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COMMENTS TO RESEARCH ARTICLES

# Whether or not to ventilate with self-inflating bag-valve-mask (Ambú®) before urgent intubation. Were there any doubts?☆

# Ventilar o no ventilar con mascarilla-bolsa autoinflable (Ambú®) antes de la intubación urgente, ¿había alguna duda?

Casey JD, Janz DR, Russell DW, Vonderhaar DJ, Joffe AM, Dischert KM, Brown RM, Zouk AN, Gulati S, Heideman BE, Lester MG, Toporek AH, Bentov I, Self WH, RiceTW, Semler MW; PreVent Investigators and the Pragmatic Critical Care Research Group. Bag-Mask ventilation during tracheal intubation of critically ill adults. N Engl J Med. 2019;380(9):811-821. doi: 10.1056/NEJ-Moa1812405. PubMed PMID: 30779528.

## Abstract

**Objective** To determine the effect of ventilating with a self-inflating bag-valve-mask (Ambú®) on hypoxaemia during tracheal intubation in critically ill patients. The hypothesis put forward is that ventilation with self-inflating bag-valve-mask during the interval from induction to anaesthesia up to laryngoscopy improves $SpO_2$, compared with non-ventilation.

**Design** Pragmatic, unblinded clinical trial, with random assignation in 7 Intensive Care Units in USA from March 2017 to May 2018. Given the nature of the intervention, the patients, medical and research staff were familiar with the group to which the patient had been assigned.

**Patients** Inclusion criteria: adults >18 years of age who underwent induction of anaesthesia and tracheal intubation.

Exclusion criteria: Immediate need for intubation which prevented randomisation; consideration by the doctor in charge of the need for ventilation with a self-inflating bag-valve-mask due to extremely severe hypoxaemia or acidaemia, contraindication for ventilation due to high risk of aspiration from vomiting, haematemesis or hemoptisis; pregnant women; detainees.

The causes for exclusion were: emergency indication for ventilation (42%), emergency indication for intubation (35%), contraindication for ventilation (22%), others (1%).

## Interventions to compare with

Ventilation group: The patients assigned to this group were provided with ventilation by the personnel responsible for the procedure, using the self-inflating bag-valve-mask during the interval from induction of anaesthesia to the beginning of the laryngoscopy. The ventilation with the self-inflating bag-valve-mask included the use of oxygen to a flow of, at least, 15 litres per minute, a valve linked to the expiratory flow port of the self-inflating bag-valve-mask to generate a positive end –expiratory pressure (PEEP) of 5–10 $cmH_2O$, an oropharyngeal cannula, a mask which is sealed with two hands by the physician responsible for the intubation with a bow of the head and raising of the chin and a ventilation of 10 breaths per minute with the lowest volume required to observe chest movement.

Non-ventilation group: The patients assigned to this group were not given ventilation with the self-inflating bag-valve-mask during the interval from the induction of anaesthesia to the beginning of the laryngoscopy, except when the first attempt at intubation as a hypoxaemia treatment failed ($SpO_2$ < 90%) or when the physician in charge considered it was necessary for the safety of the patient.

The majority of patients in the two groups (98%) received preoxygenation prior to induction.

## Outcomes

Primary: $SpO_2$ lower during the interval from the induction of anaesthesia until the beginning of the laryngoscopy.

Secondary: Serious incidence of hypoxaemia defined as $SpO_2$ < 80% during the interval from the induction of anaesthesia until the beginning of the laryngoscopy.

Safety: Broncoaspiration, pneumothorax, the need for vasopressor agents after induction, cardiac arrest within 1 h after intubation.

## Results

Primary outcome: the median of the lower $SpO_2$ was 96% (interquartile range 87–99) in the ventilation group vs. 93% (interquartile range, 81–99) in the non-ventilation group ($p = .01$).

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Secondary outcome: in the ventilation group, 21 patients (11%) had a $SpO_2$ under 80% compared with 45 patients (23%) in the non-ventilation group (relative risk .48; confidence interval for 95%: .30−.77).

