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Clinical paper

Association of advanced airway device with chest compression fraction during out-of-hospital cardiopulmonary arrest☆

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ABSTRACT

Background: Select Emergency Medical Services (EMS) practitioners substitute endotracheal intubation (ETI) with supraglottic airway (SGA) insertion to minimize CPR chest compression interruptions, but the resulting effects upon chest compression fraction (CCF) are unknown. We sought to determine the differences in CCF between adult out-of-hospital cardiac arrest (OHCA) receiving ETI and those receiving SGA.
Methods: We studied adult, non-traumatic OHCA patients enrolled in the Resuscitation Outcomes Consortium (ROC) Prehospital Resuscitation using an Impedance valve and an Early vs. Delayed analysis (PRIMED) trial. Chest compressions were measured using compression or thoracic impedance sensors. We limited the analysis to those receiving ETI or SGA (Combitube, King Laryngeal Tube, or Laryngeal Mask Airway) and >2 min of chest compression data before and after airway insertion. We compared CCF between ETI and SGA before and after airway insertion, adjusting for age, sex, witnessed arrest, bystander CPR, shockable initial rhythm, public location, PRIMED trial arm, and regional ROC center. We also compared the change in CCF for each airway technique.
Results: Of 14,955 patients enrolled in the ROC PRIMED trial, we analyzed 2767 cases, including 2051 ETI, 671 SGA, and 45 both. Among subjects in this investigation the mean age was 66.4 years with a male predominace, 46% with witnessed event, 37% receiving bystander CPR, and 22% presenting with an initially shockable rhythm. Pre- and post-airway CCF was higher for SGA than ETI (SGA pre-airway CCF 73.2% [95%CI: 71.6–74.7%] vs. ETI 70.6% [95%CI: 69.7–71.5%]; post-airway 76.7% [95%CI: 75.2–78.1%] vs. 72.4% [95%CI: 71.5–73.3%]). After adjusting for potential confounders, these significant changes persisted (pre-airway difference 2.2% favoring SGA, p-value = 0.046; post-airway 3.4% favoring SGA, p = 0.001).
Conclusion: In patients with OHCA, we detected a slightly higher rate of CCF in patients for whom a SGA was inserted, both before and after insertion. However, the actual differences were so small, that in the context of this observational, secondary analysis, it is unclear if this represents a clinically significant difference.

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Background

Out-of-Hospital Cardiac Arrest (OHCA) is a major public health problem affecting greater than 325,000 persons annually in the United States with a mortality rate approaching 90%.[1] Current OHCA guidelines emphasize minimizing cardiopulmonary resuscitation (CPR) chest compression interruptions to maintain a chest compression fraction (CCF—the amount of time with active chest compressions) greater than 80%.[2]

The choice of advanced airway inserted during resuscitation has been identified as an opportunity to improve CCF. Prior literature has demonstrated that endotracheal intubation (ETI) performed during pulselessness may cause over 90 s of chest compression interruptions.[3] Though initially designed as a rescue airway in the event of failed ETI in the operating room, SGA insertion has rapidly gained favor in the prehospital environment due to its rapid, technically simpler technique for insertion. Some EMS practitioners favor primary SGA over primary ETI to avoid chest compression interruptions. However, there have been few direct evaluations of the effect of advanced airway devices upon CCF.

The objective of this study was to evaluate the impact of advanced airway management device type upon CCF in OHCA enrolled in the Resuscitation Outcomes Consortium (ROC) Prehospital Resuscitation using an Impedance valve and an Early vs. Delayed analysis (PRIMED) trial.

Methods

Study design

This study was a secondary analysis of data prospectively collected as part of the ROC PRIMED trial. The ROC PRIMED study was conducted using Exception from Informed Consent (EFIC) under United States regulations (21 CFR 50.24) and the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Additional approvals were sought and obtained from the US Food and Drug Administration (FDA) and Health Canada, as well as institutional review boards and research ethics boards at the respective institutions where the research was conducted.

Study setting

ROC is a multi-center research network in North America conducting out-of-hospital and clinical intervention trials focused upon cardiac arrest and traumatic injury. ROC consists of more than 250 EMS agencies spread among 10 communities: Seattle/King County, WA; San Diego, CA; Milwaukee, WI; Pittsburgh, PA; Portland, OR; Dallas, TX; Birmingham, AL; Toronto, Ontario; Ottawa, Ontario; and British Columbia. Of these, 150 EMS agencies participated in the study. Centralized data collection and management was provided by the data coordinating center in Seattle.

