Bench Comparative Assessment of Mechanically Assisted Cough Devices

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BACKGROUND: Mechanically assisted cough devices are used in patients with impaired cough to avoid secretion accumulation. We compared 5 mechanically assisted cough devices by bench testing using a breathing simulator and assessed their user-friendliness. METHODS: We measured inspiratory and expiratory airway pressures and peak expiratory flow, the strongest indicator of cough efficacy. We performed 2 bench tests: 1) to ascertain the differences between preset and actual settings in 3 different machines of each mechanically assisted cough device and 2) to assess the effects of varying respiratory impedance and air leaks on performance of the devices. We also evaluated the user-friendliness of the devices by measuring the time required and errors in accomplishing 4 tasks by 10 physicians unfamiliar with mechanically assisted cough devices compared with product specialists from the distributing companies. Physicians also scored the ease of use. RESULTS: Four mechanically assisted cough devices during insufflation and all 5 during exsufflation showed differences between preset and actual airway pressures. All but one device showed uneven actual pressure values between models of the same type. Peak expiratory flow was significantly influenced by the mechanical properties in 2 devices and by air leaks in 4 devices. The median time to accomplish all tasks by the product specialist (10 [interquartile range of 2–29] s) was overall significantly shorter compared with all physicians (from 19 [14–65] to 36 [19–116] s). The number of procedural errors, but not the perceived ease of use, differed significantly between the devices. CONCLUSIONS: The performance of different mechanically assisted cough devices was erratic and included variance between models from the same manufacturer; it was affected by respiratory system impedance and air leaks. Time and rate of errors for performing procedures were elevated. These findings indicate that the devices are not interchangeable and that the settings should be targeted for each patient with the specific machine being used. Improvements in reliability, performance, and user-friendliness are advisable. Key words: cough; physical therapy modalities; respiratory therapy; pulmonary medicine; mechanical ventilators; critical care. [Respir Care 2015;60(7):975–982. © 2015 Daedalus Enterprises]

Introduction

Impaired cough with retention of tracheobronchial secretions is a common complication of neuromuscular disorders. Ineffective cough can lead to tracheotomy for the sole purpose of airway suctioning in patients with severe respiratory failure.1 Accordingly, intensive chest physical

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therapy, including cough assistance, is often prescribed to enhance secretion clearance.\(^2,3\)

Cough assistance is traditionally based on inspiratory volume increase and manual abdominal thrust and/or chest compression. Mechanically assisted cough devices can also be used for this purpose, with either an endotracheal artificial airway\(^4\) or a mask.\(^5\) These devices sequentially apply positive and negative (subatmospheric) pressure to the airway, creating a pressure gradient to promote a peak expiratory flow (PEF) sufficient to remove secretions from the large airways.

Several studies have demonstrated the effectiveness of mechanically assisted cough devices and, in some cases, superiority to manual techniques\(^6-8\) in achieving secretion clearance in both acute\(^9,10\) and chronic\(^11,12\) subjects with ineffective cough with shorter periods of treatment.\(^13\) As a result, these devices are being increasingly used, and their commercial availability in Europe has risen concomitantly. The use of mechanically assisted cough devices has been proposed for ICU patients as a means to facilitate successful extubation.\(^9\)

Despite the increased availability of mechanically assisted cough devices, to our knowledge, no study has evaluated and compared different devices to ascertain whether their performances are equivalent. As the performances of other devices such as home ventilators have been shown in bench studies to vary significantly,\(^14\) we designed this bench study to evaluate and compare 5 mechanically assisted cough devices that are commercially available in Europe with respect to reliability, intra-device reproducibility, and response to varying respiratory mechanics and presence of air leaks. Moreover, considering the lack of homogeneity among mechanically assisted cough devices with respect to control screens and buttons, we also evaluated the user-friendliness of these 5 devices for ICU physicians.

**Methods**

The study was performed on 2 consecutive days in November 2012 in the laboratory of the Department of Clinical Engineering at the Niguarda Ca’ Granda Hospital in Milan, Italy. The 5 mechanically assisted cough devices tested are listed in Table 1. The devices were connected to a breathing simulator (ASL 5000, IngMar Medical, Pittsburgh, Pennsylvania). Two different bench tests were conducted. Both tests were performed in automatic mode, with the inspiratory and expiratory airway pressures (Paw) set at \(-40\) and \(+40\) cm H\(_2\)O, respectively, and the inspiratory (TI) and expiratory (TE) times both set 3 s, without pause in between. Immediately after the first cycle of insufflation-exsufflation, 5 consecutive respiratory cycles were recorded and averaged. Both bench tests were performed once by the same bioengineer in the Laboratory of Clinical Engineering, without familiarity with the devices under evaluation. In addition, we performed a test to evaluate the user-friendliness of the 5 devices.

