

Comparison of intravenous injection of magnesium sulfate and lidocaine effectiveness on the prevention of laryngospasm and analgesic requirement in tonsillectomy

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Abstract

The aim of the present study is to compare the effect of intravenous (IV) injection of magnesium sulfate and lidocaine on the prevention of laryngospasm, and analgesic requirement in tonsillectomy surgeries. In this double-blinded clinical trial, 62 children are randomly selected and categorized into two groups. Two minutes after intubation, group A received 15 mg/kg IV magnesium sulfate, while group B received 1 mg/kg IV 2% lidocaine. Laryngospasm frequency, nausea and vomiting, hemodynamic status (in 15 minutes after extubating), sedation score, analgesic requirement, and duration of recovery were compared between the two groups. Data were analyzed using SPSS software version 21 and with a 95% confidence interval. Both groups had no significant difference based on the age and weight means, as well as sex frequency. 10 patients (32.3%) in the lidocaine group and 3 patients in the magnesium group (9.7%) had stridor, and the difference between the two groups was statistically significant ($p = 0.026$). Laryngospasm only occurred in a patient of the lidocaine group. The frequency of nausea and vomiting, agitation and analgesic requirement in the lidocaine group were higher than the magnesium group ($p = 0.001$). However, sedation score and recovery time were higher in the magnesium group ($p = 0.001$). No statistically significant difference was seen between the two groups in terms of hemodynamics. Magnesium sulfate and lidocaine had no difference in the incidence of laryngospasm, but magnesium sulfate was associated with a lower rate of stridor, nausea, vomiting, agitation and analgesic requirement in recovery in comparison to lidocaine.

Key Words: Laryngospasm; magnesium sulfate; lidocaine; tonsillectomy.

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Tonsillectomy is one of the common surgeries in children,¹ which is associated with many morbidities such as postoperative pain, nausea, vomiting, bleeding, dehydration and laryngospasm.² Laryngospasm is a dangerous complication caused by the strong and involuntary contraction of laryngeal muscle.³⁻⁵ The frequency of laryngospasm in children is higher than adults due to their narrow upper airways that can be blocked following edema and inflammation.^{6,7} The incidence of laryngospasm is 17 per 1000 children younger than nine years old, which increases to 96 per 1000 children with upper respiratory tract infections.⁸

Incidence rate of laryngospasm after routine extubation in tonsillectomy varies between 12 and 25%.⁸ Laryngospasm may result in cyanosis, hypoxia, hypercarbia, agitation, apnea, negative pressure pulmonary edema, irreversible brain damage and even death.^{6,9}

Therefore, laryngospasm is considered to be an emergency and its prevention is worthwhile.^{10,11} Different methods have been used to prevent post-extubation laryngospasm, which include intravenous or topical lidocaine, dexamethason, propofol and etc.⁸ Since most patients undergoing this surgery are children

that have lower pain thresholds and experience restlessness early, having negative psychological effects on them and their families.²

Postoperative pain control after the tonsillectomy has a very important role in recovery time, hospitalization duration, hemodynamic effects, bleeding, nausea, vomiting, and financial costs.¹² Recently, the use of magnesium sulfate in reducing postoperative pain has been studied.¹² Lidocaine is one of the antiarrhythmic drugs and its main mechanism of action is blocking voltage-gated Na⁺ channels that inhibit the activity of the upper laryngeal nerve and reduces the long-term blockage of the glottis. It is used locally (in the area of the tonsils) or intravenously to prevent laryngospasm, but it may reduce the seizure threshold.¹³⁻¹⁶

Magnesium, a predominantly intracellular cation, is an important cofactor in many enzymatic reactions. It has a central nervous system (CNS) depressant property, which contributes to the depth of anaesthesia.¹⁷ In addition, it has a calcium antagonist property, which provides muscle relaxation and increases flaccidity.⁸ It also has an antagonistic action on sodium channels and N-methyl-D-aspartate (NMDA) receptors and reduces the release of substance P, which decreases the airway reactivity and stress responses.^{8,17}

Therefore, Magnesium sulfate can reduce anesthetic requirement and total postoperative analgesic consumption.¹⁷ According to the mechanism of the effect of magnesium sulfate on muscle relaxation and considering the effects of magnesium sulfate in reducing postoperative pain, we decided to compare the effect of intravenous injection (IV) of magnesium sulfate and lidocaine on the prevention of laryngospasm occurrence, and analgesic requirement in tonsillectomy.

Materials and Methods

Study design and participants

The present double-blind clinical trial was performed in 2020. Sampling started after the proposal was approved with No. IR.UMSHA.REC.1398.231 by the ethics committee of the Hamadan University of Medical Sciences and registered in the Iranian clinical trial database with No. IRCT20120915010841N22. The written consent form was obtained from the patients after oral explanations.

