Evaluation of Manual and Automatic Manually Triggered Ventilation Performance and Ergonomics Using a Simulation Model

Nicolas Marjanovic MD, Soizig Le Floch MD, Morgan Jaffrelot MD, and Erwan L'Her MD PhD

BACKGROUND: In the absence of endotracheal intubation, the manual bag-valve-mask (BVM) 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 BVM ventilation. METHODS: A respiratory system bench model was assembled using a lung simulator connected to a manikin 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 BVM 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 health-care professionals using a standard numerical scale once the recordings were completed. RESULTS: The tidal volume fell within the standard range (400–600 mL) for 25.6% of breaths (0.6–45 breaths) using manual BVM ventilation, and for 28.6% of breaths (0.3–80 breaths) using the automatic manually triggered device (EasyCPR) ($P < .0002$). Peak inspiratory airway pressure was lower using the automatic manually triggered device (EasyCPR) (10.6 ± 5 vs 15.9 ± 10 cm H_2O, $P < .001$). The ventilation rate fell consistently within the guidelines, in the case of the automatic manually triggered device (EasyCPR) only (10.3 ± 2 vs 17.6 ± 6, $P < .001$). Significant pulmonary overdistention was observed when using the manual BVM device during the normal and obstructive sequences. The nurses and paramedics considered the ergonomics of the automatic manually triggered device (EasyCPR) to be better than those of the manual device. CONCLUSIONS: The use of an automatic manually triggered device may improve ventilation efficiency and decrease the risk of pulmonary overdistention, while decreasing the ventilation rate. *Key words: manual ventilation; bag-valve-mask; automated system; performance evaluation; ergonomy; simulation.* [Respir Care 2014;59(5):735–742. © 2014 Daedalus Enterprises]

Introduction

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

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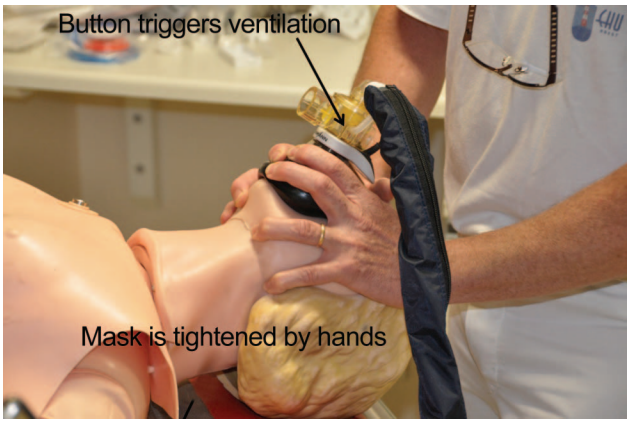

Fig. 1. The automatic manually triggered device (EasyCPR) in use on the simulation model. The mask can be tightened to the face of the model with both hands, thus decreasing leaks and improving mandibular subluxation; ventilation is triggered pressing the knob on the mask with the thumb.

QUICK LOOK

Current knowledge

Manual ventilation with a self-inflating bag and face mask is commonly the first method of ventilation following cardiac arrest. A litany of issues conspire to obfuscate successful manual ventilation including caregiver skill, hand size, fatigue, mask fit, and device design.

What this paper contributes to our knowledge

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

maintained, excessive V_T may be responsible for pulmonary overdistention 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 health-care professionals to provide guideline-based standard ventilatory parameters.

Methods

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

Materials

Fifty providers from five different groups of professional health-care professionals (paramedics, emergency department nurses, senior emergency physicians, emergency medicine residents, and advanced paramedics; $n = 10$ per group) were included in the study. Each professional health-care provider evaluated both ventilation systems, a BVM (AMBU Silicone Resuscitator adult, 1.5 L) and an automatic manually triggered device (Medumat EasyCPR, Weinmann Geräte für Medizin, Hamburg, Germany), in a randomized order. The advanced paramedics category included specialized nurses dedicated to prehospital care with training in endotracheal intubation and ventilation.

