



ORIGINAL ARTICLE

The in-vitro performance of a modern portable respirator in different lung models and as an alternative intensive care respirator

A simulation based cohort study

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BACKGROUND Transporting ventilated patients safely and without loss of efficacy is a challenge. Portable ventilators are generally used to transport critically ill patients, but their performance is often limited.

OBJECTIVE This study aimed to compare the in-vitro performance of a modern portable respirator with a modern intensive care respirator for different lung settings.

DESIGN An in-vitro testing of a portable and an intensive care respirator.

SETTINGS Anaesthesia Department at the University Children's Hospital Zurich.

MAIN OUTCOME MEASURES The portable respirator Hamilton T1 was compared with the established intensive care respirator bellavista1000 (BV) while applying different settings with the ASL 5000 (ASL) device. The ASL can simulate neonatal, paediatric, and adult lung settings with normal or impaired lung function. Accuracy of delivered tidal

volumes, proximal and distal airway pressures and mechanical lung properties were assessed.

RESULTS Bland-Altman analyses showed higher accuracy for applied tidal volumes delivered by the portable respirator, 12.6% [95% confidence interval (CI) -8.9 to 34.2], compared with the intensive care respirator, 15.9% (95% CI -18.5 to 50.3). In neonatal and infant lung models particularly, the accuracy of delivered tidal volumes by the portable respirator, 13.2% (95% CI -8.9 to 35.3) was superior to those delivered by the intensive care respirator, 20.9% (95% CI -15.9 to 57.7). Lung compliance estimation was performed more accurately by the intensive care respirator, whereas the portable respirator measured airway resistance more accurately. However, both respirators showed only moderate overall accuracy when assessing lung mechanics.

CONCLUSION The tested portable respirator proved to be a useful device for invasive ventilation of critically ill patients. The overall performance is non-inferior to a conventional intensive care respirator.

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KEY POINTS

- The portable ventilator we tested delivered tidal volumes with comparable accuracy to a modern established intensive care ventilator across a wide age range.
- With limitations, both ventilators were able to measure mechanical lung properties across the entire range of neonate to adult.
- The portable ventilator proved to be an accurate tool for both transport and long-term ventilation of children and adults in the intensive care unit.

Introduction

Transfer of patients with invasively ventilated lungs is often challenging.¹ Five percentage of all reported adverse events in paediatric anaesthesia are associated with transportation.² The safety of manual bag ventilation in critically ill patients has been increasingly questioned in recent years.³ In neonates particularly, manual bag ventilation has been associated with the application of excessive tidal volumes and peak inspiratory pressures, and inadequate respiratory rates.^{4–6}

Recently the use of portable mechanical respirators has become increasingly widespread for in-hospital, inter- or pre-hospital transportation of patients, due to their reduced size and improved performance. However, physicians are often concerned about performance limitations when using portable respirators in critically ill patients with impaired lung function. He 2019 coronavirus disease (COVID-19) pandemic continued to demonstrate the importance of safe transportation and how limited resources in intensive care units were in terms of staffing and the availability of non-portable ventilators. Hence, knowing the characteristics of "back-up" portable respirators to be applied in these circumstances is fundamental. Hence

The objective of this in-vitro study was to assess and compare the performance of a modern portable respirator with an established modern ICU respirator in simulated patients of different ages with normal and pathological lung function.

Materials and methods

In this in-vitro study, the performance of a modern portable respirator was compared to a well established modern intensive care respirator in different neonatal, paediatric and adult lung settings, using the ASL 5000 (ASL) test lung monitor (ASL; Active Servo Lung, IngMar Medical, Pittsburgh, PA, USA). The ASL employs a combination of software models and physical sensors to simulate the lungs, airways, and respiratory mechanics of children and adults. It can be used as a test lung monitor or as a breathing simulator. Based on a

computer controlled movable piston it allows measuring or generating inspiratory and expiratory tidal volumes $(V_{\rm T})$, inspiratory and expiratory times, pressures and work of breathing, while lung compliance and airway resistance can be specified according to a patient's age, weight and lung function. In this context, the ASL was shown to be an effective way of validating neonatal and paediatric respiratory models.¹³ It can also be used as a lung simulator to measure the interactive performance of respirators such as the applied tidal volumes or airway pressures generated by the device. 14-16 High-precision sensors are used for the monitoring and recording of the volume of air displaced by the piston and the resulting pressure changes. The recordings are used to calculate the applied tidal volume and distal airway pressures using specialised software (ASL5000 SW3.6) that integrates the entered resistance and compliance values of the lung model. In this study, we used the single-compartment lung model and for each of the six lung models (Table 1), the defined airway resistance, the pulmonary compliance and the residual capacity were entered in the ASL. Furthermore, the ASL offers high-fidelity simulation, enabling the replication of intricate respiratory behaviour, including air trapping, delayed alveolar filling and variable pressures throughout the respiratory cycle. Most of the information regarding the ASL was obtained from the 'ASL 5000 -User's Manual', provided by IngMar Medical/USA.

