The Effects of Mouth Opening and Throat Pack Placement on Uncuffed Nasal Endotracheal Tube Leakage and Delivered Tidal Volumes in Mechanically Ventilated Pediatric Patients Undergoing Dental Procedures

Katie E. Bradford, DDS, Louis I. Siegelman, DDS, and Walter J. Psoter, DDS, PhD

Dental Anesthesiology, New York University–Lutheran Medical Center, Brooklyn, New York, and University of Rochester, Eastman Institute for Oral Health, Rochester, New York

Intubation for pediatric patients is frequently performed with an uncuffed endotracheal tube (ETT), which may result in an incomplete tracheal seal, resulting in gas leakage (leak). The purpose of this study was to assess the effect of (1) mouth opening and (2) throat pack placement in sealing and/or minimizing this leak to an acceptable level while providing adequate tidal volumes in mechanically ventilated patients. This prospective study of 2- to 6-year-olds undergoing general anesthesia with nasal intubation for dental procedures in the New York University–Lutheran Medical Center operating room was conducted between March 2015 and October 2015. Three sequential tidal volume (V_T) measurements were recorded: postintubation with the neck extended, with mouth opened, and after throat pack placement. Twenty-five subjects were included in the analyses. For subjects in whom no leak was detected, only throat pack placement statistically improved V_T . This is in marked contrast to numerically large, statistically significant effects, relative to baseline, for mouth opening (± 23.2 mL, $p < .009$, 21% increase from baseline) and throat pack placement (± 46 mL, $p < .009$, 41% increase from baseline) when a leak was detected. In children 2–6 years of age, nasal intubation with uncuffed ETTs that have incomplete tracheal seal have improved V_T with mouth opening and throat pack placement. This finding suggests that the intubation procedure is a process that extends through positioning, mouth opening, and throat pack placement.

Key Words: Uncuffed endotracheal tubes; Pediatric nasal intubation; Endotracheal tube leakage.

Uncuffed endotracheal tubes (ETTs) are often used in patients younger than 8–10 years of age because of the anatomy of the pediatric airway.^{1–3} Proponents of uncuffed ETTs often cite decreased risk of iatrogenic tracheal injury^{2,3} and the ability to use larger internal-diameter ETTs, which reduces resistance to air flow, decreasing the work of breathing in the spontaneously breathing patient,^{1–3} as the main reasons for choosing uncuffed ETTs in the pediatric population. Those who support the use of cuffed ETTs often cite the ability to seal the trachea by inflating the cuff. This eliminates the potential need to exchange a too small ETT for a larger

ETT,³ increasing risk to the patient for adverse airway events, as the number one reason cuffed ETTs should be used in all patients, regardless of age. A recent systematic review and meta-analysis suggests that cuffed ETTs may be the preferred approach in the pediatric population.⁴ However, consensus is elusive, and practice remains variable.

Minimizing uncuffed tube leakage would address a major disadvantage. We hypothesized that in pediatric nasal intubations with uncuffed tubes, both mouth opening and throat pack placement may minimize leakage and the need to exchange ETTs by compressing the soft tissue of the upper airway around the ETT. We have been unable to identify reports in the literature that specifically evaluate the effects of mouth opening and/or neck extension on uncuffed ETT leakages. Sanuki et al have conducted 3 oral surgery studies evaluating the effects of mouth opening and neck extension on leaks around, and the cuff pressures of, laryngeal mask

Received August 11, 2017; accepted for publication January 9, 2018.

Address correspondence to Dr Katie E. Bradford, 139 Rose Garden Lane, Goodlettsville, TN 37072; dr.katie.bradford@gmail.com.

Anesth Prog 65:237–243 2018 | DOI 10.2344/anpr-65-03-13
© 2018 by the American Dental Society of Anesthesiology

airways.^{5–7} They report that excessive mouth opening with an laryngeal mask airway resulted in increased leak pressure and intracuff pressure, which could result in ventilation difficulties, gastric insufflation, and sore throat.^{5,6} They concluded that a mouth opening of 3 cm and a head-neck extension of 45° resulted in “acceptable airway conditions” when using a laryngeal mask airway.^{6,7}

Given that the practice of using uncuffed nasal ETTs continues, it is important to identify best practices to ensure appropriate V_T and minimal leaks. The purpose of this study was to evaluate the ability of opening the mouth with a mouth prop or bite block and placing a throat pack (2 procedures routinely performed in dental surgeries) to seal and/or minimize uncuffed nasal ETT leak to an acceptable level as well as provide adequate V_T in children undergoing dental surgery under general anesthesia.

