Optimizing bag-valve-mask ventilation with a new mouth-to-bag resuscitator

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Abstract

When ventilating an unintubated patient with a self-inflating bag, high peak inspiratory flow rates may result in high peak airway pressure with subsequent stomach inflation; this may occur frequently when rescuers without daily experience in bag-valve-mask ventilation need to perform advanced airway management. The purpose of this study was to assess the effects of a newly developed self-inflating bag (mouth-to-bag resuscitator; Ambu, Glostrup, Denmark) that limits peak inspiratory flow. A bench model simulating a patient with an unintubated airway was used, consisting of a face mask, manikin head, training lung (lung compliance, 100 ml/0.098 kPa (100 ml/cm H\textsubscript{2}O)); airway resistance, 0.39 kPa/l per second (4 cm H\textsubscript{2}O/l/s), oesophagus (LESP, 1.96 kPa (20 cm H\textsubscript{2}O)) and simulated stomach. Twenty nurses were randomised to ventilate the manikin for 1 min (respiratory rate: 12 per minute) either with a standard self-inflating bag or the mouth-to-bag resuscitator, which requires the rescuer to blow up a single-use balloon inside the self-inflating bag, which in turns displaces air towards the patient. When supplemental oxygen is added, ventilation with up to 100% oxygen may be obtained, since expired air is only used as the driving gas. The mouth-to-bag resuscitator therefore allows two instead of one hand sealing the mask on the patient’s face. The volunteers were blinded to the experimental design of the model until completion of the experimental protocol. The mouth-to-bag resuscitator versus standard self-inflating bag resulted in significantly (*P < 0.05*) higher mean ± S.D. mask tidal volumes (1048 ± 161 vs. 785 ± 174 ml) and lung tidal volumes (911 ± 148 vs. 678 ± 157 ml), longer inspiratory times (1.7 ± 0.4 vs. 1.4 ± 0.4 s), but significantly lower peak inspiratory flow rates (50 ± 9 vs. 62 ± 13 l/min) and mask leakage (10 ± 4 vs. 15 ± 9%); peak inspiratory pressure (17 ± 2 vs. 17 ± 2 cm H\textsubscript{2}O) and stomach tidal volumes (16 ± 30 vs. 18 ± 35 ml) were comparable. In conclusion, employing the mouth-to-bag resuscitator during simulated ventilation of an unintubated patient in respiratory arrest significantly decreased inspiratory flow rate and improved lung tidal volumes, while decreasing mask leakage.

Keywords: Respiration-artificial; Bag-valve ventilation; Unprotected airway; Lung ventilation; Stomach inflation; Basic life support; Mouth-to-bag resuscitator

Resumo

Quando se ventila um doente não intubado com insuflador manual, os elevados fluxos de pico inspiratório podem provocar distensão gástrica; o que pode ocorrer com frequência quando os socorristas sem experiência diária em ventilação insuflador-máscara tem de fazer suporte avançado da via aérea. O objectivo deste estudo foi avaliar os efeitos de um novo auto-insuflador (reanimador boca-máscara; Ambu, Glostrup, Dinamarca) que limita o fluxo inspiratório de pico. Usou-se um modelo com via aérea não intubada e que consistia numa máscara facial, cabeça de manequim e pulmão de treino (compliance pulmonar 100ml (0.098 KPa (100ml/cm H\textsubscript{2}O)); resistência da via aérea 0.39 KPa/l por segundo (4 cmH\textsubscript{2}O/l/s), esófago (LESP, 1.96 KPa (20 cm H\textsubscript{2}O)) e estômago.

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simulado. Foram randomizadas 20 enfermeiras para ventilar o manequim durante 1 minuto (frequência respiratória 12/min) com o auto-insuflador padrão ou com o reanimador boca-insuflador, que necessita que o socorrista encha um balão descartável no interior do insuflador, que por sua vez desloca o ar para o doente. Quando é adicionado oxigênio, pode-se conseguir ventilar com O₂ até 100% já que o ar expirado é utilizado apenas como gás condutor. O reanimador boca-insuflador permite que duas mãos em vez de uma façam a selagem da máscara na face do doente. Os voluntários desconheciam o projecto experimental e o modelo utilizado até cumprirem o protocolo experimental. A comparação do reanimador boca-insuflador vs auto-insuflador padrão resultou em volumes correntes médios ± SD significativamente (P < 0.05) maiores na máscara (1048 ± 161 vs 785 ± 174 ml), volumes correntes pulmonares (911 ± 148 vs 678 ± 157 ml), tempos inspiratórios maiores (1.7 ± 0.4 s vs 1.4 ± 0.4 s), mas taxas de pico de fluxos inspiratórios (50 ± 9 vs 62 ± 13 l/min) e fugas na máscara (10 ± 4 vs 15 ± 9%) significativamente menores; o pico de pressão inspiratória (17 ± 2 vs 17 ± 2 cm H₂O) e volumes correntes no estômago (16 ± 30 vs 18 ± 35 ml) foram comparáveis. Em conclusão, utilizar o reanimador boca-insuflador durante a ventilação simulada de um doente não intubado em paragem respiratória, diminuiu significativamente o fluxo inspiratório, melhorou os volumes pulmonares e diminuiu a fuga na máscara.

