JARSS 2019;27(3):174-179
doi: 10.5222/jarss.2019.46036

Özgün Araştırma / *Original Article*

Comparison of Pressure Volume Loop Closure with Just to Seal Technique to Guide Endotracheal Tube Cuff Inflation and to Assess the Incidence of Sore Throat, Cough and Hoarseness of Voice - A Prospective Randomized Controlled Trial

Amresh Narayan
Ramkumar Dhanasekaran
Thamarai Selvi Krishnasamy

Endotrakeal Tüp Kafının Şişirilmesine Yön Vermek İçin Basınç Hacim Halkası Kapanması ile Hava Geçirmeyecek Kadar Tekniğinin Karşılaştırılması ve Boğaz Ağrısı, Öksürük ve Ses Kısıklığı İnsidansının Değerlendirmesi-Prospektif Randomize Kontrollü Bir Çalışma

ABSTRACT

Objective: *Several methods of endotracheal cuff (ETT) inflation methods were investigated to ensure proper cuff inflation to avoid short, and long term airway morbidities. Pressure Volume Loop (PV-L) closure was found to be a new technique to guide ETT cuff inflation with a lower cuff pressures. Hence, we assessed whether PV-L was a useful guide in inflating the ETT with adequate cuff pressure when compared to Just to Seal (JS) technique.*
Method: *A prospective randomized double-blinded study was done with eighty-four patients undergoing surgeries under general anesthesia using endotracheal tubes. The ETT cuffs were inflated using PV-L closure in PV-L group and using stethoscope in JS group. The cuff pressure was measured as the primary outcome of the study. The cuff volume, postoperative sore throat, cough and hoarseness of voice were assessed as secondary outcomes.*
Results: *In our study, PV-L group had statistically significantly lower post-intubation (24.5±4.97 cm of H_2O in PV-L group, 28.6±6.39 cm of H_2O in group JS, p-0.002) and pre- extubation cuff pressures (24.9±4.923 cm of H_2O in Group PV-L, 29.0±5.624 cm of H_2O in Group JS, p-0.001) when compared with the JS method.*
Conclusion: *Pressure Volume Loop-guided endotracheal tube cuff inflation was an effective way to seal the airway with lower cuff pressures and was associated with a lower incidence of postoperative ETT cuff-related complications when compared with Just to Seal method.*

Keywords: *Pressure volume loop, endotracheal cuff pressures, postoperative airway morbidity*

ÖZ

Amaç: *Kısa ve uzun vadeli hava yolu morbiditelerini önlemek için uygun kaf inflasyonunu sağlayacak pek çok endotrakeal kaf (ETT) şişirme yöntemi incelenmiştir. Basınç Hacim Halkası (BH-H) kapanması, daha düşük kaf basınçları ile ETT kaf inflasyonuna kılavuzluk eden yeni bir teknik olarak bulunmuştur. Bu nedenle, BH-H'nın, hava geçirmeyecek kadar (HGK) tekniği ile karşılaştırıldığında ETT'nin yeterli kaf basıncı ile şişirilmesinde yararlı bir rehber olup olmadığını değerlendirdik.*
Yöntem: *Endotrakeal tüp ile uygulanan genel anestezi altında ameliyat edilen seksen dört hastaya prospektif randomize çift kör bir çalışma yapıldı. ETT kafları, BH-H grubunda BH-H kapanması kullanılarak ve HGK grubunda stetoskop kullanılarak şişirildi. Kaf basıncı, çalışmanın birincil sonucu olarak ölçüldü. Kaf hacmi, postoperatif boğaz ağrısı, öksürük ve ses kısıklığı ikincil sonuçlar olarak değerlendirildi.*
Bulgular: *Çalışmamızda, BH-H grubunda, HGK yöntemi ile karşılaştırıldığında, entübasyon sonrası kaf basıncı (BH-H grubunda 24.5±4.97 cm H_2O, HGK grubunda 28.6±6.39 cm H_2O, p-0.002) ve ekstübasyon öncesi kaf basıncı (BH-H grubunda 24.9±4.923 cm H_2O, HGK grubunda 29.0±5.624 cm H_2O, p - 0.001) istatistiksel olarak anlamlı derecede düşüktü.*
Sonuç: *Endotrakeal tüp kafının Basınç Hacim Halkası rehberliğinde şişirilmesi, hava geçirmeyecek kadar yöntemi ile karşılaştırıldığında, hava yolunu daha düşük kaf basınçları ile kapatmanın etkili bir yoluydu ve daha düşük postoperatif ETT kaf ilişkili komplikasyon sıklığına sahipti.*

