A Randomized Trial of Stylets for Intubating newborn Infants

WHAT’S KNOWN ON THIS SUBJECT: Endotracheal intubation of newborn infants is a common procedure. Competency in this skill is mandatory for many pediatric training programs. The safety and benefits of using a stylet for intubating newborn infants are unknown.

WHAT THIS STUDY ADDS: Pediatric trainees are commonly unsuccessful at performing endotracheal intubation. Adverse events of using a stylet are uncommon. The use of a stylet does not increase success rates.

abstract

OBJECTIVE: Endotracheal intubation of newborn infants is a common and potentially lifesaving procedure but a skill that trainees find difficult. Despite widespread use, no data are available on whether the use of a stylet (introducer) improves success rates. We aimed to determine whether pediatric trainees were more successful at neonatal orotracheal intubation when a stylet was used.

METHODS: An unblinded randomized controlled trial conducted between July 2006 and January 2009 at a tertiary perinatal center, the Royal Women’s Hospital, Melbourne, Australia. Eligible participants were newborn infants in the delivery room or NICU requiring endotracheal intubation for respiratory support. Infants were intubated by pediatric residents or fellows. Infants were randomized to have the tracheal intubation for respiratory support. Infants were intubated by using either an endotracheal tube alone or with a stylet. Successful intubation at the first attempt assessed by colorimetric detection of expired carbon dioxide was the primary outcome.

RESULTS: Three hundred two intubations were performed in 232 infants (residents performed 75%, fellows 25%). Intubation was successful in 57% of the stylet group and 53% of the no stylet group ($P = .47$); odds ratio 1.18 (95% confidence interval 0.75–1.86). There were no differences in the duration of attempts or in the rate of upper airway trauma between the 2 groups. These results were consistent across subgroups of infants based on birth weight, gestational age, and site of intubation (delivery room or NICU).

CONCLUSIONS: Using an endotracheal stylet did not significantly improve the success rate of pediatric trainees at neonatal orotracheal intubation. Pediatrics 2013;131:e198–e205

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KEY WORDS infant, newborn, intubation, endotracheal, neonatal resuscitation, delivery room

ABBREVIATIONS DR—delivery room
ETT—endotracheal tube
HR—heart rate
ID—internal diameter
IQR—interquartile range
RWH—Royal Women’s Hospital
$SpO_2$—pulse oxygen saturation

Drs Kamlin and O’Connell designed the study with assistance from Dr Dawson, Dr O’Donnell, and Dr Morley; data collection was completed by Drs Kamlin, O’Connell, and Dawson; statistical advice and generation of randomization sequence was provided by Dr Donath; Drs Kamlin, O’Connell, and Dawson analyzed the data; Dr Kamlin prepared the first draft of the manuscript; and all coauthors contributed to the editing process.

This trial has been registered at www.anzctr.org.au (identifier 12627001864559).

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FINANCIAL DISCLOSURE: Dr Morley has consultancies with Drager, Fisher and Paykel Healthcare, and Laerdal. Although these companies make equipment to provide respiratory support for infants, they do not manufacture stylets. These companies were not involved in the trial at any stage. The other authors have indicated they have no financial relationships relevant to this article to disclose.

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Consensus statements note that effective ventilation is the key to successful neonatal resuscitation.1–3 It is therefore mandatory for trainees to acquire skills in face-mask ventilation and endotracheal intubation.1–7 However, studies in North America and Australia suggest that trainees struggle to achieve competence in neonatal intubation.8–10 The Neonatal Resuscitation Program previously recommended limiting the duration of intubation attempts to 20 seconds.11 This limit was increased to 30 seconds, reflecting the inability of trainees to meet this standard.9,12

Studies in the United States suggest that more than half of intubation attempts are unsuccessful.12–17 A Canadian study found that neonatal residents and fellows were less successful at intubation than respiratory therapists.10 Falck et al found no pediatric trainee met their definition of competence for intubation (successful at first or second attempt ≥80% of the time) over a 2-year period.8 With decreasing opportunities for trainees to acquire and maintain proficiency in this skill, there is an urgent need to improve training10,17 and investigate the use of adjuncts to improve rates of successful neonatal intubation.

