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Characterization of the mechanical behavior of intrapulmonary percussive ventilation

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Abstract
A new device delivering intrapulmonary percussive ventilation (IPV), called Impulsator (Percussionaire Corporation, Sandpoint, ID, USA), has recently been introduced in an effort to provide effective clearance and to promote homogeneity of ventilation in the lungs of patients with cystic fibrosis. In order to optimize the treatment based on its use, a better understanding of its functioning is still necessary. In fact, up to now, a complete characterization of this device has not been carried out, thus reducing its effective utilization in clinical practice. With the aim of overcoming this lack, in this study, data concerning flow and pressure delivered during in vitro IPV were acquired under different combinations of device settings and respiratory loads. Quantitative information was obtained about the physical variables administered by the device like percussive frequency, ratio of inspiratory to expiratory time, flow and pressure magnitudes and volume exchanged. The analysis of the data determined the relations among these variables and between them and the mechanical loads, laying the basis for an optimal clinical application of the device.

Keywords: biomedical signal processing, intrapulmonary percussive ventilation, in vitro, respiratory physiotherapy, cystic fibrosis

1. Introduction
Intrapulmonary percussive ventilation (IPV) is an airway clearance technique introduced as an alternative to conventional chest physiotherapy to facilitate airway clearance and to preserve lung function in patients with chronic obstructive pulmonary diseases (COPD) and, in particular, with cystic fibrosis (Chatburn 2007, Flume et al 2009, Morrison and Agnew

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IPV is an adaptation of high frequency percussive ventilation, which promotes airway vibrations by injecting rapid bursts of air into the lung via the mouth (Riffard and Toussaint 2012). The air pulses, superimposed on a normal spontaneous breathing pattern, are believed to go deep into the lung loosening the mucus, enhancing clearance of secretions and, on the whole, delaying lung damage (Rogers and Doull 2005, Marks 2007). Despite the potential benefits of IPV, device settings are a crucial factor in the management of the treatment (Nava et al 2006, Toussaint et al 2012): they vary the physical variables administered by the device, changing the effects in the lungs and possibly affecting the effectiveness of the therapy.

Recently, a new transportable device providing noninvasive IPV, called Impulsator® (Percussionaire Corporation, Sandpoint, ID, USA), has been introduced for home therapy in COPD subjects with the aim to foster patients’ independence. Nevertheless, there is a lack of detailed information concerning the percussive frequencies, the pulse inspiratory and expiratory durations and the magnitudes of flow and pressure delivered by the system under the different setting conditions provided by the device. In fact, it is not possible to monitor the actual working conditions because neither the flows nor the pressures are measured by the ventilator. The inability to ascertain these variables could compromise the effect of the treatment and prevent the optimization of its use. In order to better understand the behavior of this device, this work presents an in vitro quantification of the variables involved in IPV performance (flow, pressure and volume) on varying device settings and mechanical loads. Moreover, the relation between flow and airway pressure was analyzed, suggesting two approaches to estimate the impedance of the mechanical load applied to the system.

2. Material and methods

2.1. Equipment

The Impulsator® is basically composed of a flow generator, which provides pulsatile flow, and of a mouthpiece, called Phasitron® Duo™ (Percussionaire Corporation), connected by specific tubing to the generator (figure 1). The system presents simplified settings compared to other IPV systems designed for hospital and intensive care (like IPV®-1 and VDR-4®; Percussionaire Corporation) but it shares with them the principles of operation (Riffard and Toussaint 2012). The Impulsator® only allows a joined adjustment of frequency and amplitude of percussions of the air flow generator by turning a knob, passing from ‘easy’ (E) to ‘hard’ (H) through ‘average’ (A) position. The control knob varies the flow provided by the generator, while the flow actually delivered by the whole system is mechanically adjusted through the
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Phasitron® Duo™, according to the Venturi effect. The airflow supplied by the high pressure air generator causes a piston to move back and forth inside the Phasitron® Duo™, producing a supplementary airflow entrance from a side port. The amount of the flow entering in the mouthpiece is inversely proportional to the pressure reached at the level of the airways, thus assuring the flow adaptation to the mechanical properties of the subject’s respiratory system. This original characteristic of the system protects the lungs from possible barotrauma during the treatment, but it also prevents users from knowing beforehand the actual flow delivered to the patient (Lucangelo et al. 2003). Moreover, the Phasitron® Duo™ presents a vent hole, placed below the piston and before the patient’s port, which can be manually closed or open with a thumb by the patient. To our knowledge, its role is not well-known yet, but, as quantified in this work, it largely influences the delivered flows and pressures.

