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Original Article

Can first responders achieve and maintain normocapnia when sequentially ventilating with a bag-valve device and two oxygen-driven resuscitators? A controlled clinical trial in 104 patients

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Summary

Background and objective: To evaluate the capability of first responders to achieve and maintain normal ventilation of the lungs of victims employing a bag-valve device and two oxygen-driven resuscitators.

Methods: Prospective, controlled, blinded, single-centre clinical trial using a bag-valve device and one of two FR-300® devices, with 20 cmH_2O working pressure, and flows of either 24 or 30 $L\,min^{-1}$. One hundred and four patients were analysed. Induction of anaesthesia followed by ventilation of the lungs with a bag-valve device and an Oxylator® in manual and automatic modes performed by a fireman first responder. Each series was repeated for three conditions (anaesthesia; anaesthesia plus muscle relaxation, both with facemask; anaesthesia plus relaxation using an endotracheal tube).

Results: Patients age 49 ± 17 yr; 47% males, 48–132 kg. Normocapnia was achieved and maintained in 66% (bag-valve device), 82% (Oxylator®).

Conclusions: The use of an oxygen-driven device improves the ability of first responders to achieve and maintain normocapnia even when distracted. Use of the Oxylators® improves performance ($P < 0.001$) vs. the bag-valve device significantly.

Keywords: EQUIPMENT AND SUPPLIES, ventilators, mechanical; EMERGENCY TREATMENT, respiration artificial, first aid; HEALTHCARE QUALITY ASSESSMENT AND EVALUATION, technology assessment, biomedical.

Adequate ventilation of the lungs and oxygenation is an absolute priority in critical care. Bag-valve device (BVD) ventilation of the lungs is an accepted standard in both emergency and clinical medicine either in combination with a facemask or with an endotracheal tube. Hazards, including inadequate or excessive alveolar ventilation and barotrauma, have been regularly reported [1]. Inadequate lung ventilation may be due to poor technique [2], an incompletely cleared airway or leakage around the mask. Excessive ventilation may follow incorrect technique, distraction or excess flow. Several studies with BVD have evaluated the ease of use and the tidal volumes (V_t) attained on manikin models [3–8]. However, since the objective of ventilation in critical care is normocapnia or, perhaps, slight hyperventilation, manikin studies must be interpreted carefully [9]. In clinical studies, the degree of training and the target volumes needed to maintain

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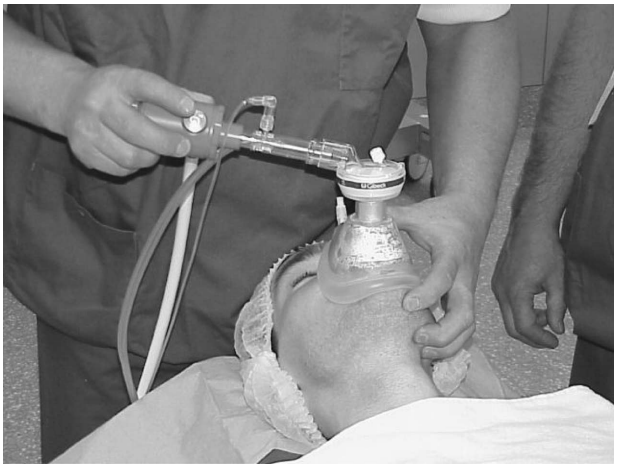

Figure 1.
The Oxylator® FR-300®. Use during the study. Oxylator® with D-Lite®, filter and mask attached.

normocapnia have also been difficult to determine [2,3,9]. Even caregiver characteristics have been implicated as a relevant variable [5,10]. Optimal V_t or minute volumes (V_{min}) have not been determined, with recommendations varying from 8–15 mL kg^{-1} and 12–15 breaths min^{-1} to V_t of 400–600 mL [11].

Oxygen-driven devices, such as the 'demand valve', have long been available, but, due to concern for gastric insufflation and barotrauma under high flows (up to 100 L min^{-1}, working pressure 50 cmH_2O) [6,11,12], have fallen into disuse. The modern, patented, technology for the Oxylator® (CPR Medical Devices Corp., Markham, Ontario, Canada) family of resuscitators, currently including the EM-100® and FR-300® series, uses lower flows and working pressure, with low resistances in order to allow spontaneous breathing through the device (Fig. 1). Although these devices are in current clinical practice in several countries, little clinical data has been published [7,13,14]. Suggested advantages are the simplicity of use, the 'feedback' offered by the apparatus when the airway is not cleared or when there is significant leakage and the ability of a caregiver to evaluate V_t based on the fixed flow. In this manuscript the ability of first responders to achieve and maintain normocapnia is evaluated under controlled clinical conditions based on the international liaison committee on resuscitation (ILCOR) guidelines.

