Heliyon 8 (2022) e11504

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

Comparison of laryngeal mask airway (LMA) insertion with and without muscle relaxant in pediatric anesthesia; a randomized clinical trial

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ARTICLE INFO

Keywords:
Laryngeal mask airway (LMA)
Pediatrics anesthesia
Muscle relaxant

ABSTRACT

Introduction: This study aimed to evaluate the effectiveness of using muscle relaxant on the ease of laryngeal mask airway (LMA) insertion and possibility of its related complications.

Methods: This double-blind, randomized clinical trial was performed on 60 children aged 1–4 years with ASA (American Society of Anesthesiology) I or II with upper limb injuries who were candidates for surgery. The patients were randomly allocated to the two groups receiving atracurium group as muscle relaxant (MR) or saline group (S).

Results: Regarding ease of placement, the LMA was inserted in 66.7% and 63.3% of patients straightforwardly in the MR and S groups, respectively. While it was performed with one maneuver in 23.3% and 26.7% of cases in the MR and S groups, respectively ($p = 0.955$). Moreover, LMA dislodgment in the two groups was 36.7% in the MR group and 20.0% in the S group without a meaningful difference ($P = 0.152$). The only complication observed in the two groups was laryngospasm, which occurred in 0.10% and 13.3% in the MR and S groups, respectively ($p = 0.688$).

Conclusion: In some pediatric anesthesia, the use of atracurium, as a muscle relaxant had no significant effect on capability of LMA insertion, maintaining airway patency, LMA seal pressure and oxygenation variations. Moreover, it did not have a preventive effect on the occurrence of complications such as laryngospasm.

1. Introduction

Laryngeal mask airway (LMA), first announced in 1983, is a special type of ventilation tube placed blindly in the larynx. The LMA does not compel a laryngoscope to visualize the glottis, so it is implausible to manipulate or damage the larynx [1, 2, 3]. The application of LMA is very advantageous for keeping the airway open and is usually applied in outpatient and short surgeries in adults and children under general anesthesia [4, 5]. In fact, there is no need to enter the trachea and cardiovascular stimulation [6]. Moreover, it can be used in patients with difficult airway [7].

The use of LMA as an airway management technique is common in the pediatric anesthesia because of its less irritating effect on the airways due to its location in the upper larynx [8]. Various studies have compared LMA and endotracheal intubation and have shown a remarkable increase in the occurrence of respiratory complications with endotracheal tubes in pediatrics [9, 10]. However, LMA insertion is much more complicated in pediatrics compared to adults. Distinctive features of children's airways, including a larger tongue, larger epiglottis, and hypertrophic tonsils interfering with the ideal insertion of the LMA [11]. Blind endotracheal tube intubation using standard LMA has been correlated with a wide range of failure rates in different investigations, ranging from 10% to 70% in patients with normal airway [12]. Therefore, enough depth of anesthesia level is essential for the LMA insertion and prevention of the complications [13]. Increasing patient's sedation level along with relaxing muscles makes LMA insertion more comfortable. Although propofol is the selective hypnotic for effective LMA placement, its use is associated with some complications, including coughing, hiccups, laryngospasm, and patient movement during the procedure [14]. Therefore, administration of lidocaine, opioids or ketamine can sometimes reduce

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https://doi.org/10.1016/j.heliyon.2022.e11504
Received 2 May 2022; Received in revised form 14 September 2022; Accepted 3 November 2022

the required dosage of propofol and significantly increase the success of the LMA placement [15].

In this regard, various muscle relaxants have been used and conflicting results have been reported on their effectiveness in reducing complications during LMA insertion. For instance, Cheam et al. [16] reported that adding mivacurium and fentanyl is helpful to insert the LMA. In contrast, Chen [17] showed that muscle relaxants had little effect on patients with LMA placement in respect of recovery time or hospital expenses.

Because of the limited evidence for the impact of muscle relaxants on the success rate of airway management by LMA in pediatrics, we compared LMA insertion with and without neuromuscular relaxants in pediatric anesthesia.

