

Efficacy of Laryngeal Mask Airway in Neonatal Resuscitation

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ABSTRACT

Aim: This study aimed at evaluating the use of LMA for resuscitation in the delivery room among newborn infants whom positive pressure ventilation (PPV) by bag and mask had failed.

Materials and methods: This is a single center, prospective, unblinded, randomized clinical trial of LMA ventilation versus ETT on neonates during resuscitation upon delivery at Ain Shams Maternity Hospital during the period between January 2012 and January 2015. The Study included 80 newborns delivered in the Maternity hospital, Ain Shams University with gestational age of 34 weeks or more who needed neonatal resuscitation in the delivery room which was performed according to the current guidelines for neonatal resuscitation by the American Academy of Pediatrics. **Results:** In Our Study, there was significant correlation between the LMA and the ETT as both of them succeeded to achieve adequate ventilation of the resuscitated infants. Both groups showed statistical significant improvement between their Oxygen saturation at 1 minute & at 5 minutes. The ETT showed more improvement as the mean difference between 1 & 5 minutes was -27.4 ± 3.07 compared to -26.5 ± 3.4 among the LMA, but with insignificant difference between both groups. Comparison between Apgar score at 1 & 5 minutes in both groups is apparent, which showed statistical significant improvement in the 2 groups. However, the ETT group showed more improvement (although non-significant) as the mean difference between 1 & 5 minutes was -5.02 ± 0.9 compared to -4.6 ± 0.7 among the LMA group.

Conclusion: The Laryngeal Mask Airway can be used as an efficient and successful alternative to endotracheal intubation in newborns > 2000 Gms who require neonatal resuscitation.

Keywords: LMA, Neonatal Resuscitation, ETT, LMA.

INTRODUCTION

Difficult airway management in neonates and young infants still remains a challenge, even for well-trained pediatricians or anesthesiologists. This holds true particularly when a difficult airway is encountered unexpectedly, e.g. after induction of anesthesia or in respiratory emergencies. If mask ventilation and/or direct laryngoscopy fails, supraglottic airway devices, i.e. pediatric-sized laryngeal masks (LMA), have been demonstrated to be a reliable rescue device¹. The LMA is an airway device that is inserted through the mouth without instrumentation and forms a low-pressure seal around the glottis rather than passing through the glottis. It has been used as an effective and less invasive alternative to endotracheal intubation (ETT)². Complications associated with ETT such as esophageal intubation, bronchial intubation, bronchospasm, drying of mucosa and effects on mucociliary function, laryngospasm and acute traumatic complications as injury to the lips, teeth, tongue, nose, pharynx, larynx, trachea and bronchi can occur during laryngoscopy and intubation. Also, noxious autonomic reflexes as hypertension, tachycardia, arrhythmias, intracranial and intraocular hypertension as well as esophageal, tracheal and

bronchial perforation². So we aimed at our study to evaluate the effectiveness of LMA compared to endotracheal tube in resuscitation of newborn infants who fail to respond to bag and mask ventilation.

PATIENTS AND METHODS

This is a single center, prospective, unblinded, randomized clinical trial of LMA ventilation versus ETT on neonates during resuscitation upon delivery at Ain Shams Maternity Hospital during the period between January 2012 and January 2015.

Ethics committee of Ain Shams University Hospital approved the study and a written informed consent was obtained from a parent by a member of the neonatal team involved in the study before delivery.

Patients

The Study included 80 newborns delivered in the Maternity hospital, Ain Shams University with gestational age of 34 weeks or more and who needed neonatal resuscitation in the delivery room which was performed according to the current guidelines for neonatal resuscitation by the American Academy of Pediatrics³.

The studied patients were randomly assigned into 2 groups:- Group A: included 40 newborns, who were

resuscitated by LMA as the secondary airway alternative.

- Group B: included 40 newborns, who were resuscitated by ETT as the secondary airway alternative.

In both groups, if 2 attempts to introduce the LMA in the 1st group or the ETT in the 2nd group failed, the other alternative was used.

Inclusion criteria

Inborn infants satisfying the following inclusion criteria were eligible to participate in the study:

1. Gestational age ≥ 34 weeks.
2. Expected birth weight $> 2,000$ gm.
3. Need for PPV (positive pressure ventilation) at birth; the need for PPV was determined by the presence of apnoea or gasping, or heart rate < 100 beats per minute (bpm) after initial resuscitation measures (providing warmth, positioning, clearing the airway, drying and stimulation) over the first 30 seconds, then ambu bagging for another 30 seconds by face mask.

