



Flush Rate Oxygen for Emergency Airway Preoxygenation

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Study objective: Recent data suggest that emergency airway preoxygenation with a bag-valve-mask (BVM) device (held with a tight mask seal but without squeezing the bag) is superior to a nonrebreather (NRB) mask at standard oxygen flow rates. We seek to determine whether preoxygenation with an NRB mask with flush rate oxygen (>40 L/min by fully opening a standard oxygen flowmeter) is noninferior to BVM device with standard-flow oxygen (15 L/min). We also seek to compare the efficacy of preoxygenation with NRB mask at flush rate oxygen with both NRB mask with oxygen at 15 L/min and simple mask at flush rate oxygen.

Methods: We performed a crossover trial using healthy volunteers. In random sequence, subjects underwent 3-minute trials of preoxygenation with nonrebreather mask with oxygen at 15 L/min (NRB-15), nonrebreather mask with flush rate oxygen (NRB-Flush), BVM device with oxygen at 15 L/min (BVM-15), and simple mask with flush rate oxygen. The primary outcome measure was the FeO₂ in a single exhaled breath. We compared the FeO₂ of NRB-Flush to other study groups, using a prespecified noninferiority margin of 10%.

Results: We enrolled 26 subjects. Mean FeO₂ values for NRB-15, NRB-Flush, BVM-15, and simple mask with flush rate oxygen were 54% (95% confidence interval [CI] 50% to 57%), 86% (95% CI 84% to 88%), 77% (95% CI 74% to 81%), and 72% (95% CI 69% to 76%), respectively. FeO₂ for NRB-Flush was noninferior to BVM-15 (difference 8%; 95% CI 5% to 11%). FeO₂ for NRB-Flush was higher than both NRB-15 (FeO₂ difference 32%; 95% CI 29% to 35%) and simple mask with flush rate oxygen (FeO₂ difference 13%; 95% CI 10% to 17%).

Conclusion: Preoxygenation with NRB-Flush was noninferior to BVM-15. NRB with flush rate oxygen may be a reasonable preoxygenation method for spontaneously breathing patients undergoing emergency airway management. [Ann Emerg Med. 2017;69:1-6.]

Please see page 2 for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

Oxygen desaturation is an important and unwanted adverse event of emergency airway management.¹ Clinicians often perform preoxygenation to reduce the risk of hypoxemia during airway management. Although preoxygenation is widely practiced, the optimal method for it remains unclear. Common devices used for preoxygenation in the emergency department (ED) for spontaneously breathing patients include the bag-valve-mask (BVM) device, the simple face mask, and the nonrebreather (NRB) mask.

In the spontaneously breathing patient, effective preoxygenation with a BVM device requires a 1-way

valve at the exhalation port and a tight mask seal against the face. Many standard BVM devices do not have built-in 1-way valves, resulting in a fraction of delivered oxygen similar to room air.² Also, many critically ill ED patients requiring intubation are dyspneic or agitated and unable to tolerate the required tight mask seal.³ An NRB mask with oxygen flow at 15 L/min similarly delivers a relatively low fraction of inspired oxygen inadequate for preoxygenation.^{4,5}

Older studies suggest that a face mask with high flow rate oxygen (48 L/min) can effectively denitrogenate the lungs.^{6,7} High “flush rate” oxygen flow can be achieved with most standard medical oxygen flowmeters by turning the adjustor knob past the highest gradation on the flowmeter until it cannot be rotated farther.

Editor's Capsule Summary*What is already known on this topic*

Before emergency airway management, clinicians commonly perform preoxygenation using bag-valve-mask (BVM) device or nonrebreather (NRB) mask.

What question this study addressed

Is preoxygenation by NRB mask with flush rate oxygen as good as BVM device at 15 L/min?

What this study adds to our knowledge

In this randomized trial on 26 healthy volunteers, the FeO_2 for flush rate NRB mask was noninferior to BVM device at 15 L/min.

How this is relevant to clinical practice

Although requiring validation in clinical emergency department patients, flush rate oxygen by NRB mask may aid emergency airway management preoxygenation efforts.

Importance

If an NRB mask at a high flow rate could perform similarly to a BVM device in spontaneously breathing patients, then effective preoxygenation could be achieved without the need for a BVM device with a 1-way valve and the burden of maintaining a tight mask seal during preoxygenation.

