

Tracheal tube cuff inflation guided by pressure volume loop closure associated with lower postoperative cuff-related complications: Prospective, randomized clinical trial

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ABSTRACT

Background: The main function of an endotracheal tube (ETT) cuff is to prevent aspiration. High cuff pressure is usually associated with postoperative complications. We tried to compare cuff inflation guided by pressure volume loop closure (PV-L) with those by just to seal technique (JS) and assess the postoperative incidence of sore throat, cough and hoarseness. **Materials and Methods:** In a prospective, randomized clinical trial, 100 patients' tracheas were intubated. In the first group (n = 50), ETT cuff inflation was guided by PV-L, while in the second group (n. = 50) the ETT cuff was inflated using the JS technique. Intracuff pressures and volumes were measured. The incidence of postoperative cuff-related complications was reported. **Results:** Demographic data and durations of intubation were comparable between the groups. The use of PV-L was associated with a lesser amount of intracuff air [4.05 (3.7-4.5) vs 5 (4.8-5.5), $P < 0.001$] and lower cuff pressure than those in the JS group [18.25 (18-19) vs 33 (32-35), $P \leq 0.001$]. The incidence of postextubation cuff-related complications was significantly less frequent among the PV-L group patients as compared with the JS group patients ($P \leq 0.009$), except for hoarseness of voice, which was less frequent among the PV-L group, but not statistically significant ($P \leq 0.065$). Multiple regression models for prediction of intra-cuff pressure after intubation and before extubation revealed a statistically significant association with the technique used for cuff inflation ($P < 0.0001$). **Conclusions:** The study confirms that PV-L-guided ETT cuff inflation is an effective way to seal the airway and associates with a lower ETT cuff pressure and lower incidence of cuff-related complications.

Key words: tracheal tube, cuff-related complications, cuff pressure, cuff volume, pressure volume loop closure

Key Message: Endotracheal tube cuff inflation guided by pressure volume loop closure is associated with the use of a lower cuff volume, and results in a lower cuff pressure and lower incidence of postoperative cuff-related complications when compared with the conventional cuff inflation technique of just to seal.

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INTRODUCTION

The main function of an endotracheal tube (ETT) cuff is to maintain adequate sealing of airway, prevent gastro-pharyngeal contents aspiration and ensure effective lung ventilation.^[1] Overinflation of the ETT cuff might lead to serious complications, ranging from tracheal mucosa pressure necrosis^[2] to tracheal rupture^[3,4] and tracheoesophageal fistula formation.^[5,6] Adequacy of ETT cuff inflation is usually checked by one of the following techniques: Manual palpation of the pilot balloon, disappearance of audible air leak through the mouth or

the use of either an aneroid manometer or continuous automatic ETT cuff pressure controller.^[7] Pressure–volume loop (PV-L) is one of the continuous real-time pulmonary graphic incorporated in the monitoring system of anesthesia machines and mechanical ventilators. Usually, it is used for the assessment of dynamic lung compliance, detection of lung over-inflation or presence of air leak.^[8] In this prospective, randomized study, we tried to compare the use of PV-L closure as an indicator of adequate ETT cuff function to one of the commonly used methods of cuff inflation: Just to seal (JS) technique, and to compare the postoperative cuff-related complications in both groups.

MATERIALS AND METHODS

This prospective, randomized controlled clinical trial was conducted in a tertiary care hospital between 1 March 2012 and 15 December 2012. After approval from the Research and Ethics Committee, 105 patients of both genders were screened for eligibility to participate in the study. Written informed consent was obtained from 100 patients over the age of 18 years, American Society of Anaesthesiologists (ASA) physical status I or II and scheduled for elective surgery requiring tracheal intubation.

Exclusion criteria were patients with anticipated difficult airway; patients with chronic lung diseases; prone position; risk of pulmonary aspiration; preoperative cough, hoarseness of voice or sore throat; postextubation blood-stained ETT tip; and coughing with extubation.

