

ORIGINAL ARTICLE

Assessment of endotracheal tube placement in newborn infants: a randomized controlled trial

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OBJECTIVE: International resuscitation guidelines recommend clinical assessment and exhaled CO₂ to confirm tube placement immediately after intubation. However, exhaled CO₂ devices can display false negative results. In comparison, any respiratory function monitor can be used to measure and display gas flow in and out of an endotracheal tube. However, neither method has been examined in detail. We hypothesized that a flow sensor would improve the assessment of tracheal vs esophageal tube placement in neonates with a higher success rate and a shorter time to tube placement confirmation when compared with the use of a quantitative end-tidal CO₂ (ETCO₂) detector.

STUDY DESIGN: Between December 2013 and September 2014, preterm and term infants requiring endotracheal intubation were eligible for inclusion and randomly allocated to either ETCO₂ ('ETCO₂ group') or flow sensor ('flow sensor group'). All infants were analyzed according to their group at randomization (that is, analysis was by intention-to-treat).

RESULT: During the study period, a total of 110 infants ($n = 55$ for each group) were randomized. Successful endotracheal tube placements were correctly identified in 100% of cases by the flow sensor compared with 72% of cases with the ETCO₂ detector within 10 inflations ($P < 0.05$). The median (interquartile range) number of inflations needed to identify successful tube placement was significantly lower in the flow sensor group with 2 (1 to 3) inflations vs 8 (6 to 10) inflations with the ETCO₂ detector ($P < 0.001$).

CONCLUSION: A flow sensor would improve the assessment of successful endotracheal tube placement with a higher success rate and a shorter time compared with an ETCO₂ detector.

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INTRODUCTION

The current gold standard to confirm endotracheal tube position is an anterior–posterior chest radiograph; however, this is often delayed.¹ Rapid confirmation of correct tube placement at the point of care is important because in addition to ineffective respiratory support, tube malposition is associated with serious adverse outcomes, including hypoxemia, pneumothorax, right upper lobe collapse and death.^{2–4} This has led to the development of various methods to confirm endotracheal tube placement, including clinical assessment, end-tidal CO₂ (ETCO₂) or gas flow.^{5,6}

Clinical signs of endotracheal tube placement include a prompt increase in heart rate, chest wall movement and visualization during direct laryngoscopy of the tube passing through the vocal cords, presence of breath sounds in the axillae and absence of breath sounds in the epigastrium and condensation in the tube during expiration.⁷ These clinical signs are unreliable even in experienced hands.⁸ Recognition of esophageal intubation, using clinical signs alone, may take several minutes.^{9–12}

ETCO₂ can be detected using colorimetric devices or measured quantitatively by capnography using main-stream, side-stream or micro-stream devices.^{10,11,13} International resuscitation guidelines recommend clinical assessment and exhaled CO₂ to confirm endotracheal tube placement immediately after intubation.⁷ Although ETCO₂ or exhaled CO₂ devices are frequently used to assess tube placement,^{14–17} false negative results may occur, particularly when the infant is in severe respiratory failure, the inflation pressure is not high enough to ventilate the lungs or if

there is inadequate or no cardiac output.^{18–20} A false negative may also occur in the presence of a large leak resulting from intubation with an inadequately sized endotracheal tube. This may lead the clinician to believe that the intubation is esophageal, when in fact it is tracheal. Although observational studies have evaluated side-stream or micro-stream CO₂ detectors on tube placement using capnography technique, neither have been evaluated in randomized trials in neonates.

Any respiratory function monitor can be used to measure and display gas flow,²¹ and measuring gas flow with a flow sensor placed between the tube and the ventilation device has been used to determine tube placement.²² Schmölder *et al.*²² compared gas flow signals to colorimetric CO₂ detection in an ovine model of neonatal resuscitation, and reported that both methods identified all tube placements correctly.²² However, the colorimetric CO₂ detector required at least 3 and up to 10 inflations to identify tube location compared with 1–2 inflations with the flow sensor. Further, colorimetric CO₂ detectors may fail to change color despite correct tube placement in up to one-third of cases and therefore may mislead clinicians in the course of providing respiratory care to intubated infants in the delivery room.

