AccuCuff™ for continuous cuff pressure monitoring: results of a clinical trial

Utilização do AccuCuff™ para monitorização contínua da pressão do cuff: um ensaio clínico

Nathalia Prado de Melo *
Rayssa Bruna Holanda Lima
Maryelle Desirée Cardoso Daniel
Carmira Fernandes Jerônimo
Karla Luciana Magnani Seki

Universidade Federal de Mato Grosso do Sul (UFMS), Campo Grande, MS, Brazil

Date of first submission: March 11, 2024
Last received: July 3, 2025
Accepted: August 21, 2025
Associate editor: Aldo Fontes-Pereira

***Correspondence:** nmprado.nm@gmail.com

Abstract

Introduction: Mechanical ventilation is commonly used in patients with respiratory failure and delivered through an endotracheal tube. This tube includes an inflatable cuff that requires regular pressure monitoring to ensure adequate sealing between the tube and the trachea, thereby preventing air leaks and associated complications. **Objective:** To evaluate the use of a low-cost device for continuous cuff pressure monitoring and compare clinical outcomes. **Methods:** A randomized clinical trial was conducted in an adult intensive care unit with intubated patients who had been on mechanical ventilation for up to 48 hours. Patients were followed throughout the study according to group allocation. In the intervention group, cuff pressure was continuously monitored using the AccuCuff™ Cuff Pressure Indicator, while in the control group cuff pressure was intermittently measured with a handheld manometer, following standard care. **Results:** A total of 55 patients of both sexes were enrolled, 27 in the AccuCuff™ group and 28 in the standard care group. Baseline characteristics were similar between groups. Both groups experienced episodes of cuff pressure reduction, with comparable frequencies and no significant difference in the need for adjustments across time periods ($p = 0.307$). **Conclusion:** Continuous cuff pressure monitoring with AccuCuff™ is a viable alternative, providing measurements consistent with device specifications and facilitating bedside monitoring. Its use in the hospital setting may be beneficial, and implementing regular measurement intervals is recommended to prevent prolonged periods of low cuff pressure.

Keywords: Intensive care unit. Critical care. Mechanical ventilation.

Resumo

Introdução: *A ventilação mecânica é um recurso utilizado em pacientes com insuficiência respiratória, oferecido através de uma prótese ventilatória, que é composta pelo* cuff*, um balonete que necessita de aferição, responsável por vedar o espaço entre a prótese ventilatória e a traqueia, evitando complicações respiratórias ou vazamentos durante a ventilação.* ***Objetivo:*** *Analisar a utilização de um dispositivo de baixo custo para a monitorização contínua da pressão do* cuff *e comparar os desfechos clínicos.* ***Métodos****: Trata-se de um ensaio clínico randomizado, realizado em uma unidade de terapia intensiva adulta com pacientes intubados em ventilação mecânica em até 48 horas. Acompanhou-se os pacientes em todos os períodos, conforme sua alocação. O dispositivo AccuCuffT™ foi empregado para a mensuração contínua da pressão do* cuff*, sendo comparado aos cuidados convencionais, que utilizaram o cuffômetro como instrumento de avaliação.* ***Resultados:*** *Participaram do estudo 55 pacientes, de ambos os sexos, sendo 27 com o uso do AccuCuff™ e 28 no grupo de cuidados convencionais. Os resultados mostraram homogeneidade das características entre os grupos. Em relação ao comportamento da pressão do* cuff*, ambos os grupos tiveram somente ocorrência de queda de pressão, com porcentagem semelhante e sem diferença significativa em relação à necessidade de ajustes entre os períodos (p = 0,307).* ***Conclusão:*** *O dispositivo de mensuração contínua do* cuff *representa uma alternativa viável, por produzir valores em consonância com suas especificações e facilidade na monitorização, tornando-se uma alternativa dentro do ambiente hospitalar. Recomenda-se a implementação de intervalos regulares entre as mensurações para prevenir prolongados períodos de baixa pressão.*

Palavras-chave: *Unidade de terapia intensiva. Cuidados críticos. Ventilação mecânica.*