Study inclusion criteria were children aged 3-14, class 1 and 2 American Society of Anesthesiologists (ASA), candidates for adeno-tonsillectomy surgery, with parental consent for participation in the study.

Study exclusion criteria included withdrawal from participation in the study, the presence of cardiovascular and kidney diseases, a recent history of upper respiratory tract infections and febrile illnesses, history of allergy to magnesium sulfate and lidocaine, difficult intubation, history of corticosteroid use, cardiac arrhythmias, history of myasthenia gravis, and surgeries of duration longer than one hour.

Sample size

The sample size of this study was calculated based on Heidari et al.(2013)¹³ according the following formula and considering 5% type 1 error and 80% test power:

$$N = (z_{1-\alpha/2} + z_{1-\beta})^2 [p_1(1-p_1) + p_2(1-p_2)] \div (p_1 - p_2)^2$$

$$P_1 = 52\%; P_2 = 20\%; Z_{1-\alpha/2} = 1.96; Z_{1-\beta} = 0.84$$

P1 and P2 were based on the frequency of stridor according the previous study.¹³ Accordingly, the total sample size was calculated to be 62 patients, i.e., 31 patients in each group.

Study randomization and blindness

The children who had all the inclusion criteria were randomly placed in the two groups A or B. Two minutes after intubation, group A received 15 mg/kg IV magnesium sulfate, while group B received 1 mg/kg IV 2% lidocaine. Block randomization is performed based on the computer software. To make medicines unknown to the patients and researchers, they were prepared in syringes with similar size and shape, and labeled and injected by the anesthesia assistant. Thus, the anesthesiologist who studied the results did not know the type of injected drug.

