Tracheal tube leak test - is there inter-observer agreement?

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Although the leak test is recommended as a method of assessing the appropriate size of uncuffed endotracheal tubes for use in children, the reproducibility of this test has not been validated. Patients from newborn to ten years of age requiring tracheal intubation for elective surgery were studied. The endotracheal tube size was calculated using the formula: $(\text{age} + 16) \div 4$ for patients $\geq$ two years of age and at the discretion of the attending anaesthetist for patients $<$ two years of age. After the induction of anaesthesia and administration of a non-depolarizing muscle relaxant, the patient's trachea was intubated and mid-tracheal placement was confirmed. Two of the three staff anaesthetists participating in the study assessed the leak pressure consecutively. Each participant performed a single leak determination. The leak pressure was determined as follows: the patient was supine with the head in a neutral position, fresh gas flowed into the breathing circuit at $5 \text{ L} \cdot \text{min}^{-1}$, a stethoscope was placed on the skin over the larynx and the pressure relief valve was completely closed. Pressure slowly increased in the breathing circuit until an audible leak occurred around the tracheal tube. The inter-observer difference was calculated in 212 patients. The absolute value of the difference between that of two observers increased as the mean leak pressure increased. However, the variation between observers expressed as a percent of the absolute measurement remained constant. An average variance in measurement of 38% was found at both low and high leak pressures. In conclusion, we found considerable variation between two experienced observers in assessing leak pressures. As the leak pressures increase, the difference between these observations also increases. Therefore, we believe it is unreasonable to set an upper limit of leak pressure for changing all endotracheal tubes.

Bien que le « test de fuite » d'air soit recommandé pour évaluer la conformité de la taille des canules pour intubation chez l'enfant, la reproductibilité de ce test n'a jamais été validée. Une population variée d'enfants (nouveaux-nés à dix ans) chez qui l'intubation endotrachéale est nécessaire pour une chirurgie non urgente sont étudiés. La taille de la canule est calculée selon la formule: $(\text{âge} + 16)/4$ pour les patients d'âge $\geq$ deux ans et laissée à la discrétion de l'anesthésiste pour les patients < 2 ans d'âge. Après l'induction de l'anesthésie et l'administration d'un myorelaxant non dépolarisant, la trachée est intubée et la position de la canule confirmée. Deux des trois anesthésistes participants à l'étude évaluent la pression de la fuite consécutivement. Chaque participant ne détermine la fuite d'air une seule fois. La pression de fuite est déterminée de la façon suivante: avec le malade en décubitus dorsal et la tête en position neutre, l'écoulement de gaz frais est réglé à $5 \text{ L} \cdot \text{min}^{-1}$, et un stéthoscope placé au niveau du larynx avec la soupape de surpression du circuit complètement fermée. La pression est augmentée progressivement dans le circuit jusqu'à l'apparition d'une fuite audible autour de la canule endotrachéale. La différence entre les deux observations est mesurée chez 212 patients. La valeur absolue de la différence trouvée par chacun des deux observateurs augmente à mesure que la fuite augmente. Cependant, la variation entre les deux observateurs exprimée en pourcentage de la mesure absolue demeure constante. Une variance de 38% est constatée à la fois avec les pressions de fuite hautes et basses. En conclusion, nous avons trouvé une variation considérable entre les évaluations de nos deux observateurs expérimentés. A mesure que la fuite augmente, la différence entre ces observations augmente. Nous croyons donc qu'il est illusoire de déterminer une limite supérieure de pression de fuite pour changer de canule endotrachéale.

Key words

EQUIPMENT: tubes, endotracheal.

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It is often difficult to predict accurately the most effective size of an endotracheal tube for use in paediatric patients. Textbooks of paediatric anaesthesia recommend choosing the endotracheal tube size based on the child's age and subsequently changing the endotracheal tube if the fit is too tight or too loose.¹⁻³ When the endotracheal tube is too small, assisted ventilation may be impaired, there may be increased risk of soiling the lungs, and resistance to gas flow is greater. With a tight fitting endotracheal tube, the mucosa and submucosal structures are vulner-

able to endotracheal tube compression injury at the level of the cricoid cartilage.

