



## Effectiveness of mask ventilation in a training mannikin. A comparison between the Oxylator EM100 and the bag-valve device

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### Abstract

The demands for an optimal ventilation apparatus are that it can be easily handled, achieves a sufficiently high ventilation volume, and minimizes gastric inflation. Our aim was therefore to carry out a study in a training mannikin to find out whether the Oxylator EM100, compared with the bag, obtains improved ventilation and a decrease in gastric inflation. In a randomized crossover study, 72 subjects were selected (24 physicians, 44 nurses and 4 auxiliary nurses), chosen from the operating theatre, emergency department and intensive care unit of two hospitals. We used the Ambu<sup>®</sup>-Bag Mark III with mask No. 4, the Oxylator EM100 with a pressure setting of 35 cm H<sub>2</sub>O run in the manual setting, the Ambu<sup>®</sup>-Man C mannikin as well as the Ambu<sup>®</sup>-CPR computer program. The resuscitation cycles of the standard two-rescuer's adult procedure lasted 3 min each, with a 3-min pause between the crossover procedure. The participants could improve their ventilatory volume with the Oxylator EM100 by 635 ml (95% confidence interval 578–692 ml) compared with the bag ventilation. The number of subjects who could attain a mean ventilatory volume of 800 ml or more increased from 15% to 98.6% ( $P < 0.001$ ). Compared with the bag, the increase of adequate respirations ( $\geq 800$  ml) obtained by the Oxylator EM100 for the individual participants amounted to a median of 91% ( $P < 0.001$ ). Moreover, conventional ventilation caused in 42% one or several instances of gastric inflation, whereas no such reactions occurred with the Oxylator EM100. The Oxylator EM100 showed significantly better results in the mannikin than the bag. Of most importance is a significant lowering of gastric inflation and less so a marked increase in ventilatory volume. Our trial procedure with a relatively high lung compliance and a high oesophageal sphincter opening simulated favorable conditions. Owing to a large in vivo variability of these magnitudes, a direct testing in real patients with circulatory arrest is indicated. © 1998 Elsevier Science Ireland Ltd.

*Keywords:* Mask ventilation; Training mannikin; Comparison; Oxylator EM100; Bag-valve device

### 1. Introduction

In 70–80% of cases, ventricular fibrillation is the most frequent cause of sudden cardiac death [1]. It can only be reversed in the few minutes after circulatory arrest. Hypoxemia, hypercapnia and acidosis then lower the fibrillation threshold and increase defibrillation tolerance [2]. Basic measures for resuscitation are therefore aimed at emergency oxygenation and carbon dioxide elimination. They depend, in part, on the venti-

latory volume. Respiration, however, can cause problems. As long as the patient is not intubated, the medical personnel generally use a face mask and bag. This ventilatory technique, however, is difficult to manage and frequently causes complications [3]. Large and/or rapidly administered volumes lead to high pressure peaks with gastric inflation and risk of regurgitation and aspiration. Moreover, the magnitude of respiratory volume is still unclear [2]. This uncertainty is reflected in different recommendations [1,4]. The American Heart Association (AHA) recommends an optimal ventilatory dose of 800–1200 ml of air [1]. This recommendation is difficult to achieve for many emergency

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medical technicians [5], nursing personnel [6], anaesthetists [7], and even physicians [8] with reasonable instructions and practical experience. The European Resuscitation Council (ERC) is of the opinion that 500–600 ml of ventilatory volume suffices [4]. According to the ERC, this guideline is easier to follow and definitely eliminates the risk of gastric inflation. Moreover, if air is supplemented with oxygen, sufficient oxygenation can be obtained. It is, however, questionable whether enough carbon dioxide can be exhaled. In any case, even in the presence of a minimal circulation, the occurrence of hypercapnia depends directly on ventilatory magnitude [9].

An optimal ventilation apparatus should therefore be one that can be easily handled and still attain a sufficiently high ventilatory volume without risking gastric inflation.