The ASL used in this study was regularly serviced and calibrated according to the manufacturer's instructions before starting the current experiments. As this is a pure in-vitro study without patient contact, patient data or animal experiments, ethical approval was not required. The experiments were conducted and analysed at the University Children's Hospital Zurich from around June 2021 to January 2023.

Experimental settings

For this study a portable respirator was employed, the Hamilton T1 portable respirator (Hamilton Medical, Bonaduz, GR, Switzerland) and an intensive care respirator, the bellavista1000 with a software update to allow artificial ventilation of the lungs of infants <6 kg BW (Vyair Medical, Mettawa, Illinois, USA). Three different examples of both the Hamilton T1 (T1) and the bellavista1000 (BV) were tested, and were regularly serviced and calibrated according to the manufacturer's instructions.

The T1 was equipped with a neonatal breathing hose and breathing circuit set for simulation with a programmed ideal body weight (IBW) $<10\,\mathrm{kg}$ (Dual limb, Hamilton Medical AG, Bonaduz, GR, Switzerland) and with a paediatric/adult breathing circuit set for $\ge 10\,\mathrm{kg}$ IBW simulation (Coaxial, Hamilton Medical AG, Bonaduz, GR, Switzerland) according to the manufacturer's instructions. Three different breathing circuit configurations are recommended by Hamilton Medical AG for the IBW >10 to $<20\,\mathrm{kg}$: (1) neonatal breathing tube with



Table 1 Age-adapted lung models simulated by the Active Servo Lung 5000 (ASL) with normal and pathological lung function (left half of the table) and corresponding respirator settings in the respirators (right half of the table)

Age	Weight (kg)	Length (cm)	RR _{spon} ₍ min ⁻¹)	V _{T_spon} (ml); (ml kg ⁻¹)	FRC (ml)	C_L (ml cmH ₂ O ⁻¹⁾	R (cmH ₂ O l ⁻¹ s ⁻¹)	RR _{ven} (min ⁻¹)	<i>T</i> _i (I:E) s	V _{T_ven} (ml); (ml kg ⁻¹)	PEEP (mmHg)	ETT (mm)	Pathology
26 GW	0.75	34	60	8; (10.7)	9.3	1.00	133	40	0.5; (1:2)	7.5; (10)	5	2.5	
26 GW	0.75	34	80	5; (6.7)		0.5	173	40	0.3 (1:4)	3.75; (5)	6	2.5	NRDS
40 GW	3.5	52	40	41; (11.7)	83	5.4	56	40	0.5 (1:2)	28; (8)	5	3.0	Healthy
40 GW	3.5	52	70	25; (7.1)	100	2.7	70	30	0.5 (1:3)	28; (8)	7	3.0	Meconium-A
3 months	5.5	60	34	60; (10.9)	119	8.6	45	30	0.65 (1:2)	44; (8)	5	3.0	Healthy
3 months	5.5	60	70	40; (7.27)		5.6	70	25	0.6 (1:3)	44; (8)	5	3.0	RSV-Bronch.
24 months	11.5	86	25	129; (11.2)	259	18.5	29	25	0.8 (1:2)	92; (8)	5	4.0	Healthy
24 months	11.5	86	40	100; (8.7)		10.5	35	30	1 (1:1)	80; (7)	7	4.0	Pneumonia
72 months	20	115	19	232; (11.6)	465	34	23	20	1 (1:2)	160; (8)	5	5.0	Healthy
72 months	20	115	40	150; (7.5)		18	40	30	1 (1:1)	120; (6)	10	5.0	Pneu. /ARDS
65 years	100	170	18	600	1200	65	15	12	1.6; (1:2)	450	5	8	Healthy
65 years	100	170	30	350		20	23	30	1; (1:1)	300	15	8	COVID-19

Age, weight (50th percentile of the Swiss percentile curves for girls), respiratory rate, inspiratory tidal volume and lung resistance and compliance were calculated for each simulated lung model base on published data²¹ or from clinical experience. ARDS/Pneu., acute respiratory distress syndrome/pneumonia; C₁, lung compliance; ETT, endotracheal tube; FRC, functional residual capacity; I:E, ratio inspiration/expiration time; NRDS, newborn respiratory distress syndrome; PEEP, positive end expiratory pressure; R, airway resistance; RR_{spon/ven}, spontaneous/respirator respiratory rate; RSV-Bronch., respiratory syncytial virus-bronchiolitis; T_i, inspiration time; V_{Tspon/ven}, spontaneous/respirator tidal volume.