METHODS

Study Overview

A prospective, repeated-measures panel study of 2- to 6-year-olds undergoing nasal intubation (uncuffed ETTs) for dental procedures was conducted at New York University (NYU)–Lutheran Medical Center in Brooklyn, New York, between March 2015 and October 2015. Sequential V_T measurements were taken postintubation with the neck extended (baseline), mouth opened and mouth prop placed, and following throat pack placement (with the mouth remaining propped open). Multivariate regression analysis using generalized estimating equations was conducted to account for correlation between time points. The variable V_T was regressed on the time-event point and potential confounder variables to form the final model. This study was approved by the NYU–Lutheran Institutional Review Board, and written informed consent was obtained from the parents and/or legal guardians of each study participant.

Study Design

This was a prospective observational study of the effects of mouth opening and throat pack placement on V_T (and therefore of changes of gas leakage around an ETT) using uncuffed nasal ETTs in pediatric patients undergoing dental treatment under general anesthesia. The data were collected at the time of surgery by the patient’s dental anesthesiology team.

Study Eligibility

Inclusion criteria were patients (1) <7 years of age, (2) requiring dental treatment (eg, examination, radiographs, prophylaxis, dental restorations, dental extractions) under general anesthesia, and (3) with an American Society of Anesthesiologists (ASA) physical classification ≤ 2 . Exclusion criteria were patients (1) presenting for urgent/emergent dental treatment; (2) who would not be nasally intubated; (3) with a contraindication for head extension; (4) with known or suspected difficult intubation; (5) with a known need for an abnormal ETT size (eg, patients significantly smaller or larger than expected for age); (6) with prior surgery of the larynx, trachea, neck, and/or upper esophagus; and (7) with known cranial and/or airway malformations.

Recruitment

Potential study subjects consisted of a convenience sample of pediatric patients scheduled for the NYU–Lutheran operating room (OR) for dental procedures under general anesthesia between March 2015 and October 2015 supervised by dentist anesthesiologist attendings. All potential study subjects were evaluated by the anesthesia team preoperatively. Informed consent was obtained for both dental treatment and anesthesia before the patient was deemed eligible to participate in the study. If the child met the criteria to be included in the study, informed consent for their child’s participation in the study was obtained from the patient’s parent/guardian(s).

Data Collection Instrument

Study subject demographics (eg, age, sex, height, weight, body mass index [BMI]) and medical history (from which the ASA classification was determined) were gathered from the subject’s electronic medical record, the subject’s physical perioperative chart, and interview of the subject’s parent(s) and/or guardian(s) prior to anesthesia and were recorded on the data collection instrument. Mallampati scores were obtained during the preoperative physical examination and recorded on the data collection instrument. Cormak-Lehane scores seen during intubation, method of laryngoscopy (direct or video), a description of intubation (eg, atraumatic, easy, difficult), ETT size used, V_T set on the ventilator, and whether or not there was a significant anesthesiologist-detectable leak following intubation were recorded on the data collection instrument immediately following

intubation. Significant leakage was determined by the attending anesthesiologist via audible air leakage at the mouth during manual ventilation at ≤ 20 cmH₂O pressure and/or circuit leakage alerts by the ventilator due to set V_T or pressure not being reached during mechanical ventilation. Actual delivered V_T were obtained at the 3 time points (baseline [patient intubated with head in extended position], mouth opening [mouth prop placement], and throat pack placement) from the ventilator at the time of delivery and recorded on the data collection instrument.

