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Original Article

Reliability of manikin-based studies: an evaluation of manikin characteristics and their impact on measurements of ventilatory variables

A. De Luca,[1] F. S. Sall,[2] R. Sailley,[3] G. Capellier[4] and A. Khoury[3]

1 Biomedical Research Engineer, 2 Clinical Research Engineer, Clinical Investigation Center Inserm CIC-1431, 3 Emergency Physician, 4 Chair of Department, Department of Emergency Medicine and Critical Care, University of Franche-Comté - Medical Center, Besançon, France

Summary

Findings from manikin-based studies on ventilation are commonly directly extrapolated to clinical practice. The aim of this study was to determine how the use of manikins affects measurements of ventilatory variables. We connected a lung simulator to a manikin, which was then ventilated at different inspiratory flows. We defined three experimental models to compare measurements of ventilatory variables between the mechanical ventilator and the lung simulator. Even when no leakage occurred, significant tidal volume deviations were observed; from a mean (SD) of 21 (2) ml to 49 (9) ml, and from 40 (4) ml to 88 (5) ml for invasive and non-invasive ventilation, respectively ($p < 0.001$). Significant peak pressure deviations from 0.7 (0.1) cmH_2O to 10.6 (0.3) cmH_2O were also recorded during non-invasive ventilation ($p < 0.001$). Evaluation of manikin resistance and airway dead space may be essential to limit study bias. We suggest a recalibration of the recorded data if comparisons are made between different tests performed at different inspiratory flows.

Correspondence to: A. De Luca
E-mail: alban.deluca@gmail.com
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Introduction

Since the late 1960s, human patient simulators have been developed for training healthcare professionals in airway management. Although the transfer of skills learnt on simulation tools into clinical practice has not proved to be successful [1–3], patient simulators are now used at hundreds of medical centres and universities [4]. Researchers have also repurposed this tool for the evaluation of airway devices and ventilation techniques, which avoids obtaining ethical approval for clinical research [5–8]. Indeed, clinical trials, which are difficult to implement, are not specifically required before airway devices are marketed [5]. Manikin-based studies offer significant advantages; there is no patient recruitment and no risk of severe adverse effects. They also enable stable experimental conditions, which may aid comparative studies. The extensive use of patient simulators for airway management research has led even international committees, like the European Resuscitation Council, to base their guidelines on bench studies [9]. For instance, the recommended tidal volume of 500 ml during cardiopulmonary resuscitation, was derived from a study that used a patient simulator to demonstrate that low tidal volumes avoided

gastric inflation and provided efficient oxygenation [10]. Conclusions resulting from manikin-based studies are frequently transferred directly to clinical practice without any further clinical validation [11].

But are high-fidelity manikins able to reproduce human airway anatomy and mechanics accurately? Few studies have focused on this issue, and the literature is limited. In a recent study, Schebesta et al. compared the anatomy of 20 adult patients with four high-fidelity patient simulators and two airway trainers, by performing computed tomography (CT) scans of the upper airways [12]. Hesselfeldt et al. evaluated the SimMan™ patient simulator [13], and Cook et al. studied four different manikins [14–17] to see whether it was possible to correlate the manikins' characteristics with patients' anatomy. According to these studies, all manikins differed significantly from human airways in important aspects: tissue rigidity; cervical spine mobility; and anatomical proportions, especially for the pharyngeal and the retropalatal airspace. The authors also identified variations between manikins from the same manufacturer. Manikin-based studies for the evaluation of airway devices and/or new ventilation strategies may thus be affected by these inaccuracies.

Lung simulators are also used in studies of this nature to measure respiratory variables. Many artificial lungs are able to simulate the entire respiratory system of an adult, allowing the setting of essential respiratory characteristics (lung compliance, airway resistance, etc). While the evaluation of some airway equipment can be carried out on a lung simulator alone [18, 19], most studies connect it to a manikin to model the face and airways [10, 20–26]. Evaluation of the characteristics of the manikin is rarely undertaken, and to our knowledge, nobody has studied its impact on the data collected. We therefore aimed to determine how the use of a manikin affected measurements of ventilatory variables.

Methods

No ethical approval was required for this observational bench test, which we carried out within the Department of Emergency Medicine and Critical Care of the University Hospital Centre of Besançon.

