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Experimental paper

A new physiological manikin to test and compare ventilation devices during cardiopulmonary resuscitation

François Morin[a,b,*], Laura Polard[b,c], Emeline Fresnel[d], Mathéo Richard[e], Hugo Schmit[f], Clarisse Martin-Houitte[a], Ricardo Luiz Cordioli[g], Marius Lebret[b,c,d,h], Alain Mercat[b,i], François Beloncle[b,i], Dominique Savary[a,b], Jean-Christophe Richard[b,c,i], Arnaud Lesimple[b,c]

Abstract

Background: There is a lack of bench systems permitting to evaluate ventilation devices in the specific context of cardiac arrest.

Objectives: The objective of the study is to assess if a new physiological manikin may permit to evaluate the performances of medical devices dedicated to ventilation during cardiopulmonary resuscitation (CPR).

Methods: Specific CPR-related features required to reproduce realistic ventilation were implemented into the SAM (Sarthe Anjou Mayenne) manikin. In the first place, the manikin ability to mimic ventilation during CPR was assessed and compared to real-life tracings of airway pressure, flow and capnogram from three out of hospital cardiac arrest (OHCA) patients. In addition, to illustrate the interest of this manikin, ventilation was evaluated during mechanical continuous chest compressions with two devices dedicated to CPR: the Boussignac cardiac arrest device (B-card – Vygon; Ecouen France) and the Impedance Threshold Device (ITD – Zoll; Chelmsford, MA).

Results: The SAM manikin enabled precise replication of ventilation tracings as observed in three OHCA patients during CPR, and it allowed for comparison between two distinct ventilation devices. B-card generated a mean, maximum and minimum intrathoracic pressure of 6.3 (±0.1) cmH_2O, 18.9 (±1.1) cmH_2O and −0.3 (±0.2) cmH_2O respectively; while ITD generated a mean, maximum and minimum intrathoracic pressure of −1.6 (±0.0) cmH_2O, 5.7 (±0.1) cmH_2O and −4.8 (±0.1) cmH_2O respectively during CPR. B-card allowed to increase passive ventilation compared to the ITD which resulted in a dramatic limitation of passive ventilation.

Conclusion: The SAM manikin is an innovative model integrating specific physiological features that permit to accurately evaluate and compare ventilation devices during CPR.

Keywords: Cardiopulmonary resuscitation, Cardiac arrest, Manikin, Ventilation, Functional residual capacity, Intrathoracic airway closure

Introduction

Several studies emphasized the importance of high-quality chest compressions and the challenge to deliver adequate ventilation during Cardio-Pulmonary Resuscitation (CPR).[1] International guidelines recently reaffirmed quality criteria for basic life support (BLS).[2] Regarding ventilation, areas of uncertainty persist,[3] due to the complex interactions between ventilation and circulation.[2,4] A recent study from Idris et al. showed that bag valve mask ventilation was often ineffective before advanced airway placement,[5] while a protective ventilation strategy could be preferred to prevent hyperventilation after intubation.[6] Over the years, several CPR ventilation strategies and new medical devices have been proposed, some of them interacting directly with circulation. The evaluation and comparison of the performances of various devices under standardized conditions present a significant challenge. Bench testing is now the standard approach for assessing and comparing the performances

* Corresponding author at: Department of Emergency Medicine CHU d'Angers, 4 rue Larrey, 49933 Angers Cedex 9, France.
E-mail address: Francois.Morin@chu-angers.fr (F. Morin).

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of ventilators used in emergency and ICU settings. However, specific models dedicated to the evaluation of ventilation during CPR are lacking.[7,9]

While a range of CPR manikins with different levels of fidelity are available for healthcare practitioner training,[10] they do not properly reproduce the physiological behavior of the human thorax observed during CPR, thus limiting the accurate assessment of device performances during CPR. In this context, a dedicated physiological manikin model designed to assess CPR ventilation devices or strategies was developed in Angers University Hospital. We reported hereby the description of this new manikin, whose potential benefit to evaluate performances of ventilation devices is illustrated.