Methods

Approval for this study was obtained from the Institutional Ethics Committee. The overall study was a prospective, controlled, blinded study using a random selection of ASA I–II patients admitted for elective surgery under general anaesthesia. Its purpose was twofold: to evaluate airway management by first responders and, second, to estimate adequate ventilation as expressed by achieving and maintaining normocapnia when using a BVD or one of two Oxylators® (24 L min^{-1} vs. 30 L min^{-1} flow) with a mask or after placement of an endotracheal tube. The former, including an extensive description of the methodology, is reported elsewhere in this issue.

In summary of the methodology, 13 professional firemen were recruited as first responders and briefly trained during which the study objectives were explained. The purpose of lung ventilation would be to achieve and maintain what they felt to be normocapnia, a concept that was described. Each patient's lungs would be ventilated with a BVD (adult manual resuscitator with reservoir bag; Datex-Engström AB, Bromma, Sweden) followed by the 24 L min^{-1} or the 30 L min^{-1} flow Oxylator® in manual and automatic modes cardiopulmonary resuscitation (CPR). These three steps were performed under general anaesthesia, with addition of a muscle relaxant both using a mask and an endotracheal tube which was positioned and checked by the anaesthesia team. In several patients, when the surgical procedure required radial artery cannulation, serial arterial blood samples were drawn to validate end-tidal CO_2 ($ETCO_2$) data.

Results

In total 105 patients were enrolled. Data from 104 cases were suitable for analysis, one case being lost for evaluation due to withdrawal of the caregiver during the case; 47% were males, average age was 49 ± 17 yr (range 18–91 yr). Forty-eight percent of patients were judged to be ASA II, the remainder were ASA I. Of the participants almost 49% had a history of smoking, with 11% having documented pulmonary disease. Weight varied from 48 to 132 kg (76 ± 15). Body mass index (BMI) was calculated to be 25.3 ± 4 kg m^{-2} for males and 25.3 ± 6 kg m^{-2} for females, as a consequence of obesity in 40% of the latter.

The FR-300® (30 L min^{-1}) was used in 57 cases, the FR-300® (24 L min^{-1}) in 47. There were no differences between these groups in patient characteristics, type of operation to follow the study protocol, the spread of the first responders in relation to the degree of complexity of the airway or to the Oxylator® used. Vital signs remained stable during the execution of the protocol with the exception of incidental tachycardia (increase of ⩾20% of baseline) during some Oxylator® procedures.

The main results are summarized in Table 1. V_t varied, with significant differences in V_t being seen when the Oxylators® (with facemask) were being used

Table 1. Volumes, breathing frequency and $ETCO_2$.

Max n = 104 (BVD), 47 (Oxy-24), 57 (Oxy-30)	**V_t (mL) Mean ± SD (range)**	**Frequency (breaths min^{-1}) Mean ± SD (range)**	**$ETCO_2$ mean ± SD (kPa)**
Anaesthesia (mask)			
BVD (n = 81)	712 ± 162 (354–1400)	13 ± 3 (6–21)	4.53 ± 0.67
Oxy-24/m (n = 47)	692 ± 163 (385–1310)	12 ± 3 (8–19)	4.80 ± 0.67
Oxy-30/m (n = 57)	648 ± 153 (338–1186)	12 ± 3 (7–17)	4.53 ± 0.67
Oxy-24/a (n = 47)	1020 ± 338 (301–1559)	10 ± 5 (4–26)	4.67 ± 0.80
Oxy-30/a (n = 57)	923 ± 292 (365–1650)	9 ± 4 (5–18)	4.40 ± 0.67
Anaesthesia and relaxant (mask)			
BVD (n = 91)	720 ± 156 (359–1431)	12 ± 3 (7–22)	4.53 ± 0.67
Oxy-24/m (n = 47)	725 ± 151 (330–1026)	11 ± 2 (7–16)	4.67 ± 0.67
Oxy-30/m (n = 57)	700 ± 145 (450–1116)	11 ± 2 (6–16)	4.67 ± 0.67
Oxy-24/a (n = 47)	982 ± 349 (312–1760)	11 ± 5 (5–25)	4.67 ± 0.67
Oxy-30/a (n = 57)	888 ± 299 (518–1633)	9 ± 3 (5–17)	4.13 ± 0.80
Anaesthesia and relaxant (with endotracheal tube)			
BVD (n = 104)	707 ± 162 (400–1455)	12 ± 2 (8–17)	4.80 ± 0.80
Oxy-24/m (n = 47)	711 ± 177 (200–1080)	12 ± 6 (6–50)	4.93 ± 0.80
Oxy-30/m (n = 57)	641 ± 132 (280–970)	12 ± 6 (6–21)	4.93 ± 0.80
Oxy-24/a (n = 47)	750 ± 272 (153–1400)	15 ± 9 (6–46)	5.07 ± 0.93
Oxy-30/a (n = 57)	720 ± 265 (240–1318)	11 ± 4 (5–24)	4.53 ± 0.93

