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Effect of a Strategy of a Supraglottic Airway Device vs Tracheal Intubation During Out-of-Hospital Cardiac Arrest on Functional Outcome

The AIRWAYS-2 Randomized Clinical Trial

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IMPORTANCE The optimal approach to airway management during out-of-hospital cardiac arrest is unknown.

OBJECTIVE To determine whether a supraglottic airway device (SGA) is superior to tracheal intubation (TI) as the initial advanced airway management strategy in adults with nontraumatic out-of-hospital cardiac arrest.

DESIGN, SETTING, AND PARTICIPANTS Multicenter, cluster randomized clinical trial of paramedics from 4 ambulance services in England responding to emergencies for approximately 21 million people. Patients aged 18 years or older who had a nontraumatic out-of-hospital cardiac arrest and were treated by a participating paramedic were enrolled automatically under a waiver of consent between June 2015 and August 2017; follow-up ended in February 2018.

INTERVENTIONS Paramedics were randomized 1:1 to use TI (764 paramedics) or SGA (759 paramedics) as their initial advanced airway management strategy.

MAIN OUTCOMES AND MEASURES The primary outcome was modified Rankin Scale score at hospital discharge or 30 days after out-of-hospital cardiac arrest, whichever occurred sooner. Modified Rankin Scale score was divided into 2 ranges: 0-3 (good outcome) or 4-6 (poor outcome; 6 = death). Secondary outcomes included ventilation success, regurgitation, and aspiration.

RESULTS A total of 9296 patients (4886 in the SGA group and 4410 in the TI group) were enrolled (median age, 73 years; 3373 were women [36.3%]), and the modified Rankin Scale score was known for 9289 patients. In the SGA group, 311 of 4882 patients (6.4%) had a good outcome (modified Rankin Scale score range, 0-3) vs 300 of 4407 patients (6.8%) in the TI group (adjusted risk difference [RD], -0.6% [95% CI, -1.6% to 0.4%]). Initial ventilation was successful in 4255 of 4868 patients (87.4%) in the SGA group compared with 3473 of 4397 patients (79.0%) in the TI group (adjusted RD, 8.3% [95% CI, 6.3% to 10.2%]). However, patients randomized to receive TI were less likely to receive advanced airway management (3419 of 4404 patients [77.6%] vs 4161 of 4883 patients [85.2%] in the SGA group). Two of the secondary outcomes (regurgitation and aspiration) were not significantly different between groups (regurgitation: 1268 of 4865 patients [26.1%] in the SGA group vs 1072 of 4372 patients [24.5%] in the TI group; adjusted RD, 1.4% [95% CI, -0.6% to 3.4%]; aspiration: 729 of 4824 patients [15.1%] vs 647 of 4337 patients [14.9%], respectively; adjusted RD, 0.1% [95% CI, -1.5% to 1.8%]).

CONCLUSIONS AND RELEVANCE Among patients with out-of-hospital cardiac arrest, randomization to a strategy of advanced airway management with a supraglottic airway device compared with tracheal intubation did not result in a favorable functional outcome at 30 days.

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Out-of-hospital cardiac arrest is common, sudden, and often fatal. During 2014, emergency medical services (EMS) in England attempted resuscitation in almost 30 000 people; only 25% achieved a return of spontaneous circulation and 8% were discharged alive from the hospital.¹

Few advanced life support therapies have been shown to improve outcome following out-of-hospital cardiac arrest.² There is a lack of data from high-quality randomized clinical trials (RCTs), which are challenging to conduct in patients with out-of-hospital cardiac arrest. Consequently, many current clinical recommendations are based on observational studies and expert consensus.³

Optimal airway management during out-of-hospital cardiac arrest is a key area of uncertainty because there is very little high-quality research on which to base treatment recommendations.⁴ Options range from basic or minimal airway intervention to early advanced procedures that require training and expertise.

The advanced procedure of tracheal intubation has been considered a definitive airway management technique.⁵ However, large observational studies (including >100 000 patients) have consistently favored basic airway management (eg, bag-mask ventilation) over tracheal intubation.^{6,7} The introduction of a supraglottic airway device offers an alternative advanced airway management technique during out-of-hospital cardiac arrest.

