ECRONICON OPEN ACCESS

EC PAEDIATRICS
Research Article

Simulation for Neonatal Airway Management: A Comparative Study of the Neonatal Laryngeal Mask and Endotracheal Intubation in Manikin

Ayoob Ali*

Associate Professor of Pediatrics, Department of Pediatrics, Division of Neonatal-Perinatal Medicine, Saint Louis University, United States of America

***Corresponding Author**: Ayoob Ali, Associate Professor of Pediatrics, Department of Pediatrics, Division of Neonatal-Perinatal Medicine, Saint Louis University, United States of America.

Received: January 11, 2025; P**ublished:** January 20, 2025

Abstract

Background: Endotracheal intubation (ETT) plays a crucial role in managing airways during advanced neonatal resuscitation for premature infants with respiratory distress syndrome. Despite advancements in medical technology that offer less invasive airway management options during general anesthesia, these methods still face significant limitations when applied to many pre-term and full-term infants. The Neonatal Laryngeal Mask (NLM) is a new device designed for pre-term infants that previously demonstrated safety and efficacy while inducing surgical plane anesthesia and facilitating tracheal catheterization in piglets. In this study, we aimed to observe the efficacy of the NLM when applied to neonatal mannikins in comparison to ETT.

Methods: This study compared the efficacy of the NLM to ETT using neonatal manikins, and involved six groups of healthcare professionals: PGY-1 and PGY-2 pediatrics residents, PGY-3 pediatrics residents and neonatology fellows, Neonatal Nurse practitioners, third-year medical students, attending neonatologists, and private pediatricians. Participants were trained on both devices and performed three attempts each. Outcomes measured included time to lung inflation, number of attempts, and failure rates. Statistical analysis used t-tests with a significance level of $p < 0.05$.

Results: The NLM consistently outperformed ETT in securing the airway, with significantly faster average times across all healthcare professional groups ($p < 0.001$). Average times for airway placement using ETT ranged from 18.1 to 19.8 seconds, while NLM times ranged from 9.3 to 12.8 seconds. The mean time reduction with the NLM varied by group, from 6.2 seconds among PGY-1 and PGY-2 residents to 9.1 seconds among third-year medical students. All participants successfully completed airway placements with both methods following training, with no failed attempts recorded.

Conclusion: This study demonstrates that the NLM consistently provides faster airway securing compared to ETT across various healthcare professional groups. The NLM's efficiency could improve neonatal care by reducing delays in emergency situations, especially in resource-limited settings where ETT complications are more prevalent. While promising, further research is needed to evaluate proficiency, long-term outcomes, and training strategies for broader NLM adoption.

Keywords: *Neonatal Airway; Neonatal Laryngeal Mask; Anesthesia; Airway Management; Endotracheal Tube; Mannikin; Emergent Intubation; Advanced Airway*

Abbreviations

NLM: Neonatal Laryngeal Mask; ETT: Endotracheal Intubation; BMW: Bag-Mask Ventilation; LMA™: Laryngeal Mask Airway

Introduction

Airway management is an essential component of critical-care medicine. In neonates, deficiencies in respiration and oxygenation are detrimental to physical growth and cognitive development. Approximately 5% of neonates require respiratory support during their transition from intrauterine to extrauterine life [1,2]. Ensuring effective positive pressure ventilation is crucial for successful neonatal resuscitation [2]. Typically, resuscitation begins with manual bag-mask ventilation (BMV) and progresses to endotracheal intubation (ETT) if complications in securing the airway persist. However, performing these techniques successfully can be challenging, leading to extended resuscitation or severe neonatal depression [3].

Recent advances in medical technology have reduced the burden of the technical skills required to secure advanced airways. Most notably, the Laryngeal Mask Airway (LMA™) was the first non-invasive method of airway management approved in 1999 [4-6]. However, its efficacy was limited to adults, children, and full-term newborns due to size limitations [7,8]. Premature and full-term babies under 2500 grams still lacked an alternative non-invasive means of securing the airway.

We therefore designed a new device-the Neonatal Laryngeal Mask (NLM)-that can ventilate and administer medication into the lungs of premature infants. The NLM was designed by utilizing computed tomography and magnetic resonance imaging data for gestational-age infants to compute appropriate estimates of the oropharyngeal space. The NLM consists of several parts, including a tube with an inflatable donut-shaped cap at one end. When inserted through the mouth, the NLM cap sits over the larynx and is then inflated. This inflation seals the tube's opening near the larynx, separating it from other structures in the pharynx, like the esophagus. The other end of the NLM can be connected to a resuscitation bag or ventilator for lung inflation.

Unlike the conventional LMA™, the NLM is specialized for premature and full-term babies. Its sizes of 1, 0, and 00 are capable of accommodating babies weighing between 700 and 2500 grams. We previously demonstrated that the NLM provides a safe and effective method for maintaining a patent airway and catheterizing a model system for pre-term and full-term infants [9]. However, the efficacy of the NLM in practice by healthcare providers when compared to traditional ETT is still unclear.