Study Operations

Following administration of informed consent and study enrollment, general anesthesia was induced via inhalation induction with a sevoflurane, nitrous oxide, and oxygen mixture. Oral or intramuscular premedication was administered at the discretion of the dentist anesthesiologist prior to inhalation induction. After inhalation induction, intravenous access was obtained and appropriate doses of fentanyl and propofol were administered based on the subject's weight. The subject was then nasally intubated under either direct laryngoscopy or video laryngoscopy with an appropriately sized uncuffed nasal ETT based on the formula $(\text{age} + 16)/4$. Proper placement of the ETT was verified by visualization of the ETT passing through the vocal cords, patient chest rise with ventilation, presence of end-tidal CO₂, and equal bilateral breath sounds. The ETT was then secured in place by tape to the subject's face, the head was wrapped, and the circuit was secured to prevent accidental disconnection during the case in the usual manner. The subject was positioned on a shoulder roll with the head extended and resting on a donut, as is customary in dental procedures performed under general anesthesia either just prior to, or directly following, intubation. The degree of head extension was at the discretion of the dentist anesthesiologist.

The ventilator was then set on volume control mode with a V_T set to 5–8 mL/kg and peak inspiratory pressure set to 30 cmH₂O. Actual delivered V_T at this point was recorded by the case anesthesiologist (labeled as “baseline” in the tables). With the subject remaining in a head extended position, a bite block or Molt mouth prop was then placed by a member of the pediatric dental team to open the subject's mouth in preparation for dental treatment. The degree of mouth opening was at the discretion of the pediatric dentist. A second recording of the actual delivered V_T was made immediately after mouth opening. The third (last) V_T recording was made immediately following the place-

ment of the standard OR throat pack, which consisted of a moistened 2.54-cm by 4.57-m (1-inch by 5-yards) cotton packing strip trimmed to size to provide a firm packing of the oropharynx custom to each subject. This throat pack placement was completed without delay after mouth opening and the second V_T measurement. All measurements were taken with the subject remaining in a head extended position. If a significant leak was still present following throat pack placement, the patient was to be reintubated with a larger sized ETT.

Data Management

The lead examiner oversaw data management. Data were deidentified and entered into an Excel spreadsheet and imported into SPSSv22. Data were cleaned by visual inspection (data entered into Excel was visually confirmed against the data entry sheets), frequency counts, and graphing.

Statistical Analysis

The statistical plan was created a priori. Univariate descriptive statistics were produced. Statistical significance was set at .05 for all analyses. A generalized estimating equation was used for multivariable linear regression analysis to account for correlated data. V_T was regressed using stepwise regression on the following variables: BMI, ASA classification, Mallampati score, Cormak-Lehane score, ETT size, setting for V_T , leak status, and the 3 time points of interest (neck extension/baseline, mouth opening [mouth prop placement], and throat pack placement). Pairwise comparisons between each time point were then made using a Bonferroni p value adjustment (.05). The analyses were repeated for the 2 leak strata separately.

RESULTS

Forty-three potential subjects were reviewed for eligibility. Ten participants did not meet inclusion criteria. Seven participants were excluded from analyses for missing Mallampati and Cormak-Lehane scores, and 1 participant was excluded because of a noted ETT size exclusion. Twenty-five (58%) of the potential subjects were included in the analyses. There was no statistical difference in the demographic data between the analyzed sample and 8 subjects with data collected but excluded from analyses (all p values $>.145$ by Fisher exact or Mann-Whitney U tests). Table 1 presents the analyzed

Table 1. Descriptive Statistics of Sample ($N = 25$) of Children Undergoing Nasal Intubation With Uncuffed Endotracheal Tubes

Variable	<i>N = 25 Analyzed</i>				% Increase From Baseline
	Mean (SD)	Median	Min	Max	
Age, y	4.12 (1.24)	4	2	6	
Body mass index	16.9 (2.5)	17	12.8	23.6	
Mallampati grade	1.6 (0.82)	1	1	4	
Cormak-Lehane grade	1.24 (0.52)	1	1	3	
Set tidal volume (V_T), mL	138 (30.8)	130	100	250	
V_T after head extension, mL	111.2 (35.5)	115	20	166	
V_T after mouth opening, mL	124.7 (33.8)	130	55	208	12
V_T after throat pack, mL	140.4 (38.5)	140	82	281	26
	<i>n</i>	%	<i>p Value</i> (Fisher Exact Test)		
Sex			1.000		
Female	10	40			
Male	15	60			
Total	25	100			
American Society of Anesthesiologists classification			.640		
1	17	68			
2	8	32			
Total	25	100			
Laryngoscopy method			.245		
Direct	14	56			
Video	11	44			
Total	25	100			
Endotracheal tube size			.335		
4.5	7	28			
5	14	56			
5.5	4	16			
Total	25	100			
Leak after intubation			.416		
No	12	48			
Yes	13	52			
Total	25	100			

sample's descriptive statistics and the demographic and experimental data. Sixty percent of the sample were boys; the average age was 4.12 (SD, 1.24; range 2–6) years old. Two-thirds were ASA 1, and 52% experienced a postintubation leak. Mean and standard deviations in milliliters for V_T were after head extension, 111.2 (33.5); mouth opening, 124.7 (33.8), and throat pack placement, 140.4 (38.5).