All variables were determined after steady state was achieved, and controlled by visual confirmation of the curve and spirometric data. Oxy-24 m^{-1}: FR-300 24 L min^{-1} in manual mode; Oxy-30 m^{-1}: FR-300® 30 L min^{-1} in manual mode; Oxy-24/a: FR-300® 24 L min^{-1} in automatic mode; Oxy-30/a: FR-300® 30 L min^{-1} in automatic mode. The number of cases actually managed is described as n; note that in the calculation of the adequacy of ventilation 'failed airway management' cases were not included.

in comparison with the BVD (P = 0.03), but the $ETCO_2$ did not change significantly. The largest ranges were seen when the 30 L min^{-1} Oxylator® was used (P = 0.0001, vs. the BVD). Large volumes were typically combined with the lowest frequencies (P = 0.03) but these were not seen after insertion of the endotracheal tube, which implies a higher resistance to flow. Both Oxylators cycled in automatic mode at a significantly different speed (P = 0.003, between Oxylators, but not vs. the BVD). The difference between the two Oxylators was also significant (P = 0.002) with respect to $ETCO_2$ in the automatic modes after the muscle relaxant as well as after endotracheal tube placement (Table 1). V_{min} (Fig. 2, Table 2) confirmed the expected upper-range of normoventilation in the automatic modes, demonstrating significance in anaesthesia with the Oxylator®-24 L min^{-1} in automatic (Oxy-24/a, P = 0.007), and in anaesthesia and relaxation with the Oxy-30/a (P = 0.045), when compared with the BVD. Normocapnia was achieved and maintained in only 66% of cases when using the BVD, and increased to 85% (24 L min^{-1}) and 81% (30 L min^{-1}) in the same patients while the Oxylators® were being used.

Discussion

The ability of a first responder to ventilate adequately was the principal end-point in this study. This end-point was expressed as a measure of $ETCO_2$, as oxygenation, when using a F_iO_2 of 1.0, for ethical reasons could not be at issue. The number of normocapnic patients (66% for the BVD) was much lower than the number of airways cleared, during the overall study, and is in line with results published elsewhere [2,8,9]. Despite the increasing use of the BVD, little is known about its correct use. The level of training needed to perform adequately as a caregiver remains unknown and evaluation outside the hospital is complex [3,9].

This study incorporates a standardized first responder as caregiver, and three different series of three consecutive interventions in each patient, allowing each patient to be their own control by restarting lung ventilation from a zero point nine times during the study while the clinical and haemodynamic status did not alter. In addition, clinical reality was introduced by blinding the first responder to monitoring equipment and supplying distractions. Conceptually, anaesthesia represents the comatose patient who maintains muscle tone; anaesthesia and muscle relaxation mimics the deeply unconscious patient and, finally, placement of the endotracheal tube assures a free airway but introduces a change in resistance. This final step was included to allow insight into the ability of the first responder to carry out the ventilation task, after a professional has secured a definitive airway. This may occur in both hospital and prehospital settings, when trained hands must be freed for other tasks.

