Neonatal and pediatric manual hyperinflation: Influence of oxygen flow rates on ventilatory parameters.

University of Campinas – UNICAMP - Campinas, SP, Brazil

1. Pricila Mara Novais de Oliveira, PT, PhD student at Graduate Program of Child and Adolescent Health, Department of Pediatrics, Faculty of Medical Sciences, UNICAMP, Campinas, SP, Brazil.
2. Armando Augusto Almeida-Junior, MD, MSc, Clinic’s Hospital of UNICAMP, Campinas, SP, Brazil.
3. Celize Cruz Bresciani Almeida, PT, PhD, Clinic’s Hospital of UNICAMP, Campinas, SP, Brazil.
4. Maria Ângela Gonçalves de Oliveira Ribeiro, PT, PhD, Department of Pediatrics, Faculty of Medical Sciences, UNICAMP, Campinas, SP, Brazil.
5. José Dirceu Ribeiro, MD, PhD, Department of Pediatrics, Faculty of Medical Sciences, UNICAMP, Campinas, SP, Brazil.

Corresponding author:
E-mail address: pricila.mno@gmail.com

Financial support: Coordination of Improvement of Higher Education Personnel (CAPES).

Conflict of interest statement: The authors have no conflicts of interest to disclose.
Abstract

**Background:** Although self-inflating bags are widely used for manual hyperinflation, they do not allow ventilation parameters to be set, such as pressure or volume. This study evaluated the ventilatory performance of neonatal and pediatric self-inflating bags from three manufacturers at different oxygen flow rates.

**Methods:** Twenty-two physiotherapists were asked to manually hyperinflate 2 lung models (neonatal and pediatric), using self-inflating bags from 3 manufactures (Hudson, Laerdal, and JG Moriya), with flow rates of 0, 5, 10, and 15L/min. A pneumotachograph (CO₂SMO®) recorded tidal volume (VT), peak inspiratory pressure (PIP), peak inspiratory (PIF) and expiratory flows, and inspiratory time.

**Results:** The VT, PIP, and inspiratory time delivered by Hudson, Laerdal, and JG Moriya in both neonatal and pediatric self-inflating bags were significant different ($P < .001$). The peak expiratory flow and PIF delivered were different only when using the neonatal self-inflating bags ($P < .001$). The VT, PIP, and PIF delivered using 0 L/min was lower than when receiving 15 L/min ($P < .05$) with all tested bags in neonatal and pediatric sizes.

**Conclusions:** The performance of neonatal and pediatric bags varied by manufacture and by oxygen flow rate applied. There was an increase in VT, PIP, and PIF related to the increase of oxygen flow rate from 0 L/min to 15 L/min. The neonatal bags showed higher ventilatory parameters variation when compared to the pediatric self-inflating bags.

**Keywords:** Resuscitation, Manual hyperinflation, Self-inflating bag, Pediatric, Respiratory therapy, Respiratory function monitor.
Introduction

Manual hyperinflation is used to improve secretion clearance and alveolar expansion in mechanically ventilated patients. Despite the fact that self-inflating bag (SIB) is the main device used in manual hyperinflation, it does not allow ventilation parameters to be set, such as pressures, volumes, or fraction of inspired oxygen delivered to the patient(1-3).

The American Society for Testing and Materials established standards(4) for self-inflating bags. However, significant physical and functional differences can be observed during cardiopulmonary resuscitation(5-13). These differences are among neonatal devices from different manufacturers. Several studies have confirmed that several factors might interfere with the performance of neonatal pulmonary ventilation(5,14,15). The factors are professional experience and training(12,16,17), lung compliance(18), visual feedback, pressure manometer(19), number of hands used in bag compression(20,21), and the operator's hand size(22). All these factors can affect the ventilatory parameters of manual hyperinflation. Such variance may impact clinical outcomes.

Few studies have evaluated the functional performance of neonatal SIBs according to oxygen flow rates, but they only assessed the fraction of inspired oxygen(13,23,24). There are no studies evaluating the relationship between SIB’s ventilatory parameters at different oxygen flow rates applied. Therefore, the aim of this study was to evaluate the performance of three neonatal and pediatric self-inflating bags manufacture at different oxygen flow rates during manual hyperinflation.

Methods
Design and Ethics

The study consisted in a randomized crossover design. It was approved by the University of Campinas Ethics Committee (#408/2008).

