Study proposal

- Mechanical vs Manual compression for pts with OHCA, multi-center RCT -

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Background

- OHCA : leading cause of death
  - Only 1-8% of OHCA pts survive to hospital discharge
- Early CPR / high quality CPR
  - Important for cardiac/brain resuscitation

Background

- Load-distributing band(LDB) device
  - Higher intrathoracic pressure than manual compression
  - Study by Ong ME et. al : better survival
  - Study by Hallstrom A et. al : no difference

Use of an Automated, Load-Distributing Band Chest Compression Device for Out-of-Hospital Cardiac Arrest Resuscitation

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Joseph P. Ornato, MD
David P. Edwards, MBA, EMT-P
Harinder S. Dhindsa, MD, MPH

Context Only 1% to 8% of adults with out-of-hospital cardiac arrest survive to hospital discharge.

Objective To compare resuscitation outcomes before and after an urban emergency medical services (EMS) system switched from manual cardiopulmonary resuscitation (CPR) to load-distributing band (LDB) CPR.

Table 2. Comparison of Outcomes in the Manual CPR and LDB-CPR Phases*

	Manual CPR		LDB-CPR		OR (95% CI)	
	No./Total No. of Patients	% (95% CI)	No./Total No. of Patients	% (95% CI)	Unadjusted	Adjusted
Return of spontaneous circulation†	101/499	20.2 (16.9-24.0)	96/278	34.5 (29.2-40.3)	2.08 (1.49-2.89)	1.94 (1.38-2.72)
Survival to hospital admission†	54/485	11.1 (8.6-14.2)	58/277	20.9 (16.6-26.1)	2.11 (1.41-3.17)	1.88 (1.23-2.86)
Survival to hospital discharge‡	14/486	2.9 (1.7-4.8)	27/278	9.7 (6.7-13.8)	3.23 (1.66-6.51)	2.27 (1.11-4.77)

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; LDB, load-distributing band; OR, odds ratio.
*Both crude and adjusted ORs are presented in the logistic regression models. For the LDB-CPR phase, the total number of patients is not 284 due to missing data.
†Adjusted for differences in response time intervals and percentage of EMS witnessed.
‡Adjusted for differences in response time intervals, percentage of EMS witnessed, and whether postresuscitation hypothermia was used. For the unadjusted and adjusted ORs and 95% CIs, a weighted logistic regression was performed.

Manual Chest Compression vs Use of an Automated Chest Compression Device During Resuscitation Following Out-of-Hospital Cardiac Arrest

A Randomized Trial

Al Hallstrom, PhD
Thomas D. Rea, MD, MPH
Michael R. Sayre, MD
James Christenson, MD
Andy R. Anton, MD
Vince N. Mosesso, Jr, MD

Context High-quality cardiopulmonary resuscitation (CPR) may improve both cardiac and brain resuscitation following cardiac arrest. Compared with manual chest compression, an automated load-distributing band (LDB) chest compression device produces greater blood flow to vital organs and may improve resuscitation outcomes.

Objective To compare resuscitation outcomes following out-of-hospital cardiac arrest when an automated LDB-CPR device was added to standard emergency medical services (EMS) care with manual CPR.

Table 4. Logistic Regression of Survival to Hospital Discharge*

	Adjusted for Clustering			
	Univariable OR (95% CI)†	*P* Value	Multivariable OR (95% CI)†	*P* Value
Age per y	0.97 (0.96-0.99)	.002	0.98 (0.96-0.99)	.01
PEA to VF	0.28 (0.14-0.55)	<.001	0.36 (0.17-0.75)	<.001
Asystole to VF	0.05 (0.02-0.15)	<.001	0.09 (0.03-0.28)	<.001
Witnessed	5.30 (2.80-10.20)	<.001	2.40 (1.20-4.90)	.02
Site C	3.70 (2.10-6.50)	<.001	3.70 (2.00-7.00)	<.001
Response time of first vehicle/min	0.72 (0.60-0.86)	<.001	0.70 (0.58-0.85)	<.001
Public location	4.00 (2.30-6.90)	<.001	1.80 (0.97-3.40)	.06
LDB-CPR treatment group	0.57 (0.33-0.99)	.045	0.56 (0.31-1.00)	.06

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; LDB, load-distributing band; OR, odds ratio; PEA, pulseless electrical activity; VF, ventricular fibrillation.

