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Supreme Laryngeal Mask Airway versus Face Mask during Neonatal Resuscitation: A Randomized Controlled Trial

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Objective To assess the effectiveness of supreme laryngeal mask airway (SLMA) over face mask ventilation for preventing need for endotracheal intubation at birth.

Study design We report a prospective, randomized, parallel 1:1, unblinded, controlled trial. After a short-term educational intervention on SLMA use, infants ≥34-week gestation and/or expected birth weight ≥1500 g requiring positive pressure ventilation (PPV) at birth were randomized to resuscitation by SLMA or face mask. The primary outcome was the success rate of the resuscitation devices (SLMA or face mask) defined as the achievement of an effective PPV preventing the need for endotracheal intubation.

Results We enrolled 142 patients (71 in SLMA and 71 in face mask group, respectively). Successful resuscitation rate was significantly higher with the SLMA compared with face mask ventilation (91.5% vs 78.9%; $P = .03$). Apgar score at 5 minutes was significantly higher in SLMA than in face mask group ($P = .02$). Neonatal intensive care unit admission rate was significantly lower in SLMA than in face mask group ($P = .02$). No complications related to the procedure occurred.

Conclusions In newborns with gestational age ≥34 weeks and/or expected birth weight ≥1500 g needing PPV at birth, the SLMA is more effective than face mask to prevent endotracheal intubation. The SLMA is effective in clinical practice after a short-term educational intervention. *(J Pediatr 2015;■:■-■).*

Trial Registration Registered with ClinicalTrials.gov: NCT01963936.

The ability to maintain a patent airway and provide effective positive pressure ventilation (PPV) is the main objective of neonatal resuscitation.[1,2] This is currently achieved with the use of a face mask or an endotracheal tube (ETT). In certain situations, both face mask ventilation and endotracheal intubation may prove difficult to establish an upper airway.[3,4]

In 1981, Archie Brain designed the laryngeal mask airway (LMA) with the aim of producing an airway device that would be more practical than the face mask and less invasive than the ETT.[5-7]

In adult and pediatric patients, LMA is routinely used during anesthesiology procedures.

By meta-analysis the use of LMA in pediatric anesthesia results in a decrease of common postanesthetic complications.[8]

For the neonatal resuscitation, when LMA was used by teams with expertise (ie, anesthesiologists, neonatologists), it provided effective PPV in most of the treated patients (range 95%-99%).[9-12] Two systematic reviews assessing the use of LMA vs face mask ventilation in the resuscitation of newborn infants suggest that a well-designed randomized controlled trial (RCT) comparing these 2 airway adjuncts is warranted.[13,14] In the last years, new models of LMA have been developed. Ease of insertion, high seal, and gastric access are advantages of the latest model, the supreme LMA (SLMA), over the classic LMA.[15] Furthermore, it is important to record any side effects, as in a case series of a comparison of LMA over face mask in infants in the operating theater, significantly more side effects were reported using LMA over face mask.[16]

Although previous studies showed that the LMA was effective in preterm infants weighing <2000 g,[10,11] the latest version of the International Guidelines for Neonatal Resuscitation states that "a LMA should be considered during resuscitation if face mask ventilation is unsuccessful and tracheal intubation is unsuccessful or not feasible. The LMA may be an alternative to a face mask for PPV among newborns weighing >2000 g or delivered ≥34-week gestation."[1,2] Despite this recommendation, it has not yet been by RCT whether or not LMA is more effective than face mask in resuscitation of the newborn infants. Our aim was to

ETT	Endotracheal tube
LMA	Laryngeal mask airway
NICU	Neonatal intensive care unit
PPV	Positive pressure ventilation
RCT	Randomized controlled trial
SLMA	Supreme LMA

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assess the effectiveness of SLMA over face mask ventilation in preventing need for endotracheal intubation at birth.

Methods

This was a single center, prospective, unblinded, randomized, controlled trial conducted at the National Hospital of Obstetrics and Gynecology, Ha Noi, Vietnam. This center, where about 21 000 deliveries occur every year, is a level III hospital with large referral services for maternal and neonatal care. In the Neonatal Department, there are 60 and 90 intensive care and postintensive care cots, respectively. Six mechanical ventilators and 30 continuous positive airway pressure machines are available for neonatal intensive care.