Goals of This Investigation

In this study of healthy volunteers, we sought to determine whether preoxygenation with an NRB mask with flush rate oxygen is noninferior to BVM device with oxygen at 15 L/min. We also sought to compare the preoxygenation efficacy of an NRB mask with flush rate oxygen to an NRB mask with oxygen at 15 L/min and a simple mask with flush rate oxygen.

MATERIALS AND METHODS**Study Design and Setting**

We performed a crossover study using healthy volunteers to mirror 2 recent studies.^{4,5} All trials were conducted in the Hennepin County Medical Center Emergency Department. The local institutional review board approved this study; all subjects provided informed consent.

Selection of Participants

ED staff were asked to volunteer for this investigation. Exclusion criteria included symptomatic respiratory disease at participation, smoking history greater than 5 pack-years, pregnancy, or younger than 18 years. We included subjects

with a history of well-controlled chronic respiratory disease (eg, asthma), as well as subjects with facial hair.

Interventions

After informed consent, each subject underwent 4 trials of preoxygenation in random sequence: NRB mask with oxygen at 15 L/min (NRB-15), NRB mask with flush rate oxygen (NRB-Flush), BVM with oxygen at 15 L/min, and simple mask with flush rate oxygen. 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 sequence of the 4 trials was randomized with a balanced Latin square design so that the order of trials of 1 participant was completed in the opposite order of that of another participant.

We used standard adult respiratory equipment in the trial (NRB mask: model 1059, Hudson RCI, Research Triangle Park, NC; simple mask: model 1041, Hudson RCI; BVM: 1st Response Manual Resuscitator, model V8503, Smiths Medical, St. Paul, MN) (Figure 1). The NRB and face masks were placed on the face; the metal clip was compressed against the bridge of the nose and the elastic headband was tightened. The reservoir bag for the NRB mask was inflated with oxygen before use. The BVM device contained an 850-mL reservoir. We added a 1-way disk-type valve to the exhalation port (model 533-MS-PMVEA; MedSource International, Chaska, MN). The reservoir on the BVM device was flushed with high-flow oxygen for 15 seconds to ensure it contained 100% oxygen before it was applied to the participant's face. The subject held the face 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.

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) (Figure 2). The flush rate was achieved by rotating the flowmeter dial counterclockwise until it could not be turned farther. The pressure delivered to the oxygen ports in our ED is between 50 and 55 lb/in². An independent engineer unaffiliated with the study analyzed the flush rate flow through the flowmeter and affirmed oxygen flow rate of 50 L/min at 50 lb/in², and 54 L/min at 55 lb/in². Therefore, the flush rate used in this study likely provided a flow of 50 to 54 L/min. We did not use a more precise measure of flow because we wanted to use standard ED equipment available to all emergency physicians.

Methods of Measurement and Outcome Measures

The outcome measure was the FeO_2 , measured at the end of each preoxygenation trial. FeO_2 was measured with

