Assessing respiratory function depends on mechanical characteristics of balloon catheters

Walterspacher, Stephan MD¹; Isaak, Lilli²; Guttmann, Josef PhD²; Kabitz, Hans-Joachim MD¹; Schumann, Stefan PhD²

¹ Department of Pneumology, University Hospital of Freiburg, Freiburg, Germany
² Department of Anesthesiology, Division for Experimental Anesthesiology, University Medical Center Freiburg, Germany

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JG contributed to study design, data analysis and reviewing of the manuscript.
HJK contributed to study design, data analysis and interpretation, writing and reviewing of the manuscript.
SS contributed to the study design, data analysis, acquisition and interpretation, literature search, writing and reviewing of the manuscript.

Corresponding author

Dr. Stephan Walterspacher
University Hospital of Freiburg; Department of Pneumology
Killianstr. 5; 79106 Freiburg; Germany
Phone: +49 761 270 37060; Fax: +49 761 270 37040
Email: stephan.walterspacher@uniklinik-freiburg.de
Abstract

Respiratory muscle function as well as lung and chest wall mechanics are reliably assessed by esophageal and gastric balloon catheters. This in-vitro benchmark study aimed at assessing the mechanical properties of commercially available balloon catheters using an experimental model with three defined compliances (27, 54, 90 mL/cmH₂O).

Six catheters were investigated in four conditions: a) balloon pressure during initial inflation; b) static pressure measurements at different filling volumes; c) estimation of set compliances in the experimental lung model at different levels of superimposed pressure; d) elastic balloon properties following 16 hours of inflation.

5/6 catheters showed initial pressure artifacts resulting from material adhesion. All static pressure measurements could be performed with an error <1cmH₂O. Balloon-overfilling resulted in larger errors in 4/6 catheters. Compliance determined from pressure measurements via the catheters differed <5% from that determined from direct pressure measurements. 16 hours of inflation resulted in a broader working range, i.e. overfilling effects occurred at higher filling volumes.

Reliability of pressure measurements and estimation of the lung model's compliance in the tested catheters are high. Filling volume appears critical for precise pressure measurement and compliance estimation. At first use, adhesion of the balloon material might prevent from reliable pressure measurement.

Keywords

esophagus; work of breathing; artificial respiration; pulmonary mechanics; lung compliance
1 Introduction

Assessment of esophageal and gastric pressures is a long-standing and valuable tool in examining the (patho)physiology of the respiratory system dating back to Luciani in 1878. To date, esophageal (and gastric) pressure measurement is considered the gold-standard in the discrimination of respiratory effort related arousals during sleep, indispensable in measuring lung and chest wall compliance, work of breathing, respiratory muscle function (i.e., transdiaphragmatic pressures) and valuable for the assessment of trigger function as well as patient-ventilator synchrony in mechanically ventilated patients. It assists in treatment stratification in adult respiratory distress syndrome and is currently also included into mechanical ventilation systems (e.g., AVEA®, CareFusion Corporation, San Diego, USA).

Besides careful balloon placement, especially design, geometry and filling volumes of the balloons have a major impact on the characteristics of pressure transduction thus affecting measurement quality. When measuring at extreme lung volumes such as residual volume or total lung capacity this point is even more important and filling volumes have to be adapted. For these reasons, detailed knowledge about the mechanical characteristics of the balloon catheters used is crucial. To date, the balloons’ pressure-volume characteristics of most commercially available balloon catheters have not been investigated and information provided by the manufacturers of commercial catheters is scarce. Therefore, the current study aimed at assessing the mechanical properties and validity of pressure measurements of six commercially available balloon catheter systems in a laboratory setting using an experimental lung model.
2 Materials and Methods

Six different types of invasive pressure measurement balloon catheters were investigated (For details see the Online Supplement). Three of the tested catheters were equipped with one balloon for pressure assessment (CooperSurgical (Leisegang Feinmechanik GmbH Berlin, Germany), SmartCath 16FR Adult / 8FR Adult, (VIASYS, Palm Springs, CA, USA)). The three other catheters (Bösch (Bösch GmbH, Gottenheim, Germany), nSpire (ZAN, Oberhulba, Germany), NutriVent (SIDAM s.r.l., San Giacomo, Italy)) were equipped with a second separate balloon for measuring transdiaphragmatic pressure difference (double balloon catheter; DBC). These balloons were handled separately, i.e., each of the following measurements was performed for each single balloon. The mechanical balloon characteristics were compared in four experimental setups as indicated below.