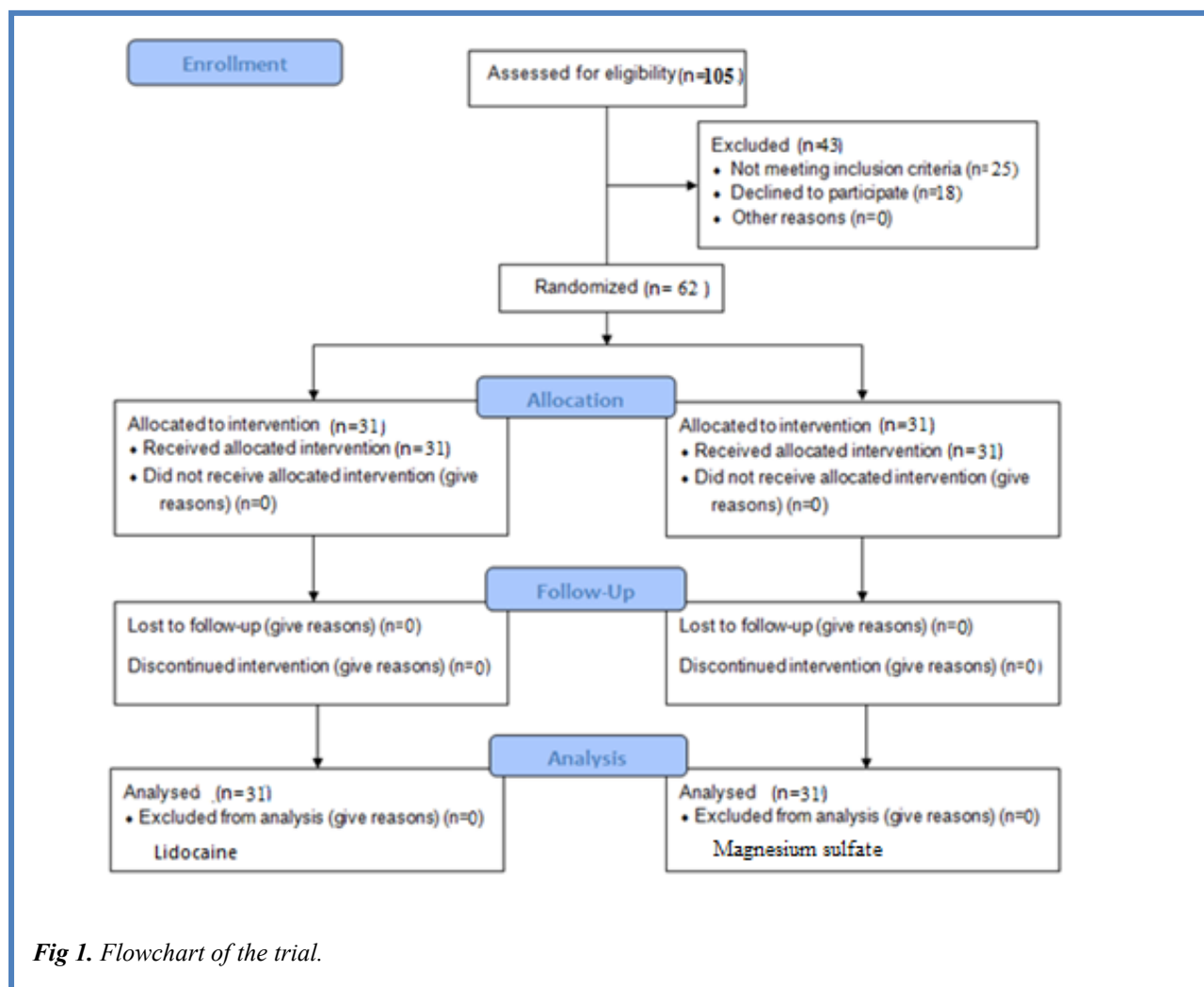
Data collection

Demographic information of the patients was entered the questionnaire (age, weight, and sex), then an IV line caught using the No.22 angiocath and midazolam 0.05 mg/kg was injected. After placement of a standard monitoring using a Saadat Model 162 monitoring device (made in Iran), induction of anesthesia was performed with fentanyl 1 µg/kg, thiopental 5 mg/kg and atracurium 0.5 mg/kg and patients were intubated with endotracheal tube of appropriate size. Then anesthesia was maintained with NO₂/O₂ 50% and minimum alveolar concentration of an inhaled anesthetic required to prevent movement in response to a defined noxious stimulus in 50% of subjects (Minimum alveolar concentration (MAC) (1.2%) of isoflurane.

Two minutes after tracheal intubation, group A received 15 mg/kg IV magnesium sulfate (20% magnesium sulfate, Iran Hormon Co, Iran), and group B received 1 mg/kg IV 2% lidocaine (Lidocaine2%, IranHormon Co, Iran) that were prepared in syringes labeled with A and B, respectively. Drugs were injected during 20-minute infusion. At the end of the surgery and after the extubating, patients were assessed at 1, 5, 10, and 15 minutes for laryngospasm and stridor (as primary outcomes), systolic, diastolic, and mean arterial pressure, heart rate, respiration rate, and Oxygen saturation (SpO₂) by an anesthetics professional. The need for using succinylcholine to manage the laryngospasm was also registered in the questionnaire. The recovery duration, sedation score, awakening time, agitation, nausea and vomiting, and the analgesic requirements (as secondary outcomes) were registered in the questionnaire.

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The Ramsey score used to assess the sedation score at recovery was based on the following categories:

1. Awaken, anxious or restlessness
2. Sleepy, answers to vocal stimulators
3. Deep sedation, answers to stronger stimulators
4. Non-ability to awaken

The recovery duration was considered from the time of entering the recovery room until the time of leaving the recovery room and transferring to the ENT department. The awakening time means the time of obeying and opening the eyes.

Statistical Analysis

All data were analyzed with SPSS software version 21. Descriptive information of qualitative data was expressed in the form of ratios and percentages. Chi-square and Fisher's exact tests were used to compare the incidence of laryngospasm, nausea and vomiting. Student's T-test and Mann-Whitney nonparametric test were used to compare systolic and diastolic blood pressure changes, Mean arterial pressure (MAP), Pulse Rate (PR), Respiratory rate (RR), Percentage of arterial blood oxygen saturation (SPO₂) and other quantitative

Table 1. Comparison of age and weight mean of children in the two groups.

Variables	Magnesium group	Lidocaine group	p-value
	Mean ± SD	Mean ± SD	
Age(Years)	7.0±2.59	6.9±3.1	0.966
Weight(Kg)	24.9±10.5	25.1±10.0	0.950

Significant difference: None.

Table 2. Frequency of nausea, agitation, sedation, and analgesic requirement in the two groups.

Variables	Magnesium group (N=31)	Lidocaine group (N=31)	p-value
	Frequency(%)	Frequency(%)	
Inspiratory stridor	3(9.7)	10(32.3)	*0.026
Nausea and vomiting	7(22.6)	15(48.4)	*0.034
Agitation	8(25.8)	19(61.3)	*0.005
Sedation	24(77.4)	11(35.5)	*0.001
Analgesic requirement	6(19.3)	25(80.6)	*0.001

Significant difference: *

variables. In all analyses, p-values less than 0.05 were considered significant.

