Preoxygenation With Flush Rate Oxygen: Comparing the Nonrebreather Mask With the Bag-Valve Mask

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Study objective: Nonrebreather masks and bag-valve masks are used for preoxygenation before emergency intubation. Flush rate oxygen delivered with a nonrebreather mask is noninferior to bag-valve mask oxygen at 15 L/min. We seek to compare the nonrebreather mask with flush rate oxygen to a bag-valve mask with flush rate oxygen (with and without inspiratory assistance) and determine whether the efficacy of bag-valve mask with flush rate oxygen is compromised by a simulated mask leak.

Methods: We conducted 2 prospective studies in healthy, adult volunteers. All devices in both studies used flush rate oxygen, achieved by rotating the flowmeter dial counterclockwise until it could not be rotated farther, which delivered oxygen at 40 to 60 L/min. Study 1 compared preoxygenation with nonrebreather mask to bag-valve mask (modified with a one-way exhalation port) with and without a simulated mask leak. Study 2 compared nonrebreather mask to bag-valve mask with inspiratory assistance. The primary outcome was FeO_2. For each comparison, we prespecified a noninferiority margin of FeO_2 for the nonrebreather mask (compared with the bag-valve mask, bag-valve mask with mask leak, and bag-valve mask with assistance) of 10%.

Results: Thirty subjects were enrolled in study 1 and 27 subjects were enrolled in study 2. For study 1, mean FeO_2 values for nonrebreather mask, bag-valve mask, and bag-valve mask with leak were 81% (95% confidence interval [CI] 78% to 83%), 76% (95% CI 71% to 81%), and 30% (95% CI 26% to 35%), respectively. FeO_2 for the nonrebreather mask was noninferior to the bag-valve mask at flush rate (difference 5%; 95% CI –1% to 10%). FeO_2 was higher for the nonrebreather mask compared with the bag-valve mask with a simulated mask leak (difference 51%; 95% CI 46% to 55%). For study 2, mean FeO_2 values for nonrebreather mask and bag-valve mask with assistance were 83% (95% CI 80% to 86%) and 77% (95% CI 73% to 80%), respectively. FeO_2 for the nonrebreather mask was noninferior to the bag-valve mask with assistance at flush rate (difference 6%; 95% CI 3% to 10%).

Conclusion: With flush rate oxygen, the nonrebreather mask is noninferior to the bag-valve mask, with and without inspiratory assistance. Bag-valve mask performed poorly with a mask leak, even with flush rate oxygen. Flush rate oxygen with a nonrebreather mask is a reasonable default preoxygenation method in spontaneously breathing patients with no underlying respiratory pathology. [Ann Emerg Med. 2018;71:381-386.]

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INTRODUCTION

Background

Hypoxemia is a frequent and unwanted complication of emergency intubation.[1] Emergency physicians perform preoxygenation for patients undergoing rapid sequence intubation to reduce the risk of peri-intubation hypoxemia by replacing alveolar nitrogen with a reservoir of oxygen. Both bag-valve masks and nonrebreather masks are commonly used to deliver high concentrations of oxygen during preoxygenation. At the traditional oxygen flow rate of 15 L/min, the nonrebreather mask provides suboptimal preoxygenation.[2-4] Increasing oxygen flow to the flush rate (achieved by rotating the flowmeter dial counterclockwise until it cannot be rotated farther) with the nonrebreather mask provides preoxygenation similar to that of the bag-valve mask at 15 L/min.[4]

Importance

Although preoxygenation with a flush rate nonrebreather mask is easy to perform in spontaneously breathing patients, many emergency physicians prefer to use a bag-valve mask (which requires maintenance of a tight seal and the presence of a one-way exhalation valve to achieve adequate

Editor's Capsule Summary

What is already known on this topic

The nonrebreather mask and bag-valve mask are often used to provide oxygenation before intubation. Creating an adequate seal and timing respirations with a bag-valve mask can be challenging.

What question this study addressed

Is nonrebreather mask with flush rate oxygen flow noninferior to bag-valve mask preoxygenation?