*Variables considered but not significant in the models: univariable: days from site start (OR, 1.00 [95% CI, 0.99-1.00]; *P* = .27 [adjusted for clustering]); before December 28 (OR, 1.50 [95% CI, 0.86-2.50]; *P* = .16 [adjusted for clustering]); men (OR, 1.40 [95% CI, 0.79-2.70]; *P* = .23 [adjusted for clustering]); CPR performed by a bystander (OR, 1.40 [95% CI, 0.82-2.50]; *P* = .21 [adjusted for clustering]); response time of advanced life support vehicle (OR, 0.94 [95% CI, 0.87-1.02]; *P* = .15 [adjusted for clustering]). Interactions considered: treatment group × days from site start, *P* = .84; treatment group × site C, *P* = .12; treatment group × rhythm (with imputed rhythm values), *P* = .37.

†The ORs higher than 1 indicate a higher likelihood of survival and conversely, eg, the odds of survival decrease by 0.98 for each year of age, decrease by 0.36 if found in PEA than in VF, etc.

Background

- Common point of two studies : ALS CPR
  - Paramedics, medication, fluid… in field

Background

- It is very different from Asian countries
  - EMT-B or EMT-I / cannot supply ALS
  - Mostly, ongoing compression on ambulance

Background

- How about LDB device in this situation???

Goal

- To compare survival outcomes in patients with OHCA treated either by the LDB device or by manual compression by EMTs

Methods

- Under the regulations for exemption from informed consent
- Multi-center
- Multi-country
  - Maybe we need some adjustment

Methods

- Any Asian country can participate in
  - BLS single tiered EMS system
  - No paramedics, no ALS management before hospital arrival(except advanced airway, limited medication)
  - EMT-I or EMT-B level

Methods

- All ED in this study
  - Should have resuscitation team
  - Should have resuscitation protocol
  - Can collect hospital data easily/precisely

Methods

- Case inclusion
  - All EMS-assessed OHCA with presumed cardiac etiology
  - Above 15 yrs

Methods

- Case exclusion
  - Cardiac arrest after EMS arrival
  - Noncardiac etiology

Methods

- Data collection
  - Fill in common data sheet(based on Utstein style)
  - Share the definition of variables
  - Can be opened web-base

Methods

- Intervention : chest compression using LDB device by EMT-I or EMT-B
- Control : manual chest compression by EMT-I or EMT-B

Methods

- Cluster randomization with crossover
  - Cluster : group of EMS stations(population base)
  - Crossover : occur at specified time interval(4wks)
  - Avoid simultaneous response
  - Not same period
- Any other effective design can be applied

