J Anesth (2014) 28:368–373
DOI 10.1007/s00540-013-1728-z

ORIGINAL ARTICLE

Temporal variation of the leak pressure of uncuffed endotracheal tubes following pediatric intubation: an observational study

Shreya Patel · Kirk Lalwani · Jeffrey Koh · Lei Wu · Rongwei Fu

Received: 13 November 2012 / Accepted: 6 October 2013 / Published online: 24 October 2013

Abstract
Purpose Uncuffed endotracheal tubes are still preferred over cuffed tubes in certain situations in pediatric anesthesia. Inaccurately sized uncuffed endotracheal tubes may lead to inadequate ventilation or tracheal mucosal damage during anesthesia. Endotracheal tube size in children is usually assessed by measuring the audible leak pressure; if the fit of the tube and the leak pressure decrease significantly with time, reintubation during surgery as a result of inability to ventilate effectively may be challenging, and could lead to patient morbidity. There is no evidence to indicate whether leak pressure increases or decreases with time following endotracheal intubation with uncuffed tubes in children.
Methods We measured leak pressure for 30 min following tracheal intubation in 46 ASA I children age 0–7 years after excluding factors known to modify leak pressure.
Results The largest mean change in leak pressure occurred between time points 0 and 15 min, an increase of 3.5 cmH_2O. Endotracheal tube size and type of procedure were associated with the leak pressure. In the final linear mixed model, there were no statistically significant variations in leak pressure over time ($P = 0.129$) in this group of children.
Conclusions We did not identify a consistent change in leak pressure within 30 min following tracheal intubation with uncuffed endotracheal tubes in this group of children.

Keywords Anesthesia · Endotracheal intubation · Leak pressure · Children

S. Patel
University of Arizona College of Medicine, Tucson, USA

K. Lalwani (✉) · J. Koh
Department of Anesthesiology and Perioperative Medicine, Oregon Health and Science University, 3181 S.W. Sam Jackson Park Road, Portland, OR 97239-3098, USA
e-mail: lalwanik@ohsu.edu

L. Wu
University of Washington Medical Center, Seattle, USA

R. Fu
Department of Public Health, Preventive Medicine, Oregon Health and Science University, Portland, OR, USA

R. Fu
Department of Emergency Medicine, Oregon Health and Science University, Portland, OR, USA

Introduction

Inaccurately sized uncuffed endotracheal tubes may lead to difficulty with ventilation or tracheal mucosal damage during anesthesia in children. Tubes that are too small may result in inadequate ventilation, leakage of anesthetic gas, and increased risk of pulmonary aspiration, whereas tubes that are too large could interfere with tracheal mucosal blood flow and lead to short- and long-term consequences as a result of tracheal mucosal ischemia [1–3]. Furthermore, if the fit of the tube and the leak pressure decrease significantly during the course of surgery, reintubation during surgery could prove challenging and may result in patient morbidity.

Despite the current popularity of cuffed endotracheal tubes in children, uncuffed tubes are preferred by many practitioners in premature infants and neonates, particularly for longer periods of airway support. Proper selection of endotracheal tubes in the pediatric population is usually verified with an initial leak pressure between 15 and 25 cm

Table 1 Patient exclusion criteria (pre-and post enrollment)

Pre-enrollment exclusion criteria	
Lack of parental consent	Tracheostomy in situ
Rapid sequence induction with cricoid pressure	Oropharyngeal, neck, laryngeal, or laparoscopic surgery
Use of neuromuscular blocking agent/s for intubation	History of previous laryngeal or tracheal surgeries or abnormalities
Active gastroesophageal reflux disease or upper respiratory tract infection	History of symptomatic neuromuscular disease or paralysis
Chronic active lung disease requiring frequent treatment, or stridor of unknown origin	History or features suggestive of a difficult airway on pre-anesthetic evaluation/physical examination
Surgery in the lateral or prone position	
Post-enrollment exclusion criteria	
No leak present up to an airway pressure of 40 cm H_2O at time 0	Level 3 intubations
Any complications or physiological derangements (unexplained persistent hypoxia, pulmonary aspiration, bronchospasm, change in patient or head position, etc.) during study period	