The Oxylator EM100 is supposed to fulfil these requirements. Since pertinent investigations have not yet been undertaken, however, our aim was to study in a training mannikin whether the Oxylator EM100 compared with the Ambu<sup>®</sup>-Bag in fact improves ventilation and reduces gastric inflation.

## 2. Participants, materials and methods

This is a randomized crossover study. The AHA recommends 10–12 respirations per minute [1]. In our experience, on the average a maximum of 5–6 proper respirations ( $\geq 800$  ml) per minute is attained. We therefore assumed that the Oxylator EM100 would attain an improvement from 6 to 9 proper respirations per minute or 27 per 3 min, respectively. Taking into account an  $\alpha$ -error of 0.05 and a power of 0.8, at least three subjects are needed to prove this effect [10].

### 2.1. Materials

We used the Ambu<sup>®</sup>-Bag Mark III with a 1300 ml maximal compression volume, O<sub>2</sub>-reservoir, an oxygen supplement of 13 l, and a No. 4 Ambu<sup>®</sup>-mask. The Oxylator EM100 is a portable, automatic ventilatory apparatus (Fig. 1). Its basic function consists of a pressure flow automatic cycling, consequently limiting the respiratory phase to an airway pressure between 25 and 50 cm H<sub>2</sub>O. As soon as the adjusted pressure has been attained, the automatic cycling changes over to the expiration phase. Only when the expiratory air current declines to a pressure value corresponding to a completed expiration, does the apparatus initiate a new ventilatory cycle. This procedure is automatic, although the Oxylator EM100 can also be switched over to a manual operation. According to the manufacturer, restricting the ventilatory air to 40 l/min prevents danger-



Fig. 1. Close-up of Oxylator EM100 with mask, attached hose and switch for pressure adjustment.

ous pulmonary and thoracic pressure conditions as well as gastric inflation, while its automatic cycling values do not admit more than 50 cm H<sub>2</sub>O. The pressure limits of the Ambu<sup>®</sup>-Bag amount to 70 cm H<sub>2</sub>O, according to the manufacturer's statements (personal communication).

According to the guidelines of the AHA and the ERC, respiration, in the absence of intubation, is given only during thoracic compression pauses. The automatic control of the Oxylator EM100 reacts immediately to the compression. Hence, the ventilatory attempts are quickly interrupted by the compression's counterpressure. We wanted to eliminate this possible adverse effect, and therefore used the manual technique. The trial procedure consisted of a dummy Ambu<sup>®</sup>-Man CPR training model 1993 (Fig. 2). With the Ambu<sup>®</sup>-Man, lung compliance is set at 50–55 ml/cm H<sub>2</sub>O, and the opening pressure for abdominal insufflation is set at 30 cm H<sub>2</sub>O. The pressure limit was therefore restricted to 35 cm H<sub>2</sub>O.



Fig. 2. Two-rescuers' CPR with Oxylator EM100 attached to mannikin.

## 2.2. Participants

We selected 72 subjects from the Department of Anaesthesia, the Emergency Department and the Intensive Care Unit of the Canton Hospital of St. Gallen (61 probands) and the Canton Hospital of Münsterlingen (11 probands). We restricted the selection to persons who were present at the qualifying dates at one of the three institutions and who could leave their place of work for a short while.

The whole sample consisted of 24 physicians (33%), 44 registered nurses (61%) and 4 auxiliary nurses (6%). The mean age was  $34 \pm 6.5$  years, and their length of occupation  $9.2 \pm 0.8$  years. The number of resuscitations carried out was a median 3.5.

## 2.3. Procedure

Ventilation was carried out by a two-rescuer's adult procedure, i.e. five thoracic compressions per one ventilation. According to our random selection, the mannikin was either ventilated with the Oxylator EM100 for 3 min, and then changed over to the Ambu<sup>®</sup>-Bag after 3 min or the reverse. Instructions as to the handling of the Oxylator lasted for a maximum of 1 min. For the mask-bag respiration we permitted a maximum of 2 min for practice. The last training on the mannikin took place at a median of 1 year.

