

Evaluation of audible leak *versus* pressure volume loop closure for polyvinyl chloride cuff and polyurethane microcuff in endotracheal tube inflated with air: a prospective randomized study

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Abstract

Cuff pressure of endotracheal tube (ETT) must be high enough to seal the trachea, and must be low enough to allow adequate perfusion of tracheal mucosa. Compared with polyvinyl chloride (PVC) cuffed tubes, polyurethane cuffed tubes protect more efficiently. Different methods of ETT cuff pressure maintenance in practice have been reported. We planned to compare ETT cuff pressure using different techniques in PVC and polyurethane microcuff tubes in a prospective randomized study. Eighty surgical patients between 16–65 years belonging to American Society of Anesthesiologists physical status I–III, scheduled for orotracheal intubation under general anaesthesia, were included. All enrolled patients were randomized into four groups ($n = 20$ per group), followed by corresponding treatments, including intubation by PVC ETT or polyurethane microcuff ETT and cuff inflation by auscultation of audible leak or pressure volume loop. Amount of air required to inflate cuff was more in polyurethane tube as compared to polyvinyl tube. While comparing the two methods of cuff inflation, less volume of air was required in pressure volume loop method. We concluded that PVC cuff tube and polyurethane microcuff tube both are safe tubes used in adult patients. However, when inflated using same technique polyurethane microcuff tubes required larger volume to inflate cuff. Further, pressure generated in polyurethane microcuff tubes in much lower than PVC tubes. The study was approved by the Institutional Ethics Committee of Pt B D Sharma, PGIMS, Rohtak (No. IEC/Th/18/Anst15) on January 20, 2018 and registered with Clinical Trials Registry-India (registration No. CTRI/2019/01/017170) on January 18, 2019.

Key words: cuff inflation; cuff pressure; manual method; microcuff; polyvinyl chloride tube; pressure volume loop; tracheal mucosa

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INTRODUCTION

Endotracheal tube (ETT) is important during anesthesia to maintain airway. Its critical function is to seal airway, prevent aspiration and leak of pharyngeal contents into trachea.¹ Cuff pressure must be high enough to seal the trachea to prevent aspiration of oropharyngeal secretions and avoid air leaks to atmosphere. Also, it must be low enough to allow adequate perfusion of tracheal mucosa.^{2,3}

The common methods used in routine clinical settings for inflation of endotracheal cuff pressure are finger palpation of pilot balloon, inflation to precise pressure (25 cmH₂O, 1 cmH₂O = 0.098 kPa) and sealing method.^{2,4} But none of them is a definitive method and an intraoperative cuff pressure monitoring by manometer or any electronic device has been developed. Currently a cuff pressure of 20–30 cmH₂O is recommended for minimal risk of complications.⁵ The aneroid manometer is the most commonly used device for monitoring cuff pressure. The pressure volume (PV) loop is the continuous real time pulmonary graphic incorporated in the monitoring system of anesthesia machines. Pressure volume loop is used for the assessment of dynamic lung compliance, detection of lung over inflation and presence of air leak.⁶ Various types of tubes are used in routine anesthesia practice with their added advantages. Most commonly used polyvinyl chloride (PVC)

tubes are cheap, easy to handle and disposable. On the other hand polyurethane cuffed tubes made of ultrathin (7 μm) material prevent leakage and microaspiration by providing a better seal.⁷

When cuff comprised of PVC material is inflated, tiny channels are created that encourage collection of secretions within the folds. For prevention of microaspiration intracuff pressures as high as more than 30 cmH₂O have been used to seal PVC cuffs. Cuff material made of ultrathin (10 μm) polyurethane allows sealing of the lumen of the trachea at pressures of 15 cmH₂O or lower.⁷ This is because of the polyurethane material draping over the irregular tracheal mucosal contours. Compared with PVC cuffed tubes, polyurethane cuffed tubes protect more efficiently against microaspiration or substantial leakage of secretions.⁸ Different methods of ETT cuff pressure maintenance in practice have been reported successfully with varied opinions about their efficacy.⁵ We conducted the following study to compare ETT cuff pressure using different techniques in PVC *versus* polyurethane microcuff ETT tubes.