Materials and methods

Description of the SAM manikin

A manikin was designed to reproduce the mechanical properties of a patient's thorax undergoing CPR. This project was funded by a grant obtained from the SAM (Sarthe Anjou Mayenne) network, which gathers professionals, researchers and industries from the healthcare systems in the west of France. The bench model is featured with several dedicated CPR modules as described below (see Fig. 1).

Lung volume and chest compressions-decompressions

A mono-compartmental bellow with a maximum capacity of 3 L is positioned at a 1.5 L state of equilibrium by means of an internal spring, allowing to reproduce the resting thoracic volume usually called functional residual capacity (FRC). The spring permits to reproduce the compliance of the respiratory system above the FRC, and the thoracic elastic properties of thorax with passive recoil below the FRC. Manual or mechanical chest compressions can be performed on the model. Thus, successive compressions and decompressions generate passive ventilation but also positive and negative intrathoracic pressures that drive theoretical circulation in real human CPR. Adjustment of the airway resistance of the thoracic model can be done by adding a parabolic resistance ranging from 5 to 50 $cmH_2O.s/L$ (PneuFlo® Parabolic Resistor, Michigan Instruments).

Intrathoracic airway closure

A Starling resistor can simulate the recently described intrathoracic airway closure phenomenon, that significantly interferes with pressures and volumes generated during CPR in humans.[11] This device consists of an elastic collapsible tube mounted inside a sealed chamber filled with air.[12] The static pressure inside the chamber is used to control the level of collapse of the tube, thus providing a variable resistance. Our model here can be seen as a flow limitation system to simulate mild to complete intrathoracic airway closure. The Starling resistor comprises a cylindrical waterproof tube made of Plexiglas (Ø4cm and length 10 cm), in which a latex tube (Comed, Strasbourg, France) with a diameter of 18 mm has been inserted.

Realistic manikin head

A manikin head (Georges, KerNel Biomedical, Rouen) with realistic upper airways was chosen as the interface between the ventilation devices and the SAM manikin.[13] The upper airways of the head

