

## Backgrounds

**Although it has been reported that therapeutic hypothermia (TH) improves neurological outcomes of patients with cardiac arrest , procedures of the hypothermia remain to be established.**

**Particularly, impact of cardiopulmonary assisted devices (PCPS) to treat the patients with prolonged cardiogenic shock under TH has not been sufficiently studied.**

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## Objective

**To investigate the efficacy of TH including PCPS in patients with return of spontaneous circulation (ROSC) after resuscitation from out-of-hospital or inhospital cardiac arrest.**

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# Study Populations

281 consecutive patients with ROSC after resuscitation treated with TH in the multicenter registry in Japan (J-Pulse-Hypo registry) for 4 years (2005-2008).

## <Inclusion criteria>

- Adult patients who remained unconscious after resuscitation from out-of-hospital or inhospital cardiac arrest.
- Presented the stable hemodynamics with treatment or mechanical supporting system including IABP or PCPS.

## <Exclusion criteria>

- pregnancy
- dissection of aorta
- pulmonary thromboembolism
- drug poisoning
- poor daily activity

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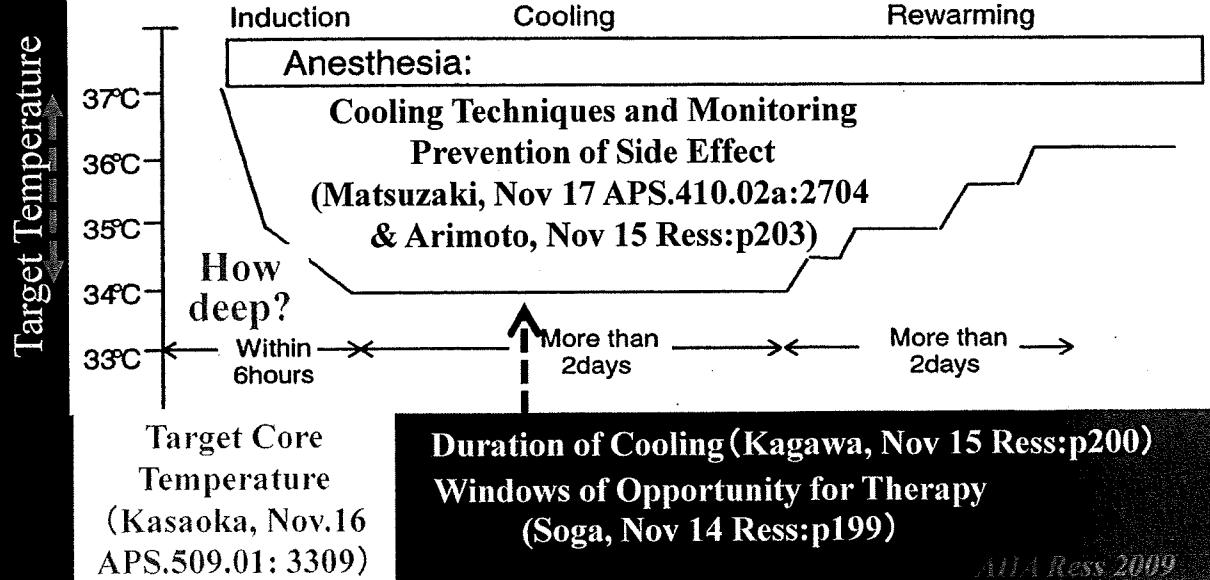
# 8 Clinical Questions from J-PULSE-Hypo in 2009

## Patients characteristic

Initial Patients Evaluation (blood exam.) (Kashiwase, Nov 15 Ress:p202)

Impact of AMI/ACS (Shirai, Nov 14 Ress: p94)

PCPS with Hemodynamic Compromised State (Kokubu, Nov 14 Ress:p95)



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# Study Organization



## Principle Investigator:

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## Working members:

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Saiseikai Senri Hospital  
Osaka City University Hospital  
Kitazato University Hospital  
Mishima Emergency critical Center  
Sumitomo Hospital

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## Methods-1

**Selection of cooling procedure was left to each institution.**

**The patients with hemodynamic compromised state were treated with PCPS (PCPS group).**



**PCPS group: n=57 (20%)  
Non-PCPS group: n=224 (80%)**

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## Methods-2

**We evaluated clinical characteristics of the patients treated with PCPS under TH, and factors to influence on favorable neurologic outcome (FNC) in patients treated with PCPS.**

**Primary end point of this study was FNC, cerebral performance category (CPC) 1 and 2 rate at 30 days.**

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### Clinical characteristics of patients treated with TH from J-pulse-hypo registry

	All patients (n = 281)
Age (years)	58±13
Male	235 (84%)
<b>Initial cardiac rhythm</b>	
Ventricular fibrillation	196 (69%)
Pulseless electrical activity	26 ( 9%)
Asystole	21 ( 8%)
Unidentified	37 (13%)
<b>Witnessed cardiac arrest</b>	247 (88%)
Bystander CPR	145 (52%)
ROSC before admission	167 (60%)
Acute coronary syndrome	170 (60%)
Emergency PCI	122 (43%)
PCPS use	57 (20%)
IABP use	108 (38%)
FNC rate at 30 days	123 (44%)

Data are presented as mean value ± SD or number (%) of patients.

CPR, cardiopulmonary resuscitation; IABP, intra aortic balloon pumping;

PCI, percutaneous coronary intervention.