2.1 Technical measurements

All pressure measurements were performed using piezoresistive pressure sensors (SI-special instruments GmbH, Nördlingen, Germany) with maximal ranges of ±20 or ±100 cmH₂O, respectively. Ventilation flow rates were measured using a Fleisch pneumotachograph (Type 2, Dr. Fenyves und Gut, Hechingen, Germany) and volume was calculated by numerical integration of the flow rate. Data were recorded using a costumer adapted software package based on LabVIEW (LabVIEW 7.1, National Instruments Corp., Austin, TX, USA) at a sample frequency of 200 Hz. Off-line analysis was performed using MatLab (R2012a, The MathWorks, Natick, USA).
2.2 Experimental setup

2.2.1 Pressure-volume curves (Experiment I)

In order to determine the pressure-volume (PV) curves of the balloon catheters we measured the balloon pressure ($P_B$) during slow continuous inflation (computer controlled injection pump, PS01-23S × 80, Controller: E1100, LinMot, Spreitenbach, Switzerland) with a rate of 0.16 mL/s or 0.24 mL/s and during stepwise inflation realizing volume steps of 0.2 mL or 0.3 mL, both depending on the balloons' maximal filling volume, respectively estimated from its geometry (Fig.1). The PV-curve was continuously recorded when inflation was performed immediately after unpacking of the catheters to focus on their characteristics during the very first inflation. The slow inflation measurement consisted of six inflation and deflation cycles in which, depending on the balloon's size, 4 or 6 mL of air were insufflated continuously (see Table in Online Supplement) within a fixed time of 25 s and subsequently extracted (dynamic model). To allow for comparison of dynamic versus static inflation, subsequently the inflation-behavior was investigated by applying and drawing the same total volumes in 15 steps of 0.2 or 0.3 mL of air (static model).

The suggested optimal filling ranges of the balloons were determined by detailed inspection of the horizontal segment (i.e., working range) of the PV-curves (Fig.2), as previously suggested $^{1,14}$. The recommended lower-limit filling volume ($V_{min}$) of a balloon was determined as the volume marking the beginning of the horizontal PV-curve segment. The recommended upper-limit filling volume ($V_{max}$) was determined as the volume marking the end of the horizontal PV-curve segment.
2.2.2 Reliability of pressure measurements under static conditions

(Experiment II)

For investigating the reliability of pressure measurements during static conditions the balloons were placed inside an air-tight chamber pressurized with 0, 4, 8, 12 and 16 cmH$_2$O, as controlled by direct pressure measurement (Fig.3). Before the measurements, first all air was sucked out of the catheter by a syringe and second the syringe was removed to allow the balloon to unfold to its “unfilled” position for avoiding negative pressures. Each balloon was tested at four filling conditions:

(i) Empty condition: no additional volume was applied.

(ii) Mid-working range: the balloon was inflated to half of the recommended $V_{\text{max}}$ as identified in the preceding experiment (see above).

(iii) Recommended $V_{\text{max}}$: the balloon was inflated to $V_{\text{max}}$ as identified in the preceding experiment (see above).

(iv) Overinflation condition: the balloon was inflated to the two-fold of $V_{\text{max}}$ volume as identified in the preceding experiment.

Each measurement was repeated five times.

2.2.3 Reliability of compliance measurements (Experiment III)

To analyze the dynamic behavior of the catheter-balloons we investigated the reliability of the determination of respiratory system compliance via catheter measurement in an experimental lung model (Fig.4).

