

Prospective Trial of Advanced Airway
Management Strategies in Out-of-Hospital
Cardiopulmonary Arrest
(Protocol Proposal)

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Disclaimers

- Idea developed within the ROC
- Many in the NETT have expressed interest
- Purpose is to gauge continued interest
- Goal is to move forward with either/both groups
- As this is a preliminary discussion, Henry has NOT officially brought this up at the ROC (yet)

100%

Die at least once

80%

Get a prehospital airway

30%

Are left at the scene (still dead)

33%

Get ROSC

25%

Get admitted

10%

Get discharged

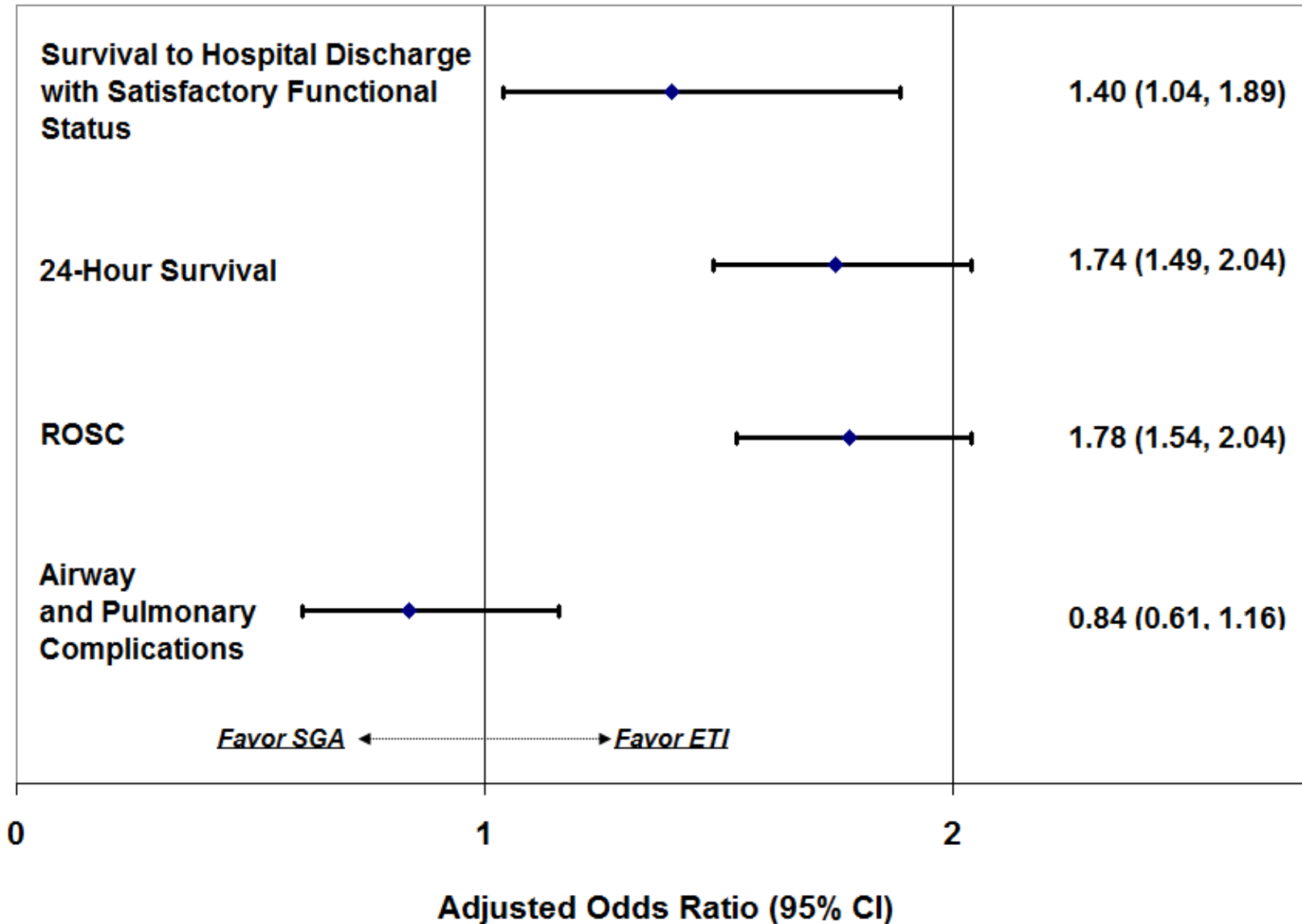
6%

Survive “neurologically intact”