The endotracheal tubes (ETTs) used may become too flexible if exposed to the radiant heater of a resuscitation table. Many operators insert a stylet (a sterile, plastic-coated wire, which can be curved) into the lumen to stiffen the ETT. It is not known whether their use increases the rate of intubation success. Current guidelines state that intubation may be performed by using an ETT with or without a stylet.5,11

This study aimed to determine the success rates of pediatric trainees using a stylet compared with no stylet for neonatal intubation.

**METHODS**

**Patients and Study Design**

This single-center randomized controlled study was conducted between July 2006 and January 2009 at the Royal Women’s Hospital (RWH), Melbourne, Australia. RWH is a tertiary perinatal center with ~6500 births and 300 infants <1500 g admitted to the NICU each year. Doctors perform all intubations. Junior medical staff are on-site 24 hours a day with a consultant on call after hours. Generally, residents have no previous intubation experience, whereas fellows have at least 12 months’ experience of neonatal intensive care. All neonatal staff attending deliveries complete a resuscitation program based on International Liaison Committee on Resuscitation18 and Australian Resuscitation Council19 guidelines. The residents are taught orotracheal intubation. The duration of an attempt is determined by the infant’s heart rate (HR) (>100 beats per minute considered acceptable) rather than a time limit.

Infants who were briefly intubated for suctioning of meconium from the trachea were not eligible because of difficulty confirming correct ETT placement. All other infants requiring orotracheal intubation were eligible for study inclusion.

For emergency first intubations (defined as intubation in the delivery room [DR] or within 24 hours after birth), a waiver of consent was used to enroll infants and retrospective consent obtained as per Australian National Health and Medical Research Council guidelines for studies in emergency medicine.20 Consent to use data were sought from the parents as soon as possible after the intubation. Infants who were intubated in the NICU after the first day were eligible if written parental consent had been obtained. When parents were approached, permission was sought to use data from the emergent intubation and to randomize future intubations during the hospital admission. Thus, an infant could be randomized several times and be allocated to either intervention group during admission.

Premarkedation was not used in the DR. Premedication with morphine or fentanyl, atropine, and suxamethonium was used in the NICU. During the course of the study, the hospital guidelines were updated and morphine was replaced by fentanyl. The study was approved by the Human Research and Ethics Committees of the Royal Women’s Hospital and registered with the Australian and New Zealand Clinical Trials Register (ACTR identifier: 1260700186459).

**Randomization**

Randomization in blocks of variable size was stratified by site of intubation (DR or NICU). Sequentially numbered sealed opaque envelopes containing computer-generated treatment groups were stored in a cupboard within the NICU. The neonatal fellow on duty carried an unopened sealed envelope to randomize the next eligible infant in the DR. Infants in the NICU were identifiable by a study label on the incubator. It was not possible to mask the intervention.

**Study Intervention**

A Neopuff Infant Resuscitator (Fisher & Paykel, Auckland, New Zealand) T-Piece was used to provide ventilation before and immediately after intubation attempts in the DR and NICU. Infants were usually monitored with pulse oximetry in the DR; all NICU infants had both pulse oximetry and electrocardiography. After it was decided to intubate the infant, the randomization envelope was opened to determine the treatment allocation: that is, intubation attempted with an ETT alone or with a stylet. Only the first attempt at intubation by a single operator was randomized. If unsuccessful, operators were free to use...
their preferred method during subsequent attempts.