A single-compartment lung simulator (Accu Lung, Fluke Biomedical, Cleveland, OH, USA) was used to assess the changes of flow and pressure under three resistive loads \((R = 5, 20, 50 \text{ cmH}_2\text{O}/(\text{L s}^{-1}))\) and three compliance loads \((C = 10, 20, 50 \text{ mL/cmH}_2\text{O})\). Flow and pressure generated during IPV were measured by using a mass airflow sensor (AWM730B5, Honeywell, Freeport, IL, USA) and a differential pressure transducer (SCX01DN, Honeywell, Freeport, IL, USA) with adequate conditioning boards (Riscica et al. 2011). The flow sensor was placed in line in front of the mouthpiece, while airway pressure was measured from a side port between the mouthpiece and the lung simulator. The airtightness of the experimental setup was carefully verified. Data were acquired at 2000 Hz with 14 bit resolution and stored in a laptop. A simplified diagram of the experimental setup is shown in figure 1.

2.2. Measurements and data analysis

Measurements were carried out for the nine possible combinations of mechanical loads and for the three device settings (E, A and H) in each of the two vent hole conditions (open or closed), for a total of 54 testing patterns. In order to ensure the constancy of the output of the flow generator, the first seconds of each test were not considered and the analysis was carried out on 20 cycles with the device working at full performance.

The percussive frequency \(f_p\) was estimated by measuring the time interval between two consecutive peaks of each waveform. The pulse inspiratory time \(i\) (i.e. the duration of the pulse flow administration) was calculated as the interval of time between the minimum of pressure and the subsequent peak; similarly, the pulse expiratory time \(e\) was measured between a positive peak and the subsequent minimum (Lucangelo et al. 2006). Peak to peak amplitudes of flow \(Q_{pp}\) and pressure \(P_{pp}\) were calculated for each cycle and averaged over the 20 considered cycles. The typical signal pattern of flow and pressure is represented in figure 2 together with the measured parameters.

The relation between flow and airway pressure was analyzed taking as a starting point a classical linear model of the respiratory system (RIC model). Subsequently, an approximate method (AP method), easier to calculate, was proposed. Both approaches were implemented to assess the total impedance of the mechanical load and the results obtained by the different approaches were compared.

The RIC model is described by the motion equation:

\[
P(t) = K + \frac{V(t)}{C} + R \cdot Q(t) + I \cdot Q'(t)
\]

(1)

where \(C\) is the compliance of the respiratory system including lung and chest wall, \(R\) is the resistance of the airways and the tissue and \(I\) the inerance of the respiratory system mainly defined by the airways and the connecting tubes, while at any instant \(t\), \(P(t)\) represents the pressure which generates instantaneous volume \(V(t)\), flow \(Q(t)\) and its derivative \(Q'(t)\); \(K\)
corresponds to the mouth pressure when \(V(t), Q(t)\) and \(\dot{Q}(t)\) are zero (Dorkin et al 1988). \(V(t)\) and \(\dot{Q}(t)\) were calculated by numerical integration (trapezoidal rule) and differentiation (central differences) of \(Q(t)\), respectively. The multiple linear regression approach (least square criterion) applied to equation (1) was used to estimate \(R, I\) and \(C\); assuming the signals sinusoidal to a first approximation (as demonstrated by its Fourier spectrum), the modulus of the global mechanical impedance \(Z\) was finally calculated as:

\[
Z_{RIC} = \sqrt{R^2 + \left(2\pi f_p I - \frac{1}{2\pi f_p C}\right)^2}.
\] (2)