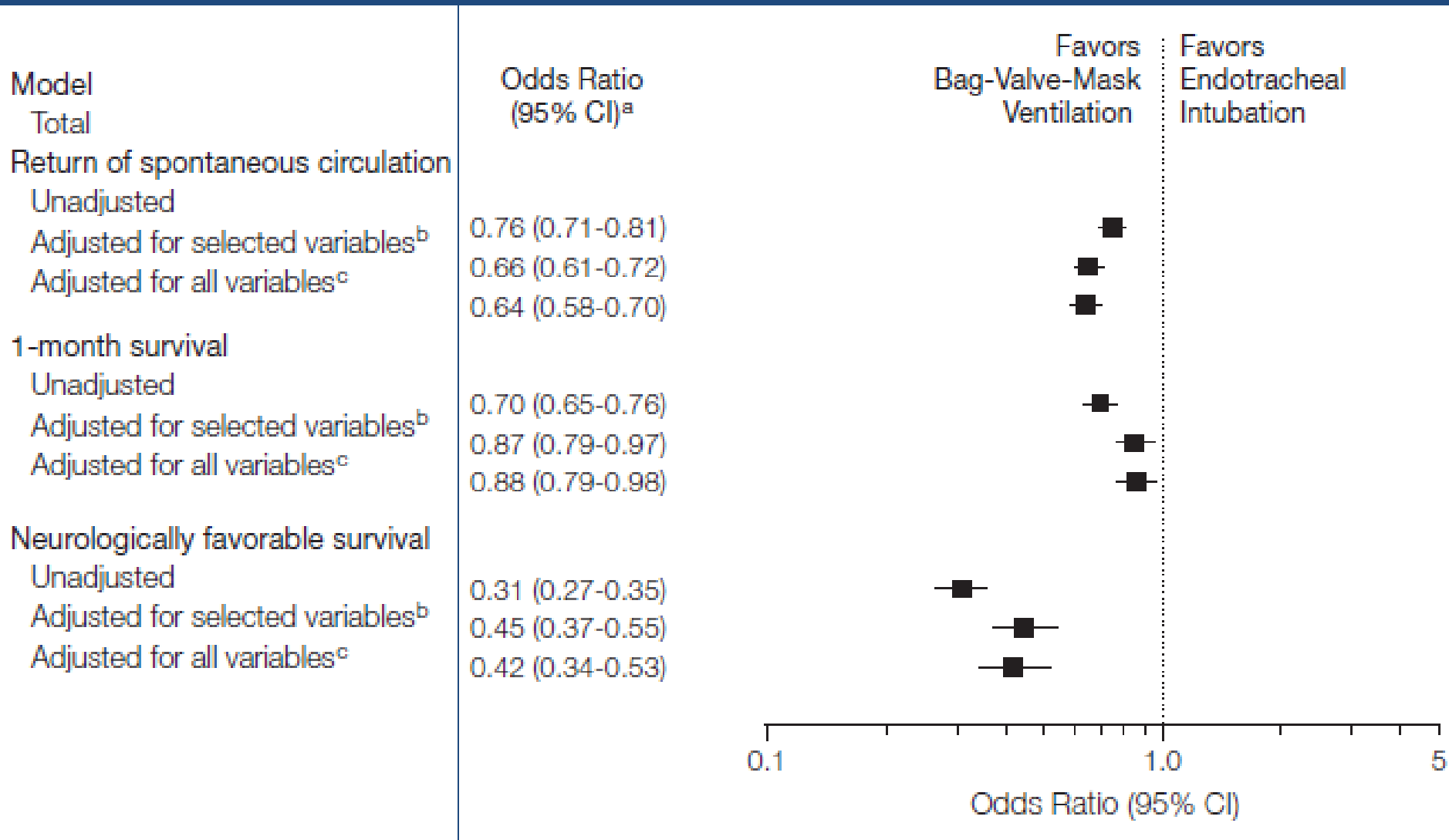
Choices Matter



Wang, Resuscitation 2012



Hasegawa, JAMA 2012



Hasegawa, JAMA 2012

Model
Total

Return of spontaneous circulation

Unadjusted

Adjusted for selected variables^b

Adjusted for all variables^c

1-month survival

Unadjusted

Adjusted for selected variables^b

Adjusted for all variables^c

Neurologically favorable survival

Unadjusted

Adjusted for selected variables^b

Adjusted for all variables^c

Odds Ratio
(95% CI)^a

0.53 (0.51-0.54)

0.54 (0.52-0.56)

0.54 (0.52-0.56)

0.63 (0.61-0.65)

0.71 (0.68-0.74)

