Use of pressure volume loop closure to check for endotracheal tube cuff function

Randomized clinical trial

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ABSTRACT

الأهداف: استخدام الرسم البياني لعروة الحجم والضغط كطريقة جديدة لتحديد صلاحية كفة الأنبوب الرغامي ومقارنة ذلك بالطرق التقليدية.

الطريقة: أُجريت هذه الدراسة العشوائية السريرية في قسم التخدير، مستشفى جامعة الملك عبدالعزيز، جدة، المملكة العربية السعودية وذلك خلال الفترة من أكتوبر 2011م إلى فبراير 2012م. شملت الدراسة 140 مريض قمنا بإجراء التبييب الرغامي لهم ونفخ كفة الأنبوب بالطرق الثلاثة الآتية: إما باستخدام كمية غير محددة من الهواء حتى ينتهي تسرب الهواء ويقر ذلك طبيب التخدير المسئول، أو باستخدام ضغط مثبت عند 20 سنتيمتر من الماء، أو باستخدام طريقة عروة الحجم والضغط.

النتائج: كان قياس الضغط في كفة الأنبوب الرغامي أقل ما يكون عند استخدام عروة الحجم والضغط مقارنة بالطرقتين الأخرتين (3.89±0.26 باستخدام طريقة عروة الحجم والضغط مقابل 4.4±0.36 للضغط المثبت المضبوط سابقاً و5.26±0.46 للجس بالبالون) (p=0.00001). كما وكان حجم الهواء الأقل مع عروة الحجم والضغط مقارنة بالطرقتين الأخرتين (18.67±0.72 باستخدام طريقة عروة الحجم والضغط مقابل 20 للضغط المثبت المضبوط سابقاً و33.48±3.49 للجس بالبالون) (p=0.00001).

خاتمة: تصاحب استخدام عروة الحجم والضغط بأقل حجم من الهواء في كفة الأنبوب الرغامي ونتج عنه أقل قياس للضغط مقارنة باستخدام كمية غير محددة من الهواء حتى ينتهي تسرب الهواء ويقر ذلك طبيب التخدير المسئول، أو باستخدام ضغط مثبت عند 20 سنتيمتر من الماء.

Objectives: To assess the efficacy of pressure volume loop (PV-L) closure as an indicator of adequate endotracheal tube cuff (ETTc) function, and to compare this with commonly used methods of checking cuff pressure.

Methods: We conducted a randomized clinical trial at the Department of Anesthesia, King Abdulaziz University Hospital, Jeddah, Kingdom of Saudi Arabia from October 2011 to February 2012. One hundred and forty patients were intubated, and the ETTc was inflated using one of 3 techniques. The intubating anesthesiologist inflated the cuff at his discretion until he detected no further air leak in the first technique. In the second technique, we maintained the ETTc pressure at 20 centimeter water, while the third technique used PV-L closure.

Results: The PV-L technique required lower amounts of air to inflate the ETTc than the other 2 techniques (3.89±0.26 for PV-L versus 4.4±0.36 for fixed preset pressure, and 5.26±0.46 for pilot balloon palpation, p=0.00001) and the mean cuff pressure was lower than other techniques (18.67±0.72 for PV-L versus 20 for fixed preset pressure, and 33.48±3.49 for pilot balloon palpation, p=0.00001).

Conclusion: The PV-L closure technique is an alternative way to check for ETTc function with a significantly lower ETTc pressure and volume than those recorded with a manually inflated cuff, or with preset cuff pressure of 20 cmH_2O.

