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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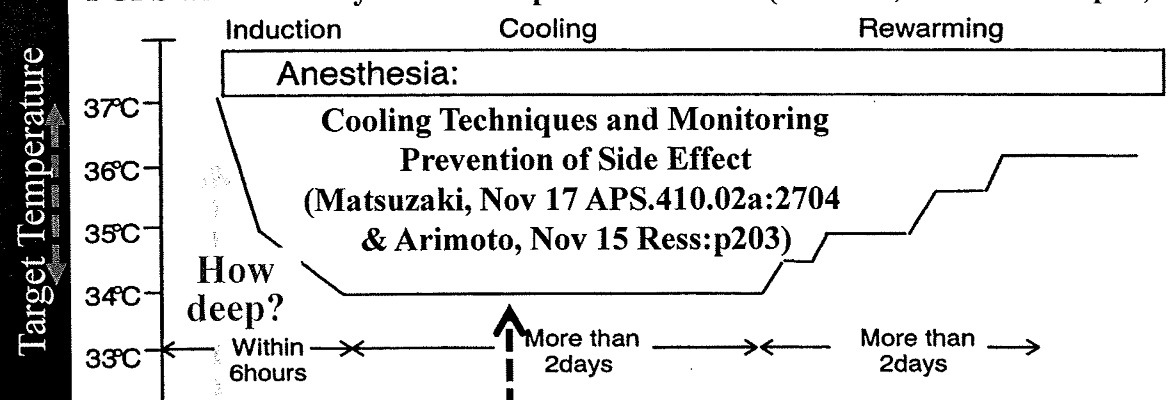
8 Clinical Questions from J-PULSE-Hypo in 2009

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)



Target Core Temperature (Kasaoka, Nov.16 APS.509.01: 3309)

Duration of Cooling (Kagawa, Nov 15 Ress:p200)

Windows of Opportunity for Therapy (Soga, Nov 14 Ress:p199)

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Study Organization

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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%)
Initial cardiac rhythm	
Ventricular fibrillation	196 (69%)
Pulseless electrical activity	26 (9%)
Asystole	21 (8%)
Unidentified	37 (13%)
Witnessed cardiac arrest	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, cadiopulmonary 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, cadiopulmonary 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
Maximam 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/l)	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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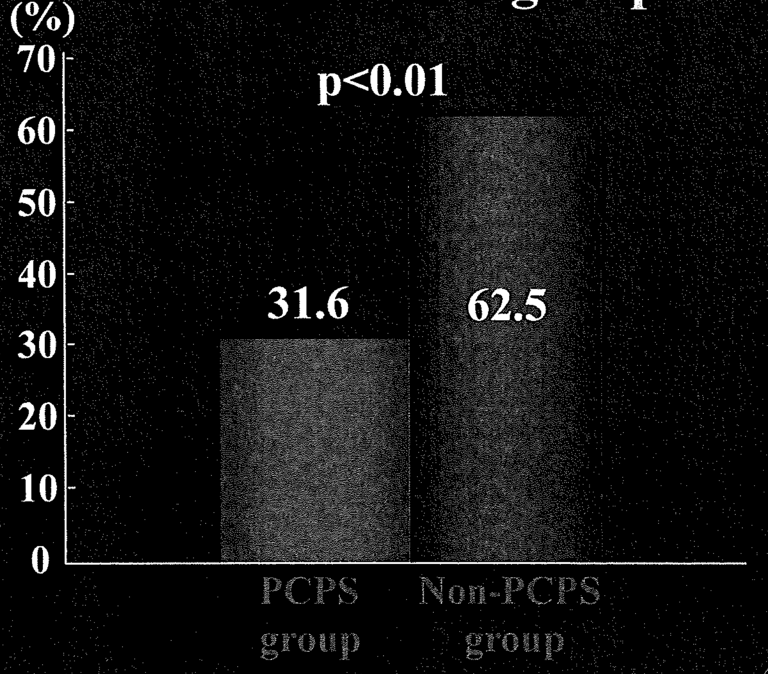
FNC rate at 30 days between PCPS group and non-PCPS group



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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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Summery

