



## Evaluation of peak inspiratory pressure and respiratory rate during ventilation of an infant lung model with a self-inflating bag

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### Abstract

**Objective:** To evaluate the peak inspiratory pressure and ventilation rate achieved by physicians when using a neonatal self-inflating bag on a lung model.

**Methods:** Fifteen physicians ventilated full term and preterm infant lung simulators while the outcomes were captured by a ventilation monitor.

**Results:** Median peak pressures in cmH<sub>2</sub>O for full term and preterm lungs were 23 (interquartile range: 15-47) and 26 (interquartile range: 14-51), being less than 20 in 41.2 and 35.8% of the pressure curves analyzed, more than 40 in 29.7 and 33.6%, and between 27 and 33 cmH<sub>2</sub>O in 8.2 and 6.5% of the curves, respectively. Median ventilation rates were 45 (interquartile range: 36-57) and 48 (interquartile range: 39-55.5) cycles per minute, being more than 30 in 9.3 and 6.7% of pressure curves and more than 60 in 12 and 13.3% of pressure curves, for the full term and preterm lungs, respectively. The differences between these medians were not statistically significant.

**Conclusions:** Ventilation rates achieved with the self-inflating bag were adequate in approximately 80% of pressure curves analyzed, but the physicians were unable to provide ventilation with minimal pressure variation, producing pressures that diverged from those defined by the neonatal resuscitation training course in 70% of the curves. This was irrespective of whether they were ventilating the lung model analogous to preterm or full term infant lungs.

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### Introduction

The most commonly used device for manual mechanical ventilation is the self-inflating bag.<sup>1</sup> It is used to treat newborn infants in the delivery room, for respiratory resuscitation during cardiorespiratory arrest, in emergency units, intensive care units (ICU), in the operating theatre, while transporting patients with respiratory failure and in respiratory physiotherapy.

When ventilating full term newborn infants in the delivery room, it is recommended that a respiratory rate (RR) of 30 to 60 cycles per minute be employed.<sup>2</sup> The Brazilian Society of Pediatrics' Neonatal Resuscitation Course adheres to the standards of the American Academy of Pediatrics' and the American Heart Association's Neonatal Resuscitation Program and the recommendation contained

in the course manual<sup>3</sup> is that peak inspiratory pressure (PIP) for newborn infants should be close to 30 cmH<sub>2</sub>O, and with upper and lower limits of 20 and 40 cmH<sub>2</sub>O. The Food and Drug Administration (FDA) uses American Society for Testing and Materials (ASTM),<sup>4</sup> minimum respirator performance standards, which specify that neonatal bags should be fitted with a pressure-release valve set to a maximum of 40±5 cmH<sub>2</sub>O.

Studies have shown that, when using bags, variations can occur in the tidal volume (VT) and PIP produced during each pulmonary inflation. These variations depend upon the size of the bag, on the existence or absence of a pressure-release valve and the performance of the valve if fitted, the size of the operator's hands, the use of one or two hands, the time the operator takes while applying pressure to the bag and on the characteristics of the mask being used and whether or not it is well-fitted to the patient's face.<sup>5,6</sup>

Mondolfi et al.<sup>7</sup> observed major variation in the tidal volume, pressure and minute volume achieved by health professionals at a pediatric emergency unit. Hird et al.<sup>8</sup> found that, even when newborn infants had normal thoracic expansion, pressures varied from 14 to 30 cmH<sub>2</sub>O and did not correlate with either weight or gestational age.