The experimental model consisted of a Dräger Evita Infinity V500 mechanical ventilator (Dräger Medical, Telford, PA, USA), an ASL5000 lung simulator (IngMar Medical, Pittsburgh, PA, USA) and a Laerdal Airway Management Trainer manikin (Laerdal Medical, Stavanger, Norway). The Evita Infinity V500 is a highly advanced ventilation unit that allowed us to achieve ventilatory settings with a high degree of precision, and to record the data via a USB port. We used the ASL5000 as a 'passive model', simulating an apnoeic patient with no inspiratory effort. Lung compliance and resistance were set to 70 ml.cmH_2O^{-1} and 3.5 cmH_2O.l^{-1}.s, respectively. We decided to set a low pulmonary resistance to detect any minor changes in the airway resistance that may have appeared when using the manikin. The manikin's lungs were bypassed, and its 'lung tubes' were connected directly to the lung simulator with a Y-connector and a short respiratory hose (internal diameter (ID) 22 mm, length 36 cm). The global dead space of the ventilation circuit, from the manikin's carina to the ASL5000 entrance, was measured at 250 ml, using an immersion method. Auscultation hoses and stomach entrance were blocked with Kocher clamps to prevent leakage. The laryngospasm simulator was set in a neutral position.

This study was conducted on three distinct experimental models, presented in Fig. 1:

- Direct model: the mechanical ventilator was directly connected to the lung simulator.
- Tube model: the manikin was connected to the lung simulator which was mechanically ventilated via a tracheal tube (ID 8 mm).
- Mask model: the manikin was connected to the artificial lung and this was mechanically ventilated via a non-invasive full-face ventilation mask (Ultra Mirage™; ResMed, San Diego, CA, USA), which was adjusted to minimise leakage.

Each phase included six ventilation tests of five minutes each, which allowed us to compare the measurements of ventilatory variables between the artificial lung and the mechanical ventilator at different peak flows (20 l.min^{-1}, 40 l.min^{-1}, 60 l.min^{-1}, 80 l.min^{-1}, 100 l.min^{-1} and 120 l.min^{-1}). The ventilator was set in VC mode (volume-controlled ventilation), and we used the same ventilation settings for each phase to make comparison possible. Ventilation rate (V_R) was set to 12 breaths.min^{-1} (bpm), inspiratory time (T_i) to

