Original Article

Preemptive local anesthetic infiltration reduces opioid requirements without attenuation of the intraoperative electrical stapedial reflex threshold in pediatric cochlear implant surgery

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Abstract

Background and Aims: Total intravenous anesthesia using remifentanil provides good surgical condition without affecting the intraoperative electrical stapedial reflex threshold (ESRT). However, remifentanil results in hyperalgesia and increases postoperative opioid requirements. Local anesthetic infiltration is alternative methods to opioid for providing analgesia. However, otologists avoids its use as it can abolish the ESRT. We investigated the effect of the preemptive local anesthetic infiltration on intraoperative ESRT and opioid requirements in pediatric cochlear implant surgery performed under TIVA.

Material and Methods: Prospective, randomized, double-blinded, controlled study including 70 child undergoing cochlear implant under TIVA were randomly assigned to a local anesthesia (LA group, $n = 35$) or control (CT group, $N = 35$). The primary outcome was the total tramadol consumption during the first 24 h postoperative, and the secondary outcomes were time to first analgesia request, postoperative pain scores, the ESRT and, propofol and remifentanil requirements. The incidence of postoperative vomiting was recorder as well.

Results: The total tramadol consumption during the first 24 h after surgery was significantly less in the LA group than in CT group (8.25 [4.3] vs. 16.5 [6.57] mg, $P < 0.01$). The time to first analgesic request was significantly prolonged in the LA group as compared with the CT group [8 [2–12] vs. 3 [0–8] h, $P < 0.01$). The postoperative Faces, Legs, Activity, Cry Consolability pain scores were significantly lower in the LA group at 15 min, 30 min, 2, 4 and 6 h postoperative. Mean remifentanil infusion rate [mean (standard deviation)] was significantly higher in in the CT group than in the LA group [0.7 (0.3) vs. 0.5 (0.2) μg/kg/min; $P = 0.001$).The ESRT response, propofol requirements, and the incidence of postoperative vomiting had no significant differences between both groups.

Conclusion: Preemptive local anesthetic infiltration reduced opioid requirements without attenuation of the ESRT in pediatric cochlear implant surgery performed under TIVA.

Keywords: Cochlear implant, ESRT, local anesthesia, pediatric anesthesia, postoperative pain, TIVA

Introduction

Cochlear implant is an established therapeutic option for patients with profound irreversible sensorineural hearing loss. The procedure today is less invasive and much faster than before, with lower patient morbidity.[1]

Anesthetic technique for cochlear implant should modified to achieve bloodless surgical field, facilitate intraoperative measurement of the electrically evoked stapedial reflex threshold (ESRT), prevent postoperative vomiting, and provide adequate analgesia.[2]

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Access this article online

Quick Response Code:

Website: www.joacp.org

DOI: 10.4103/joacp.JOACP_18_19

How to cite this article: Bakhet WZ, Wahba HA, El Fiky LM, Debis H. Preemptive local anesthetic infiltration reduces opioid requirements without attenuation of the intraoperative electrical stapedial reflex threshold in pediatric cochlear implant surgery. J Anaesthesiol Clin Pharmacol 2020;36:366-70.

Submitted: 22-Jan-2019 **Revised:** 26-Apr-2019 **Accepted:** 11-Jul-2019
Published: 26-Sep-2020

The measurement of the intraoperative ESRT during cochlear implantation is used to confirm that the implant is functioning correctly and predict later threshold (T)- and maximum comfortable (C) levels.[3]

Unlike volatile agents, TIVA with propofol and remifentanil provides good surgical conditions without affecting the intraoperative ESRT.[4] The use of TIVA is also associated with a lower incidence of postoperative nausea and vomiting.[5] However, large doses of intraoperative remifentanil usually result in postoperative hyperalgesia and increase postoperative pain.[6]

Local anesthesia is commonly used with general anesthesia in pediatrics as it reduces intraoperative anesthetic requirements, avoids the use of opioids and their associated side effects by providing good postoperative analgesia, and promotes early ambulation.[7] However, otologists are usually reluctant in the use of local anesthesia as it can diffuse and cause abolishment the ESRT and temporary postoperative facial paralysis.

