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Comparison of Laryngeal Mask Airway and Endotracheal Tube in the Early Incidence of Laryngospasm in Pediatric Patients: A Prospective Double-Blinded Block-Randomized Controlled Parallel Clinical Trial

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The approval of the Institutional Review Board of the Research Committee of Zahedan University of Medical Sciences (Zahedan, Iran) was obtained with the number IR.ZAUMS.REC.1393.1266, and the study was conducted according to the Declaration of Helsinki principles (WHO, 2013). The ethical considerations of this study were related to the patients' autonomy, confidentiality, and anonymity during the study period and the study's publication.

Introduction:

Management of the airway in a pediatric patient requires an understanding and knowledge of the differences and characteristics unique to a child's or an infant's airway, as compared to an adult airway (Patki, 2011). New techniques are continually being explored and developed to allow us to take care of infants and children better and to provide the safest and most effective means of delivering that care (Cox & Lardner, 2009). Endotracheal Tube (ETT) and Laryngeal Mask Airway (LMA) are two accepted and standard methods for maintaining an airway in different surgical procedures. The LMA gained wide acceptance as an alternative to traditional tracheal tube (TT) intubation (van Esch *et al.*, 2017), it is relatively non-invasive as compared to endotracheal intubation (Jamil *et al.*, 2009). An inflated

Abstract

The study was conducted to compare laryngeal mask airway (LMA) and endotracheal tube (ETT) in the early incidence of laryngospasm after surgery in pediatric patients. The prospective double-blind block-randomized controlled parallel clinical trial was carried out on 90 pediatric patients undergoing elective surgery. The patients selected through convenience sampling and then divided into two groups of 45 by blocked random allocation. One group received ETT and the other group received LMA. The method of anesthesia was the same for both the groups. Finally, after removing the tubes, the incidence of laryngospasm was evaluated and compared between the two groups. A total of 90 patients participated in this study, including 21 boys and 24 girls in the ETT group, and 23 boys and 22 girls in the LMA group; statistically there were no significant differences between the two groups in terms of gender and mean were evidenced. But, the mean insertion speed was 22.15 sec. in the ETT group and 13.99 sec in the LMA group which highly differed statistically. There were three cases of laryngospasm in the ETT group and only one case in the LMA; the difference between the two groups in terms of this value was statistically significant, then, the findings can be generalized in the same population. Results suggest, the use of LMA is more convenient and practical than ETT for elective outpatient surgeries in pediatric patients; then it is recommended that in the same population, the anesthesiologist use from the LMA than ETT.

cuff of LMA provides a low-pressure seal over a glottic opening and allow positive pressure ventilation (PPV) with an inspiratory pressure of 15-20cm of water (Wilson *et al.*, 1992). Recently, there is increasing an use of LMA in children (Watcha *et al.*, 1992) because of insertion of LMA requires neither the visualization of cords nor the penetration of larynx, making the placement less stimulating than tracheal tube insertion and it may provoke less sympathetic response and catecholamine release; therefore, during LMA insertion there is less likelihood of presser responses or coughing than with conventional endotracheal tube anesthesia and as a consequence the increase in intraocular pressure may be diminished; moreover, there is a decrease in the incidence of arterial oxygen desaturation and less airway stimulation with the

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use of LMA as compared to endotracheal intubation (Power *et al.*, 2001).

For patients with small outpatient surgeries, the use of LMA reduces the amount of muscle relaxant use and subsequently reduces the incidence of complications and the use of drugs such as Atropine, Glycopyrrolate and Neostigmine for reversing the effect of these relaxants; other benefits of using LMA include the lower stimulation of the airway and the vocal cords and reduced respiratory and cardiovascular complications (Aziz & Bashir, 2006); moreover, ETT is the most reliable way of maintaining the airway and preventing aspiration. Nonetheless, in cases where ETT insertion is not possible or is difficult, LMA is easier to handle and presents the least risk of airway damage (Morgan *et al.*, 2005). In this regards, one of the airway complications is laryngospasm.

Laryngospasm is a protective reflex that blocks the glottis against abnormal stimulations (Al-alamy *et al.*, 2009). There are two types of laryngospasm; Expiratory stridor, which is caused by the active closure of the secondary glottis to stimulation and inspiratory stridor, which is caused by the passive closure of the glottis with a ball-valve mechanism. If laryngospasm is prolonged, it may lead to hypoxemia and hypercapnia; in order to re-establish oxygenation, a clear management plan is required to avoid significant morbidity and even mortality (Gavel & Walker, 2013).