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The main function of an endotracheal tube cuff (ETTc) is to seal the airway and prevent aspiration of gastropharyngeal contents into the tracheobronchial tree.[1] Inadequate cuff inflation may expose the patient to the risk of microaspiration with subsequent nosocomial lung infection,[1] while over inflation of the ETTc may result in several catastrophic complications including pressure necrosis of the tracheal mucosa,[2] tracheal rupture,[3,4] and trachea-esophageal fistula.[5,6] Many methods have been developed to check the adequacy of cuff pressure inflation. Checking of the ETTc pressure by manual palpation of the pilot balloon, hearing the disappearance of the audible sound of an air leak, using an aneroid manometer, or a continuous automatic cuff controller are all considered adequate techniques to assess the ETTc pressure.[7] The pressure volume loop (PV-L) is one of the continuous real time pulmonary graphics incorporated in the monitoring system of anesthesia machines and mechanical ventilators. It is usually used for the assessment of dynamic lung compliance, detection of lung over-inflation, or presence of air leak.[8] In this study, we aimed to assess the efficacy the PV-L closure as an indicator of adequate ETTc function, and to compare this with 2 commonly used methods for checking cuff pressure; namely, manual palpation of the pilot balloon with the disappearance of audible air leak sound, and with an aneroid manometer controlling a preset cuff pressure.

Methods. We conducted this randomized interventional single blinded clinical trial in the Department of Anesthesia and Critical Care, King Abdulaziz University Hospital, Jeddah, Kingdom of Saudi Arabia between October 2011 and February 2012. Approval was granted from the local Research and Ethics Committee. According to the principles of the Helsinki Declaration, we screened 150 adult patients for eligibility to participate in this study. However, only 140 patients gave informed consent. We enrolled patients of both genders if they were 18 years old or above, American Society of Anesthesiologists (ASA) class I & II scheduled for elective surgery requiring oral endotracheal intubation. We excluded patients with features of predicted difficult intubation, history of chronic obstructive pulmonary diseases, poor pulmonary reserve or at risk of pulmonary aspiration, pregnant patients, trauma cases, or those with cervical spine diseases. We performed an automatic leak test prior to conduction of anesthesia on the anesthesia machine (Zeus, Draeger®, Lübeck, Germany) to detect any leak in the machine. All patients were premedicated with intravenous (IV) 0.03 $mg.kg^{-1}$ midazolam 10 minutes prior to arrival at the operating room. Electrocardiogram, pulse oximetry, non-invasive blood pressure, and bispectral index monitoring were used to monitor the patients. General anesthesia was induced by IV 2 μg.kg-1 fentanyl, 2 mg.kg-1 propofol, and 0.6 mg.kg-1 rocuronium as a muscle relaxant. Ventilation was maintained via a facemask and 100% oxygen for 3 minutes. An 8.0 millimeter internal diameter (mm ID) endotracheal tube (ETT) was used for male patients, and 7.0 mm ID ETT for female patients. We routinely use ETTs with high volume-low pressure cuffs (Portex Tracheal Tube®, Smith Medical International Ltd, Ashford, Kent, UK) in our center. An anesthesiologist with 10 years experience performed tracheal intubation, and the cuff was inflated using one of 3 methods according to randomization code. The order of the inflation technique was determined randomly using computer-generated codes enclosed in opaque envelopes. The ETTc inflation was performed using all the 3 techniques according to the order revealed by randomization. One technique is the allowance of the intubating anesthesiologist to inflate the ETTc at his discretion until no more air leak was audible on auscultation and acceptable palpation of the external pilot balloon was reached. In the second technique, the ETTc pressure was maintained at a precise pressure of 20 cmH_2O confirmed by aneroid manometer, while the third technique involved the use of increments of 0.5 ml of air until a complete closure of the pressure volume loop was displayed on the anesthesia machine monitor; namely, when the expiratory limb reached zero volume and met the starting point of the inspiratory limb, cuff inflation was ceased (**Figure 1**). Anesthesia was maintained with sevoflurane in a mixture of oxygen/air. An oropharyngeal airway was inserted to facilitate the insertion of the capnography sampling line for the detection of any air leak. Following induction of anesthesia and adequate inflation of the ETTc using one of the 3 techniques, a 3-way stopcock was connected to the pilot balloon and a small aneroid manometer (VBM®, Sulz, Germany) was connected to the other end of the stopcock while the third end was connected to a 10 ml syringe. A second investigator blinded to the method of cuff inflation passed a capnography sample line through the oropharyngeal airway to detect any air leak, measure the cuff pressure via the aneroid manometer, and completely deflate the cuff and measure the amount of air used for cuff inflation. Then, he was asked to leave the operating room. The ETTc was reinflated by the primary anesthesiologist according to the recommended order and the blinded investigator was asked to step into the room and repeat the whole