Before conducting the anesthesia, an automatic leak test was performed on the anesthesia machine (Zeus, Draeger®, Lübeck, Germany) to detect any leak in the machine.

All patients were premedicated with omeprazole 20 mg administered orally the night before surgery and midazolam 0.03 mg/kg intravenous (IV) on call to the operating room. Intraoperative monitoring included electrocardiography, pulse oximetry, noninvasive blood pressure end-tidal carbon dioxide concentration, nasal temperature and peripheral nerve stimulator for muscle relaxation monitoring. General anesthesia was induced by IV 2 mg/kg fentanyl, 2 mg/kg propofol and 0.6 mg/kg rocuronium as a muscle relaxant. Ventilation was maintained via a face mask and 100% oxygen with sevoflurane 2 volume%, 8 L/min for 120 s. An 8.0-mm internal diameter (mm ID) ETT was used for male patients and a 7.0 mm ID ETT for female patients. ETTs with high-volume — low pressure cuffs (Portex Tracheal Tube®, Smith Medical International Ltd., Ashford, Kent, UK) were routinely used in our center. Cuff lubricants were avoided to limit their effect on the assessment of postoperative

complications. Tracheal intubation was performed by anesthesiologists with 10 years of experience.

Patients were randomized in equal numbers using a computer-generated permuted block randomization schedule with a block size of six, and serially numbered sealed opaque envelopes [Randomization was performed using SAS for Windows Version 9.1 (SAS Institute, Cary, NC, USA)].

In the group of (PV-L) ($n = 50$): Following insertion of the ETT through the vocal cords, it was connected to the breathing circuit and volume-controlled ventilation was initiated with 7-10 mL/kg tidal volume and a ventilator rate of 10-12/min. The ETT cuff was inflated initially by 2 mL of air followed by increments of 0.5 mL till complete closure of the PV-L was displayed on the anesthesia machine monitor; namely, when the expiratory limb reached zero volume and met the starting point of inspiratory limb, cuff inflation was ceased [Figure 1]. In the second group (JS), the ETT cuff was inflated till the disappearance of audible air leak on auscultation, while gentle manual ventilation was maintained with an adjustable pressure-limiting valve turned on to 20 cm water (cmH₂O) and oxygen flow of 8 L/min. ETT cuff inflation was performed by the intubating anesthesiologist according to the randomization group. In both groups, a three-way stopcock was connected to the pilot balloon and a small aneroid manometer (VBM®, Sulz, Germany) was connected to the other end of the stop cock while the third end was connected to a 10-mL syringe. A second investigator blinded to the method of cuff inflation assessed the ETT cuff pressure by the aneroid manometer and completely deflated the cuff and measured the amount of air used for cuff inflation, then reinjected it into the cuff and ensured cuff inflation with the same amount of air. Pressure and volume measurement was performed twice, immediately after intubation following ETT cuff inflation and prior to extubation.

Anesthesia was maintained by sevoflurane 1.5-2 volume% in O₂/air mixture and minute volume was adjusted

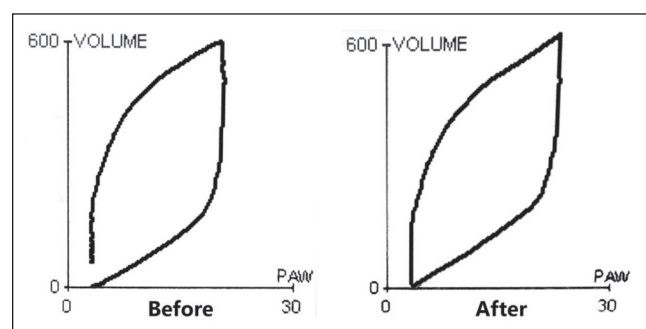


Figure 1: Pressure — volume loop before and after cuff inflation

to maintain normocapnia through volume-controlled ventilation mode. Fentanyl doses of 1 µg/kg/30 min were given as an analgesic agent and muscle relaxation was maintained with additional doses of rocuronium (0.1 mg/kg). No nitrous oxide was used throughout the procedure. The inspired and expired tidal volumes were monitored throughout the procedure to detect any air leak for which more air would be injected into the cuff for proper airway sealing. At the end of the procedure, patients were extubated in a fully awake status after reversal of the effect of residual muscle relaxants with IV neostigmine 0.04 mg/kg and glycopyrolate 10 µg/kg, breathing spontaneously at a rate higher than 12/min and tidal volume ≥7 mL/kg.