Inborn infants satisfying the following inclusion criteria were eligible to participate in the study: gestational age ≥34 weeks by best obstetric estimate (last menstrual period or early dating scan), expected birth weight >1500 g, need for PPV at birth, and written parental consent. Exclusion criteria included presence of major malformations, hydrops, and nonvigorous babies with meconium-stained amniotic fluid. The protocol was approved by the ethics committee for human investigation at the C hospital, Hanoi, Vietnam (SO:901/QD-PSTW; Ha Noi, August 9, 2012).

Before starting the study, all those involved in the neonatal resuscitation participated in a 1-day theoretical and practical (manikin) course based on the neonatal resuscitation program.[17] All participants had previously participated in at least 1 course on neonatal resuscitation.

Health care providers were trained in face mask ventilation on the manikin to ensure optimal technique. According to the neonatal resuscitation program, we recommended to use the acronym "MR SOPA" for face mask ventilation failure. In addition, 1 section was dedicated to the preparation and insertion of the size 1 SLMA (LMA Supreme, Teleflex, San Diego, California).[15]

Forty-four participants (15 physicians and 29 nurses) were trained. To reinforce all aspects on the SLMA use, we organized 2 further (internet) videoconference meetings between the principal investigator (D.T.) and the personnel involved in neonatal resuscitation, and we prepared a didactic video including all the steps of the SLMA usage. After these interventions, a period was left to routinely introduce the SLMA in the delivery rooms. A minimum of 5 successful SLMA insertions in the manikin and 3 SLMA insertions in the clinical setting were required of all participants before starting the study. Compliance with the protocol was ensured by 2 members of the project (T.C., N.H.) who were responsible for local data collection. They monitored weekly the adherence to the study protocol and input the patients' data in an Excel database (Microsoft Corp, Redmond, Washington). Written and oral information, whenever possible, was offered to parents on maternal admission. Informed written consent was signed by a parent or guardian. A senior investigator was available at all times to discuss concerns raised by parents or clinicians during the course of the trial.

Interventions

All infants were cared for based on the American Heart Association and American Academy of Pediatrics Guidelines for Neonatal Resuscitation.[1,2,17] After initial steps (warming, clearing airway, drying, and stimulation), PPV with SLMA or face mask with bag was initiated in case of apnea and/or gasping and/or heart rate <100 bpm.

PPV was administered with a 240-mL self-inflating bag with the pop-off valve limit at 35 cm H_2O (Laerdal Medical, Stavanger, Norway). Neither a manometer for measuring inspiratory pressure nor a positive end-expiratory pressure valve were available. Peak inspiratory pressure was decided by the attending resuscitator based on neonatal clinical signs (chest rise and increase of heart rate).

Silicone, round-shaped face masks (size 0 and 1) (Laerdal Medical) were available at each delivery. The neonate's trachea was intubated if the heart rate did not rise or remained less than 60 bpm after 30 seconds of PPV with the SLMA or the face mask. A maximum of 3 attempts to achieve effective PPV with a SLMA or a face mask were allowed.

Manual ventilation was initiated in room air at a frequency of 40-60 breaths per minute.[1,2,17] Oxygen concentration was increased to 100% (flow rate 6-8 L/min) in case of persistent cyanosis and/or heart rate <100 bpm after 90 seconds from the beginning of PPV. At least 1 trained person involved in the study took part in the resuscitation of all enrolled patients. Resuscitation started immediately after delivery of the infant when a stop-watch was started by a member of the resuscitation team.

Outcomes

The primary outcome of this study was the success rate of the resuscitation devices (SLMA or face mask). The success of resuscitation was defined as the achievement of an effective PPV (chest movements and increasing heart rate) preventing the need for endotracheal intubation.

Secondary outcomes included Apgar score at 5 minutes, time to first breath (defined as the first respiratory effort), time to first cry (defined as the first audible cry spontaneously emitted by the infant), death or moderate to severe hypoxic-ischemic encephalopathy within 7 days of life, according to a modification of Sarnat and Sarnat,[18,19] admission to neonatal intensive care unit (NICU)/normal nursery, and complications secondary to the procedure.