Adopting the AP method, the impedance \(Z\) was roughly estimated as the ratio of the peak to peak amplitudes of pressure and flow (\(P_{pp}\) to \(Q_{pp}\)), that is:

\[
Z_{AP} = \frac{P_{pp}}{Q_{pp}}.
\] (3)

Both estimated \(Z_{RIC}\) and \(Z_{AP}\) were compared to the nominal impedance of the lung simulator, calculated as:

\[
Z = \sqrt{R^2 + \left(\frac{1}{2\pi f_p C}\right)^2}
\] (4)

where \(R\) and \(C\) are the nominal values set in the lung simulator and the inertance \(I\) of the simulator is not reported because it is negligible.

The normalized root mean square error (NRMSE) was used to measure the differences between nominal and predicted \(Z\) values; NRMSE was calculated as:

\[
NRMSE = \sqrt{\frac{\sum_{i=1}^{n} (Z_i - \hat{Z}_i)^2}{\sum_{i=1}^{n} (Z_{max} - Z_{min})^2}}.
\] (5)

where \(Z\) was the nominal impedance, \(\hat{Z}\) the estimated one, \(n\) the number of combinations of loads and device settings in which the impedance was estimated; \(Z_{max}\) and \(Z_{min}\) were the highest and lowest nominal values of impedance, respectively.

Finally, the total exchanged volume (\(V_{tot}\)) was computed integrating separately the measured flows entering in and leaving from the lung simulator and by summing their absolute values (Lucangelo et al 2006). Hence, the slope of the line fitting \(V_{tot}\) in the time, in a least square sense, was calculated (figure 3).
Figure 3. Example of flow and volume data (knob position A, vent hole closed, \( R = 5 \) cmH\(_2\)O/(L s\(^{-1}\)), \( C = 50 \) mL/cmH\(_2\)O). Entering and leaving flows were integrated separately thus producing entering (\( V_{in} \)) and leaving (\( V_{out} \)) volumes. The sum of the absolute values of these volumes represents the total exchanged volume (\( V_{tot} \)). The slope of the line interpolating \( V_{tot} \) corresponds to the rate at which the volume is exchanged.

Table 1. Pulse \( i \) and \( e \) durations and ratio calculated while keeping the vent hole closed. The values were averaged among the mechanical loads and expressed as mean ± SD.

<table>
<thead>
<tr>
<th>Knob position</th>
<th>( i ) duration (ms)</th>
<th>( e ) duration (ms)</th>
<th>Approximated ( i/e ) ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>40.6 ± 1.0</td>
<td>43.4 ± 0.8</td>
<td>1:1.1</td>
</tr>
<tr>
<td>A</td>
<td>58.6 ± 3.3</td>
<td>112.8 ± 2.4</td>
<td>1:1.9</td>
</tr>
<tr>
<td>H</td>
<td>80.5 ± 9.8</td>
<td>262.3 ± 5.5</td>
<td>1:3.3</td>
</tr>
</tbody>
</table>

3. Results

The values of percussive frequency \( f_p \) did not change with the mechanical loads, ranging from 12 Hz in E position to 3 Hz in H position. Unexpectedly, when the percussive control knob was set to A, the frequency was significantly different whether the vent hole in the mouthpiece was open or closed: in the first case \( f_p \) was of 8 Hz and in the latter of 6 Hz. While keeping the vent hole closed and the same knob position, the duration of both \( i \) and \( e \) periods were constant among the different mechanical loads (table 1). The \( i/e \) ratio decreased from E to H position from about 1:1.1 to about 1:3.3. If the vent hole was open, \( i \) and \( e \) durations, for both E and A position, were comparable to those obtained with the vent hole closed, whereas for H position the large variability of the pressure signal around the zero during the pulse expiratory phase did not allow a correct estimation of \( i \) and \( e \) durations.

