### Prehospital Advanced Airway Management and Outcomes in Out-of-Hospital Cardiac Arrest : a Cluster Randomized Controlled Trial

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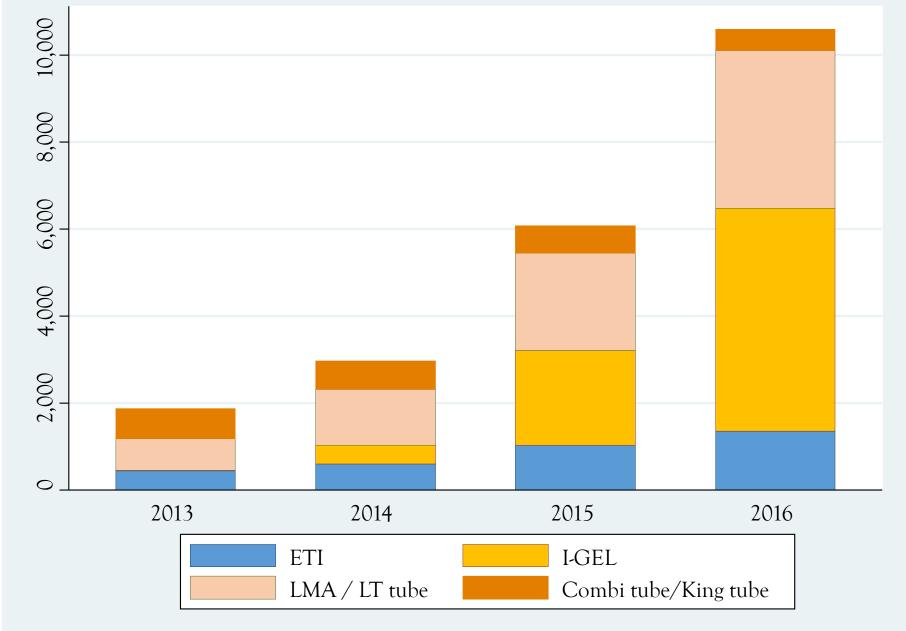
# Background

- To improve oxygenation and ventilation
  - Advanced airway placement required during ACLS
- Type of advanced airway in EMS
  - Conventional choice
    - Endotracheal intubation (ETI) / Supraglottic airway (SGA)
  - New choice
    - Videolaryngoscope assisted

## Result from previous PAROS dataset

	Total		Osaka		Seoul		Singapore		Таіреі	
			(2009 ~2010)		(2011 ~ 2012)		(2010~2012)		(2010 ~ 2011)	
	N	%	N	%	Ν	%	Ν	%	Ν	%
Total	18596		8787		5249		2205		2355	
ETI	2799	15.1	2323	26.4	122	2.3	15	0.7	339	14.4
SGA	2759	14.8	31	0.4	480	9.1	1825	82.8	423	18.0
Others	3429	18.4	3159	36.0	270	5.1	0	0.0	0	0.0
BVM	9609	51.7	3274	37.3	4377	83.4	365	16.6	1593	67.6

#### EMS advanced airway during recent years in Korea



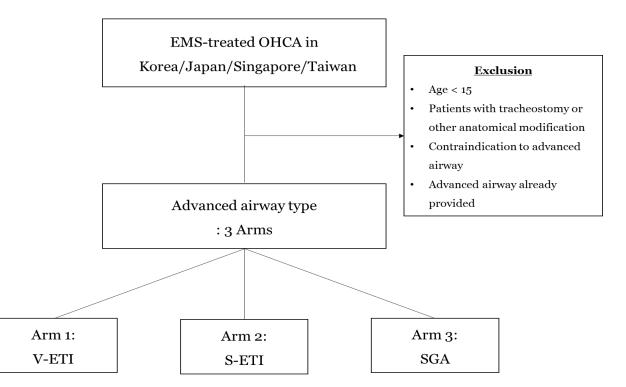
# Goal of study

- Superiority among advanced airway technique in EMS field
  - Not been revealed in clearly randomized controlled trial
  - Recent RCTs performed outside Asia

- Test effect of 3 advanced airway techniques (V-ETI / S-ETI / SGA) in prehospital EMS field in OHCA
  - On neurologic outcome of patients

# Study design

- Pragmatic cluster randomized controlled trial
  - Ambulance vehicle as unit of randomization



