PREHOSPITAL MEDICAL ADVISORY COMMITTEE MEETING AGENDA (PMAC)

PMAC MEMBERS PER POLICY 8202:

Air Transport Provider Representative
11-Kent McCurdy

American Medical Response
5-Douglas Key

BLS Ambulance Service Representative
12-Lori Lopez

Cathedral City Fire Department
5-Justin Vondriska

Corona Regional Medical Center
1-Robert Steele, MD
4-Tamera Roy

County Fire Chiefs' Non-Transport ALS Provid
10-Vacant

County Fire Chiefs' Non-Transport BLS Provid
9-Phil Rawlings (Vice Chair)

Desert Regional Medical Center
1-Joel Stillings, D.O
4-Kristie Borba

Eisenhower Health
1-Mandeep Daliwhal, MD
4-Susan Young

EMT / EMT-P Training Programs
6-Maggie Robles

EMT-at-Large
13 David Olivas

Paramedic-at-Large
14-Sarah Coonan

Hemet Valley Medal Center
1-Todd Hanna, MD
4-Victoria Moor

Idyllwild Fire Protection District
5-Patrick Reitz

Inland Valley Regional Medical Center
1-Zeke Foster MD
4-Daniel Sitar

JFK Memorial Hospital
1-Troy Cashatt, MD
4- Molly Leddy

Kaiser Permanente Riverside
1-Jonathan Dyreyes, MD
4-Carol Fuste

This Meeting of PMAC is on:
Monday, October 22, 2018
9:00 AM to 10:30 AM
The Towers of Riverwalk
4210 Riverwalk Parkway, Riverside
First Floor Conference Rooms – Lemon and Orange

1. **CALL TO ORDER & HOUSEKEEPING (3 Minutes)**
   Misty Plumley

2. **PLEDGE OF ALLEGIANCE (1 Minute)**
   Zeke Foster, MD (Chair)

3. **ROUNDTABLE INTRODUCTIONS (5 Minutes)**
   Zeke Foster, MD (Chair)

4. **APPROVAL OF MINUTES (3 Minutes)**
   July 23, 2018 Minutes— Zeke Foster, MD (Attachment A)

5. **STANDING REPORTS**
   5.1. Trauma System—Shanna Kissel (Attachment B)
   5.2. Stroke System— Dan Sitar (Attachment C)
   5.3. STEMI System— Dan Sitar (Attachment D)

6. **Other Reports**
   6.1. EMCC Report—Kristen Clements

7. **DISCUSSION ITEMS, UNFINISHED & NEW BUSINESS (60 Minutes)**
   7.1. CQI Update – Lisa Madrid (Attachment E)
   7.2. Education / Policy Update – Misty Plumley (Attachment F)
   7.3. Provider Recognitions – REMSA Clinical Team / Trevor Douville
   7.4. EMCC Physician Representation – Trevor Douville
   7.5 Airway Management in Cardiac Arrest, Article Review– Dr. V. (Attach. G)
   7.6 EMD Card 24 and 33 – Rafael Serrano, Michelle Buell (Attachment H)
   7.7 Advanced Resuscitation Training, RVCFD Proposal – Chief Rawlings
   7.8 2019 PMAC Schedule Approval – Misty Plumley (Attachment I)

8. **REQUEST FOR DISCUSSIONS**
   Members can request that items be placed on the agenda for discussion at the following PMAC meeting. References to studies, presentations and supporting literature must be submitted to REMSA three weeks prior to the next PMAC meeting to allow ample time for preparation, distribution and review among committee members and other interested parties.

Loma Linda University Med. Center Murrieta
1-Kevin Flaig, MD
4-Kristin Butler

Menifee Valley Medical Center
1-Todd Hanna, MD
4-Janny Nelsen

Kaiser Permanente Moreno Valley
1-George Salameh, MD
4-Katherine Heichel-Casas

Palo Verde Hospital
1-David Sincavage, MD
4-Carmelita Aquines

Parkview Community Hospital
1-Chad Clark, MD
4-Guillean Estrada

Rancho Springs Medical Center
1-Zeke Foster, MD (Chair)
4-Sarah Young

Riverside Community Hospital
1-Stephen Patterson, MD
4-Sabrina Yamashiro

Riverside County Fire Department
5-Scott Visyak
8-Tim Buckley

Riverside County Police Association
7-Sean Hadden

Riverside University Health System Med. Center
1-Michael Mesisca, D
4-Kay Schulz

San Gorgonio Memorial Medical Center
1-Richard Preci, MD
4-Trish Ritarita

Temecula Valley Hospital
1-Pranav Kachhi, MD
4-Jacquelyn Ramirez

Trauma Audit Comm. & Trauma Program Managers
2-Frank Ercoli, MD
3-Charlie Hendra

Ex-officio Members:
1-Cameron Kaiser, MD, Public Health Officer
2-Reza Vaezazizi, MD, REMSA Medical Director
3-Bruce Barton, REMSA Director
4-Jeff Grange, MD, LLUMC
5-Phong Nguyen, MD, Redlands Community Hospital
6-Rodney Borger, MD, Arrowhead Regional Medical Center

9. ANNOUNCEMENTS (15 Minutes)

This is the time/place in which committee members and non-committee members can speak on items not on the agenda but within the purview of PMAC. Each announcement should be limited to two minutes unless extended by the PMAC Chairperson.

10. NEXT MEETING / ADJOURNMENT (1 Minute)

January 21, 2019—4210 Riverwalk Parkway First Floor Conference Rooms

11. CASE REVIEW SESSION (60 Minutes)

This is the time/place in which committee members and invited parties will participate in case review of sentinel events, or cases that are part of trends in patient care in the EMS System. Closed case review session for PMAC members and invited personnel.

Members are requested to please sit at the table with name plates in order to identify members for an accurate count of votes

Please come prepared to discuss the agenda items. If you have any questions or comments, call or email Misty Plumley at (951) 201-4705 / mplumley@rivco.org. PMAC Agendas with attachments are available at: www.rivcoems.org. Meeting minutes are audio recorded to facilitate dictation for minutes.

PMAC Draft Minutes
July 23, 2018

TOPIC	DISCUSSION	ACTION
1. CALL TO ORDER	Misty Plumley called the meeting to order at 9:00 a.m. and reviewed housekeeping items before turning the meeting over to PMAC Chair Dr. Zeke Foster.	
2. PLEDGE OF ALLEGIANCE	Dr. Zeke Foster led the Pledge of Allegiance.	
3. ROUNDTABLE INTRODUCTIONS	Dr. Zeke Foster facilitated self-introductions.	
4. APPROVAL OF MINUTES		The April 23, 2018 PMAC meeting minutes were approved with no changes.
5. STANDING REPORTS		
5.1 Trauma System Updates	EMSA approved TXA for Local Optional Scope in March. Effective July 1st, TXA was removed from trial study - 5801 and was replaced with policy 4301 – Shock due to trauma, 4302 – Traumatic injuries and added to the drug and equipment list. A system advisory was sent out regarding the changes. Dr. Vaezazizi clarified further, the age for the patient was adjusted to align with REMSA definition of an adult patient, defined as 15 years or age or older. Ketamine trail study started April 1, 2018 and to date there has been approximately 200 administrations. Ketamine was approved by the Commission to be moved into local optional scope, pending approval for REMSA. ImageTrend trauma registry will be implemented in 2019 for trauma centers. Pre-hospital records will be able to link through ImageTrend.	Information only.
5.2 Stroke System Updates	Dan Sitar announced public comment for State Stroke regulations was re-opened for another 15 days and will close on Wednesday, July 25th. REMSA will continue to coordinate with ICEMA for a unified response to turn in. LAMS scale will be implemented in the Fall; and LAMS score will not affect stroke destinations. LAMS score will be used for data collection and analysis. Quarterly data collected from hospitals will include expanded CSR/Coverdell data	Information only.

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PMAC Draft Minutes
July 23, 2018

	elements. Meanwhile, the registry purchase will be put on hold. Stroke Committee agendas, meeting minutes and draft quarterly reports can all be found on www.remsa.us. The next stroke meeting is on August 16th from 1:00 – 3:00 p.m., following the coordinators meeting which will be held an hour before.	
5.3 STEMI System Updates	STEMI system update is the same as the stroke system update. Changes to policies regarding base contact for STEMI patients and STEMI center destination for OHCA patients will go live in the Fall. The next STEMI meeting is on Thursday, July 26th from 10:00 a.m. to noon, following the coordinators meeting which will be held an hour before.	Information only.
6. OTHER REPORTS		
6.1 EMCC Report	Kristen announced EMCC did not meet and there is nothing to report back at this time.	Information only.
7. DISCUSSION ITEMS, UNFINISHED & NEW BUSINESS		
7.1 CQI Update	CORE Measures were submitted by the deadline on June 30th. Lisa will be sharing the reports at the next PMAC meeting after reviewing the State version and REMSA version to verify for completeness and unification. Dr. Vaezazizi pointed out areas needed for improvement, which includes quality of documentation and how to move forward with fixing that problem. The last CQILT meeting was on June 21st and minutes posted on www.remsa.us. The next CQILT meeting is on Thursday, September 20th.	Information only.
7.2 Education/Policy Update	Fall protocol updates will have a stakeholder comment phase of 21 days for comment and review before Misty finalizes curriculum to push out for September education and training to complete by November. Training	PMAC members approved to move forward with no objections to: Administrative policies: REMSA 3102, 3301, 9210 and Treatment

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PMAC Draft Minutes
July 23, 2018

	will be available online along with a few in person. Most of the Fall changes are administrative policies, which includes REMSA 3102, 3301 and 9210 to add childbirth/neonatal resuscitation in place of restraints for ALS SCV. Treatment protocols include REMSA 4102, adapting patient types requiring BH contact which includes all ROSC patients to go to STEMI receiving locations regardless of capnography reading, along with REMSA 4503, 4407 and 4702.	Protocols: REMSA 4102, 4503, 4407 and 4702.
7.3 CARES Data Review	Dr. Vaezazizi reviewed the CARES summary report for Riverside County, in comparison to California and Nationally. Overall, across the board Riverside county fared closely to California and Nationally in most criteria. A few notable differences includes was an AED applied, sustained ROSC and survival rate. All of which will be identified further to improve on closing the gaps.	Information only.
	Dr. Vaezazizi requested input from PMAC on their interest in push dose epinephrine for hypotension patients. A training video was shown on how crews mix and dilute the medication into another syringe ready for use when needed. There would be no drip or further calculation beyond the newly created syringe. Overall PMAC agreed it would be beneficial to try including this method and to include into protocol with specific patient criteria. However, there were also concerns with medication errors with diluting and properly re-labeling the new syringes. Ideas of pre-made push dose epi was brought up to prevent medication errors.	Discussion only.
7.4 Provider Recognitions	Recognizing exceptional performance from our providers; Misty and Lisa congratulated and thanked first responders and their team for exceptional service in patient care during the Coachella Music Festival this past April in Indio. Awards of Excellence were given to the recipients below: Mike Wallace Monica Pintus	

DRAFT

PMAC Draft Minutes
July 23, 2018

	Cody Nickel, EMT Casey Gnadt, EMT Omar Castro, EMT Michael Landry, EMT Nicholas Graham, MEDIC Shawn Gurren, Paramedic Angela Wright, EMT Gary Denham, Paramedic Supervisor	
7.5 PMAC Membership Review	Misty will send out new member recruitment for the Training Program Manager position. Volunteers nominated will be brought to PMAC for review at the next October meeting.	
8. REQUEST FOR DISCUSSIONS	There were no requests at this time.	
9. ANNOUNCEMENTS	Kristie Borba announced she has stepped down from PLN position at DRMC and Stanley Hall will take on her role as PLN.	Information only.
10. NEXT MEETING/ADJOURNMENT	October 22, 2018 4210 Riverwalk Parkway First Floor Conference Rooms.	Information only.

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FOR CONSIDERATION BY PMAC

DATE: October 22, 2018

TO: PMAC

FROM: Shanna Kissel, RN, Assistant Nurse Manager

SUBJECT: Trauma System

1. TXA is now in local optional scope of practice and included in policies 4301, 4302 and the drug and equipment list. TXA data has been published in Western Journal of Emergency Medicine and can be found at https://escholarship.org/uc/item/9f99j268.

2. Ketamine Trial study has been approved for local optional scope, pending final letter from EMSA. Ketamine will move into affected policies in Spring 2019.

3. ImageTrend trauma registry is going through purchasing and plan to go live early 2019.

4. IVMC and RCH will be going through their ACS surveys in early November.

ACTION: PMAC should be prepared to receive the information and provide feedback to REMSA.

FOR CONSIDERATION BY PMAC

Date: October 22, 2018

TO: PMAC

FROM: Dan Sitar, Specialty Care Consultant, RN

SUBJECT: Stroke System

1. EMSA Stroke regulations were approved in September, need to go to OAL in December and anticipating finalization Spring 2019.
2. LAMS scale was implemented on October 1. Stroke destination will not be affected by LAMS score initially.
3. Stroke Committee agendas, meeting minutes, draft and final quarterly reports can all be found on www.remsa.us site at this link: http://www.remsa.us/documents/programs/stroke
4. The next Stroke meeting will be held in the Vineyard A and B at 4210 Riverwalk Parkway, Suite 300 on November 29th, 2018 from 1:00 to 3:00 PM.

Action: PMAC should be prepared to receive the information and provide feedback to the EMS Agency

FOR CONSIDERATION BY PMAC

Date: October 22, 2018

TO: PMAC

FROM: Dan Sitar, Specialty Care Consultant, RN

SUBJECT: STEMI System

1. EMSA STEMI regulations were approved in September, need to go to OAL in December and anticipating finalization Spring 2019.
2. Changes to policies regarding base contact for STEMI patients and STEMI center destination for OHCA patients went into effect October 1.
3. STEMI Committee agendas, meeting minutes, draft and final quarterly reports can all be found on www.remsa.us site at this link: http://www.remsa.us/documents/programs/stemi
4. The next STEMI meeting is to be determined for 2019. Can be found on remsa.us calendar once dates are confirmed.

Action: PMAC should be prepared to receive the information and provide feedback to the EMS Agency

FOR CONSIDERATION BY PMAC

DATE: October 8, 2018

TO: PMAC

FROM: Lisa Madrid, EMS Specialist

SUBJECT: CQI Update

The next CQILT meeting will be held on Thursday, December 20th, 2018 from 10:00 a.m. - noon. In preparation for the next meeting, please review the draft minutes from the September 20th meeting.

The agenda and minutes for all previous meetings can also be accessed at REMSA.US

At the last CQILT meeting on September 20, 2018 we discussed the data that REMSA is requesting to initiate a new CQI report that will begin in 2019. Your feedback and submissions are very important to REMSA. Please click on the link below to submit your 2018 quarter 1 data and Image Trend comments by October 31st, 2018.

Data submission is required for ALS providers only. Hospitals, please continue to use CARES registry as your reporting forum. BLS providers, if you have feedback, please contact Lisa Madrid directly.

https://docs.google.com/forms/d/e/1FAIpQLSewUq8ttBbMl6jIcPkJ7Xm68D6bYrJzM27tjQsTJMVVAtdKnQ/viewform?usp=sf_link

The link and more information can also be accessed at REMSA.US CQI page. Data submission should be coordinated with REMSA as needed.

ACTION: Information only.

FOR CONSIDERATION BY PMAC

DATE: October 1, 2018

TO: PMAC

FROM: Misty Plumley, Senior EMS Specialist

SUBJECT: Proposed Policy Changes

Proposed policy changes for 2019 have been compiled and will include:

I. EMT Certification Changes
   a. for July 2017 regulation transition training
   b. lapsed certification process clarification
II. Paramedic Accreditation/Reverification
   a. Lapsed certification process clarification
   b. CA EMSA moving to online licensing
III. Push dose epinephrine
   a. Shock due to trauma
   b. Shock Not Due to Trauma
IV. Ketamine addition to LOSOP
   a. End of trial study
   b. Integration of ketamine into traumatic injuries / burns
V. Discontinue Resuscitation criteria
   a. List of criteria to stop resuscitation
VI. Cardiac Arrest
   a. High performance CPR with psychomotor skills
   b. Re-emphasizing HP CPR components
VII. Excited Delirium
   a. Addition of specific verbiage requiring vital signs monitoring in a specific pattern.
VIII. Review AMS Protocol to be aligned with EMDAC
   a. Potential gaps:
      i. REMSA 7401 12 Lead ECG performance criteria list
      ii. COPD pulse oximetry reference of 88-92% not mentioned in our P&P
      iii. Toxidrome specifics for:
         1. Sympathomimetics/amphetamines
         2. Sodium channel blocker OD
IX. MICN Authorization changes
X. STEMI Regulation impacts for 5401 (hospital classifications)
XI. Stroke Regulation impacts for 5701 (hospital classifications)
XII. ALS IFT policy

ACTION: Information sharing, PMAC vote to confirm movement of proposed policy changes to stakeholder comment phase.

FOR CONSIDERATION BY PMAC

DATE: October 1, 2018

TO: PMAC

FROM: REMSA Clinical Team

SUBJECT: Airway Management in Cardiac Arrest – Literature Review

Strategies for airway management in cardiac arrest have been reviewed in recent literature. Tactics from PPV with the BVM, supraglottic airway placement (i.e. King or LMA), and endotracheal intubation have been employed by EMS Systems and various EMS providers.

REMSA would like to review our strategies used for airway management in cardiac arrest and compare them with recent literature reviews to align our data and standard of care.

Associated articles are attached for your review to frame our discussion.

ACTION: Information sharing, PMAC feedback during discussion will be requested.

JAMA | Original Investigation

Effect of a Strategy of Initial Laryngeal Tube Insertion vs Endotracheal Intubation on 72-Hour Survival in Adults With Out-of-Hospital Cardiac Arrest

A Randomized Clinical Trial

Henry E. Wang, MD, MS; Robert H. Schmicker, MS; Mohamud R. Daya, MD, MS; Shannon W. Stephens, EMT-P; Ahamed H. Idris, MD; Jestin N. Carlson, MD, MS; M. Riccardo Colella, DO, MPH; Heather Herren, MPH, RN; Matthew Hansen, MD, MCR; Neal J. Richmond, MD; Juan Carlos J. Puyana, BA; Tom P. Aufderheide, MD, MS; Randal E. Gray, MEd, NREMT-P; Pamela C. Gray, NREMT-P; Mike Verkest, AAS, EMT-P; Pamela C. Owens; Ashley M. Brienza, BS; Kenneth J. Sternig, MS-EHS, BSN, NRP; Susanne J. May, PhD; George R. Sopko, MD, MPH; Myron L. Weisfeldt, MD; Graham Nichol, MD, MPH

IMPORTANCE Emergency medical services (EMS) commonly perform endotracheal intubation (ETI) or insertion of supraglottic airways, such as the laryngeal tube (LT), on patients with out-of-hospital cardiac arrest (OHCA). The optimal method for OHCA advanced airway management is unknown.