Exclusion criteria

1. Lethal anomalies.
2. Hydrops.
3. Major malformations of the respiratory system.
4. Congenital heart disease.
5. Stillbirths; a stillbirth was diagnosed when a heart rate is never established
6. Neonates who require chest compressions.
7. If there was severe fetal distress or meconium-stained fluid.

Primary outcome measure

The primary outcome of this study was the proportion of newborns needing endotracheal intubation after Laryngeal Mask airway insertion.

Secondary outcome measures

1. Apgar score at 1 & 5 minutes.
2. O₂ saturation at 1 & 5 minutes.

Randomization

Eligible infants were assigned to the LMA or the ETT group in a 1:1 ratio according to simple systematic randomization. Closed envelope technique was done to identify the first case. Once eligible to be enrolled in one of the groups, the subsequent case would be assigned to the other group till the desired sample size was attained. The assigned procedure (PPV with LMA or ETT) was then performed.

Blinding

Due to the characteristics of the intervention, neither caregivers nor outcome assessors were masked for the treatment allocation.

Guidelines for management

When infants require resuscitation in the delivery room (PPV by pressure-limited self-inflating bag), pediatric resident and the obstetric nurse recorded the interventions using a standardized form including Apgar score, drugs administered.

The members of the resuscitation team completed training based upon the American Academy of Pediatrics Neonatal Resuscitation Program (NRP). In addition to the standard NRP curriculum, physician providers received a brief supervised training with the device in the form of 2 hours of practical instruction on the use of the LMA from pediatric anesthesiologists and they initially learned to place the LMA in a mannequin model followed by five supervised placements during elective procedures then complete two supervised LMA placements during neonatal resuscitation.

At birth, the newborn was provided with warmth, drying, clearing airway (if necessary) and stimulation for 30 seconds. Clinical assessment was done through observation of heart rate and respiration, if no response (apnea or gasping with heart rate less than 100 bpm); Positive pressure ventilation was done using Bag & Mask Ventilation (BMV). After 30 seconds. If an infant did not respond to BMV, the clinician selects randomly between LMA and ETT as the secondary airway alternative.

Resuscitation starts immediately after delivery of the infant, when a stop watch is switched on by one of the members of the resuscitation team. The duration of resuscitation was defined as the time period from starting resuscitation to the establishment of a spontaneous and sustained respiratory pattern of efficacious respiratory movements, which allow the neonate to maintain adequate clinical parameters (heart and respiratory rate). In this study, the size 1 LMA was used. All of the following were done to the neonates and included in the study:

1- History taking including:

- Antenatal History: 1st day of last menstrual period for GA assessment and history of PROM.
- Natal History: Mode of delivery, recorded APGAR scores at 1, 5 minutes
- Postnatal history: Admission to NICU & cause of admission.

2- Thorough clinical examination including GA assessment using modified Ballard score and birth weight measurement.

3- Follow up parameters of the studied neonates include the following:

- Failure of attempts:
A failed attempt was defined as a failure to establish an effective airway and removal of device from the mouth⁴.
- Number of attempts:
A maximum number of 2 attempts were allowed for laryngeal mask before using the endotracheal tube.
- Insertion time:
The time needed to establish an effective airway with proper chest expansion 14.8 sec ± 5.4 sec (Trevisanuto *et al.*, 2012)
- Post Resuscitation ABG (after discontinuation of PPV)
- Oxygen Saturation at 1 minute & 5 minutes recorded by pulse oximeter
- Total Time on Positive pressure ventilation.

Sample size

We researched the medical records of all babies delivered at the Ain Shams Maternity University Hospital between July 2011 and December 2011 to identify those delivered more than 34 weeks gestation, based on best obstetric estimates. The Maternity Hospital is a tertiary teaching hospital with approximately 1500 births each month. The requirement for resuscitation with positive pressure ventilation (PPV) using endotracheal tube (ETT) was recorded and analyzed. It was found to be

around 3% of total both cesarean and vaginal deliveries during these six months period. A sample size of 40 neonates was calculated to be necessary on the basis of these medical records. Of these, about 90% are newborns weighing >1,500 g or delivered ≥34 weeks gestation.

