Original Article

Airway management by first responders when using a bag-valve device and two oxygen-driven resuscitators in 104 patients

G. J. Noordergraaf *, P. J. van Dun*, B. P. Kramer*, M. P. Schors*, H. P. Hornman†, W. de Jong‡, A. Noordergraaf §

St. Elisabeth Hospital, Department of Anaesthesiology, Tilburg, The Netherlands; †Fire Department, City of Tilburg, Tilburg, The Netherlands; ‡St. Elisabeth Hospital, Department of Clinical Physics, EN Tilburg, The Netherlands; §University of Pennsylvania, Departments of Bioengineering and Anaesthesiology, PA, USA

Summary

Background and objective: To evaluate the capability of first responders to ensure an airway and ventilate the lungs of a patient 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, flows of 24 and $30 \, L \, min^{-1}$. One-hundred-and-four patients were analysed. Induction of anaesthesia was followed by ventilation of the lungs with a bag-valve device and an Oxylator® (CPR Medical Devices Corp., Markham, Ontario, Canada) in manual and automatic modes. Each series was repeated twice by a fireman first responder using a hand-held mask to seal the airway, once under anaesthesia and then again under anaesthesia with muscle relaxation.

Results: Patients' mean age 49 ± 17 yr; 47% male, 48–132 kg. Only 29% had optimal facial and airway physiognomy. Airway management was significantly poorer when the bag-valve device was used than with either Oxylator® mode ($P < 0.0001$); 23% of cases were not manageable with the bag-valve device. Gastric insufflation was markedly less with the Oxylator® ($P < 0.02$).

Conclusions: The use of an oxygen-driven device improves the ability of first responders to secure an airway and reduce gastric insufflation, even when distracted. Oxylators® perform significantly better ($P < 0.0001$) than the bag-valve device.

Bag-valve device ventilation of the lungs is an accepted standard in both emergency and clinical medicine, either with a mask or with an endotracheal tube. However, even in experienced hands, hazards, including inadequate or excessive alveolar ventilation and barotrauma are encountered regularly [1]. Inadequate ventilation may be due to poor technique [2], an incompletely cleared airway or leakage around the mask. The degree of training, and even caregiver characteristics, have been implicated as relevant variables [3–5]. Gastric insufflation [6–8] may be caused during difficulties with clearing the airway and from decreased barrier pressure. This may lead to regurgitation, aspiration and further decreased lung compliance [9]. Several studies with bag-valve devices have evaluated the ease of use on manikin models [2,10–13]. Manikin studies remain difficult to interpret as facial features do not vary, and, securing the airway and achievement of normocapnia must be simulated. This limitation also applies to evaluating gastric insufflation [14].

Correspondence to: Gerrit Noordergraaf, Department of Anaesthesiology, St. Elisabeth Hospital, Hilvarenbeekseweg 60, 5022 GC Tilburg, The Netherlands. E-mail: g.noordergraaf@elisabeth.nl; Tel: +31 (0)13 539 1313 (beeper 6440); Fax: +31 (0)13 504 4926

Automatic transport ventilators (ATM) and manually triggered ventilators (MTV) have been suggested as alternatives for bag-valve devices but tend to be bulky, are expensive and have been implicated in unintended hyperventilation. Oxygen-driven devices, such as the 'demand valve', have long been available, but, due to gastric insufflation and barotrauma under high flows (i.e. $100 \, L \, min^{-1}$, working pressure $50 \, cmH_2O$) [15], have fallen into disuse. The modern, patented, technology for the Oxylator® family, currently including the EM-100® and FR-300® series, uses lower flows and working pressures, with low resistances allowing spontaneous breathing through the device. Although these devices are in current clinical practice in several countries, little clinical data has been published to date [16–18]. 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 tidal volume based on the fixed flow [18]. Our aim was to evaluate the ability of a standardized first responder population to use a bag-valve device and one of two types of Oxylator® FR-300®s. We describe their ability under controlled clinical conditions to clear and secure the airway, and, when ventilating the lungs, the occurrence of gastric insufflation.

Methods

Approval was obtained from our hospital's Institutional Ethics Committee. The 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 to evaluate the ease of use, and gastric insufflation, of a bag-valve device, in comparison to one of two Oxylator® FR-300®s with manual or automatic triggering in the hands of first responders. End-points for the overall study were the ease in securing the airway and inadvertent gastric insufflation, which are reported here, as well as normocapnia which is reported on pages 367–372 of this issue.