What this study adds to our knowledge

In this randomized crossover trial of approximately 30 healthy volunteers, nonrebreather mask with flush rate oxygen was noninferior to bag-valve mask with flush rate oxygen, both with and without inspiratory assistance and without a simulated mask leak, however, bag-valve mask with a simulated mask leak was inferior.

How this might change clinical practice

Providers may elect to preoxygenate with a nonrebreather mask at flush rate oxygen instead of bag-valve mask.

preoxygenation)[3,5] and sometimes squeeze the bag in synchrony with patient inspiration, with the goal of augmenting oxygen delivery. These elements required for adequate bag-valve mask preoxygenation divert emergency physicians physically and cognitively from other important resuscitation tasks. However, if the bag-valve mask can provide better preoxygenation than the nonrebreather mask by using flush rate oxygen or by synchronizing bag squeezes with patient inspiration, the additional elements required for bag-valve mask preoxygenation may be worthwhile.

Goals of This Investigation

We sought to determine whether preoxygenation with a nonrebreather mask with flush rate oxygen was noninferior to bag-valve mask with flush rate oxygen, with and without inspiratory assistance (synchronizing bag squeezing with inspiration), with a primary outcome of FeO_2. We secondarily sought to determine whether the efficacy of bag-valve mask with flush rate oxygen was compromised by a simulated mask leak.

MATERIALS AND METHODS

Setting

We performed 2 crossover studies with healthy volunteers. Both studies occurred in the Hennepin County Medical Center Emergency Department. The local institutional review board approved this study; all subjects provided written informed consent.

Selection of Participants

Emergency department (ED) personnel older than 17 years were asked to volunteer for this investigation. Those with facial hair more than stubble were excluded because of potential difficulty in maintaining a mask seal; pregnant women were also excluded. We did not screen for any medical comorbidities.

Interventions

Two parallel investigations were performed in healthy subjects. In each study, subjects underwent multiple trials of preoxygenation in random sequence, all at flush flow rate.[4] In the first study, subjects underwent 3 trials: nonrebreather mask, bag-valve mask, and bag-valve mask with a simulated mask leak. In the second study, subjects underwent 2 trials: nonrebreather mask and bag-valve mask with inspiratory assistance. The sequence of techniques in the trials was randomized with a balanced Latin square design. We used standard adult respiratory equipment available in our ED, as described previously.[4] Bag-valve masks in our department do not have built-in one-way exhalation valves, so a one-way disk-type valve (model 533-MS-PMVEA; MedSource International, Chaska, MN) was added to the exhalation port of the bag-valve mask to ensure that subjects breathed air from the reservoir bag rather than room air.[5]

A mask leak was simulated by taping a 16-French nasogastric tube in place across the upper lip, extending to both cheeks, as used in previous studies.[3] Inspiratory assistance was provided by an investigator who squeezed the bag in synchrony with subject inspiration: at the start of inspiration, as detected by chest rise and inspiratory valve opening, the bag was squeezed; squeezing continued until the inspiratory phase ended. Outside of this study, to determine how much positive pressure was administered during this type of inspiratory assistance, we measured the highest pressure achieved during bag squeezing synchronized with inspiration. The pressures observed in healthy volunteers were 1 to 2 cm H_2O.

Subjects lay supine on a bed, with the head elevated to 30 degrees. Baseline FeO_2 values were obtained before the first preoxygenation trial. For each preoxygenation trial, the subject performed tidal breathing for 3 minutes.

The nonrebreather mask and bag-valve mask reservoirs were filled with oxygen for 15 seconds to ensure they contained 100% oxygen before being applied to the participant's face. In the first study, the subject held the bag-valve mask tightly against his or her face and could adjust the mask if a leak was perceived by the subject or detected by a study investigator. In the second study, the investigator maintained a tight one-handed bag-valve mask seal while assisting inhalation. This technique was used to simulate the widespread practice of a one-handed seal and bagging synchronized with inspiration, as opposed to the more effective 2-handed mask seal, which is normally used at our institution.[6,7] In both studies, the nonrebreather mask was placed on the face; the metal clip was compressed against the bridge of the nose and the elastic headband was tightened.

