

## Neonatal Endotracheal Tubes and Prevention of Bronchial Intubation

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### Abstract

**Background:** Bronchial intubation increases neonatal morbidity. Endotracheal tubes (ETT) are marked to avoid this event. No studies have specifically examined whether the markings on neonatal ETTs Reduce Right Main Stem Bronchial Intubation (RMSBI).

**Objectives:** The major research objective was to reduce pulmonary morbidity in extremely preterm infants. In Aim 1, we determined retrospectively the incidence of RMSBI after oro-tracheal placement of ETTs. In Aim 2, we conducted a prospective, randomized clinical trial to ascertain whether a new endotracheal tube design prevented bronchial intubation.

**Methods:** We reviewed chest radiographsto establish the historical incidence of RMSBI. During aclinical trial, we intubated control infants with an ETT having standard markings compared to newborns intubated with an ETT with proximally placed, colored lines. We placed ETTs in control infants using the 7-8-9 cm rule to judge the depth of insertion. We reduced the depth of insertion by 0.5 cmwhen using the new ETT design because a colored line is locatednext to the upper gingiva.

**Results:** The retrospective study showed bronchial intubation occurred in 57% of infants born at 23 to 26 weeks of gestation compared to 17% of neonates born after 26 weeks ( $p<.001$ ). In the clinical trial, 26% (8 of 31) of controls had RMSBI after the initial ETT placement, while no infants intubated with the new ETT had this complication ( $p<.001$ ).

**Conclusions:** Bronchial intubation is common in extremely preterm infants intubated with commercially marked ETTs. A new ETT design that locates a proximal colored line to the upper gingivaensuredproper placement in the mid-trachea of neonates.

**Keywords:** Endotracheal tube; Bronchial intubation; Extremely low birth weight infants; Chest radiograph; Depth of intubation; Endotracheal tube design; Endotracheal tube stabilizing devices

### Introduction

Right main stem bronchial intubation (RMSBI) causes morbidity during neonatal assisted ventilation. Over-distention of the right middle and/or lower lobes of the lung and under-ventilation and/or atelectasis of the remaining lung are the major complications of RMSBI [1,2]. Complications of RMSBI include a) over-inflation of a pulmonary lobe (lobar emphysema), b) pulmonary interstitial emphysema, c) pneumothorax, and/or d) pneumomediastinum [3]. In very pre-

term infants, pneumothorax correlates with the pathophysiology of intraventricular hemorrhage [4].

The first study that published the incidence of bronchial intubation inneonates was over four decades ago [1]. In 1971, infants with birth weights <1000 g only occasionally survived compared to today. Because of anatomy, extremely low birth weight infants (ELBW) infants have a higher risk of RMSBI because the distance from the larynx to carina is reduced compared to larger neonates [5]. Since ELBW infants also need a longer period of assisted ventilation [6], we theorized that the incidence of RMSBI is in ELBW infants is higher. We undertook a retrospective study to find out whether this assumption was correct. Furthermore, we postulated a new en-

dotracheal tube (ETT) design could reduce RMSBI in ELBW infants. We embedded colored lines proximally on ETTs. Each colored line represented a depth of insertion to the mid-trachea when the colored line was adjacent to the upper gingiva (Figure 1). Based on an initial clinical trial, we report this ETT design lowers the risk of RMSBI in ELBW infants.

## Methods

### Retrospective study

A retrospective study reviewed the incidence of RMSBI before a prospective study using the newly marked endotracheal tube began. The review studied neonates hospitalized at the University of California, Davis Medical Center over a 3-year period. Our Neonatal Intensive Care Unit (NICU) identified all intubated infants. We reviewed charts of these infants for demographic information and reports of all chest radiographs. Our protocol used in the NICU for performing chest radiographs keeps the head in the midline position with each arm extended beside the head. During the 3-year period, we used an ETT that had marks distally for localizing placement adjacent the vocal cords [1] and numbers in centimeters on the tube to determine the depth of insertion [7]. The numbers in centimeters became higher as the distance from the ETT tip to the adaptor increases. Information from the chart review established the incidence of RMSBI during the initial intubation and during the period of subsequent assisted ventilation. We correlated birth weight, gestational age, gender, and the duration of assisted ventilation with RMSBI.