Given the lack of information, we aimed to compare the use of a flow sensor to a quantitative ETCO₂ detector to assess tube placement in neonates with respiratory failure in a randomized controlled trial. We hypothesized that a flow sensor would improve the assessment of endotracheal tube placement in neonates with a higher success rate and a shorter time to tube

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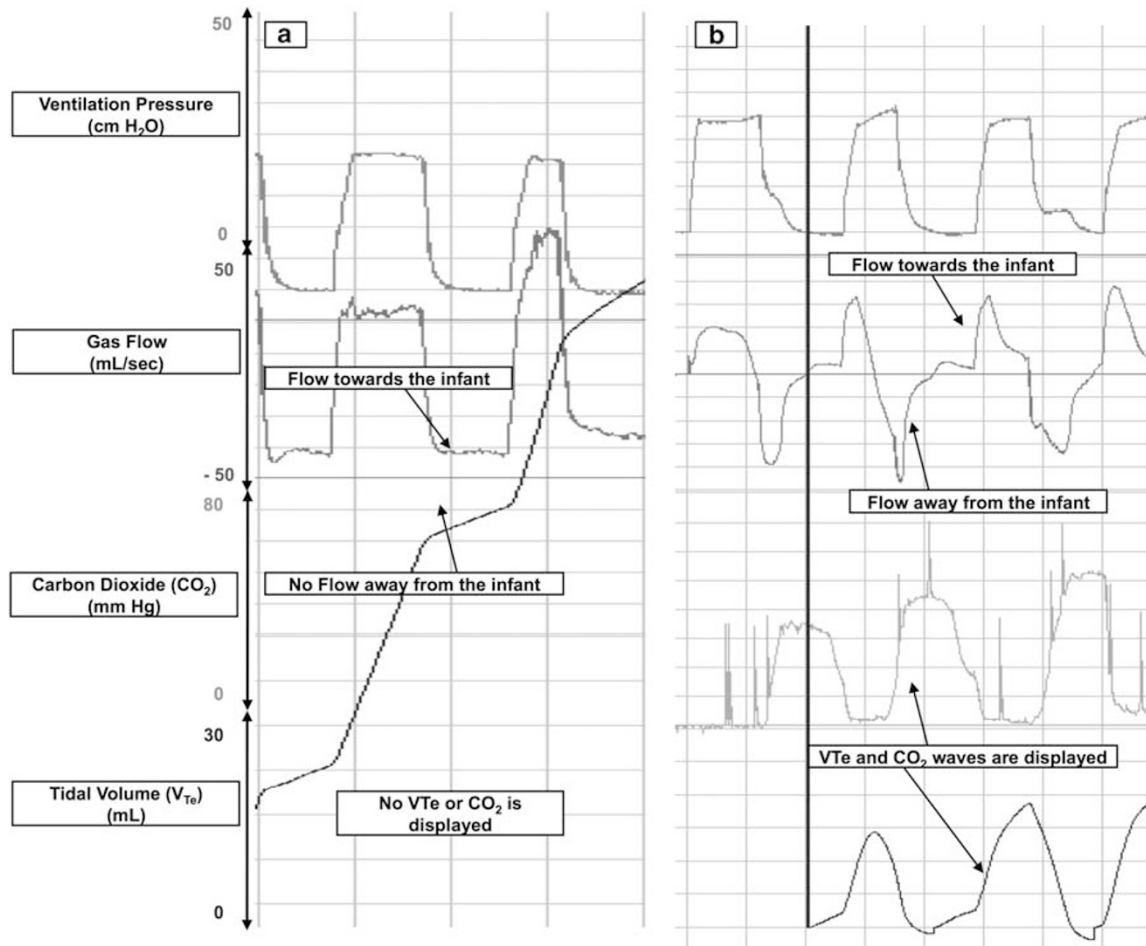


Figure 1. Flow and end-tidal CO₂ (ETCO₂) waveforms to identify endotracheal (a) or esophageal (b) tube placement.²⁴

placement confirmation when compared with the use of a quantitative ETCO₂ detector.

