

Minimal Leak Test vs Manometry for Endotracheal Cuff Pressure Monitoring: A Pilot Study

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ABSTRACT

Introduction: Optimal cuff pressure for intubated patients is 20–30 cm H₂O as routinely measured by manometry. This methodology is associated with elevated costs due to equipment requirements. The objective of this study was to evaluate another methodology, i.e., the minimal leak testing (MLT).

Materials and methods: Initial cuff pressures were measured by manometry for all mechanically ventilated patients in a surgical intensive care unit (ICU). Two critical care physicians separately performed an MLT for each subject and cuff pressure was then remeasured by manometry. The rate of ventilator-associated pneumonia (VAP) was determined.

Results: Thirty subjects with 100 patient events were evaluated. The post-MLT measured cuff pressures were highly consistent between physicians, with a Pearson correlation coefficient of 0.770 ($p = 0.01$). Average initial cuff pressures were not significantly different between manometry and MLT (25 cm H₂O vs 14 cm H₂O, $p = 0.1894$). Manometry had a higher incidence of elevated cuff pressures ($n = 13/50$ vs $2/100$, $p < 0.0001$), while MLT had higher incidences low cuff pressures ($n = 72/100$ vs $17/50$, $p < 0.0001$). No difference was observed in the VAP rate (2.8 vs 3.0 per 1,000 ventilator days, $p = 0.96$).

Conclusion: Minimal leak testing is a known method of cuff pressure monitoring that was demonstrated in this study to provide a reproducible technique.

Keywords: Critical care, Intubation, Monitoring.

ABSTRACTO

Introducción: la presión óptima del manguito para pacientes intubados es de 20–30 cm H₂O, medida de forma rutinaria por manometría. Esta metodología está asociada con costos elevados debido a los requisitos del equipo. El objetivo de este estudio fue evaluar otra metodología, es decir, la prueba de fugas mínimas (MLT).

Materiales y Métodos: las presiones iniciales del manguito se midieron por manometría para todos los pacientes con ventilación mecánica en una unidad de cuidados intensivos quirúrgicos (UCI). Dos médicos de cuidados críticos realizaron por separado un MLT para cada sujeto y la presión del manguito se volvió a medir por manometría. Se determinó la tasa de neumonía asociada al ventilador (VAP).

Resultados: Treinta sujetos con 100 eventos de pacientes fueron evaluados. Las presiones del manguito medidas después de MLT fueron altamente consistentes entre los médicos, con un coeficiente de correlación de Pearson de 0.770 ($p = 0.01$). Las presiones promedio iniciales del manguito no fueron significativamente diferentes entre la manometría y el MLT (25 cm H₂O frente a 14 cm H₂O, $p = 0.1894$). La manometría tuvo una mayor incidencia de presiones elevadas del manguito ($n = 13/50$ frente a $2/100$, $p < 0.0001$), mientras que MLT tuvo una mayor incidencia de presiones bajas del manguito ($n = 72/100$ frente a $17/50$, $p < 0.0001$). No se observó diferencia en la tasa de VAP (2.8 vs 3.0 por 1,000 días de ventilador, $p = 0.96$).

Conclusión: La prueba de fuga mínima es un método conocido de monitoreo de la presión del manguito que se demostró en este estudio para proporcionar una técnica reproducible.

Palabras clave: Cuidados críticos, Intubación, Monitoreo.

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INTRODUCTION

Intubation of the trachea with endotracheal or nasotracheal tubes (ETTs or NTTs) or tracheostomy tubes is a commonly used medical intervention in the United States, with over 20 million intubations performed annually.¹ To ensure proper functioning during mechanical ventilation, the balloon cuff of the breathing tube must be inflated to occlude the patient's airway. The inflated cuff maintains a seal permitting positive pressure ventilation with low risk of aspirating upper airway secretions that could cause pneumonia.^{2–4} However, there is a narrow acceptable range of cuff inflation pressures between 20 and 30 cm H₂O that lead to an acceptable seal with minimal side effects.^{3–15}

Several methods to monitor cuff pressure are routinely utilized. Three of the most common are manometry, MLT, and minimal

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occlusive volume (MOV). Manometry involves direct measurement of the pressure in the ETT cuff via the pilot balloon, while the MLT involves removing air from the cuff until an air leak is heard. The MOV testing involves reinflating the cuff to a small amount to provide the minimum volume necessary to occlude the airway.^{16,17}

Despite the widespread usage of these methods in ICUs, there is a paucity of data comparing these two methods.^{6,16,18,19} Therefore, the objective of this pilot study was to compare the efficacy and complication rates of these two methods in ventilated ICU patients. The primary outcome of this study was to evaluate the differences in cuff pressure measurement between these two methods. Secondary end points measured included the rate of VAP and aspiration.

