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Feasibility of Laryngeal Mask Airway Device Placement in Neonates

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Abstract

Background—The laryngeal mask airway (LMA) has been used in adult and pediatric populations for decades. While familiarity in the neonatal population is increasing, there is little data investigating its use in this population.

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 device placement.

Methods—This study is one component of a national, multi-center, randomized controlled trial investigating surfactant administration through an LMA in neonates. Videotape of LMA placement was reviewed to determine total procedure time and number of attempts required to successfully place the device. Heart rate and oxygen saturation were analyzed as change from baseline to examine physiologic stability during device placement.

Results—Videotape and physiologic data were analyzed for 36 infants. Gestational ages ranged from 29 3/7- 35 4/7 weeks (mean 33 ±1.7) with weights ranging from 1290-3180 grams (mean 2006 ± 482). Average total procedure time was 88 seconds (±136) with 64% of the procedures successfully completed in less than thirty five seconds. Successful placement was achieved on the first attempt in 69% of cases. As compared to baseline, heart rate increased an average of 1 bpm (±4.5) and oxygen saturation decreased an average of 6% (±7).

Conclusions—Successful placement was achieved in the majority of patients in less than thirty-five seconds and required only one attempt. Physiologic parameters were maintained close to

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baseline, measured by minimal fluctuation in heart rate and oxygen saturation during the procedure. Placement of the LMA is feasible in neonates.

Keywords

laryngeal mask airway; neonate; physiology

Objective

Since its development in 1981, the laryngeal mask airway (LMA) has been frequently used and studied in adult and pediatric populations as an alternate 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. While 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 >2000 grams and ≥34 weeks gestation, there is little data on characteristics and physiologic stability during placement of the device in this age group, and no data on characteristics of placement in infants < 2000 kg or < 34 weeks gestation. As familiarity and use of the LMA increases 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 feasibility of LMA placement in neonates; including those born less than 34 weeks gestation and weighing less than 2000 grams. Feasibility was determined by investigating the time and number of attempts required to successfully place the device and analyzing physiologic changes in heart rate and oxygen saturation during device placement.

Methods

This study is one component of a national, multi-center, 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 in Minneapolis, MN, St. Paul Children's Hospital in St. Paul, MN, University of California San Diego Medical Center in San Diego, CA, Loma Linda University Medical Center in Loma Linda, CA, North Memorial Medical Center in Robbinsdale, MN, Maple Grove Hospital in Maple Grove, MN, and the University of Wisconsin- Madison Meriter Hospital in Madison, WI. This study was approved by the University of Minnesota Institutional Review Board and IRB committees of all participating hospitals. Neonates between 28 0/7 to 35 6/7 weeks post menstrual age, weight ≥1250 grams, and age ≤36 hours old, with a 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 minutes 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 returned to nCPAP. For this component of the study, data 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 Corporation, Irvine, CA) were processed through a MP150 data acquisition system and AcqKnowledge software program (BioPAC Systems Inc, Goleta, CA). A core group of neonatal providers (attendings, 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 if weight 1250-1500g; 2 ml if weight >1500g to tip of tongue) and atropine (0.02 mg/kg IV over 1 minute) prior to device placement. An orogastric (OG) tube was used to aspirate gastric contents. A LMA (LMA Unique, Size 1, LMA North America, Inc, San Diego, CA) was inserted and glided through the oral cavity until the provider was unable to advance further. The cuff was then inflated with 3 cc of air. To confirm appropriate placement, color change was observed using a colorimetric CO_2 detector (PediCap, Nellcor Puritan Bennett, Pleasanton, CA) during bag-mask ventilation. If yellow color change was not visualized, the LMA was deflated and repositioned; this was considered an additional attempt. Placement attempts were discontinued if oxygen saturation fell below 75%, heart rate dropped below 100 bpm, or if the duration of the attempt exceeded 30 seconds, even if the infant remained stable. If more than one attempt was required, bag mask ventilation was administered and a repeat attempt was initiated once SaO_2 was ≥95% and heart rate was >100 bpm.

