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The Effect of Lidocaine-Epinephrine Administration in Controlling Complications after Tonsillectomy

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ABSTRACT

Background and Objective: Tonsillectomy is one of the most common surgeries in children, which is associated with pain and bleeding after the operation. This study was conducted to investigate the effect of lidocaine-epinephrine administration in controlling complications after tonsillectomy.

Methods: This clinical trial was conducted on 109 patients aged 5 to 18, who had referred to Kowsar Hospital in Sanandaj for tonsillectomy. After dividing the patients randomly, 40 mg of 1% lidocaine and 5 µg of epinephrine (a volume of 5 ml) were injected into the tonsillar bed in the intervention group before the surgery, but in the patients of the control group, surgery was started without lidocaine-epinephrine administration. Blood pressure and heart rate of the patients before, during and after surgery, and pain intensity based on Wong-Baker Faces Pain Scale at minutes 30 and 60 and 6, 12 and 24 hours after surgery, and the amount of bleeding during and after surgery were recorded and compared by calculating the volume of suction and blood pads as well as the length of stay in recovery.

Findings: The mean amount of bleeding in the intervention group was 65.5±47.1 ml and in the control group was 113.7±45.7 ml (p=0.0001). The mean pain intensity and hemodynamic changes at minutes 30 and 60, and 6, 12 and 24 hours after surgery in the intervention group were lower than the control group and showed statistically significant differences (p=0.0001). The mean time of discharge from recovery in the intervention group was 0.35±23.2 minutes and in the control group was 50.4±17.5 minutes (p=0.0001).

Conclusion: Based on the results of this study, it seems that the administration of lidocaine-epinephrine in the tonsil bed before tonsillectomy can reduce the amount of pain, bleeding, and hemodynamic changes during and after surgery, and the patient can recover sooner.

Keywords: *Tonsillectomy, Pain, Bleeding, Lidocaine, Epinephrine.*

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Introduction

Tonsillectomy with or without adenoid removal is one of the most common operations in children, which is often associated with pain and bleeding after the operation (1). Postoperative pain can cause a decrease in the quality of life as well as clinical complications such as adverse effects on nutrition, delay in discharge from the hospital and delay in returning to normal daily activities, as well as re-hospitalization after discharge. Effective pain management to control or modify physiological responses to pain has become an essential component of pediatric anesthesia (2, 3).

Various medicinal methods have been used to control pain, including the administration of non-steroidal anti-inflammatory drugs, acetaminophen, narcotics, or a combination of them (4). Furthermore, the use of steroidal anti-inflammatory drugs has been shown to be effective in controlling postoperative pain (5, 6). However, postoperative pain remains one of the common complications of this operation even in adults. The use of local anesthetic drugs or their combination with drugs such as dexamethasone or epinephrine are among the measures that, according to studies, can control pain and reduce bleeding after surgery (7). However, the use of local anesthetics in the treatment of pain after surgery has been discussed, and in some studies, its ineffectiveness in controlling pain and bleeding after surgery has been reported. Tolska et al. reported that the rate of secondary bleeding around the tonsils was higher in patients with lidocaine-epinephrine infiltration (8). Theoretically, as a preventive measure to reduce post-operative pain, this class of drugs can be used to block pain impulses and prevent these impulses from entering the central nervous system (9). It has also been stated in past studies that the combination of vasoconstrictor drugs and local anesthetics reduces bleeding, pain and nasal congestion after surgery.

In the studies conducted in this regard, drugs such as bupivacaine and ropivacaine were injected into the tonsils, while morphine, tramadol and ketamine were used locally to reduce pain after surgery and it was shown that they were effective in controlling pain and bleeding after surgery (9-12). However, the use of narcotic drugs for pain relief in these patients may be accompanied by side effects such as apnea, nausea and vomiting, itching and reduced gastrointestinal movements (13). It has also been stated in some studies that the use of non-steroidal anti-inflammatory drugs can be associated with complications. In the study of Swanson et al., it was reported that the administration of ibuprofen for analgesia after tonsillectomy was accompanied by an increase in bleeding after surgery (14).

Considering the importance of controlling pain and bleeding, as well as normal breathing and maintaining the airway after the patient regains consciousness, the necessity of using other drugs to control pain and bleeding should be taken into account in order to prevent the side effects of other drugs such as respiratory apnea, the possibility of increased bleeding and things like that. Therefore, this study was conducted with the aim of investigating the effect of local injection of lidocaine with epinephrine in the tonsillar bed on reducing pain and bleeding and hemodynamic changes, as well as the length of stay in recovery after tonsillectomy surgery.