Table 2 Level of intubation difficulty

Level/definition	Number of DL/ETT passes	Additional maneuvers
Level 1/easy	1 DL and $\leq$ 3 ETT passes	None
Level 2/moderate	1–2 DLs and/or > 3 ETT passes	Head repositioning and/or cricoid manipulation, and/or blade change, and/or use of ETT stylet after initial attempt/s
Level 3/difficult	$\geq$3 DLs and/or > 3 ETT passes	Accessory aids (gum elastic bougie, fiberoptic stylet, bronchoscope) required

DL direct laryngoscopy, *ETT* endotracheal tube

of water, as well as the more subjective lack of resistance as the tube is advanced past the subglottis. The leak pressure is known to be affected by head position and degree of neuromuscular blockade. [4] However, it is widely believed that leak pressure may either decrease over time as a result of tube softening, as it warms to body temperature, or increase as a result of tracheal mucosal edema. It is not clear whether either of these mechanisms produces a measurable clinical effect, and if they do, whether they balance each other out. However, this variation in leak pressure following intubation has not been previously studied. We evaluated this potential variation in leak pressure during the first 30 min following tracheal intubation with uncuffed tubes in a cohort of 52 pediatric patients.

Materials and methods

Following Institutional Review Board approval and informed written consent by parents or legal guardians, and child assent from children aged 7, we enrolled 52 children ages 0–7 years in this study if they met inclusion and exclusion criteria. All subjects in this study were required to be in the supine, head-neutral position without any neuromuscular blockade; pre- and post-enrollment exclusion criteria are outlined in Table 1. A sample size of 40 patients was calculated a priori using a standard deviation for leak pressure of 10.9 based on Finholt et al. [4] on the assumption that the correlation between leak pressure of two time points is 0.5 to detect a clinically meaningful 5 cm H_2O difference based on a two-sided test at 0.05 level with 80 % power.

Following premedication and inhalational anesthetic induction with sevoflurane, tracheal intubation was performed using an appropriately sized uncuffed endotracheal tube selected by an attending anesthesiologist who was blinded to the study hypothesis, based on the commonly used formula Age/4 + 4, internal diameter in millimeters. All endotracheal tubes were manufactured by Mallinckrodt. Acceptable initial leak pressures are typically 15–25 cm H_2O, although as this was an observational study only, the decision whether to change an endotracheal tube with a leak pressure outside these parameters was made by the attending anesthesiologist.

The number of direct laryngoscopy (DL) attempts, degree of difficulty (Table 2), endotracheal tube size, use of stylet or cricoid pressure, opioid use, or presence of adverse events (including coughing, hypoxia, trauma, bronchospasm, laryngospasm, regurgitation/vomiting, aspiration) were recorded. Subjects were allocated into endotracheal tube size group 'Small' if their endotracheal tube was between 3.0 and 4.5 mm, or 'Large' if their endotracheal tube was between 5.0 and 6.5 mm, to determine if endotracheal tube size was a predictor of variation in leak pressure.

We measured the leak pressure using the leak test as described by Finholt et al. [4] Immediately following successful Level 1 or 2 intubation (Table 2), one of two trained observers determined the leak pressure (time 0, or t0). Both the trained observers strictly adhered to the guidelines of the leak test and were not part of patient care. With the patient supine and head in a neutral position, fresh flow gas (any combination of oxygen, nitrous oxide, or room air) was set at 5 l/min and a stethoscope was placed on the skin over the larynx immediately above the

suprasternal notch. The observer listened with the pressure relief valve completely closed until an audible leak occurred around the endotracheal tube. The pressure needed to generate this leak was noted and recorded. The leak pressure was again recorded at 5 (t5), 10 (t10), 15 (t15), 20 (t20), and 30 min (t30). The following items were also recorded: end-tidal concentration of volatile agent, SpO_2, $EtCO_2$, Paw, ventilator settings, dosage and timing of IV opioids, as well as volume of fluids given during surgery. Patients were observed postoperatively for the presence of stridor or other complications; stridor was defined as a 'noisy, high-pitched, predominantly inspiratory sound from turbulent airflow secondary to upper airway obstruction' per *Miller's Anesthesia* [5].