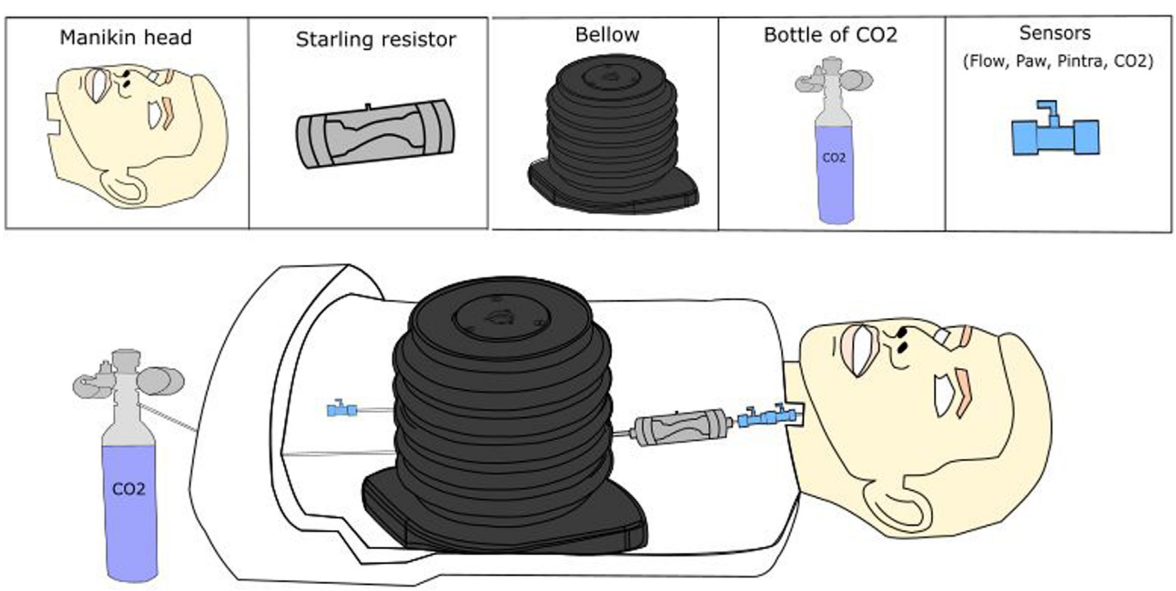

Fig. 1 – Schematic of SAM manikin. Schematic showing the different components of the SAM manikin. A realistic manikin head was designed to test invasive (endotracheal tube) and non-invasive (mask) interfaces. The head can be plugged to a Starling resistor simulating intrathoracic airway closure. This resistor can be connected to the bellow of the manikin simulating lung volume and representing a physiological functional residual capacity (FRC). Chest compressions can be performed on the chest of the manikin, and a spring was inserted within the bellow to mimic thoracic elastic properties of the thorax above and below FRC. A bottle of CO_2 can be connected at the base of the bellow to simulate CO_2 production. A flowmeter can be added to regulate the flow of CO_2 administered to the system. Additionally, a pressure sensor can be used to measure the intrathoracic pressure inside the bellow. Pressure, flow and CO_2 sensors can be also inserted at the airways, as shown on this schematic between the head and the Starling resistor.

presented a dead space of 152 ml and a resistance of 2.4 $cmH_2O.s/L$. Upper airways were designed based on data from computerized tomography scans of healthy subjects.[14] Composite 3D printing was performed using rigid material for the endoskeleton and flexible material for the airways; while the skin is made of medical silicon. The mouth can be open or closed depending on the chosen setting. The manikin upper airways can be connected to the Starling resistor, itself connected to the thorax of the SAM manikin. This manikin head allows to perform (i) non-invasive ventilation with nasal cannulas or a mask interface; (ii) invasive ventilation by using an endotracheal tube.

Simulating CO_2 production and monitoring CO_2 levels

A constant flow of CO_2 can be administered through a dedicated port in the bellow to simulate CO_2 production, considered as a surrogate of circulation within the lungs. A CO_2 cylinder can be connected to a flowmeter to regulate the continuous gas flow entering the base of the manikin's thorax. Various levels of CO_2 production can be simulated.

An illustration of the SAM manikin is shown on Fig. 1.

Validation of the SAM manikin

Protocol – All tests reported hereafter were obtained with mechanical continuous chest compressions (Life Stat Michigan Instruments, Grand Rapids, USA) at a rate of 100 compressions per minute and 3 cm of depth. The SAM manikin has a respiratory system compliance of 25 ml/cmH_2O and a resistance of 5 $cmH_2O.s/L$ close to what has been observed in real cardiac arrest patients.[15] Tests were performed in invasive ventilation configuration. CO_2 was administered continuously at a flow rate of 0.1 L/min at the base of the bellow to simulate CO_2 production.

Data acquisition and analysis – A pneumotachograph (Fleisch no. 2), a pressure transducer (TSD160series; Biopac Systems) and an infrared-based CO_2 sensor (CO_2-100C: Biopac systems, Goleta, CA, USA) were used to measure flow, airway and intrathoracic pressure and CO_2. They were converted with an analog digital converter (MP150; Biopac Systems) at a sample rate of 2000 Hz, and stored using a dedicated software (Acknowledge 4.3, Biopac Systems).

Validation of the SAM manikin against clinical data

We performed a comparative analysis between ventilation data obtained from three Out-of-Hospital Cardiac Arrest (OHCA) patients and ventilation data obtained from the SAM manikin. The objective was to assess the accurate reproducibility on the SAM manikin of physiological mechanisms observed in clinical settings.