The automatic manually triggered device (EasyCPR) is a voice-guided device designed to assist first aid responders and health-care providers with emergency ventilation and cardiopulmonary resuscitation (CPR) procedures. The CPR mode features a metronome function, which provides CPR 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 health-care professionals were given a short demonstration of the technique used to trigger ventilation. The most significant difference between the automatic manually triggered device (EasyCPR) and a standard BVM is that with the former, health-care professionals can keep both hands on the face mask.

A respiratory system analog was assembled using a lung simulator (ASL5000, Ingmar Med) connected to a standard resuscitation manikin (Resusci Anne, Laerdal Medical), thus simulating a patient with unprotected airways. The lung simulator allows mimicking clinically pertinent respiratory mechanics, and the manikin allows the skills of health-care professionals to be evaluated 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 face mask was used for both situations and devices. Flow and pressure variations were monitored using the lung simulator (ASL5000) sensors. Overall pulmonary distention was assessed by monitoring the position of the lung simulator (ASL5000) piston at the end of expiration. Calibration of the respiratory system analog was performed according to standard procedures.

Procedures

Different Respiratory Mechanics Patterns. Three different mechanical respiratory patterns were simulated in an apneic patient. Both apparatuses (BVM and the automatic manually triggered ventilation system [EasyCPR]) were tested by each individual during three 1-min sequences

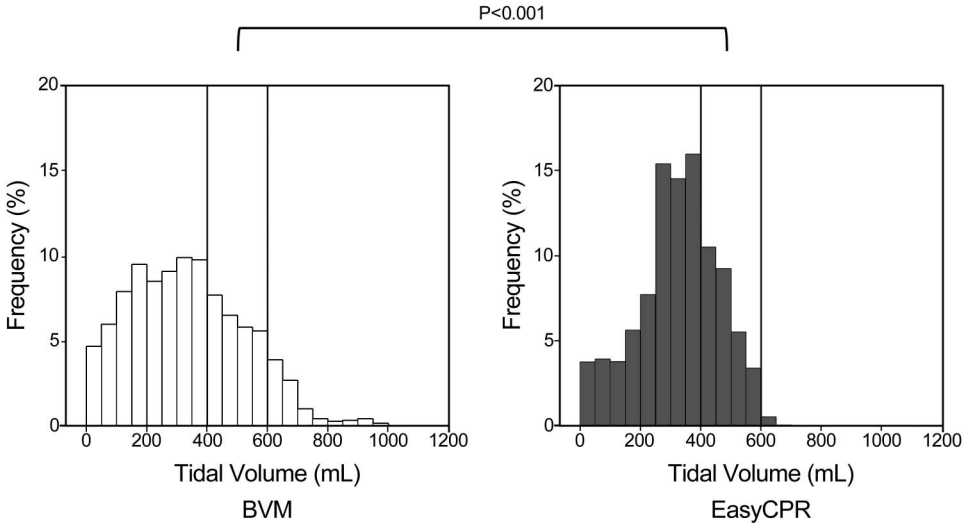

Fig. 2. Tidal volume repartition within all simulation sequences. The figure depicts tidal volume repartition for all groups and recordings. The bold vertical lines represent range values (400–600 mL). $P \leq .05$ was considered significant. V_T was more frequently measured within the range while using an automatic manually triggered device (EasyCPR) compared with BVM (29% vs 26% of the measurements, $P < .001$).

using the following different values of resistance and compliance: (1) high compliance and resistance, designed to simulate a patient with severe COPD ("Obstructive"; resistance [R] = 20 cm H_2O/L/s, compliance [C] = 120 mL/cm H_2O); (2) normal compliance and resistance ("Normal"; R = 5 cm H_2O/L/s, C = 70 mL/cm H_2O); and (3) normal resistance and low compliance ("Restrictive"; R = 5 cm H_2O/L/s, C = 30 mL/cm H_2O). These sequences were arranged in randomized order. Each sequence was separated from the next by a 1-min rest period.