Safety outcome: no significant differences were found in the bronchoaspiration rate with a lower rate in the ventilation group (2.5% vs. 4%; $p = .575$), in the pneumothorax rate (1% vs. 3%; $p = .285$), in the need for vassopressors after induction (20% vs. 23%; $p = .464$) or the incidence of cardiac arrest during the first hour after intubation (1% vs 2%; $p = .685$).

## Authors' conclusions

In critically ill patients who require tracheal intubation, those who receive ventilation with a self-inflating bag-valve-mask during the period from the induction of anaesthesia to laryngoscopy have higher $SpO_2$ and a lower rate of severe hypoxaemia than those who are ventilated.

A critical reading of the article following the Spanish Critical Appraisal Skills Programme model (CASPE) was made.

## Comments

### Is the trial aimed at a clearly defined question?

Urgent intubation with a rapid induction sequence (administration of sedatives and neuromuscular block) includes a time interval (between 45 and 90 s) when the patient is at risk of severe hypoxaemia. This is why some guides recommend avoiding this practice in general, except in cases of severe hypoxaemia to avoid the risk of aspiration which ventilation with self-inflating bag-valve-mask[1] may carry. Based on these considerations, should the main objective of the study be the effect on oxygenation of ventilation with a self-inflating bag-valve-mask? Or, due to the doubts regarding the risk of aspiration, would it have been more relevant to value this outcome? The main limitation in assessing this objective is that the rate of bronchoaspiration during intubation (4.5% in a recently published study[2]) means that a study with a very high sample size would be required to be able to obtain relevant differences.

Furthermore, the choice of this outcome as the main objective of the clinical trial has two limitations. Firstly, one exclusion criterion was severe hypoxaemia with absolute indication of ventilation prior to intubation. Secondly, the lack of standardisation of preoxygenation resulted in a difference in the proportion of ventilated patients with a self-inflating bag-valve-mask before randomisation (40% in the group assigned to ventilation vs. 11% in the group assigned to non-ventilation).

### Is the effect of treatment very high?

The difference in the median of the lowest registered $SpO_2$ between the two groups was 3.9% (96% vs. 93%) which was clinically irrelevant. More relevant was the proportion of patients who presented with severe hypoxaemia ($SpO_2 < 80\%$): 11% in the ventilation group vs. 23% in the non-ventilation group (for each 9 patients treated with the self-inflating bag-valve-mask severe hypoxaemia in one patient was predicted) or very severe hypoxaemia ($SpO_2 < 70\%$): 3.5% vs. 10%.

### Were all the patients who took part in the study appropriately considered until the end of it?

The analysis was conducted as an intention to treat. Moreover, analysis was carried out by protocol in such a way that the patients who received ventilation with self-inflating bag-valve-mask to prevent hypoxaemia prior to the first attempt at laryngoscopy were compared with patients who had not received ventilation. The patients who received ventilation after a failed attempt at laryngoscopy or as treatment for hypoxaemia were assessed in the group they had been assigned to.

### Did the benefits gained justify the risk?

Bearing in mind that the benefits of ventilation prior to intubation are known it is possible that the patients in the non-ventilation group were subjected to an unnecessary risk. The proportion of patients with severe hypoxaemia was significantly higher in the non-ventilation group

## Reviewers' conclusions

The main contribution of this clinical trial would be that for the first time a regular practice in all Intensive Care Units was assessed, which like many others, is carried out routinely without any scientific evidence to support it. However, the relevance of the results is conditioned by the choice of primary endpoint. Prior to this study, few doubts arose as to the beneficial effect of ventilation with a self-inflating bag-valve-mask on oxygenation during the period prior to intubation of critically ill patients, with a low functional reserve and high probability of presenting with hypoxaemia. Furthermore, ventilation during the interval from induction until laryngoscopy was not associated with an increase in bronchoaspiration.

As a result of all of the above, based on the findings of this study, it will still be necessary for an Ambú® to be available in the intensive care units so that the medical and nursing staff responsible for the airways during the urgent intubation procedure may ventilate the patients from the induction of anaesthesia until intubation.

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