OBJECTIVE To compare the effectiveness of a strategy of initial LT insertion vs initial ETI in adults with OHCA.

DESIGN, SETTING, AND PARTICIPANTS Multicenter pragmatic cluster-crossover clinical trial involving EMS agencies from the Resuscitation Outcomes Consortium. The trial included 3004 adults with OHCA and anticipated need for advanced airway management who were enrolled from December 1, 2015, to November 4, 2017. The final date of follow-up was November 10, 2017.

INTERVENTIONS Twenty-seven EMS agencies were randomized in 13 clusters to initial airway management strategy with LT (n = 1505 patients) or ETI (n = 1499 patients), with crossover to the alternate strategy at 3- to 5-month intervals.

MAIN OUTCOMES AND MEASURES The primary outcome was 72-hour survival. Secondary outcomes included return of spontaneous circulation, survival to hospital discharge, favorable neurological status at hospital discharge (Modified Rankin Scale score ≤3), and key adverse events.

RESULTS Among 3004 enrolled patients (median [interquartile range] age, 64 [53-76] years, 1829 [60.9%] men), 3000 were included in the primary analysis. Rates of initial airway success were 90.3% with LT and 51.6% with ETI. Seventy-two hour survival was 18.3% in the LT group vs 15.4% in the ETI group (adjusted difference, 2.9% [95% CI, 0.2%-5.6%]; *P* = .04). Secondary outcomes in the LT group vs ETI group were return of spontaneous circulation (27.9% vs 24.3%; adjusted difference, 3.6% [95% CI, 0.3%-6.8%]; *P* = .03); hospital survival (10.8% vs 8.1%; adjusted difference, 2.7% [95% CI, 0.6%-4.8%]; *P* = .01); and favorable neurological status at discharge (7.1% vs 5.0%; adjusted difference, 2.1% [95% CI, 0.3%-3.8%]; *P* = .02). There were no significant differences in oropharyngeal or hypopharyngeal injury (0.2% vs 0.3%), airway swelling (1.1% vs 1.0%), or pneumonia or pneumonitis (26.1% vs 22.3%).

CONCLUSIONS AND RELEVANCE Among adults with OHCA, a strategy of initial LT insertion was associated with significantly greater 72-hour survival compared with a strategy of initial ETI. These findings suggest that LT insertion may be considered as an initial airway management strategy in patients with OHCA, but limitations of the pragmatic design, practice setting, and ETI performance characteristics suggest that further research is warranted.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT02419573

JAMA. 2018;320(8):769-778. doi:10.1001/jama.2018.7044

Visual Abstract

Editorial page 761

Related article page 779

Supplemental content

CME Quiz at jamanetwork.com/learning and CME Questions page 834

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Out-of-hospital cardiopulmonary arrest (OHCA) affects more than 350 000 adults in the United States each year, with less than 10% surviving to hospital discharge in 2016.[1] In the United States and countries with advanced emergency medical services (EMS) systems, paramedics commonly perform endotracheal intubation (ETI) on patients with cardiac arrest to provide a direct conduit to the lungs, facilitate controlled oxygenation, and protect the lungs from aspiration of vomitus.

ETI plays a central but controversial role in contemporary EMS care. More than 30 years ago, ETI became a standard US paramedic practice under the assumption that it would improve OHCA outcomes. However, numerous studies have highlighted the challenges of paramedic ETI, including significant rates of unrecognized tube misplacement or dislodgement, need for multiple ETI attempts, and ETI insertion failure.[2-4] ETI has also been associated with iatrogenic hyperventilation and chest compression interruptions.[5,6] Furthermore, opportunities for EMS ETI training and skills maintenance are limited in the United States, with many paramedics performing only 1 live procedure annually.[7]

Alternatives to ETI include supraglottic airway (SGA) devices including the laryngeal mask airway, esophageal-tracheal combitube, i-gel, and laryngeal tube (LT). Compared with ETI, SGA insertion is rapid, simple, and requires less training, while offering ventilatory characteristics that are similar to ETI.[8] While traditionally reserved for contingency use in the event of unsuccessful ETI efforts, SGA insertion has been incorporated by many EMS agencies as the primary method of ventilation during OHCA resuscitation. However, multiple observational studies reported better outcomes associated with ETI compared with SGAs.[9-11]

To date, few randomized clinical trials have compared ETI with other airway techniques in OHCA.[12-14] This Resuscitation Outcomes Consortium Pragmatic Airway Resuscitation Trial (PART) compared the effectiveness of initial LT and initial ETI strategies on outcomes in adult OHCA.

Key Points

Question What is the effect of an initial airway management strategy using laryngeal tube insertion, compared with endotracheal intubation, on survival among adults with out-of-hospital cardiac arrest?

Findings In this cluster-crossover randomized trial of 3004 adults with out-of-hospital cardiac arrest, 72-hour survival was 18.3% for laryngeal tube insertion and 15.4% for endotracheal intubation, a significant difference.

Meaning A strategy of initial laryngeal tube insertion, compared with endotracheal intubation, was associated with greater likelihood of 72-hour survival, but given limitations in study design and findings, additional research is warranted.

Methods

Design

We conducted a multicenter cluster-crossover randomized trial. The trial methods have been previously reported, and the trial protocol is available in Supplement 1.[15] The institutional review boards of the participating institutions approved the trial under federal rules for conduct of emergency research under Exception From Informed Consent (21 CFR 50.24). Participating sites satisfied all requirements for this, including community consultation, public disclosure, and notification of patient, family members, or legally authorized representatives of enrollment.

Funding

The trial was funded by a National Heart, Lung, and Blood Institute (NHLBI) program supporting large-scale, low-cost pragmatic clinical trials.[16] This required following stipulated pragmatic trial principles, the use of existing research infrastructure, adherence as much as possible to existing clinical practice, and focus on describing outcomes rather than explanatory mechanisms. The Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2)[17] wheel for the trial is provided in eAppendix 1 in Supplement 2. The capped funding amount constrained the potential number of enrolled patients.

Data and Safety Monitoring

A trial-appointed study monitoring committee monitored EMS agency and regional center protocol compliance and data reporting. An NHLBI-appointed data and safety monitoring board approved the protocol, monitored the safety and interim results of the trial, and made recommendations for its continuation or suspension.

Study Setting and Organization

The trial included 27 EMS agencies associated with US sites of the Resuscitation Outcomes Consortium, a North American multicenter network funded by the NHLBI to conduct clinical trials of therapies for OHCA and major trauma (eTable 1 in Supplement 2). The University of Alabama at Birmingham and the University of Washington Clinical Trials Center functioned as the respective clinical and data coordinating centers for the trial.

Selection of Patients

The trial included adults (age ≥18 years or per local interpretation) with nontraumatic OHCA treated by participating EMS agencies and requiring anticipated ventilatory support or advanced airway management (eAppendix 2 in Supplement 2). Patients who received initial clinical care by EMS agencies with ETI or SGA insertion capabilities and that were not affiliated with the trial were excluded.

Interventions

The trial randomized EMS agencies to either of 2 initial advanced airway management strategies: initial LT insertion or initial orotracheal ETI (eFigure 1 in Supplement 2). Although a variety of SGA devices are available, only LT insertion was allowed because it is the most commonly

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used SGA in the United States. The protocol allowed the use of neuromuscular blocking agents or video laryngoscopy but not other techniques (eg, nasotracheal intubation) for initial intubation efforts.

The protocol did not prescribe or limit the number of initial LT or ETI insertion attempts. If the initial LT/ETI insertion efforts were unsuccessful, EMS personnel performed rescue airway management using any available airway technique, including bag-valve-mask (BVM) ventilation, ETI (including alternate ETI techniques such as nasal or digital intubation), insertion of LT or another SGA device, or needle jet ventilation or cricothyroidotomy. EMS personnel followed local protocols for confirmation of airway placement and management of OHCA, including field termination of resuscitation efforts. Patients receiving BVM ventilation only (without any LT or ETI attempts) were retained in their assigned treatment group per intention-to-treat principles. The trial did not prescribe clinical care at the receiving hospitals, including the use or replacement of the EMS airway, the provision of targeted temperature management, percutaneous coronary intervention, or the timing of withdrawal of life-sustaining therapy.[18]

While ETI is almost exclusively an advanced life support skill, basic life support clinicians at the Milwaukee and Portland sites had been trained in LT insertion.[19,20] When these EMS agencies were assigned to LT, select basic life support–only clinicians performed initial LT insertion. When assigned to ETI, these clinicians performed BVM ventilation until advanced life support arrival.

Randomization

The trial used cluster randomization with crossover. We grouped the 27 EMS agencies into 13 randomization clusters. Each cluster selected an a priori crossover interval of 3 or 5 months. Based on each cluster's selected crossover interval and projected duration of trial participation, the lead statistician created a detailed a priori randomization plan (complete with crossover dates and assigned interventions), with the goal of achieving balance within and across sites at the end of the trial. Within each cluster, treatment assignments for consecutive intervals were computer-randomized in blocks of 2 to ensure balanced exposure to both airway groups. Crossovers between study groups could occur more than once.

Practical factors influenced the execution of the randomization. We provided crossover notifications to each cluster at least 1 month prior to the scheduled crossover date, aiming to initiate crossovers on the first day of a calendar month. We allowed EMS agencies to align crossover dates with training sessions, avoid weekends, and avoid crossovers during the last month of the trial. Some clusters experienced delays in start-up, which required adjustments of planned crossover dates (but not randomization groups). If clinicians from more than 1 participating EMS agency were present on scene, the first arriving unit determined the study treatment assignment.

Among the 56 random cluster treatment group assignments, we made 2 crossover adjustments to achieve balanced enrollment between study groups. Enrollment in 1 cluster exceeded projections; we instructed this cluster to carry out 1 additional crossover. One agency ended participation in the trial prior to study completion; to compensate, we instructed another cluster to defer its final crossover. These decisions regarding changes to cluster crossover timings were made without knowledge of outcome data by randomization cluster.

Outcomes

The primary outcome was survival to 72 hours after the index arrest, determined from hospital or (in cases of field termination of resuscitation) EMS records (eTable 2 in Supplement 2). We chose this outcome because it requires a smaller sample size than traditional outcomes (eg, survival to hospital discharge) and accommodated key elements of standard postarrest care such as therapeutic hypothermia (targeted temperature management), early percutaneous coronary intervention, and delay of neurological assessment.[18,21] Secondary trial outcomes included (1) return of spontaneous circulation (presence of palpable pulses on emergency department arrival), (2) survival to hospital discharge, and (3) favorable neurological status on hospital discharge (Modified Rankin Scale score ≤3). Other secondary outcomes included EMS airway management course and hospital adverse events. Research coordinators ascertaining clinical outcomes were not blinded to the study intervention.

While postulated mechanisms influencing OHCA outcomes following advanced airway management include chest compression interruptions and hyperventilation, the pragmatic nature of the trial precluded the formal collection and analysis of chest compression and ventilation data.[6,22,23]

Study Compliance Benchmarks

Benchmarks used by the study monitoring committee for assessing EMS agency performance in the trial are listed in eAppendix 3 in Supplement 2.

Data Analysis

We estimated the sample size based on the expected frequency of 72-hour survival (eAppendix 4 in Supplement 2). Because we could not identify any prior reports of 72-hour survival after OHCA, we used data from the ROC PRIMED trial.[24,25] After limiting this analysis to US sites with active use of SGA, we estimated baseline 72-hour survival rates of 16.2% for ETI and 11.1% for SGA, suggesting a potential effect size of 5.1%. By study team consensus, we selected a more conservative value of 4.5% as the difference to power the study.

To account for patients receiving BVM only, we increased the baseline LT survival rate to 13.7%. We designed the trial to have 85% power to detect a 4.5% difference in 72-hour survival, assuming an overall 2-sided $\alpha = .05$, adjusting for number of analyses (3 interim and 1 final) and accommodating up to a 5% loss of precision due to cluster randomization with crossover. While the projected minimum sample size was 2612 patients (1306 per group) to

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allow for exclusions, loss to follow-up, and patients treated with BVM only, we aimed to enroll a total of 3000 patients. Trial-stopping boundaries followed asymmetric 2-sided designs based on the unified family of group sequential stopping rules.[26,27]

We analyzed the primary and secondary outcomes on intention-to-treat bases. In cases where rescuers used only BVM (without ETI or LT insertion), we retained the patient in their assigned randomization. To quantify the treatment effect, we used generalized estimating equations (GEEs) with an identity link and robust standard errors, accounting for randomization cluster and number of interim analyses.

We assessed whether the association of airway management strategy with the primary outcome differed by a priori–defined subgroups, including initial cardiac rhythm, bystander-witnessed arrest, EMS response time, basic life support unit capability of LT insertion, time of airway placement after first rescuer arrival on scene, use of neuromuscular blocking agents before or during airway insertion efforts, age, use of video laryngoscopy, use of BVM ventilation only, and airway placement after return of spontaneous circulation. We assessed the influence of these factors by evaluating each (intervention by subgroup) interaction term in the primary model.

To assess the effect of deviations from random assignment, we conducted a per-protocol analysis, retaining only cases in compliance with their assigned airway group (eg, assigned to ETI and received ETI or BVM). We considered instances of BVM only to be compliant with the protocol because the expected course of airway management may entail BVM ventilation.

To assess the effect of unbalanced randomization within clusters, we conducted post hoc GEE analyses of the intention-to-treat and per-protocol populations, adjusting for age, sex, bystander- or EMS-witnessed arrest, time to EMS arrival, bystander chest compressions, and initial cardiac rhythm. We repeated post hoc analysis of the intention-to-treat population with a hierarchical model (patients nested within EMS agency and EMS agency nested within randomization cluster) and a model with randomization cluster as a fixed effect. We examined the effect of randomization order (LT first vs ETI first) by fitting a treatment by order interaction term. We also conducted as-treated analyses, classifying each case to 1 of 3 groups according to airway technique received: LT, ETI, and BVM or other. We limited as-treated comparisons to LT vs ETI.

Missing data were flagged on data entry and reviewed by data entry staff for accuracy. We treated "unknown" variable categories as informative and included these as separate factors in the GEE models. We considered missing baseline data to be missing completely at random for post hoc GEE models; we did not impute values. Patients with missing data in any of the adjustment variables were excluded from the model. We used 2-sided tests with an α of .05 as the threshold for statistical significance. We conducted all analyses using the statistical package R version 3.2.5 (The R Foundation).

Results

Patient Characteristics

The trial enrolled patients from December 1, 2015, through November 4, 2017. The duration of enrollment for each cluster ranged from 11 to 23 months (eFigure 2 in Supplement 2). Enrollment clusters crossed over between interventions 1 to 6 times. Of 3840 screened patients, 3004 were included; 1505 assigned to initial LT and 1499 assigned to initial ETI (**Figure**). The proportion of LT and ETI assignments varied across randomization clusters (eFigure 3 in Supplement 2).

Baseline patient and airway management characteristics are provided in **Table 1** and eTable 3 in Supplement 2. LT and ETI protocol compliance (initial attempt with assigned airway or use of BVM only) were 95.5% and 90.7%, respectively. Elapsed time from first EMS arrival to airway start was shorter for LT than ETI (median, 9.8 vs 12.5 minutes). Initial LT and ETI success rates (excluding BVM) were 90.3% and 51.6%. Overall LT and ETI airway success rates (initial + rescue airway attempts) were 94.2% and 91.5%, respectively. Clinicians at receiving emergency departments converted 64.4% of EMS LT to ETI. Among patients receiving successful EMS ETI, emergency department clinicians performed repeat ETI in 33.1%. Outcomes of initial and rescue airway interventions are presented in eFigure 4 in Supplement 2.

A total of 352 patients received BVM only without any advanced airway insertion efforts. Reported reasons for the use of BVM only included the patient regaining consciousness (29.3%), death prior to airway insertion attempts (14.2%), jaw clenching (trismus, 11.9%), adequate ventilation with BVM (9.9%), arrival at emergency department prior to airway insertion efforts (7.7%), and other (8.8%) (eTable 4 in Supplement 2).

Primary Outcome

Seventy-two-hour survival was unknown for 4 patients (0.1%). Among the remaining patients, 72-hour survival was 18.3% in the LT group vs 15.4% in the ETI group; accounting for randomization cluster and interim analyses, this difference was 2.9% (95% CI, 0.2%-5.6%; P = .04; relative risk, 1.19 [95% CI, 1.01-1.39]) (**Table 2**).

Secondary Outcomes

Secondary outcomes in the LT group vs ETI group were return of spontaneous circulation (27.9% vs 24.3%; adjusted difference, 3.6% [95% CI, 0.3%-6.8%]; P = .03), hospital survival (10.8% vs 8.1%; adjusted difference, 2.7% [95% CI, 0.6%-4.8%; P = .01), and favorable neurological status at discharge (7.1% vs 5.0%; adjusted difference, 2.1% [95% CI, 0.3%-3.8%] P = .02). There were no statistically significant differences in treatment effects in 72-hour survival among a priori–defined subgroups (eFigure 5 in Supplement 2).

Additional Analyses

In the per-protocol group, 72-hour survival was greater for LT than ETI (18.3% vs 15.4%; risk difference, 2.9% [95% CI, 0.1%-5.7%]; P = .045).