Assessment of Ergonomics and Respiratory Measurements. The ergonomics of the two devices were scored by each subject 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 (V_T, end-inspiratory lung volume, 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 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 software of the test lung (version SW 3.1).[7] Flow and pressure transducers are presumed to have a precision of < 10 mL for volume, and 1 cm H_2O for pressure.

Statistical Analysis

A statistical software package (SPSS for Windows, IBM) was used to perform all analyses. The data are presented as the mean ± SD, unless specified otherwise. A $P \leq .05$ was considered to indicate a significant result. The nonparametric Mann-Whitney and Wilcoxon tests were performed to compare quantitative values between each group and device. The chi-square test was used to compare V_T 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 to 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 health-care groups or different pathological sequences were compared (Table 1). The residual volume was higher for all sequences making use of the BVM (156 ± 222 vs 54 ± 8 mL, $P < .001$).

Figure 3 compares the individual end-inspiratory lung volume distributions for the BVM and the automatic manually triggered device (EasyCPR), during the Obstructive pattern sequences.

Table 1. Tidal Volume Cycle Repartition Within the 400–600 mL Range for Each Device, Group, and Simulation Sequence

Group (n = 10 per group)	Sequence	V_T*		P†
		BVM	EasyCPR	
EMD	Restrictive	256/676 (37.9%)	22/349 (6.3%)	< .001
	Normal	163/608 (26.8%)	71/316 (22.5%)	.15
	Obstructive	280/620 (45.2%)	129/305 (42.3%)	.41
	All sequences	699/1,904 (36.7%)	222/970 (22.9%)	< .0001
EMR	Restrictive	3/509 (0.6%)	47/330 (14.2%)	< .001
	Normal	10/516 (1.9%)	1/316 (0.3%)	0.06‡
	Obstructive	124/576 (21.5%)	104/306 (34%)	< .001
	All sequences	137/1,601 (8.6%)	152/952 (16%)	< .0001
AP	Restrictive	156/527 (29.6%)	44/336 (13.1%)	< .001
	Normal	166/531 (31.3%)	108/291 (37.1%)	.09
	Obstructive	214/510 (42%)	194/316 (61.4%)	< .001
	All sequences	536/1,568 (34.2%)	346/943 (36.7%)	.21
EDN	Restrictive	40/492 (8.1%)	22/266 (8.3%)	.95
	Normal	88/439 (20%)	84/260 (32.3%)	< .001
	Obstructive	128/472 (27.1%)	204/254 (80.3%)	< .001
	All sequences	256/1,403 (18.2%)	310/780 (39.7%)	< .0001
PM	Restrictive	167/496 (33.7%)	9/341 (2.6%)	< .001
	Normal	142/471 (30.1%)	71/337 (21.1%)	.004
	Obstructive	89/480 (18.5%)	221/325 (68%)	< .001
	All sequences	398/1,447 (27.5%)	301/1,003 (30%)	.19
Overall cycles	All sequences	2,026/7,923 (25.6%)	1,331/4,648 (28.6%)	< .0002

The automatic manually triggered device (EasyCPR) provided more cycles within range compared with the bag-valve-mask (28.6% vs 25.6%; $P < .0002$). This benefit was markedly increased for EMR and EDN, but was not significant for PM and AP. The efficiency of the automatic manually triggered device (EasyCPR) was even lower than the BVM for EMD and during most restrictive sequences. $P \leq .05$ was considered significant.

* Values are reported as n cycles within the repartition range/N cycles (% within range of 400–600 mL).

† Chi-square nonparametric test.

‡ Fisher exact test.