RESULTS

Table (1) compare between the types of management LMA & ETT as regard qualitative data using Student’s t test & Mann Whitney U test. Regarding the insertion time, the ETT group (18.08± 4.8 sec) had longer insertion time than LMA (9.7± 3.25 sec) in a statistical significant manner (Fig. 19). In addition, the pH among ETT group was higher (7.3±0.07) compared to LMA group (7.28 ± 0.09) with highly significant difference. The PO2 was higher among ETT group (58.39 ±10.9 mmHg) compared to LMA group (52.74±13.07 mmHg) with statistical significant difference (Fig. 20). The Oxygen saturation & Apgar score showed no significant differences between the 2 groups which means that there was no bias in the distribution of neonates in the management group. The Oxygen saturation at 5 minutes was better among ETT (94±1.9) than those among LMA group (93.3±2) but with no statistically significant difference.

Table (1): Comparison between ETT & LMA groups as regards quantitative data

Variable	Management		T*	P
	ETT (Mean±SD ¹)	LMA (Mean±SD)		
Gestational age in weeks	36.2±1.8	36.3±1.8	0.1	0.9 NS
Weight in Kg	2.76±0.6	2.9±0.65	-1.38	0.1 NS
Insertion time in seconds	18.08±4.8	9.7±3.25	9.03	0.000 HS
Ventilation time (min)	5.55±0.67	5.77±1.62	-0.8	0.4 NS
PH	7.34±0.07	7.28±0.09	2.83	0.006 HS
PCO ₂ (mmHg)	48.68±4.7	49.7±4.88	-1.02	0.3 NS
PO ₂ (mmHg)	58.39±10.94	52.74±13.07	2.09	0.04 S
HCO ₃ (mmol/L)	24.94±3.6	23.27±4.42	1.84	0.07 NS
Base deficit	-6.58±5.02	-7.14±6.62	0.42	0.6 NS
O ₂ Saturation 1 minute	66.8±2.2%	66.6±2.2%	0.29	0.7 NS
O ₂ Saturation 5 minutes	94±1.9%	93.3±2%	-1.5	0.1 NS
	ETT (median (IQR) ²)	LMA (median (IQR))	Z ^{\$}	P
APGAR 1 minute	4 (3-4)	3(3-4)	-1.8	0.08
APGAR 5 minutes	8 (8-9)	8 (8-9)	-0.1	0.8
	ETT_N (%)	LMA_N (%)	X ^{2**}	P
Attempts	1	40 (51.3%)	2.05	0.1 NS
	2	0		

*Independent student T test

**Chi square test

\$ Mann Whitney U test

1SD: Standard deviation

2IQR: interquartile range

3IMV: Mechanical ventilation

NS: non-significant

S: Significant

HS: highly significant

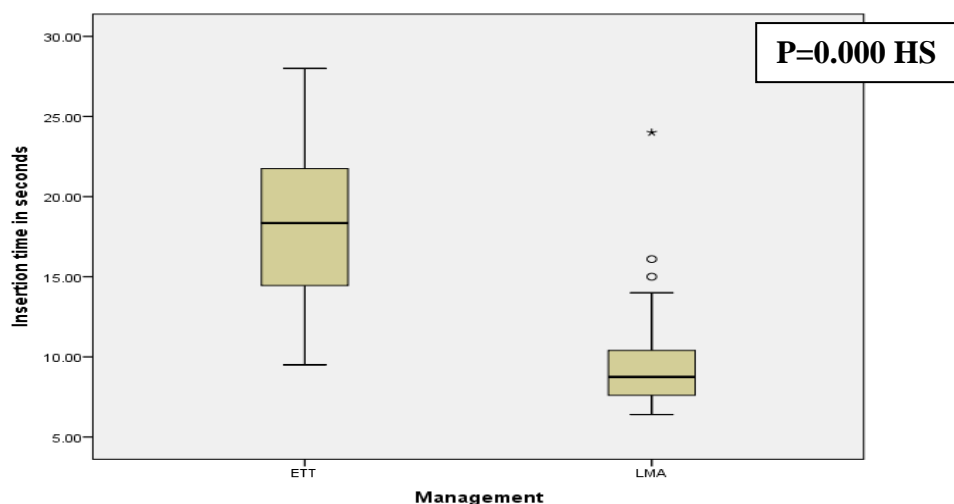


Figure (1): Boxplot comparing the insertion time in seconds between LMA & ETT groups