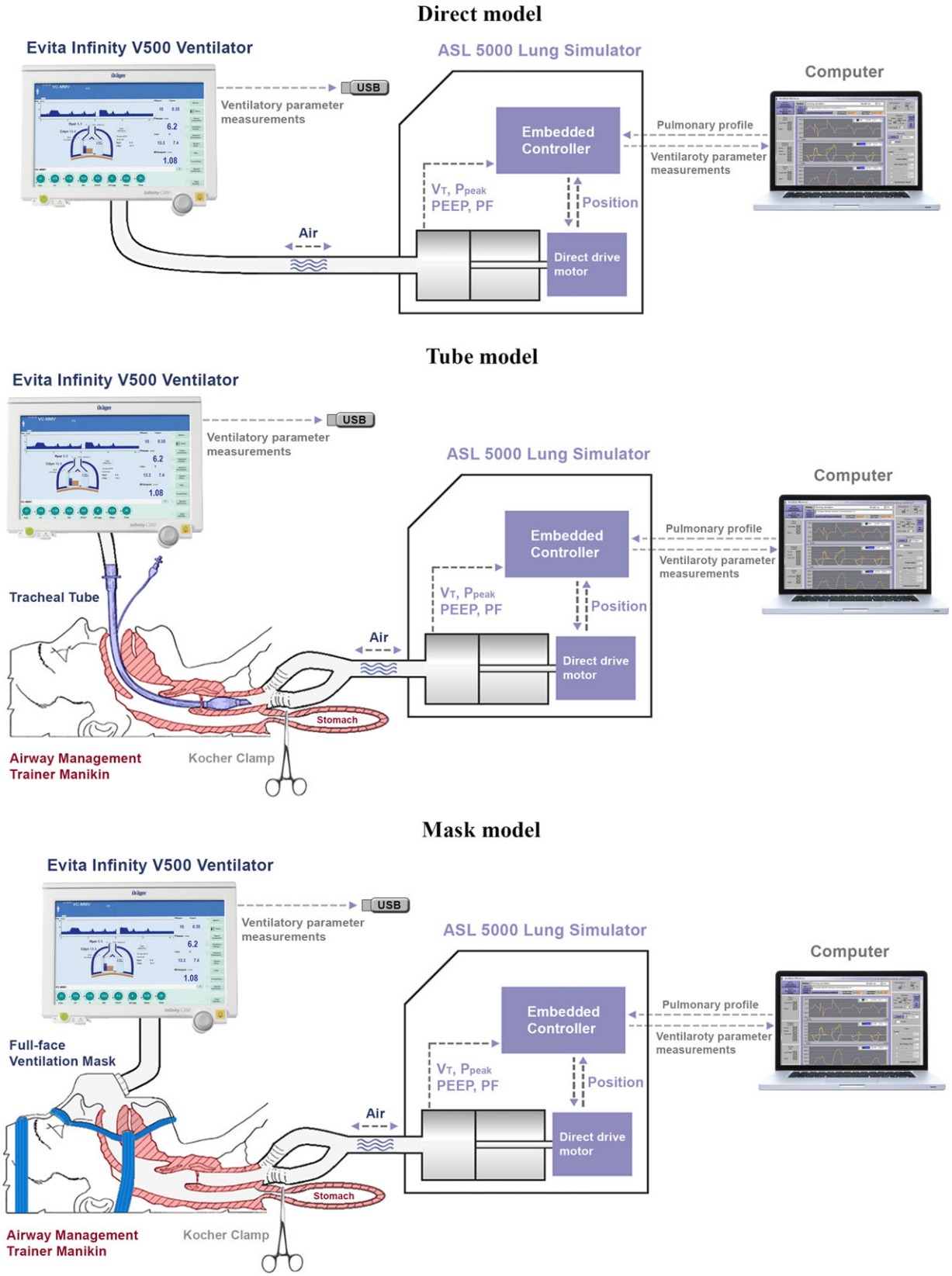

Figure 1 Diagram of the three different experimental models used in the study.

one second and positive end-expiratory pressure (PEEP) to 0 cmH_2O. As tidal volume (V_T) depends on inspiratory flow and inspiratory time, we had to change its value from one test to another. Thus, tidal volume settings varied from 300 ml to 600 ml for peak inspiratory flows ranging from 20 $l.min^{-1}$ to 120 $l.min^{-1}$.

We simultaneously recorded respiratory variables measured by both the lung simulator and the ventilator, to calculate any variance when using the manikin. We measured V_T, peak airway pressure (Ppeak), PEEP and peak flow (PF) for each ventilation cycle of each test. The difference in measurements between the ventilator and the lung simulator was calculated at each cycle for every variable, using the formula $\Delta X = X_{ventilator} - X_{lung}$. The recombined variables ΔV_T, ΔPEEP and ΔPpeak are used to evaluate the measurement deviation for each test, while ΔPF enabled us to ensure the absence of significant leakage. The global resistance of the circuit (R), from the ventilator output to the artificial lung entrance, was also calculated for each cycle using the formula:

$$R = \frac{\Delta P_{peak}}{PF}.$$

Unpaired t-tests were used to compare ΔV_T, ΔPEEP, ΔPpeak and R from one test to another. Due to the exploratory nature of the study (pilot study), no alpha adjustment was performed. We considered p values < 0.05 to be statistically significant.

Results

For each test, no significant leakage was observed, with ΔPF under 3 $l.min^{-1}$, which was the global measurement error of both ventilator and lung simulator combined. We found no significant difference in ΔPEEP between the corresponding tests of each experimental model, and ΔPEEP was negligible for all tests (mean (SD) = 0.0 (0.1) cmH_2O). However, we observed significant variations in ΔV_T between the different models. Table 1 shows the deviation in V_T measurements between the ventilator and the lung simulator, according to the peak flow and the experimental model used. The most important differences were observed for a peak inspiratory flow of 120 $l.min^{-1}$ (Table 1).

