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Karel Roubik, Josef Skola, Lenka Horakova, Vaclav Ort, Simon Walzel: Innovative design facilitated rapid production and clinical use of mechanical ventilators for COVID-19 patients in the Czech Republic

The first use in a patient and evaluation of CoroVent emergency ventilator

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Introduction

The emergency ventilator CoroVent, designed for patients with respiratory failure due to COVID-19 pandemic, was used clinically for the first time on October 31, 2020, in Masaryk Hospital, Usti nad Labem, in the Czech Republic.

This supplementary material documents this first clinical use and evaluates the performance and precision of the ventilator using an independent respiratory monitor.

Patient

The first patient was a 60-year old male, with actual body weight 131 kg (ideal body weight 66 kg) and *BMI* 45.5 $kg \cdot m^{-2}$. He was intubated and ventilated for refractory hypoxemia due to severe COVID-19. At the time of the connection to CoroVent, he had been already ventilated 17 days, currently via tracheostomy, heavily sedated, on Draeger Evita (Drägerwerk & Co. KGaA, Lübeck, Germany) BiPAP ventilation mode with *PEEP* 13 cmH_2O, *Pi* 28 cmH_2O, *RR* 20 min^{-1}, FiO_2 50 %.

CoroVent ventilator setting

CoroVent ventilator uses the volume control pressure limited mandatory ventilation. The initial setting of ventilatory parameters on CoroVent ventilator were set in order to maintain the corresponding minute ventilation. *PEEP* and FiO_2 were kept as set before. These parameters maintained airway pressures equivalent to values prior to switching from Draeger Evita to CoroVent ventilator.

Occasional interference with the ventilator was managed by an appropriate level of sedation. Throughout the 24-hour period of ventilation, the attending physicians were able to adjust the ventilatory parameters according to the current patient needs.

Monitoring

Apart from the standard monitoring of the patient, the ventilatory parameters and measured values were manually recorded from the CoroVent screen in 1-hour intervals or following an adjustment of the ventilatory parameters. The ventilator CoroVent uses a specially designed flow sensor—CoroQuant which works as a pneumotachograph. The ventilation characteristics were also monitored by an independent flow sensor D-Lite (Datex-Ohmeda, Madison, WI, USA) connected to the vital sign monitor CareScape B850 (GE Healthcare, Helsinki, Finland) and continuously recorded via ICM+ software version 8.6 (Cambridge Enterprise Ltd., Cambridge, UK). The assembly during ventilation is depicted in Fig. 1.

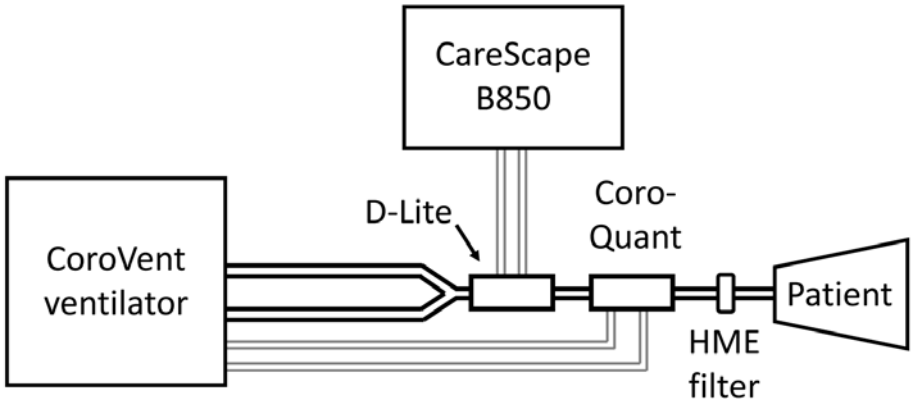

Fig. 1: CoroVent with the independent respiratory monitor during ventilation of the first patient.

Statistical analysis

The Bland-Altman plot was used to compare the set and monitored parameters measured by the ventilator and the independent monitoring system. The following respiratory parameters were compared and statistically evaluated: minute ventilation (*MV*), positive end expiratory pressure (*PEEP*), peak airway pressure (P_{max}) and fraction of inspired oxygen (FiO_2).

Results

Comparisons of the accuracy and stability of the ventilation parameters provided by the ventilator CoroVent were compared with an independent measuring system CareScape B850 connected to data recording software ICM+.

A comparison of *MV* between CoroVent and independent data recording system is presented in Fig. 2. The measured *MV* complied with the accuracy given by the standard for critical care ventilators (ISO 80601-2-12:2020).

