Online version at https://www.minervamedica.it
Minerva Anestesiologica 2022 mese;88(0):000–000
DOI: 10.23736/S0375-9393.22.16948-8

Tracheal cuff pressure control in intubated young children: a randomized crossover trial of two cuff-pressure regulators

Use of an endotracheal cuff is recommended for children receiving invasive mechanical ventilation in the pediatric Intensive Care Unit (PICU), with the exception of premature newborns.[1] To avoid intubation-related complications such as micro-aspiration and tracheal ischemia, cuff-pressure (P*cuff*) is monitored closely to ensure that the value does not exceed 25 cmH_2O.[1,2] P*cuff* can be adjusted manually via a manometer or automatically by an electronic or pneumatic regulator, which are used indifferently in PICU.[3] We previously demonstrated that pneumatic regulators were superior over manual adjustment in children weighing less than 15 kg.[4] However, no studies have compared the effectiveness of an electronic vs. a pneumatic regulator in continously maintaining P*cuff* within the desired range in pediatric patients. We therefore compared P*cuff* variability over time with an electronic device and a pneumatic device in children younger than five years. This randomized crossover open-label study in the PICU of the Robert Debré University Hospital in Paris, France, was approved by an independent ethics committee (CPP Sud Est III:2019-068B). Written consent was obtained from both parents before enrollment. Consecutive patients younger than five years of age and ventilated through an endotracheal tube equipped with a cylindrical cuff (Shiley™ Cuffed Basic Endotracheal Tube, Covidien, Dublin, Ireland) were eligible if expected to require mechanical ventilation (MV) for at least 24 hours. We did not include children who had a tracheostomy, were born prematurely, or were receiving neuromuscular blocking agents. After intubation, the initial P*cuff* was the lowest pressure (always <25 cmH_2O) required to eliminate leakage around the tube, measured by the ventilator. After enrollment, each patient had two consecutive six-hour periods of continous P*cuff* control by an electronic device (Mallinkrodt®, VBM Medizintechnik GmbH, Sulz am Neckar, Germany) and a pneumatic device (Nosten2®, Leved, Paris, France), in random order. The two periods were separated by a 30-minute washout. For randomization, a computer-generated random-assignment list in balanced blocks of four was used. The cuff was connected to the regulator *via* a three-way valve, which served to set the initial P*cuff* and to switch between the two devices without deflating the cuff. The P*cuff* signal was digitised and recorded at a frequency of 100 Hz by dedicated software (LabVIEW, National Instruments, Austin, TX, USA). The software simultaneously recorded the airway pressure transmitted by the ventilator to the Recommended Stardard-232 output link, in accordance with the MEDIBUS protocol supplied by the manufacturer (Protocol Definition, RS-232, MEDIBUS v6.0, Dräger, Lübeck, Germany). P*cuff* and airway pressure measured by the ventilator were recorded continuously. The primary outcome was the percentage of time spent with cuff under- or overinflation, defined as a greater than 15% change from the initial P*cuff*. The secondary outcome was the coefficient of variation of P*cuff* calculated as standard deviation/mean P*cuff* ×100. Device convenience was assessed by a nurse using a Likert Scale. No pediatric studies have evaluated the effect of an electronic device on the percentage of time spent with under-or overinflation of the cuff. Therefore, we assume that the percentage of time spent with over- or underinflation would differ between the two devices by 15%. When we took in account the crossover design 37 patients would be required to provide 95% power for detecting a 15% difference. Quantitative variables were described as medians [1st–3rd quartiles] and qualitative variables as number [%]. Outcomes were compared using a mixed linear model with adjustment for the period effect (R version 4.0.3; R Foundation for Statistical Computing, Vienna, Austria). Significance was set at P<0.05. From August 2020 to April 2021, we included 38 patients with median age and weight of 7.9 [2.4-25.2] months and 8.1 [5.5-12.0] kg, respectively. The most common reasons for admission were respiratory failure (44.7%) and hemodynamic failure/shock (18.4%). Their PIM-2 and PELOD-2 scores on admission were 3.45% [1.6-13.2] and 1.4% [0.6-2.2], respectively. Total duration of MV was 4.2 days [2.9-5.9] with a median length of PICU stay of 8.0 days [5.0-14.0]. Diameters of the cylindrical cuffs ranged from 3 to 5 mm. Median P*cuff* with the electronic and pneumatic devices was 12.0 cmH_2O [11.3-13.5] and 13.3 cmH_2O [12.3-14.9], respectively. The percentage of time with under- or overinflation was not different between the electronic and pneumatic devices (0.01% [0.00-0.35] and 0.00% [0.00-0.00], respectively; (P=0.754). No significant interaction was found between the study period and the assigned treatment (P=0.97). The P*cuff* coefficient of variation was higher with the electronic than with the pneumatic de-