Setting and study population

Two months prior to starting the study, 13 professional firemen, employed by the City of Tilburg, were recruited as first responders. Each had had some first aid training as part of their regular in-service training, but none with bag-valve devices or invasive airway management. A 3 h course was given, directed toward anatomy, airway management and two manikin stations where practical skills were practised with bag-valve and the oxygen-driven devices. The study objectives were explained. The firemen were instructed to secure the airway, ventilate the patient's lungs and avoid gastric insufflation. They were also advised

that they would be blinded to the monitoring equipment, which would be turned away from them. They were warned that they would be actively distracted (i.e. by being asked non-relevant questions) during the cases to mimic the clinical environment.

The study was performed in the clinical operating suite of a 635 bed, level 1 trauma centre, incorporating 15 operating rooms. The same anaesthesia team supervised all patients. Patients were not eligible for the study if they had a nasogastric tube in place, were at increased risk of regurgitation, under the age of 18 yr or known to be pregnant.

Equipment and measurements

One type of bag-valve device was used (adult manual resuscitator with reservoir bag; Datex-Engström AB, Bromma, Sweden), connected to an external oxygen source with a flow of $6–8 \, L \, min^{-1}$. The oxygen-driven device was the Oxylator® FR-300®, connected to an external oxygen source (Fig. 1). Two types were studied: $24 \, L \, min^{-1}$ ($400 \, mL \, s^{-1}$) and $30 \, L \, min^{-1}$ ($500 \, mL \, s^{-1}$) flows, both with a fixed working pressure of $20 \, cmH_2O$. This apparatus meets the American Heart Association's requirements as 'adjuncts for oxygenation' [15].
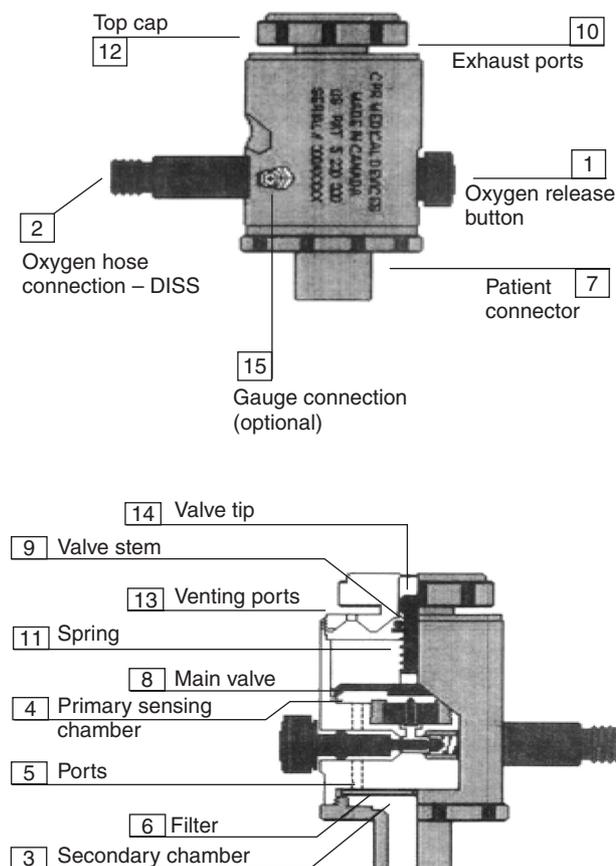

Figure 1.
Schematics of the Oxylator® FR-300®.

The Oxylator® is fist sized, weighs 500 g and withstands rough usage. A 3.0–5.5 atmosphere (303–555 mmHg) pressure source is required. It has been designed to allow use under extreme (pre-hospital) temperature conditions of $-30°C$ to $+60°C$. To ventilate the lungs of a patient a button must be depressed and held in, allowing pressure to build up. Pure oxygen is given at the fixed flow. When the maximum pressure has been reached, or when the button is released, passive exhalation is allowed. Depressing and turning the insufflation button allows the device to cycle automatically from inspiration to exhalation based on pressure regulation. As a consequence, large volumes are typically combined with small ventilation rates and *vice versa.* The apparatus provides two types of feedback: it 'ticks' if flow is restricted, such as in airway obstruction; and since it maintains flow until the working pressure equals the back pressure, leakage around the mask will be recognized by ongoing flow. The apparatus allows a patient to breathe through it spontaneously with minimal resistance.