Table 2 presents the final generalized estimating equations multivariable regression results of V_T for head-neck-mouth events during uncuffed nasal intubation. Statistically significant increased V_T measurements relative to baseline (intubated with head extended, average V_T 111.2 mL) were found for mouth opening (+13.6mL) and the throat pack placement (+29.3mL). Relative to baseline V_T , mouth opening and mouth open

Table 2. Generalized Estimating Equations Multivariable Regression Results of Tidal Volume at Head-Neck-Mouth Events During Uncuffed Nasal Intubation

Variable	Coefficient	SE	p value	% Increase From Baseline (Adjusted)
Intercept	334.8	89.2		
Head-neck-mouth events*,†				
Mouth opened	13.6	4.6	.003	12
Throat pack placed	29.3	4.6	<.009	26
Body mass index	−7.3	2	<.009	
Endotracheal tube size (4.5, 5.0, 5.5)	−57.4	16.8	.001	
Set tidal volume	1.5	0.2	<.009	
Leak detected	−34	7	<.009	

* Referent category: neck extended.

† Test for linear trend: $p = .005$.

Table 3. Pairwise Comparisons With Bonferroni Adjustment

<i>Time Points</i>	<i>Difference of V_T</i>	<i>% Increase</i>	<i>Bonferroni- Adjusted p Value</i>
Parsimonious model			
Mouth open vs baseline	13.6	12	.016
Throat pack vs baseline	29.3	26	<.009
Throat pack vs mouth open	15.7	13	.004
Leak strata only model			
Mouth open vs baseline	23.2	21	.004
Throat pack vs baseline	46.0	41	<.009
Throat pack vs mouth open	22.8	18	.005

with throat pack placed had 12% and 26% average V_T increases, respectively. BMI, ETT size, set V_T , and a detected leak were all statistically significant at the $p \leq .001$ level. Increasing BMI, ETT size, and a detectable leak were inversely associated with V_T . Increasing set V_T increased measured delivered V_T . There were no instances in which a significant leak existed after throat pack placement requiring reintubation with a larger sized ETT.

We examined the p values with a Bonferroni adjustment for the multiple statistical comparisons being conducted. The p -value adjustments found that relative to the baseline, increased V_T with mouth opening and throat pack placement remained statistically significant as did increased V_T with throat pack placement relative to mouth opening without throat pack. Each sequential procedure increased V_T when statistically tested in the most conservative manner (Table 3). The difference between mouth opening and mouth opening with the throat pack placed had a 13% increase (ie, one-half of the total V_T proportional increase from baseline to throat pack placement; 26%).

Identical regressions were then conducted for the separate “leak” and “no leak” strata. For the “no leak” patients ($n = 12$), BMI (inversely for V_T) and set V_T (positively for V_T) were statistically significant, while only the throat pack procedure statistically demonstrated improved V_T (Table 4).

These findings are in marked contrast to the “leak” patients ($n = 13$) in which numerically large, statistically significant effects relative to baseline for mouth opening (± 23.2 mL, $p < .009$, 21% increase from baseline) and throat pack placement (± 46 mL, $p < .009$, 41% increase from baseline) are observed (Table 4). This finding is stable even when adjusted with a Bonferroni p value for the multiple comparisons (Table 3).

DISCUSSION

The debate between the use of cuffed and uncuffed ETTs and the practice of using both types for nasal intubations in pediatric patients will likely continue. However, this observational study was able to demonstrate that mouth opening and throat pack placement reduce the leak around an uncuffed ETT when an initial leak exists. One of the greatest benefits of reducing this leak is the reduction of environmental pollution with anesthetic gases, including volatile anesthetics and nitrous oxide. This is especially important when the operating dentist and assistants are working within the mouth and so close to these leaked gases. Our study findings should lead to further clinical trials that may demonstrate that the use of uncuffed nasal ETTs used in pediatric dental procedures with a throat pack in place provides the benefits of the uncuffed ETT without the potential need for tube exchange with a larger ETT size.