SUBJECTS AND METHODS

Design

The prospective randomized, clinical study was conducted

in the Department of Anaesthesiology, Pt. B D Sharma Post Graduate Institute of Medical Sciences, Rohtak, India. The study was approved by the Institutional Ethics Committee of Pt B D Sharma, PGIMS, Rohtak (No. IEC/Th/18/Anst15) on January 20, 2018 and registered with Clinical Trials Registry-India (registration No. CTRI/2019/01/017170) on January 18, 2019. Writing and editing of the article was performed in accordance to the CONSolidated Standards Of Reporting Trials (CONSORT) statement. The flow chart is shown in **Figure 1**.

Subjects

Totally 104 patients between 16–65 years belonging to American Society of Anesthesiologists physical status I–III,⁹ scheduled for orotracheal intubation during elective surgery under general anesthesia, were assessed for eligibility for the study. Patients with risk of pulmonary aspiration, body mass index > 35 kg/m², and obstetric patients were excluded. Four patients were excluded as they did not meet inclusion criteria. Eighty patients after taking written informed consent were included in the study.

Anesthesia management

A standard anesthesia protocol was followed in all the patients. Either PVC (Portex[®]; Smiths Medical, Inc., Plymouth, MN, USA) or polyurethane microcuff ETT (Kimberly-Clark* MICROCUFF*; Kimberly Clark, Health Care, Atlanta, GA, USA) of size 7.0 mm ID and 8.0 mm ID was used in female and male patients respectively. ETT was checked before use and it was lubricated with water based gel. After preoxygenation with 100% oxygen by facemask, induction of anesthesia was done with injection fentanyl citrate (Fent; Neon Laboratories Limited, Mumbai, India) 2 µg/kg and injection propofol (Nerof; Neon Laboratories Limited) 2 mg/kg. Nondepolarizing neuromuscular blocking agents were used to facilitate ETT insertion. All the patients were ventilated for 3 minutes using oxygen in nitrous oxide 50% and sevoflurane to achieve minimum alveolar concentration of 1–1.3.