Descriptive statistics were used to summarize patient characteristics. Because leak pressure was a continuous outcome measured repeatedly for the same subject, a linear mixed effects model was used to assess change in leak pressure over time while adjusting for endotracheal tube size, baseline leak pressure, depth of anesthesia by MAC values, and other potential confounding variables such as age, gender, procedure type, volume of intravenous fluids, intravenous opioids, small versus large tube groups, and one versus two passes of the endotracheal tube (ETT); all these variables were tested in the model as fixed effects. The identification variable for subjects was included in the model as a random effect to account for the correlation among repeated observations at different time points within each subject. In the final linear mixed-effect model, only the time variable, important confounding, and significant variables were included to ensure a parsimonious model. Otherwise, the variables were excluded from the final model. To evaluate the robustness of results to extreme initial leak pressure, we also conducted a sensitivity analysis by fitting a linear mixed-effects model limiting to patients with an initial leak pressure between 10 and 30 cm H_2O. All analyses were performed using SAS 9.1.2 (SAS Institute, Cary, NC, USA).

Results

A total of 52 patients were enrolled. Final analysis included data from 46 patients as 6 patients had to be excluded from the study following enrollment based upon predefined exclusion criteria (Table 1). Two subjects were excluded for lack of baseline leak, two had a laryngeal mask airway or cuffed endotracheal tube placed, one received a muscle relaxant, and one had an insufficient duration of surgery. Table 3 summarizes patient demographics and clinical characteristics of the subjects. All patients were ASA physical status 1 with no adverse events or postoperative complications. None of the children in this study had acute or chronic respiratory problems or a history of difficult intubation at the time of their surgeries. The majority of patient tracheas (67.4 %) were successfully intubated on the first attempt at laryngoscopy and one ETT pass without any adjustments or the need for cricoid pressure. An ETT stylet was used prophylactically in 28.3 % of patients, but was not required in any patient after a first unsuccessful attempt at laryngoscopy or at passing the ETT. Overall, 32.5 % of patients required either two attempts at laryngoscopy ($n = 1$), or two or three ETT passes ($n = 15$), but all patients met our criteria for Level 1 intubation difficulty (Table 2).

Table 3 Demographics and clinical characteristics of Patients

Baseline ($n = 46$)	n	%
Sex		
Male	29	63.0
Female	17	37.0
Age (years)		
≤1	8	17.4
1 to ≤4	21	45.7
>4	17	37.0
Procedure		
General	5	10.9
Ophthalmic	23	50.0
Orthopedic	6	13.0
Plastic	4	8.7
Urological	8	17.4
Opioid use	36	78.3
Baseline leak pressure (cm H_2O)		
<20	28	60.9
≥20	18	39.1
Initial endotracheal tube size		
Large (5.0–6.5 mm)	24	52.2
Small (3.0–4.5 mm)	22	47.8

Pressure control (PC) ventilation was used in 39 (85 %) patients, synchronized intermittent mandatory ventilation (SIMV) in 5 (11 %), and pressure support ventilation (PSV) in 2 (4 %); some patients were transitioned from PC or SIMV to PSV only as the case progressed. Opioids were used during at least one time point in 36 (78.3 %) patients.