The overall incidence was reported by Olsson (1987) at just under 1% in both adult and pediatric practice. The incidence doubles in children and triples in the infants (since birth to 3 months of age). Further, an incidence of laryngospasm of 10% in the very young pediatric patient with reactive airways, either due to upper respiratory infection or asthma was also reported by Olsson (1987). The incidence of laryngospasm has been reported in the literature as high as 25% in patients undergoing tonsillectomy and adenoidectomy (Gavel & Walker, 2014).

The predisposing factors of laryngospasm include upper respiratory tract infections, tissue over-stimulation and insufficient anesthesia depth (Hampson-Evans *et al.*, 2008). The management of laryngospasm consists of its prevention, recognition, treatment, and post-anesthetic care. Other novel treatments were also discussed. A review in the year 2005 showed significant morbidity associated with laryngospasm in pediatric and adult anesthetic practice (Visvanathan *et al.*, 2005); although the most prominent finding was significant hypoxemia (61%), bradycardia occurred in 6% overall but in 23% of patients less than one-year-old (Gavel & Walker, 2014). Tait *et al.* (1998) compared ETT and LMA in 82 pediatric patients with active upper respiratory tract infections and found that bronchospasm, laryngospasm, coughs, and reduced arterial oxygen saturation was significantly less in the patients ventilated with LMA during their anesthesia

compared to the ETT group. Surgery in the oral cavity leads to pharyngeal bleeding, and the use of ETT reduces the potency of laryngeal protective reflexes (Burgess III *et al.*, 1980); moreover, Tanaka *et al.* (2005) reported that patients who had received ETT during their anesthesia experienced postoperative disorders of the larynx and vocal cords. Besides having the high importance of the concept, no evidence about the early incidence rate of laryngospasm in the study population is yet available. The purpose of the study was to compare the effect of laryngeal mask airway (LMA) and endotracheal tube (ETT) on the early incidence of laryngospasm after elective outpatient surgeries in pediatric patients.

Methodology:

The prospective double-blind, block-randomized, parallel controlled clinical trial was conducted to compare the effect of laryngeal mask airway (LMA) and endotracheal tube (ETT) on the early incidence of laryngospasm after elective outpatient surgeries in pediatric patients, in Ali-Ibn-Abitalib hospital, Zahedan-Iran, Apr. 2014 to Dec. 2016.

All parts of the study were reviewed according to the Consolidated Standards for reporting trials (CONSORT) statement (Hopewell *et al.*, 2008). In the first step, a convenience sampling method was used and in the second step, by using blocked randomization, patients divided into two groups of 45 each (ETT and LMA group). Block randomization was performed by a computer-generated random number list prepared by our statistician. Blocks were in groups of four, where "A" designated 'intervention' and "B" designated 'control.' Randomly allocated numbers were placed into sequential containers (*i.e.*, AABB, containers 1-4; BBAA, containers 5-8, etc.) which were kept in a secure location until allocation consignment. Allocation consignment occurred through confidential communication between the patient's nurse and a third party not involved in recruitment. Patients were blinded to the randomization group, as were the healthcare providers and statistician.

All patients who met the inclusion criteria were recruited. The inclusion criteria consisted of age 2-12 years, ASA class I, candidate for an elective outpatient surgery other than head and neck surgeries, no active upper respiratory tract infections, no endocrine disorders (diabetes, thyroid disorders or adrenal insufficiency), no congenital heart disorders, no cerebral palsy, no psychiatric disorders and no contraindication for LMA insertion. The exclusion criteria consisted of the unwillingness of the patient's guardians to continue participation in the study and a problematic intubation, defined as more than two attempts at tube insertion.

The sample size of the study was determined by using the information obtained from the previous study (Vahedian-Azimi *et al.*, 2016a). Considering a confidence level of 95% and a power of 80%, a required sample size of at

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least 40 cases was determined. In order to prevent patient attrition from affecting the results of the study, a total of 45 qualified patients were asked to participate in each group, totally, 90 patients took part in the study.

The purpose of the study was explained to all patients, and they were also informed that they were free to participate, decline participation, or withdraw from the study at any time. A written informed consent form to participate for the study was obtained from the legal guardians of the pediatric patients admitted for elective outpatient surgeries.