Data were recorded from clinical records and from a data sheet designed for this study, where all the data from the resuscitation procedures were collected by an observer not involved in the resuscitation maneuvers.

Sample Size

The sample size was based on a previous study in which the success rate of classic LMA and face mask were 99% and 84%, respectively.[20] To achieve a 90% power at a 0.05 level of significance (1-sided), at least 58 subjects per group need to be enrolled. The number of patients were increased by 20% for each group considering the possibility of dropouts, leading to a final sample of 142 subjects.

Random Assignment

Eligible infants were assigned to SLMA or face mask group 1:1 according to a computer-generated, randomized sequence. The randomized allocation was concealed in double-enclosed, opaque, sealed, and sequentially numbered envelopes.

In the delivery room or operating room, the next sequential randomization envelope was opened only when the infant was considered to be eligible by the attending operator. The assigned procedure (PPV with SLMA or face mask) was then performed. Infants of multiple births were randomized separately. Neither caregivers nor outcome assessors were masked to treatment allocation.

Statistical Analyses

Categorical data were expressed as number and percentage and compared using Fisher test. Continuous data were expressed as mean and SD or median and IQR. Normality assumption of continuous variables was evaluated using Shapiro-Wilk test. Continuous data were compared using Student t test or Mann-Whitney nonparametric test. The comparison between LMA group and face mask group in terms of rate of achievement of an effective PPV (primary outcome) was performed using a 1-tailed test, based on a previous study reporting results in favor of LMA.[20] All other comparisons (secondary outcomes) were performed were performed using 2-tailed tests. A P value of less than .05 was considered statistically significant. Statistical analysis was performed using R 2.12 language.[21]

Results

Patients were enrolled from November 3, 2012, to December 21, 2013 (trial was registered on October 11, 2013). During the study period, 756 of 25.211 infants ≥34-week gestation and/or birth weight >1500 g born at the National Hospital of Obstetrics and Gynecology needed PPV in delivery room. Of the 599 who were assessed for eligibility, 142 were randomized, 71 were assigned to SLMA group, and 71 to face mask group. No dropouts occurred (**Figure**; available at www.jpeds.com).

The 2 groups were comparable for maternal and neonatal characteristics with the exception that cesarean delivery rate was higher in SLMA group than in face mask group (90.1% vs 73.2%, respectively; P = .02). All cesarean deliveries were performed under regional anesthesia. Indication for initiating PPV was similar between the 2 groups (**Table I**).

The success rate of the resuscitation was significantly higher with SLMA than face mask (91.5% vs 78.9%; P = .03). Among the 37 patients with birth weight between 1500 and 2000 g, the success rate was 86.7% (13/15) and 59.1% (13/22) in SLMA and face mask groups, respectively (P = .14). Postnatal age at intubation was 75 seconds (45-90) and 60 seconds (30-90) for SLMA and face mask group, respectively. Apgar score at 5 minutes was higher in SLMA than in face mask group (P = .02). NICU admission rate was significantly lower in SLMA than in face mask group (P = .02). Six infants (3 in SLMA and 3 in face mask group) initially admitted to normal nursery were subsequently transferred to NICU. Time for the first breath and time for the first cry were comparable between the 2 groups. No complications related to the procedure occurred. Death or hypoxic-ischemic encephalopathy was reported in 5 patients (3 in SLMA and 2 in face mask group; P = .99) (**Table II**). Postnatal age at device insertion, number of SLMA/face mask positioning attempts for effective ventilation, time for effective ventilation, length of PPV, and max inspiratory pressure were similar between the 2 groups (**Table III**).

