Behavior of the Endotracheal Tube Cuff Pressure During a Routine Control Maneuver With Different Manometers - Bench Study

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BACKGROUND: The main functions of the endotracheal tube (ETT) cuff are to prevent macroaspiration and to allow pressurization of the respiratory system. For this purpose, it is essential to maintain adequate pressure inside the cuff, thus reducing the risks for the patient. It is regularly checked using a manometer and is considered the best alternative. The objective of this study was to evaluate the cuff pressure behavior of different ETTs during the simulation of an inflation maneuver using different manometers. METHODS: A bench study was performed. Four brands of 8-mm internal diameter single lumen with a Murphy eye ETT with cuff and 3 different brands of manometers were used. In addition, a pulmonary mechanics monitor was connected to the inside of the cuff through the body of the distal end of the ETT. RESULTS: A total of 528 measurements were made on the 4 ETTs. During the complete procedure (connection and disconnection), there was a significant pressure drop of 7 ± 1.4 cm H_2O from the initial pressure ($P_{INITIAL}$) ($P < .001$), of which 6 ± 1.4 cm H_2O was lost during connection (difference between $P_{INITIAL}$ and $P_{CONNECTION}$). The $P_{RECONNECTION}$ value was 19.1 ± 1.6 cm H_2O, showing a significant total pressure drop of 11 ± 1.6 cm H_2O (difference between $P_{INITIAL}$ and $P_{RECONNECTION}$) ($P < .001$). The P_{FINAL} mean was 29.6 ± 1.3 cm H_2O. Significant differences were found between manometers according to the time of measurement. A similar phenomenon was evidenced when analyzing different ETTs. CONCLUSIONS: Significant pressure changes occur secondary to ETT cuff measurement, which has important implications for patient safety.
Key words: endotracheal tube; artificial airway; interfaces; cuff; manometer. [Respir Care 0;0(0):1–●.

Introduction

The airway management of mechanically ventilated patients involves the use of an endotracheal tube (ETT) with a high-volume and low-pressure cuff. This device protects the airway and allows positive-pressure ventilation, sealing the airway for delivery and monitoring of positive-pressure ventilation, as well as protecting against fluid penetration from the pharyngeal space into the lower trachea and lungs.[1] Adequate tracheal sealing of the airway using an ETT cuff is a prerequisite for preventing one of the most frequent and preventable infections in mechanically ventilated patients: ventilator-associated pneumonia (VAP). The respiratory system of intubated patients is exposed to a considerable risk of aspiration, and thus the risk of developing VAP increases.[2]

The consensus regarding safe cuff pressure ranges to isolate the trachea is between 20–30 cm H_2O.[3-6] In normotensive patients, pressures > 30 cm H_2O compromise tracheal mucosal perfusion and increase the risk of injury.[6,7] Pressures < 20 cm H_2O increase the risk of macroaspiration.[4,8,9] There are different ways to monitor cuff pressure.[7] In many ICUs, periodically checking the cuff pressure using a manual manometer is standard practice. However, this procedure carries the potential of cuff pressure loss with an increased risk of repeated aspiration of pharyngeal contents.[10,11] The magnitude of these cuff pressure drops per connection is possibly influenced by the cuff pressure maneuvers and the measuring device.[12,13] Although direct measurement through a manometer is the accepted standard, pilot balloon palpation is the most commonly used method despite its lack of accuracy.[8]

There are currently no uniform guidelines for cuff pressure management, and practice varies widely between institutions.[14] Studies show that cuff pressure > 40 cm H_2O is commonly found in 55% of subjects. Although intracuff pressure monitoring with a manometer is the recommended technique, its reliability remains unclear.[10,11] The present

study aimed to evaluate the cuff pressure behavior of different ETTs during the simulation of an inflation maneuver using different manometers.

Methods

We performed this experimental study in the equipment analysis laboratory of the Hospital Británico of Buenos Aires between May–June 2022 based on a convenience sample of 44 professionals who voluntarily agreed to participate. The study was approved by the research ethics committee of Hospital Británico of Buenos Aires and was registered under number 7706.

Four brands of 8-mm inner-diameter (ID) single lumen with Murphy eye ETT with cuff were used (Portex Blue Line, Smiths Medical, Minneapolis, Minnesota; Shiley TaperGuard, Medtronic, Minneapolis, Minnesota; Elit, Zhanjiang Star Enterprise Co. Ltd, Zhanjiang, China; Medis Cuff-Safe Standard, Medis Medical Tianjin, Tianjin, China) together with 3 different brands of manometers (Portex, Smiths Medical; VBM, VBM Medizintechnik GmbH, Sulz am Neckar, Germany; and Medtronic, Minneapolis, Minnesota). In addition, FluxMed equipment (MBMed, Buenos Aires, Argentina) was connected to the inside of the cuff employing an Abbocath 16 catheter (Abbott, Abbott Park, Illinois) introduced through the Murphy eye (Fig. 1). Each ETT was placed inside an artificial trachea made of a 22-mm diameter extendable circuit fragment (Compact, Intersurgical, Wokingham, United Kingdom).

