

Evaluation of manual and automatic manually-triggered ventilation performance and ergonomics using a simulation model

Nicolas MARJANOVIC, MD₁, Soizig LE FLOCH, MD₁, Morgan JAFFRELOT, MD_{1,2}, Erwan L'HER, MD, PhD_{1,2}.

1. Emergency Department, Pôle ARSIBOU, Centre Hospitalier Universitaire de la Cavale Blanche, 29609 Brest, France.

2. Centre de Simulation en Santé, LaTim INSERM UMR 1101, Université de Bretagne Occidentale, Université Européenne de Bretagne, 29609 Brest, France

Corresponding author :

Pr Erwan L'HER, MD, PhD

Service d'Accueil des Urgences

Centre Hospitalier Universitaire de la Cavale Blanche

Bd Tanguy-Prigent

29609 Brest Cedex, France

Tel: +33 298 347 455 E-mail address: erwan.lher@chu-brest.fr

Running Head: automatic vs. manual ventilation performance

Conflict of interest statement

EasyCPR was provided free of charge by Weinmann; no other conflict of interest

ABSTRACT

BACKGROUND AND OBJECTIVES: In the absence of endotracheal intubation, the manual bag-valve is the most frequently used ventilation technique during resuscitation. The efficiency of other devices has been poorly studied. The bench-test study described here was designed to evaluate the effectiveness of an automatic, manually-triggered system, and to compare it with manual bag valve ventilation.

METHODS: A respiratory system bench model was assembled using a lung simulator connected to a manikin, in order to simulate a patient with unprotected airways. Fifty health-care providers from different professional groups (emergency physicians, residents, advanced paramedics, nurses and paramedics; n=10 per group) evaluated manual bag-valve ventilation, and compared it with an automatic manually-triggered device (EasyCPR). Three pathological situations were simulated (restrictive, obstructive, normal). Standard ventilation parameters were recorded; the ergonomics of the system were assessed by the professionals using a standard numerical scale, once the recordings were completed.

RESULTS: The tidal volume fell within the standard range (400-600ml) for 25.6% [0.6-45] of breaths using manual bag-valve ventilation, and for 28.6% [0.3-80] of breaths using the EasyCPR ($p<0.0002$). Peak inspiratory airway pressure was lower using the EasyCPR (10.6 ± 5 cm H₂O vs 15.9 ± 10 cm H₂O; $p<0.001$). The ventilation rate fell consistently within the guidelines, in the case of the EasyCPR only (10.3 ± 2 versus 17.6 ± 6 ; $p<0.001$). Significant pulmonary overdistension was observed when using the manual bag-valve device during the normal and obstructive sequences. The nurses and paramedics considered the ergonomics of the EasyCPR to be better than those of the manual device.

CONCLUSION: The use of an automatic, manually-triggered device may improve ventilation efficiency and decrease the risk of pulmonary overdistension, while decreasing the ventilation rate.

KEY-WORDS: manual ventilation, bag-valve, automated system, performance evaluation, ergonomics, simulation

INTRODUCTION

Ventilation guidelines during resuscitation were specified in the most recent consensus from the European Resuscitation Council (ERC) [1] and the American Heart Association (AHA) [2].

The bag-valve mask (BVM) is an essential device for the provision of ventilation in the absence of endotracheal intubation. However, this ventilation technique may be difficult to manage in emergency situations, even for trained teams. The BVM may lead to a large variation in the insufflated volumes (V_t) [3,4], and may require two-handed resuscitation to achieve efficiency [1,2,4,5]. Whereas insufficient V_t does not allow correct hematosis to be maintained, excessive V_t may be responsible for pulmonary overdistension and gastric inflation [6].

The objectives of this bench-test study were to assess the effectiveness of an automatic, but manually-triggered ventilation system, and to evaluate the ability of professionals to provide guideline-based standard ventilatory parameters.

MATERIAL AND METHODS

Formal ethical approval was not deemed necessary by the local ethics committee.