Table I. Maternal and neonatal characteristics

	SLMA (n = 71)	Face mask (n = 71)	*P* value
Primiparus	22 (31.0)	27 (38.0)	.48
Maternal anemia	2 (2.8)	6 (8.5)	.27
Maternal hypertension/ preeclampsia	6 (8.5)	9 (12.7)	.59
Diabetes	1 (1.4)	7 (9.9)	.06
Placenta abruption	4 (5.6)	0	.12
Amniotic fluid			.62
Clean	60 (84.5)	63 (88.7)	
Meconium stained	11 (15.5)	8 (11.3)	
Delivery			.02
Cesarean	64 (90.1)	52 (73.2)	
Vaginal	7 (9.9)	19 (26.8)	
Gestational age (wk)*	38 (36-39)	37 (35-39)	.47
Birth weight (g)*	2700 (2100-3200)	2500 (2000-3000)	.21
Patients with birth weight 1500-2000 g	22 (31.0)	15 (21.1)	.25
Male sex	36 (50.7)	39 (54.9)	.73
1-min Apgar score	4 (4-5)	5 (4-6)	.42
Indications for initiating PPV			
Heart rate <100 bpm	37 (52.1)	31 (43.7)	.40
Apnea	57 (80.3)	50 (70.4)	.24
Gasping	9 (12.7)	16 (22.5)	.19

Data expressed as n (%) or *median (IQR).

Table II. Outcomes

	SLMA (n = 71)	Face mask (n = 71)	*P* value
Primary outcome			
Success of resuscitation device	65 (91.5)	56 (78.9)	.03*
Secondary outcome			
5-minute Apgar score†			.02
0-3	1 (1.5)	1 (1.5)	
4-7	5 (7.1)	15 (22.7)	
8+	64 (91.4)	50 (75.8)	
Time to the first breath (s)‡	50 (30-60)	50 (30-60)	.51
Time to the first cry (s)‡	85 (60-91)	60 (60-90)	.38
Death or HIE	3 (4.2)	2 (2.8)	.99
Complications	None	None	-
Admission			.02
NICU	20 (28.2)	34 (47.9)	
Normal nursery	51 (71.8)	37 (52.1)	

HIE, hypoxic-ischemic encephalopathy.
Data expressed as n (%) or median (IQR).
*One-sided test.
†Data not available for 6 subjects.
‡Data not recorded in 1 subject.

Table III. Information on procedure

	SLMA (n = 71)	Face mask (n = 71)	*P* value
Postnatal age at insertion (s)	30 (30-35)	30 (30-30)	.10
Number of positioning attempts for obtaining effective ventilation*			.99
One	65 (91.6)	66 (93.0)	
Two	6 (8.4)	5 (7.0)	
Time needed for obtaining an effective ventilation (sec)*	30 (30-60)	30 (20-60)	.12
Max inspiratory pressure (cm H_2O)†			.68
≤35	67 (94.4)	69 (97.2)	
>35	4 (5.6)	2 (2.8)	
Length of PPV (s)	60 (30-90)	40 (30-60)	.15

Data expressed as n (%) or median (IQR).
*Effective ventilation was defined as presence of chest movements and increasing heart rate.
†Based on the opening of the pop-off valve.

Chest compressions and medications were administered to 4 (1 in SLMA and 3 in face mask group; $P = .62$) and 5 patients (2 in SLMA and 3 in face mask; $P = .99$), respectively. Sixty-two (87.3%) in SLMA and 64 (90.1%) infants in face mask group received exclusive breastfeeding ($P = .79$). Patients were discharged at a median postnatal age of 5 days (IQR 3-7) in SLMA group and 5 days (IQR 4-6) in face mask group ($P = .60$).

Discussion

We found that SLMA was more effective than face mask in preventing endotracheal intubation in neonates needing resuscitation at birth. In 2013, a systematic review and meta-analysis of supraglottic airways in neonatal resuscitation reported the results of 4 RCTs stating that fewer infants in the LMA group required endotracheal intubation (1.5%) compared with the face mask group (12.0%).[14] Our results confirm that effective PPV can be more frequently achieved with a supraglottic device than with a face mask in newborns needing resuscitation.

There are unique features of this trial compared with prior studies on the use of the LMA during neonatal resuscitation. All these studies enrolled patients with gestational age ≥34 weeks and birth weight >2000 g.[14] These inclusion criteria were in agreement with International Liaison Committee on Resuscitation recommendations.[1,2] Based on previous observational studies,[10-12] we included smaller patients (birth weight >1500 g) because this population is more frequently in need of resuscitation in delivery room. Our results suggest that the SLMA can be effectively and safely used also in patients with a birth weight <2000 g.

