Description and Validation of a Novel Method of Measuring Pharyngeal Pressure in New-born

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Abstract

Study background: Measurement of delivered pharyngeal pressure during continuous positive airway pressure (CPAP) therapy is not in routine practice due to lack of a simple and affordable technique of intrapharyngeal pressure measurement. To overcome the lack of the gold standard solid-state catheter-tip pressure measurement technology in our set up, we improvised a novel method of pressure measurement and tested its validity in a simulated pharynx.

Methods: A low-cost pressure transducer was improvised by attaching an orogastric tube to its one end. The other end of the orogastric tube was sealed into an artificial pharynx - a 20 ml syringe. The pressure transducer readings were compared with that obtained by a digital manometer attached to the tip of the syringe. Bland-Altman statistic was used to quantify the measurement reliability of the novel method against the digital manometer. Effect of tube length on the measurement agreement was also studied. The developed technique was applied in new-borns.

Results & conclusion: Pressures measured by this technique were in good agreement with that obtained using a digital manometer. This technique has the potential to be used as an alternative to catheter-tip pressure transducers for bedside pharyngeal pressure measurement in new-born babies, especially in under-resourced setups.

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Introduction

Continuous positive airway pressure (CPAP) is the standard of care for the treatment of respiratory distress among preterm neonates (1). The efficacy of nasal CPAP depends among other factors on the delivered pharyngeal pressures – which may be different with the type of interface used (2). The efficacy of CPAP is judged by adequate chest expansion and clinical improvement (3). Measurement of pharyngeal pressure delivered by CPAP is desirable as it can help refine the use of CPAP. A convenient and accepted method of estimating the delivered pressure is by measuring the intrapharyngeal pressure using a solid-state catheter-tip pressure transducer (4, 5). However, due to high cost and limited availability of solid state catheter, it is not a routine practice. Hence we devised a simple, low cost bedside testing to measure pharyngeal pressure being delivered by CPAP.

Objectives

To validate a simple, low cost pharyngeal pressure measurement technique using an orogastric tube and pressure transducer against a digital manometer.

Methods

The novelty is the use of low-cost pressure transducer and its improvisation to measure pharyngeal pressure in new-born babies. This study is an attempt to test its validity before it could be used routinely in pre-term babies on CPAP.

Principle:

The central theme of the study was to measure the pressure inside the proximal airway with a sensor placed outside it. We used a pressure transducer (MLT 0699, ADInstruments, New Zealand) that works on potentiometric principle for this purpose. An orogastric tube (Romsons, India) connected the pressure sensor to an artificial pharynx (made from 20 ml syringe), whose pressure was to be measured (Fig. 1). The pressure sensor was calibrated against a CE certified-digital manometer (HTC PM-6202 manometer, China) before every set of experiments. Measurement reliability between the pressure transducer and digital manometer was carried out by connecting them to a 20 ml syringe (Romsons, India) - calibration syringe by means of a three-way stopcock.

Creation of an artificial pharynx:

We used another 20 ml syringe (Romsons, India) to simulate proximal airway and create an artificial pharynx. A hole was made in the centre of its side wall to insinuate the tip of a 6 Fr orogastric tube for a length of about 2 cm, and was sealed with an epoxy adhesive, and left undisturbed overnight, to create a leak-proof chamber. The other end of the orogastric tube was connected to the pressure transducer. The tip of the syringe was connected to the digital manometer (Fig. 1). The pressure values acquired with the pressure transducer were compared against those obtained with the digital manometer.

Fig. 1: Experimental setup: A 6 Fr catheter(a) connects the pressure transducer(b) to the artificial pharynx (20 ml syringe)(c) placed in continuous infusion pump(d) to produce controlled increments in pressure. Tip of syringe is connected to the digital manometer(e).
Pressure recordings:

The digital manometer displayed pressure values accurate to single decimal place on a digital display. The pressure transducer was connected to a 16-bit digital data acquisition system (PowerLab 8/30, AD Instruments, New Zealand) through a DIN connector. Data was digitized at a sampling rate of 1 kHz and recorded using LabChart Pro version 7.0 software (AD Instruments, New Zealand). The values were noted correct to two decimal places.

Changing pressure inside the calibration syringe/artificial pharynx:

We first attempted changing the pressure inside the artificial pharynx by moving the plunger manually, which resulted in large and uncontrolled changes in pressure. To overcome this problem, we used a continuous syringe infusion pump (Atom Syringe Pump S-1235, Atom Medical Corporation, Japan) to produce and maintain increments as small as 0.1 mm Hg over a range of 1 to 10 mm Hg.

Validation procedure:

For every increment in pressure produced in the artificial pharynx/calibration syringe, the values obtained with the pressure transducer and the digital manometer were noted by two independent observers.

Statistical analysis:

Statistical analysis was carried out using GraphPad Prism software (GraphPad Software Inc., USA). Bland-Altman statistic was used to quantify the agreement between the two sets of data. Non-parametric equivalent of one-sample t-test - Wilcoxon signed-rank test, was used to test if the mean difference significantly differed from 0.

Effect of altering the tube length:

To test if the introduction of an extra length of tube between the site of pressure recording and the pressure transducer affected the agreement between measurements, we repeated the experiment with 6 Fr orogastric tubes cut to 50% and 25% of their original length.

