

# Polyurethane cuffed versus conventional endotracheal tubes: Effect on ventilator-associated pneumonia rates and length of Intensive Care Unit stay

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## ABSTRACT

**Background and Aims:** Ventilator-associated pneumonia (VAP) is a major cause of morbidity and mortality among patients in the Intensive Care Units (ICUs) and results in added healthcare costs. One of the methods of preventing VAP is to use polyurethane (PU)-cuffed endotracheal tube (ETT). This study compares the incidence of VAP and length of ICU stay in patients intubated with conventional polyvinyl chloride (PVC) ETT and PU-cuffed ETT. **Methods:** Eighty post-laparotomy patients who were mechanically ventilated for >48 h in the ICU were included in this randomised controlled trial. Patients with moderate to severe pre-existing lung conditions were excluded from the study. Patients in group PVC ( $n = 40$ ) were intubated with conventional PVC-cuffed ETT and those in group PU ( $n = 40$ ) with PU-cuffed ETT. VAP was defined as a Clinical Pulmonary Infection Score of >6 with a positive quantitative endotracheal culture in patients on ventilator for >48 h. **Results:** Overall VAP rates were 23.75%. Thirteen (32.5%) patients in group PVC and six (15%) patients in group PU developed VAP. ICU stay was significantly lesser in patients intubated with PU-cuffed ETT (group PU) (median, 6 days; range: 4–8.5) compared to patients intubated with conventional ETT (group PVC) (median, 8; range: 6–11). **Conclusion:** No statistically significant reduction in the incidence of VAP could be found between the groups. The length of ICU stay was significantly lesser with the use of ultra thin PU-cuffed ETTs.

**Key words:** Polyurethane cuff, polyvinyl chloride cuff, ventilator-associated pneumonia

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## INTRODUCTION

Ventilator-associated pneumonia (VAP) refers to pneumonia occurring in patients on mechanical ventilation for a duration exceeding 48 h. Despite advances in antibiotic therapy and mechanical ventilation strategies, VAP remains the most common hospital acquired infection in ventilated patients, occurring in about 30% of all intubated patients.<sup>[1]</sup> It is a major burden on hospital economy accounting for 25% of all Intensive Care Unit (ICU) infections and more than 50% of antibiotics prescribed in addition to prolonged ICU stay. The crude mortality rate attributed to VAP is as high as 30–70%. VAP increases the absolute mortality risk by 5.8%.<sup>[2]</sup>

Microcuff tubes are made of polyurethane (PU) cuffs which are ultrathin. This serves two purposes, there is lesser chance of folds and channel formation

thereby reducing risk of aspiration and the pressure exerted by the cuff on the tracheal mucosa is much lesser.

This study was designed to analyse the incidence of VAP and the length of ICU stay while using PU-cuffed endotracheal tubes (ETTs) and compare it with similar outcomes with the use of conventional polyvinyl chloride (PVC) ETTs.<sup>[3]</sup>

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## METHODS

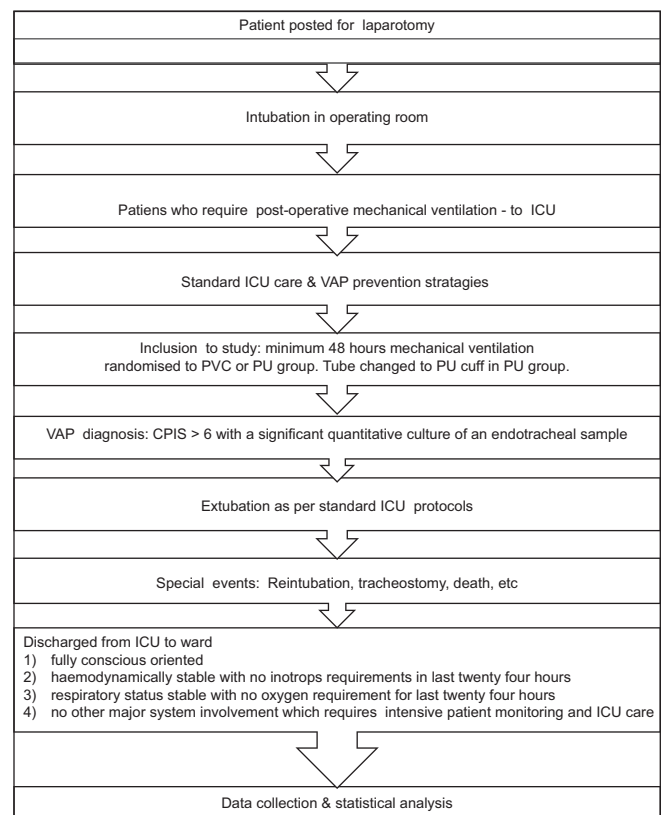
This was a prospective, randomised clinical trial conducted in the Critical Care Unit of a Tertiary Care Medical Institute in India. The study was approved by the Institute Ethics Board. Eighty post-operative patients aged 18–65 years who underwent laparotomy and who required mechanical ventilation for >48 h were included in the study. Exclusion criteria included patients with pneumonia, acute respiratory distress syndrome (ARDS), moderate to severe chronic obstructive lung disease, other lung co-morbidities, any other severe co-morbidities or Acute Physiological and Chronic Health Evaluation II (APACHE) score >20.

