



# Addition of bacterial filter alters positive airway pressure and non-invasive ventilation performances

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To the Editor:

Recently, one manufacturer of home ventilators issued an alert regarding the potential risk of serious injury related to the use of some of their positive airway pressure (PAP) and non-invasive ventilation (NIV) devices [1]. The risk is caused by the polyurethane foam used in their ventilators. In some cases, the foam broke into the blower and could have been inhaled by patients. The manufacturer and some healthcare regulatory agencies advocated, as a temporary solution, to modify PAP and NIV circuits by adding an inline bacterial filter in order to reduce the risk of inhalation [2]. However, changing ventilator circuits can alter ventilator performances during PAP and NIV [3].

Auto-titrating PAP is commonly used to reduce the need for inpatient titration [4] by the use built-in algorithm to adjust the level of pressure needed to effectively treat the patient [5, 6]. However, no study has evaluated the impact of inline bacterial filter insertion on the efficacy of auto-titrating PAP. As the insertion of an inline bacterial filter has been recommended, we sought to assess the consequences of such an addition.

The aim of our study was to assess the impact of the adjunction of an inline filter in a ventilator circuit used during NIV and fixed and auto-titrating PAP.

To assess ventilator performance, we used an experimental setup made of a three-dimensional printed head mimicking human upper airways and trachea connected to an artificial lung (ASL5000, IngMar Medical, USA) as previously described [3]. We compared ventilator performances without any filter (*i.e.* normal use of the ventilator) and with five commercial low-resistance breathing filters: Anesth-Guard (Teleflex Medical, USA), Clear-Guard 3 (Intersurgical, UK), Clear-Guard Midi (Intersurgical, UK), Eco SlimLine (L3 Medical, France) and Flo-Guard (Intersurgical, UK).

For NIV, we used Dreamstation BiPAP AVAPS, BiPAP A40 and Trilogy 100 ventilators (Philips Respironics, USA). We used a pressure support mode; inspiratory positive airway pressure (IPAP) at 15 and 25 cmH<sub>2</sub>O; expiratory positive airway pressure (EPAP) at 5 cmH<sub>2</sub>O. We computed triggering delay (ms), inspiratory pressure-time product (PTPt) (cmH<sub>2</sub>O·s), pressure differential (cmH<sub>2</sub>O), defined as the difference between the delivered inspiratory pressure and the set pressure, and tidal volume (mL). Simulated patient-ventilator asynchrony (sPVA) events were classified according the SomnoNIV group framework [7].

For PAP, we used a DreamStation PAP device (Philips Respironics, USA). We computed regulation delay (ms), PTPt (cmH<sub>2</sub>O·s) and the maximal delivered pressure (cmH<sub>2</sub>O).

For auto-titrating PAP assessment, we simulated obstructive events by applying 10 cmH<sub>2</sub>O to a Starling resistance as previously described [8]. After 6 min without any event, 20 s length obstructive events were simulated every 60 s. A total of 24 obstructive events were simulated. We assessed the EPAP reached during the last 4 min of the simulation.



Shareable abstract (@ERSpublications)

**The recommendation to add a bacterial filter on home positive pressure devices has significant negative impact on their performances and precludes auto-titrating positive airway pressure to function. These data suggest to not follow such recommendation.** <https://bit.ly/31YrWyo>

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Results are expressed as median and interquartile range, except for sPVA, which is expressed as mean and 95% confidence intervals. Chi-squared, Mann–Whitney, Wilcoxon and Friedman tests were used. Dunn's correction was applied for multiple comparisons using the setup without filter as reference. All tests were two-sided. The significance level was set at 0.05. Statistical analysis was performed with Prism 9.0.0 (GraphPad Software, USA).

The addition of filter resulted in a significant impact on NIV performances with an increased triggering delay: 11 ms (9–16 ms) ( $p=0.010$ ); a lower inspiratory pressure:  $-1.63$  cmH<sub>2</sub>O ( $-2.10$ – $-1.1$  cmH<sub>2</sub>O) ( $p<0.001$ ); a lower tidal volume:  $-61$  mL ( $-55$ – $-31$  mL) ( $p=0.025$ ); and an increase in PTPt:  $1.38$  cmH<sub>2</sub>O·s ( $0.70$ – $1.73$  cmH<sub>2</sub>O·s) ( $p<0.001$ ). The addition of filters did not significantly impact the rate of sPVA: 33% (95% CI 25–41%) versus 27% (95% CI 24–31%) ( $p=0.261$ ) (table 1).

