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Original Research Article

Validation of a novel syringe based monitor (AG CUFFILL) for measurement of endotracheal tube cuff pressure in adult patients

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Abstract

Background: Accurate measurement of endotracheal tube (ETT) cuff pressure is essential to prevent complications from under- or over-inflation. Conventional aneroid manometers are considered the gold standard but are limited by cost, bulk, and availability. The AG CUFFILL is a novel syringe-based device that allows simultaneous cuff inflation and digital pressure display. This study aimed to validate AG CUFFILL against the standard aneroid manometer in adult patients.

Materials and Methods: This prospective observational study included 85 adult patients undergoing elective surgery under general anesthesia with cuffed ETTs. After intubation, cuff pressure was measured sequentially with an aneroid manometer and AG CUFFILL using a three-way stopcock. Demographic and clinical data were recorded. Agreement between devices was analysed using paired t-test, Pearson correlation, and Bland–Altman analysis. A p-value <0.05 was considered statistically significant.

Results: The mean cuff pressure measured by AG CUFFILL (37.43 ± 13.38 cm H_2O) was comparable to that measured by the aneroid manometer (37.08 ± 13.05 cm H_2O), with no statistically significant difference ($p = 0.254$). A very strong positive correlation was observed between devices ($r = 0.979$, $p < 0.001$). Bland–Altman analysis showed minimal bias (–0.35 cm H_2O) and most measurements lay within limits of agreement, confirming good concordance.

Conclusion: AG CUFFILL demonstrated excellent agreement with the aneroid manometer for ETT cuff pressure measurement and represents a reliable, portable, and user-friendly alternative for routine clinical use, particularly in resource-limited or high-volume settings.

Keywords: Endotracheal tube, Cuff pressure, AG CUFFILL, Airway monitoring.

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1. Introduction

Endotracheal intubation with cuffed endotracheal tubes (ETTs) is an integral component of airway management during general anesthesia and critical care.[1] Inflation of the low-pressure, high-volume cuff near the distal tip of the ETT creates an effective seal that facilitates positive pressure ventilation while reducing the risk of aspiration.[2] However, both under-inflation and over-inflation of the cuff may have adverse consequences. Insufficient cuff pressure can result in inadequate sealing and micro-aspiration, whereas excessive inflation has been linked to postoperative sore throat, tracheal mucosal ischemia, rupture, and long-term complications such as subglottic stenosis.[3,4] Current guidelines recommend maintaining cuff pressure within a safe range of 20–30 cm H_2O to minimize these risks.[5,6]

Although the aneroid manometer is considered the gold standard for intermittent cuff pressure monitoring, its routine clinical use remains limited due to its cost, bulky design, and the additional time required during intraoperative care.[7] In

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recent years, the increasing use of cuffed ETTs in both adults and children has drawn greater attention to the necessity of cuff pressure monitoring.[8,9] This renewed focus has driven the search for simpler, more portable alternatives that could allow wider implementation of safe airway practices.

The AG CUFFILL device is a novel syringe-based system designed to both inflate the ETT cuff and simultaneously display its pressure digitally.[10] Its compact design, ease of use, and quick readout make it a practical bedside alternative to conventional manometers, particularly in resource-limited settings. Additionally, the disposable nature of the device reduces the risk of cross-contamination. [11] While earlier study suggests promising accuracy, there is limited data directly comparing the AG CUFFILL with the standard aneroid manometer in routine clinical practice.[10]

We hypothesized that the AG CUFFILL device would demonstrate a high degree of agreement with the aneroid manometer for measuring ETT cuff pressure. Therefore, this randomized controlled trial was conducted to evaluate the agreement and correlation between the AG CUFFILL device and the standard aneroid manometer for measuring intracuff pressure in adult patients undergoing general anesthesia.

2. Materials and Methods

This prospective observational study was conducted at a tertiary care centre, between January 2023 and June 2024, following approval from the Institutional Ethics and Research Committee [EC/NEW/INST/1527/2022/11/36]. A total of 85 consecutive adult patients scheduled for elective surgery under general anesthesia with oral endotracheal intubation using cuffed tubes (internal diameter 7.0–8.5 mm) were enrolled. Patients with cuffed tracheostomy tubes were excluded.