Results

Results of agreement between the values measured by the two devices are shown in Table I. Digital manometer served as reference and hence its values were tabulated along X-axis (Fig. 2).

As can be inferred from the table, there is a strong measurement agreement between the two devices. Observed bias of 0.03 mm Hg, although statistically significant, is too small to be clinically significant. The effect size of length of orogastric tube used to connect the pressure transducer to artificial pharynx is too small to be of clinical relevance. It is worth noting that at operational tube lengths in babies (25-50% of original length), the bias values are too small and no longer statistically significant. It appears that our improvisation of the pressure transducer in terms of its attachment to orogastric tube to measure pressure inside an artificial pharynx has also served to reduce the observed bias between the two devices in our experimental setup.

Testing in pre-term babies:

After obtaining ethical permission, the devised method was put to test in pre-term new born babies on CPAP. A sterile orogastric tube was inserted through the mouth to reach the pharynx of the baby. The device was re-calibrated in the NICU (Neo-natal Intensive Therapeutics Unit) of the hospital.

<table>
<thead>
<tr>
<th>Chamber</th>
<th>Length of orogastric tube</th>
<th>Bias (mm Hg)</th>
<th>SD of bias</th>
<th>95% limits of agreement</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower limit</td>
<td>Upper limit</td>
</tr>
<tr>
<td>Calibration syringe</td>
<td>–</td>
<td>0.03</td>
<td>0.04</td>
<td>–0.05</td>
<td>0.12</td>
</tr>
<tr>
<td>Artificial pharynx</td>
<td>25%</td>
<td>0.00</td>
<td>0.06</td>
<td>–0.11</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>50%</td>
<td>0.01</td>
<td>0.05</td>
<td>–0.10</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>0.02</td>
<td>0.03</td>
<td>–0.04</td>
<td>0.09</td>
</tr>
</tbody>
</table>
Care Unit) and the other end of the orogastric tube was connected to the pressure transducer. The Fig. 3, shows actual tracing obtained. The 60 per minute fluctuations in the pressure with an amplitude of about 0.5 mmHg are the pressure fluctuations produced by the respiratory effort of the baby over and above the positive pressure of about 2 mmHg in the baby. The presence of the respiratory fluctuations in the recording is a clear evidence that the improvised device is sensitive enough to record the low pressure fluctuations in the pharynx.

Fig. 2: Bland-Altman plots of the pressure values measured by the two devices under various conditions. (A) - Direct calibration of the pressure transducer against the digital manometer calibration syringe. Agreement in pressure values when orogastric tubes of different lengths, (B) 100%, (C) 50% and (D) 25% (of original length) connected the transducer to artificial pharynx. *p<0.05

Fig. 3: A typical record showing intrapharyngeal pressure fluctuations in mm Hg (y axis) and time in seconds (x axis) in a preterm baby on CPAP.
in the pharynx in pre-term babies on CPAP.

Discussion

Measurement of pharyngeal pressure assumes importance in babies receiving CPAP to get an estimate of distending pressures delivered to the alveoli. Studies have been conducted to model the relationship between the set pressure/flow rate and the measured pharyngeal pressure (6). As there is a high inter-subject variation in the relationship between set pressures and measured pharyngeal pressures, it would be ideal to measure pharyngeal pressure in every baby receiving CPAP. The gold standard for measuring pharyngeal pressure is the solid-state catheter-tip pressure transducer (4, 5). They employ piezoelectric crystals embedded in the catheter-tips and sense pressure by changes in deformation. There are studies from developed countries on pharyngeal pressure measurement using these transducers (7, 8). Since the technology is highly sensitive and can be manoeuvred right inside the proximal airway, they provide the most accurate values of pharyngeal pressure. However, they are quite costly, and since they need to be positioned inside the pharynx, sterilization is mandatory in between patients (9). Hence they are not suitable for routine clinical use especially in under-resourced setups. In our study, we have used a pressure transducer that works based on potentiometric principle and connected it to an artificial pharynx via an orogastric tube. We have found that values obtained with this novel method show a strong agreement with the values of a digital manometer. The length and diameter of the orogastric tube did not significantly affect the agreement bias, which suggests that the operating pressures get quickly equilibrated along the length and across various diameters of the orogastric tube. The advantage is that they are more affordable and are readily available in ethylene oxide pre-sterilized packs. However, the fact that we have compared its agreement with a digital manometer and not with a solid-state catheter tip transducer is a drawback of our study and could be addressed in future experiments. Nevertheless, our method is simple, affordable and convenient, and hence is promising for routine clinical use, which could help in establishing the efficacy and safety of CPAP. In the future, pressure sensing devices could be designed to communicate with the CPAP devices to pop-off above a critical sensed value so that undue high pressures are not delivered to the lungs protecting the babies from complications like pneumothorax and CPAP belly syndrome.

Conclusion

A novel method for measurement of pressure inside a simulated pharynx has been described. Our results show that pressures measured by this technique are in good agreement with that obtained using a digital manometer. Future clinical studies are required to test the technique on babies and compare the measurement reliability against the gold-standard solid-state catheter-tip pressure transducer technology.

References