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Vasoconstrictive and analgesic efficacy of locally infiltrated levobupivacaine in tonsillectomy patients

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ABSTRACT

Objectives: The use of preincisional plain levobupivacaine, lidocaine adrenaline and saline for perioperative blood loss and postoperative analgesia in pediatric tonsillectomy patients are compared.
Methods: Ninety patients were randomly assigned into one of the 3 groups to receive preincisional peritonsillar infiltration of levobupivacaine 0.25% (group LB), lidocaine–adrenaline 1% with 1:200,000 (group LA) and saline (group S) under general anesthesia. Intraoperative blood loss, pre- and postoperative hemoglobin (hb) and haematocrit (htc) values, hemostasis time, operation duration, number of cautery used (20 W, 1 s) and heart rates were recorded. Pain scores in PACU, at 6th, 12th and 24th hours postoperatively and the number of the patients requiring analgesic treatment for first 24 h was also recorded.
Results: There was a 30% reduction in perioperative blood loss in group LB and 63% reduction in group LA compared to group S (39 ± 6, 21 ± 4 and 55 ± 7 ml respectively) ($p < 0.001$). Eventhough all three groups have significantly lower postoperative hb and htc values with respect to preoperative levels both local anesthetic groups had significantly higher postoperative hb and htc values than saline ($p < 0.001$). Time required for hemostasis, the number of cautery used for haemostasis and operation duration were lower in groups LB and LA with respect to group S. Pain scores of the group LB revealed a significantly lower score throughout 24 h. Only 14 patients in group LB demanded additional analgesic where as all patients in the other groups had. Adding adrenaline to the local anesthetic solution showed no side effects. Also we did not happened to see any complications related to local anesthetic injections. There was no postoperative major bleeding in groups.
Conclusion: Levobupivacaine has a vasoconstrictive effect in 0.25% concentrations that may be beneficial in tonsillectomy patients and has a consistent analgesic effect.

1. Introduction

Levobupivacaine is a new long acting amide type local anesthetic that is claimed to have vasoconstrictive activity in 0.25% or less concentrations [1,2]. Although the efficacy of levobupivacaine has been tested in a wide spectrum of operations, there are few clinical studies showing vasoconstrictive activity of levobupivacaine [1].

Tonsillectomy with or without adenoidectomy is one of the most frequent performed procedures in ENT departments. Frequently tonsillectomies are associated with significant perioperative bleeding and postoperative pain [3].

Peritonsillar injection of various local anesthetics with addition of adrenaline in order to reduce posttonsillectomy pain and perioperative bleeding is one of the strategies that have been developed [4]. Lidocaine–adrenaline combination is commonly used for infiltrative anesthesia because of its rapid action and providing some degree of hemostasis [5]. However, there is also concern of complications due to systemic absorption of adrenaline in patients with arteriosclerosis, hypertension, ischemic heart diseases, anemia and preexisting liver or renal damage and endocrinologic dysfunction [6]. In pediatric tonsillectomies, peritonsillar injection of plain levobupivacaine might be advantageous due to vasoconstrictive activity as well as postoperative analgesic properties.

The aim of this study was to compare the effect of preinsicional infiltration of levobupivacaine with lidocaine–adrenaline and saline on perioperative blood loss. We also investigated postoperative analgesic efficacy of both groups in children undergoing tonsillectomies.

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2. Materials and methods

After Institutional Ethics Committee approval (02.04.2009–14) and written informed consent from their parents, 92 children aged between 2 and 10 years, of ASA 1–2 status undergoing elective tonsillectomy were enrolled in a randomized double blind study. Patients having cardiac, pulmonary, hematologic or hepatic diseases or known allergy to administered drugs, and who had received any analgesic drug last 24 h were excluded from the study.

All procedures were performed under general anesthesia by a standard anesthetic protocol. After premedication by 0.5 mg kg^{-1} midazolam orally, and routine monitorization, anesthesia was induced with either 2 mg kg^{-1} propofol intravenously or sevoflurane 7–8% in 50% nitrous oxide in oxygen via face mask. After having an i.v. line inserted on the dorsum of the hand, infusion of the lactated ringer's solution was started. Following muscle relaxation with rocuronium and tracheal entubation, anesthesia was maintained with sevoflurane 2–3% and 50% nitrous oxide in oxygen. After the induction rectal paracetamol 15 mg kg^{-1} were applied in all three study groups. Heart rates were recorded before the injection and 3 min after the injection prior to surgery. Any arrhythmia following injection, were recorded.