## 2.4. Study variables

The study protocol comprised of age, profession, previous resuscitation training, number of resuscitations carried out, ventilation frequencies/minute, ventilatory volume, percentage of volume greater than 800 ml, as well as the incidence of gastric inflation. The following physiologic values were measured and recorded: respiratory frequency, volumes and abdominal insufflation with the aid of a PC software for the Ambu<sup>®</sup>-Man CPR Trainer Module 1993. As normal values we established a ventilatory frequency of 10–12 min and a ventilatory volume of 0.8–1.2 l [1].

## 2.5. Statistics

For the symmetrically distributed data we calculated the mean value, the standard deviation, the 95% confidence interval, the paired and unpaired Student's *t*-test for differences. For asymmetric distribution, we calculated the median, respectively. The Wilcoxon test and the Mann-Whitney *U*-test. All calculations were executed with a commercially available software [11].

Table 1  
Comparison of whole group

	Devices	
	Ambu <sup>®</sup> -Bag	Oxylator EM100
<i>Mean (95% confidence interval)</i>		
Ventilatory frequency*	10.8/min (10–11.6)	9.4/min (9.1–9.7)
Ventilatory volume**	556 ml (507–605)	1196 ml (1161–1231)
<i>Median</i>		
% adequate ventilatory volume***	1%	100%
<i>% adequate ventilatory volume****</i>		
<90%	70 part. <sup>a</sup>	9 part. <sup>a</sup>
≥90%	2 part. <sup>a</sup>	63 part. <sup>a</sup>

<sup>a</sup> Part., participants.

\* $P < 0.05$ ; \*\* $P < 0.05$ ; \*\*\* $P < 0.001$ ; \*\*\*\* $P < 0.001$ .

## 3. Results

### 3.1. Group comparison

The participants obtained with the Oxylator EM100 a mean ventilatory volume of 1.196 ml (95% confidence interval of 1161–1231 ml) compared with 556 ml (95% confidence interval 507–605 ml) for the bag-valve-mask ventilation. The number of subjects who obtained an average ventilatory volume of 800 ml or more increased from 15% (11/72) with the Ambu<sup>®</sup>-Bag to 98.6% (70/72) with the Oxylator EM100 ( $P < 0.001$ ). Altogether, 46% (33/72) in the mask-bag group and 49% (35/72) in the Oxylator EM100 group were outside the normal values of respiratory frequency. With the Oxylator EM100, we obtained predominantly low values between 8–9 respirations per min. Pertinent results are summarized in Table 1.

### 3.2. Intrasubjective comparisons of the participants

With the Oxylator EM100, the participants could improve their ventilatory volume by 635 ml (95% confidence interval: 578–692 ml) compared with the standard application of the mask-bag. The increase of adequate respirations ( $\geq 800$  ml) within the individual participants, when switching from the Ambu<sup>®</sup>-Bag to the Oxylator EM100 amounted to a median of 91% (median  $P < 0.001$ ). Moreover, ventilation with the Ambu<sup>®</sup>-Bag caused one or more episodes of gastric inflation in 42% of subjects whereas no such side effects occurred with the Oxylator EM100.

#### 4. Discussion

In contrast to bag-valve-mask ventilatory volume, with the use of the Oxylator EM100, nearly all our participants obtained the ventilatory volume as recommended by the AHA. Handling of the Oxylator EM100 was simple and directions for use minimal. Moreover, no abdominal insufflations were encountered. It is particularly noteworthy that for the Ambu<sup>®</sup>-Bag, even with the low tidal volumes of 400–600 ml, which according to Baskett et al. are perceived adequate for resuscitation [12], the mean values were below those in 31% of the test subjects.

