

The Changes of Endotracheal Tube Cuff Pressure during Manual and Intermittent Controlling in Intensive Care Units

Abstract

Background: Usually, the endotracheal tube cuff pressure is controlled by cuff pressure monitoring. However, the intermittent pilot-manometer connection and disconnection may cause a change in the adjusted pressure. This study aimed to investigate changes in the endotracheal tube cuff pressure using both manual and intermittent controls. **Materials and Methods:** A semi-experimental within-subject design was conducted. Fifty-nine intubated patients in the Mazandaran Intensive Care Units (ICUs) participated through convenience sampling in 2018. In the control condition, first, the cuff pressure was adjusted in 25 cm H₂O then it was measured without manometer-pilot disconnection at 1 and 5 min intervals. In the intervention condition, cuff pressure was immediately adjusted in 25 cm H₂O then it was measured with manometer-pilot disconnection in the 1st and 5th minutes. Data analysis was performed using Independent *t*-test, Chi-square test, and Phi coefficient. **Results:** The mean and Standard Deviation (SD) change of cuff pressure after 1 minute, from 25 cm H₂O, in the intervention condition was 20.22 (3.53) cm H₂O. The mean (SD) of this change in the control condition was 25.22 (3.39) cm H₂O. This difference was significant ($t_{116} = 7.83, p < 0.001, d = 1.44$). The mean (SD) change of cuff pressure after 5 minutes, from 25 cm H₂O, in the intervention condition was 19.11 (2.98) cm H₂O. The mean (SD) of this change in the control condition was 25.47 (4.53) cm H₂O. This difference was significant ($t_{116} = 9.24, p < 0.001, d = 1.70$). **Conclusions:** The tracheal tube cuff pressure has been significantly reduced during manual intermittent measuring. Therefore, it is suggested that continuous cuff pressure monitoring and regulation should be used.

Keywords: Cuff pressure, intratracheal, intubation, trachea

Introduction

Artificial airway management is an important part of the care provided by nurses and respiratory therapists. In order to ensure reliable access to this airway, especially for connecting to the ventilator, a large number of patients admitted to the Intensive Care Unit (ICU) require Endotracheal Tubes (ETTs) or a tracheostomy.^[1] At the end of these tubes is a high volume and low pressure cuff designed to fix the tube in the trachea in order to prevent aspiration, and to stop air leakage.^[2] In order to achieve this, air is pushed into the cuff in order to achieve cuff pressure in the range of 20–30 cm H₂O^[3] but maintaining it in this range is challenging. Nseir *et al.* analyzed 808 hour of cuff pressure recordings. This study showed 18% of study patients spent 100% of recording time with normal (20–30 cm H₂O) cuff pressure. 54% of study

patients developed cuff under inflation, 73% developed cuff over inflation, and 44% developed both.^[4] If this pressure is <20 cm H₂O, it can cause complications such as air leakage, inadequate tidal volume, micro aspiration and Ventilator Associated Pneumonia (VAP). This can be severe and irreparable.^[5] However, if the cuff pressure is >30 cm H₂O, this increases the risk of ischemia, necrosis, stenosis, tracheal rupture, and fistula due to the pressure on the tracheal mucosal.^[2,4,6-12] These complications are due to chronic inflammation and laryngeal fibrosis, which occurs in 19% of patients. It is estimated that 2–16% cases had airway obstruction and laryngeal edema after extubation.^[13] This was because a cuff pressure greater than 30 cm H₂O for 15 min was sufficient to induce histological evidence of tracheal mucosal lesions.^[14] Therefore, accurate and regular monitoring of the cuff pressure is

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necessary. This may be performed in two ways: continuous and intermittent. In a continuous measurement, the cuff pressure is automatically measured and adjusted using a pneumatic or electronic instrument.^[15,16] This is a more reliable method for preventing micro-aspiration of stomach contents^[17] and respiratory infections^[18] compared to intermittent control. However, the design of this tool is currently suboptimal and requires refinement.^[18]

