of intubation was only 23% (14/60). However, this rate reached 52% (16/31) in those who were comatose during the first 24 h (defined as Glasgow coma scale ≤ 8). It has already been found that NIV can be successful in subjects with hypercapnic coma, and NIV failure rates of only 20% have been reported.[3] It is important to note that patients who succeed with NIV have a faster improvement of consciousness compared with those who need intubation.[3] Dr Briones Claudett emphasizes that subjects with altered consciousness may require higher levels of pressure support than those with normal consciousness. To support this, Briones Claudett et al[4] recently found a faster recovery from hypercapnic encephalopathy using ventilatory mode with average volume-assured pressure support compared with pressure support ventilation during NIV due to higher levels of ventilatory assistance and larger tidal volumes (V_T).

In our cohort, of the 31 subjects who developed hypercapnic coma, 15 were comatose upon admission, and 16 developed coma during the first 24 h while receiving NIV.[1] The rate of intubation was only 20% (3/15) in subjects who were comatose at admission, in line with the results found by Díaz et al.[3] By contrast, the rate of intubation was 81% (13/16) in those who developed delayed coma during NIV ($P = .001$). Subjects with hypercapnic coma upon admission had similar V_T values compared with other subjects (459 ± 175 vs 469 ± 142 mL, $P = .82$). However, they received higher pressure support levels (11.9 ± 2.7 vs 9.1 ± 2.5 cm H_2O, $P = .008$), meaning that the level of ventilatory assistance had been correctly adjusted according to our protocol that aims to target predetermined V_T. As we used exclusively ICU ventilators, inspiratory positive airway pressure, including pressure support and PEEP, reached 16.5 ± 2.8 cm H_2O in subjects who were comatose at admission, a value close to that reported in the abovementioned studies.[3,4]

We agree that adjustment of an adequate pressure support level is the key setting to reverse hypercapnic coma, and we believe that our good results are due in part to our protocol of adjusting the pressure support level to target a minimal V_T, as would average volume-assured pressure support. Altered consciousness at admission does not seem to increase the risk of NIV failure. By contrast, almost all subjects who developed delayed coma needed intubation, whereas their V_T values and their pressure support levels adjusted at admission were similar to those of other patients (417 ± 142 vs 471 ± 142 mL, $P = .27$; 9.1 ± 7.4 vs 9.2 ± 2.6 cm H_2O, $P = .88$). Therefore, NIV failure was probably due to a patient's worsening and/or failure of this treatment and not to inadequate adjustment of ventilatory settings.

Arnaud W Thille MD PhD
Réanimation Médicale
Hôpital Henri Mondor
Assistance Publique-Hôpitaux de Paris
Créteil, France

Réanimation Médicale
Centre Hospitalier Universitaire
de Poitiers
Poitiers, France

Damien Contou MD
Ana Córdoba-Izquierdo MD
Réanimation Médicale
Hôpital Henri Mondor
Assistance Publique-Hôpitaux de Paris
Créteil, France
on behalf of the authors

The authors have disclosed no conflicts of interest.

DOI: 10.4187/respcare.03247

REFERENCES

1. Contou D, Fragnoli C, Córdoba-Izquierdo A, Boissier F, Brun-Buisson C, Thille AW. Noninvasive ventilation for acute hypercapnic respiratory failure: intubation rate in an experienced unit. Respir Care 2013; 58(12):2045-2052.
2. Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). JAMA 2003;289(22):2983-2991.
3. Díaz GG, Alcaraz AC, Talavera JC, Pérez PJ, Rodriguez AE, Cordoba FG, et al. Noninvasive positive-pressure ventilation to treat hypercapnic coma secondary to respiratory failure. Chest 2005;127(3):952-960.
4. Briones Claudett KH, Briones Claudett M, Chung Sang Wong M, Nuques Martinez A, Soto Espinoza R, Montalvo M, Esquinas Rodriguez A, Gonzalez Diaz G, Grunauer Andrade M. Noninvasive mechanical ventilation with average volume assured pressure support (AVAPS) in patients with chronic obstructive pulmonary disease and hypercapnic encephalopathy. BMC Pulm Med 2013;13:12

Simulation Studies for Device Evaluation

To the Editor:

According to the Society for Simulation in Healthcare, "Simulation is the imitation or representation of one act or system by another. Healthcare simulations can be said to have 4 main purposes – education, assessment, research, and health system integration in facilitating patient safety."[1] Implicit in the concept of simulation is the understanding that the parameters of the simulation reflect realistic values of the system under study. If the model does not accurately represent the system being simulated, then any conclusions about the how the real system behaves based on how the model behaves are suspect.