The measurement process was based on recording the pressure variation inside the cuff produced by the usual maneuver using a manometer. Figure 2 shows the measurement sequence of the research protocol that is detailed as follows:

1. The cuff was inflated to 30 cm H_2O ($P_{INITIAL}$) by injecting air through the pilot balloon. This pressure was verified inside the balloon with the continuous pressure measurement system (FluxMed), and through it the pressure values were checked to verify they remained constant (+/− 0.5 cm H_2O) for 60 s to ensure the model's reliability.
2. The participant connected the manometer to the pilot balloon. The pressure measured by the continuous system ($P_{CONNECTION}$) was recorded. Participants were blinded to the continuous pressure recording.
3. The participant disconnected the manometer. The pressure measured by the continuous system was recorded ($P_{DISCONNECTION}$).
4. The participant reconnected the manometer. The pressure measured by the continuous system was recorded ($P_{RECONNECTION}$).
5. The participant insufflated the cuff with the manometer to 30 cm H_2O. The pressure achieved through the continuous system was recorded ($P_{ADJUSTED}$).
6. The participant disconnected the manometer. The pressure measured by the continuous system was recorded (P_{FINAL}).

The pressure values were recorded in real time and stored for later analysis.

An estimation of 44 measurements per ETT would be necessary to have a power of 80%, accepting a type-1 error of 5%. Mean values and SD differences were derived from a pilot study conducted by our group. Continuous variables were reported as mean and SD, as the sample size was large

QUICK LOOK

Current knowledge

The main functions of the endotracheal tube cuff are to prevent aspiration and to allow positive-pressure ventilation. For this function to be achieved, it is necessary to periodically check the cuff pressure; and for this purpose, the manometer is considered the best alternative.

What this paper contributes to our knowledge

The cuff pressure is susceptible to significant variation after connection and disconnection of the manometer. This variation is mainly due to the connection of the manometer to the pilot balloon, with potentially unsafe behavior for the patient with an artificial airway, and can be avoided by standardized measurement practice.

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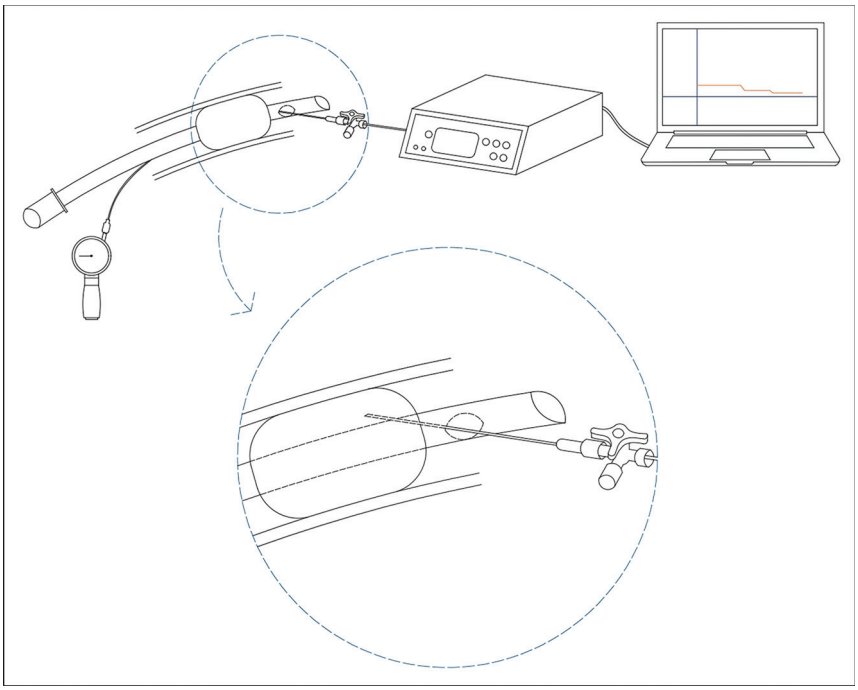

Fig. 1. Schematic illustration of the measurement model. The scheme shows the measurement model used for the study. The Abbocath needle was inserted through the Murphy eye reaching the inside of the cuff and connected through a 3-way tap to the continuous measurement system (FluxMed). Also, the connection of the manometer to the endotracheal tube pilot balloon.