Intubation was performed by using sterile, single-use, uniform internal diameter (ID), plastic ETTs (Mallinckrodt Medical, Athlone, Ireland) of an appropriate ID based on the infant’s actual or estimated birth weight (2.5 mm ID for infants <1 kg; 3.0 mm ID for infants 1–2.5 kg; 3.5 mm ID for infants >2.5 kg). For infants randomized to the stylet, a Satin Slip intubation stylet (Mallinckrodt Medical, Athlone, Ireland) was inserted into the ETT lumen. The manufacturers recommend this stylet for use with ETTs of 2.5 to 4.5 mm ID. The stylet was positioned so that the tip did not protrude beyond the ETT. The level of experience of the operator was recorded. The operator’s preference (stylet, no stylet, or no preference) was also recorded. Correct ETT placement was confirmed by a colorimetric exhaled carbon dioxide detector (PediCap, Nellcor Puritan Bennett, Pleasanton, CA). Infants admitted to the NICU had a chest radiograph to confirm ETT position.

Data were only collected for the first (randomized) intubation attempt. Baseline readings for HR and pulse oxygen saturations (SpO₂) were noted from a pulse oximeter (Masimo Radical, Sunnyvale, CA) in the infant with the laryngoscope blade into the mouth to its removal.⁹,¹²

**Primary and Secondary Outcomes**

The primary outcome was defined as intubation success on first attempt indicated by detection of exhaled CO₂. Secondary outcomes were duration of intubation attempt, changes in HR and SpO₂ from baseline, and the presence of blood-stained secretions after the procedure. Data were analyzed by intention-to-treat. Prespecified subgroup analyses investigated the effects of gestation, birth weight, premedication, and seniority of operator on intubation success.

**Sample Size and Statistical Analysis**

In a previous observational study at RWH, 60 attempts at intubation in the DR were video recorded.⁹ The residents’ success rate for the initial intubation attempt was 30%. There are no published or observational data to estimate the overall success rate using a stylet. To detect a difference in the rate of successful intubation from 30% to 46% in the stylet group, a sample size of 300 was required to achieve a power of 80% with a type 1 error rate of 5%.

An independent external data safety monitoring committee reviewed masked data at intervals of 100 intubations. Data were analyzed with Stata software (Intercooled 10, Stata Corp, College Station, TX). The data are presented as mean (SD) for normally distributed continuous variables and median (interquartile range [IQR]) when the distribution was skewed. The clinical characteristics and outcome variables were analyzed by using the Student t test for parametric and Mann-Whitney U test for nonparametric comparisons of continuous variables, and χ² for categorical variables. P values were 2-sided, and P values <.05 were considered statistically significant.

**RESULTS**

Seven hundred thirteen infants were intubated in either the DR or NICU during the study period; 481 were not enrolled (Fig 1). The 232 enrolled infants had 325 separate intubation episodes. However, 21 attempts in the NICU were not randomized. There were 304 first intubation attempts in 232 infants. Informed consent by using the waiver was obtained from all but 2 families. These 2 intubations (both stylet, 1 successful) were the only post-randomization exclusions from the analysis. Thus, 302 intubation attempts randomized to a stylet (n = 149) or no stylet (n = 153) were included in the final analyses.

The demographic characteristics of the groups were similar (Table 1). Medications were used in 98% of intubations in the NICU. Suxamethonium was used in all (144/146) NICU randomized attempts where medications were prescribed.

Residents performed 75% of intubation attempts and fellows 25%. Twenty-five (8%) infants were randomized more than once. The median of randomized intubations per infant was 1 (range 1–7). Infants randomized in the study had a median of 1 (range 1–5) attempts before an ETT was successfully secured. Difficult airways were equally represented with 8 randomizations in each of the stylet and no stylet groups requiring 4 or more attempts before a successful intubation.

The success of the first intubation attempt was 57% in the stylet group and 53% in the no stylet group (P = .47; odds ratio 1.18 [95% confidence interval 0.75–1.86]). There were 146 and 156 intubation attempts in the DR and NICU, respectively (Fig 1). Subgroup analyses are presented in Table 2. Success rates for the stylet and no stylet groups were 53% versus 54% (P = .87) for the DR and 61% versus 52% (P = .25) for the NICU. No significant differences were seen in success rates between the groups when infant weight or operators’ level of experience were considered.

