Assessment of open-source, intermediate and intensive care unit ventilators to face the COVID-19 pandemic. A bench study

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The COVID-19 pandemic triggered many strategies to challenge the risk of ventilators shortage (1-3). One was the development of n low-cost ventilator as recently proposed (4). A second strategy was a large scale production of intermediate ventilators dedicated to emergency room and patient transport with the help of non-medical industry, as it was the case in France where the government asked car manufacturer Peugeot SA to build 1500 Osiris 3 (Air Liquide Medical System, Antony, France), and in the US where government ordered the purchase of 200 000 ventilators from 11 companies in the country (5). Our goal was to assess on the bench accuracy of tidal volume (V_T) delivery from brand new low cost ventilators, intermediate machines and an ICU ventilator.

The study took place between May 13, 2020 and October 10, 2020.

Makair and e-Spiro low cost ventilators, Osiris 3, EOV150, T60, T75 (Air Liquide Medical system), E30 (Philips Respironics, Murrysville, USA) and SV300 (Mindray, Shenzhen, China) intermediate ventilators and ICU ventilator SV600 (Mindray) were connected to ASL5000 lung model set in passive condition with 10 $cmH_2O/L/s$ resistance and 40 ml/cmH_2O compliance to simulate acute respiratory distress syndrome mechanics. E30, EOV150, T60, T75, Makair and SV300 ventilators are turbine-driven. Osiris3 and SV600 are fed by compressed air. The e-Spiro works with the mechanical compression of a resuscitation bag by 3D-printed two arms moved by a stepper motor.

For e-Spiro and Osiris3 same smoothbore single limb non-vented breathing circuit (length 1.6 m, 22 mm internal diameter-ID) was used (Intersurgical Ltd., Berkshire, UK). For E30 the single-limb vented breathing circuit was the smoothbore BiPAP Breathing circuit of 1.8 m in length, 22 mm ID without pressure line (BiPAP vision circuit, Philips Respironics, Murrysville, USA). The same smoothbore double-limb breathing circuit of 1.60 m in length and 22 mm ID for each limb (Intersurgical Ltd., Berkshire, UK) was used for Makair, EOV150, T60, T75, SV300, SV600 ventilators. High Efficiency Particulate Air (Gibeck® Iso-

Gard HEPA light, Teleflex Inc., Morrisville, NC, USA) was inserted at ventilator outlet. No heated-humidifier was used.

Ventilators were first set in volume-control (except for Makair and E30) at 300, 400 and 500 ml V_T, each at 5, 10, 15 cmH_2O positive end-expiratory pressure (PEEP) and, then in pressure-control (except for e-Spiro and Osiris3) to display on the screen 400 ml V_T and 10 cmH_2O PEEP. F_IO_2 was 0.21 (0.70 with Osiris3), respiratory rate 20 breaths/min and inspiratory time 0.8 s.

A one-minute stabilization period was allowed and flow and Paw signals were recorded during a two-minute period. The last 20 cycles of each recording were used for the analysis performed through Matlab (Matlab R2019b, The Mathworks Inc.).

V_T was measured during insufflation between zero flows and expressed as BTPS in volume-control. Error was defined as ((set - measured)/set) x 100) for both V_T and PEEP. A positive error indicates under-delivery while a negative error indicates over-delivery .

Normal distribution was assessed by the Shapiro test. Values were expressed as median (first-to-third quartiles) and compared between ventilators by the Kruskal-Wallis test with pairwise differences against the SV600 ventilator, taken as the reference, tested by the Dunnett test. Error was also assessed within the ±10% boundaries for accuracy. $P<0.05$ was deemed as the statistical significance threshold. The statistical analysis was performed with R 4.0.

Errors did not follow a normal distribution. The complete results are shown in table 1. In volume-control, V_T error was within the 10% accuracy in all instances except for Osiris 3, which systematically over delivered V_T. Over all the 63 conditions, over (46%) and under (54%) delivered V_T occurrences were balanced. Better performance than control was observed at PEEP5-V_T400, PEEP10-V_T400 and PEEP15-V_T500 for T75, PEEP10-V_T400 and 500 and at PEEP15-allV_Ts for SV300, PEEP10-V_T500 and PEEP15-V_T300 and 400 for T60, EOV at PEEP15-allV_Ts and e-Spiro PEEP10-V_T400. PEEP was delivered in excess by all the ventilators in each condition. When T60, T75, SV300 and SV600 were within the 10% accuracy at any PEEP, e-Spiro and Osiris3 improved performance at PEEP 10 and 15 while EOV150 was above the 10% accuracy at each PEEP.

In pressure control Makair has the best accuracy to deliver a V_T of 400 ml, followed by SV300 and E30, EOV150, SV600, T60 and T75. As for the volume control, PEEP was systematically over delivered by the ventilator. Makair had the best accuracy delivering a PEEP of 9.9 cmH_2O for a 10 cmH_2O PEEP set.

We found that Osiris3 performed worse than any other ventilator. In a previous bench study (6), this ventilator over-delivered V_T at at F_IO_2 70%, like in the present study, but matched the target V_T at 100%F_IO_2, suggesting that the Venturi system was not optimal. Another bench study found that the Osiris3 tended to under-deliver V_T, especially in case of airway obstruction (7). Taken together, the difference in V_T delivery accuracy with the Osiris3 across the bench studies may reflect some heterogeneity in Osiris3 machines.

With e-Spiro new ventilator, the between-breaths V_T variability was higher than the control, but systematically felt within the 10% accuracy limit. The fact that Makair was significantly different from SV600 is a positive information because Makair does not under-deliver V_T and is closer to 0. Makair was also very good in delivering PEEP.

In conclusion, the two new low cost ventilators accurately delivered V_T in present bench conditions and performed as good as the ICU ventilator to deliver V_T. This finding is very encouraging, not only for the current COVID-19, but also for future pandemics and for low-income countries (3).

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