A standard oxygen flowmeter with gradations 0 to 15 L/min was used for all trials (model 8MFA; Precision Medical, Northampton, PA; maximum marked flush rate 40 to 60 L/min). Flush rate was achieved by rotating the flowmeter dial counterclockwise until it could not be turned farther. This has previously been measured to deliver between 50 and 54 L/min in our ED.[4]

Methods of Measurement and Outcome Measures

The primary outcome was FeO_2, measured at the end of each preoxygenation trial, and was selected because it quantifies denitrogenation. In healthy patients, FeO_2 at baseline is less than 20% and increases as oxygen replaces nitrogen in the lungs during preoxygenation. A high FeO_2 (high level of denitrogenation) is a necessary component of adequate preoxygenation, but it does not always reflect adequate preoxygenation (eg, a patient with acute respiratory distress syndrome may have a high FeO_2 but will also have a high alveolar-arterial gradient, making the large pulmonary oxygen reservoir difficult to access).[8] FeO_2 was measured with an oxygen gas analyzer (Handi+, model R218P12; Maxtec, Salt Lake City, UT) with a manufacturer-reported accuracy within 1% to 3%. The oxygen gas analyzer was calibrated with 100% oxygen before each preoxygenation trial.

After the 3-minute preoxygenation phase, the preoxygenation device was removed and the subject began a 10-second breath-holding period. The subject then exhaled completely during several seconds into a 15-cm-long tube (internal diameter 5 mm) connected to the gas analyzer. FeO_2 was recorded as the maximum oxygen concentration displayed at the end of exhalation. Measurements were recorded by the authors (K.C. and J.H.). Neither the investigators nor subjects were blinded to the preoxygenation device. Each trial was followed by at least 2 minutes of breathing room air to wash out the excess oxygen from the lungs. To verify adequate renitrogenation, the FeO_2 for each subject was measured between trials; the next trial could begin only after FeO_2 level had returned to the subject's baseline value.

Primary Data Analysis

The primary comparison for both investigations was whether FeO_2 after preoxygenation with a nonrebreather mask with flush rate oxygen was noninferior to the bag-valve mask device at flush rate (study 1) and the bag-valve mask device at flush rate with assistance (study 2), with a noninferiority margin of 10%; that is, if the lower limit of the 95% confidence interval (CI) for the mean FeO_2 for the nonrebreather mask was higher than the mean FeO_2 minus 10% for the bag-valve mask device groups, the nonrebreather mask group would be considered noninferior. A 10% absolute difference in FeO_2 was deemed to be clinically significant because this would provide approximately 1 additional minute of safe apnea time in a normal adult with average lung volumes. Previous evidence suggests that bag-valve mask preoxygenation at 15 L/min achieves FeO_2 of approximately 80%, with an SD of approximately 10%.[2-4] We therefore estimated needing 26 subjects in each study to have 80% power for a test of noninferiority with an absolute difference of 10% at a significance level of .05. We report the difference in mean FeO_2 and the associated 95% CIs between study interventions; the differences in means accounted for clustering by individual subject. All statistical testing was performed with Stata (version 12.1; StataCorp, College Station, TX).

RESULTS

For study 1, of the 30 subjects enrolled, mean age was 23 years (SD 4 years), 12 were men, and mean body mass index was 18 kg/m^2 (SD 3 kg/m^2). Baseline FeO_2 values and FeO_2 values after preoxygenation are displayed in Table 1. FeO_2 after nonrebreather mask at the flush rate was noninferior to bag-valve mask at the flush rate (FeO_2 difference 5%; 95% CI –1% to 10%). FeO_2 after flush rate nonrebreather mask was higher than flush rate bag-valve

Table 1. Mean FeO_2 values for study 1 (nonrebreather mask, bag-valve mask, and bag-valve mask with mask leak).

Study Group	Mean FeO_2, % (95% CI)
Baseline	16 (16–17)
NRB at flush	81 (78–83)
BVM at flush	76 (71–81)
BVM with simulated mask leak at flush	30 (26–35)

NRB, Nonrebreather mask; *BVM*, bag-valve mask.

mask with a mask leak (FeO_2 difference 51%; 95% CI 46% to 55%). Subject-level data are presented in Figure 1.