The leak test is recommended as a method of assessing the appropriate size of the endotracheal tube. The test is performed by assessing the pressure at which an audible noise can be heard as gas escapes between the endotracheal tube and the wall of the trachea. Finholt, Henry and Raphaely found that paralysis and head position effect the leak test; however, they did not report inter-observer reproducibility.⁴ The purpose of this study was to determine the reproducibility of a commonly used method for assessing the leak pressure.

Methods

Patients less than ten years of age requiring tracheal intubation for surgery were considered eligible. Patients undergoing bronchoscopy or diagnostic laryngoscopy were excluded. The endotracheal tube size was calculated using the formula: $(\text{age} + 16) \div 4$ for patients ≥ 2 yr.⁵ For patients < 2 years of age, the size of the endotracheal tube was determined by the attending anaesthetist. After induction of anaesthesia and administration of a non-depolarizing muscle relaxant, (pancuronium $0.1 \text{ mg} \cdot \text{kg}^{-1}$, atracurium $0.5\text{--}0.75 \text{ mg} \cdot \text{kg}^{-1}$, or vecuronium $0.1 \text{ mg} \cdot \text{kg}^{-1}$), the patient's trachea was intubated using an uncuffed, polyvinylchloride endotracheal tube (Mallinckrodt®). Mid-tracheal placement was confirmed by direct laryngoscopy showing the double circumferential line marker at the level of the vocal cords, or by placing the endotracheal tube two cm above the carina (identified by auscultation). Preformed, oral or nasal RAE tubes were used at the discretion of the attending anaesthetist. The RAE tubes were secured with the acute angle at the lower lip or nare.

Two of the three staff anaesthetists participating in the study assessed the leak pressure consecutively. Each participant performed a single leak determination. The leak pressure was determined as follows: the patient was supine with the head in a neutral position, fresh gas flowed into the breathing circuit at $5 \text{ L} \cdot \text{min}^{-1}$, a stethoscope was placed on the skin over the larynx and the pressure relief valve was completely closed. Pressure slowly increased in the breathing circuit until an audible leak occurred around the tracheal tube. The pressure necessary to generate this leak was read from an aneroid manometer and recorded. If the airway pressure reached $50 \text{ cm H}_2\text{O}$ the test was aborted.⁴ The two anaesthetists were blinded to each other observer's findings. The endotracheal tube was changed to a smaller size if either observer found the leak to be $\geq 40 \text{ cm H}_2\text{O}$ and the duration of surgery was expected to exceed one hour. Patients were observed prospectively for post-intubation croup defined by inspiratory stridor associated with intercostal retractions, nasal

FIGURE 1 Correlation between increasing mean value of leak pressure obtained by two observers and the inter-observer difference: Leak (observer 1) – Leak (observer 2). The diagonal line represents the line of regression.

FIGURE 2 Relationship between increasing mean value of leak pressures obtained by two observers and the inter-observer difference expressed as a percent of the mean leak pressure. The diagonal line represents the line of regression.

flaring or use of accessory muscles of respiration of at least 30 min duration.

Kappa values were determined for each pair of observers. In addition, the mean leak pressure of two observers was compared with the inter-observer difference expressed as an absolute number and expressed as a percent of the mean leak pressure of two observers.

Results

Two hundred forty-two patients were studied. Thirty patients were excluded because one or both examiners determined that no leak occurred at $50 \text{ cm H}_2\text{O}$. The absolute value of the inter-observer difference increased as the mean leak pressure of two observers increased (Figure 1). However, when the inter-observer difference was calculated as a percent of mean leak pressure, it remained constant (Figure 2). Kappa showed poor agreement

TABLE Correlation between observers

Observers	Kappa value
RS vs SS	0.14868
RS vs CP	0.01015
CP vs SS	0.06587

between each pair of observers (Table). Three percent of patients had a leak ≥ 40 cm H₂O by one observer and a leak < 40 cm H₂O by the second observer. Six percent of patients had a leak ≥ 25 cm H₂O by one observer and a leak < 25 cm H₂O by the second observer. None of the patients in this study developed post-intubation croup.

