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TESI DI LAUREA

INTUBATING LARYNGEAL MASK VS. LARYNGOSCOPE IN NEONATES: A RANDOMIZED CONTROLLED MANIKIN STUDY

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1. RIASSUNTO

Background: L'intubazione endotracheale è un'importante procedura salvavita per i neonati in condizioni critiche. Inoltre, i tempi della procedura sono spesso più lunghi di quelli raccomandati dalle linee guida internazionali e i ripetuti tentativi di intubazione sono associati a eventi avversi nei neonati instabili.

Obiettivi: Confrontare il successo e il tempo di intubazione mediante maschera laringea rispetto alla laringoscopia diretta in un manichino che simula un neonato a termine. Inoltre, è stata valutata l'opinione degli operatori sulla procedura.

Metodi: Si è trattato di uno studio pilota non cieco, randomizzato, controllato, crossover (AB/BA) sulla procedura di intubazione mediante maschera laringea vs laringoscopia diretta in un manichino che simula un neonato a termine. I partecipanti erano consulenti medici e specializzandi di terapia intensiva neonatale di III livello. La randomizzazione è stata effettuata utilizzando una lista di assegnazione casuale generata dal computer. L'outcome primario è stato il tasso di successo dell'intubazione al primo tentativo. Gli outcome secondari sono stati il tempo totale necessario per il posizionamento del tubo endotracheale (calcolato come la somma del tempo di posizionamento del dispositivo in tutti i tentativi) e l'opinione dei partecipanti sull'uso del dispositivo (valutata utilizzando una scala Likert).

Risultati: Il dispositivo maschera laringea Air-Qsp® ha consentito l'intubazione al primo tentativo nel 100% dei partecipanti, indipendentemente dalla loro esperienza, in confronto al 76% di successo quando i partecipanti hanno usato il laringoscopio. Il tempo richiesto per posizionare il tubo endotracheale si è dimostrato simile con entrambe le tecniche. I professionisti sanitari, inclusi sia specialisti che specializzandi, hanno riportato livelli di difficoltà simili nell'eseguire le due procedure.

Conclusioni: In questo studio su manichino, il successo di intubazione al primo tentativo mediante maschera laringea è risultato superiore all'intubazione effettuata con laringoscopia diretta suggerendo che questa pratica potrebbe essere considerata per questa difficile ed invasiva procedura nel neonato. Sono necessari futuri studi per confermare la validità di questo approccio nella pratica clinica.

Registrazione dello studio: Lo studio è stato registrato su clinicaltrial.gov NCT06263790.

2. ABSTRACT

Background: Endotracheal intubation is an important life-saving procedure for critically ill neonates. Furthermore, the procedure times are often longer than recommended by international guidelines and repeated intubation attempts are associated with adverse events in unstable neonates.

Objectives: To compare success and time of intubation through intubating laryngeal mask vs. direct laryngoscopy in a manikin simulating a term newborn. In addition, we will assess operator's opinion on the procedure.

Methods: This is an unblinded, randomized, controlled, crossover (AB/BA) pilot trial of intubation procedure through intubating laryngeal mask vs direct laryngoscopy in a manikin simulating a term newborn. Participants will be level III NICU consultants and residents. Randomization will be performed using a computer-generated random assignment list. The primary outcome measure was the intubation success rate at the first attempt. Secondary outcome measures were the total time needed for the endotracheal tube positioning (calculated as the sum of the time of device positioning in all attempts), and the participant's opinion on using the device (evaluated using a Likert scale).

Conclusion: In this manikin study, the success of intubation on the first attempt using an intubating laryngeal mask was superior to intubation performed with direct laryngoscopy, suggesting that this practice could be considered for this difficult and invasive procedure in the newborn. Future studies are needed to confirm the validity of this approach in clinical practice.

Trial Registration: This trial has been registered at clinicaltrial.gov NCT06263790

3. INTRODUCTION

3.1 Epidemiology of newborn resuscitation

Every year, approximately 150 million babies are born worldwide. While most newborns transition successfully from intrauterine to extrauterine life, a notable percentage require varying degrees of assistance. Roughly 10% of neonates necessitate intervention, approximately 5% of infants receive positive pressure ventilation. Extensive resuscitative measures such as intubation is necessary for 0.4% to 2% of cases. Fewer than 0.3% of infants require chest compressions, and only 0.05% need adrenaline.(1) Notably, a significant portion of these infants are born in low- and middle-income countries, highlighting the global disparities in neonatal care. (2)

3.2 Fetal to neonatal life transition

The transition from fetal to neonatal life demands rapid adjustments in the cardiorespiratory system. Primarily, this entails the activation of the lungs, which were previously filled with fluid, and their replacement with air. Additionally, there is the establishment of a regular breathing pattern, accompanied by an increase in pulmonary blood flow and a decrease in pulmonary vascular resistance.(3) For infants that fail to adapt rapidly to the new environment, do not respond adequately to initial interventions and continue to have gasping, apnea, labored breathing, cyanosis, or HR <100 bpm, further intervention is required by ensuring adequate ventilation through endotracheal tube (ETT) or laryngeal mask (LMA). (4)

3.3 Neonatal resuscitation

Effective resuscitation allows a significant reduction in infant mortality and improved outcomes for newborns who survive birth asphyxia. Intubation is often necessary during resuscitation and can be lifesaving for infants both immediately after birth and during neonatal intensive care. Reasons for intubation during neonatal resuscitation include ineffective or prolonged positive-pressure ventilation with a face mask, the need to secure the airway during cardiac compressions, administering medications directly into the trachea, and specific resuscitation scenarios such as congenital diaphragmatic hernia or clearing meconium through endotracheal suctioning.(4) Endotracheal intubation becomes essential in neonatal

intensive care settings when infants experience respiratory failure despite attempts at non-invasive respiratory support. It is also utilized for surfactant administration, managing resistant apnea in premature infants, and preparing infants for surgical procedures. Intubation may be conducted either nasotracheal or orotracheal. Therefore, it is imperative that all birth attendants, including physicians, midwives, and nurses, possess the requisite knowledge and skills for neonatal resuscitation. However, mastering endotracheal intubation is a challenging skill that requires continuous practice and maintenance, often resulting in initial attempts being unsuccessful. Successful intubation relies on the ability of the intubator to perform laryngoscopy.(5) Unfortunately, opportunities for neonatal trainees to acquire and sustain proficiency in this procedure are diminishing despite this procedure requires a long learning curve. This decline can be attributed to several factors, including the increasing utilization of non-invasive respiratory support in neonatal intensive care, reduced working hours for trainees, a rise in the number of trainees, and evolving clinical guidelines, such as the recommendation to discontinue routine intubation of infants born through meconium-stained amniotic fluid.(5)

The first Cochrane systematic review focusing on surfactant administration use for positive pressure ventilation (PPV) during neonatal resuscitation identified no eligible studies comparing supraglottic device (SA) utilization with a face mask. Only one small randomized controlled trial (RCT) comparing SA insertion with endotracheal intubation was found. The review authors concluded that SA showed promise as a device but underscored the necessity for a well-designed RCT comparing PPV administered with SA versus a face mask. Since the inception of this initial review, numerous RCTs have been conducted, comparing various SA designs with both endotracheal tube (ET) intubation and face masks. An updated Cochrane review, published in 2018, found that SAs were equally effective as ET intubation for administering PPV during neonatal resuscitation (very low certainty).(6)

3.4 Laryngeal Mask

3.4.1 Historical overview

The laryngeal mask airway is a supraglottic device that allows the establishment of an airway and for oxygenation and ventilation without going through the vocal cords. It was first described by Dr. Archie Brain in 1983, designed as a new concept

in airway management and has been gaining a firm position since it doesn't require any additional instrumentation for positioning which makes this approach to airway management more physiologic and avoids, both, side effects linked to laryngoscopy and the disadvantages of face masks.(6) Brain identified the suboptimal connection between the anatomical airway and traditional artificial airways, leading him to design an airway that would align more directly with the larynx. By studying the shape of the pharynx through plaster-of-Paris casts from cadavers, he invented the laryngeal mask in 1981, which was based on these hypopharyngeal models. That same year, he tested a prototype on a patient for the first time. The development process of this invention is thoroughly documented by Brain himself. Since its introduction to clinicians in 1988, the laryngeal mask has rapidly become an integral tool in anesthetic practice.(7)

3.4.2 Device Architecture and Features

The larynx mask is composed of a small distal elliptical mask that connects to an airway tube with a proximal universal connector, allowing it to be attached to a self-inflating bag, flow-inflating bag, T-piece resuscitator, or mechanical ventilator to administer PPV. The laryngeal mask forms an airtight seal by enclosing the larynx rather than plugging the pharynx and avoids airway obstruction in the oropharynx. The distal part of the mask conforming to the hypopharynx and the walls of the long axis of the mask facing towards the pyriform fossae. A tube is connected to the rear of the mask at an approximately 30-degree angle. This specific angle was found to be the optimal angle for tracheal intubation through the laryngeal mask. The mask comprises a cuff that can be inflated through a pilot tube and balloon, allowing the monitoring of cuff pressure. When appropriately deflated, the cuff should create a "wafer-thin leading edge" oriented away from the mask opening. Additionally, there are two vertical bars located at the distal end of the tube, which are intended to prevent the epiglottis from obstructing the tube's opening.(7)

