Masks and tubes used to support the neonatal airway – how to improve their fit, seal and correct placement

Volume 1 of 1

Thesis presented by

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For the degree of

Paediatric Medical Doctorate by Prior Published Work (CKZ49)

University College Cork
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Submitted April 2019
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Declaration

This thesis is my own work. It has not been submitted for another degree, either at University College Cork or elsewhere

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Dr Joyce E O'Shea

Chapter 1:

Introduction

Introduction

Most infants are vigorous after delivery and spontaneously establish respiration shortly after birth. However approximately 10% need assistance during this transition making stabilization of new born infants one of the most commonly applied medical interventions globally. [1-3] With decreasing gestation, the need for support becomes greater. As the need for resuscitation in this population is unpredictable, personnel skilled at neonatal resuscitation need to be quickly and reliably available anywhere infants are born and where neonatal care is being offered.

Measures to support neonatal transition from in-utero to ex-utero life include stimulation, thermal support and respiratory support. If an infant has inadequate respiration, respiratory support consists of ensuring the infant's airway is patent and if needed, providing positive pressure ventilation until the infant can do this unsupported. The aim of this thesis is to describe some of the airway adjuncts used to provide respiratory support to term and preterm infants and explore how to use each adjunct optimally.

Facemasks

If an infant has inadequate respiration, international and national neonatal resuscitation guidelines recommend placing a face mask attached to a manual ventilation device over the nose and mouth to deliver positive pressure ventilation. [1-3] However, it is known that providing effective mask ventilation is challenging. Delivery room and manikin studies have

consistently found air leak around the mask, airway obstruction and inconsistent tidal volumes. [4,5] Leak is common, variable and often not detected by the resuscitator. [4,6] The first two studies of this thesis make up chapters two and three. They look specifically at facemasks and examine methods to improve the seal between the mask and infant's face. If the seal is improved, this could potentially reduce leak around the mask and improve the effectiveness of mask positive pressure ventilation. The first study examines mask holds and the second mask size.

Facemask Holds (Chapter 2)

The evidence on how to hold and apply a facemask was limited to a small number of manikin studies which have examined different methods of applying and positioning the mask to deliver positive pressure ventilation. [5,7,8] Wood examined three different holds on a modified manikin and measured leak. (1) 'The stem hold'—where the mask stem is held between the index finger and thumb and the middle, ring and little fingers support the jaw. (2) 'The two-point top hold'—the thumb and index fingertips grip the top flat portion of the mask and apply downward pressure to the face. Here also the middle, ring and little finger support the jaw. And (3) 'The OK rim hold'— the thumb and index finger form the 'OK' hand gesture and then the thumb and index finger make a C placed around the top flat portion of the mask and apply an even pressure to the outer edge and not encroaching over the edge of the mask. She found the two-point top hold to be associated with the lowest leak. [5] In another manikin study, Tracy compared leak using a two-handed hold compared to a single-handed hold and reported a 50% reduction in leak when using a two-handed hold. [7] His single-handed hold is similar to the two-point top hold described by Wood et al. The two-

handed hold involved a two-person technique. Person one stands facing the top of the infant's head and applies the mask. She places both index fingertips and thumbs on opposite edges of the flat portion of the mask and applies downward pressure to the face, with middle, ring and little fingers supporting both sides of the jaw. Person two delivers the positive pressure ventilation.

The first study of the thesis carries on from the work of Wood and Tracy and continues the theme of examining leak using different mask holds in a modified manikin. Three holds were compared, (1) the superior hold from the Woods study - the two-point top hold, (2) the superior hold from the Tracy study – the two-handed hold and (3) a previously undescribed hold – the 'spider' hold. The spider hold involves placing the stem of the mask between the clinician's index and middle fingers and using their palm to hold the mask onto the infant's face. All five finger tips curl around the infant's jaw and provide chin-lift. A potential benefit of the spider hold was hypothesized to be a lower leak as the clinician's hand circle the mask and therefore may feel any leak.

Size of facemask (Chapter 3)

The second study of the thesis measures preterm infant's faces and compares the measurements to those of available masks. International recommendations from the UK, USA and Australia emphasise the importance of a well-fitting face mask. [9-11] They state a facemask should cover the nose and mouth, while avoiding covering the eyes, overlapping the chin or occluding the nose. Several different brands of neonatal face mask are available, and they come in different shapes and sizes. Some are round, others oval. Some have air-

filled cushioned edges, others do not. There is a range of sizes available but relative paucity of very small masks that might be appropriate for the extremely preterm infants they are often used to resuscitate. There was no published literature on the measurements of the facial dimensions of preterm infants and no recommendations available on what size mask would be appropriate for infants of varying weights and gestations. The second study aimed to fill this evidence gap by measuring preterm infants faces from 24 – 34 weeks gestational age from birth and serially until 34 weeks corrected gestation and forming recommendations about suitable mask sizes for preterm infants.

Intubation

Neonatal endotracheal intubation refers to the act of instrumenting an infant's airway with an endotracheal tube. This intervention is commonly needed and may be life-saving for infants after birth and during neonatal intensive care. It is a mandatory competency for neonatal trainees. [12] Indications for intubation include ineffective or prolonged positive-pressure ventilation delivered via face mask; intratracheal administration of medications such as surfactant; and special resuscitation circumstances such as congenital diaphragmatic hernia. [1-3]

To successfully intubate, the clinician must be able to perform laryngoscopy to visualize the airway, recognize the anatomy displayed and then insert the endotracheal tube through the vocal cords into the trachea. Intubation instruction has traditionally relied on an apprenticeship model, in which a more experienced colleague supervises the novice.

Evolution of neonatal care has led to a steady reduction in opportunities for neonatal trainees to learn and practice this skill. [13] The reasons for this are multifactorial, including improvements in antenatal care, increased use of non-invasive respiratory support, no longer routinely intubating babies delivered through meconium-stained liquor, increased use of less invasive techniques to deliver surfactant combined with increased numbers of trainees with reduced working hours compared to their predecessors.

Several studies from different countries have been published evaluating success rates of neonatal intubation. [13-19] They report a similar theme – success rates are low and falling especially for the most inexperienced trainees. O'Donnell found 62% of first intubation attempts were successful, reducing to 24% among the most inexperienced trainees. [19] Falck found first or second attempt intubation success rates of paediatric residents to be 50%, 55%, and 62% for first-, second-, and third-year residents, respectively. [17] Leone 2005 reported median success rates of 33% for first-year residents, 40% for second- or third-year residents, and 68% for neonatal fellows. [13] More recently Haubner reported an overall success rate of 44%, made up of residents 20%, fellows 72%, and attending physicians 70%. [14] Multiple publications have found that oesophageal intubation is not infrequent. [20,21] Inability to successfully intubate, or delayed recognition of unsuccessful intubation, can cause death or severe hypoxic injury. Multiple intubations or traumatic intubations increase the risk of serious glottic, subglottic, and tracheal injury. [22,23]

Strategies to compensate for the reduction in opportunity to intubate that have been studied include intubatable manikins, airway trainers, animal models, and cadaveric specimens. These are useful for demonstrating the anatomy. [14] Animal models and cadavers are however not widely available and may not be acceptable to trainees. Manikins enable

simulation of intubation. However, studies that examined the role of simulation in teaching intubation did not report improved clinical performance. [24,25]

This ongoing decrease in intubation proficiency is an internationally recognised neonatal hot topic and reversing this trend is the focus of the next series of studies presented in chapters four, five and six of the thesis. The first intubation study examines if preloading the endotracheal tube with a stylet is helpful to promote intubation success. The second examines if a videolaryngoscope is a useful training tool and the third explores the reasons behind unsuccessful intubation attempts.

Stylet (Chapter 4)

Endotracheal tubes used in infants are narrow and vary in size with internal diameter between 2 and 4 millimetres. Due to their narrow calibre, they are more flexible than those used in children and adults which can lead to difficulty directing them into the narrow airway of a small infant. For this reason, intubation may be performed with or without a stylet inserted into the lumen and secured. A stylet may increase the rigidity and curvature of the tube, perhaps making it easier to navigate between vocal cords. Or it could make the procedure more challenging and be a source of airway trauma. Published case reports have described shearing off of the stylet sheath, causing acute airway obstruction. [26,27] Current guidelines describe the stylet as an optional instrument and do not recommend routine use. [28,29] To answer the question does a stylet improve neonatal intubation success, a systematic review with meta-analysis published in the Cochrane library forms the next chapter of the thesis.

Videolaryngoscopy (Chapter 5)

Intubation, like most neonatal procedures is generally taught using an apprenticeship model, where a proficient intubator supervises a less experienced colleague. This is however very difficult in practice as the neonatal airway is so small, a shared view is not easily possible. Therefore, the supervisor generally stands next to the intubator and guides without an airway view, limiting the value of the guidance.

A videolaryngoscope is a modified laryngoscope that transmits images from the tip of the blade to a nearby monitor. The images are magnified and the view wider than that obtained by direct laryngoscopy. They are now routinely used by adult and paediatric anaesthetists and feature on many difficult airway algorithms. [30-32] They also offer a means of supervisor and intubator sharing the view of the airway in real time. This feature makes the videolaryngoscope a possible intubation teaching tool. To explore this possibility a randomised controlled trial was carried out and makes up the next chapter of the thesis and the most sizable body of work of the thesis. Neonatal intubations by junior trainees were randomised so that the videolaryngoscope screen was either visible to the supervisor or covered. The primary outcome was first attempt intubation success.

Reasons for unsuccessful intubations (Chapter 6)

This final intubation study of the thesis examines the reasons behind unsuccessful intubations. It is a sub-study of the randomised trial on videolaryngoscopy. Part of the process of learning any procedure is understanding why an attempt is unsuccessful. As the

view of the neonatal airway is not generally shared by intubator and supervisor, the ability of the supervisor to provide constructive feedback following an unsuccessful intubation attempt is limited and the reasons for unsuccessful attempts are often poorly understood. Endotracheal intubation is associated with a high rate of complications. In a prospective study, adverse events occurred in 39% of intubations and serious adverse events in 9%. [33] There are multiple reports that oesophageal intubation is a frequent endpoint of unsuccessful intubation and that this may not be realised by the intubator. [20,21]

The intubations performed as part of the randomised trial discussed in Chapter 5 were mostly recorded. This allowed a more detailed exploration of the reasons why attempts might be unsuccessful. The recorded images were from intubations where the view was either shared with the supervisor or covered. The recordings from the two groups were examined separately to see if the supervisor sharing the view changes the profile of the reasons the attempts were unsuccessful.

Devices Review (Chapter 7)

The final published work of the thesis is a review article discussing the airway adjuncts used in neonatal stabilisation combined with a brief review of the evidence for monitoring infants during resuscitation and the tools used to optimise normothermia. It gives an insight into how airway management is but one of the elements to optimally support early neonatal transition and resuscitation.

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Chapter 2:

A comparison of different mask holds for positive pressure ventilation in a neonatal manikin

Arch Dis Child Fetal Neonatal Ed 2014;99: F169–F171

Abstract

Background

Ventilation during neonatal resuscitation is typically initiated with a face mask, but may be ineffective due to leak or obstruction.

Objective

To compare leak using three methods of mask hold.

Methods

Medical and nursing staff regularly involved in neonatal resuscitation used the three holds (two-point, two-handed, spider) on a manikin in a random order to apply positive pressure ventilation (PPV) at standard settings each for 1 min while mask leak was recorded.

Results

Participants (n=53) varied in experience (1–23 years) and hand size. Combined median (IQR) leak was 14 (2–46)% and was not different among the holds.

Conclusions

There was no difference in the leak measured using the three different mask holds.

What is already known

- Face mask leak during mask positive pressure ventilation (PPV) is common and often goes unrecognised by resuscitators

What this study adds

- This study describes a new method for holding a face mask—'the spider hold'. Leak measured using this hold was similar to two other commonly used holds.

Background

International resuscitation guidelines recommend positive pressure ventilation (PPV) for newly born infants with bradycardia or inadequate respiratory effort. [1] This is usually initially performed using a facemask as the interface, but mask ventilation is not without difficulties and studies have found large and variable leak, airway obstruction and inconsistent tidal volumes, in delivery room and manikin studies. [2,3] There are a small number of manikin studies which have examined different methods of applying and positioning the mask to deliver PPV. Wood examined different single-handed holds in a manikin study and found the two-point top hold (figure 1A) to be associated with the lowest leak. [3] In another manikin study, Tracy reported a 50% reduction in leak when using a two-handed hold for two-person resuscitation (figure 1C) compared to a single-handed hold. [4] A new method for holding the mask during PPV is the 'spider hold' (figure 1B).

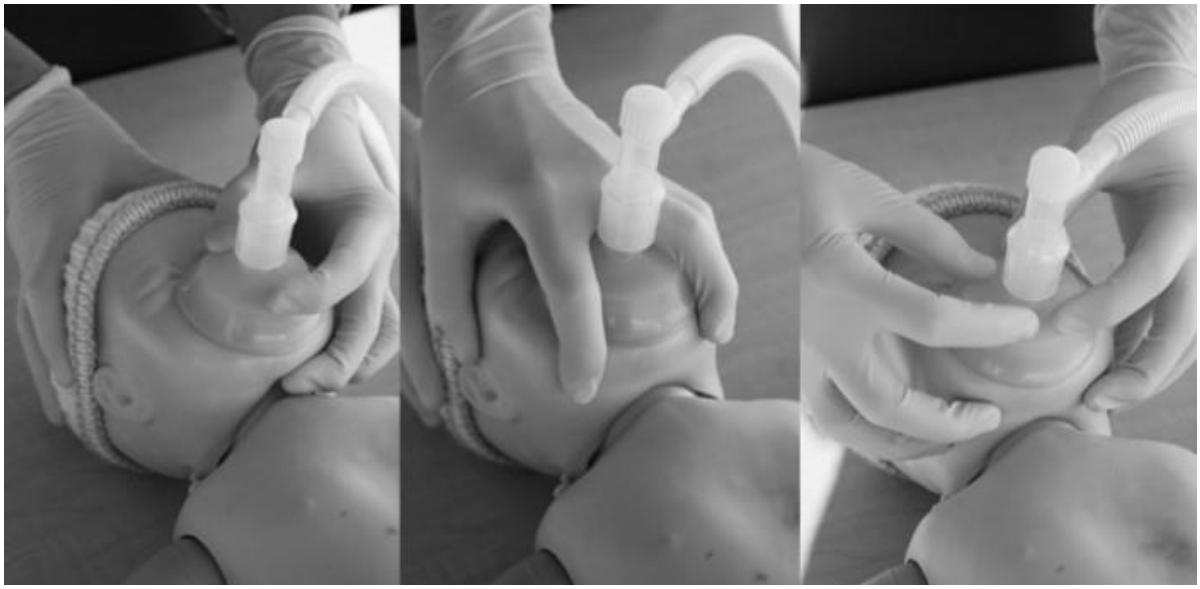

Figure 1 (from left) (A) Two-point top hold, (B) Spider hold, (C) Two-handed hold.

This method involves placing the stem of the mask between the index and middle fingers, while applying pressure with the palm of the hand to hold the mask onto the infant's face. The clinician's finger tips curl around the infant's jaw to provide chin-lift. This method has not previously been formally examined.

Aim

The aim of this study was to compare three mask holds—two-point top hold, two-handed hold and spider hold—with a primary outcome of leak between the mask and the manikin's face. Secondary analyses were conducted on the basis of participants' professional group, years of experience, glove size and hold preferences.

Methods

This study was undertaken at The Royal Women's Hospital, a tertiary perinatal centre in Melbourne, Australia. Nursing and medical staff regularly involved in neonatal resuscitation were invited to participate. The Neopuff Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand) was used with a size 0/1 Laerdal round mask (Laerdal, Stavanger, Norway). The manikin used was a Laerdal Resusci Baby, modified to ensure a leak free system. [3, 5] The modification involved removal of the manikin's stomach and lung bags and replacing them with a Laerdal test lung attached via nondistensible tubing to the manikin's mouth with an airtight seal. A Florian Respiratory Function monitor (Acutronic Medical Systems, Zug, Switzerland) was used to measure inflating pressures, tidal volumes and expiratory leak via a flow sensor between the mask and the Neopuff. The flow sensor of the Florian was calibrated when switched on and between study participants. Leak was calculated by the Florian from the volume of gas that did not return back through the flow sensor on expiration, expressed as a percentage of the inspired volume. Data were recorded on a laptop computer using Spectra software (Grove Medical, London, UK). Holds were first demonstrated by a study investigator and participants given several minutes to practice until they felt competent at each hold. They were then asked to deliver PPV to the manikin using the three holds for 1 min each in a random order, using settings of peak inflating pressure 30 cm H2O, peak expiratory pressure 5 cm H2O and a rate of 40–60/min. Hold order was determined using internet-based random number generator. The sample size was calculated using the mean leak of 70%, as measured by O'Donnell using the same manikin. [5] To detect a 15% difference in mean leak with an α value of 0.05 and power of 80%, at least 50 participants were required. We included 10 participants from each of five professional groups—neonatal consultants, neonatal fellows, neonatal registrars, midwives and neonatal

nurses. Participants' hand size measured by glove size, years of experience and usual hold were also recorded. Neither the Spectra screen nor the Florian monitor was visible to participants while ventilating the manikin. The primary outcome measure was the median leak between the mask and the manikin's face. Median leak for each participant and for each hold was calculated and compared. Median and IQRs for the primary outcome measure are displayed as box plots and tables. Results were compared using analysis of variance (ANOVA), p values were calculated using post hoc Bonferonni correction and <0.05 was considered significant. Secondary outcome was participants' hold preference. Data were analysed using Stata software (Intercooled 10, Stata Corp, Texas, USA).

Results

Fifty-three participants enrolled in the study: 10 consultants, 10 fellows, 10 registrars, 12 midwives and 11 neonatal nurses. Hand sizes ranged from a glove size of 5.5 to 8 with a median of 7. Participants' years of experience resuscitating infants ranged from less than 1 to 23 years. All consultants had greater than 5 years of experience. All fellows had between 3 and 5 years of experience. All registrars had less than 2 years of experience, Neonatal nurses and midwives had similar levels of experience ranging from less than 1 year to more than 10 years, with a median of 4 years. 7324 inflations were studied. Median (IQR) leak for all holds was 14 (2–46)%, for the two-point top hold was 19 (2–38)%, for the spider hold 10 (3–49)% and for the two-handed hold 9 (2–51)% (figure 2).

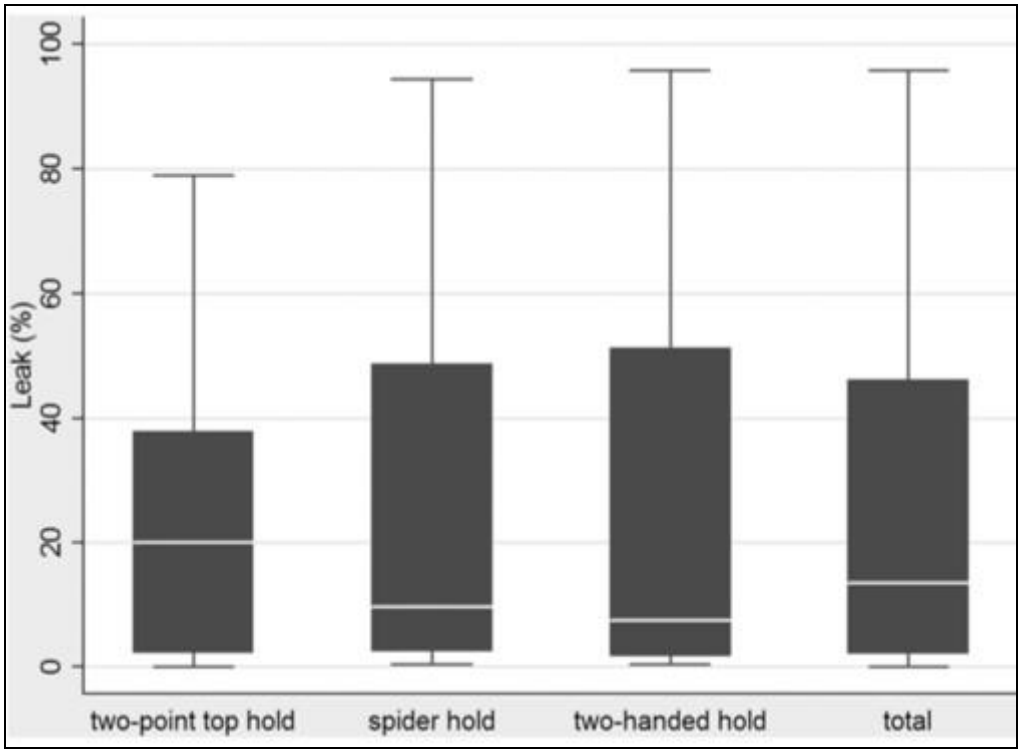

Figure 2 Box plot showing the leak for all participants using each hold type, and overall. The horizontal line is the median, the box represents the 25th and 75th centiles, and the ends of the whiskers are the 5th and 95th centiles.

There was no significant difference in leak noted between the different holds. There were no significant differences found between the holds when examined by participant's professional group, level of experience or glove size. All but two participants identified the two-point top hold as their usual hold. Twenty-seven (51%) preferred the two-point top hold, while 19 (36%) and seven (13%) chose the spider hold and the two-handed hold, respectively.

Discussion

Although there was no difference in median leak among the different holds, there was substantial variability within each of the groups suggesting that the participants were unaware of the leak. This finding is supported by previous studies that have shown leak is common

and often goes unrecognised [2, 5] and that resuscitators are also unable to accurately estimate the magnitude of their leak. [5] Our study participants demonstrated lower levels of leak than measured in previous, similarly conducted manikin studies. This may have been due to participants having time to practise using each hold. O'Donnell reported a mean (SD) leak of 70 (30)% [5] and Wood reported a mean (SD) leak of 55 (31)% [3] using the same Laerdal round mask. The more recent study by Tracy reported lower levels of leak [4] that were more comparable to our study. This is the first study that describes the spider hold. It was found to be easy to learn and more than a third ranked it as their favourite hold. Because the resuscitators' fingers extend beyond the edge of the mask, leak may be palpable and therefore more obvious to the resuscitator. A possible disadvantage of the spider hold is that the infant's face is largely covered by the resuscitator's hand. The user's ability to assess responsiveness in the infant with visual cues from the face may be hampered, although facial movements should be felt. As the edges of the mask are not completely visible, the face mask causing compression to the infant's eyes may go unnoticed. Compression of the nose may also not be appreciated and may result in inadvertent airway obstruction. It may be argued that when teaching neonatal resuscitation, it is best to teach one hold so that clinicians can practise and perfect this hold. The two-point top hold is taught and practised at our unit. One might expect that the two-point top hold would therefore be the method with the lowest leak. In this study, we found that the leak was similar using three different holds: a familiar hold to all (two-point top hold), a familiar hold to some (two-handed hold) and a new hold (spider hold). It may therefore be possible for novice resuscitators to try all three holds and allow them to choose the one they find preferable to use in clinical practice. It is also reasonable to teach more than one hold and advise the trainee to change holds if they feel the baby is ventilating ineffectively. The limitations of this study are shared by similar studies on manikins. Participants are being asked to resuscitate in an artificial environment. They know

they are being assessed on the adequacy of their ventilation. A manikin, while an effective learning tool, can never provide the same cues in relation to clinical deterioration and improvement as a neonate.

Conclusion

There was no difference in the leak measured using the three different mask holds.

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Chapter 3:

Measurements from preterm infants to guide face mask size

Arch Dis Child Fetal Neonatal Ed 2015;0:F1–F5

Abstract

Objective

International guidelines recommend that an appropriately sized face mask for providing positive pressure ventilation should cover the mouth and nose but not the eyes and should not overlap the chin. This study aimed to measure the dimensions of preterm infants' faces and compare these with the size of the most commonly available face masks (external diameter 50 mm) and the smallest masks available (external diameters 35 and 42 mm).

Methods

Infants 24-33 weeks' postmenstrual age (PMA) were photographed in a standardised manner. Images were analyzed using Image J software (National Institute of Health, USA) to calculate the distance from the nasofrontal groove to the mental protuberance. This facial measurement corresponds to the external diameter of an optimally fitting mask.

Results

A cohort of 107 infants between 24 and 33 weeks gestational age, including at least 10 infants per week of gestation was photographed within 72 hours after birth and weekly until 33 weeks PMA. 347 photographs were analysed. Infants of 24, 26, 28, 30 and 32 weeks PMA had mean (SD) facial measurements of 32 (2), 36 (3), 38 (4), 41 (2) and 43 (4) mm respectively. There were no significant differences when examined by gender or when small for gestational age infants were excluded.

Conclusion

The smallest size of some brands of mask is too large for many preterm infants. Masks of 35mm diameter are suitable for infants <29 weeks PMA or 1000g. Masks of 42 mm diameter are suitable for infants 27-33 weeks PMA or 750-2500g.

What is already known

- Preterm infants frequently receive respiratory support via a face mask
- Face mask positive pressure ventilation is frequently complicated by obstruction or leak around the mask
- International guidelines recommend criteria to determine optimal size of face mask

What this study adds

- Facial measurements of preterm infants support recommendations on suitable mask size Postnatal face growth correlates with intrauterine face growth.
- Many commonly available face masks are too large for preterm infants' faces.

Introduction

Respiratory support including intermittent positive pressure ventilation (IPPV) or continuous positive airway pressure (CPAP) is commonly delivered via a mask applied to an infant's face connected to a T piece or resuscitation bag. Delivering effective mask IPPV or CPAP is challenging. Delivery room studies have found that mask IPPV is frequently complicated by intermittent airway obstruction [4] or leak between the mask and the infant's face. [5-8] Leak is common, variable and often not detected by the resuscitator. [5-8]

International recommendations from the UK, US, and Australia regarding mask size and shape emphasize the importance of a well-fitting face mask. [9-11] These recommendations emphasize the need to cover the nose and mouth and to avoid covering the eyes, overlapping the chin, or occluding the nose. O'Donnell *et al* surveyed 46 NICUs in 23 countries and found that round face masks were used in 85% and anatomically shaped masks used in 15%. [12] Surveys have not however established which type or size of round masks are most commonly used, [13-15] and there are no recommendations regarding mask size for specific weight or gestation infants. There are many brands of round neonatal masks available in a range of sizes. Most brands start with smallest external diameter around 50mm. To our knowledge there is only one brand of smaller mask available - Infant Resuscitation Masks (Fisher & Paykel Healthcare, Auckland, New Zealand), sizes small and extra small, with external diameters of 42 and 35 mm respectively. (Figure 1)

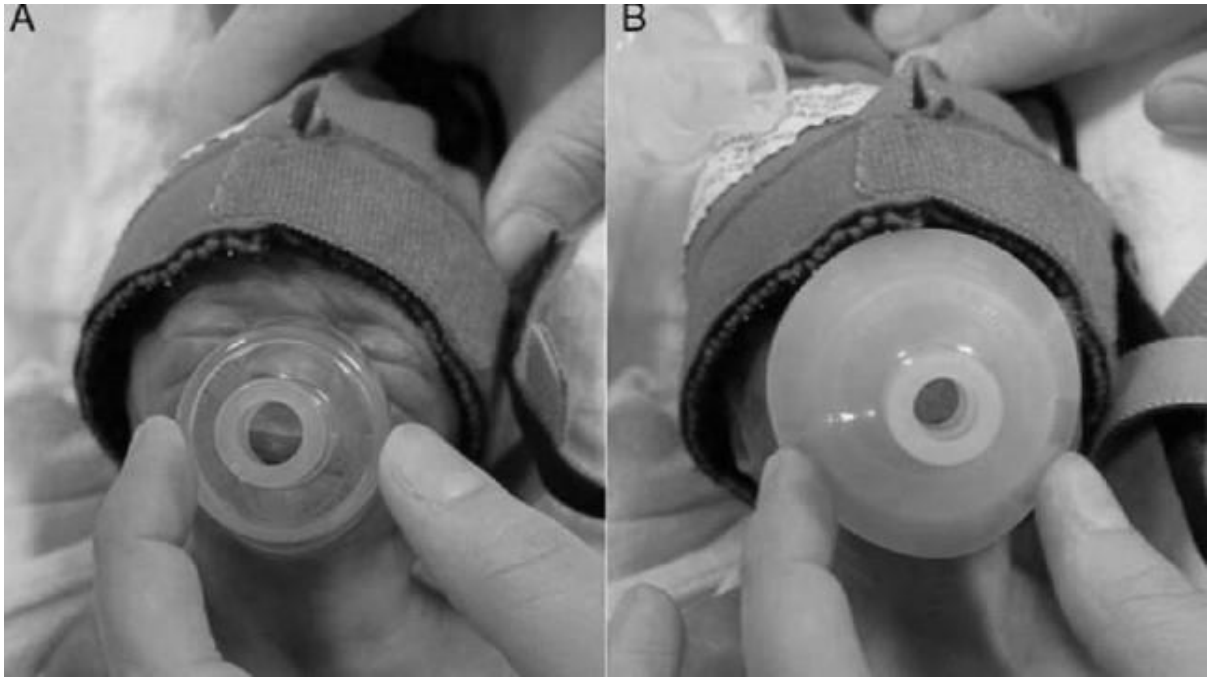

Figure 1 Newborn baby girl, 26+0 weeks' postmenstrual age, birth weight 805 g. (A) 35 mm mask applied to face; (B) 50 mm mask applied to face.

There are no data available regarding the size of preterm infants' faces or how their facial dimensions change in the weeks following preterm birth. The aims of this study were to (1) measure the dimensions of preterm infants' faces across a range of gestational ages at birth and over the first weeks of life, (2) compare these results with the dimensions of commonly available round masks and (3) make recommendations regarding appropriate mask size for preterm infants.

Methods

The study was performed at The Royal Women's Hospital, Melbourne, Australia with approval of The Royal Women's Hospital Research and Ethics Committee. Preterm infants less than 34 weeks' gestational age admitted to neonatal intensive and special care, were

eligible for inclusion. As this is the first study of its kind there were no data on which to base a sample size calculation. Therefore, a study population with a minimum of ten infants per each completed week of gestation from 24 to 33 weeks was chosen. Infants considered to have any dysmorphic features or congenital facial anomalies by the attending clinical team were excluded. Written parental consent was obtained prior to studying each infant. Demographic details were collected including gender, gestation, corrected gestation, birth weight, weight on the day of each measurement and whether or not birth weight was < 3rd centile.

Each infant was photographed whilst supine with their head in the neutral position and their jaw neutral i.e. the position in which they would be placed to receive mask IPPV. A plastic scale was placed next to and level with the infant's face and included in the photograph. Infants receiving continuous positive airway pressure (CPAP) via nasal prongs, or those who had endotracheal, nasogastric or orogastric tubes in situ were included as long as their nose and chin were not distorted and could be clearly seen. The infants receiving CPAP via nasal prongs had their photographs taken when the prongs were removed for cares whenever possible. Images were taken using a Sony NEX-3 digital SLR camera with a SEL1855 lens using a focal length of 35 mm, from a distance of 10cm directly above the centre of the infant's face. Each image was then analysed using Image J software (Figure 2), a public domain, java-based image processing program developed at the National Institute of Health. [16]

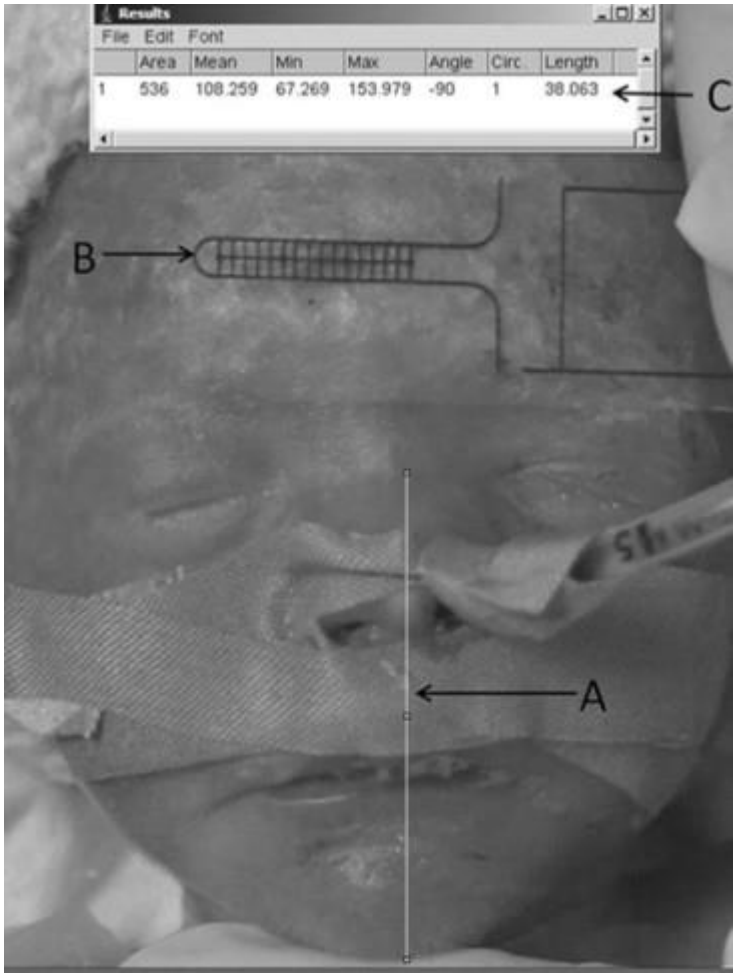

Figure 2 Example of study photograph taken and analysed. (A) Distance from the nasofrontal groove to the mental protuberance. (B) A plastic scale placed level with the infant's face. (C) Measurement calculated when analysed by Image J.

The distance from the infant's nasofrontal grove to their mental protuberance was measured (Figure 2). These landmarks were chosen because the distance between them equates to the diameter of a suitably fitting mask in accordance with international guidelines. [9-10] Infants were photographed within 72 hours after birth and weekly until they reached 33+6 weeks post menstrual age or were discharged or transferred to another hospital.

Measurements were combined to determine (i) measurements of newborns (<72 hours of age) - presented as mean (standard deviation (SD)) distance in millimetres for each completed week of gestation and by birth-weight divided into 250g cohorts, (ii) measurements of

growing infants - presented as mean (SD) distance in millimetres for each completed corrected week of gestation and by weight divided into 250g cohorts.

Measurements were compared against three different round masks – Laerdal 0/0 (Laerdal, Stavagner, Norway) and Fisher & Paykel Infant Resuscitation Masks 'small' and 'extra small'. The Laerdal 0/0 mask has an external diameter of 50 mm. It was chosen as it is the standard mask used at The Royal Women's Hospital, Melbourne and is a commonly used mask worldwide. The Infant Resuscitation Masks, sizes small and extra small are the smallest available masks and have external diameters of 42 and 35 mm respectively.

Results

A cohort of 107 infants between 24 and 33 weeks gestational age were recruited for 24 months from September 2011. There was a median (range) of 10 (10-12) infants per each completed week of gestation. Demographic details of the infants are presented in Table 1.

Number of infants	Gestational age	Birth weight (g) mean (SD)	Percentage male	Percentage small for gestational age
10	24	649 (82)	60	10
10	25	728 (143)	40	20
10	26	934 (171)	50	10
10	27	988 (208)	40	10
12	28	1102 (183)	25	8
12	29	1082 (302)	25	25
12	30	1617 (215)	67	0
10	31	1638 (335)	20	10
11	32	1839 (198)	45	0
10	33	1839 (392)	40	30

Table 1: Demographic details of the study population

There were 347 facial measurements made from photographs of the infants, median (range) of 3 (1-11) per infant. Figures 3(a) and (b) display the results. Both the initial measurements taken shortly after birth and the serial measurements of infants from birth until 33 weeks post menstrual age are presented. Figure 3(a) displays results for each completed week of gestation and figure 3(b) displays results for weight divided into 250g strata. The initial measurements for each gestational age closely parallels serial measurements for corrected gestational age suggesting that postnatal facial growth continues at a similar rate to antenatal growth despite preterm birth. Figures 3(a) and (b) also indicate the three different mask sizes alongside the measurements.

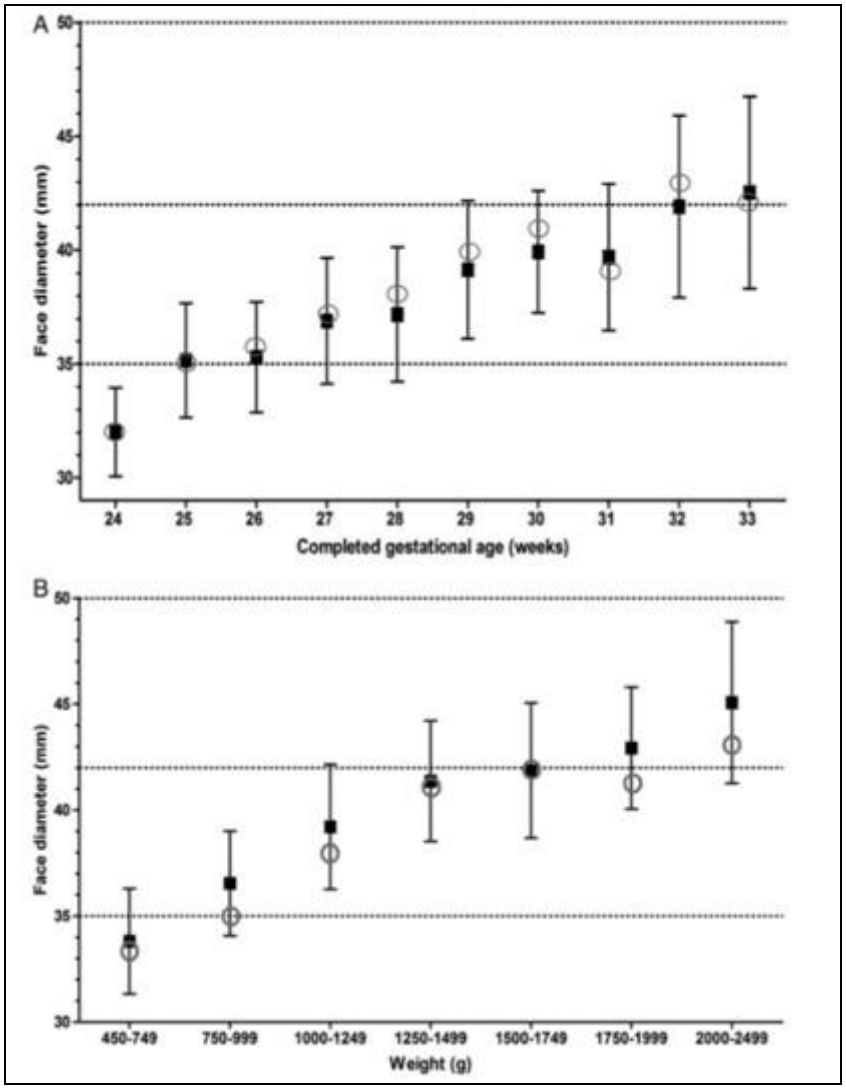

Figure 3 Mean measurements for (A) each completed week of gestation and (B) weight divided into 250 g cohorts. (A, B) The hollow circle represents the mean first measurements taken shortly after birth, and the black box and whiskers represent the mean (SD) of measurements taken from birth to 33 weeks' postmenstrual age.

No significant differences were seen in facial size between male and female infants, or when small for gestational age infants were excluded. Small for gestational age infants have smaller faces, the degree of which depends on the severity of the growth restriction. (Table 2)

Table 2 presents newborn measurements for each week of gestation for the whole group, by gender, and infants with birth weight >3rd centile.

Number of infants	Gestation (completed weeks)	Initial measurement mean (SD) mm			
		All infants	Male only	Female only	Infants with birthweight >3rd centile
10	24	32 (2)	31 (2)	34 (2)	32 (2)
10	25	35 (3)	35 (3)	35 (3)	36 (3)
10	26	36 (3)	37 (3)	35 (3)	36 (3)
10	27	37 (3)	36 (1)	37 (4)	37 (4)
12	28	38 (4)	41 (4)	37 (4)	38 (4)
12	29	40 (4)	39 (3)	39 (5)	40 (4)
12	30	41 (2)	41 (2)	41 (2)	41 (2)
10	31	39 (4)	38 (1)	40 (4)	40 (3)
11	32	43 (4)	42 (4)	44 (5)	43 (4)
10	33	42 (5)	43 (3)	42 (6)	43 (5)

Table 2: Initial measurements presented for each week of gestation for the whole study population, by sex and excluding the growth restricted infants.

Discussion

This study shows that a mask with an external diameter of 50 mm may be too large for infants <34 weeks post menstrual age. A 35 mm mask fits infants <29 weeks post menstrual age. For babies born at 27- 28 weeks gestational age, having both the 35 and 42 mm masks available allows clinicians to choose the best fitting mask for a particular baby. The 42 mm mask is appropriate for infants up to 33 weeks post menstrual age. However, having the 42 and 50 mm masks available may help select the best one for babies born at 32-33 weeks gestational age. During admission, both charts (Figure 3(a) and (b)) can be used to choose the appropriate mask size as the infants grow.

There are four studies which have examined mask IPPV in preterm infants less than 34 weeks post menstrual age. All have found a significant leak around the mask, the magnitude of which varied from a median of 29 to 55%. [5-8] All of these studies used a 50mm diameter

mask which may have been too large to form an optimal seal. To date, there are no studies assessing leak using smaller and perhaps better fitting masks. Our data could now be used to assess whether correctly sized masks result in less leak in vivo. There is more to the process of providing IPPV than simply choosing a mask of correct size. Head position, mask hold, applied pressure, ventilation rate and clinical experience also determine the effectiveness of IPPV. However, using an appropriate mask size is important and is highlighted in international training programs. [9-11]

This study has several strengths. It is the first to measure the dimensions of preterm infants' faces and to compare these measurements to those of commonly available masks. A large cohort of preterm infants was enrolled shortly after birth and followed to 33 weeks post menstrual age. The results have demonstrated that postnatal growth in these infants' facial measurements closely resembles growth in utero. The study cohort was evenly distributed across the range of gestational ages allowing for good representation of the extremely low birth weight infants. This is important because even though the extremely low birth weight infants make up a small proportion of the entire preterm population, they are the group most likely to require respiratory support. Respiratory outcomes of infants managed from birth with non-invasive versus invasive respiratory support are superior, [17] therefore it is essential that mask IPPV and CPAP are optimised. These mask size recommendations ensure a better fit and may reduce mask repositioning during resuscitation. Some masks are reusable, whereas others are single patient use, with an inherent cost implication. This study provides clinicians with the information to enable them to anticipate the appropriate mask size at birth and during admission, minimising that cost.