neonatal expiratory valve and infant flow sensor, (2) neonatal breathing tube with adult-paediatric expiratory valve/flow sensor and (3) co-axial adult breathing tube with adult-paediatric expiratory valve/flow sensor.¹⁷ All three configurations were tested for the infant lung model (11.5 kg IBW), whereas for the paediatric lung model (20 kg IBW) only the latter two configurations were tested (Table 1, Supplemental Digital Content, http://links. lww.com/EJAIC/A107). The BV was equipped with a BTS1350A breathing hose and breathing circuit set (WILAmed GmbH, Kammerstein, Germany) for simulated patients <15 kg IBW, and with an adult BTS3167A breathing hose and breathing circuit set (WILAmed GmbH, Kammerstein, Germany) for simulated patients ≥15 kg IBW (Table 1, Supplemental Digital Content, http://links.lww.com/EJAIC/A107), according to the manufacturer's instructions.

Cuffed endotracheal tubes [Microcuff PET (Microcuff, Halyard, Georgia, USA)], with an internal diameter (ID) ranging from 3.0 to 8.0 mm were employed. Age-referenced tube size selection for the Microcuff PET was as previously published^{18,19} and officially recommended by the manufacturer.²⁰ For the preterm, an ID 2.5 mm uncuffed ETT Mallinckrodt Hi-Contour oral/nasal Murphy Eye tracheal tube (Covidien Inc., Mansfield, MA, USA) was employed.

The Y-piece of the T1 or BV breathing circuit was connected directly to the ETT, which itself was glued into an inlet (Connector 22M to 15M, Intersurgical GmbH, Sankt Augustin, Germany) in the ASL to prevent any air leakage around the ETT and respective breathing circuit system.

Six different lung model simulations were calculated and designed:

Neonatal models

- (1) preterm (26 gestational weeks)
- (2) full-term (40 gestational weeks)

Paediatric models

- (3) 3 months
- (4) 24 months
- (5) 6 years Adult
- (6) adult (65 years) (Table 1)

Additionally, each lung model was programmed for normal (physiological) function and age-adapted pathological function. Age, weight, respiratory rate, inspiratory tidal volume and lung performance variables such as resistance and compliance were calculated for each simulated lung model based on published data^{13,21} or clinical experience. The weights and sizes of the simulated children corresponded to the 50th percentile of the Swiss percentile curves for girls of the corresponding age.²² Both respirator models were employed in pressure-controlled ventilation mode and prespecified expiratory tidal volumes delivered through peak-inspiratory pressure titration.

The following respiratory measurements were exported from the respirator's internal record: proximal airway pressures, inspiratory and expiratory tidal volumes, airway resistance, lung compliance, and airway leakage. Each lung model was run for at least 10 min, resulting in a total measurement time of approximately 760 min corresponding to over 20 000 recorded breaths. The inspiratory and expiratory (V_{Texp}) tidal volumes were concomitantly measured in the ASL16 reflecting the actual tidal volumes delivered to the patient's respiratory tract. Distal airway pressures were measured in the ASL. Driving pressure was calculated as $\Delta P = V_{\text{Texp}}/C_{\text{RS}}$, where C_{RS} represents the total compliance of the respiratory system.

Calculations and statistical analysis

Assessment for normal distribution was performed by the Shapiro-Wilk test and the D'Agostino & Pearson test.

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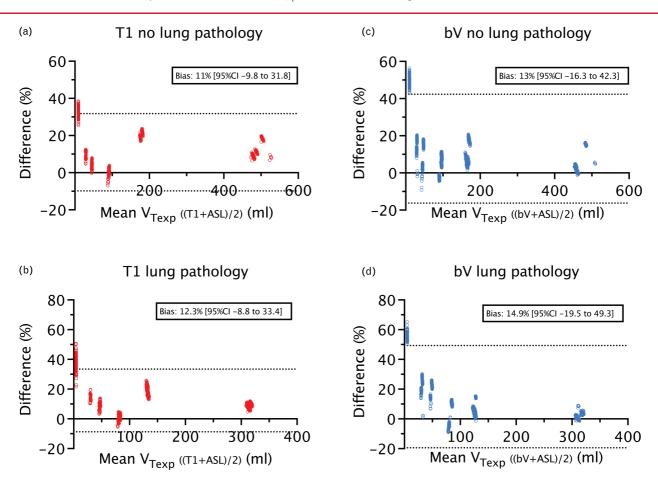
Comparison of respirators was performed using the unpaired t-test or Mann-Whitney test as appropriate. Modified Bland-Altman diagrams were constructed to assess the agreement between applied and measured volumes and pressures, in addition to estimated and simulated mechanical lung properties. A two-sided P-value < 0.05was considered to be statistically significant. For multiple testing, a Bonferroni correction was performed and statistical significance modified to a P-value <0.017. Pearson correlation coefficients were calculated between measured leakage and applied expiratory tidal volume of the T1 portable respirator. Data were compiled in Microsoft Excel 2013 (Microsoft Corporation, Redmond, WA, USA) and processed using Prism 9 (Graphpad software, La Jolla, USA) for statistical analysis. Values are presented as medians with 95% confidence intervals (95% CIs) or means with standard deviations as appropriate.