Sample size was determined based on the findings of Vijayakumar V. et al., who reported mean cuff pressures of 36.29 ± 6.36 cm H_2O using AG CUFFILL and 33.97 ± 6.16 cm H_2O using PORTEX, with a mean difference of 2.67 cm H_2O. [10] The minimum required sample was calculated as 43 patients for a paired design at 95% confidence and 80% power. To improve the precision of Bland–Altman analysis and enhance reliability, we recruited 85 patients, each of whom underwent measurement with both devices.

After standard anesthetic induction and endotracheal intubation, the endotracheal tube cuff was inflated by the attending anaesthetist using routine clinical practice, namely the subjective technique of digital palpation of the pilot balloon. A three-way stopcock was then connected to the pilot balloon port. Patients were randomly assigned to one of two measurement sequences using computer-generated random numbers: initial measurement with the aneroid manometer (Ambu) followed by the AG CUFFILL device, or the reverse sequence. The attending anaesthetist responsible for the case was blinded to all cuff pressure readings from the study devices to avoid bias, while a separate investigating researcher recorded the measurements. The initial cuff pressure measured in this study represented the pressure set by the anaesthetist using routine clinical practice before any adjustment to the target range of 24–26 cm H_2O was made; these baseline measurements were recorded for the primary comparison between devices.

For each patient, the intracuff pressure in cm H_2O was recorded from both the aneroid manometer and the AG CUFFILL device according to the randomized sequence. The volume of air in milliliters present in the cuff at the time of this initial measurement was also noted. If the initial pressures were found to be outside the target range, specifically exceeding 28 cm H_2O or below 22 cm H_2O, correction was performed using the AG CUFFILL device only after both initial measurements were complete, and the additional volume of air required to achieve the target pressure was recorded.

All data, including demographic and clinical variables, were entered into a structured proforma. Statistical analysis was performed using SPSS version 26. This involved descriptive reporting of cuff pressures and a comparison of values obtained by both devices using a paired t-test. The agreement between the two methods was assessed using Bland-Altman analysis to estimate the bias, precision, and limits of agreement, with a p-value of less than 0.05 considered statistically significant.

3. Results

The study population comprised 85 patients with a mean age of 42.6 ± 12.4 years. Males constituted a slightly higher proportion (54.1%) compared to females (45.9%). The average weight and height were 64.8 ± 11.3 kg and 162.7 ± 9.8 cm, respectively. Most patients were classified as ASA physical status I (67.1%), while the remaining 32.9% were ASA II (**Table 1**).

Table 1: Demographic characteristics of the study population (N = 85)

Variable	Mean ± SD / n (%)
Age (years)	42.6 ± 12.4
Sex (Male/Female)	46 (54.1%) / 39 (45.9%)
Weight (kg)	64.8 ± 11.3
Height (cm)	162.7 ± 9.8
ASA Physical Status (I / II)	57 (67.1%) / 28 (32.9%)

The analysis of endotracheal tube cuff pressures revealed a high degree of concordance between the novel AG CUFFILL device and the standard aneroid manometer. The mean cuff pressure measured by the AG CUFFILL device was 37.43 ± 13.38 cm H_2O, which was not significantly different from the mean pressure of 37.08 ± 13.05 cm H_2O recorded with the aneroid manometer ($p = 0.254$), with a mean difference of -0.35 cm H_2O (**Table 2**).

Table 2: Comparison of endotracheal tube cuff pressure between AG CUFFILL and aneroid manometer

Variable	Mean ± SD (cm H_2O)	t-value	p-value
AG CUFFILL	37.43 ± 13.38	0.51	0.254
Aneroid Manometer	37.08 ± 13.05		
Mean Difference	–0.35		

A strong positive correlation was found between the cuff pressure values obtained by the two methods ($r = 0.979$, $p < 0.001$), suggesting excellent consistency in their measurements (**Table 3**).