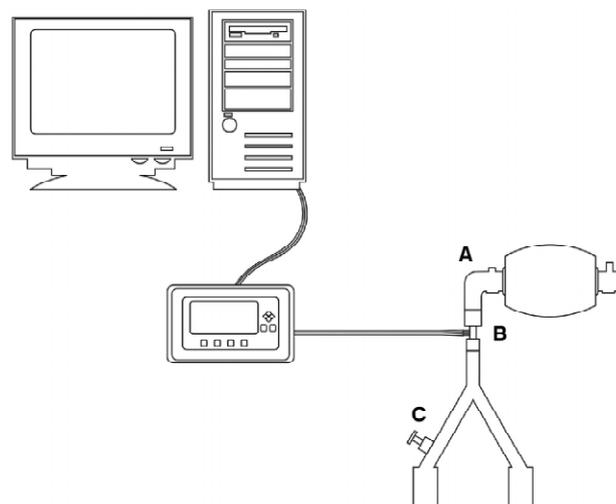
Studies have demonstrated that just a few breaths with excessive pressure or VT are enough to injure developing lungs.<sup>9,10</sup>

Nowadays there are several different types of device available for manual neonatal ventilation, and the majority of self-inflating bags do not employ manometers.<sup>11</sup> When a manual ventilation device does not allow pressure to be predefined, it is usual to control ventilation pressure by evaluating expansion of the thoracic chamber and resistance to expansion, felt by the operator's hands.<sup>12</sup> In practice, the operator is not always afforded a continuous view of the chest. During these moments there is a mechanical resource available to assess pulmonary expansion, in the form of tactile perception of resistance to inflation. Both evaluations—thoracic expansion and tactile sense – are subjective. Physicians do not tend to monitor pressures during manual ventilation and employ subjective data to adjust the force used to compress the reservoir of the self-inflating bag. This is why it is important to evaluate whether these perceptions are sufficient to guide them in adjusting the pressures applied under conditions similar to resuscitation, by means of studying the results during a procedure similar to resuscitation. Since, in the same manner, there are no means by which the ventilation rate to be used during resuscitation can be predefined, the rate achieved should also be measured.

The objective of the present study was to evaluate the peak inspiratory pressure and ventilation rate achieved by physicians using a neonatal self-inflating bag on a neonatal lung model.

## Methods

This is a descriptive and analytical experimental study, employing models analogous to lungs, constructed especially for this research, together with a ventilation monitor and a computer (Figure 1).



**Figure 1** - Schematic of data capture system

Thirty-five experienced physicians, currently working at a neonatal ICU and practiced in neonatal resuscitation, were invited to take part. Fifteen of them were then selected at random using a random number table. Neonatologists were defined as experienced if they were not recently-qualified, had completed residency in pediatrics and/or neonatology and were currently active in the field and familiar with neonatal resuscitation, both in the delivery room and neonatal ICU

The lung models used were a full term infant lung simulator with a dynamic complacency at 30 mL volume of 4.34 mL.cmH<sub>2</sub>O<sup>-1</sup> and a preterm infant lung simulator which had a complacency of 1.4 mL.cmH<sub>2</sub>O<sup>-1</sup> with an 11 mL volume. These "lungs" were filled with copper wool to reduce adiabatic pressure heating, thus attenuating the variation in volume in the presence of varying pressure. Closing the tap, labeled "C" in Figure 1, transformed the full term test lung into the preterm test lung. The model employed was similar to that utilized in a study undertaken by Connors et al.<sup>6</sup>

A Tracer 5<sup>®</sup> graphical ventilation monitor (Intermed<sup>®</sup>, São Paulo, Brazil) was connected between the test lung and the bag with a pneumotachograph (B, in Figure 1) and used to analyze pressure and RR. The pneumotachograph

captures an analogue pressure and flow signal and, by means of transducers and processors, the monitor transforms this into a digital signal.