Patients were randomised by using computer generated numbers into two groups, group PVC (conventional PVC-cuffed ETT) and group PU (PU-cuffed ETTs). ETTs were changed to PU tubes in the patients who were designated to PU group. In the ICU, identical protocols were used for both groups including head-end elevation by 40–45°, chlorhexidine mouthwash, fourth hourly intracuff pressure monitoring to maintain a pressure  $\leq 25$  cm H<sub>2</sub>O and ETT suctioning when required. Enteral feeding was started post-operatively in all possible cases based on the surgeon's opinion. Daily calories were calculated at 25–30 Kcal/Kg administered 4–6 hourly as nasogastric tube boluses after ensuring minimal gastric aspirate according to a standardised protocol. Protocol-based sedation interruption and daily assessment for weaning were done. Ceftriaxone or cefoperazone-sulbactam in combination with an aminoglycoside and anaerobic cover comprised empiric antibiotic therapy in the post-operative period. All patients received pre-operative prophylaxis with ceftriaxone. This was based on the prevalence, culture and sensitivity pattern of microbial flora in our hospital and ICU and based on Hospital Infection Control Committee recommendations.

VAP was defined as a Clinical Pulmonary Infection Score (CPIS) of >6 along with significant quantitative culture of an endotracheal sample ( $>10^6$  CFU/mL) in a patient on mechanical ventilation for over 48 h.<sup>[4]</sup> CPIS scoring was based on measurement of six clinical parameters: Temperature, total leucocyte count, quality of tracheal aspirate, oxygenation, radiographic findings and semi-quantitative culture of the tracheal aspirate [Table 1]. ICU discharge criteria included full consciousness, stable haemodynamic status

without need for inotropic/vasopressor support, free from any form of invasive ventilation for more than 48 h, no supplemental oxygen requirement for 24 h, stable respiratory status and no other major system involvement requiring intensive patient monitoring and ICU care. A flowchart describing methodology is included in Figure 1.

Age, gender, APACHE scores, CPIS scores, duration of mechanical ventilation (DOMV) and ICU stay, tracheostomy requirement, reintubation and mortality were recorded.



**Figure 1:** Flowchart methods. CPIS: Clinical Pulmonary Infection Score

**Table 1: Clinical Pulmonary Infection Scoring system**

CPIS points	0	1	2
Tracheal secretions	Absent	Not purulent	Abundant and Purulent
Leucocyte count (mm <sup>3</sup> )	>4000 and <11,000	<4000 and >11,000	<4000 or >11,000 + band forms
Temperature (°C)	>36.5 and <38.4	>38.5 and <38.9	>39 or <36
PaO <sub>2</sub> /FIO <sub>2</sub> ratio (mmHg)	>240 or ARDS	-	≤240 and no ARDS
Chest radiograph	No infiltrate	Diffuse infiltrate	Localised infiltrate
Culture of tracheal aspirate	Negative	-	Positive

ARDS – Acute respiratory distress syndrome; CPIS – Clinical Pulmonary Infection Score

