000$, and steroid vs. levobupivacaine, $p < 0.05$).
Conclusion: Peritonsillar dexamethasone infiltration was more effective than both levobupivacaine and saline in reducing post-tonsillectomy pain. It was proven to be a safe and effective method.

1. Introduction

One of the most often executed procedures in otorhinolaryngology on pediatric patients is tonsillectomy. Postoperative pain is a universal issue after adenotonsillectomy both in hospitals and at home. A number of studies have examined the impact of pre-incisional and peritonsillar injection of local anesthetic drugs in tonsillectomy on postoperative pain [1,2]. Nausea and vomiting are significant problems that can lead to extended hospitalization. As a result, efficient pain control and the prevention of nausea and vomiting in children is essential [3].

The tonsillar fossae are well innervated locally by the glossopharyngeal and trigeminal nerves, and greatly delineated in the cerebral cortex; therefore, they are extremely sensitive [4,5]. It has been shown that pain after tonsillectomy begins with tissue damage, which leads to the liberation of inflammatory mediators, and is conducted by the stimulation of C-fiber afferents found in the peritonsillar area. Not only inflammation, but also pharyngeal muscle spasms and topical nerve irritation trigger the pain [6,7]. This pain lasts until the peritonsillar muscles become covered with mucosa, 14–21 days after surgery [8]. In order to reduce the pain, local anesthetics, acetaminophen with codeine, steroids, the application of fibrin glue, and cryoanalgesia have been used [9–14].

The fundamental theory of pre-emptive analgesia is to impede the establishment of central hyper-sensitization before surgical intervention by analgesic use [15]. When local anesthetics are used

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in the peritonsillar region, they can prevent nerve conduction [16], and pre-emptive analgesia has been shown to reduce postoperative pain after several invasive procedures [16–18]. Levobupivacaine is a novel and long lasting bupivacaine. A significant characteristic of levobupivacaine is its reliability due to its low neurological and cardiac toxicities. Steroids have strong anti-inflammatory effects, and may be anticipated to enhance recovery period after surgery. Dexamethasone can reduce nausea, vomiting, and postoperative pain [4,19,20]. Additionally, a few studies have suggested that infiltration of levobupivacaine in the peritonsillar space decreases postoperative pain [21,22]. But there is no randomized controlled clinical study on tonsillectomy pain comparing both levobupivacaine and dexamethasone. Therefore, in this prospective, randomized, controlled study, we aimed to investigate the effect of the pre-emptive local infiltration of levobupivacaine and dexamethasone on postoperative pain and morbidity in pediatric adenotonsillectomy cases.

2. Materials and methods

Between September of 2011 and May of 2012, 60 patients were included in this study. After informed consent was obtained from the parents, the patients admitted for adenotonsillectomy/tonsillectomy were randomly assigned into three groups. Indications for adenotonsillectomy included recurrent tonsillitis and adenotonsillar hypertrophy leading to obstructive symptoms. Exclusion criteria were: bleeding disorder, having chronic or severe systemic disease (i.e., diabetes), synchronous another surgery in addition to tonsillectomy, peritonsillar abscess formation, being under analgesic therapy or receiving any painkiller within 24 h before surgery, and being allergic to any of the drugs used in this study. Children who received steroids, antiemetics, antihistamines, or psychoactive drugs within 24 h of surgery were excluded. The patients were allowed to eat solid food until 12 am on the day before surgery. Among the 75 children matching the study criteria, 60 (95%) included the study; 10 patients were not applied to post-operative control and 5 patients did not give their consent. Patients were randomized into 1 of 3 treatment groups. Most patients were admitted on the day of surgery and had a standard anesthetic given by a single consulting anesthetist (A.D.) or a junior member of his team. Group 1 (mean age 5.9 ± 1.6) received dexamethasone sodium phosphate (2%) (1 mg/kg, maximal dose 25 mg, $n = 20$). Group 2 (mean age 6.1 ± 2.6) received 0.25% levobupivacaine with epinephrine (1:200.000, $n = 20$). Group 3 (mean age 6.0 ± 3.4) received saline (0.9% NaCl, $n = 20$).