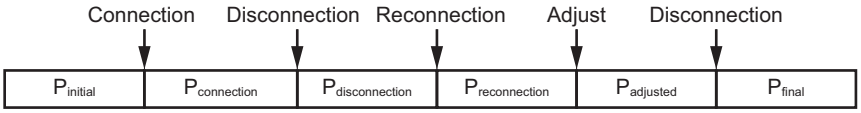

Fig. 2. Sequence used to record the obtained pressures. The figure shows the times when the 5 pressures were recorded during the study. First, the cuff was insufflated to 30 cm H_2O ($P_{INITIAL}$). Second, the manometer was connected to the pilot balloon and $P_{CONNECTION}$ was recorded. Then, it was disconnected and the $P_{DISCONNECTION}$ recorded. Next, the manometer was reconnected to the pilot balloon, and the $P_{RECONNECTION}$ was recorded. After that, it was insufflated to 30 cm H_2O when the $P_{ADJUSTED}$ was recorded. Finally, the manometer was disconnected and the P_{FINAL} was recorded. This procedure was repeated at each endotracheal tube and with each manometer. $P_{INITIAL}$ = initial pressure; $P_{CONNECTION}$ = pressure after manometer connected; $P_{DISCONNECTION}$ = pressure after manometer disconnected; $P_{RECONNECTION}$ = pressure after manometer reconnected; $P_{ADJUSTED}$ = pressure after cuff insufflated to 30 cm H_2O; P_{FINAL} = pressure after manometer disconnected.

enough to assume a normal distribution, as established by the central limit theorem. The analysis of variance test with Bonferroni correction was used to compare different ETTs and manometers in each measurement step. Barlett test was chosen to evaluate the homoscedasticity of the variables. The *t* test was used to make comparisons between the different stages. A P value $< .05$ was considered statistically significant. Stata software (release 13, StataCorp, College Station, Texas) was utilized for data analysis.

Results

A total of 528 measurements were performed on the 4 ETTs. During the complete procedure (connection and disconnection), there was a significant pressure drop of 7 ± 1.4 cm H_2O from the $P_{INITIAL}$ ($P < .001$), of which 6 ± 1.4 cm H_2O was lost during the connection of the manometer to the pilot balloon ($P_{CONNECTION}$). In addition, the pressure loss due to subsequent disconnection was 0.95 ± 1 cm H_2O ($P_{DISCONNECTION}$) (Table 1). The $P_{RECONNECTION}$ value was 19.1 ± 1.6 cm H_2O, showing a significant total pressure drop of 11 ± 1.6 cm H_2O from $P_{INITIAL}$ ($P < .001$). The P_{FINAL} mean was 29.6 6 1.3 cm H_2O. When analyzing different manometers, we observed that the pressure reduction generated by the connection to the pilot balloon ($P_{CONNECTION}$) was different ($P < .001$). However, when considering the total loss given by the connection-disconnection binomial, there was no significant difference between devices ($P = .11$) (Fig. 3).

After recording $P_{CONNECTION}$, there were significant differences between most of the ETTs (Elit vs Medis [$P < .001$], Elit vs Portex [$P < .001$], Medis vs Shiley [$P < .001$], Portex vs Shiley [$P < .001$]) except between Elit and Shiley ($P = .79$) and between Portex and Medis ($P > .99$).