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Palavras chave: Respiração artificial; Ventilação insuflador-válvula; Via aérea não protegida; Ventilação pulmonar; Insuflação gástrica; Suporte Básico de Vida; Resuscitador boca-insuflador

Resumen

Cuando se ventila un paciente no intubado con una bolsa autoinflable, los flujos inspiratorios máximos altos pueden resultar en altas presiones máximas de via aérea con insuflación gástrica secuenciente; esto puede ocurrir frecuentemente cuando reanimadores sin experiencia diaria en ventilación con bolsa autoinflable deben realizar manejo avanzado de via aérea. El propósito de este estudio fue evaluar los efectos de una bolsa autoinflable recientemente desarrollada (resucitador boca a bolsa; Ambu, Glostrup, Dinamarca) que limita el flujo inspiratorio máximo. Se usó un modelo que simula un paciente con via aérea no intubada, consistente en una máscara facial, una cabeza de maniquí, un pulmón de entrenamiento (compliance pulmonar, 100 ml/0.098 kPa (100 ml/cm H₂O); resistencia de via aérea, 0.39 kPa/l por segundo (4 cm H₂O/l/s)) esfago y LESP, 1.96 kPa (20 cm H₂O) y un estómago simulado. Se randomizaron 20 enfermeras para ventilar el maniquí por 1 minuto (frecuencia respiratoria: 12 por minuto) con bolsa autoinflable tradicional o el resucitador boca a bolsa, el que requiere que el reanimador infle un balón descartable que solo uso) dentro de la bolsa autoinflable, que a su vez desplazas aire hacia el paciente. Cuando se agrega oxigeno suplementario, la ventilación con hasta un 100% de oxigeno puede ser obtenido, ya que el aire expirado es solamente usado como gas conductor. Por lo anterior, el resucitador boca a bolsa permite usar las dos manos para sellar la máscara en la cara del paciente. Cuando se agrega oxigeno suplementario, la ventilación con hasta un 100% de oxigeno puede ser obtenido, ya que el aire expirado es solamente usado como gas conductor. Por lo anterior, el resucitador boca a bolsa permite usar las dos manos para sellar la máscara en la cara del paciente. Los voluntarios fueron ciegos al diseño experimental del modelo hasta que estuvo completado el protocolo experimental. Al ser comparado el resucitador boca a bolsa con la bolsa autoinflable, este resultó en promedios ± desviación estándar (S.D.) significativamente mayores (P < 0.05) en volumen corriente de máscara (1048 ± 161 vs. 785 ± 174 ml) y volumen corriente pulmonar (911 ± 148 vs. 678 ± 157ml), tiempos inspiratorios mas largos (1.7 ± 0.4 s vs 1.4 ± 0.4s), pero flujos inspiratorios máximos (50 ± 9 vs 62 ± 13 l/min) y filtración por la máscara (10 ± 4 vs 15 ± 9%) significativamente menores; la presión inspiratoria máxima (17 ± 2 vs 17 ± 2 cm H₂O) y los volúmenes corrientes del estómago (16 ± 30 vs 18 ± 35 ml) fueron comparables. En conclusión, el utilizar el resucitador boca a bolsa durante ventilación simulada de un paciente no intubado en paro respiratorio disminuye significativamente la velocidad de flujo inspiratorio y mejora los volúmenes corrientes pulmonares al tiempo de disminuir la filtración de la máscara.