Table 4. Generalized Estimating Equations Multivariable Regression Results by Strata (Leak/No Leak) of Tidal Volume for Head-Neck-Mouth Events During Uncuffed Nasal Intubation

<i>Strata</i>	<i>Variable</i>	<i>Coefficient</i>	<i>SE</i>	<i>% Increase From Baseline</i>	<i>p Value</i>
No leak	Intercept	96.7	18.76		
	Body mass index	−3.0	1.13		.0
	American Society of Anesthesiologists classification	−8.4	5.47		.1
	Set tidal volume	0.7	0.15		<.009
	Time points*,†				
	Mouth open	3.1	3.88	3	.4
Leak	Throat pack	11.2	3.88	10	.0
	Intercept	485.9	135.11		
	Body mass index	−7.5	2.79		.0
	Endotracheal tube size	−104.0	25.98		<.009
	Set tidal volume	1.7	0.22		<.009
	Time points*,†				
	Mouth open	23.2	6.63	21	<.009
	Throat pack	46.0	6.63	41	<.009

* Referent category: neck extended.

† Test for linear trend: $p = .005$.

due to leak around the ETT. Anytime a patient requires ETT exchange, this increases the risk to the patient for adverse airway events. Our findings also suggest that the actual placement of the mouth prop and throat pack (2 actions often completed by the operating dentist) should be done directly after intubation, by the anesthesiologist intubating the patient if necessary. This would not only reduce the leak between the time of intubation and the start of the procedure but also provide the anesthesiologist a better assessment of the seal around the ETT. Some dentists prefer to obtain radiographs prior to placement of the throat pack due to the forward displacement of the tongue caused by the throat pack. However, we would recommend placement of the throat pack prior to radiographs for the reduction of leak mentioned above and to prevent any objects (such as a deciduous tooth that is inadvertently knocked out with the radiograph sensor) from falling unnoticed into the pharynx during this time. This provides the anesthesiologist more complete control over the airway for the entirety of the procedure.

One of the major advantages to uncuffed ETTs is the ability to use a tube with a larger internal diameter.^{1–3} The addition of the ETT cuff often results in use of a tube ½ to 1 mm internal diameter smaller than the size of the uncuffed ETT in order to pass the tube through the nasal cavity and the larynx. The larger internal diameter of the uncuffed tube greatly reduces the resistance to airflow and the work of breathing in the spontaneously breathing patient.^{1–3} Most office-based dental intubated general anesthetics are completed with a spontaneously breathing patient. The major reasons for this are that paralysis is generally unnecessary for most oral or dental surgeries, and there is limited availability of mechanical ventilation in many dental office general anesthesia practices.

A recent meta-analysis conducted by Shi et al⁴ suggests that cuffed ETTs may be the preferred approach in pediatric patients. This review concluded that “cuffed ETTs may be associated with a lower ETT exchange rate” but that other negative outcomes (eg, postextubation stridor, required reintubation after planned extubation) were similar between cuffed and uncuffed ETTs.⁴ The most common reason for ETT exchange for uncuffed tubes was determined to be an anesthesiologist-determined excessive gas leak around the ETT (something that could be corrected with cuffed ETTs by inflating the cuff).⁴ The major limitation of this review was that only 4 studies were included (2 randomized controlled trials and 2 prospective cohort studies) composed of 3782 total cases, although there have been hundreds of studies conducted on this topic.⁴ Another important point is that none of the studies examined in this review attempted to correct excessive

leak around uncuffed ETTs with positioning, mouth opening, or throat pack placement. The findings reported here suggest that both mouth opening and throat pack placement can reduce this leak without the necessity of an ETT exchange. Upon mouth opening, the mandible moves toward the larynx, decreasing the thyromental distance and physically compressing the soft tissue in between. Throat pack placement also aids in compression of the soft tissue of the upper airway. This compression of the soft tissue onto the ETT, combined with the compression from and physical presence of the throat pack, is what improves the seal and reduces leak. This is why, as seen in our study, if there is little to no leak to begin with, mouth opening and throat pack placement will have little effect on increasing V_T .