Simulation for Ventilator Performance Studies

Simulation studies are often used to examine ventilator performance because models of the respiratory system are much easier to understand and experiment with than real respiratory systems (either human or animal). More importantly, models do not vary with time, so the differences observed in measurements are presumed to be related only to performance differences among the ventilators in the study. The simplest model of the respiratory system used for ventilator studies is the single-compartment model, composed of a single-flow resistance and a single-elastic compartment, represented by the equation of motion for the respiratory system (Equation 1).

$$P_{TR}(t) + P_{mus}(t) = EV(t) + R\dot{V}(t) + \text{auto-PEEP} \quad [1]$$

where $P_{TR}(t)$ = the change in transrespiratory pressure difference (ie, airway opening pressure minus body surface pressure) as a function of time (t), measured relative to end-expiratory airway pressure. This is the pressure generated by a ventilator during an assisted breath; $P_{mus}(t)$ = ventilatory muscle pressure difference as a function of time (t); the theoretical chest wall transmural pressure difference that would produce movements identical to those produced by the

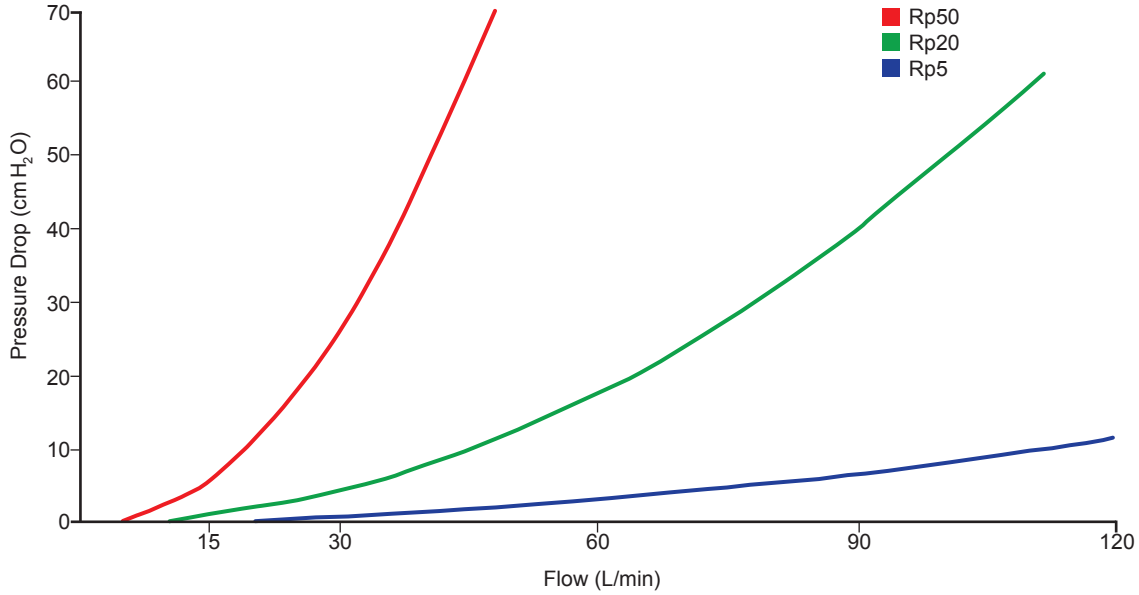

Fig. 1. Pressure-flow curves of nonlinear ("parabolic") resistors used in the Michigan Instruments model 1600 Dual Adult Training Test Lung (modified from the operator's manual). Rp50 = parabolic resistor 50 cm H_2O. Rp20 = parabolic resistor 20 cm H_2O. Rp5 = parabolic resistor 5 cm H_2O.

ventilatory muscles during breathing maneuvers (positive during inspiratory effort, negative during expiratory effort); V(t) = volume change relative to end-expiratory volume as a function of time (t); $\dot{V}(t)$ = flow as a function of time (t), the first derivative of volume with respect to time; E = elastance (inverse of compliance (C); E = 1/C); and R = resistance.