MATERIALS AND METHODS

A prospective study of all positive pressure mechanically ventilated patients over a 2-month period from April to May 2013 in a 20-bed surgical ICU was conducted after obtaining appropriate institutional review board approval. Patients requiring positive end-expiratory pressure (PEEP) >16 were excluded to prevent provoking desaturation and hypoxemia from loss of PEEP during MLT. Flowchart 1 shows the study design.

Data collected for each patient included ventilator mode, amount of PEEP, pressure support, peak inspiratory pressure (PIP), mean airway pressure (MAP), fraction of inspired oxygen (FiO₂), respiratory rate (RR), and tidal volume (TV). Breathing tube type and size were also recorded.

Cuff pressure measurements were obtained with a manometer (8199 Cufflator Endotracheal Tube Inflator and Manometer; Posey Products, LLC) per the standard protocol. Minimal leak test was performed separately for each of the subjects by two different critical care physicians by following a standardized protocol. For the purpose of this study, the MLT technique performed included measuring MOV. First, secretions were suctioned from the patient’s airway and oropharynx above the cuff to minimize aspiration risk. The cuff was slowly deflated using a 10-cc syringe until an air leak was audible at PIP, then the cuff was reinflated slowly with small amounts of air until the air leak was no longer audible. Manometry was then used to measure the corresponding cuff pressure at the end of each physician’s MLT. Cuff pressures were adjusted twice a day by respiratory therapy staff after initial

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Conflict of interest: None

evaluation and measurement by the physicians per the standard protocol.

The cuff pressures corresponding to each MLT measured by the two physicians were compared by calculating a Pearson’s correlation coefficient (SPSS, version 23). Study groups were compared using a Student’s unpaired two-tailed *t* test for continuous variables and a Chi-square test for categorical variables (GraphPad Prism, version 5.0). The VAP rate per 1,000 ventilator days was calculated for the study population and compared to the rate for the same ICU population over the 2 months prior to the study using a Chi-square test. Ventilator-associated pneumonia was defined using standard CDC criteria.²⁰ A *p* value <0.05 was considered to be statistically significant.

RESULTS

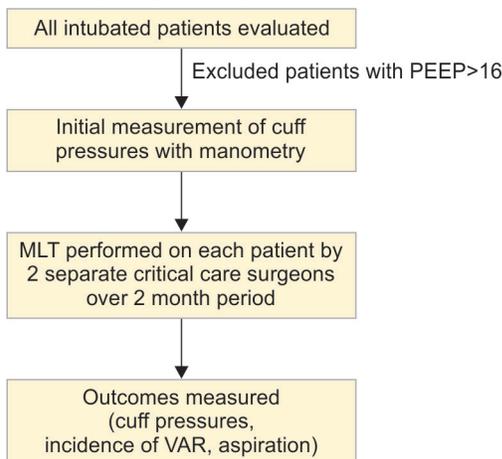
Demographics

A total of 30 subjects met the inclusion criteria. A total of 50 events were identified, as some patients met the study inclusion criteria on multiple days. Average age of the patients was 53.4 years (range, 15–96 years). Males represented 63% (*n* = 19/30) of the study population. Average body mass index was 29.2 kg/m² (range, 18.4–78.8 kg/m²). Average initial cuff pressures for all study patients were 24.9 ± 3.3 cm H₂O. Endotracheal tubes were used in 78% of patients (*n* = 39/50), 20% *via* tracheostomy (*n* = 10/50) and 2% with an NTT (*n* = 1/50). The most common breathing tube sizes were 8 (40%, *n* = 20/50) and 7.5 (38%, *n* = 19/50). Table 1 shows the demographic data for the study population.