3.4.3 Categorization

Larynx masks are classified by the shape of the airway tube and the type of seal over the glottis (**Tab. 1**). Based on the cuff, there are three different ways for the LMA to achieve the seal: most models include an inflatable cuff, with a syringe attached to an inflation tube that allows the user to pump 2-6 mL of air into the cuff after positioning; another version, the (I-gel®) doesn't require any inflatable pieces,

thanks to its silicone constitution, it achieves its target solely thanks to the rigid structure; one last way to achieve the seal over the glottis is by using the airflow from positive-pressure ventilation to self-inflate and dynamically adjust the cuff inflation pressure (Air-Q®sp3). A manikin study comparing 7 models of neonatal SAs, and 2 types of face masks showed that leak was significantly lower with this cuffless SA. There are no clinical studies directly comparing different SA models in the neonatal population.(6)

There is no comparability between the sizing of different manufacturers, each design is different from others produced by the same company or by other ones. Similarly, there is no industry standard guiding regarding at which weight the laryngeal mask is safe for use. Out of all the different models available on the market only one is eligible to be used on newborns <2 kg (Air-Q®sp3).(6) However, there was one study by Parmigiani et al. in which I-gel® mask was used in infants weighing from 1500 gr.(8)

Second generational SAs have a channel that allows insertion of an additional tube for gastric air decompression (see **Tab. 1**), few neonatal models include this gastric access channel. One model, Air-Q3™, or similar to it Air-Q®sp3, has been described as an intubating device. The manufacturer proposes a method utilizing a detachable proximal connector, a curved airway tube, and an integrated "ramp" within the inflatable mask, suggesting that an endotracheal tube (ET) size 3.0 or 3.5 mm can be inserted into the main airway tube of the device and guided "blindly" through the mask opening into the glottis. This technique is intriguing and has the potential to offer a novel approach for less invasive surfactant administration.(6)

3.4.4 Models available on the market

Tab. 1 Neonatal SA models (6)

Model	Size	Inflatable cuff	Gastric access	Company	Comments
LMA® Classic™	1	+	-	Teleflex Medical Europe, Westmeath, Ireland.	The original first-generation SA. A re-useable device with a silicone mask. Not available in the USA.
LMA® Unique™	1	+	-	Teleflex, Morrisville, North Carolina, USA. Teleflex Medical Europe, Westmeath, Ireland.	Updated version of the original first-generation SA. A single-use device with a silicone mask (USA) or PVC mask (Europe).
LMA® ProSeal™	1	1	+	Teleflex Medical Europe, Westmeath, Ireland.	First SA with a gastric access channel. A re-useable device with a silicone mask. Not available in the USA.

LMA® Unique EVO™	1	+	-	Teleflex, Morrisville, North Carolina	A single-use device with a silicone mask, pre-curved airway tube, and proximal connector allows fiberscope-assisted intubation through the device.
LMA® Supreme™	1	+	+	Teleflex, Morrisville, North Carolina	First SA with a pre-curved tube to facilitate insertion. Single-use PVC mask with gastric access channel (6 FR OG tube).
I-gel®	1	-	-	Intersurgical, East Syracuse, New York.	First cuffless SA. A single-use device. Flexible, pre-curved airway tube.
Solus™	1	+	-	Intersurgical, East Syracuse, New York	A single-use, first-generation device.
Ambu® AuraGain™	1	+	+	Ambu Inc. Columbia, Maryland	A single-use device with pre-curved tube and gastric access channel (6 FR OG tube). Proximal

					connector allows fiberscope-assisted intubation (3.5 mm ET) through the device.
Ambu® Aura-I™	1	+	-	Ambu Inc. Columbia, Maryland	A single-use device with pre-curved tube. Proximal connector allows fiberscope-assisted intubation (3.5 mm ET) through the device.
Ambu® AuraOnce™	1	+	-	Ambu Inc. Columbia, Maryland	A single-use device with pre-curved tube. Also available in a steam-autoclavable, re-useable design (Aura40TM)
Ambu® AuraStraight™	1	+	-	Ambu Inc. Columbia, Maryland	A single-use, first-generation device.
Air-Q3®	0, 0.5	+	-	Cookgas/Sun Med, Grand Rapids, Michigan.	Single-use, pre-curved device. Described as an “intubating” SA, with the insertion of an ET (size 3.0 or 3.5 mm) through

					the detachable proximal. Manufacturer recommends size 0 for < 2 kg, size 0,5 for 2-4 kg. The original Air-Q™ is available as a disposable (size 1) and re-useable (size 0.5 and 1) device.
Air-Q® sp3	0, 0.5	+	+/-	Cookgas/Sun Med, Grand Rapids, Michigan.	Like the Air-Q3® but does not require cuff inflation by the user. A self-pressurizing cuff uses gas flow from positive-pressure ventilation to fill and regulate intracuff pressure. Available with or without gastric access channel (6 FR OG tube).

Abbreviations: ET, endotracheal tube; FR: French; kg, kilograms; LM, laryngeal mask; mm, millimeters; OG, orogastric; PVC, polyvinyl chloride; SA, supraglottic airway.

3.4.5 Positive Pressure Ventilation administration

Approximately 5% of newborns, or about 6 million globally each year, require positive pressure ventilation (PPV) at birth. Choosing the most suitable device for delivering PPV is crucial, as inflating the newborn's lungs is the single most important step in neonatal resuscitation. It is essential to identify which device best aerates the newborn's lungs while minimizing the risk of lung injury, which can lead to short-term complications such as pneumothorax and intraventricular hemorrhage (IVH), as well as long-term issues like bronchopulmonary dysplasia (BPD).(9)

In neonates, the laryngeal mask airway (LMA) has been deemed safe and has shown to diminish the necessity for intubation as well as reduce ventilation duration. Moreover, healthcare providers demonstrate a rapid learning curve with the laryngeal mask, which is also less invasive compared to endotracheal intubation. These benefits imply that LMA could be a viable option for healthcare providers in level I–III hospitals during neonatal resuscitation in interhospital care settings. However, literature regarding this aspect remains limited.(10)

Failure of PPV with a face mask is mainly due to three causes: inadequate seal around the mask, upper airway obstruction, and the need for higher inflation pressures due to low pulmonary compliance. A study comparing the performance of personnel in a low-resource setting when they used the I-gel cuffless neonatal laryngeal mask or a face mask on a neonatal airway management manikin showed that both skilled and unskilled participants were able to quickly learn how to ventilate the manikin using the uncuffed supraglottic airway device. All participants successfully achieved effective positive pressure ventilation (PPV) on the manikin during each attempt. Additionally, PPV could be initiated more rapidly with the supraglottic airway device, although this difference did not reach statistical significance. Notably, several participants struggled to establish PPV within 30 seconds using the face mask. These findings confirm that it is indeed a challenge to achieve an effective seal with a face mask and maintaining optimal ventilation. Notably all participants had previous clinical experience with the face mask, while it was their first experience inserting a SA device.(2) ET intubation of the newborn is also a difficult skill to acquire and maintain.

3.4.6 Guidelines for supraglottic devices

In the last update of neonatal resuscitation by the American Heart association and the Academy of Pediatrics, the use of a supraglottic device as a primary device to administer PPV instead of a face mask in newborn infants delivered at ≥34 0/7 weeks' gestation is indicated as a class 2B recommendation.(11) They looked at a meta-analysis of six randomized controlled trials (involving 1823 infants born at or after 34 weeks' gestation) and discovered that using a supraglottic airway device reduced the likelihood of failing to improve with the assigned device, as well as the need for endotracheal intubation in the delivery room. The concept of "failure to improve with the assigned device" was chosen as a practical measure to evaluate whether using a supraglottic airway or a face mask for positive pressure ventilation (PPV) improved outcomes for newborns undergoing resuscitation after birth. Additionally, the duration of PPV and the time taken for the heart rate to surpass 100 beats per minute were shorter when using the supraglottic airway.(11)

However, it's important to note that this recommendation is limited to newborn infants ≥34 0/7 weeks' gestation, as all the studies included in the meta-analysis were conducted in settings with limited resources. First attempt SA insertion was highly successful in low-resource settings with minimal hands-on training. Furthermore, there have been no studies comparing face masks with supraglottic devices for initiating PPV during neonatal resuscitation in settings with ample healthcare resources. Therefore, the findings of this meta-analysis may not be directly applicable to settings where there are more healthcare practitioners with advanced skills and well-trained neonatal resuscitation teams.

The American Heart Association and American Academy of Pediatrics developed the Neonatal Resuscitation Program (NRP) to promote an evidence-based approach to newborn care. According to the NRP algorithm, tracheal intubation is recommended when face mask ventilation proves ineffective or is required for an extended period. However, pediatric trainees often struggle with intubation and have limited opportunities to practice this skill. For newborns weighing more than 1500 grams, a supraglottic airway (SGA) is a suitable alternative when face mask ventilation is inadequate and endotracheal intubation is either unsuccessful or not feasible.(11)

3.4.7 Advantages of SAs compared to endotracheal tube

Nevertheless, compared to endotracheal (ET) intubation, research on supraglottic airways (SAs) consistently demonstrates a high rate of successful insertion on the first attempt with minimal training (over 90%), along with a reduced risk of tracheal injury, less airway stimulation leading to milder hemodynamic fluctuations, decreased risk of upper airway injury, and relatively easier positioning. Additionally, the learning curve for SA insertion in neonates has been shown to be significantly shorter than that for ET intubation. While some published literature mentions side effects associated with SA use, such as soft tissue edema, vomiting, and abdominal distension, systematic reviews indicate that the probability of soft tissue injury and complications is not heightened with SAs. However, using SAs for mechanical ventilation over an extended period lacks sufficient study and cannot be recommended currently.