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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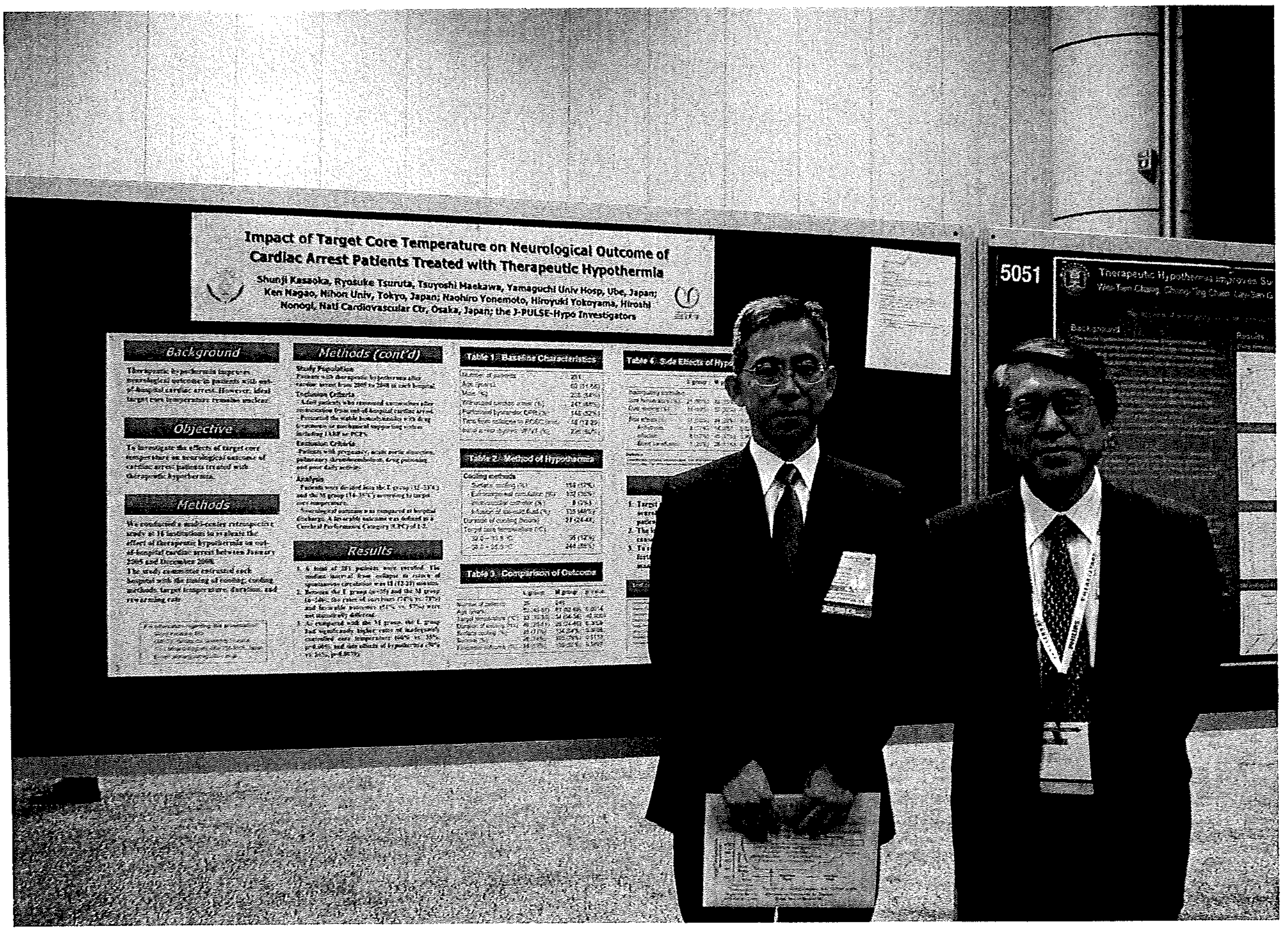
Impact of Target Core Temperature on Neurological Outcome of Cardiac Arrest Patients Treated with Therapeutic Hypothermia
Shunji Kasaoka, Ryosuke Tsuruta, Tsuyoshi Maekawa, Yamaguchi Univ Hosp, Ube, Japan; Ken Nagao, Nihon Univ, Tokyo, Japan; Naohiro Yonemoto, Hiroyuki Yokoyama, Hiroshi Nonogi, Natl Cardiovascular Ctr, Osaka, Japan; the J-PULSE-Hypo Investigators
Background
Objective
Methods
Methods (cont'd)
Results
Table 1 Baseline Characteristics
Table 2 Method of Hypothermia
Table 3 Comparison of Outcome
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Early Hospital Arrival Improves Outcome at Discharge in Ischemic but Not Hemorrhagic Stroke: A Prospective Multicenter Study

