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;167:286-91).*

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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Supported by a development program of the Autonomous Provence of Trento, Italy, implemented in Vietnam by the Association Amici della Neonatologia Trentina (Trento, Italy), in collaboration with East Meets West Foundation (Oakland, CA). Laryngeal Mask Airway Co (Teleflex, San Diego, CA) provided SLMA used in this study. The authors declare no conflicts of interest.

http://dx.doi.org/10.1016/j.jpeds.2015.04.051

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.