Neither the firemen nor the professionals monitoring the case were aware of which oxygen-driven device was being used. All patients were monitored using a Side Stream Spirometry®/D-Lite® (Datex-Ohmeda, Särkkä Oy, Finland), placed between the Oxylator® and the mask. It was incorporated into an AS/3® anaesthesia monitor as part of the integral anaesthesia delivery unit. An inline bacterial/viral filter (Humid-Vent® model 18401®/19401®; Gibeck, Väsby, Sweden) was used in all cases to protect the anaesthesia breathing system.

For the overall study, major data items were the identity of the caregiver and the code for the FR-300®. The patient's gender, ASA score, age, type of surgery, height (cm) and weight (kg), and complicating factors for the airway, such as a beard or false teeth were noted. Vital signs (heart rate (HR), blood pressure (BP) and oxygen saturation (S_PO_2)) were routinely monitored. Ventilatory variables included ventilatory rate (RR), end-tidal CO_2 ($ETCO_2$) with a sketch of the curve, inspiratory and expiratory tidal volume (V_t), minute volume (V_{min}) at steady state, airway pressures (P_{peak}, P_{mean}, PEEP), R_{airway} and compliance. The number of airway manipulations needed, repositioning of the mask, change of hand position, the use of an oropharyngeal airway, the type and severity of unsealed/obstructed airway, and suspicion of gastric insufflation were documented. Gastric insufflation was identified by auscultation [3,7].

Procedure

After inclusion, the unpremedicated patients were moved to the operating room. They were placed on the operating table and baseline data were acquired.

All patients anaesthetized using propofol (1.5–2 mg kg^{-1}) and sufentanil (0.1 µg kg^{-1}). Propofol was continued for maintenance of anaesthesia. The airway was secured for mask ventilation and the patient was then ventilated using the bag-valve device until a steady-state $ETCO_2$ was reached. Next, the airway was released, the FR-300® attached to the mask, the airway secured again and manual ventilation re-established until the steady state was attained. Finally, the airway was again released in order to change to automatic FR-300® ventilation. The airway was re-established. These three techniques were repeated after the addition of muscle relaxant. A final series was repeated after endotracheal intubation by the anaesthesia team, which is not reported here. After completion of the protocol, patients were placed on the regular anaesthesia ventilator and anaesthesia continued with sevoflurane.

Data analysis

Data was collected and coded for an SPSS® (SPSS Inc., Chicago, IL, USA) (v11) database. The code for the type of Oxylator® was opened when the patient trial was finished. Data are reported as mean ± standard deviation. As appropriate, data were analysed using two-tailed paired value *t*-test (tidal volumes, ventilation frequency, minute volume), with correlation sought using Pearson's statistic (two-tailed) (weight-obstruction), while non-parametric data were evaluated using the Wilcoxon (two-tailed) signed rank *U*-test (patient characteristics data, airway pressure, obstruction, gastric insufflation), and Spearman's two-tailed rho (correlations). $P < 0.05$ was taken to be significant.

Results

In total 105 patients were enrolled. Data from 104 cases were suitable for analysis, one case being lost due to withdrawal of the caregiver during the case; 47% were male, ages 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, reflecting obesity in 40% of the latter.

Before starting, the physiognomy of the airway was inspected and scored by an observer. Specifically, the potential fit for the mask or the simplicity for a jaw-thrust manoeuvre was evaluated. The results are reported in Table 1. Missing dentures or presence of a dental prosthesis were evaluated for their effect on

Table 1. Evaluation of facial features relevant for mask ventilation ($n = 104$). For explanation see text.

Findings	Males (%)	Females (%)
Normal	9	20
Complicating factors		
(just) missing dentures	16	7
(just) no cheeks (collapse/poor fit)	2	4
(just) mandibula hidden	2	3
neither prosthesis nor cheeks	4	4
neither prothesis, jawline nor neck	5	11
'horrendous' (i.e. obesity with all of above and/or beard)	9	4
Total	47	53

creating a seal with one of the set of (three) masks. Difficult airways were those, which the observing anaesthesiologist considered not easily suitable for simple management solely with a facemask.

The $30\,L\,min^{-1}$ model was used in 57 cases, the $24\,L\,min^{-1}$ in 47 cases. There were no differences between these groups in patient characteristics, type of operation following 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 protocol with the exception of incidental tachycardia (increase of $\geq 20\%$ of baseline) during some procedures.