Results

Accuracy of tidal volumes

Throughout the 20 000 recorded breaths measured by the ASL 5000 in all 12 models, the effectively applied V_{Texp} ranged from 3.1 to 550.4 ml. Overall, the portable respirator T1 generated more accurately applied V_{Texp} than the intensive care respirator BV irrespective of the presence or absence of lung pathology: T1: 12.6% (95% CI -8.9 to 34.2) versus BV: 15.9% (95% CI -18.5 to 50.3; Fig. 1). This effect was most prominent in the "younger" lung models (preterm infant, neonate, infant), where the T1 presented an accuracy of 13.2% (95% CI -8.9 to 35.3) compared to the BV, 20.9% (95% CI -15.9 to 57.7) (Fig. 2a-d; Figure 1a and b, Supplemental Digital Content, http://links.lww.com/EJAIC/A107). In the "older" lung models (child, adult) this effect was inverted, and the BV, 4.7% (95% CI -5 to 14.4) was more accurate than the T1, 14.6% (95% CI 3.3 to 25.8) (Fig. 2e and f;

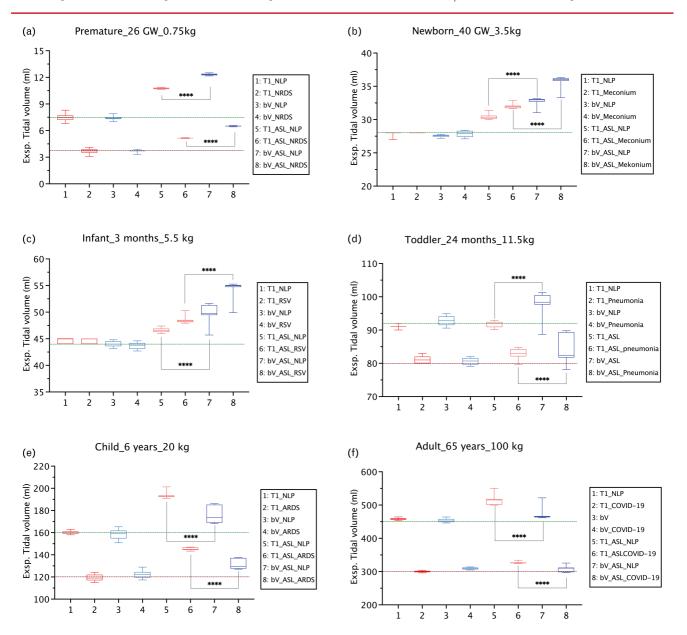
Fig. 1 Modified Bland-Altman plot showing agreement between applied expiratory tidal volumes (V_{Texp}) of the Hamilton T1 portable respirator (T1) or bellavista1000 intensive care respirator (BV) and measured V_{Texp} in the Active Servo Lung 5000 (ASL).



(a) Accuracy of applied $V_{\rm Texp}$ by T1 in lung models with no lung pathology (NLP) stimulated and measured with the ASL. (b) Accuracy of applied $V_{\rm Texp}$ by T1 in lung models with lung pathology (LP) stimulated and measured with the ASL. (c) Accuracy of applied $V_{\rm Texp}$ by BV in lung models with NLP stimulated and measured with the ASL. (d) Accuracy of applied $V_{\rm Texp}$ by BV in lung models with LP stimulated and measured with the ASL.



Fig. 2 Applied and measured expiratory tidal volumes with the Hamilton T1 portable respirator (T1) or the bellavista1000 intensive care respirator (BV) in lung models of different ages with or without lung disease and associated measured V_{Texp} in the Active Servo Lung 5000 (ASL).