EMD = senior emergency physicians

EMR = emergency residents—juniors

AP = advanced paramedics

EDN = emergency department nurses

PM = paramedics

V_T = tidal volume

Figure 4 illustrates the differences between the data for the two devices within the different professional health-care 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 automatic manually triggered device (EasyCPR), between 9 and 11 breaths/min for 93% of the recordings (see Fig. 4), but not with BVM (10.3 ± 2 vs 17.6 ± 6 breaths/min, respectively, $P < .001$).

Peak inspiratory airway pressure was lower using the automatic manually triggered device (EasyCPR) (10.6 ± 5 vs 15.9 ± 10 cm H_2O, $P < .001$).

Device Ergonomics

The ergonomics of the automatic manually triggered device (EasyCPR) were considered to be superior by two professional health-care groups (emergency department nurses and paramedics) when compared to those of the BVM ($P = .04$ and $P = .006$, respectively). The various expressions used to characterize these devices were "tiredness" (7 of 50 health-care professionals; 14%) and "better control" (3 of 50 health-care professionals; 6%) for the BVM, and "better fitting of the mask thanks to the use of both hands," "fewer leaks" (6 of 50 health-care professionals; 12%), and "fewer feelings" (6 of 50 health-care professionals; 12%) for the automatic manually triggered device (EasyCPR).

Discussion

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

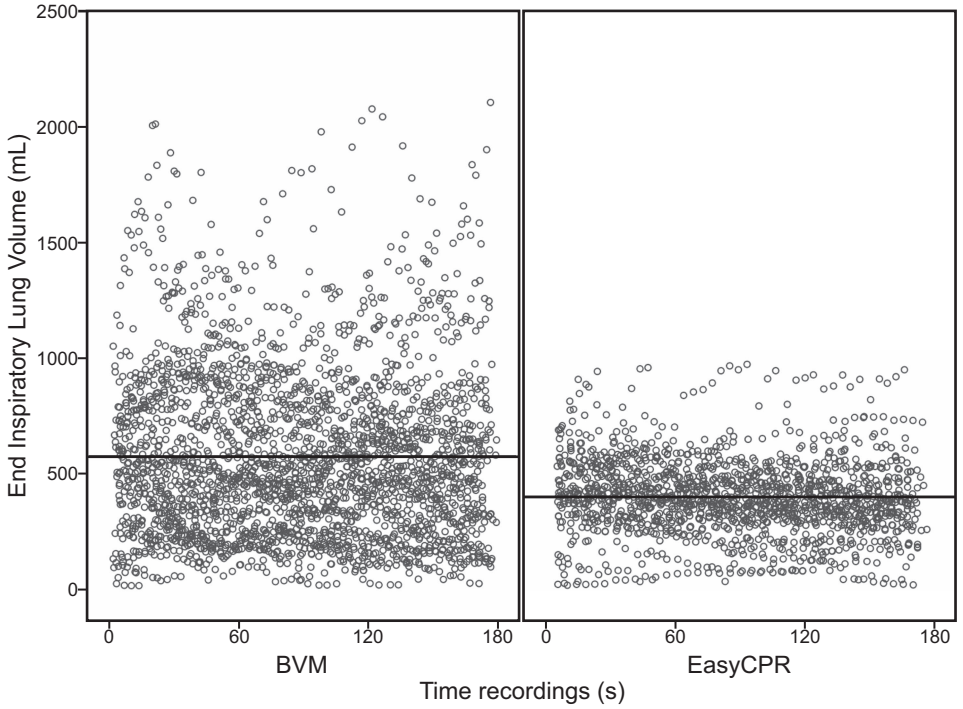

Fig. 3. Individual end-inspiratory lung volume distributions for the BVM and automatic manually triggered device (EasyCPR), during the Obstructive pattern sequences. The figure depicts individual end-inspiratory lung volume distribution during the obstructive sequences, for bag-valve-mask (BVM) and the automatic manually triggered device (EasyCPR). Bold lines corresponded to end-inspiratory lung volume mean values for each device. No significant difference was observed for the mean tidal volume value, but the overall distribution and extreme values favor the use of the automatic manually triggered device (EasyCPR).