Respiratory system compliances were imitated by glass bottles filled with copper-wool to ensure isothermal conditions. Two bottles (54 L and 27 L, respectively) were used separately and connected in parallel to reflect three different compliances.

The model was ventilated in volume controlled mode using a commercially available...
intensive care ventilator (Evita 4, Dräger Medical, Lübeck, Germany). Tidal volume was set to 500 mL, breathing frequency was set at 15/min.

To simulate additional hydrostatic pressure, the balloons were placed in a water basin at various water depths, reflecting superimposed pressures of 0, 3, 6 and 9 cmH₂O, respectively. Each catheter was filled to a volume corresponding to the mean of the respective Vₘᵢₙ and Vₘᵃₓ.

Compliance of the mechanically ventilated experimental model was determined from the pressure-volume relationship resulting from:

(i) direct pressure measurement (Pᵰ)

(ii) pressure measurement via the respective balloon (Pᵱ)

(iii) as calculated from the ventilator based on expiratory tidal volume divided by the difference between end-inspiratory pressure and end-expiratory airway pressure (VTₑₓ/(Pₐₑⁱ-Pₐₑₑ) ).

This compliance model is proposed to reflect the physiological dynamics of a mechanically ventilated human respiratory system. Of note, the determination of compliance is influenced by the shape of the catheter’s (non-linear) pressure-volume curve.

### 2.2.4 Long-term usage characteristics (Experiment IV)

To investigate the long-term characteristics of the balloons following intensive usage the measurements of Experiment I were repeated following Experiment III after all catheters had been inflated to the twofold of their individual Vₘᵃₓ and left unchanged for 16 h. By this overinflation we simulated a continuous mechanical load of the balloons during longterm measurements in situ. Overinflation was also applied in
order to test the tensile strength and to magnify the possible changes in the balloons compliance due to long-term usage.

3 Statistics

The pressure and volume measurement precision of a typical mechanical ventilator are given with ±2 cmH\textsubscript{2}O, respectively with ±10% of the measured value (Manual of Evita 4, Dräger Medical, Lübeck, Germany). Therefore absolute deviations in pressure measurement of >1 cmH\textsubscript{2}O and in compliance determination of >10% were ex ante defined as relevant \textsuperscript{14}. Unless otherwise stated, values are normally-distributed and given as mean ± standard deviation (SD). Comparisons between pressure and compliance estimation via catheter and direct pressure measurements were analyzed using Student’s paired \textit{t}-test. The influence of factors (balloon type, method of determination and superimposed pressure) on compliance estimation was analyzed using multifactorial ANOVA, applying Fisher’s protected least significant difference (PLSD) test. Statistical significance was defined as p<0.05. Statistical results were calculated using StatView (Ver 5.0, SAS Incorporated, Cary, NC, USA).

4 Results

The detailed characteristics (e-Table 1) and pressure-volume curves for all tested balloons according to the experimental setup are available in the Online Supplement (e-Figure 1).

4.1 Initial pressure-volume relationships (Experiment I)

All catheters presented distinct pressure-volume relationships. All catheters but nSpire showed a clear deviation of the first inflation profile (see Online Supplement)
with respect to the following measurements. In four catheters deviations ceased with
the second inflation (Nutrivent, Cooper, both SmartCath). Initial pressure deviation
was most prominent for both balloons of Bösch’s DLC, which showed rapid pressure
increases to values above the sensor’s pressure range during the first inflation, and
large nearly constant pressure transmission for a wide volume range for the following
inflations. All catheters except nSpire showed a distinct volume range with constant
pressure transmission. In contrast, the nSpire catheter featured a nonlinear behavior
throughout the measured volume range; \( V_{\text{min}} \) and \( V_{\text{max}} \) as presented in Table 1 are
suggested according to the range with the least pressure-volume related change.
The pressure-volume relationships during stepwise inflation were similar to those
measured during continuous inflation (see Online Supplement). Table 1 lists \( V_{\text{min}} \) and
\( V_{\text{max}} \) as identified from the pressure-volume curves for each investigated balloon
catheter.