Table 3 shows the experience of the operators; 49% had <7 months experience in neonatal pediatrics and 51% had ≥7 months. For operators who had never successfully intubated, the
success rate at 31 randomized intubation attempts was 53% and 31% (P = .21) in the stylet and no stylet groups, respectively.

Data on the operators’ preferred method (stylet/no stylet/no preference) were collected from 268 intubations. Operators at 42% of attempts preferred a stylet, 24% preferred no stylet, and 34% had no preference. Operators who preferred to use a stylet had a higher success rate when using a stylet than when not. This difference was not statistically significant: 67% versus 53%, odds ratio 1.8 (95% confidence interval 0.84–3.84).

The median duration of attempts was 43 (IQR 30–60) and 38 (IQR 27–57) seconds for stylet and no stylet groups (P = .23), respectively (Fig 2). Only 25% of all intubations took <30 seconds.

The most frequent reason cited by the operators for unsuccessful intubation was inadequate view of the vocal cords resulting in esophageal intubation (63% and 69% of unsuccessful attempts in the stylet and no stylet groups, respectively).

Safety

Pulse oximetry data were available for 277 (121 in DR, 156 in NICU) attempts in 215 infants (Fig 3 A and B). The HR and SpO2 fell significantly during intubation in both groups (P < .001). There were no significant differences in the lowest
TABLE 1 Demographics of Participants

<table>
<thead>
<tr>
<th></th>
<th>Stylet (N = 149)</th>
<th>No Stylet (N = 153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth wt, g</td>
<td>925 (689–1473)</td>
<td>862 (714–1586)</td>
</tr>
<tr>
<td>Gestational age, wk</td>
<td>28.5 (5.0)</td>
<td>28.7 (5.2)</td>
</tr>
<tr>
<td>≤&lt;1000 g at intubation</td>
<td>75 (50)</td>
<td>78 (51)</td>
</tr>
<tr>
<td>Corrected gestational age ≤29 wk at intubation</td>
<td>80 (54)</td>
<td>77 (50)</td>
</tr>
<tr>
<td>5 min Apgar</td>
<td>7 (6-8)</td>
<td>7 (6-8)</td>
</tr>
<tr>
<td>Caesarean delivery</td>
<td>93 (62)</td>
<td>97 (64)</td>
</tr>
<tr>
<td>HR (beats per minute)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before intubation</td>
<td>149 (50)</td>
<td>145 (54)</td>
</tr>
<tr>
<td>Lowest recorded during intubation</td>
<td>128 (36)</td>
<td>121 (37)</td>
</tr>
<tr>
<td>Male infants</td>
<td>86 (58)</td>
<td>92 (60)</td>
</tr>
<tr>
<td>Premedication received</td>
<td>76 (51)</td>
<td>80 (52)</td>
</tr>
</tbody>
</table>

Data are presented as n (%), proportions, mean (SD), or median (IQR).

TABLE 2 Intubation Success: Primary Outcome and Subgroup Analyses

<table>
<thead>
<tr>
<th></th>
<th>Stylet</th>
<th>No Stylet</th>
<th>OR (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Overall</td>
<td>85/149</td>
<td>81/153</td>
<td>1.18 (0.75–1.86)</td>
</tr>
<tr>
<td>Site of intubation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR</td>
<td>38/72</td>
<td>40/74</td>
<td>0.95 (0.50–1.82)</td>
</tr>
<tr>
<td>NICU</td>
<td>47/77</td>
<td>41/79</td>
<td>1.45 (0.77–2.74)</td>
</tr>
<tr>
<td>Seniority of operator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellow</td>
<td>22/33</td>
<td>20/41</td>
<td>0.83 (0.31–2.22)</td>
</tr>
<tr>
<td>Resident</td>
<td>63/116</td>
<td>52/112</td>
<td>1.37 (0.82–2.31)</td>
</tr>
<tr>
<td>Wt at randomization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1000 g</td>
<td>40/75</td>
<td>46/77</td>
<td>0.77 (0.41–1.47)</td>
</tr>
<tr>
<td>≥1000 g</td>
<td>45/74</td>
<td>35/76</td>
<td>1.82 (0.95–3.48)</td>
</tr>
</tbody>
</table>

CI, confidence interval; OR, odds ratio. Data are presented as n (%) and ORs with 95% CI.