Data are presented as boxplots with minimum to maximum whiskers. * indicates difference between applied V_{Texp} from T1 and BV measured in the ASL. **** P < 0.0001. (a) Premature lung model: in red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the bV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: defined V_{Texp} , which should be applied by the respirators in premature lung model with no lung pathology (NLP). Dashed red line: Defined V_{Texp} , which should be applied by the respirators in the premature lung model with neonatal respiratory distress syndrome (NRDS). (b) Newborn lung model: in red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the bV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: defined V_{Texp} , which should be applied by the respirators in newborn lung models with no lung pathology (NLP) and meconium aspiration (Meconium). (c) Infant lung model: In red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the bV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: the TT (1 and 2) and measured in the ASL (3 and 6). In blue applied V_{Texp} by the bV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: defined V_{Texp} , which should be applied by the respirators in infant lung models with no lung pathology (NLP) and respiratory syncytial virus broncholitis (RSV). (d) Toddler lung model: In red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the bV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: defined V_{Texp} , which should be applied by the respirators in toddler lung model with no lung pathology (NLP). Dashed red line: defined V_{Texp} , which should be applied by the respirators in the toddler lung model with pneumonia. (e) Child lung model: In red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the V(3 and 4) and measured in the ASL (7 and 8). Dashed green line: defined V_{Texp}, which should be applied by the respirators in child lung model with no lung pathology (NLP). Dashed red line: Defined V_{Texp} , which should be applied by the respirators in the child lung model with acute respiratory distress syndrome (ARDS). (f) Adult lung model: In red applied V_{Texp} by the T1 (1 and 2) and measured in the ASL (5 and 6). In blue applied V_{Texp} by the BV (3 and 4) and measured in the ASL (7 and 8). Dashed green line: Defined V_{Texp} , which should be applied by the respirators in adult lung model with no lung pathology (NLP). Dashed red line: Defined V_{Texp} , which should be applied by the respirators in the adult lung model with coronavirus disease 2019 (COVID-19) ARDS.

Figure 1a and b, Supplemental Digital Content, http://links.lww.com/EJAIC/A107).

In the 10 to 20 kg BW age group, the T1 theoretically offers three different breathing circuit configurations: (1) with a fully relaxed patient, the neonatal breathing tube (duo limb) with neonatal valve and infant flow sensor (neo), (2) the neonatal breathing tube with adult-paediatric expiratory valve/flow sensor (mixed) or (3) the co-axial breathing tube with the adult-paediatric expiratory valve /flow sensor (adult). These three configurations were tested in the toddler lung model (24 months, 11.5 kg). The T1 applied V_{Texp} most accurately in the neonatal breathing circuit configuration (neo), whereas the adult breathing circuit configuration (adult) exhibited the lowest accuracy of all three tested configurations: neo 1.1% (95% CI -1.9 to 4.1), mixed 11.3% (95% CI 0.8 to 21.7), adult 18.6% (95% CI 4.4) to 32.7) (Fig. 3a). Similarly, in the paediatric lung model the combination of neonatal breathing tube and adultpaediatric expiratory valve/ flow sensor provided a more accurately applied V_{Texp} of 5.6% (95% CI 2.3 to 9) compared to the adult co-axial breathing circuit configuration, 19.7% (95% CI 14.4 to 24.9) (Fig. 2e; Fig. 2a, Supplemental Digital Content, http://links.lww.com/EJAIC/A107). The difference between applied and measured V_{Texp} correlated positively with the measured leakage in the portable respirator's respiratory circuit system in both the infant (Pearson coefficient: 0.96, P < 0.0001; Fig. 3c) and paediatric lung models (Pearson coefficient: 0.74, P < 0.0001; Figure 2b, Supplemental Digital Content, http://links. lww.com/EJAIC/A107).

Airway pressures

Overall, the T1 applied lower proximal airway pressures than the BV, which translated to lower distal (measured) airway pressures (Fig. 4a). The BV configuration induced slightly higher auto-PEEP levels across pathological and healthy lung models (Fig. 4b). The generated driving pressure of the T1 was lower in "younger" models at $8.06 \, \mathrm{cmH_2O}$ (95% CI 8.04 to 8.55) than the BV at $8.56 \, \mathrm{cmH_2O}$ (95% CI 8.53 to 8.92; P < 0.0001) and higher in "older" lung models at $8.06 \, \mathrm{cmH_2O}$ (95% CI 8.05 to 8.08) compared to the BV at $7.21 \, \mathrm{cmH_2O}$ (95% CI 7.2 to 7.6; P < 0.0001) (Fig. 4c).