4.2 Reliability of static pressure measurement (Experiment II)
Static pressure as assessed via direct pressure measurement exceeded the pressure
measured via the catheter in 94% of all measurements. If the filling volume was set to
mid-working range volumes or \( V_{\text{max}} \) the difference between directly and via catheter
measured pressure was <0.2 cmH\(_2\)O, except if the nSpire catheter was used.
Pressure measurement via the catheter led to larger underestimations of the
pressure as identified by direct measurement if the balloons were overinflated (Table
2). Corresponding mean differences were >1 cmH\(_2\)O in two catheters (Bösch, nSpire).
4.3 Determination of compliance (Experiment III)

By direct pressure measurement the compliances of the respiratory system models were determined as 85.5 ± 2.7, 61.5 ± 1.9 and 29.6 ± 1.1 mL/cmH₂O, respectively. On average, the compliance estimated by the ventilator was 2.0 ± 1.7 mL/cmH₂O larger (p<0.001), and by catheter measurement 0.9 ± 0.9 mL/cmH₂O larger (p<0.001) than the compliance determined by direct pressure measurement. Balloon type, method of determination and superimposed pressure all influenced the compliance results (all p<0.002). Each difference in estimated compliance between direct and via catheter pressure measurement determined with any catheter and in any situation of superimposed pressure was less than 4.5%. Across all measurements the relative difference between compliance measured directly and via catheter was 0.8 ± 0.9%, 1.6 ± 0.9%, 2.2 ± 1.2% and 1.4 ± 0.9% for 0, 3, 6 and 9 cmH₂O of superimposed pressure, respectively. Calculated compliances from all conditions are displayed in the Online Supplement.

4.4 Long-term pressure-volume relationships (Experiment IV)

After 16 h of overinflation four of six catheters featured a transition of Vmax to higher filling volumes compared to Experiment I (Table 1), whereas Vmin remained constant in all catheters. Detailed information on all pressure-volume curves are available in the Online Supplement.

5 Discussion

The main findings of this study can be summarized as (i) pressure recordings critically depend on balloon design and (ii) on filling volumes with increasing
pressures along with rising balloon filling volumes \(^\text{18}\). Since these characteristics are usually not reported by the manufacturers it is essential for the user to reflect on these circumstances whenever using balloon catheters for pressure measurements. Interestingly, the current study revealed that the non-linear pressure-volume characteristics of each balloon catheter differs and that \(V_{\text{min}}\) and \(V_{\text{max}}\) need to be known by the user for correct application.

Balloon material adhesion at the initial inflation following unpacking of the catheter proved to be a consistent factor of incorrect pressure transduction in all catheters and was consistently eliminated by balloon inflation and deflation following the first balloon inflation. The pressure-volume characteristics of the balloons differed according to the balloons’ geometry and material characteristics; in all but the nSpire catheter the pressure-volume characteristic exhibited a nearly linear relationship within a defined volume range characterized by a horizontal course of the PV-curve. This horizontal segment of the balloon’s PV-curve defines the key feature of any balloon catheter. Within the limits of the horizontal PV-curve segment the balloon pressure is independent from the filling volume \(^\text{14}\). Consequently this horizontal PV-curve segment limited by \(V_{\text{min}}\) and \(V_{\text{max}}\) defines the operating range of the balloon catheter with respect to the filling volume \(^\text{114}\).