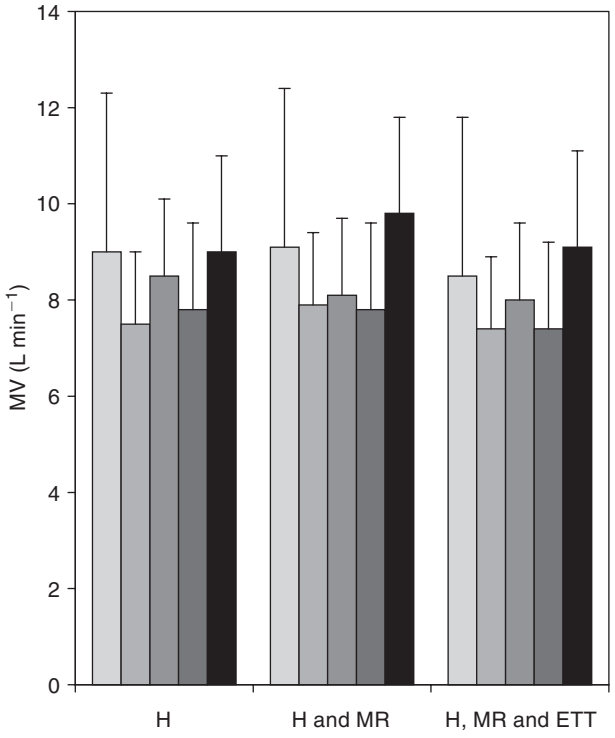

Figure 2.
V_{min} *by type of intervention and conditions (*n = *104). Ventilation was attempted in all patients using the BVD: 57 with the FR-300® 30 L min^{-1} and 47 with the 24 L min^{-1} models. Statistics are reported in Table 2. H: anaesthesia; H and MR: anaesthesia and muscle relaxation; ETT: endotracheal tube* in situ*; Oxy-24/m: FR-300® 24 L min^{-1} in manual mode; Oxy-30/m: FR-300 30 L min^{-1} in manual mode; Oxy-24/a: FR-300 24 L min^{-1} in automatic mode; Oxy-30/a: FR-300 30 L min^{-1} in automatic mode; MV: mitral valve. □: BVD; □: Oxy-24/m; ■: Oxy-30/m; ■: Oxy-24/a; ■: Oxy-30/a.*

Table 2. *P* values for Figure 2 (minute ventilation).

Condition	*P*
Anaesthesia (mask)	
BVD vs. Oxy-24/m	0.0001
BVD vs. Oxy-30/m	ns
BVD vs. Oxy-24/a	0.007
BVD vs. Oxy-30/a	ns
Oxy-24/m vs. Oxy-24/a	ns
Oxy-30/m vs. Oxy-30/a	ns
Anaesthesia and relaxant (mask)	
BVD vs. Oxy-24/m	ns
BVD vs. Oxy-30/m	ns
BVD vs. Oxy-24/a	ns
BVD vs. Oxy-30/a	0.045
Oxy-24/m vs. Oxy-24/a	ns
Oxy-30/m vs. Oxy-30/a	0.0001
Anaesthesia and relaxant (with endotracheal tube)	
BVD vs. Oxy-24/m	0.0001
BVD vs. Oxy-30/m	ns
BVD vs. Oxy-24/a	0.001
BVD vs. Oxy-30/a	ns
Oxy-24/m vs. Oxy-24/a	ns
Oxy-30/m vs. Oxy-30/a	0.0001

Oxy-24 m^{-1}: FR-300 24 L min^{-1} in manual mode; Oxy-30 m^{-1}: FR-300® 30 L min^{-1} in manual mode; Oxy-24/a: FR-300® 24 L min^{-1} in automatic mode; Oxy-30/a: FR-300® 30 L min^{-1} in automatic mode; ETT: ventilation via endotracheal tube; ns: not significant.

In addition, it allowed insight, for the professional, into the capability of the Oxylators® under conditions in which they might use this apparatus themselves. To our knowledge, there have been no similar studies reported.

Adequate ventilation results in normocapnia as part of a dynamic balance between metabolism, circulation and ventilation. In our study, the range of 4.0–4.7 kPa $ETCO_2$ was chosen in combination with the expectation that 80–120 mL kg^{-1} V_{min} would be required to maintain this level of $ETCO_2$ in our unpremedicated, nervous, hyperdynamic, but overtly healthy patients [11]. In the FR-300® the working pressure is 20 cmH_2O with fixed flows of 400 and 500 mL s^{-1}, respectively in the 24 L min^{-1} and 30 L min^{-1} models. The duration of ventilation is controlled by the caregiver in manual mode up to the maximum pressure and only by the pulmonary back-pressure (compliance) in automatic mode. A 2 s insufflation time is suggested by the manual.