2. Methods and materials

The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.FMD.REC.1399.550) and registered in the Iranian Clinical Trials Registry database (IRCT20110513006465N3). In addition, after detailed explanations, written informed consent was obtained from the parents or legal guardians of the participants. This randomized clinical study was conducted from July 2021 to December 2021 on children aged 1–4 years referred to Fatima Plastic and Reconstructive Surgery Hospital affiliated with Iran University of Medical Sciences, candidates for general anesthesia for surgery the upper limbs. The patients were randomly assigned to the two groups based on a block randomization. In the first group, LMA was introduced using a muscle relaxant (MR group) and in the second group, LMA was used with saline (S group). Sampling was stopped after reaching the required number of patients. According to the study by Sung et al. [18], considering alpha of 0.05, beta of 0.2, P1 of 0.4, and P2 of 0.1, 60 participants entered in the study group in both MR and S groups using the following formula:

$$n = \frac{\left(Z_{(1-\alpha/2)} + Z_{(1-\beta)}\right)^2 (p_1(1-p_1) + p_2(1-p_2))}{d^2}$$

Inclusion criteria were included age between 1 and 4 years with ASA class I or II with an upper extremity injury who was candidates for surgery. Exclusion criteria were length of operation more than 2 h, possibility of difficult intubation, upper airway infections, congenital diseases with unusual airway anatomy, any history of seizures and neurological diseases and those with a high risk of pulmonary aspiration. NPO time was considered for all participants according to their age. The study flowchart is depicted in Figure 1.

2.1. Randomization and blinding

In this study, we used "Block Randomization" method through 15 blocks of 4. Excel software using "rand between" function was used to generate random order inside each block. When each participant's intervention was determined, patients were assigned a unique four-digit code (due to obfuscation). The nurse of anesthesia prepared the syringes and was the only one who knew about the content of syringes as well as the patients were unconscious and could not be aware of the groups. Also, the data analyzer received the groups as group A (with relaxant) and group B (without relaxant) so this study was double-blinded.

2.1.1. The procedure

At first, intravenous access (IV line) was performed with parental presence and then midazolam (0.05 mg/kg) was administered. The patients entered the operating room and underwent electrocardiogram, Spo2, non-invasive blood pressure, and Etco2. Fentanyl (2 μ/kg) and atropine 0.01 (mg/kg) were injected. Thereafter, for induction, 1.5 mg/kg propofol was given. Patients in the MR group received 0.2 mg/kg atracurium and those in the S group received the same amount of normal saline in identical syringes. Size #2 for LMA was selected. LMA was inserted by an experienced anesthesiologist. Attempts to LMA insertion were recorded as per easily without maneuver, with one maneuver and more than one maneuver needed. After 10 min of beginning, the expiratory valve of anesthesia circuit was closed with upper limit of 30 cmH2O at a constant 100% oxygen flow of 3 L/min to measure LMA seal pressure. Isoflurane with 1.2% and N2O 50% concentrations were used as maintenance (a total of 1.5 MAC during the operation). Due to administration of N2O during the operation, the LMA cuff pressure was checked at half-hour intervals to maintain the pressure at about 60 cmH2O. LMA displacement was noticed by end tidal CO2 drop to below 5 mmHg. Neither atracurium nor any other anesthetic agent was used during the operation. At the end of the operation, patients received identical syringes containing either neostigmine (0.04 mg/kg) with atropine (0.02 mg/kg) or normal saline for MR and S groups, respectively. All patients were in the supine position throughout the procedure. Complications such as laryngospasm, sore throat, bleeding and stridor were assessed.

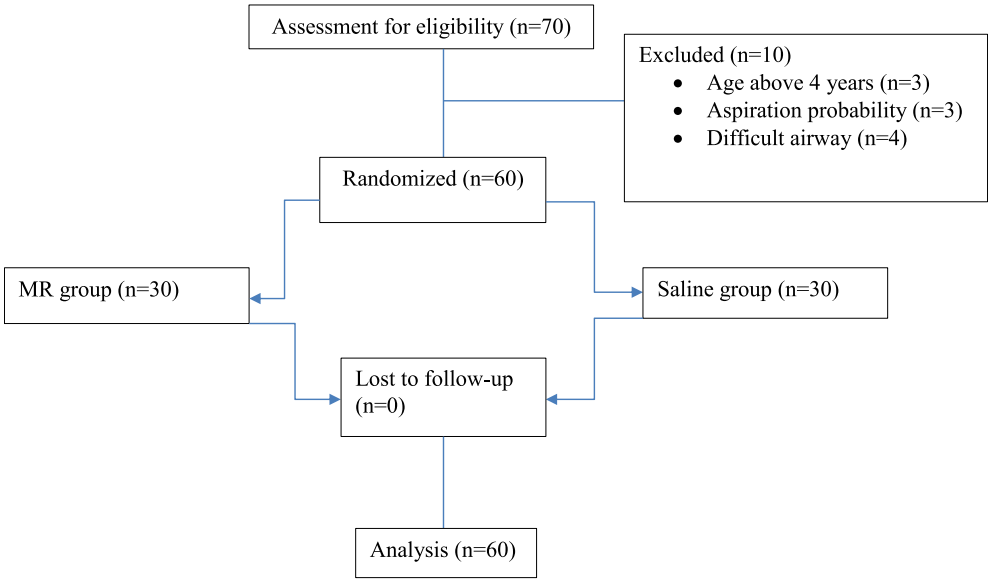

Figure 1. The study consort flowchart.