Based on our experiences, continuous cuff pressure measurement is not routinely used in ICUs in Iran. The usual method for measuring cuff pressure of the ETT is to use intermittent measurement methods such as Minimum Leakage Technique (MLT), Minimal Occlusive Volume (MOV), palpation and cuff pressure manometer. In the MLT method, the endotracheal cuff is filled in such a way as to minimize the air leakage through the end of ETT. In the MOV method, the cuff is filled in such a way that the sound of air leakage is not heard at the maximum inspiratory pressure level, in palpation method, the cuff pressure is estimated by touching the outer pad. In the cuff pressure monitoring method, the cuff pressure is set to the normal range by manometer manually.^[14] In this regard, using a manometer is more appropriate than other intermittent methods^[2,4,8,9] because two other methods cannot be expected to maintain a normal range.^[2] In this method, the manometer is connected to the pilot of cuff and the cuff pressure is shown on the screen. If the pressure is <20 or >30 cm H₂O, air is manually inflated or deflated from the cuff until the pressure is within safe limits,^[2,12] and then the manometer would be disconnected from the pilot. Studies have shown that cuff pressure is affected by various factors such as head posture, patient position, movement and displacement, suctioning, talking attempt, hospitalization days, body mass index, passing time, and core temperature.

Cuff pressure is measured and adjusted using a manometer at least every 6 h.^[5,6,19,20] It is necessary to connect the manometer to the pilot of the cuff and separate it after adjustment in order to measure the cuff pressure. This may result in leakage of some air from the cuff and a reduction in cuff pressure.^[21] A meta-analysis of Randomized Controlled Trials (RCTs) showed that the continuous control of cuff pressure significantly reduced the incidence of cuff pressure <20 cm, cuff pressure >30 cm H₂O and VAP when compared with intermittent control of cuff pressure.^[22] Aeppli *et al.* (2018) hypothesized that a decrease in pressure could be due to the pressure integration between the relative gas volume of the pressure inside the cuff and the gas balloon pilot without pressure in the tube and balloon of the measuring instrument.^[23] This decrease in pressure may reach an unsecured range (<20 cm H₂O). Inattention to this reduction in pressure increases the risk of VAP.^[24,25]

It is necessary to estimate the amount of air loss and cuff pressure reduction each time the manometer is

connected to and disconnected from the pilot. The use of a manometer is the preferred measurement method for the intermittent recording of cuff pressure in most studies.^[2] No consideration has been given to the hypothesis that connecting or disconnecting the manometer from a balloon pilot can have a clinically significant negative effect on regulatory pressure, although *in vitro* assessment on artificial tracheas showed routine manual cuff pressure control maneuvers in ETT cuffs result in considerable cuff pressure drops.^[23] Therefore, the present study was conducted to examine changes in the ETT cuff pressure using both manual and intermittent controls.

Materials and Methods

A semi-experimental within-subject design was conducted on patients admitted to the ICU of Mazandaran hospitals between May and December 2018. In a within-subject design, each participant serves as his or her own control. A pilot study was initially performed on five patients (who were not participants in the main study) in order to estimate the sample size. The cuff pressure of the ETT was reduced by an average of 2.20 cm H₂O during the disconnection and connection of the pilot. Therefore, the sample size was determined using G*Power_{3.0.10} as 59 patients with $\alpha < 0.05$, power 0.8, and effect size 0.10. Convenience sampling was used. The inclusion criteria were ETT insertion, 18 years of age and over, body mass index more than 30, positive pressure mechanical ventilation, stable hemodynamics parameter, and normal axillary temperature (between 35 and 37.50°C).^[26] The exclusion criteria of the study were the head position and the head-of-bed angle changing, suctioning, tracheostomy, high-frequency oscillatory ventilation, identified air way abnormally, and prone position.

The setting of the ventilator was based on ideal weight and patient conditions. All ETTs were from the same manufacturer. Their types were high volume and low pressure cuff at distal end and pilot cuff with non-return valve. All of the tracheal tubes have healthy cuffs certified by the ICU physician. Internal diameter of patients' ETT were 7.50–8.50 mm. Intubation duration times were 1–7 days. The ETT cuff pressure was measured with a cuff manometer (VBM Medizintechnik GmbH, Sulz am Neckar, Germany) that was calibrated in advance.^[25] Firstly, All selected patients were initially placed in the neutral line position (the neutral line position is the position of a patient who is lying in bed in a supine position with the head-of-bed at approximately 30–45°). Then, the cuff pressure was measured by two raters. Agreement between raters was assessed by a two way mixed Intraclass Correlation Coefficients (ICC) for absolute agreement. A value greater than 0.80 is interpreted as good. The agreement was estimated at 0.88 with a CI 95% (0.83–0.92). The cuff pressure was seen and confirmed by the patient's nurse to control for bias at each measurement. All measurements were approved by the nurses. Cuff