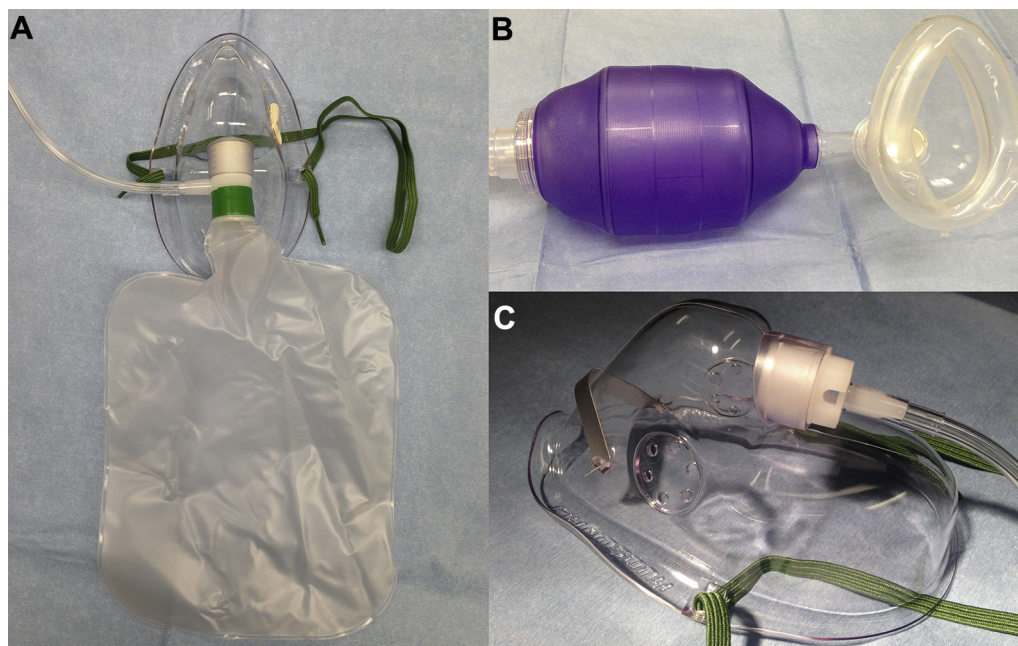


Figure 1. A, NRB mask (model 1059; Hudson RCI). B, BVM device (1st Response Manual Resuscitator, model V8503; Smiths Medical). C, Simple mask (model 1041; Hudson RCI).

a commercially available 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, 4 times per subject.

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 value of oxygen concentration displayed at the end of exhalation. Measurements were recorded by the authors (B.E.D., R.L.K., and E.K.C.). Neither the investigators nor subjects were blinded to the preoxygenation device. Each trial was followed by 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

Recent literature has suggested that the BVM device is superior to NRB mask for preoxygenation.^{4,5} Therefore, the prespecified primary outcome for this investigation was whether FeO_2 after preoxygenation with an NRB mask with flush rate oxygen (50 to 54 L/min) was noninferior to the BVM device at 15 L/min, 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 NRB mask at the flush rate group was higher than the mean FeO_2 minus 10% for the BVM device group, the NRB 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.⁸ Previous evidence demonstrates that BVM device preoxygenation at 15 L/min achieves FeO_2 of approximately 80%, with an SD of approximately 10%.^{4,5} We therefore estimated needing a total of 26 subjects to have 80% power for a test of noninferiority with an absolute difference of 10% at a significance level of .05. We determined the difference in mean FeO_2 and the associated 95% CIs between study interventions. All statistical testing was performed with Stata (version 12.1; StataCorp, College Station, TX).

RESULTS

Twenty-six subjects participated in the study. Mean subject age was 31 years (SD 5 years) and mean body mass index was 24 kg/m² (SD 2 kg/m²). Thirteen participants were men, and 5 had facial hair.

Mean baseline FeO_2 was 17.3% (95% CI 16.9% to 17.6%). Mean FeO_2 values after preoxygenation are displayed in the Table. FeO_2 after NRB-Flush was noninferior to BVM device with oxygen at 15 L/min (FeO_2 difference 8%; 95% CI 5% to 11%). FeO_2 after NRB-Flush was higher than both NRB-15

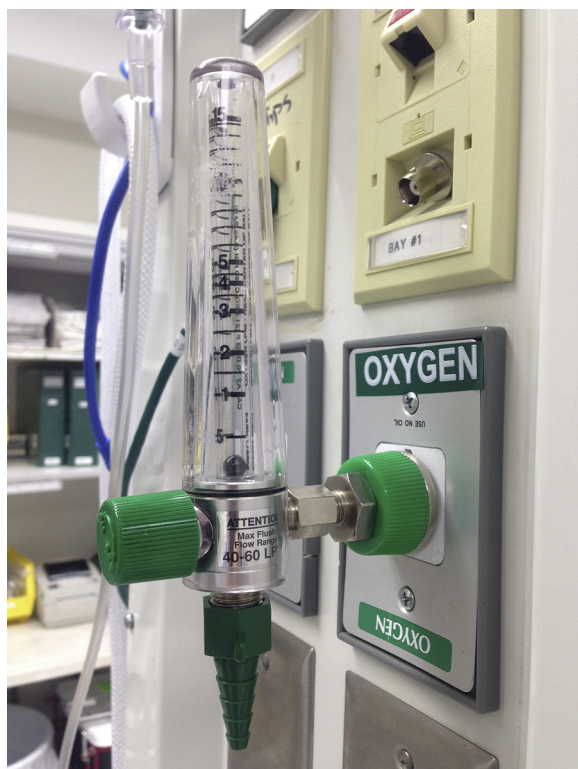


Figure 2. Study flowmeter. This standard flowmeter has gradations from 0 to 15 L/min. The maximum flush rate (40 to 60 L/min) is marked on the side of the device.

(FeO₂ difference 32%; 95% CI 29% to 35%) and simple mask with flush rate oxygen (FeO₂ difference 13%; 95% CI 10% to 17%). Subject-level data are presented in Figures 3 and 4.