2.1.2. Statistical analysis

The data were presented as percentage, frequency, mean and standard deviation. Comparisons between quantitative variables were performed by independent t-test. Qualitative variables were analyzed using chi-square or Fisher's exact test. SPSS Version 23 (SPSS Inc. Chicago, IL, USA) was used for the statistical analysis. The level of significance was assumed to be less than 0.05.

3. Results

Sixty patients were randomly assigned to the two groups since 30 patients underwent LMA insertion with muscle relaxant and 30 patients underwent LMA insertion without muscle relaxant. The mean age in the MR and S groups was 31.20 ± 10.32 and 27.90 ± 12.19 months, respectively. There was no statistically significant difference regarding gender, age, weight, and duration of the operation between the two groups. Baseline demographics of the study population are presented in Table 1.

There was no significant difference between the two groups in regarding ease of LMA insertion (p = 0.955). Furthermore, the frequency of LMA dislodgement in the two groups of with and without muscle relaxation were 36.7% and 20%, respectively (P = 0.152). All dislodgements were resolved by minimal maneuvers ensuring airway patency except in one patient that ventilation was compromised, hence an attempt was made to change the LMA. There was no need to replace LMA with endotracheal tube in any patient. Table 2 shows the details of consequences in the two groups.

The only complication observed in the two groups was laryngospasm, which was eliminated by maneuvering and using CPAP (Continuous Positive Airway Pressure) in the both groups. In one patient, laryngospasm developed at the end of operation and was not relieved by maneuvering and using CPAP, therefore 0.1 mg/kg succinylcholine was used to overcome the spasm. However, there was no significant difference between the two groups in terms of laryngospasm rate (P = 0.688). The same was true for arterial oxygen saturation (SPO2), as it did not fall below 95% in any patient in either group (P = 0.134). Seal pressure or laryngeal cuff pressure were not different (23 ± 0.4 vs. 22 ± 0.51 cmH_2o in the MR and S groups) (p = 0.310).

4. Discussion

The use of LMA in pediatric anesthesia is growing. Since the LMA is located above the larynx, the airways are less directly mechanically stimulated. Several reports have compared LMA and endotracheal tube insertion and have exhibited a substantial increase in the incidence of intraoperative respiratory complications with endotracheal tube use in children [19, 20, 21].

Various researches have claimed that muscle relaxants can expedite LMA placement. They have resulted in higher success rates, higher seal pressure, lower leak volume, and less adversity in a LMA insertion in adults [22, 23, 24]. In contrast, Chen et al. revealed that cuff and airway pressure, sore throat and successful placement rate do not depend on the administration of the muscle relaxants [25]. It is indistinct whether the use of muscle relaxants can accelerate LMA placement, and whether such an action can counteract potential complications such as hemodynamic instability, laryngospasm, bronchospasm, and traumatic injury during placement. The results of clinical trials have been somewhat contradictory.

In our investigation, the use of muscle relaxants did not simplify LMA placement or reduce the risk of LMA dislodgment. Also, there was no notable difference in the occurrence of laryngospasm in both groups. In other words, administration of atracurium as a routine relaxant had no effect on improving LMA placement, risk of dislodgment, or possible succeeding complications.

In a clinical trial by Nasseri et al. reported a higher success rate in the atracurium-receiving group than the control group because their study revealed that atracurium, the most commonly used relaxant, caused relaxation in the jaw. The average time to place the LMA was 5.06 vs. 5.76 s, respectively. The hemodynamic changes after LMA were the same in both groups [26]. Possible reasons for the shorter insertion time in their study may be the use of different pretreatments, the technique of calculating the insertion time, and the skills of the anesthesiologist. That is why some studies stated longer time for LMA insertion following the use of atracurium [27, 28, 29].

Despite the similarity of the sample size, difference in the type of drug and the used dosage, the results of their study were completely different from our investigation. Besides, we should consider the method of insertion, classic versus rotational, because both of methods work well in pediatric [30].