For study 2, of the 27 enrolled subjects, mean age was 23 years (SD 5 years), 13 were men, and mean body mass index was 24 kg/m^2 (SD 4 kg/m^2). Baseline FeO_2 values and FeO_2 values after preoxygenation are displayed in Table 2. FeO_2 after flush rate nonrebreather mask was noninferior to flush rate bag-valve mask with the bag squeezed in synchrony with inhalation (FeO_2 difference 6%; 95% CI 3% to 10%). Subject-level data are presented in Figure 2.

LIMITATIONS

Results of studies that enroll healthy volunteers can be difficult to generalize to critically ill ED patients undergoing intubation. However, these data should apply to most spontaneously breathing ED patients, provided they are not hypoventilating or intrapulmonary shunt physiology is not present (in which case preoxygenation with positive pressure is usually required).[9] Additionally, if a patient's maximum inspiratory flow rate exceeds the oxygen flow rate (sometimes observed in severe dyspnea), room air will be entrained and the fraction of inspired oxygen will decrease.[10]

We added a one-way exhalation valve to our standard bag-valve mask. Bag-valve masks without one-way exhalation valves are present in many EDs and will perform poorly for spontaneously breathing patients because mostly room air is inspired.[5] Although we used a standard flowmeter, which was present in our ED, not all flowmeters can achieve flow rates greater than 40 L/min. The maximal flow rate is usually marked on the side of the flowmeter. Some experts advocate the purchase and use of flowmeters with higher marked gradations (to 70 L/min) for preoxygenation, which are commercially available.[11]

Subjects in study 1 held the bag-valve mask against their face while both the subject and investigator monitored for an air leak. In study 2, a one-handed mask seal was used instead of the preferred 2-handed seal.[6,7] Although these 2 techniques allow the possibility of a mask leak for some subjects, our FeO_2 values in the bag-valve mask groups in both studies were similar to those of previous studies in which the investigator maintained a tight mask seal.[2,3] Additionally, if even small leaks that are difficult to perceive threaten adequate preoxygenation, this speaks to the limitation of the bag-valve mask as a preoxygenation device in spontaneously breathing patients.

Table 2. Mean FeO_2 values for study 2 (nonrebreather mask and bag-valve mask with synchronized bag squeezing).

Study Group	Mean FeO_2, % (95% CI)
Baseline	16 (15–16)
NRB at flush	83 (80–86)
BVM at flush with assistance	77 (73–80)

DISCUSSION

In this study of healthy volunteers undergoing trials of preoxygenation with flush rate oxygen with different masks, we observed that the nonrebreather mask is noninferior to the bag-valve mask, whether or not the bag is squeezed for

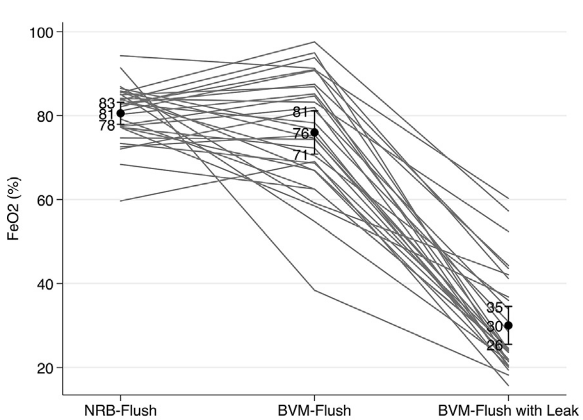

Figure 1. FeO_2 values by device. Each subject's data are displayed as a single line denoting the FeO_2 achieved with each respective device. *Flush*, Flush rate.

