

Evaluation of Cuff Pressure Behavior in Neonates During Mechanical Ventilation Using Endotracheal Microcuff Tubes: An *In-Vitro* Study on a Neonatal Lung Model

Christina Böck¹, Wanda Lauth^{2,3} and Martin Wald^{1*}

¹Division of Neonatology, Department of Pediatrics and Adolescent Medicine, Paracelsus Medical University, Salzburg, Austria

²Team Biostatistics and Big Medical Data, IDA Lab Salzburg, Paracelsus Medical University, Salzburg, Austria

³Research Programme Biomedical Data Science, Paracelsus Medical University, Salzburg, Austria

***Corresponding author:** Martin Wald, Department of Neonatology, Division of Pediatrics and Adolescent Medicine, Paracelsus Medical Private University, Müllner-Haupt-Str. 48, 5020 Salzburg, Austria

ARTICLE INFO

Received:  January 16, 2025

Published:  January 22, 2025

Citation: Christina Böck, Wanda Lauth and Martin Wald. Evaluation of Cuff Pressure Behavior in Neonates During Mechanical Ventilation Using Endotracheal Microcuff Tubes: An *In-Vitro* Study on a Neonatal Lung Model. Biomed J Sci & Tech Res 60(2)-2025. BJSTR. MS.ID.009434.

ABSTRACT

Background: Newborns in neonatal intensive care units are often intubated and ventilated with cuff tubes, e.g. during surgery. During mechanical ventilation with neonatal microcuffs, there is often an unexpected loss of cuff pressure. The aim of this study was to determine how constant the cuff pressure remains during conventional ventilation. A further aim was to investigate the influence of different patient constitutions and the question of whether a fatal drop in cuff pressure can be prevented.

Method: The study was conducted as an in vitro study using a neonatal lung model. The model was used to simulate four newborns with different tracheal diameters and/or respiratory parameters. The cuff pressure of endotracheal micromesh cuffs (ID 3.0 mm) was measured during mechanical ventilation. Three-hour ventilation cycles after a single inflation of the cuff to 15 mbar were evaluated individually. An automatic cuff manometer was used as a control.

Results: The average pressure drop after three hours of ventilation was 9.15 mbar (± 1.648) for the 5 mm trachea and 8.43 mbar (± 1.074) for the 6 mm trachea ($p=0.015$). The pressure drop was 8.9 mbar (± 1.746) in healthy lungs and 8.62 mbar (± 1.012) in diseased lungs ($p=0.315$). When using an automatic cuff pressure gauge, the cuff pressure remains constant during ventilation.

Conclusion: After a single inflation, the cuff remains wrinkled, and the pressure drops quickly because these wrinkles move. The cuff requires sufficient space for wrinkle-free inflation. The use of cuff tubes in infants weighing less than 3 kg is highly questionable due to the small tracheal diameter. However, the use of automatic cuff manometers can prevent dangerous pressure drops in the cuff.

Keywords: Microcuff Tube; Cuff Pressure; Cuffed Endotracheal Tube; Neonates; Endotracheal Intubation

Introduction

Cuffed endotracheal tubes present a fundamental status in modern and safe infantile airway management. However, the application has not always been endorsed [1,2]. As things stand today, cuffed tubes are safely used in small infants and exhibit important advantages compared to uncuffed, especially in critical situations [3-5]. Due to controlled cuff volume, the damaging pressure on the mucosa and larynx is lower with cuffed tubes [6-8]. A better seal reduces the

risk of aspiration, allows better ventilation, oxygenation and reduces anaesthetic gas emissions [9,10]. Swelling of mucosa or mechanical tracheal expansion, can be compensated by a cuff. Fewer re-intubations, and therefore associated enhanced manageability of ventilation are the result [6-9]. Airway compromises from cuffed endotracheal tubes arises through incorrect sizing and lack of cuff pressure control [3,7,11,12]. To prevent injuries, anatomical and technical recommendations for correct cuff tubes must be followed closely. Regular

cuff pressure and leakage observance during mechanical ventilation is indispensable [11,12]. In case of cuffed tubes in neonates, both over pressure and under pressure in the cuff must be avoided to prevent associated airway damage [3,7]. Desired cuff pressures must be approached carefully. Most adult anesthetic apparatuses and ventilators control the cuff pressure automatically. Thus, some neonatal care units already use automatic cuff pressure manometers, it is still not standard practice as neonatal ventilators are not equipped to provide this feature. In clinical practice without, inconsistency of cuff pressure during the use of cuffed endotracheal tubes in neonates is observed. Particularly noticeable are declines below recommended range, resulting in underinflation. Due to such incidents, prevention of possible undesirable consequences, as well as beneficial properties, can no longer be guaranteed [12]. The aim of this study was to provide conduction of cuff pressure during mechanical ventilation in neonates using endotracheal microcuff tubes. Special attention paid to maximal pressure decline and inconsistency. Further, it was investigated, where and why under inflation occurs. A supplemental question is intended to show, whether the application of automatic cuff pressure manometers can counteract pressure instability and eliminate associated risks.

