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Clinical paper

The mouth-to-bag resuscitator during standard anaesthesia induction in apnoeic patients☆,☆☆

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ABSTRACT

Aim: Ventilation of a non-intubated emergency patient by inexperienced rescuers with a standard bag-valve device may result in high inspiratory flow rates and subsequently high airway pressures with stomach inflation. Therefore, a self-inflating bag has been developed that requires lay rescuers to blow up a single-use balloon inside an adult bag-valve device, which, in turn, displaces air within the bag towards the patient. This concept has been compared to standard adult bag-valve devices earlier in bench models but not in patients.

Methods: An anaesthetist who was blinded to all monitor tracings ventilated the lungs of 40 apnoeic patients during routine anaesthesia induction either with a standard bag-valve device or with the mouth-to-bag resuscitator in a random order. Study endpoints were peak inspiratory flow rates, peak airway pressure, tidal volumes and inspiratory time.

Results: Peak inspiratory flow was $40 \pm 10\,l\,min^{-1}$ for the standard bag-valve device versus $33 \pm 13\,l\,min^{-1}$ for the mouth-to-bag resuscitator ($P < 0.0001$); peak airway pressure was 17 ± 5 cmH_2O versus 14 ± 5 cmH_2O ($P < 0.0001$); inspiratory tidal volume was 477 ± 133 ml versus 644 ± 248 ml ($P < 0.001$) and inspiratory time was 1.1 ± 0.3 s versus 1.9 ± 0.6 s ($P < 0.0001$).

Conclusion: Employing the mouth-to-bag resuscitator during simulated ventilation of a non-intubated patient in respiratory arrest significantly decreased peak inspiratory flow and peak airway pressure and increased inspiratory tidal volume and inspiratory times compared to a standard bag-valve device.

Introduction

Ventilation of an emergency patient with a bag-valve device can be a major challenge for rescuers, such as emergency medical technicians, first responders, fire fighters and rescue swimmers,[1] without daily experience in airway management but having access to advanced airway devices. One of their major problems is to seal the face mask tightly to the patient's face, which is the major precondition of a ventilation attempt through a face mask.[2,3] Holding the face mask with two hands may improve its sealing, but then a second rescuer is needed to squeeze the bag-valve device.

Therefore, a ventilation device has been developed (mouth-to-bag resuscitator; Ambu, Glostrup, Denmark; Figures 1–3) that requires a lay rescuer to blow up a single-use balloon inside a self-inflating adult bag-valve device with his own breath, which, in turn, displaces the gas within the bag towards the patient.[4] On stopping inflation and releasing the mouthpiece of the balloon within the mouth-to-bag resuscitator, the balloon recoils immediately due elasticity and empties itself into the ambient air. Without requiring to squeeze the bag-valve device manually, the mouth-to-bag resuscitator therefore allows both hands instead of one to seal the mask onto the patient's face. The mouth-to-bag resuscitator is designed for use by all levels of health-care providers, especially for first responders without daily experience in bag-valve ventilation. The practicability of this ventilation device had been tested earlier in bench models and compared to special flow-limiting ventilation devices in patients.[4–6] However, the features of mouth-to-bag resuscitator in patients compared to a standard adult bag-valve device are yet unknown. So we ventilated the lungs of 40 apnoeic patients during routine anaesthesia induction randomly with either a standard self-inflating bag or a mouth-to-bag resuscitator. Study endpoints were peak inspiratory flow rates, peak airway pressure,

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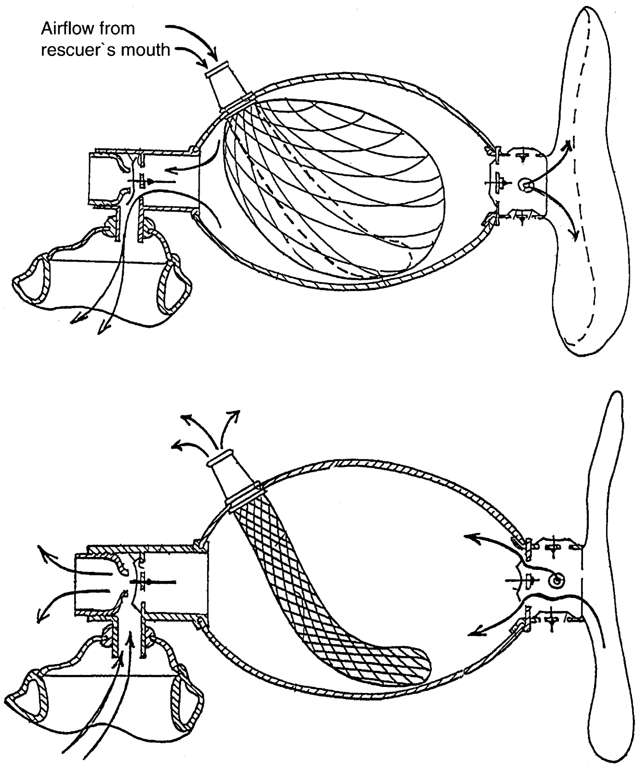

Figure 1. The mouth-to-bag resuscitator requires blowing up a single-use balloon inside the self-inflating bag that subsequently displaces air from the ventilation device into the patient; this manoeuvre enables the rescuer to seal the mask on the manikin's face with two hands. The design enables the rescuer to apply assisted ventilation with ambient air. When supplemental oxygen is added, ventilation with up to 100% may be obtained, since expired air is only used as driving gas. Also, the mouth-to-bag resuscitator may be used as a standard bag-valve-mask ventilation device, rendering its employment flexible.

tidal volumes and inspiratory time. Our formal hypothesis was that there would be no differences between groups.

