Bench evaluation of COVIDair non-invasive ventilator

Nils Correvon, Jean-Bernard Michotte, Olivier Contal
Haute Ecole de Santé Vaud (HESAV), HES-SO Haute Ecole Spécialisée de Suisse occidentale.

Introduction

Non-invasive pressure support ventilation is most often performed with turbine ventilators. In order to allow optimal ventilation of the patient, they must meet a certain number of criteria and technical performance. Following the strong demand for ventilatory support techniques linked to the COVID-19 pandemic, few low-cost ventilator development projects have emerged.(1).

Among these projects, the COVIDair device developed by BCD microtechnique SA during the critical period of spring 2020, aims to ventilate, in a non-invasive manner, patients with severe respiratory pathologies.

In partnership with BCD microtechnique SA, we evaluated the triggering delay time of the inspiratory trigger, the pressurization time and the performance of the inspiratory:expiratory (I:E) cycling of COVIDair on a test bench simulating physiological characteristics of breathing.

Méthodologie

This bench study was performed at the cardio-respiratory laboratory of the Haute École de Santé Vaud (HESAV) in Lausanne.

The tests were performed on a bench using a spontaneous breathing simulator (ASL 5000, IngMar Medical, Pittsburgh, USA). The COVIDair was connected to the test bench with a standard 2-meter ventilation single-limb circuit and an exhalation leak valve (Whisper Swivel II, Respironics Inc, Murrysville, USA) directly connected to the simulator (no interface). In order to assess the performance of the device, different scenarios were set using different lung dynamics and ventilation settings.

Two types of respiratory dynamics were simulated, the first as normal and the second one as severe restrictive type, mimicking an acute respiratory distress syndrome encountered in severe COVID-19 cases (Table 1). In the normal type simulation, the following lung characteristics were set on the simulator (2) : a tracheal resistance of 5 $cmH_2O/l/sec$, a compliance of 80 ml/cmH_2O, a respiratory rate of 15 cycles/min and a inspiratory muscle effort of -5 cmH_2O with a rise time of 30% and a release time of 10%. The pulmonary characteristics of the severe restrictive type simulation were as follows: a tracheal resistance of 5 $cmH_2O/l/sec$, a compliance of 20 ml/cmH_2O, a respiratory rate of 30 and 40 cycles/min and an inspiratory muscular effort of -15 cmH_2O with a rise time of 25% and a release time of 25%

Performance evaluation was carried out in timed spontaneous ventilation (S/T) mode with various device settings. In the different scenarios, the inspiratory and expiratory pressurization slopes as well as the respiratory rate were set to a minimum, i.e. 100 msec and 3 cycles/min in order to avoid any interference with spontaneous breathing. Under normal conditions, the expiratory pressure setting

(EPAP) was 5 cmH_2O and the inspiratory pressure (IPAP) was 15 cmH_2O. Two levels of inspiratory triggers and two levels of I:E cycling were tested at 2 and 5 l/min, and 10 and 25%, respectively. In the severe restrictive situation, the ventilator was adjusted in two ways. First, with an EPAP of 5 cmH_2O, an IPAP of 15 cmH_2O, an inspiratory trigger at 5 l/min, which do not generate any self-triggers, and I:E cycling of 10 and 25%. Then, in a second step, with an EPAP set at 10 cmH_2O, an IPAP at 20 cmH_2O, an inspiratory trigger at 5 l/min (absence of self-triggering) and an I:E cycling at 10%.

Table 1 : Evaluated characteristics

Scenarios	Pulmonary mechanic	EPAP/IPAP, cmH_2O	I:E cycling, %	Inspiratory trigger, l/min
1	Normal	5/15	25	2
2	Normal	5/15	25	5
3	Normal	5/15	10	2
4	Normal	5/15	10	5
5	COVID-19 (RR 30)	5/15	10	5
6	COVID-19 (RR 30)	5/15	25	5
7	COVID-19 (RR 30)	10/20	10	7
8	COVID-19 (RR 40)	10/20	10	7

During the different scenarios, the flow as well as the muscle pressure and airway pressure were recorded continuously for 60 seconds. The performance evaluation of COVIDair was performed by measuring the inspiratory trigger delay (determined by the difference between the start of inspiratory effort and the start of pressurization corresponding to the minimum airway pressure measure), time of pressurization (determined by the difference between the onset of pressurization and when the measured airway pressure reaches the preset pressure (i.e. IPAP setting on the NIV device), as well as the actual measure of the I:E cycling corresponding to the effective ratio between the measurement of the peak expiratory flow (PEF) and the flow measured at the end of the pressurization of the device, corresponding to the release of the pressurization curve (2). These measurements were carried out manually using the ASL 5000 analysis software. They were carried out over the five respiratory cycles following the 20th second of the various scenarios.