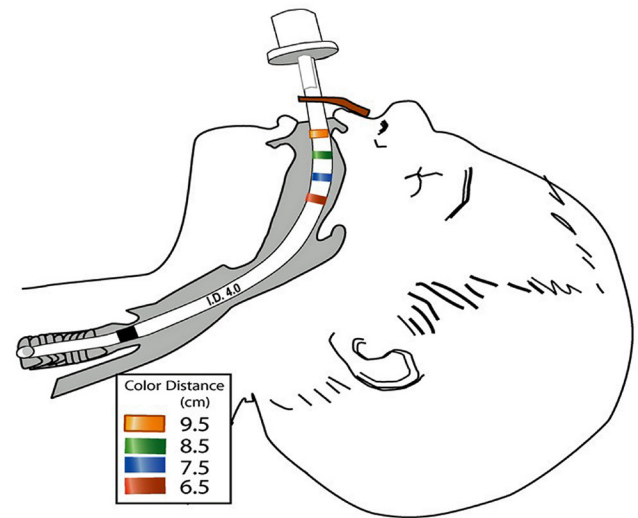
### Prospective study

The second phase of this study enrolled 62 infants at University of California, Davis Medical Center at Sacramento, California. We estimated the sample size per the recommendations of Cohen [8] for a chi-square analysis. Using an effect size of 0.50, a power of .80,  $u = 1$ , and an alpha of 0.05, a total of 31 infants were necessary for the study.

Inclusion criteria consisted of newborn infants regardless of birth weight and gestational age who required a) oro-tracheal intubation and b) infants who had parents who gave written informed consent for the prospective study. The exclusion criteria for newborn infants included babies with head, neck, or thoracic anomalies. Both groups received "State of the Art" neonatal care. The institutional review board of the University of California, Davis School of Medicine approved the retrospective and prospective studies.

During the prospective study, we randomized infants to one of two groups based on the type of neonatal ETT used. We designated that the control have the same ETT placed during the retrospective study. The ETT in the control group had a) circumferential stripes near the distal end for vocal cord localization and b) centimeter numbers along its side to inform the distance from ETT tip to an upper lip or the point of tube fixation, to the ETT tip in the trachea. The treatment group used the same ETT as controls except these tubes had bright circumferential colored lines placed proximally at 6.5, 7.5, 8.5 and 9.5 centimeters from the tip (Figure 1). The ETT in the treatment group infants had one colored line localized

next to the upper gingiva. In this study, the experimental ETT consisted of non-toxic and tightly adherent tape that was 0.25 cm wide. Tubes with the adherent tape were prepared and gas



**Figure 1:** Representation of a new endotracheal tube design. We introduced the new tube into the trachea, and one of its proximally placed colored lines is next to the upper gingiva. We based the distance of insertion on an infant's weight in kilograms and the color of the line designates the depth of insertion for the different weights:

- 4 kg infant has a 9.5 cm distance of insertion and the colored line is "ORANGE",
- 3 kg infant has a 8.5 cm distance of insertion and the line is colored "GREEN"
- 2 kg infant has a 7.5 cm distance of insertion the line is colored "BLUE"
- 1 kg infants has a distance of insertion of 6.5 cm and the line is colored "RED".

We measured the depth of insertion from the upper gingiva to the tip of the endotracheal tube, and at this distance, the tip of the tube should be located to the mid-trachea.

sterilized before use.

We followed oro-tracheal intubation procedure described in the Textbook of Neonatal Resuscitation, American Academy of Pediatrics, 6th Edition, 2011, Elk Grove, IL, to place ETTs in control and treated infants. Table 1 reviews the rule used to place ETT in control infants. The rule uses a 7, 8, or 9 cm depth of oro-tracheal insertion from lip to the tip when the birth weight is 1, 2 or 3 kg, respectively [2,9,10]. The physician responsible for an individual infant decided the depth of insertion in centimeters based on either an estimated fetal weight or the actual birth weight. We based the estimated fetal weight on the average weight for the calculated gestational age of a fetus determined by either the last menstrual period or the fetal ultrasound examination. For control subjects, we based the depth of insertion on centimeter marks imprinted on the tube. For endotracheal tubes with colored lines, we used the estimated fetal weight or actual birth weight to determine placement, however, we reduced the depth of insertion by 0.5 cm (Table 1). The reason for reducing the depth of insertion for ETTs with Colored Lines was one of the lines was located at the mid-point of the upper gingival ridge rather than locating a centimeter number to the mid-upper lip. To prevent movement of the ETT, we placed the Colored Line on an ETT at a fixed anatomic structure, the upper gingiva, rather than the