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## Clinical characteristics between PCPS group and non-PCPS group

	PCPS group (n = 57)	Non-PCPS group (n = 224)	p value
Age (years)	59 ± 9	58 ± 14	0.56
Male	52 (91%)	183 (82%)	0.06
Initial cardiac rhythm			0.32
Ventricular fibrillation	35 (61%)	161 (72%)	
Pulseless electrical activity	6 (10%)	20 (9%)	
Asystole	4 (7%)	17 (7%)	
Unidentified	12 (21%)	25 (11%)	
Witnessed cardiac arrest	50 (88%)	197 (88%)	0.96
Bystander CPR	33 (58%)	112 (50%)	0.29
ROSC before admission	13 (23%)	154 (69%)	<0.01
Acute coronary syndrome	41 (72%)	129 (58%)	0.04
Emergency PCI	36 (63%)	86 (38%)	<0.01
IABP use	43 (75%)	65 (29%)	<0.01

Data are presented as mean value ± SD or number (%) of patients.

CPR, cardiopulmonary resuscitation; IABP, intra aortic balloon pumping; PCI, percutaneous coronary intervention.

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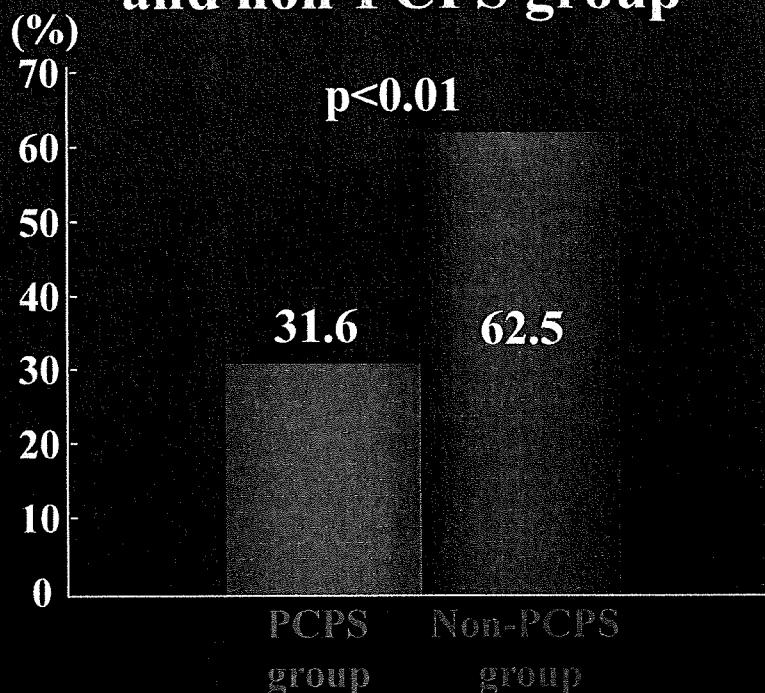
## Cooling parameters and laboratory value on admission between PCPS group and non-PCPS group

	PCPS group (n = 57)	Non-PCPS group (n = 224)	p value
Maximum BP after ROSC	110 ± 39	132 ± 34	<0.01
Initiation cooling to target temperature (min)	124 ± 137	293 ± 248	<0.01
Cooling duration (hour)	32 ± 13	35 ± 15	0.24
Arterial blood pH	7.06 ± 0.19	7.17 ± 0.18	<0.01
Arterial blood Base Excess(mmol/l)	-16.3 ± 6.5	-11.5 ± 6.2	<0.01
Blood Sugar(mg/dl)	297 ± 120	256 ± 85	<0.01
Creatinine(mg/dl)	1.3 ± 1.3	1.5 ± 1.8	0.32
Potassium(mEq/dl)	4.2 ± 1.0	4.1 ± 0.1	0.43
Hemoglobin(g/dl)	13 ± 2	14 ± 2	0.07

Data are presented as mean value ± SD or number (%) of patients.

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## FNC rate at 30 days between PCPS group and non-PCPS group



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## Comparison between FNC(CPC1/2) category and Non-FNC(CPC 3/4) category in PCPS group

	FNC group (CPC1/2) (n = 18)	Non-FNC group (CPC3/4) (n = 39)	p value
ROSC before admission	9 (50%)	4 (10%)	<0.01
Acute coronary syndrome	16 (89%)	25 (64%)	0.04
Emergency PCI	11 (61%)	25 (64%)	0.83
IABP use	12 (67%)	31 (79%)	0.30
Maximam BP after ROSC(mmHg)	136± 44	96± 28	<0.01
Initiation cooling to target temperature(min)	113 ± 105	145± 185	0.43
Arterial blood pH	7.11± 0.20	7.03 ± 0.20	0.17
Arterial blood Base Excess(mmol/l)	-14.9± 7.8	-17.0± 5.7	0.27
Blood Sugar(mg/l)	260± 114	316± 119	0.11

Data are presented as mean value ± SD or number (%) of patients

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## Summary

To compare with non-PCPS group, PCPS group showed much less FNC rate at 30 days.

There was no significant inter-group difference, in gender, the presence of witness, bystander CPR, initial ECG findings and cooling duration. Although PCPS group showed much hemodynamic compromised state in maximum blood pressure, rate of ROSC before admission, blood sugar, pH and base excess of arterial blood gas at admission, PCPS group was more treated with PCI and IABP than in non-PCPS group.

Patients with FNC in PCPS group showed higher maximum blood pressure, more often coronary artery syndrome and higher rate of ROSC before admission than patients without FNC.