Patients were assessed in the postoperative period for cuff-related complications, mainly sore throat, cough or hoarseness of voice, 2 and 24 h postoperatively. The assessment was carried out by an anesthesiologist who was blinded to the study groups using a scale from 0 to 3. Table 1 presents the scale used for the assessment of postoperative complications based on a replicate of an earlier study scale.^[9]

Statistical Analysis

Statistical analysis was performed on a personal computer using Stata® version 11.1 (StataCorp LP, College Station, TX, USA).

The required sample size was estimated using G*Power version 3.1.0 (Institut für Experimentelle Psychologie, Heinrich Heine Universität, Düsseldorf, Germany). The primary outcome measure was the difference in intracuff pressure between the two study groups. The secondary outcomes were cuff-related complications, mainly sore throat, cough and hoarseness of voice. A previous study

published by the authors^[10] demonstrated that the mean (SD) intracuff pressure associated with the PV-L closure technique was 18.67 (0.72). Thus, it was estimated that a sample of 50 patients in each study group would achieve a power of 84% to detect an effect size (*d*) of 0.6 using the two-sided unpaired t test and setting the type I error at a conventional level of 0.05.

Normality of numerical data distribution was tested using the Shapiro–Wilk test. Because these data were skewed, they were presented as median and interquartile range, and between-group differences were compared nonparametrically using the Mann–Whitney U test. Categorical data were presented as number and percentage, and differences between the two groups were compared using the Pearson chi square test (for nominal data) or the chi square test for trends (for ordinal data). Fisher's exact test was used in place of the Pearson chi square tests if >20% of the cells in any cross-tabulation had an expected count of <5.

Multiple regressions were used to compare both study groups after adjusting for the effect of other variables that could influence the outcome of interest, i.e. intracuff pressure. Predictors included in the regression model were selected based on their having a plausible impact on the outcome variable. Besides the randomization group, the size of the endotracheal tube used and the duration of intubation (when applicable) were included. Because intracuff pressure and the duration of intubation did not meet the assumption of normality, these variables were transformed into their natural logarithms (ln) and included in the regression model. The enter method was used for regression analysis to avoid automatic exclusion of pertinent variables from the model.

All *P*-values are two-tailed. A *P*-value < 0.05 was considered statistically significant.

Table 1: Scoring system for postoperative sore throat, cough and hoarseness

Sore throat	
0	No sore throat at any time since the operation
1	Minimal sore throat
2	Moderate sore throat
3	Severe sore throat
Cough	
0	No cough at any time since the operation
1	Minimal cough or scratchy throat
2	Moderate cough
3	Severe cough
Hoarseness	
0	No evidence of hoarseness at any time since the operation
1	No evidence of hoarseness at the time of interview
2	Hoarseness at the time of interview noted by patient only
3	Hoarseness that is easily noted at the time of interview

RESULTS

One hundred and five patients were screened for eligibility to participate in this study; three patients did not meet the inclusion criteria and two declined to participate. One hundred patients gave written informed consent to participate in the trial. Table 2 represents the comparable demographic data and durations of intubation between the groups.

