

Comparative Evaluation of the Usability of Two Endotracheal Cuff Pressure Measuring Devices in Mechanically Ventilated Patients: A Prospective Randomized Cohort Study

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Abstract

Objective: compare a disposable cuff pressure device with a traditional analogue manometer in terms of ease of use, time efficiency, and user preference. **Design:** prospective randomised cohort study. **Subjects/Patients:** Intensive care unit patients >18 years, intubated on mechanical ventilation. **Methods:** 121 patients, randomly allocated into two groups for measurement of cuff pressure by device A and B respectively; by trained operators. Time to measurement and ease-of-use scores (5-point Likert scale) were recorded. User preference was assessed using McNemar's test. Missed opportunities to measure cuff pressure were documented. Proportional differences in missed measurements were analyzed using a z-test. **Results:** Device B showed significantly faster measurement time (38.6 ± 5 seconds) compared to Device A (49.2 ± 8 seconds). Ease-of-use scores were higher for Device B (4.2 ± 0.5) than Device A (3.5 ± 0.3). 27 users preferred Device B, while 6 preferred Device A ($p < 0.001$). Missed cuff pressure measurements were fewer with Device B (36/1289; 2.79%) compared to Device A (71/1276; 5.56%), with a statistically significant difference ($z = 3.48$, $p < 0.001$). **Conclusion:** Disposable device B definitely demonstrated superior usability, efficiency, and user preference compared to the routine analogue device. Its adoption may enhance adherence to cuff pressure monitoring protocols and improve safety standards.

Keywords: cuff pressure, endotracheal tube, monitoring, usability, McNemar's test.

Introduction

The use of cuff pressure measuring devices is paramount in the care of patients undergoing invasive mechanical ventilation. Endotracheal tubes (ETTs) and tracheostomy tubes are commonly utilized to maintain a patent airway and facilitate mechanical ventilation in critically ill patients. Proper cuff pressure management is crucial to ensure patient safety and optimize respiratory support.

Cuff pressure refers to the pressure exerted by the inflatable balloon cuff surrounding the distal end of the endotracheal or tracheostomy tube. This cuff serves multiple purposes, including preventing air leakage around the tube, protecting the airway from aspiration, and facilitating positive pressure ventilation. Monitoring and maintaining an appropriate cuff pressure is essential to prevent complications such as mucosal damage, tracheal stenosis, and micro aspiration and VAE (ventilator associated events) ^[1,2].

Using a cuff pressure measuring device allows healthcare providers to accurately assess and adjust cuff pressure, ensuring it remains within a safe and effective range. The recommended cuff pressure typically falls between 20 and 30 cm H₂O, but individual patient factors may influence the target range. Regular monitoring of cuff pressure is especially critical in patients at higher risk for

complications, such as those with prolonged mechanical ventilation, altered anatomy, or compromised mucosal integrity.

In this context, the cuff pressure measuring device serves as a valuable tool to enhance patient care. Through precise monitoring and adjustment of cuff pressure, healthcare providers can contribute to improved patient outcomes and minimize the risk of complications associated with mechanical ventilation.

In usual scenario, a single cuff pressure gauge is used for this purpose at bedside after sterilization with standard precautions. We wanted to know the ease of using disposable device and if it brings any change in rate of incidence of complications due to high or low cuff pressures.

Primary Objective: To compare the usability (time to measurement, ease of use, and user preference) of two cuff pressure devices. group A: analogue cuff pressure device and group B: disposable light weight device.

Methods

This is a single-center, prospective, randomized study carried out in patients admitted at critical care unit of Sevasadan Lifeline Superspeciality Hospital, Miraj from August 2024 to February 2025

after IEC (Institutional Ethical Committee) approval. A total of 121 patients were enrolled in the study.

Inclusion criteria: age > 18 years, patients on invasive mechanical ventilation (cuffed endotracheal or tracheostomy tube). Informed consent.

Exclusion criteria: Known anatomical airway abnormalities.