PRIMED sought to compare two interventions employing a factorial design: (1) a strategy of early (immediate) verses late (∼180 s) initial ECG analysis and subsequent defibrillation as appropriate and (2) the use of an impedance threshold device (ITD) vs. a sham device. Both arms of the ROC PRIMED study were halted at an interim analysis for futility, as there was no detectable difference in outcomes among participants in any arm.[4,5]

Study population

This analysis consisted of patients enrolled in the ROC PRIMED trial (1) receiving successful ETI or SGA insertion and (2) with CPR process data available for at least 2 min immediately before and immediately after advanced airway insertion. SGA devices used by EMS agencies in the ROC PRIMED trial included King Laryngeal Tube (Ambu, Inc., Noblesville, IN), Combitube (Covidien, Inc., Mansfield, MA), and Laryngeal Mask Airway (LMA North America, San Diego, CA). Selection of ETI vs SGA was at provider discretion or local medical direction and not dictated by study protocol (ROC PRIMED or other ROC investigation). CPR process data was collected by either changes in thoracic impedance recorded from external defibrillation electrodes or via an accelerometer interface between the rescuer and the patient's chest, depending on the defibrillator manufacturer used (Zoll Medical Corporation, Chelmsford, MA; Physio-Control, Redmond, WA; Royal Phillips, Amsterdam, The Netherlands). The authors chose to exclude patients enrolled at the Seattle/King County site *a pirori* as no SGA devices used during the study period.

At the time of the PRIMED trial, only two sites allowed BLS personnel to perform advanced airway maneuvers. At the Ottawa site, three agencies allowed BLS providers to perform King LT insertion. At the San Diego site, BLS providers were also allowed to use the King LT, but the majority of OHCA received initial advanced airway care from ALS providers.

Methods of measurement

The PRIMED trial followed uniform data collection and reporting guidelines consistent with Utstein standards.[6] Prehospital care provided was described on either electronic or paper care reports, including details of airway and resuscitation management. Each coordinating center was responsible for determining outcomes and complications from prehospital, receiving hospital, and publically available death records as appropriate.

In addition, digital CPR process recordings of the two minute intervals immediately before and after documented advanced airway insertion were evaluated for the presence and frequency of chest compressions. (Fig. 1) CCF was defined as the proportion of resuscitation time without spontaneous circulation during which CPR was administered, averaged over the 2 min pre- or post-airway period in question.

Outcome measures

The primary outcome of this analysis was chest compression fraction (CCF), defined as the portion of each elapsed treatment time with active chest compressions. The method of CPR performance (i.e., 30:2 or continuous chest compressions) was left to local agencies. Consistent with previous PRIMED sub-studies, active chest compressions were defined as any measured attempt to compress the chest, regardless of quality. Any pause of greater than 2 s (the smallest interval measureable by the software packages used) was considered an interruption for the purposes of calculating CCF. CCF was measured both before and after airway insertion and without regard to the appropriateness of pauses (i.e., pausing CPR for an appropriately timed ventilation or pulse check) to ensure comparison with other CPR studies. We included all CPR process data available for the two minute periods before and after successful airway management.

The key exposure was the type of advanced airway device, defined as ETI or SGA. We included only successful insertions. In the few instances where a patient received both successful ETI and

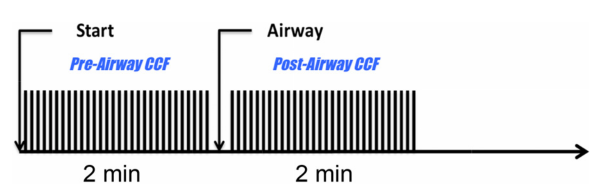

Fig. 1. Theoretical Model of CCF Surrounding Advanced Airway Insertion.

SGA, we classified the patient as receiving SGA. Airway success was based upon EMS personnel reports. We combined all SGA into a single group. The specific SGA device used was unknown for 27.3% (196/716) of cases.

Covariates used for risk adjustment included: age, sex, witnessed arrest (bystanders or EMS), bystander CPR, presenting electrocardiogram (ECG) rhythm, ROC site, and PRIMED trial arm. Presenting ECG rhythm was classified as shockable (shock advised by automated external defibrillator, pulseless ventricular tachycardia, or fibrillation) or non-shockable (no shock advised by automated external defibrillator pulseless electrical activity or asystole). As previously reported, ROC PRIMED trial arms included early vs. late ECG rhythm analysis, and ITD vs. sham device.