Our study did have several limitations. First, data were collected by 7 different anesthesiology teams. Although each participant was given detailed instructions on all aspects of the study, we could not guarantee that all data were collected in the same way or at the exact same points in time. A second potential limitation was that leak determination was determined by the practitioner. An introduced, nonrandom practitioner classification bias of the V_T scores is highly unlikely, as the leak-related study purpose was unknown by the recorders, while a random misclassification of the scores would have the effect of minimizing the likelihood of observing a statistical significant difference. What may be considered a potential limitation is the range of accepted V_T settings (5–8 mL/kg). However, actual V_T settings were included in the statistical models to minimize potential confounding due to the individual V_T setting variations. The magnitude of the effect of mouth opening and throat pack placement is evident in that statistical significance was observed even with only 25 subjects included in the final analysis. However, when subjects were further divided into those with a leak ($n = 13$) and those with no leak ($n = 12$), the sample size was even further reduced. These small samples may have resulted in spurious “not significant” findings of the covariates examined (eg, Mallampati score). These variables, however, are important only in an attempt to define a fully-specified predictive model rather than a focus on the clinically applicable primary variables of mouth opening and throat pack placement (adjusted for by the few influential covariates). Likewise, unmeasured potential variables such as the magnitude of mouth opening and angle of neck extension reflect patient and practitioner clinical variability (ie, “real world” activity that strengthens the applicability of these findings). The findings of this study were limited to mechanically ventilated children, and thus, the findings’ applicability

to spontaneously breathing patients under general anesthesia would be speculative.

An important strength of this study was that analyses adjusted for measurement variations that were patient and practitioner determined (eg, baseline ventilator settings), resulting in better accuracy of the primary variables point estimates. Despite the small sample size, the data support the idea that after nasal intubation with an uncuffed ETT, both mouth opening and throat pack placement each increase delivered V_T (ie, decrease leak around the ETT) when an initial leak exists.

We believe that further studies should be conducted of uncuffed ETTs with larger sample sizes powered to detect clinically meaningful differences of the nonleak cases, if any, and for exploring fully-specified predictive models. Based on the results of this study, we estimate that 250 subjects will be necessary. We also suggest that a study of these procedures in spontaneously breathing patients would be beneficial as many dental procedures are completed with spontaneously breathing patients.

We conclude that in children 2–6 years of age, nasal endotracheal intubation with uncuffed ETTs, with clinically determined leaks, demonstrate improved V_T with mouth opening (mouth prop or bite block placement) and throat pack placement during mechanical ventilation. This finding suggests that the nasal uncuffed ETT intubation procedure is a process that extends through positioning, mouth opening, and throat pack placement. Therefore, anesthesiologists or the

operating surgeon should place the throat pack as soon as practical after ETT placement in mechanically ventilated pediatric patients.

REFERENCES

1. Taylor C, Subaiya L, Corsino D. Pediatric cuffed endotracheal tubes: an evolution of care. *Ochsner J*. 2011;11:52–56.
2. Weiss M, Dullenkopf A, Gysin C, Dillier CM, Gerber AC. Shortcomings of cuffed paediatric tracheal tubes. *Br J Anaesth*. 2004;92:78–88.
3. Khine HH, Corddry DH, Kettrick RG, et al. Comparison of cuffed and uncuffed endotracheal tubes in young children during general anesthesia. *Anesthesiology*. 1997;86(3):627–631.
4. Shi F, Xian Y, Xiong W, Zhou Q, Huang X. Cuffed versus uncuffed endotracheal tubes in children: a meta-analysis. *J Anesth*. 2016;30:3–11.
5. Sanuki T, Sugioka S, Hirokane M, et al. The influence of mouth opening on oropharyngeal leak pressure, intracuff pressure, and cuff position with the laryngeal mask airway. *J Oral Maxillofac Surg*. 2010;68:1038–1042.
6. Sanuki T, Sugioka S, Hirokane M, et al. Optimal degree of mouth opening for laryngeal mask airway function during oral surgery. *J Oral Maxillofac Surg*. 2011;69:1018–1022.
7. Sanuki T, Sugioka S, Son H, Uda R, Akatsuka M, Kotani J. Effect of head-neck extension on abnormality of laryngeal mask airway function resulting from opening the mouth. *J Oral Maxillofac Surg*. 2011;69:1311–1315.