Mastering the use of supraglottic airways (SGA) has the potential to minimize interruptions in positive pressure ventilation (PPV), therefore improve resuscitation outcomes.

The anatomical factors leading to failed ventilation with either face masks or ETs are less likely to interfere with correct positioning of SAs. Therefore, insertion of an SA should be considered immediately when a difficult airway situation is encountered. Multiple published case reports have shown that infants with congenital upper airway malformations and emergency “cannot intubate, cannot oxygenate” situations, the SA was a lifesaving device.(6)

3.4.8 Latest innovation in SAs

Video-assisted supraglottic airways (SA) represent the latest advancement in SA design. This device integrates a videoscope into a second-generation SA, allowing for visualization during insertion and confirmation of correct positioning. Additionally, this innovation enables endotracheal intubation through the main channel of the SA with direct visualization. Although a neonatal size is not currently available, this innovation could significantly facilitate endotracheal intubation and less invasive surfactant administration, representing a major advancement in neonatal airway management.

The SA has proven to be an effective device for respiratory support during anesthesia across a broad spectrum of pediatric patients. Additionally, the SA serves as a conduit for diagnostic bronchoscopy, facilitating respiratory support while guiding a flexible bronchoscope for intubation. Ultrasound has also been used for evaluating airway sealing pressure in anesthetized pediatric patients, proving to be a valuable tool for detecting SA misplacement.

3.5 Endotracheal Tube

3.5.1 Indication for intubation

Neonatal endotracheal intubation involves placing an endotracheal tube (ET) within an infant's airway. This procedure is often necessary and can be lifesaving after birth and during neonatal intensive care. Indications for intubation during neonatal resuscitation include ineffective or prolonged positive-pressure ventilation via face mask, the need to secure the airway during cardiac compressions, intratracheal medication administration, and special resuscitation circumstances like congenital diaphragmatic hernia or endotracheal suctioning for meconium. Endotracheal intubation is also required in neonatal intensive care for infants in respiratory failure despite non-invasive respiratory support, for surfactant administration, treating resistant apnea of prematurity, and preparing infants for surgery. Intubation can be either performed through the nose or through the mouth.(5)

3.5.2 Device Architecture and Features

Endotracheal tubes feature a built-in safety mechanism at the distal tip known as Murphy's eye, an additional opening located on the distal lateral wall of the tube. If the main distal end of the ETT becomes obstructed by the tracheal wall or the carina, gas flow can still proceed through Murphy's eye, thereby preventing complete obstruction of the tube. ETT connectors allow to attach the ETT to mechanical ventilator tubing or an Ambu bag, and it is standard practice to use a universal 15 mm connector for both adult and pediatric ETTs.

3.5.3 Intubation procedure

Laryngeal exposure through laryngoscopy with visualization of the glottis is crucial for successful endotracheal intubation. During direct laryngoscopy, a traditional laryngoscope is inserted into the mouth and lifted to visualize the vocal cords,

applying pressure to the base of the tongue. This maneuver can cause tissue trauma and trigger adverse reactions. In neonates, intubation often results in adverse events such as esophageal intubation, airway trauma, significant bradycardia, and severe intraventricular hemorrhage. Recent studies indicate that videolaryngoscopy can reduce these adverse events and enhance intubation success rates, particularly among less experienced medical staff. Videolaryngoscopy can use blades similar to traditional curved (Macintosh) and straight (Miller) blades or modified ones. A hyperangulated blade, in particular, offers a 60–90-degree view of laryngeal structures compared to the 15–30-degree view provided by Macintosh or Miller blades, allowing visualization of the glottis without needing to align the oral cavity, pharynx, and larynx. However, with this type of videolaryngoscope, the vocal cords cannot be directly visualized, so the endotracheal tube should be inserted using a preangled stylet that matches the blade's curvature.

Recent study findings (by Cavallin et al.) indicate that less force is required during intubation with videolaryngoscopy compared to direct laryngoscopy in a neonatal mannequin. Additionally, the study found no significant difference in success rates, time to intubation, or perceived workload between the two methods.(12)

3.5.4 Cuffed vs uncuffed endotracheal tube

Historically, pediatric endotracheal tubes were uncuffed due to concerns that cuff pressure could cause tracheal damage via pressure necrosis, given that the cricoid cartilage just below the vocal cords is the narrowest part of the airway in children. In contrast, the narrowest part of the airway in adults is at the vocal cords. Nowadays, except for neonatal patients, the use of cuffed pediatric ETTs has become standard practice. A cuff is an inflatable balloon at the distal end of the ETT. When inflated, the cuff creates a seal against the tracheal wall, preventing gastric contents from entering the trachea and facilitating effective positive pressure ventilation.

The anatomy of the pediatric airway is controversial. Autopsy data and direct laryngoscopy have described the airway of neonates and infants as funnel- shaped, with the narrowest portion being the circular rigid cricoid cartilage, recent in vivo studies using imaging techniques on children and infants undergoing magnetic resonance imaging (MRI), video-bronchoscopic imaging, or computed tomography

(CT) scan, and children and infants (60 intubated) undergoing CT scan for trauma, have shown it to be circular or ellipsoid, with the narrowest point at the glottic opening and immediate subvocal cord level. The children wer asleep, sedated or anesthetized (with or without paralysis).

The first anatomical model led to the traditional use of uncuffed ETTs in neonates and children under eight years old, designed to allow leakage around the circular cricoid cartilage when properly sized. In contrast, the second model suggests that even a well-sized uncuffed ETT with reasonable leakage might exert excessive pressure on the transverse tracheal wall at the cricoid level. A smaller diameter micro-cuffed ETT, however, could provide an adequate seal without applying undue pressure on the transverse cricoid.(13)

Pediatric ETTs are nowadays available both with and without cuffs. Cuffed ETTs help reduce gas leakage around the tube, minimize the need for ETT exchange, prevent accidental extubation, and decrease healthcare workers' exposure to anesthetic gas during surgery. Standard anesthetic practice requires demonstrating an air leak around the ETT at a peak inspiratory pressure of 20 cm H_2O to 25 cm H_2O to ensure the ETT is not too tight. The cuff is usually inflated to a maximum of 20 cm H_2O, and this can be controlled by a pressure release valve. Pressure monitoring can be done continuously or intermittently. The risks and benefits of using cuffed versus uncuffed endotracheal tubes in neonates remain unclear. It is also crucial to evaluate the risks and benefits of adhering to recommendations regarding ETT type and size, as well as the implications of inflating versus not inflating the cuff.

The smallest available uncuffed ETT currently has an internal diameter of 2.0 mm. According to the Neonatal Resuscitation Program guidelines, ETT size (internal diameter) is based on weight. For cuffed ETTs, the guidelines indicate that the smallest available micro-cuffed ETT has an internal diameter of 3.0 mm and is recommended for neonates weighing 3 kg or less.(13)

A 2016 survey in Australia and New Zealand revealed that most NICUs used uncuffed ETTs for neonates weighing more than 3 kg and infants under three months of age, while most PICUs used cuffed ETTs. A randomized controlled trial (RCT) in children with cuffed ETTs found no difference in complications like

postextubation stridor, reintubation rate, ventilator-associated pneumonia rate, number of ventilator days, and length of PICU stay between the group using protocolized monitoring of cuff pressures and the group without protocol.

The endotracheal tube (ETT) is measured from its distal end and is typically marked in 2 cm increments. After successful intubation, the depth of the ETT at the teeth or lips should be recorded. This measurement serves as a baseline to ensure the tube does not shift out of or deeper into the trachea due to patient movement or transport. Since PVC is not radiopaque, a radiopaque linear material is embedded along the tube's length to aid in visualizing its placement on X-rays. For pediatric patients, the ETT is usually taped at a depth equivalent to three times the tube size (e.g., a 4.0 ETT is typically taped at around 12 cm).

3.5.5 Use of stylet

Small-diameter endotracheal tubes (ETTs) are flexible and can be used with or without a stylet. A neonatal stylet is a 6 French (2-mm diameter) malleable aluminum wire coated with lubricated plastic, which extends beyond the tip of the stylet. These stylets are compatible with tubes having an internal diameter of 2.5 mm or larger. When using a stylet, it is crucial to position it so that its tip does not extend beyond the tip of the ETT. The proximal end of the ETT is equipped with a plastic adapter for connection to a ventilator, through which the stylet is threaded and secured by bending its proximal end over the rim of the adapter to prevent slippage.