Table 3: Correlation between measurements of aneroid manometer and AG CUFFILL

Pair	Correlation (r)	p-value
Aneroid Manometer vs. AG CUFFILL	0.979	<0.001

Agreement between the two devices was further quantified using Bland-Altman analysis (**Figure 1**). The mean bias was -0.35 cm H_2O, with 95% limits of agreement ranging from -3.82 cm H_2O to +3.12 cm H_2O. This narrow range indicates that the differences between the two devices for most measurements were within a clinically acceptable margin. The Bland–Altman analysis demonstrated that the majority of data points lay within the limits of agreement (±2 SD), further supporting the reliability of AG CUFFILL in comparison with the Aneroid Manometer (**Figure 1**).

Beyond the device comparison, a critical finding was that the mean cuff pressures recorded by both devices were approximately 37 cm H_2O, which is substantially above the recommended safe range of 20–30 cm H_2O. This consistently elevated pressure across the cohort highlights a prevalent issue of cuff over-inflation during routine clinical practice when the initial setting is based on subjective palpation.

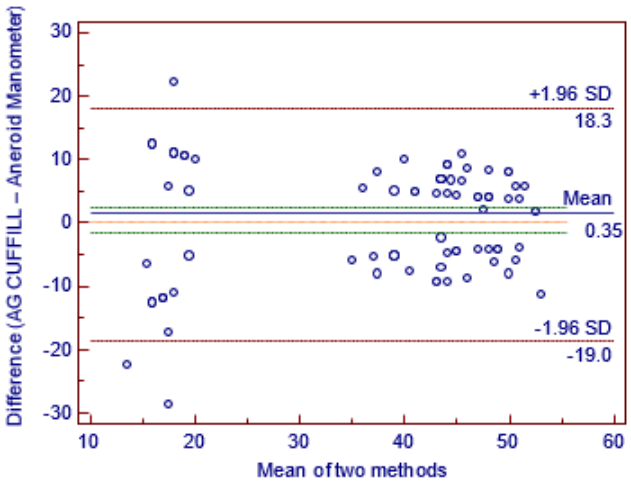

Figure 1: Bland–altman plot

4. Discussion

Maintaining endotracheal tube (ETT) cuff pressure within the recommended safe range of 20–30 cm H2O is crucial for preventing both under- and over-inflation–related complications.[6] Caring for patients in the perioperative setting frequently entails the placement of an airway device, a procedure that carries several potential complications, including postoperative sore throat (POST), hoarseness of voice (HOV), dysphagia, and, in rare cases, serious events such as tracheal rupture.[8] It is therefore essential for every physician performing intubation to be aware of these risks and the potentially severe consequences of tracheal rupture.[9] Impairment of tracheal mucosal blood flow is a key factor contributing to tracheal morbidity following intubation.[10] Several studies suggest that POST following GA with Supraglottic Airway Device (SAD) is observed more often in women than in men, and there are multiple risk factors involved in its development, with cuff pressure being one of the most critical.[12-14] Leakage of colonized subglottic secretions around the ETT cuff remains the most significant risk factor for pneumonia within the first eight days of intubation.[15] Despite these well-documented risks, routine cuff pressure monitoring is still frequently neglected in clinical practice, particularly in resource-limited settings where conventional manometers may not be readily available.

Also, in routine clinical practice, the initial inflation of the endotracheal tube cuff is frequently guided by subjective techniques, such as digital palpation of the pilot balloon or volume estimation, which are notoriously inaccurate and have a well-documented tendency towards overinflation.[12] This widespread reliance on imprecise methods underscores the critical importance of objective monitoring to ensure patient safety.

In the present study, we evaluated the performance of the novel syringe-based AG CUFFILL device against the conventional aneroid manometer. Our results demonstrate that the AG CUFFILL provides measurements comparable to this gold standard. The mean cuff pressures recorded by the two devices were nearly identical (37.43 ± 13.38 cm H_2O vs. 37.08 ± 13.05 cm H_2O), with a minimal and statistically non-significant mean difference of –0.35 cm H_2O ($p = 0.254$). This excellent agreement was further confirmed by a very strong positive correlation ($r = 0.979$, $p < 0.001$) and Bland-Altman analysis, collectively affirming that this syringe-based system is a reliable tool for routine clinical use.