In Equation 1, pressure, volume, and flow are variables, although elastance and resistance are parameters (assumed to be constants). This happens to be the same model used by ventilators that calculate and display R and C values of patients. The compliance of the model is generally assumed to be linear for ventilator performance studies, in the form of C = Δvolume/Δpressure. Resistance is modeled as either linear (R = Δpressure/Δflow) or nonlinear (eg, parabolic). A "parabolic" resistor has a pressure versus flow curve that looks like Figure 1. Note that for a parabolic resistor, the resistance is defined as Δpressure/Δflow at a particular flow value. For example, the resistance of Rp5 (parabolic resistor 5 cm H_2O) in Figure 1 is specified as having a pressure drop of 2.7 cm H_2O at a flow of 60 L/min, or R = 2.7 cm H_2O/L/s, which is about the normal airway resistance of a nonintubated adult.[2] This means that the equivalent linear resistance is different for each flow at which it is evaluated. In other words, using a parabolic resistor, the resistive load of the lung model changes as flow changes.

Most of the studies reporting ventilator performance[3,4] use some version of the Training and Test Lung (TTL) simulator (Michigan Instruments, Grand Rapids, Michigan). This device has one or two spring-loaded bellows to model compliance (adjustable spring tension varies compliance values) connected in series with parabolic flow resistors. The TTL is a passive device. To simulate inspiratory effort (P_{mus} in Equation 1), researchers have improvised by linking the 2 bellows and using one to drive the other by connecting it to a separate ventilator.[5] Thus, the larger the tidal volume (V_T) and the higher the inspiratory flow of the "drive" ventilator, the higher the simulated inspiratory effort. A good way to quantify the inspiratory effort is by measuring the occlusion pressure (also called $P_{0.1}$) as described by Boussen et al[6]

Many recent studies[7-9] have used a more sophisticated device: the ASL 5000 lung simulator (IngMar Medical, Pittsburgh, Pennsylvania). This is a computer-driven piston controlled by the equation of motion (Equation 1) to model any value of resistance and compliance for either a single- or double-compartment lung model. It can simulate both passive and active breathing. The latter is accomplished by modeling the P_{mus} waveform in addition to setting the model resistance and compliance. It is also possible to introduce a calibrated (nonlinear) leak (eg, for evaluation of noninvasive features of ventilators). The ASL 5000 can measure F_{IO_2}, making it useful for evaluating devices other than ventilators, such as those used for oxygen therapy.[10]

Appropriate Selection of Model Parameters

An unfortunate fact about ventilator performance studies is that there is no consistency among researchers regarding the selection of lung model parameters. This makes it impossible to aggregate data across studies. There are some standards that were intended for manufacturers to use for product testing, namely American Society for Testing and Materials (ASTM).[11] For example, the ASTM standard specifies both linear and parabolic resistances and linear compliances over a range of values representing adults, children, and infants. These "standard conditions" are shown in Table 1. There are several problems with this standard. First, the values for R and C are not referenced in any way to actual data from human studies, that is, they are not evidence-based. Second, the values are referenced to patient age, not disease type (whereas many ventilator performance studies attempt to

Table 1. Standard Conditions for Ventilator Performance Testing Recommended by ASTM F1100

Patient	Compliance (mL/cm H_2O)	Resistance			Tidal Volume (mL)	Frequency (breaths/min)
		Linear (cm H_2O/L/s)	Parabolic			
			(cm H_2O)	at (L/s)		
Adult	50	5	2.70	1	500	20
Child	20	20	4.40	0.5	300	20
Infant	3	50	6.79	0.25	30	30

Table 2. Respiratory System Model Parameters Based on Data for Ventilated Patients