Neonatal ETTs internal diameters range from 2.0 mm to 4.0 mm. The flexibility of these tubes increases as the internal diameter decreases, particularly when exposed to the heat of an overhead radiant warmer. Utilizing a stylet can enhance the rigidity and curvature of the tube, potentially facilitating easier navigation through the vocal cords. However, current guidelines (Richmond 2011; AAP 2016) do not advocate for the routine use of a stylet in orotracheal intubation, considering it an optional tool. While some practitioners may prefer the increased rigidity and curvature provided by a stylet and may achieve higher success rates, this rigidity can also pose risks, including potential airway damage. There have been documented cases of the stylet sheath shearing off, resulting in acute airway obstruction (Cook 1985;

Zmyslowski 1989; Bhargava 1998; Rabb 1998; Boyd 1999; Chiou 2007). As for the cost of stylets it is comparable to that of endotracheal tubes. (5)

3.5.6 Learning curve

Endotracheal intubation is a mandatory competency for neonatal trainees. However, it is a difficult skill to learn and maintain, and initial attempts are often unsuccessful. Prior studies conducted on anesthetized adult patients in a controlled operating room environment have suggested that around 50 intubations are necessary to attain a 90% success rate on the first attempt. First attempt neonatal intubation success rates are generally around 50%, with a range from 42% for residents to 64% for neonatology attendings. A recent study of graduating neonatology fellows found that only 45% achieved procedural competence during their training. For those who did reach competence, the number of intubations required to meet this standard ranged from 8 to 46 procedures(6) but this information has not been previously reported for neonatal patients.(14)

An Australian study (O'Donnell 2006) reported a 62% success rate for first intubation attempts overall, but only 24% among the least experienced trainees. An American study analyzing intubation success rates over a decade (Leone 2005) found median success rates of 33% for first-year residents, 40% for second- and third-year residents, and 68% for neonatal fellows, with significant differences between groups ($P < 0.001$). However, success rates for pediatric residents were similar for delivery room (DR) non-meconium intubations and neonatal intensive care unit (NICU) intubations (36% vs. 36.5%). The most recent US study (Haubner 2013) reported an overall success rate of 44%, with notable differences between experienced and inexperienced providers: 20% for residents, 72% for fellows, and 70% for attending physicians. The study also found that birth weight and gestation did not affect success rates. Research at US tertiary academic centers involving neonatologists, fellows, residents, and respiratory therapists, using exhaled carbon dioxide detection to confirm tube placement, indicates that esophageal intubation is relatively common (Roberts 1995; Aziz 1999; Repetto 2001; Lane 2004). (5)

The previous version of Neonatal Resuscitation Program (7th Edition, AAP 2016) recommends limiting intubation attempts to 30 seconds. This is an increase from the 20-second recommendation in the 5th Edition (Kattwinkel 2006). The change

followed a study of delivery room intubations, mainly performed by residents and fellows (Lane 2004), which found that 30 seconds was a more realistic time for intubation.(5)

Laryngeal exposure with visualization of the glottis is a key determinant of success or failure for endotracheal intubation. This is achieved through laryngoscopy, a manoeuvre that aligns the pharynx, larynx, and trachea axes, allowing direct insertion of a tracheal tube from the mouth into the trachea. During direct laryngoscopy, a traditional rigid laryngoscope is inserted into the mouth and lifted to visualize the vocal cords by applying force to the base of the tongue. This manoeuvre can cause direct trauma to the tissues and induce adverse reactions. In neonates, laryngoscopy can be particularly challenging, with success rates for neonatal intubation ranging from 20% to 70% among paediatric residents and neonatology fellows. Additionally, this procedure has a high rate of adverse events, including oesophageal intubation, airway trauma, significant bradycardia, and even cardiac arrest. (12)

3.5.7 Video laryngoscopy

In 2018, Pouppirt et al. found that video laryngoscopy was associated with decreased adverse events during neonatal intubation. Moreover, Zhou et al. reported that video laryngoscopy improved the success rate of neonatal tracheal intubation for novices, though it did not significantly enhance success rates for experienced medical staff. Video laryngoscopy provides an indirect view of the larynx. The blade of the video laryngoscope is equipped with a video camera connected to a separate display screen that shows the glottis. Video laryngoscopes may use blades similar to the traditional curved (Macintosh) and straight (Miller) blades or may utilize modified blades. Notably, a hyper angulated blade offers a 60- to 90-degree view of laryngeal structures, compared to the 15- to 30-degree view provided by the Macintosh or Miller blades. The hyper angulated blade video laryngoscope allows visualization of the glottis without needing to align the oral cavity, pharynx, and larynx. Direct visualization of the vocal cords is not possible with this approach; instead, the endotracheal tube (ETT) must be introduced using a pre-angled stylet that matches the blade’s curvature.(12)

3.5.8 Premedication

Failure to perform successful endotracheal tube placement, or delayed recognition of incorrect placement, can lead to death or severe hypoxic injury. Multiple intubations or traumatic intubations increase the risk of serious glottic, subglottic, and tracheal injury (Meneghini 2000; Wei 2011). Studies have demonstrated that administering premedication to infants using different types of induction agents enhances the speed of successful intubation and lowers the probability of associated adverse effects (Marshall 1984; McAuliffe 1995; Cook-Sathler 1998). Premedication has been demonstrated to notably enhance intubating conditions and decrease both the number of attempts needed for successful intubation and the risk of intubation-related airway trauma (also see **Tab. 3**).(5)

Tracheal intubation (TI) is a critical but potentially dangerous procedure for neonates in life-threatening situations. This invasive procedure is not only painful and stressful but also linked to immediate adverse effects such as laryngospasm, hemodynamic changes, and an increased risk of intracranial haemorrhage. To mitigate these physiological responses, the use of specific premedication including analgesic and/or sedative drugs, with or without a vagolytic agent has been recommended for nonemergent neonatal TI since 2001, with an update from the American Academy of Pediatrics (AAP) in 2010. Despite this guidance, the staff awareness of neonatal pain and its consequences, and numerous recent studies on effective drug combinations, many neonatal and pediatric intensive care units (NICUs/PICUs) and individual caregivers have yet to routinely incorporate the practice of neonatal premedication.

In 2005, a large regional longitudinal study in France, known as the Epidemiology of Procedural Pain in Neonates (EPIPPAIN 1), was conducted across 13 tertiary care centers in the Paris region. The study found that infants who did not receive specific premedication were younger at the time of intubation (median age: 0.7 days compared to 2.0 days for those who were medicated). Additionally, these infants manifested a higher frequency of spontaneous breathing at the time of intubation (31% versus 12%) and received a higher percentage of analgesia for other painful procedures (median values: 16% versus 6%). The rate of specific premedication was 56%, primarily consisting of opioids (67%) and midazolam (53%), with propofol and sufentanil being used alone or in combination.(15)

Synthetic opioids can induce chest wall rigidity, which can be prevented by muscle relaxants. These have been shown to reduce the risk of adverse effects, decrease the number of attempts, and shorten the total procedure time. Midazolam has been replaced by propofol, as it should not be used for tracheal intubation (TI) alone due to its long onset time and lack of analgesic effects. Propofol, on the other hand, is an acceptable hypnotic agent for TI and has been shown to be a suitable sedative with good tolerance for non-emergent TI.(15)

Despite a 20-year-old international consensus statement advocating for premedication before tracheal intubation in neonates, specific premedication rates decreased from 56% to 47% between 2005 and 2011. Three reasons may account for the challenges in implementing evidence-based medicine for this procedure, especially when it is non-urgent: the lack of a specific protocol, the challenge in selecting the most suitable drug(s) for individual neonates, and the perception among trained practitioners that premedication is unnecessary and time-consuming.(15)

The commonly cited arguments suggesting that premedication is unnecessary for practitioners and a waste of time for performing the procedure need to be reconsidered. Numerous studies have demonstrated that premedication, particularly when combined with a muscle relaxant, reduces the number of attempts and the time required to complete the procedure. This ultimately decreases its adverse effects, even among extremely low birth weight infants. Additionally, premedication has been shown to alleviate team stress and enhance the self-confidence of pediatric residents and fellows who may have fewer opportunities to perform this procedure than in the past.(15)

The implementation of a premedication algorithm or guideline, particularly if computerized, has been shown to increase the premedication rate while enhancing practitioners' confidence with the medication regimens utilized. It also serves to reduce team stress and standardize practices within a unit. To facilitate premedication administration and gain time for the drugs preparation, ready-to-use kits could be provided, alongside anticipated prescriptions for high-risk children, in each Intensive Care Unit (ICU). Given the decreasing frequency of tracheal intubation due to noninvasive ventilation, it's imperative to establish training sessions and standardized processes for preparing and administering premedication

in every unit. However, findings from the EPIPPAIN study reveal that even in centers with specific protocols, premedication rates remained low, not exceeding 45%. This underscores that the mere implementation of a protocol may not sustainably improve quality without regular monitoring and ongoing education to ensure effectiveness.(15)

Tab. 2 Comparison of laryngeal mask, face mask, and endotracheal intubation. (6)

Characteristic	**SA**	**FM**	**ET**
Leak around the mask	+	+++	-
Ability to provide high airway pressures if needed	+	++	+++
Stimulation of trigeminal nerve	-	+	-
Risk of device placement in the right bronchus or esophagus	-	-	+
Invasiveness	+	-	+++
Safety	+++	+++	+
Short learning curve	+++	++	+

Abbreviations: SA, laryngeal mask; FM, face mask; ET, endotracheal tube

3.5.9 Endotracheal intubation related injuries

Endotracheal intubation in neonates poses risks of airway injury, such as laryngeal edema (up to 17%) and subglottic stenosis (0.3% to 11%). Stridor, characterized by abnormal, noisy breathing, as an outcome, when absent doesn't necessarily indicate a significant airway injury. Diagnosis of airway injury like subglottic stenosis requires endoscopy to be ruled out. In the past, prolonged intubation was linked to 12% to 20% of subglottic stenosis cases. However, optimization ETT and ventilator management have reduced the incidence of acquired subglottic stenosis in neonates with prolonged intubation history to as low as 1%.(13)

There is a higher risk for airway injury when using an endotracheal tube type or size that does not meet recommendations for age or weight, duration of intubation, and number of intubations. (13)

In addition to suboptimal intubation success rates, adverse events complicate 18 % of neonatal intubations, with rates ranging from 9 to 50 % across centers. Neonates experience much higher rates of tracheal intubation associated adverse events compared with older patients, likely due to the unique anatomic and physiologic characteristics. (16) NEAR4NEOS made a comprehensive list of adverse tracheal intubation associated events (TIAEs). This is the most frequently used tool to assess neonatal intubation safety. The rate of severe oxygen desaturation, which is defined as a decline of ≥20 % in peripheral oxygen saturation (SpO2), is reported separately.