As it happens in other IPV devices, thanks to the Phasitron\textsuperscript{®}, flow and pressure amplitudes were sensitive to the impedance of the mechanical load: high resistive loads determined higher mean and peak pressures and, conversely, smaller peak flows (Lucangelo et al 2004). Figure 4 shows the mean values (±1SD) of \( Q_{pp} \) and pressure \( P_{pp} \), for all the testing conditions.

It is worth noting that even if \( Q_{pp} \) decreases as \( C \) increases for \( R = 5 \) cmH\(_2\)O/(L s\(^{-1}\)) and H setting, the positive peak values of flow are constant. This decrease is due only to a reduction in the negative dips of the flow waveform (figure 5).

Figure 6 depicts the impedances values estimated by the two approaches previously described compared to the nominal one. Data are referred to the combinations of settings in which the vent hole was closed. The RIC model approach had a NRMSE of 0.10, whereas the other method presented a NRMSE of 0.14.
Figure 4. Peak to peak amplitudes (± SD) of flow (a) and pressure (b) in the different combination of setting position, mechanical loads and vent hole condition. The values were averaged over 20 cycles.

Figure 5. Flow waveforms recorded under $R = 5$ cmH$_2$O/(L s$^{-1}$) and H setting. While C increases, the negative dips of the waveform reduce.
Figure 6. Impedance estimation by RIC model (left) and by approximate method (right) in the 18 test conditions with $R = 5$ and 20 cmH$_2$O/(L s$^{-1}$) and the vent hole closed.

Figure 7. Total volume exchanged in 1s, calculated as the slope of the line interpolating $V_{tot}$ in the time. For each $R$, the values were averaged over the different $C$ (some SD are not visible due to narrow intervals).

Because the volume originated from flow, the total volume exchanged during IPV depended on both mechanical loads and device settings. The dependence of $V_{tot}$ on $C$ was negligible (for each $R$, fluctuations were generally lower than 4% of the maximum value), so in figure 7 only mean values ($\pm$ SD) of the slope interpolating $V_{tot}$ at different $R$ values were reported. Decreasing $R$ and passing from E to H setting progressively increased $V_{tot}$. Moreover, the closing of the vent hole, which produces a flow increase, further improved the exchanged volumes up to a maximum of about 0.5 L s$^{-1}$.

4. Discussion

The percussive frequency and the $i/e$ ratio decreased passing from E to H setting, thus suggesting that E and A positions could promote mobilization of secretions, whereas H position enhances alveolar ventilation and clearance. In fact, frequencies over 5 Hz (like in E
Figure 8. Example of $P(t)$ versus $Q(t)$ under different device settings, with the vent hole closed. In this case the imposed mechanical load was $R = 20$ cmH$_2$O/(L s$^{-1}$) and $C = 20$ mL/cmH$_2$O.

and A) increase mucus movement while lower frequencies (like in H) improve gas exchange (Riffard and Toussaint 2012a) and low $i.e$ ratios (like in H) determine the effectiveness of mucus clearance (Toussaint et al 2003, 2012). All the other measured parameters were sensitive to the mechanical load applied at the mouthpiece. It follows that it is not possible to determine these variables in advance of the patient's treatment, because they are instantly adjusted by the mouthpiece.