Material

Fifty professionals from five different groups of healthcare providers professionals (*Paramedics [PM], Emergency Department's Nurses [EDN], Emergency M.D [EMD], Emergency Medicine Residents [EMR] and Advanced Paramedics [AP]*), $n = 10$ per group) were included in the study. Each professional evaluated both ventilation systems: a BVM (Ambu® Silicone Resuscitator adult, 1.5 L) and an automatic, manually-triggered device (EasyCPR) (Medumat® EasyCPR®, Weinmann Geräte für Medizin, Germany), in a randomized order. AP category included specialized nurses dedicated to prehospital care, with endotracheal intubation and ventilation training.

The EasyCPR® is a voice-guided device designed to assist first aid responders and healthcare providers with emergency ventilation and CPR procedures. The CPR mode features a metronome function which provides Cardiopulmonary Resuscitation at the correct frequency (not tested in this study) and ventilation assistance that can be manually triggered at the mask (Fig.1).

Ventilation can be set with a rotary dial, and is time-controlled and volume-constant (fixed respiratory rate for a set volume). When the triggering is activated, V_t is automatically delivered at the set respiratory rate. Prior to the study, the professionals were given a short demonstration of the technique used to trigger ventilation. The most significant difference between the EasyCPR and a standard BVM is that with former, professionals can keep both hands on the face mask. A respiratory system analogue was assembled built up using a lung simulator (ASL5000, Ingmar Med) connected to a standard resuscitation manikin (Resusci Anne, Laerdal Medical), thus simulating in order to simulate a patient with unprotected airways. The lung simulator allows mimicking clinically pertinent relevant respiratory mechanics to be mimicked, and the manikin allows professional skills to be interfered with, when fitting the mask to the patient's face and performing ventilation. Although chest rise assessment is not possible with the model, providers can check ventilation curves on the screen.

The same facial mask was used for both situations and devices. Flow and pressure variations were monitored using ASL5000 sensors. Overall pulmonary distension was assessed by monitoring the position of the ASL 5000 piston at the end of expiration. Calibration of the respiratory system analogue was performed according to standard procedures.

Methods

Different respiratory mechanics patterns

Three different mechanical respiratory patterns were simulated in an apneic patient. Both apparatuses (BVM and automatic manual-triggered ventilation system) were tested by each individual during three one-minute sequences, using different values of resistance and compliance: i- high compliance and resistance, designed to simulate a severely COPD patient ("*Obstructive*"; $R = 20 \text{ cm H}_2\text{O/l/s}$ - $C = 120 \text{ ml/cm H}_2\text{O}$); ii- normal compliance and resistance

(“Normal”; $R = 5 \text{ cm H}_2\text{O/l/s}$ - $C = 70 \text{ ml/cm H}_2\text{O}$); iii- normal resistance and low compliance (“Restrictive”; $R = 5 \text{ cm H}_2\text{O/l/s}$ - $C = 30 \text{ ml/cm H}_2\text{O}$). These sequences were arranged in randomized order. Each sequence was separated from the next by a one-minute rest period.

Assessment of ergonomics and respiratory measurements

The ergonomics of the two devices were completed by each subjects and recorded at the end of each complete experimental sequence, using a standardized numerical scale (from 1-very difficult to 5-very easy to use). Qualitative assessment of the devices was allowed, using short sentences or a small number of words. All quantitative respiratory measurements (tidal volume [Vt], end inspiratory lung volume [EILV], peak inspiratory pressure [PIP] and ventilation rate [VR]) were performed at atmospheric pressure, constant room temperature (22°C), and constant lung temperature (cylinder temperature 37°C). Measurements were performed on a mean 5 to 10 cycle’s period after signal stabilization, using the test lung pressure and flow transducers (ASL 5000, Ingmar, Pittsburgh, Pennsylvania), which we calibrated daily, according to standard procedures. Signal curves were analyzed using the graphics (LabView, National Instruments, Austin, Texas) and the data-acquisition softwares of the test lung (version SW 3.1) [7]. Flow and pressure transducers are presumed to have a precision below 10 mL for volume, and 1 cm H₂O for pressure.

Statistical analysis

The SPSS statistical package (SPSS© for Windows, IMB Corporation) was used to perform all analyses. The data is presented in the form of mean±SD, unless specified otherwise. A p-value equal ≤ 0.05 was considered to indicate a significant result. The non-parametric Mann-Whitney and Wilcoxon tests were performed to compare quantitative values between each group and device. The Chi-squared test was used to compare Vt distributions within groups.