The mean (SD) leak pressure for each time point overall and by selected patient characteristics is reported in Table 4. The mean (SD) of selected clinical variables for each time point is reported in Table 5. In the final linear mixed model, there were no statistically significant variations in leak pressure over time ($P = 0.129$). The largest numerical mean change in leak pressure was seen between time points 0 and 15 min, an increase of 3.5 cmH_2O (Table 4; Fig. 1). After adjusting for age and baseline leak pressure, and taking the correlation among repeated observations at different time

Table 4 Mean (SD) of leak pressure (cm H_2O) at each time point overall and by selected patient characteristics

Variable	Time (min)					
	0	5	10	15	20	30
Overall	17.5 (7.3)	19.3 (9.9)	20.7 (10.8)	21.0 (10.5)	20.2 (9.0)	20.8 (9.9)
Minimum–Maximum	5.0–35.0	5.0–40.0	5.0–40.0	8.0–40.0	8.0–40.0	8.0–40.0
Gender						
Male	17.6 (7.2)	20.5 (10.7)	22.1 (11.9)	22.5 (11.5)	21.7 (9.3)	21.5 (10.1)
Female	17.3 (7.6)	17.1 (8.2)	18.4 (8.4)	18.4 (8.2)	17.7 (8.2)	19.5 (9.9)
Age (years)						
≤1	19.3 (4.9)	22.9 (10.2)	24.5 (13.0)	23.3 (12.5)	20.1 (8.2)	20.0 (10.6)
1 to ≤4	17.4 (7.7)	17.0 (8.5)	18.0 (9.1)	18.6 (9.2)	19.6 (9.0)	20.8 (10.1)
>4	16.8 (7.8)	20.4 (11.1)	22.4 (11.4)	22.9 (11.2)	20.9 (9.8)	21.1 (10.1)
Procedure						
General surgery	20.4 (6.2)	31.6 (9.2)	33.6 (9.3)	33.4 (10.5)	27.2 (10.4)	24.4 (7.5)
Ophthalmic	15.4 (7.3)	16.2 (8.3)	16.3 (7.9)	17.0 (7.6)	16.3 (7.5)	17.4 (8.3)
Orthopedic	21.7 (8.5)	16.2 (8.2)	18.3 (10.0)	18.3 (11.2)	20.0 (8.2)	21.5 (11.3)
Plastic	14.8 (7.1)	20.8 (12.8)	27.0 (14.5)	27.0 (14.1)	21.3 (7.5)	22.5 (12.4)
Urological	19.9 (5.8)	21.9 (9.5)	24.0 (11.2)	23.8 (9.9)	26.5 (9.1)	26.9 (11.8)
Baseline leak pressure (cm)						
<20	12.8 (3.8)	14.1 (7.0)	15.9 (8.0)	16.6 (8.1)	16.6 (7.4)	15.8 (6.5)
≥20	24.9 (4.7)	27.2 (8.4)	28.3 (10.4)	27.9 (10.3)	25.8 (8.6)	28.5 (9.6)
Endotracheal tube size						
Small (3.0–4.5 mm)	17.8 (6.3)	18.1 (8.9)	19.2 (10.6)	19.6 (10.0)	19.1 (8.0)	20.0 (9.5)
Large (5.0–6.5 mm)	17.2 (8.2)	20.3 (10.8)	22.1 (11.1)	22.3 (11.0)	21.2 (9.9)	21.5 (10.5)
Opioid use						
No	16.9 (7.1)	14.9 (7.5)	14.0 (7.1)	15.5 (6.9)	14.3 (5.8)	14.4 (5.6)
Yes	18.5 (7.5)	22.9 (10.2)	23.9 (10.8)	22.7 (10.9)	21.8 (9.1)	22.5 (10.2)