Lung ventilation was continued until steady state was achieved in each case. Even in the most obese patient (135 kg) the 20 cmH_2O was sufficient for adequate ventilation, the V_t becoming smaller at a high cycle frequency. Concerns that the 24 L min^{-1} Oxylator® would have insufficient 'power' to ventilate could not be demonstrated, the heaviest patient for the 24 L min^{-1} model being 118 kg. In this study no cases were discontinued because of hyperventilation. Hypoventilation may become a concern under high CO_2 production conditions such as sepsis or CPR. However, suggestions have been made that excessive lung ventilation will not increase the removal of CO_2 during CPR, the circulation, and not ventilation, being the limiting factor. Additional, controlled, studies are needed to explore this area.

Control of V_t was easy to perform using the Oxylators®, even with very little training and lag time between training and employment in our first responders; the fixed flow made this easy to understand. When asked how the first responders were able to estimate the volumes needed to reach the abstract 'normocapnia', the vast majority stated that they were able to see the thoracic cavity increase in volume, and could feel how the Oxylator® was working. This supported our observation that during manual ventilation, 90% of the breaths were

stopped by the caregiver before the automatic cut off at 20 cmH_2O.

An unexpected clinical finding was that tachycardia was seen during some of the procedures involving the Oxylator®, but not during bag-valve ventilation. It appears to be attributable to the use of positive-pressure ventilation in conjunction with the increase of positive end-expiratory pressure (PEEP) (*circa* 4 cmH_2O) generated by the Oxylator®. This phenomenon is associated with better airway control (no cases with difficulties in airway management demonstrated this phenomenon). The study model was set up to allow increased susceptibility to a low venous-return state due to fasting and the use of propofol to induce and maintain anaesthesia, as found by von Spiegel and colleagues [15]. This supposition seems to be supported by the attenuation of the tachycardia in most cases when a fluid challenge was given. That the tachycardia was not the result of insufficient anaesthesia, was confirmed by the blood pressure (BP) demonstrating the typical propofol dip and, when tested in a number of patients, the lack of any effect of additional propofol in attenuating the tachycardia.

Another finding was the appearance of some $ETCO_2$ curves compatible with (severe) bronchiolar constriction, without clinical wheezing, notable changes in airway pressure or significant air-trapping. Possible explanations vary from airway resistance due to the PEEP, reactivity to the Oxylator® flows, insufficient depth of anaesthesia or poor airway technique.

There were experimental limitations in our model. $ETCO_2$ was monitored between the Oxylator® and the mask, leakage around the facemask could have altered the reliability of this measurement. Validation was attempted by monitoring the shape of the $ETCO_2$ curve, the inspiratory and expiratory volumes and by performing arterial blood gases during each of the steps in some of the cases. The six sets of arterial–$ETCO_2$ checks were all well within the expected range. The use of the inline D-Lite® (Datex-Ohmeda, Helsinki, Finland) and the bacterial/viral filter, with up to 25 mL volume and some additional airway resistance may have altered the findings.

While we consider $ETCO_2$ monitoring to be an accepted standard, we limited our first responders to lung ventilation without the feedback supplied by this monitor. This may have influenced the outcome of our study, particularly for the BVD, where feedback is severely limited.

The Oxylator® can be safely used by first responders, even after minimal training and a lag time of months, and its use demonstrates significantly improved achievement and maintenance of normocapnia even when real patients with a wide range of airway and facial physiognomy are studied under sub-optimal conditions. $ETCO_2$ can be brought to and maintained in safe ranges using both the 24 $L\,min^{-1}$ and the 30 $L\,min^{-1}$ Oxylators®, when used by first responders. Its use led to significant improvement in the number of patients with normocapnia. These improvements were 85% with the 24 $L\,min^{-1}$ Oxylator® and 81% with the 30 $L\,min^{-1}$ Oxylator® vs. 66% with the BVD. The 24 $L\,min^{-1}$ Oxylator® may be susceptible to causing hypoventilation if used for an excessively long time or if there is a high CO_2 production. Significant hyperventilation is not a cause for concern.

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