RESULTS

Ventilation parameters

The mean inspiratory V_t was measured below 500 ml with both devices and for all pathological conditions, and within the range from 400-600 mL for a small number of recordings (**Fig. 2**). The V_t distribution was significantly different for both devices, and was highly heterogeneous when either different professional groups or different pathological sequences were compared (**Table 1**). The RV was higher for all sequences making use of the BVM (156 ± 222 ml vs. 54 ± 8 ml; $p < 0.001$). **Fig. 3** compares the individual EILV distributions for the BVM and EasyCPR, during the “Obstructive” pattern sequences.

Fig. 4 illustrates the differences between the data for the two devices within the different professional groups, during the “Normal” pattern sequences. A similar difference distribution was observed for the two devices in the case of the “Obstructive” sequence. The VR was consistent with guidelines while using the EasyCPR, between 9 and 11 breaths/min for 93% of the recordings (**Fig. 4**), but not with BVM (10.3 ± 2 versus 17.6 ± 6 respectively; $p < 0.001$).

Peak inspiratory airway pressure was lower using the EasyCPR (10.6 ± 5 cm H₂O vs 15.9 ± 10 cm H₂O; $p < 0.001$).

Device ergonomics

The ergonomics of the EasyCPR were considered to be superior by two professional groups (EDN and PM), when compared to those of the BVM ($p = 0.04$ and $p = 0.006$, respectively). The various expressions used to characterize these devices were “tiredness” (7/50; 14%) and “better control” (3/50; 6%) for the BVM, and “better fitting of the mask thanks to the use of both hands”, “fewer leaks” (6/50; 12%) and “fewer feelings” (6/50; 12%) for the EasyCPR.

DISCUSSION

This experimental bench-test study describes improved compliance with guidelines [1] when an automatic, manually-triggered ventilation device is used (lower ventilation rate and PIP, more regular Vt values, less overdistension), when compared to a BVM.

Depending on the experimental setting and type of device, contradictory results have been described in the literature. In some cases, a BVM may induce higher peak airway pressure and gastric insufflation, when compared to pressure-cycled, manually-triggered devices [8-12]. In a recent experimental study, EasyCPR has not proved to be superior to BVM, either in terms of tidal volumes, inspiratory time and intrapulmonary pressures in a group of 74 medical students [13].

These differences may arise either from the settings used in the case of pressure-cycled devices, and/or from the use of simulated resistance and compliance settings. In the study by Bergrath *et al.* [13], respiratory mechanics of the model were not monitored and it seems obvious that conditions mimicking COPD condition were not used, which may have induced more significant differences between the devices. The results found with such trials, combined with the fact that manually-triggered devices are much more expensive than BVM devices and require an oxygen sources have not allowed the ERC and AHA to provide consistent guidelines concerning the use of manually-triggered devices [14].

To the best of our knowledge, the experimental study described here is the first to evaluate multiple ventilation parameter recordings, in the context of clinically relevant pathological situations, and within various professional groups.

Impact of single versus two-handed resuscitation

In this study, the mean Vt always remained below 500 mL, whatever the device or type of sequence. Several studies have shown that resuscitation using both hands may be more efficient than that using one hand, in terms of Vt delivery (higher mean value and lower variation) [3-5,15]. Our results show that the EasyCPR is more efficient in terms of Vt delivery, since with this device all professionals used both hands to keep the mask in place and control leaks. However, the mean Vt always remained below 500mL, and fell outside the (400-600 mL) range limits for 66% less than 72% of the recordings, whatever the device used. With the EasyCPR, the Vt can be easily modified, by adjusting certain settings (which are however related to the VR), whereas BVM ventilation requires the presence of a second rescuer and regular training.

Although there is no statistical difference between the two types of device in terms of mean Vt, a very broad Vt distribution was observed for the BVM.

Ventilation rate

Several clinical studies have demonstrated that hyperventilation and/or ventilation at a rate higher than the standard recommendation was frequent in patients with cardiac arrest, both outside and within the hospital [16,17]. Our data are consistent with such findings, whatever the professional group. Conversely, the ventilation rates obtained with the EasyCPR were more

consistent, as a result of its controlled ventilation rate. This outcome may be of importance, since hyperinflation is a known problem in CPR because it increases intrathoracic pressure, which reduces the haemodynamic effectiveness of chest compressions [18]. In experimental animal studies, Aufderheide *et al.* demonstrated that hyperventilation decreased coronary perfusion pressures and arterial blood pressure, thus resulting in lower survival rates [19,20].