Methods

All data were generated with a neonatal lung model (Dr. Schaller Medizintechnik, Dresden, Germany) called Gina. It operates as active lung simulator which utilizes a human lung by means of a glass cylinder with electromechanically controllable graphite piston and upstream contrived lower and upper airways. Various compliance and resistance parameters including breathing modes with different intensity and frequency can be emulated. An artificial trachea was connected to the lung model, and further intubated with a microcuff tube (Kimberly-Clark, Dallas, USA). The cuff pressure line of the endotracheal tube was connected to the pressure measurement port Py on the Gina via a three-way valve. The tube itself was connected to

the Y-piece on the ventilation tube of the neonatal ventilator Sophie (Fritz Stephan GMBH, Gackebach, Germany). The experimental setup is shown in Figure 1. In this in vitro study four different settings were investigated to represent ventilated infants with 2.5 and 3.5 kg body weight respectively with healthy or diseased lungs. The patient size was defined by the diameter of the artificial trachea. A tracheal diameter of 5.0 mm corresponds to a newborn with a body weight of approx. 2.5 kg, 6.0 mm corresponds to approx. 3.5 kg, measured after the cricoid cartilage. The condition of the lungs was defined by the setting of lung compliance. The control group was a test lung setting for a 3.5 kg infant with healthy lungs who was ventilated with an automatic cuff manometer [13].

The respective settings of Gina and Sophie are listed in Table 1. The size of the microcuff tube used was 3.0 mm inner diameter, according to specific size tables and recommendations for infants weighing 2.5 to 3.5 kg [14]. It is important to note that the outer diameter of a 3.0 mm cuff tube is equivalent to an uncuffed 3.5 mm tube when using the appropriate product. One cycle of mechanical ventilation per setting lasted nine hours. At the beginning and then every three hours, the cuff pressure was inflated to 15mbar with a 1 ml syringe attached to a three-way valve [6,14]. For each setting, data were recorded six times, therefore eighteen 3- hour intervals of mechanical ventilation were recorded per setting. Thirty cycles of ventilation were measured for the four settings including control. Cuff pressure was measured via the external pressure measurement Py on the Gina. To measure the progression of pressure and maximal pressure decline in the cuff, the trend of the Py value was followed. During one respiratory cycle, cuff pressure was documented seventy-nine times. For the first three hours, every minute for ten minutes, then every five minutes, and after one hour, every ten minutes. In the second and third three hours, cuff pressure was measured for ten minutes every minute, then every ten minutes, and after one hour every fifteen minutes. The estimated leakage volume of the neonatal ventilator was documented equivalently.