Condition	V_T (mL)	Frequency (breaths/min)	Resistance (cm H_2O/L/s)	Compliance (mL/cm H_2O)	Reference
Normal	558	13	12	49	Belliato et al[12]
	NA	NA	16	40	Arnal et al[13]
	NA	NA	13	51	Iotti et al[14]
COPD	723	9	25	65	Belliato et al[12]
	NA	NA	21	48	Arnal et al[13]
	NA	NA	20	55	Iotti et al[14]
ARDS	513	16	13	26	Belliato et al[12]
	NA	NA	15	27	Arnal et al[13]
	NA	NA	16	34	Iotti et al[14]
Pediatric					
4 kg	24	50	50	2	Morrow et al[15]
13 kg	98	30	30	13	Harikumar et al[16]

V_T = tidal volume
NA = not available

simulate disease states like ARDS and COPD). Finally, the standard was withdrawn by the ASTM without replacement in 2004. Researchers are thus left to their own opinions about model parameter values, and few, if any, provide justification for their selections.

A recent study in this journal by Boussen et al[6] illustrates how questionable selection of model parameters can lead to potentially misleading conclusions. These researchers evaluated transport ventilators using the TTL lung simulator. Their model parameters were as follows: normal: R = 5 cm H_2O/L/s and normal C = 100 mL/cm H_2O; ARDS: high R = 20 cm H_2O/L/s and low C = 30 mL/cm H_2O; airway obstruction: very high R = 50 cm H_2O/L/s and normal C = 100 mL/cm H_2O. The resistances were the parabolic resistors supplied with the TTL. Some of the ventilators were set to a volume control mode with constant inspiratory flow, and some were set to a pressure control mode, which delivers a decaying exponential flow throughout inspiration. The simulator was ventilated with V_T values of 300, 500, and 800 mL. One of the outcome variables was volume delivery error (%), although the authors never explained how the error was calculated.

There are several potential problems with the lung model parameters in this study. In the first place, the values of R and C ascribed to normal, ARDS, and airway obstruction disease states are not evidence-based, so we have no way of generalizing the study data to actual use of these ventilators in humans. However, evidence-based data for simulation do exist. For example, Table 2 shows just a few of many studies that could have provided better model parameters. The values for R of 5 or 50 cm H_2O/L/s and for C of 100 mL/cm H_2O are in particular unrealistic.

Second, because some of the ventilators were operated at constant inspiratory flow and others were operated with variable flow and because nonlinear resistances were used in the lung models, the ventilators were actually subjected to different resistive loads (see Fig. 1). The point is that when comparing the performance of different devices, they should all be subjected to the same experimental conditions. Failing that, some of the variability of the outcome variables might be attributed to the experimental conditions rather than variability in device performance.

Third, the authors observed that one of the ventilators was unable to deliver an accurate V_T of 300 mL in the normal condition. This particular ventilator could not deliver 300 mL because it delivers only pressure control modes, and it is designed to deliver no less than 5 cm H_2O inspiratory pressure. Hence, the minimum V_T it could be expected to deliver to a lung model with a compliance of 100 mL/cm H_2O would be 500 mL. This would imply that the ventilator might be inappropriate for use on a normal patient requiring a V_T of 300 mL. Indeed, the authors stated that "pediatric pa-

tients usually have high compliance and need low V_T (< 300 mL)." To see how this might be misleading, we first question the assertion that "pediatric patients usually have high compliance." Compared with what? Sharp et al[17] studied 50 infants and children undergoing elective surgery under general anesthesia. They provide a nomogram for estimating total respiratory system compliance with values ranging from 10 to 80 mL/cm H_2O for patients aged 1–18 y. They also provide a prediction equation: compliance (mL/cm H_2O) = 2.04 × age (y) + 0.328 × height (cm). If we assume a normal V_T of ~7 mL/kg, then a V_T of 300 mL would correspond to a patient weighing ~43 kg, or ~94 pounds. Consulting a chart relating age and weight based on guidelines and growth charts provided by the Centers for Disease Control and Prevention and the World Health Organization,[18] we see that a male pediatric patient weighing 94 pounds would be ~13 y old and ~63 cm tall. Using the prediction equation above, we would thus estimate a pediatric patient requiring a V_T of 300 mL to have a compliance of only 47 mL/cm H_2O. If Boussen et al[6] had used an evidence-based lung model compliance of ~50 mL/cm H_2O, then the ventilator in question would have been expected to deliver a V_T down to 250 mL. Thus, it would have "passed the test."