Tab. 3 Adverse TIAEs captured in NEAR4NEOS listed in order of frequency(16)

Severe TIAEs	**Non-severe TIAs**
Esophageal intubation, delayed recognition	Esophageal intubation, immediate recognition
Cardiac compression < 1 min	Dysrhythmia[a]
Laryngospasm	Mainstem intubation
Cardiac arrest, patient survived	Gum or dental trauma
Emesis with aspiration	Emesis without aspiration
Pneumothorax/ pneumomediastinum	Pain/ agitation requiring additional medication
Direct airway injury	Epistaxis
Hypotension requiring intervention	Lip trauma
Cardiac arrest, patient died	

TAIE: Tracheal Intubation Associated Events.
NEAR4NEOS: National Emergency Airway Registry for Neonates.
[a] Including bradycardia <60 beats per minute without chest compressions.

3.6 Difficult airway

A standard definition of a difficult airway is not found in the available literature. A difficult airway is defined as a situation where a conventionally trained anesthesiologist has trouble with facemask ventilation of the upper airway, tracheal intubation, or both. This difficulty results from a complex interaction between patient factors, the clinical setting, and the practitioner's skills. To analyze this interaction effectively, precise data collection and communication are necessary.

The Task Force encourages clinicians and researchers to use clear and explicit descriptions of difficult airways. (17) Descriptions that can be categorized or quantified are particularly useful, as they facilitate aggregate analysis and cross-study comparisons. Suggested descriptions include, but are not limited to:

- Difficult facemask or supraglottic airway (SGA) ventilation: adequate ventilation cannot be provided by the anesthesiologist due to issues such as an inadequate mask or SGA seal, excessive gas leak, or excessive resistance to gas flow. Signs of inadequate ventilation include, but are not limited to, absent or inadequate chest movement, absent or inadequate breath sounds, auscultatory signs of severe obstruction, cyanosis, gastric air entry or dilation, decreasing or inadequate oxygen saturation (SpO2), absent or inadequate exhaled carbon dioxide, absent or inadequate spirometric measures of exhaled gas flow, and hemodynamic changes associated with hypoxemia or hypercapnia (e.g., hypertension, tachycardia, arrhythmia). (17)
- Difficult SGA placement: Placement of the SGA requires multiple attempts, regardless of the presence of tracheal pathology.
- Difficult laryngoscopy: No portion of the vocal cords can be visualized after multiple attempts at conventional laryngoscopy.
- Difficult tracheal intubation: Tracheal intubation requires multiple attempts, regardless of the presence of tracheal pathology.
- Failed intubation: The endotracheal tube cannot be placed after multiple attempts.

The Danish Society for Anesthesiology and Intensive Care Medicine endorses the guidelines from the UK Difficult Airway Society for managing difficult airways. These guidelines recommend using a supraglottic airway device as a 'plan B' after unsuccessful facemask ventilation and up to three attempts at tracheal intubation, with a fourth attempt permitted if performed by a more experienced clinician.(18)

Numerous congenital conditions can complicate airway management. Positioning the head to align the pharyngeal and tracheal axes optimally may be challenging if the head is misshapen, as seen in craniosynostosis conditions like Apert or Crouzon syndrome, or in cases of macrocephaly. Facial asymmetry or underdevelopment, common in certain congenital syndromes (**Tab. 3**), can make it difficult to achieve a proper seal with a mask, complicating bag-mask ventilation. Microstomia, a

feature of Freeman-Sheldon and Hallermann-Streiff syndromes, can hinder mouth opening for laryngoscopy. Additionally, children with small mandibles or palatal abnormalities, such as high arched or cleft palates, have smaller oral cavities, which can make laryngoscopy and control of oral structures difficult. A large tongue can also obstruct the airway during bag-mask ventilation or be challenging to control during laryngoscopy.

Tab 4. Congenital features associated with airway abnormalities (19)

Features	**Abnormalities**
Misshapen head	Apert syndrome, Crouzon syndrome, Pfeiffer syndrome
Maxillary hypoplasia	Apert syndrome, Crouzon syndrome, Pfeiffer syndrome
Abnormal neck mobility	Apert syndrome, Crouzon syndrome, Pfeiffer syndrome
Microstomia	Freeman-Sheldon syndrome, Hallermann-Streiff syndrome
Mandibular hypoplasia	Hallermann-Streiff syndrome, Pierre-Robin sequence, Treacher-Collins syndrome, unilateral hypoplasia of the mandible (Goldenhar syndrome)
High arched or narrow palate	Achondroplasia, Apert syndrome, Crouzon syndrome, de Lange syndrome, Hallermann-Streiff syndrome, Pfeiffer syndrome, Treacher-Collins syndrome
Cleft palate	Branchio-Oculo-Facial syndrome, Cleft lip sequence, Ectrodactyly-Ectodermal Dysplasia-Clefting syndrome
Large or protuding tongue	Beckwith-Wiedemann syndrome, Down syndrome, mucopolysaccharidoses, Pierre-Robin sequence
Neck masses	Cystic hygroma, hemangioma
Laryngeal or subglottic abnormalities	Laryngeal cystes or webs, subglottic stenosis

In addition, children with underlying airway abnormalities who acquire an acute condition (such as croup or an upper respiratory tract infection) may quickly develop respiratory compromise. (19)

Approximately 1% of neonates require intubation at birth. The implementation of a less invasive approach has significantly reduced the exposure of healthcare providers to neonatal intubation. Previous studies have reported a wide range of success rates (20-70%) for pediatric residents and neonatology fellows. During direct laryngoscopy, the traditional laryngoscope is introduced into the mouth and lifted to visualize the vocal cords, applying force to the base of the tongue. This maneuver may cause direct trauma to tissues and precipitate adverse reactions. In neonates, intubation has a high rate of adverse events, such as esophageal intubation, airway trauma, significant bradycardia, and severe intraventricular hemorrhage.

Using the laryngeal mask as a guide to introduce a tracheal cannula avoids direct laryngoscopy and may increase the success rate of intubation while reducing laryngoscopy-related adverse events, especially among less experienced personnel. Recently, intubating laryngeal masks have become available in neonatal sizes.

The PICO question of this study is:

- **P**: In a manikin simulating a term neonate,
- **I**: Does the intubating laryngeal mask (air-Qsp®),
- **C**: Compared to direct laryngoscopy,
- **O**: Change the success of the first attempt and the time of device positioning?

The main objective of this trial will be to compare the success of the first attempt with the intubating laryngeal mask versus direct laryngoscopy in a manikin simulating a term neonate. Further objectives will be to compare the time of device positioning and the participants' opinions on the difficulty of the procedure.

4. OBJECTIVES

The main objective of this trial was to compare the success of the first attempt with intubating laryngeal mask vs. direct laryngoscopy in a manikin simulating a term neonate.

Further objectives were to compare the time of device positioning and participant's opinion on difficulty of the procedure.

5. METHODS

5.1 Study design

This was an unblinded, randomized, controlled, crossover (AB/BA) pilot trial of intubation procedure through intubating laryngeal mask vs direct laryngoscopy in a manikin simulating a term newborn. Participants were level III NICU consultants and residents. Randomization was performed using a computer-generated random assignment list. The primary outcome measure was the intubation success rate at the first attempt. Secondary outcome measures were the total time needed for the endotracheal tube positioning (calculated as the sum of the time of device positioning in all attempts), and the participant's opinion on using the device (evaluated using a Likert scale). The study has been registered on ClinicalTrials.gov after Ethics Committee approval (NCT06263790). Written informed consent was obtained from participants.

5.2 Setting

This simulation study was conducted at the University Hospital of Padua (Italy) as coordinating center and the Fondazione Poliambulanza of Brescia (Italy) as a participating center on 3rd and 8th April 2024. The scenario consisted of a full-term newborn manikin requiring intubation (neonatal simulator manikin: Newborn Anne, Laerdal Medical Corporation, Stavanger, Norway).

5.3 Participants

Level III NICU consultants and residents were eligible to participate in the study. There were no exclusion criteria.

5.4 Randomization

All participants were randomly assigned to AB or BA arms in a 1:1 ratio using a computer-generated random assignment list. The group assignments were placed in sequentially numbered, sealed opaque envelopes.

5.5 Procedure

Participants in AB arm were assigned to perform the procedure with the laryngeal mask (air- Qsp®), followed by the procedure with direct laryngoscopy. Participants in BA arm were assigned to the reverse sequence. A washout period of 6 hours (one procedure in the morning and one in the afternoon) was included to reduce any

carryover effect. During each simulation, an external observer recorded the study outcomes. After the first attempt, the correct positioning was evaluated by the external observer using a laryngoscope after careful removal of the laryngeal mask (during the attempt with the laryngeal mask) or a laryngoscope (during the attempt with the direct laryngoscope).
The procedure was repeated until correct positioning of the device was achieved. The total time of device positioning was calculated as the sum of the times of all attempts needed to achieve a correct device positioning.