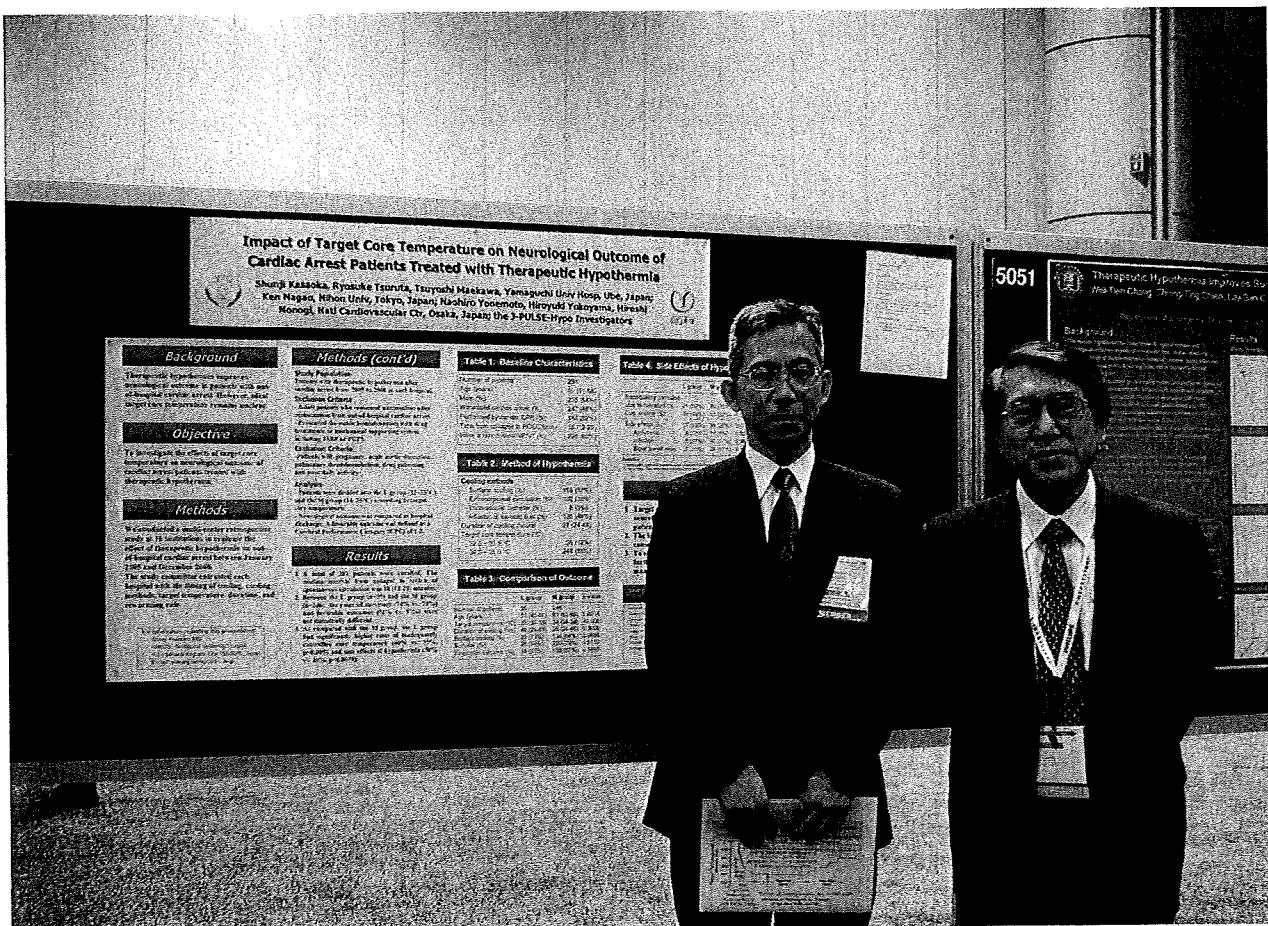
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## Conclusions

The patients treated with TH using PCPS, even who were in very ill condition, were reached FNC at 30 days up to 31.6%.

Higher maximum blood pressure, cardiac arrest due to acute coronary syndrome and ROSC before admission were important factors of FNC in PCPS group.

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# 日本循環器学会資料

- J-Hypo
- J-RCPR

J-Hypo

抄録・スライド

Impact of Percutaneous Coronary Intervention and Mild Hypothermia therapy for Patients with out-of-hospital Cardiac Arrest of Acute Coronary Syndrome from Multicenter Hypothermia Registry in Japan.

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Naohiro Yonemoto, Hiroyuki Yokoyama, Hiroshi Nonogi, National Cardiovascular Center and J-PULSE-Hypo Investigators.

Object: The purpose of this study was to evaluate favorable neurological outcomes (cerebral performance category [CPC] 1 and 2) at 30 days for unconscious patients with ROSC after out-of hospital cardiac arrest. Method: Three years (2005-2007) data were available for the 281 patients treated with MH in the multicenter registry (12 institutions) of the J-PULSE-Hypo in Japan. Of those 122 were diagnosed as ACS by coronary angiography after ROSC (age 60+/-11, man 95%) and were treated with MH and PCI. IABP or PCPS were used in shock state. Result: Mean core temperature was 33.9 degrees C and mean cooling duration was 32 hours. Mean time interval from collapse to ROSC was 30min and IABP was used in 61.5% (N=75), and PCPS in 29.5% (N=36). Favorable outcome rate at 30 days was 52.3% (N=64, CPC 1=58), including 59.4% in Vf, 27.4% in PEA and 10.0% in asystole. In multivariate analysis, age, diabetes, and time interval from collapse to ROSC were the independent predictors of 30-day favorable outcome. Conclusion: MH with PCI for patients with ROSC after out-of-hospital cardiac arrest of ACS was effective for improvement of 30 days neurologic outcome even in the case of hemodynamic unstable and in any rhythm.