Ventilation tracings from three OHCA patients were obtained during the VENT-AC clinical study on ventilation during CPR at Annecy Hospital (clinical trial id: NCT06175689). These patients correspond to the first patients of the cohort and were chosen arbitrarily. Airway pressure, flow, and capnograms were recorded using the Monnal T60 ventilator's black boxes (Air Liquide Medical Systems, Antony, France). A non-synchronized bi-level pressure-mode ventilation, CPV, was used to deliver active ventilation during CPR. To enable direct comparison, CPV was also applied to the SAM manikin using the Monnal T60, alongside chest compressions using the Life Stat system.

The mean airway pressure (Paw_{mean}), the volumes generated by passive ventilation during compression (V_{comp}) and decompression (V_{decomp}) as well as tidal volume (Vti) during active ventilation were measured. The maximum CO_2 value measured during expiration that reflects alveolar CO_2[16] was also collected. Those parameters were averaged over four chest compressions cycles for passive ventilation (Paw_{mean} – V_{comp} – V_{decomp}) and over four insufflations for active ventilation (Vti) for each recording (OHCA and SAM manikin).

Evaluation of two ventilation devices during CPR using the SAM manikin model

The Boussignac cardiac arrest device (B-card – Vygon; Ecouen France) and the Impedance Threshold Device (ITD – Zoll; Chelmsford, MA) were evaluated on the SAM manikin. B-card system is based on continuous flow insufflation (CFI) working principle. It provides positive pressure to a level that generates air entrainment. ITD system aims to reduce intrathoracic pressure by creating a negative pressure vacuum during decompression.

The B-card was set with an oxygen flow rate of 15 L/min and was directly connected to the endotracheal tube; the ITD was positioned between the manikin and a bag-valve-device (Ambu, Ballerup, Denemark) filled with 15 L/min of oxygen. Ventilation data from B-Card and ITD were compared. A recording of one minute of continuous chest compressions was performed for each configuration.

The mean ($Pintra_{mean}$), the amplitude ($Pintra_{P\text{-}P}$), the maximum ($Pintra_{max}$) and the minimum ($Pintra_{min}$) intrathoracic pressure induced by chest compressions were measured, as well as the volumes generated by compression (V_{comp}) and decompression (V_{decomp}). Those parameters were averaged over four chest compressions cycles.

Results

Comparison between the SAM manikin and clinical data

Comparison of tracings obtained on three OHCA patients and on the SAM manikin are displayed on Fig. 2. Mean passive ventilation of the three patients and the manikin was characterized by a V_{comp} of 24 (±11) ml and 22 (±4) ml respectively; and a V_{decomp} of 30 (±10) ml and 22 (±11) ml respectively; Paw_{mean} was 7.6 (±0.3) cmH_2O and 5.8 (±0.1) cmH_2O respectively, while the insufflated tidal volume (Vt_i) for active ventilation was 232 (±26) ml and 173 (±34) ml respectively. The maximum CO_2 value recorded during expiration was 39 (±3) mmHg and 40 (±0) mmHg respectively. From a qualitative point of view, tracings recorded with the SAM manikin for flow, pressure and CO_2 exhibited similar patterns to those obtained from real-life patients.

Performances of continuous flow insufflation and impedance threshold devices assessed by the SAM manikin

Illustrations of passive ventilation with chest compressions only, B-card and ITD are displayed on Fig. 3. $Pintra_{mean}$, $Pintra_{P\text{-}P}$, $Pintra_{max}$, $Pintra_{min}$, V_{comp} and V_{decomp} are shown in Table 1. B-card and ITD systems generated a mean intrathoracic pressure of 6.3 (±0.1) cmH_2O and −1.6 (±0.0) cmH_2O. Adding a B-card increased V_{comp} and V_{decomp} compared to the reference with chest compressions only, while the ITD showed dramatically reduced passive ventilation.