The subjects who entered the study underwent non-invasive cardiac monitoring, pulse oximetry, and blood pressure control. To initiate the anesthesia process, the patients in both groups were first hyperventilated with 100% pure oxygen for 3 minutes. Atropine (0.02 mg/kg) and then fentanyl (1 µg/kg of BW) were intravenously injected as premedication. Anesthesia was then induced with sodium thiopental (5 mg/Kg) and atracurium (0.5 mg/kg). After three minutes of ventilation, one group was intubated with classic LMA and the other group with ETT with sizes matching the children. The time of insertion was calculated from the time of holding the tube until the emergence of the first capnography wave. Anesthesia was maintained by 50-150 µg/kg/min of propofol, nitrous oxide 50% and oxygen 50%. At the end of the surgery, when the child started spontaneous breathing, neostigmine (0.05 mg/kg) and atropine (0.025 mg/kg) were used to reverse the patients. The ETT and LMA were removed when the patients were able to create a negative inspiration force or NIF >-20 cmH₂O and a tidal volume of more than 5cc/kg, maintain stable vital signs, arterial oxygen pressure, and carbon dioxide at the end of expiration, and swallow and cough. The patients then received 6 lit/min of oxygen through a mask and were monitored for the incidence of laryngospasm. The symptoms of laryngospasm were defined as high-frequency inspiration or expiration stridor, arterial oxygen saturation drop of more than 20% of the basal value, and aphonia and cyanosis.

All the statistical analyses were done using SPSS 22.0 (SPSS Inc., Chicago, IL). The comparisons of background variables including age and sex were investigated between the two groups using t-test

Results:

A total of 90 patients participated in this study, which included 44 boys and 46 girls. There were 21 boys and 24 girls in the ETT group, and 23 boys and 22 girls in the LMA group. No significant difference between the two groups in terms of gender as per the Chi-square test ($p \geq 0.698$) was found. The mean age was 8.5 ± 8.2 in the ETT group and 7.5 ± 6.3 in the LMA group; there was no significant difference between the two groups as per the independent t-test ($p \geq 0.961$). The mean ETT and LMA insertion speeds were 22.15 and 13.99 seconds, suggesting a significant

difference ($p < 0.003$). There were three cases of laryngospasm in the ETT group and only one case in the LMA; although the value was statistically significant, examining the incidence rate by age and gender was not possible due to the very small sample size.

A comparison of the two groups showed that the complications of intubation were higher in the ETT group, and there was a significant difference between the two groups in the case of damage to the lips and teeth and coughing according to the Chi-square test (Table-1).

Table-1: Frequency of the complications due to intubation between groups

Complications	LMA	ETT	p values
Sore throat	5	9	≥ 0.245
Hoarseness	3	6	≥ 0.292
Vomiting	4	6	≥ 0.502
Damage to lips and teeth	1	9	< 0.001
Coughs	8	21	< 0.003

A comparison of the two groups in terms of the patients' hemodynamic using the repeated measures ANOVA showing the mean heart rate and systolic blood pressure of the two groups were significantly different only at minutes 1 & 4 after insertion (Tables-2, Fig.-1).

The paired t-test was used to compare the patients' vital signs in each group before and after intubation. In the LMA group, the mean changes in heart rate differed significantly before intubation and then at minutes 1, 4, 6 & 10 after intubation ($p < 0.0001$). In the ETT group, the mean heart rate differed significantly before intubation and at minutes 1, 4 & 10 after intubation ($p < 0.0001$), but not at minute 6 of the intubation ($p \geq 0.277$). In the LMA group, systolic blood pressure differed significantly before intubation and at all the subsequent times ($p < 0.0001$). In the ETT group, systolic blood pressure differed significantly before intubation and at all the subsequent

Figure-1: A comparison of the two groups in terms of changes in hemodynamic variables before and after insertion. (a: Diastolic Blood Pressure; b: Systolic Blood Pressure; c: Mean Arterial Pressure; d: Heart Rate).

Table 2: Some comparisons of the two groups in terms of changes in hemodynamic variables before and after insertion

