Bag-Valve-Mask Ventilation After Induction for Intubation: PreVenting Hypoxemia?

July 2019 Annals of Emergency Medicine Journal Club

Guest Contributors

William T. Davis, MD; Ryan P. Radecki, MD, MS; Rory J. Spiegel, MD

0196-0644/$-see front matter

https://doi.org/10.1016/j.annemergmed.2019.05.021

Editor's Note: *You are reading the 72nd installment of* Annals of Emergency Medicine *Journal Club. As the Journal Club enters its second decade of publication, we are making a number of changes to the format. The Journal Club format has been revised and will focus on a monthly succinct review of high-impact articles from this journal and other premier medical journals relevant to emergency medicine. The reviews are followed by questions demonstrating principles by which readers—be they clinicians, academics, residents, or medical students—may critically appraise the literature. We are interested in receiving feedback about this feature. Please e-mail journalclub@acep.org with your comments.*

ARTICLE IN REVIEW

Casey JD, Janz DR, Russell DW, et al. Bag-mask ventilation during tracheal intubation of critically ill adults. *N Engl J Med*. 2019;380:811-821.

What Question Did This Investigation Aim to Answer?

In adult patients admitted to the ICU who require intubation, does bag-valve-mask ventilation between induction and laryngoscopy improve the lowest measured oxygen saturation during laryngoscopy and the immediate postintubation period?

What Study Design Did the Authors Choose?

Design: Prospective, pragmatic, multicenter, parallel-group, unblinded, randomized trial. ClinicalTrials.gov NCT03026322.

Setting: The trial was conducted at ICUs in 5 US academic hospitals (5 medical ICUs, 1 neurologic ICU, and 1 trauma ICU).

Population: All adult patients who were admitted to a participating ICU and required intubation. Patients were excluded from enrollment if they were pregnant or prisoners, or the treating physician thought the patient condition made delay for study procedures unsafe or a specific ventilation strategy was needed during the peri-intubation period.

Intervention: After administration of induction medication for intubation, the intervention group received bag-valve-mask ventilation until the beginning of the first laryngoscopy attempt. The control group received routine preoxygenation treatment, but noninvasive ventilation between induction and laryngoscopy was not allowed unless oxygen saturation decreased below 90%.

Primary Outcome: The lowest oxygen saturation measured by pulse oximetry from induction until 2 minutes after intubation.

Secondary Outcomes: Incidence of severe hypoxemia (oxygen saturation <80%), visualization of aspiration by the operator performing intubation, new opacity on chest radiograph 48 hours after intubation, new pneumothorax, peri-intubation hypotension, mortality, and number of ventilator-free days during the next 28 days.

Sponsors: National Center for Advancing Translational Sciences, National Institutes of Health.

How Did the Authors Interpret the Results?

The authors found that the primary outcome of lowest oxygen saturation was higher in the group receiving bag-valve-mask ventilation (median 96%; interquartile range 87% to 99%) than in the group receiving no ventilation (median 93%; interquartile range 81% to 99%). The group receiving bag-valve-mask ventilation had fewer episodes of severe hypoxemia (10.9%) versus the no ventilation group (22.8%), with a number needed to treat of 9 patients to prevent 1 episode of severe hypoxia in this study population. The authors found no difference in aspiration events between the bag-valve-mask ventilation and no ventilation groups, with a prevalence, respectively, of 2.5% versus 4.0% for witnessed aspiration during laryngoscopy and 16.4% versus 14.8% for appearance of a new opacity on chest radiograph at 48 hours after intubation.

How Might This Study Affect Your Clinical Practice in the Emergency Department?

In this high-quality randomized trial of adult patients admitted to the ICU, bag-valve-mask ventilation during the

period from induction to laryngoscopy reduced episodes of hypoxemia. Although the study was not powered to find a difference in aspiration events, it found no difference in incidence of aspiration between the 2 study arms.[1]

Bag-valve-mask ventilation could be considered during the apneic period after induction for intubation in emergency department (ED) patients assessed to be at high risk for hypoxemia. Important caveats include the specific techniques used for bag-valve-mask ventilation in this study and unclear generalizability of aspiration risk in ED patients.