Methods

This double-blind clinical trial was conducted after being approved by the ethics committee of Kurdistan University of Medical Sciences with the code IR.MUK.REC.1398.227 and registered in the Iranian clinical trial system with the code IRCT20210314050703N1. All the parents and patients examined in the study signed the consent form to participate in the study after being informed about the way the study will be conducted.

In this study, 112 patients aged 5 to 18 years, placed in the clinical status of the American Society of Anesthesiology 1 and 2, who had referred to the operating room of Kowsar Hospital in Sanandaj for tonsillectomy under general anesthesia, were examined. Patients with a history of cardiovascular disease, sensitivity to local anesthetic drugs, as well as life-threatening conditions during the study, or the patient's withdrawal from the study, were excluded from the study. Randomization of allocation of patients to study groups (group 1 receiving the combination of lidocaine 1% with epinephrine 1% in 100,000 and group 2 not receiving the combination of lidocaine and epinephrine and performing the routine procedure of the operating room) was performed by a methodologist through generating random numbers using random allocation software.

According to the study of Sener et al. (15), with a study power of 90%, 5% type 1 error, the mean and standard deviation of pain after surgery in the intervention group and the control group were 40.4±31 and 56.6±31, respectively. The sample size for repeated measurement analysis was calculated 56 people in each group using Gpower software.

Blinding of the study was done in such a way that the patients did not know which group they were placed in. Also, observations and data collection were done by a nurse who was not aware of the patient group and was not present at the beginning of the surgery during the injection of the drug in the tonsillar bed and this nurse filled out the questionnaire. Before starting the surgery, the patients were taught how the research will be conducted, and how to express pain using the Wong-Baker Faces Pain Scale.

An intravenous access was established for the patients and fluid therapy was performed to compensate for the NPO period. Patients underwent continuous pulse oximetry monitoring, three-lead electrocardiography, non-invasive blood pressure and temperature control. Pre-oxygenation was performed for 3 minutes with current volume for the patients. After receiving 5 ml per kilogram of body weight of Ringer's Solution, induction of anesthesia was done by the anesthesiologist with fentanyl (2 micrograms per kilogram of body weight), sodium thiopental (5 mg per kilogram of body weight), and atracurium (0.5 mg per kilogram of body weight). If necessary, atropine was prescribed as prophylaxis with a dose of 15 micrograms per kilogram of body weight. Anesthesia was maintained with 1.2% isoflurane and oxygen with nitrous oxide (at a rate of 3.3 liters per minute). An appropriate size cuffed endotracheal tube was used to manage the airway.

In the first group (intervention group), four milliliters of 1% lidocaine (40 mg) combined with 5 micrograms of epinephrine were injected by the surgeon in the tonsil bed and around the right tonsil with an insulin needle. Patients' vital signs were monitored immediately after injection. If there were no clinical changes, an injection was performed in the left tonsil and around its base. In the control group, lidocaine and epinephrine were not prescribed and surgery was performed in the usual way. After stopping the anesthetics and after the patient was awake, the tracheal tube was removed and respiratory support was performed with a mask.

Heart rate and mean arterial pressure of patients were recorded 30 minutes before induction of anesthesia, during induction of anesthesia and 15 and 30 minutes after anesthesia. Moreover, it was measured and recorded during awakening from anesthesia, entering recovery and 30 and 60 minutes after awakening from anesthesia and 6, 12 and 24 hours after the end of anesthesia. In 30 and 60 minutes after the end of anesthesia, the pain level of the patients was evaluated with the Wong-Baker Faces Pain Scale, and the amount of bleeding was also measured. In addition, 6, 12 and 24 hours after discharge from recovery, the bleeding and pain levels of the patients were evaluated.

To measure pain, the Wong-Baker Faces Pain Scale with a range of 0-10 (with smiley faces) was used. This tool is also recommended for evaluating pain in children over 3 years of age, as well as oral and maxillofacial surgery (16). The amount of bleeding was also calculated based on the number of blood-

soaked gauzes during surgery, considering that each small gauze can absorb 4-5 cc of blood and each large gauze can absorb 20 cc of blood (blood pads and blood in the suction glass minus the amount of serum used for washing). The time of discharge from recovery was also recorded for all patients.

In case of pain in patients, injectable acetaminophen was used at the rate of 24 mg per kilogram of body weight (every 6 hours) (17). The amount of prescribed medication was also recorded.