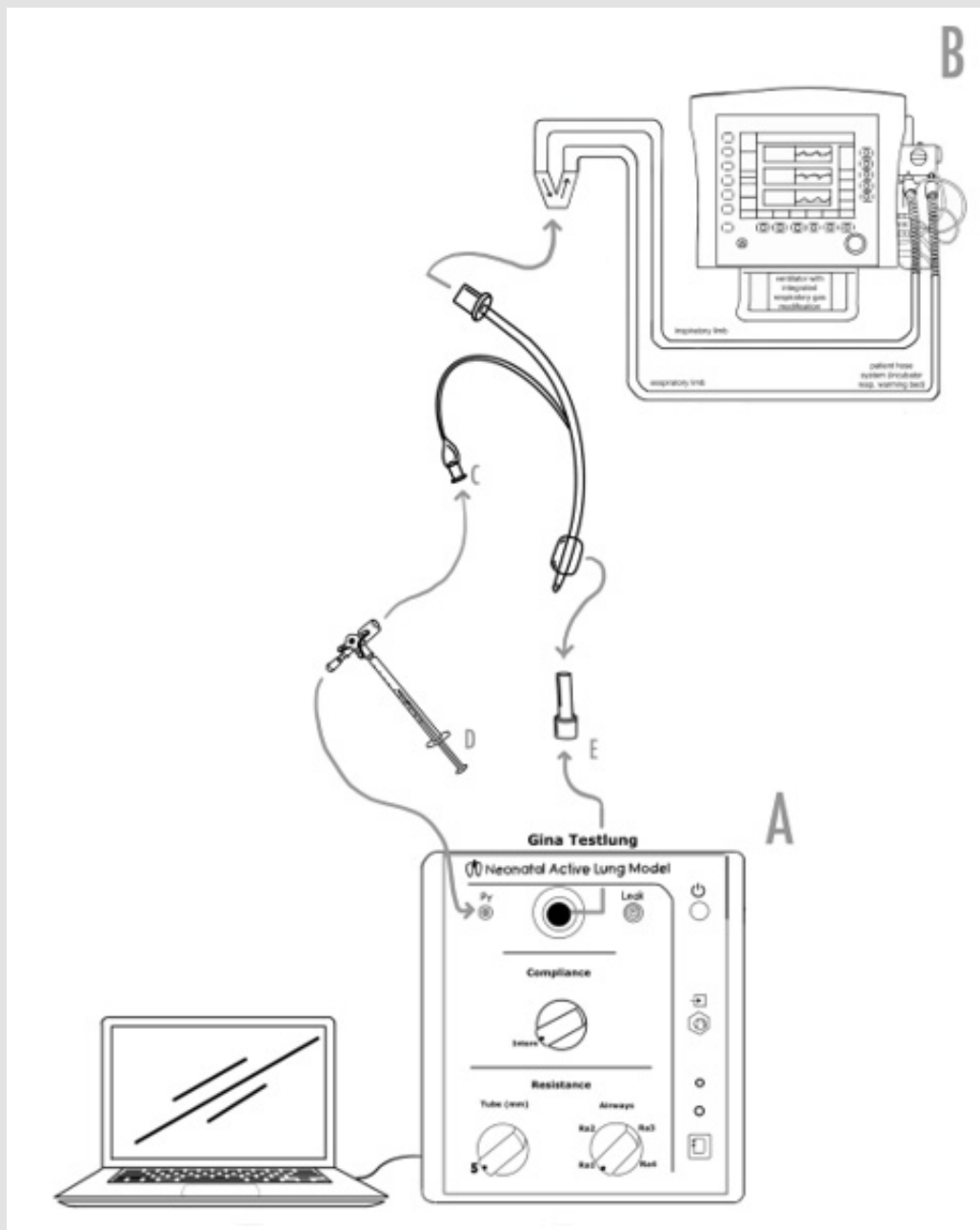


Figure 1: Schematic representation of the experimental set up.

- A. Neonatal Active Lung Model Gina (Dr. Schaller Medizintechnik, Dresden, Germany).
- B. Neonatal respirator Sophie (Fritz Stephan GMBH, Gackebach, Germany).
- C. Endotracheal Microcuff Tube with an internal diameter of 3.0 mm (Kimberly Clark, Dallas, USA).
- D. 1 ml syringe for cuff inflation attached to a three-way valve. E: artificial trachea with different diameters.

Table 1: Settings of the used active lung model Gina (Dr. Schaller Medizintechnik, Dresden, Germany) and the used ventilator Sophie (Fritz Stephan GMBH, Gackebach, Germany).

		Setting 1	Setting 2	Setting 3	Setting 4	Control Setting
Gina	Artificial tracheal diameter (mm)	5.0	5.0	6.0	6.0	6.0
	Lung Compliance (ml/hPa)	2.0	0.5	2.8	0.7	2.8
	Lower lung volume	0	10	0	10	0
	Tube (mm)	5.0	5.0	5.0	5.0	5.0
	Airways	Ra1	Ra1	Ra1	Ra1	Ra1
Sophie	Positive end- expiratory pressure	5	5	5	5	5
	(mbar)	20	20	20	20	20
	Tidal volume (ml)	(target volume)	(target volume)	(target volume)	(target volume)	(target volume)
	Ventilatory rate (min-1)	40	40	40	40	40
	Inspiratory to expiratory time ratio	1:02	1:02	1:02	1:02	1:02
Microcuff tube ID (mm)	3	3	3	3	3	3

Note: The artificial trachea diameter was used to define the patient size. A tracheal diameter of 5.0mm corresponds to a newborn with a body weight of approx. 2.5 kg, 6.0mm corresponds to approx. 3.5 kg. The condition of the lungs could be defined by the adjustment of the lung compliance. The adjustment of the lower lung volume allows a lower initial position of the piston in the internal compliance cylinder of the Gina. The position then changes depending on the positive end-expiratory pressure (PEEP) setting of the ventilator according to the set lung compliance. By adjusting accordingly, the full breath volume can be achieved even at higher compliance. The Tube and Airway settings define the internal resistance of the Gina. After an external endotracheal tube was used, the internally selectable tube was set to 5mm, which corresponds to spontaneous breathing in the range. The Airway defines the resistance of the deeper airway. Since the resistance depends on the flow velocity and is therefore variable, the setting is unit less. Ra1 corresponds to the deeper airways of a newborn around term. No peak pressure was set on the ventilator. The breath volume defined as the target volume allowed the machine to define the peak pressure itself.