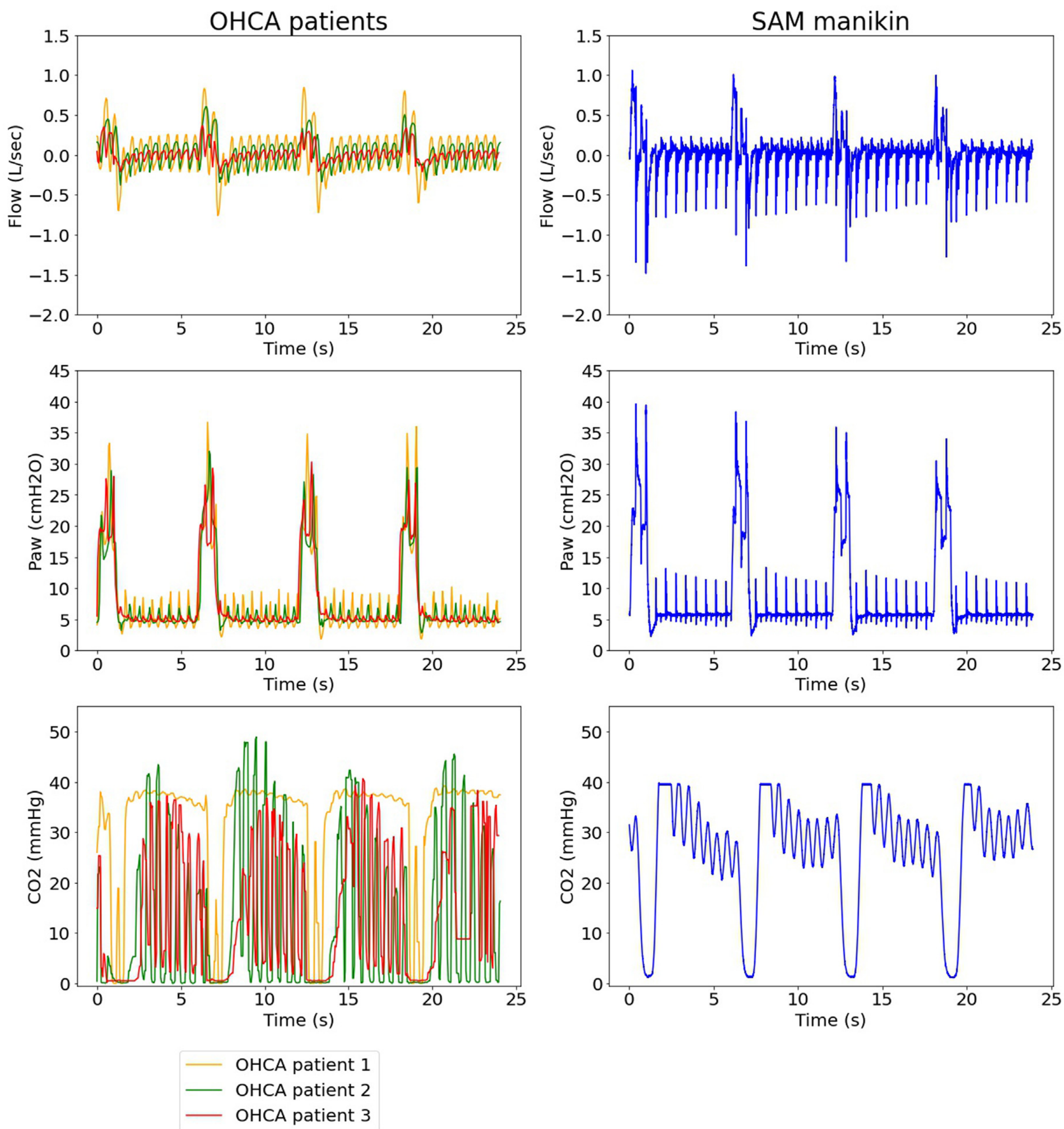

Fig. 2 – Comparison of flow, airway pressure and CO_2 tracings obtained during CPR between three out of hospital cardiac arrest (OHCA) patients and SAM manikin. This figure depicts from top to bottom the airway flow, airway pressure (Paw), and CO_2 tracings over time obtained from three out of hospital cardiac arrest patients (on the left) and on the SAM manikin (on the right) during continuous chest compressions. Active ventilation was delivered using a Monnal T60 ventilator with the CPV mode of ventilation and default settings. Four ventilation cycles are represented.