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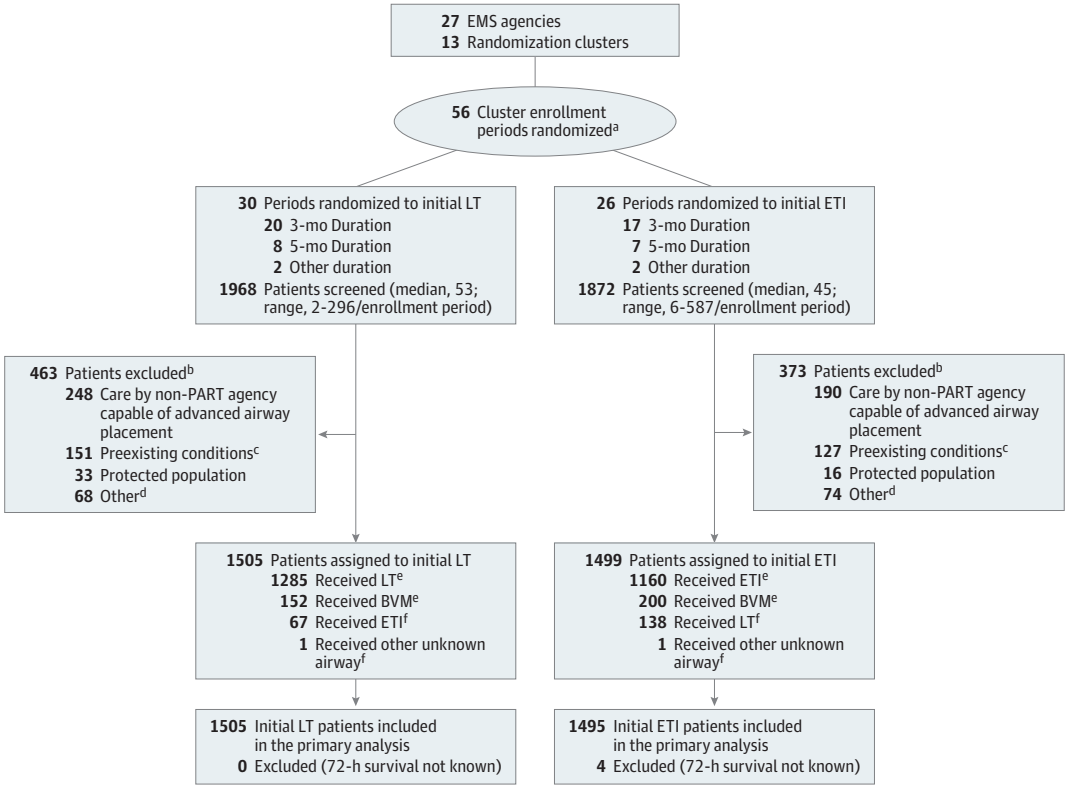
Figure. Flow of Patients in the Pragmatic Airway Resuscitation Trial



Randomization of clusters and screening and inclusion of patients in the trial. EMS indicates emergency medical services; ETI, endotracheal intubation; LT, laryngeal tube; PART, Pragmatic Airway Resuscitation Trial.

[a] Cluster enrollment periods depicted in eFigure 2 in Supplement 2. Twenty-seven EMS agencies were grouped into 13 randomization clusters, with each cluster selecting an a priori crossover interval of 3 or 5 months.

[b] Screened patients may have been excluded for more than 1 reason.

[c] Preexisting conditions include preexisting tracheostomy; preexisting do-not-attempt-resuscitation orders; patient with advanced airway inserted prior to EMS arrival; patients with left ventricular assist device or total artificial heart; and patients with a do-not-enroll bracelet.

[d] Other exclusions include major bleeding or exsanguination, obvious asphyxial cardiac arrest, interfacility transports, and traumatic etiology of arrest.

[e] Protocol compliance.

[f] Protocol deviation.

Adverse events are summarized in **Table 3**. Compared with LT, patients in the ETI group were more likely to experience 3 or more airway insertion attempts (18.9% vs 4.5%). Unsuccessful initial airway insertion was higher for ETI than LT (44.1% vs 11.8%). Unrecognized airway misplacement or dislodgement was higher for ETI than LT (1.8% vs 0.7%). EMS personnel reported inadequate ventilation more often in LT than ETI (1.8% vs 0.6%). Pneumothoraces (7.0% vs 3.5%) and rib fractures (7.0% vs 3.3%) were more common with ETI than LT. There were no significant differences in oropharyngeal or hypopharyngeal injury (0.2% vs 0.3%), airway swelling (1.1% vs 1.0%), or pneumonia or pneumonitis (26.1% vs 22.3%) in the LT vs ETI groups.

Post-Hoc Analyses

In the intention-to-treat population, after post hoc adjustment for age, sex, initial cardiac rhythm, response time, witnessed status, and bystander chest compressions, the difference in 72-hour survival between LT and ETI was not statistically significant (adjusted difference, 2.1% [95% CI, −0.5% to 4.8%]; P = .11; Table 2). In a hierarchical model with patients nested within agency and agency nested within randomization cluster and applying independent correlation structure, the difference in 72-hour survival between LT and ETI was 1.8% (95% CI, −0.9% to 4.5%). In a linear regression model with randomization cluster included as a fixed effect, the difference in 72-hour survival between LT and ETI was 1.5% (95% CI, −1.2% to 4.3%).

When stratifying by order of randomization (LT first or ETI first), the differences in 72-hour survival were 2.5% (95% CI, −0.9% to 5.9%) for LT first and 3.6% (95% CI, −0.9% to 8.2%) for ETI first (interaction P = .69). After post hoc multivariable adjustment, the difference in 72-hour survival in the per-protocol analysis was not statistically significant (adjusted difference, 2.3% [95% CI, −0.4% to 5.1%]; P = .09; Table 2).

In the as-treated analysis, the initial airway devices used on enrolled patients were ETI in 1224 patients, LT in 1423, and BVM or other in 354; there was no significant difference in

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Table 1. Characteristics of Patients Included in Intention-to-Treat Population

Characteristic	Laryngeal Tube (n = 1505)	Endotracheal Intubation (n = 1499)
Age, median (IQR), y	64 (53-76)	64 (53-76)
Male, no./total No. (%)	928/1503 (61.7)	901/1499 (60.1)
Witnessed arrest, no./total No. (%)	n = 1357	n = 1399
EMS witnessed	180 (13.3)	179 (12.8)
Bystander witnessed	511 (37.7)	529 (37.8)
Not witnessed	666 (49.1)	691 (49.4)
Unknown[a]	148 (9.8)	100 (6.7)
Bystander chest compressions, no./No. (%)	n = 1258	n = 1279
Yes	698 (55.5)	709 (55.4)
No	560 (44.5)	570 (44.6)
Unknown[a]	247 (16.4)	220 (14.7)
Time from dispatch to first arrival of EMS		
Median (IQR), min	5.0 (3.9-6.3)	5.3 (4.1-6.8)
≤4 min, no./total No. (%)	408/1444 (28.3)	305/1405 (21.7)
Unknown	61 (4.1)	94 (6.3)
Time between EMS arrival and start of chest compressions		
Median (IQR), min	2.1 (1.1-3.8)	2.1 (1.0-3.7)
≤10 min, no./total No. (%)	1243/1347 (92.3)	1189/1279 (93.0)
First electrocardiogram rhythm, no./total No. (%)		
Shockable rhythm (ventricular fibrillation, ventricular tachycardia, or delivery of AED shock)	301 (20.0)	270 (18.0)
Nonshockable (asystole, pulseless electrical activity, or AED nonshockable)	1160 (77.1)	1197 (79.9)
Other	44 (2.9)	32 (2.1)
Epinephrine administered before hospital arrival, no./total No. (%)	1385 (92.0)	1405 (93.7)
Compliance with assigned airway intervention, no./total No. (%)[b]	1437 (95.5)	1360 (90.7)
Transported to hospital, no./total No. (%)	906 (60.2)	889 (59.3)
Hospital procedures, no./total No. (%)[c]		
Therapeutic hypothermia	242/460 (52.6)	185/400 (46.3)
Coronary catheterization	109/460 (23.7)	73/400 (18.3)
Patients per randomization cluster[d]		
Mean	116	115
Median (range)	94 (3-314)	66 (12-382)

Abbreviations: AED, automated external defibrillator; EMS, emergency medical services; IQR, interquartile range.

[a] For "unknown" values, denominator is total cases in group.

[b] Episodes were considered compliant if the randomized airway was initially attempted or if only bag-valve-mask was used. Episodes were considered noncompliant if another airway device was used.

[c] Percentage of those transported to hospital and survived for at least 1 hour.

[d] Total of 13 randomization clusters.

72-hour survival between those receiving initial LT and initial ETI (16.0% vs 13.5%; $P = .07$) (eTable 5 in Supplement 2).

Treatment effects varied among randomization clusters (eFigure 6 in Supplement 2) and EMS agencies (eFigure 7 in Supplement 2) and showed a tendency toward favoring LT only in clusters with lower baseline ETI survival.

The primary outcome (72-hour survival) was missing for 4 of 3004 enrolled patients (0.1%), all assigned to ETI. Because of the low number of missing cases, we did not apply multiple imputation. Among the 4 patients with missing 72-hour outcome, there were 16 possible combinations of 72-hour survival; only 1 (all 4 patients surviving to 72 hours) would have altered the primary trial results. Given the observed 15.4% 72-hour survival rate in the ETI group, the probability of all 4 cases surviving to 72 hours was 0.06%.

Discussion

In this trial of 3004 adults with OHCA, a strategy of initial LT was associated with modest but significantly greater 72-hour survival than a strategy of initial ETI. There were also statistically significant associations with survival to hospital discharge and favorable neurological status at hospital discharge that favored the LT group. The trial offers preliminary observations that may potentially guide EMS airway management practices and serve as the basis for future research.

The trial demonstrated the effectiveness of an LT-based strategy of advanced airway management, not the efficacy of the LT airway device. OHCA resuscitation requires the careful

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Table 2. Outcomes of Patients Included in the Primary and Secondary Analyses

Characteristic	No. (%) Laryngeal Tube (n = 1505)	No. (%) Endotracheal Intubation (n = 1499)	Difference, % (95% CI)[a]	*P* Value
Primary Outcome				
Survival to 72 h (intention-to-treat population)	275 (18.3)	230/1495 (15.4)	2.9 (0.2 to 5.6)	.04
Secondary Outcomes				
Return of spontaneous circulation on emergency department arrival	420 (27.9)	365 (24.3)	3.6 (0.3 to 6.8)	.03
Survival to hospital discharge	163/1504 (10.8)	121/1495 (8.1)	2.7 (0.6 to 4.8)	.01
Favorable neurologic status at discharge (Modified Rankin Scale score ≤3)	107/1500 (7.1)	75/1495 (5.0)	2.1 (0.3 to 3.8)	.02
Modified Rankin Scale score	n = 1500	n = 1495		
0-No symptoms	17 (1.1)	14 (0.9)		
1-No significant disability	32 (2.1)	29 (1.9)		
2-Slight disability	22 (1.5)	12 (0.8)		
3-Moderate disability	36 (2.4)	20 (1.3)		
4-Moderately severe disability	26 (1.7)	24 (1.6)		
5-Severe disability	26 (1.7)	22 (1.5)		
6-Dead	1341 (89.4)	1374 (91.9)		
Additional Analyses				
Per-protocol analysis-survival to 72 h	263/1437 (18.3)	209/1356 (15.4)	2.9 (0.1 to 5.7)	.045
Intention-to-treat post hoc adjusted analysis[b]			2.1 (−0.5 to 4.8)	.11
Per-protocol post hoc adjusted analysis[b]			2.3 (−0.4 to 5.1)	.09

[a] For the primary analysis, the estimated difference in 72-hour survival accounted for interim monitoring and clustering via robust standard errors. All other comparisons accounted for clustering.

[b] Post hoc analyses adjusted for age, sex, rhythm, response time, witness status, and bystander chest compressions. A total of 163 patients were omitted from post hoc models due to missing data.

Table 3. Out-of-Hospital and In-Hospital Adverse Events[a]

Characteristic	Laryngeal Tube (n = 1505)	Endotracheal Intubation (n = 1499)	Difference, % (95% CI)	*P* Value
Out-of-Hospital Adverse Events				
Multiple (≥3) insertion attempts[b]				
Initial airway	6/1353 (0.4)	18/1299 (1.4)	−0.9 (−1.7 to −0.2)	.01
Across all airways	61/1353 (4.5)	245/1299 (18.9)	−14.4 (−17.0 to −11.7)	<.001
Unsuccessful insertion[b]				
First airway technique	159/1353 (11.8)	573/1299 (44.1)	−32.4 (−35.6 to −29.1)	<.001
All airway techniques	78/1353 (5.8)	111/1299 (8.5)	−2.8 (−4.8 to −0.8)	.01
Unrecognized airway misplacement or airway dislodgement	10/1353 (0.7)	24/1299 (1.8)	−1.1 (−2.0 to −0.3)	.01
Inadequate ventilation	25/1353 (1.8)	8/1299 (0.6)	1.2 (0.3 to 2.1)	.01
In-Hospital Adverse Events				
Pneumothorax (first chest x-ray)[c]	17/485 (3.5)	30/428 (7.0)	−3.6 (−6.5 to −0.7)	.02
Rib fractures (first chest x-ray)[c]	16/485 (3.3)	30/428 (7.0)	−3.8 (−6.9 to −0.7)	.01
Oropharyngeal or hypopharyngeal injury (first 24 h)[d]	1/460 (0.2)	1/400 (0.3)	0 (−0.7 to 0.6)	.92
Airway swelling or edema (first 24 h)[d]	5/460 (1.1)	4/400 (1.0)	0.1 (−1.3 to 1.4)	.90
Pneumonia or aspiration pneumonitis (first 72 h)[d]	120/460 (26.1)	89/400 (22.3)	3.7 (−2.1 to 9.6)	.21

[a] Out-of-hospital adverse events were based on emergency medical services personnel reports. In-hospital adverse events were determined from review of medical records.

[b] Excludes cases receiving bag-valve-mask ventilation only.

[c] Includes patients who were admitted to emergency department and underwent a chest x-ray.

[d] Includes patients who were admitted to emergency department and survived for at least 1 hour.

coordination of multiple interventions, including initiation and maintenance of chest compressions, controlled ventilation, vascular access, drug administration, and defibrillation. The simpler LT technique may better integrate with and facilitate these other treatments. Although the 2 groups reported similar procedural duration, the elapsed time from EMS arrival to first airway attempt was 2.7 minutes shorter in the LT than ETI group. Also, LT required fewer insertion attempts than ETI. This pragmatic trial did not assess mechanisms underlying the effect of airway type on chest compression quality (in particular, chest compression continuity), which may potentially influence OHCA outcomes.[5,28]

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The ETI success rate of 51% observed in this trial is lower than the 90% success rate reported in a meta-analysis.[29] The reasons for this discordance are unclear. Prior reports of higher success rates may be susceptible to publication bias. Another possibility is that some medical directors encourage early rescue SGA use to avoid multiple unsuccessful intubation attempts and to minimize chest compression interruptions.[5] Few of the study EMS agencies had protocols limiting the number of allowed intubation attempts, so the ETI success rate was not the result of practice constraints. While the ETI proficiency of study clinicians might be questioned, the trial included a diverse range of EMS agencies and likely reflects current practice. It is not clear whether clinicians with more advanced ETI skills or experience would have altered these results. However, this pragmatic trial highlights the outcomes of care resulting from existing EMS airway clinical and training practices; supplementing the trial with specialized airway management training would have limited the generalizability of the findings.

Some limitations of a cluster-crossover design include imbalance in patient allocation, group baseline characteristics, and variations in within-cluster treatment effects. Post hoc adjustment for these factors influenced the observed associations with 72-hour survival, underscoring the importance of even small imbalances. Post hoc analyses also suggested that the benefit of LT may have been amplified in clusters with lower baseline ETI 72-hour survival. The reasons for these intercluster differences are unknown. Post hoc analyses are extremely difficult to interpret in the context of a clinical trial. While cluster-crossover designs have been successfully used in trials enrolling patients with OHCA, additional study must evaluate the nuances of this approach in the context of airway management.[24,30]

These results contrast with prior studies of OHCA airway management. Observational studies have reported higher survival with ETI than SGA, but they were nonrandomized, included a range of SGA types, and did not adjust for the timing of the airway intervention.[9,10,31-34] A trial of 830 children found no difference in survival or neurological outcomes between those randomized to BVM-only ventilation vs BVM+ETI, but the study occurred in 1994-1997, used clinicians who were newly trained in pediatric ETI, and included a range of medical conditions in addition to OHCA.[12] A recent trial of 2043 adult OHCA cases in France and Belgium found no OHCA survival differences between BVM and ETI, but care was rendered by physician-staffed EMS units, a model less common in the United States and countries with similar paramedic-based EMS systems.[35] In the United Kingdom, enrollment has been completed in Airways-2, a trial comparing i-gel SGA with ETI on OHCA outcomes.[36] The current trial focused on LT, which is more commonly used in the United States.

While prior studies suggest higher survival with BVM than with advanced airway devices, similar inferences should not be made based on the as-treated analysis of this trial. The BVM-only group exhibited higher rates of witnessed arrest, bystander chest compressions, and shockable rhythms than LT or ETI, and almost a third regained consciousness prior to advanced airway intervention, suggesting influence from resuscitation time bias.[37] These and other biases cannot be overcome by post hoc analytic techniques. A randomized trial comparing BVM and LT would be needed to assess their relative efficacy.

Limitations

This study has several limitations. First, the pragmatic trial evaluated strategies of LT and ETI under existing clinical protocols and educational practices without additional training or quality improvement monitoring. Second, the stipulations of the grant award influenced many elements of the study design such as limiting the available sample size. Third, the trial could not assess the influence of chest compression or ventilation quality. Fourth, the trial focused on LT use and not other SGAs. Fifth, many elements of the trial were not blinded, including the interventions, allocation, crossover timings, and outcomes ascertainment, and adjustments were made to the crossover plan to balance allocation. Sixth, these results pertain to the out-of-hospital environment and may not apply to the in-hospital setting.

Conclusions

Among adults with OHCA, a strategy of initial LT insertion was associated with significantly greater 72-hour survival compared with a strategy of initial ETI. These findings suggest that LT insertion may be considered as an initial airway management strategy in patients with OHCA, but limitations of the pragmatic design, practice setting, and ETI performance characteristics suggest that further research is warranted.

ARTICLE INFORMATION

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REFERENCES

1. Benjamin EJ, Virani SS, Callaway CW, et al; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2018 Update: a report from the American Heart Association. *Circulation*. 2018; 137(12):e67-e492.

2. Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. *Ann Emerg Med*. 2001;37(1):32-37.

3. Wang HE, Yealy DM. How many attempts are required to accomplish out-of-hospital endotracheal intubation? *Acad Emerg Med*. 2006; 13(4):372-377.

4. Wang HE, Kupas DF, Paris PM, Bates RR, Yealy DM. Preliminary experience with a prospective, multi-centered evaluation of out-of-hospital endotracheal intubation. *Resuscitation*. 2003;58(1): 49-58.

5. Wang HE, Simeone SJ, Weaver MD, Callaway CW. Interruptions in cardiopulmonary resuscitation from paramedic endotracheal intubation. *Ann Emerg Med*. 2009;54(5):645-652.e1.

6. Aufderheide TP, Lurie KG. Death by hyperventilation: a common and life-threatening problem during cardiopulmonary resuscitation. *Crit Care Med*. 2004;32(9)(suppl):S345-S351.

7. Wang HE, Kupas DF, Hostler D, Cooney R, Yealy DM, Lave JR. Procedural experience with out-of-hospital endotracheal intubation. *Crit Care Med*. 2005;33(8):1718-1721.