Total Volume, Residual Volume and Inspiratory Peak Pressure

To the best of our knowledge, this is the first study to have concomitantly examined Vt delivery and overall pulmonary distension during resuscitation. Extremely variable delivery volumes were observed with the manual device, whereas more regular volumes were delivered while using the automatic device. This difference can be at least partially explained by the differences between the two devices, in terms of ventilation rate and therefore expiratory time variation. As a consequence, residual volume and overall distension may also increase, thus making ventilation more difficult due to higher intrapulmonary pressures and increased leakage.

Gastric inflation and opening of the lower esophagus sphincter is clearly related to peak inspiratory pressure [6,21]. Very few experimental studies have evaluated gastric inflation during CPR. Osterwalder JJ *et al.* demonstrated differences in terms of gastric inflation proportion between BVM and automatic ventilators (42% vs. 0%) in a manikin study [9], and explained this difference by a higher PIP while using a BVM. In another study, a decrease in lower esophagus sphincter opening pressure, within the first minutes of cardiac arrest, was suggested [22].

Although such gastric inflation was not recorded during our study, higher gastric inflation could have occurred during use of a BVM or EasyCPR device, due to a significantly increased PIP.

Differences between the three different pathological situations

Few experiments have detailed the differences that could be induced during manual ventilation, according to patients' respiratory mechanics. The results presented herein provide new insights about the major differences that are to be expected between the patients, even if all of these differential effects are consistent with standard knowledge on respiratory mechanics.

Beside the strict application of guidelines, our results are consistent with the fact that in real patients with pulmonary diseases, ventilation rate should be adjusted. In a COPD condition, a ventilation rate equal or below the guidelines (10 breaths/min) should be a major goal, while an increase of the rate immediately induces hyperinflation and elevated peak pressure; in a restrictive patient, an increased ventilation rate may not have such deleterious effects and may in fact increase minute ventilation, while tidal volumes are usually smaller.

Study limitations

Several limitations of this study should be emphasized. Firstly, although care was taken to ensure correct respiratory mechanics, the experimental settings may have been different to those encountered in real-life situations. In physiological terms, the patient-to-mask interface and airways are not strictly identical to those observed in real patients. Even though we carefully chose the components used in our respiratory analog, these may not have exactly duplicated in-vivo ventilation and the variability encountered with real patients. Secondly, not all of the parameters of interest could be integrated into our evaluation, due to the specific design of the respiratory analog. The absence of chest rise, due to direct connection of the manikin airways to the lung simulator, may have modified the professional ventilation patterns, whereas most training courses use chest rise as the sole indicator of ventilation adequacy. Nevertheless, this specificity of the model was emphasized at the beginning of the experiment, and the professionals were able to check the ventilation curves. Third, we may also consider that the small number of providers in each group makes comparison difficult. For this reason, most of our analysis was focused on the overall results (50 subjects), rather than on individual differences.

Conclusion

The use of an automatic, manually-triggered ventilation device for resuscitation may present valuable advantages over standard manual bag-valve ventilation. Such devices may improve ventilation efficiency and decrease the risk of pulmonary overdistension, while at the same time decreasing ventilation rate. Clinicians should however be aware that the performance of such devices depends strongly on each patient's pathology, and on the user's individual experience. It is essential that *in-vivo* studies be implemented, in order to evaluate the potential impact of automatic, manually triggered devices in the clinical setting.

Acknowledgements

NM designed the study, performed the recordings and wrote the article; SLF and MJ participated to the study design, managed the data and reviewed the article; ELH conceived and designed the study, wrote the article and endorses responsibility for the paper as a whole.