The aim of this study was to evaluate the effect of preemptive local anesthetic infiltration on the intraoperative measurement of the ESRT and opioid requirements in pediatric cochlear implant surgery performed under TIVA.

Material and Methods

This prospective, randomized, double-blind study was carried out during the period from August 2014 to August 2016 after approval of the local research ethics committee (07/07/2014) and registered in Clinical trials.gov with an identification number of NCT03721081. After written informed consent was obtained from the parents of all children, 70 patients were included for the study. Inclusion criteria were ASA I-II physical status, age between 1 and 6 year, and scheduled for cochlear implant. Exclusion criteria were patients with known allergy to local anesthetics, contraindication to laryngeal mask airway (LMA) or predicted operative difficulty such as syndromic hearing loss, congenital cochlear abnormalities, or cochlear ossification.

After inclusion, children were randomized by an independent investigator in blocks of eight to one of two equal groups, i.e., local anesthesia (LA group, $n = 35$) or control (CT group, $n = 35$), using a computer-generated list of random numbers and delivered in opaque envelopes. On the day of surgery, all solutions were prepared by an anesthetic nurse as per the randomization either local anesthesia or normal saline in identical syringes. The anesthesiologist who managed the anesthesia and recorded data, the otologist who performed the skin infiltration and nurse who did all the follow-up procedures were all blind to the group assignment.

All patients were premedicated with oral midazolam (0.5 mg/kg), 1 h before surgery. In addition to standard monitoring, bispectral index (BIS) (BIS; Covidien, Ireland) was applied. General anesthesia (GA) was induced with sevoflurane (up to 8%) with fio2 = 1. After induction, a 22-gauge intravenous (IV) line was placed. After an IV bolus of 2 mg/kg propofol, an appropriate size flexible LMA (FLMA) was placed. The patient's lungs were ventilated with a pressure-controlled mode of 15 cm H2O, and the respiratory rate was adjusted to achieve an end expiratory CO2 concentration of 30-35 mmHg.

GA was maintained with 50% air in oxygen, and TIVA using a propofol and, remifentanil infusions. Propofol infusion was initially set at 250 mcg/kg/min, then titrated to keep the BIS between 45 and 55 and, remifentanil infusion was initially set at 0.25 mcg/kg/min, then titrated up or down by 0.15 to 0.3 mcg/kg/min to maintain the mean arterial blood pressure (MAP) between 50--60 mmHg. A bolus of 0.5 mcg/kg of IV remifentanil was given if any signs of inadequate analgesia (change in heart rate, HR and/or blood pressure, patient movement). A crystalloid infusion at a rate of 5 ml/kg/h was started.

Five minutes before the start of surgery, the surgeon infiltrated the skin along a 3 cm extended endaural incision with a 23 G hypodermic needle with 0.5 ml/kg lidocaine 1% in in adrenaline 1:200,000 (group LA) or 0.5 ml/kg of normal saline in adrenaline 1:200,000 (group CT).

The basic surgical technique consisted of a small extended endaural incision. Cortical mastoidectomy, posterior tympanotomy, and round window cochleostomy were then performed. After drilling of the device seat in a tight periosteal pocket, all children were implanted unilaterally using MED-EL® SONATA Ti implant system with standard electrode. The surgeon assessed the ESRT responses by visual monitoring of the stapedius muscle using direct microscopic examination[8] at the basal, middle, and apical areas of the electrode array.

Intraoperatively, hemodynamic variables (MAP and HR) were continuously monitored throughout surgery and recorded after induction, 1 min after surgical incision, Hypotensive period, end of surgery, 1 min after LMA removal and, at postanesthesia care unit (PACU) admission. Bradycardia (HR <60 bpm) was treated with IV atropine 0.015 mg/kg and hypotension (MAP <50 mmHg) was treated with decrease drug infusion rate, IV 10 ml/kg 0.9% saline and ephedrine 0.3 mg/kg.