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Palabras clave: Respiración artificial; Ventilación bolsa máscara; Vía aérea no protegida; Ventilación Pulmonar; Insuflación gástrica; Suporte vital básico; Resuscitador boca a bolsa

1. Introduction

Bag-valve-mask ventilation is a standard procedure in the emergency medical service, operating room and various other places. Performing basic life support ventilation with a bag-mask device is regarded as a relatively simple task that can be handled by all healthcare personnel with little training. Unfortunately, it has been shown that due to the respiratory characteristics in an unconscious or cardiac arrest patient, stomach ventilation may be favoured over pulmonary ventilation, so that bag-valve-mask ventilation may cause severe or even fatal ventilation problems [1,2]. During bag-valve-mask ventilation, even experienced paramedics were unable to prevent significant levels of stomach ventilation or employed respiratory rates of ≈ 40 instead of ≈ 15 per minute [3] and inspiratory times of ≈ 0.5 instead of ≈ 1.5 s [4]. At least some of these problems may be related to stress in the rescuer, resulting in increased tidal volumes, increased respiratory rates and shorter inspiratory times. In the past, it has been suggested to make the rescuer aware of these problems with a whistle-type signal if the inspiratory flow is too high, thus preventing forced ventilation; unfortunately, these devices were never marketed. While stress may result in excessive ventilation attempts and subsequent stomach ventilation, the issue of mask leak is less well recognised. In a previous study, mask leak
comprised of up to $\approx 50\%$ of the applied tidal volume [5]. In fact, stomach inflation and mask leak in bag-valve-mask ventilation may not be obvious; accordingly, a non-anaesthesiologist may not be able to distinguish a ventilation problem quickly.

To prevent these ventilation problems, a bag-valve-mask device that limits inspiratory flow and prolongs inspiratory time in order to decrease stomach inflation and decreases mask leak to improve ventilation efficacy has been designed. The mouth-to-bag resuscitator (Ambu, Glostrup, Denmark) allows the rescuer to seal the mask to the face with two hands, while displacing ambient air into the patient’s lungs with mouth-to-mouth ventilation. When supplemental oxygen is added to the mouth-to-bag resuscitator, ventilation with up to 100% oxygen may be obtained, since expired air is only used as driving gas. In addition, it can be used as a conventional bag-valve-mask device. We compared the mouth-to-bag resuscitator with a standard bag-valve-mask device in an established bench model, simulating an unintubated respiratory arrest patient in order to assess their effects on respiratory mechanics, lung and stomach volume. Our hypothesis was that there would be no differences with either ventilation device in regard to study endpoints.

2. Materials and methods

The experimental protocol of this study was approved by the Institutional Review Board of the study institution. Twenty nurses of the Leopold-Franzens-University Hospital, Innsbruck, Austria, certified in basic life support volunteered as participants for this study. All participants were instructed to treat the experimental model as an adult patient in respiratory arrest and to ventilate the manikin in a randomised manner via a face mask with a standard self-inflating bag (max volume: 1.500 ml) or with a new self-inflating bag (mouth-to-bag resuscitator, max volume: 1.500 ml, Ambu), respectively.

In the experimental model, the upper airway was provided by an airway management trainer manikin (Airway Management Trainer, Laerdal, Armonk, NY), with the head fixed in a hyperextended position. After the test lung (LS 800, Draeger, Lübeck, Germany) was connected to the tracheal outlet of the manikin head, lung compliance was adjusted to 100 ml/0.098 kPa (100 ml/cm H$_2$O); airway resistance to 0.39 kPa/l per second (4 cm H$_2$O/l per second)). The oesophageal outlet of the manikin head was connected to an adjustable positive end-expiratory pressure (PEEP) valve, which represented lower oesophageal sphincter pressure that was calibrated to 1.96 kPa (20 cm H$_2$O). A second outlet from the PEEP-valve was connected to a spirometer (Wrights Respirometer) to record gastric inflation. A flow sensor was inserted between either the standard bag-valve-mask ventilation device or the mouth-to-bag resuscitator; another flow sensor was inserted into the simulated trachea to measure lung ventilation. The flow sensors were connected to respiratory monitors to measure ventilation variables.

Fig. 1. Modification of a previously described bench model of positive-pressure ventilation with an unprotected airway. The upper airway was provided by an airway management trainer manikin. The tracheal outlet of the manikin head was connected to a mechanical test lung (lung compliance: 100 ml/0.098 kPa (100 ml/cm H$_2$O); airway resistance: 0.39 kPa/l per second (4 cm H$_2$O/l per second)). The oesophageal outlet of the manikin head was connected to an adjustable positive end-expiratory pressure (PEEP) valve, which represented lower oesophageal sphincter pressure that was calibrated to 1.96 kPa (20 cm H$_2$O). A second outlet from the PEEP-valve was connected to a spirometer (Wrights Respirometer) to record gastric inflation. A flow sensor was inserted between either the standard bag-valve-mask ventilation device or the mouth-to-bag resuscitator; another flow sensor was inserted into the simulated trachea to measure lung ventilation. The flow sensors were connected to respiratory monitors to measure ventilation variables.
Novametrix, Wallingford, CT) was inserted between either the self-inflatable bag or the mouth-to-bag resuscitator and the face mask to measure respiratory variables (Figs. 1–3). The mouth-to-bag resuscitator requires a single-use balloon to be inflated inside the self-inflating bag that subsequently displaces air. When supplemental oxygen is added to the mouth-to-bag resuscitator, ventilation with up to 100% oxygen may be obtained, since expired air is only used as the driving gas. Also, the mouth-to-bag resuscitator may be used as a standard bag-valve-mask device, rendering it flexible in use.