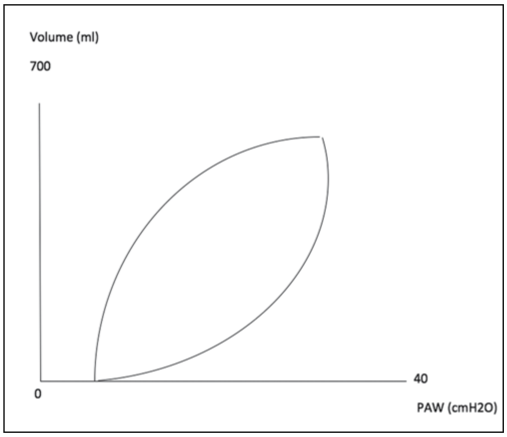

Figure 1 - An illustration of a complete closure of pressure volume loop indicates good tracheal tube cuff function.

Table 1 - Measured volume of air and pressure in the endotracheal cuffs among various study techniques.

Study technique	Volume of air (ml)*	Cuff pressure (cm H_2O)*
Pilot balloon palpation	5.26±0.46	33.48±3.49
Fixed preset pressure	4.44±0.36	20.00±0.00
Pressure volume loop	3.89±0.26	18.67±0.72

*p=0.00001

procedure to check for air leaks, measure cuff pressure, and volume of air used for cuff inflation. Finally, the cuff was reinflated again, using the third technique. The blinded investigator was asked for the last time to repeat the measurement event, checking for any carbon dioxide leak, and recording both the cuff pressure and volume.

Statistical analysis. Descriptive statistics were calculated for all the variables and repeated measure ANOVA was applied to verify whether the ETT pressure was significantly different among the 3 techniques. Quantitative continuous data were compared using Student t-test for the comparisons between the 2 techniques. The ANOVA was used to determine the differences among the 3 approaches. A repeated measure ANOVA with a Greenhouse-Geisser correction was used to determine the differences in the repeated mean volume of air used to inflate the endotracheal cuff over the 3 approaches. Post hoc test using the Bonferroni correction was conducted to detect any further difference among the 3 approaches regarding the volumes and pressure used. All statistical procedures were performed using IBM® Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 19. Results are presented as mean±SD and frequency as appropriate, and significance was defined as $p<0.05$.

Results. One hundred and fifty patients were screened for eligibility to participate in this study; 4 patients did not meet the inclusion criteria and 6 declined to participate. One hundred and forty patients provided written informed consent to participate in the trial. An equal number of females and males (n=70) were enrolled in the study with an overall mean age of 40±7.5 years (males' age 39.9±7.6 years, and females' age 40.1±7.4 years). Body mass index (BMI) was similar among both men ((25.4±2.9) and women (26.4±2.9). **Table 1** illustrates that the use of the PV-L closure technique was associated with lower amounts of air to inflate the ETTc than the other 2 techniques, and the mean cuff pressure was lower than the other techniques. Both readings of the PV-L technique were significantly lower than that recorded for either the pilot balloon technique or the fixed precise pressure technique (p=0.00001). Post hoc test using the Bonferroni correction revealed that the lowest pressure was recorded in the PV-L closure technique, and the highest was detected with the pilot balloon palpation technique when compared to the preset pressure at 20 cmH_2O. This also revealed that the least volume of air was used in the PV-L closure technique, and the largest was used with the pilot balloon palpation technique. Pairwise testing confirmed that the differences between each pair of techniques were statistically significant (p=0.00001). None of the study patients had a detectable air leak both when capnography was used or on auscultation of audible air leak.

