**STUDY PROTOCOL**

Official Title: The Airway Pressures During Bag-Valve-Mask Ventilation: A Randomized Crossover Trial

Document Date: 29 April 2026

NCT Number: To be assigned

## 1. Study Protocol

### 1.1 Scientific Background and Objective

Emergency department (ED) patients are considered to have an elevated risk of gastric distention and aspiration of gastric contents, making rapid sequence induction (RSI) the preferred intubation procedure. Pre-oxygenation is the most critical step in RSI, as it extends the safe apnea duration. Although a facemask with a high FiO2 oxygen reservoir is recommended, bag-valve-mask (BVM) ventilation is frequently used. However, excessive positive pressure can lead to gastric distention and negative cardiovascular effects. This study aims to investigate airway pressure changes during BVM ventilation using different techniques (one-hand, two-hand CE, and two-hand TE) and clinical scenarios (normal and difficult airway).

### 1.2 Study Design and Setting

This is a randomized crossover trial conducted in a tertiary care university hospital simulation laboratory between July 15, 2024, and August 15, 2024.

### 1.3 Participants and Eligibility

Participants are emergency medicine residents ranging from postgraduate year 1 (PGY1) to PGY4. All participants provided written informed consent prior to the study.

### 1.4 Methodology and Interventions

- Simulation Model: Participants performed BVM ventilation on a Resusci Anne QCPR airway manikin.
- Techniques: Three different hand techniques were evaluated: one-hand, two-hand CE, and two-hand TE.
- Scenarios: Each technique was performed in two scenarios: Normal airway and Difficult airway (simulated using a cervical collar).
- Data Collection: Airway pressures were recorded using a calibrated pressure sensor placed between the facemask and the ventilation bag. Participants were asked to provide sufficient air to raise the manikin's chest and repeat this 10 times in a randomized order.

### 1.5 Outcome Measures

● Primary Outcome: Peak Airway Pressure (measured in cmH2O) during each ventilation.

● Secondary Outcome: The number of ventilations where pressure exceeded 20 cmH2O (the theoretical threshold for opening the lower esophageal sphincter).

**2. Statistical Analysis Plan (SAP)**

2.1 Statistical Software

All statistical analyses were performed using SPSS software version 16.0 for Windows (SPSS Inc., Chicago, IL, USA).

2.2 Data Summarization

Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as percentages. Non-normally distributed data are presented as medians (interquartile range).

2.3 Analysis Methods

● Unit of Analysis: For each scenario and technique, the individual participant was considered the unit of analysis.

● Primary Analysis: The highest pressure value among the 10 ventilations for every participant was recorded.

● Secondary Analysis: The chi-square test was used to compare the incidence of ventilations exceeding 20 cmH2O across different PGY levels.

● Significance Level: A p-value $< 0.05$ was accepted as statistically significant.

**3. Ethical Considerations**

The study protocol was approved by the Akdeniz University Medical Scientific Research Ethics Committee (Decision Date: July 03, 2024, Decision No: TBAEK-478). The study was conducted in accordance with the Helsinki Declaration.