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Group (n=10 per group)	Sequence	Vt (% within range – 400-600mL)		p*
		BVM	EasyCPR	
EMD	Restrictive	256/676 (37.9%)	22/349 (6.3%)	<0.001
	Normal	163/608 (26.8%)	71/316 (22.5%)	0.15
	Obstructive	280/620 (45.2%)	129/305 (42.3%)	0.41
	All sequences	699/1904 (36.7%)	222/970 (22.9%)	<0.0001
EMR	Restrictive	3/509 (0.6%)	47/330 (14.2%)	<0.001
	Normal	10/516 (1.9%)	1/316 (0.3%)	0.06**
	Obstructive	124/576 (21.5%)	104/306 (34%)	<0.001
	All sequences	137/1601 (8.6%)	152/952 (16%)	<0.0001
AP	Restrictive	156/527 (29.6%)	44/336 (13.1%)	<0.001
	Normal	166/531 (31.3%)	108/291 (37.1%)	0.09
	Obstructive	214/510 (42%)	194/316 (61.4%)	<0.001
	All sequences	536/1568 (34.2%)	346/943 (36.7%)	0.21
EDN	Restrictive	40/492 (8.1%)	22/266 (8.3%)	0.95
	Normal	88/439 (20%)	84/260 (32.3%)	<0.001
	Obstructive	128/472 (27.1%)	204/254 (80.3%)	<0.001
	All sequences	256/1403 (18.2%)	310/780 (39.7%)	<0.0001
PM	Restrictive	167/496 (33.7%)	9/341 (2.6%)	<0.001
	Normal	142/471 (30.1%)	71/337 (21.1%)	0.004
	Obstructive	89/480 (18.5%)	221/325 (68%)	<0.001
	All sequences	398/1447 (27.5%)	301/1003 (30%)	0.19
Overall cycles	All sequences	2026/7923 (25.6%)	1331/4648 (28.6%)	<0.0002

Table 1: Tidal volume cycles repartition within the 400-600mL range for each device, group, and simulation sequence

EMD: senior emergency physicians; EMR: emergency residents – juniors; AP: advanced paramedics; EDM: emergency department nurses; PM: paramedics; n=10 for each group; Sequence: three sequences of different respiratory mechanics were tested for a one-minute duration each; Restrictive: resistance (R)=5 cmH₂O/L/s and compliance (C)=30 mL/cmH₂O; Normal: R=5 cmH₂O/L/s and C=70 mL/cmH₂O; Obstructive: R=20 cmH₂O/L/s and C=120 mL/cmH₂O.

Results are expressed as the number of cycles within the 400-600 mL range, over all registered ventilatory cycles (%); *chi² non parametric test; **Fisher’s test; A p value equal or below 0.05 was considered significant.

EasyCPR provided more cycles within range, as compared with BVM (28.6 vs. 25.6%; p<0.0002). This benefit was markedly increased for EMR and EDN, but was not significant for PM and AP. EasyCPR efficiency was even lower than BVM for EMD and during most restrictive sequences.

Legends of figures

Figure 1 – EasyCPR in use on the simulation model

The mask can be tightened to the model's face with both hands, thus decreasing leaks and improving mandibular subluxation; ventilation is triggered pressing the knob on the mask with the thumb.

Figure 2 – Tidal volume repartition within all simulation sequences

The figure depicts tidal volumes repartition, for all groups and recordings. The bold vertical lines represent range values (400-600 mL). A p value equal or below 0.05 was considered significant.

Tidal volume was more frequently measured within range while using EasyCPR, as compared to BVM (29% vs 26% of the measurements; $p < 0.001$).

Figure 3 – Individual end-inspiratory lung volume distributions for the bag-valve mask and EasyCPR, during the “Obstructive” pattern sequences

The figure depicts individual end-inspiratory lung volume distribution during the obstructive sequences, for BVM and EasyCPR. Bold lines corresponded to EIV mean values for each device.

No significant difference was observed for the mean tidal volume value, but the overall distribution and extreme values favors the use of the EasyCPR.