Twenty minutes before the end of surgery, all patients received paracetamol 15 mg/kg IV to provide postoperative analgesia and, dexamethasone 0.2 mg/kg IV and ondansetron 0.06 mg/kg IV as prophylaxis for postoperative vomiting.

At the end of the surgery, remifentanil and propofol were stopped and the patient was allowed to emerge from anesthesia while breathing spontaneously on FiO2 = 1.0 and the FLMA was removed and, the children were transferred to PACU.

Postoperative pain was assessed at 15 min, 30 min, 1 h, 2 h, 4 h, 6 h, 12 h, and 24 h postoperatively using the pediatric observational Faces, Legs, Activity, Cry Consolability (FLACC) score[9] range from 0–10 (0 = no pain, 10 = worst). Postoperative analgesia during the first 24 h postoperatively was given depending on FLACC pain score. If pain score <4, rectal diclofenac sodium 1 mg/kg was given, if pain score ≥4, IV tramadol 0.5 mg/kg was given. Incidence of postoperative complications such as vomiting and facial paralysis was recorded.

The primary outcome of the study was the total tramadol consumption during the first 24 h after surgery. The secondary outcome was time to first analgesia request, postoperative FLACC pain scores, the intraoperative ESRT, propofol, and remifentanil requirements and the hemodynamic variables (MAP and HR). Moreover, we assessed any adverse events including incidence of postoperative vomiting, postoperative facial paralysis, and signs of local anesthetic toxicity.

Statistical analysis

Sample size calculation

The mean and standard deviation of the postoperative tramadol consumption from a previous study were respectively 18.25 mg and 11.57 mg.[10] A minimum sample size should be 30 patients per group was needed to detect a 8.5 mg reduction in tramadol consumption, with a significance level 5% and a power of 90%. A total sample size of, 70 patients were included to allow for a dropout rate of 15%.

Data analysis

Data were analyzed using SPSS version 10.0 (SPSS, Chicago, IL). Descriptive data are expressed as mean ± SD or as numbers "percentage." The student's *t*-test was used to compare the mean differences between the study groups. Repeated-measures analysis of variance was used for HR and blood pressure comparison. Mann–Whitney U test (MWU) was used for nonparametric variables (e.g., FLACC). While, Chi-square test was used to compare the categorical variables, a *P* value of ≤0.05 was considered to be statistically significant.

Results

A total of 80 children undergoing cochlear implant were identified. Five children had to be excluded because not meeting inclusion criteria and five refused to participate. And 70 children were equally randomized to either the CT group ($n = 35$) or the LA group ($n = 35$). The demographic and anesthesia requirements (propofol and remifentanil) are shown in Table 1. Apart from the remifentanil requirements, there were no significant differences among the two groups.

Mean remifentanil infusion rate [mean (standard deviation)] was significantly higher in in the CT group than in the LA group [0.7 (0.3) vs. 0.5 (0.2) μg/kg/min; $P = 0.001$).

The total tramadol consumption during the first 24 h after surgery was significantly less in the LA group than in CT group (8.25 [4.3] vs. 16.5 [6.57] mg, $P < 0.01$), Student's *t*-test). The time to first analgesic request was significantly prolonged in the LA group as compared with the CT group [8 [2–12] vs. 3 [0– 8] h, $P < 0.01$, Student's *t*-test).

The assessment of postoperative FLACC pain scores was statistically lower in the LA group than the CT group at 15 min, 30 min, 2, 4, and 6 h. However, no significant difference at 12 and 24 h after surgery was found (MWU) [Table 2].

Analysis of hemodynamic variables MAP [Figure 1] and HR [Figure 2] showed no significant difference between groups at baseline, after induction, hypotensive period or at the end of surgery. However, MAP and HR were significantly lower in the LA group after surgical incision, after LMA removal and at PACU admission (all, $P < 0.05$).