Data analysis

We analyzed the data using multivariate linear regression, modeling CCF as the dependent variable and advanced airway type (ETI vs SGA) as the primary exposure. We first determined differences in pre- and post-airway insertion CCF between ETI and SGA. We then compared the changes between pre- and post-airway CCF for each airway device. We adjusted the estimates for the confounding effects of age, sex, witnessed arrest event, provision of bystander CPR, presenting ECG rhythm, ROC site location, and ROC PRIMED trial arm. Analysis was conducted using R version 3.1 (GNU General Public License, University of Auckland, New Zealand) and SAS version 9.3 (SAS Institute Inc., Cary North Carolina, USA).

Results

During the ROC PRIMED trial 14,955 adult OHCA were treated by participating ROC EMS agencies. Of those, 10,630 received a successful advanced airway with sufficient documentation to identify the timing of the airway maneuver. Of the 7191 subjects with any CPR process data available, 2767 had data for two minutes immediately before and after airway placement. Of the 2767 cases included in the study, 2051 received ETI, 671 received SGA, and 45 received both. (Fig. 2).

Subjects included in this investigation were similar to the larger population experiencing OHCA in the ROC PRIMED trial: approximately 46% with witnessed events (vs. 51% in the larger PRIMED trial), 37% receiving bystander CPR (vs. 35%), and 22% presenting with an initially shockable rhythm (vs. 24%). Those subjects managed with a successful ETI were older and less likely to be male than those receiving SGA. (Table 1).

Pre- and post-airway CCF was higher for SGA than ETI (SGA pre-airway CCF 73.2% [95%CI: 71.6–74.7%] vs. ETI 70.6% [95%CI: 69.7–71.5%]; post-airway 76.7% [95%CI: 75.2–78.1%] vs. 72.4% [95%CI: 71.5–73.3%]). The difference in mean CCF persisted independent of the presenting rhythm (shockable vs. non-shockable) except in the case of those patients with shockable rhythm receiving ETI. The magnitude of this difference in CCF with successful SGA placement did not exceed 4.3%. (Fig. 3).

When adjusted for Utstein and ROC PRIMED covariates, the analysis favoring the impact of SGA placement on CCF was consistent with the univariate analysis. However, when stratified by presenting rhythm, differences in CCF were only significant post-airway insertion in the multivariate analysis. Similar to the unadjusted analysis, the maximum magnitude of this difference was 4.5% (Table 2).

Discussion

In this study we observed that SGA use resulted in a small improvement in CCF when compared with ETI both pre- and post-advanced airway maneuver. Furthermore, these results were consistent independent of the presenting rhythm. Multiple factors support the external validity of these findings. Our analysis is derived from the ROC PRIMED trial, the largest comparative multicenter study of OHCA management in North American contemporary practice. In addition, SGA insertion techniques do not require direct laryngoscopy. Performing direct laryngoscopy for ETI without interrupting CPR requires a high level of operator operator skill.[7,8] The observed difference may also be due to unmeasured factors influencing care delivered resulting in EMS providers choosing SGA over ETI (i.e., the selection of SGA in more viable OHCA patients due to perception of its impact on CCF, etc.). Our findings are novel as they represent the largest observational series of OHCA airway management to have CPR process data concurrently measured.