Discussion

The study demonstrates that when the leak pressure is determined by two anaesthetists, the inter-observer difference in leak pressure determination increases at higher pressures. However, the variation between observers expressed as a percent of the absolute measurement remains constant. An average error in measurement of 38% was found at both low and high leak pressures. While this degree of variation is unimportant at low leak pressures, it gains clinical importance with leak pressures that are recommended as at upper limits.¹⁻³

Finholt, Henry and Raphaely found that degree of neuromuscular blockade and head position affected the reproducibility of the leak test. They reported the mean leak observed in 80 patients using a standard method of leak assessment and varying head position, gas flow rate, and degree of neuromuscular blockade. They did not report the reproducibility of the leak test in individual patients.

An appropriate sized uncuffed endotracheal tube used for paediatric patients will create a seal between the tracheal mucosa and the endotracheal tube at the level of the cricoid. When the tube is too small, assisted ventilation may be compromised, there may be increased risk of soilage of the lungs, and resistance to gas flow is greater. An endotracheal tube which is too tight may damage the subglottic region of the trachea. Ulceration of the trachea mucosa at the level of the cricoid cartilage and submucosal oedema have been found on histological examination of the larynges of monkeys intubated with oversized endotracheal tubes.⁶

The optimal limits of the leak pressure used to avoid laryngeal injury and provide adequate ventilation have not been clearly defined. Koka *et al.* found a higher incidence of post-intubation croup when the leak pressure was > 25 cm of H₂O.⁷ They also found a higher incidence of croup to be associated with age one to four years, duration of surgery greater than one hour, and a change

of position during surgery. Lee, Templeton and Dougal found no association between endotracheal tube fit and post-intubation croup in patients without a history of croup.⁸ However, patients with a previous history of croup had a greater incidence of post-intubation croup when the leak pressure was > 20 cm H₂O. More recently, Litman and Keon reported the incidence of post-intubation croup to be lower than in previous studies. They used more stringent criteria to define croup and routinely changed the endotracheal tube if the leak was > 40 cm of H₂O.⁹ We evaluated prospectively 242 patients in which the endotracheal tube was changed if the leak pressure was ≥ 40 cm H₂O and the duration of surgery was expected to exceed one hour. None of the patients in this study developed post-intubation croup.

In our current anaesthetic practice we utilize the leak test to determine adequacy of tube size and change the endotracheal tube when the leak is ≥ 40 cm H₂O and place a tighter fitting tube only when ventilation is impaired. In this study, one observer found a leak ≥ 40 cm H₂O and the second observer found a leak < 40 cm H₂O in eight of the patients studied. Thus, in 3% of patients, one observer would have changed the endotracheal tube and the second observer would not have changed it. Using an upper limit of 25 cm H₂O suggested by Koka,⁷ 6% of determinations would be discrepant. We did not change any endotracheal tubes for too loose a fit. Whether the practitioner of paediatric anaesthesia uses 20, 25 or 40 cm H₂O as an upper limit for changing endotracheal tubes, this study shows that there can be considerable observer discordance in leak pressure determinations.

It remains unclear what anatomical changes occur in the patient's airway when air escapes audibly between the endotracheal tube and the tracheal wall. As airway pressure increases, the tracheal mucosa will be gradually pulled away from the endotracheal tube until finally there is escape of gas around the endotracheal tube producing an audible noise. A loose fitting endotracheal tube would require minimal or no pressure to displace secretions and thus peel the tracheal mucosa away from the endotracheal tube. However, a tighter fitting tube may require a higher airway pressure to compress and peel the mucosa away from the endotracheal tube. Upon reapplication of the same technique for assessing the leak test, the mucosa may be more or less adherent to the endotracheal tube. We did not find that the second observer routinely observed a lower or higher value for the leak. We also did not find a consistent difference between the two observers, i.e., observer one did *not* find a consistently higher or lower value than observers two or three.

In conclusion, we have found considerable variation between two experienced observers in assessing leak pres-

tures. As the leak pressure increases, the difference between these observations also increases. Therefore, we believe it is unreasonable to set a rigid upper limit of leak pressure for the changing of all endotracheal tubes. We suggest that other factors such as duration of surgery, difficulty of intubation, risk of aspiration of gastric contents, surgical position, and history of croup or other airway abnormalities be considered when deciding if tight fitting endotracheal tubes should be changed.

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