<table>
<thead>
<tr>
<th>Ventilator</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nippy cough assistor</td>
<td>B&amp;D Electromedical (Warwickshire, UK)</td>
</tr>
<tr>
<td>CoughAssist</td>
<td>Philips Healthcare (Best, The Netherlands)</td>
</tr>
<tr>
<td>New Negavent DA-3 PLUS Pegaso</td>
<td>Dima Italia (Bologna, Italy)</td>
</tr>
<tr>
<td>New Negavent DA-3 PLUS Mini Pegaso</td>
<td>Dima Italia</td>
</tr>
<tr>
<td>Pulsar</td>
<td>Siare Engineering International Group (Bologna, Italy)</td>
</tr>
</tbody>
</table>
Bench Test 1

Three different machines of each mechanically assisted cough device were tested in a single experimental condition (simulated compliance of 40 mL/cm H₂O, simulated resistance of 10 cm H₂O/L/s, no air leaks).

Bench Test 2

We used the best performing of the 3 machines evaluated in bench test 1 for each mechanically assisted cough device. The response to varying simulated respiratory mechanical properties, with and without air leaks, was evaluated mimicking 4 conditions: (1) compliance of 40 mL/cm H₂O and resistance of 10 cm H₂O/L/s without air leaks, (2) compliance of 40 mL/cm H₂O and resistance of 10 cm H₂O/L/s with air leaks, (3) compliance of 60 mL/cm H₂O and resistance of 20 cm H₂O/L/s without air leaks, and (4) compliance of 60 mL/cm H₂O and resistance of 20 cm H₂O/L/s with air leaks.

User-Friendliness Test

One product specialist for each mechanically assisted cough device, indicated by the company distributors, and 10 physicians, randomly drawn by lot from the neuro-ICU medical staff and without previous experience with any of the 5 devices under evaluation, were selected to test user-friendliness. One week before the test, the physicians received information on the functions of all 5 devices.15 Physicians were asked to perform a 4-task test for each mechanically assisted cough device. The order of evaluation of the devices was randomized for each physician. The test consisted of 4 separate phases: (1) start-up (starting the assembled device), (2) recognizing parameters (inspiratory and expiratory Paw, Tᵢ, Tₑ, and the pause in between, requested according to a randomized sequence), (3) varying settings (inspiratory Paw of 40 cm H₂O, expiratory Paw of −40 cm H₂O, Tᵢ of 4 s, Tₑ of 3 s, pause of 1 s), and (4) stop (ie, turning off the machine and activating the standby mode, if available).

Data Analysis

Data of the 2 bench tests were recorded from the ASL 5000 data output array and analyzed offline. Tᵢ, Tₑ, PEF, and inspiratory tidal volume (VT) were obtained from the flow tracing, whereas inspiratory and expiratory Paw and time to reach 90% of preset inspiratory and expiratory Paw (T₉₀ᵢ and T₉₀ₑ, respectively) were obtained from the Paw tracing.

In bench test 1, inspiratory and expiratory Paw were analyzed to evaluate whether the difference between preset and actual values was in accordance with the 4% tolerance limit indicated by the European Commission requirements (51.104-CEI EN 60601-2-12).16 To assess variability of each model, the test was performed on 3 machines obtained from the commercial distributors.

In bench test 2, we evaluated the performance of the mechanically assisted cough devices under different simulated conditions. Inspiratory and expiratory Paw, PEF, Vᵢ, T₉₀ᵢ, and T₉₀ₑ were determined for each device and compared.

In the user-friendliness test, the time required to perform tasks was measured with a precision stopwatch by a second bioengineer in the laboratory of the Department of Clinical Engineering with extensive knowledge of all 5 mechanically assisted cough devices and awareness of the tasks to be accomplished. For all tasks, the time measurement was interrupted upon achievement of the specific objective or at a maximum limit of 5 min. In addition, the physicians graded the ease of use of each device, both overall and separately for each single task, using a visual analog scale on a 10-cm line marked with 0 on the left for very difficult and 10 on the right for very easy. Finally, the errors made by the physicians during test execution were counted and expressed both as absolute values and percent of the overall actions required during the test.