Statistics

To determine differences between settings, the time span over nine hours was divided into three periods, each describing pressure decline until re-inflation. Thus, period one describes zero seconds to three hours, period two three hours to six hours, and period three six hours to nine hours. A descriptive comparison of the sections was carried out. The total pressure decline per period was calculated (difference between the first measured pressure and the last per period), resulting in three time points per cycle. Nonparametric ANOVA-type tests [15] were applied to compare the patterns of the results between settings. Post hoc pairwise comparisons were performed using Bonferroni analysis. Second, measurements regarding pressure decline in relation to tracheal diameter were investigated comparing the trachea with 6 mm in diameter to the trachea with 5 mm regardless of the lung condition. Third, measurements regarding pressure decline in relation to lung compliance were investigated comparing healthy to diseased lung regardless the tracheal diameter. Second and third were calculated using t-test analysis. The two-sided level of five percent was used for all hypothesis tests. Results of all analyses were calculated using the statistical software package R [16]. In addition, a visual cuff analysis was created. All cuffs were photographed at the beginning and end of each 3-hour interval. Further, longitudinal cuff extent was measured. The results of the four settings and the control were compared.

Results

The mean cuff pressure endpoint of all three-hour intervals regarding the parameters of a 5 mm trachea with a healthy lung compliance of 2.0 mL/hPa (setting one) was 5.6 mbar (±0.28). The mean cuff pressure endpoint of all three-hour intervals regarding the parameters of a 6 mm trachea with a diseased lung compliance of 0.5 mL/hPa (setting two) was 6.3 mbar (±0.63). The mean cuff pressure endpoint of all three-hour intervals regarding the parameters of a 5 mm trachea with a healthy lung compliance of 2.8 mL/hPa (setting three) was 6.82 mbar (±0.75). The mean cuff pressure endpoint of all three-hour intervals regarding the parameters of a 6 mm trachea with a diseased lung compliance of 0.7 mL/hPa (setting four) was 6.75 mbar (±0.54). The mean cuff pressure end point of all three-hour intervals regarding the parameters of a 6 mm trachea with a healthy lung compliance of 2.8 mL/hPa and the use of an automatic cuff pressure manometer (control setting) was 14.67 mbar (±0.20). Mean cuff pressure decline during the three-hour periods was 0.03 mbar (±0.04). Comparing the means of all 3-hour intervals per setting shows a significant difference (p-value: <0.001). In post hoc analysis, a significant difference is visible between the control and all test settings. The four test settings do not differ significantly among each other (p-value: 0.124). The values of all test settings as well as the distribution of the results during each period are graphically shown in Figure 2 & Table 2. The mean cuff pressure decline for all three-hour periods measured

with the 5 mm diameter trachea was 9.15 mbar (± 1.648) and with 6 mm trachea 8.43mbar (± 1.074). The comparison of the results for these two tracheal settings, independent of lung condition, shows significant differences (p-value: 0.015). The mean cuff pressure drop for all three-hour periods was 8.96 mbar (± 1.746) for healthy lung condition (2.0 and 2.8 ml/mbar/kg) and 8.62 mbar (± 1.012) for diseased lung condition (0.5 and 0.7 ml/mbar/kg).