METHODS

This study was carried out at The Royal Alexandra Hospital, Edmonton, a tertiary perinatal center admitting approximately 1500 infants to the Neonatal Intensive Care Unit (NICU) annually. Between December 2013 and September 2014, preterm and term infants requiring endotracheal intubation in the NICU were eligible for inclusion. Infants were excluded if their parents refused to give consent to this study. Several studies are currently ongoing in the delivery room at the Royal Alexandra Hospital; and therefore, the study was limited to the NICU. The Northern Alberta Neonatal Program Research Committee and Health Ethics Research Board, University of Alberta, approved the study, granted deferred consent, and the trial was registered at Clinicaltrials.gov NCT01870622.

Randomization

Eligible infants were randomly allocated to either ETCO₂ ('ETCO₂ group') or flow sensor ('flow sensor group'). Randomization was 1:1 between groups, and allocation was block randomized with various block sizes of 4 to 8. Randomization was achieved using sequentially numbered, sealed, brown opaque envelopes containing treatment allocation on a folded card. The research team immediately opened the envelope before intubation. The folded card indicated the unique trial number with the treatment allocation 'ETCO₂ group' or 'flow sensor group'. Twins and triplets were randomized as individuals.

Blinding

For each intubation, the clinical team was blinded to the opposite intervention (for example, when randomized to ETCO₂ the clinical team was blinded to flow waves and vice versa). Both the data collector and outcome assessor were unaware of the group allocation.

Description of interventions

Intervention in both groups. Respiratory support during the intubation procedure was performed using an appropriately sized round silicone face mask and a Neopuff T-piece device (both from Fisher and Paykel Healthcare, Auckland, New Zealand), a continuous flow, pressure-limited device with a built-in manometer and a positive end expiratory pressure valve. The default settings used were a gas flow of 8 l min⁻¹, a peak inflation pressure of 24 cmH₂O and a positive end expiratory pressure of 6 cmH₂O. Staff members performing intubations were trained to use this device. The research team was not involved in the clinical care of the infants.

Intubation. At the NICU of the Royal Alexandra Hospital, oral endotracheal intubation is the preferred method. Staff members performing intubations included Respiratory Therapists, Neonatal Nurse Practitioners, Transport Nurses, Pediatric Residents, Neonatal Fellows or Neonatal Consultants. Intubation was performed either for surfactant administration with extubation shortly afterwards or for ongoing continuous mechanical ventilation. Criteria of intubation were oxygen requirement >40%, >6 apneas requiring stimulation over a period of 6 h, 1 × apnea requiring mask ventilation. Before intubation, all infants received premedications consisting of 0.02 mg kg⁻¹ Atropine (Sandoz Canada Inc., Boucherville, QC, Canada), 5 μm kg⁻¹ Fentanyl (Sandoz Canada Inc.) and 2 mg kg⁻¹

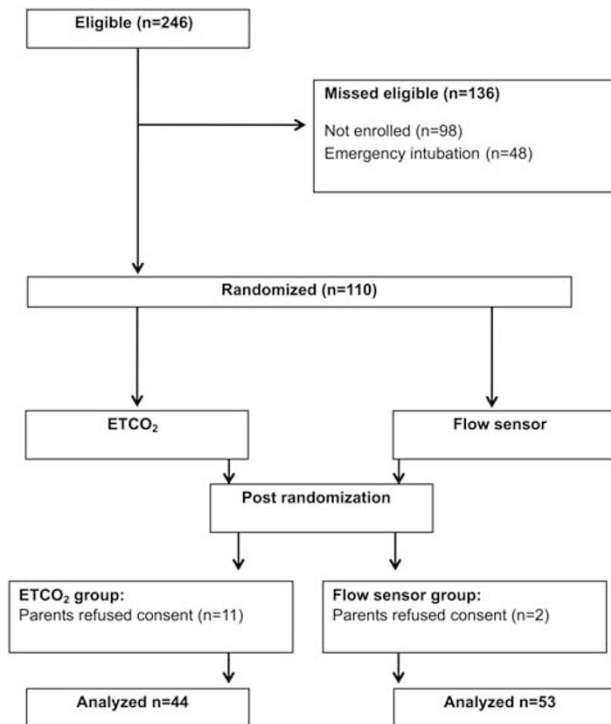


Figure 2. Study flow chart. ETCO₂, end-tidal CO₂.