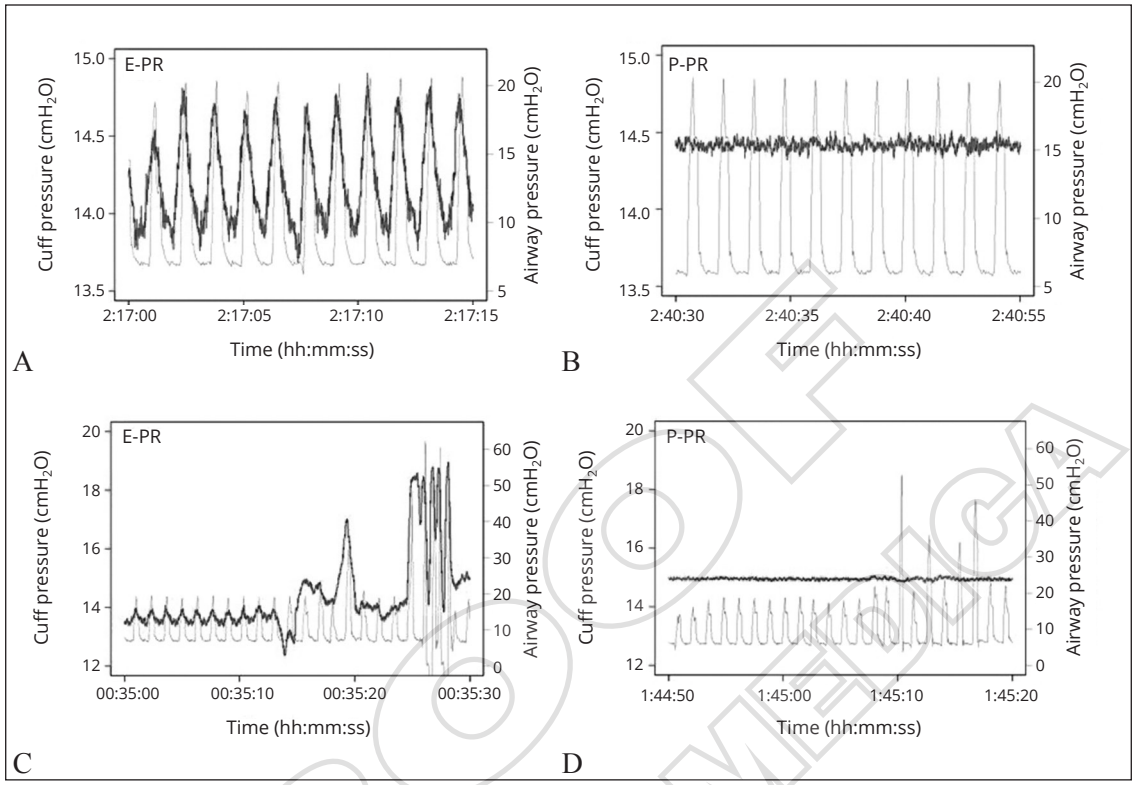

Figure 1.—Example of cuff pressure (dark gray; red in the online version) and airway pressure (light grey) in a 32-month-old patient. The cuffed endotracheal tube was connected to: A) an electronic cuff-pressure regulator (E-PR); or B) to a pneumatic cuff-pressure regulator (P-PR). Example of cuff pressure during periods of increased airway pressure; the cuffed endotracheal tube was connected to: C) an electronic cuff-pressure regulator (E-PR); or D) to a pneumatic cuff-pressure regulator (P-PR).