Statistical Analysis

Data are expressed as median (interquartile range) unless specified otherwise and were compared by analysis of variance on ranks (Kruskal-Wallis test). The Dunn post hoc test was used to ascertain differences between either selected pairs of conditions (bench test 2) or all mechanically assisted cough devices (user-friendliness test), as appropriate. We considered P < .05 to be significant.

Results

Bench Test 1

As shown in Figure 1A, the discrepancy between preset and actual inspiratory and expiratory Paw was within the 4% tolerance limits for 2 mechanically assisted cough devices (Nippy and Pulsar) only. Furthermore, all devices but one (Nippy) showed uneven inspiratory and expiratory Paw with the 3 machines tested. As shown in Figure 1B, discrepancies were observed between preset and actual Tᵢ and Tₑ. All devices but one (Pulsar) for Tᵢ and all but 2 devices (Nippy and Pulsar) for Tₑ showed erratic values with the 3 machines tested.

Bench Test 2

Figure 2A shows inspiratory Paw, Vᵢ, and T₉₀ᵢ, and Figure 2B shows expiratory Paw, PEF, and T₉₀ₑ. Inspira-
tory Paw was significantly affected by mechanical properties with one device only (Pegaso) and to varying extents by the presence of air leaks with the other 4 devices. VT was affected by the simulated mechanical properties with the Nippy device and to varying extents by air leaks with the other 4 devices. T90I was unaffected by mechanical properties or air leaks with the CoughAssist; by mechanical properties with the Pegaso, Mini Pegaso, and Pulsar; and by air leaks with the Nippy. Expiratory P_{aw} was affected by mechanical properties with the Pegaso and to varying extents by air leaks with the other 4 devices. PEF was influenced by mechanical properties with the Mini Pegaso and Pulsar and by air leaks with the Nippy, CoughAssist, Pegaso and Mini Pegaso. T90E was affected by mechanical properties with the Mini Pegaso and by air leaks with the other 4 devices.

**User-Friendliness Test**

All 10 physicians completed all 4 tasks. Table 2 shows (1) the median (interquartile range) of the time spent by the 10 physicians to accomplish the 4 tasks individually and overall, (2) the scores on the ease of accomplishment of the tasks by the physicians, and (3) the errors made by the physicians during task execution. Overall, the Pegaso and Pulsar showed the shortest and longest times of execution, respectively. In addition, there were wide and significant differences between the mechanically assisted cough devices with respect to the individual tasks. The scores on the ease of use were no different overall and showed significant differences only for the start-up and recognizing-parameters tasks. The CoughAssist resulted in significantly more errors overall, as opposed to the Pegaso (P = .04), Mini Pegaso (P = .04), and Pulsar (P = .03). This was due primarily to the recognizing-parameters task. The Nippy showed no significant difference with respect to all tasks compared with the other devices.

As shown in Figure 3, the overall median time spent to accomplish the 4 tasks by the product specialists using each of the 5 devices (gray bar) was significantly shorter compared with that achieved by the 10 physicians (white bars) (P = .02).

**Discussion**

In this study, we found that only 2 of the 5 mechanically assisted cough devices complied with the 4% tolerance limit for the discrepancy between preset and actual inspiratory and expiratory P_{aw}. Moreover, for all devices but one, the actual inspiratory and expiratory P_{aw} of the 3 machines tested were discrepant. In addition, the performance of the 5 devices was affected differently by the simulated mechanical properties, the air leaks, or both. Finally, the time spent to accomplish 4 tasks (separately and overall) assigned to 10 ICU physicians was largely and significantly different between devices. The ease of accomplishment of the tasks was not significantly different between the devices overall, whereas there were relatively small significant differences between devices with respect to 2 individual tasks (ie, start-up and recognizing parameters).

Our bench study is the first to evaluate and compare several mechanically assisted cough devices. In a previously published bench study comparing the Nippy and CoughAssist operating with varying mechanical properties (but without considering air leaks), PEF was found to be greater with the Nippy. It is of note that in a previous bench evaluation performed to assess the impact of various artificial airways on the performance of the CoughAssist, the same authors reported quite different PEF values with an identical setup. In keeping with these contradictory findings, we found uneven inspiratory and expiratory P_{aw} (see Fig. 1A) and T_I and T_E (see Fig. 1B) between the 3 machines tested for each device. Furthermore, though all
5 devices had the European Conformity mark, only 2 devices conformed overall to the European Community 4% tolerance limit for mechanical ventilators with respect to the difference between preset and actual Paw. In addition, although the 4% tolerance limit corresponds in our study to a difference between preset and actual inspiratory and expiratory Paw of only 1.6 cm H2O (a relatively small value of limited clinical importance), some machines markedly exceeded the 4% limit (see Fig. 1A). These discrepancies may be more relevant in particular scenarios, such as when the mechanically assisted cough device is applied with a tracheotomy or endotracheal tube rather than de-
livered via a face mask or mouthpiece. Furthermore, we do not know whether the variance between actual and preset values is greater or less marked at insufflation-exsufflation pressure settings other than $40$ to $40$ cm H$_2$O.