## Study intervention

- 3 types of advanced airway placement
  - Endotracheal intubation with videolaryngoscope (V-ETI)
  - Standard endotracheal intubation with direct laryngoscope (S-ETI)
  - Sugraglottic airway insertion (SGA)

# Videolaryngoscope

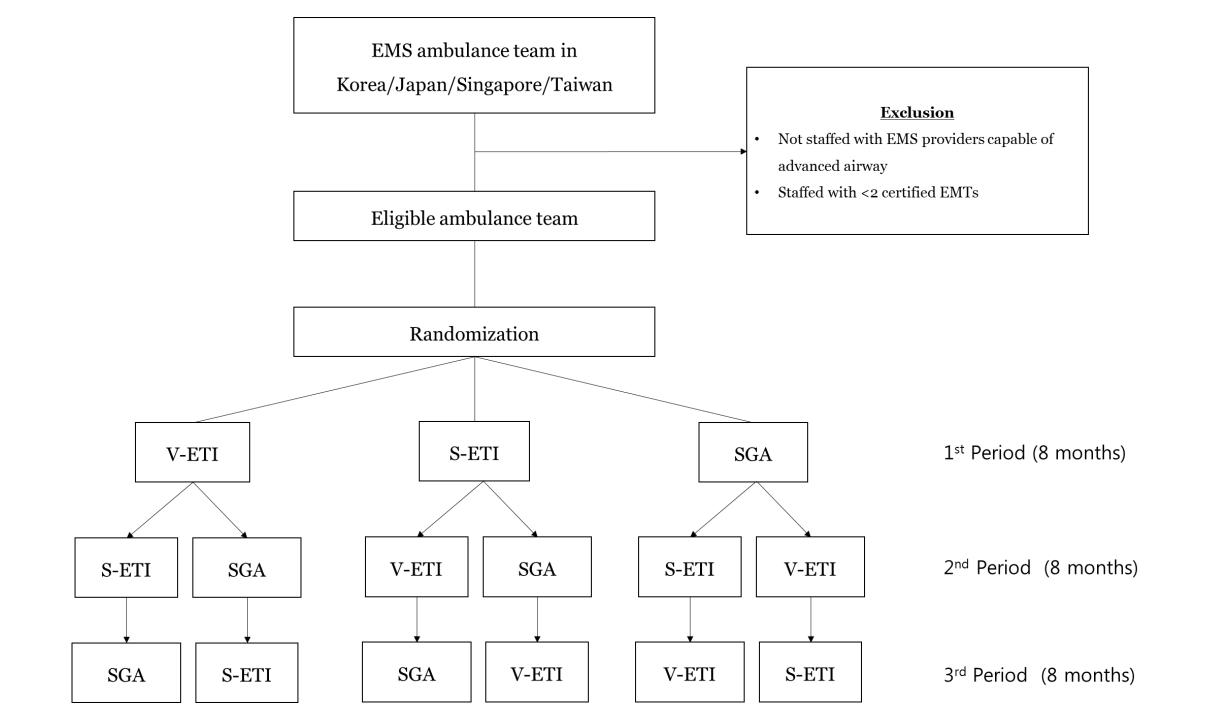
• consists of camera implanted inside the blade of laryngoscope

- obtaining real time video inside patient throat
- Higher success rate for ETI
  - Medical students
  - EMS providers



## Randomization and allocation

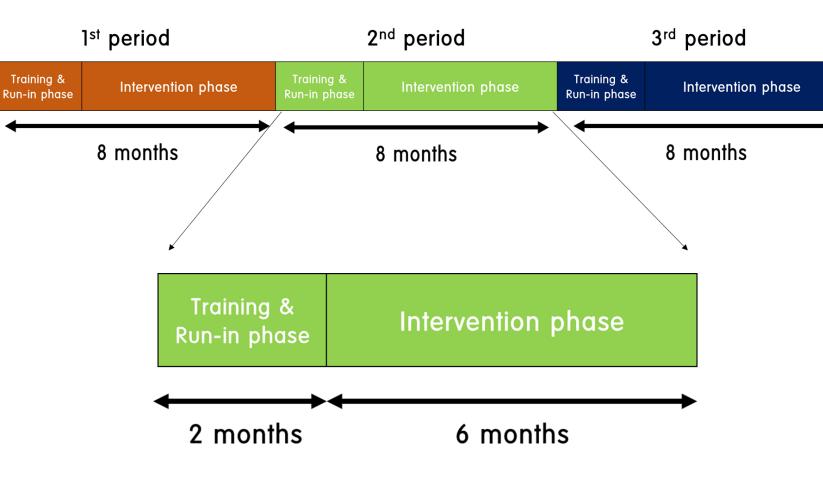
- Randomized crossover design and allocation
  - Inclusion criteria for enrolled ambulance unit
    - Team with certified EMS providers capable of advanced airway placement ( ex> level-1 EMT in Korea)
    - Team with at least 2 certified EMS providers or ACLS unit
      - Available advanced airway technique in field



