



## Article Appraisal

**Article:** Effect of Bag-Mask Ventilation vs Endotracheal Intubation During Cardiopulmonary Resuscitation on Neurological Outcome After Out-of-Hospital Cardiorespiratory Arrest: A Randomized Clinical Trial

**Date of Journal Club:** March 20, 2018

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### Background and Study Objective(s):

The two airway strategies used during out-of-hospital cardiac arrest are Bag-Mask Ventilation (BMV) and Endotracheal Intubation (ETI). However, the optimal management of a patient's airway during out-of-hospital cardiac arrest (OHCA) remains an area of controversy and debate. While some studies have found improved outcomes with ETI, recent large studies have found increased mortality with ETI. BMV has several practical advantages, including its ease of initiation and decreased interference with ongoing CPR. This randomized non-inferiority trial investigated whether the choice of BVM or ETI during OHCA impacted survival and neurological outcomes.

### Study Design:

This randomized, parallel group, non-inferiority trial took place in France and Belgium, and involved 20 prehospital emergency medical services centers. The EMS response systems in these two countries involves a tiered response, including highly trained physicians. A block randomization strategy was used, and randomization was stratified by center. Adults aged 18 years or older with out-of-hospital cardiac arrest who received resuscitative efforts were included. Those who were suspected of having a massive aspiration before resuscitation, had a known do-not-resuscitate order, known pregnancy, or imprisonment were excluded.

Over a 22-month period, 2043 patients enrolled. Patients who were randomized to the BMV group were supervised by the physician, who could intervene and perform ETI anytime during the resuscitation. If a return of spontaneous circulation was achieved in the out-of-hospital setting, ETI would be immediately performed. A 28-day follow-up was completed for patients who achieved ROSC at the scene.

The authors chose their margin of inferiority based on prior large studies that compared ETI to BMV in cardiac arrest patient. Using the data from these past studies, the authors selected a margin of inferiority of 1% absolute difference in favorable functional survival at 28 days (defined as a Glasgow-Pittsburgh Cerebral Performance Categories of 2 or less). Secondary outcomes included rate of survival at 28 days, rate of ROSC, difficult intubation (defined by Intubation Difficulty Scale score), BMV difficulty (defined by a visual analogue scale and by the Han mask

ventilation classification), and rate of RMV or ETI failure.

## Results:

The primary outcome occurred in 44 of 1018 patients in the BMV group (4.3%) and 43 of 1022 patients in the ETI group (4.2%), representing a difference of 0.11% (1-sided 97.5% CI: -1.64% to infinity). Noninferiority was not demonstrated as the lower limit of the confidence interval (1.64%) was greater than the predefined noninferiority margin (1%). Similar results were obtained in the per-protocol analysis as in the intention-to-treat analysis.

With regards to the secondary outcomes, the rate of ROSC was greater in the ETI group compared to the BMV group (38.9% vs. 34.2% CI: -8.8% – -0.5%), in the intention-to-treat analysis. Survival to hospital admission and survival at day 28 were not significantly different between ETI and BMV groups.

In the adverse events analysis, complications were found to be significantly more frequent in the BMV group compared with the ETI group, including airway management difficulty (18.1% BMV group vs. 13.4% ETI group CI: 1.5% – 7.9%), regurgitation of gastric contents (15.2% BMV group vs. 7.5% ETI CI: 4.9% – 10.4%), and failure of the airway intervention (6.7% BMV vs. 2.1% ETI CI: 2.8% – 6.4%).

## Generalizability of Results:

The sense of Journal Club attendees was that the demographics of the included patients was similar to our cardiac arrest patient population in Canada. However, a unique aspect of the Emergency Medical System (EMS) where the study took place is the physician participation and role. It was also noted that time to ACLS and the relatively low percentage of initial v-fib rhythm (approximately 15%) differed from many North American centres. The authors noted that previous studies have found similar outcomes, including intubation success, between advanced care paramedics and physicians. The general sense of the abovementioned differences was that as both arms of the study would experience them equally, they would be unlikely to significantly significantly impact the effect of BVM and ETI relative to one-another.

## The Bottom Line:

The consensus was that this was an extremely well-designed and well-executed study. However, despite a sample size of over 2000 subjects, the results were inconclusive regarding the non-inferiority of BMV compared to ETI in OHCA. However, despite the technically inconclusive results, the data from the study provides convincing evidence of the potential for similar outcomes with BMV as compared to ETI in OHCA patients, and adds to prior research supporting such a conclusion. The sense of Journal Club attendees was that this study adds to a growing body of literature regarding BMV in the management of cardiac arrest patients, and suggests that BMV can be a valid alternative to ETI in patients experiencing cardiac arrest in the out-of-hospital setting. To definitively answer this question, however, would require a far larger study, and in the absence of that, EMS directors will need to take a practical approach to their policies that include consideration of local resources, capabilities, and feasibility.