Anahtar kelimeler: *Basınç hacim halkası, endotrakeal kaf basıncı, postoperatif hava yolu morbiditesi*

Alındığı tarih: 30.03.2019
Kabul tarihi: 23.05.2019
Yayın tarihi: 26.07.2019

Atıf vermek için: Narayan A, Dhanasekaran R, Krishnasamy TS. Comparison of pressure volume loop closure with just to seal technique to guide endotracheal tube cuff inflation - a prospective randomized controlled trial. JARSS 2019;27(3):174-9.

Ramkumar Dhanasekaran
No 1, Ramachandra Nagar, Porur,
600116 Chennai - India
docram82@gmail.com
ORCİD: 0000-0001-6112-2595

A. Narayan 0000-0001-7531-3763
T.S. Krishnasamy 0000-0002-4047-1494
Department of Anesthesiology and Pain Medicine,
Sri Ramachandra Institute of Higher Education and Research,
Chennai, India

INTRODUCTION

Erroneous endotracheal tube (ETT) cuff inflation may jeopardize the patients under the risk of microaspiration [1] and several catastrophic ischemic complications [2-5]. Several techniques were practised to ensure proper cuff inflation [6,7]. Pressure Volume Loop (PV-L) closure is a new technique to achieve ETT cuff inflation with a lower volume of air and lesser cuff pressure [8,9]. We tested the hypothesis that the PV-L was useful in inflating the ETT cuff adequately and thereby reduced the incidence of tracheal morbidities when compared to Just to seal (JS) technique.

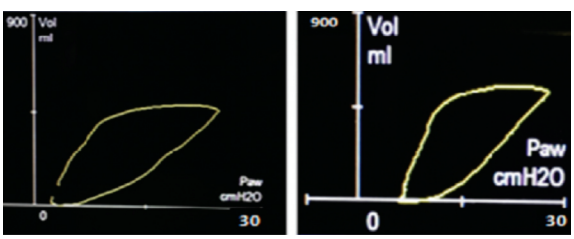
MATERIAL and METHODS

This study was a prospective randomized double blinded study done in a tertiary healthcare centre after obtaining institutional ethics committee approval and patient informed consent. Eighty-four ASA I-II patients aged between 18 to 60 years who underwent surgeries under general anesthesia using endotracheal tubes were included in the study. Patients carrying the risk of pulmonary aspiration including gastro-esophageal reflux, anticipated difficult airway, chronic lung diseases, airway surgeries, surgeries requiring more than one attempt of intubation, frequent change of head position, prone position, use of throat packs, naso or oropharyngeal airways and nasal intubation, patients with preoperative cough, hoarseness of voice or sore throat, those with post-extubation blood stained ETT tip and patients not willing to participate were excluded from the study.

The sample size was calculated as 78 patients with 39 cases in each group that had a power of 90 and an alpha error of 5%, based on a pilot study using 10 patients in each group with effect size of 0.737 and mean difference in cuff pressure of 4.19 cm H_2O between the groups. Considering the probability of drop outs from the study, 90 patients were included in the study. After receiving written informed consent, patients were randomized into two groups, Group PV-L-Pressure Volume Loop and Group JS-Just to seal, using computer generated randomization. A complete preoperative evaluation was done on the day before surgery. Preanesthetic automatic test was performed using the anesthesia machine (Avance CS^2, GE Health Care, USA) to detect any leak and ventilator malfunction. Pulse oximetry, noninvasive blood pressure, end-tidal carbon dioxide ($ETCO_2$) measurements, and a 5 lead ECG examination were instituted before induction of anesthesia.