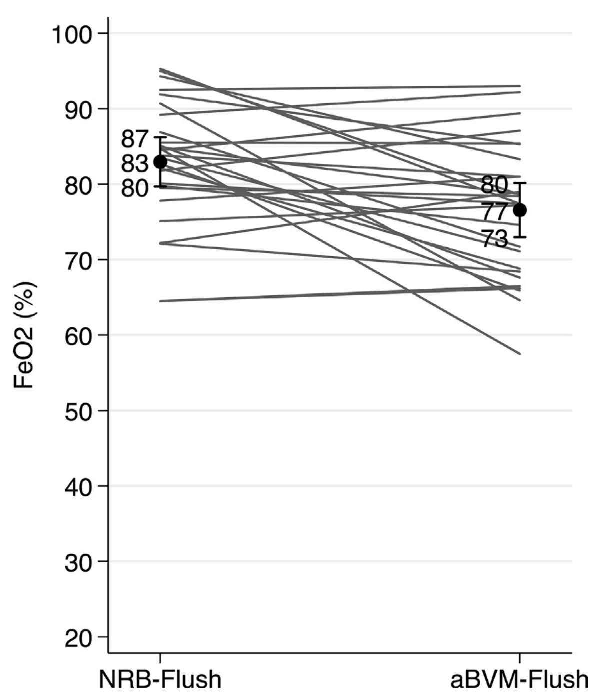

Figure 2. FeO_2 values by device. Each subject's data are displayed as a single line denoting the FeO_2 achieved with each respective device. *aBVM*, BVM with inspiratory assistance.

synchronous inspiratory airflow during spontaneous breathing. Additionally, the bag-valve mask performed poorly when a simulated mask leak was present, even when flush rate oxygen was used. A simple preoxygenation method is highly desirable before emergency intubation. Because the nonrebreather mask performs like the bag-valve mask yet is simpler to use, these data support the nonrebreather mask as a reasonable default preoxygenation device for spontaneously breathing ED patients who do not require positive pressure for preoxygenation. Positive pressure would be required for spontaneously breathing patients with hypoventilation and those with shunt physiology from pneumonia, atelectasis, or other pathology that prevents achievement of an oxygen saturation greater than 95% after a preoxygenation attempt with a source delivering high concentrations of oxygen.[9]

A nonrebreather mask at flush rate oxygen was recently demonstrated to be noninferior to the bag-valve mask with oxygen at 15 L/min.[4] The current study demonstrates that increasing the bag-valve mask flow to flush rate does not improve the performance of the bag-valve mask; this is intuitive because if a good mask seal is maintained, the patient inspires 100% oxygen both at 15 L/min and at flush rate, provided that no room air is entrained during inspiration (which should not occur unless the patient's minute ventilation exceeds the flow rate).

Squeezing the bag-valve mask bag in synchrony with patient inspiration is common for preoxygenation and is believed to augment oxygen delivery to spontaneously breathing patients, perhaps by making it more likely that inspired air is received from the bag and room air is not entrained from the exhalation port (if no one-way valve is present) or from around the mask if a small leak is present. These data indicate that even with this practice, which requires a tight mask seal and extra attention paid to the patient's respiratory cycle, the preoxygenation achieved is similar to that with the nonrebreather mask at flush rate. The provision of positive inspiratory pressure during preoxygenation has previously been shown to speed time to adequate preoxygenation and delay hypoxemia during apnea.[12,13] However, the preoxygenation technique of timing bag squeezing with inspiration in patients with adequate ventilation provides only a small amount of positive pressure (1 to 2 cm H_2O) and should not be viewed as a technique that provides meaningful positive pressure. The addition of positive end-expiratory pressure can improve preoxygenation when a continuous or bilevel positive airway pressure machine is used.[14,15] Although it is possible that the addition of a positive end-expiratory pressure valve to the bag-valve mask in this study would have improved bag-valve mask FeO_2, a previous study of spontaneously breathing healthy volunteers demonstrated that comparable FeO_2 values were obtained by bag-valve mask and bag-valve mask+positive end-expiratory pressure valve.[2]

In a recent study, bag-valve mask preoxygenation with oxygen at 15 L/min was poor when a simulated mask leak was created.[3] In the current study, flush rate oxygen did not mitigate this poor performance. Bag-valve masks have inspiratory valves that open only with sufficient positive or negative pressure; oxygen is delivered only if the bag is squeezed or the patient creates enough negative pressure with inhalation to open the valve.[16] For many subjects in the current study, the bag-valve mask leak prevented attainment of the tight seal required to generate negative pressure to open the inspiratory valve, and only room air was inspired. With a high enough oxygen flow rate, it may be possible to generate a small amount of positive pressure inside the bag-valve mask, which would open the inspiratory valve, allowing some oxygen delivery. We did not measure this, but if it occurred in this study, the effect was negligible. These data also refute the practice of allowing a bag-valve mask to hover above a patient's face, which, analogous to significant mask leak, provides no supplemental oxygen.