Figure 1. Qr-code redirecting to a video on how to perform intubation through a laryngeal mask (air- Qsp®).

5.6 Outcome measures

The primary outcome measure was the success of the first attempt. The secondary outcome measures was the total time of device positioning and participants' opinion

on difficulty of the procedure. The success of the first attempt was defined as the achievement of the correct positioning of the endotracheal tube in the trachea as assessed by the external observer. The total time of device positioning was calculated as the sum of the time of device positioning in all attempts, as the procedure was repeated in case of incorrect positioning, with a 30 seconds time limit as endorsed by the Neonatal Resuscitation Program guidelines. Participants reported their opinion on insertion difficulty and overall difficulty using a Likert scale (1= not difficult, 5=very difficult).

5.7 Data collection

Data were recorded in a data sheet designed for this study and maintained in order to protect confidentiality before, during, and after the trial by the principal investigator in a personal computer protected by password. All data was collected by an observer not involved in the simulation. The following information were registered: randomization sequence, participant age and experience, study outcomes (as described before).

5.8 Sample size

The literature did not offer any useful information on the primary outcome measure that could be used to inform the sample size calculation during the study design. Hence, we aimed to enroll all eligible subjects in the participating centers during the trial period (24 to 34 participants). In a crossover design, such sample sizes had the chance of detecting an effect size ranging from 20% to 26% with 80% power and ranging from 23% to 31% with 90% power. Sample size calculation was performed using R 4.3 (R Foundation for Statistical Computing, Vienna, Austria).

5.9 Recruitment

Written and oral information was offered to the participants by a competent professional who is trained in neonatal resuscitation. Consent to use the data was obtained by all participants.

5.10 Blinding

Due to the characteristics of the intervention, neither caregivers nor outcome assessors were masked to treatment allocation. However, the statistician performing data analysis was masked to treatment allocation.

5.11 Guidelines for Management

Before starting the study, the participants joined a meeting where all the details of the study protocol were presented. During each simulation, an external observer recorded the study outcomes.

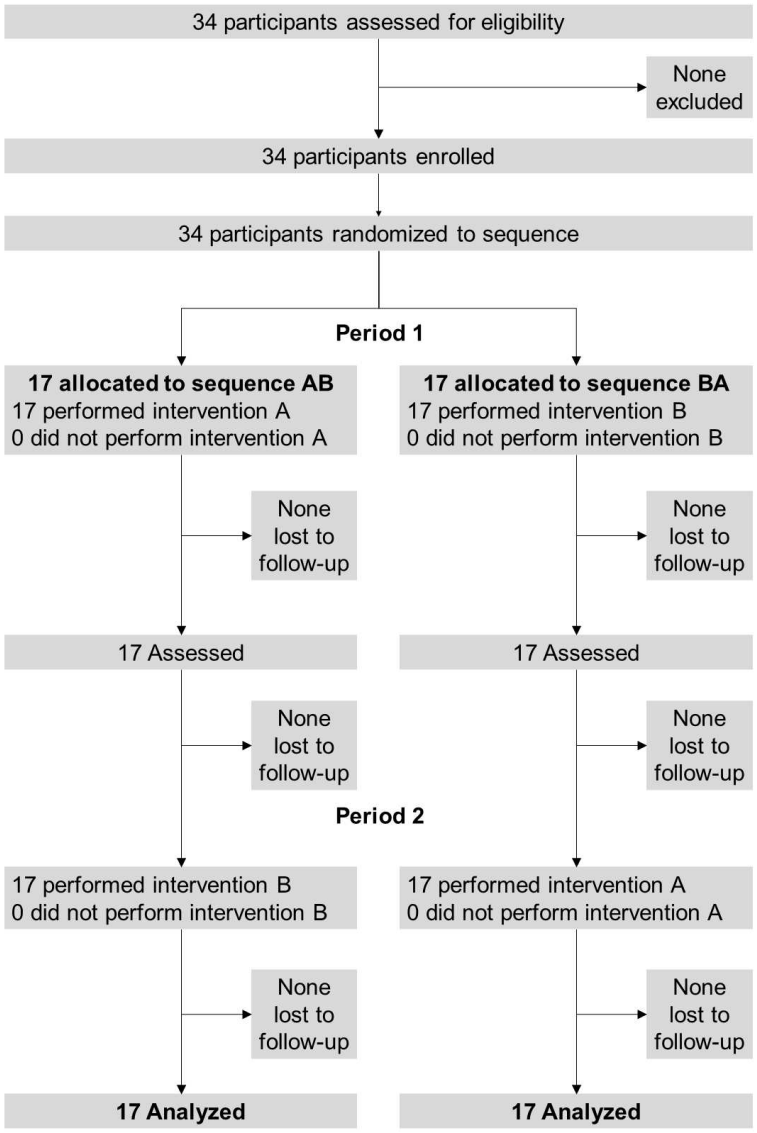
6. STATISTICAL ANALYSIS

The crossover design implemented an AB/BA scheme, which is uniform within sequences and periods (thus removing any period and sequence effects) and included a reasonable washout period to prevent any carryover effects. The categorical variables were summarized as absolute frequency and percentage, and the numerical variables as median and interquartile range (IQR). The binary outcome measure (correct positioning of the endotracheal tube in the trachea at the first attempt) was compared between the study arms using the McNemar test, and the effect size was reported as difference in proportion for paired data with 95% confidence interval. The numerical outcome measures (total time of device positioning and participant's opinion were compared between the study arms using the quantile test, and the effect sizes were reported as median difference with bootstrap 95% confidence interval. All tests were 2-sided and a p-value less than 0.05 was considered statistically significant. Statistical analysis was performed using R 4.3 (R Foundation for Statistical Computing, Vienna, Austria).

7. RESULTS

The trial included 34 participants (10 males and 24 females) who were randomly assigned to the trial arms (**Figure 2**). Median experience in neonatal intensive care was 3 years (IQR 1-14).

Figure 2. CONSORT flow diagram.



Experience in positioning a laryngeal mask in newborns was >20 cases in four participants, 10-20 cases in two participants, 5-10 cases in three participants and <5 cases in 25 participants. Experience in intubating newborns using a direct

laryngoscope was >20 cases in 16 participants, 10-20 cases in three participants, 5-10 cases in five participants and <5 cases in 10 participants.

Experience in positioning a laryngeal mask in neonatal manikins was >20 cases in seven participants, 10-20 cases in four participants, 5-10 cases in six participants and <5 cases in 17 participants. Experience in intubating neonatal manikins using a direct laryngoscope was >20 cases in 11 participants, 10-20 cases in eight participants, 5-10 cases in five participants and <5 cases in 10 participants.

The correct positioning of the endotracheal tube in the trachea was achieved at the first attempt by all participants with the laryngeal mask (100%) and 26 participants with the direct laryngoscope (76%) (difference in percentage 24%, 95% confidence interval 5% to 41%; p=0.008) (**Table 5**).

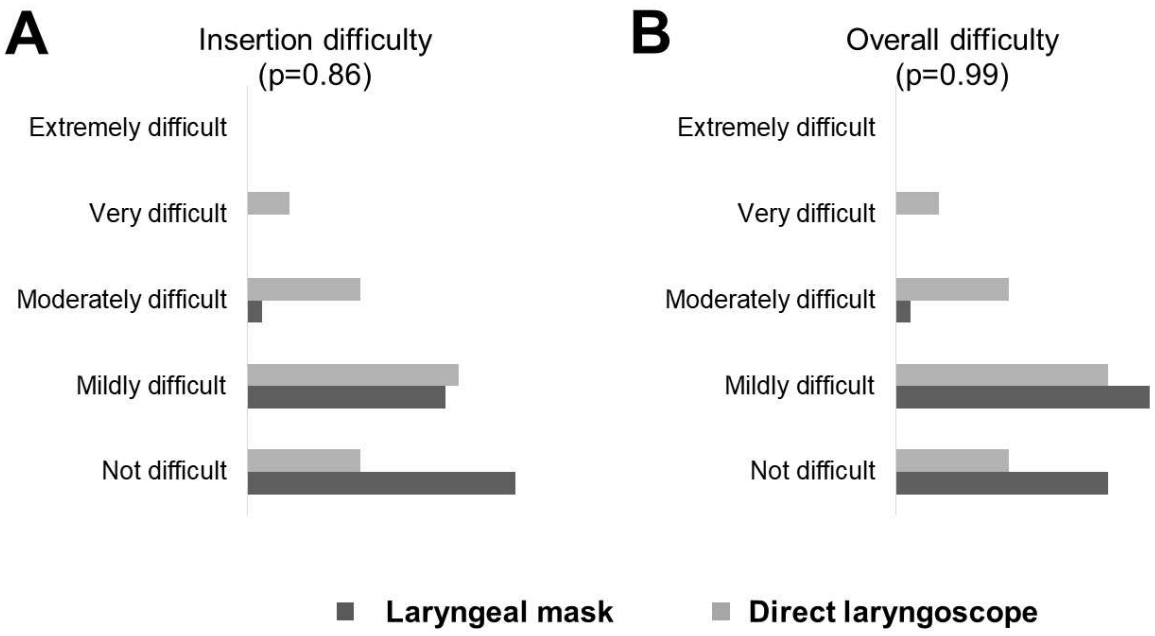
Median time of device positioning was 24 seconds (IQR 19-30) with both the laryngeal mask and the direct laryngoscope (p=0.99) (**Table 5**).