Key Word

Hypothermia, Acute coronary Syndrome, Percutaneous coronary intervention, Sudden cardiac death

# J-PULSE-Hypo registry: Mild Hypothermia Therapy for Acute Coronary Syndrome

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and for the J-PULSE Hypo registry Investigators.

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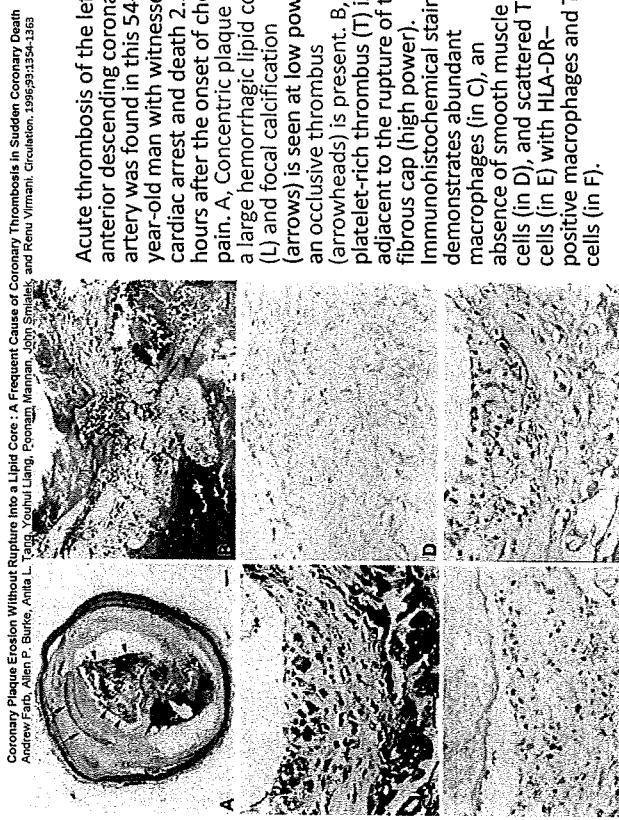
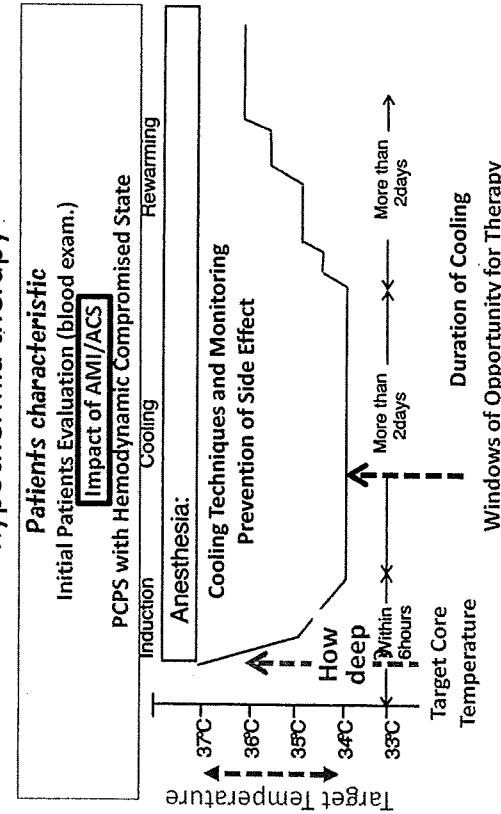
# J-PULSE Hypo registry

Mild Hypothermia Therapy for Acute Coronary Syndrome

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There are many unsolved questions in mild hypothermia therapy



Courtesy of Hiroyuki Yokoyama

## COMPARISON OF ANGIOPLASTY WITH STENTING, WITH OR WITHOUT ABCIXIMAB, IN ACUTE MYOCARDIAL INFARCTION



N Engl J Med 2002;346:957-66.

Acute coronary angiographic findings in survivors of out-of-hospital cardiac arrest

Characteristic	No significant CAD (n = 26)	Significant CAD (n = 46)	P	Total (n = 72)
Electrocardiographic patterns on admission*	2 (7.7)	21 (45.7)	.000*	23 (31.9)
ST-segment elevation	6 (23.0)	15 (32.6)	.4	21 (29.2)
ST-segment depression	4 (15.4)	8 (17.4)	1.0	12 (16.7)
Left bundle branch block	6 (23.0)	4 (8.7)	.02	12 (16.7)
Unspecific ST or T changes	5 (19.2)	6 (13.0)	.2	11 (15.3)
Normal	6 (23.0)			

Pattern of ECG change immediately after ROSC.

ECG did not reflect the severity of coronary lesion.: in some cases, no significant change or normal pattern was found in the case of coronary block. Therefore, no ECG change immediately after ROSC could not conclude that the reason of cardiac arrest was due to the coronary ischemia.  
 => Emergency coronary angiography immediately after ROSC should be performed to establish the adequate diagnosis and treatment in order to improve the prognosis

Am Heart J 2009;157:312-8.