pressure was measured in two phases. First, the manometer was connected to the pilot of cuff and the cuff pressure was adjusted to 25 cm H₂O. Then, the cuff pressure was measured without separating the manometer from the cuff at 1 and 5 min intervals. If a change was observed, the cuff pressure was set again to 25 cm H₂O. No aggressive interventions or position changes were made during this phase. This stage was considered the control condition. In order to eliminate the effect of confounding factors, in the second phase, the same patient was re-evaluated while the position, ventilator settings, and body temperature did not change with the first phase. The manometer was connected to the pilot of the cuff. The cuff pressure was measured and set to 25 cm H₂O. Then, the manometer was disconnected from the pilot. It was reconnected after 1 and 5 min and the pressure recorded. If a change in the cuff pressure was observed at each measurement, the cuff pressure was set to 25 cm H₂O and the manometer was disconnected from pilot. No aggressive interventions or position changes were made during this stage. The researchers were careful not to add any pressure when disconnecting the cuff. The sample was excluded from the study if this happened to the patients. This stage was considered as an intervention condition.

For data analysis, the normal distribution of data was first estimated using the Kolmogorov–Smirnov test. Data were then analyzed using descriptive statistics. Independent *t*-test, Chi-square test, and Phi coefficient were used to assess the hypotheses of the study. Data analysis was performed using SPSS₁₆ (SPSS Inc., Chicago, Illinois) and GPower_{3.1} software. The level of significance was less than 0.05.

Ethical considerations

The study was approved by the Ethics Committee of the Mazandaran university of medical sciences (Code: IR.MAZUMS.REC.1397.184). Informed consent was obtained from the family of the patients (due to lack of consciousness in patients). No additional consumables were used which would result in increased financial burden to the patients. Each patient was free to exit from study at any time.

Results

Most of the participants in this study were male ($n = 42$, 71.20%) and the mean (SD) age was 58.27 (24.18) years.

Most of the patients had an ETT with an internal diameter of 8 mm ($n = 41$, 68.49%), and the remainder had an ETT with 7.50 mm internal diameter.

The results of statistical analysis using an Independent *t*-test as well as an evaluation of the variances equality using Leven's test indicated that the mean (SD) change of cuff pressure after 1 min, from the primary cuff pressure of 25 cm H₂O, in the intervention condition, was 20.22 (3.53) cm H₂O. The mean (SD) of this change in the control condition was 25.22 (3.39) cm H₂O. This difference was significant in the intervention condition compared to the control condition ($t_{116} = 7.83$, $p < 0.001$, $d = 1.44$). The mean (SD) change of cuff pressure after 5 minutes, from the primary cuff pressure of 25 cm H₂O, in the intervention condition was 19.11 (2.98) cm H₂O. The mean (SD) of this change in the control condition was 25.47 (4.53) cm H₂O. This difference was significant in the intervention condition compared to the control condition ($t_{116} = 9.24$, $p < 0.001$, $d = 1.70$).

Table 1 indicates the frequency distribution the cuff pressure cuff measurements considering the pressure in the normal range (20–30 cm H₂O), lower than normal (<20 cm H₂O), and higher than normal (>30 cm H₂O) after 1 and 5 min. The most frequent group was a group of patients that the manometer was disconnected from the pilot cuff and reconnected in order to measure the cuff pressure after 5 minutes. Moreover, the cuff pressure of this group was <20 cm H₂O. Generally, the effect size of the different distribution ratio in the disconnected and connected groups after 5 minutes (Cramers V = 0.63, $p < 0.001$) was more than in the first group (Cramers V = 0.55, $p < 0.001$) based on the cuff pressure [Table 1].