Following standard anesthesia induction with propofol, fentanyl, and atracurium, or mask inhalation with sevoflurane, maintenance was achieved using nitrous oxide in oxygen and sevoflurane without any premedication. The study drug was supplied as a syringe of liquid, identical in volume and color but indicated by a letter, for the each groups. All nurses, physicians, parents, and patients were blinded to the children's assignments to the study groups. The study drug was prepared in the injector creating a total of 10 ml by the anesthesiologist, who was excluded from postoperative evaluation.

Before the tonsillectomy, the study drug was superficially infiltrated into the peritonsillar space at the upper pole, the lower pole, between the two, and into the posterior tonsillar pillar (5 ml per tonsil) using the aspiration injection technique. The injections were superficial and ballooned out the submucosal tissues of the tonsillar pillar. For infiltrations, a straight 23-G needle was used, and 5 min after the injection surgery was initiated. During adenotonsillectomies, none of the patients did not receive additional analgesic [23]. Adenoidectomy was performed using adenoidal curettes of the appropriate size. A gauze swab was placed in the nasopharynx for homeostasis, and the swab was left in place during the tonsillectomy. A standard dissection and snare technique was used for the tonsillectomies, done by the same otolaryngologist, and homeostasis was obtained by bi-polar cautery. After surgery, patients were transferred to the post-anesthesia care unit. When they were fully awake, stable, and comfortable, they were transferred to the Ear Nose Throat ward.

Three hours after surgery, the children were offered 100 cc of water if they were free of postoperative nausea and vomiting (PONV). If children had PONV, they were given metoclopramide (0.1 mg/kg intravenously for children younger than 6 years old, and 2.5–5 mg intravenously for children older than 6 years old). Adverse events, such as breathing difficulties bleeding and hypotension were recorded. The children were considered to be ready for discharge when they satisfied the institutional criteria: they were awake, alert, able to drink liquids, comfortable, had stable vital signs, no nausea or vomiting, and no bleeding. The patients were discharged on the day after surgery in all cases. The parents were instructed to follow the pain medication schedule diligently. All patients were given the same antibiotic pediatric suspension (amoxicillin–clavulanic acid 25/3.6 mg/kg) twice daily for one week postoperatively and the same painkiller suspension (paracetamol 15 mg/kg/dose, PO) was used in all groups upon request.

Age weight, gender, operation time, operation type, anesthesia time, and adverse effects, such as arrhythmia and allergic reactions, were recorded. Pain scores at 1, 4, 8, 12, 16, and 20 hours, and the first, second, third, and seventh days post-operatively were attained by the parents using McGrath's face scale (Fig. 1) [24]. The time for the first request for postoperative analgesia and total number of analgesic interventions for 0, 1, 2, 3, and 7 days, as well as post-operative information about bleeding, fever, nausea, vomiting, otalgia, trismus, and halitosis was gathered. The ethics committee of the faculty of medicine has been approved the design of this study (protocol number: B.30.2. ATA.0.01.00/36).

In our preliminary study, when the difference mean pain scores of two groups was 0.10 at 4th h early postoperative, we found that standard deviation was 0.10 in steroid group and 0.11 in levobupivacaine group. Accordingly, we determined the number of patients required for every group as 18 with a power of 80% when the alpha error was taken as 0.05, and beta error was taken as 0.20.

The data were analyzed using the Kruskal–Wallis test (SPSS version 20.0.0, SPSS Inc. Chicago, IL), and the Mann–Whitney U-test was used to analyze the differences between the groups in pairs. Categorical variables were analyzed using the Fisher's exact test. Data were presented as a mean ± SD, and differences were considered significant at $p < 0.05$.

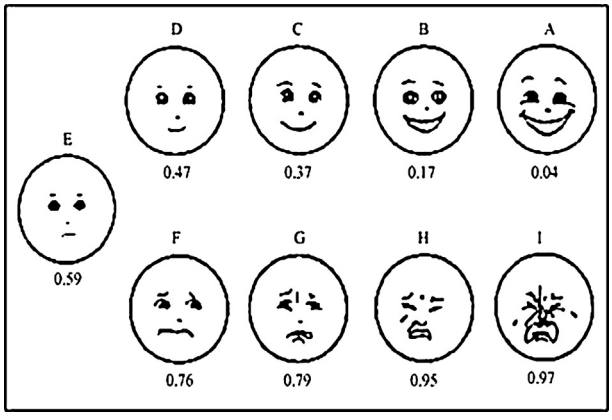

Fig. 1. McGrath's face scale (happy to sad, nine face scale).