Patients were pre-oxygenated with 100% O_2 for 3 minutes. After administration of fentanyl (2 mcg kg^{-1}), anesthesia was induced with propofol (2 mg kg^{-1}) and vecuronium (0.1 mg kg^{-1}) to facilitate intubation using ETTs with an internal diameter (ID) of 8.0 mm in males and 7.0 mm in females. The integrity of ETT cuffs were checked before attempting intubation in all patients. Preservative-free 2% lignocaine at a dose of 1.5 mg kg^{-1} was given 90 seconds prior to intubation to obtund intubation response. Cuff lubricants were avoided in our study. Intubation was done by a trained anesthesiologist.

After intubation, volume-controlled ventilation was initiated with a tidal volume of 7-10 mL kg^{-1} and respiratory frequency of 12-14 per minute. The ETT cuff was inflated initially by 2 mL of air followed by increments of 0.5 mL till the complete closure of the PV-L and the inaudible air leak on auscultation in the JS group were achieved [8]. The required volumes were noted and cuff inflation was stopped. The closure of the PV-L was considered complete when the loop reached its baseline configuration at the end of expiration, and so at the start of inspiration [8] (Figure 1). In both groups, a three-way stopcock was connected to the pilot balloon with a cuff manometer (VBM Medizintechnik GmbH, Germany) connected to the opposite end and a 10 mL syringe to the third end of the stopcock.



a) Before cuff inflation **b) After cuff inflation**

Figure 1. Pressure - Volume loop before and after cuff inflation

After securing ETT, the cuff was completely deflated and the amount of air used for cuff inflation was measured and then the same volume of air was refilled into the cuff. Cuff pressure and volume measure-

ments were assessed immediately after intubation following ETT cuff inflation and prior to extubation before switching off the delivery of the inhalational agent by the investigator blinded to the cuff inflation method.

Nitrous oxide free anesthesia was maintained by sevoflurane 1.5-2 volume % in O_2/air mixture. Tidal volume and respiratory rate were adjusted to maintain eucapnia through volume-controlled mode. Intermittent boluses of fentanyl (0.5 mcg kg^{-1}) for every hour and vecuronium injections (0.02 mg kg^{-1}) were repeated when a curare cleft was noted in the capnogram so as to maintain adequate analgesia and muscle relaxation respectively. The inspired and expired tidal volumes along with intermittent cuff pressure monitoring were done to detect any leak intraoperatively. If leak occurs, additional amount of air would be injected into the cuff to ensure adequate sealing and these additional volumes were noted. The safe cuff pressure in our study protocol was considered as any pressure less than 25 cm H_2O. At the end of the procedure, patients were extubated after reversal of neuromuscular blockade and adequate suctioning using soft catheters was achieved. The primary outcome of the study was to assess the post intubation and pre extubation cuff pressures. The secondary outcomes were the post-intubation and pre-extubation cuff volumes along with the incidence of cuff-related complications such as sore throat, cough or hoarseness of voice (Table I) at 2 and 24 hours postoperatively [10], assessed by an anesthesiologist who was blinded to the study group.

Table I. Scoring system for postoperative sore throat, cough and hoarseness of voice

Score	Sore throat	Cough	Hoarseness of voice
0	No sore throat at any time after the surgery	No cough at any time after the surgery	No evidence of hoarseness at any time after the surgery
1	Minimal-patient answered in the affirmative when enquired about	Minimal cough or scratchy throat	Minimal change in quality of speech. Patient answered in the affirmative only when asked about
2	Moderate - patient complained of sore throat on his/her own	Moderate cough	Moderate change in quality of speech as complained by the patient
3	Severe - patient is in obvious distress	Severe cough	Gross change in the quality of voice as noted by the observer

Statistical analysis

The collected data were analysed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics, frequency analysis and percentage analysis were used for categorical variables. The mean and standard deviation were used for continuous variables. To find the significant difference between the bivariate samples in independent groups, the unpaired samples t-test and the Mann-Whitney U test were used. To find the significance in categorical data, chi-square test was used. In all the above statistical tools the probability p value 0.05 was considered as significant.