LIMITATIONS

We performed this study on healthy volunteers without active respiratory illness. The noninferiority of NRB mask at the flush rate of oxygen to BVM device must be confirmed on critically ill ED patients undergoing emergency airway management. However, there are few anatomic or physiologic reasons that the findings in this study would not translate to a patient preparing for emergency intubation,⁹ provided he or she is not hypoventilating and does not have atelectasis or shunt physiology, in which case noninvasive positive-pressure ventilation may be helpful. Additionally, if

Table. Mean FeO₂ values after preoxygenation.*

Device	Mean FeO ₂ , % (95% CI)
NRB mask at 15 L/min	54 (50–57)
NRB mask at flush rate	86 (84–88)
BVM device at 15 L/min	77 (74–81)
Simple mask at flush rate	72 (69–76)

*Mean FeO₂ values by device and flow rate.

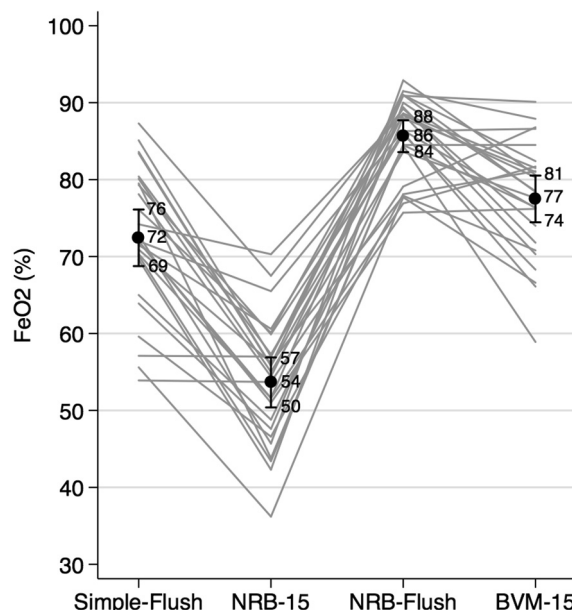


Figure 3. FeO₂ values by device. Each subject's data are displayed as a single line denoting the FeO₂ achieved with each respective device. Flush, Flush rate; 15, 15 L/min.

a patient is severely dyspneic, with maximum inspiratory flow rates exceeding the flush flow rate, room air may be entrained and the fraction of oxygen delivered will accordingly decrease.⁷

To adequately preoxygenate at 15 L/min, the BVM system requires a tight mask seal to avoid the entrainment of room air. Subjects in this study held the mask tightly

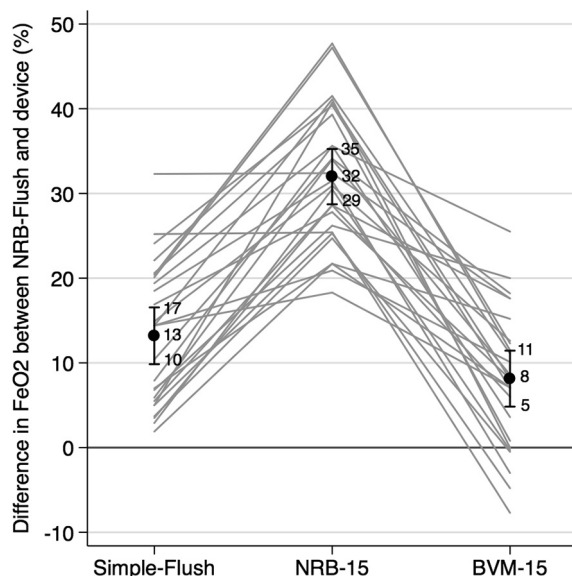


Figure 4. Difference in FeO₂ values between the NRB at the flush rate and each respective device. Each subject's data are displayed as a single line. Values above zero are instances in which the subject's FeO₂ when using an NRB mask at the flush was higher than when using the respective device.

against their face so that if a leak was detected, they could adjust to maintain the seal. Although an investigator monitored all subjects for a mask leak, it is nonetheless possible that a leak was present for some subjects, which would underestimate the true efficacy of the BVM as a preoxygenation device. However, this also speaks to the difficulty of using a BVM device for preoxygenation; if even small leaks threaten optimal preoxygenation, then BVM device technique will be difficult to perform for many ED patients. Our FeO_2 values in the BVM device group are similar to those of previous studies in which the investigator maintained mask seal.^{4,5}

This study was not designed to demonstrate superiority of NRB-Flush compared with NRB-15 or simple mask with flush rate oxygen. Because we included these latter 2 groups in the study to provide context for common preoxygenation methods rather than for formal comparison testing, we did not account for multiple comparisons when performing sample size calculations. Therefore, although formal claims of superiority when comparing the NRB-Flush to NRB-15 or simple mask with flush rate oxygen cannot be made, the large difference in FeO_2 between the groups is nonetheless compelling evidence that suggests NRB-Flush provides better preoxygenation.