Suxamethonium (Alveda Pharmaceutical Inc., Toronto, ON, Canada). Further doses of suxamethonium and/or fentanyl were given if indicated. For intubation for surfactant administration with extubation shortly afterwards, the fentanyl dose was halved to 2.5 $\mu\text{g kg}^{-1}$.

Estimation of correct endotracheal tube insertion. Hospital policy recommends to estimate the correct depth (cm) of tube placement by using the '7-8-9 rule'²³ when the endotracheal tube is placed orally. Using this formula, an infant weighing 1 kg would be intubated to a depth of 7 cm, a 2-kg infant to a depth of 8 cm and a 3-kg infant to a depth of 9 cm from the upper lip.

Confirmation of endotracheal tube placement immediately after intubation. At the NICU of the Royal Alexandra Hospital, confirmation of endotracheal tube placement immediately after intubations is done by using clinical signs and ETCO₂. Clinical signs of endotracheal tube placement include a prompt increase in heart rate, chest wall movement and visualization during direct laryngoscopy of the tube passing through the vocal cords, presence of breath sounds in the axillae and absence of breath sounds in the epigastrium and condensation in the tube during expiration.⁷ For the purpose of the study, clinical signs along with either capnographic ETCO₂ or gas flow measurement were used to identify endotracheal tube placement as defined as tube placement in the esophagus or trachea. In all cases, capnographic ETCO₂ and flow sensors were connected in series and maintained in their relative position (that is, capnographic ETCO₂ sensor closer to the patient and the flow sensor closer to the ventilation device) for each intubation.

ETCO₂ group. Infants who were randomized into the 'ETCO₂ group' received the primary confirmation of tube placement using a Philips MicrostreamCO₂ side-stream Filterline (Philips Healthcare, Philips Electronics Ltd., Markham, ON, Canada). In addition, the number of inflations needed to identify tube placement via gas flow was recorded for comparison. The capnography waveform and the ETCO₂ values were measured using the IntelliVue MP70 monitor (Philips Healthcare). The dead space of the side-stream ETCO₂ sensor is approximately 1 ml.

Flow sensor group. For infants who were randomized to the 'flow sensor group', the tube placement was confirmed using a Dräger VN500 heated wire anemometer neonatal flow sensor (Dräger, Lübeck, Germany). In

addition, the number of inflations needed to identify tube placement via ETCO₂ was recorded for comparison. The flow sensor waveform and gas flow values were displayed on the Dräger VN500 monitor. The dead space of the flow sensor is approximately 1 ml. Detection of expiratory flow indicates placement of the tube endotracheally (Figure 1), whereas the presence of inspiratory flow with no expiratory flow indicated that the tube was not in the trachea (Figure 1).^{19,21,24}

Assessment for tube placement for infants only receiving surfactant. In infants who were intubated solely for surfactant administration, assessment of tube placement was performed by clinical assessment and the either technique mentioned above depending on group allocation. This approach potentially could have caused removal of a tube placed in the trachea because of negative ETCO₂ or flow wave reading.

Chest X-ray for tube placement for ongoing ventilation. An anterior-posterior chest radiograph was used to confirm tube position within the trachea for babies receiving ongoing continuous mechanical ventilation. A neck brace was used to keep the infant's head straight to avoid tube movements because of flexion or extension.²⁵ Hospital policy recommends only an anterior-posterior chest radiograph; and therefore, no lateral chest radiograph was obtained for the assessment of tube placement. Our guidelines for tube placement recommend that the lower limit for tube position be measured in relation to the carina. The tube tip should be between 0.2 and 2 cm above the carina depending on the infant's age;^{1,26} the first thoracic vertebrae was also used as a reference point.²⁷ Position assessment of chest X-rays included correct tube position, just above the carina (< 0.2 cm); right main bronchus, or high in the trachea (> 2 cm or above the first thoracic vertebrae).

Monitoring systems during intubation. IntelliVue MP70 monitor (Philips Healthcare) was used to continuously measure heart rate and percutaneous oxygen saturation. Heart rate was measured using three Micro-Premie Leads (Vermed, Bellows Falls, VT, USA). A pulse oximeter (Masimo Corporation, Irvine, CA, USA) probe set at maximum sensitivity and 10 s averaging was placed around the infant's right hand or wrist to measure oxygen saturation.