Using continuous PAP (CPAP), the addition of filter resulted in an increased regulation delay: 237 ms (168–386 ms) ( $p<0.001$ ); a lower inspiratory pressure:  $-0.81$  cmH<sub>2</sub>O ( $-0.74$ – $-0.90$  cmH<sub>2</sub>O) ( $p<0.001$ ); and an increase in PTPt:  $14.92$  cmH<sub>2</sub>O·s ( $8.60$ – $23.41$  cmH<sub>2</sub>O·s) ( $p<0.001$ ) (table 1).

The addition of filter resulted in a lower delivered pressure during auto-adjusting PAP:  $-3.18$  cmH<sub>2</sub>O ( $-3.29$ – $-3.08$  cmH<sub>2</sub>O) ( $p<0.001$ ) (table 1). With auto-adjusting PAP, 93% of cycles were correctly classified as obstructive events by the device without filter. With a filter, the percentage of correctly identified events dropped down to 25% of cycles (Flo-guard) ( $p<0.001$ ) (table 1).

Following recommendations suggesting the use of inline bacterial filter to reduce the risk of particle inhalation, our experimental model shows that 1) during NIV, adding a bacterial filter significantly increased the work of breathing and decreased the delivered volume; 2) during PAP, adding a bacterial filter increased the work of breathing and decreased the delivered pressure; and 3) during auto-titrating PAP, the use of bacterial filter resulted in lower pressure and inaccurate characterisation of respiratory events.

Home NIV is delivered to patients with advanced chronic respiratory failure [9] who have a poor prognosis [10]. As the addition of filters leads to an increase of work of breathing and a lower tidal volume, they may aggravate hypoventilation and thus dramatically impact on NIV efficacy and worsen prognosis. If physicians were to follow the recommendation to add an inline filter, our data suggest to closely monitor patients and to adjust NIV settings to alleviate the impact on the work of breathing and on the delivered volume.

With PAP, the delivered pressure was lower both with CPAP ( $-0.81$  cmH<sub>2</sub>O) and auto-adjusting PAP ( $-3.18$  cmH<sub>2</sub>O). Such a drop in the delivered pressure is likely to have clinical consequences with poorer control of upper airway.

In our study, we have demonstrated that adding an inline filter greatly altered the automated detection of obstructive events. Clinicians should therefore not base their clinical decision using the residual event data provided by a PAP device when using an inline filter.

Our results show that the addition of an inline filter could strongly impact on the effectiveness of the auto-adjusting PAP device tested. Indeed, we have shown that the addition of filters resulted in a lower delivered pressure and a higher number of residual obstructive events. We hypothesise that filters impact the efficacy of this device by interfering with the detection of obstructive respiratory events leading to an increase in the residual apnoea–hypopnoea index reported by the device. Our results show that auto-adjusting PAP should not be used with an inline filter.

In line with previous bench studies [3, 11], our results highlight that PAP and NIV devices should be used as per their user manual without any alteration on their regular setup. Indeed, any change may impair their efficacy.

There are some limitations in our study. First, we only performed a bench model study. However, a clinical trial assessing six different types of experimental condition, and three different type of lung mechanics would have not been feasible especially given the night-to-night variability [12]. Second, we identified significant differences between filters, but we did to evaluate their clinical relevance or their long-term consequences. Third, we did not assess the impact of filter insertion on the volatile organic compound. Finally, these results may not be extensible to other machines and manufacturers.

