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Simulation and education

Design and implementation of the Resuscitation Outcomes Consortium Pragmatic Airway Resuscitation Trial (PART)☆

Henry E. Wang[a,*], David K. Prince[b], Shannon W. Stephens[a], Heather Herren[b], Mohamud Daya[c], Neal Richmond[d], Jestin Carlson[e,f], Craig Warden[c], M. Riccardo Colella[g], Ashley Brienza[f], Tom P. Aufderheide[g], Ahamed H. Idris[h], Robert Schmicker[b], Susanne May[b], Graham Nichol[b]

[a] Department of Emergency Medicine, University of Alabama School of Medicine, Birmingham, AL, United States
[b] Clinical Trials Center, Department of Biostatistics, University of Washington, Seattle, WA, United States
[c] Department of Emergency Medicine, Oregon Health and Science University, Portland, OR, United States
[d] MedStar, Inc., Fort Worth, TX, United States
[e] St Vincent's Medical Center, Erie, PA, United States
[f] Department of Emergency Medicine, University of Pittsburgh, Pittsburgh, PA, United States
[g] Department of Emergency Medicine, Medical College of Wisconsin, Milwaukee, WI, United States
[h] Department of Emergency Medicine, University of Texas Southwestern Medical Center, Dallas, TX, United States

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ABSTRACT

Airway management is an important component of resuscitation from out-of-hospital cardiac arrest (OHCA). The optimal approach to advanced airway management is unknown. The Pragmatic Airway Resuscitation Trial (PART) will compare the effectiveness of endotracheal intubation (ETI) and Laryngeal Tube (LT) insertion upon 72-h survival in adult OHCA. Encompassing United States Emergency Medical Services agencies affiliated with the Resuscitation Outcomes Consortium (ROC), PART will use a cluster-crossover randomized design. Participating subjects will include adult, non-traumatic OHCA requiring bag-valve-mask ventilation. Trial interventions will include (1) initial airway management with ETI and (2) initial airway management with LT. The primary and secondary trial outcomes are 72-h survival and return of spontaneous circulation. Additional clinical outcomes will include airway management process and adverse events. The trial will enroll a total of 3000 subjects. Results of PART may guide the selection of advanced airway management strategies in OHCA.

Introduction

Out-of-hospital cardiopulmonary arrest (OHCA) is a major public health problem affecting almost 400,000 adults in the United States each year, with less than 10% surviving.[1,2] To optimize delivery of oxygen during cardiac arrest resuscitation, clinicians may perform endotracheal intubation (ETI). ETI provides a direct conduit to the lungs, facilitating easier and more controlled oxygen delivery, and potentially protecting the lungs from aspiration of vomitus.

Paramedics in North America commonly perform ETI when resuscitating OHCA. Although a standard paramedic practice for over 30 years, many studies underscore the complexity and pitfalls of ETI, including unrecognized tube misplacement, multiple and failed ETI attempts, iatrogenic hyperventilation, and prolonged interruptions in cardiopulmonary resuscitation chest compressions.[3–11] US paramedic ETI training and individual opportunity to perform the procedure are also limited.[12,13]

An alternative to ETI is the supraglottic airway (SGA), including devices such as the Laryngeal Mask Airway (LMA – LMA North America, San Diego, California, United States), Combitube

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* Corresponding author at: Department of Emergency Medicine, University of Alabama School of Medicine, 619 19th St South, OHB 251, Birmingham, AL 35249, United States.

E-mail addresses: hwang@uabmc.edu (H.E. Wang), dprince@uw.edu (D.K. Prince), swstephens@uabmc.edu (S.W. Stephens), hherren@uw.edu (H. Herren), dayam@ohsu.edu (M. Daya), nrichmond@medstar911.org (N. Richmond), jcarlson@svhs.org (J. Carlson), wardenc@ohsu.edu (C. Warden), colella@mcw.edu (M.R. Colella), brienzaam@upmc.edu (A. Brienza), taufderh@mcw.edu (T.P. Aufderheide), aidris@sbcglobal.net (A.H. Idris), rschmick@uw.edu (R. Schmicker), sjmay@uw.edu (S. May), nichol@uw.edu (G. Nichol).

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(Covidien, Inc., Mansfield, Massachusetts, United States), i-gel (Intersurgical, Workingham, Berkshire, United Kingdom) and Laryngeal Tube (LT – King Systems, Inc, Noblesville, Indiana, United States).[14,15] Compared with ETI, clinicians and medical directors believe that SGAs entail easier insertion technique and lower skill acquisition and maintenance thresholds, while exhibiting similar ventilatory characteristics. However, the comparative effectiveness of SGA over ETI upon OHCA outcomes remains unclear, with some observational cohort studies suggesting similar or better functional and overall survival with ETI than SGA.[16–22] There have been no randomized controlled clinical trials comparing ETI and SGA in adult OHCA.[23,24]

In this paper we describe the rationale for and design of the Resuscitation Outcomes Consortium Pragmatic Airway Resuscitation Trial (PART), a multicenter pragmatic randomized clinical trial comparing the effectiveness of ETI and LT insertion upon outcomes after OHCA.