Figure 2 reveals that the use of the PV-L technique was associated with the use of a lower amount of air to inflate the ETT cuff than the amount of air used in the JS technique [4.05 mL (3.7-4.5) vs 5 mL (4.8-5.5), *P* < 0.001], while Figure 3 presents a similar finding regarding the

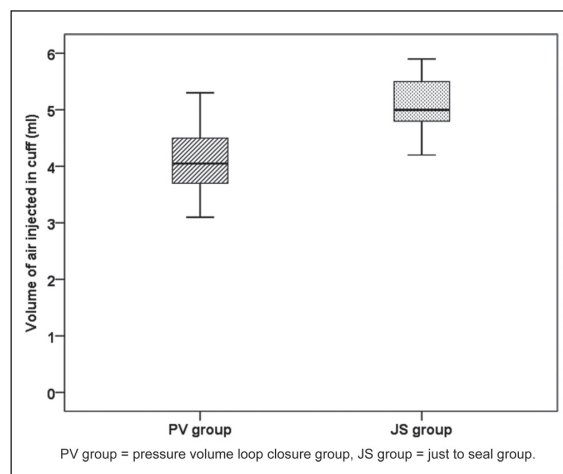


Figure 2: Represents the volume of air used to inflate the endotracheal tube cuff in both groups

Table 2: Demographic and intubation characteristics' data

Variable	PV-L group (n=50)	JS group (n=50)	P-value
Age (years)	41 (36-50)	42.5 (37-51)	0.417
Male/female	26/24	26/24	1.0
Weight (kg)	69.5 (65-80)	70.5 (66-82)	0.051
Height (cm)	171 (167-173)	170 (166-172)	0.133
Cormack-Lehane class I/II	37/13	37/13	1.0
Duration of intubation (min)	105.5 (93-128)	110 (95-130)	0.465

PV: Pressure — volume loop closure; JS: Just to seal

measured cuff pressure, both after intubation and before extubation [18.25 cmH₂O (18-19) vs 33 cmH₂O (32-35), $P < 0.001$]. The incidence of postextubation cuff-related complications was significantly less frequent among the PV-L group patients as compared with the JS group patients ($P \leq 0.009$), except for hoarseness of voice, which was less frequent among the PV-L group, but the difference was not statistically significant (Table 3, $P \geq 0.065$).

The multiple regression model for prediction of intracuff pressure after intubation is shown in Table 4. There was a statistically significant association between the technique used for cuff inflation and the intracuff pressure after adjustment for the effect of tube size ($P < 0.0001$). Analysis of variance showed a statistically significant multiple correlation coefficient ($F, 455.031; P < 0.001$) and as much as 90.2% of variation in the intracuff pressure could be explained by the model (adjusted $R^2, 0.902$).

Table 5 shows the multiple regression model for prediction of intracuff pressure before extubation. Of the included variables, the randomization group was the only independent predictor for intracuff pressure ($P < 0.0001$).

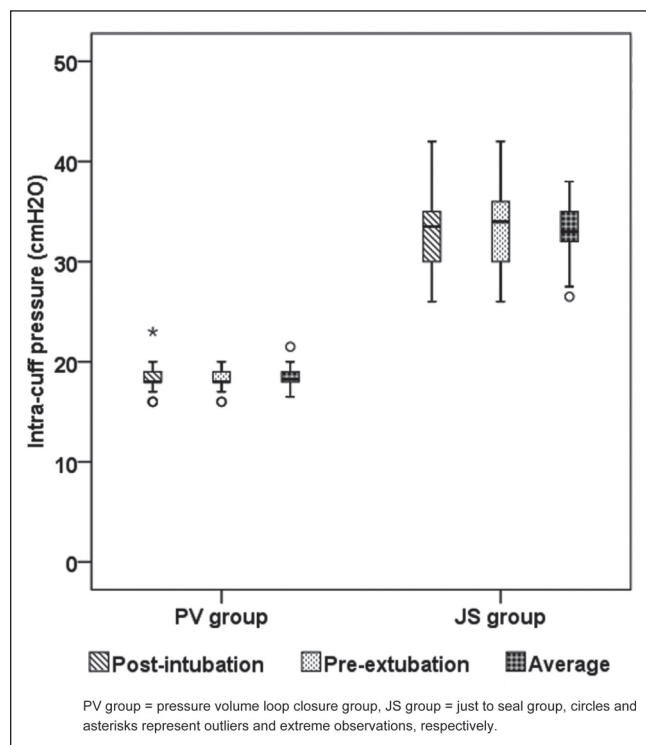


Figure 3: Intracuff pressure measurements: Postintubation, preextubation and average values in cmH₂O between the groups