Participants' opinions about insertion difficulty and overall difficulty when intubating via the laryngeal mask or the direct laryngoscope are displayed in **Figure 3**. The comparison of the insertion difficulty (p=0.86) and the overall difficulty (p=0.99) did not provide any statistically significant difference between the laryngeal mask and the direct laryngoscope (**Table 5**).

Table 5 Outcome measures

Primary outcome measure	Intubation via laryngeal mask (n=34)	Intubation via direct laryngoscope (n=34)	Comparison of laryngeal mask vs. direct laryngoscope	
			p-value (McNemar test)	Difference in percentage for paired data (95% confidence interval)
Correct positioning of the endotracheal tube in the trachea at the first attempt: n (%)	34 (100%)	26 (76%)	0.008	24% (5% to 41%)
Secondary outcome measure			p-value (quantile test)	Median difference (bootstrap 95% confidence interval)
Total time of device positioning, seconds: median (IQR)	24 (19-30)	24 (19-30)	0.99	0 (-4 to 4)
Participant's opinion on insertion difficulty of the procedure, Likert scale (1= not difficult, 5= very difficult): median (IQR)	1 (1-2)	2 (2-3)	0.86	-1 (-1 to 0)
Participant's opinion on overall difficulty of the procedure, Likert scale (1= not difficult, 5= very difficult): median (IQR)	2 (1-2)	2 (2-3)	0.99	-0.5 (-1 to 0)

Figure 3. Participants' opinions about insertion difficulty (A) and overall difficulty (B) when intubating via the laryngeal mask or the direct laryngoscope (evaluated using a Likert scale).



8. DISCUSSION

Approximately 1% of neonates require intubation at birth. The implementation of a less invasive approach has significantly reduced the exposure of healthcare providers to neonatal intubation. Previous studies have reported a wide range of success rates (20-70%) for pediatric residents and neonatology fellows.

In our study, we aimed to evaluate the success of the first attempt with the intubating laryngeal mask (air-Qsp®), which allows for the insertion of a tube through it, compared to the traditional laryngoscope. This resulted in a 100% success rate for the laryngeal mask, compared to 76% for traditional laryngoscopy on the first attempt. This result reflects the initial hypothesis and the primary outcome measure based on which the study was built.

Intubation is a required skill for all birth attendants, consultants and residents that work with newborns, but is a difficult skill to aquire with a longer learning curve and the opportunities for neonatal trainees to aquire and sustain proficiency are diminishing. Prior studies conducted on anesthetized adult patients in a controlled operating room environment have suggested that around 50 intubations are necessary to attain a 90% success rate on the first attempt. First attempt neonatal intubation success rates are generally around 50%, with a range from 42% for residents to 64% for neonatology attendings. A recent study of graduating neonatology fellows found that only 45% achieved procedural competence during their training. For those who did reach competence, the number of intubations required to meet this standard ranged from 8 to 46 procedures (6) but this information has not been previously reported for neonatal patients. In a review of 150 intubations performed by a pediatric trainee over a five-year residency, Doglioni et al. observed that circa 100 intubations were required to acquire proficiency but the learning curve may be steeper if the neonates are sedated and paralyzed.(14)

In a study of 7708 intubations across 17 sites, Singh et al. demonstrated significant increase in the aOR (adjusted odds ratio) of any TIAE (tracheal intubation assosciated events), a severe TIAE and severe desaturation with each additional attemp. Neonatal endotracheal intubation is a challenging procedure, often marked by suboptimal success rates and associated adverse events. Implementing strategies to enhance intubation success typically correlates with improved safety

outcomes.(16) This issue could be adressed by implementing intubation through laryngeal mask in the protocols for everyday practice seen the promising results, moreover considering that most of infants who need intubation at birth are born in low- and middle income countries. Emergency airway management in resource-limited settings presents unique challenges that demand innovative approaches. Unlike well-equipped medical facilities, these environments often face shortages of critical resources such as intubation equipment, medications, and trained personnel.(20) In this enviroments conventional approaches to airway management may prove impractical or suboptimal. Successful first intubation in resource-limited settings hinges on several key factors. Clinical expertise is paramount, requiring experienced healthcare providers to ensure swift and effective intubation. Thorough patient assessment is critical for identifying potential airway challenges, such as facial trauma or anatomical abnormalities. Additionally, access to functional intubation equipment, including laryngoscopes and endotracheal tubes, is essential.(20) Intubation through laryngeal mask doesn't require any additional instrumentation for positioning, avoiding both the side effects linked to laryngoscopy and the need to sustain the expenses for laryngoscopes.

In 2018, Pouppirt et al. found that video laryngoscopy was associated with decreased adverse events during neonatal intubation. Moreover, Zhou et al. reported that video laryngoscopy improved the success rate of neonatal tracheal intubation for novices, though it did not significantly enhance success rates for experienced medical staff. A study by Ruetzler et al. showed that an excellent view on every intubation attempt (100%) was documented for the GlideScope, McGrath, and King Vision video laryngoscopes. The C-MAC and Airtraq video laryngoscopes achieved an excellent view in 96% of cases, while the direct laryngoscopy achieved this in 78% of cases. (21)

As for the secondary outcomes measured, the median time for total device positioning was 24 seconds for both procedures. Although this result is not statistically significant, the positioning of the laryngeal mask allows for intermediate ventilation before the removal of the mask and the definitive placement of the endotracheal tube. Infants have a smaller functional residual capacity and higher oxygen consumption compared with adults and larger children, leading to more rapid oxygen desaturation during apnea. This results in a shorter

duration of apneic time for providers to safely perform the intubation.(16) Infants frequently deteriorate during intubation attempts.(22) Having the laryngeal mask in place allows for intermediate ventilation of the newborn, making it possible to both check the correct positioning of the mask and re-oxygenate the child before proceeding further. To mitigate hypoxia, preoxygenation is essential together with limiting each intubation attempt to a reasonable maximum duration (30 seconds), maintaining careful observation and monitoring throughout the procedure—especially with pulse oximetry—and verifying correct tube placement using exhaled carbon dioxide detection are necessary practices.(23) The use of an exhaled carbon dioxide detector or flow signals may be useful in determining endotracheal tube position more quickly than clinical assessment alone.(14) Intubation attempts are often unsuccessful, and successful attempts frequently require more than 30 seconds. Greater experience is associated with greater success rates and shorter duration of successful attempts. But still, in a review by O'Donnell CPF et al. they observed that some infants deteriorate during attempts of 30 seconds' duration, but others had already done so by 20 seconds.(22)

As per participants opinion on the insertion difficulty, it was not statistically significant with a mean score of 1, not difficult, for LMA and of 2, mildly difficult, for the endotracheal intubation. When looking at the experience of the participants there is a notable difference between both procedures. 17 participants had an average experience of less than 5 laryngeal mask positioning on a manikin, and 25 positioned it less than 5 time on a newborn versus 10 participants that intubated less than 5 times using a direct laryngoscope respectively on a manikin and a newborn.

Unfortunately, opportunities for neonatal trainees to acquire and sustain proficiency in intubation procedures are diminishing despite this procedure requires a long learning curve. This decline can be attributed to several factors, including the increasing utilization of non-invasive respiratory support in neonatal intensive care, reduced working hours for trainees, a rise in the number of trainees, and evolving clinical guidelines, such as the recommendation to discontinue routine intubation of infants born through meconium-stained amniotic fluid.(5)

In a review of 150 intubations performed by a pediatric trainee over a five-year residency, Doglioni et al. noted that the trainee's learning curve, complicated by working with preterm infants and in a peripheral hospital environment during the

stabilization of critically ill patients needing transfer, may account for the higher number of attempts (approximately 100) required to achieve proficiency. This contrasts with previously reported experiences of physicians who performed intubations on selected adult patients in the controlled setting of an operating room. To improve teaching programs, it would be interesting to know if residents' exposition to intubation procedure could be different during the weekdays and day-hours or the weekends and night-hours. This trainee was exposed to a significant higher number of intubations during the night-time or weekends in comparison with daytime or weekdays. Even if purely descriptive, these data suggest that, along with other educational formats, such as mock resuscitations or standardized patient encounters, there are relevant teaching opportunities for residents during night-time and weekends.(14) Greater experience is associated with greater success rates and shorter duration of successful attempts. (22)

When evaluating the overall difficulty of both procedures, the participants gave an average score of 2, mildly difficult, for the positioning of the tube with either the laryngeal mask airway or the laryngoscope, so there is no statistical significance for this parameter.

The strengths of this trial are the design (this is a randomized, controlled crossover (AB/BA) trial), the use of materials normally used in the clinical practice, and the use of a manikin which is very close to reality. A further strength regards the wide experience of participants who were enrolled in the study; indeed, there were not only experienced consultants but also pediatric residents with less experience, which makes it a heterogeneous group and allows the results to be generalized also to non-level III NICUs.

This study has some limitations that should be acknowledged. First, we used only one model of manikin and laryngeal mask size. Second, the manikin eliminates the anatomical heterogeneity among patients. Third, the generalizability of the findings should be limited to healthcare givers with similar experience.