Fourth, Boussen et al[6] also noted that 2 ventilators failed to deliver 800 mL in the airway obstruction model. These ventilators were operated in a pressure control mode. Again, the problem can be traced to unrealistic values for the lung model. Airway obstruction was modeled as having R = 50 cm H_2O/L/s and C = 100 mL/cm H_2O, which, as noted above, represent excessive values for both parameters compared with actual human data. These values of R and C yield a time constant of 2.5 s. This time constant, in combination with a ventilating frequency of 20 breaths/min, results in an auto-PEEP level of 13 cm H_2O. As a result, the ventilator would have to generate an inspiratory pressure change of 62 cm H_2O to deliver a V_T of 800 mL. Not only that, but a patient with a height of 85 cm has a predicted ideal body weight of 80 kg. Because the maximum pressure limits of the 2 ventilators in question were below 62 cm H_2O, they "failed" the test. But implying that these 2 ventilators would not be able to ventilate a COPD patient with an inspiratory pressure of 62 cm H_2O and a V_T of 10 mL/kg is perhaps an unrealistic and misleading expectation. The fact that the other ventilators could do it may be irrelevant. On the contrary, suppose we use lung model parameters from human data (eg, average of all COPD values; see Table 2), namely R = 22 cm H_2O/L/s and C = 56 mL/cm H_2O. As a result, a V_T of 822 mL is achievable with an inspiratory pressure of only 30 cm H_2O, and auto-PEEP is reduced to 4 cm H_2O. We come to a different conclusion about ventilator performance: the 2 ventilators that had failed under unrealistic conditions now succeed using evidence-based lung model parameters. Note that the time constant is still long (1.2 s), and thus, V_T is highly dependent not only on inspiratory pressure but also on inspiratory time (ie, the inspiratory time setting becomes a potential surrogate for direct V_T adjustment in a passive patient).

The calculations for auto-PEEP and inspiratory pressure were performed with a mathematical ventilator-patient simulator that is free to download at https://app.box.com/s/fdayqtzi6v1nm4ycpha6. Simulators like this are quite useful for educational purposes and for simple "reality checks" when trying to interpret study data.

Correction for Gas Condition

Ventilator performance studies that attempt to assess volume delivery error are particularly problematic due to the many factors that contribute such error. Theoretically, the difference between set and measured values for V_T can be accounted for by several mechanisms including (1) leaks, (2) inaccurate calibration of either the independent measurement device or the ventilator, (3) volume lost due to compression in the patient circuit, and (4) changes in gas temperature and pressure. Discounting leaks and inaccuracies, we have 2 main factors that need to be accounted for.

Again, the study by Boussen et al[6] provides an illustration of how failure to consider these complications can lead to ambiguous results. Although these authors did not provide the equation they used to calculate percentage error for volume delivery, one version is as follows: error (%) = [(set V_T − measured V_T)/measured V_T] × 100%. With this equation, if the set V_T was less than the measured volume, the error would be negative, and we would say the set value underestimates the true value.[19] Boussen et al[6] reported volume delivery errors ranging from −30 to +53%, but we do not know what a negative error indicates without the equation used to calculate it.

Volume lost due to compression would tend to make error positive (ie, set volume is larger than measured volume). Some ventilators have gas compression compensation, meaning that the volume delivered from the ventilator's output control valve will be adjusted above the set value. Inaccuracy of the compensation algorithm contributes to volume delivery error. Some ventilators use flow sensors at the airway opening, which could potentially make compression compensation algorithms unnecessary. Boussen et al[6] did not note which ventilators in their study did or did not have compression compensation algorithms. Nevertheless, any error due to compression is a "legitimate" error in the context of the study.