Materials and methods

With ethics committee approval and written informed consent, we studied 40 healthy adult ASA (ASA; The American Society of Anesthesiologists classification system) physical status I and II patients, with no underlying respiratory or cardiac disease, who were scheduled for routine surgical procedures. Patients were excluded if they had a respiratory disease, oropharyngeal or facial pathology, a body mass index >30 kg m^{-2}, or if they had signs or history of gastro-oesophageal reflux.

After fasting overnight, patients received oral midazolam 7.5 mg 1 h preoperatively. Anaesthesia was in the supine position with the patient's head on a standard pillow 5 cm in height. A standard anaesthesia protocol was followed and with routine monitoring. Fentanyl 1.5 μg kg^{-1} was administered. After preoxygenation for 3 min, anaesthesia was induced with propofol 2.5 mg kg^{-1} given over 30 s and maintained with propofol 8–10 mg kg^{-1} h^{-1}. After loss of lash reflex and confirmation of apnoea, ventilation was started through face mask with the anaesthesia machine with 100% O_2. When ventilation was safe without using any oro- or naso-pharyngeal devices, patients were randomised for ventilation with either a standard bag-valve device or with the mouth-to-bag resuscitator by a single anaesthetist who was blinded to all monitor tracings. Using the mouth-to-bag resuscitator, the anaesthetist sealed the face mask with both hands on the patient's face, and thus held the mouth-to-bag resuscitator as well, since its valve is fixed in the face mask. Then he inflated the elastic balloon inside the mouth-to-bag resuscitator, which, in turn, displaced the oxygen within the bag through the valve and inflated the patient's lungs. Using both the devices, inflation was stopped at the personal discretion of the anaesthetist based on chest movements as he was blinded to all monitor tracings. As the ventilation gas in the mouth-to-bag resuscitator and the balloon that displaces this gas towards the patient (due to inflation by the rescuer) are completely separated and do not mix, we provided ventilation with 100% oxygen after connecting the mouth-to-bag resuscitator to an external oxygen source.

The following data were recorded: oxygen saturation, respiratory rate, non-invasive mean arterial pressure and heart rate throughout the experiment; end-tidal carbon dioxide was recorded only before baseline when the patient was ventilated with the anaesthesia machine. Each patient was ventilated with one bag-valve device for 2 min with a respiratory rate of 15 min^{-1} while respiratory mechanics were being measured with a respiratory monitor (CP-100, Bicore, Irvine, CA, USA) and an oxygen saturation monitor (Datex AS 3, Helsinki, Finland). A blinded examiner performed epigastric auscultation to detect air entering the stomach, which is sufficiently sensitive to detect gastric inflation of more than 4 ml.[7] After the study phase, either a laryngeal mask airway was inserted directly or neuromuscular blocking agents were injected for endotracheal intubation.

Sample size was selected for a type I error of 0.05 and a power of 0.9 and was based on a pilot study of five patients with a measured difference in the peak airway pressure of 30% between the two groups. Statistical analysis was performed with Wilcoxon rank-sum test. Unless otherwise noted, data are presented as mean ± SD. SPSS 12.0 (SPSS Inc., Chicago, IL, USA) was used for analysis and a probability level of $P < 0.05$ was determined to be statistically significant.

Results

There were no important differences in patient characteristics (Table 1). When compared with the standard self-inflating bag, the new mouth-to-bag resuscitator resulted in significantly decreased peak inspiratory flow and peak airway pressure, increased inspiratory tidal volume and longer inspiratory times (Figure 4, Table 2). No stomach inflation was detected; we did not measure any ventilation attempts and patients were apparently apnoeic throughout the study phase. The anaesthetist estimated the work of breathing as moderate using the mouth-to-bag resuscitator, although the fatigue factor was judged higher when compared to the standard bag-valve device.

Table 1
Baseline characteristics of the patients ($n = 40$).

Variable	Standard BVD ($n = 20$)	Mouth-to-bag ($n = 20$)	P
Age (years)	41 ± 12	42 ± 16	NS
Weight (kg)	70 ± 13	73 ± 11	NS
Height (cm)	169 ± 11	172 ± 10	NS
BMI (kg m^{-2})	24 ± 4	25 ± 3	NS
S_pO_2 (%)	98 ± 1	98 ± 1	NS
MAP (mmHg)	95 ± 18	93 ± 17	NS
HR (min^{-1})	77 ± 20	73 ± 6	NS
$etCO_2$ (mmHg)	35 ± 2	34 ± 2	NS
Sex (M:F)	12:8	9:11	
ASA grade;			
1	13 (65%)	12 (60%)	
2	7 (35%)	8 (40%)	

BVD, bag-valve-device; mouth-to-bag, mouth-to-bag resuscitator; BMI, body mass index; S_pO_2, oxygen saturation; MAP, mean arterial pressure; HR, heart rate; $etCO_2$, end-tidal carbon dioxide.