Feasibility of Laryngeal Mask Airway Device Placement in Neonates

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Key Words

Laryngeal mask airway · Neonate · Physiology

Abstract

Background: The laryngeal mask airway (LMA) has been used in adult and pediatric populations for decades. While the familiarity of its use in the neonatal population is increasing, there are few data investigating this. **Objective:** The objective of this study was to determine the feasibility of LMA placement in neonates by investigating the time and number of attempts required for successful placement and physiologic stability during the placement of the device. **Methods:** This study is one component of a national, multicenter, randomized controlled trial investigating surfactant administration through an LMA in neonates. Videotape of LMA placement was reviewed to determine the total procedure time and the number of attempts required to successfully place the device. Heart rate and oxygen saturation (SaO₂) were analyzed as change from baseline, in order to examine physiologic stability during device placement. **Results:** Videotape and physiologic data were analyzed for 36 infants. Gestational age ranged from 29^{3/7} to 35^{4/7} weeks (mean 33 ± 1.7) with the birth weight ranging from 1,290 to 3,180 g (mean 2,006 ± 482). Average total

procedure time was 88 s (±136) with 64% of the procedures successfully completed in <35 s. Successful placement was achieved on the first attempt in 69% of the cases. Compared to baseline, heart rate increased by an average of 1 bpm (±4.5) and SaO₂ decreased an average of 6% (±7). **Conclusions:** Successful placement was achieved in the majority of patients in <35 s and required only one attempt. Physiologic parameters were maintained close to baseline, measured by minimal fluctuation in heart rate and SaO₂ during the procedure. Placement of the LMA is feasible in neonates.

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Introduction

Since its development in 1981, the laryngeal mask airway (LMA) has been frequently used and studied in adult and pediatric populations as an alternative artificial airway to provide positive pressure ventilation. While multiple large-scale studies have been conducted in these populations [1, 2], there is a paucity of literature evaluating LMA use in human neonates. Guidelines from the American Academy of Pediatrics Neonatal Resuscitation Program (NRP), the European Resuscitation Council

(ERC) and the International Liaison Committee on Resuscitation (ILCOR) recommend the LMA as an alternative airway device in newborns >2,000 g and ≥ 34 weeks' gestation, there is little data on characteristics and physiologic stability during the placement of the device for this age group and no data on the characteristics of placement in infants <2,000 g or <34 weeks' gestation. As familiarity and use of the LMA increase in the NICU setting, it is important to closely examine the feasibility of LMA placement in this population.

The purpose of this study was to determine the feasibility of LMA placement in neonates, including those born <34 weeks' gestation and weighing <2,000 g. Feasibility was determined by investigating the time and number of attempts required to successfully place the device and also analyzing physiologic changes in heart rate and oxygen saturation (SaO₂) during device placement.

Methods

This study is one component of a national, multicenter, randomized controlled trial investigating the use of an LMA for surfactant administration in neonates (clinicaltrials.gov ID NCT01116921). Subjects were recruited at the University of Minnesota Masonic Children's Hospital, Minneapolis, Minn.; St. Paul Children's Hospital, St. Paul, Minn.; the University of California San Diego Medical Center, San Diego, Calif.; the Loma Linda University Medical Center, Loma Linda, Calif.; the North Memorial Medical Center, Robbinsdale, Minn.; Maple Grove Hospital, Maple Grove, Minn.; the University of Wisconsin Madison Meriter Hospital, Madison, Wis., USA. The study was approved by the University of Minnesota IRB and IRB committees of all participating hospitals. Neonates between 28^{0/7} and 35^{6/7} weeks postmenstrual age, weighing $\geq 1,250$ g and with an age ≤ 36 h, with clinical and radiographical presentation of respiratory distress syndrome (RDS) requiring supplemental oxygen of 0.30–0.40% on nasal continuous positive airway pressure (nCPAP) for at least 30 min prior to enrollment were eligible for the study. Infants were not eligible if they received prior mechanical ventilation or surfactant administration, were born with congenital abnormalities or had respiratory distress secondary to conditions other than RDS (i.e. pneumothorax, pneumonia, meconium aspiration, etc.).