RESULTS

Ninety patients were enrolled in the study. The study was proceeded with 84 patients as 3 patients in each group were excluded from the study due to requirement of more than one intubation attempt following change of smaller size ETT and use of oropharyngeal airways (Figure 2). The two groups were comparable with age, height, weight, body mass ındex (BMI), sex, duration of surgery, airway pressure, $ETCO_2$ values (Table II) without any statistical significance.

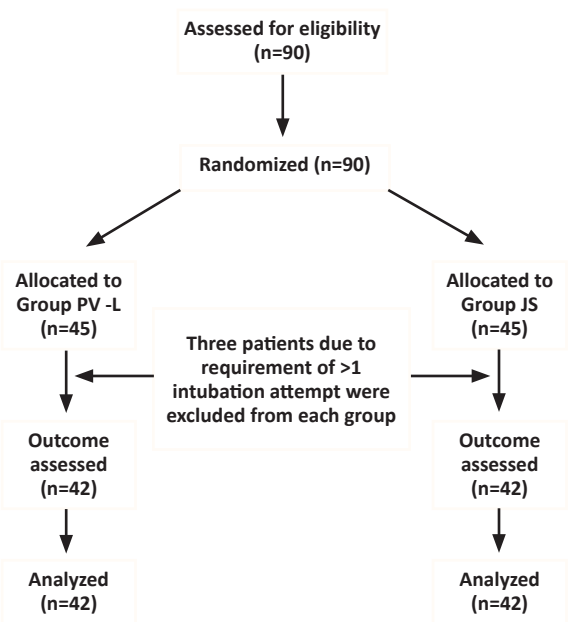


Figure 2. Study flowchart

Tablo II. Comparison of patient characteristics, ventilation parameters and duration of surgery

Parameters	Group (n=42 in each group)	Mean ± Standard Deviation	p value
Age (years)	PV-L	42.8±12.6	0.271
	JS	46.0±14.2	
Height (cm)	PV-L	161.5±7.1	0.138
	JS	159.2±7.2	
Weight (kg)	PV-L	64.4±10.4	0.760
	JS	63.7±11.0	
BMI (kg m^{-2})	PV-L	25.4±3.5	0.790
	JS	25.6±4.0	
Sex (M:F)	PV-L	24:18	0.505
	JS	20:22	
$EtCO_2$ (mmHg)	PV-L	34.1±2.5	0.801
	JS	33.9±1.8	
Tidal volume (mL)	PV-L	460.4±61.2	0.923
	JS	468.8±76.5	
Airway pressure (cm H_2O)	PV-L	17.9±0.8	0.845
	JS	18.8±0.9	
Duration of Surgery (minutes)	PV-L	124.7±45.2	0.800
	JS	123.1±58.1	

BMI - Body Mass Index, PV-L - Pressure volume Loop, JS - Just to Seal

Tablo III. Comparison of endotracheal cuff volumes and pressures

Parameters		Mean ± Standard Deviation		p value
		Group PV-L	Group JS	
Cuff volume (mL)	Post intubation	4.77±0.9	5.74±0.9	0.0005
	Pre extubation	4.77±0.9	5.73±0.9	0.0005
Cuff pressure (cm H_2O)	Post intubation	24.5±4.9	28.6±6.3	0.002
	Pre extubation	24.9±4.9	29.0±5.6	0.001

PV-L - Pressure volume Loop, JS - Just to Seal

Table IV. Comparison of postoperative endotracheal cuff related complications

Variables	Group	Mean	Standard deviation	z value	p value
Sore throat at 2 hours	PV-L	0.64	0.69	2.763	0.006
	JS	1.10	0.79		
Sore throat at 24 hours	PV-L	0.14	0.42	4.075	0.0005
	JS	0.64	0.66		
Cough at 2 hours	PV-L	0.33	0.57	1.974	0.048
	JS	0.64	0.76		
Cough at 24 hours	PV-L	0.10	0.30	3.505	0.0005
	JS	0.50	0.63		
Hoarseness of voice at 2 hours	PV-L	0.19	0.45	2.835	0.005
	JS	0.55	0.67		
Hoarseness of voice at 24 hours	PV-L	0.02	0.15	2.217	0.027
	JS	0.17	0.38		