What is more concerning, however, is the error introduced as a result of the researchers failing to account for temperature and pressure. Ventilator performance studies typically do not use humidifiers because of the additional complexities involved. However, just as some ventilators have compression compensation algorithms, some also have compensation for gas expansion due to the change from atmospheric temperature and pressure dry (ATPD) conditions leaving the ventilator to body temperature and pressure saturated (BTPS) in the lungs.[20,21] Going from ATPD to BTPS can increase the V_T by as much as 12% (Table 3).[22] Thus, ventilator correction algorithms attempt to decrease the volume coming out of the ventilator compared with the set value if the set value is displayed in BTPS. In the study by Boussen et al[6], some of the ventilators had correction algorithms for BTPS, and some did not. However, the authors did not note this, nor did they assure us that the final values for volume error percentage took such compensation into account. For example, the Dräger Carina and Oxylog 3000+ (Dräger Medical, Lübeck, Germany) ventilator operator's manuals state that volume and minute ventilation displays are corrected for BTPS. The Hamilton-T1 and Hamilton-C1 (Hamilton Medical, Reno, Nevada) manuals say that pressure, flow, and volume measurements are based on readings from the flow sensor, and they are expressed as BTPS. I do not know how the other ventilators handle this issue. Boussen et al[6] did not state whether their measurements were corrected for BTPS conditions but only that the pneumotach calibration was checked with a Super Syringe.

Table 3. Tidal Volume Changes Due to Changing Environmental Conditions

Temperature	P_B (mm Hg)	ATPD (mL)	ATPS (mL)	BTPS (mL)	STPD (mL)
21°C	760	445	456	500	413
		Difference (%)	3	12	−7
	P_{H_2O} (mm Hg)				
70°F	18.7				

P_B = barometric pressure
P_{H_2O} = water vapor partial pressure
ATPD = ambient temperature and pressure dry
ATPS = ambient temperature and pressure saturated
BTPS = body temperature and pressure saturated
STPD = standard temperature and pressure dry

This suggests that their measurements may have been values closer to ATPD then BTPS. For example, if the operator set a V_T of 500 mL, and the ventilator displayed the set value as BTPS, then a measurement made assuming ATPD conditions would indicate only 445 mL. Thus, if the experimenter was not aware of the ventilator compensation, he might incorrectly report an error on the order of +12%. Note that if a ventilator did not compensate for compressed gas but did compensate for BTPS, the errors would tend to cancel each other.

Conclusion

Lung simulators are very useful for ventilator performance evaluation studies. However, care must be taken to select lung model parameters that are evidence-based and reflect actual human lung conditions. Otherwise, the results of the simulation cannot be generalized to actual ventilator use and may in fact be misleading. Furthermore, when reporting volume delivery error, appropriate corrections must be applied relative to ventilator compensation algorithms that may be in effect for compressed gas and ATPD versus BTPS conditions.

Robert L Chatburn MHHS RRT-NPS FAARC
Respiratory Institute
Cleveland Clinic
Department of Medicine
Lerner College of Medicine of Case
Western Reserve University
Cleveland, Ohio

The author is a paid consultant for Invacare, Philips, Covidien, Breathe Technologies, Dräger, IngMar Medical, Hamilton Medical, and ResMed.