TABLE 3 Experience of Operators Performing Intubation Attempts

<table>
<thead>
<tr>
<th></th>
<th>Stylet (n = 149)</th>
<th>No Stylet (n = 153)</th>
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<tbody>
<tr>
<td>Seniority of operator, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellow intubating</td>
<td>33 (11)</td>
<td>41 (14)</td>
</tr>
<tr>
<td>Resident intubating</td>
<td>116 (58)</td>
<td>112 (37)</td>
</tr>
<tr>
<td>Previous successful intubations, n (%) a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>15 (5)</td>
<td>16 (6)</td>
</tr>
<tr>
<td>1–4</td>
<td>48 (17)</td>
<td>39 (14)</td>
</tr>
<tr>
<td>≥5</td>
<td>77 (28)</td>
<td>85 (30)</td>
</tr>
</tbody>
</table>

a Data collected from 280 intubations.

recorded SpO2 and HR during randomized attempts between the groups in the DR and NICU, respectively. Only 1 infant in the trial received chest compressions. This infant had an antenatal diagnosis of tricuspid atresia and was randomized to the no stylet group.

No patients had tracheal or esophageal perforation. The rates of blood stained aspirates within the first 24 hours were 10% and 13% (P = .49) in the stylet and no stylet groups, respectively. Because some infants were randomized more than once and allocated to both groups, we are unable to report neonatal morbidity and mortality data.

DISCUSSION

This is the first randomized study to investigate the use of a stylet to facilitate orotracheal intubation of the newborn infant. The use of an ETT with a stylet did not improve overall rates of intubation success by pediatric trainees. Results were consistent across subgroups based on site of intubation (DR or NICU) and infant size. There were no serious side effects attributable to the stylet.

Our results are similar to others who have reported success rates of intubations by pediatric residents between 57% and 63%.10,21 Our study also shows unsuccessful intubation attempts by pediatric trainees are common irrespective of experience of trainee, gestational age, weight of infant, or premedication.

Our success rate was higher than that seen in our previous study8 which was used to inform our sample size calculation. During the study, training in intubation was changed to include regular tutorials, video recordings of intubations in the DR, visual aids identifying and reminding learners of the appearance of the laryngeal inlet, and simulation-based sessions by using low-tech task trainers. Improved training and greater supervision of intubation attempts with debriefing may have led to the higher than expected success rates.22,23

From our observations, a resident has a median of 8 (range 0–13) intubation attempts in 6 months. Opportunities for trainees to learn and practice neonatal intubation continue to decline, with negative consequences for proficiency.8–10

The failure rate of intubations in this study remains high and may be difficult to improve because trainees are working fewer hours, have shortened training programs, and are exposed to fewer infants being intubated.24–26 In contrast, in the adult literature, the recommended minimum number of attempts required by nonanesthetic practitioners before attaining proficiency is 40.27 Respiratory therapists in NICU are expected to have 10 supervised intubations before being allowed to intubate independently and must do at least 4 a year to maintain competency.10 Currently there are no guidelines for neonatal training programs to assess competency and proficiency in key skills such as endotracheal intubation of the neonate.

There are case reports of neonatal intubation causing oropharyngeal and esophageal trauma, tracheal or bronchial injury, and surgical emphysema of...
upper chest and neck. The stylet sheath can shear away, causing airway obstruction. There were no significant differences between the groups in the rate of blood-stained aspirates. We did not see any direct trauma or problems with the stylet sheath. Overall, the incidence of adverse events remains low with both methods of intubation. Our study was not powered to detect significant differences in rare events. Therefore, the choice of whether to use a stylet or not when there are no differences in success rates may rest on an individual’s preference. Our data show a trend toward the most inexperienced operators benefiting from using a stylet. Therefore, it may be appropriate for training programs to include instruction on how to use this device.