There are limitations to this study. Although photographs of the infants were taken in a standardised way to minimise distortion, the facial measurements were made indirectly. In addition we have measured the face only in the horizontal plane and have not attempted to assess variations in dimensions in the sagittal plane. These variations are difficult to assess but may be important in influencing the amount of mask leak. Many of these infants were unwell and could not tolerate excessive handling. We therefore felt it would not have been appropriate to take measurements directly. Studies comparing measurements of photographs with direct measurements have found the method to be accurate and have very high interrater and intrarater reliability. [18-23] The software package, Image J that we used to measure the photographs is a public domain, java based, image processing program developed at the National Institute of Health in 1997. [16] The program has been used for a diverse range of applications including wound measurement, assessing skin texture, measuring orbital tumours and measuring motion of soft tissue. [19,24-25]. There were no infants recruited who were less than 24 weeks corrected gestational age. More immature infants may require even smaller masks than those currently available.

The mask sizes discussed in this study are all defined by their external diameter. However, the masks all have a rim of varying thickness and therefore a smaller internal diameter. If the external diameter of the mask fulfils the recommended criteria but has a rim that is wide enough to compress the infant's nose then it may not be an effective interface for positive pressure ventilation. This study is limited in that the measurements were taken to assess the optimal external diameter for a suitable mask fit but the differing sized masks were not studied during clinical use on different sized infants. Future studies are needed to assess effectiveness of different sized masks in preterm infants.

Conclusion

The findings of this study suggest that round masks with an external diameter of 50 mm are too large for many preterm infants, in particular the extremely low birth weight infants. Smaller masks with external diameters of 35 and 42mm are suitable for infants less than 29 weeks post menstrual age or less than 1000g and 29-33 weeks post menstrual age or 1000-2500g respectively.

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Chapter 4:

Orotracheal intubation in infants performed with a stylet versus without a stylet.

Cochrane Database of Systematic Reviews 2017, Issue 6. Art. No.: CD011791

Abstract

Background

Neonatal endotracheal intubation is a common and potentially life-saving intervention. It is a mandatory skill for neonatal trainees, but one that is difficult to master and maintain. Intubation opportunities for trainees are decreasing and success rates are subsequently falling. Use of a stylet may aid intubation and improve success. However, the potential for associated harm must be considered.

Objectives

To compare the benefits and harms of neonatal orotracheal intubation with a stylet versus neonatal orotracheal intubation without a stylet.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library; MEDLINE; Embase; the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and previous reviews. We also searched cross-references, contacted expert informants, hand searched journals, and looked at conference proceedings. We searched clinical trials registries for current and recently completed trials. We conducted our most recent search in April 2017.

Selection criteria

All randomised, quasi-randomised, and cluster-randomised controlled trials comparing use versus non-use of a stylet in neonatal orotracheal intubation.

Data collection and analysis

Two review authors independently assessed results of searches against predetermined criteria for inclusion, assessed risk of bias, and extracted data. We used the standard methods of the Cochrane Collaboration, as documented in the Cochrane Handbook for Systemic Reviews of Interventions, and of the Cochrane Neonatal Review Group.

Main results

We included a single-centre non-blinded randomised controlled trial that reported a total of 302 intubation attempts in 232 infants. The median gestational age of enrolled infants was 29 weeks. Paediatric residents and fellows performed the intubations. We judged the study to be at low risk of bias overall. Investigators compared success rates of first-attempt intubation with and without use of a stylet and reported success rates as similar between stylet and no-stylet groups (57% and 53%) (P = 0.47). Success rates did not differ between groups in subgroup analyses by provider level of training and infant weight. Results showed no differences in secondary review outcomes, including duration of intubation, number of attempts, participant instability during the procedure, and local airway trauma. Only 25% of all intubations took less than 30 seconds to perform. Study authors did not report neonatal morbidity nor mortality. We considered the quality of evidence as low on GRADE analysis, given that we identified only one unblinded study.

Authors' conclusions

Current available evidence suggests that use of a stylet during neonatal orotracheal intubation does not significantly improve the success rate among paediatric trainees. However, only one brand of stylet and one brand of endotracheal tube have been tested, and researchers

performed all intubations on infants in a hospital setting. Therefore, our results cannot be generalised beyond these limitations.

Plain Language Summary

Rates of successful intubation performed with a stylet in infants compared with rates of successful intubation performed without a stylet

Review question

Does use of a stylet increase success rates of newborn intubation without increasing risk of harm?

Background

Intubation consists of placement of a breathing tube (endotracheal tube) into the baby's windpipe or trachea to maintain an open airway. This common procedure may be needed both at birth and in the neonatal intensive care unit if the baby is not able to breathe well for himself. Trainee doctors must learn this difficult skill and sometimes must make more than one attempt to get the tube in the right place. The breathing tube is a narrow, plastic, flexible tube. A stylet, which is a malleable metal wire coated with plastic, can be inserted into the breathing tube to make it more rigid; this might make it easier to get the tube in the right place on the first attempt. However, use of a stylet may increase the risk of harm to the patient during the procedure.

Study characteristics

In literature searches updated in April 2017, we found one randomised controlled trial (302 intubations) that met the inclusion criteria of this review.

Results

Rates of successful intubation at first attempt with or without use of a stylet as an aid were similar, at 57% and 53%, respectively. Success rates with and without use of a stylet did not differ between infants of different weights, or between trainee paediatric doctors with different levels of experience. The length of time it took to intubate and the number of attempts made before successful intubation were comparable between groups. The incidence of a drop in a patient's oxygen level and in heart rate was equivalent between groups, as was the reported incidence of trauma to the airway associated with the procedure.

Quality of the evidence

The quality of evidence was low. We downgraded the level because we included only one unblinded study.

Stylet compared with no stylet for neonatal intubation

Patient or population: neonates requiring endotracheal intubation
Settings: neonatal intensive care unit or delivery room or theatre
Intervention: a stylet inserted into the endotracheal tube
Comparison: no stylet inserted into the endotracheal tube

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of intubations (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Stylet				
First intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**529 per 1000**	**570 per 1000** (466 to 698)	**RR** 1.08 (0.88 to 1.32)	302 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Gestational age of the infant	no data	no data	no data	no data	absence of evidence	
Professional category of the intubator - fellow: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**707 per 1000**	**667 per 1000** (488 to 548)	**RR** 0.94 (0.69 to 1.29)	74 (1)	⊕⊕○○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Professional category of the intubator - resident: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**464 per 1000**	**543 per 1000** (418 to 705)	**RR** 1.17 (0.90 to 1.52)	228 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Level of experience of the intubator	no data	no data	no data	no data	absence of evidence	
Premedication given - no premedication given: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**540 per 1000**	**528 per 1000** (389 to 713)	**RR** 0.98 (0.72 to 1.32)	146 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Premedication given - no premedication given: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**519 per 1000**	**610 per 1000** (462 to 804)	**RR** 1.18 (0.89 to 1.55)	156 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Timing of intubation - just after birth in the delivery room: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**540 per 1000**	**528 per 1000** (389 to 713)	**RR** 0.98 (0.72 to 1.32)	146 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Timing of intubation - following admission to NICU: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**519 per 1000**	**610 per 1000** (462 to 804)	**RR** 1.18 (0.89 to 1.55)	156 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Type of stylet	no data	no data	no data	no data	absence of evidence	
Weight < 1000 g (outcome achieved at time of intubation attempt and not followed up)	**597 per 1000**	**533 per 1000** (400 to 704)	**RR** 0.89 (0.67 to 1.18)	152 (1)	⊕⊕⊕○[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study

*The basis for the **assumed risk** (e.g. median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on assumed risk in the comparison group and **relative effect** of the intervention (and its 95% CI)
CI: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate

[a] High risk of detection bias (due to lack of blinding of caregivers and outcome assessors)
[b] Serious imprecision (due to small number of events and small sample sizes; 95% CIs include null effects)

Summary of Findings Table for the Main Comparison

Background

Description of the condition

Neonatal endotracheal intubation refers to placement of an endotracheal tube (ETT; breathing tube) within an infant's airway. This intervention is commonly needed and may be life-saving for infants after birth and during neonatal intensive care. Indications for intubation during neonatal resuscitation include ineffective or prolonged positive-pressure ventilation delivered via face mask; need to secure the airway when cardiac compressions are performed; intratracheal administration of medications; and special resuscitation circumstances such as congenital diaphragmatic hernia or endotracheal suctioning for meconium (ILCOR 2005; Perlman 2010). Endotracheal intubation is necessary when neonatal intensive care is provided for infants in respiratory failure, despite non-invasive respiratory support, as well as for administration of surfactant, for treatment of resistant apnoea of prematurity, and for preparation of infants undergoing surgery. Intubation can be performed by the nasotracheal (through the nose) or orotracheal (through the mouth) route. This review will focus solely on orotracheal intubation; whenever intubation is mentioned, we will be referring to orotracheal intubation. We will not consider nasal intubation here, as it is not possible to use a stylet safely during nasal intubation. 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. Successful intubation relies on the ability of the intubator to perform laryngoscopy (using a laryngoscope inserted into the patient's mouth to obtain a view of the infant's airway) and to recognise the anatomy displayed. Opportunities for neonatal trainees to acquire and maintain proficiency in endotracheal intubation are decreasing (Leone 2005), likely owing to increased use of non-invasive respiratory support in neonatal intensive care, reduced working hours for trainees, increased numbers of trainees, and changes in clinical

recommendations, such as to discontinue routine intubation of babies delivered through meconium-stained liquor. Studies evaluating success rates for neonatal endotracheal intubation report that more than one attempt is frequently required for successful intubation. An Australian study (O'Donnell 2006) reported that 62% of total first intubation attempts were successful, but the success rate was only 24% among the most inexperienced trainees. In a study conducted in the United States (Falck 2003), paediatric residents successfully intubated neonates on the first or second attempt at rates of 50%, 55%, and 62% for first-, second-, and third-year residents, respectively. None of these residents met the study authors' definition of procedural competence for intubation (successful at first or second attempt 80% or more of the time) over a two-year period. Another American study examining intubation success rates over a 10-year period (Leone 2005) reported median success rates of 33% for first-year residents, 40% for second or third-year residents, and 68% for neonatal fellows. Success rates were significantly different between groups ($P < 0.001$), but success rates for paediatric residents were not significantly different for delivery room (DR) non-meconium intubations than for neonatal intensive care unit (NICU) intubations (36% vs 36.5%). The most recent US study examining endotracheal intubation success rates (Haubner 2013) reported an overall success rate of 44%. Investigators again found significant differences between experienced and inexperienced providers - residents 20%, fellows 72%, and attending physicians 70%. Researchers observed that participant characteristics of birth weight and gestation did not impact success rates. Studies of intubation performed at US tertiary academic centres by neonatologists, fellows, residents, and respiratory therapists, in which detection of exhaled carbon dioxide was used to confirm correct tube placement, suggest that oesophageal intubation is not infrequent (Roberts 1995; Aziz 1999; Repetto 2001; Lane 2004). Inability to successfully perform ETT placement, or delayed recognition of unsuccessful placement, can cause death or severe hypoxic injury. Multiple intubations or

traumatic intubations increase the risk of serious glottic, subglottic, and tracheal injury (Meneghini 2000; Wei 2011). The current Neonatal Resuscitation Program 7th Edition (AAP 2016) recommends that intubation attempts should be limited to 30 seconds. This has been expanded from the 20-second recommendation provided in the 5th Edition (Kattwinkel 2006) following a study of delivery room intubations performed mainly by residents and fellows (Lane 2004), which found that a more realistic time needed for intubation was 30 seconds without apparent adverse effects. Studies have demonstrated that premedicating infants with various types of induction agents increases the speed of successful intubation and reduces the likelihood of associated adverse sequelae (Marshall 1984; McAuliffe 1995; Cook-Sathler 1998). Premedication has been shown to improve intubating conditions significantly and to reduce the number of attempts required for successful intubation and risk of intubation-related airway trauma.(Dempsey 2006; Roberts 2006; Carbajal 2007; Ghanta 2007; Silva 2007; Lemyre 2009). Strategies for improving training are being developed to compensate for the reduced clinical experience of practitioners. Airway trainers, animal models, and cadaveric specimens are useful for demonstrating the anatomy (Haubner 2013). Simulation is a tool that is used increasingly in medical education. However, studies that examined the role of simulation in teaching intubation (Nishiasaki 2010; Finan 2012) did not report improved clinical performance. Videolaryngoscopy (use of a laryngoscope to transmit images from the tip of the blade to a nearby monitor) allows the teacher to share the view of the trainee intubator and may be useful for improving intubation success.

Description of the intervention

As small-diameter ETTs are flexible, intubation may be performed with or without a stylet inserted into the lumen (hollow centre of the ETT) and secured. A neonatal stylet is a 6 French (2-mm diameter) malleable aluminium wire covered with lubricated plastic, which

extends beyond the tip (RuschFlexi-Slip™ Stylet, Teleflex Medical, Research Triangle Park, NC, USA; Satin-Slip Stylet, Mallinckrodt Medical, Athlone, Ireland). Available stylets are suitable for use with tubes of 2.5-mm internal diameter and greater. The stylet is positioned so that its tip does not extend beyond the tip of the tube. The proximal (top) end of the ETT is attached to a plastic adapter that connects to the ventilator. The stylet is threaded through the adapter into the ETT and is positioned so that the tip of the stylet does not extend beyond the tip of the tube. The proximal end of the stylet is then bent over the rim of the adapter to prevent further slipping of the stylet. Endotracheal tubes for neonates are made of pliable plastic and have a small internal diameter of 2.0 mm to 4.0 mm. They become increasingly flexible with decreasing internal diameter, especially if exposed to the heat of an overhead radiant warmer. A stylet may increase the rigidity and curvature of the tube, perhaps making it easier to navigate between vocal cords. Current guidelines (Richmond 2011; AAP 2016) do not recommend routine use of a stylet for orotracheal intubation but rather classify it as an optional instrument. Some operators may prefer the rigidity and curvature afforded by this technique and may achieve higher success rates. However, this rigidity could provide a disadvantage and may cause airway damage. Published case reports have described shearing off of the stylet sheath, causing acute airway obstruction (Cook 1985; Zmyslowski1989; Bhargava1998; Rabb1998; Boyd1999; Chiou 2007). Stylet costs are similar to those of an endotracheal tube.

How the intervention might work

A stylet increases the rigidity of the ETT and may facilitate placement within the airway.

Why it is important to do this review

Neonatal intubation is a commonly needed life-saving intervention. Success rates, especially among inexperienced trainees, are suboptimal. If use of a stylet could improve intubation success, then it should be recommended for routine use. However, if use of a stylet does not improve success, or if its use may cause harm, it should not be recommended.

Objectives

To compare the benefits and harms of neonatal orotracheal intubation with a stylet versus neonatal orotracheal intubation without a stylet.

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), quasi-RCTs, and cluster RCTs.

Types of participants

We defined our population as infants of 44 weeks' postmenstrual age or less who required endotracheal intubation. Infants who were intubated on more than one occasion were included again for subsequent intubation episodes, and we included only the first intubation attempt per episode. We excluded studies that enrolled infants with craniofacial or airway anomalies and those that enrolled infants born through meconium-stained liquor who were

intubated for tracheal suctioning, owing to difficulty confirming ETT placement within the trachea.

Types of interventions

Orotracheal intubation performed with a stylet versus without a stylet.

Types of outcome measures

Primary outcomes

- Rate of successful first attempt at orotracheal intubation
    - An attempt was defined as introduction of the ETT into the infant's mouth after laryngoscopy. Successful placement within the tracheobronchial tree was confirmed immediately post intubation attempt, objectively, through a predetermined method, for example, by observation of colour change on an exhaled colorimetric carbon dioxide detector, misting within the ETT, or auscultation of the chest.

Secondary outcomes

- Duration of the intubation in seconds
    - This measures time from insertion until removal of the laryngoscope
- Number of intubation attempts
- Patient instability during the procedure, as measured by:
    - heart rate (HR) < 100 during the procedure; and
    - desaturation to < 70% (with 100% showing full oxygen saturation).

- Local trauma to the airway or surrounding soft tissue diagnosed by the presence of blood-stained endotracheal aspirates or oral sections over the 24 hours after the attempt (number per thousand infant population)
- Evidence of airway damage, for example, post-extubation stridor, subglottic stenosis, or vocal cord paralysis (number per thousand infant population)

Search methods for identification of studies

Electronic searches Two review authors independently searched electronic databases, including the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 3) in the Cochrane Library; MEDLINE (1966 to April 2017); Embase (1980 to April 2017); and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to April 2017). We also searched previous reviews including cross-references, contacted expert informants, and hand searched journals. We searched MEDLINE, Embase, and CINAHL for relevant articles, using the following search terms: (intubation AND stylet) OR (intubation (explode) [MeSH heading] AND stylet) plus database specific limiters for neonates and randomised controlled trials. We applied no language restrictions.

Searching other resources

The search strategy included communication with expert informants and searches of bibliographies of systematic reviews and trials for references to other trials. We examined previous reviews, including cross-references, abstracts, and conferences, and symposium proceedings of the Perinatal Society of Australia and New Zealand and of the Pediatric Academic Societies (American Pediatric Society, Society for Pediatric Research, and European Society for Pediatric Research) from 1990 to 2015. If we were to identify any unpublished trial, we planned to contact study author to request information. We considered

unpublished studies and studies reported only as abstracts as eligible for inclusion in the review if study authors reported final trial data and did not perform an interim analysis. We planned to contact the authors of identified RCTs to ask for additional study data when needed. We searched clinical trial registries to April 2017 for current and recently completed trials (clinicaltrials.gov; controlled-trials.com; who.int/ictrp), as well as the Australia and New Zealand Clinical Trials Register (ANZCTR).

Data collection and analysis

We used the standard methods of the Cochrane Collaboration, as documented in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011a), and of the Cochrane Neonatal Review Group (CNRG).

Selection of studies

Two review authors independently assessed all studies identified via the search strategy for possible inclusion in the review. We planned to resolve disagreements through discussion or, if required, through consultation with a Cochrane review arbiter. Specifically, we performed the following tasks. Merged search results by using reference management software and removed duplicate records of the same report. Examined titles and abstracts to remove irrelevant reports. Retrieved full texts of potentially relevant reports. Linked multiple reports of the same study. Examined full-text reports for study compliance with eligibility criteria. Corresponded with investigators, when appropriate, to clarify study eligibility. Noted reasons for inclusion and exclusion of articles at all stages (we resolved disagreements through consensus, or sought assistance with arbitration from the editorial base of the CNRG, if needed). Made final decisions on study inclusion and proceeded to data collection. Resolved all discrepancies through a consensus process.

Data extraction and management

Two review authors independently extracted data from full-text articles using a specially designed spreadsheet to manage the information. We resolved discrepancies through discussion, or, if required, we planned to consult a review arbiter. We entered data into Review Manager software (RevMan 2014) and checked them for accuracy. When information regarding any of the above was missing or unclear, we attempted to contact authors of the original reports to clarify and provide additional details.

Assessment of risk of bias in included studies

We used the standardised review methods of the CNRG (http://neonatal.cochrane.org/en/index.html) to assess the methodological quality of included studies. Review authors independently assessed study quality and risk of bias using the criteria documented in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011b). See Appendix 2 for the 'Risk of bias' tool.

Measures of treatment effect

We analysed the results of included studies using the statistical package Review Manager software (RevMan 2014). We used the standard method of the CNRG and applied a fixed-effect model for meta-analysis (Deeks 2011).

Unit of analysis issues

The unit of analysis is an intubation attempt. We included the first attempt for each intubation episode. We excluded further attempts by the same intubator or by other intubators. A participant who had more than one intubation episode could be included more than once;

however, we would treat each intubation as a separate study event and would randomise it separately. We planned to combine cluster-RCTs and individually randomised RCTs in a single meta-analysis using the generic inverse variance method. We planned to adjust cluster-RCTs for their intracluster correlation coefficient.

Assessment of heterogeneity

We planned to use RevMan 5.3 (RevMan 2014) to assess the heterogeneity of treatment effects between trials. We planned to use the two formal statistics described below.

- Chi^2 test for homogeneity. We planned to calculate whether statistical heterogeneity was present by performing the Chi2 test for homogeneity ($P < 0.1$). As this test has low power when the number of studies included in the meta-analysis is small, we set probability at the 10% level of significance (Deeks 2011).
- I^2 statistic to ensure that pooling of data was valid (Higgins 2003). We planned to quantify the impact of statistical heterogeneity by using I2 statistics available in RevMan 2014, which describe the percentage of total variation across studies due to heterogeneity rather than to sampling error. We planned to grade the degree of heterogeneity as follows: < 25% no heterogeneity, 25% to 49% low heterogeneity, 50% to 74% moderate heterogeneity, and ≥ 75% high heterogeneity.

When we found evidence of apparent or statistical heterogeneity, we planned to assess the source of the heterogeneity by performing sensitivity and subgroup analyses to look for evidence of bias or methodological differences between trials.

Data synthesis

We performed statistical analyses according to the recommendations of CNRG (http://neonatal.cochrane.org/en/index.html). We analysed all infants randomised on an

intention-to-treat (ITT) basis. We planned to analyse treatment effects in individual trials and planned to use a fixed-effect model for meta-analysis in the first instance to combine data. When we noted substantial heterogeneity, we planned to examine the potential cause of heterogeneity by performing subgroup and sensitivity analyses. If we judged meta-analysis to be inappropriate, we planned to analyse and interpret individual trials separately. For estimates of typical risk ratio (RR) and risk difference (RD), we planned to use the Mantel-Haenszel(MH) method (Mantel1959;Greenland1985). For measured quantities, we planned to use the inverse variance method. When assessing treatment effects, we used RR and RD, with 95% confidence intervals (CIs), for dichotomous outcomes. When the RD was statistically significant, we calculated the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH) (1/RD). For outcomes measured on a continuous scale, we used mean difference (MD) with 95% CI.

Quality of evidence

We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, as outlined in the GRADE Handbook (Schünemann 2013), to assess the quality of evidence for the following (clinically relevant) outcomes: first intubation attempt success rate; first attempt success rate for intubations without premedication; first attempt success rate for intubations with premedication; first attempt success rate for experienced intubators; first attempt success rate for inexperienced intubators; and first attempt success rate for intubations in infants weighing less than 1 kilogram. We considered evidence from RCTs as high quality but downgraded the evidence one level for serious (or two levels for very serious) limitations according to the following: design (risk of bias), consistency across studies, directness of evidence, precision of estimates, and presence of publication bias. The

GRADE approach provides an assessment of the quality of a body of evidence according to one of four grades.

- High: We are very confident that the true effect lies close to the estimate of effect.
- Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
- Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
- Very low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Two review authors independently assessed the quality of the evidence for each of the outcomes above. We used the GRADEpro GDT Guideline Development Tool to create a 'Summary of findings' table to report evidence quality.

Subgroup analysis and investigation of heterogeneity

We carried out the following subgroup analyses.

- Gestational age: < 28 weeks, 28 to 37 weeks, ≥ 37 weeks.
- Professional category of person performing intubation: neonatologists, neonatal fellows, resident doctors, respiratory therapists, nurses, and neonatal nurse practitioners.
- Level of experience of intubators: < 1 year, 1 to 4 years, ≥ 5 years.
- Premedications: intubations for which premedication is given; intubations performed without premedications.
- Timing of intubation: during resuscitation following birth; during neonatal intensive care stay.

- Type of stylet used: a plastic-coated malleable wire inserted into the ETT; any other type of stylet.

Results

Description of studies

See Characteristics of included studies and Characteristics of excluded studies tables.

Results of the search

For this review, we found and assessed 38 titles and abstracts in electronic format after we had removed duplicates. Of the 38 titles and abstracts screened, we assessed five as relevant, and one study met the inclusion criteria (Figure 1, Study flow diagram).

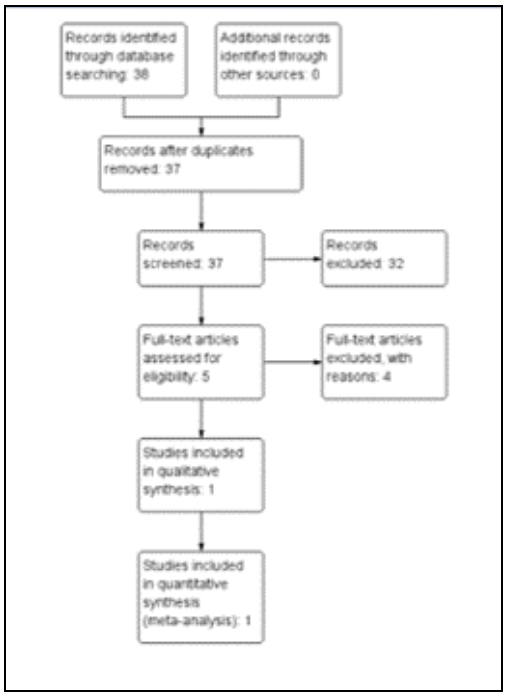

Figure 1 Study flow diagram

Included studies

Kamlin 2013 is a single-centred RCT conducted at an Australian tertiary neonatal unit between July 2006 and January 2009. The study included 304 first intubation attempts in 232 infants. Intervention: Investigators randomised intubations to use of a stylet inserted in to the ETT lumen or no stylet inserted. ETTs used were sterile, single-use, uniform internal diameter (ID), plastic ETTs (Mallinckrodt Medical, Athlone, Ireland) of appropriate ID based on infants' actual or estimated birth weight; the stylet used was a Satin Slip intubation stylet (Malinckrodt Medical, Athlone, Ireland). Researchers confirmed correct ETT placement by using a colourimetric exhaled carbon dioxide detector (Pedicap, Nellcor Puritan Bennett, Pleasanton, CA, USA). Infants admitted to the NICU had a chest radiograph to confirm ETT position. Study authors recorded the level of experience of the operator, as well as the operator's preference (i.e. stylet, no stylet, no preference). Investigators randomised the first attempted intubation by a single operator. If unsuccessful, the operator was free to choose his or her preferred method for sub sequent attempts. Doctors performed all intubations. In general, residents had no previous intubation experience, whereas fellows had at least 12 months' experience in neonatal intensive care. Researchers defined an attempted intubation as laryngoscopy followed by introduction of the ETT past the lips. They defined the duration of an attempt, timed by a digital stop watch, as the interval from introduction of the laryngoscope blade into the mouth to its removal. Intubation attempts were limited by the infant's heart rate (> 100 beats per minute deemed acceptable) rather than by a time limit. Study authors obtained baseline readings for heart rate and pulse oxygen saturations by using a pulse oximeter and recorded the lowest heartrate and oxygen saturations during the attempt. Investigators did not use premedication for emergency intubations following delivery. They used premedication with morphine or fentanyl, atropine, and suxamethonium for elective intubations within the NICU. During the course of the study, researchers updated hospital

guidelines and replaced morphine with fentanyl. Participants: Infants requiring orotracheal intubation were eligible for study inclusion. Excluded infants had facial or airway anomalies or were briefly intubated for suctioning of meconium from the trachea, as tube placement was difficult to confirm. The first attempted intubation of each intubation episode was eligible for randomisation. Therefore, if an infant was intubated again later during the inpatient course, researchers could randomise further intubations. Outcomes: The primary outcome was intubation success on first attempt indicated by detection of exhaled carbon dioxide. Secondary outcomes included duration of the intubation attempt, changes in heartrate and oxygen saturation from baseline, and the presence of blood-stained secretions after the procedure. Prespecified subgroup analyses examined the effects of gestation, birth weight, premedication, and level of experience of the operator on intubation success.

Excluded studies

We excluded four potentially relevant studies from this original review because study design did not meet the criteria for included studies. We excluded two studies that did not randomise infants to the assigned treatment - one that was a case series (Shukry 2005), and another that was a prospective observational trial (Fisher 1997). We excluded two other RCTs, as the comparisons did not match our criteria: MacNab 1998 compared three different types of stylets but did not include a 'no-stylet' arm; Yamashita 2015 compared two different methods of confirming that the ETT was in the trachea - not the main-stem bronchus.

Risk of bias in included studies

We deemed the included study to be at low risk of bias overall. See the risk of bias graph (Figure 2) and summary (Figure 3).

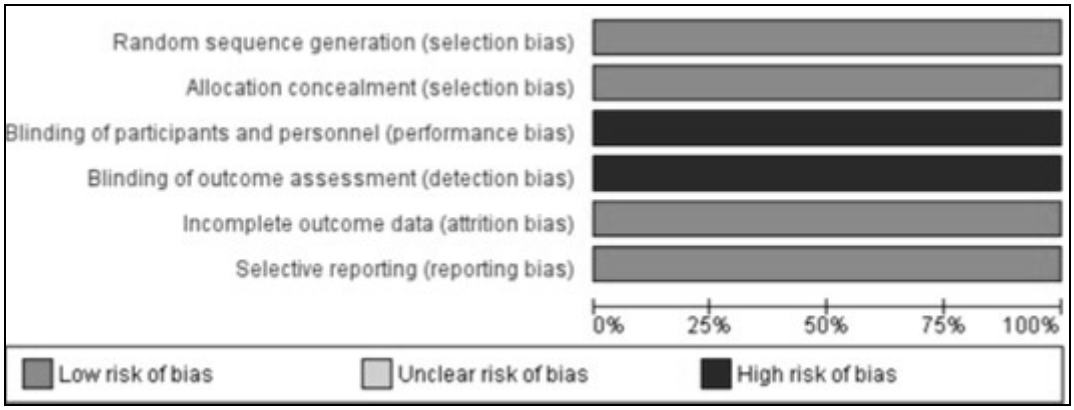

Figure 2 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3 Risk of Bias Summary: review authors' judgements about each risk of bias item for each included study.

Allocation

Investigators performed randomisation in blocks of variable size, stratified by site of intubation (delivery room or NICU) (low risk of bias for generation of random sequence). Researchers concealed allocation by using sequentially numbered sealed opaque envelopes containing computer-generated treatment groups (low risk of bias). The neonatal fellow on

duty would bring an unopened sealed envelope to the delivery room to randomise the next eligible infant. Infants in the NICU were identified by a study label placed on the incubator.

Blinding

This unblinded trial did not perform blinded outcome assessment (high risk of bias).

Incomplete outcome data

Researchers presented a complete flow chart for all intubations performed during the study period. They accounted for all exclusions and missed eligibles and for two post-randomisation exclusions (low risk of bias).

Selective reporting

The study protocol is available, and study authors reported all prespecified primary and secondary outcomes (low risk of bias).

Other potential sources of bias

We identified no other sources of bias.

Effects of interventions

See: Summary of findings for the main comparison

Primary outcomes

Rate of successful first attempt at orotracheal intubation. Intubation was successful on the first attempt in 57% of the stylet group and in53% of the no-stylet group (P =0.47; RR1.08, 95% CI 0.88 to 1.32) (Figure 4).

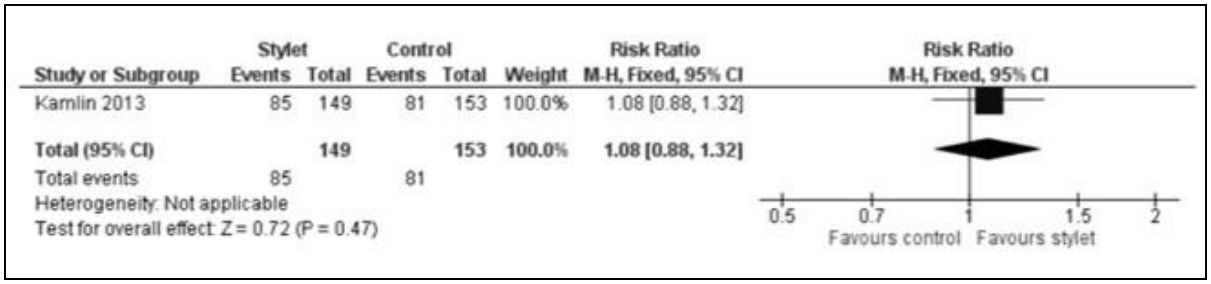

Figure 4 Forest plot of comparison: 1 First intubation attempt success rate with use of stylet versus non‐use of stylet, outcome: 1.1 First intubation attempt success rate.

Subgroup analyses

- Gestational age: < 28 weeks, 28 to 37 weeks, ≥ 37 weeks; analysis was not possible owing to lack of data
- Professional category of person performing intubation
    - Success by fellows was 67% with a stylet and 71% without a stylet (RR 0.94, 95% CI 0.69 to 1.29) (Figure 5)

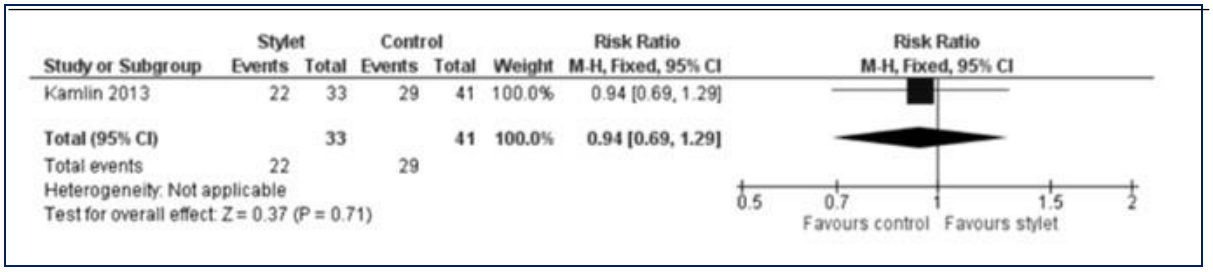

Figure 5 Forest plot of comparison: 2 Intubation success: Professional category, outcome: 2.1 Fellow: first intubation attempt success rate.

- Success by residents was 54% with a stylet and 46% without a stylet (RR 1.17, 95% CI 0.9 to 1.52) (Figure 6)

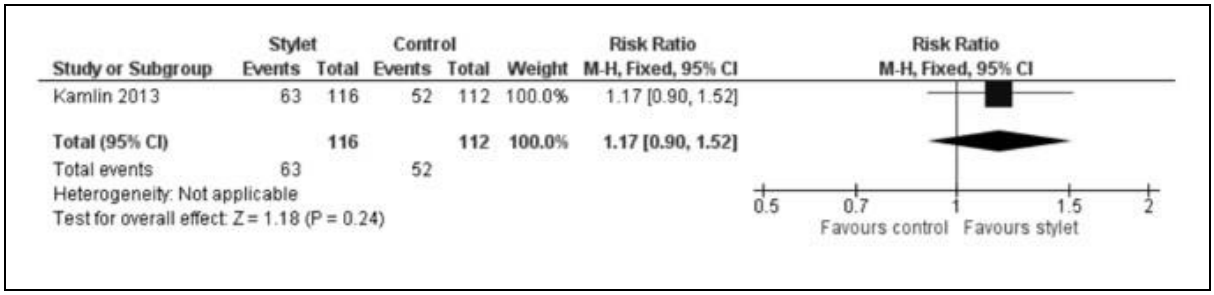

Figure 6 Forest plot of comparison: 2 Intubation success: Professional category, outcome: 2.2 Resident: first intubation attempt success rate.

- Doctors carried out all intubations in Kamlin 2013

- Level of experience of intubators - analysis was not possible owing to lack of data

- Effect of premedication

  - Success rate without premedication was 53% with a stylet and 54% without a stylet (RR 0.98, 95% CI 0.72 to 1.32) (Figure 7)

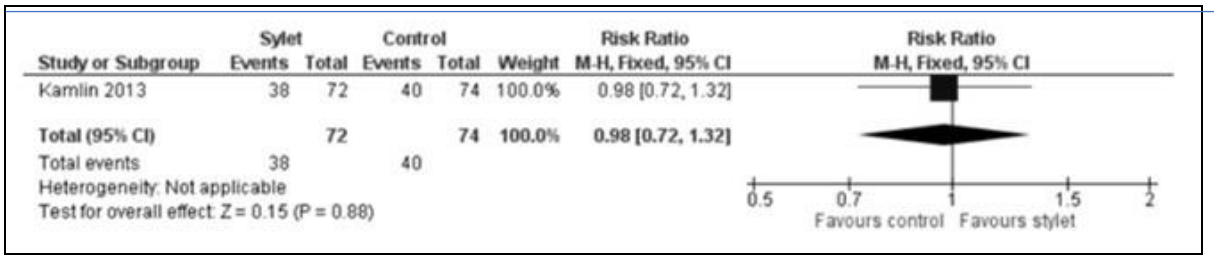

Figure 7 Forest plot of comparison: 3 Intubation success: use of premedication, outcome: 3.1 Intubations without premedication given to the infant.

- Success rate with premedication was 61% with a stylet and 52% without a stylet (RR 1.18, 95% CI 0.89 to 1.55) (Figure 8)

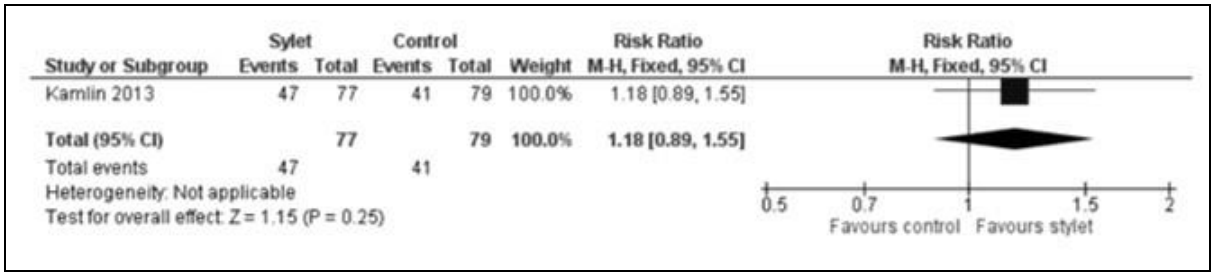

Figure 8 Forest plot of comparison: 3 Intubation success: use of premedication, outcome: 3.2 Intubations following premedication given to the infant.

- Timing of intubation.
    - Success rate during resuscitation following birth was 53% with a stylet and 54% without a stylet (RR 0.98, 95% CI 0.72 to 1.32)
    - Success rate during neonatal intensive care stay was 61% with a stylet and 52% without a stylet (RR 1.18, 95% CI 0.89 to 1.55)
- Type of stylet
    - Success rate with Satin Slip intubation stylet was 57% in the stylet group and 53% in the no-stylet group (P = 0.47; RR 1.08, 95% CI 0.88 to 1.32) (Figure 4)
- Weight of infant at the time of intubation
    - Success in infants weighing less than 1 kilogram at the time of intubation was 53% with a stylet and 60% without a stylet (RR 0.89, 95% CI 0.67 to 1.18)
    - Success in infants weighing 1 kilogram or more at the time of intubation was 61% with a stylet and 46% without a stylet (RR 1.32, 95% CI 0.97 to 1.79)

Secondary outcomes

Duration of the intubation in seconds

The median duration of intubation attempts was similar in the two groups: 43 (interquartile ratio (IQR) 30 to 60) and 38 (IQR27 to 57) seconds for stylet and no-stylet groups (P =0.23), respectively. Only 25% of all intubations took less than 30 seconds.

Number of intubation attempts

The median number of intubation attempts reported per infant before an ETT was successfully passed was one (range 1 to 5). Difficult airways appear to have been equally represented, with eight randomisations in each of the stylet and no-stylet groups requiring four or more attempts before successful intubation.

Participant instability during the procedure

Investigators measured participant instability during the procedure by assessing:

- heart rate (HR) < 100 during the procedure; and
- desaturation to < 70% (with 100% indicating full oxygen saturation).

In Kamlin 2013, trial pulse oximetry data were available for 277 intubation attempts in 215 infants (121 in DR, 156 in NICU). Investigators reported no significant differences between groups in lowest recorded oxygen saturation and heart rate during randomised attempts in the DR and the NICU, respectively. The mean lowest heart rate recorded for the stylet group was 128 beats per minute (standard deviation (SD) 36) compared with 121 (SD 37) for the non-stylet group. Only one infant in the trial received chest compressions. This infant had an antenatal diagnosis of tricuspid atresia and was randomised to the no-stylet group. No published data were available with regards to lowest oxygen saturation for the stylet group versus the non-stylet group during intubation attempts.

Local trauma to the airway or surrounding soft tissue

Researchers diagnosed local trauma to the airway or surrounding soft tissue by the presence of blood-stained endotracheal aspirates or oral secretions during the 24 hours following the

attempt (number per thousand infant population). Rates of blood-stained aspirates within the first 24 hours were 10% and 13% (P = 0.49) in stylet and no-stylet groups, respectively.

Evidence of airway damage

As some infants were randomised more than once (8% of infants) and were allocated to both groups, Kamlin 2013 did not report neonatal morbidity and mortality data. Of note, no participants were reported to have had tracheal or oesophageal perforation following intubation attempts.

Discussion

Summary of main results

Of 38 titles screened, we included one study with a total of 304 first intubation attempts in 232 infants (Kamlin 2013).This study, an unblinded randomised controlled trial (RCT) carried out in an Australian tertiary perinatal centre, compared use of a stylet as an aid during intubation of the newborn infant versus intubation without use of a stylet. The included trial assessed the primary outcome and most of the secondary outcomes of this review, while excluding assessment of airway damage. The salient result from this included trial suggests that using a stylet did not significantly improve the success rate of paediatric trainees in performing neonatal orotracheal intubation when compared with intubation performed without using a stylet. Results reported were consistent across subgroups according to site of intubation and birth weight of the infant. Investigators reported no serious side effects resulting from intubation with the use of a stylet.

Overall completeness and applicability of evidence

The effectiveness of stylet use during intubation has been evaluated in only one study, which evaluated the use of one particular make of stylet (Stain Slip intubation stylet, Malinckrodt Medical, Athlone, Ireland),one brand of endotracheal tube, in one country, by doctors with a minimum of six months' neonatal experience, among a population of newborn infants. Thus, results cannot be generalised beyond this population and use of this particular make of stylet in a hospital setting.