DOI: 10.4187/respcare.03047

REFERENCES

1. Society for Simulation in Healthcare. What is simulation? http://ssih.org/about-simulation. Accessed on 11/5/13.
2. Comroe JH, Forster RE, Dubois AB, Briscoe WA, Carlsen E. The lung: clinical physiology and pulmonary function tests. Chicago: Year Book Medical Publishers; 1977:184.
3. Blakeman TC, Branson RD. Evaluation of 4 new generation portable ventilators. Respir Care 2013;58(2):264-272.
4. Wallon G, Bonnet A, Guérin C. Delivery of tidal volume from four anaesthesia ventilators during volume-controlled ventilation: a bench study. Br J Anaesth 2013; 110(6):1045-1051.
5. Blakeman TC, Rodriquez D Jr, Hanseman D, Branson RD. Bench evaluation of 7 home-care ventilators. Respir Care 2011; 56(11):1791-1798.
6. Boussen S, Gainnier M, Michelet P. Evaluation of ventilators used during transport of critically ill patients: a bench study. Respir Care 2013;58(11):1911-1922.
7. Gonzales JF, Russian CJ, Gregg Marshall S, Collins KP. Comparing the effects of rise time and inspiratory cycling criteria on 6 different mechanical ventilators. Respir Care 2013;58(3):465-473.
8. Oto J, Chenelle CT, Marchese AD, Kacmarek RM. A comparison of leak compensation during pediatric non-invasive positive pressure ventilation: a lung model study. Respir Care 2014;59(2):241-251.
9. Drevhammar T, Nilsson K, Zetterström H, Jonsson B. Comparison of nasal continuous positive airway pressure delivered by seven ventilators using simulated neonatal breathing. Pediatr Crit Care Med 2013; 14(4):e196–e201.
10. Chatburn RL, Williams TJ. Performance comparison of 4 portable oxygen concentrators. Respir Care 2010;55(4):433-442.
11. American Society for Testing and Materials. ASTM F1100-90(1997) standard specification for ventilators intended for use in critical care. http://www.astm.org/standards/f1100.htm. Accessed 11/5/13.
12. Belliato M, Palo A, Pasero D, Iotti GA, Mojoli F, Braschi A. Evaluation of adaptive support ventilation in paralysed patients and in a physical lung model. Int J Artif Organs 2004;27(8):709-716.
13. Arnal JM, Wysocki M, Nafati C, Donati S, Granier I, Corno G, Durand-Gasselin J. Automatic selection of breathing pattern using adaptive support ventilation. Intensive Care Med 2008;34(1):75-81.
14. Iotti GA, Polito A, Belliato M, Pasero D, Beduneau G, Wysocki M, et al. Adaptive support ventilation versus conventional ventilation for total ventilatory support in acute respiratory failure. Intensive Care Med 2010;36(8):1371-1379.
15. Morrow B, Futter M, Argent A. Effect of endotracheal suction on lung dynamics in mechanically-ventilated paediatric patients. Aust J Physiother 2006;52(2):121-126.
16. E. Harikumar G, Egberongbe Y, Nadel S, Wheatley E, Moxham J, Greenough A, Rafferty GF. Tension-time index as a predictor of extubation outcome in ventilated children. Am J Respir Crit Care Med 2009;180(10): 982-988.
17. Sharp JT, Druz WS, Balagot RC, Bandelin VR, Danon J. Total respiratory compliance in infants and children. J Appl Physiol 1970; 29(6):775-779.
18. Buzzle. Proper weight for height and age. http://www.buzzle.com/articles/proper-weight-for-height-and-age.html. Accessed on 11/5/13.
19. Chatburn RL. Handbook for health care research, 2nd edition. Sudbury: Jones and Bartlett Publishers; 2011:93-120.
20. Lyazidi A, Thille AW, Carteaux G, Galia F, Brochard L, Richard JC. Bench test evaluation of volume delivered by modern ICU ventilators during volume-controlled ventilation. Intensive Care Med 2010;36(12): 2074-2080.
21. Duchateau P, Guérin C. Tidal volume delivery from ICU ventilators at BTPS con-

ditions: a bench study. Respir Care 2013; 58(4):623-632.
22. Chatburn RL, Mireles-Cabodevila E. Handbook of respiratory care, 3rd edition. Sudbury: Jones & Bartlett Learning 2011; 123.

Simulation Studies for Device Evaluation—Reply

In Reply:

Mr Chatburn begins his letter explaining what should be simulation in medicine. Many of the ventilator bench studies published before are only bench tests, as our study, and not a simulation of a more complex reality. The goal of this study was to test transport ventilators under conditions similar to those used in previous studies and to assess their performance limits. Moreover, we have pointed out that bench studies are not for commercial advertising. In our study,[1] we were not interested in giving any awards for a particular ventilator, and we had no interest in any of the manufacturers. This is not the case for Mr Chatburn, who is paid consultant for a testing device company (which he cites in his letter) and three manufacturers of ventilators that we have studied in this work.

We have tried to show that there has been major improvement in the field of transport ventilators in comparison with older technology. Therefore, we implemented the same experiment as that performed in an older study (10 y ago)[2] using the same parameters for the static portion; used the same dynamic experiments as used in many previous bench studies.[3-8]

In addition, we showed that the most recent turbine transport ventilators are a breakthrough in the field of transport ventilators even if they have some limitations, and their performances are close to those of ICU ventilators.

Choice of Lung "Simulator"

Mr Chatburn criticizes the choice of the Training and Test Lung (TTL) simulator (Michigan Instruments, Grand Rapids, Michigan) instead of the ASL 5000 lung simulator (IngMar Medical, Pittsburgh, Pennsylvania). Unfortunately, we do not have this device. To our knowledge, there are no scientific studies proving that this device is more "realistic" than the TTL simulator in passive conditions. The ASL 5000 lung simulator is probably very interesting to test in dynamic conditions. Studies using a TTL simulator are numerous,[3-8] and Mr Chatburn cites only three recent studies using the ASL 500 simulator. To allow better comparison with these more numerous studies carried out using all types of ventilators (transport, home, and ICU), we used the TTL simulator.