# Study period

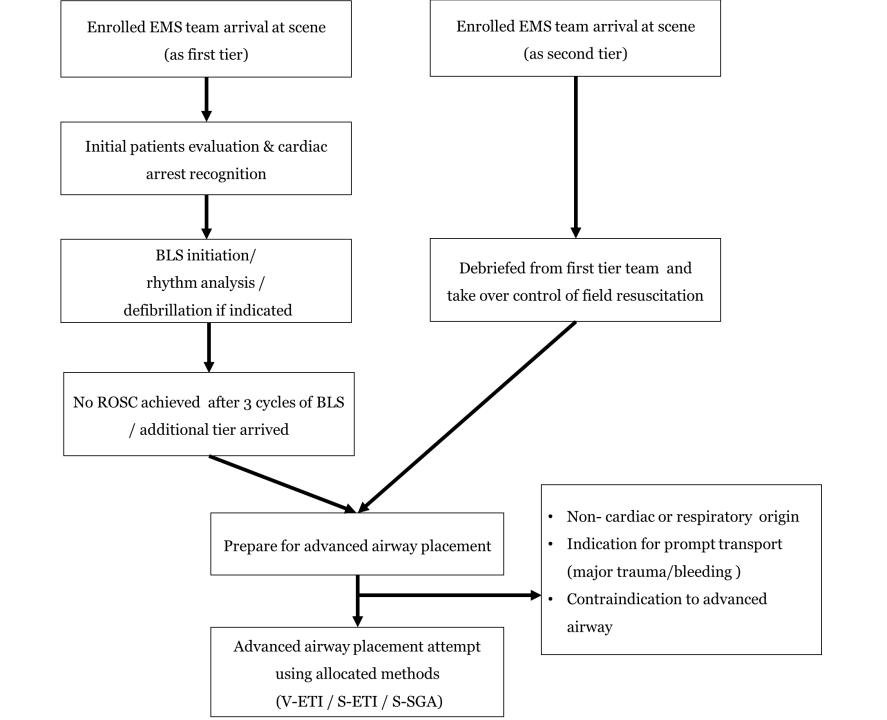
• 3 periods

- 1 airway for 1 period
  - Training & Run-in
    - 2 months
  - Intervention
    - 6 months



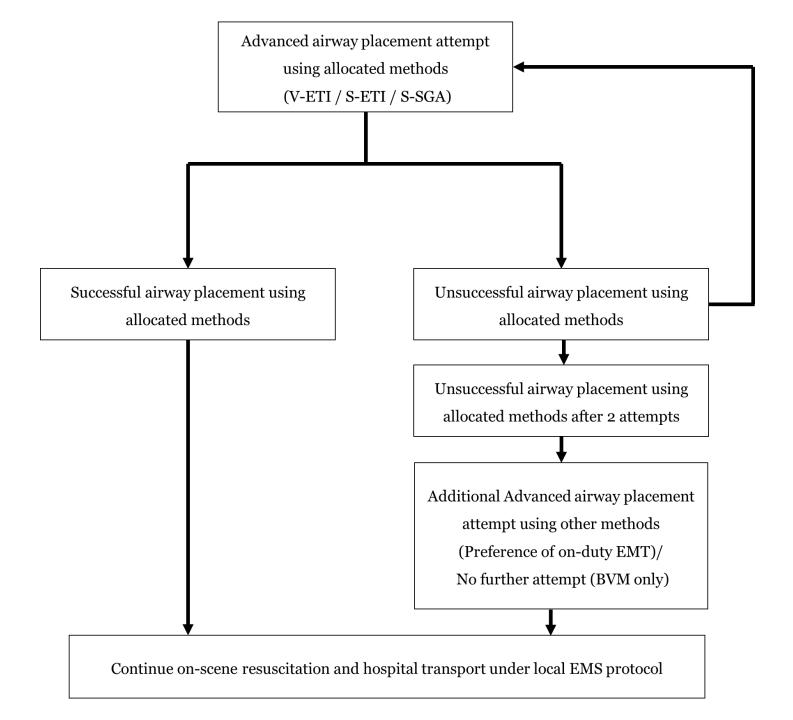
# Protocol (1)