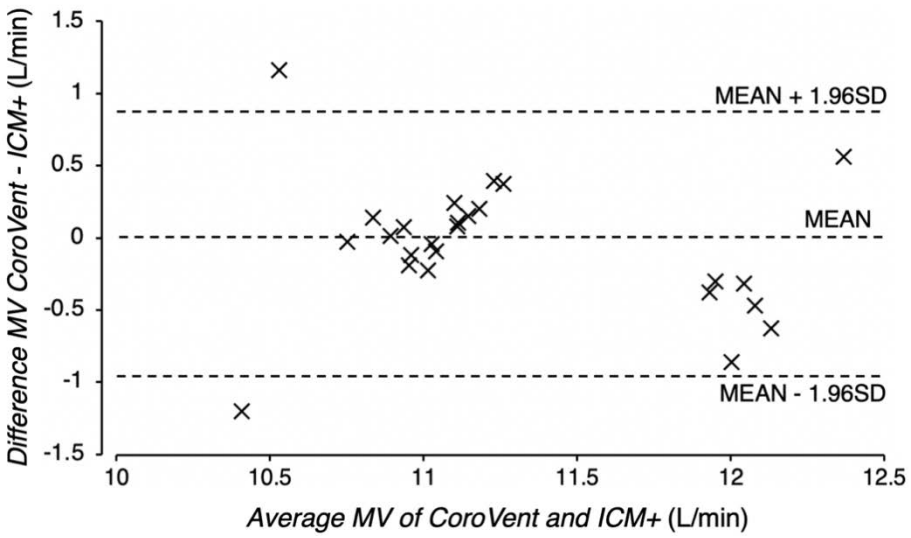

Fig. 2: Bland-Altman plot of differences in minute ventilation (*MV*) measured by CoroVent and by CareScape B850 and recorded by ICM+ vs. the mean of the two measurements.

The set *PEEP* values on ventilator CoroVent were in a good agreement with the data recorded by the ICM+ system presented in Fig. 3 and within the limits of the international standard for critical care ventilators (± (2 hPa (2 cmH_2O) + 4 % of real value).

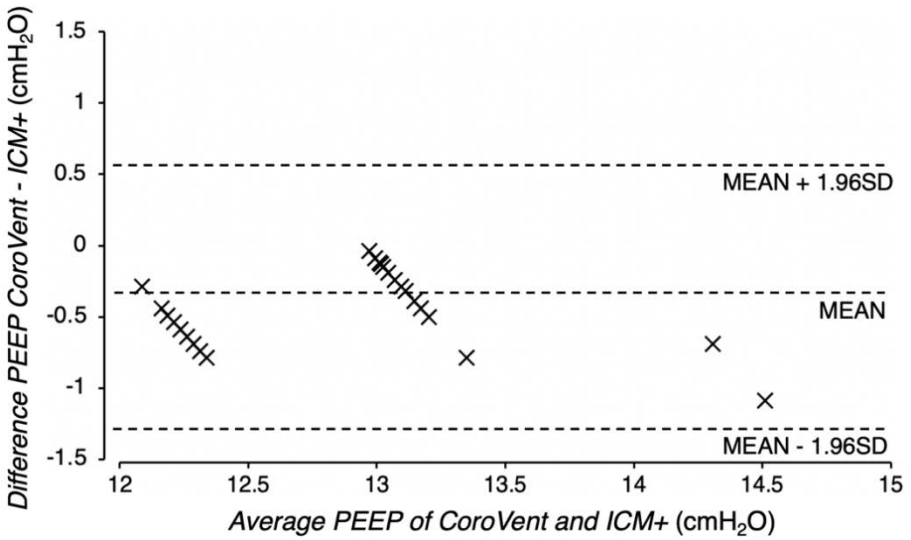

Fig. 3: Bland-Altman plot of differences in *PEEP* measured by CoroVent and by CareScape B850 and recorded by ICM+ vs. the mean of the two measurements.

The estimated P_{max} difference measured by CoroVent and by CareScape B850 and recorded by ICM+ is presented in Fig. 4. The P_{max} measured by the ventilator CoroVent was on average by 0.85 cmH_2O lower than the P_{max} measured by the data recording system, but within the limits of the technical standard for critical care ventilators (± (2 hPa (2 cmH_2O) + 4 % of real value).

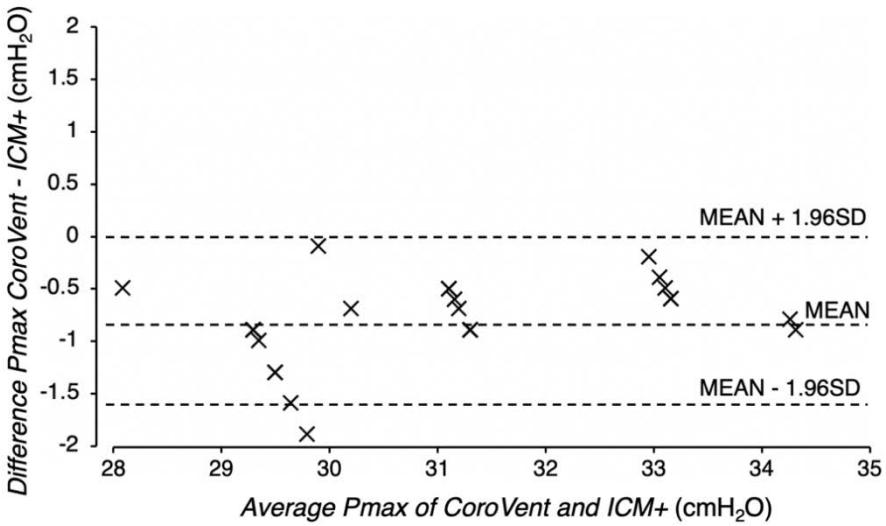

Fig. 4: Bland-Altman plot of differences in P_{max} measured by CoroVent and by CareScape B850 and recorded by ICM+ vs. the mean of the two measurements.