Table 1. Changes with Each Manometer and ETT at Specified Measurement Times

	Connection pressure ($P_{CONNECTION}$)		
	Covidien	Portex	VBM
Elit	23.3 (1.6)	24.1 (1.3)	23.3 (1.9)
Medis	24.3 (0.3)	24.6 (0.4)	24.6 (0.4)
Portex	23.8 (1.6)	25.6 (1.3)	24.5 (1.2)
Shiley	23.3 (0.8)	23.4 (0.9)	23 (0.9)
	Disconnection pressure ($P_{DISCONNECTION}$)		
	Covidien	Portex	VBM
Elit	21.7 (1.4)	22.2 (1)	22 (1.5)
Medis	24 (0.8)	24 (0.6)	24.4 (0.4)
Portex	22.9 (1.5)	23.8 (1.2)	23.5 (0.9)
Shiley	22.7 (0.8)	22.5 (0.9)	22.6 (0.8)
	Reconnection pressure ($P_{RECONNECTIONN}$)		
	Covidien	Portex	VBM
Elit	18 (1.7)	18.6 (1.2)	17.8 (1.7)
MEDIS	20.3 (0.7)	20.5 (0.9)	20.5 (0.5)
Portex	19.1 (1.7)	20.6 (1.4)	19.7 (1.5)
Shiley	18.3 (0.8)	18.1 (1)	18.1 (1.1)
	Adjusted pressure ($P_{ADJUSTED}$)		
	Covidien	Portex	VBM
Elit	29.6 (0.6)	31.6 (0.7)	30.1 (0.8)
Medis	30 (0.7)	31.7 (0.9)	30.4 (0.8)
Portex	29.9 (0.7)	31.9 (0.8)	30.3 (0.9)
Shiley	29.9 (0.5)	31.4 (0.7)	30.2 (0.5)
	Final pressure (P_{FINAL})		
	Covidien	Portex	VBM
Elit	28.2 (1.2)	29.8 (1.2)	28.6 (1.4)
Medis	29.7 (0.6)	31.1 (0.8)	30 (1)
Portex	29 (0.7)	30.1 (1.7)	29 (1.6)
Shiley	29.3 (0.7)	30.4 (0.8)	29.3 (0.7)

When observing $P_{DISCONNECTION}$, there were statistically significant differences in the resulting pressure between all the ETTs (Elit vs Medis [$P < .001$], Elit vs Portex [$P < .001$], Medis vs Shiley [$P < .001$], Portex vs Shiley [$P < .001$], Elit vs Shiley [$P < .001$], and between Portex and Medis [$P < .001$]). Regarding $P_{RECONNECTION}$, pressure measurements were similar to $P_{CONNECTION}$. However, pressure varied between the ETT brands (Elit vs Medis [$P < .001$], Elit vs Portex [$P < .001$], Medis vs Shiley [$P < .001$], Portex vs Shiley [$P < .001$], and between Portex and Medis [$P = .001$] except for the Elit and Shiley [$P > .99$]) (Fig. 4).

Discussion

Among the main findings of this study, we can describe the 23% pressure drop from baseline after connecting and disconnecting the manometer to the pilot balloon without intermediate adjustment. We also found that 86% of this pressure loss is generated by simply connecting the manometer to the pilot balloon. Moreover, the values recorded by the respective manometers and ETTs were different, with potentially unsafe behavior for clinical practice.

The pressure drop is most likely related to compressible volume loss of the different manometers, as the connection maneuver favors leakage into the device, so pressure drops. Although this pressure drop has been previously reported, the value in these studies was lower than ours.[15] This discrepancy could be associated with the baseline pressure selected in these studies, which was close to the recommended lower limit, which generates a lower pressure change between the cuff and the manometer.[12,16] However, in clinical practice, it is recommended to use inflation pressures close to the upper

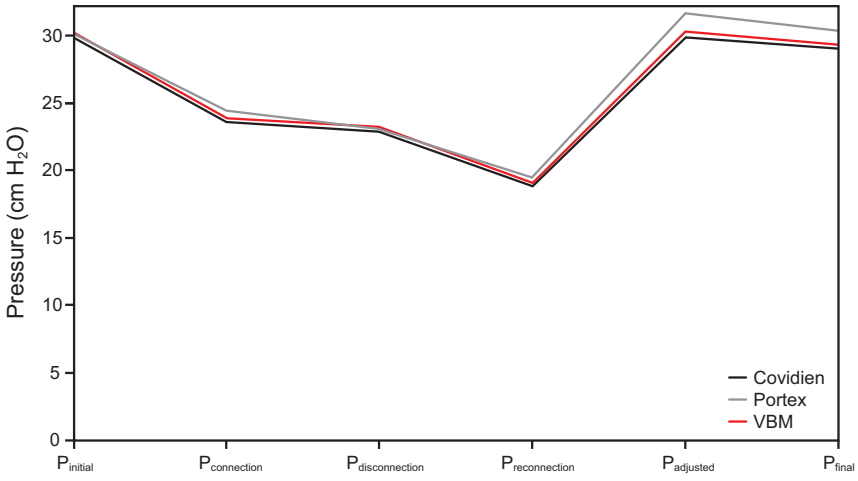

Fig. 3. Cuff pressure behavior with each manometer. $P_{INITIAL}$ = initial pressure; $P_{CONNECTION}$ = pressure after manometer connected; $P_{DISCONNECTION}$ = pressure after manometer disconnected; $P_{RECONNECTION}$ = pressure after manometer reconnected; $P_{ADJUSTED}$ = pressure after cuff insufflated to 30 cm H_2O; P_{FINAL} = pressure measured after manometer disconnected.