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Key Words
Infarction · Intracerebral hemorrhage · Cohort studies · Outcome, stroke

Abstract
Background: Our purpose was to determine whether the onset-to-arrival time affects the outcome of stroke patients. ***Methods:*** We carried out a prospective multicenter study involving 1,817 patients with ischemic stroke and 1,226 with intracerebral hemorrhage who presented to hospitals within 24 h of symptom onset. The primary outcome was independent activity of daily living corresponding to a modified Rankin Scale (mRS) score ≤2 at discharge approximately 3 weeks after stroke. ***Results:*** In ischemic stroke patients, the initial NIH Stroke Scale (NIHSS) score decreased as the onset-to-arrival time increased: 9 (median) in the earliest tertile group (<3 h), 5 in the second tertile group (3–8 h) and 4 in the latest tertile group (≥8 h, p < 0.001). The median mRS scores at discharge in these groups were 3, 2 and 2, respectively (p < 0.001). After adjustment for underlying features and the initial NIHSS score, the independent activity of daily living at discharge was 1.73 times more common in patients in the earliest group than in the latest group (95% CI = 1.24–2.42, p = 0.001). A similar tendency was shown in the subanalysis for large-artery atherosclerosis and cardioembolic stroke. In intracerebral hemorrhage patients, both the initial NIHSS score and the mRS score at discharge decreased as the onset-to-arrival time increased. After multivariate adjustment, the independent activity of daily living was 2.33 times (p<0.001) and 1.69 times (p = 0.006) less common in patients in the earliest (<1.2 h) and second tertile groups (1.2–3.5 h), respectively, than in the latest tertile group (≥3.5 h). ***Conclusions:*** Early hospital arrival improved the clinical outcome in ischemic stroke patients but not in patients with intracerebral hemorrhage.
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Introduction

Since it is said that 'time is brain', rapid diagnosis and treatment of stroke are thought to give stroke victims better recovery. For this strategy, the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care [1] focused on the initial prehospital assessment, including rapid recognition and reaction to stroke warning signs and rapid emergency medical services system transport to hospitals. In particular, the establishment of intravenous (IV) recombinant tissue plasminogen activator (rt-PA) as standard therapy for hyperacute stroke has increased the impor-

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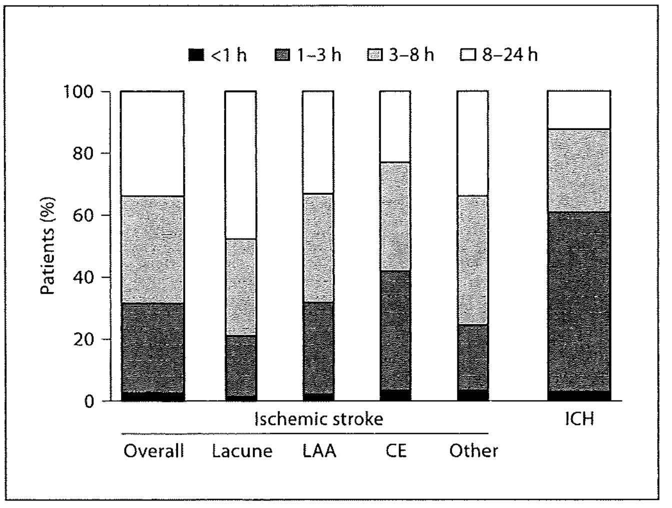

Fig. 1. Onset-to-arrival time for each stroke type. LAA = Large-artery atherosclerosis; CE = cardioembolism.

tance of rapid initiation of stroke therapy within 3 h of symptom onset [2–4]. However, previous studies have generally shown that patients who arrived at a hospital early after ischemic stroke onset had a worse functional outcome and higher mortality than those who arrived later [5, 6]. Major causes of this discouraging result might be that stroke patients with severer initial disability have a tendency to visit a hospital earlier [5–12], as well as the fact that previous studies did not adjust patient outcome for initial neurological severity. Although intracerebral hemorrhage (ICH) is associated with a poorer outcome than ischemic stroke, the positive relationship between early hospital visit and initial severity was reported only in studies based on relatively small numbers of patients [13, 14].