Introduction

Mechanical ventilation is widely used in hospitals to support gas exchange and improve respiratory function in patients with respiratory failure. Invasive mechanical ventilation is delivered by connecting a mechanical ventilator to the patient via an endotracheal tube (ETT) or a tracheostomy cannula.[1]

The cuff, an inflatable balloon located at the distal end of the ETT, seals the space between the tube and the trachea.[2] In intensive care unit (ICU) patients, cuff pressure is routinely monitored and maintained within the recommended range of 20-30 cmH_2O to prevent tracheal injury at higher pressures and air leaks at lower pressures. Excessive cuff pressure can cause tracheal wall ischemia, tracheomalacia, stenosis, and respiratory discomfort, while insufficient pressure can result in aspiration, inadequate ventilation due to leaks, and respiratory tract infections such as pneumonia.[3]

Cuff pressure is influenced by several factors, including patient repositioning, head and neck movement, bed bathing, and prone positioning, which was frequently applied during the SARS COV-2 pandemic.[4] These changes can compress or decompress the ETT, altering cuff pressure. Prompt measurement and adjustment by the care team are therefore essential.[5]

The optimal frequency of cuff pressure measurement remains uncertain. The Brazilian Thoracic Society[6] recommends at least four measurements per day or after procedures.[7] The gold standard is the handheld cuff pressure manometer, a portable device that measures and adjusts cuff pressure.[8] Although reliable, its use is limited by cost and the need for regular calibration.[3] A simpler and less costly alternative is manual inflation of the cuff with a syringe, but this method is inaccurate and considered subjective, making it unsuitable for clinical practice.[9] Despite advances in healthcare technology, evidence on cuff pressure monitoring in intensive care remains limited, with relatively few recent studies addressing the issue.[3] New technologies must therefore be evaluated for their potential to provide effective, low-cost, continuously monitored alternatives to streamline ICU workflows. This study aimed to assess the outcomes of continuous cuff pressure monitoring with a low-cost device in critically ill patients, and compare general data and clinical outcomes (hospital discharge or in-hospital mortality) between patients managed with AccuCuffTM and those receiving intermittent measurements with a handheld manometer, representing standard care.

Methods

This was a randomized clinical trial conducted in the Adult ICU of Associação Beneficente de Campo Grande – Santa Casa de Misericórdia, in Mato Gross do Sul state, Brazil, from June to August 2023, to evaluate the

effectiveness of the AccuCuff™ Cuff Pressure Indicator compared with a handheld manometer (standard care). The study was approved by the Research Ethics Committee of Santa Casa and the Teaching and Research Management Division (protocol number 5.920.934), under CAAE: 66977623.5.0000.0134.

Participants included critically ill patients admitted to the Neocritical ICU (15 beds) or General ICU (18 beds), who were placed under mechanical ventilation within 48 hours of admission. Patients ventilated for more than 48 hours were excluded to minimize bias related to delayed enrollment, which could affect sample reliability. Eligible patients required an ETT, were over 18 years old, and provided written informed consent through a legally authorized representative. Exclusion criteria were patients requiring cuff pressures above the normal range due to suspected tracheomalacia, ETT replacement, or those experiencing accidental extubation.

Prior to data collection, a bench test was performed with the AccuCuff™ to evaluate its functionality. The device was connected to a three-way stopcock, an ETT, and a cuff manometer. Inflation was performed using a syringe, allowing the cuff to be pressurized via the device's continuous monitoring system. During testing, the device's color-coded visual indicator was compared with the values displayed on the cuff manometer. When the marker was within the green zone, it corresponded to the target range of 20-30 cmH_2O on the manometer (Figure 1).

After enrollment, demographic and clinical data were collected, including sex, age, primary diagnosis, attending medical specialty, disease severity according to the Acute Physiology and Chronic Health Evaluation II (APACHE II) score, and ICU outcome (hospital discharge or death), to characterize the sample and support statistical analysis.

The study sample was divided into two groups by random allocation using concealment procedures. Randomization was performed at the start of the project using Matlab v.7.2 software, with participants allocated to two groups: the standard care group (SCG) and Accu Cuff™ group (ACG). The program used a random binary generator to create a numeric vector that determined participant allocation to the two study groups. Allocations were concealed in sealed, sequentially numbered envelopes, and the groups were monitored using a standardized data collection instrument.