In a bench test of one mechanically assisted cough device (CoughAssist) at 3 different preset inspiratory and expiratory Paw with 4 simulated mechanical properties, Guérin et al$^{18}$ showed that varying the size of the artificial airway (ie, the additional airway resistance imposed by the tube) affects PEF, which is the strongest indicator of cough efficacy. Our study expands this observation, demonstrating that the performance of these devices is affected by the mechanical properties of the respiratory system and by the presence of air leaks. In fact, we found not only PEF, but also VT, the actual inspiratory and expiratory Paw,T90I, and T90E to fluctuate with all mechanically assisted cough devices, although to remarkably varying extents. As shown in Figure 4, VT, actual inspiratory and expiratory P$_{aw}$, T$_{90I}$, and T$_{90E}$ are all determinants of PEF.

Gonzalez-Bermejo et al$^{19}$ reported the limited user-friendliness of home ventilators and stressed the importance of this considering the increasing number of medical and nonmedical health-care professionals required to manage the technical aspects of these machines when caring for patients receiving home ventilation. The authors found that for most ventilators, the ICU physicians were slower than the specialist technician in completing the required tasks. Furthermore, the physicians scored the overall ease of use as no different between ventilators. With a similar study design, the present study extends those observations to mechanically assisted cough devices. The time taken by each task differed between devices, and overall, ICU physicians were slower than the product specialist. Also, consistent with the former study, physicians scored ease of

### Table 2. Time, Ease of Use, and Errors for Accomplishment of Tasks

<table>
<thead>
<tr>
<th></th>
<th>Nippy</th>
<th>CoughAssist</th>
<th>Pegaso</th>
<th>Mini Pegaso</th>
<th>Pulsar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time, s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start-up</td>
<td>13 (12–22)</td>
<td>3 (2–4)</td>
<td>26 (22–34)$^a$</td>
<td>37 (32–58)$^b$</td>
<td>76 (57–111)$^{a,d}$</td>
</tr>
<tr>
<td>Recognizing parameters</td>
<td>20 (18–22)</td>
<td>68 (44–84)$^c$</td>
<td>17 (14–19)$^f$</td>
<td>19 (16–38)$^f$</td>
<td>23 (17–30)$^b$</td>
</tr>
<tr>
<td>Varying settings</td>
<td>103 (91–139)</td>
<td>83 (52–113)</td>
<td>67 (62–92)</td>
<td>83 (63–112)</td>
<td>153 (153–154)$^{a,i}$</td>
</tr>
<tr>
<td>Stop</td>
<td>67 (22–91)</td>
<td>7 (5–17)$^e$</td>
<td>5 (3–72)$^c$</td>
<td>8 (7–14)$^c$</td>
<td>23 (17–62)$^c$</td>
</tr>
<tr>
<td>Overall</td>
<td>217 (169–269)</td>
<td>151 (116–224)</td>
<td>127 (105–157)$^{a,i}$</td>
<td>181 (125–213)</td>
<td>309 (249–354)$^{a,i}$</td>
</tr>
<tr>
<td>Visual analog scale ease of use, cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start-up</td>
<td>9.4 (8.1–9.7)</td>
<td>9.6 (9.1–9.9)</td>
<td>7.2 (6.6–8.5)$^a$</td>
<td>7.2 (6.3–9.1)$^n$</td>
<td>5.4 (3.4–7.8)$^{a,d}$</td>
</tr>
<tr>
<td>Recognizing parameters</td>
<td>9.5 (8.7–9.8)</td>
<td>7.2 (3.7–7.5)$^o$</td>
<td>9.4 (8.3–9.7)$^a$</td>
<td>9.4 (7.7–9.7)$^p$</td>
<td>8.3 (7.0–9.3)</td>
</tr>
<tr>
<td>Varying settings</td>
<td>9.2 (8.4–9.5)</td>
<td>7.0 (4.0–8.9)</td>
<td>8.9 (8.3–9.4)</td>
<td>8.1 (6.6–8.8)</td>
<td>7.3 (5.2–8.6)</td>
</tr>
<tr>
<td>Stop</td>
<td>8.9 (7.4–9.2)</td>
<td>9.3 (5.9–9.7)</td>
<td>9.4 (8.4–9.7)</td>
<td>8.8 (8.3–9.7)</td>
<td>6.4 (4.7–9.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>8.8 (7.4–9.3)</td>
<td>7.7 (6.4–9.1)</td>
<td>8.8 (7.9–9.5)</td>
<td>8.9 (7.5–9.3)</td>
<td>6.9 (4.6–8.7)</td>
</tr>
<tr>
<td>Errors, % ($n$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start-up</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
</tr>
<tr>
<td>Recognizing parameters</td>
<td>0 (0–20), (4)</td>
<td>40 (15–45), (18)</td>
<td>0 (0), (1)$^p$</td>
<td>0 (0), (2)$^p$</td>
<td>0 (0), (0)$^k$</td>
</tr>
<tr>
<td>Varying settings</td>
<td>0 (0–30), (7)</td>
<td>0 (0–40), (10)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (1)</td>
</tr>
<tr>
<td>Stop</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
<td>0 (0), (0)</td>
</tr>
<tr>
<td>Overall</td>
<td>0 (0–21), (11)</td>
<td>21 (12–31), (28)</td>
<td>0 (0), (1)$^p$</td>
<td>0 (0), (2)$^p$</td>
<td>0 (0), (1)$^p$</td>
</tr>
</tbody>
</table>