Analysis of ESRT response showed no significant difference between the two groups ($P > 0.05$) [Figure 3]. The ESRT

Table 1: Patient characteristics and anesthesia requirements

Parameters	CT group (*n*=35)	LA group (*n*=35)	*P*
Age in years	2.9 (1-6)	2.8 (1.5-6)	0.8
Gender (girls and boys)	15/20	13/22	0.8
Weight in kg	16 (3)	17 (4)	0.2
ASA classification (I/II)	30/5	28/7	0.7
Duration of surgery in minutes	65 (6)	63 (5)	0.1
Duration of anesthesia in minutes	73 (5)	75 (6)	0.1
Propofol infusion rate μg/kg/min	160 (40)	150 (35)	0.2
Remifentanil infusion rate μg/kg/min	0.7 (0.3)	0.5 (0.2)	0.001*

*Numerical data represented as mean (SD) or median (range). Categorical data as gender and ASA classification represented as numbers. P<0.05 considered significant. *Significant to the CT group*

could be obtained in all children in both groups. The thresholds ranged from 12.5 to 25.5 current units (CUs).

The frequency of postoperative emesis over the first 24 h tended to be higher in the CT group than the LA group [one (2.8%) vs. 7 (20%) children], but no statistically significant difference was observed, $P = 0.054$. No other adverse events were reported.

Discussion

In this study, we noted that the local anesthetic infiltration in pediatric cochlear implant surgery performed under TIVA significantly decreased the total tramadol consumption during the first 24 h after surgery, increased time to first analgesia request and less postoperative pain scores. However, this intervention had no effect on the intraoperative ESRT. TIVA using propofol and remifentanil anesthesia provides satisfactory surgical conditions as they can be titrated to the desired mean arterial blood pressure, not interfere with the ESRT testing, allows rapid emergence from anesthesia with a faster discharge from the PACU,[10,11] and less postoperative nausea and vomiting.[12] However, large doses of intraoperative remifentanil usually result in hyperalgesia and there is more need of postoperative opioid rescue[13] Opioid analgesics compound the problem of PONV, cause excessive sedation, and delay discharge.[14] Preemptive regional analgesia.[15] and local anesthetic infiltration[15,16] are alternative methods to opioid for providing postoperative analgesia.

In agreement with our results, Nuala and William reported that local an aesthetic infiltration using lidocaine 1% in adrenaline 1:200,000 and regional nerve block using bupivacaine 0.5% are effective and comparable forms of analgesia post otoplasty, with a low requirement for opioids and a low incidence of PONV in the absence of opioids.[15] Suresh *et al.* found that regional anesthesia is better than opioid in postoperative pain relief in children undergoing tympanomastoid surgery.[17]

Table 2: FLACC pain score in both groups

	LA group (n=35)	CT group (n=35)	P
15 min	1 (0-2)	2.5 (0-5)	<0.01*
30 min	1 (0-2)	3.5 (1-6)	<0.01*
2 h	3 (2-4)	4 (2-5)	<0.01*
4 h	3 (2-5)	4.5 (2-7)	<0.01*
6 h	2 (1-5)	3 (2-6)	0.01*
12 h	3 (1-5)	3 (2-5)	0.4
24 h	2 (0-3)	2 (1-3)	0.5

*Data represented as median (range). LA=Local anesthesia group; CT=Control group. P<0.05 considered significant. *Significant to CT group*

Unlike regional nerve block, local anesthetic infiltration is easy to perform, requiring no great technical skill and the addition of adrenaline to LA prolongs the duration of action from 1.25 h to 6.6 h because of vasoconstriction.[18] Also, this reduce bleeding and improve hemostasis and optimize surgical field. Finally, with regional nerve block there is the possibility of local anesthetic spreading from the subcutaneous tissues into the deeper planes of the neck, especially in young children, with the risk of vascular spread and even the remote chance of phrenic nerve blockade.[15]

Otologists are usually avoiding the use of local anesthesia in cochlear implant as it can abolish the ESRT and temporary facial paralysis postoperatively. However, the ESRT response