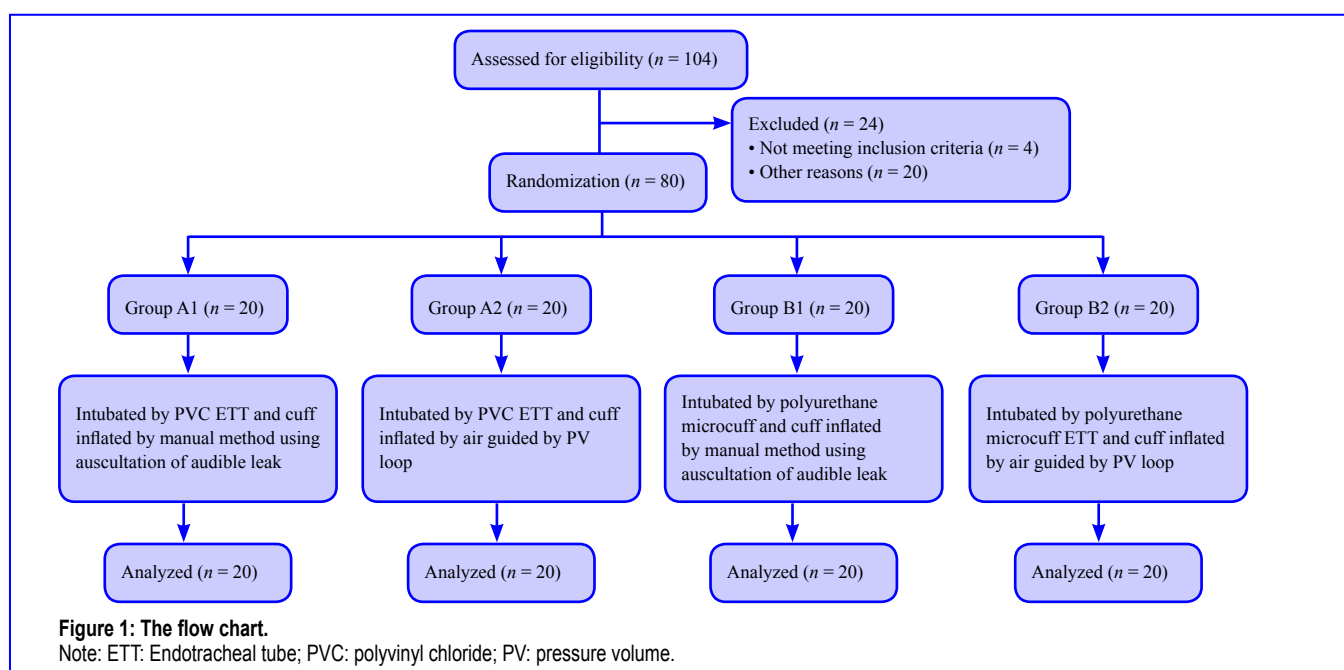
Group allocation

Using computer generated randomization number table, the patients were divided in 4 groups with 20 in each group. Endotracheal intubation with the ETT assigned was done by direct laryngoscopy in standard sniffing position by PVC tube or polyurethane microcuff tube (**Figure 2A** and **B** respectively). ETT cuff was inflated with air (mL) and fixed after checking square wave capnogram and bilateral equal air entry. Group A1 ($n = 20$): Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak. Group A2 ($n = 20$): Patients were intubated by PVC ETT and cuff inflated with air guided by PV loop (Primus[®]; Drager India Pvt. Ltd., Mumbai, India). Group B1 ($n = 20$): Patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak. Group B2 ($n = 20$): Patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. Once stabilized, the pressure was checked with aneroid manometer by connecting pilot balloon of ETT via stopcock. Anaesthesia was maintained by inhalational agents or intravenous propofol as per discretion of anaesthesiologist. Neuromuscular blockade was maintained with supplemental dosages of nondepolarizing neuromuscular blocking agent.

Measurements

Amount of air required to inflate cuff

In audible leak technique group, ETT cuff was inflated initially by 2 mL of air followed by increments of 0.5 mL air using 2 mL syringe till disappearance of harsh audible sounds on auscultation and acceptable palpation of the external pilot balloon was attained. Total amount of air required was recorded. In PV loop technique group, ETT cuff, both types PVC tube or polyurethane microcuff, were inflated initially by 2 mL of air followed by increments of 0.5 mL air using 2 mL syringe until the complete closure of the PV loop is displayed on the Drager Anesthesia Work Station monitor, i.e., when the expiratory limb reached at zero volume and met the starting



point of inspiratory limb. Total amount of air required was recorded (**Figure 3**).

Intra-cuff pressure

Once adequate seal was achieved intra-cuff pressure was measured using pressure manometer (Portex Smith, Norwell, MA, USA) and was recorded.

Tidal volume discrepancy

Measure the effect of decreasing lung compliance on the difference between effective tidal volume and tidal volume at the ETT in the patient with no leak around the ETT.

Changes in intra-cuff pressure

Cuff pressure was recorded again after 1 hour and at the end of surgery. Any change in pressure was noted, if pressure exceeds more than 20 cmH₂O, air of cuff was aspirated to maintain intra-cuff pressure of 20 cmH₂O in aliquots of 1 mL air. Volume of air aspirated was noted.

Cuff volume before extubation

Before extubation, volume of air aspirated for complete deflation was recorded from ETT.

Tube inspection

Tube was visibly inspected for any secretions on distal portion of the cuff.

Complications

Patient was enquired for any evidence of sore throat, hoarse-

ness of voice, and cough 30 minutes post-extubation and thereafter, was reassessed for above complaints next day in the ward.

Sample size

Our sample size calculation done by using <https://www.openepi.com/SampleSize/SSCohort.htm> based on Almarakbi and Kaki¹⁰ recorded the amount of air to inflate the ETT cuff in PV loop technique in comparison to the audible Leak technique using PVC ETT. Assuming these as reference values, the minimum required sample size at 5% level of significance and 95% power was calculated as at least nine patients in each group. However, keeping in mind the duration of study and also a large number of such patients reporting to our hospital, we proposed to take 20 patients in each group.

Statistical analysis

The entire data was entered in Microsoft excel file and analyzed using Statistical Package for the Social Sciences version 17.0 software (SPSS Inc., Chicago, IL, USA). The quantitative variables in all groups were expressed as mean \pm standard deviation (SD) and one-way analysis of variance followed by F test was used for intergroup comparison. For multiple comparisons, *post hoc* analysis was done with Tukey's test. Categorical variable were analyzed using Chi-square test. A *P*-value < 0.05 was considered statistically significant.

RESULTS

Demographic profile was comparable within all groups (**Table 1**).



Figure 2: The morphology of polyvinyl chloride endotracheal tube (A) and polyurethane microcuff endotracheal tube (B).



Figure 3: Pressure volume loop method of cuff inflation.