- Depend on enrolled EMS team arrival timing at scene
  - If advanced unit arrived as first tier
    - Advanced airway placement initiation
      - After 3 cycles of BLS or
      - As soon as 2<sup>nd</sup> tier arrives
  - If advanced unit arrived as second tier after basic unit
    - As soon as advanced team is debriefed and finished taking over control of scene resuscitation



## Protocol (2)

- Advanced airway placement after 3 cycles
  - Up to 2<sup>nd</sup> attempt
    - Allocated airway device
  - Failure after 2<sup>nd</sup> attempt
    - Airway of EMT preference or no advanced airway



# Study population

- Inclusion criteria
  - Adult EMS-assessed OHCA
  - Presumed cardiac etiology

# Study population

- Exclusion
  - DNR or obvious sign of death
  - Arrest during hospital transport in ambulance
  - ROSC before EMS arrival to scene
  - ROSC during early resuscitation by EMS resuscitation
    - Prior to 3 cycles of BLS
    - Prior to arrival of enrolled EMS team or 2<sup>nd</sup>-tier
  - Tracheostomy or anatomical modification
  - Airway deformity

# Study outcome

- Primary outcome
  - Cerebral performance category (CPC) scale 1 or 2 upon hospital discharge
- Secondary outcome
  - Survival upon hospital discharge
  - Rate of successful airway placement at scene

## Other measurement

- Existing PAROS variable
- Advanced airway variables (additional variables)
  - Type of allocated device
  - Number of attempts
  - Successful airway placement
  - Reason for failure , etc..

## Statistical analysis

- Comparison between 3 groups
  - Per protocol & intention-to-treat technique
- Association of advanced airway to outcome
  - Multivariable logistic regression model

# Sample size calculation

- No survival outcome comparison including V-ETI
  - ETI -> SGA : approx. 1% increase
- Hypothesizing 1% increase in neurological outcome
  - Sample size per 1 group
    - 3,000 ~ 4,000 patients

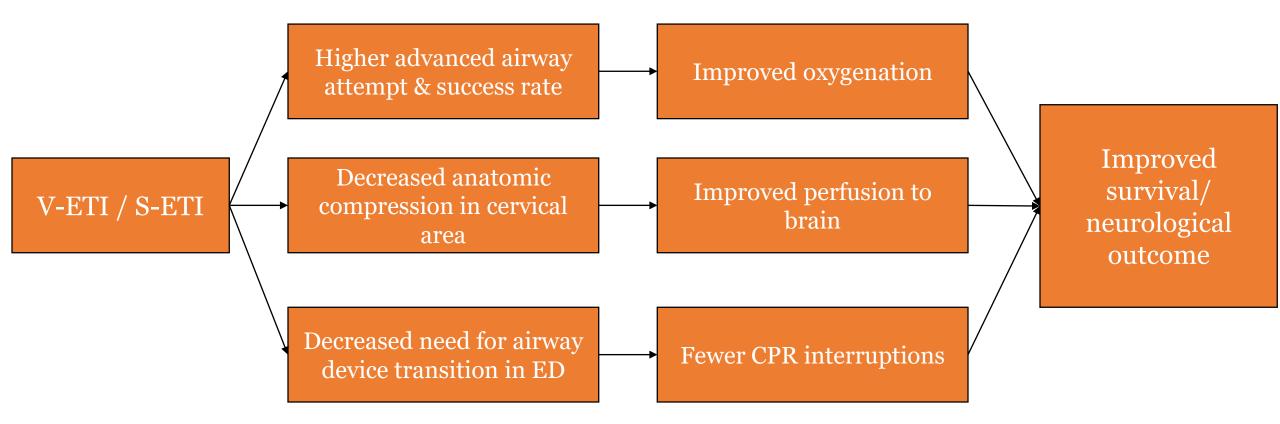
#### Previous reports regarding ETI vs. SGA