Variable	Group	Before Induction	p*	1 Min. after Intubation	p*	4 Min. after Intubation	p*	6 Min. after Intubation	p*	10 Min. after Intubation	p*
HR	LMA	114.78 ± 11.25	0.867	120.18 ± 11.43	0.0001*	116.04 ± 11.5	0.007*	112.78 ± 11.4	0.164	109.18 ± 11.29	0.287
	ETT	115.13 ± 8.74		127.99 ± 9.57		121.91 ± 8.6		115.80 ± 8.8		111.33 ± 9.11	
SBP	LMA	106.04 ± 6.52	0.073	111.13 ± 6.48	0.014*	106.62 ± 6.57	0.023*	100.36 ± 7.06	0.118	94.89 ± 6.44	0.023*
	ETT	103.6 ± 6.23		114.6 ± 6.68		109.84 ± 6.59		102.09 ± 6.95		97.91 ± 5.91	
DBP	LMA	55.18 ± 6.32	0.88	59.31 ± 6.55	0.005*	55.8 ± 6.44	0.06	51.89 ± 6	0.176	48.24 ± 6	0.121
	ETT	54.29 ± 5.56		63.52 ± 5.65		58.24 ± 5.6		53.53 ± 5.35		50.13 ± 5.35	
MAP	LMA	72.74 ± 6.29	0.26	76.59 ± 6.31	0.005*	72.74 ± 6.29	0.035*	68.04 ± 6.16	0.119	63.79 ± 5.93	0.054*
	ETT	75.44 ± 5.69		80.21 ± 5.71		75.44 ± 5.69		69.92 ± 5.06		66.06 ± 5.06	

HR- Heart rate; SBP- Systolic blood pressure; DBP- Diastolic blood pressure; MAP- Mean arterial pressure. *statistically significant

times for all the cases ($p < 0.05$). In the ETT group, systolic blood pressure differed significantly before intubation and at all the subsequent times ($p < 0.0001$). Diastolic pressure and the mean arterial pressure differed significantly before intubation and at all the subsequent times in both groups ($p < 0.0001$).

Discussion:

The results showed that the incidence of laryngospasm caused by intubation is very low; however, the sample size of the study was not large enough for the results to be considered an accurate estimation of the incidence of laryngospasm caused by insertion with a high-reliability coefficient. The important point is the shorter insertion time of LMA and the greater complications of ETT. In line with these results, Acquaviva *et al.* (2014) reported that LMA was a better method than ETT for maintaining the airway in children and also has a shorter insertion time. Further, they also reported laryngospasm and asthma attack in two patients and one patient, respectively in three patients which were in ETT group.

The incidences of nausea and vomiting were also higher in the ETT group. The study populations differed in the two studies and the subjects in the cited study underwent Elective Esophagogastroduodenoscopy (EGD); therefore, their higher nausea and vomiting compared to the patients in the present study is justified even though both groups received intravenous ondansetron at a dose of 0.1 to 4 mg/kg (Acquaviva *et al.*, 2014). Jamil *et al.* (2009) who studied 50 children undergoing elective surgery, reported that LMA insertion was easy in 94% of the cases, while easy ETT insertion was possible only in 53% of the cases and it supports our findings.

Hemodynamic complications were found to be more prevalent and long-lasting in the ETT group for our study. Although the hemodynamic changes observed in the present study differed significantly between the two groups only at minutes 1 and 4 after the surgery, the changes were higher in the ETT group throughout the entire study.

As per our results, the frequency of complications caused by surgery, such as soft tissue injury and laryngospasm, was higher in the ETT group as compared to

the LMA group. In a study based on 16 clinical trials conducted on pediatric patients Patki (2011) reported a lower incidence of postoperative coughs, sore throat, and vomiting in the LMA group. However, the incidence of bronchospasm and laryngospasm did not differ between the two groups, as evidenced in our study. In a study by Yu & Beirne (2010) the incidence of hoarseness, laryngospasm, coughs and sore throat was higher in the ETT group compared to the LMA group.

Nausea and vomiting showed no statistically significant differences between the two groups, and except for the results on laryngospasm rest of the results obtained with regard to all the complications were similar to our findings. In general, the use of LMA reduces the incidence of laryngospasm, hoarseness and coughs, while ETT reduces aspiration rates, as only one case of aspiration was reported in the ETT group in all the reviewed studies (Vahedian-Azimi *et al.*, 2016b). In a study by Âgha Âlishiri *et al.* (2010) the amount of intraocular pressure was higher in the ETT group compared to the LMA group, and LMA was found to be a better device for use in ocular surgeries for reducing intraocular pressure. Jahanbakhsh *et al.* (2014) found postoperative nausea and vomiting not to differ significantly between the ETT and LMA groups, which is consistent with the our findings.

Conclusion:

According to the results of our study, laryngeal mask airway (LMA) is more appropriate for elective outpatient surgeries in pediatric patients due to its fewer hemodynamic changes and complications, ease of insertion in cases where endotracheal tube (ETT) insertion gets difficult, and also faster insertion. A multicenter study with a large sample size is recommended to be conducted to evaluate the incidence of laryngospasm caused by the insertion of both devices so that the superiority of one of the two devices over the other can be determined with greater certainty.

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