Discussion. Tracheal intubation constitutes a routine practice in the operating rooms and in the critical care units. The use of high endotracheal cuff pressure is associated with impaired tracheal perfusion, and the latter could lead to mucosal ischemia, ulcerations complicated by tracheal stenosis, tracheal rupture, and trachea-esophageal fistula.[3-6,9-11] An increased awareness of the hazards of high cuff pressure on tracheal blood flow led to changes in ETTc design from high pressure-low volume cuffs, to low pressure-high volume ones.[12] Despite these changes, the inflated cuff pressures are commonly detected above the recommended limits.[13,14]

Several methods have been described for cuff inflation.[15-19] Cuff inflation with an undetermined volume of air according to the anesthesiologist discretion,[19] and the stethoscope-guided inflation of the ETTc until the disappearance of the harsh sound of air are among the commonly used techniques to inflate the ETTc.[19] Most of the newly designed anesthesia machines and mechanical ventilators display a continuous monitoring of PV-L to allow proper adjustment of mechanical ventilator setting, monitoring of lung compliance and lung volume, and detection of air leak, especially in neonates.[20] The PV-L begins at the inspiratory limb where the increase in pressure delivered is concomitantly associated with an increase in the volume of air delivered to the lung. This is followed by the expiratory limb where both pressure and volume fall as the lung empties, and the loop is completed.[20] An air leak will be reflected by an incomplete loop, namely, the expiratory limb will not reach the starting point. Depending on these findings we developed our technique where increments of air were used to inflate the ETTc until complete closure of the PV-L was achieved (**Figure 1**). In our study all 3 techniques managed to maintain an adequate airway seal as indicated by the lack of detectable carbon dioxide in the pharyngeal cavity and the disappearance of audible air sounds, however, the measured amounts of air and ETTc pressures were variable among the 3 groups. The PV-L closure technique was associated with the lowest measurable pressure and the smallest volume of air in comparison with the other techniques. This finding will raise a question regarding the real amount of air needed to inflate the ETTc and the pressure produced by that volume. It seems that we tend to overestimate the needed amount of air to inflate the cuff and the pressure produced by that volume. This was the finding in Braz et al's study[14] where manual palpation of the pilot balloon was the routinely used method for cuff inflation, and the measured cuff pressure exceeded 40 cmH_2O in 91% of patients in the post anesthesia care unit (PACU) following nitrous oxide anesthesia, 45% of patients in the PACU after anesthesia without nitrous oxide, and 55% of patients in the intensive care unit. Similarly, Chapman et al[21] concluded that 64.7% and 49% of pre-hospital intubated patients had a measured cuff pressure higher than 30 and 40 cmH_2O. They recommended immediate measurement of cuff pressure after intubation to avoid any damaging effect on the trachea. On the other hand, Dullenkopf et al[22] revealed that a cuff pressure of 19.1 cmH_2O was sufficient for maintenance of airway sealing. Kumar and Hirsch,[23] using stethoscope-guided ETTc inflation, reported that 16% of the cuff pressures were below 20 cmH_2O and no air leak was detected among them. Our study agrees with the results of the 2 previous studies as the PV-L closure technique detected no air leak in any patients at a mean cuff pressure lower than 20 cmH_2O (18.59 cmH_2O for size 7.0mm ID ETT, and 18.76 cmH_2O for size 8.0 mm ID ETT).

In our study, we utilized only expert anesthesiologists to ensure adequate assessment of manual pilot balloon palpation following inflation of undetermined air. However, similarly to previously published studies, there was no correlation between the level of intubating personnel experience and the accurate manual assessment of cuff pressure.[13,19,24]

Although aneroid manometers are used to regulate the cuff pressure, their availability cannot be guaranteed,[25] and they are not used routinely in anesthesia practice.[26,27] The availability of PV-L in most mechanical ventilators and anesthesia machines creates a good opportunity for its use to regulate ETTc pressure.

One limitation of our study is that we assessed the PV-L closure technique among healthy patients without any lung diseases that may affect the inspiratory pressure and necessitate the use of higher inflation volumes. A second limitation is the inability to assess any post intubation complications related to each technique as we performed all 3 techniques among all patients. The unavailability of PV-L monitoring systems in all anesthesia machines and in all mechanical ventilators will limit its use for this propose. We were unable to identify any previous studies on the use of the PV-L closure technique as a guide for cuff inflation, and further studies are needed to assess its use among various age groups, in unhealthy lungs, and to measure the ETTc pressure throughout the intubation period.

In conclusion, the PV-L closure technique is an alternative method to check ETTc function and prevent air leaks, and this is achieved at significantly lower ETTc pressure and air volume than those recorded with the manually inflated cuff or with a preset cuff pressure of 20 cmH_2O.

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