Although we used a standard flowmeter available in our ED, other flowmeter flush rates will vary by model. In our experience, the flush rate is generally marked on the side or the back of the flowmeter. In accordance with our results and previous data,^{6,7,10} it seems likely that the findings of this investigation will remain valid, provided the flush rate is greater than 35 L/min.

DISCUSSION

In this study of healthy volunteers, we observed that preoxygenation with NRB-Flush was noninferior to BVM device with oxygen at 15 L/min. NRB-Flush also achieved higher FeO_2 values than both NRB-15 and simple mask with flush rate oxygen. Adequate preoxygenation delays the onset of oxyhemoglobin desaturation during emergency airway management, such as rapid sequence intubation. Because rapid sequence intubation is often performed on critically ill ED patients, a simple, ubiquitous, and efficacious preoxygenation device is highly desirable.

A cushioned, tightly sealed face mask attached to a BVM device or anesthetic circuit is the standard approach for preoxygenation in the operating room. In practice, a tight BVM device seal not only requires the active participation of a physician or other resuscitation team member but also is difficult to achieve in dyspneic, anxious, or agitated patients. Furthermore, many BVM devices lack the 1-way

valve needed to achieve adequate oxygenation.² Our results suggest that an NRB with flush rate oxygen achieves preoxygenation goals without requiring a tight mask seal and without specialized equipment.

Two previous studies^{4,5} evaluated preoxygenation using standard flow oxygen (15 L/min), finding FeO_2 similar to that observed in the current study but lower than that observed with flush rate techniques. Hayes-Bradley et al⁵ demonstrated that preoxygenation with an NRB at 15 L/min can be improved with the addition of nasal cannula at 10 L/min (FeO_2 improvement from 52% to 67%). However, this technique requires 2 devices, and the reported FeO_2 is lower than that with preoxygenation with the flush rate in the current study.

Despite its name, an NRB mask is not a closed system, as evidenced by recent data demonstrating equivalent preoxygenation with an NRB mask with and without a simulated mask leak.⁵ To provide near 100% inspired oxygen with a nonsealed system (ie, to avoid entraining room air during inhalation), the oxygen flow rate must exceed the inspiratory flow rate of the patient, and the dead space nitrogen in the mask and upper airway must be flushed out between breaths. Flush rate oxygen appears to accomplish both of these aims.¹¹ Traditional high-flow oxygen therapy, delivered by large-bore nasal cannula with a humidified, heated circuit and titratable fraction of inspired oxygen, is similarly capable of washing out upper airway dead space.^{11,12} However, high flow nasal cannula circuits require time to set up and are not yet widely available in EDs. Furthermore, features incorporated into standard high flow nasal cannula circuits (heat and humidity) are of questionable utility during time-limited, emergency preoxygenation.

Contrary to previous reports,^{6,7} the simple face mask at the flush rate of oxygen did not achieve adequate preoxygenation. The simple face mask used in this study has small intake holes adjacent to where the oxygen tubing connects to the mask inlet (Figure 1C); it is possible that as the flow of oxygen reached the mask inlet, room air was entrained in the oxygen stream through jet mixing,^{13,14} thereby reducing the oxygen content of inspired air. The performance of a simple mask may be improved with a different model.

The efficacy of preoxygenation with both a sealed patient interface (eg, BVM device) and flush rate oxygen flow is not known, although available data suggest that excellent preoxygenation should be attained. Using a cushioned mask similar to that used in the current study, Russell et al¹⁰ observed that an anesthesia circuit at the flush rate (35 L/min) with a mask leak performed better than the anesthesia circuit with a good seal at 15 L/min. This further supports the concept that high-flow oxygen is crucial for preoxygenation, especially when using a

nonsealed device. Although the BVM device can presumably perform well in the presence of a leak, provided high-flow oxygen is used, it is still more technically difficult to use than the NRB mask, which can be placed quickly and left in place while the team prepares for intubation.

In summary, preoxygenation with an NRB mask with flush rate oxygen was noninferior to a BVM device with oxygen at 15 L/min. NRB mask with flush rate oxygen is a reasonable preoxygenation method for spontaneously breathing patients undergoing emergency airway management.

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