This observational study aimed to compare the time required to place the NLM versus ETT in premature manikins in order to assess the efficacy and overall practicality of utilizing the NLM to secure a neonate's airway. We hypothesized that the overall average time required to secure the neonatal airway would be reduced when utilizing an NLM as opposed to traditional ETT across all healthcare professional groups assessed. Moreover, we further hypothesized that the observed reduction in time required to secure the airway via NLM would be most profound among the groups with the least amount of experience in neonatal resuscitation.

Materials and Methods

Materials

A prototype neonatal laryngeal Msk-NLM constructed as shown in figure 1.

Model system

This study was designed to be performed on neonatal manikins to assess the efficacy of NLM in securing the airway when compared with the use of ETT. All aspects of the study were approved by the Institutional Review Board at Saint Louis University School of Medicine.

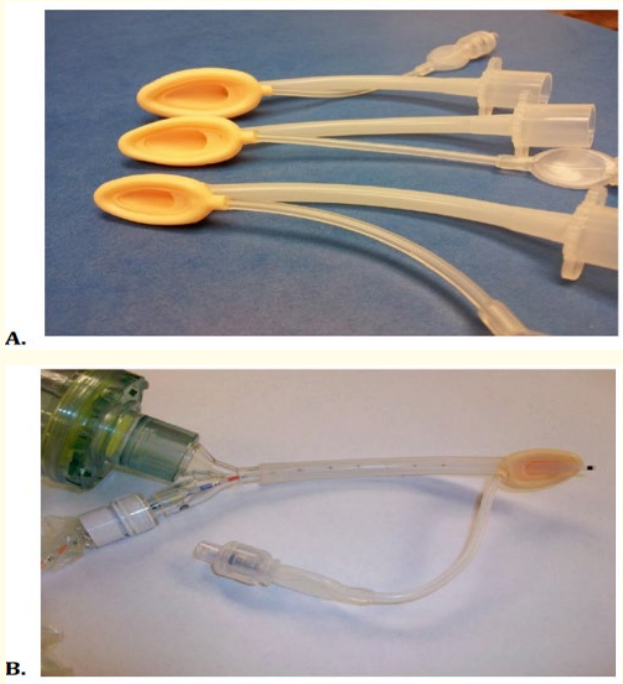

Figure 1: *Structural and functional design of the NLM.*

The NLM consists as shown (A). A long tube with an inflatable donut-shaped cuff at one end lies over the larynx once it enters through the open mouth. This cuff is then inflated, allowing for the NLM to seals off from other structures that open into the pharynx (e.g. the esophagus). The other end of the NLM can then be attached to a resuscitation bag or mechanical ventilator using a v-adapter to provide mechanical ventilation (B). This device provides a more direct connection to the trachea than does a face mask and is less invasive than endotracheal tube intubation.

Study design

This study employed a prospective, comparative design to assess the efficacy of the NLM in facilitating airway access in neonates compared to traditional endotracheal intubation. The study involved six distinct groups of healthcare professionals: PGY-1 and PGY-2 pediatrics residents, PGY-3 pediatrics residents and neonatology fellows, Neonatal Nurse practitioners, third-year medical students, attending neonatologists, and private pediatricians. Each participant underwent training, including an orientation to the NLM device, insertion techniques for the NLM, and practice attempts for both endotracheal intubation and NLM placement on a neonatal manikin. Once trained and oriented, three separate attempts were recorded for each participant.

Specified outcomes

The primary outcomes measured in this study were:

1. Time taken from picking up the NLM device to the first inflation of the manikin's lungs.
2. Number of insertion attempts made for each size of the NLM and endotracheal intubation.
3. Incidence of failed attempts to establish an airway, defined as the inability to inflate the manikin's lungs using a self-inflating bag.

Sample size

The study sample comprised 60 participants, distributed across the aforementioned six groups of healthcare professionals. Each group consisted of an equal number of participants to ensure a balanced representation of various levels of expertise in neonatal airway management.

Statistical analysis

Statistical significance was determined using appropriate methods, such as t-tests, to compare the time taken for NLM placement and endotracheal intubation among the different healthcare professional groups. The significance level was set at $p < 0.05$ to indicate statistical significance.

Results

The average time required to secure the airway via ETT varied among the different groups of healthcare professionals. Specifically, the average times for each group were as follows: Pediatrics residents at PGY-1 and PGY-2 levels: 19 seconds (Figure 2A), Pediatrics residents at PGY-3 and neonatology fellows: 18.1 seconds (Figure 2B), Neonatal Nurse practitioners: 18.9 seconds (Figure 2C), Third-year medical students: 18.4 seconds (Figure 2D), Attending neonatologists: 18.8 seconds (Figure 2E), and Private pediatricians: 19.8 seconds (Figure 2F).