**Table 1:** Oro-tracheal Tube Insertion: Lip-to-Tip versus Upper Gingiva-to-Tip Distance

Weight, kg	Mid-Line Depth of Oro-tracheal Tube Insertion	
	Centimeters from upper lip*	Centimeters from upper gum line
1♦	7	6.5
2	8	7.5
3	9	8.5
4	10	9.5

\* Textbook of Neonatal Resuscitation (2)

♦ Babies weighing <750 g require a 6 centimeter depth of insertion from tip-to-lip (2). Caregivers consider this recommendation when inserting an emergency endotracheal tube into infants below this weight.

more mobile upper lip, a traditional location for securing an ETT.

Following insertion, we secured the ETT in control and treatment group infants to the upper lip using a described method [11]. Briefly, we applied a protective skin agent on the upper lip (No Sting Skin Prep™ (Smith & Nephew, Memphis, TN)). Next, we exactly cut an Elastoplast bandage (Tensoplast™ elastic adhesive bandage, BSM Medical, Charlotte, NC) and applied this adhesive to the upper from one corner of the mouth to the other. The middle of the Elastoplast dressing had a 0.25 cm central fold. We passed a 4-0 silk suture with a cutting needle through the fold and then passed the needle through the wall of the EET taking care to avoid the lumen (4-0 black silk Ethicon suture 18", J-1 cutting). Two square knots secured the ETT to the Elastoplast bandage. We cut white adhesive tape into an H-shape. We placed the upper half of the adhesive tape on the Elastoplast bandage, while we wrapped the lower half circumferentially around the ETT. We then covered the adhesive tape with soft silicone tape (Mepitac silicone tape, Mölnlycke Health Care, Brunswick, ME) from either side of the cheek, over the lip and around the ETT. This pink supportive tape avoided oral secretions from wetting and loosening the adhesive tape. We selected this technique for stabilizing the ETT because our NICU had 30 years of experience with the method. Moreover, we used this procedure for securing tubes in the retrospective study.

After intubation in the delivery suite and after re-intubation in the NICU, we secured the H-shaped adhesive tape secured to the upper lip and we reinforced the adhesive tape with silicone soft tape. Thereafter, a chest radiograph identified the location of the ETT tip. Then we applied the permanent method of stabilizing the ETT as described above.

After intubation, the initial and subsequent chest radiographs were performed with the ETT in a midline position and the neck located in a neutral position without either flexion, extension, or rotation because such movements can change the position of the ETT in the trachea [5, 12]. We adjusted an ETT to a mid-tracheal position after the initial radiograph. Subsequently, we performed follow-up chest radiographs depending on the clinical status and at the discretion of the attending neonatologist. A radiologist unaware of the assignment to the treatment or control group independently confirmed the location of the ETT on these radiographs.

During the course of assisted ventilation, the nursing staff, the respiratory care practitioners, or physicians assessed the proper location of the endotracheal tube by examining either the centimeter numbers on the ETT in control infants or by looking at placement of the colored line next to the upper gingival ridge in treated infants.

We recorded the following characteristics in both groups: birth weight, gestational age, gender, and the position of the endotracheal tube on chest radiograph.

## Statistical Analysis

We stored clinical information and performed statistical analyses using SPSS version 22 (IBM, Chicago, Illinois). We conducted an inferential analysis using the Student's t test and a one-sample Chi-square test based on the data being analyzed [13].

## Results

### Retrospective Study

**Table 2:** Demographic Findings in the Retrospective Study

Gestational Age in Weeks of the Infants*	Number of Intubated Infants
23-26	60
27-29	104
30-33	84
34-36	87
37-42	112
Gender	
Male	237
Female	210