Setting

The study was conducted at the Biomedical Engineering Center of the University of Campinas. Twenty-two physiotherapists were recruited at the Clinic's Hospital of the University of Campinas. Eleven physiotherapists recruited had clinical experience with bagging critically ill neonates and children and eleven did not. No prior training was conducted with the participants. They were instructed to manually hyperinflate with slow inflation, rapid inspiratory pause, followed by fast bag release.

The manual hyperinflation was simulated to set up the respiratory mechanics of a neonate and a pediatric intubated patient in a test lung model (Ventilator tester 2, Biotek, Winooski - VT, USA) (Fig. 1). For the purpose of this study, the investigation in a leak free and intubated model was chosen. Measurements were recorded at different values of pulmonary compliance and resistance in order to simulate two clinical distinct situations: a healthy lung (normal respiratory mechanics) and a restrictive lung (decreased pulmonary compliance). The lung resistance test was adjusted for newborns at 50 cm H\textsubscript{2}O/L/s and for children at 20 cm H\textsubscript{2}O/L/s. The pulmonary compliance value for a healthy newborn was simulated at 3 mL/cm H\textsubscript{2}O and 1 mL/cm H\textsubscript{2}O for reduced compliance. In the pediatric model, a physiological situation was simulated as compliant at 10 mL/cm H\textsubscript{2}O and reduced at 3 mL/cm H\textsubscript{2}O. The values of compliance and resistance were based on a previous study\textsuperscript{(20)}. The test lung apparatus was calibrated considering the environmental temperature, atmospheric pressure, and relative air humidity before its use in the experiment.
The participants only used their dominant hand. They were encouraged to ventilate the test lung as they would ventilate a patient and to rest between tests avoiding fatigue; they were allowed to familiarize themselves with the equipment and environment. The tests were randomized. No visual or verbal feedback was provided during the tests. After the tests end, these professionals were submitted to a standardized interview about what they felt of the SIBs performance.

**Self-inflating bag**

Each participant used six new SIBs units. They were obtained from three different manufacturer: Hudson RCI (Research Triangle Park, North Carolina, United States), Laerdal Medical (Stavanger, Norway), and JG Moriya (São Paulo, Brazil) (Fig. 1). All SIBs were used in the two models: neonatal and pediatric. The SIBs were connected to a 50-psig source of 100% oxygen source, and oxygen flow rates of 0, 5, 10, and 15 L/min were delivered. The oxygen reservoir was attached to the units when the oxygen flow meter was set above 5 L/min. The pressure valve relief was kept unlocked.

The volumes of SIBs used were: Hudson neonatal = 280 mL, Hudson pediatric = 500 mL, Laerdal neonatal = 240 mL, Laerdal pediatric = 500 mL, JG Moriya neonatal =130 mL, and JG Moriya pediatric = 250 mL.

The bias was reduced by not telling the participants what was being investigated. The order of the SIB handling, compliance settings, and experience levels of the subjects were randomly assigned. The oxygen flow rates were used sequentially: 0, 5, 10, and 15 L/min. Nevertheless physiotherapists were unaware of this assignment.

All physiotherapists performed 10 manual hyperinflation with each of the three SIBs manufactures (JG Moriya, Hudson, and Laerdal) in each of the bags’ sizes (neonatal
and pediatric) in two clinical settings (normal and reduced compliance) with each one of the four flow rates tested (0, 5, 10, and 15 L/min).

**Pneumotachograph**
A sensor CO₂CAPNOSTAT® (Novametrix Inc., Wallingford, CT, USA) attached to the pneumotachograph CO₂SMO™ (Novametrix Inc., Wallingford, CT, USA) was fitted at the interface between the test lung and SIBs with no significant increase in dead space. The signals were recorded by the Analysis Plus software (Novametrix Inc., Wallingford, CT, USA) for further analysis. Physiotherapists were blinded to the pneumotachograph outcomes.

The variables measured were tidal volume (VT), peak inspiratory pressure (PIP), peak expiratory flow, peak inspiratory flow (PIF), and inspiratory time.

**Statistical analysis**
Statistical analysis was performed using the Statistical Analysis System 9.1.3 (SAS Institute Inc., Cary, NC, USA) for Windows. The Kolmogorov Smirnov-test was used to assess data distribution. Data did not present normal distribution, so all variables were transformed into ranks. The mean of 10 breaths per individual test was calculated.

The ventilatory parameters were compared at different SIB’s manufacture and flow rates applied using repeated measures analysis of variance (ANOVA). Then within-subjects contrasts test for post hoc analysis was applied. There was no significant period effect in this study because it consisted in an experimental setting. The results were reported as median (95% Confidence interval). The significance level for the statistical analysis was \( P < .05 \).