Infants randomized to the LMA group had an LMA placed and received surfactant via the LMA prior to removal of the device and were then returned to nCPAP. For this component of the study, data that was specific to the placement of the LMA was investigated (data obtained during the administration of surfactant was analyzed separately). A custom-designed data-acquisition system was used to simultaneously record video information and analog physiologic data. Digital video data obtained from a digital video camera (Logitech Webcam C210) was time-stamped and analog signals from the oximeter (Radical, Masimo Corp., Irvine, Calif., USA) were processed through a MP150 data-acqui-

sition system and AcqKnowledge software program (BioPAC Systems Inc., Goleta, Calif., USA). A core group of neonatal providers (attending, fellows and nurse practitioners) were trained in the study protocol and LMA placement procedure. Providers had little or no prior experience with LMA placement in neonates.

Neonates were positioned supine and administered 'Sweet-Ease' oral sucrose solution (1 ml for 1,250–1,500 g and 2 ml for >1,500 g body weight) to the tip of the tongue, and atropine (0.02 mg/kg i.v. over 1 min) prior to device placement. An orogastric (OG) tube was used to aspirate gastric contents. An LMA (LMA Unique, size 1, LMA North America, Inc., San Diego, Calif., USA) was inserted and glided through the oral cavity until the provider was unable to advance further. The cuff was then inflated with 3 cm³ of air. To confirm appropriate placement, color change was observed using a colorimetric CO₂ detector (PediCap, Nellcor Puritan Bennett, Pleasanton, Calif., USA) during bag-mask ventilation. If a yellow color change was not visualized, the LMA was deflated and repositioned; this was considered an additional attempt. Placement attempts were discontinued if SaO₂ fell below 75%, heart rate dropped below 100 bpm or if the duration of the attempt exceeded 30 s, even if the infant remained stable. If >1 attempt was required, bag mask ventilation was administered and a repeat attempt was initiated once the SaO₂ was $\geq 95\%$ and the heart rate was >100 bpm.

Videotape of the procedure was reviewed to determine the total duration of the procedure, the length of time the LMA was in the mouth for each attempt and the number of attempts required to successfully complete the procedure. An attempt was defined as insertion of the LMA into the infant's mouth until inflation of the cuff. If >1 attempt was required, the start of the next attempt was defined based on the extent of removal of the LMA during the prior attempt. If the LMA was fully removed from the infant's mouth, the next attempt began with its reinsertion into the mouth. If the LMA was repositioned in the larynx without full removal from the mouth, the start of the attempt began with deflation of the cuff. In both cases, the reinflation of the cuff denoted completion of the attempt. Total procedure time was defined as the duration from first insertion of the LMA until proper placement was confirmed (includes all placement attempts and recovery time between attempts). Total LMA time was defined as the sum of time the LMA was in the mouth during each attempt (excluding recovery time between attempts).

Both the video signal and physiology data could be played back and viewed on the same screen, thereby allowing accurate identification of the initiation and completion of any intervention to the nearest second. For heart rate and SaO₂, baseline values were obtained for 30 s prior to the first device placement attempt. Data were analyzed as change from baseline, with the averages and highest and lowest values computed.

Study data were collected and managed using REDCap electronic data-capture tools hosted at the University of Minnesota [3]. All statistical analyses were conducted using R v3.1.1. [4]. Continuous variables were summarized with averages, standard deviations, medians and range, including change from baseline values for physiologic outcomes. Confidence intervals for averages were based on *t* distribution. Confidence intervals for binomial proportions were based on inverting the score test. Heart rate data were analyzed as change from average baseline values to average values during procedural time.

Results

During the study period (February 2011 to April 2015), 50 infants were enrolled in the LMA group. Videotape of the placement procedure was available for 36 infants (72%), heart rate data were available for 20 and SaO₂ data for 15 infants. Data were not available for all enrolled infants due to technical problems resulting in an absence of recorded data or staff not being available to video-record the procedure. Gestational age ranged from 29^{3/7} to 35^{4/7} weeks (mean 33 ± 1.7) with weight ranging from 1,290 to 3,180 g (mean 2,006 ± 482). Twenty-six infants were <34 weeks' gestation (26/36 = 72%) and 18 weighed <2,000 g (18/36 = 50%). Demographic characteristics of the infants enrolled in the LMA group are included in table 1.