The sample size was calculated based on a previous study where a reduction in VAP rate from 42% to 23% was observed.<sup>[5]</sup> Expecting a similar rate of reduction from the current rate of 30% in our ICU, the sample size was estimated to be 40 per group for a power of 80% and  $\alpha$ -error of 5%. The distribution of data related to categorical variables such as patient's clinical conditions, co-morbidities, treatment and clinical outcome was expressed as frequency and percentage. Chi-square or Fisher's exact test was used to compare these variables and the difference in incidence of VAP between the groups. Age, APACHE-II score, DOMV and duration of ICU stay was expressed as mean with standard deviation or median with range. The comparison of these variables between the groups was carried out by using independent Student's *t*-test or Mann-Whitney U-test based on distribution of data. The comparison of continuous variables in relation to the VAP incidence was carried out by epidemiological tables from incidence rate ratio calculator by using STATA 11.2 software (Statacorp. 2009. Stata Statistical Software: Release 11. College Station, TX: Statacorp LP.) A  $P < 0.05$  was considered statistically significant.

## RESULTS

A total of eighty patients were included in the study. Patients were comparable in terms of demographics and baseline characteristics [Table 2]. The APACHE scores were also comparable with a mean of 16 in the PU group and 17 in group PVC. The general admission diagnosis for all the included patients is represented in Table 3.

The overall incidence of VAP rate based on clinical scoring and culture reports was 23.75%. Thirteen (32.5%) patients in group PVC and six (15%) patients in group PU developed VAP. The VAP rate in group PVC was 51.38/1000 ventilator days and in group PU, it was 25.86/1000 ventilator days. Although there was a 50% reduction in the incidence of VAP with the use of PU-cuffed ETT, this did not reach statistical significance.

There was a statistically significant reduction in ICU stay from a median of 8 (6–11) days in group PVC to 6 (4–8.5) days in the group PU [Table 4]. The total duration of ICU stay was 365 h in group PVC and 279 h in group PU. DOMV was comparable in both the groups at 253 h (group PVC) and 232 h (group PU). The rate of reintubation, tracheostomy requirement

and initiation of enteral feeds were not significantly different between the groups [Table 5]. There was no difference found in their mortality rates [Table 4].

Gram-negative organisms were more commonly isolated from tracheal aspirate, pseudomonas being

**Table 2: General characteristics of group polyvinyl chloride and polyurethane**

Patient characteristics	Group PVC (n=40)	Group PU (n=40)	P
Age (years, mean±SD)	53.95±10.03	54.5±8.82	0.80
Gender (male: female ratio)	21:19	23:17	0.65
APACHE II score median (IQR)	16 (14.5-18)	17 (15-17.5)	0.40

$P < 0.05$  was considered as significant. APACHE – Acute Physiological and Chronic Health Evaluation; SD – Standard deviation; IQR – Interquartile range; PVC – Polyvinyl chloride; PU – Polyurethane

**Table 3: Patient characteristics of group polyvinyl chloride and polyurethane, diagnosis and co-morbidities**

Diagnosis	Group PVC (n=40)	Group PU (n=40)
Perforation peritonitis	18	22
Intestinal obstruction	6	4
Obstructed inguinal hernia	4	3
Blunt trauma abdomen	3	1
Gut gangrene	2	3
Others	7	7
Co-morbidities (severe co-morbidities excluded)		
Diabetes	5	4
Hypertension	9	8
Chronic obstructive pulmonary disease (mild)	3	2
Endocrine disorders	1	1
Others	2	1

PVC – Polyvinyl chloride; PU – Polyurethane

**Table 4: Study outcome of group polyvinyl chloride and polyurethane**

Outcomes	Group PVC (n=40)	Group PU (n=40)	P
VAP cases (%)	13 (32.5)	6 (15)	0.07
Duration of ventilation days; median (IQR)	6 (4-8)	4 (3-7.5)	0.25
VAP rate (per 1000 ventilator days)	51.38	25.86	0.44
Duration of ICU stay days; median (IQR)	8 (6-11)	6 (4-8.5)	0.04*
CPIS; median (IQR)	5 (4-7)	4 (3-5)	0.01*
Mortality (%)	2 (5)	1 (2.5)	0.56

\* $P < 0.05$  was considered as statistically significant. VAP – Ventilator-associated pneumonia; ICU – Intensive Care Unit; IQR – Interquartile range; CPIS – Clinical Pulmonary Infection Score

**Table 5: Other interventions in the group polyvinyl chloride and polyurethane**

Interventions	Group PVC (n=40)	Group PU (n=40)	P
Reintubation, n (%)	6 (15)	5 (12.5)	0.75
Enteral nutrition, n (%)	24 (60)	25 (62.5)	0.82
Tracheostomy, n (%)	7 (17.5)	5 (12.5)	0.53

PVC – Polyvinyl chloride; PU – Polyurethane

the most frequently isolated species followed by *Acinetobacter*. There was one methicillin-resistant *Staphylococcus aureus* isolated from group PVC.