Study	Airway	Ν	ROSC (%)	Admit (%)	Survival (%)	Neurological outcome (%)
Cady 2009	ETI	4335	1558 (35.9)	1112 (25.7)	279 (6.4)	
	SGA	1487	508 (34.2)	377 (25.4)	97 (6.5)	
Hanif 2010	ETI	1027	244 (24)	152 (15)	38 (4)	
	SGA	131		5 (4)	0 (0)	
Kajino 2011	ETI	1679	802 (47.8)	688 (41)	180 (10.7)	61(3.6)
	SGA	3698	1643 (44.4)	1412 (38.2)	361 (9.8)	133(3.6)
McMullan 2014	ETI	5591	1890 (33.8)	1487 (26.6)	464 (8.3)	302(5.4)
	SGA	3110	793 (25.5)	666 (21.4)	208 (6.7)	162(5.2)
Nagao 2012	ETI	10	1 (10)			
	SGA	189	36 (19)			
Noda 2007	ETI	4	2 (40)	2 (40)	1 (20)	0(0)
	SGA	24	5 (20.8)	4 (16.7)	3 (12.5)	0(0)
Shin 2012	ETI	250		55 (22)	20 (8)	
	SGA	391		80 (20.5)	22 (5.6)	
Tanabe 2013	ETI	12992	853 (6.6)		474 (3.7)	162(1.3)
	SGA	29640	1386 (4.7)		1060 (3.6)	310(1.1)
Wang 2012	ETI	8487				399(4.7)
	SGA	1968				77(3.9)
Yanagawa 2010	ETI	158	18 (11.4)			2(1.3)
	SGA	478	37 (7.7)			6(1.3)

## Case Report Form

		Serial number (					
Ad	dvanced airway placement attempt	□ Yes □ No					
Reason for no advanced airway attempt		<ul> <li>□ Anatomic injury of airway</li> <li>□ Staff shortage</li> <li>□ Field condition not sufficient for procedure</li> </ul>					
	Attempted airway device	$\Box V-ETI  \Box S-ETI  \Box SGA ( )$					
	Device selected as allocated	$\Box$ Yes $\Box$ No					
First attempt	Reason for not selecting allocated device	<ul> <li>Device shortage</li> <li>Device malfunction</li> <li>Technical difficulty of EMT</li> <li>Other cause</li> <li>( )</li> </ul>					
	Successful airway	$\Box$ Yes $\Box$ No					
	Reason for failure	<ul> <li>Failure of visualizing vocal fold (only for V-ETI &amp; S-ETI)</li> <li>Failure of placing and advancing airway device in adequate position</li> <li>Failure of fixation of inserted advanced airway</li> <li>Failure of ballooning device (only for V-ETI &amp; S-ETI)</li> <li>Device malfunction (ex&gt;videolaryngoscope malfunction, low batteries, deformity of airway device)</li> <li>Removed because of evidence of air leakage when positive pressure ventilation is delivered</li> <li>Other reason: ( )</li> </ul>					
F	Final prehospital advanced airway	$\Box$ V-ETI $\Box$ S-ETI $\Box$ SGA $\Box$ BVM					
Adverse events during advanced airway placement		<ul> <li>No adverse event</li> <li>Broken tooth or any orofacial injury caused by advanced airway placement</li> <li>Soft tissue injury, uncontrolled bleeding or any penetration injury of pharyngeal space</li> <li>Extubation or leaving fixed position of airway device (Self or accidental)</li> <li>Chest compression interruption (&gt; 30 seconds) due to airway placement</li> <li>Other adverse event ( )</li> </ul>					

## Expected outcome of study



## Update in Korea

- Launching ALS ambulance-"Special EMS team"n Korea
  - 2<sup>nd</sup> tier ALS providing EMS team
    - Available to provide IV medication and dispatched for all OHCA
    - Equipped with videolaryngoscope and USG
  - Advanced airway training sessions for all ALS teams in Seoul

Lecture (09:00 ~ 10:20, 20mins for each session)

- A. Advanced airway, preparation and general consideration
- B. Videolaryngoscope endotracheal intubation
- C. Confirmation using ultrasound
- D. Suparglottic airway and EtCO2

Hands on training (10:30~12:30, 30 mins for session)

Team 1	Team 2	Team 3	Team 4	
А	В	С	D	30 min
В	С	D	А	30 min
С	D	А	В	30 min
D	А	В	С	30 min

Field Protocol (12:30~12:40)

Team Approach Protocol( 12:40~13:00)

Debriefing (13:00~)

- 6 Training classes with approximately 180 ALS team crews(level-1 EMT)
  - From Feb 2019 ~ June 2019



## Future plan

• Accomplish training all ALS ambulance crews within June

- Detailed discussion for research protocols and launching plans
  - With Seoul Metropolitan Fire headquarters and other Fire headquarters in Korea

## Thank you for attention