vice (2.77% [2.24-3.47] versus 0.95% [0.63-1.46], respectively; P<0.0001). Although the COMFORT-B values were not different between the two periods (12.75 [10.62-14.25] and 11.75 [10.12-13.75], respectively; P=0.94), P*cuff* variations with airway-pressure changes occurred only with the electronic device (Figure 1). Finally, our nursing staff experienced no difficulties using either device. This is the first randomized study, to our knowledge, to compare P*cuff* variability over time with an electronic and a pneumatic device in children. In summary, the electronic and pneumatic devices were both effective in automatically regulating P*cuff* in young children, with an extremely low percentage of time out of range for both devices. The time time spent with over- or underinflation was much lower than values reported with monitoring *via* a manometer.[2, 4] The sedation level, which may influence the variability of P*cuff*, was similar and in normal range during both periods as demonstrated by COMFORT-B values. Two mechanisms may explain the higher P*cuff* coefficient of variation with the electronic device. First, in contrast to the pneumatic device, the electronic device had a ±1 cmH_2O dead band around the initial P*cuff* value (Figure 1). Second, the pneumatic device responded almost instantaneously to airway-pressure increases, whereas the electronic device had a lag time (Figure 1). Study strengths are the cross-over design, the evaluation of sedation level by the COMFORT-B scale and the evaluation of P*cuff* variation with airways-pressure. A limitation is that our study design did not allow us to assess the possible effects of continuous P*cuff* control using an automatic device on intubation-related complications, such as tracheal ischemia or post-extubation respiratory distress. Indeed, the clinical impact of these devices remains uncertain[2, 3, 5] and need to be specifically evaluated on critically ill children. In conclusion, the electronic and pneumatic cuff-pressure regulators were similarly effective in children younger than five years old. Nevertheless, further studies are needed to evaluate possible effects of electronic and pneumatic cuff-pressure regulators on intubation-related complications such as post-extubation respiratory distress.

Boris LACARRA [1, 2] *, Guillaume GESLAIN [1], Arielle MARONI [1, 2], Jérôme NAUDIN [1], Boris MATROT [3], Stéphane DAUGER [1, 2, 3]

[1]Pediatric Intensive Care Unit, Robert-Debré University Hospital, Assistance Publique - Hopitaux de Paris (AP-HP), Paris, France; [2]Paris Cité University,

Paris, France; [3]NeuroDiderot, FHU I2-D2, Paris Cité University, INSERM, Paris, France

*Corresponding author: Boris Lacarra, Pediatric Intensive Care Unit, Robert Debré University Hospital, Assistance Publique - Hopitaux de Paris (AP-HP), Boulevard Serrurier 48, 75019 Paris, France. E-mail: boris.lacarra@aphp.fr

References

1. Van de Voorde P, Turner NM, Djakow J, de Lucas N, Martinez-Mejias A, Biarent D, *et al.* European Resuscitation Council Guidelines 2021: Paediatric Life Support. Resuscitation 2021;161:327–87.

2. Nseir S, Zerimech F, Fournier C, Lubret R, Ramon P, Durocher A, *et al.* Continuous control of tracheal cuff pressure and microaspiration of gastric contents in critically ill patients. Am J Respir Crit Care Med 2011;184:1041–7.

3. Jaillette E, Martin-Loeches I, Artigas A, Nseir S. Optimal care and design of the tracheal cuff in the critically ill patient. Ann Intensive Care 2014;4:7.

4. Vottier G, Matrot B, Jones P, Dauger S. A cross-over study of continuous tracheal cuff pressure monitoring in critically-ill children. Intensive Care Med 2016;42:132–3.

5. Marjanovic N, Boisson M, Asehnoune K, Foucrier A, Lasocki S, Ichai C, *et al.*; AGATE Study Group. Continuous Pneumatic Regulation of Tracheal Cuff Pressure to Decrease Ventilator-associated Pneumonia in Trauma Patients Who Were Mechanically Ventilated: The AGATE Multicenter Randomized Controlled Study. Chest 2021;160:499–508.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions.—All authors equally contributed to the study conception and design; Boris Matrot, Boris Lacarra and Stéphane Dauger contributed to the study preparation; Boris Lacarra, Guillaume Geslain, Arielle Maroni, Jérôme Naudin, and Stéphane Dauger to the data collection; Boris Lacarra and Boris Matrot contributed to the data analysis; Boris Lacarra contributed to the manuscript draft. All authors read and approved the final version of the manuscript.

Congresses.—The present study was presented at the French Congress of Anesthesiology on September 24, 2021 by Boris Lacarra.

History.—Article first published online: _____. - Manuscript accepted: September 22, 2022. - Manuscript received: August 22, 2022.

(*Cite this article as*: Lacarra B, Geslain G, Maroni A, Naudin J, Matrot B, Dauger S. Tracheal cuff pressure control in intubated young children: a randomized crossover trial of two cuff-pressure regulators. Minerva Anestesiol 2022;88:000-000. DOI: 10.23736/S0375-9393.22.16948-8)