Our findings are consistent with and reinforce the growing body of evidence supporting the use of innovative cuff pressure monitors. The results align closely with those of Vijayakumar et al., who also evaluated the AG CUFFILL device and reported a mean difference of 2.67 cm H_2O compared to a PORTEX manometer.[10] While the mean difference in our study was smaller (–0.35 cm H_2O), both values fall within a clinically acceptable range, collectively

affirming the device's accuracy. Furthermore, the very strong correlation we observed ($r = 0.979$, $p < 0.001$) is comparable to the excellent linear correlation (0.9989) reported by Ramesh et al. in their validation of a similar syringe-based monitor.[14] These consistent results across independent studies strengthen the proposition that such devices are not merely experimental but are reliable, portable, and affordable alternatives to conventional manometers. By corroborating these key metrics of agreement and precision, our study adds substantial weight to the argument for integrating syringe-based systems like the AG CUFFILL into real-world perioperative settings to bridge the gap between guideline recommendations and clinical practice.

A highly significant finding of this study was that the mean cuff pressures measured by both devices were approximately 37 cm H_2O, a value consistently above the recommended safe range of 20–30 cm H_2O.[15,16] This demonstrates a critical issue of routine cuff overinflation in clinical practice, which likely occurs due to the common reliance on inaccurate subjective inflation methods. This practice exposes patients to an elevated risk of complications such as tracheal mucosal injury, postoperative sore throat, and hoarseness. Our results strongly affirm the necessity of routine objective cuff pressure monitoring to prevent these adverse outcomes.

The AG CUFFILL device is well-suited to address this clinical need. Its practical advantages over conventional manometers include a compact, lightweight, and disposable design, which reduces the risk of cross-contamination and eliminates the storage and cleaning issues associated with bulky equipment.[7] Furthermore, its dual function—allowing for both cuff inflation and pressure measurement in a single step—simplifies the workflow for the clinician.[10] This integrated design is particularly beneficial in high-volume operating rooms, ICUs, and resource-limited settings where efficiency and portability are crucial for consistent and safe airway management

This study had several limitations that should be considered. As a single-center investigation with a specific patient cohort, the generalizability of our findings to other populations, such as pediatric patients or those requiring prolonged intubation in the ICU, may be limited. Moreover, our study design focused on validating the device through intermittent pressure measurements; we did not evaluate its role in continuous monitoring, which may offer additional benefits in preventing micro aspiration. Finally, while we established the device's accuracy, this study did not assess patient-centered outcomes such as postoperative sore throat or hoarseness. Future research should directly investigate whether the routine use of the AG CUFFILL device leads to a measurable reduction in these clinically important complications, which would provide the most compelling evidence for its widespread adoption.

5. Conclusion

The AG CUFFILL device demonstrated excellent agreement with the aneroid manometer for measuring endotracheal tube cuff pressure. The minimal bias, strong correlation, and narrow limits of agreement confirm its reliability. Its compact, user-friendly design offers a practical alternative for routine monitoring. By providing an accurate and practical solution to the prevalent issue of cuff over-inflation, the AG CUFFILL device represents a significant step toward enhancing patient safety in airway management.

6. Source of Funding

None

7. Conflict of Interest

None declared.

8. Author Contributions

All authors contributed substantially to the conception and design of the study. Material preparation, data collection, and analysis were performed by K.S., M.S., S.R., and P.S.C. The first draft of the manuscript was written by K.S. and S.R., and all authors critically reviewed and revised previous versions of the manuscript. R.S.S., A.M., and S.J. provided overall supervision, and guidance. All authors read and approved the final manuscript.