Figure 1 - Bench test of the continuous cuff pressure monitoring device (AccuCuff™ Cuff Pressure Indicator) connected to a conventional handheld cuff pressure manometer via a three-way stopcock.

The AccuCuff™, manufactured by Medis Medical Tianjin Company Ltd., is a single-use, disposable device designed for continuous cuff pressure monitoring. It remains connected to the external inflation line for up to 24 hours and is intended for up to 29 days of use. Pressure adjustments can be made rapidly and easily with a syringe. The device features a silicone interface that connects to the external pilot ballon of the ETT or tracheostomy tube, while the opposite end provides a port for syringe connection for verification with a cuff pressure manometer. It uses a three-zone color system: green (target range, correct pressure), black (below recommended pressure, risk of air leak), and red (above recommended pressure, risk of tracheal injury). The devices used in this study were supplied by Cirúrgica Fernandes.

The ACG was assessed during three time periods. In the morning, cuff pressure was measured using a Portex® analog cuff pressure manometer, which was connected to the AccuCuff™ device to quantitatively verify the accuracy of the color-coded indicator. In the afternoon and at night, cuff pressure was assessed by visually inspecting the indicator and adjusted with a syringe if the indicator was outside the target range. The indicator reading was recorded at each time point. For both groups, each measurement was classified as adequate (20-30 cmH_2O), low (< 20 cmH_2O) or high (> 30 cmH_2O).[3]

In the SCG, cuff pressure was monitored three times daily (morning, afternoon, and night) with a handheld manometer connected to the pilot balloon of the ETT. The device includes a unidirectional valve for cuff inflation and deflation, as well as a manual pump for measurement. In the ACG, cuff pressure was adjusted using a syringe in the afternoon and night periods, or as needed, to assess the effectiveness and practicality of this method within the hospital routine and determine its feasibility. By contrast, the SCG relied on a handheld manometer, consistent with the institutional protocol for standard practice. At the time of measurement, patients in both groups were placed in the supine position, with the head of the bed elevated to 30° and the cervical spine in a neutral position.

Statistical analysis included both descriptive and inferential approaches. Descriptive statistics were expressed as absolute and relative frequencies and mean ± standard deviation. Data normality was assessed using the Shapiro-Wilk test to determine the appropriate statistical tests. For each group, the total number of cuff pressure measurements per period (absolute), the mean and proportion of adequate measurements (relative), and the scheduled monitoring checks were calculated.

Group comparisons for general variables such as age, APACHE II score, attending medical specialty, ICU outcome (discharge or death), duration of mechanical ventilation, and length of ICU stay were performed using the unpaired Student's t-test and Fisher's exact test, as appropriate.

The number of cuff pressure adjustments performed in both groups across the three time periods (morning, afternoon, and night) was expressed as mean ± standard deviation and analyzed using two-way repeated measures ANOVA followed by Tukey's post hoc test. All inferential statistical analyses were performed using Graphpad Prism (version 6.0), with a 5% significance level.

Results

During data collection, 116 patients were screened for eligibility upon admission to the ICU. Of these, 49 did not meet the inclusion criteria and 12 were excluded. As shown in Figure 2, 55 patients were included in the study, with 27 allocated to the ACG and 28 to the SCG.