Discussion

We reported in the present study an original and novel manikin permitting to reproduce realistic behavior of the thorax during CPR. Ventilation tracings from the SAM manikin were similar to those obtained from three OHCA patients, including passive and active ventilation. This manikin also permitted to assess ventilation performances and demonstrated the different working principles of both the B-card and the ITD devices.

Is there a need for a physiological CPR bench model?

Over the years, different ventilation strategies and devices have been proposed to improve the management of cardiac arrest.[17,18] Recently, specific CPR ventilation modes have been implemented on ventilators with the purpose to facilitate ventilation and to limit its harmful effects on circulation.[19] The precise functioning and the potential benefit of those innovative developments is not easily assessed. Consequently, a physiological CPR bench model may be required, first to understand the working principle and expected

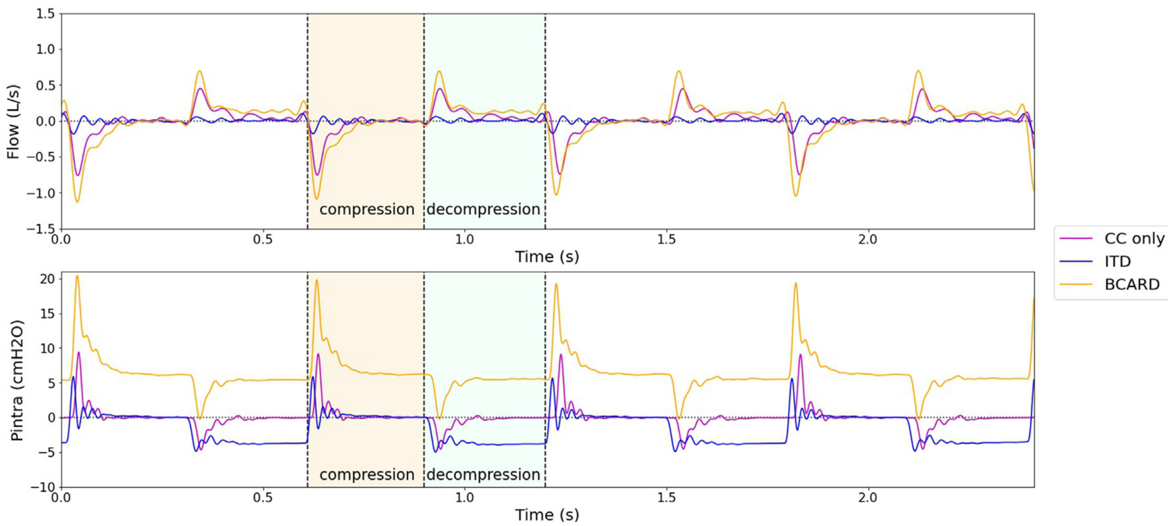

Fig. 3 – Evaluation of passive ventilation during continuous chest compressions with B-card and ITD on the SAM manikin. This figure depicts the flow and the intrathoracic pressure (Pintra) tracings over time obtained on the SAM manikin during continuous chest compressions. Three configurations were tested: chest compressions (CC) only (purple curve), chest compressions with B-card system (orange curve) and chest compressions with ITD system (blue curve). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Table 1 – Evaluation of passive ventilation during continuous chest compressions with B-card and ITD on the SAM manikin.