**Results**
VT, PIP, and inspiratory time delivered by Hudson, Laerdal, and JG Moriya bags with both neonatal and pediatric bags were statistically different ($P < .001$). The peak expiratory flow and PIF delivered were different only when using neonatal SIBs. These data were obtained independently of the flow rate applied (Table 1). Also, table 1 presents the within-subjects contrasts.

The PIP delivered ranged from 0 to 46 cm H$_2$O on 528 tests using neonatal SIBs. Only one participant provided PIP higher than 40 cm H$_2$O using the Hudson neonatal SIB. When testing the pediatric SIBs, the PIP ranged from 12 to 52 cm H$_2$O and, 16 of 22 participants exceeded the limit of 40 cm H$_2$O. All these measures were obtained with the Hudson pediatric SIB. It is necessary to emphasize that a minimum PIP of 20 cm H$_2$O was not reached in 121 (22.92%) tests with neonatal SIBs and 116 (21.97%) tests with pediatric SIBs. During manual hyperinflation, 18 physiotherapists failed to deliver PIP greater than 20 cm H$_2$O with the neonatal SIB and 19 with the pediatric SIB. The distribution of PIP values provided by the manufactures tested is presented in Table 2.

The values of VT, PIP, PIF, and inspiratory time were different at oxygen flow rates of 0, 5, 10 and 15 L/min (Fig. 2). The ventilatory parameters increased according to the increase of the flow rate. The ventilatory parameters delivered were significant different at the oxygen flow rates of 0 and 15 L/min ($P < .001$). This result was obtained independently of the SIB’s manufacture.

The experienced and inexperienced physiotherapists were similar in their overall manual hyperinflation performance; the only difference was the observation of the highest PIF in the results from the experienced group ($P = .03$ for neonatal and .03 for pediatric). The ventilatory parameters were different between the normal and reduced compliance settings ($P < .001$). The participants delivered a lower VT in the low
compliance setting than in the physiological compliance setting \((P < .001)\). The physiological compliance setting also showed a lower PIP than the reduced compliance setting \((P < .001)\). Furthermore, the PIF analysis also showed a significant difference between the low and high compliance settings \((P < .001)\). The comparison of ventilatory parameters delivered by the experience levels and by compliances was previously published\(^{16}\).

**Discussion**

This is the first study to determine the influence of oxygen flow rates on functional performance of three neonatal and pediatric self-inflating bags. The present study showed functional and physical differences between self-inflating bags manufactures. These differences were documented during neonatal resuscitation\(^{1,7,25}\). In addition, during neonatal or pediatric manual hyperventilation there was an increase in tidal volume, peak inspiratory pressure, and peak inspiratory flow according to the rise of oxygen flow rate. Few studies evaluating the neonatal SIB’s performance confirmed that fraction of inspired oxygen varied by oxygen flow rate applied. Nevertheless, these studies did not measure VT, PIP or PIF \(^{13,23,24}\).

In clinical practice, the choice of the oxygen flow rate applied varies according to the patient’s oxygenation. However the North American Neonatal Resuscitation Program recommended a gas flow from 5 to 10 L/min into SIB’s inlet when it is connected to a 100% oxygen source\(^{26}\). Often the manufacturers’ recommendations are unknown or not respected. The lack of difference in some ventilatory parameters between the flow rates of 5 and 10 L/min demonstrate the safety of using this flow rate range in daily practice.
The observations of the heterogeneous levels of PIPs delivered by SIBs in this study are in agreement with the other studies\(^{(9,27)}\). SIBs with a pop-off valve set to open up at a PIP value of 35 cm H\(_2\)O in Laerdal bag, and 40 cm H\(_2\)O in JG Moriya and in Hudson were used. However, PIP observed during the analysis often exceeded 40 cm H\(_2\)O in the pediatric bags despite the pop-off valve. This fact becomes even more significant during the preterm ventilation which require more accurate VT and PIP. Furthermore, it is intriguing to notice how often the PIP cut off of 20 cm H\(_2\)O was not reached. This outcome may lead the child to a hypoventilation risk and can affect alveolar recruitment during manual hyperinflation.