Table 5 Mean (SD) of selected variables over time

Variable	Time (min)					
	0	5	10	15	20	30
Depth of anesthesia (MAC value)	1.1 (0.4)	0.9 (0.3)	0.9 (0.3)	1.0 (0.3)	0.9 (0.3)	0.9 (0.3)
$EtCO_2$ (mmHg)	36.7 (8.2)	35.9 (8.8)	35.8 (8.2)	36.1 (9.8)	36.7 (11.0)	37.2 (10.1)
SpO_2 (%)	99.7 (0.9)	99.6 (0.9)	99.5 (1.0)	99.3 (1.2)	99.4 (1.1)	99.6 (0.9)
Airway pressure (Paw, cmH_2O)	13.3 (2.1)	12.9 (2.1)	12.2 (2.3)	12.2 (2.4)	12.1 (2.5)	11.9 (2.8)
Total crystalloid IVF (ml/kg of LR[a])						12.9 (5.4)

[a] Lactated Ringer's solution

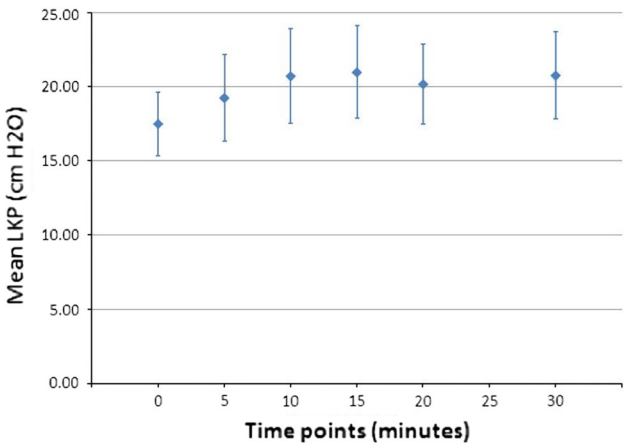

Fig. 1 Variation of mean leak pressure (LKP) over time (min)

points within each subject into account, endotracheal tube size and type of procedures were shown to be significantly associated with the magnitude of leak pressure itself. Larger

endotracheal tube sizes (5.0–6.5 mm) had a mean leak pressure 3.45 cmH_2O higher (95 % CI 0.35, 6.54; $P = 0.030$) compared those with smaller endotracheal tube sizes (3.0–4.5 mm). The type of procedures was also associated with leak pressure ($P = 0.0097$). Compared to patients undergoing general surgery, the mean leak pressure was 4.69 cmH_2O lower (95 % CI 1.30, 8.09; $P = 0.008$) in patients undergoing ophthalmic surgery, 8.40 cmH_2O lower (95 % CI 3.94, 12.86; $P = 0.0005$) in patients undergoing plastic surgery and 4.38 cmH_2O lower (95 % CI 0.46, 8.31; $P = 0.029$) in patients undergoing urologic surgery. Gender, depth of anesthesia by MAC values, intravenous fluids given, intravenous opioids, and number of passes of ETT were not significantly associated with leak pressure and are not included in the final model. Results from the sensitivity analysis were similar and are therefore not reported separately.

Discussion

This study did not detect a statistically significant difference in leak pressure over time; however, it is possible that changes in leak pressure caused by mucosal edema may have been balanced to some degree by increased compliance of the warmer endotracheal tubes. The association between mean leak pressure and tube size is small and is probably of little clinical significance as it is unlikely that practitioners would modify their practice based on changes in leak pressure of <4 cm H_2O. The association between type of procedure and leak pressure cannot be explained on the basis of type of surgical procedure only; it could, perhaps, also be indicative of practitioners tolerating different initial leak pressures based on the type of surgery, although this seems unlikely. No evidence exists demonstrating any change in leak pressure with surgical incision or other similar events, unless accompanied by changes in head position or neuromuscular blockade, both of which were excluded in this study. None of the other potential confounding variables had any association with the mean leak pressure.