Conversely, the corresponding participants took varying durations to secure the airway using the Neonatal Laryngeal Mask (NLM), with average times as follows: Pediatrics residents at PGY-1 and PGY-2 levels: 12.8 seconds (Figure 2A), Pediatrics residents at PGY-3 and neonatology fellows: 12 seconds (Figure 2B), Neonatal Nurse practitioners: 10 seconds (Figure 2C), Third-year medical students: 9.3 seconds (Figure 2D), Attending neonatologists: 9.9 seconds(Figure 2E), Private pediatricians: 11.1 seconds (Figure 2F).

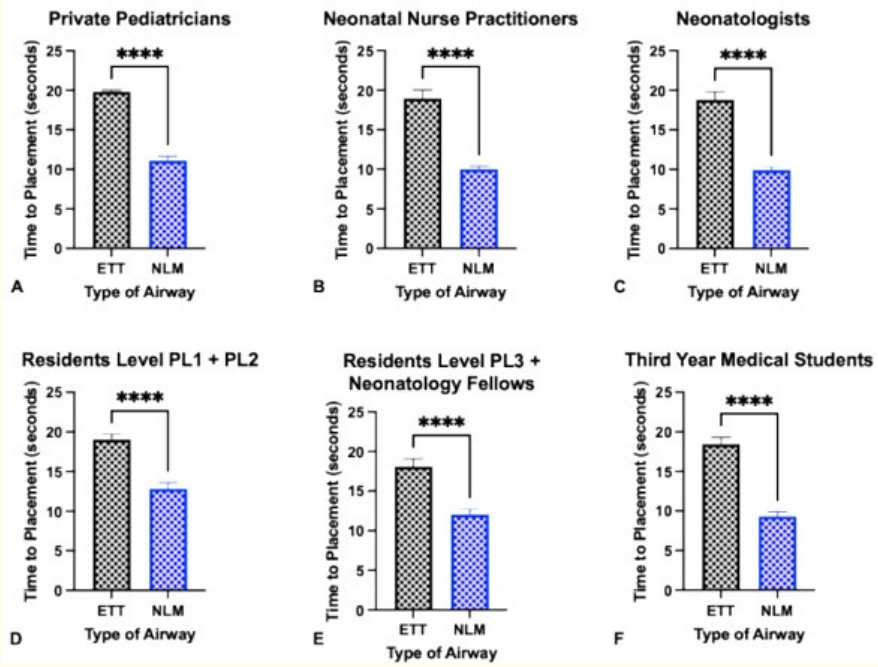

Figure 2: *Time required to successfully secure the mannikin airway via ETT and NLM placement, stratified by health care profession.*

All pairwise t-tests comparing the average times for ETT and NLM placements demonstrated statistical significance with a $p < 0.001$, indicating significant differences between the methods across the various healthcare professional groups (Figure 2 and 3). Moreover, the mean difference in time required to secure the airway was calculated to be a reduction of 6.2 seconds by pediatrics PGY-1 and PGY-1 residents, 6.1 seconds by pediatrics PGY-3 residents and neonatology fellows, 8.9 seconds in neonatal nurse practitioners, 9.1 seconds by third-year medical students, and 8.9 seconds in attending neonatologists, and 8.7 seconds in private pediatricians all while using the NLM as opposed to an ETT.

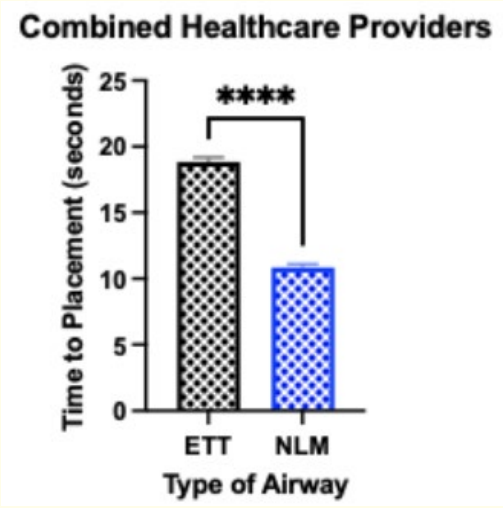

Figure 3: *Time required to secure the mannikin airway via ETT and NLM placement, combined across all observed healthcare professions.*

It is also important to mention that following orientation to both the NLM device and ETT protocol, all participants successfully placed all NLM and ETT airways without failed attempts when recording the official time.