Ventilator Settings

Different types of ventilator modes included in this study are continuous mandatory ventilation (*n* = 32/50, 64%), pressure support ventilation (*n* = 8/50, 16%), pressure-controlled continuous mandatory ventilation, synchronized intermittent mechanical ventilation (*n* = 3/50, 6%), airway pressure release ventilation (*n* = 1/50, 2%), and proportional assist ventilation (*n* = 1/50, 2%). Ventilator settings were recorded at the onset of the study and did not change

Flowchart 1: Study design of cuff pressure measurement



MLT, minimal leak test; VAP, ventilator associated pneumonia

Table 1: Study demographics and endotracheal tube (ETT) characteristics

Demographics (<i>n</i> = 30)	
Avg age, year (range)	53.4 (15–96)
Male gender, <i>n</i> (%)	19 (63)
Avg BMI kg/m ² (range)	29.2 (18.4–78.8)
ETTs* (<i>n</i> = 39)	
Tube distance measured at lip, mean cm (SEM)	24 (0.2)
Initial cuff pressures, cm H ₂ O, mean (SEM)	24.9 (3.3)
ETT size, <i>n</i> (%)	
Size 8	15 (38)
Size 7.5	17 (44)
Size 7	7 (18)

*One patient had a nasotracheal tube and 10 patients had tracheostomy tubes

BMI, body mass index; SEM, standard error of the mean.



Table 2: Ventilator modes and settings for the study population

Initial ventilator settings, mean (range) (n = 100 events)	
Fraction of inspired oxygen, %	45 (28–70)
Respiratory rate, breaths/minute	21 (14–42)
Positive end-expiratory pressure, cm H ₂ O	6 (0–16)
Tidal volume, mL	540 (300–850)
Mean airway pressure, cm H ₂ O	12.5 (7–25)
Peak inspiratory pressure, cm H ₂ O	25.6 (10–40)
Ventilator mode, n (%) (n = 100 events)	
Volume control	32 (64)
Pressure support	8 (16)
Pressure control continuous mandatory ventilation	5 (10)
Synchronized intermittent mandatory ventilation	3 (6)
Airway pressure release ventilation	1 (2)
Proportional assist ventilation	1 (2)

Table 3: Outcomes for the manometry vs minimal leak test study groups

Outcome	Manometry (n = 50)	Minimal leak test (n = 100)	p value
Cuff pressure, mean cm H ₂ O (range)	25 (0–56)	14 (0–32)	0.19
Cuff pressure, <20 cm H ₂ O (range)	17 (34)	72 (72)	<0.001
Cuff pressure, >30 cm H ₂ O (range)	13 (26)	2 (2)	<0.001
Ventilator associated pneumonia per 1,000 ventilator days, n	2.8	3.0	0.96

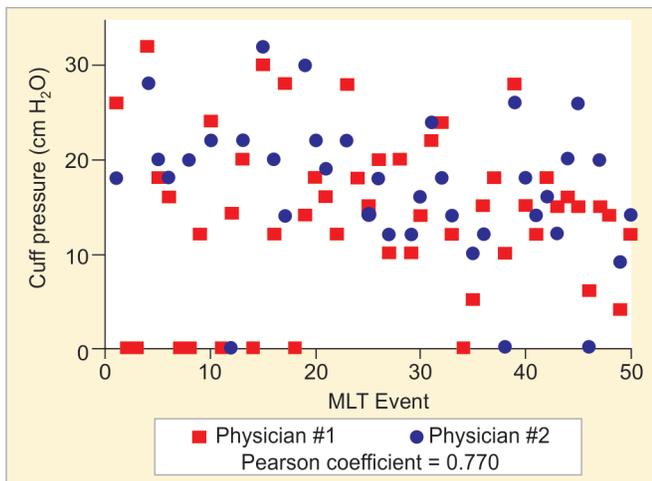


Fig. 1: Correlation of measurement of minimal leak test cuff pressures between physician evaluators. MLT, minimal leak test

significantly during the course of the investigation. The average parameters for the ventilator settings are presented in Table 2.

Correlation between Physician Measurements

Post-MLT cuff pressures measured by manometry were compared between the two physician evaluators. Correlation between evaluators was measured using the Pearson correlation coefficient, which was measured to be 0.770 (p = 0.01). This result demonstrates that the post-MLT manometry measurements were consistent between the two physicians (Fig. 1).