Previous experiments provide evidence that this in vitro linear relationship also corresponds to in vivo measurements \(^\text{1,13,18}\). Especially measurements at near total lung capacity exhibit an artificial increase of esophageal pressures with increasing balloon volume \(^\text{15,18}\). Therefore, catheters used in the thoracic compartment should be filled with respect to \(V_{\text{min}}\) in order to retain optimal pressure transduction \(^\text{14,17}\). Pressures in the abdominal compartment are contrary in the respiratory cycle with respect to thoracic pressures. Accordingly, gastric balloons should be inflated to \(V_{\text{max}}\)
in order to ensure optimal assessment of e.g. transdiaphragmatic pressures \(^{17}\). This can be also be derived from Experiment II (Table 2, Fig. 3) where errors in the balloons pressure transmission remain low if filling volumes are adjusted to higher volumes.

This study is – to the best of our knowledge – first in assessing the long-term usage characteristics of balloon catheters as it occurs during e.g. sleep laboratory studies or in esophageal-pressure guided mechanical ventilation. This is of special importance, since distending forces due to the balloon’s filling volume might interfere with the pressure-volume characteristics of the balloons and influence the recorded pressures for the reasons mentioned above. Following the extensive testing due to experiments I, II and III, all catheters were kept filled with the twofold of their individual \(V_{\text{max}}\) for 16 hours. Four of six catheters exhibited a right-shifted pressure-volume curve which however led to an extended horizontal pressure-volume curve segment. This is suggested to be of minor importance for long-term pressure measurements since this leads to an extended working range of the balloon \(^{14}\).

The balloon’s filling volume, the method of determination and superimposed pressure all impacted on the determined compliance value of the experimental lung model. Of note, the resulting measurement errors in determined compliance were well below the \textit{a priori} defined cut-off values. Compliance values as assessed by the balloon catheter measurements proved to more closely reflect the compliance of the lung model used when compared to a state-of-the-art intensive care mechanical ventilator. These findings were consistent for all compliance models and catheters used - making them a reliable tool for physiological studies and therapy guidance.
In a clinical perspective, incorrect filling volumes of balloons may lead to incorrect pressure transduction especially in patients with acute respiratory distress syndrome (ARDS) and high PEEP-pressures (as shown in Experiment II; Table 2). In esophageal-pressure guided mechanical ventilation PEEP is adjusted to avert alveoli collapse or pulmonary overdistension and maintain transpulmonary pressures of e.g. 0-10 cm H$_2$O $^{11}$. Therefore, errors $>$1 cm H$_2$O may lead to deleterious decisions with false adjustments of PEEP levels. These errors may lead to a wrong interpretation as depicted in a false loss of compliance in physiological studies $^{14}$.

5.1 Critique of methods

All experiments were performed with only one catheter for each manufacturer; therefore consistency of manufacturing and processing might not have been adequately addressed. However, the “randomly picked” scenario reflects real-life conditions in which the user has to rely on a stable manufacturing process and cannot compare several catheters from different production lines within one manufacturer before usage.

Previous studies have addressed the pressure signal transmission of commercially available esophageal balloon catheters, showing that catheters vary greatly in signal transmission $^{8}$. Signal transmission does not solely rely on the balloons’ resistance, but also on the volume displacement coefficients accounting to the volume of air in the balloon, tubing and pressure transducers $^{20}$. This issue has not been addressed in this study due to its high variability with regard to the tubing systems and pressure transducers used with respect to the previous studies $^{14,20}$. 

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The current study exclusively performed *in vitro* assessment of balloon catheter characteristics. It cannot be excluded with certainty that *in vivo* measurements would have revealed different results. However, the current approach was chosen in order to minimize non-material related variability and to keep the environmental factors as stable as possible to most accurately assess the mere material characteristics rather than pressure transmission related to individual patient/subject characteristics.

### 6 Conclusion

Pressure measurements, compliance estimation and long-term characteristics were assessed in six commercially available balloon catheter systems. However, to prevent from artifacts caused by material adhesion the balloons should be inflated and deflated prior to placement. Pressure-volume characteristics and appropriate filling volumes vary greatly among different balloon catheters and are crucial for pressure measurement. Users should be well aware of the accurate filling volume of the corresponding balloon catheter system applied.
References


Figure legends

Figure 1
Schematic setup for Experiment I: Direct pressure measurement ($P_B$) of the balloon (B) at various filling volumes. During the measurements the syringe was disconnected from the balloon site via a valve to prevent from volume reflux.