A further relevant aspect to consider is that all previous studies were performed with a classic LMA.[14] In this trial, we used a more advanced model of LMA, the SLMA. The studies conducted in adult and pediatric anesthetized patients showed the efficacy and the safety of SLMA.[22,23] The SLMA was superior to the classic LMA with regard to insertion time and oropharyngeal seal pressure[24]; a further advantage is gastric access.

A previous neonatal manikin study confirmed these findings, including higher level of satisfaction expressed by users.[25] The results of this study add that a neonatal SLMA (size 1) is effective and safe also when used in the context of neonatal resuscitation. In the SLMA group, 6 out of 71 (8.5%) patients needed intubation. This percentage, however, was higher than that reported in previous studies where a classic LMA was used (1.5%).[14] The discrepancy could be due to the different experience in LMA use of resuscitators involved in the studies or to the features of the devices. For example, different from the classic LMA, the SLMA is equipped with a rigid tube that can lead to positioning difficulties in patients of different sizes.[15] Only a prospective RCT comparing the classic LMA and the SLMA will define the most appropriate supraglottic device to use in newborns needing PPV at birth.

In 2006, we conducted a theoretical and practical course on neonatal resuscitation at Kinshasa Hospital, Democratic Republic of Congo. All participants (7 midwives and 21 physicians), expressed a high degree of approval with regard to neonatal resuscitation by LMA and defined it a sustainable and cost-effective procedure.[26] The present study, conducted in a middle resource setting after a short training of the staff, confirms these features. As the effectiveness and safety of the SLMA as well as the grade of satisfaction expressed by the staff were high, we believe that using LMA use for neonatal resuscitation might be easier than tracheal intubation, especially in settings where staffs are not familiar with tracheal intubation. Furthermore, it is important that our results are in agreement with a recent RCT showing that basic life support trained nurses were able to ventilate more efficiently with SLMA than with face mask or laryngeal tube suction-disposable after 1 hour of introductory training.[26] The findings of our study are important for other units/settings in high as well low resource countries where neonatal resuscitation is more often performed by pediatricians, midwives, or nurses. In agreement with the study by Zhu et al, our results confirm that a short-term educational program on the LMA use is effective in the clinical practice.[20]

In the SLMA group, the 5-minute Apgar score was significantly higher than in the face mask group. As in this RCT, the baseline characteristics of the patients and the 1-minute Apgar score were comparable between the 2 groups; we believe that the Apgar score at 5 minutes after birth was the result of an effective resuscitative management, including PPV.

Another interesting result of this study was that the infants resuscitated with the SLMA were less frequently admitted to the NICU in comparison with those who were ventilated with the face mask.

Our group reported the same finding in a previous observational, retrospective study including near-term infants.[12] As in that study, the choice of PPV device was left at the clinician's discretion, we hypothesized a risk of selection bias. In this study, based on a more robust design (RCT) and conducted in a different setting, we observed the same "protective effect" of the SLMA on the need of NICU admission.

Although this observation remains to be explained, it has to be considered in future studies.

In this study, we strictly monitored and collected potential complications and side effects because of the SLMA. Fortunately, there were no side effects or complications with either device (SLMA and face mask). These findings are in agreement with previous work and suggest the SLMA can be safely managed by users with limited experience in neonatal resuscitation (ie, nurses, midwives, and pediatricians) after an educative program.[9-13,20]

In addition to improving PPV at birth, there are significant cost implications associated with using face mask (cost per face mask ~5 € [$6.70] each compared with SLMA ~€ 15 [$20.10] each). Both the SLMA and face mask are single-use devices. The SLMA is 3 times the price of the face mask. However, if using the SLMA-reduced intubation and other clinically important outcomes, the difference in cost between them may be much smaller than the cost of using an ETT and ventilator circuit, or caring for an infant with hypoxic-ischemic brain injury.

There are some limitations to this study. Because of the characteristics of the intervention, neither caregivers nor outcome assessors were masked to treatment allocation. In addition, most of the outcomes, such as Apgar scores and "need" for intubation or NICU admission, are subjective. To minimize bias, strict criteria and definitions were maintained during the trial. The consent and enrollment process meant that the infants did not represent all resuscitated infants.