To avoid a biased performance, specific tidal volumes or peak flow rates to be applied were not suggested to the volunteers; however, the tidal volume applied was limited by the size of the self-inflatable bags. Each volunteer performed a 1-min attempt to ventilate the bench model with a self-inflating adult bag with 12 breaths per minute, while the study endpoints were recorded. The manikin, except for the head, was covered with a cloth to blind the rescuers to the measurement of stomach inflation and lung ventilation. However, the rescuers were able to watch the artificial lungs rise during ventilation, as in a clinical situation. The design of the model and the results of the measurements were revealed to the volunteers only after the experiment was completed.
All values are expressed as mean ± S.D. Mask leakage was calculated by subtracting expiratory mask tidal volume and stomach tidal volume from inspiratory mask tidal volume; this value was subsequently calculated to reflect a percentage. Comparisons were made with one-factor analysis of variance and with Newman–Keul’s multiple comparison procedure. Alpha was set at 0.05 for statistical significance.

3. Results

Twenty nurse volunteers (nine women, 11 men) certified in basic life support performed bag-mask ventilation with a standard adult self-inflating bag or with the mouth-to-bag resuscitator. The mouth-to-bag resuscitator versus standard self-inflating bag resulted in significantly ($P < 0.05$) higher mean ± S.D. mask tidal

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**Fig. 3.** Representative inspiratory flow and peak airway pressure tracings of a standard self-inflating bag and mouth-to-bag resuscitator.
Table 1
Effects of the mouth-to-bag resuscitator on respiratory variables in a bench model of a patient with an unprotected airway

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standard BVM</th>
<th>Mouth-to-bag resuscitator</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mask tidal volume (ml)</td>
<td>785±174</td>
<td>1048±161</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Peak inspiratory flow (l/min)</td>
<td>62±13</td>
<td>50±9</td>
<td>&lt;0.0028</td>
</tr>
<tr>
<td>Peak inspiratory pressure (cm H₂O)</td>
<td>17±2</td>
<td>17±2</td>
<td>NS</td>
</tr>
<tr>
<td>Inspiratory time (s)</td>
<td>1.4±0.4</td>
<td>1.7±0.4</td>
<td>&lt;0.0022</td>
</tr>
<tr>
<td>Lung tidal volume (ml)</td>
<td>678±157</td>
<td>911±148</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stomach tidal volume (ml)</td>
<td>18±35</td>
<td>16±30</td>
<td>NS</td>
</tr>
<tr>
<td>Leakage (%)</td>
<td>15±9</td>
<td>10±4</td>
<td>&lt;0.042</td>
</tr>
</tbody>
</table>

Results are given as mean ± S.D.; standard BVM, standard self-inflating bag-valve-mask device; mouth-to-bag resuscitator as described in Section 2; NS, nonsignificant.

4. Discussion

The distribution of ventilation volume between lungs and stomach in an unprotected airway depends on patient variables, such as lower oesophageal sphincter pressure, airway resistance and respiratory system compliance; and components applied by the rescuer, such as inspiratory flow rate and time and upper airway pressure [6]. Since lower oesophageal sphincter pressure may decrease shortly after cardiac arrest from 1.96 to 0.49 kPa (≈ 20–5 cm H₂O) during the first 5 min of untreated cardiac arrest [7] and respiratory system compliance decreases from ≈100 to ≈ 50 ml/0.098 kPa (≈ 100–50 ml/cm H₂O) [8,9], the respiratory mechanics of a simulated cardiac arrest victim may actually favour stomach inflation instead of lung ventilation. This phenomenon may subsequently result in a ‘vicious circle’ of increasing stomach inflation and decreasing lung ventilation and subsequent catastrophic complications [10,11]. While the adverse conditions in a cardiac arrest patient for ventilation with an unprotected airway may be relatively obvious, problems in a respiratory arrest patient may also be present as well. In this study, we have assessed the safety and efficacy of the mouth-to-bag resuscitator in comparison with a standard bag-valve-mask device in a clinically realistic bench model simulating an unintubated respiratory arrest patient. We found that the mouth-to-bag resuscitator versus standard self-inflating bag increased inspiratory times and decreased mask leak significantly. Although the mouth-to-bag resuscitator resulted in ≈35% greater lung tidal volumes, stomach inflation was not increased compared with standard bag-valve-mask ventilation.