Slightly higher FiO_2 (by 2 % on average) was delivered by the ventilator CoroVent and measured by the CareScape B850 monitor compared to the set value on CoroVent in the whole 24-hour period of ventilation, as presented in Fig. 5. Nevertheless, the measured FiO_2 difference is lower than the FiO_2 accuracy of the CareScape B850 declared by the manufacturer.

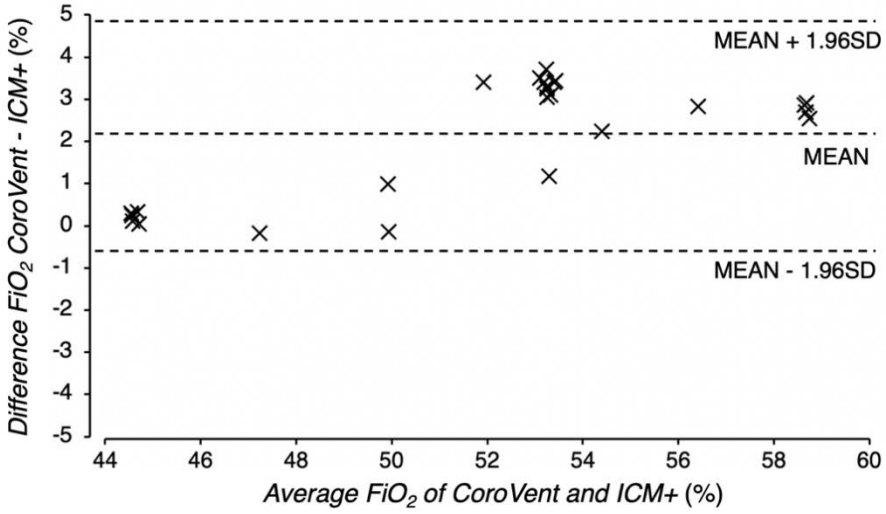

Fig. 5: Bland-Altman plot of differences in FiO_2 measured by CoroVent and by CareScape B850 and recorded by ICM+ vs. the mean of the two measurements.

Discussion

The first patient completed 24 hours of ventilation using CoroVent, as planned, without any adverse effect. During the transfer from the standard ventilator to CoroVent, the attending physician was easily able to set all the ventilation parameters and subsequently adjust them according to the physiological changes and needs. Moreover, the patient was morbidly obese with *BMI* 45.5 $kg \cdot m^{-2}$, and this fact did not present additional problems when ventilated by CoroVent, compared to previously used ventilator.

The zero-average of the *MV* difference between the CoroVent ventilator and the independent measuring system indicates a good function of the device. Nevertheless, isolated deviations of *MV* from an independent measuring system comply with the international technical standard ISO 80601-2-12, which requires the accuracy of measuring volumes up to 4mL + 15% real delivered value.

The monitored parameters were in a good agreement with the values recorded by the independent monitor. There were only systematically lower measurements of P_{max} and *PEEP* on CoroVent. Concerning *PEEP*, the small difference of −0.35 cmH_2O is less than the resolution of the monitoring system of CoroVent which is 1 cmH_2O. Concerning P_{max}, a certain reduction of the pressure amplitude can be expected, as the CareScape B850 sensor D-lite represents a certain resistance to the flow (Fig. 1). The pressure drop developed on the D-lite sensor causes lower P_{max} reading on the CoroVent measured by the CoroQuant flow sensor.

However, the accuracy of the CareScape B850 monitor declared by the manufacturer (1 cmH_2O) was not considered in the above assessment of *PEEP* and P_{max}. Despite the limited accuracy of CareScape B850 monitor, pressure measurement performed by CoroVent complies with the required accuracy for critical care ventilators defined by the standard ISO 80601-2-12:2020, which is ± 2 cmH_2O + 4 % of real value.

The design of the ventilator and the principle of operation ensures very accurate oxygen dosing in the mixture during inspirium, and this small deviation of FiO_2 from the set value is within the accuracy of the vital sign monitor used.

There were several triggered alarms during period of ventilation. All the alarms were associated with occasional interference of the patient's breathing effort with the ventilator. However, this was solved by appropriate level of sedation and adjustment of ventilatory parameters.

Conclusion

The first use of the ventilator CoroVent in clinical practice has demonstrated sufficient device performance and stability. CoroVent can help to manage the situation in the case of a critical shortage of conventional critical care ventilators in hospitals. The attending physicians were easily able to set and adjust all the ventilation parameters, which complied with the accuracies specified by the ISO 80601-2-12 standard for critical care ventilators.