Quality of the evidence

We assessed the quality of evidence using GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) methods (Guyatt 2008). We judged the included study to be at low risk of bias overall. We stratified randomisation in blocks of variable size by site of intubation (delivery room or neonatal intensive care unit (NICU)). In terms of allocation concealment, researchers used sequentially numbered sealed opaque envelopes containing computer-generated treatment groups to determine allocation status. Study authors provided no evidence of incomplete outcome data. Researchers accounted for infants and eligible intubations that were excluded and provided reasons for these exclusions. Exclusions after randomisation were minimal. The study protocol was available, and all prespecified outcomes were reported as intended. One limitation of this study is that the trial was unblinded. Hospital staff and family members were unblinded to the intervention, and no evidence suggests that a blinded outcome assessment was conducted. It is unclear if the trial would have been improved by blinding of outcome assessment because of the objective nature of measured outcomes. The study is also limited in that investigators tested one brand of stylet and one brand of endotracheal tube. Endotracheal tubes likely have different degrees of rigidity. Amore rigid tube may hold its shape better, and practitioners may note less benefit

with use of a stylet, whereas a more floppy flexible tube may not hold its shape, and use of a stylet may be beneficial. Results show no differences in the incidence of blood-stained endotracheal aspirates between groups. However, if the initial attempt was unsuccessful, a stylet was used for subsequent attempts, at the clinician's discretion. This result should be interpreted cautiously. Another limitation is that some infants were randomised more than once, and some were included in both study arms. This makes assessment of longer-term outcomes impossible. In addition, inclusion of the same participant more than once leads to reduced power of the trial because of lack of independence of each intubation studied. This is somewhat ameliorated by the fact that premature infants are an atypical population that changes rapidly as the result of rapid growth (thereby posing different challenges for the operator) and changes to the upper airway resulting from each intubation and perhaps from steroid therapy. Therefore, a later intubation may be considered an independent event. Data were also derived from a single study with a moderately small number of participants. We downgraded the quality of evidence to low for these reasons.

Potential biases in the review process

We conducted a thorough search of the literature and did not apply language restrictions to minimise selection bias. We conducted the review robustly, according to good systematic review standards. It is unlikely that we have overlooked relevant high-quality large studies examining use versus non-use of a stylet during intubation of the newborn infant. Therefore, we believe that the probability of bias in the review process is low. A potential source of bias in the review as a whole is that three of the contributing authors of this Cochrane review and protocol are authors of the included study.

Agreements and disagreements with other studies or reviews

No other neonatal studies have examined whether a stylet can increase intubation success rates.

Authors' Conclusions

Implications for practice

We found no evidence to support the use of a stylet.

Implications for research

Neonatal intubation success rates are falling, especially those of junior trainees (Leone 2005). It is unlikely that future trials examining the use of stylets will present findings that will reverse this trend. Therefore, further research could focus on other variables that may influence intubation success to a greater degree, for example, educational interventions such as simulation or videolaryngoscopy. As opportunities for trainees to learn and practice neonatal intubation continue to decline, it is vital that training techniques are developed and intubation attempt success rates are continually audited to assess the effects of such training.

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∗ Indicates the major publication for the study

Chapter 5:

Videolaryngoscopy to Teach Neonatal Intubation: A Randomised Trial

Pediatrics. 2015 Nov;136(5):912-9

Abstract

Background

Endotracheal intubation is a necessary skill for paediatric and neonatal trainees. However, success rates have fallen to <50% amongst junior doctors, largely due to declining opportunities to intubate. Videolaryngoscopy allows instructor and trainee to share the same view of the pharynx. We compared neonatal intubations guided by an instructor watching images on a videolaryngoscope screen with the traditional method where the instructor does not have this view.

Methods

A randomised, controlled trial at a tertiary neonatal centre recruited from February 2013 until May 2014. Eligible intubations were performed orally on infants without facial or airway anomalies, in the delivery room or neonatal intensive care, by doctors with less than six months tertiary neonatal experience. Intubations were randomized to having the videolaryngoscope screen visible to the instructor or covered (control). The primary outcome was first attempt intubation success rate confirmed by colorimetric detection of expired carbon dioxide.

Results

206 first attempt intubations were analysed. Median (IQR) infant gestation 29 (27-32) weeks and weight were 1142 (816 - 1750)g. The success rate when the instructor was able to view the videolaryngoscope screen was 66% (69/104) compared to 41% (42/102) when the screen was covered, ($p<0.001$), OR 2.81 (95%CI 1.54-5.17). When premedication was used, the

success rate in the intervention group was 72% (56/78) compared to 44% (35/79) in the control group ($p<0.001$), OR 3.2 (95%CI 1.6 – 6.6).

Conclusions

Intubation success rates of inexperienced neonatal trainees significantly improved when the instructor was able to share their view on a videolaryngoscope screen.

Introduction

Endotracheal intubation is a common, potentially life-saving intervention for newborn infants with respiratory failure.[1] Intubation is a necessary skill for paediatric and neonatal trainees; however, it is a difficult skill to learn and maintain, and initial attempts are often unsuccessful. [2-9] Reported first attempt success rates of intubators with variable experience is between 44 – 73% and residents have the lowest success rates of 20 – 63%. [2-9] Three recent studies report success by residents in less than 25% of attempts. [2,3,5] With increasing use of non-invasive respiratory support, [10] reductions in trainees' working hours, [11] increasing numbers of trainees and changes in clinical recommendations, such as discontinuing routine intubation of infants delivered through meconium-stained liquor, [1] there are fewer opportunities for neonatal trainees to acquire and maintain proficiency and their success rates are subsequently falling. [4]

Strategies have been developed to compensate for the reduction in clinical experience. A meta-analysis of studies of technology enhanced simulation to teach adult intubation showed that this method was superior to no intervention. [12] However, studies using simulation to teach neonatal and paediatric intubation have not demonstrated improved clinical performance. [13,14] Animal models and cadaveric specimens are useful to demonstrate the anatomy but are very expensive and have limited availability. [15]

Successful intubation relies on the intubator being able to perform laryngoscopy to obtain a view of the infant's airway and then recognizing the anatomy displayed. Many novice intubators initially find this very challenging. Intubation instruction has traditionally relied on an apprenticeship model where a more experienced colleague supervises the novice.

However, the instructor's ability to provide guidance is limited by restricted access to the trainee's view of the airway, (Figure 1).

Figure 1 The supervisor cannot share the view of the infant's airway with the trainee. Videolaryngoscopy offers a solution to this problem.

Videolaryngoscopy offers a potential solution to this problem. Videolaryngoscopes use camera technology to visualize airway structures and facilitate endotracheal intubation. A recent systematic review found that insufficient evidence exists to recommend or refute the use of videolaryngoscopy for endotracheal intubation in neonates and called for randomized controlled studies to address efficacy and safety. [16] The aim of our study was to determine if supervision using a modified traditional Miller videolaryngoscope improves paediatric residents' first attempt neonatal intubation success rates.

Methods

Patients and Study Design

This single-centre unblinded randomized controlled trial was conducted between February 26, 2013 and May 26, 2014 at The Royal Women's Hospital, Melbourne, Australia, a tertiary perinatal centre with ~7500 births and 300 infants <1500g admitted to the neonatal intensive care unit (NICU) per year. Infants were eligible if they needed intubation and the intervention was going to be performed orally by a paediatric resident in their first six months of tertiary neonatal training. At the start of their neonatal rotation, all residents received intubation training including practice on neonatal manikins. Their participation in the study was voluntary and prior verbal informed consent was obtained. The need for intubation was determined by the clinical team and occurred either during resuscitation following birth or in the NICU. Infants were excluded if they had a facial, oral or airway anomaly or were intubated nasally. The study was approved by The Royal Women's Hospital research and ethics committees and registered with Australian New Zealand Clinical Trials Registry, number 12613000159752.

Prospective written consent by the infants' parents or guardians was obtained whenever possible. If delivery was imminent, or the mother was in active labour or was recovering from the birth, it was considered inappropriate to approach before the intubation. Therefore, for infants less than 48 hours of age, when prospective consent was not possible, a deferral of consent was used as per the Australian National Health and Medical Research Council guidelines for studies in emergency medicine. [17] The intubation was randomised and retrospective consent to use data was obtained as soon as possible after the event. Consent

was also requested to randomise further intubations if required. The process of deferred consent was approved by The Royal Women's Hospital Ethics Committee.

All intubations were performed using a modified traditional Miller videolaryngoscope (LaryFlex videolaryngoscope, Acutronics AG, Hirzel, Switzerland). A flexible fibreoptic cable threaded through the laryngoscope transmitted images from the blade tip to a nearby monitor. Two trolleys containing the videolaryngoscope system were kept within the NICU and the delivery suite. Intubation was performed after direct laryngoscopy with an additional view displayed on a computer-sized monitor (Figure 1). Reusable Miller blades size 1, 0 and 00 were used for term infants, preterm infants > 1kg and infants weighing less than 1kg respectively. The blades and fibreoptic cables were sterilized before each use and kept in sterile, sealed trays.

Premedication with fentanyl, atropine and suxamethonium was used for elective intubations A Neopuff Infant Resuscitator (Fisher & Paykel, Aukland, New Zealand) T-Piece was used to provide ventilation. Intubations were performed using sterile, single use, uniform internal diameter, plastic endotracheal tubes (Mallinckrodt Medical, Athlone, Ireland). A stylet (Satin Slip intubation style, Mallinckrodt Medical, Athlone, Ireland) was available to stiffen the endotracheal tube at the resident's request. Endotracheal tube placement was confirmed by a colorimetric exhaled carbon dioxide detector (Pedicap, Nellcor Puritan Bennett, Pleasanton, CA). Chest radiograph was performed to define tube position.

Randomisation

A computer generated, variable size block-randomization sequence was used. Allocation was stratified by the use of premedication (premedication used; no premedication used).

Sequentially numbered opaque envelopes containing the randomization cards were kept on the videolaryngoscope trolleys. If an intubation was anticipated by the clinical team, the research team was notified, and the equipment was set up. If this subsequently led to an intubation attempt by an eligible doctor, a randomization envelope was opened just before the intubation attempt. The unit of randomisation was the endotracheal intubation. Infants reintubated subsequently were eligible for randomisation again. However, only the first intubation attempt on each date was eligible for inclusion.

Study Intervention

Attempts were supervised by one of six study investigators (JO'S, LMG, CR, MT, OK, JJ). All six were trained to use the equipment, were shown several intubation recordings and observed at least three supervised videolaryngoscopic intubations before supervising an intubation attempt. In the intervention group, the instructor was able to see the videolaryngoscope screen and offer verbal assistance during the intubation attempt (Figure 2).

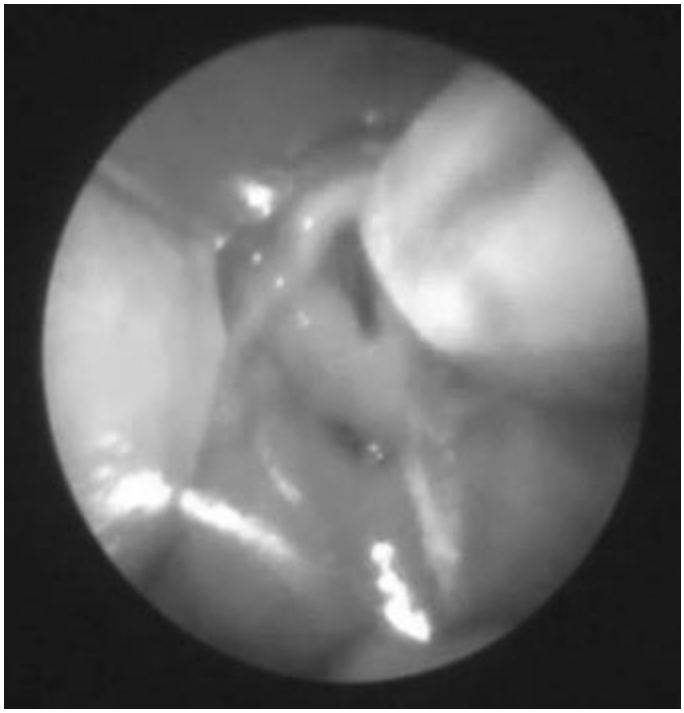
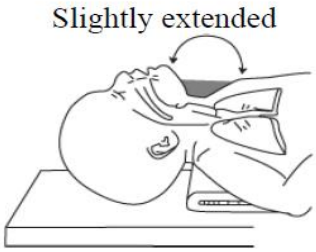


Figure 2 Still image from the videolaryngoscope screen.

In the control group, the instructor also offered verbal assistance, but did not have access to images on the screen. The videolaryngoscope kept within NICU had an attached laptop with the capacity to record images from the videolaryngoscope screen. Both intervention and control intubations within the premedication stratum were recorded. A standardised proforma on how to guide the intubation attempts was agreed by all study investigators before study commencement (Table 1).

During intubation

- Check correct head position and need for neck/shoulder roll to have the airway in the optimal position shown below.



- If the clinician is struggling to open the mouth, please help them.
- Guide them to insert the laryngoscope into the mouth above the tongue and avoiding the upper gum.
- Reassure that baby is anaesthetised (if premeds have been given).
- Instructor's hand on infant's neck should be able to feel laryngoscope when it is correctly positioned +/- give cricoid pressure if necessary
- Guide them through the advancement of the laryngoscope and insertion of the tube
    - Direct to keep them midline
    - Advise them when to lift the scope to reveal the airway
    - If laryngoscope has gone off midline or advanced too far or not far enough, talk them through how to correct this
    - Advise if suction is necessary
    - Hand them ET tube and advise them to pass it in from the side
    - Pull back infants' upper lip if necessary, to give them more room to insert and guide tube
    - If heading towards oesophagus, stop and redirect
    - If tube catching at the vocal cords, advise them to straighten up and decrease the angle or twist the tube gently
    - Stop them once ETT tip advanced past black marking
    - Remind them to not let go of the ETT when removing the scope

Table 1. Proforma used to guide intubation attempts

A senior clinician who was not a member of the research team attended the intubation and decided when to terminate an unsuccessful attempt. Criteria to stop an attempt included falling heart rate, hypoxia with oxygen saturations less than 70%, an intubation attempt of >60 seconds duration or at the attending clinician's discretion. Standardized debriefing was offered as soon as possible after the attempt. The resident was shown the video of the attempt

(if recorded). They were encouraged to reflect on the positive and negative aspects of the attempt. The instructor then advised on what was done well and what could be improved. The resident was then allowed to watch the video again if they wished.

Study Outcomes

The primary outcome was first attempt intubation success rate. Secondary outcomes included the infant's lowest heart rate and oxygen saturation and duration of the attempt (defined as the time interval from insertion of the laryngoscope blade into the infant's mouth until its removal). An independent data safety monitoring committee reviewed study outcomes after 100 intubations.

Statistical Analysis

On the assumption of an incidence of 50% for the primary outcome, [7] we needed 103 infants in each group to have a statistical power of 80% to detect a 20% absolute reduction in the risk of failure of intubation. All analyses were performed on an intention to treat basis. Data were analysed using Stata software (Intercooled 13, Stata Corp, College Station, Texas, USA). The data are presented as mean (standard deviation) for normally distributed variables and median (interquartile range) when the distribution was skewed. The clinical characteristics and outcome variables were analysed using Chi squared test, t test and Mann-Whitney U test as appropriate. The results were adjusted for clustering by operator. P values were 2-sided and values of less than 0.05 were considered statistically significant.

Results

Study Patients

A total of 213 intubations in 168 infants (median 1 intubation per infant, range 1-4) were randomized during the study period and 206 were included for analysis (104 screen visible and 102 screen covered), (Figure 3).

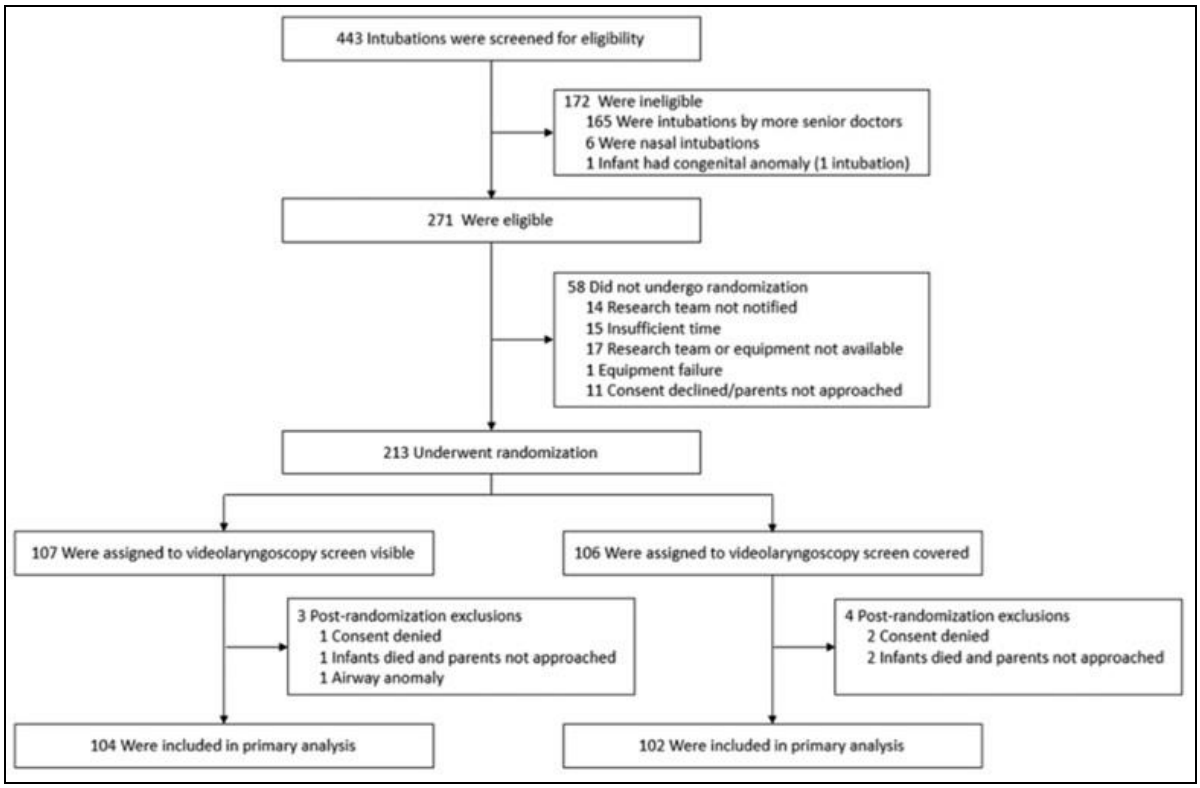


Figure 3 Enrolment and outcomes.

Demographic details of the infants are provided in Table 2.

	Intervention group n=104	Control group n=102	p value
Birth weight (g)*	1091 (795 - 1799)	1027 (757 - 1562)	0.3
Gestation (weeks)*	28 (26 - 32)	28 (26 - 30)	0.5
Weight at time of intubation (g)*	1173 (819 - 1884)	1125 (816 - 1569)	0.35
Corrected gestation (weeks)*	29 (27 - 32)	29 (27 - 32)	0.82
Five minute Apgar score*	8 (6 - 9)	8 (6 - 9)	0.67
Indication for intubation n (%)			
Respiratory Failure	62 (60%)	61 (60%)	0.98
Resuscitation	26 (25%)	23 (23%)	0.68
Apnoea	10 (10%)	12 (12%)	0.62
Other	6 (6%)	6 (6%)	0.97
First intubation for infant	69 (66%)	61 (60%)	0.33
Given premedication	78 (75%)	79 (77%)	0.84

*median (interquartile range)

Table 2. Demographic Details of the Infants

At the time of inclusion 43% of infants weighed less than one kilogram. Study intubations were performed by 36 residents. They performed a median of 7 randomized intubations each, range 2 – 11. Details of the residents' previous intubation experience are provided in Table 3.

Number of previous successful intubations	Intervention group n=104 (%)	Control group n=102 (%)
0	17 (16)	25 (25)
1 - 2	33 (32)	27 (26)
3 – 5	33 (32)	24 (24)
6 – 9	14(13)	19 (19)
≥ 10	7 (7)	7 (7)

Table 3. Details of the Residents' Previous Intubation Experience at the time of randomisation

Images from the videolaryngoscope screen were recorded for 125 intubations (79.6% of premedicated intubations, 60.7% of total study cohort).

Primary Outcome

The first attempt intubation success rate when the instructor was able to watch the videolaryngoscope screen was 66% (69/104) compared to 41% (42/102) when the screen was covered; unadjusted odds ratio (OR) 2.81 (95% confidence interval (CI) 1.54-5.17), p<0.001, adjusted OR 2.82 (95% CI 1.44 - 5.52) (adjusted for clustering by resident). When premedication was given the success rate in the intervention group was 72% (56/78) compared to 44% (35/79) in the control group, OR 3.2 (95%CI 1.6 – 6.6), p<0.001. When no premedication was given success rates in the intervention and control groups were 50% (13/26) and 30% (7/23) respectively, OR 2.3 (95%CI 0.6 – 8.8), (p = 0.164). Success rates for stratified by level of experience of the resident are presented in Table 4.

Number of previous successful intubations	Intervention group n=104 (%)	Control group n=102 (%)
0	17 (16)	25 (25)
1 - 2	33 (32)	27 (26)
3 – 5	33 (32)	24 (24)
6 – 9	14(13)	19 (19)
≥ 10	7 (7)	7 (7)

Table 4. Details of the residents' success rates for each experience category

Secondary Outcomes

Secondary outcomes are presented in Table 5.

	Intervention group n=104	Control group n=102	p value
Lowest oxygen saturation (%)*	70 (48 – 83)	69 (46 – 82)	0.88
Lowest heart rate (beats per min)*	150 (135 – 164)	151 (139 – 162)	0.99
Duration (s)*	51 (39 - 63)	53 (41 - 70)	0.15

Table 5. Secondary Outcomes

There were no significant differences in rates of hypoxia or bradycardia or in the duration of the attempt between the intervention and control groups.

Discussion

The intubation success rates of paediatric residents using direct laryngoscopy improved significantly when an instructor was able to provide guidance based on the shared view of the upper airway. This result was achieved without evidence of harm, as this finding was not associated with increased hypoxia, bradycardia, or a longer duration of intubation attempt.

This is the first study to use a videolaryngoscope to assist junior doctors learning the skills of direct laryngoscopy and intubation in neonates. Infants of a wide range of gestational ages and weights were included. Extremely low birth weight infants were well represented. Both elective (premedicated) and emergency (non-premedicated) intubations were included. Intubations were individually randomized, thereby reducing selection bias and a high percentage of all eligible intubations were included (76%). This technique is relevant to other professionals involved in neonatal resuscitation and airway management (e.g. respiratory therapists) and could also be used to facilitate training in paediatric and adult intubation.

Videolaryngoscopes have been available for over ten years [18] and are now an established tool for acute airway management. [19-21] The videolaryngoscope screen displays an improved, magnified, wider laryngeal view (Figure 2) compared with direct laryngoscopy. [22] Previously, this technique has typically involved the intubator performing videolaryngoscopy looking at the screen during an intubation attempt rather than performing direct laryngoscopy looking in the patient's mouth. Experienced intubators success rates using videolaryngoscopy in this manner compared to direct laryngoscopy are equally high or

slightly higher in patients with normal airways, [23-25] and significantly higher in patients with anticipated difficult airways [20, 26-27] Inexperienced intubators using videolaryngoscopes compared to laryngoscopes had greater success intubating healthy adults with normal airways. [28]

However, learning to intubate using videolaryngoscopy may not translate into the same ability using a traditional laryngoscope. Videolaryngoscopes take time to set up, need maintenance and are expensive. Therefore, proficiency needs to be achieved at intubation using direct laryngoscopy. There is only one previous randomized study where the intubator performed direct laryngoscopy and the instructor was either able to see the images on the screen or not. This was a crossover study performed by Howard-Quijano et al. [29] Intubations were randomized in blocks of six to either three with the screen visible to the instructor followed by three with the screen covered or the order reversed. The six intubations occurred over a several day period. There were 37 intubators, medical students or non-anaesthetic trainees, all with less than six previous intubation attempts. All intubations were performed on healthy adults with normal airways. The instructors were anaesthesiologists trained to teach intubation and use the equipment. The success rate was significantly higher when the instructor was able to see the screen (69% compared to 55%, p=0.04). [29]

Videolaryngoscopes vary in style from modified traditional Miller or Macintosh laryngoscopes, to devices with a short angulated blade and guide channel. Our hope was that the resident's experience performing laryngoscopy with the videolaryngoscope would be comparable to standard direct laryngoscopy so that the skill they learned could translate to standard practice. To achieve this, ideally the laryngoscope handle and blades would be comparable. Several Miller neonatal laryngoscope blades are available. [30] They have subtle

differences in size and shape but are straight and mostly either flat bottomed or have a slight midline trough. [31] We chose the Laryflex videolaryngoscope for the study because it is possible to perform direct laryngoscopy as well as videolaryngoscopy and its blades most closely resemble commonly used neonatal laryngoscope blades. The blade is straight until a slight downward slope near the tip and the midline trough is deeper. This necessitates the endotracheal tube curling around a relatively higher lip of the blade to approach the larynx, which is held in a slightly different position. It is possible that these subtle differences could limit translation of the results from our study to standard direct neonatal laryngoscopy. These findings may encourage manufacturers to minimize differences between blades. The device that was used in this study had a free-standing monitor that was placed alongside the infant's incubator. This resulted in the instructor looking at the infant while the blade was introduced in the mouth, and then looking away from the infant to see the screen. Other videolaryngoscopes link to smaller screens that can be placed closer to the patient, allowing the instructor to watch the images and the trainee intubating simultaneously. Future devices may improve this design, for example linking wirelessly to a handheld tablet or smartphone.

This study did not assess whether the improved rate of successful intubation when using a videolaryngoscope resulted in retention of the skill when the operator was unassisted. However recent work by Moussa *et al* showed that success rates of residents who learned intubation using videolaryngoscopy were maintained when they converted to classic laryngoscopy. [32]

We found higher success rates when the infant was given premedication beforehand. This is consistent with previous studies that have shown premedication improves intubating conditions, reduces the number of attempts and decreases the risk of airway trauma. [33-38]

It has been previously reported that inexperienced intubators have a longer attempt duration than their more experienced colleagues. [5-7] The intubation durations reported in this study are similar to those of other studies. [6-7] We used a standardized approach to providing instruction and feedback both during and after an attempt. Intubation instruction using traditional methods is challenging in that the instructor's ability to offer concurrent feedback during the attempt is limited. The intervention in this study allowed the instructor to provide accurate, precise, concurrent instruction and feedback during an attempt. This allowed for informed guidance but also quick correction of errors and positive reinforcement of what was being done correctly. As part of a standardised debrief following the intubation, the residents watched video recordings of most of their attempts (both control and intervention intubations). This may have reinforced what they did well and helped explain an unsuccessful attempt. This method was reported favourably by the residents and is likely to have been contributory to the high success rates found in this study.

There are limitations to this study. Only one of a number of available videolaryngoscopes was tested. Results using other devices may differ. The number of instructors was limited to a small core group who were trained to supervise according to specific guidelines. Instructors with less training may be less successful in supervising inexperienced residents.

Currently, paediatric residents and neonatal fellows learning intubation face the challenge of reduced opportunity to practice. A US study found that from 1994 to 2002 the number of intubating opportunities per resident decreased by more than two thirds and success rates almost halved. [4] The anaesthetic literature suggests 40 or more intubations are necessary to become proficient (defined as success rates of eighty percent or more). [39,40] It is becoming increasingly challenging for trainees to log high numbers of intubation attempts. However,

the technique described in this study may enable trainees to become proficient faster. The intervention described in this study has produced the highest reported success rate for novice neonatal intubators. This method, which allows the instructor to share the view of the trainee, may offer a solution to the low and falling intubation success rates of neonatal trainees.

Acknowledgments

We would like to thank the infants, their parents and the residents for their participation in the study. We would also like to thank the nursing, medical and research staff at the Royal Women's Hospital and the members of the Data Safety Monitoring Committee. Finally, we would like to thank In Vitro Technologies and Acutronics AG for their generous lease of the videolaryngoscope for its use during the trial.

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Chapter 6:

Analysis of unsuccessful intubations in neonates using videolaryngoscopy recordings

Arch Dis Child Fetal Neonatal Ed. 2018 Sep;103(5):F408-F412

Abstract

Objectives

Neonatal intubation is a difficult skill to learn and teach. If an attempt is unsuccessful, the intubator and instructor often cannot explain why. This study aims to review videolaryngoscopy recordings of unsuccessful intubations and explain the reasons why attempts were not successful.

Study Design

A descriptive study examining videolaryngoscopy recordings obtained from an RCT that evaluated if neonatal intubation success rates of inexperienced trainees were superior if they used a videolaryngoscope compared to a laryngoscope. All recorded unsuccessful intubations were included and reviewed independently by two reviewers blinded to study group. Their assessment was correlated with the intubator's perception as reported in a post-intubation questionnaire. The Cormack-Lehane (CL) classification system was used for objective assessment of laryngeal view.

Results

Recordings and questionnaires from 45 unsuccessful intubations were included, (15 intervention and 30 controls). The most common reasons for an unsuccessful attempt were oesophageal intubation or failure to recognize the anatomy. In 36 (80%) of intubations, an intubatable view was achieved but was then either lost, not recognised or there was an apparent inability to correctly direct the endotracheal tube. Suctioning was commonly performed but rarely improved the view.

Conclusions

Lack of intubation success was most commonly due to failure to recognize midline anatomical structures. Trainees need to be taught to recognise the uvula and epiglottis and use these landmarks to guide intubation. Excessive secretions are rarely a factor in elective premeditated and routine suctioning should be discouraged. Better blade design may make it easier to direct the tube through the vocal cords.

What is already known on this topic

- Intubation is a difficult skill to learn and teach.
- Endotracheal intubation is a mandatory skill for neonatal trainees.
- Currently, if an attempt is unsuccessful, the intubator and their supervisor often do not know why.

What this study adds

- Lack of success was most commonly due to failure to recognize anatomical structures.
- Excessive secretions in elective intubations are rarely a factor and routine suctioning should be discouraged.

Introduction

Endotracheal intubation is a lifesaving procedure in the neonatal intensive care unit (NICU). It is a mandatory competency for General Paediatric Training by the Royal College of Paediatrics and Child Health. [1] Intubation skills are difficult to acquire. Reported success rates of intubators are between 20 – 73% and inexperienced intubators have the lowest success rates. [2-9] Increased reliance on non-invasive ventilation and discontinuation of routine intubation of infants born through meconium stained liquor has led to a reduction in the number of neonates being intubated. This coupled with increasing numbers of trainees and reduction in trainee working hours increases the difficulty of achieving proficiency. Success rates also appear to be falling. Three recent studies report success in less than 25% of attempts. [2,3,5] Endotracheal intubation is associated with a high rate of complications. In a prospective study, adverse events occurred in 39% of intubations and serious adverse events in 9%. [10]

Neonatal intubation is generally taught using an apprenticeship model where the trainee observes and then later attempts the procedure while supervised. One of the challenges is that the trainer is not able to share the trainee's view during laryngoscopy. Therefore, if an attempt is unsuccessful, it is often difficult for the trainer to understand why and to provide constructive feedback. Videolaryngoscopy allows intubator and trainer to share the view and has been shown in a recent randomised controlled trial (RCT) to improve intubation success rates. [11] Recording images also allows for review after an attempt.

The objective of this study was to review videolaryngoscopy recordings of unsuccessful intubations and identify why the attempt failed and also to compare this to the reasons reported by the intubators.

Methods

Settings and Practice

This is a descriptive study using data obtained from an RCT evaluating videolaryngoscopy for neonatal intubation.[11] The study was conducted from February 2013 to May 2014 at the Royal Women's Hospital, Melbourne, Australia, a tertiary perinatal centre with ~7500 births and 300 infants with birth weights less than 1500g admitted annually to the NICU. Included intubations were those performed orally, on infants without facial or airway anomalies by a paediatric trainee with less than six months tertiary neonatal experience. Pre-medication with fentanyl, atropine and suxamethonium was used for elective intubations and the use of a stylet was routine. The attending clinician, not the research team decided what intubations could be performed by trainees with limited experience. The primary outcome was the first attempt intubation success rate.

Study Intervention

All intubations were performed using a videolaryngoscope (LaryFlex, Acutronics, Hirzel, Switzerland). This is a modified traditional Miller laryngoscope that contains a fibreoptic cable whose tip replaces the bulb and transmits images from the blade tip to a nearby monitor. To enable recording, a Macbook Pro was connected to the videolaryngoscope and video images were recorded with Videoglide for Mac (EchoFX, Duluth, GA, USA) It took a few minutes to enable recording so if there were time constraints, this step was left out. Intubations in the delivery room were not recorded.

The trainee performed direct laryngoscopy and did not look at the video screen. Intubations were randomised to the video screen being visible to the instructor (intervention group) or covered (control group). The supervisor guided the intubations in a standardized way; this included helping to optimize the position of the infant. [11] The view on the screen was similar to the direct view differing only in being wider and magnified. A senior clinician who was not a member of the research team determined when to stop the intubation attempt, based on pre-set clinical criteria. Each intubation was followed by debriefing and feedback. The trainees also completed a questionnaire that included a list of reasons for unsuccessful intubation that had been compiled by the authors (JO'S, OK, MT, PGD). The questionnaire was piloted before the RCT on neonatal trainees not participating in the trial and adjusted following their feedback. The reasons for unsuccessful attempts listed on the questionnaire used during the RCT included - (1) an inability to advance the laryngoscope beyond the lips, tongue or oral cavity, (2) an inability to visualize the vocal cords, (3) too many secretions or inadequate suction, (4) a poorly positioned infant, (5) the oesophagus was intubated, (6) the infant became clinically unstable and therefore the procedure was abandoned and (7) other reasons. More than one reason could be selected if appropriate. The Royal Women's hospital research and ethics committees approved the study.

Analysis of Videolaryngoscopy Recordings

Videos of unsuccessful intubations were included in this study. As delivery room intubations were not recorded, all intubations in this study were elective and premedicated. Both intervention and control videos are included but described separately. The control videos are representative of a real world situation. The intervention videos are presented to explore

whether using this technique changed the reasons why an attempt was unsuccessful. Only the first attempted intubation was included in this study.

Two reviewers (JOS and PL) independently reviewed all the videos blinded to study group. Before assessing the videos, the reviewers developed a list of potential reasons for failure of intubation. The agreed list was - (1) an inability to advance the laryngoscope beyond the oral cavity, (2) successfully advancing beyond the oral cavity but unable to achieve an intubatable view, (3) excessive secretions, (4) oesophageal intubation, (5) failure to or delay in recognizing the vocal cords, (6) inability to correctly direct the ETT despite having an intubatable view and (7) successful intubation followed by accidental extubation. As the infant's position and clinical condition could not be seen on the recordings, these were not included. The reasons did not need to be mutually exclusive. Failure to or delay in recognizing the vocal cords was defined as the trainee obtaining an intubatable view but either not attempting to place the ETT or attempted placement delayed 15 seconds or more. Inability to direct the ETT was used to describe when an intubatable view was obtained and the operator repeatedly attempted to pass the ETT but could not direct it through the vocal cords. Excessive secretions was listed as a reason when secretions blocked the view and was not cleared by the resident. When the operator performed suction but clearly had the laryngoscope misplaced, secretions were not felt to be contributory. It was possible that more than one reason contributed to failure of the attempt. Inter-observer agreement between the two reviewers was assessed. Discrepancies were resolved by discussion. The final reviewers' decision was compared with the trainee's perception as reported in the post intubation questionnaire.

To objectively describe the view of the infant's airway, the reviewers also graded the best view of the infant's larynx achieved and the view visible during ET tube insertion using the Cormack-Lehane classification system. [12] This system was described in 1984 as a way of simulating potential scenarios that trainee anaesthetists might face. Grade 1 describes a full view of the glottis being achievable. Grade 2 refers to a partial glottic view being visible. Grade 3 is when the epiglottis but not the glottic opening can be seen and grade 4 is when neither glottis nor epiglottis seen. This classification system for assessment of laryngeal view was used, as this system was designed for beginners, [13] simple to use, and used commonly in paediatric research. [14] For the purposes of this study, an intubatable view was defined as a C-L Grade 1 or 2 view during the intubation attempt. Infants with facial or airway anomalies were excluded; therefore it is reasonable to expect that an experienced intubator would have achieved an intubatable view in all of these infants.

Data Analysis and Statistics

Descriptive statistics for population characteristics are presented. Categorical variables are presented as proportions and 95% confidence intervals (CI), while numerical variables are presented as mean (SD) for normally distributed data or median (IQR) for skewed data. Fisher's exact test, student t test and Mann Whitney U test were used as appropriate. P values of <0.05 were considered statistically significant.

Outcome for agreement between the trainee and the reviewer were nominal (yes /no agreement). Inter-observer variability was determined using nominal kappa statistics with bootstrapped bias and corrected 95% confidence intervals. Kappa values can be classified as follows: below zero=poor, zero to 0.20=slight, 0.21 to 0.4=fair, 0.41 to 0.6=moderate, 0.61 to

0.8=substantial, 0.81 to 1=almost perfect. The STROBE checklist for reporting observational studies was used.

Results

Intubations were performed by 36 trainees who performed a median of 7 each, range 2 to 11. Questionnaires were completed after all intubations (100% response rate). Forty-five unsuccessful intubations were recorded and included in this study; 30 control and 15 intervention (Figure 1).

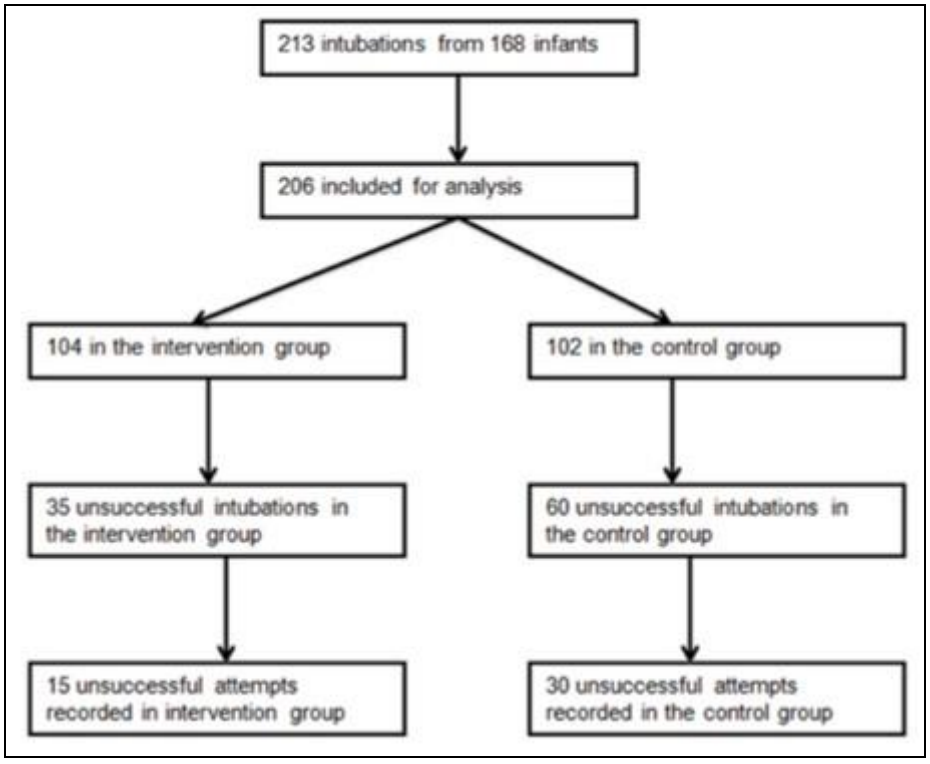

Figure 1 Study flow diagram.

All included intubations were premedicated elective intubations. Baseline characteristics of infants and trainees are presented in table 1.

Characteristic	Control group (n=30)	Intervention group (n=15)
Infant Characteristics		
Mean gestational age (SD) weeks	28.6 (4.1)	29.3 (3.0)
Mean corrected gestational age at the time of intubation (SD) weeks	30.0 (3.5)	30 (3.3)
Mean Birth weight (SD) g	1272 (726)	1316 (502)
Mean weight at the time of intubation (SD) g:	1344 (502)	1520 (634)
Causes for intubation (%)	respiratory failure 25 (83) apnea of prematurity 4 (13) intraventricular hemorrhage with secondary apnea 1 (3)	respiratory failure 10 (67) apnea of prematurity 3 (20) necrotising enterocolitis 1(7) sepsis 1 (7)
Intubator Characteristics		
Median number of attempts (range)	2 (2 - 5)	2 (2 - 4)
First Intubation (%)	15 (50)	7 (47)
Median number of previous successful intubations (range)	3 (0 - 20)	1 (1 - 6)

*SD: Standard Deviation

Table 1: Baseline characteristics of the Study Population

Results are described in Table 2 and the best view classification and classification while attempting to pass ETT are described in Table 3.

	Control Group (n=30)	Intervention group (n= 15)	p value
Couldn't advance beyond the oral cavity, n (%)	1 (3)	1 (7)	1.00
Couldn't achieve an intubatable view, (CL 3-4)[#], n (%)	7 (23)	2 (13)	1.00
Excessive secretions, n (%)	2 (7)	2 (13)	0.85
Oesophageal intubation, n (%)	14 (47)	5 (33)	0.59
Vocal cord not recognized, n (%)	9 (30)	1 (6)	0.16
Couldn't direct ET, n (%)	10 (33)	9 (60)	0.16
Accidental extubation during strapping, n (%)	1 (3)	2 (14)	1.00

Note: There may be overlap of numbers as there could be multiple factors responsible for each unsuccessful intubation.