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References

1. Sharma S, Mehta N, Charak DS. Comparative evaluation of airway assessment tests and their correlation with laryngoscopy. *Indian J Clin Anaesth.* 2015;2(1):19–26.
2. Mariyaselvam MZ, Marsh LL, Bamford S, Smith A, Wise MP, Williams DW. Endotracheal tubes and fluid aspiration: an in vitro evaluation of new cuff technologies. *BMC Anesthesiol.* 2017;17(1):36. https://doi.org/10.1186/s12871-017-0328-0.
3. Balakrishnan S, Jacob KK. Cuff pressure manometer - a luxury or necessity?. *Indian J Clin Anaesth.* 2016;3(4):588–92. https://doi.org/10.18231/2394-4994.2016.0019
4. Sultan P, Carvalho B, Rose BO, Cregg R. Endotracheal tube cuff pressure monitoring: a review of the evidence. *J Perioper Pract.* 2011;21(11):379–86. https://doi.org/10.1177/175045891102101103.
5. Lavanya PVS, Ganesh MV, Lakshmi AS. Assessment of endotracheal tube cuff pressure: finger pressure technique versus minimum leak technique. *Asian J Pharm Clin Res.* 2022;15(3):108–12. https://doi.org/10.22159/ajpcr.2022.v15i3.44095
6. Das S, Kumar P. Comparison of minimal leak test and manual cuff pressure measurement technique method for inflating the endotracheal tube cuff. *Indian J Clin Anaesth.* 2015;2(2):78–81.
7. Kumar AA. Endotracheal Cuff-pressure Monitoring in ICU: A standard of care yet to be standardized, and often neglected. *Indian J Crit Care Med.* 2024;28(1):8–10. https://doi.org/10.5005/jp-journals-10071-24624
8. Chen Z, Zuo Z, Zhang L, Gong M, Ye Y, Jin Y, et al. Postoperative sore throat after tracheal intubation: An updated narrative review

and call for action. *J Pain Res.* 2025;18:2285–2306. https://doi.org/10.2147/JPR.S498933

9. Chauhan P, Punera DC, Palaria U, Joshi KN. Changes in endotracheal tube cuff pressure during the open and laparoscopic surgery. *Indian J Clin Anaesth*. 2020;7(3):526–32. https://doi .org/10.18231/j.ijca.2020.093.
10. Vijayakumar V, Singla B, Shetti AN. To study the efficacy of AG CUFFILL (Digital) compared to that of standard PORTEX cuff inflator/pressure analog gauge for the measurement of endotracheal tube cuff pressure. *Int J Pharm Chem Anal.* 2022;9(2):105–8. https://doi.org/10.18231/j.ijpca.2022.017.
11. Hung WC, Ko JC, Weil AB, Weng HY. Evaluation of endotracheal tube cuff pressure and the use of three cuff inflation syringe devices in dogs. *Front Vet Sci.* 2020;7:39. https://doi.org/10.3389 /fvets.2020.00039.
12. Feng TR, Ye Y, Doyle DJ. Critical importance of tracheal tube cuff pressure management. *World J Anesthesiol.* 2015;4(2):10–2. https://doi.org/10.5313/wja.v4.i2.10
13. Athiraman U, Gupta R, Singh G. Endotracheal cuff pressure changes with change in position in neurosurgical patients. *Int J Crit Illn Inj* Sci. 2015;5(4): 237–41. https://doi.org/10.4103/2229-5151.170841.
14. Ramesh AS, Krishna SG, Denman WT, Tobias JD. An in vitro and in vivo validation of a novel monitor for intracuff pressure in cuffed endotracheal tubes. *Paediatr Anaesth.* 2014;24(9):1005–8. https://doi.org/10.1111/pan.12498.
15. Sengupta P, Sessler DI, Maglinger P, Wells S, Vogt A, Durrani J, Wadhwa A. Endotracheal tube cuff pressure in three hospitals, and the volume required to produce an appropriate cuff pressure. *BMC Anesthesiol*. 2004;4(1):8. https://doi.org/10.1186/1471-2253-4-8.
16. Mu G, Wang F, Li Q, Yu X, Lu B. Reevaluating 30 cmH2O endotracheal tube cuff pressure: risks of airway mucosal damage during prolonged mechanical ventilation. *Front Med (Lausanne).* 2024; 11:1468310. https://doi.org/10.3389/fmed.2024.1468310.

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