Despite self-inflating bags tested were suitable for each age group, the JG Moriya provided lower VT and PIP values than other manufactures. This manufacture PIF was also the lowest among the neonatal bags. When compared to the others manufactures tested JG Moriya provides less ventilation. Regardless of international consensus defining the SIB as the main instrument for manual ventilation, studies have shown that there is no unanimity in the guidelines for SIB’s use in the neonatal ventilation\(^{(6,8,14)}\). Lee \textit{et al}.\(^{(28)}\) report that the volumes delivered using the SIB vary widely and do not encourage the self-inflating bag use for careful and precise ventilation.

The ventilatory parameters variation during neonatal manual hyperinflation could be explained by the fact that the neonatal bag (150 mL) is pressurized faster and also distended, when compared to the pediatric bags. This results in higher pressures and volumes delivered by neonatal bags. Furthermore, an increased plateau pressure due to the low adjusted compliance at the infant setting could reflect in an increased PIP and VT.
There is a wide range of commercial neonatal, and pediatric self-inflating bags manufacture. The differences in the ventilatory performance between SIB’s manufacture could be explained mainly by their physical characteristics including bag and reservoir volume, valve types and valve resistances\(^{(29)}\), manufacturing materials, elasticity, density, and bag shape and texture\(^{(30)}\). In order to select the appropriate SIB for each clinical setting, the professional should be familiar with the equipment used and check it before use. The choice of an inadequate SIB for the patient's weight or the underlying disease could be dangerous.

The majority of participants (77%) reported increased resistance squeezing the JG Moriya SIB when compared to the Laerdal and Hudson SIBs. The JG Moriya bag’s silicone percentage could explain the reported increased resistance. Although the devices had similar bag formats, participants also described differences with respect to the bags’ texture. The Laerdal bag has a shape and texture that provide greater adherence between the equipment and the professional’s hand. Mazzolini-Jr and Marshal\(^{(30)}\) indicated that differences in bags' design and texture affect the fraction of inspired oxygen delivered by the SIB. According to the authors, the bags’ shape influences the gripping efficiency, consequently on the ventilation performance. The bags’ texture and their design increase the capacity to perform inflation and prevents SIB from slipping when handled. The bags’ manufacturing material can also affect the inflation pressures adjust \(^{(18)}\). Therefore, the ability of clinicians to sense compliance changes could interfere with the ventilatory parameters.

These present results were based on an experimental setting. The participants could not be blinded to the SIB used, and we were not able to test the SIB’s manufacturing materials. Further studies testing different SIB’s manufacture evaluating pressures and volumes delivery could contribute to the current results application. To recommend the
use of an optimal gas flow rate for a safe manual hyperinflation, more clinical studies are needed.

The SIB’s use for manual ventilation still presents several advantages over other devices. It does not require a continuous gas flow or a power source to be connected\(^5\); besides, it is portable and it is easy to use\(^0,31\). Based on the results, it is recommended that the SIB’ manufacture and the flow rate applied should be chosen carefully to avoid an adverse impact on clinical outcomes. Although there are several guidelines for resuscitation, recommendations about flow rates use during manual ventilation from the European Respiratory Society or American Thoracic Society were not found.

In agreement with Jones et al.\(^{31}\) the present study suggests that SIB’s selection should match the professionals’ experience and skills. Until manual hyperinflation clinical evidence is available, it is suggested that healthcare professionals to use a pneumotachograph or at least a manometer that allows the clinician to ensure a safe ventilation. It is necessary to learn about SIBs’ physical and functional characteristics and check the SIB before its use for the patients safety\(^{32}\). The SIBs’ use by untrained hands can be potentially dangerous\(^16\).

**Conclusions**

The performance of neonatal and pediatric bags varied during manual hyperinflation by manufacture and by oxygen flow rate applied. There was an increase in VT, PIP, PIF, and inspiratory time related to the increase of the oxygen flow rate from 0 L/min to 15 L/min. The neonatal bags showed higher ventilatory parameters variation when compared to the pediatric self-inflating bags. This research allows alerting
professionals about differences in manual hyperinflation ventilator parameters in order to be conducted a safe maneuver performance.

Acknowledgments

The authors are grateful for the financial support from the Coordination of Improvement of Higher Education Personnel (CAPES) and Biomedical Engineering Center from the University of Campinas.

References


**Fig. 1.** a) Neonatal self-inflating bags: Laerdal, Hudson, and JG Moriya, b) Test lung model: Ventilator tester 2.

**Fig. 2.** Comparison of the ventilatory parameters delivered according to flow rates attached to neonatal and pediatric self-inflating bags. a) Tidal volume (VT); b) Peak inspiratory pressure (PIP); c) Peak inspiratory flow (PIF). *Represent significant differences on each graph.
Table 1. Comparison between ventilatory parameters delivered by neonatal and pediatric self-inflating bags from 3 manufactures.