[#] CL- Cormack-Lehane classification system

Table 2: Comparison of unsuccessful intubations factors between the control group and the intervention group

Grade	Description	Best C-L grade in control videos (n=30) n (%)	Best C-L grade in intervention videos (n=15) n (%)	C-L Grade when inserting ETT in control videos (n=25)* n (%)	C-L Grade when inserting ETT in intervention videos (n=14)** n (%)
1	full view of glottis	17 (57)	11 (73)	8 (32)	8 (57)
2	partial view of glottis	6 (20)	2 (13)	11 (44)	4 (29)
3	only epiglottis seen, none of glottis seen	5 (17)	0 (0)	2 (8)	0 (0)
4	neither glottis nor epiglottis seen	2 (7)	2 (13)	4 (16)	2 (14)

*in 5 attempts there was no insertion of ETT
** in 1 attempt there was no insertion of ETT

Table 3: Cormack-Lehane classification system for assessment of laryngeal view

In the control group, an intubatable view was achieved in 23 attempts (77%). A further 3 (10%) achieved a view of the epiglottis but apparently did not recognize it as a landmark to help find the vocal cords. One trainee (4%) lost the view when trying to insert the ETT and in another 8 (35%) attempts the grade of the view obtained worsened when the trainees' attention was directed at passing the ETT (Table 3). In nine attempts (30%) the trainee had no or delayed recognition that they had a view of the larynx; in 4 of these attempts, there was no effort to pass the ETT and in the other 5 the attempt was delayed and unsure. There were 14 (47%) oesophageal intubations; 9 of these were despite an intubatable view. In 10 (33%) attempts it was apparent that the trainee was trying to direct the ETT towards the vocal cords

but was unable to direct the ETT through the cords. During 8 (27%) attempts, the infant's tongue was to the right of the laryngoscope blade and may have been an obstacle to inserting the ETT. However, in only 3 of these attempts did the trainee report that they could not direct the tube. Suctioning was performed in 11 control intubations. However in 9 (82%), excessive secretions were not apparent and suctioning did not improve the view. The duration of suctioning ranged from 3 – 16 seconds (mean 8s). One (3%) intubation attempt was successful but then accidentally dislodged while securing the tube.

In 86% of the intervention group attempts, an intubatable view was achieved. No trainee lost the view while inserting the tube and in 2 (13%) attempts, the grade of the view worsened when trying to insert the tube (Table 3). Inability to direct the ETT was the most commonly reported reason for attempt failure and seen in 60% of attempts. During 3 attempts, suction was performed; in 2 of these excessive secretions were blocking the view.

In a majority of the videos there is substantial (60-80%) or almost perfect (>80%) inter-rater agreement between the two investigators and between the investigators and the trainee (Table 4).

	Agreement between Investigator 1 & 2	Agreement between Investigator & Trainee
Grading of laryngeal view	100%	#
Vocal cord not recognized	87%	#
Couldn't advance beyond oral cavity	100%	100%
Couldn't visualise Vocal cords	77%	100%
Excessive secretions	77%	100%
Oesophagus was intubated	100%	60%

Table 4: Inter-Rater agreement

Trainees correctly identified when they couldn't advance beyond the oral cavity (kappa 1.0), couldn't achieve an intubatable view (kappa 1.0) or were hampered by excessive secretions (kappa 1.0). Trainees were less certain when they had intubated the oesophagus (kappa 0.60 (95%CI 0.36-0.85)).

Discussion

This study describes the reasons why neonatal intubation attempts were unsuccessful. These findings can hopefully contribute to improving how intubation is taught. In order to successfully intubate, the intubator has to be able to achieve, recognize and maintain an intubatable view. The majority of the residents did achieve a view, but many of them did not recognize it or struggled to maintain it when their focus moved from laryngoscopy to inserting the ETT. There were other instances where the epiglottis was seen but the scope not advanced further to reveal the vocal cords.

The basis of successful intubation training is to establish an understanding of the anatomy of the infant's airway. The trainee should be advised to look for midline structures like the uvula and the epiglottis and use them to identify the midline and as landmarks to direct them to the vocal cords. Having images and videos easily available to the trainee may help them better recognize the anatomy. Showing them videos of successful and unsuccessful intubations may also be helpful. A small study demonstrated improved skills score and decreased intubation time with prior viewing of smart phone application demonstrating the airway anatomy and intubation procedure. [15]

Interestingly, in 33% of control and 60% of intervention intubations, despite an intubatable view, the ETT could not be directed in through the vocal cords. There are many possible reasons for this including laryngoscope blade shape or rotation and the infant's head position. Optimizing head position and blade rotation was part of the agreed proforma that the supervisors used to guide but assessing if this was achieved was unfortunately not possible using the methodology of this study. [11] There is little standardization in laryngoscope blade design. Miller's original description was a slightly curved flat blade 10cm long. [16] Some blades have remained true to this original description whereas others including the one used in this study have a midline trough. Perhaps this trough was added to facilitate feeding the ETT along the blade to the vocal cords. However, if the ETT is inserted along the blade, the operator is not be able to visualize it passing though the cords and therefore cannot be sure they have placed it correctly. Therefore, trainees are taught to feed the ETT in from the side. However, in several cases in this study, trainees found the lip of the laryngoscope blade to be an obstacle.

It is common for suction to be used during an intubation attempt. In the majority of occasions where suction was used in this study, it did not lead to an improved view. Suction is time consuming, may stimulate a vagal response and at least in elective intubations, rarely helps. A small number of intubations were successful, but the tube was dislodged during securing, emphasizing the need for particular care during this part of the procedure.

We presented the results of the intervention attempts in order to explore whether having the instructor share the view would change the profile of reasons for extubation failure. A higher percentage achieved an intubatable view; a lower percentage didn't recognize the view or

didn't maintain the view, a higher percentage had difficulty directing the ETT and less performed suction. However oesophageal intubations were still seen as were a small number of accidental extubations.

Our study has several strengths. It provides insight into an important but under-investigated problem. Two investigators analysed the videos independently. Both investigators were blinded to the study group while analysing the data. This study was also able to include the trainee's perception of events. This use of the C-L classification system gave an objective grading of laryngeal view.

This study has limitations. The sample size is small and made up of elective intubations. All intubations were carried out with one laryngoscope and therefore may yield a different result profile if a different model with a flatter blade was used. It was not possible to comment on the infant's position or physiological stability.

Conclusion

The majority of unsuccessful intubations performed by inexperienced paediatric trainees were due to oesophageal intubation or failure to recognize the laryngeal airway or structures that can lead to it. Routine suctioning during elective intubations should be discouraged. A proportion of unsuccessful intubations were due to difficulty in directing the ET tube around a laryngoscope blade with a midline trough; improvement of blade design might help in these situations.

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Chapter 7:

Devices used for stabilisation of newborn infants at birth

Arch Dis Child Fetal Neonatal Ed. 2018 Jan;103(1):F66-F71

Abstract

This review examines devices used during newborn stabilization. Evidence for their use to optimize the thermal, respiratory and cardiovascular management in the delivery room is presented. Mechanisms of action and rationale of use are described, current developments presented and areas of future research highlighted.

Key Points

- International guidelines on newborn stabilization advocate support of breathing by means of non-invasive respiratory support.
- A baby's temperature is a sensitive prognosticator for morbidity and mortality. Deviations from the advised optimal body temperature (36.5 - 37.5°Celsius) should be avoided.
- Methods for maintaining optimal body temperature include ambient temperature control, use of heated, humidified gas, use of polyethylene wraps, head covers or hats, and active heating by radiant warmers and thermo-active mattresses.
- Immediately following delivery, non-invasive respiratory support is best given via an appropriately sized facemask, attached to a pressure-controlled ventilation device.
- Newly emerging evidence on Laryngeal mask airways suggests they may have benefits over face masks.
- Oxygen should be administered judiciously and the effect of giving supplemental oxygen needs to be continuously monitored by using pulse oximetry.

- Heart rate is the most sensitive indicator for successful transition. Heart rate can be continuously monitored directly after birth by using the pulse oximeter or electrocardiography.

Background and Aims

It is estimated that 3-8% of all babies receive some intervention to help with transition at birth. [1] A small fraction of these will indeed need active medical management to assist their stabilisation. The recent surge in refined animal model and human studies of the physiology of foetal to neonatal transition has significantly advanced our understanding of the physiologic processes at the time of birth. [2] Consequently, a paradigm shift has taken place from the former focus on providing resuscitation at birth, in particular when caring for preterm infants, to a more permissive approach of providing assistance with stabilization unless resuscitative measures are urgently required. [4-6] This does not discount that newborn infants do not on occasion require intensive medical attention at birth. This review examines devices used for newborn stabilization, as advised in the current guidelines from the international liaison committee on resuscitation (ILCOR), [4] the European Resuscitation Council (ERC) [5] and the UK Resuscitation Council. [6] As the devices and methods used for providing stabilization largely serve both the purpose of supporting transition as well as aiding full cardio-pulmonary resuscitation therefore describe the devices used in the context of delivery room (DR) management and give reference to the specifics of neonatal resuscitation where appropriate. Our aim is to promote an understanding for the different devices or modalities, hence the scientific background for their use, particular technical aspects and practical guidance for their handling is provided and attention is drawn to areas of urgently needed research.

Training staff to recognise normal transition at birth and to identify the newborn infant in need for resuscitation

All senior personnel attending deliveries need to have an in-depth understanding of the normal physiologic sequence of foetal to neonatal transition and be able to recognise the deviations from the gestational age (GA) appropriate transition at birth. Therefore, all staff should be trained in newborn life support (NLS) to appropriately care for all newborn infants. [4-6] The appropriate equipment for newborn stabilisation and resuscitation must be readily available at all times. Preparation of staff and equipment is the key to successful handling of the newborn infant in distress. As it is oftentimes possible to predict the need for resuscitation beyond stabilisation based on the ante- and perinatal history, neonatal teams need to pay close attention to the obstetric history to prepare for the anticipated events timely and as well as possible.

Maintaining normothermia after birth.

It is recommended that the temperature of newly born, non-asphyxiated infants should be maintained between 36.5°C and 37.5°C. [4-6, 7] However, the newborn is particularly susceptible to heat loss through evaporation, thermal radiation, convection and conduction. The World Health Organization categorizes hypothermia into mild (body temperature 36.0-36.5°C), moderate (32.0-35.9°C) and severe (<32.0°C). Hypothermia is a very common problem in DRs in both high and low resource setting [8, 9]. Particularly in preterm babies, hypothermia is associated with increased morbidities such as respiratory distress syndrome and increased susceptibility to late onset sepsis; a 28% increase in mortality has been estimated for every 1°C below 36.5°C. [8] Whilst singular interventions may be effective to improve temperature maintenance, they have not been shown to improve mortality

prospectively, but quality improvement programmes utilising a number of different approaches have demonstrated a reduction in morbidity. [10, 11] Hence, the approach most likely to result in successful temperature maintenance will be a combination of interventions, tailored depending upon the local situation and the clinical setting. Below we describe several interventions to successfully maintain the body temperature of the newborn.

Environmental Temperature

The suggested optimal DR temperature is >25°C. [4-7] Cool and dry air conditioning for the comfort of staff should be avoided in the interest of the baby.

Radiant warmers

A baby, gently towelled down with a dry towel and placed under a radiant warmer, has a 5-fold decrease in heat loss in comparison to one left wet at ambient temperature. [12]

Covering the infant: Hats, towels and wraps

Woolen, gamgee lined and polyethylene hats have all been shown to improve admission temperatures. [7] Occlusive polyethylene wraps (PEW) in conjunction with a radiant warmer are effective at increasing admission temperatures and should be available for infants less than 28-32 weeks GA. PEWs have been successfully used in infants from 30 weeks to 36 weeks GA

in lower resource settings to improve postnatal temperature. [13, 14] When using PEWs an external heat source, for instance an over-head heater, is still necessary to maintain body

temperature. However, as birth weight and gestational age increases so does the risk of hyperthermia. [15]

Exothermic mattresses

Exothermic mattresses can be used together with radiant warmers. A disc activated gel thermal mattress reaches its maximum of 40°C and lasts up to 2 hours. Use of a thermal mattress is effective and significantly associated with reductions in heat loss and admission hypothermia in VLBWI. [16]. However, a larger RCT, comparing the combined use of an exothermic mattress with a PEW (bag) or the use of a PEW alone was stopped early when the data monitoring committee identified significantly fewer infants in the 'bag+mattress' had temperatures within the target range (p=0.002) and more had temperatures >37.5°C (46% vs 17%, p=0.009). [17] Therefore, exothermic mattresses cannot be generally recommended for all infants born <32 weeks gestation, but may be used as part of an individualised, local strategy to maintain normothermia in certain babies and situations. [4, 6]

Heated Humidified gases

Standard piped DR gases are dry and delivered at or below room temperature, however, they can be warmed and humidified by use of a conventional medical humidifier. [18] An observational study of infants < 33 weeks GA suggested benefit in addition to PEW and radiant heat in improving admission temperatures. [19] A RCT of infants < 32 weeks GA found that heated humidified air did not make a difference in admission temperature for the overall cohort but did significantly reduce hypothermia in infants of less than 28 weeks' GA (31% vs 59%, p=0.03). [20]

Thermo control during transfer to NICU

Measures to prevent hypothermia when transferring infants to the neonatal unit are very dependent on the available resources. Comparisons of infants born at <28 weeks' GA and wrapped in a PEW after birth who were transported either on a resuscitaire with a radiant warmer or in a heated transport incubator showed no difference in admission temperatures. [21] Checking the infant's temperature before leaving the DR, wrapping the baby in warmed towels and in heat reflective foil may further assist thermostability.

Objective assessment of the newborn infant: Measuring heart rate and oxygen saturation status in the delivery room

Heart rate

Algorithms for neonatal resuscitation [4-6] use HR as a major action point for interventions, such as, providing positive pressure ventilation (PPV) and/or cardiac compressions. The natural progression of HR in uncomplicated, healthy newborn infants after birth has been characterized by Dawson et al. [22] During newborn resuscitation, the increase in HR is considered a good marker of effective resuscitation, particularly when it exceeds 100 beats per minute (bpm). [4-6] Continuous assessment of HR in the DR can be done through auscultation, palpation of the umbilical cord, electrocardiography (ECG) and pulse oximetry (PO). Auscultation and palpation have been shown to be imprecise and systematically underestimate the true HR by 20 bpm, [23] therefore, PO has become the mainstay for

measuring HR after the first 1-2 minutes of life. Very recently, conflicting evidence emerged regarding the value of ECG for HR assessment and accuracy in the DR. Katheria et al. reported that an ECG displays the HR sooner than PO. In this study the median HR display time was two seconds (s) for ECG compared with 24s for PO. [24] Van Vonderen and co-workers also compared the performance of PO and ECG for assessing HR in the DR. [25] In the latter study, HR measured by PO was significantly lower compared with ECG (94 (67-144) vs 150 (91-153) bpm at 60 seconds of life ($p < 0.05$), respectively). Wider experience from clinical trials of using ECG in the DR is pending. It is important to point out that whichever method is used to measure HR, it is important to assess the quality of the data before altering clinical management. When using ECG regular QRS complexes should be present and for PO, there should be a regular plethysmograph. Some oximeter models have additional features to improve signal quality.

Oxygen saturation

The foetus thrives in its naturally hypoxic environment. During foetal-to-neonatal transition, prolonged hypoxia as much as hyperoxia should be avoided to aide physiological cardio-pulmonary transition. [4-6, 26]. Provision of an air-oxygen mix by means of an oxygen blender is advised and tapering the FiO2 based on preductal SpO2 and HR measurements to keep infants within gestational age specific oxygenation and HR targets is recommended. [4-6] As clinical assessment for signs of peripheral and central cyanosis have been shown to be inaccurate, PO measures oxygen saturation, without the need for calibration and correlates closely with arterial oxygen saturation when SpO2 is > 70%. [24, 25] Preductal PO measurements from the right hand or wrist are preferred as they give an approximation of cerebral oxygen saturation. However, it will easily take more than one minute to obtain a

reliable signal and low oxygenation status, a weak pulse wave, interference with ambient light as well as motion artefacts can significantly delay a reliably, stable reading. Some hints for obtaining rapid and reliable PO readings are as follows: To quickly obtain a PO signal, first turn on the monitor, then secure the sensor to the infant wrist and lastly connect the sensor cable to the monitor. The PO should be set to maximum sensitivity and if possible to a short averaging time. Use of a foam wrap prevents misalignment of optical components in the sensor and protects the sensor against interfering ambient light. [27, 28] Outlook: Whilst the above-mentioned target ranges have been derived from populations of well infants from an era of immediate cord clamping, observational data from Smit et al. suggests that for infants transitioning on the umbilical cord altered reference ranges for SpO2 and HR progression might need to be applied. [29]

Providing Initial Respiratory Support

Masks and other device-patient interfaces

Sufficient respiratory support can be delivered by a hand held face mask (FM) applied to an infant's face connected to a T-piece device or self-inflating bag (SIB). Several studies have shown how FM ventilation is frequently complicated by airway obstruction and that mask leak is common, variable and often not detected by the resuscitator. [30, 31] Thus, effective respiratory support of newborns by FMs can be challenging. Infants have relatively large heads that can be difficult to correctly position. Their tongue is large and can easily obstruct the airway and pharyngeal tone can be reduced. Facial dimensions are irregular and furrowed therefore it can be difficult to create a seal with a mask. [31] Both round and anatomically

shaped FM are available and although there is no evidence of one being superior over the other, surveys have shown that round masks are most frequently used. To optimise mask ventilation, it seems sensible to ensure that the FM is appropriately sized even if here is yet no evidence that using different FM size improves the outcome of respiratory support at birth. It is also noteworthy that FM sizes are independently labelled by the manufacturers and are not reflective of an international standard. Recently, a large cohort study of preterm infants found that most commonly available FM were too large for preterm infants' faces. [33] A 35 mm FM fits infants <29 weeks' postmenstrual age. The 42 mm FM is appropriate for infants up to 33 weeks' postmenstrual age. However, most ranges of infant resuscitation FM start with an external diameter of 50mm. Further, different FM holds (two-point top hold, spider hold and two handed hold (Figure 1) have been evaluated in manikin studies which found both methods of FM hold techniques to be similarly effective. [32]

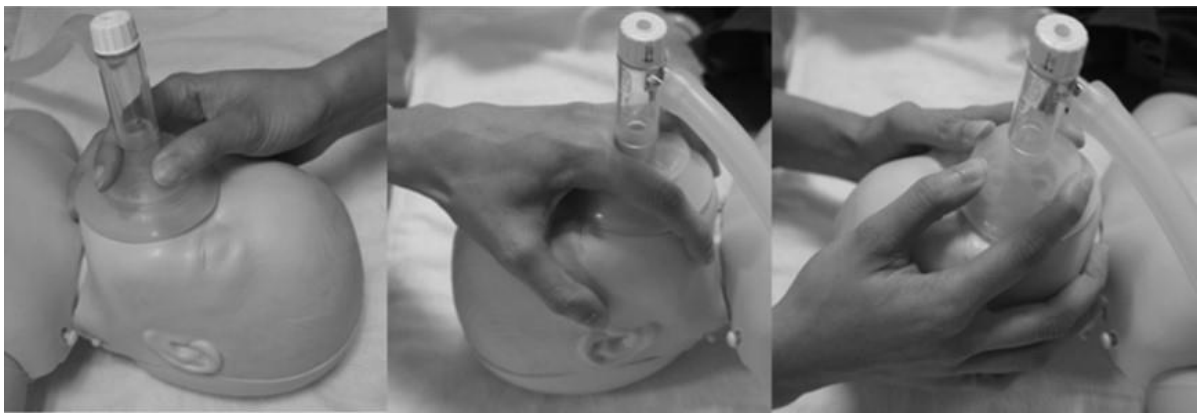

Figure 1 Different face mask holds: two-point top hold, spider hold and two handed hold (left to right).

In situations where the infant is not responding to FM ventilation, the most likely thing is the FM technique is unsatisfactory and so the baby is not being ventilated properly. It would be reasonable to reposition the infant and try a different hold before escalating the level of care.

Compared to FMs, nasal tubes were found inferior as interfaces for stabilization of very preterm infants. [33] However, a very recent pilot study found that a binasal CPAP driver modified to deliver IPPV was also suitable for delivering PIP and PEEP whilst having a low resistance breathing circuit. [34] This interface needs to be studied in a larger clinical trial.

Self-Inflating Bags, Flow-Inflating Bags and T-Piece Devices

Devices for providing respiratory support to infants, include SIBs, flow-inflating bags, and pressure limited resuscitation devices, commonly referred to as T piece resuscitators or devices (named after the shape of the connector between the device and the patient interface, i.e. the face mask or endotracheal tube), and, of course, mechanical ventilators. The common principle of these devices is the provision an oxygen-gas mix, preferentially with a tight control of the FiO2 via an air-oxygen blender, and peak-inspiratory pressure (PIP), positive end-expiratory pressure (PEEP) and tidal volume (Vt) provision at an operator denoted inflation rate. Worldwide, SIBs are the most commonly considered manual resuscitation devices, used in over 90% of NICUs. SIBs are intermittent flow devices operated by manual compression of a breathing bellow. Depending on the vigour of the operator's squeeze they will provide varying pressures and consequently varying Vts, in particular as there is a large variety of SIBs available, with varying volumes, ranging between 220ml and 500ml for neonatal patients. Therefore, supra physiological Vts are easily applied and iatrogenic lung injury can be inflicted.

Studies confirmed that intra-operator and inter-operator provision of PIP and Vt varies widely when using SIBs and were in poor relation to the operator's clinical expertise or level of training. [35] SIBs are now increasingly equipped with pressure manometers, which have been shown to improve adherence to target pressures during resuscitation. [36] Advantages of

using a SIB include their relatively low expense, their compactness and that they can be operated without an external gas source (Figure 2).

	Pro	Contra
SIB	► delivers air independent of gas source ► small, easy and quick to change applied ventilation pressures ► relatively inexpensive ► easy to transport and store	► unsuitable to reliably and consistently provide ventilation pressures (PIP and PEEP) ► unsuitable for giving sustained inflations ► continuous training required to gauge delivered ventilation pressures ► difficult humidification of breathing gases
T-piece device	► delivers constant ventilation pressures (PIP and PEEP) ► suitable for giving sustained inflations ► robust ► relatively easy to use in hands of inexperienced	► dependent on external gas source ► relatively cost intense
Ventilator	► delivers constant ventilation pressures (PIP and PEEP) and rates ► suitable for giving sustained inflations ► easy heating and humidification	► expensive ► requires electrical power and medical gas sources ► risk of prolonged ventilation and of ventilator-induced lung injury
Face mask	► adequately fitted masks improve ventilation	► mask size often inadequate
Nasal prongs	► good CPAP transfer with binasal prongs	► challenging to affix ► risk of obstruction, dislodgement, nasal trauma
Guedel	► potentially helpful to remain patent airway	► challenging to affix, dislodges frequently
LMA	► good PIP and Vt delivery ► ease of use and insertion	► only available for baby >1200 g body weight

LMA, laryngeal mask airway; PEEP, positive end-expiratory pressure; PIP, peak inspiratory pressure; SIB, self-inflating bag; Vt, tidal volume.

Figure 2 Advantages and disadvantages of devices used for respiratory support in the delivery room.

Among the disadvantages of using SIBs are the variability in PIP provision, flow and tidal volume provision and inability to provide constant inspiratory pressures when providing prolonged inspiratory breaths. Also, when used in conjunction with PEEP-Valves, the provided PEEP is often very variable, which depends largely on the age and the quality of the PEEP-Valve. [37] As shown by Hartung et al. the process of thermo-sterilization, which includes autoclavation at 134°C and 3170 mbar, together with the repeated disassembly process, damages multi-use PEEP Valves and reduces their reliability significantly. [37] Comparative studies have shown that compared to T-piece resuscitators, flow-inflating bags, similarly to SIBs, are less reliable regarding the provision of PIP, PEEP and tidal volumes. [38] Flow inflating bags, whilst commonly used in the United States of America, appear to be infrequently used outside the USA, according to several investigators. Conversely, T-piece devices have be become the accepted standard in most high-resource area DRs, either as portable, stand-alone devices or integrated in modern resuscitation platforms. Their advantages, presumed due to the continuous patient directed gas flow, include steady delivery

of a set PIP as well as steady PEEP provision, so they can therefore deliver IPPV and CPAP. The breathing gases, delivered through the T-piece at a pre-set flow rate can be heated and humidified by adding a compatible humidifier into the circuit. [19] The T-piece resuscitators' dependence on external gas sources may be seen as one of its disadvantages.

Airway Adjuncts – Laryngeal mask airways

Different airway adjuncts are available to support non-invasive respiratory support and provide an alternative to endotracheal intubation. Laryngeal masks airways (LMAs) have shown promise both as a resuscitation tool and a device to deliver surfactant without need for intubation. Use of LMA appears to be easy but, unfortunately, currently not available to fit infants smaller than 1250g, thereby limiting their use in neonatology to the more mature infants. A recent, randomised clinical trial conducted in Uganda compared LMA and FM use in infants with a birth weight >2000 g who required PPV at birth. The main outcome was time to spontaneous breathing. The study found that time to spontaneous breathing was shorter in LMA arm than in FM arm, and, whilst all resuscitations were effective in the LMA arm, a significant number of patients receiving FM were converted to LMA due to poor response to FM ventilation. [40] In a recent manikin study, comparing different makes of LMAs and found the i-gel LMA to have the lowest leak even with high PIPs. [41]

Intubation and Videolaryngoscopy

At times, endotracheal intubation in the DR is unavoidable; therefore, it is a skill that needs to be quickly and consistently available anywhere neonatal care is provided. This is a challenging standard to provide as intubation is a difficult skill to acquire and maintain and initial attempts are often unsuccessful. Success rates of neonatal trainees are falling as a result

of an overall reduction in intubating opportunities. Further, junior intubators have been found to have superior success at elective premedicated intubations compared to DR intubations where the infant is not generally premedicated. Recently, videolaryngoscopy has demonstrated benefit as an intubation training tool. [42] Success rates of junior neonatal trainees were significantly improved when their instructor was able to share their view on a videolaryngoscope screen compared to a control where the supervisor guided without a shared view (traditional method) (66% compared to 41%, $p<0.001$). The effect was greatest for intubations where the infant was given premedication (72% compared to 44%, $p<0.001$). Qualitative feedback from trainees found videolaryngoscopy to be useful. They appreciated calm, clear, consistent guidance and a controlled, supportive environment. They found intubations in the delivery room, audiences and parental presence more stressful. [42] To date, there are only few neonatal videolaryngoscopes available where the videolaryngoscope blade closely resembles the traditional Miller neonatal blades but further models are in development. Videolaryngoscopes are available that have blades of different shapes and that cannot be used as conventional laryngoscopes. These can be successfully used to intubate neonates but learning to use them is a different skill that also takes time and needs practice. Opportunities to practice intubation are in very short supply for novice intubators therefore necessitating learning a different skill to use equipment that is not universally available may hinder rather than help learning how to intubate.

Assessing successful intubation

Successful endotracheal intubation is most commonly assessed at the cot side via qualitative exhaled CO2 measurement, using an in-line colorimetric sensor. [4-6, 43] Exhaled CO2 may also be used during FM ventilation to demonstrate adequate ventilation. [44] Minimal cardiac

output and adequate dead space clearance are necessary to obtain a positive signal from the CO2 sensor and contamination with moisture should be carefully avoided.

Administration of drugs and emergency i.v. access

Resuscitation drugs like epinephrine are required in less than 0.1% of deliveries but, if indicated, should be given via a central venous route as an effective tracheal dose has not been defined. [45] Therefore, equipment for emergency central access and an umbilical catheter must be available. Umbilical venous and arterial access will be possible in most babies but for those rare instances when it is not, or i.e. in the emergency department, an intraosseous needle should also be available [4-6] to administer drugs and fluid during resuscitation.

Current Developments

Delayed cord clamping (DCC) in preterm infants reduces the incidence of intraventricular haemorrhage and necrotising enterocolitis and need for blood transfusion. In term babies DCC is associated with decreased anaemia but increased jaundice. Until recently delivering DCC to infants has meant delaying initiation of neonatal care. Of late, modified resuscitaires and trolleys have been developed to enable respiratory and thermal support to be provided to infants while the cord is intact. These were used in a recently published RCT of 137 infants (median gestation 29 weeks), that compared cord clamping at greater or equal to 2 minutes combined with immediate respiratory and thermal care to clamping at less than or equal to 20 seconds and neonatal care after clamping. Mortality was 5% in the DCC group and 11% in

the controls; risk difference (RD) −5.9% (95% CI −12.4% to 0.6%). [46] Stabilisation close to the mother may be preferable to families also. Larger trials are planned.

New methods of monitoring infants during stabilisation and thereafter are being developed rapidly. Bhatia et al. used electrical impedance tomography to measure regional lung volume and guide changing CPAP pressure and showed that atelectasis could be reversed and lung volume optimised. [47] Respiratory function monitors (RFMs) are available that can measure in real time tidal volumes, flow and pressure waves and leak. A pilot study has shown they can be used to guide positive pressure ventilation and improve mask ventilation technique and larger RCTs are ongoing. [48] A digital stethoscope attached to a smart device was recently found to be equivocal to ECG and superior to pulsoximetry in length of time to detect heart rate. [49] Recently hand held doppler devices were shown to be similar to ECG to monitor heart rate. [50, 51] The use of colorimetric capnography beyond assessing successful endotracheal tube placement has been investigated by Blank et al. who found that in infants with bradycardia receiving mask PPV during neonatal resuscitation colour change in the pedi-cap device precedes a significant increase in HR during neonatal resuscitation. [52]

Urgently required evidence and further developments to optimize provision of medical support in the delivery room

Despite much improvement over the past decade, the list of desired improvements remains long. With advanced camera technology, microprocessors and their integration in mobile device technologies and apps, non-touch, miniature and hand-held devices are constantly

evolving to improve patient monitoring and management in the DR. Amongst other developments, devices for monitoring the newly born during physiologically DCC, monitoring cardio-pulmonary transition and the effect of assisted ventilation; assessment of HR and other vital parameters; use of ultrasound during foetal-to-neonatal transition or near infrared spectroscopy at delivery as well as for video-assisted DR care; means and devices to minimize heat loss in the DR and during transfer are under way. It is hoped that with the emerging evidence from such trials, further evidence-based recommendations on which technology to use for specific circumstances and patients can soon be confidently formulated.

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Chapter 8:

Discussion and Conclusion

Discussion

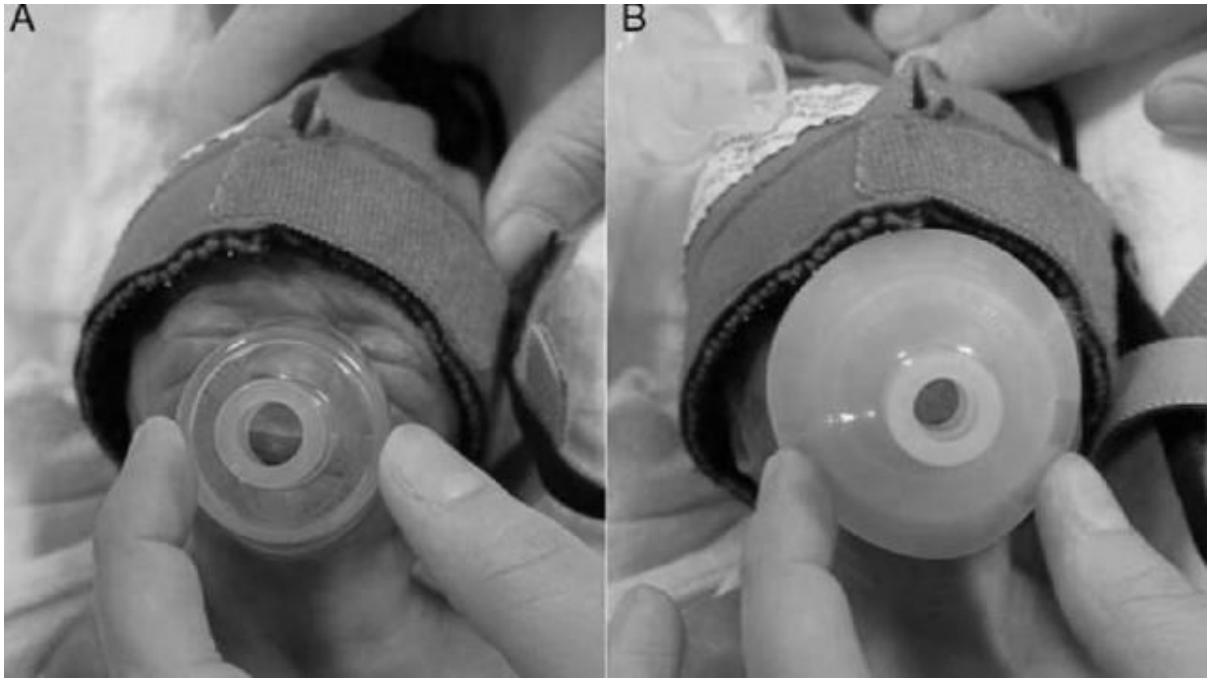
The aim of this body of work summarised in this thesis was to examine some facemasks and endotracheal tubes with view to (1) devising methods to improve mask intermittent positive pressure ventilation and (2) improve the success and safety commonly used neonatal airway adjuncts, specifically of neonatal intubation.

Facemasks

Mask intermittent positive pressure ventilation is first line intervention for an apnoeic infant. [1-3] It is well described that leak between the infant's face and the mask is common, variable in size, often not realised by the operator and can result in ineffective intermittent positive ventilation. [4-6] However, despite this being such a commonly performed procedure, there was little evidence examining how to optimise the technique. The works presented in this thesis start by focusing on mask holds to see if there is a superior option. Three holds were compared, the two-point top hold, the two-handed hold and the spider hold. The first two were chosen as they had found superior in previous manikin work. [5,7] The third, because it had not previously been studied and as the operator's fingers encircled the mask, the leak may be more palpable. The study found that median leak was similar in all three holds and very variable in magnitude. Perhaps the greatest strength of this study was to draw attention to mask leak and give resuscitators options if the infant is not responding to mask intermittent positive pressure ventilation. The limitations of this study mainly relate to the use of a manikin which while a good learning tool, cannot replace human studies.

I think it is unlikely that there is an optimal hold that minimises leak. The infant's face is three dimensional and is therefore difficult to make a seal with a flat mask edge. Different operators have different size hands and apply different amounts of pressure to the mask. Infants' faces come in different shapes and sizes and therefore masks should probably be available in a range of shapes and sizes as well.

Before this work was carried out there were very few very small face masks available for preterm infants. Mask positive pressure ventilation was commonly attempted in this population with masks that were clearly too big.



There was no published information on the sizes of infants' faces. The second study successfully fills this gap. A large cohort of preterm infants had serial measurements of their faces enabling recommendations to be made about suitable mask sizes for extremely preterm infants. Masks with external diameters of 35 mm are suitable for infants <29 weeks'

postmenstrual age or <1000g and masks with external diameter of 42mm is suitable for infants 29–33 weeks' postmenstrual age or 1000–2500g, respectively.

This study was not able to answer if a better fit would translate into less leak and more effective intermittent positive pressure ventilation. This question has subsequently been carried out by O Currain et al who compared leak when using smaller facemasks (35 mm or 42 mm) with the standard mask (50 mm) while delivering positive pressure ventilation to preterm infants. [8] Disappointingly no difference was found. The smaller masks as well as the control mask both had sizable leak and the leak increased with decreasing gestational age and size of the infant. Both facemasks performed poorly when providing positive pressure ventilation to preterm infants < 26 weeks' gestation. I still however think it is sensible to use a mask that fits, so still recommend smaller masks for smaller infants.

Despite the contribution of these studies, mask ventilation remains challenging and further research is needed to optimise the technique. Perhaps there needs to be a complete change in the design of masks or other airway adjuncts need to be considered. Other adjuncts studied include nasopharyngeal tubes, oropharyngeal airways, binasal prongs and laryngeal masks. Kamlin et al found that compared with facemasks, nasopharyngeal tubes were inferior as interfaces for stabilisation of very preterm infants. [9] Kamlin et al have also found oropharyngeal airways compared to masks to increase airway obstruction in preterm infants. [10] Perhaps providing intermittent positive pressure via nasal prongs would be more effective than via face mask. Pilot work is encouraging [11] and a larger randomised trial is ongoing. [12] The most promising adjunct emerging is the laryngeal mask airway, showing promise both as resuscitation tool [13] and device to deliver surfactant without need for intubation. [14] The limited currently available evidence suggests that the use of laryngeal

mask airways is a feasible and safe alternative to mask ventilation in late preterm and term infants. The products currently available unfortunately do not fit infants smaller than 1250g, thereby limiting their use in neonatology to the more mature infants. However, case reports of successful resuscitation of premature infants with birth weights as low as 800 g have been reported. [15]

Intubation

The remaining studies of the series examined neonatal intubation and perhaps were more successful in achieving their aim. The systematic review of using a stylet to improve intubation success found that a stylet did not improve success rates. The content of the review was limited to one randomised trial therefore repeated larger studies may find differently. Despite the limitations of the review, I feel that routine use of stylets should not be recommended as their use is not evidence based but also because they add additional variables. While carrying out the intubation research, I have seen stylets that were inserted too far, and not far enough, stylets moulding endotracheal tubes to be much curved or entirely straight, or so that the pointed tube tip is not the leading point. I think all these variables make intubation more difficult to learn and could make the endotracheal tube more difficult to direct. I have also seen several unplanned extubations because the stylet could not be removed. I therefore do not recommend stylets. I do recommend that the endotracheal tubes are kept away from the heat of the resuscitaire so that the heat does not make them softer and more difficult to direct.

The randomised controlled trial examining the use of a videolaryngoscope to teach intubation was the most substantial study of the series and is the most important work. It found that videolaryngoscopy was a useful tool that can lead to improved intubation success rates. I believe it is the most useful tool currently available to facilitate learning intubation. The study looking at reasons for unsuccessful intubations found that trainees frequently cannot recognise the airway or the structures that can lead them to the airway. Using a videolaryngoscope to share the view between novice and supervisor can solve this and is most likely why it is helpful. Neonatal intubation success rates are falling as opportunities to intubate and therefore practice the skill are steadily decreasing for trainees. [16-22] In the trial therefore, the videolaryngoscope was used as a traditional laryngoscope so that the skill learned could translate to being able to use a traditional laryngoscope. A quality improvement project started in May 2018 and currently ongoing at the Royal Hospital for Children, Glasgow is finding that since the introduction of a videolaryngoscope for junior intubations, success rates have more than doubled from baseline (currently unpublished data).

There are limitations in using a videolaryngoscope as a teaching tool including their expense, their size, needing to be set up and lack of disposable blades. The scopes are expensive; therefore, it is a sizable investment to stock a videolaryngoscope in each resuscitaire and emergency trolley as would be optimal practice if they are to replace traditional laryngoscopes. At the Royal Hospital for Children, Glasgow there is one videolaryngoscope that is moved as needed but that takes time and intubation is often an emergency procedure with little warning. Most videolaryngoscopes with their monitors are reasonably large and take up room that can be limited. They also need set up which again takes time. Most scopes do not come with disposable blades necessitating the need for sterilisation.

In my opinion however, the most challenging limitation to videolaryngoscopes emerging as the intubation tool of choice is that the currently available videolaryngoscope blades having subtle differences to the traditional blades. This has recently been examined by Kirolos et al who found that the most marked difference is that conventional blades have a ledge that lifts the infant's upper lip and widens the direct view. [23] No currently available neonatal videolaryngoscope blade has this ledge and their direct view is narrower as a result. This can be overcome if the supervisor lifts the infant's lip. [23] The blade differences although subtle result in experienced intubators initially finding the videolaryngoscope more challenging to intubate with and could potentially limit the translation of the skill for novice intubators. As with any new piece of equipment, there is a learning curve that needs to be ascended by intubation supervisors who want to embrace this technology. Hopefully videolaryngoscopes of the future will have blades more like the traditional blades.

An additional benefit to using videolaryngoscopy for intubation is the ability to record the images and use them to provide feedback. The penultimate paper of the series is an examination of a series of recordings from the randomised controlled trial to explain the reasons for unsuccessful intubation. This paper confirms that unsuccessful intubation is frequently due to the trainee not recognising the anatomy of the airway. It also finds that secretions are not a frequent obstacle to elective intubation and routine suctioning should be discouraged. The value of the videolaryngoscope is also highlighted as the profile of reasons was different when the supervisor could see the images in real time. In this group, a higher percentage achieved and maintained an intubatable view. The most common reason in the intervention group was difficulty directing the endotracheal tube around the videolaryngoscope blade, a reason that may become less frequent if the differences between videolaryngoscope blades and traditional blades were reduced.

The intubation papers from this work have made a valuable contribution to the neonatal intubation literature and videolaryngoscopy is gaining momentum within the neonatal community. [24] However, intubation remains a difficult skill for trainees to master and I suspect their exposure to it will continue to decline in the future as less-invasive methods to administer surfactant improve and primary non-invasive ventilation becomes the universal initial approach for preterm infants. The anaesthetic literature suggests that at least 40 intubations are necessary before a trainee is competent. [25,26] Most current trainees will not log that many until late in their training or even into consultancy. In the United Kingdom tracheal intubation of a term infant is a mandatory competence of basic level paediatric training. [27] I believe that is no longer achievable for trainees at that level and an unrealistic expectation.

There is emerging evidence that laryngeal mask airways are a suitable alternative to intubation during resuscitation [13] or for the administration of surfactant. [14] The evidence relating to its efficacy and safety are relatively limited but show huge promise. The skill needed to learn how to insert a laryngeal mask airway is minimal and can be learned very quickly. [28] Their use is currently limited to late preterm or term infants due to size restrictions, but future products will hopefully be created to fit even the most preterm infant. I think with time; laryngeal mask airways will replace emergency and short-term intubation negating the need for universal competence in intubation for paediatric trainees.

The final paper of the series is a review article describing devices used during infant stabilisation after delivery. It discusses how the airway adjuncts described throughout this

thesis form but a part of the total package necessary to successfully support neonates during their transition from foetus to infant.

Conclusion

Mask ventilation in neonates is difficult. An appropriately sized mask should be used. If the infant is not responding the mask should be repositioned and an alternative hold considered. Other airway adjuncts including laryngeal mask airways are an alternative if an infant is not responding to mask ventilation despite optimising hold and position, needs prolonged positive pressure ventilation, or intubation is unavailable or unsuccessful.

Intubation is a difficult skill to learn and maintain. Novice intubators frequently do not recognise the anatomy of the airway. Their intubation success rates are superior if they intubate using a videolaryngoscope with their supervisor guiding watching the screen.