The collected data were analyzed using SPSS version 18 software. First, the data were summarized using descriptive indices such as mean, standard deviation, frequency and relative frequency. The normality of dependent quantitative variables was evaluated using the Kolmogorov Smirnov test. Chi-square tests and independent t-tests were used to analyze the relationships between variables, and repeated data analysis of variance was used to compare pain intensity, restlessness, blood pressure, and heart rate in two groups during the intervention period, and $p<0.05$ was considered significant.

Results

In this study, the data of 109 patients were analyzed and evaluated after meeting the inclusion criteria (Figure 1).

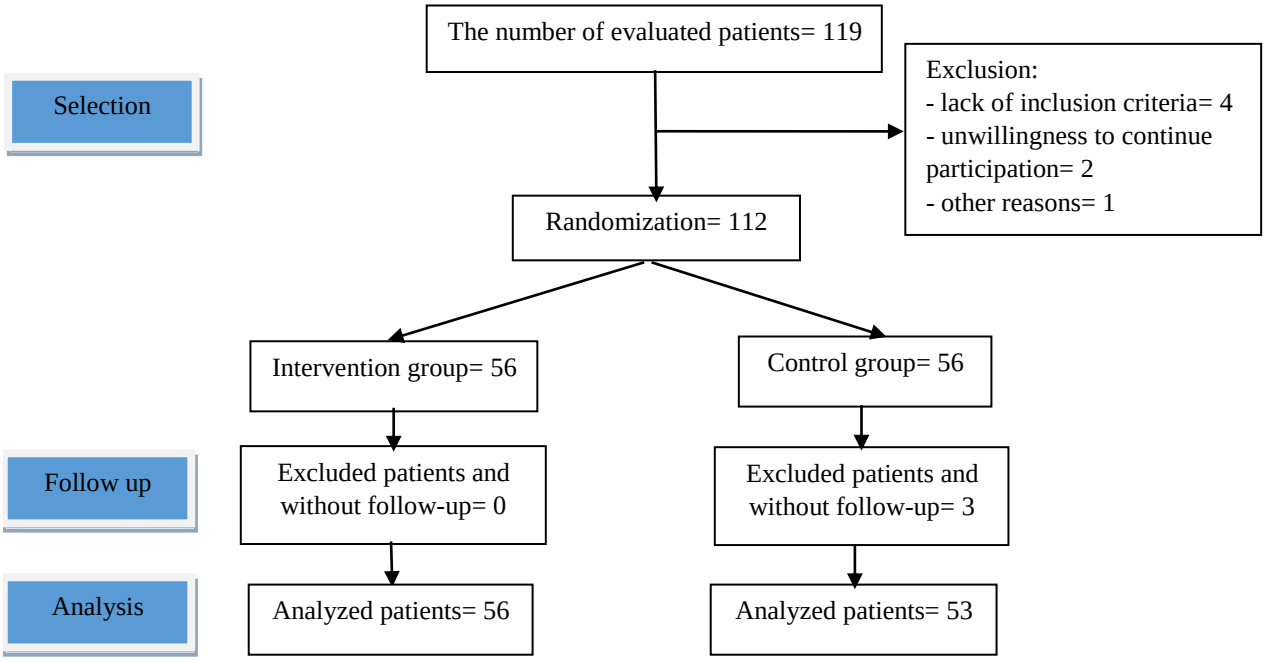

Figure 1. Flowchart of selection and inclusion of patients in the study

The mean age of the participating patients in the control group was 10.3±5.7 years and in the lidocaine-epinephrine group was 11.6±6.8 years, and no statistically significant difference was observed in the two groups. The frequency of female gender was 51.8% in the lidocaine group and 54.7% in the control group. There was no statistically significant difference in body mass index between the two groups (18.8±4.3 in the control group compared to 19.3±4.7 in the lidocaine group). The mean arterial blood pressure and heart rate of the two intervention and control groups before and during induction of anesthesia did not have a statistically significant difference, but from 15 minutes after the start of surgery to the first 24 hours after surgery, there was a statistically significant difference (p=0.001) (Table 1).

Based on the repeated measures ANOVA regarding the mean score of pain intensity in the two studied groups, during the 5 stages of evaluation (30 and 60 minutes, 6, 12 and 24 hours) after surgery, a statistically significant difference was observed between the two groups (p=0.0001) (Table 2 and Figure 2).