8. Ritter SC, Guyette FX. Prehospital pediatric King LT-D use: a pilot study. *Prehosp Emerg Care*. 2011; 15(3):401-404.

9. Wang HE, Szydlo D, Stouffer JA, et al; ROC Investigators. Endotracheal intubation versus supraglottic airway insertion in out-of-hospital cardiac arrest. *Resuscitation*. 2012;83(9):1061-1066.

10. McMullan J, Gerecht R, Bonomo J, et al; CARES Surveillance Group. Airway management and out-of-hospital cardiac arrest outcome in the CARES registry. *Resuscitation*. 2014;85(5):617-622.

11. Benoit JL, Gerecht RB, Steuerwald MT, McMullan JT. Endotracheal intubation versus supraglottic airway placement in out-of-hospital cardiac arrest: a meta-analysis. *Resuscitation*. 2015; 93:20-26.

12. Gausche M, Lewis RJ, Stratton SJ, et al. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome: a controlled clinical trial. *JAMA*. 2000;283(6):783-790.

13. Frascone RJ, Russi C, Lick C, et al. Comparison of prehospital insertion success rates and time to insertion between standard endotracheal intubation and a supraglottic airway. *Resuscitation*. 2011;82(12):1529-1536.

14. Benger JR, Voss S, Coates D, et al. Randomised comparison of the effectiveness of the laryngeal mask airway supreme, i-gel and current practice in the initial airway management of prehospital cardiac arrest (REVIVE-Airways): a feasibility study research protocol. *BMJ Open*. 2013;3(2):e002467.

15. Wang HE, Prince DK, Stephens SW, et al. Design and implementation of the Resuscitation Outcomes Consortium Pragmatic Airway Resuscitation Trial (PART). *Resuscitation*. 2016;101:57-64.

16. Department of Health and Human Services. Low-cost, pragmatic, patient-centered randomized controlled intervention trials (UH2/UH3). https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-019.html. Published 2013. Accessed April 3, 2018.

17. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147.

18. Callaway CW, Donnino MW, Fink EL, et al. Part 8: post-cardiac arrest care: 2015 American Heart Association Guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2015;132(18)(suppl 2):S465-S482.

19. Ochs M, Vilke GM, Chan TC, Moats T, Buchanan J. Successful prehospital airway management by EMT-Ds using the combitube. *Prehosp Emerg Care*. 2000;4(4):333-337.

20. Cady CE, Pirrallo RG. The effect of combitube use on paramedic experience in endotracheal intubation. *Am J Emerg Med*. 2005;23(7):868-871.

21. Peberdy MA, Callaway CW, Neumar RW, et al; American Heart Association. Part 9: post-cardiac arrest care: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2010; 122(18)(suppl 3):S768-S786.

22. Aufderheide TP, Sigurdsson G, Pirrallo RG, et al. Hyperventilation-induced hypotension during cardiopulmonary resuscitation. *Circulation*. 2004; 109(16):1960-1965.

23. Benoit JL, Prince DK, Wang HE. Mechanisms linking advanced airway management and cardiac arrest outcomes. *Resuscitation*. 2015;93:124-127.

24. Stiell IG, Nichol G, Leroux BG, et al; ROC Investigators. Early versus later rhythm analysis in patients with out-of-hospital cardiac arrest. *N Engl J Med*. 2011;365(9):787-797.

25. Aufderheide TP, Nichol G, Rea TD, et al; Resuscitation Outcomes Consortium (ROC) Investigators. A trial of an impedance threshold device in out-of-hospital cardiac arrest. *N Engl J Med*. 2011;365(9):798-806.

26. Kittelson JM, Emerson SS. A unifying family of group sequential test designs. *Biometrics*. 1999; 55(3):874-882.

27. Pampallona S, Tsiatis AA. Group sequential designs for one-sided and two-sided hypothesis testing with provision for early stopping in favor of

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the null hypothesis. *J Stat Plan Inference*. 1994;42:19-35. doi:10.1016/0378-3758(94)90187-2

28. Kurz MC, Prince DK, Christenson J, et al; ROC Investigators. Association of advanced airway device with chest compression fraction during out-of-hospital cardiopulmonary arrest. *Resuscitation*. 2016;98:35-40.

29. Hubble MW, Brown L, Wilfong DA, Hertelendy A, Benner RW, Richards ME. A meta-analysis of prehospital airway control techniques part I: orotracheal and nasotracheal intubation success rates. *Prehosp Emerg Care*. 2010;14(3):377-401.

30. Nichol G, Leroux B, Wang H, et al; ROC Investigators. Trial of continuous or interrupted chest compressions during CPR. *N Engl J Med*. 2015;373(23):2203-2214.

31. Kajino K, Iwami T, Kitamura T, et al. Comparison of supraglottic airway versus endotracheal intubation for the pre-hospital treatment of out-of-hospital cardiac arrest. *Crit Care*. 2011;15(5):R236.

32. Hanif MA, Kaji AH, Niemann JT. Advanced airway management does not improve outcome of out-of-hospital cardiac arrest. *Acad Emerg Med*. 2010;17(9):926-931.

33. Hasegawa K, Hiraide A, Chang Y, Brown DF. Association of prehospital advanced airway management with neurologic outcome and survival in patients with out-of-hospital cardiac arrest. *JAMA*. 2013;309(3):257-266.

34. Park MJ, Kwon WY, Kim K, et al. Prehospital supraglottic airway was associated with good neurologic outcome in cardiac arrest victims especially those who received prolonged cardiopulmonary resuscitation. *Acad Emerg Med*. 2017;24(12):1464-1473.

35. Jabre P, Penaloza A, Pinero D, et al. Effect of bag-mask ventilation vs endotracheal intubation during cardiopulmonary resuscitation on neurological outcome after out-of-hospital cardiorespiratory arrest: a randomized clinical trial. *JAMA*. 2018;319(8):779-787.

36. Taylor J, Black S, J Brett S, et al. Design and implementation of the AIRWAYS-2 trial: a multi-centre cluster randomised controlled trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest. *Resuscitation*. 2016;109:25-32.

37. Andersen LW, Grossestreuer AV, Donnino MW. "Resuscitation time bias": a unique challenge for observational cardiac arrest research. *Resuscitation*. 2018;125:79-82.

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Association of Prehospital Advanced Airway Management With Neurologic Outcome and Survival in Patients With Out-of-Hospital Cardiac Arrest

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Importance It is unclear whether advanced airway management such as endotracheal intubation or use of supraglottic airway devices in the prehospital setting improves outcomes following out-of-hospital cardiac arrest (OHCA) compared with conventional bag-valve-mask ventilation.

Objective To test the hypothesis that prehospital advanced airway management is associated with favorable outcome after adult OHCA.

Design, Setting, and Participants Prospective, nationwide, population-based study (All-Japan Utstein Registry) involving 649 654 consecutive adult patients in Japan who had an OHCA and in whom resuscitation was attempted by emergency responders with subsequent transport to medical institutions from January 2005 through December 2010.

Main Outcome Measures Favorable neurological outcome 1 month after an OHCA, defined as cerebral performance category 1 or 2.

Results Of the eligible 649 359 patients with OHCA, 367 837 (57%) underwent bag-valve-mask ventilation and 281 522 (43%) advanced airway management, including 41 972 (6%) with endotracheal intubation and 239 550 (37%) with use of supraglottic airways. In the full cohort, the advanced airway group incurred a lower rate of favorable neurological outcome compared with the bag-valve-mask group (1.1% vs 2.9%; odds ratio [OR], 0.38; 95% CI, 0.36-0.39). In multivariable logistic regression, advanced airway management had an OR for favorable neurological outcome of 0.38 (95% CI, 0.37-0.40) after adjusting for age, sex, etiology of arrest, first documented rhythm, witnessed status, type of bystander cardiopulmonary resuscitation, use of public access automated external defibrillator, epinephrine administration, and time intervals. Similarly, the odds of neurologically favorable survival were significantly lower both for endotracheal intubation (adjusted OR, 0.41; 95% CI, 0.37-0.45) and for supraglottic airways (adjusted OR, 0.38; 95% CI, 0.36-0.40). In a propensity score–matched cohort (357 228 patients), the adjusted odds of neurologically favorable survival were significantly lower both for endotracheal intubation (adjusted OR, 0.45; 95% CI, 0.37-0.55) and for use of supraglottic airways (adjusted OR, 0.36; 95% CI, 0.33-0.39). Both endotracheal intubation and use of supraglottic airways were similarly associated with decreased odds of neurologically favorable survival.

Conclusion and Relevance Among adult patients with OHCA, any type of advanced airway management was independently associated with decreased odds of neurologically favorable survival compared with conventional bag-valve-mask ventilation.

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OUT-OF-HOSPITAL CARDIAC arrest (OHCA) is a major public health problem, occurring in 375 000 to 390 000 individuals in the United States each year.[1] The rate of survival after OHCA has increased with advances in care via initiatives such as the American Heart Association's 5-step Chain of Survival.[2] However, the rate is still low, with recent estimates reporting 8% to 10%.[3-5] Better survival has been associated with the improvement in early access to emergency medical care, early cardiopulmonary resuscitation (CPR), rapid defibrillation, and integrated post–cardiac arrest care.[6] Early advanced life support is often considered of benefit in that it provides intravenous drug therapy and advanced airway management.[6]

Although advanced airway management, such as endotracheal intubation or insertion of supraglottic airways, has long been the criterion standard for airway management of patients with OHCA,[7] recent studies have challenged the survival benefit of advanced airway management compared with conventional bag-valve-mask ventilation in this clinical

For editorial comment see p 285.

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setting.[8-14] However, large-scale studies evaluating the association between advanced airway management and patient-centered outcomes such as neurological status do not exist. Thus, whether prehospital advanced airway management by emergency medical service (EMS) personnel increases or decreases the rate of favorable neurological outcome among adults with OHCA remains to be determined.[15,16]

The purpose of the current study was to examine whether CPR with any type of out-of-hospital advanced airway management by EMS personnel, compared with CPR with conventional bag-valve-mask ventilation, would be associated with favorable neurological outcome in adult OHCA. In addition, we postulated that both advanced airway techniques (endotracheal intubation or use of supraglottic airways) would be similarly associated with favorable neurological outcome after OHCA.

METHODS

Study Design and Participants

The All-Japan Utstein Registry of the Fire and Disaster Management Agency (FDMA) is a prospective, nationwide, population-based registry system of OHCA in adults and children, with Utstein-style data collection.[17] This study enrolled all adults aged 18 years or older who had had OHCA and for whom resuscitation was attempted by EMS personnel with subsequent transport to medical institutions from January 1, 2005, to December 31, 2010. Patients were excluded from the analysis if out-of-hospital airway management or age was not documented. Cardiac arrest was defined as the end of cardiac mechanical activity determined by the absence of signs of circulation.[17-19] The ethics committees of Kinki University Faculty of Medicine and Massachusetts General Hospital approved the study with a waiver of informed consent.

Study Setting

The population of Japan was roughly 128 million in 2010, with approximately 107 million people aged 18 years or older.[20] The EMS system in Japan has been described previously.[21] Briefly, in Japan, municipal governments provided EMS through 802 fire stations with dispatch centers. All EMS personnel performed CPR according to the Japanese CPR guidelines, which are based on the American Heart Association and the International Liaison Committee on Resuscitation.[2,22,23] In most cases, an ambulance crew consisted of 3 EMS personnel, including at least 1 emergency lifesaving technician who had completed extensive training. These technicians were authorized to insert an intravenous line, to use semiautomated external defibrillators, and to lead CPR. In 1991, emergency lifesaving technicians were also permitted to use supraglottic airway devices (laryngeal mask airway, laryngeal tube, and esophageal-tracheal twin-lumen airway device) for patients with OHCA under medical control direction.[21] Beginning in 2004, endotracheal intubation could be performed by specially trained emergency lifesaving technicians who had completed an additional 62 hours of training sessions and performed 30 supervised successful intubations in operating rooms.[24]

Under medical control direction in the placement of an advanced airway device, the choice of either endotracheal intubation or supraglottic airway was at the discretion of each specially trained emergency lifesaving technician. Advanced airway management was performed, with efforts limited to a total of 2 attempts, after checking initial rhythm and using defibrillation when appropriate, along with chest compression and bag-valve-mask ventilation. Advanced airway device placement with successful ventilation was confirmed by an esophageal detection device and/or an end-tidal carbon dioxide monitor (quantitative or colorimetric).[24] The performance of CPR including prehospital advanced airway management was reviewed by local medical control committees.

Data Collection and Quality Control

Data were collected prospectively with an Utstein-style data form that included sex, age, etiology of arrest, bystander witness status, first documented cardiac rhythm, presence and type of CPR by bystander, administration of epinephrine by EMS personnel, and technique of airway management. A series of EMS times of call receipt, vehicle arrival at the scene, contact with patients, initiation of CPR, and hospital arrival were recorded based on the clock used by each EMS system. Outcome measures included return of spontaneous circulation before hospital arrival, 1-month survival, and neurological status 1 month after the event. To collect 1-month follow up data, the EMS personnel in charge of each patient with OHCA queried the medical control director at the hospital. Patient neurological status was determined by the treating physician; the EMS received a written response. If the patient was not at the hospital, the EMS personnel conducted a follow-up search.

Data forms were completed by the EMS personnel caring for the patients, and the data were integrated into the Utstein registry system on the FDMA database server. Forms were logically checked by the computer system and were confirmed by the FDMA. If the data form was incomplete, the FDMA returned it to the respective fire station and the data were reconfirmed.

Study End Points

The primary end point was favorable neurological outcome 1 month after cardiac arrest, defined a priori as Glasgow-Pittsburgh cerebral performance category 1 (good performance) or 2 (moderate disability).[17] The other categories—3 (severe cerebral disability), 4 (vegetative state), and 5 (death)—were regarded as unfavorable neurological outcomes.[17] Secondary outcome measures were return of spontaneous circulation before hospital arrival and 1-month survival.

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Statistical Analysis

We compared outcomes between any advanced airway management and bag-valve-mask ventilation for all adult OHCA. Then, we compared outcomes between either advanced airway technique (endotracheal intubation or supraglottic airways) and bag-valve-mask ventilation. With the full cohort, 3 unconditional logistic regression models (unadjusted, adjusted for selected variables, and adjusted for all covariates) were fit using each of the 3 end points as a dependent variable. A set of potential confounders was chosen a priori based on biological plausibility and a priori knowledge. These selected variables included age, sex, cause of cardiac arrest, first documented rhythm, witnessed status, type of bystander CPR, use of a public access automated external defibrillator, epinephrine administration, and time intervals from receipt of call to CPR by EMS and from receipt of call to hospital arrival. All covariates included the selected variables above and year, lifesaving technician presence, physician presence in ambulance, defibrillation by EMS personnel, insertion of intravenous line, and prefecture.

Our data derive from 367 837 patients who underwent bag-valve-mask ventilation and 281 522 who underwent advanced airway management. On the assumption of an incidence of 3.0% favorable neurological outcomes in the bag-valve-mask group, the study has 90% power to detect a difference as small as 0.16% between the groups for the primary outcome with a 2-sided significance level of $P<.05$.

Prehospital advanced airway management was not randomly assigned in the study population; therefore, we used a propensity score approach to condition on potential selection bias and confounding. With a multivariable logistic regression model that did not take end points into account, we computed the propensity score, which represented the probability that a patient with cardiac arrest would undergo prehospital advanced airway management. Specifically, a full nonparsimonious model was fit with advanced airway management as the dependent variable, which included the variables in TABLE 1 in addition to dummy variables for the 47 prefectures in Japan as the independent variables. To maximize the efficacy of propensity score matching, missing values for categori-

Table 1. Out-of-Hospital Cardiac Arrest Population Baseline Characteristics According to Airway Management[a]

Characteristics	No. (%)	
	Advanced Airway Management (n = 281 522)	Bag-Valve-Mask Ventilation (n = 367 837)
Patients per year		
2005	44 503 (15.8)	55 988 (15.2)
2006	47 568 (16.9)	55 940 (15.2)
2007	46 398 (16.5)	57 404 (15.6)
2008	46 479 (16.5)	63 617 (17.3)
2009	47 244 (16.8)	64 924 (17.7)
2010	49 325 (17.5)	69 951 (19.0)
Age, mean (SD), y	73.2 (15.5)	72.7 (16.9)
Male sex	167 094 (59.4)	213 071 (57.9)
Etiology of cardiac arrest		
Cardiac	165 310 (58.7)	194 423 (52.9)
Noncardiac	116 212 (41.3)	173 414 (47.1)
External causes[b]	46 315 (16.5)	70 693 (19.2)
Respiratory disease	15 557 (5.5)	22 382 (6.1)
Cerebrovascular disease	13 960 (5.0)	17 522 (4.8)
Malignant tumor	7095 (2.5)	14 824 (4.0)
Other	33 285 (11.8)	47 993 (13.0)
Initial cardiac rhythm		
Ventricular fibrillation or tachycardia	21 867 (7.8)	26 366 (7.2)
Pulseless electrical activity/asystole	259 655 (92.2)	341 471 (92.8)
Bystander witness status[c]		
No witness	159 014 (58.1)	208 689 (58.1)
Layperson	100 647 (36.8)	111 992 (31.2)
Health care practitioner	14 227 (5.2)	38 666 (10.8)
CPR by bystander		
No bystander CPR	160 622 (58.0)	234 811 (64.7)
Compression-only CPR	76 562 (27.7)	85 971 (23.7)
Conventional CPR	39 567 (14.3)	42 396 (11.7)
Use of public-access AED by bystander	1299 (0.5)	1998 (0.6)
CPR by emergency responder		
Emergency lifesaving technician present in ambulance	279 954 (99.5)	333 151 (90.6)
Physician present in ambulance	6754 (2.4)	10 269 (2.8)
Defibrillation by emergency responder	33 016 (11.8)	36 937 (10.1)
Epinephrine administered	29 515 (10.6)	10 709 (2.9)
Insertion of intravenous line	102 586 (36.5)	38 132 (10.4)
Time from call to CPR by emergency responder, median (IQR), min	8 (7-11)	9 (7-12)
Time from call to hospital arrival, median (IQR), min	32 (26-39)	28 (23-36)
Time from CPR by emergency responder to ROSC, median (IQR), min[d]	14 (8-20)	6 (3-12)

Abbreviations: AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; IQR, interquartile range; ROSC, return of spontaneous circulation.
[a] Data are expressed as No. (%) of population unless otherwise indicated. All baseline characteristic comparisons between the 2 groups were statistically significant at $P<.001$.
[b] Defined as cardiac arrest due to trauma, hanging, drowning, intoxication, or asphyxia.
[c] Percentages do not sum to 100 because of missing data.
[d] Calculated for cases with ROSC.