Discussion

Our results indicate that connecting and disconnecting the manometer during manual intermittent control reduces the cuff pressure by 4.78 cm H₂O and 5.89 cm H₂O of the primary measurement (25 cm H₂O) after 1 and 5 minutes, respectively. This decrease in cuff pressure was significant in the intervention group compared to the control condition ($d = 1.70$, $p < 0.001$). When *d* is higher than 1.2, it indicates that the effect size is very strong^[27] and emphasizes the clinical importance of this finding. Other studies have also pointed to the decrease of cuff pressures following each

Table 1: Frequency distribution of the intubated patients according to endotracheal tube cuff pressure

Endotracheal tube cuff pressure	Frequency (%)			Chi-square test
	<20 cm H ₂ O (less than normal)	20-30 cm H ₂ O (normal range)	>30 cm H ₂ O (more than normal)	
First minute				
Intervention condition	32 (54.24)	27 (45.76)	0 (0.00)	$\chi^2=35.94$, df=2, $p<0.001$
Control condition	3 (5.08)	52 (88.14)	4 (6.78)	
Fifth minute				
Intervention condition	41 (69.49)	18 (30.51)	0 (0.00)	$\chi^2=47.23$, df=2, $p<0.001$
Control condition	5 (8.48)	50 (85.74)	4 (6.78)	

manometer connection to the pilot of cuff.^[4,19,21,28] Although these studies declared that the pressure reduction is due to losing air of cuff, they did not provide information about the amount of air wasted and its impact on the cuff pressure. Aeppli *et al.* (2018) reported a drop in pressure during the manometer connection to the pilot of cuff and to a lesser extent when the manometer was disconnected which could be due to the weakness and missed use of intermittent manual control. Moreover, this can be because of air integration between the pilot of the cuff and pressure gauge during connection.^[23] However, in this study cuff pressure changes were recorded in laboratory conditions.

Another of our results indicated that the cuff pressure of the intervention and control condition did not exceed high than the safe range after 1 and 5 min. However, cuff pressure was lower than the safe range in many of the patients. Several studies stated that repeated use of the manometer for measuring the cuff pressure can reduce the cuff pressure from the normal range and increases a micro-aspiration risk.^[15,25,29] However, in the study conducted by Aeppli *et al.* (2018) which examined the cuff pressure changes on the artificial trachea under laboratory conditions, a cuff pressure drop was reported in 100% of cases caused by the initial connection. They also reported that disconnecting the manometer after the control maneuver caused a cuff pressure drop in 78.10% of cases.^[23] Aeppli *et al.* showed that a change in the cuff pressure of the ETT tube happens when the manometer is connecting or disconnecting from the pilot. Some suggestions for healthcare systems have been made to resolve this problem. The first recommendation for healthcare providers (including ICU nurses) is to reduce the frequency of cuff pressure control manually.^[23] Levitin *et al.* (2018) claim that repeated and frequent cuff pressure monitoring has no clinical superiority to intermittent follow-up.^[11] The second recommendation for researchers and medical engineers is to design a device which can be placed between the balloon pilot and pressure gauge in order to prevent the pressure drop.^[30] The third recommendation for healthcare providers (including ICU nurses) is to use a continuous cuff pressure regulator. This tool has been invented and used in studies such as Nseir (2011) which compared the micro-aspiration in two groups of continuous and intermittent evaluation.^[17] Moreover, Dat (2018) used this tool to assess the respiratory infection and mortality rate in the two above-mentioned groups which indicated the lower rate of complications in the group that cuff pressure measured continuously.^[18] Due to the inadequacy of alternate cuff pressure monitoring methods, continuous cuff pressure control looks better which not only reduces cuff leakage, risk of micro-aspiration and VAP, but also can decrease the nurse workload due to less time spent on adjusting cuff pressure.^[29] Therefore, many researchers have suggested the use of continuous cuff pressure measuring instruments^[15,17,21,24,25,31] which do not require frequent connection of the manometer to the pilot.^[18]

The main limitation of the present study was that the patients' anatomical differences were not related to the diameter and pressure inside the ETTs. Another limitation was that it was not possible to recognize if the air leakage and cuff pressure reduction happened during the manometer connection to the pilot cuff or when it was disconnected. It is suggested that in future studies, ETTs should be used which have a pressure sensor in their cuff and pressure is recorded directly and compared with manometer records.

Conclusion

The results of our study indicate that the cuff pressure of the ETT is reduced during manual intermittent controlling during connecting and disconnecting of the pilot cuff to the manometer. In many cases the reduction of the cuff pressure falls out with the safe range. The reason for this reduction can be due to the loss of cuff air pressure or integration of air between the pilot cuff and manometer during connection and disconnection. Therefore, it is suggested to use appropriate measurement tools (continuous cuff pressure regulator) instead of manual intermittent controlling of the endotracheal tube cuff pressure. If this was to be instigated into practice then the complications caused by increasing or decreasing the cuff pressure are thus minimized.

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Conflicts of interest

Nothing to declare.

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