Past, Present and Future

Despite the many changes in perinatal medicine in the last fifty years, infants still often and unpredictably need assistance with their breathing. Positive pressure delivered through a facemask remains the almost universal initial approach. Despite many years of research into mask ventilation it is still very challenging. Despite different sizes and shapes of mask, despite improvements in technology enabling much more detailed monitoring of the infant and the support they receive, facemask leak and airway obstruction remain a problem. Perhaps it is time to lessen our reliance on facemasks and embrace other airway devices that are showing promise, particularly the laryngeal mask. Further research on their efficacy as a

resuscitation tool and an adjunct through which to deliver surfactant is necessary as is the urgent development and testing of smaller laryngeal masks.

Universal intubation competency is no longer feasible but universal competency on the use of laryngeal masks probably is. This urgently needs to be addressed in paediatric training programs. By still trying to train every paediatric trainee and advanced neonatal nurse practitioner how to intubate, we are taking away intubation opportunities from the neonatologists of the future and potentially compromising their proficiency at the skill. In centres staffed by personnel that cannot maintain intubation competency, the expectation of being able to intubation needs to be lifted and alternative planning put in place. Videolaryngoscopy is a promising tool that improves junior intubators success rates. To master intubation many intubations are still necessary but the videolaryngoscope allows the slope of the learning curve to steepen. Development is necessary to design scopes of the future that are inexpensive, easily portable and user friendly.

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A comparison of different mask holds for positive pressure ventilation in a neonatal manikin

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Received 3 June 2013
Revised 13 September 2013
Accepted 23 September 2013
Published Online First 16 October 2013

To cite: Wilson EV, O'Shea JE, Thio M, *et al*. *Arch Dis Child Fetal Neonatal Ed* 2014;**99**: F169–F171.

ABSTRACT

Background Ventilation during neonatal resuscitation is typically initiated with a face mask, but may be ineffective due to leak or obstruction.

Objective To compare leak using three methods of mask hold.

Methods Medical and nursing staff regularly involved in neonatal resuscitation used the three holds (two-point, two-handed, spider) on a manikin in a random order to apply positive pressure ventilation (PPV) at standard settings each for 1 min while mask leak was recorded.

Results Participants (n=53) varied in experience (1–23 years) and hand size. Combined median (IQR) leak was 14 (2–46)% and was not different among the holds.

Conclusions There was no difference in the leak measured using the three different mask holds.

What is already known

Face mask leak during mask positive pressure ventilation (PPV) is common and often goes unrecognised by resuscitators

What this study adds

This study describes a new method for holding a face mask—'the spider hold'. Leak measured using this hold was similar to two other commonly used holds.

BACKGROUND

International resuscitation guidelines recommend positive pressure ventilation (PPV) for newly born infants with bradycardia or inadequate respiratory effort.[1] This is usually initially performed using a facemask as the interface, but mask ventilation is not without difficulties and studies have found large and variable leak, airway obstruction and inconsistent tidal volumes, in delivery room and manikin studies.[2 3]

There are a small number of manikin studies which have examined different methods of applying and positioning the mask to deliver PPV. Wood examined different single-handed holds in a manikin study and found the two-point top hold (figure 1A) to be associated with the lowest leak.[3] In another manikin study, Tracy reported a 50% reduction in leak when using a two-handed hold for two-person resuscitation (figure 1B) compared to a single-handed hold.[4]

A new method for holding the mask during PPV is the 'spider hold' (figure 1C). This method involves placing the stem of the mask between the index and middle fingers, while applying pressure with the palm of the hand to hold the mask onto the infant's face. The clinician's finger tips curl around the infant's jaw to provide chin-lift. This method has not previously been formally examined.

AIM

The aim of this study was to compare three mask holds—two-point top hold, two-handed hold and spider hold—with a primary outcome of leak between the mask and the manikin's face. Secondary analyses were conducted on the basis of participants' professional group, years of experience, glove size and hold preferences.

METHODS

This study was undertaken at The Royal Women's Hospital, a tertiary perinatal centre in Melbourne, Australia. Nursing and medical staff regularly involved in neonatal resuscitation were invited to participate.

The Neopuff Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand) was used with a size 0/1 Laerdal round mask (Laerdal, Stavanger, Norway). The manikin used was a Laerdal Resusci Baby, modified to ensure a leak free system.[3 5] The modification involved removal of the manikin's stomach and lung bags and replacing them with a Laerdal test lung attached via non-distensible tubing to the manikin's mouth with an airtight seal. A Florian Respiratory Function monitor (Acutronic Medical Systems, Zug, Switzerland) was used to measure inflating pressures, tidal volumes and expiratory leak via a flow sensor between the mask and the Neopuff. The flow sensor of the Florian was calibrated when switched on and between study participants. Leak was calculated by the Florian from the volume of gas that did not return back through the flow sensor on expiration, expressed as a percentage of the inspired volume. Data were recorded on a laptop computer using Spectra software (Grove Medical, London, UK).

Holds were first demonstrated by a study investigator and participants given several minutes to practice until they felt competent at each hold. They were then asked to deliver PPV to the

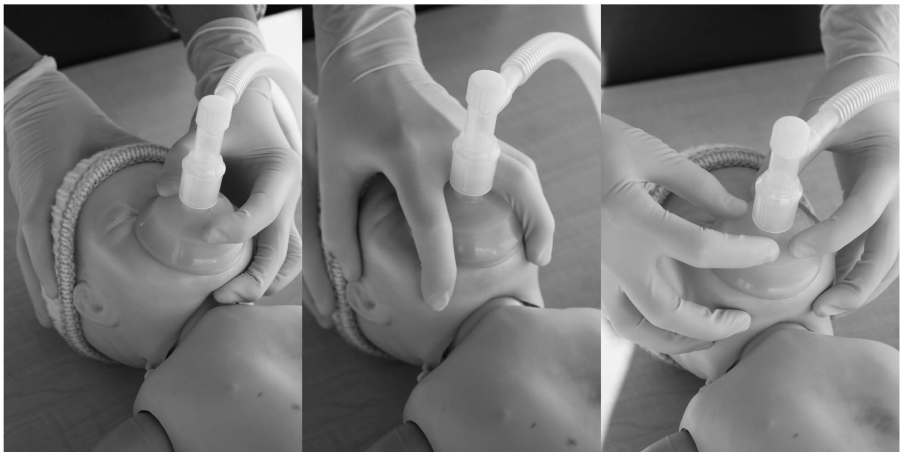

Figure 1 (A) Two-point top hold, (B) Spider hold, (C) Two-handed hold.

manikin using the three holds for 1 min each in a random order, using settings of peak inflating pressure 30 cm H_2O, peak expiratory pressure 5 cm H_2O and a rate of 40–60/min. Hold order was determined using internet-based random number generator.

The sample size was calculated using the mean leak of 70%, as measured by O'Donnell using the same manikin.[5] To detect a 15% difference in mean leak with an α value of 0.05 and power of 80%, at least 50 participants were required. We included 10 participants from each of five professional groups—neonatal consultants, neonatal fellows, neonatal registrars, midwives and neonatal nurses. Participants' hand size measured by glove size, years of experience and usual hold were also recorded. Neither the Spectra screen nor the Florian monitor was visible to participants while ventilating the manikin.

The primary outcome measure was the median leak between the mask and the manikin's face. Median leak for each participant and for each hold was calculated and compared. Median and IQRs for the primary outcome measure are displayed as box plots and tables. Results were compared using analysis of variance (ANOVA), p values were calculated using post hoc Bonferonni correction and <0.05 was considered significant. Secondary outcome was participants' hold preference. Data were analysed using Stata software (Intercooled 10, Stata Corp, Texas, USA).

RESULTS

Fifty-three participants enrolled in the study: 10 consultants, 10 fellows, 10 registrars, 12 midwives and 11 neonatal nurses. Hand sizes ranged from a glove size of 5.5 to 8 with a median of 7. Participants' years of experience resuscitating infants ranged from less than 1 to 23 years. All consultants had greater than 5 years of experience. All fellows had between 3 and 5 years of experience. All registrars had less than 2 years of experience, Neonatal nurses and midwives had similar levels of experience ranging from less than 1 year to more than 10 years, with a median of 4 years.

7324 inflations were studied. Median (IQR) leak for all holds was 14 (2–46)%, for the two-point top hold was 19 (2–38)%, for the spider hold 10 (3–49)% and for the two-handed hold 9 (2–51)% (figure 2). There was no significant difference in leak noted between the different holds.

There were no significant differences found between the holds when examined by participant's professional group, level

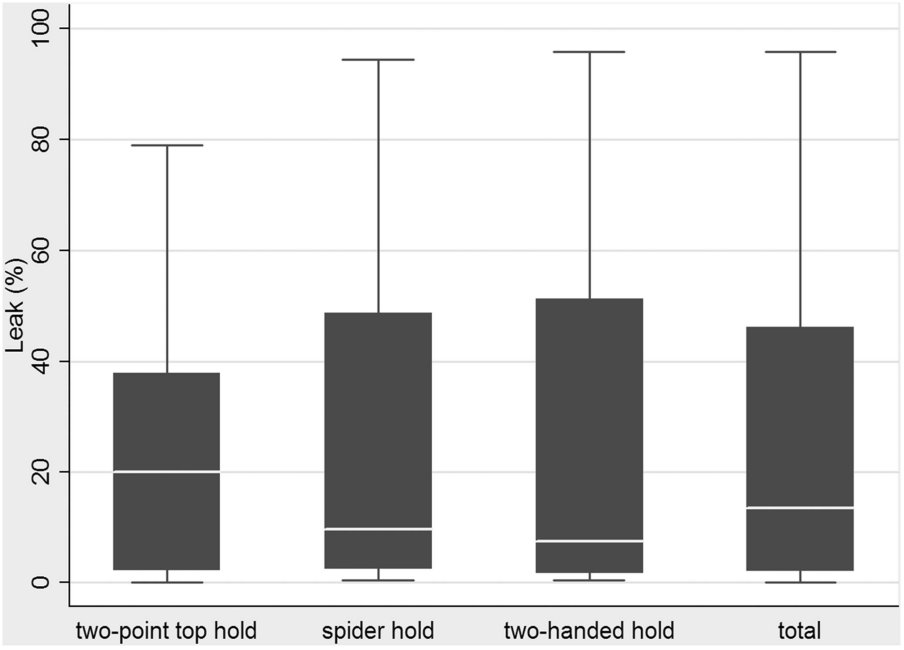

Figure 2 Box plot showing the leak for all participants using each hold type, and overall. The horizontal line is the median, the box represents the 25th and 75th centiles, and the ends of the whiskers are the 5th and 95th centiles.

of experience or glove size. All but two participants identified the two-point top hold as their usual hold. Twenty-seven (51%) preferred the two-point top hold, while 19 (36%) and seven (13%) chose the spider hold and the two-handed hold, respectively.

DISCUSSION

Although there was no difference in median leak among the different holds, there was substantial variability within each of the groups suggesting that the participants were unaware of the leak. This finding is supported by previous studies that have shown leak is common and often goes unrecognised[2 5] and that resuscitators are also unable to accurately estimate the magnitude of their leak.[5] Our study participants demonstrated lower levels of leak than measured in previous, similarly conducted manikin studies. This may have been due to participants having time to practise using each hold. O'Donnell reported a mean (SD) leak of 70 (30)%[5] and Wood reported a mean (SD) leak of 55 (31)%[3] using the same Laerdal round mask. The more recent study by Tracy reported lower levels of leak[4] that were more comparable to our study.

This is the first study that describes the spider hold. It was found to be easy to learn and more than a third ranked it as their favourite hold. Because the resuscitators' fingers extend beyond the edge of the mask, leak may be palpable and therefore more obvious to the resuscitator. A possible disadvantage of the spider hold is that the infant's face is largely covered by the resuscitator's hand. The user's ability to assess responsiveness in the infant with visual cues from the face may be hampered, although facial movements should be felt. As the edges of the mask are not completely visible, the face mask causing compression to the infant's eyes may go unnoticed. Compression of the nose may also not be appreciated and may result in inadvertent airway obstruction.

It may be argued that when teaching neonatal resuscitation, it is best to teach one hold so that clinicians can practise and perfect this hold. The two-point top hold is taught and practised at our unit. One might expect that the two-point top hold would therefore be the method with the lowest leak. In this study, we found that the leak was similar using three different holds: a familiar hold to all (two-point top hold), a familiar hold to some (two-handed hold) and a new hold (spider hold). It may therefore be possible for novice resuscitators to try all three holds and allow them to choose the one they find preferable to use in clinical practice. It is also reasonable to teach more than one hold and advise the trainee to change holds if they feel the baby is ventilating ineffectively.

The limitations of this study are shared by similar studies on manikins. Participants are being asked to resuscitate in an artificial environment. They know they are being assessed on the adequacy of their ventilation. A manikin, while an effective learning tool, can never provide the same cues in relation to clinical deterioration and improvement as a neonate.

CONCLUSION

There was no difference in the leak measured using the three different mask holds.

Contributors EVW recruited participants, collected data and wrote the first draft of the manuscript. JEO wrote the protocol, recruited participants, collected and analysed the data and wrote the subsequent drafts of the manuscript. MT was involved in study design and has reviewed the manuscript. JAD was involved in initial study design, analysed data, supervised the project and has reviewed the manuscript. PGD was the overall supervisor of the project and has reviewed the manuscript.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

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A comparison of different mask holds for positive pressure ventilation in a neonatal manikin

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Arch Dis Child Fetal Neonatal Ed 2014 99: F169-F171 originally published online October 16, 2013
doi: 10.1136/archdischild-2013-304582

ADC-FNN Online First, published on April 10, 2015 as 10.1136/archdischild-2014-307350

Measurements from preterm infants to guide face mask size

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Received 12 August 2014
Revised 18 February 2015
Accepted 24 February 2015

ABSTRACT

Objective International guidelines recommend that an appropriately sized face mask for providing positive pressure ventilation should cover the mouth and nose but not the eyes and should not overlap the chin. This study aimed to measure the dimensions of preterm infants' faces and compare these with the size of the most commonly available face masks (external diameter 50 mm) and the smallest masks available (external diameters 35 and 42 mm).

Methods Infants 24–33 weeks' postmenstrual age (PMA) were photographed in a standardised manner. Images were analysed using ImageJ software (National Institute of Health, USA) to calculate the distance from the nasofrontal groove to the mental protuberance. This facial measurement corresponds to the external diameter of an optimally fitting mask.

Results A cohort of 107 infants between 24 and 33 weeks' gestational age, including at least 10 infants per week of gestation, was photographed within 72 h after birth and weekly until 33 weeks' PMA. 347 photographs were analysed. Infants of 24, 26, 28, 30 and 32 weeks' PMA had mean (SD) facial measurements of 32 (2), 36 (3), 38 (4), 41 (2) and 43 (4) mm, respectively. There were no significant differences when examined by gender or when small for gestational age infants were excluded.

Conclusions The smallest size of some brands of mask is too large for many preterm infants. Masks of 35 mm diameter are suitable for infants <29 weeks' PMA or 1000 g. Masks of 42 mm diameter are suitable for infants 27–33 weeks' PMA or 750–2500 g.

What is already known on this topic

- Preterm infants frequently receive respiratory support via a face mask.
- Face mask positive pressure ventilation is frequently complicated by obstruction or leak around the mask.
- International guidelines recommend criteria to determine the optimal size of a face mask.

What this study adds

- Facial measurements of preterm infants support recommendations on suitable mask size.
- Postnatal face growth correlates with intrauterine face growth.
- Many commonly available face masks are too large for preterm infants' faces.

INTRODUCTION

Respiratory support including intermittent positive pressure ventilation (IPPV) or continuous positive airway pressure (CPAP) is commonly delivered via a mask applied to an infant's face connected to a T piece or resuscitation bag. Delivering effective mask IPPV or CPAP is challenging. Delivery room studies have found that mask IPPV is frequently complicated by intermittent airway obstruction[1] or leak between the mask and the infant's face.[2–5] Leak is common, variable and often not detected by the resuscitator.[2–5]

International recommendations from the UK, USA and Australia regarding mask size and shape emphasise the importance of a well-fitting face mask.[6–8] These recommendations emphasise the need to cover the nose and mouth and to avoid covering the eyes, overlapping the chin or occluding the nose. O'Donnell *et al*[9] surveyed 46 neonatal intensive care units in 23 countries and found that round face masks were used in 85% and anatomically shaped masks used in 15%. Surveys have not however established which type or size of round masks are most commonly used,[10–12] and there are no recommendations regarding mask size for specific weight or gestation infants. There are many brands of round neonatal masks available in a range of sizes. Most brands start with smallest external diameter around 50 mm. To our knowledge, there is only one brand of smaller mask available—Infant Resuscitation Masks (Fisher & Paykel Healthcare, Auckland, New Zealand), sizes small and extra small, with external diameters of 42 and 35 mm, respectively.

There are no data available regarding the size of preterm infants' faces or how their facial dimensions change in the weeks following preterm birth. The aims of this study were to (1) measure the dimensions of preterm infants' faces across a range of gestational ages at birth and over the first weeks of life, (2) compare these results with the dimensions of commonly available round masks and (3) make recommendations regarding appropriate mask size for preterm infants.

METHODS

Preterm infants <34 weeks' gestational age admitted to neonatal intensive and special care were eligible for inclusion. As this is the first study of its kind, there were no data on which to base a sample

To cite: O'Shea JE, Thio M, Owen LS, *et al*. *Arch Dis Child Fetal Neonatal Ed* Published Online First: [*please include* Day Month Year] doi:10.1136/archdischild-2014-307350

size calculation. Therefore, a study population with a minimum of 10 infants per each completed week of gestation from 24 to 33 weeks was chosen. Infants considered to have any dysmorphic features or congenital facial anomalies by the attending clinical team were excluded. Demographic details were collected including gender, gestation, corrected gestation, birth weight, weight on the day of each measurement and whether or not birth weight was <3rd centile.

Each infant was photographed while supine with their head in the neutral position and their jaw neutral, that is, the position in which they would be placed to receive mask IPPV. A plastic scale was placed next to and level with the infant's face and included in the photograph. Infants receiving CPAP via nasal prongs or those who had endotracheal, nasogastric or orogastric tubes in situ were included as long as their nose and chin were not distorted and could be clearly seen. The infants receiving CPAP via nasal prongs had their photographs taken when the prongs were removed for cares whenever possible. Images were taken using a Sony NEX-3 digital SLR camera with a SEL1855 lens using a focal length of 35 mm from a distance of 10 cm directly above the centre of the infant's face. Each image was then analysed using ImageJ software (National Institute of Health, USA) (figure 1), a public domain, java-based image processing program developed at the National Institute of Health.[13]

The distance from the infant's nasofrontal grove to their mental protuberance was measured (figure 1). These landmarks were chosen because the distance between them equates to the diameter of a suitably fitting mask in accordance with international guidelines.[6 7] Infants were photographed within 72 h after birth and weekly until they reached 33+6 weeks' postmenstrual age or were discharged or transferred to another hospital.

Measurements were combined to determine (i) measurements of newborns (<72 h of age)—presented as mean (SD) distance in millimetres for each completed week of gestation and by birth weight divided into 250 g cohorts; and (ii) measurements of growing infants—presented as mean (SD) distance in millimetres for each completed corrected week of gestation and by weight divided into 250 g cohorts.

Measurements were compared against three different round masks—Laerdal 0/0 (Laerdal, Stavagner, Norway) and Fisher & Paykel Infant Resuscitation Masks 'small' and 'extra small'. The Laerdal 0/0 mask has an external diameter of 50 mm. It was chosen as it is the standard mask used at The Royal Women's Hospital, Melbourne, and is a commonly used mask worldwide. The Infant Resuscitation Masks, sizes small and extra small, are the smallest available masks and have external diameters of 42 and 35 mm, respectively.

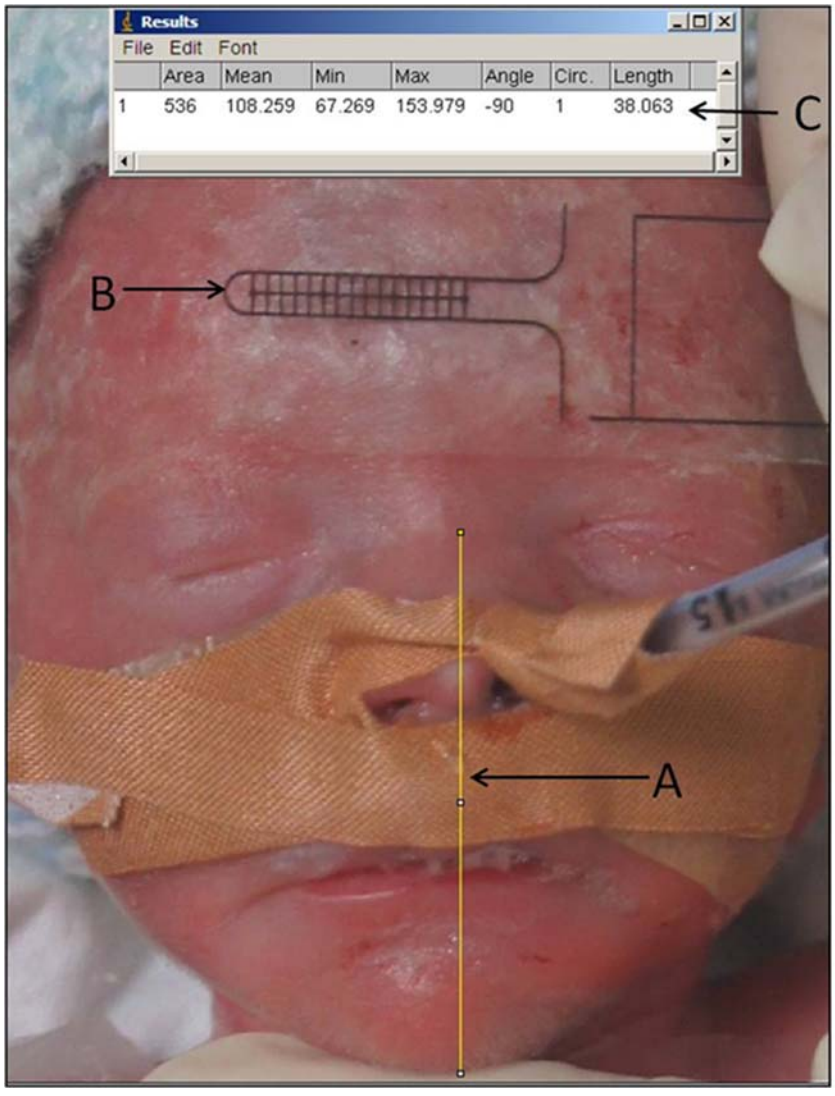

Figure 1 Example of study photograph taken and analysed. (A) Distance from the nasofrontal groove to the mental protuberance. (B) A plastic scale placed level with the infant's face. (C) Measurement calculated when analysed by ImageJ.

Table 1 Demographic details of the study population

Number of infants	Gestational age	Birth weight (g) mean (SD)	Percentage male	Percentage small for gestational age
10	24	649 (82)	60	10
10	25	728 (143)	40	20
10	26	934 (171)	50	10
10	27	988 (208)	40	10
12	28	1102 (183)	25	8
12	29	1082 (302)	25	25
12	30	1617 (215)	67	0
10	31	1638 (335)	20	10
11	32	1839 (198)	45	0
10	33	1839 (392)	40	30

RESULTS

A cohort of 107 infants between 24 and 33 weeks' gestational age were recruited between September 2011 and September 2013. There was a median (range) of 10 (10–12) infants per each completed week of gestation. Demographic details of the infants are presented in table 1.

There were 347 facial measurements made from photographs of the infants, median (range) of 3 (1–11) per infant. Figure 2A, B displays the results. Both the initial measurements taken shortly after birth and the serial measurements of infants from birth until 33 weeks' postmenstrual age are presented. Figure 2A displays the results for each completed week of gestation, and figure 2B displays the results for weight divided into 250 g strata. The initial measurements for each gestational age closely parallel serial measurements for postmenstrual age, suggesting that postnatal facial growth continues at a similar rate to antenatal growth despite preterm birth. Figure 2A, B also indicates the three different mask sizes alongside the measurements.

Table 2 presents newborn measurements for each week of gestation for the whole group, by gender, and infants with birth weight >3rd centile.

No significant differences were seen in facial size between male and female infants, or when small for gestational age infants were excluded. Small for gestational age infants have

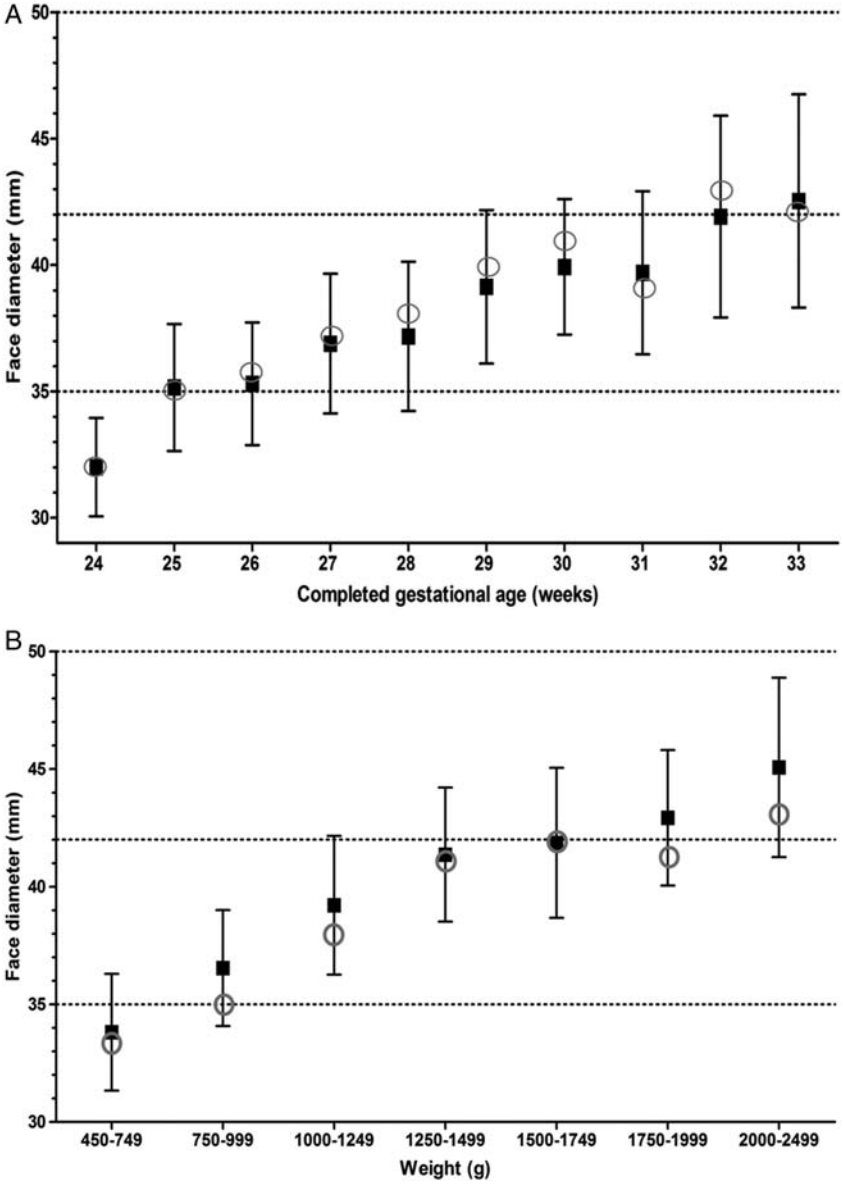

Figure 2 Mean measurements for (A) each completed week of gestation and (B) weight divided into 250 g cohorts. (A, B) The hollow circle represents the mean first measurements taken shortly after birth, and the black box and whiskers represent the mean (SD) of measurements taken from birth to 33 weeks' postmenstrual age.

Table 2 Initial measurements presented for each week of gestation for the whole study population by sex and excluding the growth-restricted infants

Number of infants	Gestation (completed weeks)	Initial measurement mean (SD) mm			
		All infants	Male only	Female only	Infants with birth weight >3rd centile
10	24	32 (2)	31 (2)	34 (2)	32 (2)
10	25	35 (3)	35 (3)	35 (3)	36 (3)
10	26	36 (3)	37 (3)	35 (3)	36 (3)
10	27	37 (3)	36 (1)	37 (4)	37 (4)
12	28	38 (4)	41 (4)	37 (4)	38 (4)
12	29	40 (4)	39 (3)	39 (5)	40 (4)
12	30	41 (2)	41 (2)	41 (2)	41 (2)
10	31	39 (4)	38 (1)	40 (4)	40 (3)
11	32	43 (4)	42 (4)	44 (5)	43 (4)
10	33	42 (5)	43 (3)	42 (6)	43 (5)

smaller faces, the degree of which depends on the severity of the growth restriction.

DISCUSSION

This study shows that a mask with an external diameter of 50 mm may be too large for infants <34 weeks' postmenstrual age. A 35 mm mask fits infants <29 weeks' postmenstrual age. For babies born at 27–28 weeks' gestational age, having both 35 and 42 mm masks available allows clinicians to choose the best-fitting mask for a particular baby. The 42 mm mask is appropriate for infants up to 33 weeks' postmenstrual age. However, having the 42 and 50 mm masks available may help select the best one for babies born at 32–33 weeks' gestational age.

During admission, both charts (figure 3A, B) can be used to choose the appropriate mask size as the infants grow.

There are four studies that have examined mask IPPV in preterm infants <34 weeks' postmenstrual age. All have found a significant leak around the mask, the magnitude of which varied from a median of 29–55%.[2–5] All of these studies used a 50 mm diameter mask that may have been too large to form an optimal seal. To date, there are no studies assessing leak using smaller and perhaps better-fitting masks. Our data could now be used to assess whether correctly sized masks result in less leak in vivo. There is more to the process of providing IPPV than simply choosing a mask of correct size. Head position, mask hold, applied pressure, ventilation rate and clinical experience also determine the effectiveness of IPPV. However, using an appropriate mask size is important and is highlighted in international training programmes.[6–8]

This study has several strengths. It is the first study to measure the dimensions of preterm infants' faces and to compare these measurements with those of commonly available masks. A large cohort of preterm infants was enrolled shortly after birth and followed to 33 weeks' postmenstrual age. The results have demonstrated that postnatal growth in these infants' facial measurements closely resembles growth in utero. The study cohort was evenly distributed across the range of gestational ages allowing for good representation of the extremely low birthweight infants. This is important because even though the extremely low birthweight infants make up a small proportion of the entire preterm population, they are the group most likely to require respiratory support. Respiratory outcomes of infants managed from birth with non-invasive versus invasive respiratory support are superior;[14] therefore, it is essential that mask IPPV and CPAP are optimised. These mask size recommendations ensure a better fit and may reduce mask repositioning during resuscitation. Some masks are reusable, whereas others are single-patient use, with an inherent cost implication. This study provides clinicians with the information to enable them to anticipate the appropriate mask size at birth and during admission, minimising that cost.

There are limitations to this study. Although photographs of the infants were taken in a standardised way to minimise distortion, the facial measurements were made indirectly. In addition, we have measured the face only in the horizontal plane and have not attempted to assess variations in dimensions in the sagittal plane. These variations are difficult to assess but may be important in influencing the amount of mask leak. Many of these infants were unwell and could not tolerate excessive handling. We therefore felt it would not have been appropriate to take measurements directly. Studies comparing measurements of photographs with direct measurements have found the method to be accurate and have very high inter-rater and intra-rater reliability.[15–20] The software package ImageJ that we used to measure the photographs is a public domain, java-based, image processing program developed at the National Institute of Health in 1997.[13] The program has been used for a diverse range of applications, including wound measurement, assessing skin texture and measuring orbital tumours and motion of soft tissue.[16 21 22]

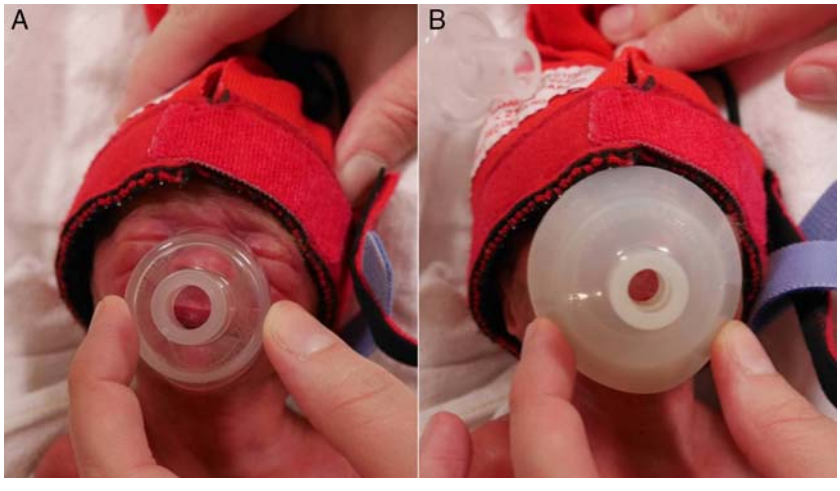

Figure 3 Newborn baby girl, 26+0 weeks' postmenstrual age, birth weight 805 g. (A) 35 mm mask applied to face; (B) 50 mm mask applied to face.

The mask sizes discussed in this study are all defined by their external diameter. However, the masks all have a rim of varying thickness and therefore a smaller internal diameter. If the external diameter of the mask fulfils the recommended criteria but has a rim that is wide enough to compress the infant's nose, then it may not be an effective interface for positive pressure ventilation. This study is limited in that the measurements were taken to assess the optimal external diameter for a suitable mask fit but the differing-sized masks were not studied during clinical use on different-sized infants. Future studies are needed to assess the effectiveness of different-sized masks in preterm infants.

CONCLUSION

The findings of this study suggest that round masks with an external diameter of 50 mm are too large for many preterm infants, particularly the extremely low birthweight infants. Smaller masks with external diameters of 35 and 42 mm are suitable for infants <29 weeks' postmenstrual age or <1000 g and 29–33 weeks' postmenstrual age or 1000–2500 g, respectively.

Contributors JEO was involved in study design, patient recruitment, data collection and analysis and has written the manuscript. MT was involved in study design, patient recruitment, data collection and analysis and has also reviewed and contributed to each draft of the manuscript. LSO was involved in study design and has reviewed and contributed to each draft of the manuscript, CW was involved in study design, patient recruitment, data collection and has approved the manuscript. JAD was involved in study design and has contributed to each draft of the manuscript. PGD was involved in study design, project supervision and has seen and contributed to each draft of the manuscript.

Funding The Royal Women's Hospital, Melbourne, Australia.

Competing interests None.

Patient consent Obtained.

Ethics approval The study was performed at The Royal Women's Hospital, Melbourne, Australia, with approval of The Royal Women's Hospital Research and Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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Measurements from preterm infants to guide face mask size

Joyce E O'Shea, Marta Thio, Louise S Owen, Connie Wong, Jennifer A Dawson and Peter G Davis

Arch Dis Child Fetal Neonatal Ed published online April 10, 2015

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Orotracheal intubation in infants performed with a stylet versus without a stylet (Review)

O'Shea JE, O'Gorman J, Gupta A, Sinhal S, Foster JP, O'Connell LAF, Kamlin COF, Davis PG

O'Shea JE, O'Gorman J, Gupta A, Sinhal S, Foster JP, O'Connell LAF, Kamlin COF, Davis PG.
Orotracheal intubation in infants performed with a stylet versus without a stylet.
Cochrane Database of Systematic Reviews 2017, Issue 6. Art. No.: CD011791.
DOI: 10.1002/14651858.CD011791.pub2.

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[Intervention Review]

Orotracheal intubation in infants performed with a stylet versus without a stylet

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Editorial group: Cochrane Neonatal Group.
Publication status and date: New, published in Issue 6, 2017.

Citation: O'Shea JE, O'Gorman J, Gupta A, Sinhal S, Foster JP, O'Connell LAF, Kamlin COF, Davis PG. Orotracheal intubation in infants performed with a stylet versus without a stylet. *Cochrane Database of Systematic Reviews* 2017, Issue 6. Art. No.: CD011791. DOI: 10.1002/14651858.CD011791.pub2.

ABSTRACT

Background

Neonatal endotracheal intubation is a common and potentially life-saving intervention. It is a mandatory skill for neonatal trainees, but one that is difficult to master and maintain. Intubation opportunities for trainees are decreasing and success rates are subsequently falling. Use of a stylet may aid intubation and improve success. However, the potential for associated harm must be considered.

Objectives

To compare the benefits and harms of neonatal orotracheal intubation with a stylet versus neonatal orotracheal intubation without a stylet.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library; MEDLINE; Embase; the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and previous reviews. We also searched cross-references, contacted expert informants, handsearched journals, and looked at conference proceedings. We searched clinical trials registries for current and recently completed trials. We conducted our most recent search in April 2017.

Selection criteria

All randomised, quasi-randomised, and cluster-randomised controlled trials comparing use versus non-use of a stylet in neonatal orotracheal intubation.

Data collection and analysis

Two review authors independently assessed results of searches against predetermined criteria for inclusion, assessed risk of bias, and extracted data. We used the standard methods of the Cochrane Collaboration, as documented in the *Cochrane Handbook for Systemic Reviews of Interventions,* and of the Cochrane Neonatal Review Group.

Main results

We included a single-centre non-blinded randomised controlled trial that reported a total of 302 intubation attempts in 232 infants. The median gestational age of enrolled infants was 29 weeks. Paediatric residents and fellows performed the intubations. We judged the study to be at low risk of bias overall. Investigators compared success rates of first-attempt intubation with and without use of a stylet and reported success rates as similar between stylet and no-stylet groups (57% and 53%) (P = 0.47). Success rates did not differ between groups in subgroup analyses by provider level of training and infant weight. Results showed no differences in secondary review outcomes, including duration of intubation, number of attempts, participant instability during the procedure, and local airway trauma. Only 25% of all intubations took less than 30 seconds to perform. Study authors did not report neonatal morbidity nor mortality. We considered the quality of evidence as low on GRADE analysis, given that we identified only one unblinded study.

Authors' conclusions

Current available evidence suggests that use of a stylet during neonatal orotracheal intubation does not significantly improve the success rate among paediatric trainees. However, only one brand of stylet and one brand of endotracheal tube have been tested, and researchers performed all intubations on infants in a hospital setting. Therefore, our results cannot be generalised beyond these limitations.

PLAIN LANGUAGE SUMMARY

Rates of successful intubation performed with a stylet in infants compared with rates of successful intubation performed without a stylet

Review question: Does use of a stylet increase success rates of newborn intubation without increasing risk of harm?

Background: Intubation consists of placement of a breathing tube (endotracheal tube) into the baby's windpipe or trachea to maintain an open airway. This common procedure may be needed both at birth and in the neonatal intensive care unit if the baby is not able to breathe well for himself. Trainee doctors must learn this difficult skill and sometimes must make more than one attempt to get the tube in the right place. The breathing tube is a narrow, plastic, flexible tube. A stylet, which is a malleable metal wire coated with plastic, can be inserted into the breathing tube to make it more rigid; this might make it easier to get the tube in the right place on the first attempt. However, use of a stylet may increase the risk of harm to the patient during the procedure.

Study characteristics: In literature searches updated in April 2017, we found one randomised controlled trial (302 intubations) that met the inclusion criteria of this review.

Results: Rates of successful intubation at first attempt with or without use of a stylet as an aid were similar, at 57% and 53%, respectively. Success rates with and without use of a stylet did not differ between infants of different weights, or between trainee paediatric doctors with different levels of experience. The length of time it took to intubate and the number of attempts made before successful intubation were comparable between groups. The incidence of a drop in a patient's oxygen level and in heart rate was equivalent between groups, as was the reported incidence of trauma to the airway associated with the procedure.

Quality of the evidence: The quality of evidence was low. We downgraded the level because we included only one unblinded study.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Stylet compared with no stylet for neonatal intubation

Patient or population: neonates requiring endotracheal intubation
Settings: neonatal intensive care unit or delivery room or theatre
Intervention: a stylet inserted into the endotracheal tube
Comparison: no stylet inserted into the endotracheal tube

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of intubations (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Stylet				
First intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**529 per 1000**	**570 per 1000** (466 to 698)	**RR** 1.08 (0.88 to 1.32)	302 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Gestational age of the infant	no data	no data	no data	no data	absence of evidence	
Professional category of the intubator - fellow: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**707 per 1000**	**667 per 1000** (488 to 548)	**RR** 0.94 (0.69 to 1.29)	74 (1)	⊕⊕◯◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study

Professional category of the intubator - resident: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**464 per 1000**	**543 per 1000** (418 to 705)	**RR** 1.17 (0.90 to 1.52)	228 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Level of experience of the intubator	no data	no data	no data	no data	absence of evidence	
Premedication given - no premedication given: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**540 per 1000**	**528 per 1000** (389 to 713)	**RR** 0.98 (0.72 to 1.32)	146 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Premedication given - no premedication given: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**519 per 1000**	**610 per 1000** (462 to 804)	**RR** 1.18 (0.89 to 1.55)	156 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Timing of intubation - just after birth in the delivery room: first intubation attempt success rate (outcome achieved at time of intubation at-	**540 per 1000**	**528 per 1000** (389 to 713)	**RR** 0.98 (0.72 to 1.32)	146 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study

tempt and not followed up)						
Timing of intubation - following admission to NICU: first intubation attempt success rate (outcome achieved at time of intubation attempt and not followed up)	**519 per 1000**	**610 per 1000** (462 to 804)	**RR** 1.18 (0.89 to 1.55)	156 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study
Type of stylet	no data	no data	no data	no data	absence of evidence	
Weight < 1000 g (outcome achieved at time of intubation attempt and not followed up)	**597 per 1000**	**533 per 1000** (400 to 704)	**RR** 0.89 (0.67 to 1.18)	152 (1)	⊕⊕⊕◯[a,b] **low**	Unblinded trial with no blinded outcome assessment Single study

*The basis for the **assumed risk** (e.g. median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on assumed risk in the comparison group and **relative effect** of the intervention (and its 95% CI)
CI: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate

[a]High risk of detection bias (due to lack of blinding of caregivers and outcome assessors)
[b]Serious imprecision (due to small number of events and small sample sizes; 95% CIs include null effects)

BACKGROUND

Description of the condition

Neonatal endotracheal intubation refers to placement of an endotracheal tube (ETT; breathing tube) within an infant's airway. This intervention is commonly needed and may be life-saving for infants after birth and during neonatal intensive care. Indications for intubation during neonatal resuscitation include ineffective or prolonged positive-pressure ventilation delivered via face mask; need to secure the airway when cardiac compressions are performed; intratracheal administration of medications; and special resuscitation circumstances such as congenital diaphragmatic hernia or endotracheal suctioning for meconium (ILCOR 2005; Perlman 2010). Endotracheal intubation is necessary when neonatal intensive care is provided for infants in respiratory failure, despite non-invasive respiratory support, as well as for administration of surfactant, for treatment of resistant apnoea of prematurity, and for preparation of infants undergoing surgery. Intubation can be performed by the nasotracheal (through the nose) or orotracheal (through the mouth) route. This review will focus solely on orotracheal intubation; whenever intubation is mentioned, we will be referring to orotracheal intubation. We will not consider nasal intubation here, as it is not possible to use a stylet safely during nasal intubation.