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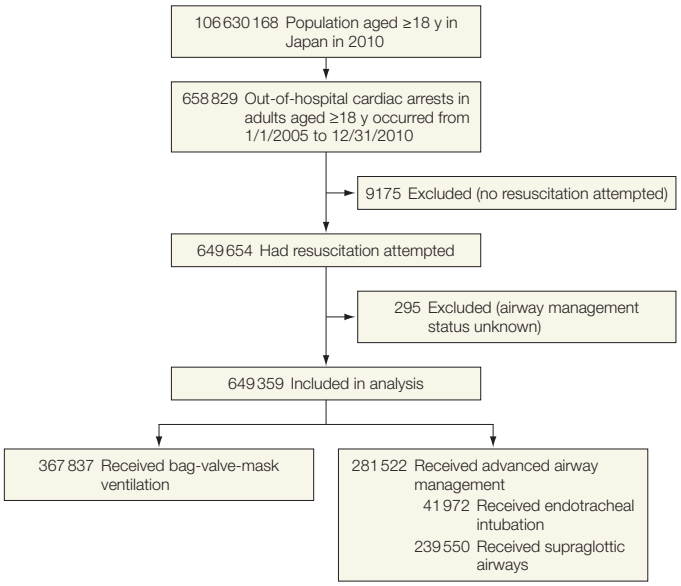
Figure 1. Study Participant Selection



cal variables included in the propensity score model (bystander witness status, bystander CPR, use of a public access automated external defibrillator, use of epinephrine, defibrillation by EMS, and insertion of intravenous line) were dummy coded using the missing indicator method (eTable 1; available at http://www.jama.com). Using the match algorithm by Parsons,[25] based on propensity score, a subgroup of patients with cardiac arrest requiring advanced airway management were matched with unique control patients who underwent bag-valve-mask ventilation. Then, 3 conditional logistic regression models (unadjusted, adjusted for selected variables, and adjusted for all covariates) were fit with each of the 3 end points as a dependent variable.

All statistical analyses were performed with SAS statistical software, version 9.3 (SAS Institute Inc). All statistical tests were 2-tailed. The chosen type 1 error rate was $P<.05$, except when testing the subgroup of patients with endotracheal intubation or supraglottic airways for which a Bonferroni adjustment for multiplicity was used ($P<.025$).

RESULTS

A total of 658 829 adult patients with OHCA were documented. Among 649 654 resuscitation attempts, 295 arrests with unknown airway management status were excluded (FIGURE 1). Of the remaining 649 359 patients, 367 837 (56.7%; 95% CI, 56.5%-56.8%) underwent bag-valve-mask and 281 522 (43.4%; 95% CI, 43.2%-43.5%) underwent advanced airway management, including 41 972 (6.5%; 95% CI, 6.4%-6.5%) with endotracheal intubation and 239 550 (36.9%; 95% CI, 36.8%-37.0%) with supraglottic airways.

Table 1 shows the demographic characteristics for adult OHCA by type of airway management. The mean age of all patients was 73 years; the majority were male. TABLE 2 summarizes survival outcomes by airway management among all patients. Overall, rates of return of spontaneous circulation, 1-month survival, and neurologically favorable survival were 6.5% (95% CI, 6.5%-6.6%), 4.7% (95% CI, 4.7%-4.8%), and 2.2% (95% CI, 2.1%-2.2%), respectively. The rates of neurologically favorable survival were 1.0% (95% CI, 0.9%-1.1%) in the endotracheal intubation group, 1.1% (95% CI, 1.1%-1.2%) in the supraglottic airway group, and 2.9% (95% CI, 2.9%-3.0%) in the bag-valve-mask ventilation group. The unadjusted model using the full cohort demonstrated significant negative associations between any advanced airway management and the 3 end-point measures ($P<.001$ for all) (Table 2). Similarly, in the adjusted model using the selected variables and all variables, both advanced airway techniques (endotracheal intubation and supraglottic airways) were independent negative predictor of all 3 outcomes ($P<.001$for all; Table 2).

To assess the robustness of the results, we performed a series of sensitivity analyses (TABLE 3). First, in an analysis of patients lost to follow-up, when assuming that all missing patients in the bag-valve-mask group (n=444) had an unfavorable neurological outcome and all missing patients in the advanced airway group (n=366) had a favorable outcome, advanced airway management was still a significant negative predictor of favorable neurological outcome after adjusting for selected variables (adjusted odds ratio [OR], 0.43; 95% CI, 0.42-0.45). When adjusting for achievement of return of spontaneous circulation in addition to the selected variables, the adjusted association of endotracheal intubation and supraglottic airways with poor neurological outcome persisted (OR, 0.51 [95% CI, 0.45-0.56] and OR, 0.52 [95% CI, 0.49-0.54], respectively) (Table 3). Similarly, the adjusted association persisted with stratification by achievement of return of spontaneous circulation, etiology of cardiac arrest, first documented rhythm, and type of witness status (Table 3).

Demographic characteristics were similar between the propensity-matched groups (TABLE 4). FIGURE 2 and eTable 2 summarize survival outcomes by airway management among propensity-matched patients. The unadjusted model showed significant negative associations between advanced airway management, regardless of its technique, and the 3 end-

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point measures ($P<.001$ for all). In the multivariable models using selected and all variables, significant negative associations were detected between any type of advanced airway management and the 3 outcome measures (Figure 2). In particular, the adjusted OR for neurologically favorable survival was 0.45 (95% CI, 0.37-0.55; $P<.001$) for endotracheal intubation and 0.36 (95% CI, 0.33-0.39; $P<.001$) for supraglottic airways compared with bag-valve-mask ventilation after controlling for the selected variables.

COMMENT

In this nationwide population-based cohort study of patients with OHCA, we found that CPR with advanced airway management was a significant predictor of poor neurological outcome compared with conventional bag-valve-mask ventilation. Unlike an earlier study that was underpowered to identify this clinically important association,[11] our study was sufficiently large to clearly demonstrate the negative association between advanced airway management and neurologically favorable survival after cardiac arrest. Furthermore, both endotracheal intubation and supraglottic airways were similarly associated with a decreased chance of favorable neurological outcome. The observed associations were large and persisted across different analytic assumptions.

Our clinical data are consistent with findings from several studies in trauma and pediatric patients.[7,8] These studies have suggested that prehospital endotracheal intubation may lead to a decreased rate of favorable neurological outcome, and only a few studies have demonstrated benefit from endotracheal intubation.[7] Additionally, several studies of OHCA have demonstrated the association between endotracheal intubation and decreased survival to hospital discharge.[9,10,13] An important unanswered question regards the mechanism connecting endotracheal intubation with poor outcomes. It has been well documented that prehospital intubation is a complex psychomotor task and that EMS personnel have difficulty gaining and maintaining competency in this skill.[7] Endotracheal intubation by unskilled practitioners can produce ad-

Table 2. Unconditional Logistic Regression Analyses for Outcomes Comparing Prehospital Advanced Airway Management vs Bag-Valve-Mask Ventilation

Model	Total No. of Patients	Bag-Valve-Mask Ventilation, No. (%)	Advanced Airway Management					
			Overall		Endotracheal Intubation		Supraglottic Airway	
			No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]
Total	649 359	367 837 (56.7)	281 522 (43.4)		41 972 (6.5)		239 550 (36.9)	
Return of spontaneous circulation								
Unadjusted	649 326	25 904 (7.0)	16 299 (5.8)	0.81 (0.79-0.83)	3514 (8.4)	1.21 (1.16-1.25)	12 785 (5.3)	0.74 (0.73-0.76)
Adjusted for selected variables[b]				0.67 (0.66-0.69)		0.86 (0.82-0.89)		0.64 (0.62-0.65)
Adjusted for all variables[c]				0.57 (0.56-0.58)		0.73 (0.70-0.77)		0.54 (0.52-0.55)
One-month survival								
Unadjusted	649 350	19 643 (5.3)	10 933 (3.9)	0.72 (0.70-0.73)	1757 (4.2)	0.77 (0.74-0.81)	9176 (3.8)	0.71 (0.69-0.72)
Adjusted for selected variables[b]				0.73 (0.71-0.75)		0.83 (0.79-0.88)		0.72 (0.70-0.74)
Adjusted for all variables[c]				0.62 (0.60-0.64)		0.69 (0.65-0.73)		0.61 (0.59-0.63)
Neurologically favorable survival								
Unadjusted	648 549	10 759 (2.9)	3156 (1.1)	0.38 (0.36-0.39)	432 (1.0)	0.35 (0.31-0.38)	2724 (1.1)	0.38 (0.37-0.40)
Adjusted for selected variables[b]				0.38 (0.37-0.40)		0.41 (0.37-0.45)		0.38 (0.36-0.40)
Adjusted for all variables[c]				0.32 (0.30-0.33)		0.32 (0.29-0.36)		0.32 (0.30-0.33)

Abbreviation: OR, odds ratio.
[a] $P<.001$ for all.
[b] Selected variables are a predefined set of potential confounders including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by bystander, use of a public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by emergency medical service, and time from receipt of call to hospital arrival.
[c] Adjustment for all variables included in Table 1 and dummy variables for the 47 prefectures in Japan.

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verse events, such as unrecognized esophageal intubation, tube dislodgement, iatrogenic hypoxemia, and bradycardia.[26] Furthermore, prehospital intubation may influence patient outcome by affecting the execution of simultaneous basic life support procedures, resulting in ineffective chest compressions with significant interruptions.[7]

Most studies of prehospital airway management using supraglottic airways have focused on process measures, such as success rates and speed of placement. Most of these found higher success rates and faster placement for the supraglottic airways.[27-29] From a physiological perspective, one might expect this to translate into better outcomes because of fewer interruptions of chest compressions. However, we observed that not only endotracheal intubation but also supraglottic airways were independently associated with a lower rate of neurologically favorable survival. Our finding is consistent with a recent study that failed to demonstrate a survival advantage with supraglottic airways in patients with OHCA.[12] Assuming the validity of our study, a more secure airway, regardless of its technique, would be detrimental. Previous studies have shown that inadvertent hyperventilation after advanced airway management can cause increased intrathoracic pressure, leading to decreased coronary and cerebral perfusion pressure among intubated patients with OHCA.[30,31] The literature has also reported that hyperoxia among patients following resuscitation from cardiac arrest was associated with increased mortality.[32,33] These unanticipated physiologic effects may offset the potential benefits of proper advanced airway management.

High-quality prospective clinical trials of prehospital airway management would be instrumental in revealing causality between airway manage-

Table 3. Sensitivity and Stratified Analyses of Multivariable Associations With Neurologically Favorable Survival and Airway Management in the Total Patient Population[a]

Model	Total No. of Patients	Bag-Valve-Mask Ventilation, No. (%)	Advanced Airway Management					
			Overall		Endotracheal Intubation		Supraglottic Airway	
			No. (%)	OR (95% CI) vs Bag-Valve-Mask[b]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[b]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[b]
Sensitivity analysis								
Including loss to follow-up	649 359	10 759 (2.9)	3522 (1.3)	0.43 (0.42-0.45)	457 (1.1)	0.44 (0.39-0.48)	3065 (1.3)	0.43 (0.41-0.45)
Adjusted for ROSC[c]	648 517	10 759 (2.9)	3156 (1.1)	0.51 (0.45-0.56)	432 (1.0)	0.51 (0.45-0.56)	2724 (1.1)	0.52 (0.49-0.54)
Stratification by achievement of ROSC prior to hospital arrival								
ROSC[d]	42 203	8660 (33.5)	2184 (13.4)	0.61 (0.57-0.65)	297 (8.5)	0.65 (0.57-0.75)	1887 (14.5)	0.60 (0.56-0.64)
No ROSC	607 123	2098 (0.6)	969 (0.4)	0.65 (0.60-0.71)	134 (0.4)	0.71 (0.59-0.85)	835 (0.4)	0.65 (0.59-0.70)
Stratification by etiology								
Cardiac origin	359 733	8199 (4.2)	2410 (1.5)	0.36 (0.34-0.38)	293 (1.3)	0.36 (0.32-0.41)	2117 (1.5)	0.36 (0.34-0.38)
Noncardiac origin	289 626	2560 (1.5)	746 (0.6)	0.46 (0.42-0.50)	139 (0.7)	0.51 (0.43-0.61)	607 (0.6)	0.45 (0.41-0.49)
Stratification by initial rhythm								
Ventricular fibrillation or ventricular tachycardia	48 233	5296 (20.1)	1697 (7.8)	0.36 (0.34-0.39)	189 (6.6)	0.34 (0.29-0.40)	1508 (8.0)	0.37 (0.34-0.39)
Pulseless electrical activity/asystole	601 126	5463 (1.6)	1459 (0.6)	0.40 (0.38-0.43)	243 (0.6)	0.47 (0.42-0.54)	1216 (0.6)	0.39 (0.37-0.42)
Stratification by witness status								
Not witnessed	367 363	1635 (0.8)	665 (0.4)	0.49 (0.44-0.53)	80 (0.4)	0.47 (0.37-0.59)	585 (0.4)	0.49 (0.44-0.54)
Witnessed by layperson	212 639	5690 (5.1)	2068 (2.0)	0.39 (0.37-0.41)	303 (1.8)	0.43 (0.38-0.49)	1765 (2.1)	0.38 (0.36-0.43)
Witnessed by EMS	52 893	3383 (8.8)	383 (2.7)	0.29 (0.26-0.32)	43 (2.3)	0.27 (0.20-0.37)	340 (2.8)	0.29 (0.26-0.33)

Abbreviations: EMS, emergency medical service; OR, odds ratio; ROSC, return of spontaneous circulation.

[a] Unconditional logistic regression models adjusted for selected variables including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by bystander, use of a public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by EMS, and time from receipt of call to hospital arrival.

[b] $P < .001$ for all.

[c] Adjusted for achievement of ROSC in addition to the above selected variables.

[d] Adjusted for time from cardiopulmonary resuscitation by EMS to ROSC in addition to the above selected variables.

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ment and outcomes. However, such trials are logistically and methodologically difficult in this clinical setting.[26,34] Additionally, as trials are often designed to address specific questions in select groups, the characteristics of trial populations may differ significantly from those of the general population. As an alternative, our prospective nationwide cohort data reflect the effectiveness of prehospital airway management in the natural setting of a "real" population and current clinical practice, therefore enhancing the potential generalizability of the findings. In addition, multiple studies arrived at similar conclusions despite differing populations, disease groups, and designs.[7-10,12,13] There are plausible mechanisms to support this conclusion. Thus, our data lend significant support to the concept that prehospital intubation and its alternatives are less effective, or even harmful, than was previously believed.

Should clinicians avoid advanced airway management during CPR based on the best available observational evidence? Although one option would be to remove advanced airway management from the skill set of all out-of-hospital rescuers, that approach would disregard situations in which advanced airway management would be expected to be efficacious, especially for long-distance transfers and respiratory failure not yet with cardiac arrest.[35] Future research will need to identify whether there are subsets of patients for whom prehospital advanced airway management is beneficial. In addition, as observational studies cannot establish causal relationships in the way that randomized trials can, a rigorously conducted and adequately powered clinical trial evaluating this criterion standard in patients with OHCA now seems timely and necessary. While awaiting results of such a trial, we believe that decision makers for communities and national organizations should rethink the approach to prehospital airway management and need to invest more resources in optimizing the first 3 links in the chain of survival for the promotion of better outcomes among patients with OHCA.

This study has several limitations. First, as with any observational study, the negative association between any type of out-of-hospital advanced airway management and favorable neurological outcome does not necessarily prove causality and might be confounded by unmeasured factors. Despite a rigorous adjustment for confounding factors with a propensity score–matched analysis, there are other variables that may have contributed for which our study was unable to control or that were not collected a priori. Examples of potential confounding variables include rural or urban distinction, location of cardiac arrest, time interval from cardiac arrest onset to CPR among unwitnessed cardiac arrests, individual rescuer training levels, hospital-level variables, and postresuscitation care such as induced hypothermia therapy. Additionally, one might surmise that patients

Table 4. Baseline Characteristics of Propensity-Matched Patients With Out-of-Hospital Cardiac Arrest According to Airway Management

Characteristics	No. (%)[a] Advanced Airway Management (n = 178 614)	No. (%)[a] Bag-Valve-Mask Ventilation (n = 178 614)
Patients per year		
2005	27 058 (15.1)	27 795 (15.6)
2006	28 002 (15.7)	28 367 (15.9)
2007	28 448 (15.9)	28 494 (16.0)
2008	30 771 (17.2)	30 284 (17.0)
2009	31 294 (17.5)	30 784 (17.2)
2010	33 041 (18.5)	32 892 (18.4)
Age, mean (SD), y	72.9 (15.8)	72.9 (16.8)
Male sex	104 427 (58.5)	104 575 (58.5)
Etiology of cardiac arrest		
Cardiac	99 383 (55.6)	99 586 (55.8)
Noncardiac	79 231 (44.4)	79 028 (44.2)
Initial cardiac rhythm		
Ventricular fibrillation or tachycardia	13 519 (7.6)	13 557 (7.6)
Pulseless electrical activity/asystole	165 095 (92.4)	165 057 (92.4)
Bystander witness status[b]		
No witness	102 437 (57.4)	102 435 (57.3)
Layperson	60 143 (33.7)	60 581 (33.9)
Health care practitioner	11 704 (6.6)	11 149 (6.2)
CPR by bystander[b]		
No bystander CPR	106 591 (59.7)	105 753 (59.2)
Compression-only CPR	46 814 (26.2)	47 290 (26.5)
Conventional CPR	22 850 (12.8)	23 224 (13.0)
Use of public access AED by bystander	921 (0.5)	924 (0.5)
CPR by emergency responder		
Emergency lifesaving technician present in ambulance	177 076 (99.1)	178 316 (99.3)
Physician present in ambulance	4772 (2.7)	4581 (2.6)
Defibrillation by emergency responder	19 509 (10.9)	19 584 (11.0)
Epinephrine administered	10 159 (5.7)	9744 (5.5)
Insertion of intravenous line	37 602 (21.1)	36 051 (20.2)
Time from call to CPR by emergency responder, median (IQR), min	8 (7-11)	8 (7-11)
Time from call to hospital arrival, median (IQR), min	31 (25-38)	29 (23-37)

Abbreviations: AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; IQR, interquartile range.
[a] Data are expressed as No. (%) of population unless otherwise indicated.
[b] Percentages do not sum to 100 because of missing data.