Table 3: Side-effects reported postoperatively among patients in both groups at 2 and 24 h

Variable	Scoring system	PV-L group (n=50)	JS group (n=50)	P-value
Sore throat at 2 h	0	38 (76%)	28 (56%)	0.002*
	1	9 (18%)	5 (10%)	
	2	3 (6%)	14 (28%)	
	3	0	3 (6%)	
Sore throat at 24 h	0	40 (80%)	29 (58%)	0.001*
	1	9 (18%)	7 (14%)	
	2	1 (2%)	12 (24%)	
	3	0	2 (4%)	
Cough at 2 h	0	47 (94%)	38 (76%)	0.009*
	1	3 (6%)	9 (18%)	
	2	0	3 (6%)	
	3	0	0	
Cough at 24 h	0	48 (96%)	39 (78%)	0.007*
	1	2 (4%)	9 (18%)	
	2	0	2 (4%)	
	3	0	0	
Hoarseness at 2 h	0	47 (94%)	44 (88%)	0.090
	1	3 (6%)	1 (2%)	
	2	0	5 (10%)	
	3	0	0	
Hoarseness at 24 h	0	48 (96%)	44 (88%)	0.065
	1	2 (4%)	2 (4%)	
	2	0	4 (8%)	
	3	0	0	

Data are presented as number (percentage); PV-L: Pressure — volume loop closure; JS: Just to seal

Table 4: Multiple regression model for prediction of intracuff pressure after intubation

Independent variables	B	SE of B	t	P-value
JS group*	0.575	0.019	30.142	<0.0001
ETT size 8†	0.024	0.019	1.241	0.218
Constant	2.904			
Model diagnostics				
F-ratio	455.031			
P-value for F	<0.001			
R ²	0.904			
R ² adjusted	0.902			

B: Regression coefficient; ETT: Endotracheal tube; F: F statistic; In: Natural logarithm; R²: Coefficient of determination; SE: Standard error; t: T statistic;
 *Referenced to PV group; †Referenced to ETT size 7

Table 5: Multiple regression model for prediction of intracuff pressure before extubation

Independent variables	B	SE of B	t	P
JS group*	0.583	0.019	30.317	<0.0001
ETT size 8†	0.012	0.019	0.616	0.539
Ln duration of intubation (min)	-0.001	0.051	-0.015	0.988
Constant	2.902			
Model diagnostics				
F-ratio	307.452			
P-value for F	<0.001			
R ²	0.906			
R ² adjusted	0.903			

B: Regression coefficient; ETT: Endotracheal tube; F: F statistic; In: Natural logarithm; R²: Coefficient of determination; SE: Standard error; t: T statistic;
 *Referenced to PV group; †Referenced to ETT size 7

Analysis of variance showed a statistically significant multiple correlation coefficient (F, 307.452, $P < 0.001$) and the model could explain 90.3% of variation in the outcome variable (adjusted R², 0.903).

No air leak was detected throughout the procedures among both groups.

DISCUSSION

The major finding of our study is that the use of PV-L closure to guide the inflation of ETT cuff required a smaller amount of air to seal the airway and resulted in a significantly lower cuff pressure when compared with the JS method. The incidence of postoperative complications was significantly less frequent among the PV-L group patients, which was in contrast to that of the JS group patients.