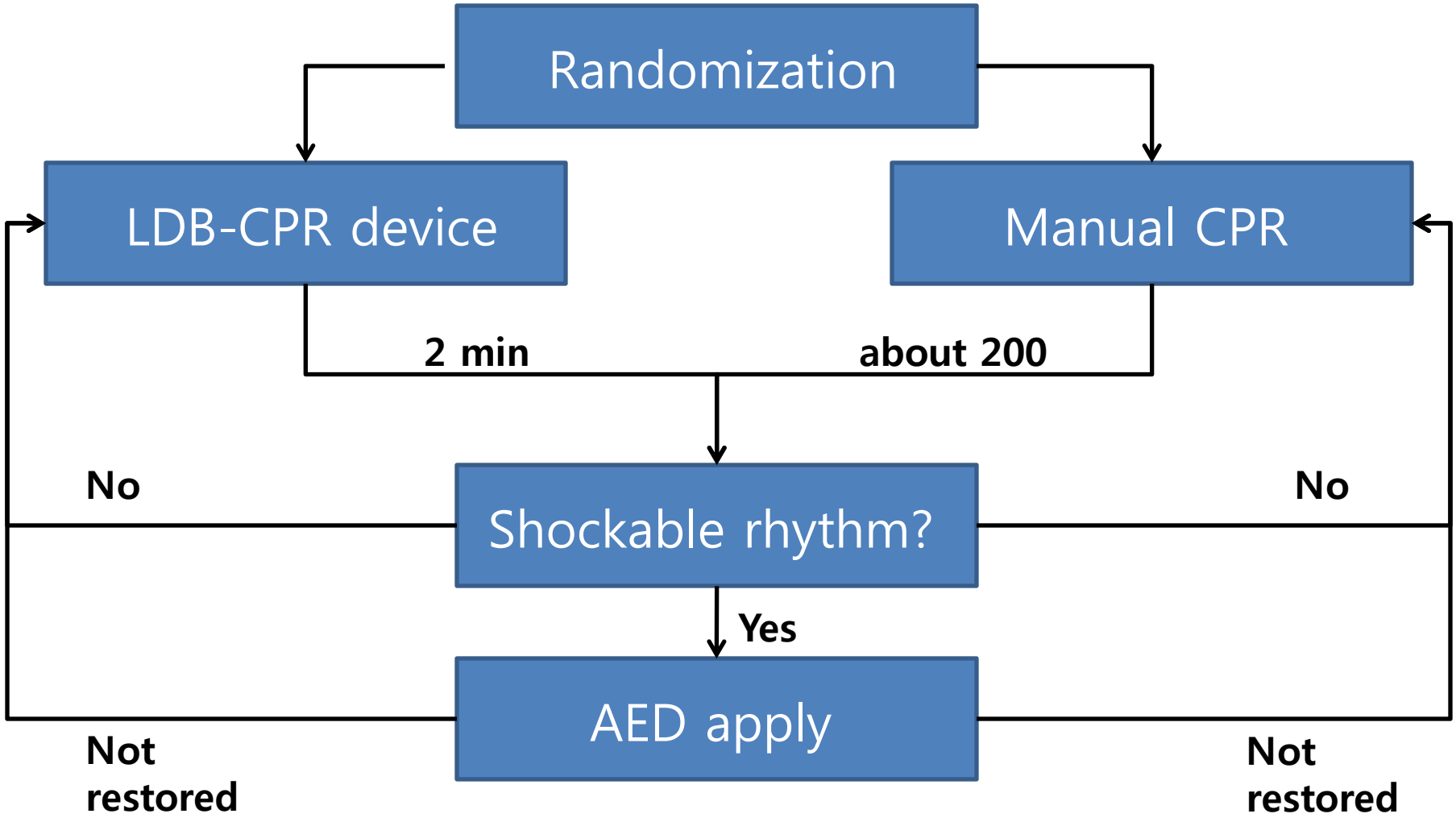
Methods

- Study protocol(intervention group)
  - Pt's upper body clothing should be removed
  - Place patient on the backboard with supine position
  - 8-inch wide LDB(anchored to the backboard) is wrapped around the pt's chest(with velcro)
  - Start device-regulated, repetitive shortening

Methods

- Run-in period
  - At least 2 months
  - Initial training : hands-on skill practice using the device with a mannequin / video presentation
- Refresher training will not be specified

Methods


Randomization
LDB-CPR device
Manual CPR
2 min
about 200
Shockable rhythm?
No
No
Yes
AED apply
Not restored
Not restored

Methods

- Outcome
  - Primary outcome : survival to admission
  - Secondary outcome : survival to discharge
  - Additional outcome : rate of any ROSC

Methods

- Sample size
  - Survival to admission : 10% in control group
  - Survival to admission : 20% in intervention group
  - Need 532 pts (power of 90% using a 2-sided test with a level of 0.05)

Methods

- Statistical analysis
  - Intention-to-treat assignment
  - Logistic regression will be applied
  - Subgroup analysis : based on initial ECG rhythm

Request

- Please, participate!
- Let’s overcome many barriers!
- Let’s contribute OHCA survival improvement!

Thank you !!!