In Group A patients, analogue device was used for cuff pressure measurement, while for group B disposable device was used. Randomization into groups was done using computer sequence. The moments of measurement were defined as every four hourly and after procedure. Device A or analogue scale was required to be wiped with disinfectant with every usage, while Device B was single disposable unit for every patient

Operators identified were skilled, trained nursing staff, respiratory therapist and clinicians. Training imparted for usage of both devices.

Data collected was usual demographic, diagnosis, ventilated days, along with study specific data time to measurement (seconds), Ease of use (5-point Likert scale) and User preference.

Continuous variables were reported as mean \pm SD or median (IQR). Categorical variables presented as frequencies and percentages. Paired t-test or Wilcoxon test for time and ease of use comparisons.

McNemar's test for user preference. SPSS software 2.0 was used.

Results

The demographic data collected is recorded in Table 1. 121 patients were enrolled. 4 were disqualified for missing data. There were 59 patients in Group A while 58 in group B. The median age for group A was 52.6 ± 2.3 and 54.6 ± 2.5 for group B; Male to female percentage 58:42 in group A and 60:40 in group B. total ventilated days in group A was 247 with 1276 moments for cuff pressure measurement identified. While, in group B total ventilated days 251 with 1289 moments for cuff pressure measurement identified. There was no significant difference noted in the demographic data of both groups.

The time required for measurement of cuff pressure was recorded as follows, Device A 49.2 ± 8 seconds while that for device B was 28.6 ± 5 seconds. This was a statistically significant difference, with a $p < 0.001$. Ease of use was assessed using a Likert scale. It was noted that usability was significantly higher for Device B mean score 4.2 ± 0.5 compared to Device A 3.5 ± 0.3 ($p < 0.001$).

The user preference was assessed as simple yes, no, both or neither. Only 6 operators preferred device A while 27 operators preferred device B. 8 operators were comfortable with both devices, neither opted out. The number of discordant pairs (Device A only vs. Device B only) was significantly different (27 vs. 6), yielding a McNemar's chi-square statistic of 13.36 with 1 degree of freedom ($p < 0.001$). These results indicate a statistically significant preference for Device B over Device A.

A total of 1276 and 1289 cuff pressure measurement opportunities were recorded in Group A and Group B, respectively. Missed opportunities occurred in 71 cases (5.56%) in Group A and 36 cases (2.79%) in Group B. The difference in missed measurement rates was statistically significant ($z = 3.48$, $p < 0.001$), indicating better compliance with cuff pressure monitoring in Group B.

There were 5 recorded VAE's (ventilator associated events) in group A while 3 in group B with no statistically significant difference.

Table 1: Demographics and variables results

Variables	Group A	Group B	P value
Age	52.6 ± 2.3	54.6 ± 2.5	$p > 0.05$
Male: Female %	58:42	60:40	
Total ventilated days	247	251	$p > 0.05$
Moments of cuff pressure measurement identified	1276	1289	
Moments missed	71	36	$z = 3.48$, $p < 0.001$
Time required for measurement (seconds)	49.2 ± 8	28.6 ± 5	$p < 0.001$
Ease of usability	3.5 ± 0.3	4.2 ± 0.5	$p < 0.001$
User preference	6	27	$p < 0.001$
VAE	5	3	$p > 0.05$

Abbreviation: VAE: Ventilator associated events



Fig. 1: Analogue device (A)



Fig. 2: Disposable device (B)

Discussion

Cuff pressure measurement remains the standard form of care in patients undergoing mechanical ventilation. There is evidence to prove the importance of routine cuff pressure measurement in preventing complications of invasive ventilation. Bernon *et al.*^[2] in

their study concluded that in order to prevent the injuries to patients' tracheal mucosa caused from high cuff pressure it must be controlled with incumbent instruments. Liu J *et al.*^[3], concluded in their randomized control trial that proper control over endotracheal cuff pressures helps reducing post-operative endotracheal tube related respiratory complications like sore throat, cough and blood streak expectoration.

Thus, it can be safely concluded that high cuff pressures above 30cmH₂O cause tracheal mucosal injury and stenosis while pressures below 20cmH₂O cause microaspirations and VAE.