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. Successful intubation relies on the ability of the intubator to perform laryngoscopy (using a laryngoscope inserted into the patient's mouth to obtain a view of the infant's airway) and to recognise the anatomy displayed. Opportunities for neonatal trainees to acquire and maintain proficiency in endotracheal intubation are decreasing (Leone 2005), likely owing to increased use of non-invasive respiratory support in neonatal intensive care, reduced working hours for trainees, increased numbers of trainees, and changes in clinical recommendations, such as to discontinue routine intubation of babies delivered through meconium-stained liquor.

Studies evaluating success rates for neonatal endotracheal intubation report that more than one attempt is frequently required for successful intubation. An Australian study (O'Donnell 2006) reported that 62% of total first intubation attempts were successful, but the success rate was only 24% among the most inexperienced trainees. In a study conducted in the United States (Falck 2003), paediatric residents successfully intubated neonates on the first or second attempt at rates of 50%, 55%, and 62% for first-, second-, and third-year residents, respectively. None of these residents met the study authors' definition of procedural competence for intubation (successful at first or second attempt 80% or more of the time) over a two-year period. Another American study examining intubation success rates over a 10-year period (Leone 2005) reported median success rates of 33% for first-year residents, 40% for second- or third-year residents, and 68% for neonatal fellows. Success rates were significantly different between groups ($P < 0.001$), but success rates for paediatric residents were not significantly different for delivery room (DR) non-meconium intubations than for neonatal intensive care unit (NICU) intubations (36% vs 36.5%). The most recent US study examining endotracheal intubation success rates (Haubner 2013) reported an overall success rate of 44%. Investigators again found significant differences between experienced and inexperienced providers - residents 20%, fellows 72%, and attending physicians 70%. Researchers observed that participant characteristics of birth weight and gestation did not impact success rates. Studies of intubation performed at US tertiary academic centres by neonatologists, fellows, residents, and respiratory therapists, in which detection of exhaled carbon dioxide was used to confirm correct tube placement, suggest that oesophageal intubation is not infrequent (Roberts 1995; Aziz 1999; Repetto 2001; Lane 2004). Inability to successfully perform ETT placement, or delayed recognition of unsuccessful placement, can cause death or severe hypoxic injury. Multiple intubations or traumatic intubations increase the risk of serious glottic, subglottic, and tracheal injury (Meneghini 2000; Wei 2011).

The current Neonatal Resuscitation Program 7th Edition (AAP 2016) recommends that intubation attempts should be limited to 30 seconds. This has been expanded from the 20-second recommendation provided in the 5th Edition (Kattwinkel 2006) following a study of delivery room intubations performed mainly by residents and fellows (Lane 2004), which found that a more realistic time needed for intubation was 30 seconds without apparent adverse effects.

Studies have demonstrated that premedicating infants with various types of induction agents increases the speed of successful intubation and reduces the likelihood of associated adverse sequelae (Marshall 1984; McAuliffe 1995; Cook-Sathler 1998). Premedication has been shown to improve intubating conditions significantly and to reduce the number of attempts required for successful intubation and risk of intubation-related airway trauma.(Dempsey 2006; Roberts 2006; Carbajal 2007; Ghanta 2007; Silva 2007; Lemyre 2009).

Strategies for improving training are being developed to compensate for the reduced clinical experience of practitioners. Airway trainers, animal models, and cadaveric specimens are useful for demonstrating the anatomy (Haubner 2013). Simulation is a tool that is used increasingly in medical education. However, studies that examined the role of simulation in teaching intubation (Nishiasaki 2010; Finan 2012) did not report improved clinical performance. Videolaryngoscopy (use of a laryngoscope to transmit images from the tip of the blade to a nearby monitor) allows the teacher to share the view of the trainee intubator and may be useful for improving intubation success.

Description of the intervention

As small-diameter ETTs are flexible, intubation may be performed with or without a stylet inserted into the lumen (hollow centre of the ETT) and secured**.** A neonatal stylet is a 6 French (2-mm diameter) malleable aluminium wire covered with lubricated plastic, which extends beyond the tip (Rusch Flexi-Slip™ Stylet, Teleflex Medical, Research Triangle Park, NC, USA; Satin-Slip Stylet, Mallinckrodt Medical, Athlone, Ireland). Available stylets are suitable for use with tubes of 2.5-mm internal diameter and greater. The stylet is positioned so that its tip does not extend beyond the tip of the tube. The proximal (top) end of the ETT is attached to a plastic adapter that connects to the ventilator. The stylet is threaded through the adapter into the ETT and is positioned so that the tip of the stylet does not extend beyond the tip of the tube. The proximal end of the stylet is then bent over the rim of the adapter to prevent further slipping of the stylet. Endotracheal tubes for neonates are made of pliable plastic and have a small internal diameter of 2.0 mm to 4.0 mm. They become increasingly flexible with decreasing internal diameter, especially if exposed to the heat of an overhead radiant warmer. A stylet may increase the rigidity and curvature of the tube, perhaps making it easier to navigate between vocal cords. Current guidelines (Richmond 2011; AAP 2016) do not recommend routine use of a stylet for orotracheal intubation but rather classify it as an optional instrument. Some operators may prefer the rigidity and curvature afforded by this technique and may achieve higher success rates. However, this rigidity could provide a disadvantage and may cause airway damage. Published case reports have described shearing off of the stylet sheath, causing acute airway obstruction (Cook 1985; Zmyslowski 1989; Bhargava 1998; Rabb 1998; Boyd 1999; Chiou 2007). Stylet costs are similar to those of an endotracheal tube.

How the intervention might work

A stylet increases the rigidity of the ETT and may facilitate placement within the airway.

Why it is important to do this review

Neonatal intubation is a commonly needed life-saving intervention. Success rates, especially among inexperienced trainees, are suboptimal. If use of a stylet could improve intubation success, then it should be recommended for routine use. However, if use of a stylet does not improve success, or if its use may cause harm, it should not be recommended.

OBJECTIVES

To compare the benefits and harms of neonatal orotracheal intubation with a stylet versus neonatal orotracheal intubation without a stylet.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), quasi-RCTs, and cluster RCTs.

Types of participants

We defined our population as infants of 44 weeks' postmenstrual age or less who required endotracheal intubation. Infants who were intubated on more than one occasion were included again for subsequent intubation episodes, and we included only the first intubation attempt per episode. We excluded studies that enrolled infants with craniofacial or airway anomalies and those that enrolled infants born through meconium-stained liquor who were intubated for tracheal suctioning, owing to difficulty confirming ETT placement within the trachea.

Types of interventions

Orotracheal intubation performed with a stylet versus without a stylet.

Types of outcome measures

Primary outcomes

- Rate of successful first attempt at orotracheal intubation
    - An attempt was defined as introduction of the ETT into the infant's mouth after laryngoscopy. Successful placement within the tracheobronchial tree was confirmed immediately post intubation attempt, objectively, through a predetermined method, for example, by observation of colour change on an exhaled colorimetric carbon dioxide detector, misting within the ETT, or auscultation of the chest.

Secondary outcomes

- Duration of the intubation in seconds
    - This measures time from insertion until removal of the laryngoscope
- Number of intubation attempts
- Patient instability during the procedure, as measured by:
    - heart rate (HR) < 100 during the procedure; and
    - desaturation to < 70% (with 100% showing full oxygen saturation).
- Local trauma to the airway or surrounding soft tissue diagnosed by the presence of blood-stained endotracheal

aspirates or oral sections over the 24 hours after the attempt (number per thousand infant population)

- Evidence of airway damage, for example, post-extubation stridor, subglottic stenosis, or vocal cord paralysis (number per thousand infant population)

Search methods for identification of studies

Electronic searches

Two review authors independently searched electronic databases, including the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 3) in the Cochrane Library; MEDLINE (1966 to April 2017); Embase (1980 to April 2017); and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to April 2017). We also searched previous reviews including cross-references, contacted expert informants, and handsearched journals. We searched MEDLINE, Embase, and CINAHL for relevant articles, using the following search terms: (intubation AND stylet) OR (intubation (explode) [MeSH heading] AND stylet) plus database specific limiters for neonates and randomised controlled trials (see Appendix 1). We applied no language restrictions.

Searching other resources

The search strategy included communication with expert informants and searches of bibliographies of systematic reviews and trials for references to other trials. We examined previous reviews, including cross-references, abstracts, and conferences, and symposium proceedings of the Perinatal Society of Australia and New Zealand and of the Pediatric Academic Societies (American Pediatric Society, Society for Pediatric Research, and European Society for Pediatric Research) from 1990 to 2015. If we were to identify any unpublished trial, we planned to contact study author to request information. We considered unpublished studies and studies reported only as abstracts as eligible for inclusion in the review if study authors reported final trial data and did not perform an interim analysis. We planned to contact the authors of identified RCTs to ask for additional study data when needed. We searched clinical trial registries to April 2017 for current and recently completed trials (clinicaltrials.gov; controlled-trials.com; who.int/ictrp), as well as the Australia and New Zealand Clinical Trials Register (ANZCTR).

Data collection and analysis

We used the standard methods of the Cochrane Collaboration, as documented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a), and of the Cochrane Neonatal Review Group (CNRG).

Selection of studies

Two review authors independently assessed all studies identified via the search strategy for possible inclusion in the review. We planned to resolve disagreements through discussion or, if required, through consultation with a Cochrane review arbiter. Specifically, we performed the following tasks.

- Merged search results by using reference management software and removed duplicate records of the same report.
- Examined titles and abstracts to remove irrelevant reports.
- Retrieved full texts of potentially relevant reports.
- Linked multiple reports of the same study.
- Examined full-text reports for study compliance with eligibility criteria.
- Corresponded with investigators, when appropriate, to clarify study eligibility.
- Noted reasons for inclusion and exclusion of articles at all stages (we resolved disagreements through consensus, or sought assistance with arbitration from the editorial base of the CNRG, if needed).
- Made final decisions on study inclusion and proceeded to data collection.
- Resolved all discrepancies through a consensus process.

Data extraction and management

Two review authors independently extracted data from full-text articles using a specially designed spreadsheet to manage the information. We resolved discrepancies through discussion, or, if required, we planned to consult a review arbiter. We entered data into Review Manager software (RevMan 2014) and checked them for accuracy. When information regarding any of the above was missing or unclear, we attempted to contact authors of the original reports to clarify and provide additional details.

Assessment of risk of bias in included studies

We used the standardised review methods of the CNRG (http://neonatal.cochrane.org/en/index.html) to assess the methodological quality of included studies. Review authors independently assessed study quality and risk of bias using the criteria documented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). See Appendix 2 for the 'Risk of bias' tool.

Measures of treatment effect

We analysed the results of included studies using the statistical package Review Manager software (RevMan 2014). We used the standard method of the CNRG and applied a fixed-effect model for meta-analysis (Deeks 2011).

Unit of analysis issues

The unit of analysis is an intubation attempt. We included the first attempt for each intubation episode. We excluded further attempts by the same intubator or by other intubators. A participant who had more than one intubation episode could be included more than once; however, we would treat each intubation as a separate study event and would randomise it separately. We planned to combine cluster-RCTs and individually randomised RCTs in a single meta-analysis using the generic inverse variance method. We planned to adjust cluster-RCTs for their intracluster correlation coefficient.

Assessment of heterogeneity

We planned to use RevMan 5.3 (RevMan 2014) to assess the heterogeneity of treatment effects between trials. We planned to use the two formal statistics described below.

- Chi^2 test for homogeneity. We planned to calculate whether statistical heterogeneity was present by performing the Chi^2 test for homogeneity ($P < 0.1$). As this test has low power when the number of studies included in the meta-analysis is small, we set probability at the 10% level of significance (Deeks 2011).
- I^2 statistic to ensure that pooling of data was valid (Higgins 2003). We planned to quantify the impact of statistical heterogeneity by using I^2 statistics available in RevMan 2014, which describe the percentage of total variation across studies due to heterogeneity rather than to sampling error. We planned to grade the degree of heterogeneity as follows: < 25% no heterogeneity, 25% to 49% low heterogeneity, 50% to 74% moderate heterogeneity, and ≥ 75% high heterogeneity.

When we found evidence of apparent or statistical heterogeneity, we planned to assess the source of the heterogeneity by performing sensitivity and subgroup analyses to look for evidence of bias or methodological differences between trials.

Data synthesis

We performed statistical analyses according to the recommendations of CNRG (http://neonatal.cochrane.org/en/index.html). We analysed all infants randomised on an intention-to-treat (ITT) basis. We planned to analyse treatment effects in individual trials and planned to use a fixed-effect model for meta-analysis in the first instance to combine data. When we noted substantial heterogeneity, we planned to examine the potential cause of heterogeneity by performing subgroup and sensitivity analyses. If we judged meta-analysis to be inappropriate, we planned to analyse and interpret individual trials separately. For estimates of typical risk ratio (RR) and risk difference (RD), we planned to use the Mantel-Haenszel (MH) method (Mantel 1959; Greenland 1985). For measured quantities, we planned to use the inverse variance method. When assessing treatment effects, we used RR and RD, with 95% confidence intervals (CIs), for dichotomous outcomes. When the RD was statistically significant, we calculated the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH) (1/RD). For outcomes measured on a continuous scale, we used mean difference (MD) with 95% CI.

Quality of evidence

We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, as outlined in the *GRADE Handbook* (Schünemann 2013), to assess the quality of evidence for the following (clinically relevant) outcomes: first intubation attempt success rate; first attempt success rate for intubations without premedication; first attempt success rate for intubations with premedication; first attempt success rate for experienced intubators; first attempt success rate for inexperienced intubators; and first attempt success rate for intubations in infants weighing less than 1 kilogram.

We considered evidence from RCTs as high quality but downgraded the evidence one level for serious (or two levels for very serious) limitations according to the following: design (risk of bias), consistency across studies, directness of evidence, precision of estimates, and presence of publication bias.

The GRADE approach provides an assessment of the quality of a body of evidence according to one of four grades.

- High: We are very confident that the true effect lies close to the estimate of effect.
- Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
- Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
- Very low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Two review authors independently assessed the quality of the evidence for each of the outcomes above. We used the GRADEpro GDT Guideline Development Tool to create a 'Summary of findings' table to report evidence quality.

Subgroup analysis and investigation of heterogeneity

We carried out the following subgroup analyses.

- Gestational age: < 28 weeks, 28 to 37 weeks, ≥ 37 weeks.
- Professional category of person performing intubation: neonatologists, neonatal fellows, resident doctors, respiratory therapists, nurses, and neonatal nurse practitioners.
- Level of experience of intubators: < 1 year, 1 to 4 years, ≥ 5 years.
- Premedications: intubations for which premedication is given; intubations performed without premedications.

- Timing of intubation: during resuscitation following birth; during neonatal intensive care stay.
- Type of stylet used: a plastic-coated malleable wire inserted into the ETT; any other type of stylet.

RESULTS

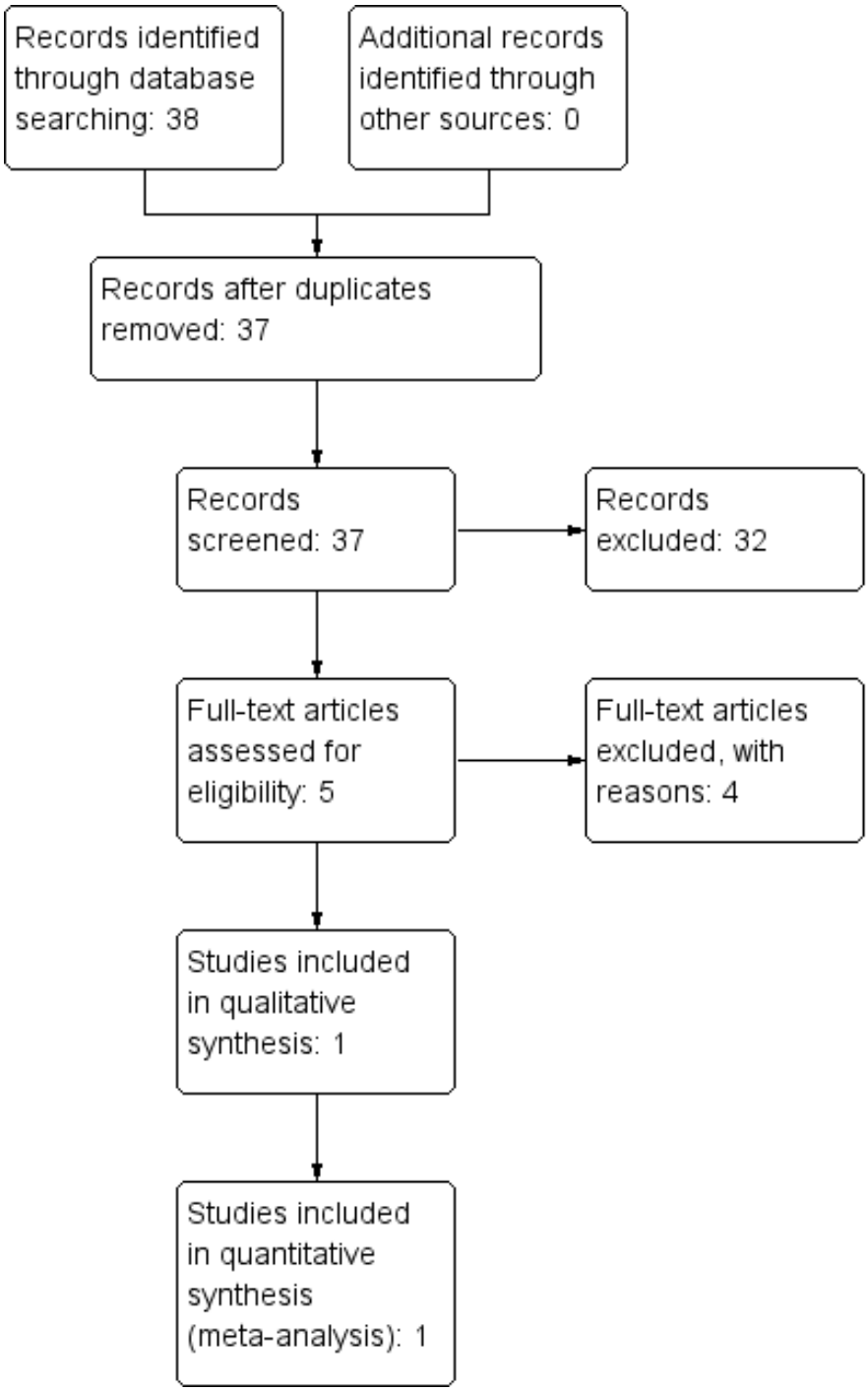
Description of studies

See Characteristics of included studies and Characteristics of excluded studies tables.

Results of the search

For this review, we found and assessed 38 titles and abstracts in electronic format after we had removed duplicates. Of the 38 titles and abstracts screened, we assessed five as relevant, and one study met the inclusion criteria (Figure 1, Study flow diagram).

Figure 1. Study flow diagram.



Included studies

Kamlin 2013 is a single-centred RCT conducted at an Australian tertiary neonatal unit between July 2006 and January 2009. The study included 304 first intubation attempts in 232 infants.

Intervention: Investigators randomised intubations to use of a stylet inserted into the ETT lumen or no stylet inserted. ETTs used were sterile, single-use, uniform internal diameter (ID), plastic ETTs (Mallinckrodt Medical, Athlone, Ireland) of appropriate ID based on infants' actual or estimated birth weight; the stylet used was a Satin Slip intubation stylet (Malinckrodt Medical, Athlone, Ireland). Researchers confirmed correct ETT placement by using a colourimetric exhaled carbon dioxide detector (Pedicap, Nellcor Puritan Bennett, Pleasanton, CA, USA). Infants admitted to the NICU had a chest radiograph to confirm ETT position. Study authors recorded the level of experience of the operator, as well as the operator's preference (i.e. stylet, no stylet, no preference).

Investigators randomised the first attempted intubation by a single operator. If unsuccessful, the operator was free to choose his or her preferred method for subsequent attempts. Doctors performed all intubations. In general, residents had no previous intubation experience, whereas fellows had at least 12 months' experience in neonatal intensive care. Researchers defined an attempted intubation as laryngoscopy followed by introduction of the ETT past the lips. They defined the duration of an attempt, timed by a digital stop watch, as the interval from introduction of the laryngoscope blade into the mouth to its removal. Intubation attempts were limited by the infant's heart rate (> 100 beats per minute deemed acceptable) rather than by a time limit. Study authors obtained baseline readings for heart rate and pulse oxygen saturations by using a pulse oximeter and recorded the lowest heart rate and oxygen saturations during the attempt.

Investigators did not use premedication for emergency intubations following delivery. They used premedication with morphine or fentanyl, atropine, and suxamethonium for elective intubations within the NICU. During the course of the study, researchers updated hospital guidelines and replaced morphine with fentanyl.

Participants: Infants requiring orotracheal intubation were eligible for study inclusion. Excluded infants had facial or airway anomalies or were briefly intubated for suctioning of meconium from the trachea, as tube placement was difficult to confirm. The first attempted intubation of each intubation episode was eligible for randomisation. Therefore, if an infant was intubated again later during the inpatient course, researchers could randomise further intubations.

Outcomes: The primary outcome was intubation success on first attempt indicated by detection of exhaled carbon dioxide. Secondary outcomes included duration of the intubation attempt, changes in heart rate and oxygen saturation from baseline, and the presence of blood-stained secretions after the procedure. Prespecified subgroup analyses examined the effects of gestation, birth weight, premedication, and level of experience of the operator on intubation success.

Excluded studies

We excluded four potentially relevant studies from this original review because study design did not meet the criteria for included studies. We excluded two studies that did not randomise infants to the assigned treatment - one that was a case series (Shukry 2005), and another that was a prospective observational trial (Fisher 1997). We excluded two other RCTs, as the comparisons did not match our criteria: MacNab 1998 compared three different types of stylets but did not include a 'no-stylet' arm; Yamashita 2015 compared two different methods of confirming that the ETT was in the trachea - not the main-stem bronchus.

Risk of bias in included studies

We deemed the included study to be at low risk of bias overall. See the risk of bias graph (Figure 2) and summary (Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

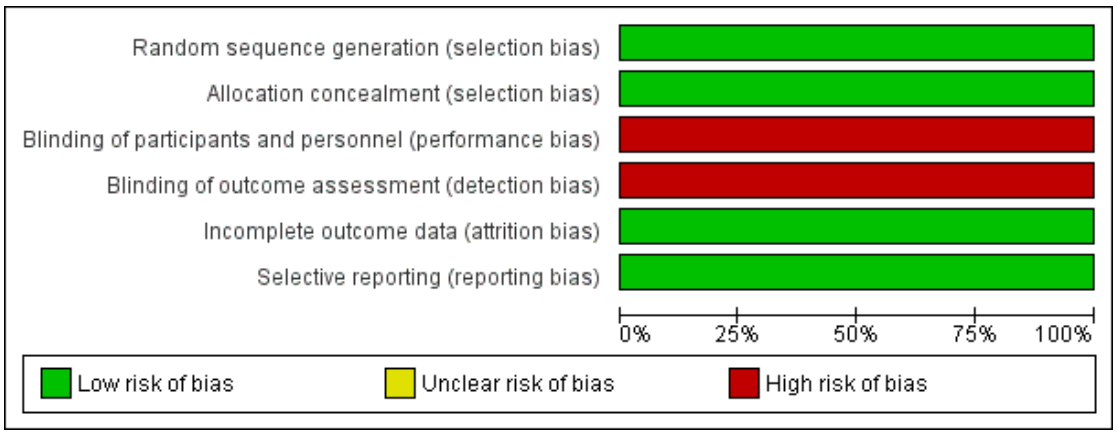
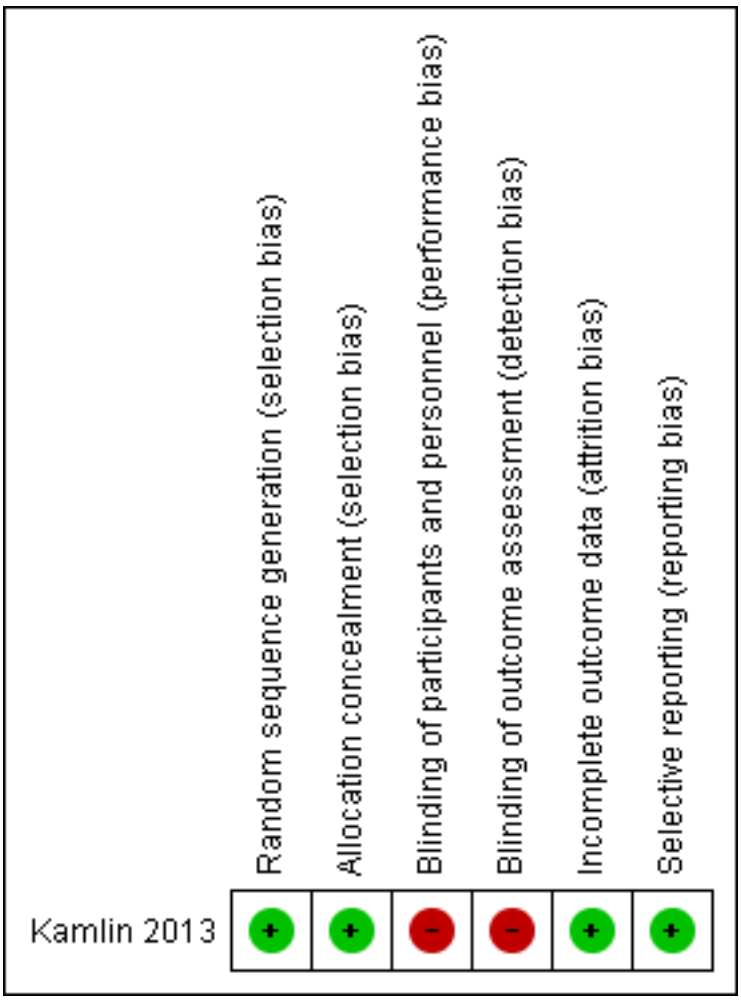


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Investigators performed randomisation in blocks of variable size, stratified by site of intubation (delivery room or NICU) (low risk of bias for generation of random sequence).

Researchers concealed allocation by using sequentially numbered sealed opaque envelopes containing computer-generated treatment groups (low risk of bias). The neonatal fellow on duty would bring an unopened sealed envelope to the delivery room to randomise the next eligible infant. Infants in the NICU were identified by a study label placed on the incubator.

Blinding

This unblinded trial did not perform blinded outcome assessment (high risk of bias).

Incomplete outcome data

Researchers presented a complete flow chart for all intubations performed during the study period. They accounted for all exclusions and missed eligibles and for two post-randomisation exclusions (low risk of bias).

Selective reporting

The study protocol is available, and study authors reported all prespecified primary and secondary outcomes (low risk of bias).

Other potential sources of bias

We identified no other sources of bias.

Effects of interventions

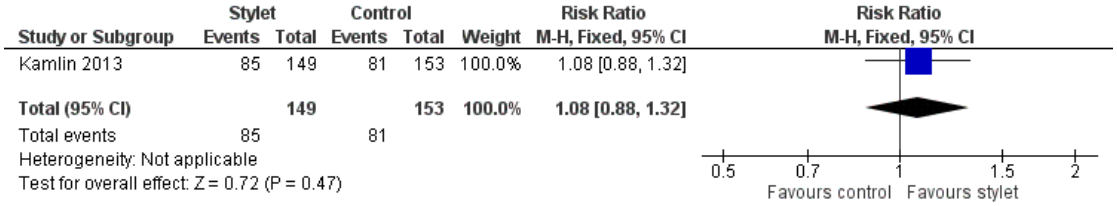
See: **Summary of findings for the main comparison**

Primary outcomes

Rate of successful first attempt at orotracheal intubation (Analysis 1.1)

Intubation was successful on the first attempt in 57% of the stylet group and in 53% of the no-stylet group (P = 0.47; RR 1.08, 95% CI 0.88 to 1.32) (Figure 4).

Figure 4. Forest plot of comparison: 1 First intubation attempt success rate with use of stylet versus non-use of stylet, outcome: 1.1 First intubation attempt success rate.



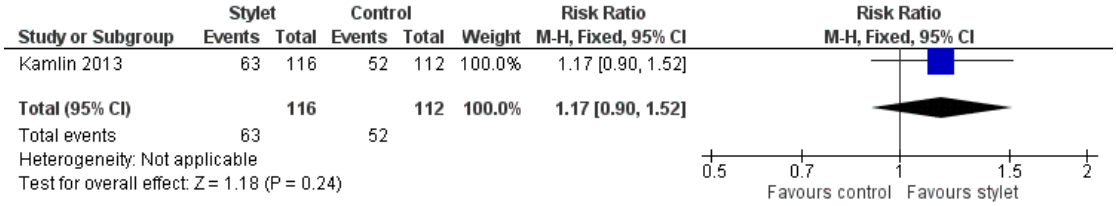
Subgroup analyses

- Gestational age: < 28 weeks, 28 to 37 weeks, ≥ 37 weeks; analysis was not possible owing to lack of data
- Professional category of person performing intubation
    - Success by fellows was 67% with a stylet and 71% without a stylet (RR 0.94, 95% CI 0.69 to 1.29) (Analysis 2.1;Figure 5)

Figure 5. Forest plot of comparison: 2 Intubation success: Professional category, outcome: 2.1 Fellow: first intubation attempt success rate.

○ Success by residents was 54% with a stylet and 46% without a stylet (RR 1.17, 95% CI 0.9 to 1.52) (Analysis 2.2;Figure 6)

Figure 6. Forest plot of comparison: 2 Intubation success: Professional category, outcome: 2.2 Resident: first intubation attempt success rate.



○ Doctors carried out all intubations in Kamlin 2013

- Level of experience of intubators - analysis was not possible owing to lack of data

- Effect of premedication

- ○ Success rate without premedication was 53% with a stylet and 54% without a stylet (RR 0.98, 95% CI 0.72 to 1.32) (Analysis 3.1Figure 7)

Figure 7. Forest plot of comparison: 3 Intubation success: use of premedication, outcome: 3.1 Intubations without premedication given to the infant.

○ Success rate with premedication was 61% with a stylet and 52% without a stylet (RR 1.18, 95% CI 0.89 to 1.55) (Analysis 3.2Figure 8)

Figure 8. Forest plot of comparison: 3 Intubation success: use of premedication, outcome: 3.2 Intubations following premedication given to the infant.

- Timing of intubation.
  - Success rate during resuscitation following birth was 53% with a stylet and 54% without a stylet (RR 0.98, 95% CI 0.72 to 1.32) (Analysis 4.1)
  - Success rate during neonatal intensive care stay was 61% with a stylet and 52% without a stylet (RR 1.18, 95% CI 0.89 to 1.55) (Analysis 4.2)
- Type of stylet
  - Success rate with Satin Slip intubation stylet was 57% in the stylet group and 53% in the no-stylet group (P = 0.47; RR 1.08, 95% CI 0.88 to 1.32) (Analysis 1.1; Figure 4)
- Weight of infant at the time of intubation
  - Success in infants weighing less than 1 kilogram at the time of intubation was 53% with a stylet and 60% without a stylet (RR 0.89, 95% CI 0.67 to 1.18) (Analysis 5.1)
  - Success in infants weighing 1 kilogram or more at the time of intubation was 61% with a stylet and 46% without a stylet (RR 1.32, 95% CI 0.97 to 1.79) (Analysis 5.2)

Secondary outcomes

Duration of the intubation in seconds

The median duration of intubation attempts was similar in the two groups: 43 (interquartile ratio (IQR) 30 to 60) and 38 (IQR 27 to 57) seconds for stylet and no-stylet groups (P = 0.23), respectively. Only 25% of all intubations took less than 30 seconds.

Number of intubation attempts

The median number of intubation attempts reported per infant before an ETT was successfully passed was one (range 1 to 5). Difficult airways appear to have been equally represented, with eight randomisations in each of the stylet and no-stylet groups requiring four or more attempts before successful intubation.

Participant instability during the procedure

Investigators measured participant instability during the procedure by assessing:

- heart rate (HR) < 100 during the procedure; and
- desaturation to < 70% (with 100% indicating full oxygen saturation).

In Kamlin 2013, trial pulse oximetry data were available for 277 intubation attempts in 215 infants (121 in DR, 156 in NICU). Investigators reported no significant differences between groups in lowest recorded oxygen saturation and heart rate during randomised attempts in the DR and the NICU, respectively. The mean lowest heart rate recorded for the stylet group was 128 beats per minute (standard deviation (SD) 36) compared with 121 (SD 37) for the non-stylet group. Only one infant in the trial received chest compressions. This infant had an antenatal diagnosis of tricuspid atresia and was randomised to the no-stylet group. No published data were available with regards to lowest oxygen saturation for the stylet group versus the non-stylet group during intubation attempts.

Local trauma to the airway or surrounding soft tissue

Researchers diagnosed local trauma to the airway or surrounding soft tissue by the presence of blood-stained endotracheal aspirates or oral sections during the 24 hours following the attempt (number per thousand infant population). Rates of blood-stained aspirates within the first 24 hours were 10% and 13% (P = 0.49) in stylet and no-stylet groups, respectively.

Evidence of airway damage

As some infants were randomised more than once (8% of infants) and were allocated to both groups, Kamlin 2013 did not report neonatal morbidity and mortality data. Of note, no participants were reported to have had tracheal or oesophageal perforation following intubation attempts.

DISCUSSION

Summary of main results

Of 38 titles screened, we included one study with a total of 304 first intubation attempts in 232 infants (Kamlin 2013). This study, an unblinded randomised controlled trial (RCT) carried out in an Australian tertiary perinatal centre, compared use of a stylet as an aid during intubation of the newborn infant versus intubation without use of a stylet. The included trial assessed the primary outcome and most of the secondary outcomes of this review, while excluding assessment of airway damage. The salient result from this included trial suggests that using a stylet did not significantly improve the success rate of paediatric trainees in performing neonatal orotracheal intubation when compared with intubation performed without using a stylet. Results reported were consistent across subgroups according to site of intubation and birth weight of the infant. Investigators reported no serious side effects resulting from intubation with the use of a stylet.

Overall completeness and applicability of evidence

The effectiveness of stylet use during intubation has been evaluated in only one study, which evaluated the use of one particular make of stylet (Stain Slip intubation stylet, Malinckrodt Medical, Athlone, Ireland), one brand of endotracheal tube, in one country, by doctors with a minimum of six months' neonatal experience, among a population of newborn infants. Thus, results cannot be generalised beyond this population and use of this particular make of stylet in a hospital setting.

Quality of the evidence

We assessed the quality of evidence using GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) methods (Guyatt 2008). We judged the included study to be at low risk of bias overall. We stratified randomisation in blocks of variable size by site of intubation (delivery room or neonatal intensive care unit (NICU)). In terms of allocation concealment, researchers used sequentially numbered sealed opaque envelopes containing computer-generated treatment groups to determine allocation status. Study authors provided no evidence of incomplete outcome data. Researchers accounted for infants and eligible intubations that were excluded and provided reasons for these exclusions. Exclusions after randomisation were minimal. The study protocol was available, and all prespecified outcomes were reported as intended.

One limitation of this study is that the trial was unblinded. Hospital staff and family members were unblinded to the intervention, and no evidence suggests that a blinded outcome assessment was conducted. It is unclear if the trial would have been improved by blinding of outcome assessment because of the objective nature of measured outcomes. The study is also limited in that investigators tested one brand of stylet and one brand of endotracheal tube. Endotracheal tubes likely have different degrees of rigidity. A more rigid tube may hold its shape better, and practitioners may note less benefit with use of a stylet, whereas a more floppy flexible tube may not hold its shape, and use of a stylet may be beneficial. Results show no differences in the incidence of blood-stained endotracheal aspirates between groups. However, if the initial attempt was unsuccessful, a stylet was used for subsequent attempts, at the clinician's discretion. This result should be interpreted cautiously. Another limitation is that some infants were randomised more than once, and some were included in both study arms. This makes assessment of longer-term outcomes impossible. In addition, inclusion of the same participant more than once leads to reduced power of the trial because of lack of independence of each intubation studied. This is somewhat ameliorated by the fact that premature infants are an atypical population that changes rapidly as the result of rapid growth (thereby posing different challenges for the operator) and changes to the upper airway resulting from each intubation and perhaps from steroid therapy. Therefore, a later intubation may be considered an independent event. Data were also derived from a single study with a moderately small number of participants.

We downgraded the quality of evidence to low for these reasons.

Potential biases in the review process

We conducted a thorough search of the literature and did not apply language restrictions to minimise selection bias. We conducted the review robustly, according to good systematic review standards. It is unlikely that we have overlooked relevant high-quality large studies examining use versus non-use of a stylet during intubation of the newborn infant. Therefore, we believe that the probability of bias in the review process is low.

A potential source of bias in the review as a whole is that three of the contributing authors of this Cochrane review and protocol are authors of the included study.

Agreements and disagreements with other studies or reviews

No other neonatal studies have examined whether a stylet can increase intubation success rates.

AUTHORS' CONCLUSIONS

Implications for practice

We found no evidence to support the use of a stylet.

Implications for research

Neonatal intubation success rates are falling, especially those of junior trainees (Leone 2005). It is unlikely that future trials examining the use of stylets will present findings that will reverse this trend. Therefore, further research could focus on other variables that may influence intubation success to a greater degree, for example, educational interventions such as simulation or videolaryngoscopy. As opportunities for trainees to learn and practice neonatal intubation continue to decline, it is vital that training techniques are developed and intubation attempt success rates are continually audited to assess the effects of such training.