Seegobin and his group reported that tracheal mucosal blood flow was diminished at an inflated cuff pressure more than 30 cmH₂O and ceased when the cuff pressure was more than 50 cmH₂O.^[11] Tracheal mucosal ischemia causes inflammation of the tracheal cartilage and ulcerations leading to tracheal stenosis, rupture and

acquired tracheoesophageal fistula.^[3-6] The design of ETT cuff has been changed from a high pressure low volume to a low pressure high volume one following the increased awareness about cuff pressure-related complications affecting the tracheal mucosal vascularity.^[12] Although efforts were made to keep the ETT cuff pressure within the recommended pressure range, there is no reliable method to ensure its occurrence.^[13,14] Several methods were developed to ensure proper cuff inflation, such as minimal leak technique,^[15] minimal occlusive volume,^[16] ETT cuff inflation to a minimum pressure level,^[17] stethoscope-guided cuff inflation^[18] and the conventional technique in which an undetermined volume of air is used to inflate the cuff.^[19] Fernandez *et al.* in their study found that inflated ETT cuffs were associated with various levels of cuff pressures while manual balloon palpation by anesthetists estimated a cuff pressure of 30 cmH₂O in 69% of the cases only.^[13] Pressure-regulating devices were developed to regulate ETT cuff pressures,^[20-22] but their continuous availability might not be feasible. Some studies recommended a minimum cuff of 20 cmH₂O for proper airway sealing.^[19,23] Sole and his colleagues reported a drop in cuff pressure over 3 h from 21 to 17 cmH₂O,^[24] while others detected an earlier drop in cuff pressure that started 3 min after intubation.^[23] In this study, the measured cuff pressure in the PV-L group was 18.25 cmH₂O, and no air leak was detected, which is similar to the findings of Dullenkopf *et al.*, in which a cuff pressure of 19.1 cmH₂O was sufficient for airway sealing.^[25] Kumar and Hirsch revealed in their study that despite 16% of the measured cuff pressures being below 20 cmH₂O, no air leak was detected.^[18]

We included multiple logistic regressions in our statistical analysis to determine the effect of the predictors while adjusting for other confounding factors, in contrast to simple correlation analysis. As shown in the results section, several potential predictors of intracuff pressure were correlated, and multiple regressions were, thus, applied to identify the strongest predictors. We found that the method to guide cuff inflation was strongly correlated to cuff pressure.

Real-time PV-L displayed on the anesthesia machine monitor might be a good alternative to check for proper ETT cuff inflation, avoid high cuff pressure and monitor for air leak, and it is available in most of the anesthesia machines models.

Two previous studies reported the use PV-L closure or volume–time curve as a new technique to guide ETT cuff inflation with a lower volume of air and lesser cuff pressure,^[10,26] but none of them assessed the incidence of postoperative complications. Sore throat, hoarseness, pain

and cough were among the most common complaints expressed by patients after tracheal extubation.^[27-30] In our study, we demonstrated that a low cuff pressure in the PV-L group was associated with a lower incidence of postoperative cuff-related complications. These results were similar to previously published studies by Jianhui and his group, in which they reported that proper control of cuff pressure reduced postprocedural respiratory complications.^[31] In an attempt to determine the effect of cuff pressure on postoperative complications, we avoided the use of large sizes of ETT, cuff lubrications, administration of nitrous oxide and any intraoperative movement of ETT. Because the volume of air in the ETT cuff did not alter the incidence of postintubation complications,^[32] we could assume that low cuff pressure might be the main contributor to the low incidence of postoperative complications.

In this study, we did not use a fiberoptic bronchoscope to assess ETT position, tracheal mucosal injury or blood-streaked expectorant to avoid any delay in the starting time of surgery and to limit upper airway trauma. A second limitation of our study is the short duration of intubation (h) in healthy patients. Further studies are required to assess the incidence of cuff-related complications among patients with prolonged (days) endotracheal intubation and the possibility of using the PV-L technique among patients with unhealthy airway or diseased lungs.

In conclusion, this study confirms that PV-L-guided tracheal tube cuff inflation is an effective way to seal the airway and is associated with a lower incidence of sore throat, cough and hoarseness of voice.

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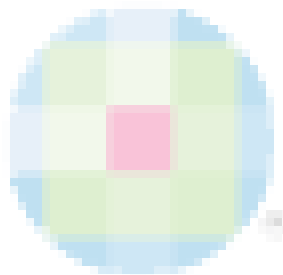
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