Average total procedure time was 88 s (SD ± 136, range 12–500, median 30). The LMA was successfully placed within 35 s in 64% of cases, with 72, 75 and 81% successfully placed by 45, 60 and 90 s, respectively. Average total LMA time was 32 s (SD ± 19, range 12–81, median 28). A total of 54 attempts were required for LMA placement in the 36 infants. Successful placement was achieved on the first attempt in 69% of cases and 83% of the procedures were successful in ≤2 attempts. Ultimately, the LMA was successfully placed in all neonates. Numbers of attempts required for placement varied only slightly by provider's level of training (table 2).

Physiologic measures of heart rate and SaO₂ fluctuated minimally during placement of the LMA. Compared to baseline, heart rate increased on average by 1 bpm (SD ± 4.5, range –9 to +11) and SaO₂ decreased by an average of 6% (SD ± 7, range –24 to +1). Results for heart rate and SaO₂ below the stated thresholds are presented in table 3.

Discussion

While previous publications have described the successful use of the LMA in the neonatal population, ours is the first to characterize the time and number of attempts required for its successful placement and to rigorously evaluate and analyze the impact on the physiologic stability of the infant during the placement procedure.

Our results show that successful placement was achieved in the majority of patients in a single attempt and was completed within 35 s. We found that providers with all levels of training (attending, fellow and neonatal nurse practitioner) were highly successful on the first attempt. This suggests that placement of an LMA is a skill that can

Table 1. Infant characteristics

Birth weight, g	2,006 ± 482 (1,290–3,180)
Gestational age, weeks	33 ± 2 (29.4–35.6)
Males, n (%)	22 (61)
Baseline heart rate, bpm	166 ± 15 (137–191)
Baseline SaO ₂ , %	91 ± 8 (74–99)

Values are mean ± SD (range) unless otherwise indicated.

Table 2. Number of attempts required for successful placement of the LMA in the infants based on the provider's level of training

Neonatal nurse practitioner	
1 attempt	12 (70%)
2 attempts ^a	2 (12%)
3 attempts	2 (12%)
>3 attempts	1 (6%)
Fellow	
1 attempt	10 (72%)
2 attempts	2 (14%)
3 attempts	2 (14%)
>3 attempts	0 (0%)
Attending	
1 attempt	4 (67%)
2 attempts	2 (33%)
3 attempts	0 (0%)
>3 attempts	0 (0%)

There were 36 infants and 37 providers.

^a One infant experienced an unsuccessful placement by a neonatal nurse practitioner, followed by a successful placement by an attending.

be learned quickly and effectively across multiple levels of training. Of the 54 attempts that were required to successfully place an LMA in the 36 infants, 12 (22%) were successful or stopped by 15 s, 33 (61%) by 20 s, 41 (76%) by 25 s, 44 (81%) by 30 s and 49 (91%) were successful or stopped by 35 s. These data demonstrate that the majority of attempts can be completed within a short period of time. In addition, there was a high level of adherence to the study protocol, which limits an attempt to 30 s, indicating that our results for the time taken and the number of attempts to successfully place an LMA are accurate and in line with NRP guidelines which recommend limiting endotracheal tube (ETT) placement attempts to 30 s [5].

No infant experienced bradycardia (defined as a heart rate <100 bpm). Nine experienced SaO₂ <85% with the lowest SaO₂ levels ranging from 47 to 80% if the outlier was excluded. The outlier was an infant that required 494 s (8 min 14 s) to successfully place the LMA; 3 at-

Table 3. Physiologic episodes of bradycardia or oxygen desaturation

	HR <100 bpm (n = 20)	SaO ₂ <85% (n = 15)	SaO ₂ <75% (n = 15)	SaO ₂ <60% (n = 15)	SaO ₂ <40% (n = 15)
All data					
n (%)	0 (0)	9 (60)	6 (40)	5 (33)	1 (7)
Duration, s	0±0 (0)	41±101 (3–397)	27±62 (11–241)	13±35 (5–137)	3±11 (0–41)
Outlier removed					
n (%)	0 (0)	8 (57)	5 (36)	4 (29)	0 (0)
Duration, s	0±0 (0)	15±21 (3–69)	11±18 (11–55)	4±8 (5–23)	0±0 (0)

HR = Heart rate. Values are mean ± SD (range) unless otherwise indicated.

tempts were required, with a cumulative total for the duration of attempts of 61 s and the remaining time being for recovery between attempts when the infant received bag-mask ventilation and suctioning. The lowest SaO₂ was 11% and SaO₂ was <40% for 41 s; despite the desaturation, this infant did not experience bradycardia. This is likely due to the fact that all infants received atropine prior to the procedure. This is similar to a study investigating premedication for elective intubations where all infants received atropine prior to the procedure and of the 6 infants who experienced SaO₂ <40%, 5 maintained a heart rate >100 bpm and the remaining infant had the lowest heart rate, i.e. 92 bpm [6].