We have shown in numerous studies that decreasing tidal volumes from ≈1000 to ≈500 ml when ventilating a patient with an unprotected airway may be a good trade-off for basic life support ventilation to provide reasonable ventilation, while avoiding massive gastric inflation [12,13]. Accordingly, the both the American Heart Association and the European Resuscitation Council now recommend 6–7 ml/kg body weight (≈ 500 ml) tidal volume with an FIO₂ > 0.4 for bag-valve-mask ventilation of a cardiac arrest victim [14,15]. Although this strategy reflects a certain built-in protocol for bag-valve-mask ventilation, high peak flow rates of ≈120 l/min and the usual ≈25–40% mask leak are significant issues that are left uncontrolled. If two hands instead of one are used to seal the mask on the patient’s face, mask leak may be substantially decreased [16]. Further, if peak flow rate and therefore peak airway pressure, is kept below a certain level, stomach inflation possibly could be minimised [17]. In our study, prolonged inspiratory times with the mouth-to-bag resuscitator resulted in reduced inspiratory flow; interestingly, this did not result in decreased peak airway pressure. Although reducing the inspiratory flow with the mouth-to-bag resuscitator would suggest that a reduction in stomach ventilation is likely, this was not the case. For both ventilation devices, stomach ventilation was comparable. However, both mask and lung tidal volumes with the mouth-to-bag resuscitator were ≈35% greater than with the standard bag-valve-mask ventilation device; stomach ventilation with the mouth-to-bag resuscitator should have been greater by this amount, but did not occur. Accordingly, the benefit of the mouth-to-bag resuscitator with regard to reducing stomach ventilation was masked by a substantially greater tidal volume. Extrapolating these results to comparable tidal volumes in both groups, the mouth-to-bag resuscitator will most likely decrease stomach inflation. This needs to be confirmed in future studies.

The mouth-to-bag resuscitator enables a single rescuer to seal the mask with two hands, while blowing up a single-use balloon inside the device that displaces air. The force of gas flow into the patient is less powerful compared with gas flow induced by manually squeezing...
a standard bag-valve-mask ventilation device. We have observed in the past that when a rescuer observes a decreased chest rise and therefore decreased lung tidal volumes, bag-valve-mask ventilation tends to be performed in a more forceful manner [4]. While this reaction seems to be understandable at first sight, it paradoxically reflects a strategy that increases inspiratory flow, inspiratory pressure and therefore, stomach inflation. Thus, a well-mean intention to ventilate the patient adequately may cause a catastrophic ‘vicious circle’ of increasing stomach ventilation and decreasing lung ventilation [1]. The mouth-to-bag resuscitator may prevent these problems due to its built-in safety features. Forceful ventilation attempts are limited simply by the force from the rescuer’s cheeks and not their hands. Thus, this device may be able to provide built-in patient safety in terms of controlling mask leak, tidal volume and peak flow rate. In addition, this device can be used as a standard bag-valve-mask ventilation device as well, rendering it a flexible device with rapid use possible.

Some limitations in our study should be noted. First, although the components of respiratory mechanics in our bench model have been carefully chosen, they cannot exactly duplicate the respiratory mechanics in an unconscious or cardiac arrest patient. Second, the only information about lower oesophageal sphincter pressure changes following cardiac arrest is from an animal investigation; investigations about lower oesophageal sphincter pressure physiology in human beings have not been carried out yet. However, some lower oesophageal sphincter pressure reduction after respiratory or cardiac arrest in human beings may be assumed, as suggested by the high incidence of regurgitation and aspiration in victims of cardiac arrest [17], especially when the phase of ventilation with an unprotected airway is prolonged [18]. Thirdly, the stomach in our model was represented by a volumeter only and had no compliance. Also, since no randomised controlled clinical trial evaluating the mouth-to-bag resuscitator has been performed to date, the present data must be deemed to be preliminary and its value needs to be confirmed.

In conclusion, employing the mouth-to-bag resuscitator during simulated ventilation of an unintubated patient in respiratory arrest significantly decreased inspiratory flow rate and improved lung tidal volumes, while decreasing mask leakage.

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