Sample size calculation

Our primary outcome measure was percentage of successful endotracheal tube placement. Our observational data showed that tube placement was confirmed in 75% of infants using ETCO₂ measurement. We speculated that the percentage of endotracheal placed tubes would increase to 90% in the 'flow sensor group'. For this increase, 51 (in each group) are needed with 80% power and a two-tailed alpha error of 0.05.

Secondary outcomes included duration of intubation attempt (time from end of mask ventilation to start of ventilation), number of inflations until confirmation, time in seconds to confirm endotracheal or esophageal placement, changes in heart rate and saturation during intubation procedure, ventilator days, days of respiratory support and rate of chronic lung disease.

Statistical analysis

Demographics of study infants were recorded. The data are presented as mean (s.d.) for normally distributed continuous variables and median (interquartile range) when the distribution was skewed. All infants were analyzed according to their group at randomization (that is, analysis was by intention-to-treat). Data were compared using Student's *t*-test for parametric and Mann-Whitney *U*-test for non-parametric comparisons of continuous variables, and Fisher's exact test for categorical variables. *P*-values were two-sided and *P* < 0.05 was considered as statistically significant. Statistical analyses were performed with Stata (Intercooled 10, Statacorp, College Station, TX, USA).

RESULTS

During the study period, a total of 110 infants (*n* = 55 for each group) were randomized; 13 parents declined consent, which left 97 infants (*n* = 44 in ETCO₂ group and *n* = 53 in flow sensor group) (Figure 2). A total of 48 infants were < 28 weeks, 33 infants between 28⁺⁰ and 31⁺⁶ weeks, 12 infants between 32⁺⁰ and 36⁺⁶ weeks and 4 infants were born at term. Demographics are

Table 1. Demographics of study infants

	ETCO ₂ group (n = 44)	Flow sensor group (n = 53)	P-value
Birth weight (g)	1245 (550–3490)	1232 (490–4000)	0.927
Gestational age (weeks) ^a	26 (25–30)	28 (26–29)	0.483
Male (n) ^b	22 (50%)	33 (62%)	0.304
Antenatal steroids (n) ^b	26 (59%)	30 (56%)	1.000
Apgar 1 min ^a	4 (3–6)	5 (3–6)	0.460
Apgar 5 min ^a	6 (6–8)	7 (6–8)	0.141
Successful intubation after #1 attempt	31 (70%)	44 (83%)	0.154
Successful intubation after #2 attempt	5 (11%)	7 (13%)	1.00
Successful intubation after #3 attempt	8 (18%)	2 (4%)	0.02

Abbreviations: ETCO₂, end-tidal CO₂; IQR, interquartile range. Data are presented as mean (s.d.), unless indicated. ^aMedian (IQR). ^bn (%).

presented in Table 1. Infants were intubated for increase in oxygen requirement ($n = 59$), apnea ($n = 28$), accidental extubation ($n = 6$) and elective re-intubation ($n = 4$). Overall, 72 (74%) intubations were performed for mechanical ventilation and 25 (26%) for surfactant administration with extubation within 30 min. We recorded a total of 130 intubation attempts (ranging from 1 to 3) for the 97 intubations. Airway injury during intubation was observed in 13 cases (13%) (blood ($n = 10$), swollen cords ($n = 2$) and vocal cord redness ($n = 1$)). Intubation attempts were performed by Pediatric Residents ($n = 13$), Neonatal Fellows ($n = 18$), Respiratory Therapists ($n = 39$), Transport Nurses ($n = 31$), Neonatal Nurse Practitioners ($n = 23$) or Neonatal Consultants ($n = 6$). Success rates and duration of intubation are presented in Table 2. All infants received at least one dose of Atropine, Fentanyl and Suxamethonium. Nine (9%) and eighteen (19%) infants received a second dose of Fentanyl and Suxamethonium, respectively.