Airway management was evaluated during each of six of the nine steps involving mask ventilation. Using the bag-valve device with a mask, the first responders were able to ventilate the lungs in less than 50% of all cases while anaesthetized without retrying to secure the airway, the use of an oropharyngeal airway or assistance (Fig. 2). This increased to 56% when muscle relaxation was added to the anaesthetic ($P = 0.001$). Initial clearing and maintaining the airway with the Oxylator® and mask was better than 91% overall, when compared to the bag-valve device ($P < 0.0001$). The different flows in the two oxygen-driven devices could not be related to any differences in incidence of obstruction ($P > 0.1$ in all groups). There is a strong correlation ($P = 0.006$) between the estimated potential for difficulty in managing the airway (Table 1) and actual difficulties during the case when the bag-valve device was used by the first responder. This correlation remained, becoming $P = 0.03$ for both the Oxylator® types, under manual conditions while management improved (10 of 14 cases readily managed, even in the most difficult category 'horrendous'). In absolute terms, after repositioning and in some (six) cases use of the oropharyngeal airway, the first responders were able to clear and maintain an airway in all patients when using an Oxylator®. When the bag-valve device was used a cleared, adequate, airway
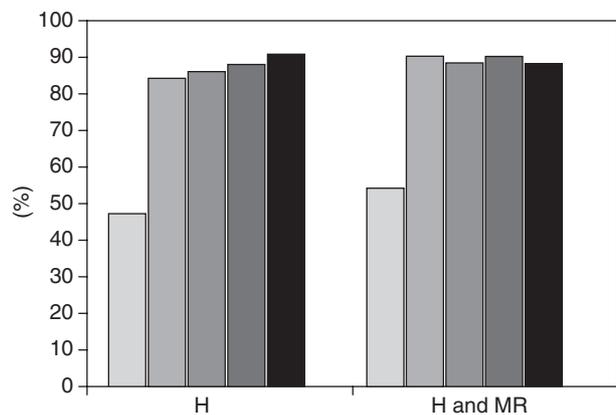
Figure 2.

Airways managed (without the use of a Mayo tube, n = 104*). Ventilation was attempted in all patients using the bag-valve device: 57 with the Oxylator® 30 L min^{-1} model and 47 with the 24 L min^{-1} model. P < 0.0001 when comparing any of the Oxylator® conditions to the BVD. There are no significant differences between any of the eight Oxylator® conditions. H: anaesthesia; H and MR: anaesthesia and muscle relaxation; BVD: bag-valve device; 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. ☐: BVD; ▨: Oxy-24/m; ▨: Oxy-30/m; ▨: Oxy-24/a; ■: Oxy-30/a.*

could not be achieved at all in 13–23% of patients. The first responders had significantly more difficulty managing the airway as weight increased when using the bag-valve device ($P = 0.03$), but not when an Oxylator® was used ($P = 0.39$).

Gastric insufflation, related to peak airway pressure ($P = 0.045$), was extensive when using the bag-valve device (Table 2). More than 15% of all cases had airway pressures $>30\,cmH_2O$ with pressures of $40-50\,cmH_2O$ occurring. Gastric insufflation was virtually absent when the first responders used the Oxylators® (1–4% of cases). There were no differences between the 24 and $30\,L\,min^{-1}$ devices with respect to gastric insufflation, both having a working pressure limited to $20\,cmH_2O$.

Discussion

Bag-valve devices are used daily, both inside and outside of the hospital. The use of a bag-valve device with a mask is complex, involving separate psychomotor activities and two hands. The mask is placed over the face, the mandible lifted and supported, while the other hand holds the bag and moves the correct volume by compression and supportive flow. At the same time the caregiver must listen and feel for air loss around the mask, look for chest and/or abdominal movement to verify ventilation and look for misting of the mask to verify exhalation. The level of training needed to perform adequately as a caregiver remains

Table 2. Airway pressure and gastric inflation ($n = 104$).