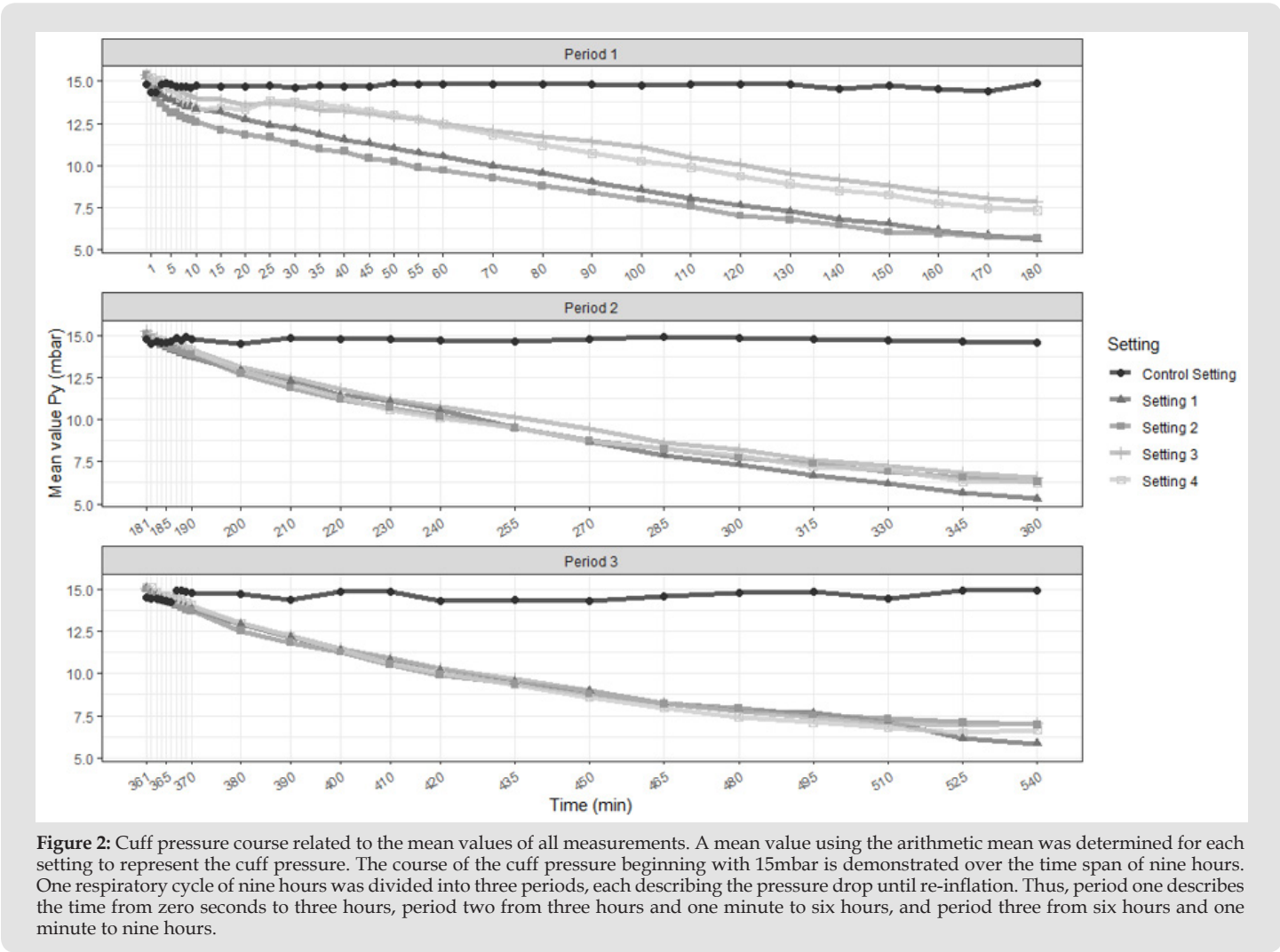


Table 2: An overview of the statistically evaluated results from setting one to four as well as the control.

	Mean cuff pressure end-point first three hours	Mean cuff pressure end-point hours three to six	Mean cuff pressure end-point hours six to nine	Mean cuff pressure decline during the three-hour periods	Mean cuff pressure start point
Setting one	5.64 (± 1.63) mbar	5.30 (± 1.9) mbar	5.85 (± 2.59) mbar	9.51 mbar	15.11 (± 0.14)
Setting two	5.72 (± 0.067) mbar	6.30 (± 0.73) mbar	6.98 (± 1.26) mbar	8.78 mbar	15.12 (± 0.18)
Setting three	7.55 (± 1.51) mbar	6.05 (± 0.57) mbar	6.86 (± 1.08) mbar	8.41 mbar	15.23 (± 0.16 .)
Setting four	7.33 (± 1.38) mbar	6.26 (± 0.59) mbar	6.67 (± 0.67) mbar	8.45 mbar	15.21 (± 0.15)
Control setting	14.32 $\pm$ (0.73) mbar	14.51 $\pm$ (0.51) mbar	14.26 $\pm$ (0.78) mbar	0.03 mbar	14.7 (± 0.16)

Note: An overview of the statistically evaluated results from setting one to four as well as the control is presented in this table. The first column describes the mean cuff pressure endpoints of the first three-hours. The second column describes the mean cuff pressure endpoints of hours three to six. The third column describes the mean cuff pressure endpoints of hours six to nine. The fourth column describes the mean cuff pressure decline during the three-hour periods. The last column describes the mean cuff pressure start point.

The comparison of the results, independent of tracheal diameter, showed no significant differences (p-value: 0.315). The average course of the pressure drops as a function of tracheal diameter and lung compliance is shown in more detail in Figure 3. Regarding the measurements of the leak parameter on the neonatal ventilator an increasing trend equivalent to the falling cuff pressure was observed from setting one to setting four over all nine-hour ventilation cycles. Accordingly, the control setting obtained consistent values in terms of leakage. The measured leakage values were not statistically compared or evaluated in further detail. Visually, differences in cuff material

folding between the four settings and the control were observed. With cuff pressure manometer and continuous pressure compensation an increase in cuff length was measured. In settings without, according to settings one to four, the unfolding of the cuff was dynamic, as the pleating altered over time, but without changes in length. Visual presentation of setting 3 compared to the control shows the size of the microcuff after one minute of mechanical ventilation and after nine hours (Figure 4). Considering setting 3, the cuff measured a length of 10 mm and after nine hours 10 mm. The control provided an increase in cuff length from 10 mm to 12 mm within equal time.