Table 1: Demographic profile in surgical patients using different techniques in PVC versus polyurethane microcuff ETT tubes

	Group A1	Group A2	Group B1	Group B2	<i>P</i> -value
Age (yr)	43.65 \pm 13.93	44.65 \pm 12.14	37.85 \pm 16.32	40.80 \pm 12.74	0.409
Weight (kg)	59.25 \pm 8.75	57.9 \pm 10.32	61.6 \pm 4.93	63.80 \pm 4.30	0.074
Height (m)	1.60 \pm 0.07	1.61 \pm 0.07	1.65 \pm 0.09	1.65 \pm 0.08	0.085
Body mass index (kg/m ²)					
Mean \pm SD	23.08 \pm 2.10	22.23 \pm 3.30	22.7 \pm 2.63	23.35 \pm 2.02	0.459
Sex					0.112
Female	14 (70)	17 (85)	10 (50)	12 (60)	
Male	6 (30)	3 (15)	10 (50)	8 (40)	
American Society of Anesthesiologists physical status					0.491
I	16 (80)	17 (85)	13 (65)	15 (75)	
II	4 (20)	3 (15)	7 (35)	5 (25)	

Note: Group A1: Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak; group A2: patients were intubated by PVC ETT and cuff inflated with air guided by PV loop; group B1: patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak; group B2: patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. Quantitative data are expressed as the mean \pm SD, and analyzed by one way analysis of variance followed by *F* test. Categorical data are expressed as number (percentage), and were analyzed by Chi-square test. ETT: Endotracheal tube; PV: pressure volume; PVC: polyvinyl chloride.



Comparison of different types of tracheal tubes

Tables 2 and 3 reveal that the amount of air required to inflate cuff is more in polyurethane tube as compared to polyvinyl tube (group B1 vs. group A1: $P < 0.001$, group B2 vs. group A2: $P = 0.335$). Mean pressure of cuff is less in polyurethane tube (group B1 vs. group A1: $P < 0.001$, group B2 vs. group A2: $P = 0.039$). After one hour, intracuff pressure was less in polyurethane tube (group B1 vs. group A1: $P = 0.025$, group B2 vs. group A2: $P = 0.006$). Removal of 1 mL of air to maintain intracuff pressure at 20 cmH₂O was required in only one patient with polyurethane cuff as compared to 18 patients with PVC tube (group B1 vs. group A1: $P = 0.044$, group B2 vs. group A2: $P < 0.001$). Till the end of surgery intra-cuff pressure again increased to a higher extent in PVC tube as compared to polyurethane tube (group A1 and A2 vs. group B2: $P = 0.031 < 0.001$, group A2 vs. group A1: $P = 0.031$, group B2 vs. group A1: $P < 0.001$).

Comparison of different methods of cuff inflation

While comparing the two methods of cuff inflation, less volume of air was required in PV loop method (group A1 vs. group A2: $P = 0.99$, group B1 vs. group B2: $P < 0.001$;

Tables 2 and 3).

Side-effects of different types of tracheal tubes or cuff inflation

It was observed that under group A1, 85% of the patients had nil secretions, 5% each had mucous plugs, secretions and blood respectively. For group A2, 80% patients had no secretions, 10% had blood and 5% each had Mucous Plugs and light secretions. For group B2, 95% patients had no secretions while 5% had secretions. For group B2, 95% had no secretions and 5% had Mucous Plugs. Further, it was observed that there was a significant difference in secretion distribution among four groups ($P < 0.001$; **Table 4**).

None of the patients had hoarseness of voice in all the groups after 30 minutes as well as after 24 hours. There was no significant difference in distribution of patients with cough and sore throat between the four groups after 30 minutes as well as after 24 hours (**Table 5**).

DISCUSSION

Volume of air to inflate cuff was more in polyurethane ETT than the PVC ETT. A significant reduction of required air in PV loop technique used for cuff inflation in polyurethane

Table 2: Variation in intra-cuff air with reference to different stages in surgical patients using different techniques in PVC versus polyurethane microcuff ETT tubes

	Group A1	Group A2	Group B1	Group B2
Amount of air required to inflate cuff (mL)	4.48±0.87	4.44±1.08	6.12±0.72	4.90±0.68
Mean pressure of cuff (cmH ₂ O)	16.95±3.27	16.95±5.86	12.65±1.35	12.90±1.35
Volume of discrepancy (mL)	6.80±5.73	11.85±14.86	6.15±4.59	5.00±3.69
Intracuff pressure at 1 h (cmH ₂ O)	20.85±5.83	21.50±8.39	16.05±3.83	14.15±1.42
Air withdrawn at 1 h				
0 mL	13(65)	9(45)	19(95)	20(100)
1 mL	7(35)	11(55)	1(5)	0
Intracuff pressure at end (cmH ₂ O)	19.50±3.55	16.00±3.91	17.85±5.59	15.10±1.55
Air withdrawn at end				
0 mL	14(70)	19(95)	19(95)	20(100)
1 mL	6(30)	1(5)	1(5)	0
Cuff volume before extubation (mL)	4.93±0.92	4.90±1.01	6.35±0.76	5.30±0.68