## DISCUSSION

The overall incidence of VAP in our study was 23.75%. This is consistent with VAP rates in developing countries where the rate is around 15–30%.<sup>[6]</sup> According to Western literature, VAP occurs at a rate of 9–27% of all intubated patients.<sup>[1]</sup> Usefulness of a PU-cuffed ETT in preventing VAP as compared to the conventional PVC-cuffed tube was studied here. Among the forty patients randomised to receive a PU-cuffed tube, six developed VAP. There was a reduction of about 50% in the VAP rate while using this cuff (relative risk of 0.46,  $P = 0.07$ ). This reduction though clinically looked significant did not reach statistical significance. This could be due to a smaller sample size.

High-volume low-pressure cuffs like the PVC tubes that are currently used were introduced to provide adequate seal of the upper airway while preserving the mucosal blood supply of the trachea. However, several studies have shown leakages occurring down the longitudinal fold on the cuff membrane when inflated.<sup>[7,8]</sup> These micro-aspirations of contaminated oropharyngeal and gastric secretions could be the cause for developing VAP in patients on prolonged ventilation. PU -cuffed tube, made with ultrathin (around 7  $\mu\text{m}$ ) material, prevents leakage and microaspiration by providing a better seal. When conventional tubes and PU-cuffed ETTs are compared on a vertical PVC tracheal model for fluid leakage, it was found that PU-cuffed ETTs were the only ones to produce effective seal within the acceptable tracheal cuff pressure. Another study conducted on 50 patients confirmed these findings.<sup>[7]</sup>

A study in post-operative patients following cardiac surgery observed a significant reduction in early pneumonia in patients intubated with PU cuff as compared to the conventional PVC tubes (28 vs. 15,  $P = 0.026$ ). PU cuffs were found to be protective with an adjusted odds ratio of 0.31.<sup>[5]</sup> When all PVC tubes were replaced with PU-cuffed ETTs, there was a significant decrease in VAP.<sup>[9]</sup> There was a significant reduction in VAP rates when subglottic secretion drainage was combined with PU-cuffed tubes. However, this reduction rate could not be attributed to any one of the two interventions.<sup>[3]</sup>

Our study showed a statistically and clinically significant reduction in the number of days patients spent in the ICU when ventilated with PU-cuffed tubes. A significant reduction in the median ICU stay was found in patients intubated with PU-cuffed tubes when compared to patients who were on conventional cuffed tubes (17–11 days).<sup>[10]</sup> The presence of hospital-acquired pneumonia (HAP) is known to increase hospital stay by 7–9 days. The incidence of HAP is noted to be 20 times higher in patients who are mechanically ventilated.<sup>[1]</sup> The reduction in the number of days spent in the ICU has a great impact on the overall morbidity of the patient, in addition to increasing the cost of treatment. The micro-organisms isolated on tracheal aspirate culture are comparable to other studies. *Pseudomonas aeruginosa* followed by *Acinetobacter* were the most common organisms isolated in both the groups.<sup>[11]</sup>

This study was performed in a single ICU and hence, the results may not be applicable to all ICUs. The incidence of VAP varies in surgical and non-surgical patients and also depends on the type of surgery. Further, VAP was diagnosed based on a quantitative tracheal sample. While some studies insist on collection of more invasive sample collection methods using bronchoscopy, other studies have found no significant difference between the two types of sampling techniques in diagnosing VAP. Our study did not differentiate between early and late VAP. Finally, our sample size may be inadequately powered to detect a difference. We also observed some hitherto unreported problems with the PU-cuffed tube. The cuff tends to collect moisture and water after a week of intubation which might necessitate change of tube.

## CONCLUSION

While comparing PU-cuffed ETTs with conventional PVC ETTs in ICU patients, this study found a reduction in the incidence of VAP in patients intubated with PU tubes, which was not statistically significant. The length of days spent in the ICU was significantly lesser in patients when intubated with PU-cuffed ETTs.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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