Cuff Pressures Measurements

Initial measured cuff pressures ranged from 0 to 56 cm H₂O, with an average of 24.9 ± 3.3 cm H₂O for all patients. A total of 100 MLT events were recorded as there were 50 subject events with two measured MLT pressures (one per physician). No difference was found between the average cuff pressures when comparing conventional manometry vs MLT (25 cm H₂O, range 0–56 cm H₂O vs 14 cm H₂O, range 0–32 cm H₂O, p = 0.1894). The MLT group had a higher incidence of aberrant cuff pressures with 74% of measurements not falling within the acceptable range of

20–30 cm H₂O. The manometry group had an increased amount of high measured cuff pressures (n = 13/50, 26% vs 2/100, 2%, p < 0.0001). The incidence of initial cuff pressure >30 cm H₂O was not significantly different between the first and second months of the study (19% vs 31%, p = 0.38). However, of the subjects with unacceptably high cuff pressures, the mean was significantly higher during the first month of our study compared to the second (47.5 ± 7.7 vs 38.9 ± 5.3 cm H₂O, p = 0.038) as was the mean elevation above the normal range (17.5 ± 7.7 vs 8.9 ± 5.3 cm H₂O, p = 0.038). The MLT group had a higher incidence of low cuff pressures compared to manometry measurements (n = 72/100, 72% vs 17/50, 34%, p < 0.0001). Of the MLT patients with cuff pressure <20 cm H₂O, 18/72 (25%) had a post-MLT cuff pressure of 0 cm H₂O. This signified that no air leak was identified in spite of the complete cuff deflation.

Incidence of VAP

The incidence of VAP was measured during the study period and compared to a control population. No difference in VAP rate using MLT compared to manometry was found during this study period (2.8 vs 3.0 VAP per 1,000 ventilator days, p = 0.96). Results are shown in Table 3.

DISCUSSION

Minimal leak test has been previously proposed as a safe and effective way to monitor the cuff pressure of breathing tubes. However, few studies compare it directly to manometry.^{6,16,18,19} Given the high incidence of ICU patients who require mechanical ventilation, it is imperative to define the optimal methods to monitor cuff pressures. This study demonstrated that MLT was a reproducible indicator of endotracheal cuff pressures with good interobserver reliability between the two physician evaluators conducting the test.

A recent study by Harvie and colleagues found similar results with high interoperator reliability between nurses and physician investigators.¹⁸ Thus, it can likely be concluded that MLT has high reproducibility for maintaining cuff pressures. Overall, the average cuff pressures were found to be similar by manometry and MLT measurements. However, one of the most important observations from this study was a significant discrepancy in cuff pressures not falling within the acceptable range of 20–30 cm H₂O. Pressures below 20 cm H₂O provide an inadequate barrier against secretions and thus increase the risk of aspiration and pneumonia,^{3–7} while pressures above 30 cm H₂O have been found to impede tracheal capillary blood flow and increase the risk of ischemia and necrosis.^{8–13}

Pressures >50 cm H₂O completely occluded capillary blood flow.^{10–15} This study demonstrated that while MLT provided a higher incidence of cuff pressures below 20 cm H₂O, while manometry showed an increase in cuff pressures above 30 cm H₂O. Interestingly, a similar evaluation by Harvie and colleagues found that MLT resulted in unacceptably high cuff pressures more frequently than low cuff pressures, with 14 (31%) of 45 subjects having cuff pressures >30 cm H₂O and 11 (24%) of 45 patients having cuff pressures <20 cm H₂O.¹⁸ Future studies from a larger sample size are needed to evaluate the ramifications of this discrepancy between measurement techniques.

No significant difference in the rate of VAP was found between manometry and MLT despite the discrepancies in cuff pressures, with MLT producing lower values. A study by Rello et al. previously demonstrated that ETT cuff pressures lower than 20 cm H₂O are an independent risk factor for VAP development in a subset of mechanically ventilated patients.⁸ However, this study demonstrated no significant increase in pneumonia events over the course of the study.

This study has several limitations that need to be discussed. First, it represents a pilot study at a single institution with a small sample size. The number of VAP events was low, given the small sample size. It would be important to determine whether similar results are observed with a larger study population. In addition, ventilator modes varied among patients, which could have influenced the cuff pressure and the volume necessary to seal a leak after cuff deflation.

In conclusion, this study showed that MLT is a reliable indicator of cuff pressure shown to consistently prevent unacceptably high cuff pressures for surgical ICU patients. However, it could result in pressures that are lower than the accepted safe range. The incidence of VAP did not significantly increase with additional MLT during our pilot study, suggesting MLT is a safe adjunct for cuff pressure monitoring. Further prospective studies are warranted to continue to evaluate MLT in this patient population and should focus on the influence of different types of ventilator modes on the cuff pressures.