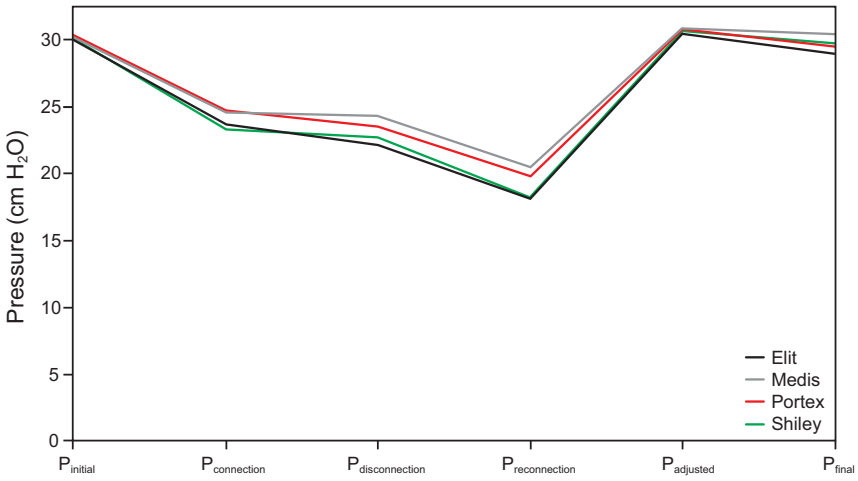

Fig. 4. Cuff pressure behavior in each endotracheal tube. $P_{INITIAL}$ = initial pressure; $P_{CONNECTION}$ = pressure after manometer connected; $P_{DISCONNECTION}$ = pressure after manometer disconnected; $P_{RECONNECTION}$ = pressure after manometer reconnected; $P_{ADJUSTED}$ = pressure after cuff insufflated to 30 cm H_2O; P_{FINAL} = pressure after manometer disconnected.

limit. Thus, our results have a higher correlation with clinical practice.[3,4,17]

During disconnection, the pressure drop was more delicate than that caused by connection. However, when preceded by operator inflation of the cuff to 30 cm H_2O, in most cases (99%) the final cuff pressure was within the recommended safe range.[3,4] In addition, all measurements reflected a value > 20 cm H_2O, considered the point at which the risk of VAP can increase exponentially.[8] This finding may have implications in daily practice by minimizing tracheal injury while reducing the risk of macroaspiration. Given this and justified by the high probability that the pressure decrease from connection and disconnection will result in pressure below the recommended safety values, our results demonstrate the importance of insufflating the cuff to a pressure of 30 cm H_2O during each maneuver.

The Portex manometer showed a lower pressure drop upon connection, which could be related to the difference in the compressible volume of the devices.[13,18] However, when analyzing the pressure change, that is, the pressure recorded after connecting and disconnecting the manometer, the differences disappear, as the Portex manometer showed a higher pressure drop upon removal. This could be just by chance or could also be a result of the smaller diameter of the coupling connector of the manometer to the pilot balloon valve. Despite this, we did not find this difference during the evaluation of the manometers. However, the P_{FINAL} was always within the safety range; and on that basis, we could say that when it comes to pressure control any of the 3 manometers will offer a similar guarantee.

The choice of ETT brand may influence cuff pressure behavior. However, at the clinical level, they would not have a huge impact as they do not expose, with adequate control as reported in our study, to risks in terms of underpressurization or overpressurization. Multiple factors can modify the cuff pressure in a mechanically ventilated patient.[18,19] In this context, it would be important to implement a measurement maneuver to ensure adequate pressure as proposed in this study, where each control is followed by a recalibration insufflation.

Our study has limitations. Our methods were conducted in an experimental trachea model. In this sense, the pressure change can vary when the ETT is inside a human trachea. However, this model was chosen to isolate the cuff from the environment, thus avoiding any external influence on the measurement, and providing some elastic resistance to expansion, as would occur in a natural airway. All types of ETTs used in this study had high-volume, low-pressure cuffs. Therefore, the results may not apply to high-pressure cuffs or other types of tubes, such as double-lumen tubes, bronchial blockers, or tracheostomy tubes. Furthermore, our study only evaluated 8-mm ID ETTs, so the resulting behavior cannot necessarily be extrapolated to all other sizes. This diameter was chosen because it is the most used in more than half of the cases in clinical practice (unpublished demographic data from the database of the Hospital Británico of Buenos Aires).

Conclusions

Standard cuff measurement practices may lead to changes in cuff pressures, which may influence patient safety. A standardized cuff pressure maneuver could mitigate these discrepancies and ensure safe cuff pressure.

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