Insertion of a supraglottic airway device is simpler and faster than tracheal intubation,⁸ and proficiency requires less training and ongoing practice.⁹ Observational evidence has suggested a possible survival advantage for tracheal intubation compared with a supraglottic airway device.¹⁰ However, a large-scale RCT is required to identify the optimal approach to advanced airway management during out-of-hospital cardiac arrest.

The objective of this trial was to estimate the between-group difference in modified Rankin Scale score at hospital discharge or 30 days after out-of-hospital cardiac arrest for patients treated by paramedics randomized to use either a supraglottic airway device or tracheal intubation as their initial advanced airway management strategy.

Methods

Study Design and Paramedic and Patient Populations

The trial protocol and statistical analysis plan for this multicenter, cluster RCT appear in Supplement 1; the trial protocol has been published.¹¹ Paramedics were recruited from 4 large EMS provider organizations (ambulance services) in England, which respond to emergencies for approximately 21 million people (40% of England's population). The trial population was adults who had a nontraumatic out-of-hospital cardiac arrest.

The patient inclusion criteria were (1) known or believed to be aged 18 years or older; (2) nontraumatic out-of-hospital cardiac arrest; (3) treated by a paramedic participating in the trial who was either the first or second paramedic to arrive at

Key Points

Question Does an initial strategy of a supraglottic airway device for advanced airway management during nontraumatic out-of-hospital cardiac arrest result in a better functional outcome compared with tracheal intubation?

Findings In this cluster randomized clinical trial that included 1523 paramedics and 9296 patients with out-of-hospital cardiac arrest, favorable functional outcome (modified Rankin Scale score in 0-3 range) at hospital discharge or after 30 days (if still hospitalized) occurred in 6.4% of patients in the supraglottic airway group vs 6.8% of patients in the tracheal intubation group, a difference that was not statistically significant.

Meaning In this study, a strategy of using a supraglottic airway device for advanced airway management did not provide a superior functional outcome.

the patient's side; and (4) resuscitation was commenced or continued by emergency medical services personnel.

The patient exclusion criteria were (1) detained by Her Majesty's Prison Service; (2) previously recruited to the trial (determined retrospectively); (3) resuscitation deemed inappropriate (using guidelines from the Joint Royal Colleges Ambulance Liaison Committee¹²); (4) advanced airway already in place (inserted by another paramedic, physician, or nurse) when a paramedic participating in the trial arrived at the patient's side; (5) known to be enrolled in another prehospital RCT; and (6) the patient's mouth opened less than 2 cm.

Paramedics could not be blinded to their allocation and mechanisms were required to avoid the risk of differential recruitment by paramedics based on the patient's perceived likely outcome. Therefore, every eligible patient treated by a participating paramedic was automatically enrolled in the study under a waiver of consent provided by the confidentiality advisory group (reference No. 14/CAG/1030).