Table 1 Tidal volume measurement deviation (ΔV_T) between the mechanical ventilator and the lung simulator according to the peak flow and the experimental model used. Values are mean (SD). All p values were < 0.001 for comparisons between the different models.

	ΔV_T; ml		
Peak flow; $l.min^{-1}$	Direct	Tube	Mask
20	17 (1)	21 (2)	40 (4)
40	19 (1)	23 (3)	43 (3)
60	20 (1)	40 (3)	59 (5)
80	23 (3)	44 (5)	65 (4)
100	24 (4)	46 (6)	79 (5)
120	26 (6)	49 (9)	88 (5)

Table 2 shows the deviations in peak pressure measurements according to peak flows. The pressure drop was significantly greater for the Mask and Tube models than for the Direct model. Significant differences in peak pressure deviation are the consequences of different circuit resistances (R) between the three models, as shown in Fig. 2. The resistance of the Direct model did not vary, and was about 1 $cmH_2O.l^{-1}.s$. However, the circuit resistance of the Mask and Tube models increased significantly, from 2 $cmH_2O.l^{-1}.s$ to 5 $cmH_2O.l^{-1}.s$ and from 5 $cmH_2O.l^{-1}.s$ to 23 $cmH_2O.l^{-1}.s$, respectively.

Discussion

We have demonstrated deviations in measurements of ventilatory variables between the ventilator and the lung simulator. The Direct model has been used as a reference to evaluate the drop in Ppeak and V_T that can be attributed to the compliance of the ventilation circuit, and to the measurement error of both devices.

The results show that tidal volume measurement is impacted by the use of the manikin, especially when using a facemask. This additional loss of V_T ranges from 1 ml to 23 ml for the Tube model, and from 23 ml to 62 ml for the Mask model when compared with the Direct model. This significant deviation in V_T could be as a consequence of important inaccuracies in the upper airway anatomy of manikins. A recent study by Schebesta et al. concluded that the Laerdal

Table 2 Peak pressure measurement deviation (ΔPpeak) between the mechanical ventilator and the lung simulator according to the peak flow and the experimental model used. Values are mean (SD). All p values were < 0.001 for comparisons between the different models.

	ΔPpeak; cmH_2O		
Peak flow; $l.min^{-1}$	Direct	Tube	Mask
20	0.4 (0.1)	1.6 (0.2)	0.7 (0.1)
40	0.7 (0.1)	5.2 (0.1)	1.8 (0.1)
60	0.7 (0.1)	9.6 (0.1)	2.9 (0.2)
80	1.5 (0.2)	15.7 (0.2)	5.4 (0.2)
100	2.2 (0.3)	32.8 (0.2)	8.7 (0.3)
120	2.8 (0.4)	45.7 (0.3)	10.6 (0.3)

Airway Management Trainer manikin has an oral airspace of 74.0 ml, a retropalatal airspace of 16.9 ml and a pharyngeal airspace of 65.9 ml, while their actual mean values as measured in 20 adult patients were 4.3 ml, 5.1 ml and 13.5 ml, respectively [12]. This additional dead space may significantly influence the results of manikin-based studies. For instance, Barnes et al. used the Laerdal Airway Management Trainer manikin in a comparative study that focused on tidal volume and leakage measurements between different devices [22]. The peak inspiratory flows varied significantly from one test to another, and from one device to another (from 28.7 $l.min^{-1}$ to 82.1 $l.min^{-1}$), but they did not take this into account. Our results indicate that tidal volume deviation is clearly dependent on peak inspiratory flow, and this may have affected the results of this study and others that used this manikin under similar experimental conditions, without giving any indication as to whether they assessed manikin characteristics before reaching their conclusions [21, 26].