REFERENCES

- Grant T. Do current methods for endotracheal tube cuff inflation create pressures above the recommended range? *J Perioper Pract* 2013;23(12):292–295. DOI: 10.1177/175045891302301205.
- Bolzan D, Guizilini S, Faresin S, et al. Endotracheal tube cuff pressure assessment maneuver induces drop of expired tidal volume in the postoperative of coronary artery bypass grafting. *J Cardiothorac Surg* 2012;7:53. DOI: 10.1186/1749-8090-7-53.
- Bernhard W, Cottrell J, Sivakumaran C, et al. Adjustment of intracuff pressure to prevent aspiration. *Anesthesiology* 1979;50(4):363–366. DOI: 10.1097/00000542-197904000-00018.
- Tobin MJ, Grenvik A. Nosocomial lung infection and its diagnosis. *Crit Care Med* 1984;12(3):191–199. DOI: 10.1097/00003246-198403000-00008.
- Guyton D. Endotracheal and tracheotomy tube cuff design: influence on tracheal damage. *Crit Care Update* 1990;1:1–10.
- Stewart S, Secrest J, Norwood B, et al. A comparison of endotracheal tube cuff pressures using estimation techniques and direct intracuff measurement. *AANA J* 2003;71(6):443–447.
- Kalil A, Metersky M, Klompas M, et al. Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Infect Dis* 2016;63(5):e61–e111. DOI: 10.1093/cid/ciw353.
- Rello J, Sonora R, Jubert P, et al. Pneumonia in Intubated patients: role of respiratory airway care. *Am J Respir Crit Care Med* 1996;154(1):111–115. DOI: 10.1164/ajrccm.154.1.8680665.
- MacKenzie C, Klose S, Browne D. A study of inflatable cuffs on endotracheal tubes. Pressures exerted on the trachea. *Br J Anaesth* 1976;48(2):105–110. DOI: 10.1093/bja/48.2.105.
- Black A, Seegobin R. Pressures on endotracheal tube cuffs. *Anaesthesia* 1981;36(5):498–511. DOI: 10.1111/j.1365-2044.1981.tb10286.x.
- Seegobin R, van Hasselt G. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study effects of four large volume cuffs. *Br Med J (Clin Res Ed)* 1984;288(6422):965–968. DOI: 10.1136/bmj.288.6422.965.
- Cooper J, Grillo H. Evolution of tracheal injury due to ventilator assistance through cuffed tubes: a pathological study. *Ann Surg* 1969;169(3):334–348. DOI: 10.1097/00000658-196903000-00007.
- Hilding A. Laryngotracheal damage during intratracheal anesthesia. Demonstration by staining the unfixed specimen with methylene blue. *Ann Otol Rhinol Laryngol* 1971;80(4):565–581. DOI: 10.1177/000348947108000420.
- Mehta S, Mickiewicz M. Pressure in large volume, low pressure cuffs: its significance, measurement and regulation. *Intensive Care Med* 1985;11(5):267–272. DOI: 10.1007/BF00260364.
- King K, Mandava B, Kamen J. Tracheal tube cuffs and tracheal dilatation. *Chest* 1975;67(4):458–462. DOI: 10.1378/chest.67.4.458.
- Rose L, Redl L. Survey of cuff management practices in intensive care units in Australia and New Zealand. *Am J Crit Care* 2008;17(5):428–435.
- Crimlisk J, Horn M, Wilson D, et al. Artificial airways: a survey of cuff management practices. *Heart Lung* 1996;25(3):225–235. DOI: 10.1016/S0147-9563(96)80033-1.
- Harvie D, Darvall J, Dodd M, et al. The minimal leak test technique for endotracheal cuff maintenance. *Anaesth Intensive Care* 2016;44(5):599–604. DOI: 10.1177/0310057X1604400512.
- Das S, Kumar P. Comparison of minimal leak test and manual cuff pressure measurement technique method for inflating the endotracheal tube cuff. *Indian J Clin Anaesth* 2015;2:78–81. DOI: 10.5958/2394-4994.2015.00002.5.
- Centers for Disease Control and Prevention. Ventilator-Associated pneumonia, 2002, https://www.cdc.gov/nhsn/PDFs/slides/VAP-DA_gcm.pdf.