In summary, when flush rate oxygen is used the nonrebreather mask is noninferior to the bag-valve mask, whether or not inspiratory airflow is augmented by squeezing the bag. The bag-valve mask at flush rate oxygen performs poorly in the presence of a mask leak. In accordance with these data, the nonrebreather mask with flush rate oxygen is a reasonable default preoxygenation technique for spontaneously breathing patients with no underlying respiratory pathology.

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REFERENCES

1. Bodily JB, Webb HR, Weiss SJ, et al. Incidence and duration of continuously measured oxygen desaturation during emergency department intubation. *Ann Emerg Med*. 2016;67:389-395.
2. Groombridge C, Chin CW, Hanrahan B, et al. Assessment of common preoxygenation strategies outside of the operating room environment. *Acad Emerg Med*. 2016;23:342-346.
3. Hayes-Bradley C, Lewis A, Burns B, et al. Efficacy of nasal cannula oxygen as a preoxygenation adjunct in emergency airway management. *Ann Emerg Med*. 2016;68:174-180.
4. Driver BE, Prekker ME, Kornas RL, et al. Flush rate oxygen for emergency airway preoxygenation. *Ann Emerg Med*. 2017;69:1-6.
5. Nimmagadda U, Ramez Salem M, Joseph NJ, et al. Efficacy of preoxygenation with tidal volume breathing: comparison of breathing systems. *Anesthesiology*. 2000;93:693-698.
6. Hart D, Reardon R, Ward C, et al. Face mask ventilation: a comparison of three techniques. *J Emerg Med*. 2013;44:1028-1033.
7. Joffe AM, Hetzel S, Liew EC. A two-handed jaw-thrust technique is superior to the one-handed "EC-clamp" technique for mask ventilation in the apneic unconscious person. *Anesthesiology*. 2010;113:873-879.
8. Mosier JM, Hypes CD, Sakles JC. Understanding preoxygenation and apneic oxygenation during intubation in the critically ill. *Intensive Care Med*. 2017;43:226-228.
9. Weingart SD, Levitan RM. Preoxygenation and prevention of desaturation during emergency airway management. *Ann Emerg Med*. 2012;59:165-175.e1.
10. Ooi R, Joshi P, Soni N. A high flow semi-open system for preoxygenation: an evaluation. *Br J Anaesth*. 1992;68:39-42.
11. Sakles JC. Maintenance of oxygenation during rapid sequence intubation in the emergency department. *Acad Emerg Med*. 2017; https://doi.org/10.1111/acem.13271.
12. Hanouz J-L, Lammens S, Tasle M, et al. Preoxygenation by spontaneous breathing or noninvasive positive pressure ventilation with and without positive end-expiratory pressure: a randomised controlled trial. *Eur J Anaesthesiol*. 2015;32:881-887.
13. Baillard C, Fosse J-P, Sebbane M, et al. Noninvasive ventilation improves preoxygenation before intubation of hypoxic patients. *Am J Respir Crit Care Med*. 2006;174:171-177.
14. Herriger A, Frascarolo P, Spahn DR, et al. The effect of positive airway pressure during pre-oxygenation and induction of anaesthesia upon duration of non-hypoxic apnoea. *Anaesthesia*. 2004;59:243-247.
15. Gander S, Frascarolo P, Suter M, et al. Positive end-expiratory pressure during induction of general anesthesia increases duration of nonhypoxic apnea in morbidly obese patients. *Anesth Analg*. 2005;100:580-584.
16. Khoury A, Hugonnot S, Cossus J, et al. From mouth-to-mouth to bag-valve-mask ventilation: evolution and characteristics of actual devices—a review of the literature. *Biomed Res Int*. 2014;2014:762053.