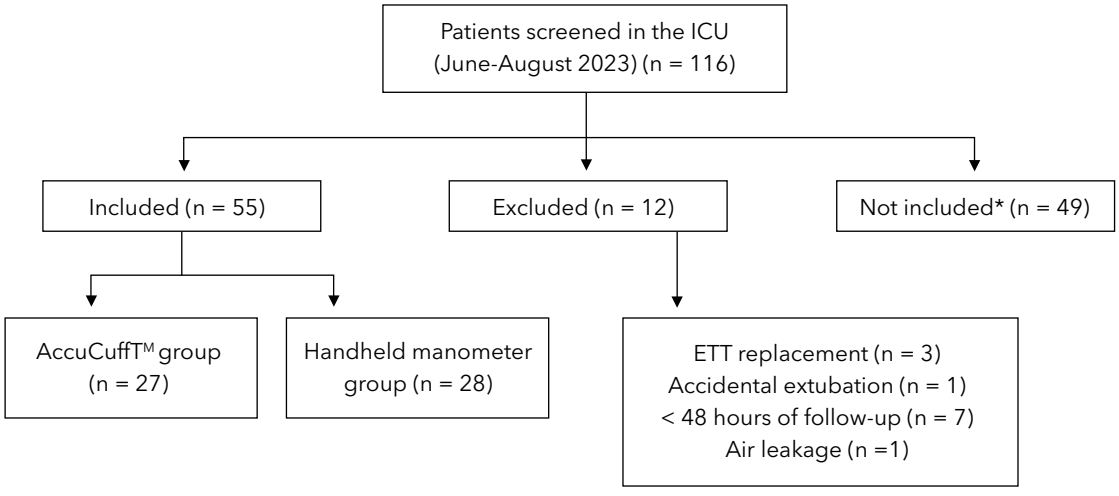

Figure 2 - Participant flow diagram.

Note: *Did not meet the criteria. ICU = intensive care unit; ETT = endotracheal tube.

Table 1 presents the baseline characteristics and general information of the study population. Most participants were men, and the main reason for ICU admission was neurological conditions. Both groups were homogeneous, with no statistically significant differences in the variables analyzed.

Cuff pressure management in both groups was qualitatively analyzed based on cuff pressure behavior. The need for pressure adjustment was more pronounced in the morning, and all adjustments were due to decreases in cuff pressure. In the remaining time periods (afternoon and night), only occasional adjustments were needed, prompted by cuff pressure reductions observed via the device's color-coded indicator or the presence of air leaks.

In the SCG, measurements were performed according to the hospital ICU safety protocol, which requires one cuff pressure check and adjustment per period, with additional assessments whenever the staff identified irregularities and notified the clinician responsible.

Table 2 shows the total number of adjustments performed across the three time periods, as well as those specifically attributable to cuff pressure reductions.

In the ACG, 67% of morning cuff pressure adjustments were prompted by low pressures detected with the cuff manometer. Adjustment rates decreased to 28% in the afternoon and 21% at night, when the indicator showed pressures below the green zone or in the presence of air leaks.

Rates in the SCG were 48% in the morning, 35% in the afternoon, and 21% at night, with adjustments made after cuff manometer measurements identified pressures below the recommended range.

Overall, there were no significant intragroup differences in the need for cuff pressure adjustments across the three time periods. However, a time-dependent difference was observed between the SCG morning and ACG night periods ($p < 0.05$, post hoc analysis), reflecting the distinct pressure management strategies applied in the study protocol.

Table 1 - Baseline characteristics of the study population by group

Variable	ACG (n = 27)	SCG (n = 28)	p-value
Sex*			
Men	20 (74.0)	22 (78.5)	0.758
Women	7 (26.0)	6 (21.5)	
Age (years)*	52.0 ± 19.0	50.5 ± 19.5	0.785
APACHE II (points)**	25.5 ± 5.0	23.0 ± 6.5	0.181
ICU length of stay (days)**	11.5 ± 6.5	10.0 ± 5.0	0.290
IMV duration (days)**	6.0 ± 2.5	6.5 ± 3.0	0.543
ICU outcome*			
Discharge	22 (81.5)	21 (75.0)	0.745
Death	5 (18.5)	7 (25.0)	
Reason for admission*			
Neurology	16 (52.0)	21 (75.0)	-
Vascular	3 (14.0)	1 (3.5)	-
General medicine	2 (12.0)	1 (3.5)	-
Plastic surgery	4 (15.0)	4 (14.5)	-
Urology	-	1 (3.5)	-
Orthopedics	-	1 (3.5)	-
Gynecology	-	1 (3.5)	-
Cardiology	-	1 (3.5)	-

Note: *Data expressed as absolute (relative) frequency; Fisher's exact test. **Data expressed as mean ± standard deviation; unpaired Student's t-test. ACG = AccuCuff™ group; SCG = standard care group; ICU = intensive care unit; IMV = invasive mechanical ventilation.