Primary outcome

There was no non-endotracheal placement of tube in both study groups. Successful tube placement within the trachea was identified in 100% of cases by the flow sensor within 10 inflations compared with 72% of cases with the ETCO₂ detector within 10 inflations ($P < 0.05$). The median (range) number of inflations needed to identify tube placement was significantly lower in the flow sensor group with 2 (1 to 7) inflations vs 8 (1 to 30) inflations with the ETCO₂ detector ($P < 0.001$). Overall 100% of intubations were correctly identified by the flow sensor. In the ETCO₂ group, 36 of 43 (84%) intubations were correctly identified by ETCO₂ detector ($P = 0.001$ vs the flow sensor group), whereas ETCO₂ displayed a false negative result in 7 intubations resulting in removal of the tube and reintubations.

Heart rate and oxygen saturation after intubation

The lowest heart rate and oxygen saturation at the end of intubation in the ETCO₂ and flow sensor groups were 148 (28)/min vs 159 (18)/min ($P < 0.05$) and 71 (23) vs 80 (17)% ($P < 0.05$), respectively.

Assessment of chest X-rays

In 72 intubations (29 in the ETCO₂ group and 43 in the flow sensor group ($P = 0.106$)) where mechanical ventilation was required, tube position within the trachea was assessed by anterior–posterior chest X-ray. A good tube position within the trachea was observed in 14 (19%), a high tracheal position in 9 (13%), low tube position in the trachea in 29 (40%) and in the right main bronchus in 20 (28%). We had no esophageal intubation that remained unrecognized until chest X-ray.

Other neonatal outcomes

In all, 3 out of 44 infants in the ETCO₂ group died before discharge with five having intraventricular hemorrhage grade 3 or 4. Two of fifty-three infants died in the flow sensor group and five having intraventricular hemorrhage grade 3 or 4. Chronic lung disease defined as supplemental oxygen requirement at post-conceptual age of 36 weeks (in those born < 32 weeks gestational age) occurred in 17 and 15 surviving infants in the ETCO₂ and flow sensor groups, respectively.

DISCUSSION

Tracheal intubation remains a common procedure in the delivery room or NICU.^{12,19,27} CO₂ is exhaled from the lungs at concentrations much higher than present in air. It can be detected using colorimetric devices or measured quantitatively using main-stream, side-stream or micro-stream devices.^{9–11,13,19} Although ETCO₂ devices are frequently used to assess tube placement,^{14–17} false negative results may occur, particularly when the infant is in severe respiratory failure and the inflation pressure is not high enough to ventilate the lungs.^{18–20} Studies using colorimetric devices showed that these devices have a false negative rate of up to 33%.^{10,19} Aziz *et al.*¹⁰ reported that a colorimetric device was unable to identify tube placements in three cases; and Schmölzer *et al.*¹⁹ reported that a colorimetric device failed to change color on 12 of 35 occasions when the tube was endotracheal placed.¹⁹ Studies comparing main-stream, side-stream or micro-stream measurement of ETCO₂ to clinical assessment reported that the median time to determine tube placement was significantly reduced⁹ and have higher accuracy.^{11,13} In this randomized controlled trial, we found that using a flow sensor would improve the assessment of tube placement in neonates with a higher success rate and a shorter time to tube placement confirmation when compared with the use of a quantitative ETCO₂ detector (100 vs 72% and 2 vs 8 inflations, respectively).

Rates of tube placement, particularly for junior medical staff, are less than 50%; and accidental esophageal intubation is not uncommon.^{12,19,27,28} Guidelines of the Neonatal Resuscitation Program developed by the American Academy of Pediatrics recommend that the intubation procedure is completed within 30 s.⁷ In practice, 50 to 60% of intubation attempts are successful, with the majority occurring within 30 s.^{12,29} In the current study, the average duration of intubation was longer for all professional groups (Table 2). This may be because we used changes in heart rate and oxygen saturation as our main indicators to conclude the completion of intubation. The lowest heart rate we observed was 98 beats per minute. This suggests that using changes in heart rate and oxygen saturation to determine lengths of the intubation procedure is possible.

