TITLE
Airway support during neonatal resuscitation: How effective is a laryngeal mask?

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Airway support during neonatal resuscitation: How effective is a laryngeal mask?

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TYPE OF INVESTIGATION
Treatment

Population: In neonates born at ≥34 weeks of gestation and/or with a birth weight >1500g,
Intervention: is supreme laryngeal mask airway (SLMA)
Comparison: compared with face mask ventilation
Outcome: more effective in preventing the need for endotracheal intubation
Time: at birth?

METHODS
• Design: Randomized controlled trial
  • Allocation: 1:1 random assignment of the intervention according to computer-generated sequence. Multiple births were randomized as individuals
  • Blinding: Allocation was blinded using sealed, opaque, sequentially-numbered envelopes. Envelopes were opened when eligibility for the trial had been confirmed in the delivery room. There was no blinding of care-givers or those assessing outcomes.
  • Follow-up period: Data were collected for the period of resuscitation at birth until admission to the neonatal unit. Death and hypoxic-ischemic encephalopathy were measured at 7 days. There was no long-term follow-up.
  • Setting: This was a single centre study, in a large tertiary neonatal intensive care centre in Vietnam.
  • Patients: Infants born at ≥34 weeks of gestation at birth and with a birth weight of ≥1500g were eligible to participate if they were judged to require positive pressure ventilation (PPV) at birth (apnea and/or gasping and/or heart rate <100 beats per minute
Infants with major congenital anomalies or hydrops fetalis, and those born through meconium-stained liquor who were not vigorous at birth were excluded from the study.

- **Intervention:** Immediately after birth, a stop-watch was started and infants were managed according to recognised AAP resuscitation guidelines. An appropriately trained member of the resuscitation team ensured basic airway and temperature management was carried out. Following confirmation of eligibility and randomization, PPV was started delivered via either SLMA or face mask, using a 240ml, self-inflating bag with pressure limiting valve of 35cmH₂O. Manual ventilation was initiated at 40 to 60 breaths per minute in room air using a flow rate of 6-8 litres per minute, at peak inspiratory pressures at discretion of the resuscitator. The oxygen concentration was increased to 100% where the heart rate remained below 100 bpm at 90 seconds or cyanosis persisted. Ventilation pressures were not measured, and were delivered according to the clinical assessment by the person stabilizing the infant. Up to three attempts to achieve satisfactory PPV with either device were allowed. Endotracheal intubation was performed if there was no rise in heart rate above 60 bpm after 30 seconds of PPV.

- **Outcomes:** The primary outcome was the success rate of the devices used for resuscitation, defined as the achievement of effective PPV preventing the need for endotracheal intubation. Secondary outcomes were: Apgar score at 5 minutes; time to first respiratory effort; time to first cry; death or moderate/severe hypoxic-ischaemic encephalopathy within the first 7 days of life; admission for neonatal intensive care; complications related to the intervention.

- **Analysis and Sample Size:** The sample size calculation for this study used results of a previous study reporting a success rate of 99% for classic LMA and 84% for face mask. It was calculated that 58 infants in each group would be required to achieve 90% power, at the significance level of 0.05 to detect this difference. The final sample size included an increase of 20% in each group to allow for attrition. For the primary outcome, analysis was carried out using a one-tailed test in view of the previous results favoring LMA. Comparisons for secondary outcomes were based on two-tailed tests.

- **Patient follow-up:** There was no follow-up in this study.

**MAIN RESULTS**

In this study, intubation was avoided in the majority of babies in both study groups. PPV was initiated for bradycardia, apnea and gasping with similar frequencies in both groups of infants. However, in those who received resuscitation, this was significantly more successful in babies using an SLMA rather than a face mask (91.5% vs. 78.9%; P=0.023. The number of babies admitted for neonatal intensive care was lower in the SMLA group than the face-mask group. All other outcomes were similar between the two groups and no complications from the procedure arose in either group.
CONCLUSION
SLMA is more effective than facemask for avoiding endotracheal intubation at delivery in babies born at ≥ 34 weeks of gestation and with birth weight ≥1500g.

COMMENTARY, limited to 500 words
Laryngeal mask airways (LMA) have been available as useful adjuncts in airway management for adults and children. However, only recently have potential benefits been recognized in neonates and advancing technology has enabled the production of devices suitable for smaller, more fragile airways. Evidence from studies in term and larger preterm infants has lead to international newborn resuscitation guidelines suggesting that laryngeal masks might be considered for use in babies >2000g where facemask ventilation is unsuccessful or is not feasible. The supreme laryngeal mask (SLMA) used in this study has potential advantages over the classical LMA that has been more widely used previously.

Previous research has been mainly observational and mostly in the field of anesthesia. This study adds to the accumulating literature by using a randomized design, and by broadening the inclusion criteria. This trial included infants from 1500g birth weight. The results are in line with previous research, suggesting LMAs can offer benefit over facemasks in reducing the need for intubation in the first minutes of life without introducing unwanted complications. In those babies born between 1500g and 2000g, there was also a high rate of success with the device. However, the number of babies requiring intubation (13/15 (86.7%) SLMA vs 13/22 Face mask (59.1%) was somewhat higher than that previously reported with the use of a classical LMA, suggesting further work is needed to identify the optimum device for use in neonates.

The use of LMA for resuscitation is attractive for a number of reasons. Firstly, for resource poor countries, it introduces new possibilities for infants requiring a safe alternative for securing the airway post delivery where the option of ventilation is not available. In such settings, large numbers of late preterm and early term babies stand to benefit, as well as those born at full term who require more than the most basic support and stabilization.

Changes in the practice of neonatal medicine brought about by the introduction of surfactant, antenatal corticosteroids and non-invasive respiratory support mean fewer infants are ventilated in neonatal intensive care units in developed countries. For those requiring mechanical ventilation, the duration is generally kept to a minimum. We therefore find ourselves in a situation where the opportunities to learn and refine intubation skills are fewer, and the experience of junior clinicians delivering “front-line” support at the time of delivery is considerably more limited than in the past. The addition of alternative means to maintain a challenging airway is equally attractive in this environment.

It seems reasonable that LMAs should be available for use in neonatal resuscitation and that staff caring for newborn infants should be trained in their use. One caveat is that, despite availability of effective and less invasive devices, we should not overlook the need to ensure adequate training in intubation for those attending deliveries. There will always be babies for whom optimum management will require more intensive intervention - we must work to maintain the skills needed to deliver this safely, effectively and in a timely way.
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CONFLICTS OF INTEREST
None

REFERENCES, only for the Commentary section and limited to 9