Cuffed endotracheal tubes have become very popular in children with the advent of newer, softer, polyurethane high-volume/low-pressure cuffs, and do not appear to increase the incidence of complications. The study by Weiss et al. [6] showed that risk of postintubation stridor does not differ between cuffed and uncuffed endotracheal tube (4.4 vs. 4.7 %) and that high-volume/low-pressure cuffed tubes are associated with a reduction in endotracheal tube exchanges. However, the use of cuffed tubes is not universal, as many practitioners prefer uncuffed tubes in neonates and premature infants, or when the smaller internal diameter of a cuffed tube may be contribute to high airway pressures or difficulty with airway suctioning. Cuff pressure monitoring at regular intervals is recommended, especially if nitrous oxide is used, although this may not always be available.

There are no data about changes in leak pressure that may occur following intubation with uncuffed endotracheal tubes. The traditional upper limit of allowable leak pressure (25 cmH_2O) is an adult value; mucosal perfusion pressure in children is probably even lower [7]. Children found to not have an air leak of at 25 cmH_2O have been shown to be 2.8 times more likely to have postintubation adverse events, including laryngospasm, or a drop in saturation or heart rate >10 % of the value preceding extubation [8]. On the other hand, advocates of uncuffed tubes consider the reassurance of the presence of a leak at pressures <20 cm H_2O as an indication that tracheal mucosal compression is absent or minimal; with cuffed tubes, this reassurance can only be achieved with cuff pressure monitoring, which can easily be measured repeatedly over time. In this study, we did not mandate any change in practice such as requesting a change of endotracheal tube if the initial leak pressure was >25 cm H2O as it was an observational study only, and clinical decisions were left to the attending anesthesiologist.

Limitations of this study exist. Observers were unable to follow trends developing >30 min following intubation. Although both observers were trained to measure leak pressure accurately and consistently, interobserver variability may be present. It is not known whether the extent of development of tracheal mucosal edema differs between neonates, infants, and older children following mucosal irritation after tracheal intubation, or whether it is often simply more obvious clinically in smaller-diameter airways as a result of Poiseuille's law.

In conclusion, this study did not reveal any consistent change or trend in leak pressure during the first 30 min following intubation with an uncuffed endotracheal tube in children. Further studies specifically targeting neonates and infants may determine if consistent changes in leak pressure following tracheal intubation are demonstrable in this subgroup of children.

Acknowledgments This study was funded by the Foundation for Anesthesia Education and Research.

Conflict of interest The authors have each declared no competing interests related to this study.

References

1. Holzki J. Laryngeal damage from tracheal intubation. Paediatr Anaesth. 1997;7:435–7.
2. Sherman JM, Nelson H. Decreased incidence of subglottic stenosis using an "appropriate-sized" tracheal tube in neonates. Pediatr Pulmonol. 1989;6:183–5.

3. Fine GF, Borland LM. The future of the cuffed endotracheal tube. Paediatr Anaesth. 2004;14:38–42.
4. Finholt DA, Henry DB, Raphaely RC. Factors affecting leak around endotracheal tubes in children. Can Anaesth Soc J. 1985;32:326–9.
5. Feldman MA, Patel A. Anesthesia for eye, ear, nose and throat surgery. In: Miller RD, Eriksson LI, Fleisher LA, Wiener-Kronish JP, Young WL. editors. Miller's anesthesia. 7th ed. Orlando: Churchill Livingstone; 2009. p. 2360.
6. Weiss M, Dullenkopf A, Fischer JE, Keller C, Gerber AC, European Paediatric Endotracheal Intubation Study Group. Prospective randomized controlled multi-centre trial of cuffed or uncuffed endotracheal tubes in small children. Br J Anaesth. 2009;103:867–73.
7. Seegobin RD, van Hasselt GL. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs. Br Med J. 1984;288:965–8.
8. Suominen P, Taivainen T, Tuominen N, Voipio V, Wirtavuori K, Hiller A, Korpela R, Karjalainen T, Meretoja O. Optimally fitted tracheal tubes decrease the probability of postextubation adverse events in children undergoing general anesthesia. Paediatr Anaesth. 2006;16:641–7.