Note: Group A1: Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak; group A2: patients were intubated by PVC ETT and cuff inflated with air guided by PV loop; group B1: patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak; group B2: patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. Quantitative data are expressed as the mean ± SD, and categorical data are expressed as number (percentage). ETT: Endotracheal tube; PV: pressure volume; PVC: polyvinyl chloride.

Table 3: P values in different types of tracheal tubes and different types of cuff inflation methods in surgical patients using different techniques in PVC versus polyurethane microcuff ETT tubes

	A1 vs. A2	A1 vs. B1	A1 vs. B2	A2 vs. B1	A2 vs. B2	B1 vs. B2
Amount of air required to inflate cuff	0.99	< 0.001	0.396	< 0.001	0.335	< 0.001
Mean pressure of cuff	1.00	< 0.001	< 0.001	0.026	0.039	0.993
Volume of discrepancy	0.670	0.99	0.816	0.519	0.302	0.948
Intracuff pressure at 1 h	1.00	0.025	< 0.001	0.079	0.006	0.258
Air withdrawn at 1 h	0.204	0.044	0.005	0.001	< 0.001	1.00
Intracuff pressure at end	0.031	0.852	< 0.001	0.79	0.92	0.243
Air withdrawn at end	0.091	0.091	0.020	1.00	1.00	1.00
Cuff volume before extubation	1.00	< 0.001	0.508	1.00	0.452	0.001

Note: Group A1: Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak; group A2: patients were intubated by PVC ETT and cuff inflated with air guided by PV loop; group B1: patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak; group B2: patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. Quantitative data are analyzed by one-way analysis of variance followed by F test, and categorical data are analyzed by Chi-square test. ETT: Endotracheal tube; PV: pressure volume; PVC: polyvinyl chloride.



Table 4: Comparison of any secretions over distal cuff among surgical patients with different types of tracheal tubes

	Group A1	Group A2	Group B1	Group B2
None	17 (85)	16 (80)	19 (95)	19 (95)
Mucous Plugs	1 (5)	1 (5)	0	1 (5)
Thick secretions	1 (5)	0	1 (5)	0
Blood	1 (5)	2 (10)	0	0
Light Secretions	0	1 (5)	0	0
Total	20 (100)	20 (100)	20 (100)	20 (100)

Note: Group A1: Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak; group A2: patients were intubated by PVC ETT and cuff inflated with air guided by PV loop; group B1: patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak; group B2: patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. There was a significant difference in secretion distribution among four groups ($P < 0.001$). Data are expressed as number (percentage), and were analyzed by Chi-square test. ETT: Endotracheal tube; PV: pressure volume; PVC: polyvinyl chloride.

tube. These observations were strengthened by Kaki and Al-marakbi⁶ evaluated use of PV loop closure to check for ETT cuff inflation. They observed that the lower volume of air was required in PV loop technique than the other two techniques. Amount of volume was used in pilot balloon palpation method and fixed preset pressure was 5.26 ± 0.46 mL and 4.4 ± 0.36 mL, respectively. Searched literature was silent about amount of air required to inflate polyurethane microcuff in elective surgeries in adult patients.

There was an apparent reduction in cuff pressures in polyurethane cuff tubes. Mali et al.⁴ observed higher cuff pressures in their study group further the cuff pressures were significantly lower in sealing group compared with constant pressure group and highest in finger palpation group. Mahmoodpoor et al.⁷ evaluated comparison of prophylactic effects of polyurethane cylindrical or tapered cuff and PVC cuff ETTs on ventilator associated pneumonia and maintained mean cuff pressure in PVC ETT was 24.20 ± 0.47 mmHg, in polyurethane taperguard ETT was 24.10 ± 0.49 mmHg and 24.07 ± 0.48 mmHg was for polyurethane sealguard ETT ($P > 0.05$). Mhamane et al.¹¹ evaluated use of microcuff ETTs in pediatric laparoscopic surgeries. They observed mean sealing pressure was 11.72 cmH₂O. We have also noted similar values of sealing pressure despite our population being different that is adult population. We observed in our study cuff pressure was lower in polyurethane microcuff ETT than the PVC ETT. Searched literature was silent on comparing cuff pressure in between PVC ETT and polyurethane microcuff ETT in elective surgeries.