Results

In the present clinical trial, 62 children who had the inclusion criteria were randomly grouped into two 31-patients groups experiencing a therapeutic process using magnesium sulfate or lidocaine 2% (Figure 1).

Based on the findings of Table 1, the two groups had no statistically significant difference based on age and weight.

14 children (45.2%) in the lidocaine group and 16 children (51.6%) in the magnesium group, were female. According to gender, there was no statistically significant difference between two groups (p=0.852).

Considering the results of the Table 2, the frequency of stridor in the lidocaine group was higher than in the magnesium group, and the difference between the two groups was statistically significant. Only one patient in the lidocaine group experiences laryngospasm that was treated using positive pressure ventilation and succinyl injection. None of the patient in the magnesium group

experienced laryngospasm. The frequency of nausea, vomiting, agitation and analgesic requirement in recovery was significantly higher in the lidocaine group than the magnesium group. The frequency of sedation (score ≥ 2) was higher in the patients of magnesium group and the difference was statistically significant.

Based on findings of the Table 3, there was no statistically significant difference between the two groups in terms of mean arterial pressure, heart rate and respiratory rate. Also in terms of SPO₂, the difference between the two groups was not statistically significant. Based on the findings of Table 4, there was no statistically significant difference in terms of awaking time (opening eyes) in the two groups. On the other hand, magnesium group of patients had a recovery duration significantly longer than the lidocaine group patients.

Discussion

The aim of the present interventional study was to compare the effect of IV magnesium sulfate and lidocaine 2% injection on the prevention of

Table 3. Mean arterial pressure, heart rate, and respiratory rate between the two groups in different times.

Time (Min)	Mean Arterial Pressure Mean ±SD		p-value	Heart Rate(Min) Mean ±SD		p-Value	Respiratory Rate(Min) Mean ±SD		p-value
	L	Mg		L	Mg		L	Mg	
1	85.9±5.9	82.9±8.6	0.12	122.7±9.8	120.4±8.5	0.337	16.1±1.8	16.2±1.8	0.774
5	82.2±5.3	80.1±7.5	0.196	112.1±8.1	113.8±8.8	0.413	15.9±1.5	16.1±1.7	0.534
10	78.8±4.5	75.3±12.4	0.146	104.9±8.4	106.6±10.5	0.559	1.4±15.7	16.2±1.7	0.228
15	75.2±3.4	75.8±4.0	0.59	103±13.3	101.8±11.8	0.724	15.7±1.4	16.1±1.7	0.381

Table 4. Comparison of awaking time and the recovery duration between the two groups.

Variables	Magnesium group	Lidocaine group	p-value
	Mean ± SD	Mean ± SD	
Awaking time(Min)	13.2±3.3	12.4±5.1	0.483
Recovery duration(Min)	38.4±8.1	32.3±6.0	*0.001

Significant difference: *.

laryngospasm occurrence and analgesic requirement in the tonsillectomy surgery. Results of this study showed that magnesium sulfate and lidocaine were not significantly different in terms of the incidence of laryngospasm, awaking time and hemodynamic status. but magnesium sulfate was associated with a lower rate of respiratory problems (stridor), nausea, vomiting, agitation, analgesic requirement and a higher rate of sedation and recovery time in comparison to lidocaine.

A study performed by Malik et al. (2016)¹⁸ on 150 children who were tonsillectomy candidates with a mean age of 8 years showed that the lidocaine group had a lower laryngospasm in comparison to the placebo group (normal saline). A meta-analysis study performed by Mihara et al. (2014)¹⁹ showed that in 9 studies performed on 787 children, lidocaine consumption (IV and local) decreased the laryngospasm occurrence risk. Results of a meta-analysis performed by Qi et al. (2016)²⁰ showed that in 12 clinical trials performed on 1416 children experienced general anesthesia, lidocaine consumption (injection and/ or gel) can be significantly effective in the laryngospasm prevention. Gharaei et al. (2015)²¹ also showed that lidocaine consumption (IV or local) can be significantly effective in the prevention of laryngospasm. Our findings are also in concordance with a study performed by Aljonaieh et al. (2018)²² in Saudi Arabia to assess the effect of lidocaine injection during surgery compared with placebo to prevent laryngospasm after extubation in laparoscopic gallbladder surgery in adults. Seventy two patients were randomly grouped into two placebo, and Bolus lidocaine at a rate of 1 mg/kg after discontinuation of desflurane groups. In this study, lidocaine usage caused a reduction in the laryngospasm occurrence in comparison to the placebo group. The authors concluded that lidocaine IV injection can be helpful in patients that have a high laryngospasm risk.