9. CONCLUSIONS

In this manikin study, the success of intubation on the first attempt using an intubating laryngeal mask was superior to intubation performed with direct laryngoscopy, suggesting that this practice could be considered for this difficult and invasive procedure in the newborn. Future studies are needed to confirm the validity of this approach in clinical practice.

10. TRIAL REGISTRATION

This trial has been registered at clinicaltrial.gov NCT06263790.

11. BIBLIOGRAPHY

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12. APPENDIX 1 – PROTOCOL OF THE STUDY

Study design: This is an unblinded, randomized, controlled, crossover (AB/BA) pilot trial of intubation procedure through intubating laryngeal mask vs direct laryngoscopy in a manikin simulating a term newborn.

Setting: The study will be conducted at the University Hospital of Padova as coordinating center (daniele.trevisanuto@unipd.it) and Fondazione Poliambulanza of Brescia as participating center (paolo.villani@poliambulanza.it).

Inclusion criteria: Level III NICU consultants and residents will be eligible to participate in the study.

Exclusion criteria: There are no exclusion criteria.

Randomization: All participants will be randomly assigned to AB or BA arms in a 1:1 ratio using a computer-generated random assignment list. The group assignments were placed in sequentially numbered, sealed opaque envelopes.

Procedure: Participants in AB arm were assigned to perform the procedure with the laryngeal mask (air- Qsp®), followed by the procedure with direct laryngoscopy. Participants in BA arm will be assigned to the reverse sequence. A washout period of 6 hours (one procedure in the morning and one in the afternoon) will be included to reduce any carryover effect. During each simulation, an external observer will record the study outcomes. After the first attempt, the correct positioning will be evaluated by the external observer using a laryngoscope after careful removal of the laryngeal mask (during the attempt with the laryngeal mask) or a laryngoscope (during the attempt with the direct laryngoscope). The procedure will be repeated until correct positioning of the device will be achieved. The total time of device positioning will be calculated as the sum of the times of all attempts needed to achieve a correct device positioning.

Outcome measures: The primary outcome measure will be the success of the first attempt. The secondary outcome measures will be the total time of device positioning and participant's opinion on difficulty of the procedure. The success of the first attempt will be defined as the achievement of the correct positioning of the endotracheal tube in the trachea as assessed by the external observer. The total time of device positioning will be calculated as the sum of the time of device positioning in all attempts, as the procedure will be repeated in case of incorrect positioning.

Participants will report their opinion on insertion difficulty and overall difficulty using a Likert scale (1= not difficult, 5=very difficult).

Sample size: The literature does not offer any information on the primary outcome that could be used for a mathematical calculation of the sample size. Hence, the study will use a convenience sample and we aim to enroll all eligible 30-50 participants in the centers.

Recruitment: Written and oral information will be offered to the participants by a competent professional who is trained in neonatal resuscitation. Consent to use the data will be obtained by all participants.

Blinding: Due to the characteristics of the intervention, neither caregivers nor outcome assessors will be masked to treatment allocation. However, the statistician performing data analysis will be masked to treatment allocation.

Guidelines for management: Before starting the study, the participants will join a meeting where all the details of the study protocol will be presented. During each simulation, an external observer will record the study outcomes.

Data collection: Data will be recorded in a data sheet designed for this study and maintained in order to protect confidentiality before, during, and after the trial by the principal investigator in a personal computer protected by password. All data will be collected by an observer not involved in the simulation. The following information will be registered: randomization sequence, participant age and experience, study outcomes (as described before).

Statistical analysis: This crossover study will use an AB/BA scheme, which is uniform within sequences and periods (thus removing any period and sequence effects), and will include a washout period to reasonably prevent any carryover effects. Since tests for carryover effect are generally underpowered, the inclusion of an adequate washout period is strongly recommended to prevent carryover effects. (6) Continuous data will be expressed as mean and standard deviation or median and interquartile range, and categorical data as number and percentage. Continuous outcome measures will be compared between the two procedures using the paired Student t test or the Wilcoxon signed-rank test. Binary outcome measures will be compared the two procedures using the McNemar test. Effect sizes will be

reported as mean difference with 95% confidence interval, median difference with bootstrap 95% confidence interval, or difference in proportion for paired data with 95% confidence interval, as appropriate. All tests will be 2-sided and a p-value less than 0.05 will be considered statistically significant. Statistical analysis will be performed using R 4.3 (R Foundation for Statistical Computing, Vienna, Austria).

Duration of the study: After obtaining approval from the Ethics Committee, we expect to perform the study in two weeks.

Ethical consideration: The trial is being submitted to the Ethics Committees of the participating centers. All participants will provide written informed consent and all data will be anonymized.

Compliance to protocol: Compliance will be defined as full adherence to protocol. Compliance with the protocol will be ensured by the principal investigator and the local collaborators; they will be responsible for local data collection.

Dissemination policy: The results of the trial are expected to be published in a scientific journal and to be presented in medical seminars and conferences. The final reporting will follow the CONSORT Report guidelines (http://www.consort-statement.org).

Competing intrests: The authors declare that they have no competing interests.

13. APPENDIX 2 – CFR OF THE STUDY

CASE REPORT FORM

TITOLO: l'utilizzo della maschera laringea per intubazione endotracheale è efficace e cambia la percentuale di successo al primo tentativo? Uno studio randomizzato controllato crossover su manichino.

Informazioni sul partecipante
Nome _____ Cognome _____ Medico: □ specialista □ specializzando Età _____ Anni di esperienza in TIN _____ Numero di intubazioni endotracheali su neonato: □ <5 □ 5-10 □ 10-20 □ >20 Numero di posizionamenti di maschera laringea su neonato: □ <5 □ 5-10 □ 10-20 □ >20 Numero di intubazioni endotracheali su manichino: □ <5 □ 5-10 □ 10-20 □ >20 Numero di posizionamenti di maschera laringea su manichino: □ <5 □ 5-10 □ 10-20 □ >20

Procedura 1 **indicare il device usato: □ TET □ MASCHERA LARINGEA**		
Outcome		
Outcome	**Definizione**	**Risultato**
Tempo totale di posizionamento (in secondi)	Tempo dall'inizio della laringoscopia o dall'inizio del posizionamento della maschera laringea al corretto posizionamento del TET in trachea. Il tempo limite per ciascun tentativo è di 30 secondi. Se sono necessari più tentativi, va sommato il tempo di ciascun tentativo.	
Tempo senza supporto ventilatorio (in secondi)	Tempo totale di posizionamento a cui viene sottratto il tempo durante il quale il neonato viene ventilato (valido solo per posizionamento della maschera laringea)	
Successo al primo tentativo (si/no)	È stato ottenuto il corretto posizionamento del TET in trachea al primo tentativo?	
Numero di tentativi	Quanti tentativi sono stati necessari per ottenere il corretto posizionamento del TET in trachea?	

Procedura 2

indicare il device usato: □ MASCHERA LARINGEA □ TET

Outcome

Outcome	Definizione	Risultato
Tempo totale di posizionamento (in secondi)	Tempo dall'inizio della laringoscopia o dall'inizio del posizionamento della maschera laringea al corretto posizionamento in trachea del TET. Il tempo limite per ciascun tentativo è di 30 secondi. Se sono necessari più tentativi, va sommato il tempo di ciascun tentativo.	
Tempo senza supporto ventilatorio (in secondi)	Tempo totale di posizionamento a cui viene sottratto il tempo durante il quale il neonato viene ventilato (valido solo per posizionamento della maschera laringea)	
Successo al primo tentativo (si/no)	È stato ottenuto il corretto posizionamento del TET in trachea al primo tentativo?	
Numero di tentativi	Quanti tentativi sono stati necessari per ottenere il corretto posizionamento in trachea?	

Procedura 1 **indicare il device usato: □ TET □ MASCHERA LARINGEA**		
Soddisfazione del partecipante		
Aspetto	**Definizione**	**Risposta**
Maneggiare il device	Hai sperimentato difficoltà nel maneggiare il device?	□ 1 per nulla □ 2 un po' □ 3 abbastanza □ 4 molto □ 5 moltissimo
Inserimento del TET in trachea	Hai sperimentato difficoltà nell'inserire il TET in trachea?	□ 1 per nulla □ 2 un po' □ 3 abbastanza □ 4 molto □ 5 moltissimo
Difficoltà complessiva	Qual è stata la difficoltà complessiva che hai sperimentato nell'usare il device?	□ 1 nessuna difficoltà □ 2 lieve difficoltà □ 3 moderata difficoltà □ 4 molta difficoltà □ 5 elevata difficoltà

Procedura 2 **indicare il device usato: □ MASCHERA LARINGEA □ TET**		
Soddisfazione del partecipante		
Aspetto	**Definizione**	**Risposta**
Maneggiare il device	Hai sperimentato difficoltà nel maneggiare il device?	□ 1 per nulla □ 2 un po' □ 3 abbastanza □ 4 molto □ 5 moltissimo
Inserimento del TET in trachea	Hai sperimentato difficoltà nell'inserire il TET in trachea?	□ 1 per nulla □ 2 un po' □ 3 abbastanza □ 4 molto □ 5 moltissimo
Difficoltà complessiva	Qual è stata la difficoltà complessiva che hai sperimentato nell'usare il device?	□ 1 nessuna difficoltà □ 2 lieve difficoltà □ 3 moderata difficoltà □ 4 molta difficoltà □ 5 elevata difficoltà