After the proper positioning, children were randomly allocated into three groups using a shuffled, sealed, opaque and numbered envelopes to receive 6 ml 0.25% levobupivacaine (group LB, $n = 30$), 6 ml lidocaine 1% with 1:200,000 adrenaline (group LA, $n = 30$) or 6 ml of saline (group S, $n = 30$) preinsicionally. The trial was undertaken in a double blind manner, neither children nor parents and the surgeons were unaware of the injected drugs. The drugs were prepared into the enjector making totally 6 ml by the anesthesiologist who was not included in the peri and postoperative evaluation and the injections were performed by the two senior surgeons each were blinded to the injected drug with 23 G needle using aspiration-injection technique. A total of 6 ml, 3 ml for each tonsil into the pericapsular plane as follows: 1 ml into the superior pole, 1 ml in between and 1 ml into the lower pole was injected. The operation was started 3 min after the injection. Mucosal incisions were performed with cold knife and for tonsillectomy blunt dissection technical was used. Hemostasis was achieved by bi-polar cauterization. After removing the first tonsil a saline soaked gauze applied to surgical field. After removing the second tonsil hemostasis achieved by bipolar cauterization if needed. At the end of the surgery intraoperative blood loss, number of the cautery used, time to achieve hemostasis (time registered use of swabs and diathermy), and operation duration (time to begin dissection till achieving hemostasis bilaterally) were recorded. The blood loss was measured by estimating the suction bottle and weighing the swabs.

At the end of the surgery, neuromuscular blockade was reversed with 0.02 mg kg^{-1} atropin and 0.05 mg kg^{-1} neostigmine. After the airway reflexes were secured patients were extubated and the children were transferred to PACU for 30 min follow up.

The intensity of pain in PACU was assessed by using a modified Hannallah pain score [7] – an observational pain score (OPS) developed and tested for validity and reliability in children – at every 0, 15th and 30th minutes by an anesthesiologist who was unaware of the studied drugs. For rescue analgesia, if the modified Hannallah pain score is 4 and more, metimasol sodium i.v. is administered. If the children vomited more than twice, 0.2 mg kg^{-1} metoclopromid i.v. was planned to give as an antiemetic. Patients were transferred to the related service after 30 min follow up with reaching the Aldrete score of 9.

At the surgical service for pain assessment 4 point (0–3) scale was used: 0, no pain; 1, mild pain, 2, moderate pain; 3, severe pain by the observers who were unaware to the studied drug [8] at 6th, 12th and 24th hours. The children were administered paracetamol suppository (40 mg kg^{-1} d^{-1}) or paracetamol suspension (40 mg kg^{-1} d^{-1}) only if their pain scale were 2 or more according to 4 point (0–3) pain scale. The number of the patients who had paracetamol was recorded. Postoperative hemorrhage was recorded as well. At postoperative 24th hour, 2 ml of blood was collected for the measurement of hemoglobin and hematocrit. All patients stayed in the hospital for at least 24 h and discharged with oral paracetamol 4 times daily for 5 days. Also they were instructed to return hospital in case of postoperative bleeding.

2.1. Power analysis

A power calculation ensured that 27 patients were recruited to provide 95% power for a 30% reduction in bleeding volume in any two groups at the 5% significance level. The knowledge of 30% reduction was based on a previous study [9].

2.2. Statistical analysis

Statistical Analysis Data analysis was performed by using Statistical Package for Social Sciences (SPSS) version 11.5 software (SPSS Inc., Chicago, IL, United States). Shapiro–Wilk test was used to test the normality of distribution for continuous variables were expressed as mean ± standard deviation. The mean differences were compared by Student's t test, between groups. Nominal data were analyzed by Pearson Chi-square or Fisher's exact test, where appropriate.

While the differences among measurement times regarding for MAP, HR were analyzed by ANOVA with Benferonni Adjustment or Friedman test with Benferonni Adjusted Wilcoxon Sign Rank test was used. A p value less than 0.05 was considered statistically significant. The Benferonni Correction was applied for all possible multiple controlling Type I error.

3. Results

A total of 90 children completed the study. One child from the saline group was excluded from the study because of not meeting the inclusion criteria and one child from LB group who refused to give blood sample was also excluded (Fig. 1).

Demographic data (age, gender, weight and ASA) of all subjects were similar in all three groups (Table 1). There was a 30% reduction in perioperative blood loss in group LB ($p < 0.001$) and 63% reduction in perioperative blood loss in group LA ($p < 0.001$) compared to group saline. Furthermore, blood loss in group LA was remarkably lower than group LB ($p < 0.001$). Time required for hemostasis, the number of cautery used for hemostasis and operation duration were significantly lower in groups LB and LA with respect to group saline ($p < 0.001$). In addition to the aforementioned parameters group LA was significantly superior than group LB ($p < 0.001$) (Table 2).

No statistically significant difference was found between the groups in heart rate before the injection and 3 min after the injection (102 ± 10 vs 103 ± 10 in group LB, 104 ± 12 vs 105 ± 11 in

Table 1
Demographic data.

Variables	Group LB ($n = 30$)	Group LA ($n = 30$)	Group S ($n = 30$)	p
Age (y)	6 ± 2	6 ± 2	6 ± 2	NS
Gender (M/F)	16/14	14/16	15/15	NS
Weight (kg)	24 ± 6	24 ± 6	23 ± 6	NS
ASA (I/II)	26/4	28/2	27/3	NS

The data were expressed as mean ± SD.