Videotape of the procedure was reviewed to determine total duration of the procedure, duration of time the LMA was in the mouth for each attempt, and number of attempts required to successfully complete the procedure. An attempt was defined as insertion of the LMA into the infants’ mouth until inflation of the cuff. If more than one attempt was required, 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 infants’ mouth, the next attempt began with reinsertion into the mouth. If the LMA was repositioned in the larynx without full removal from the mouth, start of the attempt began with deflation of the cuff. In both cases, re-inflation of the cuff denoted the 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 oxygen saturation, baseline values were

obtained for thirty seconds prior to the first device placement attempt. Data were analyzed as change from baseline, with averages, highest values 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 the 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-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 infants and oxygen saturation data was available 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 available to video record the procedure. Gestational ages ranged from 29 3/7- 35 4/7 weeks (mean 33 ±1.7) with weights ranging from 1290-3180 grams (mean 2006 ± 482). Twenty-six infants were <34 weeks gestation (26/36=72%) and eighteen weighed <2000g (18/36=50%). Demographic characteristics of infants enrolled in the LMA group are included in Table 1.

Average total procedure time was 88 seconds (SD±136, range 12-500, median 30). The LMA was successfully placed within 35 seconds in 64% of cases, with 72%, 75% and 81% successfully placed by 45, 60 and 90 seconds, respectively. Average total LMA time was 32 seconds (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. Number of attempts required for placement varied only slightly by provider's level of training (Table 2).

Physiologic measures of heart rate and oxygen saturation fluctuated minimally during placement of the LMA. As compared to baseline, heart rate increased on average 1 beat per minute (SD±4.5, range -9-11) and oxygen saturation decreased an average of 6% (SD±7, range -24-1). Results for heart rate and oxygen saturation below stated thresholds are presented in Table 3.

Discussion

While previous publications describe successful use of the LMA in the neonatal population, our study is the first to characterize time and number of attempts required for successful placement and to rigorously evaluate and analyze the impact on the physiologic stability of the infant during placement of the device.

Our results show that the successful placement was achieved in the majority of patients in a single attempt and completed within 35 seconds. We found that providers of 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 be learned quickly and effectively across multiple levels of training. Of the 54 attempts that were required to successful place an LMA in the 36 infants, 12 (22%) were successful or stopped by 15 seconds, 33 (61%) by 20 seconds, 41 (76%) by 25 seconds, 44 (81%) by 30 seconds and 49 (91%) were successful or stopped by 35 seconds. 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 limited an attempt to 30 seconds indicating that our results for time and number of attempts to successfully place an LMA are accurate and in line with NRP guidelines which recommend limiting ETT placement attempts to 30 seconds.[5]

No infant experienced bradycardia (defined as heart rate < 100 bpm). Nine infants experienced SaO2< 85% with the lowest SaO2 levels ranging from 47-80% if the outlier is excluded. The outlier is an infant that required 494 seconds (8 min 14 sec) to successfully place the LMA. Three attempts were required with the cumulative total for the duration of attempts of 61 seconds. The remaining time was recovery between attempts where the infant received bag-mask ventilation and suctioning. The lowest SaO2 was 11% and SaO2 was < 40% for 41 seconds. Despite the desaturation, the 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 of the 6 infants maintained HR > 100 bpm with the remaining infant having a lowest heart rate of 92 bpm.[6]