DISCUSSION POINTS

1. *Discuss specific elements of the bag-valve-mask ventilation intervention in the referenced study.*

In many trials relevant to emergency medicine, the intervention is easily understood and translates simply to ED practice. For example, the intervention in a trial comparing intravenous diltiazem with metoprolol for control of rapid ventricular rate in atrial fibrillation could be easily replicated in clinical practice. The performance of bag-valve-mask ventilation involves multiple components that may affect the efficacy and safety of this intervention.

Training was the first part of the bag-valve-mask ventilation intervention in this trial. All intubation operators received structured training in best practices for bag-valve-mask ventilation before initiation of the study. A reminder of these best practices was included in the study materials for any patient assigned to the bag-valve-mask ventilation group.

The study appendix describes the recommended practices for bag-valve-mask ventilation in this trial. Best practices included use of a 2-handed mask seal technique combined with a positioning of head-tilt chin lift, connection of the bag-valve-mask to oxygen flow of at least 15 L/min and a positive end expiratory pressure valve set between 5 and 10 cm of water, consideration of oropharyngeal airway insertion, and provision of a ventilation rate of 10 breaths/min with the smallest tidal volume to produce a visible chest rise. The recommended technique for bag-valve-mask ventilation was a 2-person activity, with the intubation operator providing a 2-handed mask seal and another person squeezing the bag to deliver breaths. Bag-valve-mask ventilation of patients in the intervention arm was compliant with these practices because the median number of delivered breaths per minute was 9 and 83% of patients received jaw-thrust or head-tilt chin-lift maneuvers (Appendix Table S10 in the article by Casey et al). If these practices of proper bag-valve-mask ventilation are not followed, then the potential safety of this intervention as demonstrated by Casey et al may not be generalizable to other clinical settings.

2. *The incidence of aspiration events was similar between patients in the bag-valve-mask ventilation and no ventilation arms of the referenced study. Discuss differences in characteristics of patients requiring intubation in the ED versus the ICU that limit generalizability of this study finding to the ED setting.*

Patients in the bag-valve-mask ventilation arm had 1.5% fewer episodes (95% confidence interval –4.9% to 2.0%) of operator-reported aspiration compared with the no ventilation arm. Patients were excluded if the treating clinician determined that bag-valve-mask ventilation was contraindicated because of ongoing emesis, hemoptysis, or another factor that increased risk of aspiration. Appendix Figure S1 in the article by Casey et al displays the reasons for the exclusion of 51 patients determined to have a contraindication to ventilation after induction for intubation. The majority of these patients were excluded for ongoing emesis at intubation, and 3 patients were excluded for having a full stomach.

The relative safety of bag-valve-mask ventilation during induction found in this study may not be generalizable to ED patients because of differences in ED and ICU patient characteristics. Trauma patients were a minority of enrolled patients in this study, but represented 27% of intubations in a recent multicenter ED study.[2] Large gastric volumes may be more common in ED patients; a recent prospective cohort study of 250 patients requiring emergency surgery found that 56% of them had a full stomach as measured by gastric ultrasonography.[3] A recent prospective observational study reported that 8% of patients intubated in an urban ED developed aspiration pneumonia within 48 hours of intubation.[4] These findings suggest aspiration after intubation in the ED is not rare. In summary, differences between ED and ICU patients warrant caution in nonselective application of bag-valve-mask ventilation after induction for intubation in the ED.

3. *The primary outcome of the study was the lowest oxygen saturation measured by pulse oximetry during induction and the immediate postintubation period. Discuss why the authors chose that outcome and the difference between surrogate and clinical outcomes.*

Many potential study outcomes could be chosen when a trial is developed to examine ventilation after induction for intubation. One option would be to evaluate the safety of ventilation after induction because concern in regard to aspiration has been a barrier to adoption of this practice. Another option would be to examine a dichotomous

outcome, such as the prespecified secondary outcome of incidence of severe hypoxemia. The authors explain in the discussion that operator-visualized aspiration during intubation was not selected as a study outcome because a sample size estimate of 4,000 patients made this an unfeasible strategy. Similarly, use of a dichotomous outcome typically requires a larger sample size than use of a continuous outcome.[5]