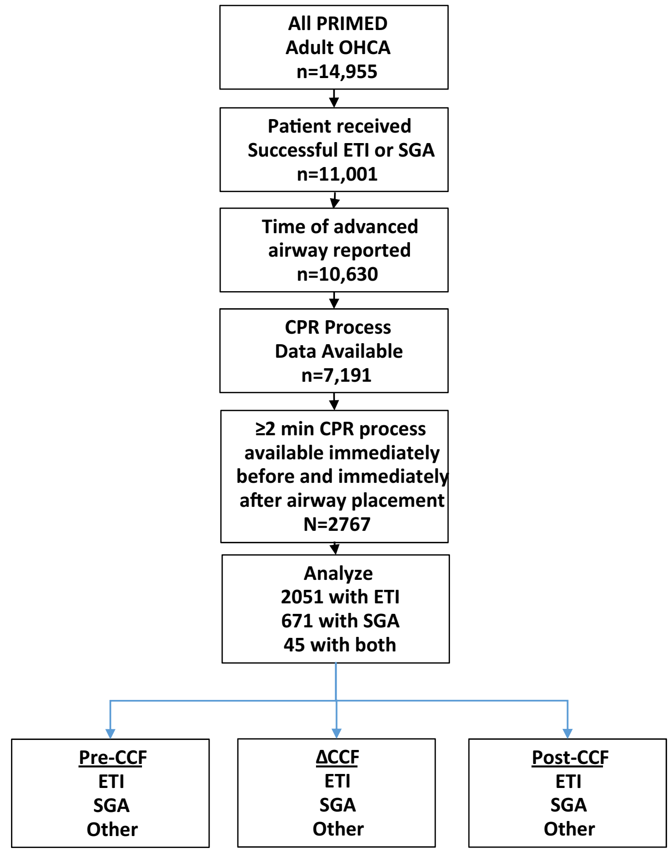

Fig. 2. Selection of study population. This figure depicts the total number of patients treated for out-of-hospital cardiac arrest during the PRIMED trial, the criteria used to identify those eligible for inclusion, the rationale for those excluded, and the distribution for analysis.

Our investigation demonstrated a measureable improvement of up to 4.5% in CCF with the use of SGA vs. ETI. While our results were statistically significant, we must also examine their clinical significance. CCF has been associated with OHCA outcomes.[9,10] Christenson previously demonstrated 1.11 OR of survival with each 10% improvement in CCF.[9] Though difficult to compare directly to this investigation due to differences in methodology, it suggests the impact of airway choice upon CCF detected in this sub study maybe insufficient to alter survival.

Paradoxically, this same PRIMED cohort has previously demonstrated association between ETI and ROSC, 24 h survival, and neurologically intact survival to discharge when compared to SGA use.[11,12] The existence of such seemingly contradictory findings from two analysis of the same trial data suggests that there are other factors, temporally associated but unmeasured, that contribute

Table 1
Characteristics of out-of-hospital cardiac arrests receiving advanced airway management. Includes patients receiving endotracheal intubation or supraglottic airway insertion efforts. Descriptive statistics (confounders listed above) for patient population and broken down by advanced airway status (successful ETI vs. successful SGA vs. neither successful).

Variable	ETI *n* = 2051	SGA *n* = 716	Not included[a] *n* = 8234
Age, mean (sd)	67.3 (16.1)	63.7 (15.7)	66.7 (16.9)
Sex, % male	63.7	68.9	64.8
Witness status, *n* (%)			
Not witnessed	1077 (52.5)	390 (54.5)	3968 (48.2)
Bystander witnessed	823 (40.1)	281 (39.3)	3389 (41.2)
EMS witnessed	151 (7.4)	45 (6.3)	877 (10.7)
Bystander CPR, *n* (%)	716 (34.9)	293 (40.9)	2918 (35.4)
Initial EMS rhythm, *n* (%)			
VF/VT	454 (22.1)	161 (22.5)	1983 (24.1)
PEA	499 (24.3)	154 (21.5)	1857 (22.6)
Asystole	991 (48.3)	373 (52.1)	3463 (42.1)
AED, unknown rhythm[b]	102 (5.0)	27 (3.8)	844 (10.3)
Other or unknown	5 (0.2)	1 (0.1)	87 (1.1)
Public location, *n* (%[c])	277 (13.5)	109 (15.2)	1281 (15.6)
PRIMED trial arms			
Sham	846 (41.2)	274 (38.3)	2913 (35.4)
ITD	859 (41.9)	279 (39.0)	2914 (35.4)
Analyze late	964 (47.1)	328 (45.8)	3842 (46.7)
Analyze early	1066 (52.0)	383 (53.5)	4174 (50.6)
Site, *n* (column %)			
A	25 (1.4)	3 (0.4)	148 (1.8)
B	147 (7.2)	2 (0.3)	1228 (14.9)
C	66 (3.2)	123 (17.2)	503 (6.1)
D	261 (12.7)	76 (10.6)	578 (7.0)
E	455 (22.2)	168 (23.5)	1515 (18.4)
F	156 (7.6)	85 (11.9)	228 (2.8)
G	188 (9.2)	117 (16.3)	641 (7.8)
H	174 (8.5)	86 (12.0)	232 (2.8)
I	579 (28.2)	56 (7.8)	3161 (38.4)

[a] These are patients with successful prehospital advanced airway but CPR measures are not available.
[b] Instance where AED was used, no shock was delivered and no ECG tracing was available to determine rhythm.
[c] Percent is of those known.

to favorable outcome following an advanced airway maneuver. These factors could include unmeasured prehospital influences (i.e., perhaps less skilled EMS providers preferentially use SGA) or physiologic issues such as impaired cerebral perfusion.[13,14] In addition, the current investigation consisted of a relatively small subset of data that contained CPR process data and is subject to selection bias despite randomization in the PRIMED trial.