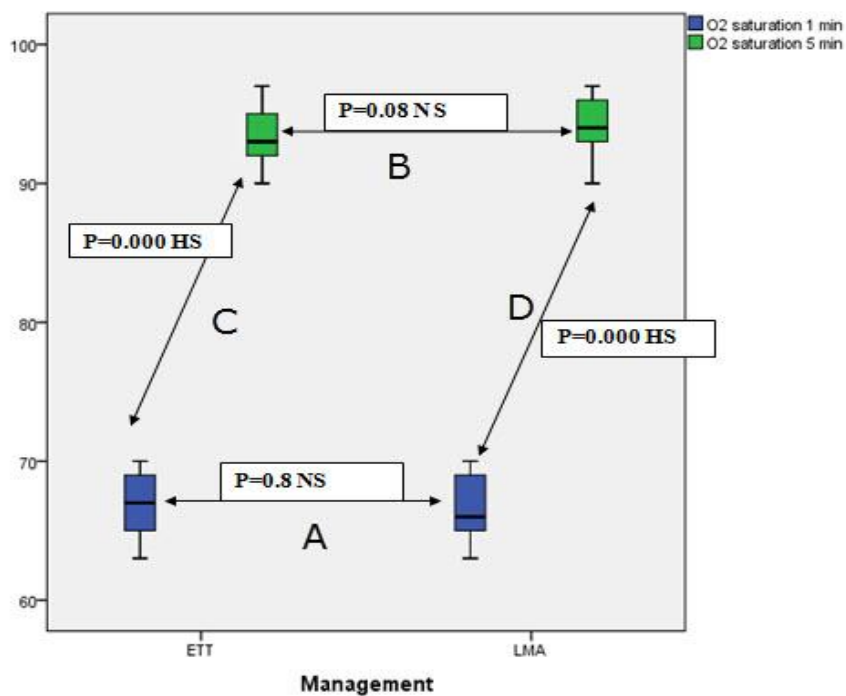


Figure (2): Boxplot showing comparison between Oxygen saturation at 1 & 5 minutes among study group

Table (2): Comparison between the management variable & the rate of improvement in APGAR score at 1 & 5 minutes

Management		Improved	Mean±SD	Difference of the mean ±SD	Z*	P
LMA ¹ n=40	APGAR 1 minutes	40	3.5±0.5	-4.6±0.7	-5.6	0.001 HS
	APGAR 5 minutes		8.1±0.7			
ETT ² n=40	APGAR 1 minutes	40	3.1±0.6	-5.02±0.9	-5.58	0.000 HS
	APGAR 5 minutes		8.17±0.7			

*Z : Wilcoxon Rank test

1LMA: Laryngeal mask airway

HS: highly significant

2ETT: Endotracheal tube

DISCUSSION

In our study the mean gestational age was 36 wks in both LMA &ETT groups. Some studies such as **Paterson *et al.*⁵**, **Gandini & Brimacombe⁶** and **Esmail *et al.*⁷** included newborns without specified gestational age limits. **Zhu *et al.*⁸** concluded that the LMA was safe, effective and easy to implement for the resuscitation of neonates with a gestational age of 34 or more weeks. **Trevisanuto *et al.*** conducted a study in a middle-income country, confirmed that the neonatal LMA supreme was more effective than a face mask in preventing endotracheal intubation in newborns with a gestational age of 34 weeks or more and/or an expected birth weight of at least 1500 g needing PPV at birth¹¹.

The mean body weight on delivery in ETT group was 2.700 gms and in LMA group was 2.900 gms. The most suitable neonatal weight for usage of LMA size 1 for optimum sealing and fixation is between 2 and 4 kgs **Brimacombe *et al.*⁶** In contrast **Paterson *et al.*⁵**, **Gandini & Brimacombe⁶**, and **Esmail *et al.*⁷** (included newborns without specified weight limits. Gandini's subjects included 29 "low birth weight" newborns with newborns < 1500 grams. In our study, we used the size-1 LMA-Classic (**size-1 LMA-Classic™, The Laryngeal Mask Company Limited, UK**) to perform LMA ventilation. However, according to **Anand *et al.***, the new models of LMA such as LMA supreme were proposed to have a better laryngeal seal or second generation supraglottic devices such as the i-gel might be more effective¹⁰.

We used Laryngeal Mask size 1 in our study as it is the least available size and used by other studies and current resuscitation guidelines do not recommend the LMA for neonates weighing less than 2000 gms¹¹.