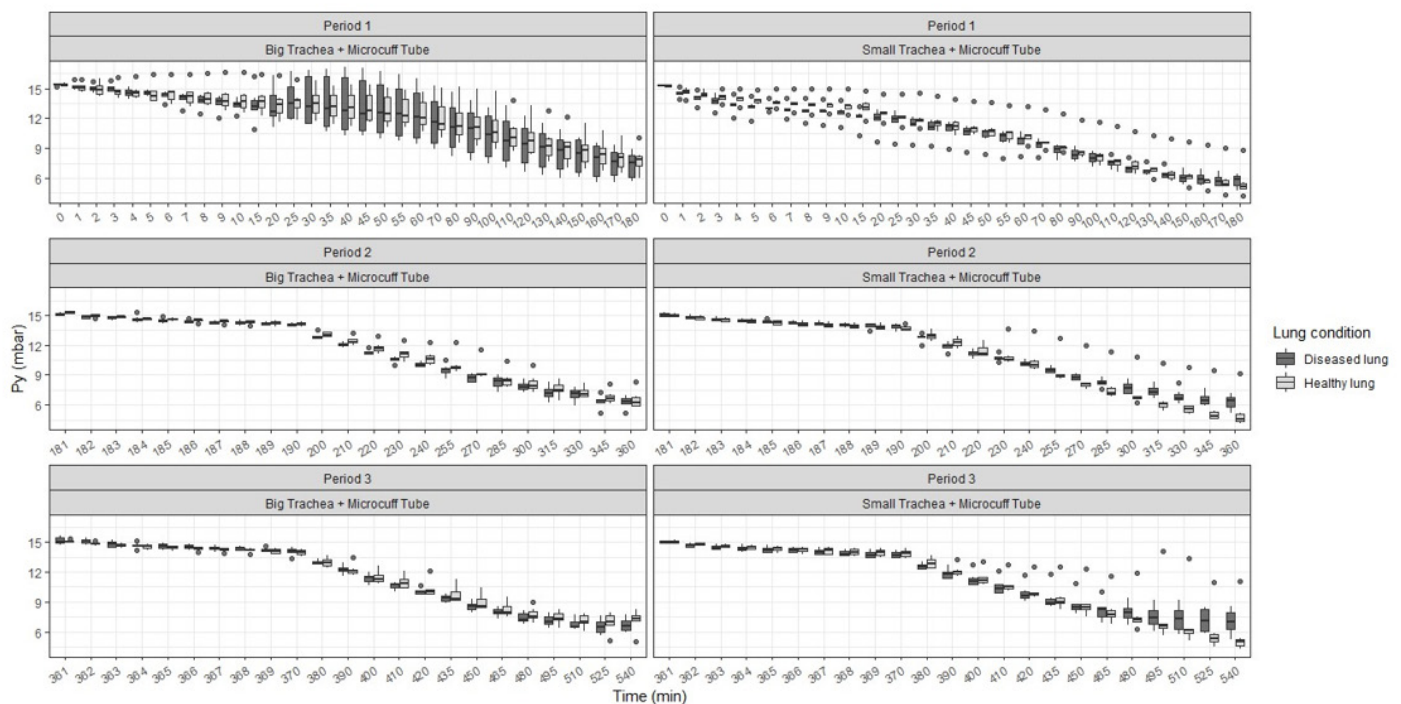


Figure 3: Cuff pressure course related to all measurements from setting one to four. Graphical representation of all measurements regarding a tracheal diameter of 6.0 mm (left) and 5.0 mm (right). For descriptive comparison, the settings regarding the two different compliances used (healthy lung vs. diseased lung) were visualized using boxplots. To compare the settings, the time span over nine hours was divided into three periods, each describing the pressure drop until re-inflation. Thus, period one describes the time from zero seconds to three hours, period two from three hours and one minute to six hours, and period three from six hours and one minute to nine hours.