PV-L - Pressure volume Loop, JS - Just to Seal, z value - Standard normal value

Table III reveals that the use of the PV-L technique was associated with the use of a lower volume of air to inflate and maintain the ETT cuff pressure post intubation (p=0.0005) and pre- extubation (p=0.0005) than the amount of air used in the JS technique, which was statistical significant. There was statistically significant difference in post-intubation (p=0.002) and pre-extubation (p=0.001) cuff pressures between the groups (Table III). None of the patients had leak or any significant difference between inspired and expired tidal volumes in both groups. The incidence of postoperative sore throat, cough and hoarseness of voice were statistically significantly different between both groups (Table IV).

DISCUSSION

The major finding of our study was that the use of PV-L closure method to guide the inflation of ETT cuff required a lower volume of air to seal the airway and resulted in a significantly lower cuff pressure when compared to JS method. Similarly in a previous study by Kaki et al. [8], the use of PV-L was associated with a lower amount of intra-cuff air and lower cuff pressure than those required in the JS group.

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. In an attempt to determine the effect of cuff pressure on postoperative complications, we avoided the use of large sizes of ETT and multiple attempts of intubations, cuff lubrications, use of artificial airways, administration of nitrous oxide and any intraoperative manipulation of ETT. The incidence of postextubation cuff-related complications namely sore throat, cough and hoarseness of voice assessed at 2 and 24 hours postoperatively were statistically significantly less frequent among the PV-L group patients as compared with the JS group patients.

Kaki et al. [8] also reported that the incidence of post extubation cuff related complications were significantly less frequent among the PV-L group patients as compared with the JS group patients, except for hoarseness of voice, which was-though not statistically significant it was less frequent among the PV-L group. They performed multiple logistic regression

analyses to determine the effect of the predictors while adjusting for other confounding factors and identified the strongest predictor. They found that the method to guide cuff inflation was strongly correlated to cuff pressure. These results were similar to previously published studies by Liu J et al. [11] and Hu et al. [12], in which they reported that proper control of cuff pressures, reduced postprocedural respiratory complications.

In our study, we monitored the cuff pressures and made sure that it did not exceed 25 cm H_2O. Morris et al. [13] found that monitoring cuff pressures did not reduce the incidence of overinflation. Whereas Jain et al. [7] studied the correlations between manual methods of assessing the pressure and assessments were performed with maintenance of cuff pressure within the normal range by the automated pressure controller device. He reported that endotracheal tube cuff pressure was significantly higher when endotracheal tube cuff was inflated manually and mean cuff pressure after cuff inflation was 50 cm H_2O. Thus it is recommended that ETT cuff pressures should be monitored with a manometer to avoid complications [7].

Sengupta and colleagues [14] found that there was no correlation between the measured cuff pressures and the age, sex, height, or weight of the patients. They reported that the volume of air required to achieve a cuff pressure 20 cm H_2O was similar with each tube size. Hence the difference in size of ETT between the patients in our study was considered to have least influence on the cuff pressure and the study outcomes. Similar to our study protocol they also concluded that cuff pressure should be measured with a manometer and corrected if required.

The limitation of our study was that we assessed the PV-L closure technique among healthy patients without any lung diseases which may affect the inspiratory pressure and necessitate the use of higher inflation volumes. In this study, we did not use a fiberoptic bronchoscope to assess airway complications. Further studies are required to assess the use of PV-L in patients with prolonged endotracheal intubation and in paediatric population.

CONCLUSION

In our study, PV-L closure technique was evaluated to be an effective method to achieve adequate ETT cuff seal with significantly lower cuff pressures and it was associated with a lower incidence of postoperative sore throat, cough and hoarseness when compared to Just to Seal technique.