Discussion

This study investigated the efficacy of the NLM in comparison to the traditional ETT for securing airways in neonatal manikins by different healthcare professional groups involved in neonatal care. Our results indicate that the NLM consistently allowed for faster airway securing compared to ETT use across all groups which was furthermore statistically significant ($p < 0.001$) in all pairwise comparisons. Notably, third-year medical students achieved the fastest times when using the NLM, highlighting the device's ease of use even among less experienced practitioners. In contrast, private pediatricians took the longest time on average, though they still exhibited a marked improvement with the NLM. Interestingly, the greatest reduction in average time to secure the airway with the NLM was found among third-year medical students, followed by attending neonatologists as well as neonatal nurse practitioners.

The consistent reduction in airway management time across all groups suggests that the NLM could streamline procedures in neonatal emergencies, potentially improving patient outcomes by minimizing delays in critical interventions. In fact, this is further strengthened by the similar degree of improvement seen among both medical students with minimal intubation or procedural experience as well as neonatal nurse practitioners and attending neonatologists with the highest level of experience specific to neonatal resuscitation.

Although ETT is a highly effective method for airway management, it is often associated with a higher risk of complications, particularly in low-resource settings where access to advanced technology and experienced providers is limited. Complications such as airway trauma, improper tube placement, and prolonged intubation attempts are more prevalent in environments where the availability of expert practitioners or advanced equipment is constrained [3,10]. These complications involve risk for adverse events like desaturation and bradycardia, further complicating neonatal resuscitation [3,10]. These risks emphasize the need for alternative methods that are not only easier to perform but also more reliable in emergent settings.

The NLM therefore offers a viable solution in such scenarios, as it has demonstrated significant time-saving benefits in our study. Importantly, the NLM is accessible to both trainees and high-level providers, providing a critical advantage in settings where time is of the essence and access to specialized care is delayed or inefficient. By reducing the complexity and risk associated with airway management, the NLM could be a key tool for improving outcomes in resource-limited environments, ensuring quicker, safer interventions when ETT may not be feasible or ideal.

While the study highlights the favorable outcomes associated with NLM use, several considerations warrant attention. Future investigations should delve deeper into assessing proficiency, comfort levels, and long-term outcomes associated with NLM adoption across diverse clinical settings. Moreover, exploring training strategies and integrating NLM insertion techniques into neonatal care curricula could be pivotal in enhancing its widespread adoption and optimizing patient outcomes.

It is also essential to acknowledge certain limitations of this study, including its simulation-based nature using manikins, which may not fully replicate the complexities of real-life clinical scenarios. Additionally, the assessment focused primarily on insertion time, without extensive evaluation of complications, anatomical variations, or the influence of other confounding factors that might impact clinical decision-making.

Conclusion

Overall, this study supports the efficacy of the NLM as a promising alternative to traditional ETT, showcasing reduced insertion times across various levels of healthcare professionals. While further research is warranted to validate these findings in clinical settings, the NLM holds potential as a valuable tool for expediting neonatal airway management, warranting consideration for its integration into clinical practice.

Acknowledgements

Author acknowledges Dr. William Keenan for reviewing the manuscript as well as his technical advice.

Conflict of Interest

Author is the co-inventor of this prototype device and plans to use it as an investigational medical device for human trials. Author has no financial conflict of interest with any medical device company to disclose.

Bibliography

1. Alanazi A. "Intubations and airway management: An overview of Hassles through third millennium". *Journal of Emergencies, Trauma, and Shock* 8.2 (2015): 99-107.

2. Reuter S., *et al*. "Respiratory distress in the newborn". *Pediatrics in Review* 35.10 (2014): 417-429.

3. Glenn T., *et al*. "Patient characteristics associated with complications during neonatal intubations". *Pediatric Pulmonology* 56.8 (2021): 2576-2582.

4. Brain AI. "The development of the Laryngeal Mask--a brief history of the invention, early clinical studies and experimental work from which the Laryngeal Mask evolved". *European Journal of Anaesthesiology Supplement* 4 (1991): 5-17.

5. Wemyss-Holden SA., *et al*. "The laryngeal mask airway in experimental pig anaesthesia". *Laboratory Animals* 33.1 (1999): 30-34.

6. Kazakos GM., *et al*. "Use of the laryngeal mask airway in rabbits: placement and efficacy". *Laboratory Animals* 36.4 (2007): 29-34.

7. Wanous AA., *et al*. "Feasibility of laryngeal mask airway device placement in neonates". *Neonatology* 111.3 (2017): 222-227.

8. Park C., *et al*. "The laryngeal mask airway in infants and children". *Canadian Journal of Anesthesia* 48.4 (2001): 413-417.

9. Ayoob Ali. "Innovative neonatal laryngeal mask for airway management in piglets: A new device for potential use in preterm and term neonates". *Acta Scientific Paediatrics* 4.10 (2021): 03-08.

10. Foglia EE., *et al*. "Factors associated with adverse events during tracheal intubation in the NICU". *Neonatology* 108.1 (2015): 23-29.

Volume 14 Issue 2 February 2025