Table 1. Mean arterial pressure (mmHg) and heart rate (bpm) during the evaluated times in intervention (lidocaine-epinephrine) and control group

Time / Variable and group	Anesthesia Mean±SD			Recovery Mean±SD	After surgery Mean±SD				
	30 minutes before	15 minutes later	end	upon arrival	30 mins	60 mins	6 hours	12 hours	24 hours
Mean arterial pressure (mmHg)									
Intervention	92.10±1.6	82.8±9.3	91.4±8.9	89.3±8.1	87.3±7.7	84.7±7.6	82.4±7.46	80.9±7.7	76.7±7.1
Control	90.8±8.1	88.1±6.7	95.5±5.6	97.6±5.8	95.4±6.0	92.3±6.3	87.5±6.4	84.7±7.3	82.8±7.2
p-value	0.07	0.0001	0.001	0.0001	0.0001	0.0001	0.001	0.001	0.001
heart rate (per minute)									
Intervention	96.6±10.3	90.6±11.8	98.5±11.5	95.9±11.0	88.7±8.7	85.7±8.5	82.1±8.0	81.3±7.6	81.6±7.61
Control	97.4±10.2	105.9±11.4	115.5±9.9	116.7±9.5	109.2±7.8	102.9±6.7	89.5±6.4	86.7±5.5	84.4±5.7
p-value	0.08	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.001	0.01

Table 2. The mean value of the Wong-Baker Faces Pain Scale to evaluate pain in the evaluated times in the study groups

Time / Group	After surgery				
	30 min Mean±SD	60 min Mean±SD	6 h Mean±SD	12 h Mean±SD	24 h Mean±SD
Intervention	4.4±0.8	2.9±0.8	1.8±0.5	1.3±0.4	0.7±0.5
Control	6.5±0.8	5.6±0.7	4.2±1.0	3.2±1.0	2.1±0.9
p-value	0.0001	0.0001	0.0001	0.0001	0.0001

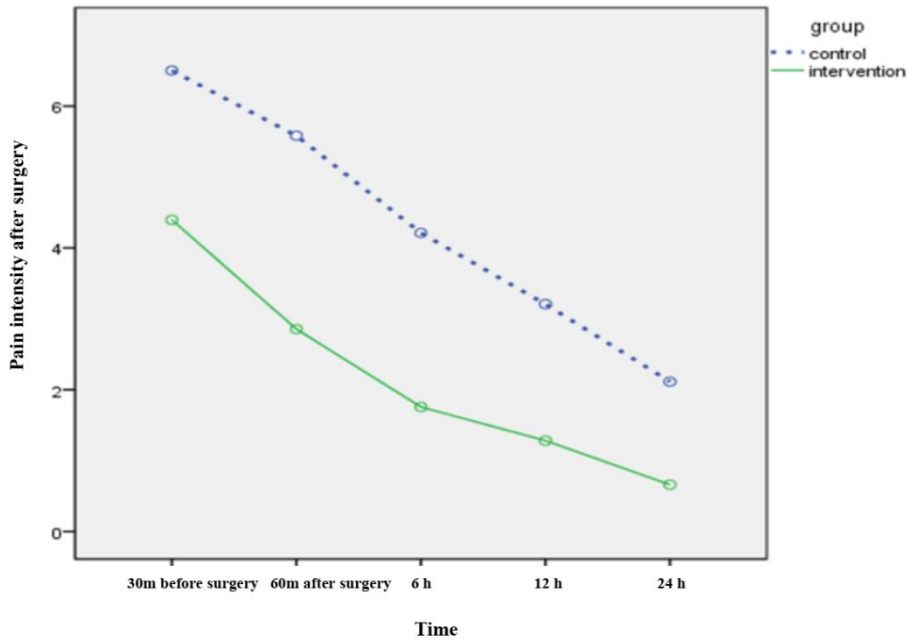

Figure 2. Diagram of mean pain intensity in two groups during the study period

The average Apotel received for pain relief in the control group was 997±430 mg, which was significantly higher than the intervention group (577±272 mg) (p=0.002). Moreover, the average amount of bleeding in the control group was 113.7±45.7 mg and in the intervention group was 65.5±1.47 mg, which is a statistically significant difference (p=0.001). Also, according to the results of the independent t test, the mean time of discharge from recovery in the patients of the intervention group was faster than the control patients (Table 3).