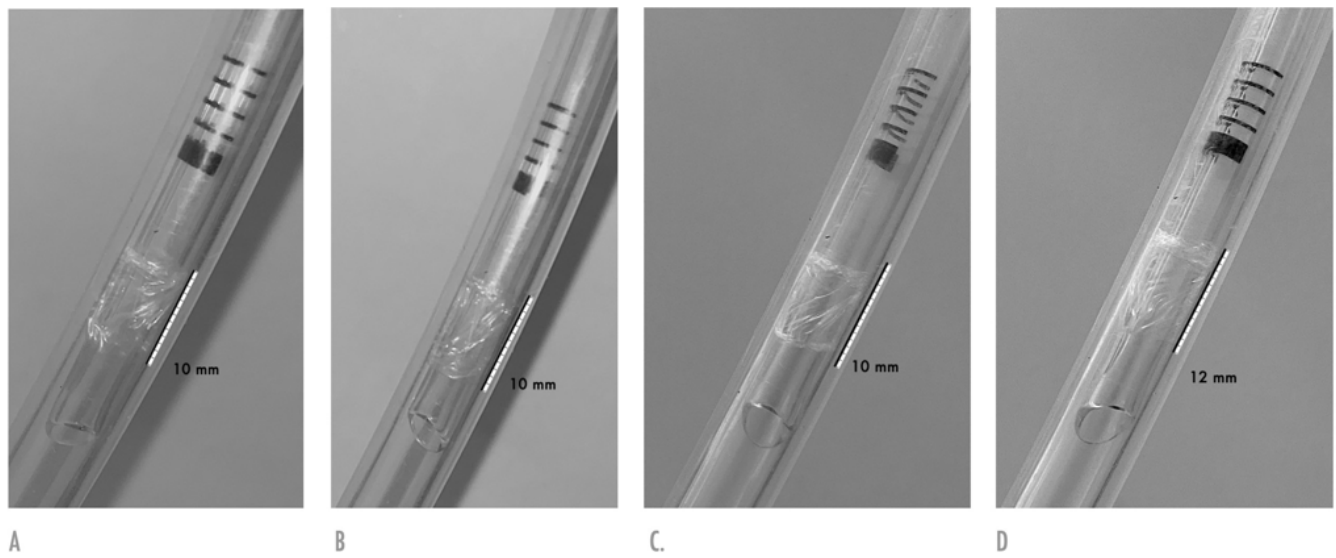


Figure 4: Visual presentation of the Microcuff and its pleating over time in Setting 3 and in the Control Setting. Graphic A and B display the visual presentation of the Microcuff in Setting 3, representing a healthy lung compliance of 2.8 ml/mbar/kg and a large trachea with 6.0 mm in diameter. The visual presentation of graphic A was taken after one minute and graphic B after nine hours of mechanical ventilation. The schematic scale corresponds to 10.0 mm. Graphic C and D display the visual presentation of the Microcuff in the Control Setting using an automatic cuff pressure gauge (equal values as in Setting 3). The visual presentation of graphic C was taken after one minute and graphic D after nine hours of mechanical ventilation. The schematic scale corresponds to 12.0 mm.

Discussion

Our study revealed that after three hours mechanical ventilation, all test-settings had considerable cuff pressure decline in common. No matter what the tracheal diameter or lung compliance set, the lowest mean cuff pressures were measured below 7mbar. With that result, cuff pressure values were incompatible with scientifically recommended values [13]. Fehler! Textmarke nicht definiert. An impressive difference was provided by the control. The lowest mean cuff pressure was 14.3 mbar. According to that, this was the only set up, in which cuff pressure remained within desired range. Studies have proven that advantages like enhanced ventilation and oxygenation [9], sealed airway character and reduced risk of pulmonary aspiration are indispensable [11,12]. Especially critical ill infants, such after meconium aspiration or diaphragmatic hernia, benefit from leak-proof tubes regardless the risk of aspiration. Thus, an important and further critical advantage of cuffed endotracheal tubes is their character to seal the trachea tightly. Literature is unanimous that cuff pressure must be measured regularly [13]. In the neonatal intensive care unit, such observations take place every three to four hours during the nursing rounds.

Our data provided that within this time, cuff pressure declines dramatically, and safe ventilation is no longer guaranteed. Only the control, using an automatic cuff manometer that continuously re-inflates, provided adequate pressure over the entire nine hours mechanical ventilation. Therefore, an automatic cuff pressure manome-

ter is necessary, to ensure safe cuff pressure over time. Throughout the experiment we observed visual cuff changes correlating to pressure behavior in all settings including the control. We analyzed the folds at the beginning and after every three hours of each ventilation. The cuff-material and precipitations of pressure behaved dynamically. In settings one to four, we documented changes in pleating of cuff material itself. The balloon unfolding in terms of length seemed to remain unchanged. In comparison, the control showed partial increase in length due to enhanced cuff unfolding. Scientific evidence indicates that a critical factor in ventilating neonates with cuff tubes is avoidance of maximal cuff inflation due to potential mucosa damage [11]. Therefore, the cuff in neonates is never fully unfolded. Different to adults, in whom hyperinflation is desired after intubation, thus ensuring initial cuff unfolding [17].