A prospective, multicenter, observational study was conducted in Japan to assess clinical evaluation indicators for stroke and acute coronary syndrome. In the present study, using the data of the stroke patients, we investigated whether early hospital arrival affected the patient outcome after adjustment for the initial severity.

Patients and Methods

The Cooperative Study on the Clinical Evaluation Indicator for Cardiovascular Diseases in Japan was conducted between January 2005 and May 2007 at 27 hospitals in Japan. The medical ethics review boards of the participating institutes approved the study protocol. To revise the study protocol in response to a new Japanese law dealing with protection of personal information, the study had a 6-month-long pause in patient registration between April and September 2005.

Consecutive patients who were admitted to our hospitals within 24 h after the onset of ischemic stroke or ICH detectable on MRI or CT were enrolled. The patients with transient ischemic attack were excluded from this study; transient ischemic attack was defined as a brief episode of neurologic dysfunction caused by focal brain ischemia, with clinical symptoms typically lasting <1 h, and without evidence of acute infarction [15]. The following data were prospectively collected using common work sheets: age, sex, hypertension (use of antihypertensive agents, or systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg before onset), diabetes mellitus (use of oral hypoglycemic agents or insulin, or fasting blood glucose levels ≥126 mg/dl), hyperlipidemia (use of antihyperlipidemic agents or serum cholesterol level ≥220 mg/dl), atrial fibrillation identified on electrocardiogram, current smoking, alcohol abuse >60 g/day, time interval between symptom onset and hospital arrival (onset-to-arrival time), baseline neurological impairment according to the National Institutes of Health Stroke Scale (NIHSS) score, subtypes of ischemic stroke according to the Trial of Org 10172 in Acute Stroke Treatment classification [small-vessel occlusion (lacune), large-artery atherosclerosis, cardioembolism and stroke of other determined or undetermined etiology] [16], site of infarcts (infratentorial or supratentorial) and activity of daily living at hospital discharge according to the modified Rankin Scale (mRS) score.

The primary outcome was independent activity of daily living at discharge, corresponding to an mRS score ≤2. The secondary outcomes included an mRS score ≤1 at discharge and in-hospital death.

Statistics

The patients with ischemic stroke were classified into 3 groups by tertiles based on the onset-to-arrival time. The patients with ICH were classified in the same manner. Among the 3 groups, baseline clinical characteristics and stroke features were compared using the χ^2 test, 1-way factorial analysis of variance or the Kruskal-Wallis test, as appropriate. To identify factors associated with the primary and secondary outcomes, multivariate logistic regression model analyses were performed using baseline clinical characteristics and stroke features. Statistical test results were considered significant with a p value <0.05. All analyses were performed using JMP version 6.0.3 statistical software (SAS Institute Inc., Cary, N.C., USA).

Results

Of a total of 3,058 patients registered, 15 were ineligible for analyses due to missing data. Thus, 3,043 patients were studied; 1,817 had ischemic stroke, and 1,226 had ICH. The ischemic stroke patients visited hospitals at a median of 4.5 h after onset [interquartile range (IQR) = 3.0–8.0 h; fig. 1]. The onset-to-arrival time differed among patients with different subtypes of ischemic stroke