Figure 4 – Box and Whisker plot for respiratory measurements during the “Normal” pattern sequences

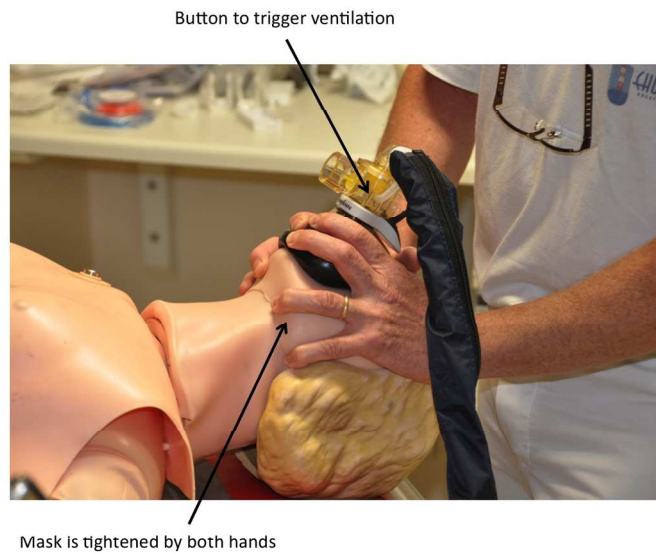
The figure depicts tidal volume, end inspiratory lung volume, ventilation rate and peak inspiratory pressure EIV, VR and PIP distribution during the “Normal” pattern sequences recordings. The boundaries on the box indicate the 25th and 75th percentile, and the line within the box indicates the median.

Whiskers above and below the box indicate the 90th and 10th percentiles. Circles represented outlying values. Stars represented exceptional values. Bolds lines corresponded to, range values for Vt, lower esophageal sphincter opening pressure, for PIP and recommended values for RV.

EMD: senior emergency physicians; EMR: emergency residents – juniors; AP: advanced paramedics; EDM: emergency department nurses; PM: paramedics; n=10 for each group; a p value equal or below 0.05 was considered significant.

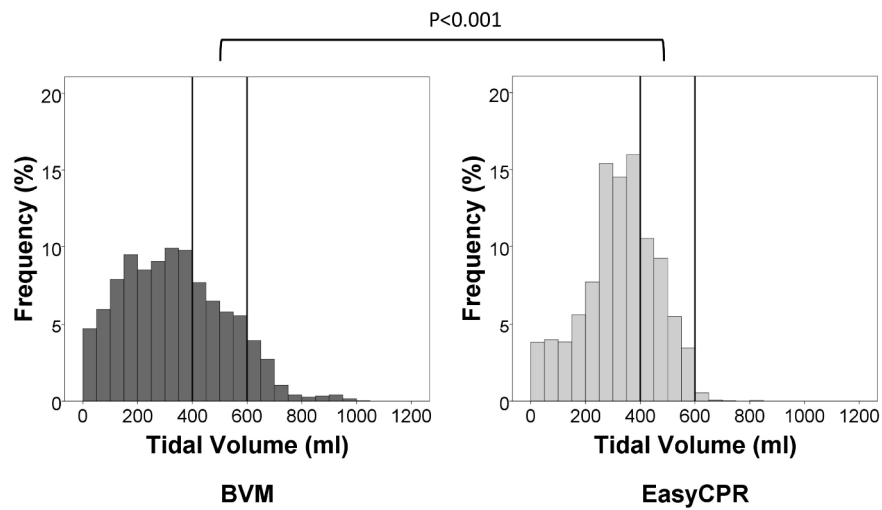
A significant difference was observed between the devices in terms of ventilation rate and peak inspiratory pressure, the two being lower and more consistent with guidelines while using the EasyCPR.

Figure 1



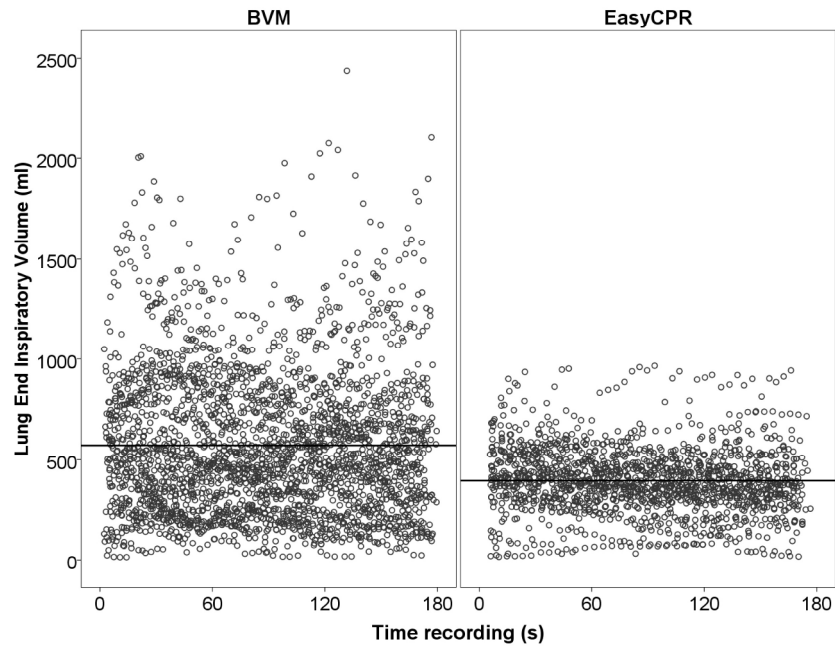
635x476mm (72 x 72 DPI)