In an investigation by Shetabi et al. The results of administration of three different doses of atracurium showed that all three different doses of atracurium had similar effects on LMA insertion. Atracurium 0.4 mg/kg accompanied by greater first-attempt LMA insertion success and fewer airway complications such as bleeding and sore throat. Besides, after using a higher dose, the success rate of LMA insertion did not change [31]. In present study, we utilized lower dose of 0.2 mg/kg and found suitable results with no specific complications and with easy insertion.

In the study by Tulgar et al., although the duration of operation was the same in the two groups, the length of anesthesia was shorter in the group receiving muscle relaxant. Recovery time was also considerably shorter in the group receiving muscle relaxants, with no difference in intragastric pressure and peak airway pressure during inspiration [32]. Furthermore, Kong et al. presented a reduction in recovery time as well as extubating time in the muscle-relaxant receiving group. However, the duration of the operation was the same [33]. In addition, in the study of Fujiwara et al. LMA placement was easier in the MR group than S group. Also, the volume of leakage from mechanical ventilation was notably lower in the rocuronium-receiving group [22].

In a double-blind clinical trial, Sung et al. randomly divided 120 children aged 2–7 years who were candidates for eye surgery into two groups. For one group, they inserted LMA using a rocuronium relaxant, and in the other group, LMA was placed without it. They stated that oropharyngeal leak pressure (OLP) or sealing pressure refers to the pressure that the LMA cuff exerts on the pharyngeal mucosa. Higher sealing pressure is a key principle in using LMA to prevent the risk of bloating and vomiting [18]. In previous studies, a positive association was found between OLP and directly measured mucosal pressure [34]. Consequently, Sung stated that since muscle relaxants loosen the pharyngeal muscles and diminish this pressure, they may reduce the

Table 1. Comparison of the baseline characteristics of the patients.

Variable	MR group	S group	P
Gender, female,%	36.7	50	0.297
Age, months	31.2 ± 10.3	27.9 ± 12.1	0.263
Weight, Kg	14.4 ± 5	15 ± 4.9	0.168
Operation duration, hours	1.5 ± 0.3	1.5 ± 0.5	0.260

Table 2. Consequences of LMA placement.

Variable		MR group	S group	P
Ease of LMA insertion, %	Easily without maneuver	66.7	63.3	0.955
	With one maneuver	23.3	26.7	
	More than one maneuver	10	10	
LMA seal pressure, cmH2O		23 ± 0.4	22 ± 0.5	0.310
LMA dislodgment, %		36.7	20	0.152
Arterial oxygen saturation, %		97 ± 2	98 ± 1	0.134
Laryngospasm, %		10	13.3	0.688

efficiency of LMA [18]. In other words, the use of atracurium as a muscle relaxant, could lessen the recovery time or the rate of some postoperative complications, but did not have any effect on the incidence of complications such as LMA dislodgement or laryngospasm. On the other hand, the use of muscle relaxants in combination with new anesthetic agents is not necessary. The LMA could be maintained during the operation with sufficient depth of anesthesia maintaining suppression of airway reflexes, undesirable movements, and hemodynamic responses without the need for administration of muscle relaxants.

However, the results were strappingly predisposed by some limitations. For instance, the small sample size was the most remarkable limitation of our study but due to randomization process, it can be result in causality. It is suggested to perform the current investigation with the use of new generation LMAs (Flexible LMA, LMA RQ) or other types of muscle relaxants. Moreover, it is recommended to assess the outcomes in older age groups (older children) and in other positions (lateral, prone). As in the lateral position, the LMA seal pressure would be changed leading to different outcomes. Time of recovery was not assessed in our study and it is recommended to be assessed in further studies in follow-up.

5. Conclusion

In some pediatric anesthesia, the use of atracurium, as a muscle relaxant had no significant effect on capability of LMA insertion, maintaining airway patency, LMA seal pressure and oxygenation variations. Moreover, it did not have a preventive effect on the occurrence of complications such as laryngospasm.

Declarations

Author contribution statement

Ziae Totonchi: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Seyed Alireza Seyed Siamdoust: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

Behrooz Zaman: Contributed reagents, materials, analysis tools or data; Wrote the paper.

Faranak Rokhtabnak: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Seyyed Amin Alavi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data availability statement

Data will be made available on request.

Declaration of interest's statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

Acknowledgements

We would like to thank the operation theater staff who kindly helped us in the procedures. Moreover, we would like to thank Farname Inc. (Canada) to help us for native English edit of the manuscript.

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