Oxygen saturation during intubation is a physiologic measure serving as a surrogate endpoint for patient-oriented outcomes such as cardiac arrest, mortality, days of mechanical ventilation, or development of hypoxic encephalopathy. A valid surrogate outcome is independently associated with the patient outcomes of interest.[6] Benefits of using surrogate outcomes include need for a smaller sample size when the clinical outcome is rare and easier measurement when the clinical outcome is infrequently measured or difficult to define. The authors therefore justify their use of oxygen saturation as a surrogate endpoint based on these pragmatic features, as well as its use in multiple recent trials.[7,8] Hypoxemia during intubation was found to have a relative risk of 23.1 (95% confidence interval 11.1 to 47.3) for cardiac arrest compared with matched controls in a cohort of critically ill adults intubated by anesthesia outside of the operating room.[9] This finding suggests that hypoxemia during intubation is associated with the clinical endpoint of cardiac arrest. In the same study, cardiac arrest occurred in only 2% of cases, making this outcome too rare to be feasible in a randomized trial.[9] In addition to being associated with patient-oriented outcomes, improvements in the surrogate outcome from the studied intervention should lead to improvements in patient-oriented outcomes.[6] Ideally, the reader would look to other randomized clinical trials of airway interventions showing that avoidance of hypoxia led to improvements in patient-oriented outcomes. If the referenced trial is used to change clinical practice, then clinicians are making an assumption that hypoxia avoidance improves clinical outcomes. Although this assumption may be valid, readers should be aware that it exists.

Section editors: Tyler W. Barrett MD, MSCI; Ryan P. Radecki, MD, MS; Rory J. Spiegel, MD

Author affiliations: From the Department of Emergency Medicine, San Antonio Military Medical Center, San Antonio, TX (Davis); the Department of Emergency Medicine, Northwest Permanente, Portland, OR, and The University of Texas Health Science Center at Houston, Houston, TX (Radecki); and the Department of Emergency Medicine, University of Maryland, Baltimore, MD (Spiegel).

Authorship: All authors attest to meeting the four ICMJE.org authorship criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

REFERENCES

1. Casey JD, Janz DR, Russell DW, et al. Bag-mask ventilation during tracheal intubation of critically ill adults. *N Engl J Med*. 2019;380:811-821.
2. April MD, Arana A, Pallin DJ, et al. Emergency department intubation success with succinylcholine versus rocuronium: a National Emergency Airway Registry study. *Ann Emerg Med*. 2018;72:645-653.
3. Bouvet L, Desgranges F-P, Aubergy C, et al. Prevalence and factors predictive of full stomach in elective and emergency surgical patients: a prospective cohort study. *Br J Anaesth*. 2017;118:372-379.
4. Driver BE, Klein LR, Schick AL, et al. The occurrence of aspiration pneumonia after emergency endotracheal intubation. *Am J Emerg Med*. 2018;36:193-196.
5. Dell RB, Holleran S, Ramakrishnan R. Sample size determination. *ILAR J*. 2002;43:207-213.
6. Bucher H, Cook D, Holbrook A, et al. Surrogate outcomes. In: Guyatt G, Rennie D, Meade MO, Cook DJ, eds. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*, 3rd ed. New York, NY: McGraw-Hill Education; 2015:419-438.
7. Semler MW, Janz DR, Russell DW, et al. A multicenter, randomized trial of ramped position vs sniffing position during endotracheal intubation of critically ill adults. *Chest*. 2017;152:712-722.
8. Miguel-Montanes R, Hajage D, Messika J, et al. Use of high-flow nasal cannula oxygen therapy to prevent desaturation during tracheal intubation of intensive care patients with mild-to-moderate hypoxemia. *Crit Care Med*. 2015;43:574-583.
9. Mort TC. The incidence and risk factors for cardiac arrest during emergency tracheal intubation: a justification for incorporating the ASA guidelines in the remote location. *J Clin Anesth*. 2004;16:508-516.