Mechanical lung properties

Patient lung compliance simulated by the ASL (Table 1) was overestimated by an average of 18.1% (95% CI 18.1 to 18.1) by the T1 and the mean underestimation of the BV was -4.3% (95% CI -4.9 to 3.9) (Figure 3, Supplemental Digital Content, http://links.lww.com/EJAIC/A107). As shown in the Bland-Altman plots (Fig. 5a and b), the measurement of lung compliance of the lung models with and without lung pathology showed reduced bias and better precision by the BV compared with T1.

In all lung models, except for the preterm lung model, the measured airway resistances were overestimated by the two respirators (Figure 4, Supplemental Digital Content, http://links.lww.com/EJAIC/A107). In the portable respirator T1 airway resistance was overestimated by an average of 48.6% (95% CI 47.1 to 48.6) and in the intensive care respirator BV by 58.6% (95% CI 58.3 to 59.6). Both respirators underestimated airway resistances in the preterm lung models (Figure 4, Supplemental Digital Content, http://links.lww.com/EJAIC/A107). In contrast to the measurement of compliance, airway resistance was measured more precisely with the T1 compared with the BV (Fig. 5c and d).

Discussion

This in-vitro study compared the performance of a modern portable respirator to a modern intensive care respirator across twelve distinctly different lung models, spanning from neonatal to adult lungs in physiological and pathological conditions. The main findings were that the T1 portable respirator was non-inferior to the BV intensive care respirator in terms of accuracy of applied tidal volumes and proximal or distal airway pressures across all age groups and simulated lung functions.

Accuracy of tidal volume delivery

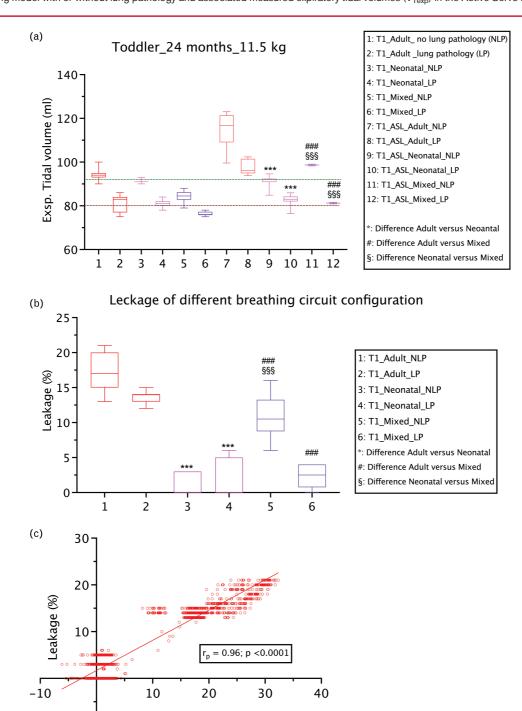
Hyperventilation and hypoventilation are well described adverse events often occurring during the transport of children or adults with artificially ventilated lungs.^{23,24} Especially in preterm neonates or children and adults with traumatic brain injury, hypocapnia may induce critical impairment of brain perfusion due to cerebral vasoconstriction, thereby worsening outcome.^{25–27} Thus, particularly in these vulnerable groups, accurately applied tidal volumes are of paramount importance.

However, none of the two tested respirators fulfilled the criteria of the American Society for Testing and Materials (ASTM), which requires a tidal volume precision of $\pm 10\%$ in simulated preterm or newborn lung models. Eurthermore, neither respirator performed within the company's predefined operating precision ranges (T1: $V_{\rm Texp}$ of ± 2 ml/ $\pm 10\%$). Nevertheless, the portable respirator performed significantly more accurately than the intensive care respirator in these "young" lung models (T1: $V_{\rm Texp}$ +2.5 ml, BV: $V_{\rm Texp}$ +3.5 ml).

Interestingly, in "older-age" lung models, for child and adult, the accuracies of the respirators were inverted and the T1 performed especially poorly in the child model, effectively applying up to 20.5% more tidal volume than set. (BV: 4.5%). The high inaccuracy of the T1's applied $V_{\rm Texp}$ positively correlated with the measured leakage by the respirator, a leakage that could not primarily be explained by "real" tidal volume leakage as the endotracheal tubes were glued into the adapters connecting the breathing circuit hose with the ASL. Furthermore, the inconsistency in leakage measurements and resulting imprecision in applied $V_{\rm Texp}$ for the child model was much more pronounced for the adult breathing hose



Fig. 3 Applied and measured expiratory tidal volumes with the Hamilton T1 portable respirator (T1) with different breathing circuit set configuration in the toddler lung model with or without lung pathology and associated measured expiratory tidal volumes (V_{Texp}) in the Active Servo Lung 5000 (ASL).