Cuff pressure measurement techniques have been studied over a period of time. Rahmani F and *et al.*^[4], in a prospective cross-sectional study tried to evaluate the most two common fixed volume and pilot balloon palpitation methods to control tracheal tube cuff pressure. However, it concluded that none of the techniques were superior to manometers. AB Ozer *et al.*^[5], had a study about estimating the pressure of TTC and they concluded ineffectiveness of pilot balloon palpation to estimate cuff pressure and suggested its replacement with manometer. Sadovy Valentyn *et al.*^[6], in their recent study also proved that evaluation of cuff pressure by palpation not being adequate, minimum occlusion volume method deserved attention.

All the literature suggests that manometers are gold standard for cuff pressure measurements. The devices have evolved from cuff pressure manometers, to pneumatic, analogue and then disposable types. In this study, we compared two endotracheal cuff pressure measuring devices—a disposable device (Device B) and a traditional analogue manometer (Device A)-with a focus on ease of use, time efficiency, and user preference.

Alexander Duguet *et al.*^[7] in their randomized control trial compared usability of pneumatic device for continuous cuff pressure measurement. The device was tested successfully for controlled cuff pressure with minimal human resource. Thus, stressing the need and feasibility of continuous cuff pressure monitoring in mechanically ventilated patients. Michikoshi J *et al.*^[8], in their study compared the performance of a new automated cuff pressure controller with currently available devices in both basic research and clinical settings. The new device was concluded to be useful in maintaining a continuous set pressure reflecting its importance in clinical settings.

We defined the moments of measurement to be four hourly, with any intervention or change in position. The number of moments identified in each group did not vary. However, the significant difference in missed opportunities to measure cuff pressure—71 in Group A versus 36 in Group B—suggests that ease of use and time efficiency may directly impact adherence to monitoring protocols. Improved usability likely reduces cognitive and time burden on staff, thereby promoting more consistent implementation of best practices. Rose L *et al.*^[9], in their survey of cuff pressure management in critical care units of Australia and New Zealand, identified similar such moments across the units and the implementation was around 22%.

The results also demonstrated that Device B required significantly less time to measure cuff pressure compared to Device A. This is clinically relevant, as rapid and accurate cuff pressure assessment is critical for preventing complications such as tracheal injury or microaspiration due to under- or over-inflation. User preference data showed a statistically significant inclination toward Device B. The ease-of-use score was higher for Device B (mean \pm SD: 4.2 \pm 0.5) compared to Device A (3.5 \pm 0.3), further reinforcing user preference. These results align with findings from previous studies that report usability as a key determinant in the clinical

adoption of medical devices, particularly in high-stress environments such as intensive care units and emergency departments^[9-10].

Klonner *et al.*^[11] in his study assessed the performance of two disposable airway manometers for endotracheal tube cuff inflation in a benchtop model. Both of the tested devices presented cost-effective and accurate alternatives to commercial cuff manometers. A similar study to assess performance of the above two devices is required.

It was found that use of either device did not have significant difference in number of VAE in both the groups, suggesting minimal impact of the type of device used on VAE.

The findings support the potential integration of disposable, easy-to-use devices like Device B into routine airway management protocols. By improving usability and efficiency, such devices may contribute to better compliance with guideline-recommended practices, ultimately enhancing patient safety.

Conclusion

The study indicates the superiority of disposable unit over analogue device demonstrated by a significantly shorter measurement time, ease of usability bedside and hence strong preference by end- users. In any practical scenario a standard protocol is better implemented when the end-users have relative ease in adhering to the steps. Thus, disposable devices can be a part of standard monitoring care of intubated patients in critical settings ensuring safety and adequacy.

Limitations

This study did not evaluate long-term device durability or cost-effectiveness. Both are important for clinical decision-making especially in a resource limited set-up catering to high volume of critical patients. The cost burden per patient will increase with use of disposable device possibly offering lower advantage at being sacrificed to cover other costs.

Additionally, while user preference and ease of use were evaluated, objective accuracy comparisons using Bland-Altman analysis were not included here but are recommended in future studies. A benchtop model study is suggested to assess the performance of both the devices.

Declaration

Acknowledgements

None

Conflict of interest

None

Funding/ financial support

None

Ethical Clearance

IEC (Institutional Ethical Committee) no objection taken

Trial details

Not applicable

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