	CC only	B-card	ITD
V_{comp} (mL)	27 (±1)	47 (±8)	3 (±1)
V_{decomp} (mL)	27 (±1)	44 (±9)	4 (±0)
$Pintra_{mean}$ (cmH_2O)	0.0 (±0.0)	6.3 (±0.1)	− 1.6 (±0.0)
$Pintra_{max}$ (cmH_2O)	8.8 (±0.2)	18.9 (±1.1)	5.7 (±0.1)
$Pintra_{min}$ (cmH_2O)	− 4.5 (±0.1)	− 0.3 (±0.2)	− 4.8 (±0.1)
$Pintra_{P-P}$ (cmH_2O)	13.3 (±0.2)	19.2 (±1,1)	10.4 (±0,2)

Data are presented as mean (±standard deviation). CC only, B-card and ITD represent the configurations with chest compressions only, use of Boussignac continuous flow insufflation system (B-card) and use of Impedance Threshold Device (ITD) respectively.

$Pintra_{mean}$: intrathoracic pressure averaged over one chest compression cycle.

$Pintra_{max}$: maximum intrathoracic pressure induced by chest compression.

$Pintra_{min}$: minimum intrathoracic pressure induced by chest decompression.

$Pintra_{P-P}$: amplitude of oscillations of intrathoracic pressure induced by chest compression.

V_{comp}: volume generated by chest compression.

V_{decomp}: volume generated by chest decompression.

effect of new medical devices, and second to assess and compare their performances as it is currently done for emergency and ICU ventilators. Results collected on the bench are limited to assess circulation but can be considered as an essential step to understand the surrounding physiological mechanisms of the CPR strategy studied. In complement of animal or cadaver studies,[20,21] it may permit to confirm expected effects before clinical applications and eventually future randomized controlled trials.

The SAM manikin to reproduce realistic ventilation tracings

Comparison of the tracings obtained from three OHCA patients and from the SAM manikin showed that the manikin was able to reproduce realistic ventilation tracings, in terms of both active and passive ventilation. The generation of passive ventilation was possible thanks to the implementation of lung volume within the manikin. Indeed, lung volume is highly important to assess recoil and thoracic pressure changes as well as passive ventilation during chest compressions.[22]

The mean volume generated during chest compression and decompression accounting for passive ventilation with the SAM manikin was 22 (±4) ml and 22 (±11) ml respectively, which is consistent with the tracings from OHCA patients investigated in the current study; but also with what has been previously reported. Studies on OHCA patients receiving compression-only CPR showed median tidal volumes varying from 7.5 ml[23] to 41.5 ml.[24] This is also in line with recent studies from Vanwulpen et al. and Azcarte et al. that reported in pre-hospital settings a median passive ventilation of 20 ml[25] and 25.6 ml[26] respectively.

In addition, respiratory mechanics measured in the SAM manikin were comparable to those of OHCA patients. In fact, compliance and resistance may vary substantially between patients and over the course of CPR, with a median compliance of 37.3 ± 10.9 ml/cmH_2O in Charbonney et al. study[21] and 40 ± 11 ml/cmH_2O in Cordioli et al. study,[11] while resistance was measured at 20.2 ± 5.3 cmH_2O/l/s.[21]

On top of that, reproducing intrathoracic airway closure in the SAM manikin is relevant as it has been observed in a significant proportion of cardiac arrest patients[6] and tends to reduce lung volume below the FRC. It significantly reduces passive ventilation and minute ventilation and can be identified by analyzing capnograms (CO_2 signal). It concerns approximately 30 % of out-of-hospital cardiac arrest patients.[16,21]

Interestingly, recent research has shown that the analysis of the CO_2 signal, known as the capnogram, could guide cardiopulmonary resuscitation and provide relevant information on both circulation and ventilation.[6] Importantly, different physiological events can be identified by the analysis of CO_2 patterns, such as intrathoracic airway closure of the small distal airways and thoracic distension,[6,16,21] that may be harmful for circulation and ventilation.[22] Thus, the ability to record CO_2 signals could be of great interest in CPR bench models.