Figure 2
Schematic of a typical catheter balloon’s pressure-volume relationship. $V_{\text{min}}$ and $V_{\text{max}}$ indicate the lower-limit and upper-limit and maximum of the filling volume range within which the pressure inside the balloon is constant - independent from the filling volume.

Figure 3
Schematic of the pressure measurement setup for Experiment II. The balloon (B) was placed in an air tight chamber, the filling conditions were applied via a syringe and the ambient pressures ($P_D$) were applied. During the measurements the syringe was disconnected from the balloon site via a valve to prevent from volume reflux. The balloon pressure ($P_B$) was directly measured for each experimental condition (refer to the manuscript for further details).

Figure 4
Schematic of the compliance measurement setup. The simulated compliance (C) was determined by one of two copper wool filled rigid glass bottles or a combination of both. In a pressure measurement chamber, connected to the compliance model the pressure was measured directly ($P_D$) or via the balloon catheter ($P_B$) under test,
placed in a water basin for simulating superimposed pressure of 0 to 9 cmH$_2$O. The lung model was ventilated by a ventilator and compliance was calculated from the pressure-volume relationship.
### Table 1

<table>
<thead>
<tr>
<th>Type</th>
<th>Balloon position</th>
<th>$V_{\text{min}}$ [mL]</th>
<th>$V_{\text{max}}$ [mL]</th>
<th>$V_{\text{max16h}}$ [mL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bösch</td>
<td>proximal</td>
<td>0.4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>distal</td>
<td>0.4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>CooperSurgical</td>
<td>single</td>
<td>0.2</td>
<td>1.2</td>
<td>2</td>
</tr>
<tr>
<td>nSpire</td>
<td>proximal</td>
<td>0.2</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>distal</td>
<td>0.2</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
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<td>single</td>
<td>0.5</td>
<td>2.4</td>
<td>3</td>
</tr>
<tr>
<td>SmartCath 8 FR</td>
<td>single</td>
<td>0.3</td>
<td>1.5</td>
<td>3</td>
</tr>
<tr>
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<td>0.5</td>
<td>3</td>
<td>4.5</td>
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<tr>
<td></td>
<td>distal</td>
<td>0.5</td>
<td>2.5</td>
<td>5</td>
</tr>
</tbody>
</table>

Minimal ($V_{\text{min}}$) and maximal ($V_{\text{max}}$) filling volumes for catheters as identified from the pressure relationships during inflation (Experiment I). Shifted maximal filling volume ($V_{\text{max16h}}$) following 16 hours of inflation (Experiment IV).
Table 2.