Figure 2

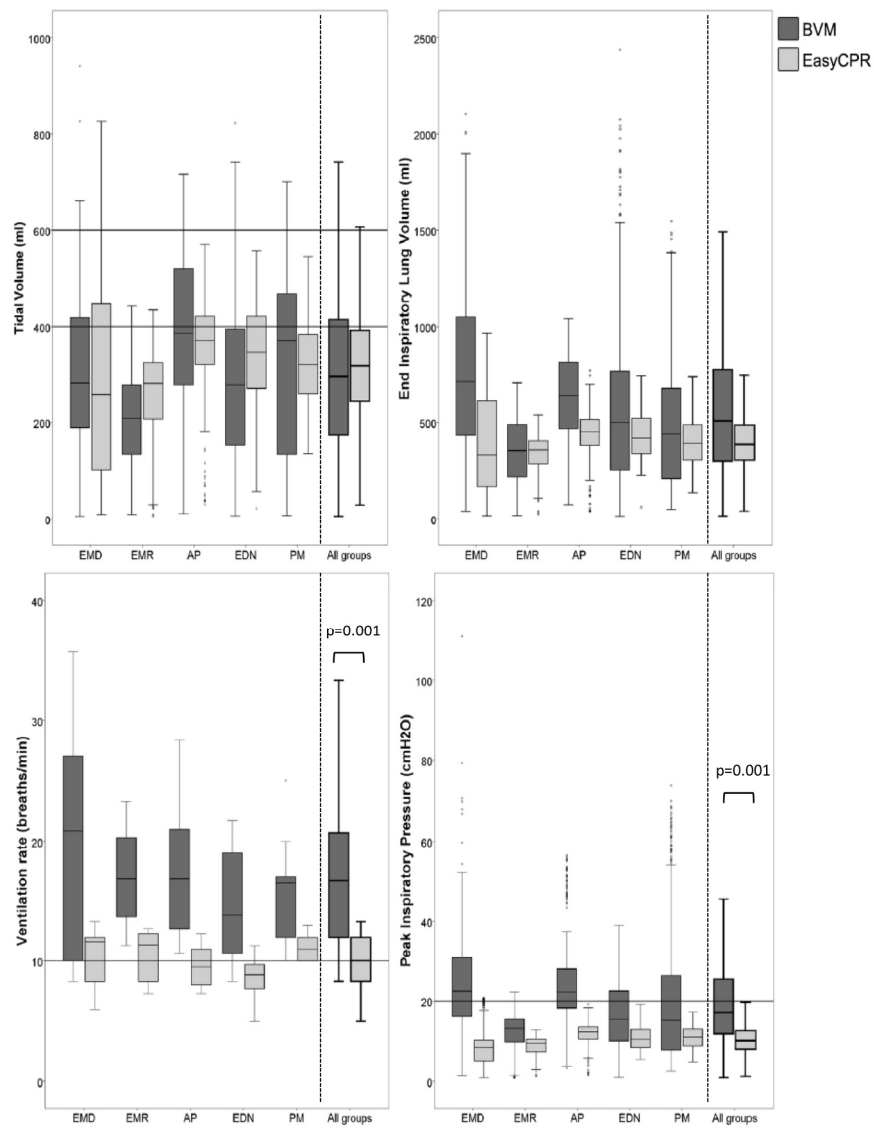


1057x793mm (72 x 72 DPI)

Figure 3



1057x793mm (72 x 72 DPI)



793x1057mm (72 x 72 DPI)