The evaluation of B-card and ITD on the SAM manikin

To illustrate the potential added value of the SAM manikin to evaluate ventilation devices in the context of CPR, the continuous flow insufflation device B-card and the ITD were tested and compared as examples since both systems are based on different working principles. In the conditions tested, the B-card delivered a positive pressure in the lungs and permitted to increase passive ventilation. As previously demonstrated,[17,27] by limiting air entry into the lungs during chest recoil, ITD decreased the negative pressure generated by chest decompression, with the objective to increase venous return. Ventilation with the ITD was dramatically reduced in our experiment due to, first the working principle of the ITD reducing passive ventilation; and second because active ventilation was not added as it is usually done in clinical practice.

Limits

The model described in this study presents several limitations. Even if the SAM manikin aims to reproduce CPR physiology, our lung model (as other lung models) did not permit to reproduce and assess gas exchange (oxygen consumption) and circulation. Moreover, to reproduce passive ventilation with realistic volumes generated by chest compressions, we had to adjust chest compression's depth lower than the value recommended in the guidelines. This passive ventilation may differ from clinical data, as it was shown to vary significantly between patients. Of note, it is not possible to reproduce with this manikin the high heterogeneity of ventilation and patients' characteristics.

Presenting a physiological manikin that only evaluates the performances of medical devices dedicated to ventilation during CPR may seem like a limitation when we know how important the quality of chest compressions is for patient survival.[2] However, it is possible to combine this manikin with a device dedicated to the monitoring of chest compressions' quality.

Conclusion

The present SAM manikin may permit to reproduce the main physiological features of cardiac arrest patients (FRC, airway closure, CO2 production) and may be used to compare different ventilation devices.

CRediT authorship contribution statement

François Morin: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Laura Polard:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Emeline Fresnel:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Mathéo Richard:** Writing – review & editing, Writing – original draft. **Hugo Schmit:** Writing – review & editing, Writing – original draft. **Clarisse Martin-Houitte:** Writing – review & editing, Writing – original draft. **Ricardo Luiz Cordioli:** Writing – review & editing, Writing – original draft. **Marius Lebret:** Writing – review & editing, Writing – original draft. **Alain Mercat:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **François Beloncle:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Dominique Savary:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Jean-Christophe Richard:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Arnaud Lesimple:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'EF is the co-founder of KerNel Biomedical society who received part of the study fund allocated to this manikin development. AL and LP are medical engineers in the Med2Lab funded by Air Liquide Medical Systems. RC is a physician working for Air Liquide Medical Systems. ML reports part time salary with Air Liquide Medical Systems and KerNel Biomedical. JCR reports part time salary for research activities (Med2Lab) from Air Liquide Medical Systems. FB reports personal consulting fees from Löwenstein Medical and Air Liquide Medical Systems, travel fees from Draeger and Air Liquide Medical Systems and research support from Covidien and GE Healthcare outside this work. FM and DS reports Grants from Fisher and Paykel and travel fees from Air Liquide Medical Systems outside this work. AM reports personal fees from Draeger, Faron Pharmaceuticals, Air Liquide Medical Systems, Pfizer, ResMed and Draeger and grants and personal fees from Fisher &

Paykel and Covidien, outside this work. None of the other authors have competing interests related to this topic.'.

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Author details

[a]Department of Emergency Medicine, University Hospital of Angers, Angers, France [b]Vent'Lab, University Hospital of Angers, Angers, France[c]Med2Lab Laboratory, ALMS, Antony, France[d]Kernel Biomedical, Bois-Guillaume, France [e]INOSystems, Antony, France[f]Department of Emergency Medicine, Annecy Genevois Hospital, Annecy, France [g]Hospital Israelita Albert Einstein, São Paulo, SP, Brazil[h]Université Paris-Saclay, UVSQ, Erphan Paris-Saclay University, Versailles, France [i]Medical Intensive Care Unit (ICU), Angers University Hospital, Angers, France

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