Table 2. Success rates and duration of intubation

	<i>Pediatric residents</i> (n = 13)	<i>Neonatal fellows</i> (n = 18)	<i>Respiratory therapists</i> (n = 39)	<i>Neonatal transport nurses</i> (n = 31)	<i>Neonatal nurse practitioners</i> (n = 23)	<i>Neonatal consultants</i> (n = 6)
<i>Duration of intubation</i>						
Duration of intubation (seconds) ^a	48 (30–70)	39 (12–69)	39 (16–90)	37 (10–80)	39 (15–180)	40 (17–68)
<i>Success rate of intubation</i>						
Overall success rate of intubation	6 (46%)	17 (94%)	26 (66%)	24 (77%)	20 (87%)	4 (66%)
First intubation (n = 97)	n = 10	n = 13	n = 31	n = 23	n = 17	n = 3
Successful intubation	4 (40%)	12 (92%)	23 (74%)	19 (83%)	15 (88%)	2 (66%)
Intubation attempt	3 (30%)		4 (13%)	4 (17%)	2 (12%)	1 (33%)
Visualization	3 (30%)	1 (8%)	4 (13%)			
Second intubation (n = 23)	n = 3	n = 4	n = 6	n = 5	n = 3	n = 2
Successful intubation	2 (66%)	4 (100%)	1 (17%)	2 (40%)	2 (66%)	1 (50%)
Intubation attempt			3 (50%)	2 (40%)	1 (33%)	1 (50%)
Visualization	1 (33%)		2 (33%)	1 (20%)		
Third intubation (n = 10)		n = 1	n = 2	n = 3	n = 3	n = 1
Successful intubation		1	2	3	3	1

Data are presented as n (%), unless indicated. ^aMean (range).

Any respiratory function monitor can be used to measure and display airway pressure, gas flow and tidal volume.²¹ In the current study, we aimed to design a very easily translatable study and used the flow sensor of our ventilator to assess tube placement. We chose this approach as it could be performed in any NICU owning a ventilator with flow sensing capability. Respiratory waves forms are more commonly used during neonatal care to assess an infant's respiratory status.^{21,24,30,31} Observational studies reported that gas flow signals to assess tube placement compared with a colorimetric CO₂ detector are faster and more reliable to identify all tube placements correctly.^{12,19,21,22,24,32} The available evidence during neonatal resuscitation is derived from two observational studies in the delivery room.^{12,19} O'Donnell *et al.*¹² reported that clinical assessment of tube position takes approximately 39 s compared with 19 s using a flow signal. Schmölder *et al.*¹⁹ reported that colorimetric CO₂ detector failed to change color despite the flow wave indicating correct placement in one-third of intubations, which may potentially affect clinicians in decision-making when intubating infants in the delivery room.

Limitations

There are several limitations in the current study. First, it needs to be emphasized that although respiratory and capnography waveforms can be used to identify tube placement, inexperience and lack of knowledge about the displayed waveforms may lead to misinterpretation of the signals. Anyone using this device must therefore be trained to interpret respiratory and capnography waveform signals. However, respiratory and capnography waveforms are now routinely used in many NICUs.³¹ Second, ETCO₂ or flow waves cannot distinguish between tube placement in the trachea or the right main bronchus, which is a major limitation of both devices. Third, leaks around the tube could cause misinterpretation of tube placement. In particular, very large leaks could cause minimal ETCO₂ or flow waves to be displayed.²⁴ Fourth, more parents in the ETCO₂ group refused to participate, which resulted in less patients than the proposed enrolment as determined by power analysis, which could have influenced the overall results of the study.

Translation into clinical practice

We used a flow sensor from a standard ventilator in the current study, which is readily available in every NICU. As this is standard equipment, no additional purchase is necessary to use flow waves

to assess tube placement in any NICU. However, standard ventilators are not readily available in many delivery rooms, which is a limitation to translate our findings into delivery rooms.

CONCLUSION

A flow sensor would improve the assessment of tube placement with a higher success rate and a shorter time compared with an ETCO₂ detector.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHOR CONTRIBUTIONS

GMS, KA, MOR and PYC contributed to conception and design. GMS, KA, SvO, KK, MOR and PYC contributed to collection and assembly of data. GMS, KA, SvO, MOR and PYC contributed to analysis and interpretation of the data. GMS, KA, MOR, PYC, SvO and KK contributed to drafting of the article. GMS, KA, MOR, SvO, KK and PYC contributed to critical revision of the article for important intellectual content. GMS, KA, SvO, KK, MOR and PYC contributed to final approval of the article.

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