Requirement of air withdrawn from cuff (if cuff pressure was more than 20 cmH₂O after 1 hour) was less in polyurethane microcuff ETT compared to PVC tube. There is an observable increase in volume of cuff air with time in PVC cuff ETTs resulting in increased pressure. Polyurethane microcuff ETTs did not show significant increase in volume with passage of time. The searched literature did not have data to compare these observations. However, the difference might have resulted from absorption or diffusion due to different characteristics of both types of cuffs. Further, we have used 50% nitrous in

Table 5: Side effects reported postoperatively among surgical patients with different types of tracheal tubes

	Group A1	Group A2	Group B1	Group B2	P-value
Sore throat					
30 min					0.416
No	16 (80)	16 (80)	19 (95)	18 (90)	
Yes	4 (20)	4 (20)	1 (5)	2 (10)	
24 h					0.238
No	18 (90)	19 (95)	20 (100)	20 (100)	
Yes	2 (10)	1 (5)	0	0	
Hoarseness of voice					1
30 min	20 (100)	20 (100)	20 (100)	20 (100)	
No					
24 h					1
No	20 (100)	20 (100)	20 (100)	20 (100)	
Cough					
30 min					0.135
No	17 (85)	16 (80)	19 (95)	20 (100)	
Yes	3 (15)	4 (20)	1 (5)	0	
24 h					0.368
No	20 (100)	19 (95)	20 (100)	20 (100)	
Yes	0	1 (5)	0	0	

Note: Group A1: Patients were intubated by PVC ETT and cuff inflated by manual method using auscultation of audible leak; group A2: patients were intubated by PVC ETT and cuff inflated with air guided by PV loop; group B1: patients were intubated by polyurethane microcuff ETT and cuff inflated by manual method using auscultation of audible leak; group B2: patients were intubated by polyurethane microcuff ETT and cuff inflated with air guided by PV loop. Data are expressed as number (percentage), and were analyzed by Chi-square test. ETT: Endotracheal tube; PV: pressure volume; PVC: polyvinyl chloride.

oxygen in our all patients. Change in cuff pressure and air withdrawn was higher in PVC ETT.

It is apparent that despite higher cuff volumes in both the groups of polyurethane ETT, the pressures maintained were significantly low which of paramount importance. Secretions over distal cuff were less in polyurethane ETT. Lower incidence of postoperative complications in polyurethane ETT compared to the PVC ETT which might be due to lower cuff pressure in polyurethane ETT.

There were few limitations to our study. Patients included belong to single geographical profile, i.e. Northern India in Asia Pacific region. Although sample size has been calculated based on literature still this small sample size may not represent whole population.

In summary, with observations made and compared with available literature it is concluded that PVC cuff tube and polyurethane microcuff tube both are safe endotracheal tubes to be used in adult patients. However, when inflated using same technique polyurethane microcuff tubes require larger volume to inflate cuff than the PVC tubes. Further, pressure generated in polyurethane microcuff tubes is much lower than PVC cuff tubes.

Author contributions

Study design: PK, JS, KK; literature search: PK, A, JS, MB, AS; data collection: PK, A, KK, MB, AS; manuscript writing: JS, MB. All au-



thors read and approved the final version of manuscript for publication.

Conflicts of interest

None declared.

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None.

Institutional review board statement

The study was approved by the Institutional Ethics Committee of Pt B D Sharma, PGIMS, Rohtak (No. IEC/Th/18/Anst15) on January 20, 2018 and registered with Clinical Trials Registry-India (registration No. CTRI/2019/01/017170) on January 18, 2019.

Declaration of patient consent

The authors certify that they have obtained patient consent forms. In the form, patient have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published.

Reporting statement

The writing and editing of the article were performed in accordance with the CONSolidated Standards Of Reporting Trials (CONSORT) Statement.

Biostatistics statement

The statistical methods of this study were reviewed by Dr. Madhur Verma from All India Institute of Medical Sciences Bathinda, Punjab, India.

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Data sharing statement

Datasets analyzed during the current study are available from the corresponding author on reasonable request.

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