Can we therefore conclude that in cases of cardiopulmonary resuscitation the Oxylator EM100 can replace the mask-bag ventilation device? The answer to this question depends on several factors:

1. How can the difference in the gastric inflation rate between the two devices be explained? Contrary to the mask-bag device, the Oxylator EM100 works at a constant flow rate. Pressure during inspiration, therefore, rises continuously, and no sudden pressure or flow burst can occur (as it often occurs with the bag). Despite that, values above 19–30 cm H<sub>2</sub>O are critical, and according to the literature, open the lower oesophageal sphincter tone [2,3]. Presumably, the correspondingly higher values have to be spread over a certain time period before abdominal insufflation will ensue. We presumed that this is a short phase with the Oxylator EM100 and would, therefore, not lead to gastric inflation.
2. Do our trial experiments correspond to the resuscitation conditions in clinical reality? Lung compliance is of a critical magnitude in cases of no intubation. It decreases during cardiopulmonary resuscitation [13]. Consequently, ventilatory pressure has to be increased to obtain adequate ventilation. At the same time, the sphincter tonus of the lower oesophagus should decrease during cardiac arrest, i.e. dropping resistance against abdominal insufflation [14,15]. Both values, lung compliance and consequently ventilatory pressure as well as oesophageal opening pressure vary and affect the abdominal insufflation rate. Lung compliance during cardiac arrest is between 25 and 50 ml/cm H<sub>2</sub>O, and the opening pressure of the oesophagus is between 19 and 30 cm H<sub>2</sub>O [2]. In our model, as per the manufacturer's unchangeable setting, lung compliance was 50–55 ml/cm H<sub>2</sub>O and the threshold at which abdominal insufflation would follow is at 30 cm H<sub>2</sub>O. For this reason, to go over the oesophageal opening pressure, we set the limit for the inspiration pressure at 35 cm H<sub>2</sub>O. The trial directions thus simulate a favorable situation, with a high threshold for abdominal insufflation and a relatively easy ventilation procedure because lung

compliance was in the lower region of the 'norm'. In the clinic, i.e. in a real resuscitation of a patient, we may encounter worse results, in particular as to the abdominal insufflation rate.

3. What are the advantages of the Oxylator EM100 method compared with the standard mask-bag ventilation procedure? It has not yet been shown that for effective CPR the ventilation volume has to be between 800 and 1200 ml [1], and that a volume between 400 and 600 ml [4] would not suffice. For that reason the significance of our results is based foremostly on the dramatic lowering of the gastric inflation rate and less on the marked increase of the ventilation volume. It is also extremely difficult to hold the mask airtight on the patient's face with one hand, and at the same time to handle the bag properly. The Oxylator EM100 has the advantage that it eliminates the tedious compression of the bag, that it can limit ventilatory pressure, and in the case of the automatic setting, both hands are free to hold the mask. If a second person is available for the cricoid pressure, gastric inflation can be avoided even in situations of higher pressure. Furthermore, the Oxylator EM100 requires much less time for respiratory instructions as well as for administration and rehearsals compared with the mask-bag system.
4. What are the disadvantages of the Oxylator EM100? When the Oxylator EM100 is used with an oxygen bottle, it is 4–5 times more expensive in Switzerland than the Ambu<sup>®</sup>-Bag Mark III. Furthermore, the system demands a certain technical maintenance. In our opinion, the Oxylator EM100 is therefore of use in hospitals in only the Emergency Departments, the Intensive Care Units, or in special departments caring for high-risk patients (e.g. in cases of coronary artery disease). For rescue operations, however, there are no restrictions to its use.

#### 5. Conclusion

In summary we came to the following conclusions:

1. With the Oxylator EM100, ventilation of a training mannikin is effective, with minimal risk of gastric inflation, simply and quickly learned.
2. In a mannikin with a lung compliance of 50–55 ml/cm H<sub>2</sub>O and an oesophageal opening pressure of 30 cm H<sub>2</sub>O, the Oxylator EM100 obtains markedly less abdominal insufflation and a higher respiratory volume than the Ambu<sup>®</sup>-Bag.
3. The trial procedure simulated a favorable situation with a high threshold for abdominal insufflation and a relatively easy ventilatory operation. However, the significance of these findings for clinical situations, where lung compliance and oesophageal opening pressures will be altered, clearly requires investigations in real patients.

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