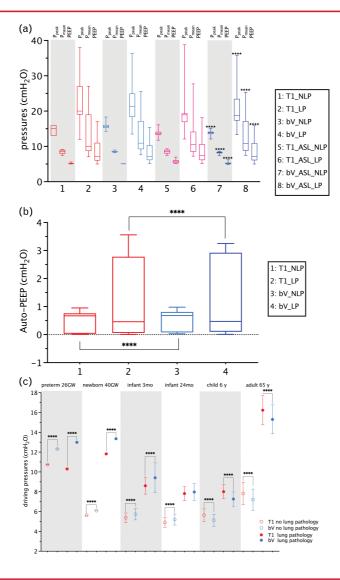


Data are presented as boxplots with minimum to maximum whiskers. (a) Applied and measured with the T1 with different breathing circuit set configuration (Nos. 1 to 6) in the toddler lung model with or without lung pathology and associated measured V_{Texp} in the ASL (Nos. 7 to 12). The three breathing circuit set configuration were (1) adult (adult valve/flow sensor and coaxial tube; red), (2) mixed (adult valve/flow sensor and neonatal tube; pink) and (3) neonatal (neonatal valve/flow sensor and neonatal tube; purple). *Difference adult versus neonatal; #difference adult versus mixed; Sdifference neonatal versus mixed. ***/###/\$§\$ P < 0.001. (b) Measured leakage in the T1 in dependence of the breathing circuit set configuration. *Difference adult versus neonatal; # difference adult versus mixed, ***/###/\$§\$ P < 0.0001. (c) Correlation of measured leakage and the difference of applied V_{Texp} by the portable respirator T1 and the measured V_{Texp} in the ASL. I_{TP} : Pearson correlation coefficient.

Differences of $V_{Tex}(ml)$

-10

Fig. 4 (a) Airway pressures overall in the twelve lung models measured either in the two respirators (proximal the endotracheal tubes) and in the Active Servo Lung 5000 (ASL) (distal the endotracheal tube). Red: measured proximal airway pressures by the portable respirator (T1) in lung models without (NLP; No. 1) or with lung pathology (LP; No. 2). Blue: measured proximal airway pressures by the intensive care respirator (BV) in lung models without (NLP; No. 3) or with lung pathology (LP; No. 4). Distal measured airway pressures in the ASL (Nos. 5 to 8). P_{peak} : peak pressure; P_{mean} : mean pressure; PEEP: positive end expiratory pressure. Data are presented as boxplots with minimum to maximum whiskers.*indicates difference between the applied airway pressures T1 and BV measured in the ASL. **** P < 0.0001. (b) Generated auto-PEEP overall in the 12 lung models measured either in the portable respirator (T1) or in the intensive care respirator (BV). Data are presented as boxplots with minimum to maximum whiskers.*indicates difference between generated auto-PEEP by T1 and BV. **** P < 0.0001. (c) Generated driving pressures to obtain the intended expiratory tidal volume by the two respirators in the twelve different lung models. Data are presented as mean with standard deviation.*indicates difference between the generated driving pressure by T1 and BV. ***** P < 0.0001.



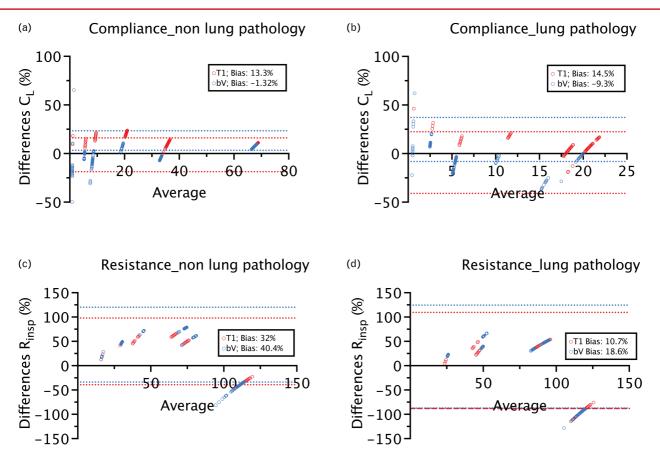
than for the combination of neonatal breathing hose with adult flow sensor/expiratory valve. Employing the neonatal breathing circuit, albeit not recommended in patients above 20 kg IBW, 17 in combination with the adult flow sensor/expiratory valve for the child model, improved the $V_{\rm Texp}$ accuracy to 6%, thus complying with the ASTM recommendations. The same observation was also made when comparing the three different breathing hose configurations in the 24-month infant model.