Results

In total, 8 scenarios were tested to assess the performance of COVIDair: 4 in a context of normal pulmonary mechanics and 4 in a context of severe restrictive pulmonary mechanics that can be found in severe cases of COVID-19. Results are expressed as mean (± SD).

Under normal pulmonary mechanics, the inspiratory trigger delay time is on average between 89.0 (± 2.1) and 135.0 (± 9.7) msec. In a situation of severe restrictive pulmonary mechanics, the inspiratory trigger delay time is on average between 80 (± 3.1) and 99.2 (± 5.5) msec. The details of the inspiratory trigger delay times are in table 2.

Table 2 : Inspiratory trigger delay time

Pulmonary mechanic	EPAP/IPAP, cmH_2O	I:E cycling, %	Inspiratory trigger, l/min	Mean inspiratory trigger delay time (SD) , msec
Normal	5/15	25	2	**90.2 (9.7)**
			5	**130.8 (15.8)**
		10	2	**89.0 (2.1)**
			5	**135.0 (9.7)**
COVID-19 (RR 30)	5/15	10	5	**99.2 (5.5)**
		25	5	**91.8 (6.3)**
	10/20	10	7	**80.0 (3.1)**
COVID-19 (RR 40)	10/20	10	7	**86.4 (2.9)**

In severe restrictive type scenarios, self-triggering events were observed when EPAP and IPAP were pre-set at 10 and 20 cmH_2O respectively and the inspiratory trigger at 5 l/min. When decreasing sensitivity of the inspiratory trigger down to 7 l/min during these two scenarios, no self-triggerings were observed.

Pressurization time to pre-set IPAP is slightly faster at higher pressure level with, on average, a pressurization time of 234.6 (± 5.5) to 250.6 (± 2.5) msec at EPAP/IPAP at 10/20 cmH_2O versus 298.8 (± 6.5) at 318. 6 (± 1.9) msec at EPAP/IPAP levels at 5/15 cmH_2O (Table 3).

Table 3 : Pressurization time

Pulmonary mechanic	EPAP/IPAP, cmH_2O	I:E cycling, %	Inspiratory trigger, l/min	Mean pressurization time (SD) , msec
Normal	5/15	25	5	**318.6 (1.9)**
COVID-19 (RR 30)	5/15	10	5	**298.8 (6.5)**
	10/20	10	7	**234.6 (5.5)**
COVID-19 (RR 40)	10/20	10	7	**250.6 (2.5)**

The absolute difference between the actual I:E cycling measure and the pre-set I:E cycling value ranged from 0.1 to 10.7 % on average. In the situations of severe restrictive pulmonary mechanics with EPAP / IPAP setting at 5/15 cmH_2O, it was not possible to observe a plateau pressure, hence to define the end of pressurization (Table 4).

Table 4 : I:E cycling

Pulmonary mechanic	EPAP/IPAP, cmH_2O	I:E cycling, %	Inspiratory trigger, l/min	Measured I:E cycling (SD), % du DEP
Normal	5/15	25	2	22.6 (0.2)
			5	24.9 (0.6)
		10	2	5.3 (1.7)
			5	7.3 (0.9)
COVID-19 (RR 30)	5/15	10	5	N.A.
		25	5	N.A.
	10/20	10	7	15.5 (2.2)
COVID-19 (RR 40)	10/20	10	7	-0.7 (4.6)

Discussion

In normal pulmonary mechanics scenarios, the performance of COVIDair meets the expected standards for non-invasive ventilators. For example, when the trigger sensitivity (inspiratory trigger) is optimally set, the trigger delay times observed in this study are better than those obtained by Chen et al., with average values greater than 120ms. It should be mentionned that no issue with self-triggering or asynchrony were observed during the different tests. The values measured for the pressurization time and the I:E cycling performance are comparable to the values in Chen et al. study (3).

In severe restrictive pulmonary mechanics scenarios, the performance of COVIDair regarding inspiratory trigger sensitivity remains the same. With optimal setting, the inspiratory trigger delay time is always less than 100 msec. No auto-triggering were observed with the tested settings, which might be an advantage in the management of severely restrictive patients.

References

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