In Our Study, There was only one attempt of insertion for all patients except 2 patients who needed 2 attempts in the LMA group. While the study carried out by **Paterson *et al.*⁵** and **Brimacombe⁶** showed the success rate of 95%. So, LMA was used successfully as a tool in neonatal resuscitation. The placement of LMA was considered easier and more successful by the trainees in anaesthesia. While the test on neonatal intubation trainee model have shown that junior doctors can obtain a clear airway more rapidly with LMA than ETT and with fewer failures. The number of attempts required for insertion of LMA was 1-2 with only one failure. Internationally the number of attempts is mostly one³. Another study showed that, the LMA was inserted successfully during the first

attempt in all 104 newborns and effective ventilation was achieved in 103/104. Compared with ETT, the potential advantages of using an LMA include rapid insertion without requiring laryngoscopy and a higher first attempt success rate, even among novice providers¹².

In ETT group, the Insertion mean time was 18.08 seconds with a standard deviation time of 4.8 seconds, while in LMA group the mean was 9.7 seconds with standard deviation of 3.25 seconds. In the Study by **Brimacombe** the average time for insertion for LMA was 18.08 sec, while **Paterson** showed an average time for LMA placement was 8.6 ± 1.4 seconds. In all the published data most of the insertion was successful in less than 20 sec. **Vadhera and Feroze *et al.*** stated in their study that time for LMA insertion was 9 ± 1.4 (8-12) sec and for ETT insertion, it was 9.5 sec. In **Yang *et al.*** study, both devices were quickly inserted and they found no difference in the insertion time (LMA in 36 subjects: 7.58 ± 1.15 seconds vs ETT in 32 subjects 7.89 ± 1.52 seconds)¹².

In our Study, The median Apgar was 3 at 1 minute in LMA group and 4 for the ETT group while the score was 8 at 5 minutes for both groups. In the study done by **Yang *et al.*** there were no statistically significant differences between these two groups in success rate of resuscitation or the Apgar scores at 1 and 5 min after birth. **Trevisanuto *et al.*** concluded that in cases of an Apgar score <5 at 5 min, subsequent intensive care unit admission, and respiratory insufficiency requiring mechanical ventilation were significantly lower in the LMA group than in the ETT group due to many complications avoided by using LMA⁴.

In our study, the ETT group pH value was 7.34 ± 0.07 while that for LMA was 7.28 ± 0.09 . PCO₂ in ETT was 48.68 mmHg, while in LMA it was 49.7 mmHg. Po₂ in ETT was 58.39 mmHg and in LMA it was 52.74 mmHg. A case report by **Yolanda** in 2004 showed improved ABG values with use of LMA in a distressed neonate with micrognathia as follows PH improved from 7.18 to 7.35, PO₂ 128 to 250 and PCO₂ from 56 to 40¹⁶.

Study conducted by **Yang *et al.*** showed that pH after using LMA was 7.27 ± 0.95 while in ETT it was 7.23 ± 0.74 . PCO₂ was 49.78 ± 13.02 mmHg after using LMA while it was 44.85 ± 14.55 mmHg after using ETT. PO₂ was 80.03 ± 12.40 mmHg after LMA while it was 84.93 ± 10.39 mmHg with ETT. Oxygen Saturation at 1 minute was $66.8 \pm 2.2\%$ and $66.6 \pm 2.2\%$

for ETT and LMA respectively and at 5 minutes it was $94 \pm 1.9\%$ and $93.3 \pm 2\%$ for ETT and LMA respectively¹⁵. As regards, the problems of neonatal intubation, including varying success rates and number of attempts, **Zhu *et al.***⁸ have demonstrated a high success rate for LMA placement at the first attempt (202/205 infants; 99%). This matches the previously reported success rates of **Gandini and Brimacombe**⁶ (99%) and **Trevisanuto *et al.*** (99%). This is reassuring, because different investigators have documented these high success rates⁵.

CONCLUSION

So, we concluded that the Laryngeal Mask Airway can be used as an efficient and successful alternative to endotracheal intubation in newborns > 2000 Gms who require neonatal resuscitation.

The LMA had similar effectiveness to ETT when resuscitating moderate/severely depressed newborns. It may be used as the first alternative airway instead of ETT, to provide positive-pressure ventilation among newborns who do not respond to face mask ventilation. Also, it can be used as a faster alternative for less trained medical staff until senior assistance is available or when ETT is unfeasible, and in the case of difficulty of intubation in congenital anomalies.

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