A study performed by Gulhas et al. (2003)¹⁷ assessed the magnesium efficiency for prevention of laryngospasm in the patients who were tonsillectomy candidates. In this study, 40 children (3-12 years old) were assessed that 20 of them received 15 mg/kg magnesium sulfate 2 minutes after intubation. No patients who received magnesium sulfate experienced laryngospasm, while 25% of the patients in the control group (receiving normal saline) experienced

laryngospasm with a significant difference. In the present study, none of the magnesium sulfate group of patients experienced laryngospasm. In a study performed by Savran-Karadeniz et al. (2016)²³ on 2 to 12 years old children who were candidates for esophageal dilatation, the findings showed that the magnesium-receiving group had less laryngospasm than the placebo group. Our results are also in concordance with a meta-analysis study performed by Cho et al. (2018)²⁴ Their analysis of 9 studies (615 patients) showed that magnesium sulfate administration (regardless of the way it is used) may reduce the pain after surgery and laryngospasm in patients who experienced tonsillectomy. Our results I are in concordance also with the meta-analysis performed by Xie et al. (2017)² assessing 10 studies (655 patients) that showed that magnesium sulfate administration may reduce laryngospasm and agitation at the end of anesthesia. The study of Marzban et al. (2014)⁸ is in concordance with our results that show the preventive effect of magnesium sulfate on laryngospasm reduction. A study performed by Heidari et al. (2013)¹³ on 100 children who were candidates for tonsillectomy, patients were divided into 4 groups, and received magnesium sulfate (15 mg / kg), lidocaine (1.5 mg / kg), propofol (0.5 mg / kg), and/or normal saline with a total volume of 15 ml before extubation. Then, they compared the groups in terms of the incidence of laryngospasm, stridor and reduction of SPO₂. Results of this study showed that all three medicines were effective in the reduction of respiratory complications in comparison to the placebo; however, none of the magnesium sulfate, lidocaine, and propofol had no priority over the others. This is in contradiction to our results that showed that stridor occurrence is lower in the magnesium sulfate group. This disagreement may be the result of differences in the drug administration time and sample size. Based on previous studies, restlessness or agitation occurrence in children has been reported to be 10-80 percent.²⁵ The restlessness in the children appears as the movement of the limbs, bothering cry, dizziness, and incompatibility.²⁶ Although these complications are often short-term, they may need a drug intervention, long-term recovery hospitalization, parent's concerns, damage to catheters and dressings, and disconnection of monitoring cables.^{27,28} In the study of Manouchehrian et

al. (2022)²⁹ 102 children aged 3 to 14 years who were candidates for tonsillectomy were studied in two groups. Patients in the lidocaine group received 1 mg / kg lidocaine and in the propofol group received 0.5 mg / kg propofol intravenously two minutes before extubation. After extubation, the two groups were compared in terms of frequency of laryngospasm, nausea, vomiting and agitation.

The study showed that the frequency of laryngospasm, nausea, vomiting and agitation and the mean heart rate in the propofol group were lower than the lidocaine group, while in terms of mean arterial pressure, awaking time and staying in recovery there was no difference between the two groups which is consistent with the present study. The results of a meta-analysis performed by Xie et al. (2017)² are in concordance with the findings of the present study, and showed that the rate of analgesic requirement in the magnesium group was significantly lower than the control group, but in contradiction to our findings, the rate of nausea and vomiting had no difference with the control group. Results of a clinical trial performed by Hamed et al. (2015)¹² on 60 children who were tonsillectomy candidates (30 patients received IV magnesium sulfate (30 mg/kg) and 30 patients received paracetamol (10 mg/kg)) showed that the magnesium sulfate group had lower pain and analgesic requirement in comparison to the paracetamol group.

This is in concordance with results of the present study whose limitations are the low sample size and the lack of a control group.

In conclusion the findings of the present study showed that magnesium sulfate and lidocaine had no difference in the incidence of laryngospasm, but magnesium sulfate was associated with a lower rate of stridor, nausea, vomiting, agitation and analgesic requirement during recovery in comparison to lidocaine.

List of acronyms

ASA - American Society of Anesthesiologists
CNS - Central nervous system
ENT - Ear, Nose and Throat
IV - Intravenous
MAC - Minimum alveolar concentration
MAP-. Mean arterial pressure
NMDA - N-methyl-D-aspartate
PR - Pulse Rate
RR - Respiratory rate
SpO₂ - Percentage of arterial blood oxygen saturation

Contributions of Authors

NM, RA, NJ, RMB: Study conception and design; Data analysis and interpretation; Critical revision of the article. All authors have read and approved the final edited typescript.

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Conflict of Interest

The authors declare no conflict of interests.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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