Primary percutaneous coronary intervention and mild induced hypothermia in comatose survivors of ventricular fibrillation with ST-elevation acute myocardial infarction



(Conclusion)

Our preliminary experience indicates that primary PCI and MIH are feasible and may be combined safely in comatose survivors of ventricular fibrillation with signs of STEMI. Such a strategy may improve survival with good neurological recovery.

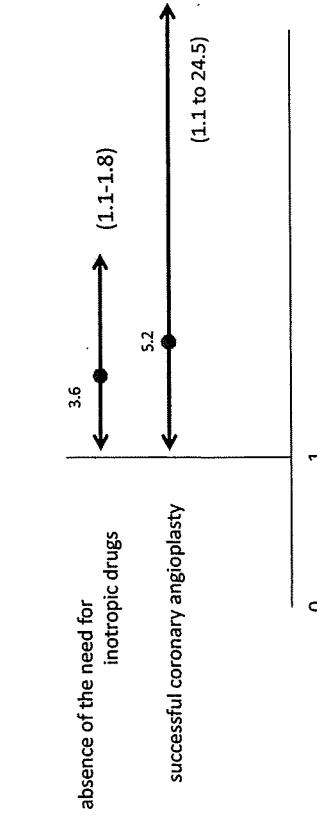
Percutaneous coronary intervention with mild hypothermia therapy improved the neurologic outcomes for comatose survivors after cardiac arrest with ST-elevation myocardial infarction (STEMI).

However, this study was limited to the patients with STEMI and ventricular fibrillation.

Resuscitation (2007) 74, 227–234

N Engl J Med 1997;336:1629-33.

## IMMEDIATE CORONARY ANGIOGRAPHY IN SURVIVORS OF OUT-OF-HOSPITAL CARDIAC ARREST



Multivariate logistic-regression analysis revealed that successful angioplasty was an independent predictor of survival (odds ratio, 5.2; 95% C.I., 1.1 to 24.5; P=0.04)

## Introduction

Resuscitated patients from sudden cardiac death (SCD) had a poor prognosis because of not only high mortality but also severe neurologic disability.

Ischemic heart disease was reported to be the main causes of SCD. Myocardial infarction was the main causes of SCD, therefore, emergency revascularization therapy might be the most effective for improving the mortality for the patients with cardiac arrest due to acute ischemic coronary artery disease, even without ST segment elevation in ECG.

For the patients with post cardiac arrest syndrome (PCAS), 'bundled' therapy was recommended, that is, early coronary revascularization, temperature control was mandatory treatment strategy. Percutaneous coronary intervention (PCI) with mild hypothermia therapy (MHT) was effective for the cardiac arrest patients with ST elevation MI.

## Methods

The exclusion of this study was 1) less than 15 years old, 2) pregnant woman, 3) aortic dissection with or without cardiac tamponade 4) cerebral hemorrhage or subarachnoid hemorrhage, 5) known terminal disease.

Non-shockable rhythm such as asystole or pulseless electrical activity (PEA) and complicating cardiogenic shock were enrolled in this study. All of suspicious patients of acute coronary ischemic events or without clear etiology of arrest were transferred to catheter laboratory immediately after ROSC even without ST segment elevation in ECG and with compromised hemodynamic. If the thrombotic stenosis or occlusion was found in the culprit coronary artery, percutaneous coronary intervention was attempted, followed by stent implantation if needed.

## End-point of this analysis

Primary endpoint of this study was to evaluate favorable neurological outcomes (cerebral performance category [CPC] 1 and 2) at 30 days for unconscious patients with ROSC after out-of-hospital cardiac arrest.

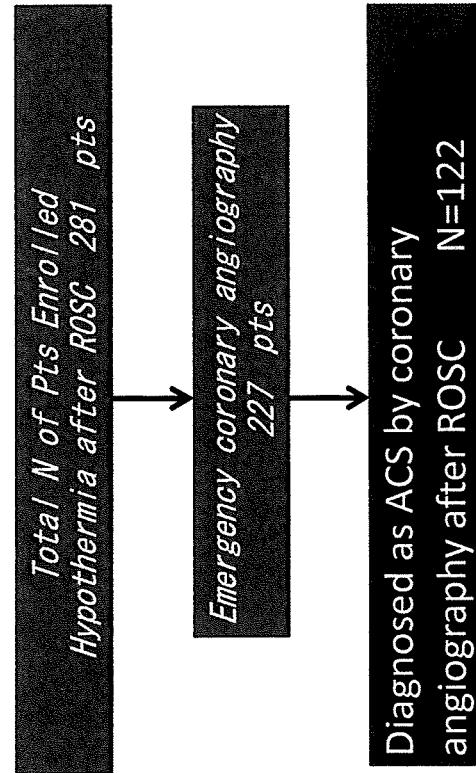
Secondary Endpoint of this study was to predict the 30 days neurologic outcomes.

Intra-aortic balloon pumping (IABP) or percutaneous cardio-pulmonary support (PCPS) were used for the patients with compromised hemodynamic state at the discretion of the operator.

Cerebral performance category (CPC) with levels 1 (Normal mental performance), 2 (moderate disability), 3 (severe disability), 4 (vegetative state) was used at 30 days. Favorable outcome was defined in CPC 1 or 2.