Another important point is the significant airway resistance of the manikin. When compared with the Direct model, the additional airway resistance increased with peak flows from 1 $cmH_2O.l^{-1}.s$ to 4 $cmH_2O.l^{-1}.s$ for the Mask model, and from 4 $cmH_2O.l^{-1}.s$ to 22 $cmH_2O.l^{-1}.s$ for the Tube model. Despite the use of the tracheal tube in the Tube model drastically increasing the resistance by reducing the diameter of the ventilation circuit, the manikin continued to have an impact on peak pressure measurements. The maximum deviation in non-invasive ventilation was 10.6 cmH_2O for a peak inspiratory flow of 120 $l.min^{-1}$. This may lead to significant underestimation of peak inspiratory pressures if the sensor is placed at the level of the lung. Marjanovic et al. [24] compared two devices by mea-

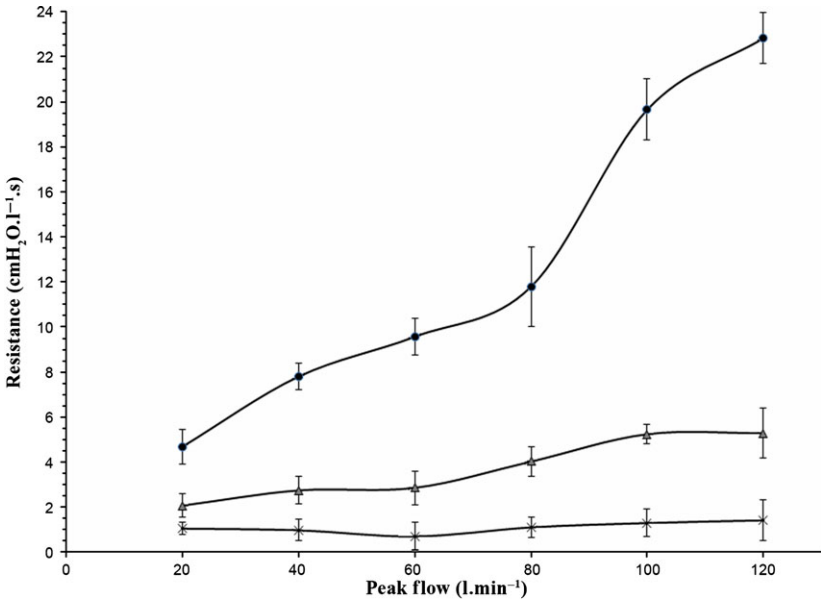

Figure 2 Circuit resistances (R) calculated at different peak inspiratory flows for the Direct model (–×–), the Mask model (–▵–) and the Tube model (–●–). All comparisons between models are significantly different.

suring peak inspiratory pressures and tidal volumes inside an ASL5000 lung simulator linked to a manikin. Fifty healthcare professionals had to provide non-invasive ventilation to three different patient models: a 'normal'; 'obstructive'; and 'restrictive'. They assessed the performance of ventilation under these clinical situations by adjusting the compliance and resistance of the lung simulator. However, they did not evaluate the intrinsic resistance of their manikin, which could potentially have affected the airway characteristics and the peak pressure measurement of their models. The evaluation of the manikin resistance is almost never considered in bench studies, but it may be crucial for a comparative study or, even more, for the evaluation of a single ventilation device. An appropriate definition of the patient model is important, especially if peak pressure measurement is a primary endpoint.

Our study has some limitations. First, we conducted our experiments on a single manikin, and are thus unable to draw general conclusions. Although we evaluated a manikin that is commonly used in bench studies, the intrinsic resistance and airway dead space may depend on the manikin model, as several studies have highlighted significant differences in their characteristics [12–17]. Second, we only used one pulmonary model, with lung compliance and resistance set to 70 $ml.cmH_2O^{-1}$ and 3.5 $cmH_2O.l^{-1}.s$, respectively. These settings were chosen to simulate an apnoeic patient without respiratory pathology. The impact of the manikin's airway resistance on peak pressure deviation may diminish when increasing pulmonary resistances. Conversely, the use of a restrictive patient model with low pulmonary compliances may accentuate tidal volume deviations. Deviation in ventilatory variables should thus be linked to the specific manikin and the experimental model used for each study.

In conclusion, the use of a manikin can impact peak pressure, tidal volume and leakage measurements, according to the experimental model used. Researchers should evaluate the characteristics of their manikin to take into account its intrinsic resistance and airway dead space for the definition of their patient model. A recalibration of the recorded ventilatory variables may also be necessary, especially if comparisons are made between different devices, techniques or rescuers, whose ventilations may have been provided at different peak inspiratory flows. Overlooking this step may lead to biased results and mistaken conclusions.

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Competing interests

None of the authors has any conflict of interest to declare.

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