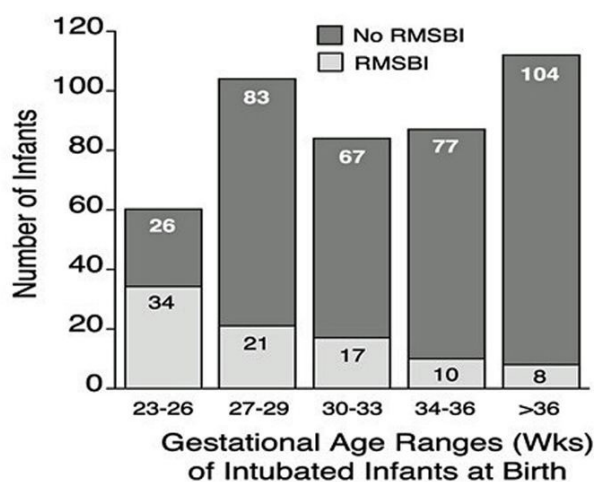
\* Birth weights ranged from 455 to 4185 grams.

During a 3-year period, 447 neonates required intubation during hospitalization. Table 2 shows the demographic findings. The overall incidence of RMSBI was 20%; however, Figure 2 shows that infants born at 23 - 26 weeks of gestation had a 57% chance of bronchial intubation either right after the initial intubation or during the course of assisted ventilation ( $\chi^2 = 54.93$ ,  $P < .001$ ). When infants born at 23 - 26 and 27 - 29 weeks of gestation were compared to infants born at  $\geq 37$  weeks of gestation, there was a higher risk of RMSBI at the younger gestational age ( $\chi^2 = 49.27$ ,  $P < .001$  and  $\chi^2 = 6.81$ ,  $P < .01$ , respectively). An analysis of chest radiographs during assisted ventilation revealed that a longer period of ventilatory support increased the risk of RMSBI. Infants born between 23 - 26 weeks of gestation had the longest duration of ventilator care.

### Prospective Study

Table 3 shows the demographic findings of subjects in the prospective study. There was no statistical difference in birth weight, gestational age, or gender between the groups. Levene's Test for the Equality of Error Variances was not significant ( $P > .05$ ), and we assumed equal variances in the control and treated groups.

In the control group, 8 of 31 (26%) of the subjects had RMSBI either after an initial ETT placement or during subsequent



**Abbreviations:** RMSBI = right main stem bronchial intubation

**Figure 2:** Relationship between gestational age and the incidence of bronchial intubation in neonates. This figure shows the gestational age at birth (in the weeks after conception) on the “x” axis, and we display the number of subjects that did or did not have bronchial intubation on the “y” axis. The internal legend shows infants in each gestational age category that did have (light-colored fill) or did not have (dark-colored fill) right main stem bronchial intubation. The inverse relationship between advancing gestational age and a reduction in the risk of bronchial intubation is evident.

**Table 3:** Demographics of Infants in the Control Group [Endotracheal Tubes with commercial markings] and the Treatment Group [Endotracheal Tubes with Proximally Placed Colored lines]

Range Gestational Age (wks)	* No Colored Line (n = 31)		Colored Lines (n = 31)	
	n	(% of n)	n	(% of n)
23 – 26	2	6	5	16
27 – 29	7	23	8	26
30 – 33	8	26	9	29
34 – 36	3	10	5	16
37 – 42	11	35	4	13
	31		31	
<b>Gender</b>				
Male	19	61	18	58
Female	12	39	13	42

\* Birth weight ranged from 567 to 4100 grams.

ventilator care. Three infants had RMSBI after the initial intubation, while five had RMSBI during subsequent ventilator care. None of the 31 infants in whom the colored striped ETT was inserted had RMSBI initially or during subsequent ventilatory assistance on chest radiography ( $x^2 = 34.13$ ,  $P < .001$ ).

## Discussion

Kuhns and Poznanski first proposed that manufacturers place centimeter numbers on ETTs with the higher numbers indicating a greater distance from the tip of the tube [1]. These numbers gave rise to the 7-8-9 rule that relates to the depth of insertion of an oro-tracheal ETT in a neonate of a specific weight [2,9,10]. Loew and Thibeault described an alternative method to control the depth of insertion during intubation [7]. A black safety line was located proximal to the tip of the

ETT. This vocal cord localizer on ETT is as a fetyline placed at the level of the larynx under direct vision during laryngoscopy to prevent RMSBI. A report, however, suggests vocal cord localizers on ETTs do not always accurately localize the tube in a proper position [14]. Our retrospective review showed that intubations still carry an unacceptable risk of bronchial intubation with an occurrence of about 20 to 26%. This percentage is, however, lower than the 50% incidence reported in 1971 [1].