Table 3. Comparison of the time from the end of anesthesia till discharge from the recovery in the two study groups

Variable and group	Number	Mean±SD	t	p-value
The time interval between entering recovery and the end of anesthesia (minutes)				
Control	53	5.2±0.15	0.1	0.98
Intervention	56	5.7±0.21		
Time interval between discharge from recovery and entry (minutes)				
Control	53	50.4±17.5	3.9	0.0001
Intervention	56	35.0±23.2		

Discussion

According to our results, the amount of intraoperative bleeding in the intervention group was lower than the control group. In the study of Özkiriş et al. (18), they investigated the effect of ropivacaine, bupivacaine and lidocaine in the management of pain after tonsillectomy. Their evaluation was done on four groups. Group one: local lidocaine with epinephrine 1 per million, group two: bupivacaine hydrochloride 0.25% with epinephrine 1 per hundred thousand, group three: ropivacaine 0.5% and group four: normal saline solution 0.9%. The mean intraoperative blood loss in the lidocaine group was significantly lower than the other three groups. However, the average intraoperative blood loss in normal saline group, ropivacaine group and bupivacaine group was not statistically significant. But in the study of Tolska et al. (8), the most common complication was bleeding after tonsillectomy and they stated that the use of lidocaine with epinephrine increases the risk of bleeding after tonsillectomy. In the study of Tolska et al., non-steroidal anti-inflammatory drugs, acetaminophen and tramadol were used for post-operative analgesia. Epinephrine was also administered at a dose of 10 micrograms. The difference in the obtained results may be due to difference in administered drugs to control postoperative pain and the difference in the dosage of administered drugs.

Based on the results obtained in our study, the mean score of pain intensity in the two studied groups, during 5 stages of evaluation (30 and 60 minutes, 6, 12 and 24 hours) after surgery in the group receiving lidocaine-epinephrine was significantly lower than the control group. Although the process of pain reduction was similar in both groups, the intensity of pain in the intervention group was significantly lower than the control group in all 5 stages. In the study of Bameshki et al. (19), which was conducted to compare the effect of administration of bupivacaine 0.5% with epinephrine 1% and placebo during and after tonsillectomy in children, it was shown that the intensity of pain in the first 6 hours after surgery in bupivacaine-epinephrine group was lower than placebo group. In the study of Özkiriş et al. (18), the difference in mean pain intensity in ropivacaine and bupivacaine groups was not statistically significant. However, the difference in the mean pain score of these two groups compared to lidocaine and normal saline

was statistically significant and they concluded that the penetration rate of ropivacaine is as effective as bupivacaine for pain control after tonsillectomy in children. In another study conducted by Tolska et al. (20) regarding the effectiveness of topical ropivacaine (pad impregnated with ropivacaine and packing for 5 minutes at the surgical site) in preventing pain after tonsillectomy, it was shown that ropivacaine had no effect on pain relief. Although there are differences in the results of different studies on the effect of local anesthetic drugs, the effectiveness in reducing pain may be related to the administered dose and method of use, as well as the use of epinephrine.

In our study, the duration of discharge from recovery in the intervention group was significantly less than the control group. In the study of Özkiriş et al. (18), the mean operation time of the three groups was statistically significant compared to the placebo group; the mean operation time in the local lidocaine with epinephrine group was less than the other three groups, which is consistent with our findings.

In our study, mean arterial blood pressure did not differ half an hour before anesthesia, and during anesthesia induction, but there was a statistically significant difference 15 minutes after anesthesia, after consciousness, and especially during recovery. In general, the trend of arterial blood pressure in the indicated times in the control group was significantly higher than the group receiving lidocaine-epinephrine. Furthermore, the mean heart rate of the two intervention and control groups showed a decreasing trend in the intervention group and an increasing trend in the control group, and the difference was significant. Therefore, it can be concluded that the simultaneous use of lidocaine and epinephrine in tonsillectomy are effective in reducing arterial blood pressure and heart rate.

The findings showed that the amount of painkiller received in the control group was significantly different from the intervention group. Thus, the mean dose of painkillers received in the patients of the control group was higher and the time of receiving the first painkillers was earlier than the patients of the intervention group. This is due to the analgesic effect of lidocaine mixed with epinephrine.

In the study of Sarafraz et al. (2), which was done to compare the effect of injection of lidocaine, ketamine, tramadol, and placebo around the tonsils to control pain after surgery, it was shown that the number of painkillers received in the lidocaine and tramadol group was less than the placebo group, which is in line with the findings of our study.

In all studied patients, no complications such as anesthetic poisoning, seizure, cardiac arrest, hemorrhage, airway obstruction, and dehydration were observed, which is consistent with other similar studies.

The results of this study showed that the injection of lidocaine1% with epinephrine 1% in the tonsil bed before tonsillectomy in children can be effective in controlling pain after the operation without causing any complications and reduces painkiller consumption after the operation, while reducing the bleeding during and after the operation.

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