Table 2 - Cuff pressure adjustments

Groups	Time period			p-value		
	Morning	Afternoon	Night	Group	Time	Interaction
ACG	3.7 ± 2.3	3.7 ± 1.4	0.9 ± 0.8	0.307	0.012	0.615
SCG	5.7 ± 9.2	3.5 ± 9.2	1.9 ± 5.0			

Note: Data are expressed as mean ± standard deviation. p-value for the independent factors. Two-way repeated measures ANOVA with Tukey's post hoc test. ACG = AccuCuff™ group; SCG = standard care group.

Discussion

This study evaluated the use of a continuous cuff pressure monitoring device in an ICU setting, highlighting the importance of maintaining adequate cuff pressure for safer ventilation and fewer complications. The Accucuff™ proved to be a reliable and easily applicable alternative in the hospital setting.

Duarte et al.[10] found that more than 80% of ETT cuffs were underinflated, consistent with the results of the present study, and underscored the need for continuing education and objective measurement methods to ensure safe and consistent care.

Our results showed episodes of suboptimal cuff pressure in both groups studied, likely due to routine bedside activities such as bathing and patient repositioning, which directly affect cuff pressure.[11] Conversely, Yurtlu et al.[12] reported that anesthesiologists often inflated cuffs above recommended levels before procedures. This discrepancy illustrates how both underinflation and overinflation remain common in clinical practice, reflecting the limitations of subjective cuff pressure measurement and the need for standardized training and monitoring strategies.

Although the cuff manometer is considered the gold standard for cuff pressure management, its high cost, need for regular calibration and maintenance, and limited availability in many ICUs restrict its use.[3,13] Moreover, air leakage during device connection or disconnection can lead to unintended reductions in balloon pressure, even when initially adjusted to appropriate levels.[10] Another critical aspect of continuous cuff pressure monitoring is the potential to reduce healthcare-associated infections. However, reusing devices across patients without strict disinfection protocols may increase the risk of infection.[14]

The multidisciplinary team of physical therapists, nurses, nursing technicians, and physicians were actively engaged in monitoring the Accucuff™ indicator during data collection, which enabled timely detection of pressure deviations and corrective action when necessary. This engagement is particularly relevant in the ICU, where many professionals lack adequate awareness and training in cuff pressure management. Providing targeted education and structured training for staff can reduce inappropriate adjustments and ensure safer outcomes for patients.[15]

Furthermore, establishing structured routines through institutional protocols is essential to prevent complications during cuff pressure measurement in hospital settings. Juliano et al.[13] reported irregular measurements in ICUs, highlighting the need for standardized monitoring to minimize risks.

Although the study protocol for the Accucuff™ proposed only one scheduled adjustment per period, not all the patients required adjustments within 24h. In some cases, the device indicator remained in the green zone, with the cuff manometer confirming adequate pressure, while in others, adjustments were needed within 24h or during the day, when the indicator approached the lower limit of the green zone or dropped below it. Although the AccuCuffT™ manual[16] states that the indicator should remain in the green zone, these observations suggest that positioning it closer to the upper limit of the zone may help prevent pressures below the recommended range.

This study has several limitations that should be acknowledged. It was not possible to determine whether continuous cuff pressure control reduces ventilator-associated pneumonia (VAP) rates, since VAP prevention involves multiple elements beyond cuff pressure monitoring, making it difficult to attribute effects to a single intervention.

Future studies should explore the use of this device in other settings, such as general wards and home care, particularly for tracheostomized patients. Despite these limitations, this research is pioneering in evaluating the AccuCuff™ in the intensive care context.

Conclusion

The AccuCuff™ device is a viable, low-cost alternative for continuous cuff pressure monitoring, providing measurements consistent with its specifications and facilitating routine surveillance. It also enables active participation of the entire care team in cuff pressure management, making it a practical option in the ICU. Regular monitoring intervals, including during nighttime, are recommended to prevent prolonged periods of low cuff pressure.

The authors acknowledge that this study involved the use of the AccuCuff™ device, manufactured by Cirúrgica Fernandes. Considering the study design and the potential relationship between researchers and the manufacturer, a potential conflict of interest is recognized.

Authors' contributions

NPM was responsible for the study design, data tabulation, and drafting the manuscript. RBHL contributed to the methodological review and statistical analysis. MDCD and CFJ contributed to the study design and field data collection. KLMS was responsible for overall supervision and reviewing the manuscript.

Data availability statement

Research data is not available.

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