**TABLE 1** Impact of the addition of an inline bacterial filter on ventilator performances in non-invasive ventilation (NIV), continuous positive airway pressure (CPAP) and auto-adjusting positive airway pressure (PAP) for each type of filter

	No filter	Anesth-Guard filter (F1)	Clear-Guard 3 filter (F2)	Clear-Guard Midi Filter (F3)	Eco SlimLine Filter (F4)	Flo-Guard filter (F5)	p-value
<b>NIV</b>							
Time to trigger (ms)	94.9 (69.2–142)	105 (78.0–159)*	112 (82.6–172)*	106 (76.2–162)*	104 (74.6–158)*	101 (74.1–153)*	<0.001
Pressure differential (cmH <sub>2</sub> O)	0.250 (0.160–0.315)	−1.44 (−1.68–−1.02)*	−2.13 (−3.08–−1.71)*	−1.64 (−2.13–−1.22)*	−1.24 (−1.51–−0.91)*	−0.82 (−1.06–−0.59)*	<0.001
Tidal volume (mL)	859 (614–946)	815 (595–889)*	758 (568–868)*	793 (579–878)*	811 (598–891)*	829 (603–908)*	<0.001
PTPt insp. (cmH <sub>2</sub> O·s)	3.29 (2.02–3.81)	4.69 (2.79–5.66)	5.54 (3.06–6.72)	4.95 (2.75–5.77)	4.57 (2.59–5.37)	4.20 (2.50–4.69)	<0.001
Asynchrony index (%)	32.9 (24.6–41.2)	25.5 (17.8–33.1)	29.8 (22.0–37.6)	28.4 (20.6–36.2)	26.6 (18.8–34.4)	25.6 (17.9–33.4)	0.261
<b>CPAP</b>							
Regulation delay (ms)	146 (127–206)	374 (297–593)*	464 (344–637)*	412 (309–604)*	375 (280–594)*	331 (253–515)	<0.001
Pressure level (cmH <sub>2</sub> O)	9.99 (9.83–10)	9.17 (9.08–9.2)*	8.86 (8.76–8.88)*	9.13 (9.01–9.14)*	9.29 (9.15–9.3)*	9.50 (9.37–9.53)	<0.001
Pressure differential (cmH <sub>2</sub> O)	0.039 (0.033–0.040)	−0.779 (−0.797–−0.765)*	−1.12 (−1.12–−1.12)*	−0.858 (−0.863–−0.852)*	−0.698 (−0.704–−0.697)*	−0.47 (−0.471–−0.469)	<0.001
PTPt insp. (cmH <sub>2</sub> O·s)	4.47 (4.21–4.69)	20.2 (11.9–24.8)*	32.5 (16.8–40.3)*	24.2 (13.2–29.7)*	18.7 (11.6–22.8)*	14.1 (8.91–19.1)	<0.001
<b>Auto-adjusting PAP</b>							
Mask pressure (cmH <sub>2</sub> O)	10.19 (10.16–10.22)	6.88 (6.74–7.07)*	7.48 (7.43–7.61)*	7.78 (7.71–7.88)*	6.98 (6.84–7.13)*	7.01 (6.87–7.14)*	<0.001
Apnoea–hypopnea detected by the built-in software (n)	14	24	24	24	24	24	0.132
Central event according to built-in software	1 (7%)	14 (58%)	6 (25%)	16 (66%)	15 (63%)	18 (75%)	<0.001
Obstructive event according to built-in software	13 (93%)	10 (42%)	18 (75%)	8 (34%)	9 (37%)	6 (25%)	
Residual obstructive apnoeic event measured in the simulated patient <sup>#</sup>	5 (21%)	24 (100%)	10 (42%)	8 (33%)	24 (100%)	24 (100%)	<0.001
Residual obstructive hypopnoeic event measured in the simulated patient <sup>¶</sup>	19 (79%)	0 (0%)	14 (58%)	16 (77%)	0 (0%)	0 (0%)	

\*: significantly different from control (no filter). #: residual obstructive apnoeic events were defined by a reduction of 90% of baseline flow  $\geq 10$  s measured by the artificial lung; ¶: residual obstructive hypopnoeic events were defined by a reduction between 30% and 90% of baseline flow  $\geq 10$  s measured by the artificial lung. PTPt insp.: inspiratory pressure-time product.

We have shown that the addition of inline filters has meaningful consequences for ventilator performance. The addition of these filters alters the detection of, and results in lower control of, obstructive events. Therefore, we suggest not using inline filters during auto-titrating PAP. If used during NIV and CPAP, these bacterial filters require a close monitoring and setting adjustments.

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