	Peak airway pressure (cmH$_2$O) Mean $\pm$ SD	P oxy vs. BVD	Gastric insufflation (% of cases)	P oxy vs. BVD
Anaesthesia (mask)				
BVD	24 ± 8	n/a	29	n/a
Oxy-m (24 and 30 L min^{-1})	17 ± 4	$P = 0.0001$	4	$P = 0.001$
Oxy-a (24 and 30 L min^{-1})	21 ± 1	$P = 0.01$	4	$P = 0.001$
Anaesthesia and relaxant (mask)				
BVD	23 ± 8	n/a	15	n/a
Oxy-m (24 and 30 L min^{-1})	16 ± 3	$P = 0.0001$	1	$P = 0.001$
Oxy-a (24 and 30 L min^{-1})	21 ± 1	$P = 0.027$	4	$P = 0.02$
P between oxy-m vs. oxy-a		0.0001 in all conditions		Not significant in any condition

Ventilation of the lungs was attempted in all patients using the bag-valve device. As the Oxylator® (24 and 30 L min^{-1}) outcomes overlapped these are incorporated into the table. BVD: bag-valve device; Oxy-m (24 and 30 L min^{-1}): FR-300® 24 and 30 L min^{-1} in manual mode; Oxy-a (24 and 30 L min^{-1}): FR-300® 24 and 30 L min^{-1} in automatic mode.

unknown and evaluation outside the hospital is complex.

The central issue in this study was the ability of a first responder to support life by securing an airway in order to ventilate while avoiding gastric insufflation in a controlled, clinical, setting. In an age of increasing resistance to mouth-to-mouth ventilation, first responders have accepted the bag-valve device as their alternative. Sufficient reasons exists to seek improvements is this area. However, most studies evaluating efficacy of bag-valve devices have incorporated smaller series of patients in non-standardized conditions [1,6], mixed groups of caregivers [6,13] or the use of an *in-vitro* model [2,9,13]. This study incorporates a standardized first responder as caregiver, and two different series of three consecutive mask interventions in each patient, allowing each patient to be their own control. Some clinical reality was introduced by blinding the first responder to monitoring equipment while supplying distractions. Conceptually, anaesthesia represents the comatose patient who maintains muscle tone; anaesthesia and muscle relaxation mimics the deeply unconscious patient. To our knowledge, similar studies have not been reported.

While we expected muscle relaxation to increase difficulties in airway management, our results contradicted this as shown in Figure 2. This seems to be due to improvement in the forward displacement of the mandible when decreased muscle tone facilitates the movement in the maxillo-mandibular double joint.

Our study found that between 13% and 23% of airways could not be secured by the first responder in patients (under anaesthesia with muscle relaxation and anaesthesia alone respectively), even in the controlled environment and after multiple attempts. Under emergency conditions this might have severe consequences. The results appear to support earlier data suggesting that accurate and correct use of a bag-valve device is difficult, with between 50% and 75% being the 'manageable' airways for professionals, such as emergency medical technicians (EMTs). In their studies, Menegazzi and colleagues [19] and Johannigman [12] demonstrated that even many EMTs had difficulties creating a good seal using one hand, as confirmed in our study for first responders.

Concerns about lower oesophageal barrier pressure have recently led to suggestions that smaller tidal volumes are better, decreasing the chance of regurgitation [14]. Low thoracic compliance may cause additional difficulties when using a bag-valve device in cases, such as cardiovascular collapse. In this study, we found that the flow and working pressures for the FR-300®s were suitable for use, with markedly lower pressures monitored than with the bag-valve device while control of ventilation remained easy to perform. Even with very little training and several months time-lag between training and employment in our first responders, the fixed flow system was easily understood and remembered. Updike and colleagues [11], in a manikin study using EMT paramedic candidates as caregivers, found excessive gastric insufflation with the bag-valve device, but none with the MTV.

Some experimental limitations are inherent in our study. One was the use of an inline bacterial/viral filter, and the D-Lite® between the Oxylator® and the patient. The dead space in this filter was 25 mL, and the airway resistance, which would be detected by the Oxylator®, was 2 cmH$_2$O. The D-lite® was also inline, making it impossible for the caregiver to perform manual ventilation while holding the mask with two hands in any of the conditions except when the Oxylator® was used in automatic mode.

Only when the airway could not be secured was an oropharyngeal airway or assistance by a second rescuer designated to hold the mask allowed [13]. Guidelines, including those in our hospital, may

require the use of an oropharyngeal tube in emergency conditions and recommend two rescuers for mask ventilation as the method of preference. Our intentions were to simulate a realistic case, correcting to some degree the advantages offered by the clinical situation.

First responders can safely use the Oxylator®, even after minimal training and a time-lag of months. Its use demonstrates significantly improved airway management, and less gastric insufflation even when real patients with a wide range of airway and facial physiognomy are studied under suboptimal conditions ($P < 0.0001$). While up to 23% of airways could not be secured by ventilation with the bag-valve device, these same airways all could be secured by using an Oxylator®. Decreased gastric insufflation was noted when the oxygen-driven apparatus was used.

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