## Results

### Baseline Characteristics (1)



	Man (%)	95.1
Age		60+/-11
Bystander CPR (%)	54.1	
Shockable Rhythm (%)	82.8	
Mean no flow time (min)	3.0	
OMI (%)	2.5	
History of Heart Failure (%)	4.9	
Stroke (%)	5.7	
Hypertension (%)	35.0	
Diabetes (%)	15.6	
Mean GCS	3.8	
ROSC before ER (%)	55.7	
Hb (mean g/dl)	14.0+/-1.6	
Serum K (mEq/l)	4.1+/-0.9	
Cre>1.5 (%)	12.3	

### Baseline Characteristics (2)

mean B.E.	-12.9
mean CA-ROSC	30 +/- 24
Cold saline use (%)	52.7
Surface cooling (%)	56.0
Over cooling during Tx (%)	28.6
cooling start to target temperature (min)	239.8+/- 211.4
Mean cooling time (hrs)	32.6+/-14.0
Rewarming	
24 hours>=(%)	24.6
24-48 hours (%)	30.3
48-72 hours (%)	33.6
72 hours<	9.0
Multivessel disease (%)	41.0
Anterior MI (%)	63.1
Left main culprit (%)	4.0
IABP use (%)	61.5
PCPS use (%)	29.5

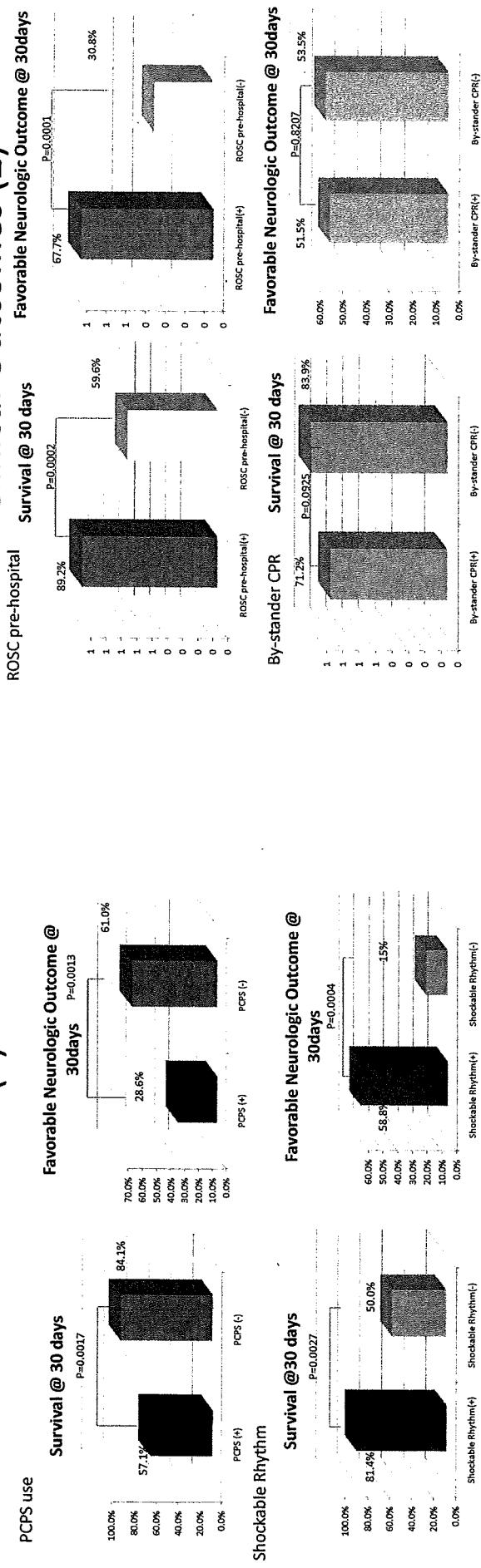
### Clinical Outcomes

Alive @ 30days      77.0%  
Favorable Neurologic      52.0%

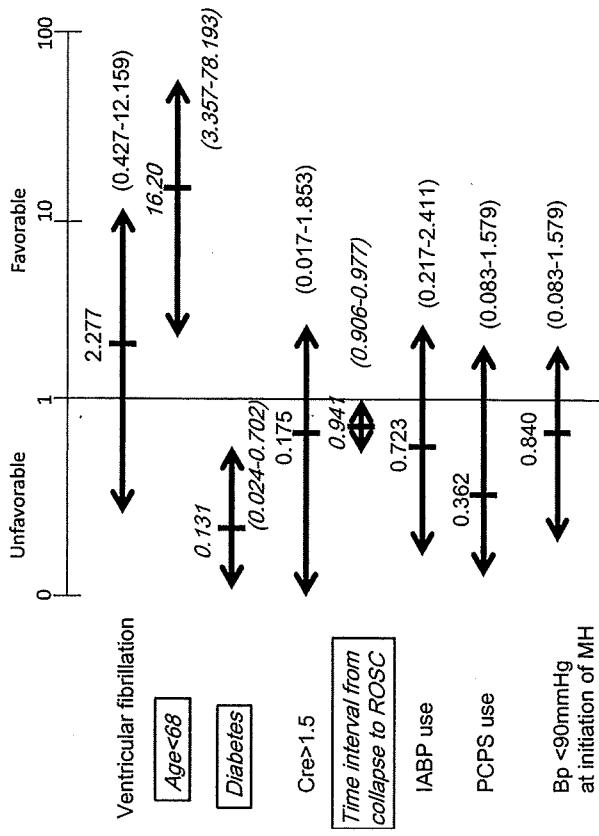
Including cardiogenic shock required PCPs

## Clinical Outcomes (2)

## Clinical Outcomes (2)



- ### Summary
- 1) Mild Hypothermia therapy with coronary intervention for ACS patients complicated by cardiac arrest was safe and effective for improving mortality and neurological outcomes compared with previous reports even in this high-risk cohorts.
  - 2) Very high-risk patients with profound shock requiring PCPS was high-mortality and less favorable-outcome, however, for almost one-third of the shock patients, MHT with PCI was effective to achieve favorable outcome.
  - 3) Early ROSC was one of the contributor for intact neurologic survival, therefore, early establishment of circulation might be effective by using extracorporeal circulation assist device.