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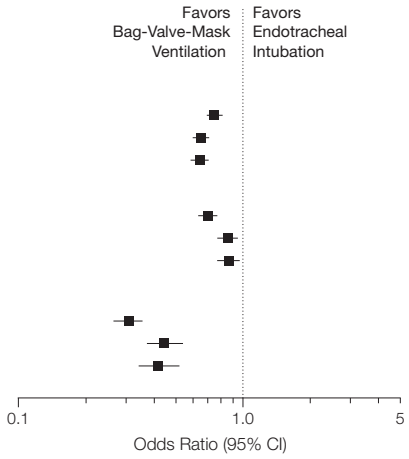
with return of spontaneous circulation prior to any airway management would have subsequently received bag-valve-mask ventilation rather than advanced airway management. These patients may have had neurologically favorable survival more frequently because of early return of spontaneous circulation rather than choice of airway management. However, the subgroup analysis limited to patients who achieved return of spontaneous circulation prior to hospital arrival demonstrated that advanced airway management, regardless of its type, still remained a significant negative predictor for the outcome even after adjusting for time interval from CPR to return of spontaneous circulation. Similarly, in the subgroup analysis of patients who did not achieve return of spontaneous circulation, the adjusted association of advanced airway management with poor neurological outcome persisted. Both suggest that this choice of airway management is the important variable.

Our study is also limited by the absence of information regarding the process of intubation. Indeed, up to 20% of out-of-hospital tracheal intubation efforts may fail.[36] However, we defined advanced airway management as suc-

Figure 2. Results of Conditional Logistic Regression Models Using One of the End Points as a Dependent Variable With Propensity-Matched Patients

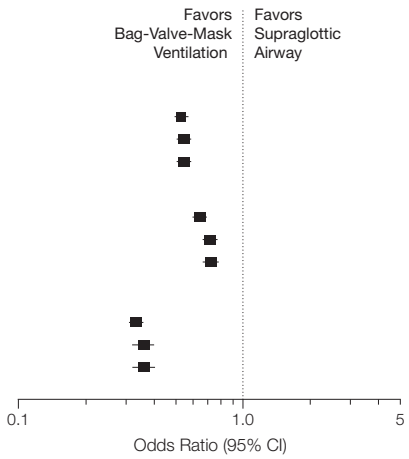
A Endotracheal intubation vs bag-valve-mask ventilation

Model	Total No. of Patients	No. (%) Endotracheal Intubation	No. (%) Bag-Valve-Mask Ventilation	Odds Ratio (95% CI)[a]
Total		26 013 (7.3)	178 614 (50.0)	
Return of spontaneous circulation				
Unadjusted	357 228	1734 (6.7)	14 824 (8.3)	0.76 (0.71-0.81)
Adjusted for selected variables[b]				0.66 (0.61-0.72)
Adjusted for all variables[c]				0.64 (0.58-0.70)
1-month survival				
Unadjusted	357 228	1069 (4.1)	10 373 (5.8)	0.70 (0.65-0.76)
Adjusted for selected variables[b]				0.87 (0.79-0.97)
Adjusted for all variables[c]				0.88 (0.79-0.98)
Neurologically favorable survival				
Unadjusted	357 228	257 (1.0)	5799 (3.2)	0.31 (0.27-0.35)
Adjusted for selected variables[b]				0.45 (0.37-0.55)
Adjusted for all variables[c]				0.42 (0.34-0.53)



B Supraglottic airway vs bag-valve-mask ventilation

Model	Total No. of Patients	No. (%) Supraglottic Airway	No. (%) Bag-Valve-Mask Ventilation	Odds Ratio (95% CI)[a]
Total		152 601 (42.7)	178 614 (50.0)	
Return of spontaneous circulation				
Unadjusted	357 228	6933 (4.5)	14 824 (8.3)	0.53 (0.51-0.54)
Adjusted for selected variables[b]				0.54 (0.52-0.56)
Adjusted for all variables[c]				0.54 (0.52-0.56)
1-month survival				
Unadjusted	357 228	5718 (3.8)	10 373 (5.8)	0.63 (0.61-0.65)
Adjusted for selected variables[b]				0.71 (0.68-0.74)
Adjusted for all variables[c]				0.72 (0.68-0.75)
Neurologically favorable survival				
Unadjusted	357 228	1697 (1.1)	5799 (3.2)	0.33 (0.32-0.35)
Adjusted for selected variables[b]				0.36 (0.33-0.39)
Adjusted for all variables[c]				0.36 (0.33-0.40)



Full models for the primary outcome analysis are included in eTable 2.
[a] For all odds ratios, $P < .001$.
[b] Selected variables are a predefined set of potential confounders including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by a bystander, use of public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by emergency medical service, and time from receipt of call to hospital arrival.
[c] All variables included all covariates in Table 1 and variables for 47 prefectures in Japan.

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cessful endotracheal intubation or supraglottic airway placement only. Thus, in our study, failed advanced airway management cases reverted to and were classified as bag-valve-mask ventilation cases. This would have biased our conclusions toward the null.

Another limitation is that our analysis of a nationwide population-based cohort describes that in Japan only. Similar studies with data from other countries may result in different findings. In particular, one might hypothesize that training of airway management for Japanese EMS personnel is relatively suboptimal, resulting in poor outcomes. However, the certification process for EMS personnel credentialed to perform endotracheal intubation in Japan is stricter than that in other countries. Indeed, the national paramedic curriculum in the United States requires students to perform 5 successful endotracheal intubations to graduate; 25 successful intubations are required in the United Kingdom and 30 are required in Japan.[37-39] Furthermore, existing literature suggests that intubation proficiency is attained by EMS personnel after 15 to 20 successful endotracheal intubations (predicted intubation success threshold of 90%).[40] This would serve not to reduce the potential generalizability of our inference to other settings.

Finally, as with all epidemiological studies, data integrity, validity, and ascertainment bias are potential limitations. The use of uniform data collection on the basis of Utstein-style guidelines for reporting cardiac arrest, large sample size, and a population-based design were intended to minimize these potential sources of biases.

This large, nationwide, population-based cohort study showed that CPR with prehospital advanced airway management, whether endotracheal intubation or supraglottic airways, was independently associated with a decreased likelihood of favorable neurological outcome compared with conventional bag-valve-mask ventilation among adults with OHCA. Our observations contradict the assumption that aggressive airway intervention is associated with improved outcomes and provide an opportunity to reconsider the approach to prehospital airway management in this population.

Author Contributions: Dr Hasegawa had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Hasegawa, Brown.
Acquisition of data: Hasegawa, Hiraide.
Analysis and interpretation of data: Hasegawa, Chang, Brown.
Drafting of the manuscript: Hasegawa.
Critical revision of the manuscript for important intellectual content: Hasegawa, Hiraide, Chang, Brown.
Statistical analysis: Hasegawa, Chang.
Obtaining funding: Hiraide.
Administrative, technical, or material support: Brown.
Study supervision: Hasegawa, Hiraide, Brown.
Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.
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Role of the Sponsor: The Fire and Disaster Management Agency gathered and managed the data but had no role in the design and conduct of the study; analysis and interpretation of the data; or preparation, review, or approval of the manuscript.
Disclaimer: The article contents are solely the responsibility of the authors and do not necessarily represent the official views of the Fire and Disaster Management Agency.
Online-Only Material: eTables 1 and 2 are available at http://www.jama.com.
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REFERENCES

1. Roger VL, Go AS, Lloyd-Jones DM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation*. 2012;125(1):e2-e220.
2. Field JM, Hazinski MF, Sayre MR, et al. Executive summary: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2010;122 (18)(suppl 3):S640-S656.
3. Rea TD, Eisenberg MS, Becker LJ, Murray JA, Hearne T. Temporal trends in sudden cardiac arrest: a 25-year emergency medical services perspective. *Circulation*. 2003;107(22):2780-2785.
4. Nichol G, Thomas E, Callaway CW, et al. Regional variation in out-of-hospital cardiac arrest incidence and outcome. *JAMA*. 2008;300(12):1423-1431.
5. McNally B, Robb R, Mehta M, et al. Out-of-hospital cardiac arrest surveillance—Cardiac Arrest Registry to Enhance Survival (CARES), United States, October 1, 2005–December 31, 2010. *MMWR Surveill Summ*. 2011;60(8):1-19.
6. Berg RA, Hemphill R, Abella BS, et al. Adult basic life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2010;122 (18)(suppl 3):S685-S705.
7. Wang HE, Yealy DM. Out-of-hospital endotracheal intubation: where are we? *Ann Emerg Med*. 2006; 47(6):532-541.
8. Gausche M, Lewis RJ, Stratton SJ, et al. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome: a controlled clinical trial. *JAMA*. 2000;283(6):783-790.
9. Hanif MA, Kaji AH, Niemann JT. Advanced airway management does not improve outcome of out-of-hospital cardiac arrest. *Acad Emerg Med*. 2010; 17(9):926-931.
10. Studnek JR, Thestrup L, Vandeventer S, et al. The association between prehospital endotracheal intubation attempts and survival to hospital discharge among out-of-hospital cardiac arrest patients. *Acad Emerg Med*. 2010;17(9):918-925.
11. Nagao T, Kinoshita K, Sakurai A, et al. Effects of bag-mask vs advanced airway ventilation for patients undergoing prolonged cardiopulmonary resuscitation in pre-hospital setting. *J Emerg Med*. 2012; 42(2):162-170.
12. Shin SD, Ahn KO, Song KJ, Park CB, Lee EJ. Out-of-hospital airway management and cardiac arrest outcomes: a propensity score matched analysis. *Resuscitation*. 2012;83(3):313-319.
13. Egly J, Custodio D, Bishop N, et al. Assessing the impact of prehospital intubation on survival in out-of-hospital cardiac arrest. *Prehosp Emerg Care*. 2011; 15(1):44-49.
14. Wang HE, Szydlo D, Stouffer JA, et al. Endotracheal intubation vs supraglottic airway insertion in out-of-hospital cardiac arrest. *Resuscitation*. 2012; 83(9):1061-1066.
15. Neumar RW, Otto CW, Link MS, et al. Adult advanced cardiovascular life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2010;122(18)(suppl 3):S729-S767.
16. Lecky F, Bryden D, Little R, Tong N, Moulton C. Emergency intubation for acutely ill and injured patients. *Cochrane Database Syst Rev*. 2008;(2): CD001429.
17. Jacobs I, Nadkarni V, Bahr J, et al; International Liaison Committee on Resuscitation; American Heart Association; European Resuscitation Council; Australian Resuscitation Council; New Zealand Resuscitation Council; Heart and Stroke Foundation of Canada; InterAmerican Heart Foundation; Resuscitation Councils of Southern Africa; ILCOR Task Force on Cardiac Arrest and Cardiopulmonary Resuscitation Outcomes. Cardiac arrest and cardiopulmonary resuscitation outcome reports: update and simplification of the Utstein templates for resuscitation registries: a statement for healthcare professionals from a task force of the International Liaison Committee on Resuscitation (American Heart Association, European Resuscitation Council, Australian Resuscitation Council, New Zealand Resuscitation Council, Heart and Stroke Foundation of Canada, InterAmerican Heart Foundation, Resuscitation Councils of Southern Africa). *Circulation*. 2004;110(21):3385-3397.
18. Cummins RO, Chamberlain DA, Abramson NS, et al. Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein style: a statement for health professionals from a task force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council. *Circulation*. 1991;84 (2):960-975.
19. Zaritsky A, Nadkarni V, Hazinski MF, et al. Recommended guidelines for uniform reporting of pediatric advanced life support: the pediatric Utstein style: a statement for healthcare professionals from a task force of the American Academy of Pediatrics, the American Heart Association, and the European Re-

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suscitation Council. *Circulation*. 1995;92(7):2006-2020.
20. 2010 Population Census of Japan. Tokyo: Japan Statistical Association; 2011.
21. Hagihara A, Hasegawa M, Abe T, Nagata T, Wakata Y, Miyazaki S. Prehospital epinephrine use and survival among patients with out-of-hospital cardiac arrest. *JAMA*. 2012;307(11):1161-1168.
22. *Japanese Guidelines for Emergency Care and Cardiopulmonary Resuscitation 2010.* Tokyo, Japan: Health Shuppansha; 2010.
23. ECC Committee, Subcommittees, and Task Forces of the American Heart Association. 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2005;112(24)(suppl):IV1-IV203.
24. Ambulance Service Planning Office of Fire and Disaster Management Agency of Japan. Airway Management With Endotracheal Intubation by Emergency Life Saving Technicians . 2004. http://www.mhlw.go.jp/shingi/2009/03/dl/s0325-12g_0001.pdf. Accessed July 10, 2012.
25. Parsons LS. Reducing Bias in a Propensity Score Matched-Pair Sample Using Greedy Matching Techniques. http://www2.sas.com/proceedings/sugi26/p214-26.pdf. Accessed July 10, 2012.
26. Wang HE, Lave JR, Sirio CA, Yealy DM. Paramedic intubation errors: isolated events or symptoms of larger problems? *Health Aff (Millwood)*. 2006;25(2):501-509.
27. Abo BN, Hostler D, Wang HE. Does the type of out-of-hospital airway interfere with other cardiopulmonary resuscitation tasks? *Resuscitation*. 2007;72(2):234-239.
28. Hoyle JD Jr, Jones JS, Deibel M, Lock DT, Reischman D. Comparative study of airway management techniques with restricted access to patient airway. *Prehosp Emerg Care*. 2007;11(3):330-336.
29. Nickel EA, Timmermann A, Roessler M, Cremer S, Russo SG. Out-of-hospital airway management with the LMA CTrach—a prospective evaluation. *Resuscitation*. 2008;79(2):212-218.
30. Pitts S, Kellermann AL. Hyperventilation during cardiac arrest. *Lancet*. 2004;364(9431):313-315.
31. Aufderheide TP, Lurie KG. Death by hyperventilation: a common and life-threatening problem during cardiopulmonary resuscitation. *Crit Care Med*. 2004;32(9)(suppl):S345-S351.
32. Kilgannon JH, Jones AE, Shapiro NI, et al; Emergency Medicine Shock Research Network Investigators. Association between arterial hyperoxia following resuscitation from cardiac arrest and in-hospital mortality. *JAMA*. 2010;303(21):2165-2171.
33. Ferguson LP, Durward A, Tibby SM. Relationship between arterial partial oxygen pressure after resuscitation from cardiac arrest and mortality in children. *Circulation*. 2012;126(3):335-342.
34. Stiell IG, Wells GA, Field B, et al; Ontario Prehospital Advanced Life Support Study Group. Advanced cardiac life support in out-of-hospital cardiac arrest. *N Engl J Med*. 2004;351(7):647-656.
35. Thomas MJ, Benger J. Prehospital intubation in cardiac arrest: the debate continues. *Resuscitation*. 2011;82(4):367-368.
36. Wang HE, Yealy DM. How many attempts are required to accomplish out-of-hospital endotracheal intubation? *Acad Emerg Med*. 2006;13(4):372-377.
37. National Highway Traffic Safety Administration. Emergency Medical Technician Paramedic: National Standard Curriculum (EMT-P). http://icsw.nhtsa.gov/people/injury/ems/emt-p/. Accessed July 10, 2012.
38. Institute of Healthcare Development Training Requirement for Endotracheal Intubation: Joint Recommendation From AETAG/JRCALC Airway Group. 2008. http://jrcalc.org.uk/guidelines.html. Accessed July 10, 2012.
39. Ambulance Service Planning Office of Fire and Disaster Management Agency of Japan. Airway Management With Endotracheal Intubation by Emergency Life Saving Technicians. http://www.fdma.go.jp/emergency_rescue/kyukyu_kyujo_tuchi/2011/20110801-1.pdf. Accessed July 10, 2012.
40. Wang HE, Balasubramani GK, Cook LJ, Lave JR, Yealy DM. Out-of-hospital endotracheal intubation experience and patient outcomes. *Ann Emerg Med*. 2010;55(6):527-537.

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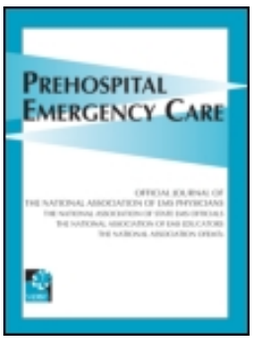

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Alternate Airways in the Prehospital Setting (Resource Document to NAEMSP Position Statement)

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Alternate Airways in the Prehospital Setting (Resource Document to NAEMSP Position Statement)

Francis X. Guyette, MD, MS, Mark J. Greenwood, DO, JD, Diana Neubecker, BSN, EMT-P, Ronald Roth, MD, Henry E. Wang, MD, MPH

Introduction

In the United States, advanced level rescuers often use endotracheal intubation (ETI) to provide oxygenation and ventilation to apneic or hypoventilating patients. Alternate airways are devices that facilitate oxygenation and ventilation without the use of an endotracheal tube (Table 1). Other terms used to describe an alternate airway include rescue airway device, alternative airway, secondary airway, failed airway device, difficult airway device, salvage airway and backup airway, among others. Although rescuers typically use alternate airways when ETI is not feasible, these devices are occasionally used as the primary airway device. This resource document reviews the rationale and data supporting the availability and use of alternate airways in prehospital airway care.

Need and Rationale for Alternate Airway Devices

Although paramedics in the United States are trained to perform ETI, the intervention is often unsuccessful or not possible. Prior studies have described unsuccessful ETI rates ranging from 8% to over 30%.[1–4] Although unsuccessful ETI may result from inadequate relaxation, many prehospital intubation failures occur on patients in cardiac arrest or without protective reflexes. This suggests that rescuers are often not able to visualize airway structures through laryngoscopy, whether due to the nature of airway anatomy, airway injury, rescuer skill, compromised patient position, or inadequate rescuer access.

Bag-valve-mask (BVM) ventilation is often used in the event of failed ETI efforts. However, despite its perception as a fundamental skill, this technique is extremely difficult to perform both in controlled and clinical settings.[5,6] BVM ventilation performance may improve by using a two-rescuer technique, but this may be difficult during prolonged transport or when there is a limited number of rescuers.[7]

In light of these observations, all prehospital services that perform ETI should have alternate airways available for clinical application. This resource document reviews the current literature and provides recommendations regarding the use of prehospital alternate airways.

Alternate Airway Devices

Blindly Inserted Airways

Blindly inserted airways are placed in the oropharynx without directly visualizing laryngeal structures. Designed for placement in either the supraglottic or infraglottic positions, these devices use one or more inflatable balloon cuffs to establish and isolate a patent airway.