Each professional was invited to ventilate the test lung using a new 280 mL neonatal bag, Lifesaver® brand (Hudson RCI®, Temecula, CA, USA), without a pressure monitor fitted. For purposes of the study the pressure-release valve (A, in Figure 1) was stopped. Ventilation was performed directly into the "airway", simulating an intubated patient. Some minutes before starting ventilation proper, the physicians were allowed to try out the test lungs, but without sight or knowledge of the data on the monitor, although they could see the test lungs. Each physician was asked to their best to simulate ventilation during neonatal resuscitation. Simultaneously data collection was started and continued for the next 5 minutes of continuous ventilation with the model set to full term lungs. Data were captured and recorded on a computer by Wintracer® software (Intermed®, São Paulo, SP, Brazil). After a short rest period of no more than 5 minutes, the physician was monitored ventilating the preterm test lung, also for 5 minutes, and data were recorded once more. The Tracer® software captured data continuously, but only the first 20 seconds of each minutes were recorded on the computer. Each pressure curve was analyzed separately, and maximum values input on a spreadsheet and then the variations within each curve were analyzed. The number of ventilation cycles produced in each 20-second sample was counted and then multiplied by three to obtain RR per minute. Throughout the experiment VT values were also recorded.

The study objectives were explained to all of the health professionals involved, as was the form in which data would be published. Therefore, during the enrollment interview, each participant was asked to sign a free and informed consent form.

The degree of competence of the professionals being studied was gauged through the application of a questionnaire containing the following questions: Do you perform cardiorespiratory resuscitation maneuvers with frequency? Do you habitually use self-inflating bags? Do you feel that you are qualified to perform this type of activity? What would you say was your degree of confidence with the use of self-inflating bags for cardiorespiratory resuscitation? Have you had training on a resuscitation course? If you answered "yes" to the previous question, please give the approximate length of time since the course.

Data were analyzed using Excel and SigmaStat software packages. The normality of data was verified with the Kolmogorov-Smirnov test and, since data distribution was non-parametric, the Wilcoxon Mann-Whitney test was used to compare median values, while the level of significance adopted was  $\alpha = 0.05$ .

This research project has been approved by the Research Ethics Committee of the Department of Health of the Distrito Federal.

## Results

A total of 1,151 curves were analyzed for the full term test lung, with a median PIP of 23 (interquartile range: 15-47) cmH<sub>2</sub>O, while the median for the 1,177 curves analyzed from the preterm test lung was 26 (interquartile range: 14-51) cmH<sub>2</sub>O (Figure 2). Median ventilation rate for the full term test lung was 45 (interquartile range: 36-57) cycles per minute, and for the preterm test lung it was 48 (interquartile range: 39-55.5) cycles per minute. The differences between these medians were not statistically significant ( $p = 0.135$  and  $p = 0.447$ , for PIP and RR respectively). With the full term test lung, pressures were within the range considered adequate, of 30 cmH<sub>2</sub>O $\pm$ 10%, in 9.3% of pressure curves, while for the preterm lung this figure was 6.5%. Pressures were less than 20 cmH<sub>2</sub>O in 41.2% of cases for the full term test lung and in 35.8% for the preterm model. Pressures were greater than 40 cmH<sub>2</sub>O in 29.7% of curves with the full term test lung and in 33.6% with the preterm simulator. Ventilation rate was slower than 30 cycles per minute in 9.3% of curves for the full term and 6.7% for the preterm models, while passing 60 cycles per minute in 12% of cases for the full term and 13.3% for the preterm lungs (Table 1).

Eighty-seven percent of the physicians performed cardiorespiratory resuscitation frequently and 67% of them use self-inflating bags. Fourteen of them had completed the neonatal resuscitation course, 29% of them less than 1 year previously, 29% between 1 and 2 years previously and 42% more than 3 years. The participants broke down by self-perceived confidence with the procedure as follows: totally confident (7%), very confident (46%) and averagely confident (47%). None of them judged themselves to be under confident.

## Discussion

Despite the fact that they were ventilating a test-lung with dynamic complacency (CDyn) similar to that of the respiratory systems of full term or preterm infants, the physicians were unable to maintain ventilation pressure at around 30 cmH<sub>2</sub>O as recommended by international protocols.