The best way to clarify the intersection of advanced airway management in the prehospital setting, CCF, and OHCA outcomes is through a randomized trial. Such a trial will be able to explicitly mitigate the numerous opportunities for introducing bias that exist in contemporary airway literature. Two such investigations, one in the United States, Pragmatic Airway Resuscitation Trial (PART, Clinicaltrials.gov identifier: NCT02419573), and one in the United Kingdom, REVIVE-Airways are currently underway.[15] PART is a multi-center, cluster randomized comparison of ETI vs. Laryngeal Tube (King Systems, Noblesville, IN) which will enroll 3000 subjects and is powered to measure 72 h survival. All agencies involved in PART have the potential to collect CPR process data to specifically delineate the impact of airway choice on CCF. In contrast, the REVIVE-Airways trial will cluster randomize OHCA victims to ETI, i-gel (Intrasurgical Inc., Liverpool, NY), or laryngeal mask airway supreme (LMAS, Teleflex, Morrisville, NC), the latter two being newer SGA models with technical advantages in insertion speed and ease. It is powered for both the primary outcome of ventilation success and secondary outcomes including technical aspects of the airway, and ROSC, neurologically intact survival at discharge and quality of life. These trials collectively represent our best opportunity to decide which, if either, advanced airway maneuver, is more advantageous.

Table 2
Adjusted chest compression fraction and out-of-hospital cardiac arrest airway management. Estimates are adjusted for: age (continuous), sex, witnessed arrest (bystander vs. EMS vs. not witnessed), bystander CPR (bystander attempted vs. not attempted), initial ECG rhythm (VF/VT vs. PEA, asystole, AED no shock, no strip vs. unknown.), public location, PRIMED trial arm (ITD vs. sham, analyze early vs. late), and ROC regional center. Negative values (Italics) favor SGA.

Variable	Before airway insertion	After airway insertion	Difference (After airway–Before airway)
All ECG rhythms			
ΔCCF (ETI–*SGA*); 95%CI	**−*0.022*; −0.043, 0.000**	**−*0.034*; −0.055, −0.013**	−0.012; −0.036, 0.012
p-value	**0.046**	**0.001**	0.320
Shockable ECG rhythms only			
ΔCCF (ETI–*SGA*); 95%CI	−0.019; −0.062, 0.024	**−*0.045*; −0.087, −0.003**	−0.026; −0.077, 0.025
p-value	0.382	**0.035**	0.320
Non-shockable ECG rhythms only			
ΔCCF (ETI–*SGA*); 95%CI	−0.023; -0.047, 0.001	**−*0.028*; −0.052, −0.005**	−0.005; −0.033; 0.022
p-value	0.061	**0.018**	0.701

Bold indicates statistical significance. CCF = chest compression fraction, SGA = supraglottic airway, ETI = endotracheal intubation, ECG = electrocardiogram.