## Conclusions

MH with PCI for patients with ROSC after out-of-hospital cardiac arrest of ACS was effective for improvement of 30 days neurologic outcome even in the case of hemodynamic unstable and in any rhythm.

タイトル：

Early Induction of Hypothermia using intravenous Ice-cold Fluids Improves Neurological Outcome (J-PLUSE-Hypo registry) and Its Optimal Monitoring of Core Temperature

抄録用図表の有無：なし

抄録本文：

**Background** Intravenous ice-cold fluids alone cannot be used to maintain hypothermia, but this cooling method can be used to institute easily and inexpensively.

**Methods** The J-PLUSE-Hypo was conducted as a multi-center hypothermia study. We added a study of optimal monitoring places of core temperature during intravenous 2000mL of normal saline at 4° C using high-pressure infusion bags to the J-PLUSE-Hypo. **Results** In the J-PULSE-Hypo, 165 survivors from out-of-hospital VF cardiac arrest were treated with mild hypothermia (34° C for 1 to 3 days). Of those, 74 were treated with intravenous ice-cold fluids (IV group), and 91 induced hypothermia without ice-cold fluids (no-IV group). The two groups had similar cooling-to-34° C interval (median; 168 min vs. 195 min, p=0.68), but a significant difference was seen in a favorable neurological outcome (72% vs. 52%, p=0.009). In our additional study, a mean administrated interval of ice-cold fluids was 14 minutes. Significant differences were seen in mean core temperatures among 3 places before and after initiation of ice-cold fluids (before ice-cold fluids; 34.4±2.3° C in esophagus vs. 37.0±1.2° C in rectum vs. 36.5±1.2° C in bladder, p<0.001; After 30 minutes; 32.5±2.5° C in esophagus vs. 34.8±1.7° C in rectum vs. 35.0±1.5° C in bladder, p<0.001). **Conclusions** Early induction of hypothermia using intravenous ice-cold fluids was associated with better neurological outcomes. During ice-cold fluids, esophagus temperature was not suitable as a core temperature monitoring.

# Efficacy of Early Induction of Hypothermia Using Intravenous Ice-cold Fluids (J-PULSE-Hypo registry) and Its Optimal Monitoring Places of Core Temperature Group

Masakazu Matsuzaki, Ken Nagao, Hiroshi

Nonogi, Hiroyuki Yokoyama, Naohiro Yonemoto and J-

PULSE-Hypo investigators/ J-PULSE-Hypo Registry

Monitoring Places of Core Temperature

Group  
Nihon University Hospital

Kimio Kikushima, Kazuhiro Watanabe, Yoshihito Tominaga, Katsuhige Tada, Mitsuru Ishii, Nobutaka Chiba, Kei Nishikawa, Taketomo Soga, Yutaka Tateda, Harumi Ikeda and Tsukasa Yagi/ Surugadai