Esophageal Tracheal Combitube (Esophageal Tracheal Dual Lumen Airway, Combitube)

The Esophageal Tracheal Combitube (ETC, The Kendall Company, Mansfield, Massachusetts) is a dual-lumen airway that is inserted blindly into the oropharynx. The ETC was originally developed as an alternate airway management device for cardiopulmonary resuscitation.[8] It was designed to provide a temporary airway for providers not skilled in endotracheal intubation.[9] The ETC was first described as a prehospital alternate device by Atherton and Johnson.[10]

The ETC has both theoretical and proven features. It can be inserted blindly and may provide some protection from aspiration.[11,12] The ETC protects against aspiration via a distal esophageal balloon.[13,14] Hagberg et al. suggested that the ETC protects against aspiration better than the laryngeal mask airway (LMA).[15] Prior efforts have verified the ease of its use.[9] Complications associated with ETC use include unrecognized tracheal intubation, pneumomediastinum, pneumoperitoneum, subcutaneous emphysema, perforation of the piriform sinus and those associated with ventilation of the wrong lumen.[16–18] Preliminary evidence suggests that these complications are rare, occurring in less than 1%.[17]

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Table 1. Types of Alternate Airways

Blindly Inserted airways
Laryngeal Mask Airway (LMA)
Esophageal Tracheal Combitube (ETC)
King Laryngeal Tube
Cobra Perilaryngeal Airway (Cobra PLA)
Magboul (Cuffed Oropharyngeal Airway - COPA)
Pharyngeal Tracheal Lumen Airway
Esophageal Obturator Airway (EOA)
Surgical airways
Open Cricothyroidotomy
Percutaneous Cricothyroidotomy
Transtracheal Jet Ventilation

The ETC is widely recognized in the United States, and its use in prehospital settings has been well described.[10,19,20,21] Ochs et al. demonstrated that EMT-Ds could successfully manage 79% of the airways in cardiac arrest cases with the ETC alone.[20] Davis et al. demonstrated the feasibility of ETC use as an alternate airway after failed neuromuscular blockade-assisted intubations.[21] Several authors have described ETC use by basic-level rescuers.[18,20]

Laryngeal Mask Airway

The laryngeal mask airway (LMA, North America, Inc., San Diego, CA, USA) was developed by Brain in 1981 as an alternative to BVM and ETI.[22,23] It was approved for use in the United States in 1991. Although the LMA is used primarily in the operating room setting, several authors have promoted its use in the emergency department and other in-hospital settings.[24–28]

The LMA is believed to cause less damage to the airway than other airway devices.[27] Because there is no balloon securing the device beneath the vocal cords, the risk of aspiration is theoretically higher with the LMA than the ETC or ETI.[15] However, there are currently no data specifically evaluating this phenomenon in the prehospital setting. The LMA may be of limited utility in patients with certain anatomic abnormalities or supraglottic airway obstruction.[24]

Limited studies have described LMA use in the prehospital setting. In a series of 470 prehospital patients, Rumball and McDonald collected arterial blood gas measurements on patients receiving prehospital ETC, pharygotracheal-laryngoscopy, and LMA; the LMA compared similarly with the other devices.[29,30] The LMA is used as a prehospital primary airway device in many countries such as the United Kingdom and Japan.[31,32] Experts have suggested the LMA as an alternate to prehospital ETI for pediatric patients, but supportive data are limited.[33–35]

King Laryngeal Tube (King LT) Airway

The King LT Airway (King Systems Corporation, Noblesville, Indiana) is a relatively new device that is similar in appearance to the ETC.[36] Like the ETC, the King LT device is placed blindly. However, the King LT has only a single lumen, and its shape facilitates more consistent placement in the correct esophageal position. The King LT was specifically designed for prehospital use. Anecdotal reports describe King LT use in prehospital and combat settings, but large-scale clinical data do not yet exist.

Surgical Airways

Surgical airways involve insertion of an airway tube or catheter into the trachea through an incision in the neck. In the United States, three types of surgical airways are commonly available in the prehospital environment: (1) open cricothyroidotomy, (2) percutaneous cricothyroidotomy, and (3) transtracheal jet ventilation.

Open Cricothyroidotomy

Open cricothyriodotomy involves the use of surgical tools (i.e., scalpel, etc.) to facilitate exposure of and insertion of a tracheal tube through the cricothyroid membrane.[37] This technique has been used for over 45 years.[38] Although described as a safe and rapid procedure, the technique requires adequate training for proper execution.[39–42] Cricothyroidotomy has been studied in the hospital and emergency department settings as both a primary and alternate airway.[43,44] Because of the plasticity of the pediatric airway, it is contraindicated in children less than 8 years old.

Several efforts have described cricothyroidotomy use in the prehospital environment.[42,45] Although widely taught, the prehospital application of cricothyroidotomy appears to be rare and associated with significant complications and poor outcomes.[37,42,46,47]

Percutaneous Cricothyroidotomy

Percutaneous cricothyroidotomy uses a modified Seldinger (guidewire) technique to facilitate location of and insertion of a tracheal tube through the cricothyroid membrane. Commercially packaged kits contain the equipment necessary to perfom the procedure.[48] The technique is believed to have fewer complications than open cricothyroidotomy.[49–51]

Percutaneous cricothyroidotomy was first described as an in-hospital alternate airway by Fischer.[52] Percutaneous cricothyroidotomy has been described in the anesthesia literature for difficult airway management.[53,54] Use of the percutaneous cricothyroidotomy was first described in the emergency department in 1992.[55]

The prehospital use of percutaneous cricothyroidotomy was proposed over a decade ago.[55] Several studies using cadavers and human simulators

have demonstrated the prehospital feasibility of this technique.[39,49,50] However, descriptions of clinical prehospital experience with percutaneous cricothyroidotomy are limited.

Transtracheal Jet Ventilation

Transtracheal jet ventilation involves the insertion of a large bore flexible catheter through the cricothyroid membrane to facilitate insufflation of high-pressure oxygen.[56] Although some passive exhalation of carbon dioxide occurs, the technique theoretically does not facilitate ventilation. The pressures generated from conventional oxygen regulators and BVM devices are insufficient for TTJV. Special regulators delivering oxygen at 50 psi must be used with TTJV.[57,58] TTJV is contraindicated in supraglottic obstruction, because no means of exhalation would be present.[59] It is the only form of surgical airway that can be used in small children.[60–62]

Several authors have described the use of TTJV for alternate airway management in the operating room and emergency department settings.[58,63,64] TTJV has been proposed as an alternative to prehospital cricothryoidotomy.[56,58,65] Field studies of TTJV do not exist.

Bag Valve Mask Ventilation and Other Alternate Airway Techniques

Other alternate airway management techniques merit comment. Although all prehospital rescuers are trained to use Bag-Valve-Mask (BVM) ventilation, the technique is relatively difficult. During BVM ventilation, it may be difficult for a single rescuer to simultaneously open the airway, maintain a mask seal, and deliver sufficient tidal volume. Two-rescuer BVM techniques may be more effective, but these approaches may not be practical under the constraints of the prehospital environment. Thus, while some services rely on BVM ventilation as a backup for unsuccessful ETI, because of its difficulty, the BVM is not recommended as the sole alternate airway technique.

The Esophageal Obturator Airway (EOA) was developed in the 1970s and used as a prehospital alternate device for many years. The device consists of a single lumen with a large balloon to obstruct the esophagus and indirectly ventilate the trachea. It has fallen out of favor because of significant complications, including inadvertent tracheal intubation and esophageal trauma.[69,70]

Other airway management devices include the Cuffed Oropharyngeal Airway (COPA, Mallinckrodt Inc., St. Louis, Missouri, USA), the Cobra Perilaryngeal Airway (Engineered Medical Systems, Inc., Indianapolis, Indiana, USA) and other single and multi-lumen airways such as the Pharyngeal Tracheal Lumen Airway (PTL). Descriptions of these devices in either in-hospital or prehospital application are limited.

RECOMMENDATIONS FOR PREHOSPITAL ALTERNATE AIRWAYS

Availability of Alternate Airways

Alternate airway devices should be available to all prehospital rescuers who perform ETI. In addition to the BVM device, all agencies should have at least one blindly inserted airway device available for clinical use.

The role of and need for prehospital surgical airway techniques are not clear at this time. Current data allude to significant concerns including complications and poor outcomes associated with prehospital surgical airway management. In addition, the training needed to maintain these skills is substantial. However, there may be clinical situations where surgical airway management is the only option (e.g., in cases of severe facial trauma). Medical directors must determine the need for prehospital surgical airways on an individual agency basis. Agencies should not rely on surgical airways as the sole alternate airway management technique.

Training in Alternate Airway Use

Medical directors must ensure adequate training in the use of available alternate airways. Acquisition and maintenance of alternate airway skills are important because their clinical use may occur infrequently and under emergent conditions. Training should encompass didactic, simulated, and practical experiences.[71–73] Although training on live patients in controlled settings is desirable, this may not be practical for most alternate airways. For example, operating room patients rarely receive elective cricothyroidotomy, and Combitubes are rarely used in the operating room. Although LMAs are used widely in the operating room, rescuers using LMAs should receive additional training in urgent and emergent contexts.

Clinical Indications for Alternate Airway Use

Clinical indications for alternate airway use have not been formally or scientifically derived. However, a practical recommendation is that alternate airways should be used after failed ETI attempts or in situations where initial or ongoing ETI efforts are predicted to be difficult or futile. "Difficult" conditions may include situations involving difficult airway anatomy, severe airway trauma, or inadequate operator skill, among others. Difficult airway conditions may be identified before or after initial intubation attempts. In situations where airway management difficulty clearly exceeds the skill of the operator, it is recommended that rescuers defer ETI efforts and proceed directly to alternate airway insertion.

Clinical protocols should define broad guidelines for alternate airway use. Scientific and consensus guidelines suggest that ETI efforts should be abandoned (and alternate airway inserted) after no more than three ETI attempts (insertion of blade).[74,75] The prompt availability of online medical command may help to facilitate prudent airway management decision making in scenarios involving failed ETI or alternate airway use. However, because of the emergent nature of airway management efforts, clinical protocols should permit alternate airway insertion without online medical command authorization.

Primary Use of Alternate Airways

Many international EMS agencies use alternate airways in a primary capacity.[76,77] Several sources describe alternate airway use by basic level rescuers.[18,20] Current Advanced Cardiac Life Support recommendations suggest that when adequately skilled personnel are not available, ETI may be substituted with an alternate airway device.[78] Although this strategy has not been formally evaluated or compared with ETI, this approach does have many appealing features, including the simplification of airway management and the reduction of potential impact on other concurrent interventions. In a trial using human simulators, Abo et al. showed that compared with traditional ETI, ETC insertion reduced the time to airway placement as well as the time without chest compressions.[79] This area merits additional scientific study.

Quality Assurance and Quality Improvement

Alternate airway use should be monitored by a comprehensive quality assurance and quality improvement program. EMS medical directors should participate in continuous quality improvement (CQI) activities and have access to all the reviewed airway data. All uses of alternate and salvage airways should be documented as described in the NAEMSP position paper "Recommended Guidelines for Uniform Reporting of Data from Prehospital Airway Management."[80]

Collection of alternate airway data should include (1) indications for invasive airway management, (2) number of attempts at ETI and alternate airway, (3) relevant clinical and physiological factors, (4) methods and devices used, (5) outcomes (success at alternate airway placement), (6) outcomes (success of overall effort), (7) method of confirming proper placement of the airway, (8) physiological changes in patient condition during and after airway management, (9) critical complications encountered in airway management, and (10) reasons for failed ETI or primary use of the alternate airway device. Patient follow-up including linkage to in-hospital course is strongly recommended; these records often are the only indicators of prehospital airway management complications.

Considerations for Future Research

Additional scientific study is needed to improve our understanding of the use of alternate and surgical airways. Specific areas requiring evaluation include (1) clinical indications for alternate airway use; (2) device monitoring, including the identification of physiological response to insertion of, and ventilation through, alternate airways; (3) clinical outcomes after alternate airway use, including morbidity and mortality; (4) education programs and training using both live patients and human simulation; and (5) comparisons of cost and operational impacts.

Conclusion

All prehospital agencies and rescuers that perform endotracheal intubation should have the availability of at least one blindly inserted alternate airway device. All rescuers should receive adequate training in alternate airway use. Medical directors should closely monitor the use of alternate airways.

References

1. Wang HE, Sweeney TA, O'Connor RE, Rubinstein H. Failed prehospital intubations: an analysis of emergency department courses and outcomes. Prehosp Emerg Care. Apr-Jun 2001;5(2):134–141.
2. Wang HE, Kupas DF, Paris PM, Bates RR, Yealy DM. Preliminary Experience with a Prospective Multi-centered Evaluation of Out-of-Hospital Endotracheal Intubation. Resuscitation 2003;58:49–58.
3. Krisanda TJ, Eitel DR, Hess D, Ormanoski R, Bernini R, Sabulsky N. An analysis of invasive airway management in a suburban emergency medical services system. Prehospital Disaster Med. Apr-Jun 1992;7(2):121–126.
4. Wang HE, O'Connor RE, Schnyder ME, Barnes TA, Megargel RE. Patient Status and Time to Intubation in the Assessment of Prehospital Intubation Performance. Prehospital Emergency Care. 2001;5:10–18.
5. Kurola J, Harve H, Kettunen T, et al. Airway management in cardiac arrest–comparison of the laryngeal tube, tracheal intubation and bag-valve mask ventilation in emergency medical training. *Resuscitation.* May 2004;61(2):149–153.
6. Kurola JO, Turunen MJ, Laakso JP, Gorski JT, Paakkonen HJ, Silfvast TO. A comparison of the laryngeal tube and bag-valve mask ventilation by emergency medical technicians: a feasibility study in anesthetized patients. Anesth Analg. Nov 2005;101(5):1477–1481.
7. Davidovic L, LaCovey D, Pitetti RD. Comparison of 1- versus 2-person bag-valve-mask techniques for manikin ventilation of infants and children. Ann Emerg Med. Jul 2005;46(1):37–42.
8. Frass M, Frenzer R, Ilias W, Lackner F, Hoflehner G, Losert U. [The esophageal tracheal Combitube (ETC): animal experiment results with a new emergency tube]. Anasth Intensivther Notfallmed. Jun 1987;22(3):142–144.

9. Frass M, Frenzer R, Mayer G, Popovic R, Leithner C. Mechanical ventilation with the esophageal tracheal combitube (ETC) in the intensive care unit. Arch Emerg Med. Dec 1987;4(4):219–225.
10. Atherton GL, Johnson JC. Ability of paramedics to use the Combitube in prehospital cardiac arrest. Ann Emerg Med. Aug 1993;22(8):1263–1268.
11. Agro F, Frass M, Benumof JL, Krafft P. Current status of the Combitube: a review of the literature. J Clin Anesth. Jun 2002;14(4):307–314.
12. Mercer MH. An assessment of protection of the airway from aspiration of oropharyngeal contents using the Combitube airway. Resuscitation. Nov 2001;51(2):135–138.
13. Hartmann T, Krenn CG, Zoeggeler A, Hoerauf K, Benumof JL, Krafft P. The oesophageal-tracheal Combitube Small Adult. Anaesthesia. Jul 2000;55(7):670–675.
14. Urtubia RM, Carcamo CR, Montes JM. Complications following the use of the Combitube, tracheal tube and laryngeal mask airway. Anaesthesia. Jun 2000;55(6):597–599.
15. Hagberg CA, Vartazarian TN, Chelly JE, Ovassapian A. The incidence of gastroesophageal reflux and tracheal aspiration detected with pH electrodes is similar with the Laryngeal Mask Airway and Esophageal Tracheal Combitube–a pilot study. Can J Anaesth. Mar 2004;51(3):243–249.
16. Richards CF. Piriform sinus perforation during Esophageal-Tracheal Combitube placement. J Emerg Med. Jan-Feb 1998;16(1):37–39.
17. Vezina D, Lessard MR, Bussieres J, Topping C, Trepanier CA. Complications associated with the use of the Esophageal-Tracheal Combitube. Can J Anaesth. Jan 1998;45(1):76–80.
18. Lefrancois DP, Dufour DG. Use of the esophageal tracheal combitube by basic emergency medical technicians. Resuscitation. Jan 2002;52(1):77–83.
19. Deakin CD. Prehospital management of the traumatized airway. Eur J Emerg Med. Dec 1996;3(4):233–243.
20. Ochs M, Vilke GM, Chan TC, Moats T, Buchanan J. Successful prehospital airway management by EMT-Ds using the combitube. Prehosp Emerg Care. Oct-Dec 2000;4(4):333–337.
21. Davis DP, Valentine C, Ochs M, Vilke GM, Hoyt DB. The Combitube as a salvage airway device for paramedic rapid sequence intubation. Ann Emerg Med. Nov 2003;42(5):697–704.
22. Brain AI. The laryngeal mask–a new concept in airway management. Br J Anaesth. Aug 1983;55(8):801–805.
23. Brain AI. The laryngeal mask airway–a possible new solution to airway problems in the emergency situation. Arch Emerg Med. Dec 1984;1(4):229–232.
24. Pollack CV, Jr. The laryngeal mask airway: a comprehensive review for the Emergency Physician. J Emerg Med. Jan 2001;20(1):53–66.
25. Dob DP, Shannon CN, Bailey PM. Efficacy and safety of the laryngeal mask airway vs Guedel airway following tracheal extubation. Can J Anaesth. Feb 1999;46(2):179–181.
26. Verghese C, Brimacombe JR. Survey of laryngeal mask airway usage in 11,910 patients: safety and efficacy for conventional and nonconventional usage. Anesth Analg. Jan 1996;82(1):129–133.
27. Springer DK, Jahr JS. The laryngeal mask airway. Safety, efficacy, and current use. Am J Anesthesiol. Mar-Apr 1995;22(2):65–69.
28. Reardon RF, Martel M. The intubating laryngeal mask airway: suggestions for use in the emergency department. Acad Emerg Med. Aug 2001;8(8):833–838.
29. Rumball CJ, MacDonald D. The PTL, Combitube, laryngeal mask, and oral airway: a randomized prehospital comparative study of ventilatory device effectiveness and cost-effectiveness in 470 cases of cardiorespiratory arrest. Prehosp Emerg Care. Jan-Mar 1997;1(1):1–10.
30. Barbieri S, Michieletto E, Di Giulio M, et al. Prehospital airway management with the laryngeal mask airway in polytraumatized patients. Prehosp Emerg Care. Jul-Sep 2001;5(3):300–303.
31. Ridgway S, Hodzovic I, Woollard M, Latto IP. Prehospital airway management in Ambulance Services in the United Kingdom. Anaesthesia. Nov 2004;59(11):1091–1094.
32. O'Malley RN, O'Malley GF, Ochi G. Emergency medicine in Japan. Ann Emerg Med. Oct 2001;38(4):441–446.
33. Patterson MD. Resuscitation update for the pediatrician. Pediatr Clin North Am. Dec 1999;46(6):1285–1303.
34. McNiece WL, Dierdorf SF. The pediatric airway. Semin Pediatr Surg. Aug 2004;13(3):152–165.
35. Berry AM, Brimacombe JR, Verghese C. The laryngeal mask airway in emergency medicine, neonatal resuscitation, and intensive care medicine. Int Anesthesiol Clin. Spring 1998;36(2):91–109.
36. Hagberg C, Bogomolny Y, Gilmore C, Gibson V, Kaitner M, Khurana S. An evaluation of the insertion and function of a new supraglottic airway device, the King LT, during spontaneous ventilation. Anesth Analg. Feb 2006;102(2):621–625.
37. Xeropotamos NS, Coats TJ, Wilson AW. Prehospital surgical airway management: 1 year's experience from the Helicopter Emergency Medical Service. Injury. Apr 1993;24(4):222–224.
38. Nelson TG, Rumer GF, Nicholas TH. Cricothyroidotomy in complete airway obstruction. Am J Nurs. Nov 1961;61:74–76.
39. Wong DT, Prabhu AJ, Coloma M, Imasogie N, Chung FF. What is the minimum training required for successful cricothyroidotomy?: a study in mannequins. Anesthesiology. Feb 2003;98(2):349–353.
40. Chang RS, Hamilton RJ, Carter WA. Declining rate of cricothyrotomy in trauma patients with an emergency medicine residency: implications for skills training. Acad Emerg Med. Mar 1998;5(3):247–251.
41. O'Connor D, Longhorn R, Heard A. Emergency surgical airway training in Western Australia. Anaesthesia. Sep 2004;59(9):919.
42. Salvino CK, Dries D, Gamelli R, Murphy-Macabobby M, Marshall W. Emergency cricothyroidotomy in trauma victims. *J Trauma.* Apr 1993;34(4):503–505.
43. Bair AE, Panacek EA, Wisner DH, Bales R, Sakles JC. Cricothyrotomy: a 5-year experience at one institution. J Emerg Med. Feb 2003;24(2):151–156.
44. Jones I, Roberts K. Towards evidence based emergency medicine: best BETs from the Manchester Royal Infirmary. To stab or slash: the percutaneous dilatation or standard surgical approach to cricothyroidotomy in prehospital care. Emerg Med J. Sep 2002;19(5):434.
45. Granholm T, Farmer DL. The surgical airway. Respir Care Clin N Am. Mar 2001;7(1):13–23.
46. Bulger EM, Copass MK, Maier RV, Larsen J, Knowles J, Jurkovich GJ. An analysis of advanced prehospital airway management. J Emerg Med. Aug 2002;23(2):183–189.
47. Fortune JB, Judkins DG, Scanzaroli D, McLeod KB, Johnson SB. Efficacy of prehospital surgical cricothyrotomy in trauma patients. J Trauma. May 1997;42(5):832–836; discussion 837–838.
48. Melker JS, Gabrielli A. Melker cricothyrotomy kit: an alternative to the surgical technique. Ann Otol Rhinol Laryngol. Jul 2005;114(7):525–528.
49. Keane MF, Brinsfield KH, Dyer KS, Roy S, White D. A laboratory comparison of emergency percutaneous and surgical cricothyrotomy by prehospital personnel. Prehosp Emerg Care. Oct-Dec 2004;8(4):424–426.
50. Johnson DR, Dunlap A, McFeeley P, Gaffney J, Busick B. Cricothyrotomy performed by prehospital personnel: a comparison of two techniques in a human cadaver model. Am J Emerg Med. May 1993;11(3):207–209.
51. Schaumann N, Lorenz V, Schellongowski P, et al. Evaluation of Seldinger technique emergency cricothyroidotomy versus standard surgical cricothyroidotomy in 200 cadavers. Anesthesiology. Jan 2005;102(1):7–11.
52. Fisher JA. A "last ditch" airway. Can Anaesth Soc J. May 1979;26(3):225–230.