As this study was conducted in a middle resource setting, some relevant information, such as transcutaneous saturations and/or blood gas analyses immediately after birth, were not available.

A very high percentage of patients enrolled in this trial were born by cesarean delivery, and cesarean delivery rate was higher in the SLMA group. In part, this feature reflects the hospital population, where high-risk pregnancies are concentrated. The cesarean delivery rate for all (enrolled + nonenrolled) infants ≥34 weeks born at the hospital during the study period was 56%. As the rate in the present study was higher, it may be a reflection of the requirement for antenatal consent.

In this study, we did not measure and record peak inspiratory pressures because manual ventilation was administered using a self-inflating bag without a manometer and a positive end-expiratory pressure valve. It is not possible to know if equivalent peak inspiratory pressures were used in both groups and if the results in favor of the SLMA could be explained by this issue.

In this RCT, we assessed the effectiveness and the safety of the neonatal SLMA in administering PPV at birth. The SLMA was more effective than face mask in preventing endotracheal intubation in newborns with gestational age ≥34 weeks and/or expected birth weight ≥1500 g needing resuscitation at birth. It is safe and effective in clinical practice after a short-term educational program. ■

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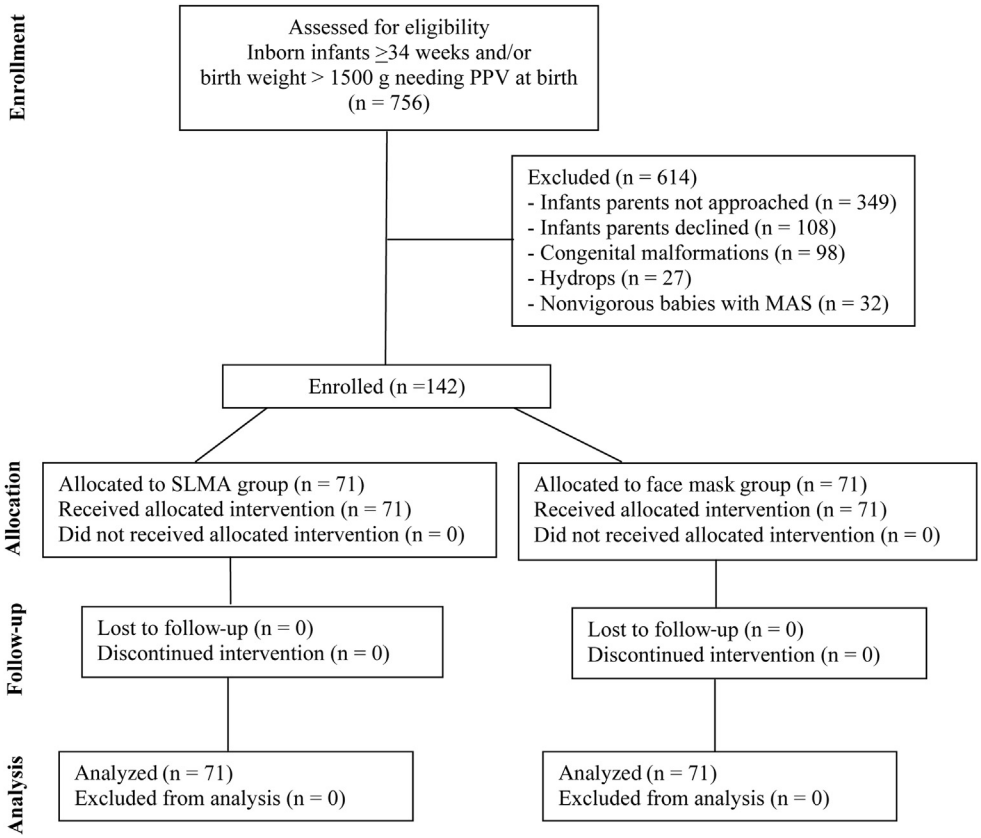

Figure. Flow of participants through screening stage, enrollment, and completion of the study protocol. *MAS*, meconium aspiration syndrome.