動物実験ならびに臨床試験において、心停止蘇生後早期に脳低体温療法を導入することが、神経学的予後に蓄することができる。

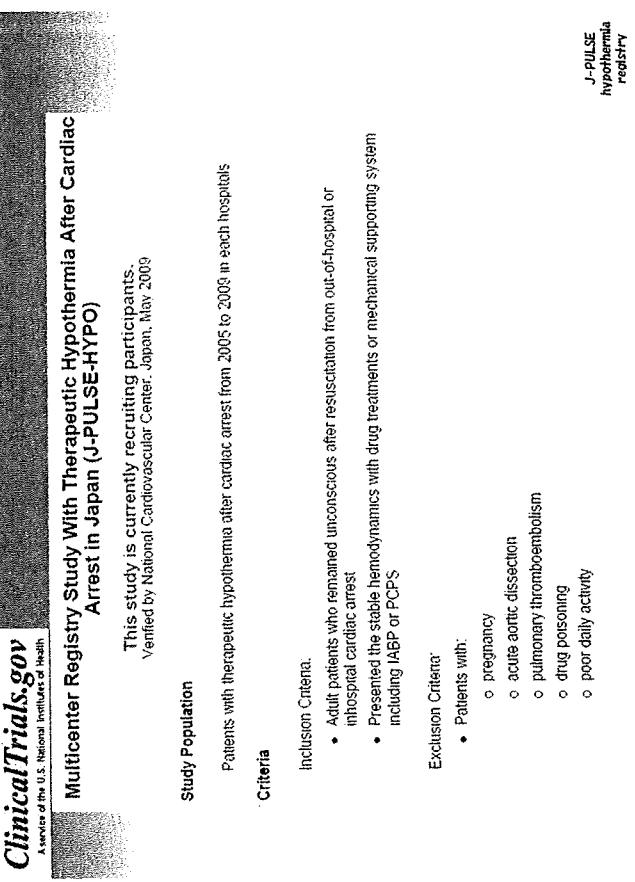
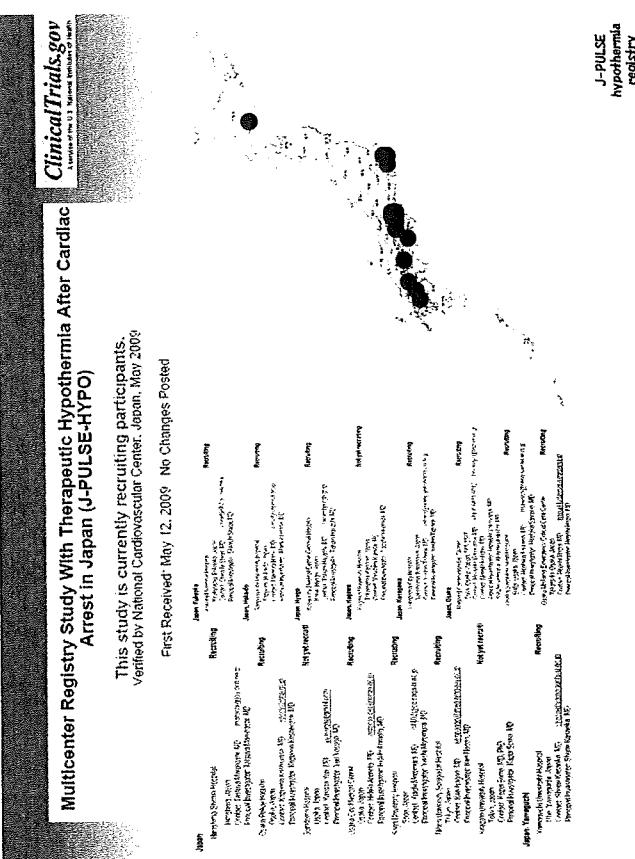
院外VF心停止蘇生後患者には、より早期に32～34°Cの低体温を12～24時間持続することが提案されているが、脳低体温療法の目標温度、導入方法、維持方法、復温方法などについては未だ確立されていない。

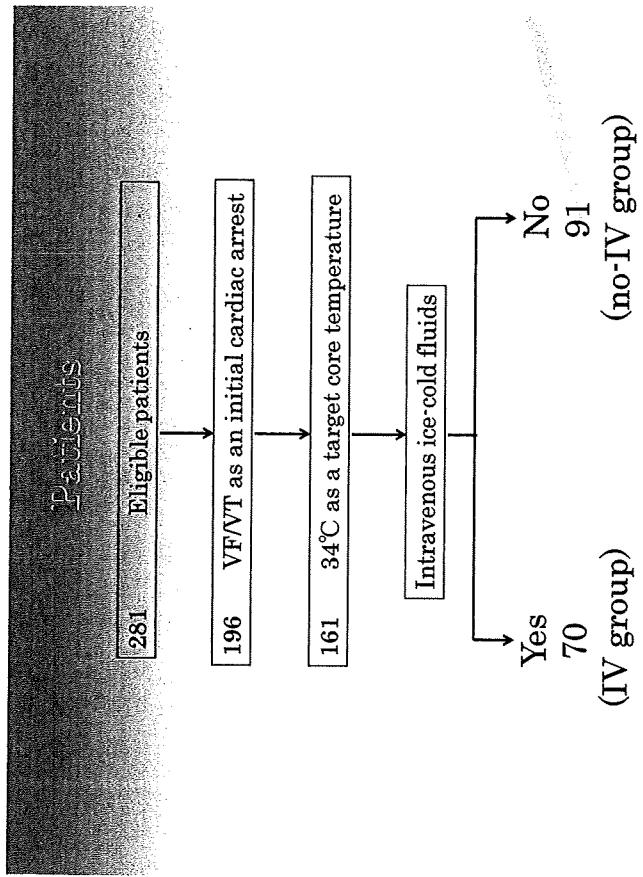
脳低体温療法の導入方法としては、氷嚢やクーリングブランケットの使用、胃洗浄、冷却水輸液、冷却ガス吸入などが試されてきた。なかでも冷却水輸液は低体温の維持には不向きではあるが簡便、安価であり、その有用性が報告されてきた。

*Resuscitation 2003; 56: 9-13.*

*Circulation 2005; 112: 715-719*

*Circulation 2007; 115: 3064-3070 . etc*





### Baseline Characteristics of Participants

	IV Group (n=70)	no-IV Group (n=91)	P*
Age (mean±SD, years)	57±12	60±13	0.11
Men	65 (93%)	75 (82%)	0.09
Witnessed cardiac arrest	60 (86%)	82 (90%)	0.54
Bystander CPR	31 (44%)	42 (46%)	0.93
From collapse to hospital arrival (median, min)	24	23	0.23
From collapse to ROSC* (median, min)	21	25	0.09
Use of IABP after ROSC	25 (36%)	28 (31%)	0.51
Use of PCPS after ROSC	9 (13%)	21 (23%)	0.10
Causes of cardiac arrest			
<i>Acute coronary syndrome</i>	51 (73%)	59 (65%)	
<i>Arrhythmia</i>	7 (10%)	16 (17%)	
<i>Cardiomyopathy</i>	7 (10%)	6 (7%)	
<i>Unknown</i>	5 (7%)	10 (11%)	0.37

\*Based on t,  $\chi^2$  or log-rank test on appropriate, + Return of Spontaneous Circulation