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, an automatic manually triggered device (EasyCPR) did not prove to be superior to BVM in terms of V_T values, 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 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 source have not allowed the European Resuscitation Council and American Heart Association 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 health-care groups.

Impact of Single-Handed versus Two-Handed Resuscitation

In this study, the mean V_T always remained < 500 mL, whatever the device or type of sequence. Several studies[3-5,15] have shown that resuscitation using both hands may be more efficient than resuscitation using one hand, in terms of V_T delivery (higher mean value and lower variation). Our results show that the automatic manually triggered device (EasyCPR) is more efficient in terms of V_T delivery, since with this device all health-care professionals used both hands to keep the mask in place and control leaks. However, the mean V_T always remained at < 500 mL and fell outside the range limit (400–600 mL) for less than 72% of the recordings, whatever the device used. With the automatic manually triggered device (EasyCPR), the V_T 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.

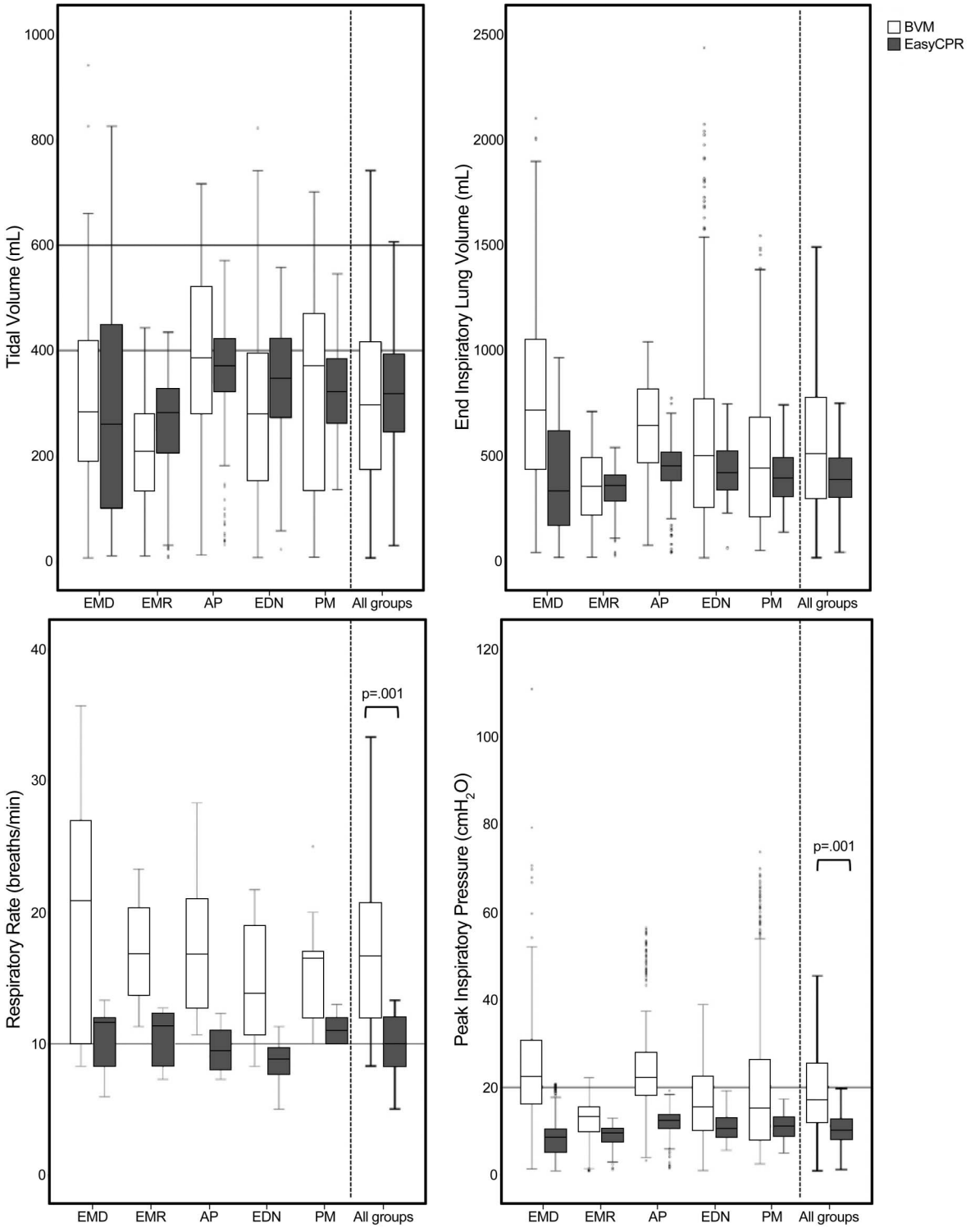

Fig. 4. Box and whisker plot for respiratory measurements during the Normal pattern sequences. Tidal volume, end-inspiratory lung volume, ventilation rate, and peak inspiratory pressure distribution during the Normal pattern sequences recordings. The boundaries on the box indicate the 25th and 75th percentiles, 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. Bold lines correspond to range values for tidal volume, lower esophageal sphincter opening pressure, peak inspiratory pressure, and recommended values for residual volume. EMD= senior emergency physicians; EMR= emergency residents—juniors; AP= advanced paramedics; EDN= emergency department nurses; PM= paramedics; $n = 10$ for each group; $P \leq .05$ was considered significant. A significant difference was observed between the devices in terms of VR and PIP, the two being lower and more consistent with guidelines while using the automatic manually triggered device (EasyCPR).

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

VR