Ethics Committee Approval: Sri Ramachandra University Instutitional Ethics Committee aproval was obtained. (IEC/17/APR/132/19).
Conflict of Interest: None
Funding: None
Informed Consent: The patients' consent were obtained.

Etik Kurul Onayı: Sri Ramachandra University Instutitional Ethics Committee aproval was obtained. (IEC/17/APR/132/19).
Çıkar Çatışması: Yoktur
Finansal Destek: Yoktur
Hasta Onamı: Hastaların onayı alındı.

REFERENCES

1. Hamilton VA, Grap MJ. The role of the endotracheal tube cuff in microaspiration. Heart Lung J Crit Care. 2012;41:167-72. https://doi.org/10.1016/j.hrtlng.2011.09.001
2. Feng TR. Critical importance of tracheal tube cuff pressure management. World J Anesthesiol. 2015;4:10. https://doi.org/10.5313/wja.v4.i2.10
3. Reed MF, Mathisen DJ. Tracheoesophageal fistula. Chest Surg Clin N Am. 2003;13:271-89. https://doi.org/10.1016/S1052-3359(03)00030-9
4. Striebel HW, Pinkwart LU, Karavias T. Tracheal rupture caused by overinflation of endotracheal tube cuff. Anaesthesist. 1995;44:186-8. https://doi.org/10.1007/s001010050146
5. El-Orbany M, Salem MR. Endotracheal Tube Cuff Leaks: Causes, Consequences, and Management. Anesth Analg. 2013;117:428-34. https://doi.org/10.1213/ANE.0b013e318292ee21
6. Tsaousi G, Oloktsidou I, Tsiaousi A, Gkinas D, Vasilakos D. Assessment of four methods of endotracheal tube cuff inflation in terms of optimal cuff sealing. Eur J Anaesthesiol [19AP4-5]. 2014;31:278-9. https://doi.org/10.1097/00003643-201406001-00805
7. Jain M, Tripathi C. Endotracheal tube cuff pressure monitoring during neurosurgery - Manual vs. automatic method. J Anaesthesiol Clin Pharmacol. 2011;27:358. https://doi.org/10.4103/0970-9185.83682
8. Kaki A, Almarakbi W. Tracheal tube cuff inflation guided by pressure volume loop closure associated with

lower postoperative cuff-related complications: Prospective, randomized clinical trial. Saudi J Anaesth. 2014;8:328. https://doi.org/10.4103/1658-354X.136422
9. Kaki AM, Almarakbi WA. Use of pressure volume loop closure to check for endotracheal tube cuff function. Saudi J Anaesth. 2012;33:1185-9.
10. Rajan S, Tosh P, Paul J, Kumar L. Effect of inhaled budesonide suspension, administered using a metered dose inhaler, on post-operative sore throat, hoarseness of voice and cough. Indian J Anaesth. 2018;62:66. https://doi.org/10.4103/ija.IJA_382_17
11. Liu J, Zhang X, Gong W, et al. Correlations between controlled endotracheal tube cuff pressure and post procedural complications: a multicenter study. Anesth Analg. 2010;111:1133-7. https://doi.org/10.1213/ANE.0b013e3181f2ecc7
12. Hu BJ, Xu J, Zhao XH, et al. Impact of endotracheal tube cuff pressure on postoperative sore throat: A systematic review and meta-analysis. J Anesth Perioper Med. 2016;3:171-6. https://doi.org/10.24015/JAPM.2016.0022
13. Morris LG, Zoumalan RA, Roccaforte JD, Amin MR. Monitoring tracheal tube cuff pressures in the intensive care unit: a comparison of digital palpation and manometry. Ann Otol Rhinol Laryngol. 2007;116:639-42. https://doi.org/10.1177/000348940711600902
14. Sengupta P, Sessler DI, Maglinger P, et al. Endotracheal tube cuff pressure in three hospitals and the volume required to produce an appropriate cuff pressure. BMC Anesthesiol. 2004;4:8. https://doi.org/10.1186/1471-2253-4-8