<table>
<thead>
<tr>
<th>Filling volume [mL]</th>
<th>Set pressure</th>
<th>0 cmH₂O</th>
<th>4 cmH₂O</th>
<th>8 cmH₂O</th>
<th>12 cmH₂O</th>
<th>16 cmH₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bösch proximal</td>
<td>0</td>
<td>0.00 ± 0.03</td>
<td>0.02 ± 0.00</td>
<td>0.09 ± 0.01</td>
<td>0.14 ± 0.00</td>
<td>0.23 ± 0.01</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
<td>0.00 ± 0.01</td>
<td>0.01 ± 0.02</td>
<td>0.03 ± 0.02</td>
<td>0.05 ± 0.03</td>
<td>0.07 ± 0.04</td>
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<tr>
<td></td>
<td>1</td>
<td>0.00 ± 0.01</td>
<td>0.01 ± 0.01</td>
<td>0.03 ± 0.01</td>
<td>0.04 ± 0.01</td>
<td>0.06 ± 0.02</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.15 ± 0.09</td>
<td>0.48 ± 0.18</td>
<td>0.73 ± 0.22</td>
<td>0.95 ± 0.26</td>
<td>1.17 ± 0.33</td>
</tr>
<tr>
<td>Bösch distal</td>
<td>0</td>
<td>-0.02 ± 0.00</td>
<td>0.13 ± 0.05</td>
<td>0.26 ± 0.06</td>
<td>0.44 ± 0.18</td>
<td>0.71 ± 0.33</td>
</tr>
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<td>0.03 ± 0.01</td>
<td>0.06 ± 0.02</td>
<td>0.09 ± 0.04</td>
<td>0.13 ± 0.05</td>
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<td>1</td>
<td>0.02 ± 0.03</td>
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<td>0.06 ± 0.01</td>
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<td>0.06 ± 0.03</td>
<td>0.10 ± 0.07</td>
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<td>0.05 ± 0.03</td>
<td>0.06 ± 0.04</td>
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<tr>
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<td>0.02 ± 0.01</td>
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<td>0.04 ± 0.02</td>
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<tr>
<td></td>
<td>2</td>
<td>0.05 ± 0.06</td>
<td>0.42 ± 0.28</td>
<td>0.58 ± 0.25</td>
<td>0.76 ± 0.34</td>
<td>0.95 ± 0.42</td>
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<tr>
<td>nSpire proximal</td>
<td>0</td>
<td>0.01 ± 0.03</td>
<td>0.06 ± 0.03</td>
<td>0.11 ± 0.02</td>
<td>0.16 ± 0.03</td>
<td>0.22 ± 0.04</td>
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<td></td>
<td>0.4</td>
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<td>0.08 ± 0.06</td>
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<td>0.8</td>
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<td>1.04 ± 1.29</td>
<td>1.41 ± 1.76</td>
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<td></td>
<td>1.6</td>
<td>0.86 ± 0.65</td>
<td>2.07 ± 1.47</td>
<td>3.13 ± 2.24</td>
<td>4.14 ± 2.98</td>
<td>5.05 ± 3.61</td>
</tr>
<tr>
<td>nSpire distal</td>
<td>0</td>
<td>0.12 ± 0.12</td>
<td>0.17 ± 0.11</td>
<td>0.22 ± 0.12</td>
<td>0.26 ± 0.13</td>
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<tr>
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<td>0.8</td>
<td>0.05 ± 0.06</td>
<td>0.16 ± 0.21</td>
<td>0.25 ± 0.31</td>
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<td>0.41 ± 0.48</td>
</tr>
<tr>
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<td>SmartCath 8 FR</td>
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<td>Nutrivent distal</td>
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Differences between set pressure and pressure measured via balloon catheters.

Values are expressed in cm H₂O (mean ± standard deviation). Differences above 0.5 cmH₂O are highlighted in bold.
Schematic setup for Experiment I: Direct pressure measurement (PB) of the balloon (B) at various filling volumes. During the measurements the syringe was disconnected from the balloon site via a valve to prevent from volume reflux.

92x34mm (300 x 300 DPI)
Schematic of a typical catheter balloon’s pressure-volume relationship. $V_{\text{min}}$ and $V_{\text{max}}$ indicate the lower-limit and upper-limit and maximum of the filling volume range within which the pressure inside the balloon is constant - independent from the filling volume.
Schematic of the pressure measurement setup for Experiment II. The balloon (B) was placed in an air tight chamber, the filling conditions were applied via a syringe and the ambient pressures (PD) were applied. During the measurements the syringe was disconnected from the balloon site via a valve to prevent from volume reflux. The balloon pressure (PB) was directly measured for each experimental condition (refer to the manuscript for further details).

(0, 4, 8, 12, 16 cmH2O)
Schematic of the compliance measurement setup. The simulated compliance (C) was determined by one of two copper wool filled rigid glass bottles or a combination of both. In a pressure measurement chamber, connected to the compliance model the pressure was measured directly (PD) or via the balloon catheter (PB) under test, placed in a water basin for simulating superimposed pressure of 0 to 9 cmH2O. The lung model was ventilated by a ventilator and compliance was calculated from the pressure-volume relationship.