0.72 (0.68-0.75)

0.33 (0.32-0.35)

0.36 (0.33-0.39)

0.36 (0.33-0.40)

Favors
Bag-Valve-Mask
Ventilation

Favors
Supraglottic
Airway

0.1 1.0 5

Odds Ratio (95% CI)



Hasegawa, JAMA 2012

Model	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	281 522 (43.4)		41 972 (6.5)		239 550 (36.9)	
Neurologically favorable survival						
Unadjusted	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)

McMullan, AHA/NAEMSP 2013/4

Outcome	All Patients Receiving ETI or SGA (n=8,745) OR (95% CI)
Sustained ROSC	
Unadjusted	1.43 (1.27-1.62)
Adjusted for Propensity Score (quartile)†	1.37 (1.20-1.55)
Adjusted for Propensity Score and Confounders‡	1.35 (1.19-1.54)
Survival to Hospital Discharge	
Unadjusted	1.30 (1.07-1.58)
Adjusted for Propensity Score (quartile)†	1.35 (1.10-1.67)
Adjusted for Propensity Score and Confounders‡	1.41 (1.14-1.76)
Survival to Hospital Discharge with Good Neurologic Outcome	
Unadjusted	1.35 (1.06-1.70)
Adjusted for Propensity Score (quartile)†	1.39 (1.09-1.79)
Adjusted for Propensity Score and Confounders‡	1.44 (1.10-1.88)

McMullan, AHA/NAEMSP 2013/4

Outcome	All Patients (n=10,630) OR (95% CI)
Sustained ROSC	
Unadjusted	1.25 (1.12-1.39)
Adjusted for Propensity Score (quartile)†	1.11 (0.99-1.24)
Adjusted for Propensity Score and Confounders‡	1.07 (0.94-1.20)
Survival to Hospital Discharge	
Unadjusted	3.67 (3.19-4.23)
Adjusted for Propensity Score (quartile)†	2.96 (2.54-3.45)
Adjusted for Propensity Score and Confounders‡	2.96 (2.50-3.51)
Survival to Hospital Discharge with Good Neurologic Outcome	
Unadjusted	5.19 (4.42 -6.11)
Adjusted for Propensity Score (quartile)†	4.13 (3.46-4.93)
Adjusted for Propensity Score and Confounders‡	4.24 (3.46-5.20)

In OHCA patients who receive advanced airway management by EMS, is ETI, compared to SGA, associated with improved neurologic-intact survival?



Objective

- **Compare outcomes after adult out-of-hospital cardiopulmonary arrest (OHCA) between:**
 - Endotracheal intubation (ETI)
 - Supraglottic airway (SGA)



Design Overview

- **Prospective randomized trial**
 - Cluster randomization
 - Non-inferiority/equivalence design
- **Inclusion**
 - Adult OHCA requiring advanced airway
- **Exclusion**
 - Children
 - Trauma
 - DNAR
 - Advanced airway not needed
 - Supraglottic airway not available



Outcome Measures

- **Primary (survival)**
 - Sustained ROSC
 - 24-Hour Survival
 - Survival to Hospital Discharge with $MRS \leq 3$



Outcome Measures

- **Secondary (process/care)**
 - Chest compression fraction for first 10 minutes of resuscitation
 - Airway insertion success
 - Airway insertion first-pass success
 - Number of airway insertion attempts
 - Time to successful airway insertion
 - Emergency Department hyperoxia
 - Airway anatomic injury
 - Inpatient pneumonia or aspiration pneumonitis
 - Inpatient acute lung injury

Strive for FIVE

- I believe that we should be selfish (or *enthusiastic*) about supporting such a trial
- Results could impact scope of practice, training, and *clinical care* for EMS while improving your odds of meaningful survival
- *Bio-rationale*: airway management affects CPR metrics, hypervent, hyperox, ITP, ICP, etc.
- Neurologic-intact survival is *everybody's mission*

Adult OHCA

Primary ETI

BLS: BVM only

ALS: ETI first

(BVM or SGA Rescue)

Primary SGA

BLS: BVM or SGA first

(BVM Rescue)

ALS: SGA first

(BVM or ETI Rescue)

CONTINUE RESUSCITATION

Sample Size

- 18,705 Subjects
- **Assumptions:**
 - Survival with $MRS \leq 3 \rightarrow 4.7\%$
 - Based on PRIMED data - patients receiving airway only
 - 90% power
 - 25% relative change in survival
 - 6 interim analyses
 - 5% inflation for cluster randomization
 - Stopping for superiority and futility
- **Other scenarios possible**