While there is little published data on use of the LMA in neonates, available data is favorable and suggests its use is feasible in this population. In animal models which replicate the neonatal airway, one study found that glottic injury occurred in 0% of ferrets in the LMA group as compared to 100% in the endotracheal intubation (ETT) group.[7] Another animal study found successful placement of an LMA was significantly faster than placement of the ETT (19 vs 123 secs, 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 25% of neonates were resuscitated with an LMA, corresponding to a reduction in the number of tracheal intubations at delivery and demonstrating significant practice change at that institution.[9] A trial with 369 neonates greater than 34 weeks gestation and over 2000 g demonstrated 98.5% successful insertion on the first attempt and fewer adverse events as compared to bag-mask ventilation.[10] A second trial compared LMA insertion to face mask ventilation and identified equivalent average time needed to obtain effective ventilation of 30 seconds in both groups.[11] A randomized control trial with forty neonates more than 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 efficacy of the LMA for resuscitation of low birth weight neonates (1-1.5 kg) and observed improved oxygen saturation within five minutes.[13] Observational studies found the device provided adequate positive pressure ventilation in 95-99% of neonates with none of the

studies reporting gastric insufflation.[9, 13-14] A meta-analysis, which identified four trials comparing the LMA to bag-mask ventilation or an endotracheal tube for neonatal resuscitation, found 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, use of the LMA in the NICU setting is increasing. In 2006, the American Academy of Pediatrics Neonatal Resuscitation Program (NRP) textbook included LMAs 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 European Resuscitation Council (ERC) and the International Liaison Committee on Resuscitation (ILCOR) recommend the LMA as an alternative airway device in newborns >2000 grams and delivered ≥ 34 weeks gestation and states that “there is limited evidence, however, to evaluate its use for newborns weighing < 2000 grams 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 current evidence relies on case reports or small-scale studies.[29]

A strength of our study was that it was conducted in university- affiliated teaching hospitals where multiple levels of providers perform procedures, thereby making our study applicable to many NICU environments. Another strength of our study is the accuracy of the data. The ability to view the video signal and physiologic data on 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, oxygen saturation and heart rate data were collected continuously every second and downloaded directly into a computer program for analysis. Oximeter values were obtained using a two second averaging interval. This provided a more accurate measure of the true saturation level as 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 video, heart rate and/or oxygen saturation data for all infants randomized to the LMA Group.

In this study, successful placement was achieved in the majority of patients in less than thirty-five seconds and required only one attempt. Physiologic parameters were maintained close to baseline, measured by minimal fluctuation in heart rate and oxygen saturation during the procedure. We conclude that placement of the LMA is feasible and effective in neonates.

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Table 1

Infant characteristics

Birth weight, mean ± SD (range), g	2006 ± 482 (1290, 3180)
Gestational age, mean ± SD (range), wk	33 ± 2 (29.4, 35.6)
Male, n (%)	22 (61)
Baseline heart rate, mean ± SD (range), bpm	166 ± 15 (137, 191)
Baseline oxygen saturation, mean ± SD (range), %	91 ± 8 (74, 99)

Table 2

Number of attempts required for successful placement based on provider's level of training.

NNP	1 Attempts	12 (70%)
	2 Attempts*	2 (12%)
	3 Attempts	2 (12%)
	>3 Attempts	1 (6%)
Fellow	1 Attempts	10 (72%)
	2 Attempts	2 (14%)
	3 Attempts	2 (14%)
	>3 Attempts	0 (0%)
Attending	1 Attempts	4 (67%)
	2 Attempts	2 (33%)
	3 Attempts	0 (0%)
	>3 Attempts	0 (0%)

*Total n=36 infants with 37 providers given one infant experienced unsuccessful placement by NNP followed by successful placement by Attending

Table 3

Physiologic episodes of bradycardia or oxygen desaturation.

	HR < 100 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 (secs)					
mean ±SD	0 ± 0	41 ± 101	27 ± 62	13 ± 35	3 ± 11
Range	0	(3-397)	(11-241)	(5-137)	(0-41)
Outlier removed					
n (%)	0 (0)	8 (57)	5 (36%)	4 (29)	0 (0)
Duration (secs)					
mean ±SD	0 (0)	15 ± 21	11 ± 18	4 ± 8	0 ± 0
Range	0	(3-69)	(11-55)	(5-23)	(0)