<table>
<thead>
<tr>
<th></th>
<th>Manufacture</th>
<th>Neonatal</th>
<th>Pediatric</th>
<th>P</th>
<th>Pediatric</th>
<th>P&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n=1760, N=176</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tidal volume, mL</td>
<td>Hudson</td>
<td>41.23 (47.2 - 52.3)</td>
<td>169.80 (161.7 - 174.9)</td>
<td>.001</td>
<td>□</td>
<td>.001</td>
</tr>
<tr>
<td></td>
<td>Laerdal</td>
<td>41.44 (49.6 - 54.9)</td>
<td>146.49 (158.9 - 172.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>JG Moriya</td>
<td>34.76 (37.5 - 42.4)</td>
<td>111.19 (131.4 - 146.5)</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak inspiratory pressure, cm H&lt;sub&gt;2&lt;/sub&gt;O</td>
<td>Hudson</td>
<td>24.93 (25.1 - 27.2)</td>
<td>25.98 (28.8 - 32.4)</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laerdal</td>
<td>26.28 (25.8 - 27.5)</td>
<td>27.03 (26.6 - 28.6)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>JG Moriya</td>
<td>21.25 (20.0 - 22.1)</td>
<td>22.13 (22.4 - 23.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak expiratory flow, L/min</td>
<td>Hudson</td>
<td>15.74 (14.8 - 15.5)</td>
<td>39.33 (38.2 - 40.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laerdal</td>
<td>16.53 (15.7 - 16.5)</td>
<td>39.21 (38.1 - 39.8)</td>
<td>.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>JG Moriya</td>
<td>15.00 (13.5 - 14.5)</td>
<td>39.16 (37.6 - 38.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak inspiratory flow, L/min</td>
<td>Hudson</td>
<td>13.18 (12.7 - 13.9)</td>
<td>27.03 (26.9 - 29.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laerdal</td>
<td>12.22 (11.9 - 13.2)</td>
<td>28.05 (27.8 - 30.7)</td>
<td>.48</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>JG Moriya</td>
<td>11.00 (11.0 - 12.3)</td>
<td>28.42 (27.0 - 29.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspiratory time, s</td>
<td>Hudson</td>
<td>0.41 (0.4 - 0.5)</td>
<td>0.67 (0.6 - 0.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laerdal</td>
<td>0.51 (0.5 - 0.6)</td>
<td>0.75 (0.8 - 0.9)</td>
<td>□ .001</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>JG Moriya</td>
<td>0.47 (0.5 - 0.6)</td>
<td>0.65 (0.6 - 0.7)</td>
<td>.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results presented by median (95% Confidence Interval). * † ‡ indicate significant differences at the post-hoc analysis, n: number of cycles, N: number of analyzed cycles means, P: significance level of neonatal brands comparison, P<sup>1</sup>: significance level of pediatric manufactures comparison. P-value of repeated measures ANOVA.

Table 2. Distribution of peak inspiratory pressure values delivered by the self-inflating bag manufactures.

<table>
<thead>
<tr>
<th>Peak inspiratory pressure &lt; 20 cm H&lt;sub&gt;2&lt;/sub&gt;O</th>
<th>Peak inspiratory pressure &gt; 40 cm H&lt;sub&gt;2&lt;/sub&gt;O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal</td>
<td>Pediatric</td>
</tr>
<tr>
<td>Hudson</td>
<td>33 (6.25%)</td>
</tr>
<tr>
<td>Laerdal</td>
<td>18 (3.41%)</td>
</tr>
<tr>
<td>JG Moriya</td>
<td>70 (13.26%)</td>
</tr>
<tr>
<td>Total</td>
<td>121 (22.92%)</td>
</tr>
</tbody>
</table>

Results presented by absolute values (%). N= 528 tests with neonatal self-inflating bags and 528 tests with pediatric self-inflating bags.
Fig. 1. a) Neonatal self-inflating bags: Laerdal®, Hudson®, and J.G.Moryia®, b) Test lung model: Ventilator tester2®.

190x142mm (300 x 300 DPI)
Fig. 2. Comparison of the ventilatory parameters delivered according to flow rates attached to neonatal and pediatric self-inflating bags. a) Tidal volume (VT); b) Peak inspiratory pressure (PIP); c) Peak inspiratory flow (PIF). *Represent significant differences on each graph.

254x190mm (300 x 300 DPI)