There are some limitations to our study. Our findings are only applicable to pediatric trainees who spend a minimum of 6 months working in a level 3 NICU without respiratory therapists or nurse practitioners.

The use of a single stylet brand may limit generalizability, but we are not aware of inherent differences in the materials used by various brands that influence the rigidity and ability to form a curve. We did not mandate how the stylet-loaded ETT should be manipulated, and the final shape of the ETT was not standardized. The most common adjustment is to create a “hockey stick,” but some preferred keeping the stylet straight.

Our results show that operators, who had never successfully intubated before, may be more likely to succeed with the stylet. In this small subgroup, a trend favoring the use of a stylet was not statistically significant and requires confirmation in a larger trial.

Using the Pedicap as our gold standard to determine our primary outcome may have underestimated the number of successful intubations in the stylet group because some tubes may have been correctly sited but dislodged on removing the stylet. A commonly encountered problem using the stylet with smaller ET tubes (≤2.5) is the force required to remove the stylet, which may cause undesired movement of the ET tube as the stylet is withdrawn. A Pedicap is recommended for confirmation of endotracheal placement, a useful adjunct to clinical assessment in neonates. False-negative color change in the Pedicap has been reported during underventilation in a transitioning

![FIGURE 2](image) Box plot (median, IQR, and range) demonstrating the duration of intubation attempts.

![FIGURE 3](image) A. Changes in SpO2 from baseline to lowest documented level during intubation attempts (median, IQR, and range). B. Changes in HR from baseline to lowest documented level during intubation attempts (median, IQR, and range).
infant\textsuperscript{35} and cardiac arrest,\textsuperscript{16} and false-positives may occur after either intratracheal adrenaline or surfactant administration.\textsuperscript{36} The risk of misleading Pedicap readings, however, would be represented equally in both groups, so this is unlikely to be a source of bias. A strength of our study is the large proportion of infants weighing <1000 g enrolled because these are the largest group of neonates being intubated in most neonatal units in the developed world. Another strength is that half were randomized in the DR, which is where most infants are intubated. This would not have been possible without our hospital's Human Research and Ethics Committee approving this as a study of emergency medicine and permitting the use of a waiver of consent.\textsuperscript{20}

The Neonatal Resuscitation Program suggests time limits to minimize physiologic instability during intubation attempts.\textsuperscript{11} Less than a quarter of intubation attempts were completed within 30 seconds. Physiologic stability as assessed by infant HR, measured by pulse oximetry, may be an appropriate alternative clinical tool to determine duration of attempts. Physiologic instability is frequently observed during intubation attempts.\textsuperscript{9,10,37,38} In our study, we recorded bradycardia (HR <100 beats per minute) in 25% of randomized attempts. This is substantially less than the 60% observed by Marshall and colleagues\textsuperscript{37} but greater than that of Roberts, who observed bradycardia in only 10%.\textsuperscript{9} In contrast to the study by Roberts, we included emergent intubations without atropine and enforced no upper time limit on the duration of attempts. Our median lowest SpO\textsubscript{2} of 63% is similar to previous studies.\textsuperscript{21} Similarity between HR and SpO\textsubscript{2} between the groups provides some reassurance that there was no bias favoring 1 group over the other. Despite the longer attempts used in our study, success rates were similar to those seen in studies using a limit of 30 seconds for each intubation.\textsuperscript{10} In an unblinded study, a possible source of bias might have been to allow a longer-duration intubation attempt for a favored arm of the study. Because there was no significant difference in either group in the duration of the attempt or success rates, we are confident this did not occur.

**CONCLUSION**

The use of an endotracheal stylet did not improve success rates of pediatric trainees intubating newborns.

**ACKNOWLEDGMENTS**

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