The pressure variation is similar to that observed by Mondolfi et al.,<sup>7</sup> who observed variation of from 5 to 73 cmH<sub>2</sub>O. In the current study, the levels observed were not those that are desirable when performing mechanical ventilation. It is reasonable to expect that in real situations these parameters could provoke ventilatory and circulatory

**Table 1 -** Variability in PIP (cmH<sub>2</sub>O) and RR (cycles per minute)

	<b>Full term test lung 1,151 curves analyzed</b>	<b>Preterm test lung 1,177 curves analyzed</b>	<b>p</b>
Median PIP	23	26	0.135
Interquartile range	15-47	14-51	
PIP 27 to 33	9.28%	6.45%	
PIP < 20	41.23%	35.77%	
PIP > 40	29.69%	33.64%	
Median RR	44	48	0.447
Interquartile range	36-57	39-55.5	
RR 30 to 60	78.67%	80%	
RR < 30	9.33%	6.67%	
RR > 60	12%	13.33%	

RR = respiratory rate; PIP = peak inspiratory pressure.

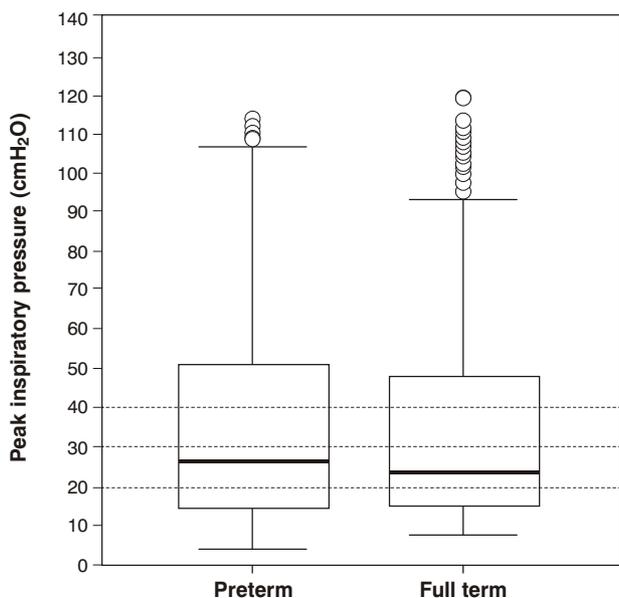
injuries, in addition to causing structural damage to the lungs.<sup>9,10</sup>

It could be argued that the variation demonstrated in our study might be limited if the pressure-release valve was unstopped and functioning correctly during every

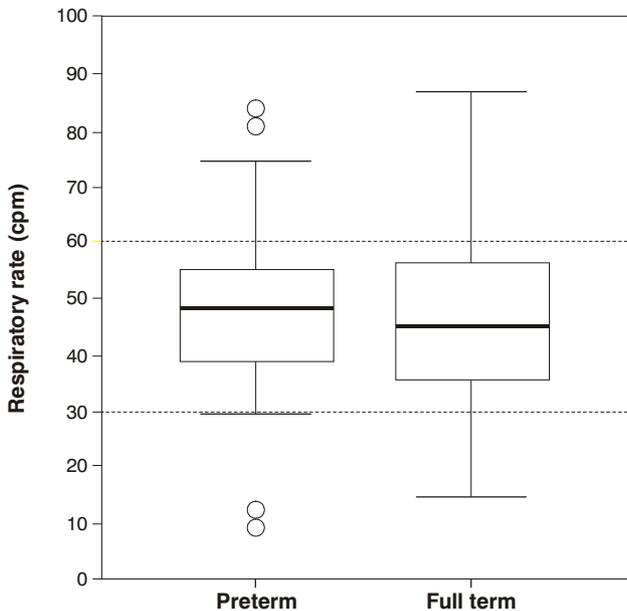
cycle. In truth, the variability dependent on the valve could be reduced if the release pressure (up to 45 cmH<sub>2</sub>O is considered acceptable by the ASTM) was constantly achieved. It is worth remembering that studies by Connors et al.<sup>6</sup> revealed two bags without release valves, another that released pressure at 50±5 cmH<sub>2</sub>O, another as 44±5 cmH<sub>2</sub>O and a fifth that did not release until 112±5 cmH<sub>2</sub>O, suggesting that these valves cannot be relied upon. Hussey et al.<sup>13</sup> observed maximum PIP of up to 75.9 cmH<sub>2</sub>O and Finer et al.<sup>14</sup> have also confirmed this variability.