Data are expressed as median (interquartile range).

$^a$ $P$ = .02 Pegaso vs CoughAssist
$^b$ $P < .001$ Mini Pegaso vs CoughAssist
$^c$ $P = .001$ Pulsar vs Nippy
$^d$ $P = .001$ Pulsar vs CoughAssist
$^e$ $P = .01$ CoughAssist vs Nippy
$^f$ $P = .01$ Mini Pegaso vs CoughAssist
$^g$ $P = .01$ CoughAssist vs Nippy
$^h$ $P = .01$ Pegaso vs CoughAssist
$^i$ $P = .001$ Pulsar vs Nippy
$^j$ $P = .001$ Pulsar vs CoughAssist
$^k$ $P < .001$ Pegaso vs Nippy
$^l$ $P = .02$ Mini Pegaso vs CoughAssist
$^m$ $P = .02$ Pulsar vs Nippy
$^n$ $P = .001$ Pulsar vs Nippy
$^o$ $P = .04$ CoughAssist vs Nippy
$^p$ $P = .04$ Pegaso vs CoughAssist
$^q$ $P = .04$ Pulsar vs Mini Pegaso
$^r$ $P = .04$ CoughAssist vs Nippy
$^s$ $P = .04$ Pulsar vs CoughAssist

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**Fig. 3.** Time for performing all the tests on all mechanically assisted cough devices by ICU physicians The graph shows the overall median time spent to accomplish all tasks by the product specialists (grey bar) compared with 10 ICU physicians (white bars). $^*$ $P = .02$, product specialists vs physicians.
Mechanically Assisted Cough Devices

Fig. 4. Determinants of peak expiratory flow (PEF), which is the strongest indicator of cough efficacy. The magnitude of PEF is directly influenced by the pressure applied to the airway opening ($P_{aw}$) during the expiratory phase, the time to reach 90% of preset expiratory $P_{aw}$ ($T_{90E}$), and the volume insufflated during the inspiratory phase (tidal volume [$V_I$]), corresponding to the pre-tussive volume and resulting from the extent of the inspiratory $P_{aw}$ and the speed of achievement of the time to reach 90% of preset inspiratory $P_{aw}$ ($T_{90I}$).

Conclusions

The performance of different mechanically assisted cough devices was extremely variable, even between machines of the same model, and is affected by respiratory system impedance and air leaks. The time taken to set up and operate the devices and the number of procedural errors made by the ICU physicians were high. These findings indicate that the devices are not interchangeable and that the settings should be targeted for each patient with the specific machine utilized. A substantial improvement in reliability, reproducibility of performance, and user-friendliness is advised.

REFERENCES

11. Bach JR, Rajaraman R, Ballanger F, Tzeng AC, Ishikawa Y, Kulessa R, Bansal T. Neuromuscular ventilatory insufficiency: effect of home country at the time the study was performed. It is notable that only one device is presently available for clinical use in North America. We are aware that some new mechanically assisted cough devices have since been introduced in the market, and the manufacturers have updated some of those evaluated here. Although we share this limitation with any study evaluating medical devices, we believe that the message of this study remains valid for both clinicians and manufacturers.


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