Since the purpose of this study was also to assess the clinical usability of the device, $R = 50$ cmH$_2$O/(L s$^{-1}$) was considered unlikely to occur in clinical practice and the attention was focused on the results obtained setting the mechanical loads at $R = 5$ cmH$_2$O/(L s$^{-1}$) and $R = 20$ cmH$_2$O/(L s$^{-1}$). Under these loads, the peak to peak amplitude of pressure, which gives an assessment of the intensity of the percussions at the mouthpiece, ranged between $1.54 \pm 0.67$ cmH$_2$O for $R = 5$ cmH$_2$O/(L s$^{-1}$), $C = 50$ mL/cmH$_2$O, E setting, vent hole open, and $34.71 \pm 0.98$ cmH$_2$O for $R = 20$ cmH$_2$O/(L s$^{-1}$), $C = 10$ mL/cmH$_2$O, H setting, vent hole closed. In particular, the $P_{pp}$ values determined at $R = 5$ cmH$_2$O/(L s$^{-1}$) by E and A settings with the vent hole closed and by H setting with the vent hole open as well as those obtained at $R = 20$ cmH$_2$O/(L s$^{-1}$) by H setting with the vent hole open, were comparable to those generated by other oscillating devices used for physical therapy (Dos Santos et al 2013), suggesting that the device, under these settings, is compatible with the clinical use in patients with increased airway secretions.

For every mechanical load and device setting, the effect of the vent hole opening was remarkable: the vent hole opening reduced the oscillations in flow and pressure, causing a drop of about 50% in both flow and pressure amplitudes. Since values of positive expiratory pressure between 10 and 20 cmH$_2$O have been suggested to determine more effectiveness in airway clearance (Darbee et al 2004), the opening of the vent hole, with the knob in E or A position, producing very low pressure oscillations (less than $5.69 \pm 0.44$ cmH$_2$O), is unsuitable for secretions removal. On the contrary, $P_{pp}$ were intensified by keeping the vent hole closed. In any case, the very high pressure value for $R = 50$ cmH$_2$O/(L s$^{-1}$) with the control knob at H was reached only instantaneously during IPV, while mean pressure was definitely reasonable, in the range 14.6–15.7 cmH$_2$O, depending on $C$.

The relation between flow and pressure is presented in figure 8 and its linearity justifies the use of the approximated method we applied. The influence of $C$, which determines the curve opening in the plot (H setting, figure 8), is more evident for lower $R$ and $f_p$ values, for
which the approximate method is less reliable, as can be appreciated in figure 6. This sort of loop present in the flow–pressure curve is due to a phase shift between flow and pressure signals, caused by the major influence of $C$ in the total impedance.

Moreover, the NRMSE was lower by using the RIC model than with the approximate one. However, the latter, for its simplicity, may be used for a first rough estimation of the impedance of the load applied to the IPV system, possibly also in case of patient’s use.

Finally, since another target of an airway clearance device is to improve pulmonary mechanics and facilitate gas exchange in addition to secretion mobilization and elimination (Myers 2007), the total volume exchanged during IPV has to be considered. As shown in figure 7, while keeping the vent hole closed, the rate at which the volume was exchanged was high (up to 0.5 L s$^{-1}$) and similar in A and H positions, whereas it resulted reduced in E position for all the mechanical loads. The opening of the vent hole caused a significant drop in the rate at which the volume was exchanged, once more suggesting that the vent hole should be kept closed in order to maximize both percussive and ventilatory properties of IPV.

A lung simulator can only partially mimic the respiratory mechanics, thus the present results have to be considered limited, as in any in vitro study. The major limitation concerns the fact that, being the simulator passive, it is not possible to consider the interaction of the IPV with breathing pattern. In vivo studies are needed to overcome this main limitation.

5. Conclusions

Pressure and flow delivered by Impulsator® into a lung simulator were measured under different combinations of mechanical loads and device settings and the variables involved in the performance of the IPV system were quantified, providing the basis for an optimal clinical application. In particular, the mobilization of mucus resulted maximized by E setting, while A or H setting intensifies the volume exchange, supporting alveolar ventilation and clearance of secretions. All these properties are maximized keeping the vent hole closed. Two methods of estimating the load impedance during IPV, which may be of clinical interest during patient’s treatment, were also proposed.

Further studies will be necessary to assess the device operational conditions when spontaneous breathing is superimposed to IPV.

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