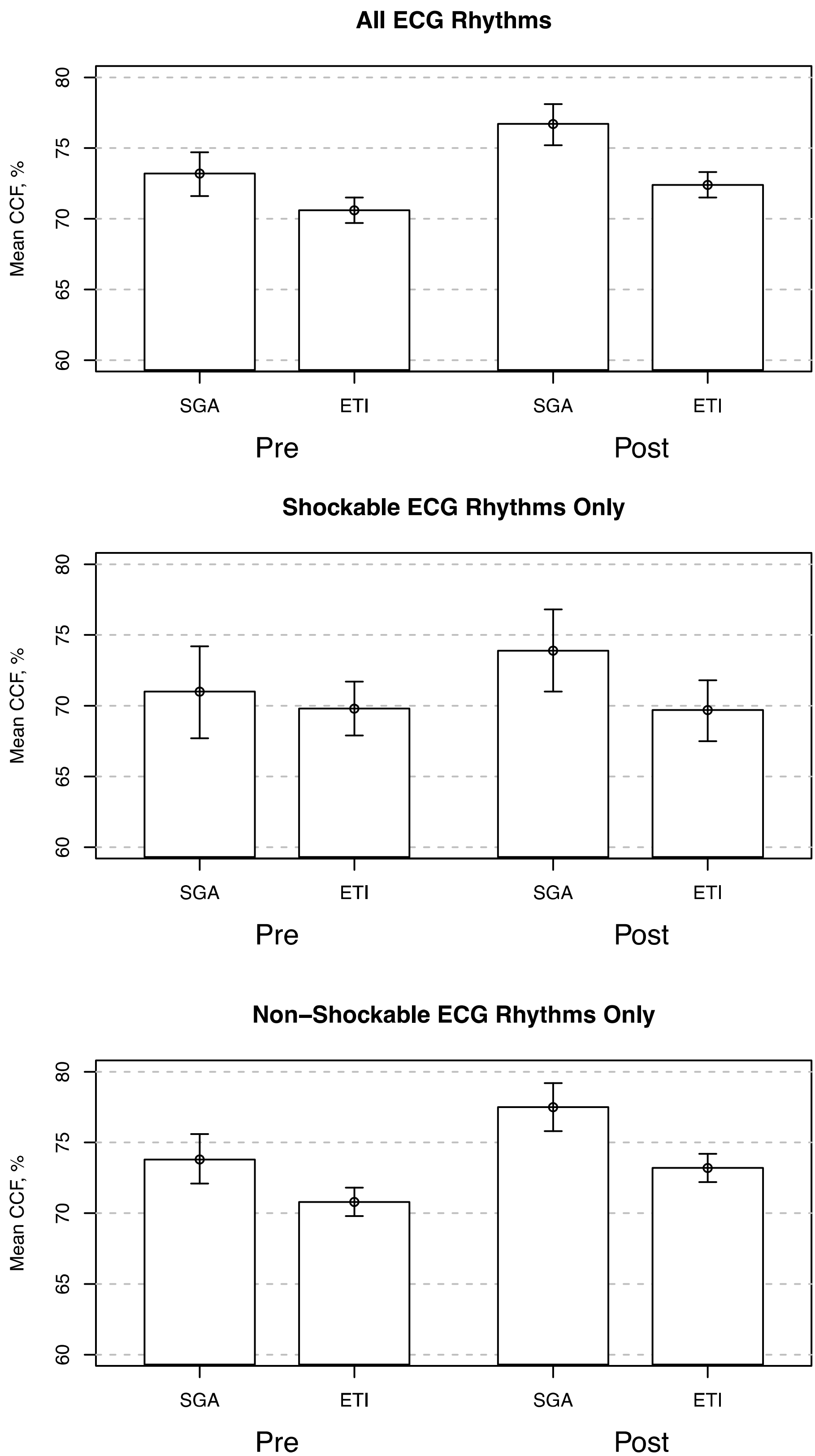

Fig. 3. Unadjusted comparison of chest compression fraction (CCF) pre-and post-airway insertion by advanced airway chosen (SGA vs. ETI). Error bars represent 95% confidence intervals for the mean.

Limitations

Important limitations of this investigation should be considered when interpreting these results. While these data were part of the ROC PRIMED trial, it was not designed or intended to evaluate advanced airway management techniques. Providers were given no direction as to which advanced airway maneuver to use beyond local medical direction and practice varied across ROC sites. SGA insertion may have acted systematically as a surrogate for patients who were more viable, easier to perform CPR upon, or had an anticipated difficult airway. While that selection bias maybe somewhat mitigated by the large numbers of subjects enrolled in the trial, the inability to fully account for confounding variables is inherent in such observational trials. For example, there were no data to describe pertinent events such as duration of advanced airway attempts, ventilation rates, or duration of peri-airway or peri-shock pauses, all of which impact CCF.

Conclusion

In this secondary analysis of the ROC PRIMED trial, SGA insertion was associated with a higher pre-insertion CCF than ETI and that difference persisted post-airway insertion independent of presenting rhythm. However, the actual differences were so small, that in the context of this observational, secondary analysis, it is unclear if this represents a clinically significant difference.

Conflict of interest statement

No conflicts of interest to declare.

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