Choice of Parameters

Mr Chatburn criticizes our choice of parameters. He argues that the studied parameters are not "realistic." Our answer is that the main goal of this study was to compare this generation of ventilators with the former[2]; we used parameters introduced in the previous studies conducted by well respected teams versed in this topic. Note that one goal is to know the limits of operation of the tested devices. It is not completely absurd to push ventilators to extreme conditions such as resistance (R) = 50 cm H_2O/L/s.

Concerning the definition of a normal compliance, there is no consensus. It is difficult to define what a "normal" value of compliance is because it is different depending on the situation: intubated versus nonintubated subjects, young versus old, etc. Several previous bench studies have used the value used in our work.[2,4,9] One can find this value also in some physiological articles.[10] Azarian et al[11] found a wide range for compliance in healthy volunteers (from 100 to 200 mL/cm H_2O). In their article, they proposed the following formula for the compliance of the respiratory system (C_{RS}): $C_{RS}\,(L \cdot kPa^{-1}) = 3.56 \times \text{height}\,(m) - 4.86$ (± 0.23). This value is 1.548 $L \cdot kPa^{-1}$ for 1.80 m (154 mL/cm H_2O). It is certainly too high for a ventilated patient, but it gives an order of magnitude of what a normal compliance is for a subject who has healthy lungs and has not been ventilated for many days. This value is found also in physiological books.[12] A study published in this Journal went as far as 120 mL/cm H_2O in evaluating performances of ventilators.[13]

We agree that ICU patients rarely have such a compliance value. Some of our patients in our ambulances are in this category (isolated neurotrauma in the first hours, for example). We would like to stress that if we take the formula given by Mr Chatburn in his letter, a young healthy man who is 18 y old and 180 cm tall has a compliance of 95 mL/cm H_2O.

Mr Chatburn cites studies using parameters that seem to him more suitable or advisable. We found several studies with the same resistance parameters,[2,8,14,15] compliance,[2] and tidal volume (V_T)[2,8,14-17] as in our study. Here again, there is no formal scientific evidence that the parameters presented by Mr Chatburn are more "realistic."

We do not want to explain again why V_T = 800 mL was used (previous studies and limits of use). We rarely ventilate patients with V_T = 800 mL, and it is rare to have R = 50 cm H_2O/L/s. We are in agreement with this. It is an extreme functioning of the ventilator, but it was tested in older studies.[2,8,14-16] It is interesting to us to know what a transport ventilator can do or not do in extreme conditions.

The limit of parabolic resistors is well known, but linear resistors are not easily available. Indeed, ventilators are not tested in very similar conditions.

We were aware that Dräger Carina and Hamilton Medical ventilators operate in a pressure control mode, but it is identified as "VAC+" (a dual mode). In this mode, the pressure is controlled by a feedback loop to deliver the V_T set by the clinician. Emergency physicians are not very familiar with these modes. We knowingly tested all of the ventilators in the VAC mode because it is the reality of their use in the field.

The age of the pediatric patients ranged from 0 to 18 y. The transport ventilators tested in our studies are not intended for neonates, who have weak lung compliance and high chest wall compliance. We showed above that the compliance of a 18-y-old boy who is 180 cm tall using the formula recommended by Mr Chatburn was ~100 mL/cm H_2O. We think that Mr Chatburn made a calculation error. A 13-y-old child measures ~160 cm (63 inches), not 63 cm; thus, his lung compliance is near 80 mL/cm H_2O, not 47. We found no study addressing the compliance measurements of teenagers, but we can infer the results of healthy young volunteers. Teenagers may have relatively high respiratory system compliance. In our article, we pointed that there is a problem with highly compliant lung in low volume for one specific ventilator. We had a patient with C = 100 mL/cm H_2O, and one should know this limitation.

We apologize that the equation used to calculate the relative error was not provided in our article. Note that the reviewers did not ask us to correct this. The equation can be found elsewhere, and it is