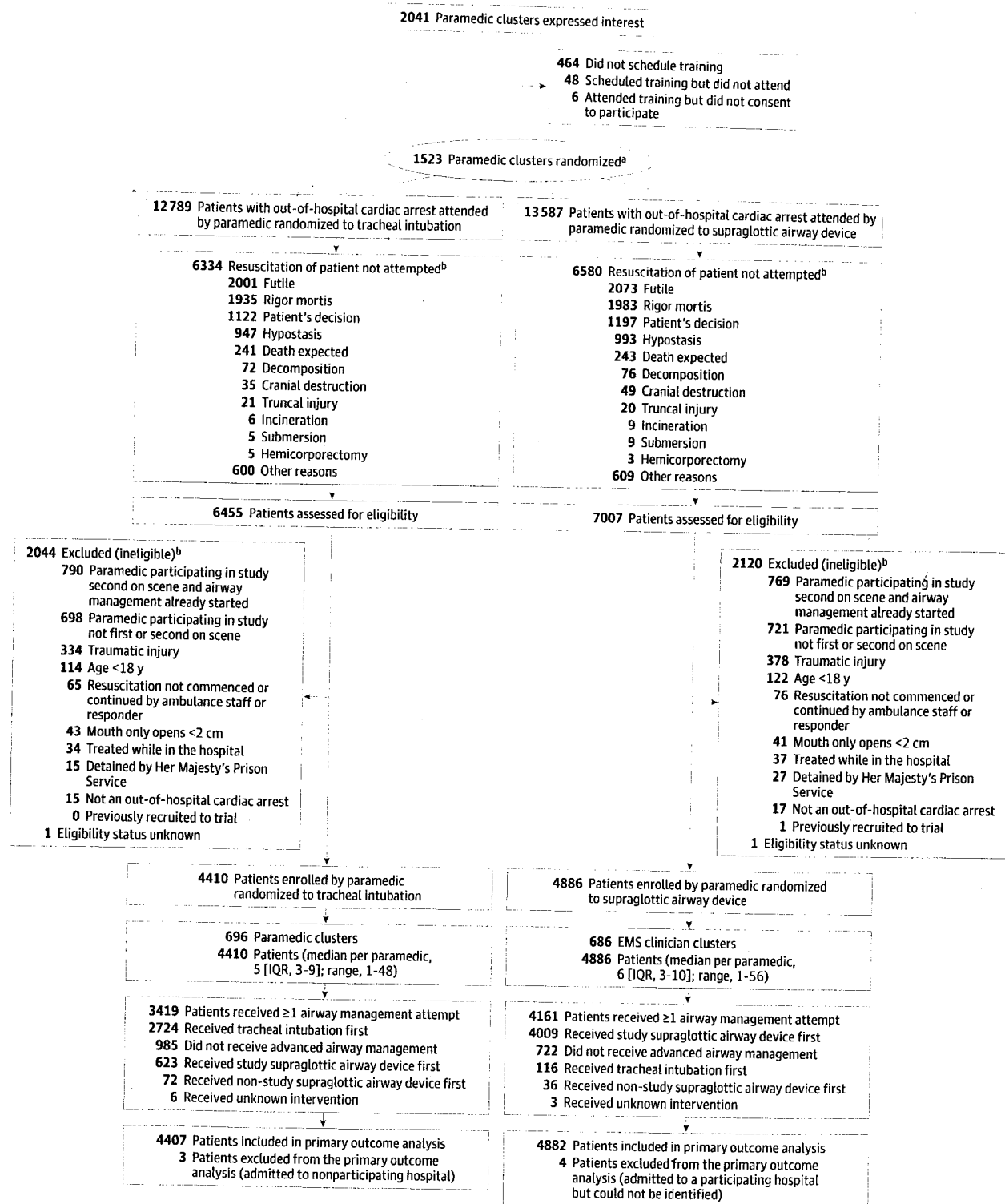
Ethics review and approval was provided by the South Central-Oxford C research ethics committee (reference No. 14/SC/1219), which included a process of written informed consent for participating paramedics. A disadvantage of automatic enrollment was that enrolled patients might not be treated according to the study protocol if the enrolling paramedic could not recall the protocol details (an out-of-hospital cardiac arrest is a relatively rare event) or if the paramedic mistakenly deemed the patient to be ineligible.

Randomization

Because out-of-hospital cardiac arrest requires immediate treatment, randomizing patients at the point of out-of-hospital cardiac arrest was considered impractical. Therefore, paramedics were randomized to use 1 of the 2 advanced airway management strategies for the eligible patients that they treated (Figure 1). This design created many clusters with a small average number of patients per paramedic that minimized the effect of intracluster correlation and lowered the risk of chance imbalances between groups.

Paramedics were randomized in a 1:1 ratio using a purpose-designed secure internet-based system. The computer-generated random sequence was done in advance using varying

Figure 1. Flow of Study Paramedics and Patients



Grouped according to the randomization assignment of the first paramedic on the scene who was participating in the study.

^a There were 113 paramedics who withdrew after randomization (58 randomized to tracheal intubation [TI] and 55 randomized to the supraglottic airway device [SGA]). The median number of patients with out-of-hospital cardiac arrest treated by a paramedic who later withdrew is 7 for TI

(interquartile range [IQR], 3-12; range, 1-54) and 6 for SGA (IQR, 4-11; range, 1-31). The median number of trial patients treated by a paramedic who later withdrew is 3 for TI (IQR, 1.0-5.5; range, 1-10) and 2 for SGA (IQR, 1-4; range, 1-12). These trial patients were retained and included in the analysis.

^b Patients can have more than 1 reason.