53. Dob DP, McLure HA, Soni N. Failed intubation and emergency percutaneous tracheostomy. Anaesthesia. Jan 1998;53(1): 72–74.
54. Wong DT, Lai K, Chung FF, Ho RY. Cannot intubate-cannot ventilate and difficult intubation strategies: results of a Canadian national survey. Anesth Analg. May 2005;100(5):1439–1446, table of contents.
55. Ciaglia P, Brady C, Graniero KD. Emergency percutaneous dilatational cricothyroidostomy: use of modified nasal speculum. Am J Emerg Med. Mar 1992;10(2):152–155.
56. Rich JM, Mason AM, Bey TA, Krafft P, Frass M. The critical airway, rescue ventilation, and the combitube: Part 1. Aana J. Feb 2004;72(1):17–27.
57. Yealy DM, Stewart RD, Kaplan RM. Myths and pitfalls in emergency translaryngeal ventilation: correcting misimpressions. Ann Emerg Med. Jul 1988;17(7):690–692.
58. Smith RB, Babinski M, Klain M, Pfaeffle H. Percutaneous transtracheal ventilation. Jacep. Oct 1976;5(10):765–770.
59. Yealy DM, Menegazzi JJ, Ward KR. Transtracheal jet ventilation and airway obstruction. Am J Emerg Med. Mar 1991;9(2): 200.
60. Auble TE, Menegazzi JJ, Nicklas KA. Comparison of automated and manual ventilation in a prehospital pediatric model. Prehosp Emerg Care. Apr-Jun 1998;2(2):108–111.
61. Yealy DM, Plewa MC, Stewart RD. An evaluation of cannulae and oxygen sources for pediatric jet ventilation. Am J Emerg Med. Jan 1991;9(1):20–23.
62. Wheeler M. Management strategies for the difficult pediatric airway. Middle East J Anesthesiol. Jun 2004;17(5):845–873.
63. Benumof JL. Management of the difficult airway. Ann Acad Med Singapore. Jul 1994;23(4):589–591.
64. Depierraz B, Ravussin P, Brossard E, Monnier P. Percutaneous transtracheal jet ventilation for paediatric endoscopic laser treatment of laryngeal and subglottic lesions. Can J Anaesth. Dec 1994;41(12):1200–1207.
65. Vitberg DA, Reed DB. Crackdown on crics. Needle cricthryotomy & percutaneous transtracheal jet ventilation explained. Jems. Mar 2001;26(3):58–62, 64–55, 78–59 passim.
66. Elling R, Politis J. An evaluation of emergency medical technicians' ability to use manual ventilation devices. Ann Emerg Med. Dec 1983;12(12):765–768.
67. Cummins RO, Austin D, Graves JR, Litwin PE, Pierce J. Ventilation skills of emergency medical technicians: A teaching challenge for emergency medicine. Ann Emerg Med. Oct 1986;15(10):1187–1192.
68. Seidelin PH, Stolarek IH, Littlewood DG. Comparison of six methods of emergency ventilation. Lancet. Nov 29 1986;2(8518):1274–1275.
69. Hankins DG, Carruthers N, Frascone RJ, Long LA, Campion BC. Complication rates for the esophageal obturator airway and endotracheal tube in the prehospital setting. Prehospital Disaster Med. Apr-Jun 1993;8(2):117–121.
70. Smith JP, Bodai BI, Seifkin A, Palder S, Thomas V. The esophageal obturator airway. A review. JAMA. Aug 26 1983;250(8):1081–1084.
71. Schaefer JJ, 3rd. Simulators and difficult airway management skills. Paediatr Anaesth. Jan 2004;14(1):28–37.
72. Berridge PD, Pollock KM, Longhorn RK, Heard AM. Emergency airway equipment and training. Anaesthesia. Mar 2005;60(3):291; author reply 292.
73. Zirkle M Blum R, Raemer DB, Healy G, Roberson DW. Teaching emergency airway management using medical simulation: a pilot program. Laryngoscope. Mar 2005;115(3):495–500.
74. Wang HE, Kupas DF, Greenwood MJ, et al. An algorithmic approach to prehospital airway management. Prehosp Emerg Care. Apr-Jun 2005;9(2):145–155.
75. Wang HE, Yealy DM. How many attempts are required to accomplish out-of-hospital endotracheal intubation? Acad Emerg Med. Apr 2006;13(4):372–377.
76. Staudinger T, Brugger S, Roggla M, et al. [Comparison of the Combitube with the endotracheal tube in cardiopulmonary resuscitation in the prehospital phase]. Wien Klin Wochenschr. 1994;106(13):412–415.
77. Tanigawa K, Shigematsu A. Choice of airway devices for 12,020 cases of nontraumatic cardiac arrest in Japan. Prehosp Emerg Care. Apr-Jun 1998;2(2):96–100.
78. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: Part 7.1: Adjuncts for Airways Control and Ventilation. *Circulation.* December 13, 2005. 2005;112(24_suppl):IV-51–57.
79. Abo BN, Hostler D, Wang HE. Does the Type of Out of Hospital Airway Interfere with Other Cardiopulmonary Resuscitation Tasks? Resuscitation (in press). Resuscitation. 2006.
80. Wang HE, Domeier RM, Kupas DF, Greenwood MJ, O'Connor RE. Recommended Guidelines for Unifrom Reporting of Data from Out-of-Hospital Airway Management: Position Statement of the National Association of EMS Physicians. Prehospital Emergency Care. 2004;8:58–72.

FOR CONSIDERATION BY PMAC

DATE: October 1, 2018

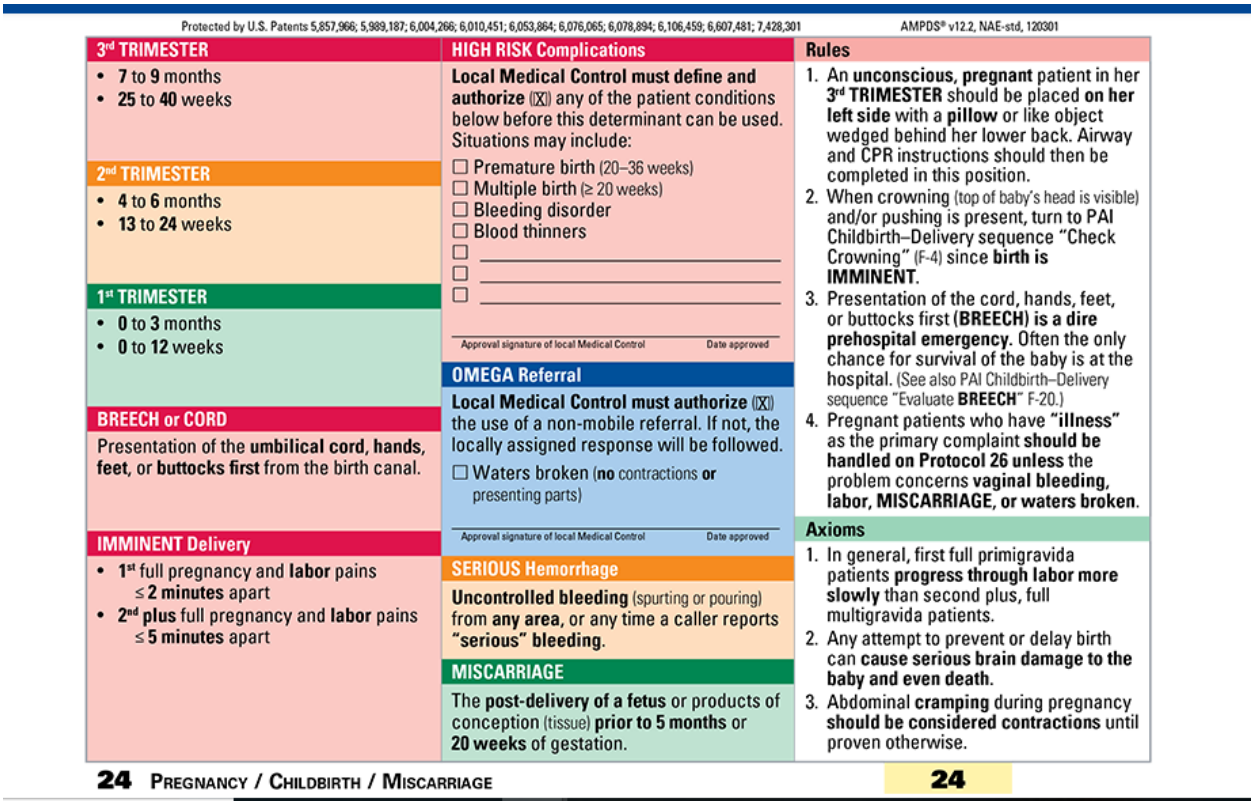
TO: PMAC

FROM: Rafael Serrano, EMS Specialist with Michelle Buell from Cal Fire/Riverside County FD

SUBJECT: Emergency Medical Dispatch Card 24 and 33

REMSA continues to work with the EMS System to further the enhancements that the Emergency Medical Dispatch system provides to EMS service in Riverside County. In those efforts, working with the Cal Fire/Riverside County FD ECC, two new EMD cards could provide added benefit to our system.

EMD Cards 24 and 33 will be discussed in the context of the call taking process with Michelle Buell from the Cal Fire/Riverside County FD ECC presenting.



Protected by U.S. Patents 5,857,966; 5,989,187; 6,004,266; 6,010,451; 6,053,864; 6,076,065; 6,078,894; 6,106,459; 6,607,481; 7,428,301

AMPDS® v12.2, NAE-std, 120301

3rd TRIMESTER
- **7** to **9** months
- **25** to **40** weeks

2nd TRIMESTER
- **4** to **6** months
- **13** to **24** weeks

1st TRIMESTER
- **0** to **3** months
- **0** to **12** weeks

BREECH or CORD

Presentation of the **umbilical cord, hands, feet,** or **buttocks first** from the birth canal.

IMMINENT Delivery
- **1st** full pregnancy and **labor** pains ≤ **2 minutes** apart
- **2nd plus** full pregnancy and **labor** pains ≤ **5 minutes** apart

HIGH RISK Complications

Local Medical Control must define and authorize (X) any of the patient conditions below before this determinant can be used. Situations may include:

- ☐ Premature birth (20–36 weeks)
- ☐ Multiple birth (≥ 20 weeks)
- ☐ Bleeding disorder
- ☐ Blood thinners
- ☐ _____
- ☐ _____
- ☐ _____

Approval signature of local Medical Control — Date approved

OMEGA Referral

Local Medical Control must authorize (X) the use of a non-mobile referral. If not, the locally assigned response will be followed.

- ☐ Waters broken (**no** contractions **or** presenting parts)

Approval signature of local Medical Control — Date approved

SERIOUS Hemorrhage

Uncontrolled bleeding (spurting or pouring) from **any area,** or any time a caller reports **"serious" bleeding.**

MISCARRIAGE

The **post-delivery of a fetus** or products of conception (tissue) **prior to 5 months** or **20 weeks** of gestation.

Rules

1. An **unconscious, pregnant** patient in her **3rd TRIMESTER** should be placed **on her left side** with a **pillow** or like object wedged behind her lower back. Airway and CPR instructions should then be completed in this position.
2. When crowning (top of baby's head is visible) and/or pushing is present, turn to PAI Childbirth–Delivery sequence "Check Crowning" (F-4) since **birth is IMMINENT.**
3. Presentation of the cord, hands, feet, or buttocks first **(BREECH) is a dire prehospital emergency.** Often the only chance for survival of the baby is at the hospital. (See also PAI Childbirth–Delivery sequence "Evaluate **BREECH**" F-20.)
4. Pregnant patients who have **"illness"** as the primary complaint **should be handled on Protocol 26 unless** the problem concerns **vaginal bleeding, labor, MISCARRIAGE,** or **waters broken.**

Axioms

1. In general, first full primigravida patients **progress through labor more slowly** than second plus, full multigravida patients.
2. Any attempt to prevent or delay birth can **cause serious brain damage to the baby and even death.**
3. Abdominal **cramping** during pregnancy **should be considered contractions** until proven otherwise.

24 PREGNANCY / CHILDBIRTH / MISCARRIAGE **24**

FOR CONSIDERATION BY PMAC

Card 24 Question to be discussed: As part of the caller interrogation process utilizing CARD 24, an EMD certified dispatcher asks "Does she have any HIGH RISK complications?"
If answer is "Yes" then proceed to "HIGH RISK Complications" box and choose which applies. This will give dispatcher a determinant code of DELTA response.

Questions for group: "Do these complications alone without associated symptoms constitute a DELTA response (lights and sirens)?"
"As part of the interrogation process and selection MUST be entered by dispatcher, which complications should be approved."

These complications need to be approved by Medical Director. *REMSA is requesting PMAC feedback for which complications, if any, should be utilized within the context of card 24.*

Complications of cervical cerclage, placenta abruption and placenta previa have already been added by EMD processes.

Card 33

33 - Transfer/ Interfacility/ Palliative Care T= Transfer/ Interfacility P= Palliative Care	33-D-1	Suspected cardiac or respiratory arrest	ALS2
	33-D-2	Just resuscitated and/or defibrillated (external)	ALS2
	33-C-1	Not alert (acute change)	ALS1
	33-C-2	Abnormal breathing (acute onset)	ALS1
33 - Transfer/ Interfacility/ Palliative Care	33-C-3	Significant hemorrhage or shock	ALS1
	33-C-4	Possible acute heart problems or MI (heart attack)	ALS1
	33-C-5	Acute severe pain	BLS
	33-C-6	Emergency response requested-ALS asymptomatic patient	ALS1
	33-A-1	Acuity I (no priority symptoms)	BLS
	33-A-2	Acuity II (no priority symptoms)	BLS (DNR-B)
	33-A-3	Acuity III (no priority symptoms)	SC/EMS

Acuity Levels I, II, III need to be approved by Medical Director, as it stands now, the call interrogation process does now allow anything lower than CHARLIE response (lights and sirens). *REMSA is requesting PMAC feedback for acuity levels I, II, III and what would meet the definition of a medical facility.*

Questions:

- What constitutes a "medical facility" (assisted living, urgent care, SNF, Home Care, Rehab facility, etc)
- Call interrogator MUST ask "Is this call a result of an evaluation by a nurse or doctor?" Please give examples of Acuity Levels from "medical facilities" and how do we determine which of those are the most common.

ACTION: Information sharing, PMAC action to determine use of all aspects of EMD Cards 24 and 33 as proposed in presentation.

FOR CONSIDERATION BY PMAC

DATE: October 1, 2018

TO: PMAC

FROM: Misty Plumley, Senior EMS Specialist

SUBJECT: Proposed Policy Changes

Proposed 2019 PMAC Schedule:

Monday, January 21, 2019 – 0900-1030 at the Towers at Riverwalk Building

Monday, April 22, 2019 – 0900-1030 at the Towers at Riverwalk Building

Monday, July 22, 2019 – 0900-1030 at the Towers at Riverwalk Building

Monday, October 21, 2019 – 0900-1030 at the Towers at Riverwalk Building

ACTION: PMAC should be prepared to receive the information and provide feedback to approve or modify the proposed schedule for 2019 to the EMS Agency.