Methods and analysis

Trial organization

PART will be carried out by EMS agencies affiliated with the Resuscitation Outcomes Consortium (ROC), a North American network dedicated to conducting clinical trials of OHCA and major trauma.[25] PART will be jointly coordinated by the Alabama Regional Coordinating Center of ROC (Department of Emergency Medicine, University of Alabama School of Medicine, Birmingham, AL) and the ROC Data Coordinating Center (Clinical Trials Center, University of Washington, Seattle, WA) (Fig. 1). EMS agencies affiliated with five United States ROC Regional Coordinating Centers (Alabama, Dallas, Milwaukee, Pittsburgh and Portland) will carry out the study.

Funding – impact on clinical design

PART is supported by a special grant (UH2-HL125163) from the National Heart, Lung and Blood Institute (NHLBI) supporting large-scale, low-cost pragmatic clinical trials.[26] This new funding mechanism introduced several requirements that influenced the design of the trial:

- **Focus on pragmatic trial design.** A pragmatic trial focuses on the evaluation of interventions in real-world contexts. Pragmatic trials emphasize clinically relevant outcomes, with less attention paid to secondary, explanatory or mechanistic endpoints.
- **Structured implementation timeline.** The award stipulated a year 1 planning phase, with initiation of trial enrollment (years 2–5) after satisfaction of initial milestones.
- **Defined funding.** The grant provided US$350,000 for the year 1 planning phase, and US$500,000 per year for the trial enrollment phase.

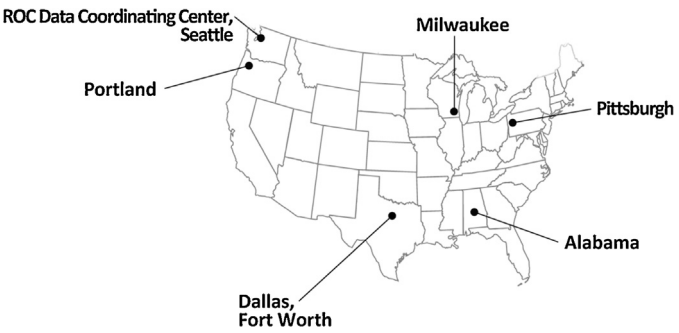

Fig. 1. Resuscitation Outcomes Consortium centers participating in PART.

Table 1
Trial inclusion and exclusion criteria. ETI, endotracheal intubation; LT, laryngeal tube; EMS, emergency medical services.

Inclusion criteria
Adult (age ≥18 years or per local interpretation), non-traumatic OHCA
Treated by EMS personnel
Requiring advanced airway insertion (ETI, LT) or ventilatory support (bag-valve-mask ventilation)
Exclusion criteria
Known pregnant women
Known prisoners
Major facial trauma
Major bleeding or exsanguination
ET tube, LT or other advanced airway insertion prior to ROC EMS arrival
Pre-existing tracheostomy
Obvious asphyxial cardiac arrest (choking or hanging)
Left ventricular assist device (LVAD) or total artificial heart (TAH),
Pre-existing "do-not-attempt-resuscitation" (DNAR) orders
Inter-facility transports
Presence of a "do not enroll" bracelet
Initial care by non-trial EMS agency capable of performing ETI, LT or other advanced airway insertion

- **Limited to US elements.** The conditions of the grant limited scientific participation to US institutions and investigators.

Trial registration

PART is registered with www.clinicaltrials.gov as trial no. NCT02419573.

Objectives

The objective of PART is to compare the effectiveness of primary ETI versus primary LT airway management strategies upon 72-h survival after OHCA.

Design

Participating EMS agencies will be clustered randomized to airway management with primary ETI (control) or primary LT insertion (intervention), with periodic crossover to the other arm.

Setting

PART will include participation by approximately 30 ground US EMS agencies associated with the Alabama, Dallas, Milwaukee, Pittsburgh and Portland Regional Clinical Centers of the Resuscitation Outcomes Consortium (Appendix 1).

Patient population (inclusion/exclusion criteria)

PART will enroll adult (age ≥18 years or per local interpretation), non-traumatic OHCA requiring bag-valve-mask ventilation. If a subject receives bag-valve-mask ventilation but not ETI or SGA, he/she will be included in the study per intention-to-treat principles, regardless of recovery of consciousness. The trial will include EMS-witnessed arrests as well as patients experiencing recurrent OHCA during the same care episode. PART will exclude subjects that receive initial clinical care by non-trial EMS agencies with ETI or SGA insertion capabilities. Detailed inclusion and exclusion criteria are listed in Table 1.

Trial interventions

PART will compare two interventions (Fig. 2):