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

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Claudio Rabec[1,2,3], Emeline Fresnel[4], Yann Rétory[5], Kaixian Zhu[5], Karima Joly[2], Adrien Kerfourn[4], Benjamin Dudoignon[6], Alexis Mendoza[3], Antoine Cuvelier[7,3], Jean-François Muir[2], Boris Melloni[2,8], Jean-François Chabot[2,9], Jésus Gonzalez-Bermejo[3,10,11,12], Maxime Patout[3,6,11]

1. Pulmonary Department and Respiratory Critical Care Unit, University Hospital Dijon, Dijon, France.
2. Fédération ANTADIR, Paris, France
3. Groupe Assistance Ventilatoire et O2 ($GAVO_2$), Société de Pneumologie de Langue Française, Paris, France
4. Kernel Biomedical, Bois-Guillaume, France
5. Centre EXPLOR, Air Liquide Healthcare, Gentilly, France
6. AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Service des Pathologies du Sommeil (Département R3S), F-75013 Paris, France
7. Normandie Univ, UNIRouen, EA3830-GRHV, Institute for Research and Innovation in Biomedicine (IRIB), Rouen, France
8. Pulmonary department, University Hospital Limoges, 87042 Limoges France
9. Département de Pneumologie, Université de Lorraine, CHU de Nancy, Vandœuvre-lès-Nancy, France
10. AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Service de Pneumologie, Médecine Intensive et Réanimation (Département R3S), F-75013 Paris, France
11. Sorbonne Université, INSERM, UMRS1158 Neurophysiologie Respiratoire Expérimentale et Clinique, F-75005 Paris, France

Corresponding author:

Dr. Maxime Patout

AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Service des Pathologies du Sommeil (Département R3S) Paris, France

47-83 boulevard de l'hôpital,

75013, Paris, France

maxime.patout@aphp.fr

Take home message:

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. Our data suggest to not follow such recommendation.

Introduction

Recently, one manufacturer of home ventilators alerted about the potential risk of serious injury related to the use of some of their positive airway pressure (PAP) and non-invasive ventilator (NIV) [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 ventilators performances during PAP and NIV [3].

Auto-titrating PAP are commonly used to reduce the need of 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 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.

Methods

To assess ventilator performances, we used an experimental setup made of a 3-D 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 5 commercially 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 a Dreamstation BiPAP AVAPS, a BiPAP A40™ and a Trilogy 100™ ventilators (Philips Respironics, USA). We used a pressure support mode; inspiratory positive airway pressure (IPAP) at 15 and 25 cmH_2O; expiratory positive airway pressure (EPAP) at 5 cmH_2O. We computed triggering delay (ms), inspiratory pressure-time product (PTP_t) ($cmH_2O.s$), pressure differential (cmH_2O), defined as the difference between the delivered inspiratory pressure and the set pressure and tidal volume (Vt) (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), PTP_t ($cmH_2O.s$) and the maximal delivered pressure (cmH_2O).

For auto-titrating PAP assessment, we simulated obstructive events by applying $10cmH_2O$ to a Starling resistance as previously described [8]. After 6 minutes without any event, 20 seconds length obstructive events were simulated every 60s. A total of 24 obstructive events were simulated. We assessed the EPAP reached during the last 4 minutes of the simulation.

Results are expressed as median and interquartile range (IQ), except for sPVA expressed as mean and 95% confidence intervals. Chi-2, 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 .05. Statistical analysis was performed with Prism 9.0.0 (GraphPad Software, USA).

Results

The addition of filter resulted in a significant impact on NIV performances with an increased triggering delay: 11ms [9 - 16] (p=0.010), a lower inspiratory pressure: -1.63 cmH_2O [-2.10 - -1.1] (p<0.001), a lower tidal volume: -61ml [-55 - -31] (p=0.025) and an increase in PTPt: 1.38cmH_2O.s [0.70 – 1.73] (p<0.001). The addition of filters did not significantly impact the rate of sPVA: 33% [25 – 41] *vs*. 27% [24 – 31] (p=0.261) (Table 1).

Using continuous PAP (CPAP), the addition of filter resulted in an increased regulation delay: 237ms [168 – 386] (p<0.001), a lower inspiratory pressure: -0.81cmH_2O [-0.74 – -0.90] (p<0.001) and an increase in PTPt: 14.92cmH_2O.s [8.60 – 23.41] (p<0.001) (Table 1).

The addition of filter resulted in a lower delivered pressure during auto-adjusting PAP: -3.18cmH_2O [-3.29 – -3.08] (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).

Discussion

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 3) during auto-titrating PAP, the use of bacterial filter resulted in lower pressure and inaccurate characterization of respiratory event.

Home NIV is delivered to patients with advanced chronic respiratory failure [9] and 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 (-0.81cmH_2O) and auto-adjusting PAP (-3.18cmH_2O). Such 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 hypothesize that filters impact the efficacy of this device by interfering with the detection of obstructive respiratory events leading to an increase in the residual AHI reported by the device. Our results shows 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 6 different type of experimental condition, 3 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.

Conclusion

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

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Authors contribution:

CR, EFR, KZ, YR, KJ, JGB, MP: conception, acquisition, analysis, interpretation, drafting the work, revising critically

AM, AC, BD, BM, AK, JFM, JFC: conception, interpretation and, revising critically

Competing Interests statement:

In the last two years, CR received fees from Philips, Resmed, Lowenstein and Fischer & Paykel for expertise, outside the submitted work.

MP reports personal fees from Resmed, Philips Respironics, grants and non-financial support from Fisher & Paykel, nonfinancial support and personal fees from Asten and ANTADIR, research grants from B&D Electromedical and Fisher & Paykel, shares in Kernel Biomedical, personal fees and non-financial support from Chiesi outside the submitted work.

In the last 2 years JGB received fees from Philips, Resmed, Breas, Lowenstein and Air Liquide for expertise, and a grant from BREAS for a trial, outside the submitted work.

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Table 1: Impact of the addition of an inline bacterial filter on ventilator performances in NIV, CPAP and auto-adjusting PAP for each type of filter (* : significantly different from control (No filter), $: residual obstructive apnoeic events were defined by a reduction of 90% of baseline flow ≥ 10 seconds measured by the artificial lung; £: residual obstructive hypopnoeic events were defined by a reduction between 30 and 90% of baseline flow ≥ 10 seconds measured by the artificial lung; Auto-adjusting PAP: auto-adjusting positive airway pressure; CPAP: continuous positive airway pressure; NIV: non-invasive ventilation)

	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
NIV							
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_2O)	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
PTP insp ($cmH_2O.s$)	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
CPAP							
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_2O)	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 diff (cmH_2O)	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
PTP insp ($cmH_2O.s$)	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
Auto-adjusting PAP							
Mask pressure (cmH_2O)	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[$]	5 (21%)	24 (100%)	10 (42%)	8 (33%)	24 (100%)	24 (100%)	<0.001
Residual obstructive hypopneic event measured in the simulated patient[£]	19 (79%)	0 (0%)	14 (58%)	16 (77%)	0 (0%)	0 (0%)	