In relation to RR, the physicians produced large variations (Figure 3), but achieving rates that were still within what is recommended by the protocols cited earlier;<sup>2,3</sup> suggesting these objectives are easier to achieve.

This study has certain limitations that should be considered. For example, it could be argued that physicians rely more on observations of the level of thoracic expansion to assess adequate lung inflation. Nevertheless, there is also evidence, in work by Baskett et al.,<sup>15</sup> that this parameter is not entirely reliable: the VT indicated as adequate when thoracic expansion was used was well below that recommended by the American Heart Association for adult patients. Notwithstanding, what we wished to evaluate with our experiment was the perception that these physicians had using their hands, and what we found was great variation. Of the 15 physicians assessed, 93% had been trained on resuscitation courses, and none of them felt under confident with performing resuscitation utilizing a self-inflating bag. Sixty-seven percent of the physicians evaluated said they habitually used a self-inflating bag, which is the same as saying that five of them



**Figure 2 -** Distribution of peak inspiratory pressures with full and preterm test lungs



**Figure 3** - Distribution of respiratory rates with full and preterm test lungs

generally used some other device for manual ventilation. All of those five physicians had attended a resuscitation course. Nevertheless, even removing their data, the remaining physicians only produced PIP between 27 and 33 cmH<sub>2</sub>O in 10% of cases with the full term test lung and 6.7% with the preterm test lung, while pressure was beyond the limits set in protocols in 69.9% of cases for the full term and 69.7% for the pre term models, without any difference with clinical significance between this partial dataset and the results from all of the physicians. Test lungs, which have already been used by other researchers,<sup>6,14,16</sup> can be considered adequate simulators for the purposes of this study; our model reproduces mechanical data similar to those defined for the respiratory systems of the full term and preterm newborn infant.<sup>17</sup> After all the data for this experiment had been captured, including VT, it was observed that mean CDyn for the full term test lung was 2.2 mL.cmH<sub>2</sub>O<sup>-1</sup> and for the preterm model it was 0.9 mL.cmH<sub>2</sub>O<sup>-1</sup>, confirming their suitability.

The statement that in order for a health professional to be successful at resuscitation, they must train or resuscitate regularly, and that competence in performing a specific multiprocedural motor skill such as cardiorespiratory resuscitation (CPR) depends on the frequency with which it is practiced,<sup>18</sup> may be an incomplete one, since, despite the fact that the physicians who participated in our study were capacitated, their results were not adequate for pulmonary ventilation.

The key to neonatal cardiorespiratory resuscitation is in the ventilation. Currently, even though international consensus statements define the self-inflating bag as the

primary instrument for manual ventilation, studies have shown<sup>11,19</sup> that there is no unanimity on what equipment should be used for neonatal resuscitation. Studies such as this one are the precursors to further experiments with animals and humans and are part of what we believe to be a field that is ripe for exploration.

We conclude that pulmonary ventilation using a self-inflating bag enabled the physicians to achieve adequate RR in approximately 80% of cases, both for the full term test lung and the preterm test lung. Nevertheless it did not allow them to produce the required minimal variability in pressure, producing levels different from those defined on the neonatal resuscitation course in 70% of cases, irrespective of whether they were ventilating a test lung analogous to the fullterm or to the preterm newborn respiratory system.

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