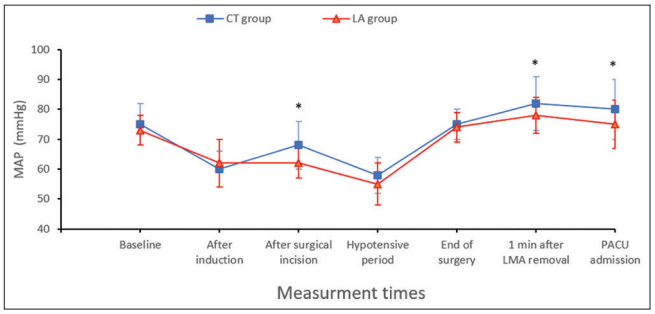

Figure 1: Mean (SD) of mean arterial blood pressure (MAP, mmHg) in both groups CT = control group; LA = Local anesthesia group; PACU = post-anesthesia care unit. P <0.05 considered significant. * Significant to the CT group

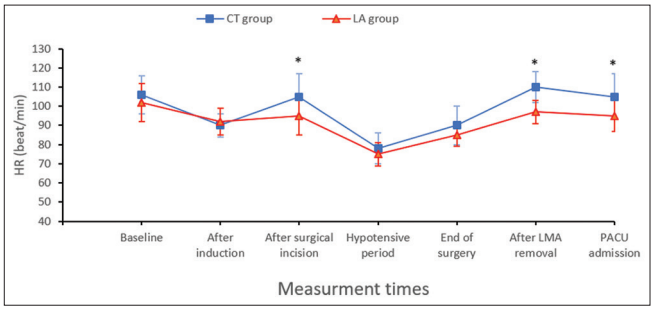

Figure 2: Mean (SD) of heart rate (HR, beat/min) in both groups. CT = control group; LA = Local anesthesia group; PACU = postanesthesia care unit. P <0.05 considered significant. * Significant to the CT group

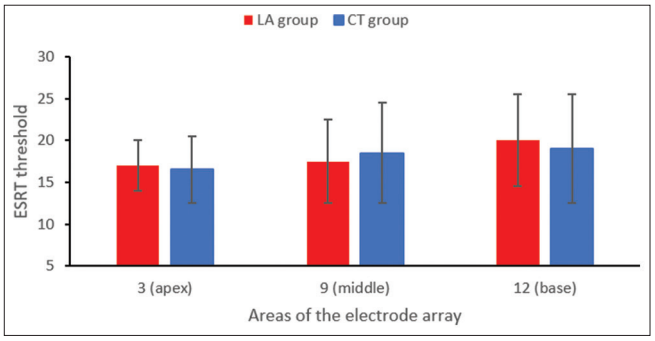

Figure 3: Mean (SD) of ESRT in both groups. LA = Local anesthesia group; CT = control group

was preserved and no patients developed postoperative facial paralysis in the LA group. This may be due to the use of an extended endaural incision, a more anterior and superior incision, away from the facial nerve at the mastoid tip.

The incidence of postoperative vomiting was 2.8% in the LA group and 20% in the CT group. The lower incidence of vomiting in the LA group may be related to a lower consumption of tramadol postoperative, since remifentanil itself had no overall impact on PONV.[19] Recording nausea is a more sensitive variable than vomiting, but as nausea is a subjective experience expressed verbally, it is hard to study in young deaf children.

We had chosen LMA as studies[20-24] have shown that the use of LMA for ear surgery has advantages over the endotracheal tube which include avoidance of the muscle relaxant, hemodynamic stability, smooth emergence, and faster awakening time. In ear surgery there are two main concerns of using LMA; displacement or coughing with head movement and suitability for prolonged surgery[25] as we use the FLMA, its flexible shaft minimizes transmission of force to the cuff, thus the risk of displacement would be expected to be less.[20]

Conclusion

Preemptive local anesthetic infiltration reduced opioid requirements, time to first analgesia request, and postoperative pain scores without attenuation of the ESRT in children undergoing cochlear implant surgery.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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