Several clinical studies[16,17] 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. Our data are consistent with such findings, no matter what professional health-care group is reporting the data. Conversely, the VR values obtained with the automatic manually triggered device (EasyCPR) were more consistent, as a result of its controlled VR. This outcome may be of importance, since hyperinflation is a known problem in CPR because it increases intrathoracic pressure, which reduces the hemodynamic effectiveness of chest compressions.[16] In experimental animal studies, Aufderheide and Lurie[18] and Aufderheide et al[19] demonstrated that hyperventilation decreased coronary perfusion pressures and arterial blood pressure, thus resulting in lower survival rates.

Total Volume, Residual Volume, and PIP

To the best of our knowledge, this is the first study to have concomitantly examined V_T delivery and overall pulmonary distention 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 VR and therefore expiratory time variation. As a consequence, residual volume and overall distention 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 PIP.[6,20] Very few experimental studies have evaluated gastric inflation during CPR. Osterwalder and Schuhwerk[9] demonstrated differences in terms of gastric inflation proportion between the BVM and automatic ventilators (42% vs 0%) in a manikin study, and explained this difference by a higher PIP while using a BVM. In another study,[21] a decrease in lower esophagus sphincter opening pressure within the first minutes of cardiac arrest was suggested. Although such gastric inflation was not recorded during our study, higher gastric inflation could have occurred during use of a BVM or automatic manually triggered device (EasyCPR) device due to a significantly increased PIP.

Differences Among 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 among the patients even if all of these differential effects are consistent with standard knowledge on respiratory mechanics.

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

Study Limitations

Several limitations of this study should be emphasized. First, although care was taken to ensure correct respiratory mechanics, the experimental settings may have been different from 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. Second, 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 health-care professional ventilation procedures, 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 health-care 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.

Conclusions

The use of an automatic, manually triggered ventilation device for resuscitation may present valuable advantages over the standard manual BVM ventilation. Such devices may improve ventilation efficiency and decrease the risk

of pulmonary overdistention while at the same time decreasing VR. 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 to evaluate the potential impact of automatic manually triggered devices in the clinical setting.

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