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Wei JL, Bond J. Management and prevention of endotracheal intubation injury in neonates. *Current Opinion in Otolaryngology & Head and Neck Surgery* 2011; **19**(6):474–7. [DOI: 10.1097/MOO.0b013e32834c7b5c; PUBMED: 21986802

Zmyslowski 1989
Zmyslowski WP, Kam D, Simpson GT. An unusual cause of endotracheal tube obstruction. *Anesthesiology* 1989;**70** (5):883. [PUBMED: 2719333]

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Kamlin 2013

Methods	**Objective:** to determine whether paediatric trainees were more successful at neonatal orotracheal intubation when a stylet was used **Study design:** unblinded randomised controlled trial **Object of randomisation:** first intubation attempt; for infants who had more than 1 episode of intubation during admission, each episode of intubation was randomised and was treated as an independent event **Recruitment:** For emergency first intubations in the delivery room or within 24 hours of birth, a waiver of consent was used to enrol infants, and retrospective consent was obtained from parents as soon as possible after the intubation attempt. Infants who were intubated in the neonatal intensive care unit (NICU) after the first day were eligible if written parental consent had been obtained. Permission from parents was also sought to randomise future intubations **Allocation:** randomly assigned **Total number of intubations:** 713 **Number of infants randomised:** 232 **Number of intubations randomised:** 304 **Method of analysis:** Data are presented as means (standard deviations) for normally distributed continuous variables and medians (interquartile ranges) when the distribution is skewed. Clinical characteristics and outcome variables were analysed by using Student's *t* test for parametric comparisons, the Mann-Whitney *U* test for non-parametric comparisons of continuous variables, and X^2 for categorical variables. *P* values were 2-sided, and *P* values < 0.05 were considered statistically significant **Follow-up:** No participants had tracheal or oesophageal perforation. Rates of blood-stained aspirates within the first 24 hours were included as a secondary outcome. No information on follow-up was provided beyond this
Participants	**Country:** Australia **Clinical setting:** delivery room and neonatal intensive care unit **Inclusion criteria:** Eligible participants were newborn infants in the delivery room or NICU requiring endotracheal intubation **Exclusion criteria:** Infants who were intubated for suctioning of meconium from the trachea were not eligible owing to the difficulty of confirming correct endotracheal tube (ET) placement **Age (weeks):** mean gestational age of participants: stylet = 28.5 (standard deviation (SD) 5.0); no stylet = 28.7 (SD 5.2) **Birth weight (grams):** stylet = 925 (interquartile ratio (IQR) 689 to 1473); no stylet = 862 (IQR 714 to 1586) **Gender:** male infants: stylet = 86 (SD 58); no stylet = 92 (SD 60) **Ethnicity:** not stated **Site of intubation:** delivery room (DR): stylet n = 72; no stylet n = 74; NICU: stylet n = 77; NICU n = 79 **Seniority of operator:** fellow: stylet 33 (SD 11); no stylet 41 (SD 14); resident: stylet 116 (SD 38); no stylet 112 (SD 37)

Interventions	**Intervention arm:** A stylet was used as an aid during orotracheal intubation of the newborn infant **Control arm:** orotracheal intubation of the newborn infant without the use of a stylet
Outcomes	**Primary outcome** Intubation success rates on first attempt with use of stylet vs non-use as indicated by detection of exhaled carbon dioxide **Secondary outcomes** • Duration of intubation attempt • Changes in heart rate and oxygen saturation from baseline • Presence of blood-stained secretions after the procedure
Notes	**Trial registration:** Australian and New Zealand Clinical Trials Register (ACTR identifier: 12607000186459)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Intervention was assigned by random sequence. Randomisation occurred in blocks of variable size stratified by site of intubation (delivery room (DR) or neonatal intensive care (NICU))
Allocation concealment (selection bias)	Low risk	Upcoming allocations were concealed from those involved in enrolment of the trial. Sequentially numbered sealed opaque envelopes contained computer-generated treatment groups, which the neonatal fellow on duty carried to the DR unopened to randomise the next eligible infant in the DR. Infants in the NICU were identifiable by a study label on the incubator
Blinding of participants and personnel (performance bias) All outcomes	High risk	Study was unblinded with regards to intervention allocation. Owing to the nature of the intervention, it was not possible to mask hospital staff or parents/guardians of the infant to the allocation status
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors of outcomes were unblinded to intervention allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for excluded infants (n = 481): intubated for meconium/before fellow arrived (n = 102); forgot/team thought inel-

		igible (n = 264); other reasons, e.g. emergencies, twins, nasal intubation, consultant intubation (n = 115). Eligible intubations that were excluded were accounted for and explained (n = 21). These were consented for prospective NICU intubations, but the team was unaware or had insufficient time owing to emergency intubation required
Selective reporting (reporting bias)	Low risk	Study protocol is available, and all prespecified primary and secondary outcomes have been reported in the prespecified way

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Fisher 1997	Prospective observational study
MacNab 1998	Comparison of lighted vs regular stylet - not of stylet vs no stylet
Shukry 2005	Non-experimental study: case report
Yamashita 2015	Randomised controlled trial comparing transillumination method vs main-stem method

DATA AND ANALYSES

Comparison 1. First intubation attempt success rate with use of stylet vs non-use of stylet

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 First intubation attempt success rate	1	302	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.88, 1.32]

Comparison 2. Intubation success: professional category

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Fellow: first intubation attempt success rate	1	74	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.69, 1.29]
2 Resident: first intubation attempt success rate	1	228	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.90, 1.52]

Comparison 3. Intubation success: use of premedication

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intubations without premedication given to the infant	1	146	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.72, 1.32]
2 Intubations following premedication given to the infant	1	156	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.89, 1.55]

Comparison 4. Intubation success: timing of intubation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intubations just after birth in the delivery room: first intubation attempt success rate	1	146	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.72, 1.32]

2 intubations following admission to NICU: first intubation attempt success rate	1	156	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.89, 1.55]

Comparison 5. Intubation success: weight at intubation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Weight < 1000 grams	1	152	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.67, 1.18]
2 Weight ≥ 1000 grams	1	150	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.97, 1.79]

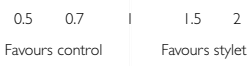
Analysis 1.1. Comparison 1 First intubation attempt success rate with use of stylet vs non-use of stylet, Outcome 1 First intubation attempt success rate.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 1 First intubation attempt success rate with use of stylet vs non-use of stylet

Outcome: 1 First intubation attempt success rate

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	85/149	81/153		100.0 %	1.08 [0.88, 1.32]
Total (95% CI)	**149**	**153**		**100.0 %**	**1.08 [0.88, 1.32]**
Total events: 85 (Stylet), 81 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.72 (P = 0.47)					
Test for subgroup differences: Not applicable					



Analysis 2.1. Comparison 2 Intubation success: professional category, Outcome 1 Fellow: first intubation attempt success rate.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 2 Intubation success: professional category

Outcome: 1 Fellow: first intubation attempt success rate

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	22/33	29/41		100.0 %	0.94 [0.69, 1.29]
Total (95% CI)	**33**	**41**		**100.0 %**	**0.94 [0.69, 1.29]**
Total events: 22 (Stylet), 29 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.37 (P = 0.71)					
Test for subgroup differences: Not applicable					

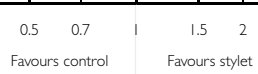
Analysis 2.2. Comparison 2 Intubation success: professional category, Outcome 2 Resident: first intubation attempt success rate.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 2 Intubation success: professional category

Outcome: 2 Resident: first intubation attempt success rate

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	63/116	52/112		100.0 %	1.17 [0.90, 1.52]
Total (95% CI)	**116**	**112**		**100.0 %**	**1.17 [0.90, 1.52]**
Total events: 63 (Stylet), 52 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.18 (P = 0.24)					
Test for subgroup differences: Not applicable					

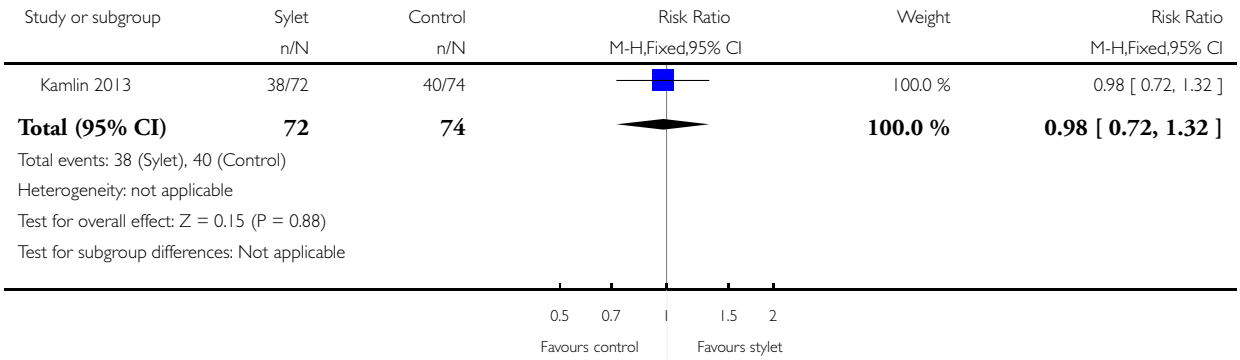


Analysis 3.1. Comparison 3 Intubation success: use of premedication, Outcome 1 Intubations without premedication given to the infant.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 3 Intubation success: use of premedication

Outcome: 1 Intubations without premedication given to the infant

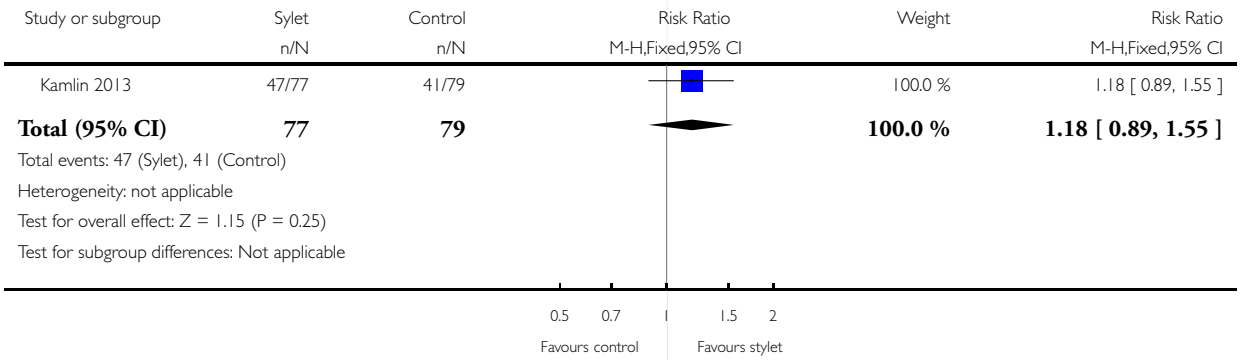


Analysis 3.2. Comparison 3 Intubation success: use of premedication, Outcome 2 Intubations following premedication given to the infant.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 3 Intubation success: use of premedication

Outcome: 2 Intubations following premedication given to the infant



Analysis 4.1. Comparison 4 Intubation success: timing of intubation, Outcome 1 Intubations just after birth in the delivery room: first intubation attempt success rate.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 4 Intubation success: timing of intubation

Outcome: 1 Intubations just after birth in the delivery room: first intubation attempt success rate

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	38/72	40/74		100.0 %	0.98 [0.72, 1.32]
Total (95% CI)	**72**	**74**		**100.0 %**	**0.98 [0.72, 1.32]**
Total events: 38 (Stylet), 40 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.15 (P = 0.88)					
Test for subgroup differences: Not applicable					

Analysis 4.2. Comparison 4 Intubation success: timing of intubation, Outcome 2 intubations following admission to NICU: first intubation attempt success rate.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 4 Intubation success: timing of intubation

Outcome: 2 intubations following admission to NICU: first intubation attempt success rate

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	47/77	41/79		100.0 %	1.18 [0.89, 1.55]
Total (95% CI)	**77**	**79**		**100.0 %**	**1.18 [0.89, 1.55]**
Total events: 47 (Stylet), 41 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.15 (P = 0.25)					
Test for subgroup differences: Not applicable					

Analysis 5.1. Comparison 5 Intubation success: weight at intubation, Outcome 1 Weight < 1000 grams.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 5 Intubation success: weight at intubation

Outcome: 1 Weight < 1000 grams

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	40/75	46/77		100.0 %	0.89 [0.67, 1.18]
Total (95% CI)	**75**	**77**		**100.0 %**	**0.89 [0.67, 1.18]**
Total events: 40 (Stylet), 46 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.79 (P = 0.43)					
Test for subgroup differences: Not applicable					

Analysis 5.2. Comparison 5 Intubation success: weight at intubation, Outcome 2 Weight ≥ 1000 grams.

Review: Orotracheal intubation in infants performed with a stylet versus without a stylet

Comparison: 5 Intubation success: weight at intubation

Outcome: 2 Weight ≥ 1000 grams

Study or subgroup	Stylet n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kamlin 2013	45/74	35/76		100.0 %	1.32 [0.97, 1.79]
Total (95% CI)	**74**	**76**		**100.0 %**	**1.32 [0.97, 1.79]**
Total events: 45 (Stylet), 35 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.79 (P = 0.073)					
Test for subgroup differences: Not applicable					

APPENDICES

Appendix 1. Standard search methods

MEDLINE: ((infant, newborn[MeSH] OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or infan* or neonat*) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh]))

Appendix 2. Risk of bias tool

We used the 'Risk of bias' table, which addresses the following questions.

Sequence generation (checking for possible selection bias). Was the allocation sequence adequately generated? For each included study, we categorised the method used to generate the allocation sequence as low risk (any truly random process, e.g. random number table; computer random number generator); unclear risk; or high risk (any non-random process, e.g. odd or even date of birth; hospital or clinic record number).

Allocation concealment (checking for possible selection bias). Was allocation adequately concealed? For each included study, we categorised the method used to conceal the allocation sequence as low risk (e.g. telephone or central randomisation; consecutively numbered, sealed, opaque envelopes); unclear risk; or high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth).

Blinding (checking for possible performance bias). Was knowledge of the allocated intervention adequately prevented during the study, at study entry, or at the time of outcome assessment? For each included study, we categorised the methods used to blind study participants and personnel from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes. We categorised the methods as low risk, high risk, or unclear risk for participants; low risk, high risk, or unclear risk for outcome assessors; low risk, high risk, or unclear risk for personnel.

Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). Were incomplete outcome data adequately addressed? For each included study, we described the completeness of data including attrition and exclusions from the analysis. We also noted reasons for attrition and exclusions if possible. We categorised the methods as low risk (< 20% missing data); unclear risk; or high risk ($\geq$ 20% missing data).

Selective reporting bias. Were reports of the study free of suggestion of selective outcome reporting? We planned to contact study authors, asking them to provide missing outcome data, when we suspected reporting bias. For each included study, we planned to describe how we investigated the possibility of selective outcome reporting bias. We planned to assess the methods as low risk (when it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported); unclear risk; or high risk (when not all of the study's prespecified outcomes have been reported).

Other sources of bias. Was the study apparently free of other problems that could put it at high risk of bias? For each included study, we described any important concerns we had about other possible sources of bias (e.g. whether a potential source of bias was related to the specific study design, whether the trial was stopped early owing to some data-dependent process). We also assessed whether each study was free of other problems that could put it at risk of bias as low risk; unclear risk; or high risk.

HISTORY

Date	Event	Description
19 November 2007	New citation required and major changes	We made substantive amendments

CONTRIBUTIONS OF AUTHORS

Joyce O'Shea: amended the protocol and co-wrote the review.

Jennifer O'Gorman: co-wrote the review.

Aakriti Gupta: wrote the first draft of the protocol.

Sanjay Sinhal: supervised the first draft of the protocol.

Jann Foster: contributed to the content of the review.

Liam O'Connell: contributed to the content of the review.

Camille Omar Farouk Kamlin: contributed to the content of the review.

Peter Davis: supervised development of the review.

DECLARATIONS OF INTEREST

Joyce O'Shea: nothing to declare.

Jennifer O'Gorman: nothing to declare.

Aakriti Gupta: nothing to declare.

Sanjay Sinhal: nothing to declare.

Jann Foster: nothing to declare.

Liam O'Connell: co-investigator on a trial that was eligible for inclusion in this review.

Camille Omar Farouk Kamlin: co-investigator on a trial that was eligible for inclusion in this review.

Peter Davis: co-investigator on a trial that was eligible for inclusion in this review.

SOURCES OF SUPPORT

Internal sources

- Royal Women's Hospital, Melbourne, Australia.
- University of Melbourne, Australia.

External sources

- National Health and Medical Reseach Council, Australia.
- Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, USA.

Editorial support of the Cochrane Neonatal Review Group has been funded by Federal funds from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, USA, under Contract No. HHSN275201600005C

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added the methods and plan for 'Summary of findings' tables and GRADE recommendations, which were not included in the original protocol. We added infant weight to the subgroup analysis.

INDEX TERMS

Medical Subject Headings (MeSH)

Gestational Age; Infant, Premature; Intensive Care Units, Neonatal [statistics & numerical data]; Intubation, Intratracheal [instrumentation; *methods; statistics & numerical data]; Pediatrics [statistics & numerical data]

MeSH check words

Humans; Infant; Infant, Newborn

Videolaryngoscopy to Teach Neonatal Intubation: A Randomized Trial

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abstract

BACKGROUND: Neonatal endotracheal intubation is a necessary skill. However, success rates among junior doctors have fallen to <50%, largely owing to declining opportunities to intubate. Videolaryngoscopy allows instructor and trainee to share the view of the pharynx. We compared intubations guided by an instructor watching a videolaryngoscope screen with the traditional method where the instructor does not have this view.

METHODS: A randomized, controlled trial at a tertiary neonatal center recruited newborns from February 2013 to May 2014. Eligible intubations were performed orally on infants without facial or airway anomalies, in the delivery room or neonatal intensive care, by doctors with <6 months' tertiary neonatal experience. Intubations were randomized to having the videolaryngoscope screen visible to the instructor or covered (control). The primary outcome was first-attempt intubation success rate confirmed by colorimetric detection of expired carbon dioxide.

RESULTS: Two hundred six first-attempt intubations were analyzed. Median (interquartile range) infant gestation was 29 (27 to 32) weeks, and weight was 1142 (816 to 1750) g. The success rate when the instructor was able to view the videolaryngoscope screen was 66% (69/104) compared with 41% (42/102) when the screen was covered ($P < .001$, OR 2.81, 95% CI 1.54 to 5.17). When premedication was used, the success rate in the intervention group was 72% (56/78) compared with 44% (35/79) in the control group ($P < .001$, OR 3.2, 95% CI 1.6 to 6.6).

CONCLUSIONS: Intubation success rates of inexperienced neonatal trainees significantly improved when the instructor was able to share their view on a videolaryngoscope screen.

WHAT'S KNOWN ON THIS SUBJECT: Endotracheal intubation is a mandatory skill for neonatal trainees. It is a difficult skill to acquire, and success rates of junior doctors are low and falling.

WHAT THIS STUDY ADDS: Videolaryngoscopy allows the supervisor to share the intubator's view of the airway and provide more informed guidance. Teaching intubation using a videolaryngoscope with the screen visible to the instructor results in significantly higher success rates for inexperienced doctors.

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Drs O'Shea and John designed the study with the assistance of Drs Kamlin and Thio and Profs Kuschel and Davis; data collection was completed by Drs O'Shea, Thio, Kamlin, McGrory, John, and Roberts and Ms Wong; Drs O'Shea and Thio and Ms Wong analyzed the data; Dr O'Shea prepared the first draft of the manuscript; and all authors contributed to the editing process and approved the final draft.

This trial is registered with Australian New Zealand Clinical Trials Registry, no. 12613000159752.

www.pediatrics.org/cgi/doi/10.1542/peds.2015-1028

DOI: 10.1542/peds.2015-1028

Accepted for publication Aug 26, 2015

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Endotracheal intubation is a common, potentially life-saving intervention for newborn infants with respiratory failure.[1] Intubation is a necessary skill for pediatric and neonatal trainees; however, it is a difficult skill to learn and maintain, and initial attempts are often unsuccessful.[2–9] Reported first-attempt success rates of intubators with variable experience are 44% to 73%, and residents have the lowest success rates of 20% to 63%.[2–9] Three recent studies report success by residents in <25% of attempts.[2,3,5] With increasing use of noninvasive respiratory support,[10] reductions in trainees' working hours,[11] increasing numbers of trainees, and changes in clinical recommendations, such as discontinuing routine intubation of infants delivered through meconium-stained liquor,[1] there are fewer opportunities for neonatal trainees to acquire and maintain proficiency, and their success rates are consequently falling.[4]

Strategies have been developed to compensate for the reduction in clinical experience. A meta-analysis of studies of technology-enhanced simulation to teach adult intubation showed that this method was superior to no intervention.[12] However, studies using simulation to teach neonatal and pediatric intubation have not demonstrated improved clinical performance.[13,14] Animal models and cadaveric specimens are useful to demonstrate the anatomy but are very expensive and have limited availability.[15]

Successful intubation relies on the intubator being able to perform laryngoscopy to obtain a view of the infant's airway and then recognize the anatomy displayed. Many novice intubators initially find this very challenging. Intubation instruction has traditionally relied on an apprenticeship model, in which a more experienced colleague supervises the novice. However, the instructor's ability to provide guidance is limited by restricted access to the trainee's view of the airway (Fig 1). Videolaryngoscopy offers a potential solution to this problem. Videolaryngoscopes use camera technology to visualize airway structures and facilitate endotracheal intubation. A recent systematic review found that insufficient evidence exists to recommend or refute the use of videolaryngoscopy for endotracheal intubation in neonates and called for randomized controlled studies to address efficacy and safety.[16] The aim of this study was to determine if supervision using a modified traditional Miller videolaryngoscope improves pediatric residents' first-attempt neonatal intubation success rates.

METHODS

Patients and Study Design

This single-center, unblinded, randomized controlled trial was conducted from February 26, 2013, to May 26, 2014 at the Royal Women's Hospital, Melbourne, Australia, a tertiary perinatal center with ~7500 births and 300 infants <1500 g admitted to the NICU per year. Infants were eligible if they needed intubation and the intervention was going to be performed orally by a pediatric resident in their first 6 months of tertiary neonatal training. At the start of their neonatal rotation, all residents received intubation training, including practice on neonatal manikins. Their participation in the study was voluntary, and prior verbal informed consent was obtained. The need for intubation was determined by the clinical team and occurred either during resuscitation after birth or in the NICU. Infants were excluded if they had a facial, oral, or airway anomaly or were intubated nasally. The study was approved by the Royal Women's Hospital research and ethics committees.

Prospective written consent by the infants' parents or guardians was obtained whenever possible. If delivery was imminent, or the mother was in active labor or was recovering from the birth, it was considered inappropriate to approach before the intubation. Therefore, for infants <48 hours of age, when prospective consent was not possible, a deferral of consent was used as per the Australian National Health and Medical Research Council guidelines for studies in emergency medicine.[17] The intubation was randomized, and retrospective consent to use data was obtained as soon as possible after the event. Consent was also requested to randomize further intubations if required. The process of deferred consent was approved by the Royal Women's Hospital Ethics Committee.

All intubations were performed by using a modified traditional Miller videolaryngoscope (LaryFlex, Acutronics, Hirzel, Switzerland). A flexible fiber-optic cable threaded through the laryngoscope transmitted images from the blade tip to a nearby monitor. Two trolleys containing the videolaryngoscope system were kept within the NICU and the delivery suite. Intubation was performed after direct laryngoscopy with an additional view displayed on a computer-sized monitor (Fig 1). Reusable Miller blades sizes 1, 0, and 00 were used for term infants, preterm infants >1 kg, and infants <1 kg, respectively. The blades and fiber-optic cables were sterilized before each use and kept in sterile, sealed trays.

Premedication with fentanyl, atropine, and suxamethonium was used for elective intubations. A Neopuff Infant Resuscitator (Fisher & Paykel, Auckland, New Zealand) T-Piece was used to provide ventilation. Intubations were performed using sterile, single-use, uniform internal diameter, plastic endotracheal tubes (Mallinckrodt Medical, Athlone, Ireland). A stylet (Satin Slip intubation style, Mallinckrodt Medical) was available to stiffen the endotracheal tube at the resident's request. Endotracheal tube placement was

FIGURE 1
The supervisor cannot share the view of the infant's airway with the trainee. Videolaryngoscopy offers a solution to this problem.

confirmed by a colorimetric exhaled carbon dioxide detector (Pedicap, Nellcor Puritan Bennett, Pleasanton, CA). Chest radiograph was performed to define tube position.

Randomization

A computer-generated, variable-size block-randomization sequence was used. Allocation was stratified by the use of premedication (yes or no). Sequentially numbered opaque envelopes containing the randomization cards were kept on the videolaryngoscope trolleys. If an intubation was anticipated by the clinical team, the research team was notified and the equipment was set up. If this subsequently led to an intubation attempt by an eligible doctor, a randomization envelope was opened just before the intubation attempt. The unit of randomization was the endotracheal intubation. Infants reintubated subsequently were eligible for randomization again. However, only the first intubation attempt on each date was eligible for inclusion.

Study Intervention

Attempts were supervised by 1 of 6 study investigators (Dr O'Shea, Dr Thio, Dr Kamlin, Dr McGrory, Dr John, and Dr Roberts). All 6 were trained to use the equipment, were shown several intubation recordings, and observed $\geq$3 supervised videolaryngoscopic intubations before supervising an intubation attempt. In the intervention group, the instructor was able to see the videolaryngoscope screen and offer verbal assistance during the intubation attempt (Fig 2). In the control group, the instructor offered verbal assistance but did not have access to images on the screen. The videolaryngoscope kept in the NICU had an attached laptop with the capacity to record images from the videolaryngoscope screen. Both intervention and control intubations in the premedication stratum were recorded. A standardized proforma on how to guide the intubation attempts was agreed on by all study investigators before study commencement (Fig 3).

A senior clinician who was not a member of the research team attended the intubation and decided when to terminate an unsuccessful attempt. Criteria to stop an attempt included falling heart rate, hypoxia with oxygen saturations $<$70%, attempt of $>$60 seconds' duration, or the attending clinician's discretion. Standardized debriefing was offered as soon as possible after the attempt. Residents were shown the video of the attempt (if recorded) and were encouraged to reflect on the positive and negative aspects of the attempt. The instructor then advised on what was done well and what could be improved. Residents were then allowed to watch the video again if they wished.

Study Outcomes

The primary outcome was first-attempt intubation success rate. Secondary outcomes included the infant's lowest heart rate and oxygen saturation and duration of the attempt (defined as the time interval from insertion of the laryngoscope blade into the infant's mouth until its removal). An independent data safety monitoring committee reviewed study outcomes after 100 intubations.

Statistical Analysis

On the assumption of an incidence of 50% for the primary outcome,[7] we needed 103 infants in each group to have a statistical power of 80% to detect a 20% absolute reduction in the risk of failure of intubation. All analyses were performed on an intent-to-treat basis. Data were analyzed by using Stata software (Intercooled 13, Stata Corp, College Station, TX). The data are presented as mean (SD) for normally distributed variables and median (interquartile range) when the distribution was

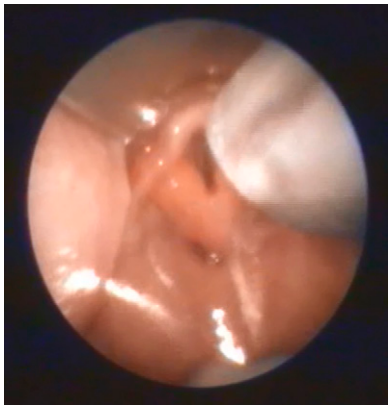

FIGURE 2
Still image from the videolaryngoscope screen.

Beforehand

- Clinician talked through intubation technique with emphasis on:
  - Head position
  - Need to open the baby's mouth and avoid injuring upper gum
  - Tube to be passed in from the side not down the blade of the laryngoscope
  - No need to suction routinely, try to get view first
  - For premedicated infants, clinician can be reassured that the infant is anesthetized and is not going to be in pain during attempt

During intubation

- Check correct head position and need for neck/shoulder roll to have the airway in the optimal position shown below.

- If the clinician is struggling to open the mouth, please help them.
- Guide them to insert the laryngoscope into the mouth above the tongue and avoiding the upper gum.
- Reassure that baby is anesthetised (if premeds have been given).
- Instructor's hand on infant's neck should be able to feel laryngoscope when it is correctly positioned +/– give cricoid pressure if necessary.
- Guide them through the advancement of the laryngoscope and insertion of the tube
  - Direct to keep them midline
  - Advise them when to lift the scope to reveal the airway
  - If laryngoscope has gone off midline or advanced too far or not far enough, talk them through how to correct this
  - Advise if suction is necessary
  - Hand them ET tube and advise them to pass it in from the side
  - Pull back infant's upper lip if necessary to give them more room to insert and guide tube
  - If heading toward esophagus, stop and redirect
  - If tube catching at the vocal cords, advise them to straighten up and decrease the angle or twist the tube gently
  - Stop them once ETT tip advanced past black marking
  - Remind them to not let go of the ETT when removing the scope

FIGURE 3
Proforma used to guide intubation attempts.

skewed. The clinical characteristics and outcome variables were analyzed by using χ^2 test, t test, and Mann-Whitney U test as appropriate. The results were adjusted for clustering by operator. P values were 2-sided, and values <0.05 were considered statistically significant.

RESULTS

Study Patients

Two hundred thirteen intubations in 168 infants (median 1 intubation per infant, range 1 to 4) were randomized during the study period, and 206 were included for analysis (104 screen visible and 102 screen covered) (Fig 4).

Demographic details of the infants are provided in Table 1. At the time of inclusion, 43% of infants weighed <1 kg. Study intubations were performed by 36 residents. They performed a median of 7 randomized intubations each, range 2 to 11. Details of the residents' previous intubation experience are provided in Table 2. Images from the videolaryngoscope screen were recorded for 125 intubations (79.6% of premedicated intubations, 60.7% of total study cohort).

Primary Outcome

The first-attempt intubation success rate when the instructor was able to watch the videolaryngoscope screen was 66% (69/104) compared with 41% (42/102) when the screen was covered: unadjusted odds ratio (OR) 2.81 (95% confidence interval [CI] 1.54–5.17), $P < .001$; adjusted OR 2.82 (95% CI 1.44–5.52) (adjusted for clustering by resident). When premedication was given, the success rate in the intervention group was 72% (56/78) compared with 44% (35/79) in the control group: OR 3.2 (95% CI 1.6–6.6), $P < .001$. When no premedication was given, success rates in the intervention and control groups were 50% (13/26) and 30% (7/23), respectively: OR 2.3 (95% CI 0.6–8.8), $P = .164$. Success rates stratified by level of experience of the resident are presented in Table 3.

Secondary Outcomes

Secondary outcomes are presented in Table 4. There were no significant differences in rates of hypoxia or bradycardia or in the duration of the attempt between the intervention and control groups.

DISCUSSION

The intubation success rates of pediatric residents using direct laryngoscopy improved significantly when an instructor was able to provide guidance based on the shared view of the upper airway. This result was achieved without evidence of harm, as this finding was not associated with increased hypoxia, bradycardia, or a longer duration of intubation attempt.

This is the first study to use a videolaryngoscope to assist junior doctors learning the skills of direct laryngoscopy and intubation in neonates. Infants of a wide range of gestational ages and weights were

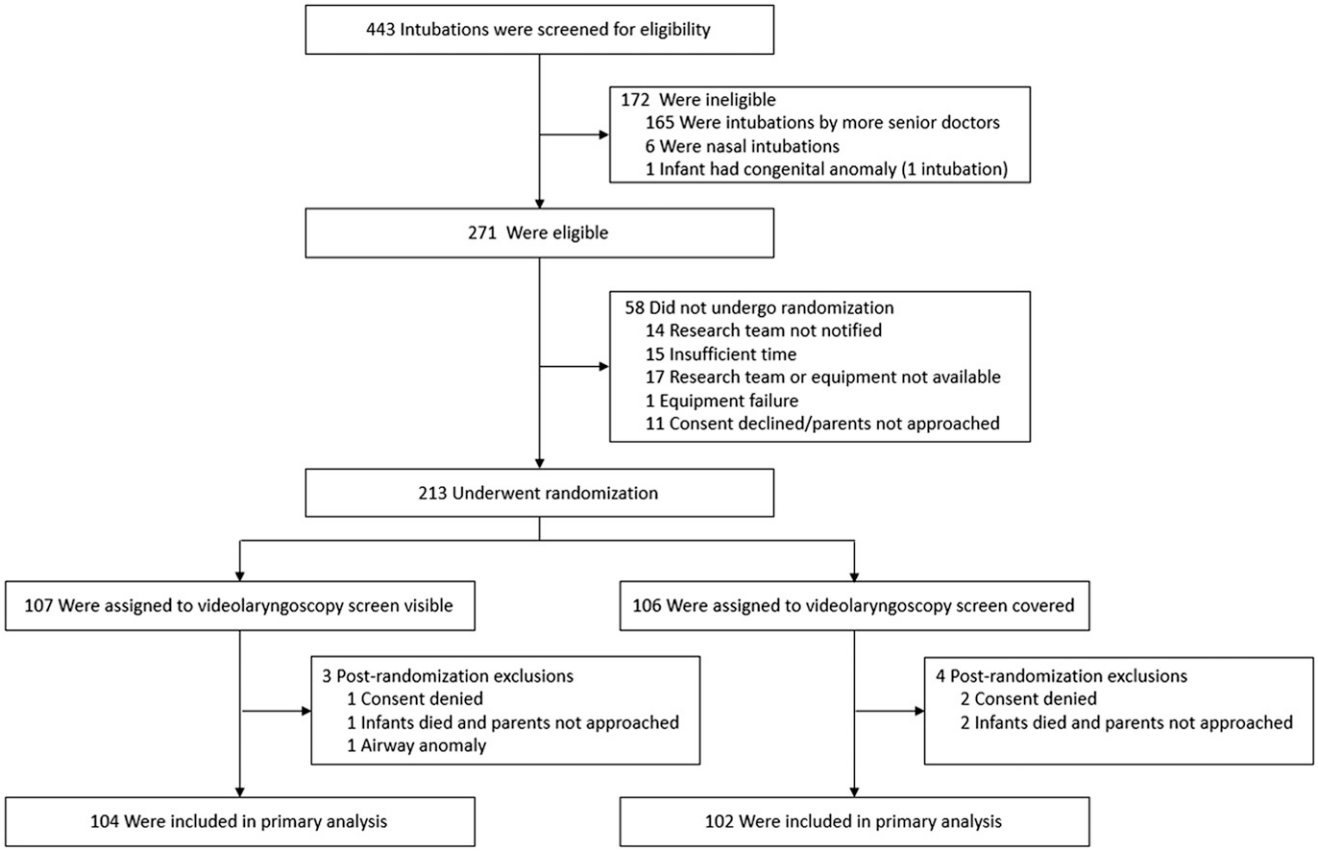

FIGURE 4
Enrollment and outcomes.

included. Extremely low birth weight infants were well represented. Both elective (premedicated) and emergency (nonpremedicated) intubations were included. Intubations were individually randomized, thereby reducing selection bias, and a high percentage of all eligible intubations were included (76%). This technique is relevant to other professionals involved in neonatal resuscitation and airway management (eg, respiratory therapists) and could also be used to facilitate training in pediatric and adult intubation.

Videolaryngoscopes have been available for >10 years[18] and are now an established tool for acute airway management.[19–21] The videolaryngoscope screen displays an improved, magnified, wider laryngeal view (Fig 2) compared with direct laryngoscopy.[22] Previously, this technique has typically involved the intubator performing videolaryngoscopy looking at the screen during an intubation attempt rather than performing direct laryngoscopy looking in the patient's mouth. Experienced intubators' success rates using videolaryngoscopy in this manner compared with direct laryngoscopy are as high or slightly higher in patients with normal airways,[23–25] and significantly higher in patients with anticipated difficult airways.[20,26,27] Inexperienced intubators using videolaryngoscopes compared with laryngoscopes had greater success intubating healthy adults with normal airways.[28]

However, learning to intubate using videolaryngoscopy may not translate

TABLE 1 Demographic Details of the Infants

Characteristic	Intervention Group	Control Group	*P*
n	104	102	
Birth weight (g)	1091 (795–1799)	1027 (757–1562)	.3
Gestation (wk)	28 (26–32)	28 (26–30)	.5
Weight at time of intubation (g)	1173 (819–1884)	1125 (816–1569)	.35
Corrected gestation (wk)	29 (27–32)	29 (27–32)	.82
Five-min Apgar score	8 (6–9)	8 (6–9)	.67
Indication for intubation			
Respiratory failure	62 (60)	61 (60)	.98
Resuscitation	26 (25)	23 (23)	.68
Apnea	10 (10)	12 (12)	.62
Other	6 (6)	6 (6)	.97
First intubation for infant	69 (66)	61 (60)	.33
Given premedication	78 (75)	79 (77)	.84

Values are expressed as median (interquartile range) or *n* (%).

TABLE 2 Details of Residents' Previous Intubation Experience at Time of Randomization

Previous Successful Intubations	Intervention Group	Control Group
0	17 (16)	25 (25)
1–2	33 (32)	27 (26)
3–5	33 (32)	24 (24)
6–9	14 (13)	19 (19)
≥10	7 (7)	7 (7)

Values are expressed as *n* (%).

into the same ability using a traditional laryngoscope. Videolaryngoscopes take time to set up, need maintenance, and are expensive. Therefore, proficiency needs to be achieved at intubation using direct laryngoscopy. There is only 1 previous randomized study in which the intubator performed direct laryngoscopy and the instructor was either able to see the images on the screen or not, a crossover study performed by Howard-Quijano et al.[29] Intubations were randomized in blocks of 6 to either 3 with the screen visible to the instructor followed by 3 with the screen covered or the order reversed. The 6 intubations occurred over several days. There were 37 intubators, medical students or nonanesthetic trainees, all with <6 previous intubation attempts. All intubations were performed on healthy adults with normal airways. The instructors were anesthesiologists trained to teach intubation and use the equipment. The success rate was significantly higher when the instructor was able to see the screen (69% compared with 55%, $P = .04$).[29]

TABLE 3 Details of Residents' Success Rates for Each Experience Category

Previous successful intubations	Intervention Group Success rate (%)	Control Group Success rate (%)
0	7/18 (39%)	7/24 (29%)
1–2	24/32 (75%)	12/28 (43%)
3–5	22/32 (69%)	11/24 (46%)
6–9	9/15 (60%)	9/19 (47%)
≥10	7/7 (100%)	3/7 (43%)

Values are expressed as number of successful intubations/total number of intubations (%).

Videolaryngoscopes vary in style from modified traditional Miller or Macintosh laryngoscopes to devices with a short angulated blade and guide channel. Our hope was that the resident's experience performing laryngoscopy with the videolaryngoscope would be comparable to standard direct laryngoscopy so that the skill they learned could translate to standard practice. To achieve this, ideally the laryngoscope handle and blades would be comparable. Several Miller neonatal laryngoscope blades are available.[30] They have subtle differences in size and shape but are straight and mostly either flat bottomed or with a slight midline trough.[31] We chose the Laryflex videolaryngoscope for the study because it can be used for direct laryngoscopy as well as videolaryngoscopy and its blades most closely resemble commonly used neonatal laryngoscope blades. The blade is straight until a slight downward slope near the tip, and the midline trough is deeper. This necessitates the endotracheal tube curling around a relatively higher lip of the blade to approach the larynx, which is held in a slightly different position. It is possible that these subtle differences could limit translation of the results from our study to standard direct neonatal laryngoscopy. These findings may encourage manufacturers to minimize differences between blades. The device used in this study had a free-standing monitor that was placed alongside the infant's incubator. This resulted in the instructor looking at the infant while the blade was introduced in the mouth, and then looking away from the infant to see the screen. Other videolaryngoscopes link to smaller screens that can be placed closer to the patient, allowing the instructor to watch the images and the trainee intubating simultaneously. Future devices may improve this design, for example linking wirelessly to a handheld tablet or smartphone.

This study did not assess whether the improved rate of successful intubation when using a videolaryngoscope resulted in retention of the skill when the operator was unassisted. However, recent work by Moussa et al showed that success rates of residents who learned intubation using videolaryngoscopy were maintained when they converted to classic laryngoscopy.[32]

We found higher success rates when the infant was given premedication beforehand. This is consistent with previous studies that have shown that premedication improves intubating conditions, reduces the number of attempts, and decreases the risk of airway trauma.[33–38] It has been previously reported that inexperienced intubators have longer attempt durations than their more experienced colleagues.[5–7] The intubation durations reported in this study are similar to those of other studies.[6,7] We used a standardized approach to providing instruction and feedback both during and after an attempt. Intubation instruction using traditional methods is challenging in that the instructor's ability to offer feedback during the attempt is limited. The intervention in this study allowed the instructor to provide accurate, precise, concurrent instruction and feedback during an attempt. This allowed for informed guidance but also quick correction of errors and positive reinforcement of what was being done correctly. As part of a standardized debrief after the intubation, the residents watched video recordings of most of their attempts (both control and intervention intubations). This may have reinforced what they did well and helped explain an unsuccessful attempt. This method was received favorably by the residents and is likely to have contributed to the high success rates found in this study.

TABLE 4 Secondary Outcomes

Outcome	Intervention Group	Control Group	*P*
n	104	102	
Lowest oxygen saturation (%)	70 (48–83)	69 (46–82)	.88
Lowest heart rate (bpm)	150 (135–164)	151 (139–162)	.99
Duration (s)	51 (39–63)	53 (41–70)	.15

Values are expressed as median (interquartile range).

There are limitations to this study. Only 1 of a number of available videolaryngoscopes was tested. Results using other devices may differ. The number of instructors was limited to a small core group who were trained to supervise according to specific guidelines. Instructors with less training may be less successful in supervising inexperienced residents.

Currently, pediatric residents and neonatal fellows learning intubation face the challenge of reduced opportunity to practice. A US study found that from 1994 to 2002, the number of intubating opportunities per resident decreased by more than two-thirds, and success rates almost halved.[4] The anesthesia literature suggests that ≥40 intubations are necessary to become proficient (defined as success rates of ≥80%).[39,40] It is becoming increasingly challenging for trainees to log high numbers of intubation attempts. However, the technique described in this study may enable trainees to become proficient faster. The intervention described in this study has produced the highest reported success rate for novice neonatal intubators. This method, which allows the instructor to share the view of the trainee, may offer a solution to the low and falling intubation success rates of neonatal trainees.

ACKNOWLEDGMENTS

We thank the infants, their parents, and the residents for their participation in the study. We also thank the nursing, medical, and research staff at the Royal Women's Hospital and the members of the Data Safety Monitoring Committee. Finally, we thank In Vitro Technologies and Acutronics AG for their generous lease of the videolaryngoscope for its use during the trial.

ABBREVIATIONS

CI: confidence interval
OR: odds ratio

FINANCIAL DISCLOSURE: In Vitro Technologies provided a videolaryngoscope for the duration of the study but had no part in study design or data analysis. The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Funded by The Royal Women's Hospital, Melbourne, Australia, and the Australian National Health and Medical Research Council Program (grant 606789).

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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Videolaryngoscopy to Teach Neonatal Intubation: A Randomized Trial

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Pediatrics 2015;136;912; originally published online October 19, 2015;
DOI: 10.1542/peds.2015-1028

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ADC-FNN Online First, published on November 21, 2017 as 10.1136/archdischild-2017-313628

Analysis of unsuccessful intubations in neonates using videolaryngoscopy recordings

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/archdischild-2017-313628).

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Received 27 June 2017
Revised 29 September 2017
Accepted 10 October 2017

To cite: O'Shea JE, Loganathan P, Thio M, *et al*. *Arch Dis Child Fetal Neonatal Ed* Published Online First: [*please include* Day Month Year]. doi:10.1136/archdischild-2017-313628

ABSTRACT

Objectives Neonatal intubation is a difficult skill to learn and teach. If an attempt is unsuccessful, the intubator and instructor often cannot explain why. This study aims to review videolaryngoscopy recordings of unsuccessful intubations and explain the reasons why attempts were not successful.

Study design This is a descriptive study examining videolaryngoscopy recordings obtained from a randomised controlled trial that evaluated if neonatal intubation success rates of inexperienced trainees were superior if they used a videolaryngoscope compared with a laryngoscope. All recorded unsuccessful intubations were included and reviewed independently by two reviewers blinded to study group. Their assessment was correlated with the intubator's perception as reported in a postintubation questionnaire. The Cormack-Lehane classification system was used for objective assessment of laryngeal view.

Results Recordings and questionnaires from 45 unsuccessful intubations were included (15 intervention and 30 control). The most common reasons for an unsuccessful attempt were oesophageal intubation and failure to recognise the anatomy. In 36 (80%) of intubations, an intubatable view was achieved but was then either lost, not recognised or there was an apparent inability to correctly direct the endotracheal tube. Suctioning was commonly performed but rarely improved the view.

Conclusions Lack of intubation success was most commonly due to failure to recognise midline anatomical structures. Trainees need to be taught to recognise the uvula and epiglottis and use these landmarks to guide intubation. Excessive secretions are rarely a factor in elective and premedicated intubations, and routine suctioning should be discouraged. Better blade design may make it easier to direct the tube through the vocal cords.

What is already known on this topic?

- Intubation is a difficult skill to learn and teach.
- Endotracheal intubation is a mandatory skill for neonatal trainees.
- Currently, if an attempt is unsuccessful, the intubator and their supervisor often do not know why.

What this study adds?

- Lack of success was most commonly due to failure to recognise anatomical structures.
- Excessive secretions in elective intubations are rarely a factor and routine suctioning should be discouraged.