Today, this reduction in RMSBI is not acceptable because more ELBW infants are born and caregivers and parents expect survival. In these immature infants, RMSBI occurs and pulmonary morbidity and mortality are serious consequences [15,16]. Following intubation but during the process of externally securing an ETT, the caregiver can no longer see the vocal cord localizer, and the ETT may become displaced during fixation. The back-up strategy for the vocal cord localizer is the numbers displayed in centimeters on side of the tube. The centimeter numbers are small and taping of the tube to the lip obscures them from view. There are currently a number of fixation devices marketed to secure the ETT rather than using the older method of taping the ETT to the upper lip and face. Nevertheless, caregivers still use taping of the ETT to the lip until chest radiograph defines the location and an adjustment of the ETT tip to a mid-trachea. Taping to the lip hinders the numbers and depth of insertion. New ETT-related fixation devices can still be problematic in identifying the centimeter numbers imprinted on the ETT. A study found one stabilizing ETT device prevented low placement compared to the tape only method [17], but unsatisfactory localization of ETTs in the trachea of neonates still persist. We theorized we could easily see colored, circumferential lines placed on ETTs. We found this was particularly true if the colored line was adjacent to a fixed anatomic structure like the upper gingiva. We saw the colored line just by lifting up the lip; this assured the examiner that the original location had not changed. We elected colored lines placed on ETTs since they have a relationship to the 7-8-9 rule [2,9,10]. Since we localized colored line ETTs to the upper gingiva rather than the lip, we had to subtract 0.5 cm from the 7-8-9 rule when placing the colored lines on the tube. We placed brightly colored lines at 6.5, 7.5, 8.5 and 9.5 centimeters from the tip of the ETT when infants weighed 1, 2, 3 or 4 kg before or at birth. The findings reported here suggest the colored lines on ETTs located at the upper gingival ridge avoids RMSBI during the initial intubation and subsequent ventilator care. Nurses and respiratory practitioners reported the colored lines more readily identified the depth of insertion compared to the small centimeter numbers affixed to ETTs. Additionally, a report says infants weighing <750 g do not conform to the 7-8-9 rule (10); and therefore, it would be appropriate to place a line at 5.5 cm from the tip for infants born between 22 to 24 weeks of gestation and/or weighing 400 to 600 grams. A recent study found that gestational age, rather than birth weight, had a linear relationship with the proper depth of insertion [18]. Investigators must consider this finding during future studies of ETT placement and proximal colored lines will prevent RMSBI in these micropreemies.

This study has limitations. We could not mask the colored lines



on the ETT from the caregivers who knew immediately the assignment to the control or treatment group. It is conceivable that medical, nursing, and respiratory care practitioners were more attentive to displacement of an ETT with colored lines. Since the Hawthorne effect, in which information available to the caregivers potentially influences their behavior, there is a potential threat to the validity of the study. Nevertheless, the endotracheal tube design and its method of localization are defensible concepts.

Additionally, inward displacement of ETT in neonates and the risk of RMSBI increases from mobility of tubes secured by tape to the lip and face. We redesigned the markings on ETTs because nurseries still secure ETTs by taping initially after intubation or during ventilator care because of convenience or the high cost of ETT attachment devices. Many attachment devices are excessively large for very preterm infants. Yet, it is conceivable that one of the newer devices to secure ETTs might have reduced RMSBI in larger neonates. However, more stable attachment devices that secure ETTs can still move. It is noteworthy that the Food and Drug Administration in the United States has approved new devices for the fixation of ETTs in neonates without requiring manufacturers to perform a safety studies RMSBI is lower when using these appliances. Additional clinical trials comparing the merits of the new ETT designs described in this report versus the benefits of new fixation devices in preventing bronchial intubation during assisted ventilation of neonates seem warranted.

## Conclusions

In the future, we propose neonatal ETTs with bright, circumferential colored lines placed proximally on the tube; these lines correspond to the distance to the tip of the tube. During oro-tracheal intubation, we align these colored lines next to the mid-upper gingiva, a stable anatomic structure that cannot move like the upper lip. This initial report suggests this innovation in endotracheal tube design appears safe and lowers the risk of bronchial intubation. Use of this endotracheal tube design may also reduce ventilator-related morbidity in ELBW infants that are prone to bronchial intubation.

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