Cuff volume itself is potentially larger than the volume of air filled with. The lack of initial deployment can cause the cuff volume to change, resulting in a drop in pressure even though the cuff is tight. This hypothesis can be supported by the observation of cuff length increase in the control, attributed to compensated pressure decline. The results depending on tracheal size, further support our assumption. Cuff pressure of the 6 mm trachea showed a significantly different progression over a nine-hour period compared to the 5 mm trachea. The smaller trachea provided a large scatter and thus many individual deviations from the mean. The larger, contributed a small scatter only in the first period, therefore an overall more constant data set around the mean. Overall, the end of each period showed lower cuff pressu-

res in the 5 mm trachea. However, these observed differences in the spread were based on graphical analyses and were not statistically evaluated. Microcuff tubes especially designed for neonatal airways, have proven worth [6,11]. The cylindrical shaped polyurethane material provides very thin wall character, ensures precise sealing and decent unfolding [6]. They are available and recommended from a size of 3.0 mm. This size can be used if sizing properties of an uncuffed tube with inner diameter of 4.0 mm are fulfilled. According to the manufacturer and given size tables, suitable for infants with 3000 grams bodyweight [14].

Studies show, that the smallest microcuff tube can also be used safely in neonates with 2000 grams bodyweight, if indicated accordingly [18]. With such small tracheas, however, the cuff cannot expand to its maximum volume. The mean terminal cuff pressure value for the small trachea in the study was 5.6 mbar, for the larger trachea 6.82 mbar. The less space the balloon had, the greater the drop in pressure. It is noteworthy that a greater overall dispersion from the mean was observed in the first period. Compared to periods two and three, in which the dispersion decreased noticeably. This observation supports our hypothesis that the cuff expands over time, which has led to more stable values. In our work, we have not investigated, at what tracheal size, therefore at what weight a microcuff tube can adequately unfold. However, the microcuff tube of size 3.0 mm had less space to unfold in a trachea of 5 mm in diameter, compared to the larger one. According to literature, a 5 mm trachea corresponds to a child with 2500 grams bodyweight. Therefore, the tubes mentioned should be suitable but may not be appropriate due to inadequate cuff expansion [14,18].

The advantage of the material, conforming to tracheal wall without wrinkling, is certainly not evident here. Regarding the settings representing healthy and diseased lung conditions, no significant differences could be measured. There is no scientific evidence of differences in cuff pressure decline related to compliance. Our study has shown that no matter lung compliance and tracheal size, a steady cuff pressure is only possible, if the cuff is continuously re-inflated during mechanical ventilation. Due to experimental design, some limitations arise. The characteristics of the lung model cannot fully represent veridical infantile behavior. The experimental setting has no mucosa and is dry. In humid environment, pressure decline could be even faster. It cannot be ruled out, that further factors, other than those mentioned, would have been relevant. The size of tracheal diameter and corresponding weight ratio at which a 3 mm microcuff tube can unfold completely should be subject of further research. One limitation of the study is certainly the experimental set-up. The simulated plastic trachea certainly does not behave in exactly the same way as a real trachea. Although attempts were made to compensate for the sliding properties of the plastic by using silicone oil as a lubricant, this is still an experimental arrangement. Nevertheless, this test arrangement confirmed the clinical observations that a drop in cuff pressure can occur after a few hours of mechanical ventilation with endotra-

cheal microcuffs. The cuff behaves dynamically during the ventilation cycles and a correlation between tracheal size and pressure drop is observed. A decisive factor is the folding of the cuff material. If the trachea is too narrow, the cuff cannot unfold properly, which leads to a greater redistribution of air within the cuff and to even greater pressure fluctuations than with a larger trachea.

Therefore, the use of microcuff tubes in very small newborns is not advisable, as they correlate with a tracheal size that is too small. It has been shown that the cuff cannot be fully inflated in both the 5 mm and 6 mm trachea. As a result, the cuff is never in full contact with the tracheal wall. A significantly larger trachea is required for this. To take full advantage of benefits and eliminate life-threatening disadvantages of airway protection in neonates, it is of absolute necessity, to use an automatic cuff pressure gauge. Declines in cuff pressure can be prevented in the future by this tool due to continuous control and the regular re-inflation of the cuff.

About Authors

Christina Böck carried out literature search, data collection and manuscript preparation, the study design was done by Martin Wald, who was also responsible for Review of manuscript together with Wanda Lauth. Wand Lauth also carried out the analysis of data. The study was conducted at the Division of Neonatology at Paracelsus Medical University Salzburg without external funding. The data or parts of the data have not yet been published or presented anywhere. Christina Böck and Wanda Lauth have no potential conflicts of interest to disclose. Martin Wald organizes annual workshops and training courses, which are also financially supported by companies such as Stephan, Dräger, Vyair, Medin, Hamilton, Medtronic and Chiesi. He also gives lectures that are financed by these companies.

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ISSN: 2574-1241

DOI: 10.26717/BJSTR.2025.60.009434

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