INTRODUCTION

Endotracheal intubation is a life-saving procedure in the neonatal intensive care unit (NICU). It is a mandatory competency for general paediatric trainees by the Royal College of Paediatrics and Child Health.[1] Intubation skills are difficult to acquire. Reported success rates of intubators are between 20% and 73% and inexperienced intubators have the lowest success rates.[2–9] Increased reliance on non-invasive ventilation and discontinuation of routine intubation of infants born through meconium-stained liquor has led to a reduction in the number of neonates being intubated. This, coupled with increasing numbers of trainees and reduction in trainee working hours, increases the difficulty of achieving proficiency. Success rates also appear to be falling. Three recent studies report success in less than 25% of attempts.[2 3 5] Endotracheal intubation is associated with a high rate of complications. In a prospective study, adverse events occurred in 39% of intubations and serious adverse events in 9%.[10]

Neonatal intubation is generally taught using an apprenticeship model where the trainee observes and then later attempts the procedure while supervised. One of the challenges is that the trainer is not able to share the trainee's view during laryngoscopy. Therefore if an attempt is unsuccessful, it is often difficult for the trainer to understand why and to provide constructive feedback. Videolaryngoscopy allows the intubator and the trainer to share the view, and has been shown in a recent randomised controlled trial (RCT) to improve intubation success rates.[11] Recording images also allows for review after an attempt.

The objectives of this study were to review videolaryngoscopy recordings of unsuccessful intubations and identify why the attempt failed, and also to compare this with the reasons reported by the intubators.

METHODS

Settings and practice

This is a descriptive study using data obtained from an RCT evaluating videolaryngoscopy for neonatal intubation.[11] The study was conducted from February 2013 to May 2014 at the Royal Women's

Hospital, Melbourne, Australia, a tertiary perinatal centre with ~7500 births and 300 infants with birth weights less than 1500 g admitted annually to the NICU. Included intubations were those performed orally on infants without facial or airway anomalies by a paediatric trainee with less than 6 months of tertiary neonatal experience. Premedication with fentanyl, atropine and suxamethonium was used for elective intubations and the use of a stylet was routine. The attending clinician, not in the research team, decided what intubations could be performed by trainees with limited experience. The primary outcome was the first attempt intubation success rate.

Study intervention

All intubations were performed using a videolaryngoscope (LaryFlex, Acutronic, Hirzel, Switzerland). This is a modified traditional Miller laryngoscope that contains a fibreoptic cable whose tip replaces the bulb and transmits images from the blade tip to a nearby monitor. To enable recording, a MacBook Pro was connected to the videolaryngoscope and video images were recorded with VideoGlide for Mac (EchoFX, Duluth, Georgia, USA). It took a few minutes to enable recording, so if there were time constraints, this step was left out. Intubations in the delivery room were not recorded.

The trainee performed direct laryngoscopy and did not look at the video screen. Intubations were randomised to the video screen being visible to the instructor (intervention group) or covered (control group). The supervisor guided the intubations in a standardised way; this included helping to optimise the position of the infant.[11] The view on the screen was similar to the direct view, differing only in being wider and magnified. A senior clinician who was not a member of the research team determined when to stop the intubation attempt, based on preset clinical criteria. Each intubation was followed by debriefing and feedback. The trainees also completed a questionnaire that included a list of reasons for unsuccessful intubation that had been compiled by the authors (JEOS, COFK, MT, PGD). The questionnaire was piloted before the RCT on neonatal trainees not participating in the trial and adjusted following their feedback. The reasons for unsuccessful attempts listed on the questionnaire used during the RCT included the following: (1) an inability to advance the laryngoscope beyond the lips, tongue or oral cavity; (2) an inability to visualise the vocal cords; (3) too many secretions or inadequate suction; (4) a poorly positioned infant; (5) the oesophagus was intubated; (6) the infant became clinically unstable and therefore the procedure was abandoned; and (7) other reasons. More than one reason could be selected if appropriate.

Analysis of videolaryngoscopy recordings

Videos of unsuccessful intubations were included in this study. As delivery room intubations were not recorded, all intubations in this study were elective and premedicated. Both intervention and control videos are included but described separately. The control videos are representative of a real-world situation. The intervention videos are presented to explore whether using this technique changed the reasons why an attempt was unsuccessful. Only the first intubation attempt was included in this study.

Two reviewers (JEOS and PL) independently reviewed all the videos blinded to study group. Before assessing the videos, the reviewers developed a list of potential reasons for failure of intubation. The agreed list included the following: (1) an inability to advance the laryngoscope beyond the oral cavity, (2) successfully advancing beyond the oral cavity but unable to achieve an intubatable view, (3) excessive secretions, (4) oesophageal intubation, (5) failure to or delay in recognising the vocal cords, (6) inability to correctly direct the ETT despite having an intubatable view and (7) successful intubation followed by accidental extubation. As the infant's position and clinical condition could not be seen on the recordings, these were not included. The reasons did not need to be mutually exclusive. Failure to or delay in recognising the vocal cords was defined as the trainee obtaining an intubatable view but either not attempting to place the ETT or attempted placement delayed 15 s or more. Inability to direct the ETT was used to describe when an intubatable view was obtained and the operator repeatedly attempted to pass the ETT but could not direct it through the vocal cords. Excessive secretions were listed as a reason when secretions blocked the view and were not cleared by the resident. When the operator performed suction but clearly had the laryngoscope misplaced, secretions were not felt to be contributory. It was possible that more than one reason contributed to failure of the attempt. Interobserver agreement between the two reviewers was assessed. Discrepancies were resolved by discussion. The final reviewers' decision was compared with the trainee's perception as reported in the postintubation questionnaire.

To objectively describe the view of the infant's airway, the reviewers also graded the best view of the infant's larynx achieved and the view visible during the endotracheal tube insertion using the Cormack-Lehane (C-L) classification system.[12] This system was described in 1984 as a way of simulating potential scenarios that trainee anaesthetists might face. Grade 1 describes a full view of the glottis being achievable. Grade 2 refers to a partial glottic view being visible. Grade 3 is when the epiglottis but not the glottic opening can be seen, and grade 4 is when neither glottis nor epiglottis is seen. This classification system for assessment of laryngeal view was used as this system was designed for beginners,[13] simple to use and used commonly in paediatric research.[14] For the purposes of this study, an intubatable view was defined as a C-L grade 1 or 2 view during the intubation attempt. Infants with facial or airway anomalies were excluded; therefore, it is reasonable to expect that an experienced intubator would have achieved an intubatable view in all of these infants.

Data analysis and statistics

Descriptive statistics for population characteristics are presented. Categorical variables are presented as proportions and 95% CIs, while numerical variables are presented as mean (SD) for normally distributed data or median (IQR) for skewed data. Fisher's exact test, Student's t-test and Mann-Whitney U test were used as appropriate. p Values of <0.05 were considered statistically significant.

Outcome for agreement between the trainee and the reviewer was nominal (yes/no agreement). Interobserver variability was determined using nominal kappa statistics with bootstrapped bias and corrected 95% CIs. Kappa values can be classified as follows: below 0=poor, 0–0.20=slight, 0.21–0.4=fair, 0.41–0.6=moderate, 0.61–0.8=substantial and 0.81–1=almost perfect. The STROBE checklist for reporting observational studies was used.

RESULTS

Intubations were performed by 36 trainees who performed a median of 7 each (range 2–11). Questionnaires were completed after all intubations (100% response rate). Forty-five unsuccessful intubations were recorded and included in this study: 30

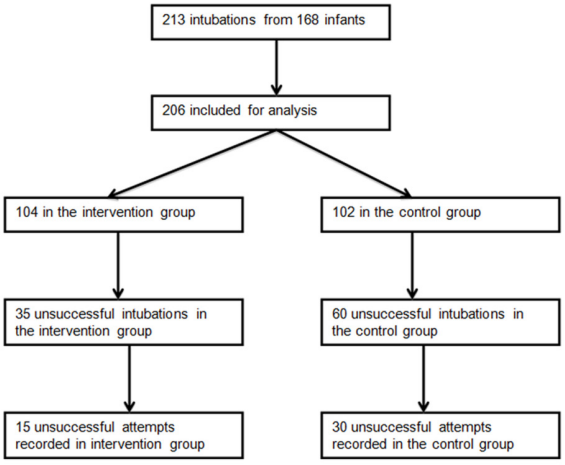

Figure 1 Study flow diagram.

control and 15 intervention (figure 1). All included intubations were premedicated and elective intubations. Baseline characteristics of infants and trainees are presented in table 1.

The results are described in table 2, and the best view classification and classification while attempting to pass ETT are described in table 3. In the control group, an intubatable view was achieved in 23 attempts (77%). A further three (10%) achieved a view of the epiglottis but apparently did not recognise it as a landmark to help find the vocal cords. One trainee (4%) lost the view when trying to insert the ETT (see online supplementary video 1), and in another eight (35%) attempts the grade of the view obtained worsened when the trainees' attention was directed at passing the ETT (table 3). In nine attempts (30%) the trainee had no or delayed recognition that they had a view of the larynx; in four of these attempts, there was no effort to pass the ETT, and in the other five the attempt was delayed and unsure (see online supplementary video 2). There were 14 (47%) oesophageal intubations (see online supplementary video 3); 9 of these were despite an intubatable view. In 10 (33%) attempts it was apparent that the trainee was trying to direct the ETT towards the vocal cords but was unable to direct the ETT through the cords (see online supplementary video 4). During eight (27%) attempts, the infant's tongue was to the right of the laryngoscope blade and may have been an obstacle to inserting the ETT. However, in only three of these attempts did the trainee report that they could not direct the tube. Suctioning was performed in 11 control intubations. However in nine (82%), excessive secretions were not apparent and suctioning did not improve the view. The duration of suctioning ranged from 3 to 16 s (mean 8 s). One (3%) intubation attempt was successful but then accidentally dislodged while securing the tube.

In 86% of the intervention group attempts, an intubatable view was achieved. No trainee lost the view while inserting the tube, and in two (13%) attempts the grade of the view worsened when trying to insert the tube (table 3). Inability to direct the ETT was the most commonly reported reason for attempt failure and seen in 60% of attempts. During three attempts, suction was performed; in two of these, excessive secretions were blocking the view.

In the majority of the videos, there is substantial (60%–80%) or almost perfect (>80%) inter-rater agreement between the two investigators and between the investigators and the trainees (table 4). Trainees correctly identified when they could not advance beyond the oral cavity (kappa 1.0), could not achieve an intubatable view (kappa 1.0) or were hampered by excessive secretions (kappa 1.0). Trainees were less certain when they had intubated the oesophagus (kappa 0.60 (95% CI 0.36 to 0.85)).

Table 1 Baseline characteristics of the study population

Characteristics	Control group (n=30)	Intervention group (n=15)
Infant characteristics		
Mean gestational age (SD), weeks	28.6 (4.1)	29.3 (3.0)
Mean corrected gestational age at the time of intubation (SD), weeks	30.0 (3.5)	30 (3.3)
Mean birth weight (SD), g	1272 (726)	1316 (502)
Mean weight at the time of intubation (SD), g	1344 (502)	1520 (634)
Causes for intubation (%)	Respiratory failure: 25 (83) Apnoea of prematurity: 4 (13) Intraventricular haemorrhage with secondary apnoea: 1 (3)	Respiratory failure: 10 (67) Apnoea of prematurity: 3 (20) Necrotising enterocolitis: 1 (7) Sepsis: 1 (7)
Intubator characteristics		
Median number of attempts (range)	2 (2–5)	2 (2–4)
First intubation (%)	15 (50)	7 (47)
Median number of previous successful intubations (range)	3 (0–20)	1 (1–6)

DISCUSSION

This study describes the reasons why neonatal intubation attempts were unsuccessful. These findings can hopefully contribute to improving how intubation is taught. In order to successfully intubate, the intubator has to be able to achieve, recognise and maintain an intubatable view. The majority of the residents did achieve a view, but many of them did not recognise it or struggled to maintain it when their focus moved from laryngoscopy to inserting the ETT. There were other instances where the epiglottis was seen but the scope not advanced further to reveal the vocal cords.

Table 2 Comparison of unsuccessful intubations factors between the control group and the intervention group

	Control group (n=30)	Intervention group (n=15)	p Value
Could not advance beyond the oral cavity, n (%)	1 (3)	1 (7)	1.00
Could not achieve an intubatable view (C-L 3–4), n (%)	7 (23)	2 (13)	1.00
Excessive secretions, n (%)	2 (7)	2 (13)	0.85
Oesophageal intubation, n (%)	14 (47)	5 (33)	0.59
Vocal cord not recognised, n (%)	9 (30)	1 (6)	0.16
Could not direct endotracheal, n (%)	10 (33)	9 (60)	0.16
Accidental extubation during strapping, n (%)	1 (3)	2 (14)	1.00

Note: There may be overlap of numbers as there could be multiple factors responsible for each unsuccessful intubation.
C-L, Cormack-Lehane classification system.

Table 3 Cormack-Lehane classification system for assessment of laryngeal view

Grade	Description	Best C-L grade in control videos (n=30), n (%)	Best C-L grade in intervention videos (n=15), n (%)	C-L grade when inserting ETT in control videos (n=25)*, n (%)	
1	Full view of glottis	17 (57)	11 (73)	8 (32)	8 (57)
2	Partial view of glottis	6 (20)	2 (13)	11 (44)	4 (29)
3	Only epiglottis seen, none of glottis seen	5 (17)	0 (0)	2 (8)	0 (0)
4	Neither glottis nor epiglottis seen	2 (7)	2 (13)	4 (16)	2 (14)

*In five attempts there was no insertion of ETT.
†In one attempt there was no insertion of ETT.
C-L, Cormack-Lehane classification system.

The basis of successful intubation training is to establish an understanding of the anatomy of the infant's airway. The trainee should be advised to look for midline structures like the uvula and the epiglottis and use them to identify the midline and as landmarks to direct them to the vocal cords. Having images and videos easily available to the trainee may help them better recognise the anatomy. Showing them videos of successful (see online supplementary video 5) and unsuccessful intubations may also be helpful. A small study demonstrated improved skills score and decreased intubation time with prior viewing of smartphone application demonstrating the airway anatomy and intubation procedure.[15]

Interestingly, in 33% of control and 60% of intervention intubations, despite an intubatable view, the ETT could not be directed in through the vocal cords. There are many possible reasons for this, including laryngoscope blade shape or rotation and the infant's head position. Optimising head position and blade rotation was part of the agreed proforma that the supervisors used to guide, but assessing if this was achieved was unfortunately not possible using the methodology of this study.[11] There is little standardisation in laryngoscope blade design. Miller's original description was a slightly curved flat blade 10 cm long.[16] Some blades have remained true to this original description, whereas others including the one used in this study have a midline trough. Perhaps this trough was added to facilitate feeding the ETT along the blade to the vocal cords. However if the ETT is inserted along the blade, the operator is not able to visualise it passing though the cords and therefore cannot be sure they have placed it correctly. Therefore trainees are taught to feed the ETT in from the side. However in several cases in this study, trainees found the lip of the laryngoscope blade to be an obstacle.

It is common for suction to be used during an intubation attempt. In the majority of occasions where suction was used in this study, it did not lead to an improved view. Suction is time-consuming, may stimulate a vagal response, and at least in elective intubations rarely helps. A small number of intubations were successful, but the tube was dislodged during securing, emphasising the need for particular care during this part of the procedure.

Table 4 Inter-rater agreement

	Agreement between investigators 1 and 2 (%)	Agreement between investigator and trainee (%)
Grading of laryngeal view	100	#
Vocal cord not recognised	87	#
Could not advance beyond oral cavity	100	100
Could not visualise vocal cords	77	100
Excessive secretions	77	100
Oesophagus was intubated	100	60

We presented the results of the intervention attempts in order to explore whether having the instructor share the view would change the profile of reasons for extubation failure. A higher percentage achieved an intubatable view; a lower percentage did not recognise the view or did not maintain the view; and a higher percentage had difficulty directing the ETT and less performed suction. However oesophageal intubations were still seen as were a small number of accidental extubations.

Our study has several strengths. It provides insight into an important but underinvestigated problem. Two investigators analysed the videos independently. Both investigators were blinded to the study group while analysing the data. This study was also able to include trainees' perceptions of events. This use of the C-L classification system gave an objective grading of laryngeal view.

This study has limitations. The sample size is small and made up of elective intubations. All intubations were carried out with one laryngoscope and therefore may yield a different result profile if a different model with a flatter blade was used. It was not possible to comment on the infant's position or physiological stability.

CONCLUSION

The majority of unsuccessful intubations performed by inexperienced paediatric trainees were due to oesophageal intubation or failure to recognise the laryngeal airway or structures that can lead to it. Routine suctioning during elective intubations should be discouraged. A proportion of unsuccessful intubations were due to difficulty in directing the endotracheal tube around a laryngoscope blade with a midline trough; improvement of blade design might help in these situations.

Correction notice This article has been corrected since it was published Online First. Additional text has been added to the Funding statement.

Contributors JEOS and PL wrote the first draft of the manuscript. All authors are responsible for the reported research. All authors have participated in the concept and design; analysis and interpretation of data; and drafting or revising the manuscript. All authors have approved the manuscript as submitted.

Funding Funded by the Royal Women's Hospital, Melbourne, Australia. COFK and MT are recipients of National Health and Medical Research Council (NHMRC) Early Career Fellowships Scholarships. PGD is a recipient of an NHMRC Practitioner Fellowship. The study was supported in part by an NHMRC Program Grant No. 384100.

Competing interests None declared.

Ethics approval The Royal Women's Hospital research and ethics committees approved the study.

Provenance and peer review Not commissioned; externally peer reviewed.

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Analysis of unsuccessful intubations in neonates using videolaryngoscopy recordings

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Arch Dis Child Fetal Neonatal Ed published online November 10, 2017

ADC-FNN Online First, published on October 27, 2017 as 10.1136/archdischild-2016-310797

Devices used for stabilisation of newborn infants at birth

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Received 31 March 2017
Revised 3 October 2017
Accepted 3 October 2017

ABSTRACT

This review examines devices used during newborn stabilisation. Evidence for their use to optimise the thermal, respiratory and cardiovascular management in the delivery room is presented. Mechanisms of action and rationale of use are described, current developments are presented and areas of future research are highlighted.

Key messages

- International guidelines on newborn stabilisation advocate support of breathing by means of non-invasive respiratory support.
- A baby's temperature is a sensitive prognosticator for morbidity and mortality. Deviations from the advised optimal body temperature (36.5°C–37.5°C) should be avoided.
- Methods for maintaining optimal body temperature include ambient temperature control; use of heated, humidified gas; use of polyethylene wraps, head covers or hats; and active heating by radiant warmers and thermoactive mattresses.
- Immediately following delivery, non-invasive respiratory support is best given via an appropriately sized face mask, attached to a pressure-controlled ventilation device. Newly emerging evidence on laryngeal mask airways suggests they may have benefits over face masks.
- Oxygen should be administered judiciously, and the effect of giving supplemental oxygen needs to be continuously monitored by using pulse oximetry.
- Heart rate is the most sensitive indicator for successful transition. Heart rate can be continuously monitored directly after birth by using the pulse oximeter or ECG.

BACKGROUND AND AIMS

It is estimated that 3%–8% of all babies receive some intervention to help with transition at birth.[1] A small fraction of these will indeed need active medical management to assist their stabilisation. The recent surge in refined animal model and human studies of the physiology of fetal to neonatal transition has significantly advanced our understanding of the physiological processes at the time of birth.[2] Consequently, a paradigm shift has taken place from the former focus on providing resuscitation at birth, in particular when caring for preterm infants, to a more permissive approach of providing assistance with stabilisation unless resuscitative measures are urgently required.[3–5] This does not discount that newborn infants do not on occasion require intensive medical attention at birth. This review examines devices used for newborn stabilisation, as advised in the current guidelines from the International Liaison Committee on Resuscitation,[3] the European Resuscitation Council[4] and the UK Resuscitation Council.[5] As the devices and methods used for providing stabilisation largely serve both the purpose of supporting transition as well as aiding full cardiopulmonary resuscitation therefore describe the devices used in the context of delivery room (DR) management and give reference to the specifics of neonatal resuscitation where appropriate. Our aim is to promote an understanding for the different devices or modalities, hence the scientific background for their use, particular technical aspects and practical guidance for their handling is provided, and attention is drawn to areas of urgently needed research.

TRAINING STAFF TO RECOGNISE NORMAL TRANSITION AT BIRTH AND TO IDENTIFY THE NEWBORN INFANT IN NEED FOR RESUSCITATION

All senior personnel attending deliveries need to have an in-depth understanding of the normal physiological sequence of fetal to neonatal transition and be able to recognise the deviations from the gestational age (GA) appropriate transition at birth. Therefore, all staff should be trained in newborn life support to appropriately care for all newborn infants.[3–5] The appropriate equipment for newborn stabilisation and resuscitation must be readily available at all times. Preparation of staff and equipment is the key to successful handling of the newborn infant in distress. As it is oftentimes possible to predict the need for resuscitation beyond stabilisation based on the antenatal and perinatal history, neonatal teams need to pay close attention to the obstetric history to prepare for the anticipated events timely and as well as possible.

MAINTAINING NORMOTHERMIA AFTER BIRTH

It is recommended that the temperature of newly born, non-asphyxiated infants should be maintained between 36.5°C and 37.5°C.[3–6] However, the newborn is particularly susceptible to heat loss through evaporation, thermal radiation, convection and conduction. The WHO categorises hypothermia into mild (body temperature 36.0°C–36.5°C),

To cite: Roehr CC, O'Shea JE, Dawson JA, *et al*. *Arch Dis Child Fetal Neonatal Ed* Published Online First: [*please include* Day Month Year]. doi:10.1136/archdischild-2016-310797

moderate (32.0°C–35.9°C) and severe (<32.0°C). Hypothermia is a very common problem in DRs in both high-resource and low-resource setting.[7 8] Particularly in preterm babies, hypothermia is associated with increased morbidities such as respiratory distress syndrome and increased susceptibility to late-onset sepsis; a 28% increase in mortality has been estimated for every 1°C below 36.5°C.[8] While singular interventions may be effective to improve temperature maintenance, they have not been shown to improve mortality prospectively, but quality improvement programmes using a number of different approaches have demonstrated a reduction in morbidity.[9 10] Hence, the approach most likely to result in successful temperature maintenance will be a combination of interventions, tailored depending on the local situation and the clinical setting. Below we describe several interventions to successfully maintain the body temperature of the newborn.

ENVIRONMENTAL TEMPERATURE

The suggested optimal DR temperature is >25°C.[3–6] Cool and dry air-conditioning for the comfort of staff should be avoided in the interest of the baby.

Radiant warmers

A baby, gently towelled down with a dry towel and placed under a radiant warmer, has a fivefold decrease in heat loss in comparison with one left wet at ambient temperature.[11]

Covering the infant: hats, towels and wraps

Woolen, gamgee-lined and polyethylene hats have all been shown to improve admission temperatures.[6] Occlusive polyethylene wraps (PEWs) in conjunction with a radiant warmer are effective at increasing admission temperatures and should be available for infants less than 28–32 weeks' GA. PEWs have been successfully used in infants from 30 weeks' to 36 weeks' GA in lower resource settings to improve postnatal temperature.[12 13] When using PEWs, an external heat source, for instance an overhead heater, is still necessary to maintain body temperature. However, as birth weight and GA increases, so does the risk of hyperthermia.[14]

Exothermic mattresses

Exothermic mattresses can be used together with radiant warmers. A disc-activated gel thermal mattress reaches its maximum of 40°C and lasts up to 2 hours. Use of a thermal mattress is effective and significantly associated with reductions in heat loss and admission hypothermia in very low birth weight infants (VLBWI).[15] However, a larger randomised controlled trial (RCT), comparing the combined use of an exothermic mattress with a PEW (bag) or the use of a PEW alone, was stopped early when the data monitoring committee identified significantly fewer infants in the 'bag +mattress' had temperatures within the target range (p=0.002) and more had temperatures >37.5°C (46% vs 17%, p=0.009).[16] Therefore, exothermic mattresses cannot be generally recommended for all infants born <32 weeks' gestation but may be used as part of an individualised, local strategy to maintain normothermia in certain babies and situations.[3 5]

Heated humidified gases

Standard piped DR gases are dry and delivered at or below room temperature; however, they can be warmed and humidified by use of a conventional medical humidifier.[17] An observational study of infants <33 weeks' GA suggested benefit in addition to PEW and radiant heat in improving admission temperatures.[18] An RCT of infants <32 weeks' GA found that heated humidified air did not make a difference in admission temperature for the overall cohort, but did significantly reduce hypothermia in infants of less than 28 weeks' GA (31% vs 59%, p=0.03).[19]

Thermocontrol during transfer to neonatal intensive care (NICU)

Measures to prevent hypothermia when transferring infants to the neonatal unit are very dependent on the available resources. Comparisons of infants born at <28 weeks' GA and wrapped in a PEW after birth who were transported either on a resuscitaire with a radiant warmer or in a heated transport incubator showed no difference in admission temperatures.[20] Checking the infant's temperature before leaving the DR, wrapping the baby in warmed towels and in heat reflective foil may further assist thermostability.

OBJECTIVE ASSESSMENT OF THE NEWBORN INFANT: MEASURING HEART RATE (HR) AND OXYGEN SATURATION STATUS IN THE DR

Heart rate

Algorithms for neonatal resuscitation[3–5] use HR as a major action point for interventions, such as providing positive pressure ventilation (PPV) and/or cardiac compressions. The natural progression of HR in uncomplicated, healthy newborn infants after birth has been characterised by Dawson *et al*.[21] During newborn resuscitation, the increase in HR is considered a good marker of effective resuscitation, particularly when it exceeds 100 beats per minute (bpm).[3–5] Continuous assessment of HR in the DR can be done through auscultation, palpation of the umbilical cord, ECG and pulse oximetry (PO). Auscultation and palpation have been shown to be imprecise and systematically underestimate the true HR by 20 bpm[22]; therefore, PO has become the mainstay for measuring HR after the first 1–2 min of life. Very recently, conflicting evidence emerged regarding the value of ECG for HR assessment and accuracy in the DR. Katheria *et al*[23] reported that an ECG displays the HR sooner than PO. In this study, the median HR display time was 2 s for ECG compared with 24 s for PO. van Vonderen and coworkers also compared the performance of PO and ECG for assessing HR in the DR.[24] In the latter study, HR measured by PO was significantly lower compared with ECG (94 (67–144) vs 150 (91–153) bpm at 60 s of life (p<0.05), respectively). Wider experience from clinical trials of using ECG in the DR is pending. It is important to point out that whichever method is used to measure HR, it is important to assess the quality of the data before altering clinical management. When using ECG, regular QRS complexes should be present, and for PO, there should be a regular plethysmograph. Some oximeter models have additional features to improve signal quality.

Oxygen saturation

The fetus thrives in its naturally hypoxic environment. During fetal-to-neonatal transition, prolonged hypoxia as much as hyperoxia should be avoided to aide physiological cardiopulmonary transition.[3–5 25] Provision of an air–oxygen mix by means of an oxygen blender is advised, and tapering the fractional inspired oxygen (FiO_2) based on preductal oxygen saturation ($SpO_{2)}$ and HR measurements to keep infants within GA-specific oxygenation and HR targets is recommended.[3–5] As clinical assessment for signs of peripheral and central cyanosis have been shown to be inaccurate, PO measures oxygen saturation, without the need

for calibration, and correlates closely with arterial oxygen saturation when SpO_2 is >70%.[23 24]

Preductal PO measurements from the right hand or wrist are preferred as they give an approximation of cerebral oxygen saturation. However, it will easily take more than 1 min to obtain a reliable signal and low oxygenation status, a weak pulse wave, interference with ambient light as well as motion artefacts can significantly delay a reliable, stable reading. Some hints for obtaining rapid and reliable PO readings are as follows: to quickly obtain a PO signal, first turn on the monitor, then secure the sensor to the infant wrist and lastly connect the sensor cable to the monitor. The PO should be set to maximum sensitivity and if possible to a short averaging time. Use of a foam wrap prevents misalignment of optical components in the sensor and protects the sensor against interfering ambient light.[26 27]

Outlook: while the above-mentioned target ranges have been derived from populations of well infants from an era of immediate cord clamping, observational data from Smit *et al*[28] suggest that for infants transitioning on the umbilical cord, altered reference ranges for SpO_2 and HR progression might need to be applied.

PROVIDING INITIAL RESPIRATORY SUPPORT

Masks and other device–patient interfaces

Sufficient respiratory support can be delivered by a hand-held face mask (FM) applied to an infant's face connected to a T-piece device or self-inflating bag (SIB). Several studies have shown how FM ventilation is frequently complicated by airway obstruction and that mask leak is common, variable and often not detected by the resuscitator.[29 30] Thus, effective respiratory support of newborns by FMs can be challenging. Infants have relatively large heads that can be difficult to correctly position. Their tongue is large and can easily obstruct the airway, and pharyngeal tone can be reduced. Facial dimensions are irregular and furrowed; therefore, it can be difficult to create a seal with a mask.[30] Both round and anatomically shaped FM are available, and although there is no evidence of one being superior over the other, surveys have shown that round masks are most frequently used. To optimise mask ventilation, it seems sensible to ensure that the FM is appropriately sized even if there is yet no evidence that using different FM size improves the outcome of respiratory support at birth. It is also noteworthy that FM sizes are independently labelled by the manufacturers and are not reflective of an international standard. Recently, a large cohort study of preterm infants found that most commonly available FM were too large for preterm infants' faces.[31] A 35 mm FM fits infants <29 weeks' postmenstrual age. The 42 mm FM is appropriate for infants up to 33 weeks' postmenstrual age. However, most ranges of infant resuscitation FM start with an external diameter of 50 mm. Furthermore, different FM holds (two-point top hold, spider hold and two handed hold (figure 1) have been evaluated in manikin studies, which found both methods of FM hold techniques to be similarly effective.[32] In situations where the infant is not responding to FM ventilation, the most likely thing in the FM technique is unsatisfactory and so the baby is not being ventilated properly. It would be reasonable to reposition the infant and try a different hold before escalating the level of care. Compared with FMs, nasal tubes were found inferior as interfaces for stabilisation of very preterm infants.[31] However, a very recent pilot study found that a binasal continuous positive airway pressure (CPAP) driver modified to deliver intermittent positive pressure ventilation (IPPV) was also suitable for delivering peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP) while having a low resistance breathing circuit.[33] This interface needs to be studied in a larger clinical trial.

SIBs, flow-inflating bags and T-piece devices

Devices for providing respiratory support to infants, include SIBs, flow-inflating bags and pressure limited resuscitation devices, commonly referred to as T-piece resuscitators or devices (named after the shape of the connector between the device and the patient interface, ie, the FM or endotracheal tube) and, of course, mechanical ventilators. The common principle of these devices is the provision of an oxygen–gas mix, preferentially with a tight control of the FiO_2 via an air–oxygen blender, and PIP, PEEP and tidal volume (Vt) provision at an operator-denoted inflation rate. World wide, SIBs are the most commonly considered manual resuscitation devices, used in over 90% of NICUs. SIBs are intermittent flow devices operated by manual compression of a breathing bellow. Depending on the vigour of the operator's squeeze, they will provide varying pressures and consequently varying Vts, in particular as there is a large variety of SIBs available, with varying volumes, ranging between 220 mL and 500 mL for neonatal patients. Therefore, supraphysiological Vts are easily applied, and iatrogenic lung injury can be inflicted. Studies confirmed that intraoperator and interoperator provision of PIP and Vt varies widely when using SIBs and were in poor relation to the operator's clinical expertise or level of training.[34] SIBs are now increasingly equipped with pressure manometers, which have been shown to improve adherence to target pressures

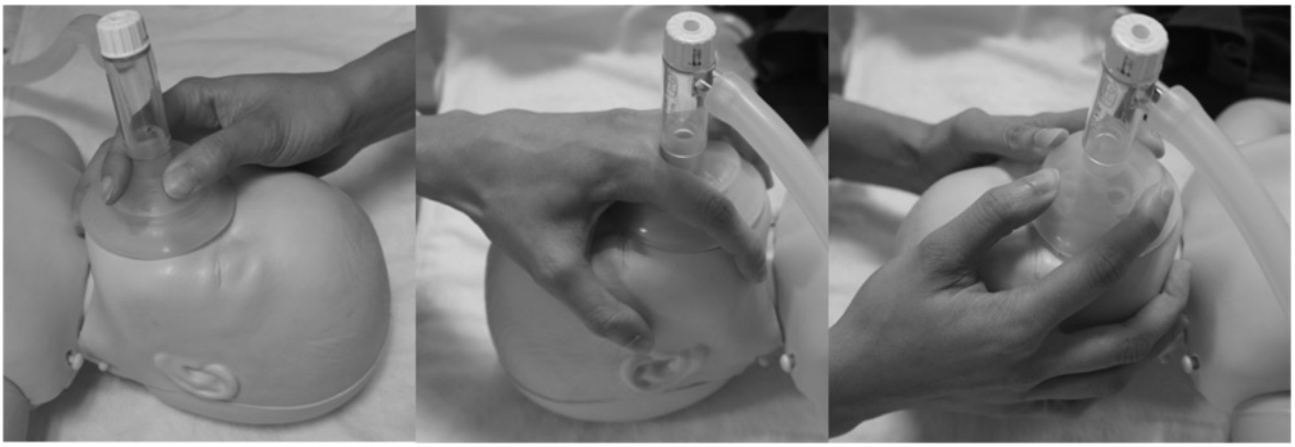

Figure 1 Different face mask holds: two-point top hold, spider hold and two handed hold (left to right).

Table 1 Advantages and disadvantages of devices used for respiratory support in the delivery room

	Pro	Contra
SIB	► delivers air independent of gas source ► small, easy and quick to change applied ventilation pressures ► relatively inexpensive ► easy to transport and store	► unsuitable to reliably and consistently provide ventilation pressures (PIP and PEEP) ► unsuitable for giving sustained inflations ► continuous training required to gauge delivered ventilation pressures ► difficult humidification of breathing gases
T-piece device	► delivers constant ventilation pressures (PIP and PEEP) ► suitable for giving sustained inflations ► robust ► relatively easy to use in hands of inexperienced	► dependent on external gas source ► relatively cost intense
Ventilator	► delivers constant ventilation pressures (PIP and PEEP) and rates ► suitable for giving sustained inflations ► easy heating and humidification	► expensive ► requires electrical power and medical gas sources ► risk of prolonged ventilation and of ventilator-induced lung injury
Face mask	► adequately fitted masks improve ventilation	► mask size often inadequate
Nasal prongs	► good CPAP transfer with binasal prongs	► challenging to affix ► risk of obstruction, dislodgement, nasal trauma
Guedel	► potentially helpful to remain patent airway	► challenging to affix, dislodges frequently
LMA	► good PIP and Vt delivery ► ease of use and insertion	► only available for baby >1200 g body weight

LMA, laryngeal mask airway; PEEP, positive end-expiratory pressure; PIP, peak inspiratory pressure; SIB, self-inflating bag; Vt, tidal volume.

during resuscitation.[35] Advantages of using a SIB include their relatively low expense, their compactness and that they can be operated without an external gas source (table 1). Among the disadvantages of using SIBs are the variability in PIP provision, flow and tidal volume provision and inability to provide constant inspiratory pressures when providing prolonged inspiratory breaths. Also, when used in conjunction with PEEP valves, the provided PEEP is often very variable, which depends largely on the age and the quality of the PEEP valve.[36] As shown by Hartung *et al*, the process of thermosterilisation, which includes autoclavation at 134°C and 3170 mbar, together with the repeated disassembly process, damages multiuse PEEP valves and reduces their reliability significantly.[36] Comparative studies have shown that compared with T-piece resuscitators, flow-inflating bags, similarly to SIBs, are less reliable regarding the provision of PIP, PEEP and Vt.[37] Flow-inflating bags, while commonly used in the USA, appear to come to very little use outside the USA, according to several investigators. Conversely, T-piece devices have become the accepted standard in most high-resource area DRs, either as portable, stand-alone devices or integrated in modern resuscitation platforms. Their advantages, presumed due to the continuous patient directed gas flow, include steady delivery of a set PIP as well as steady PEEP provision, so they can therefore deliver IPPV and CPAP. The breathing gases, delivered through the T-piece at a preset flow rate, can be heated and humidified by adding a compatible humidifier into the circuit.[18] The T-piece resuscitators' dependence on external gas sources may be seen as one of its disadvantages.

Airway adjuncts—laryngeal mask airways (LMAs)

Different airway adjuncts are available to support non-invasive respiratory support and provide an alternative to endotracheal intubation. LMAs have shown promise both as a resuscitation tool and a device to deliver surfactant without need for intubation. Use of LMA appears to be easy but, unfortunately, currently not available to fit infants smaller than 1250 g, thereby limiting their use in neonatology to the more mature infants. A recent, randomised clinical trial conducted in Uganda compared LMA and FM use in infants with a birth weight >2000 g who required PPV at birth. The main outcome was time to spontaneous breathing. The study found that time to spontaneous breathing was shorter in LMA arm than in FM arm, and while all resuscitations were effective in the LMA arm, a significant number of patients receiving FM were converted to LMA due to poor response to FM ventilation.[38] In a recent manikin study comparing different makes of LMAs, the i-gel LMA was found to have the lowest leak even with high PIPs.[39]

Intubation and videolaryngoscopy

At times, endotracheal intubation in the DR is unavoidable; therefore, it is a skill that needs to be quickly and consistently available anywhere neonatal care is provided. This is a challenging standard to provide as intubation is a difficult skill to acquire and maintain, and initial attempts are often unsuccessful. Success rates of neonatal trainees are falling as a result of an overall reduction in intubating opportunities. Furthermore, junior intubators have been found to have superior success at elective premedicated intubations compared with DR intubations where the infant is not generally premedicated. Recently, videolaryngoscopy has demonstrated benefit as an intubation training tool.[40] Success rates of junior neonatal trainees were significantly improved when their instructor was able to share their view on a videolaryngoscope screen compared with a control where the supervisor guided without a shared view (traditional method) (66% compared with 41%, $p<0.001$). The effect was greatest for intubations where the infant was given premedication (72% compared with 44%, $p<0.001$). Qualitative feedback from trainees found videolaryngoscopy to be useful. They appreciated calm, clear, consistent guidance and a controlled, supportive environment. They found intubations in the DR, audiences and parental presence more stressful.[40] To date, there are only few neonatal videolaryngoscopes available where the videolaryngoscope blade closely resembles the traditional Miller neonatal blades, but further models are in development. Videolaryngoscopes are available that have blades of different shapes and that cannot be used as conventional laryngoscopes. These can be successfully used to intubate neonates, but learning to use them is a different skill that also takes time and needs practice. Opportunities to practice intubation are in very short supply for novice intubators therefore necessitating learning a different skill to use equipment that is not universally available may hinder rather than help learning how to intubate.

Assessing successful intubation

Successful endotracheal intubation is most commonly assessed at the cot side via qualitative exhaled CO_2 measurement, using an in-line colorimetric sensor, as in refs.[3–5 41] Exhaled CO_2 may also be used during FM ventilation to demonstrate adequate ventilation.[42] Minimal cardiac output and adequate dead space clearance are necessary to obtain a positive signal from the CO_2 sensor and contamination with moisture should be carefully avoided.

Administration of drugs and emergency intravenous access

Resuscitation drugs like epinephrine are required in less than 0.1% of deliveries but, if indicated, should be given via a central venous route as an effective tracheal dose has not been defined.[43] Therefore, equipment for emergency central access and an umbilical catheter must be available. Umbilical venous and arterial access will be possible in most babies, but for those rare instances when it is not, or that is, in the emergency department, an intraosseous needle should also be available[3–5] to administer drugs and fluid during resuscitation.

CURRENT DEVELOPMENTS

Delayed cord clamping (DCC) in preterm infants reduces the incidence of intraventricular haemorrhage and necrotising enterocolitis and the need for blood transfusion. In term babies, DCC is associated with decreased anaemia but increased jaundice. Until recently, delivering DCC to infants has meant delaying initiation of neonatal care. Of late, modified resuscitaires and trolleys have been developed to enable respiratory and thermal support to be provided to infants while the cord is intact. These were used in a recently published RCT of 137 infants (median gestation 29 weeks) that compared cord clamping at greater or equal to 2 min combined with immediate respiratory and thermal care to clamping at less than or equal to 20 s and neonatal care after clamping. Mortality was 5% in the DCC group and 11% in the controls, risk difference −5.9% (95% CI −12.4% to 0.6%).[44] Stabilisation close to the mother may be preferable to families also. Larger trials are planned.

New methods of monitoring infants during stabilisation and thereafter are being developed rapidly. Bhatia *et al*[45] used electrical impedance tomography to measure regional lung volume and guide changing CPAP pressure and showed that atelectasis could be reversed and lung volume optimised. Respiratory function monitors are available that can measure in real-time Vt, flow and pressure waves and leak. A pilot study has shown they can be used to guide PPV and improve mask ventilation technique and larger RCTs are ongoing.[46] A digital stethoscope attached to a smart device was recently found to be equivocal to ECG and superior to pulsoximetry in length of time to detect HR.[47] Recently, hand-held Doppler devices were shown to be similar to ECG to monitor HR.[48 49] The use of colorimetric capnography beyond assessing successful endotracheal tube placement has been investigated by Blank *et al*, who found that in infants with bradycardia receiving mask PPV during neonatal resuscitation colour change in the pedicap device precedes a significant increase in HR during neonatal resuscitation.[50]

URGENTLY REQUIRED EVIDENCE AND FURTHER DEVELOPMENTS TO OPTIMISE PROVISION OF MEDICAL SUPPORT IN THE DR

Despite much improvement over the past decade, the list of desired improvements remains long. With advanced camera technology, microprocessors and their integration in mobile device technologies and apps, non-touch, miniature and hand-held devices are constantly evolving to improve patient monitoring and management in the DR. Among other developments, devices for monitoring the newly born during physiological DCC, monitoring cardiopulmonary transition and the effect of assisted ventilation; assessment of HR and other vital parameters; use of ultrasound during fetal-to-neonatal transition or near infrared spectroscopy at delivery as well as for video-assisted DR care; and means and devices to minimise heat loss in the DR and during transfer are under way. It is hoped that with the emerging evidence from such trials, further evidence-based recommendations on which technology to use for specific circumstances and patients can soon be confidently formulated.

Competing interests None declared.

Provenance and peer review Commissioned; externally peer reviewed.

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Devices used for stabilisation of newborn infants at birth

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Arch Dis Child Fetal Neonatal Ed published online October 27, 2017

Notes