Airway pressure

Application of 6 ml kg IBW $^{-1}$ is recommended in ARDS to reduce respirator-induced lung injury, 29 and recent evidence in ARDS is increasingly indicating the importance of limiting driving pressure to reduce the damage. 29,30 It is therefore of interest that, due to the systematically higher $V_{\rm Texp}$ applied by the intensive care respirator, especially in "younger" lung models, both the applied peak inspiratory pressure and driving pressure were higher than in the portable respirator.



Fig. 5 Modified Bland – Altman plots show the agreement between measured compliance and airway resistance by the portable respirator (T1) or the intensive care respirator (BV) and the given compliance and airway resistance of the lung models by the ASL.



Red dash-line indicate the 95% limits of agreement for T1; Blue dash lines indicate the 95% limits of agreement for the BV.

For "older age" lung models, this relationship inverted in accordance with the less accurate $V_{\rm Texp}$ applied by the portable respirator in that age range.

Unrecognised auto-PEEP can be dangerous for invasively ventilated patients especially by inducing haemodynamic instability or by contributing to patient-respirator dyssynchrony. The overall auto-PEEP generated by the BV was slightly higher than that of the T1. However, the observed difference was probably clinically insignificant due to its small magnitude. In summary, both respirators performed well and only induced residual auto-PEEP, notably so in impaired lung function models that are at higher risk of auto-PEEP induced adverse events.

Measurement of lung compliance and airway resistance

Reliable measurement of airway resistance and lung compliance is particularly important in patients with severely impaired lung function. While airway resistance was more accurately measured by the T1, compliance was more accurately measured by the BV. However, overall,

both respirators failed to measure resistance and compliance with sufficient accuracy, and not surprisingly, in impaired lung models' accuracy was worst. These results have been previously described for several neonatal respirators provided by different companies.³³ However, both respirators were capable of measuring mechanical lung properties across their whole range of values in all patient groups. The only exception was the highly elevated airway resistances in the preterm lung models, which could not be assessed by either respirator. This limitation at such high airway resistances has already been shown for other neonatal intensive care respirators.33 Nonetheless, and given the increasing importance of individualised mechanical ventilation, which, fundamentally, equates to interpretation of mechanical lung properties, it is surprising that to date no industry or company specific standards exist for respirator accuracy in the assessment of lung mechanics.

When interpreting the results presented above, certain limitations of this study must be borne in mind.

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Firstly, given the significant functional and anatomical heterogeneity of the human respiratory system in vivo, some caution must be applied in extrapolating the present in vitro results to the performance of the two respirators under real-life conditions. Furthermore, the influence of temperature and humidity, as well as gas concentration (O₂ and CO₂) variability was not reflected in the measurements performed by the ASL. Moreover, the precise tidal volume setting and, consequently, the accuracy of applied tidal volumes are contingent upon numerous additional factors. This includes the display of pressure/volume loops and automated selected respiratory cycle by the respirator to improve real-time fine tuning of ventilator settings.³⁴ In addition, employing a leak detector with automated leak compensation, 35 the setting of positive end-expiratory pressure (PEEP) with implications for haemodynamic status, the cardiopulmonary interaction and even the presetting of a transport ventilator have an impact on the tidal volume setting and therefore the size of tidal volume.36-38 On the other hand, the systematic in-vitro approach of the current study allowed for identical lung model conditions for the testing of both respirators, enabling an objective comparison which would be impossible in the clinical setting. In patients with artificially ventilated lungs, small tidal volume leaks may occur even when cuffed endotracheal tubes are used, which could then affect factors such as the accuracy of tidal volume application. Second, both the physiological as well as the pathological settings employed to set up the ASL were extracted from the literature. 13,21,39 This simplification may, especially in the case of pathological lung models, not reflect the real clinical situation. However, to date, this approach has been widely accepted to systematically study respirator performance in different lung models of different ages and lung pathologies. 14-16 Third, only pressure-controlled ventilation was employed, and results with other ventilation modes may differ. This is especially relevant for volume-controlled ventilation, which is still a widely employed mode. However, until now, no ventilation mode has been conclusively proven to be superior to others, neither in children nor in adults. 40 Therefore, and reflecting the standard of care in our paediatric centre, we chose the pressure controlled ventilation mode to simulate our routine clinical approach.

In conclusion, this study presented the performance of a modern portable respirator across a wide patient age spectrum, and its capacity to deliver tidal volumes with comparable accuracy to a modern established intensive care respirator. Keeping in mind the limitations of the portable respirator, especially in conjunction with the adult breathing circuit in children above 6 years of age, the portable respirator proved a precise working tool for both transportation and long-term intensive care ventilation in children and adults.

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