While there are few published data on the use of the LMA in neonates, the available data are favorable and suggest that the device is feasible for use in this population. In animal models which replicate the neonatal airway, 1 study found that glottic injury occurred in 0% of ferrets in the LMA group compared to in 100% in the ETT (endotracheal intubation) group [7]. Another animal study found successful placement of an LMA was significantly faster than placement of the ETT (19 vs. 123 s, $p = 0.01$) and required fewer attempts (1 vs. 2 attempts, $p = 0.03$) [8].

In the human neonatal population, the most studied application for LMA use has been resuscitation. One center reported that 25% of neonates were resuscitated with an LMA, corresponding to a reduction in the number of tracheal intubations at delivery and demonstrating significant change of practice at that institution [9]. A trial with 369 neonates of >34 weeks' gestation and weighing >2,000 g demonstrated 98.5% successful insertion on the first attempt and fewer adverse events than with bag-mask ventilation [10]. Another compared LMA insertion to face-mask ventilation, and identified an equivalent average time of 30 s needed to obtain effective ventilation, in both groups [11]. A randomized control trial with 40

neonates >35 weeks' gestational age noted few differences between LMA and ETT resuscitation with regard to overall success rate, time to normal heart rate, spontaneous breathing or Apgar scores [12]. Another study examined the efficacy of the LMA for the resuscitation of low-birth-weight (1–1.5 kg) neonates, and observed an improved SaO₂ within 5 min [13]. Observational studies have found that the device provides adequate positive pressure ventilation in 95–99% of neonates and none of these studies reports gastric insufflation [9, 13, 14]. A meta-analysis, which identified 4 trials comparing the LMA to bag-mask ventilation or an ETT, found that the neonates in the LMA group were intubated less frequently and had fewer unsuccessful resuscitation attempts with no adverse events reported [15].

Despite the lack of large-scale studies, the use of the LMA in the NICU setting is increasing. In 2006, the American Academy of Pediatrics NRP textbook included the LMA for the first time [16]. The most recent edition, published in 2011, states that, 'laryngeal mask airways may be useful in situations when positive pressure with a face mask fails to achieve effective ventilation, and when endotracheal intubation is either not feasible or unsuccessful' [5]. The ERC and the ILCOR recommend the LMA as an alternative airway device in newborns weighing >2,000 g and delivered ≥34 weeks' gestation and states that 'there is limited evidence, however, to evaluate its use for newborns weighing <2,000 g or delivered <34 weeks' gestation' [17, 18].

In addition to use in newborn resuscitation, other applications of the LMA have been reported (e.g. airway management for infants with congenital airway anomalies [19–21], during short procedures [22–24], during transport [25, 26] and for prolonged ventilation [27, 28]), though the current evidence relies on case reports or small-scale studies [29].

One strength of our study was that it was conducted in university-affiliated teaching hospitals where multiple levels of providers perform procedures, thereby making it applicable to many NICU environments. Another strength is the accuracy of the data; the ability to view the video signal and physiologic data on the same screen allows for accurate identification of the initiation and completion of any intervention and the change in physiologic parameters to the nearest second. In addition, SaO₂ and heart rate data were collected continuously every second and downloaded directly into a computer program for analysis. Oximeter values were obtained using a 2-second averaging interval. This provided a more accurate measure of the true saturation level compared to oximeters that average values over longer intervals of time. A weakness of our study is that personnel availability or technical malfunction precluded obtaining videos and heart rate and/or SaO₂ data for all infants randomized to the LMA group.

In this study, successful placement was achieved in the majority of patients in <35 s and required only 1 attempt. Physiologic parameters were maintained close to baseline, measured by the minimal fluctuation in heart rate and SaO₂ during the procedure. We conclude that placement of the LMA is feasible and effective in neonates.

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Disclosure Statement

None of the authors has any conflicts of interest to disclose.

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