Table 1. Characteristics of ischemic and hemorrhagic stroke patients

	Ischemic stroke				ICH			
	<3 h (574 cases)	3–8 h (632 cases)	≥8 h (611 cases)	p value	<1.2 h (473 cases)	1.2–3.5 h (424 cases)	≥3.5 h (329 cases)	p value
Age, years	72.1 ± 11.0	73.2 ± 12.0	72.6 ± 11.6	0.242	63.8 ± 14.1	67.7 ± 14.2	67.8 ± 13.9	<0.001
Male	338 (58.9)	385 (60.9)	369 (60.4)	0.759	252 (53.3)	219 (51.7)	166 (50.5)	0.725
Hypertension	356 (62.0)	382 (60.5)	388 (63.5)	0.561	322 (68.1)	281 (66.6)	210 (63.8)	0.455
Diabetes mellitus	128 (22.3)	140 (22.2)	151 (24.8)	0.491	40 (8.5)	41 (9.7)	31 (9.4)	0.792
Hyperlipidemia	115 (20.1)	127 (20.2)	151 (24.8)	0.079	40 (8.5)	49 (11.6)	36 (11.0)	0.256
Atrial fibrillation	234 (40.8)	205 (32.4)	148 (24.2)	<0.001	21 (4.4)	19 (4.5)	20 (6.1)	0.510
Smoking	124 (22.4)	129 (21.6)	155 (26.9)	0.053	123 (27.0)	59 (14.8)	54 (17.7)	<0.001
Alcohol abuse	24 (4.2)	32 (5.1)	23 (3.8)	0.514	30 (6.7)	18 (4.3)	18 (5.5)	0.389
Infratentorial infarct	84 (14.9)	101 (16.3)	145 (23.9)	<0.001				
Stroke subtype								
Lacune	94 (16.4)	143 (22.6)	218 (35.7)	<0.001				
Large-artery atherosclerosis	189 (32.9)	210 (33.2)	196 (32.1)					
Cardioembolism	248 (43.2)	206 (32.6)	138 (22.6)					
Other	43 (7.5)	73 (11.6)	59 (9.7)					
Initial NIHSS score	9 (4–17)	5 (2.25–11)	4 (2–7)	<0.001	8 (4–21)	8 (4–19)	6 (3–15)	0.001
mRS score at discharge	3 (1–5)	2 (1–4)	2 (1–4)	<0.001	4 (2–6)	4 (2–5)	3 (1–5)	<0.001
In-hospital death	61 (10.6)	38 (6.0)	31 (5.1)	<0.001	139 (29.5)	104 (24.8)	52 (16.0)	<0.001

Data are numbers of patients (percent), mean ± SD for age, or median (IQR) for NIHSS score and mRS score.

($p = 0.001$). The median onset-to-arrival time for the ICH patients was 2.0 h (IQR = 1.2–3.5). The median duration of hospitalization was 22 days (IQR = 14–36) in the ischemic stroke patients and 24 days (IQR = 13–42) in the ICH patients.

In the ischemic stroke patients, atrial fibrillation was less common ($p < 0.001$) and infratentorial infarcts were more common ($p < 0.001$) as the onset-to-arrival time increased (table 1). Cardioembolism was the leading subtype in the earliest tertile group visiting hospitals within <3.0 h, while lacune was the leading subtype in the latest group visiting hospitals within ≥8.0 h ($p < 0.001$). The initial NIHSS score, the discharge mRS score and the in-hospital mortality rate decreased as the onset-to-arrival time increased ($p < 0.001$ for each). After multivariate adjustment, early hospital arrival within <3.0 h was independently predictive of an mRS score ≤2 at discharge compared to arrival within ≥8.0 h as the reference [odds ratio (OR) = 1.73, 95% CI = 1.24–2.42; table 2]. In addition, advanced age (OR = 0.96, 95% CI = 0.95–0.97 per 1-year increase, $p < 0.001$), diabetes mellitus (OR = 0.85, 95% CI = 0.73–0.98, $p = 0.026$), a higher NIHSS score (OR = 0.74, 95% CI = 0.72–0.77 per 1-point increase, $p < 0.001$) and large-artery atherosclerosis (OR = 0.52, 95% CI = 0.38–0.73, $p = 0.001$ compared with lacune as the reference) were inversely predictive of an mRS score ≤2. In a similar multivariate adjustment for patients of each ischemic stroke subtype, early arrival within <3.0 h was independently related to an mRS score ≤2 at discharge for the patients with large-artery atherosclerosis (OR = 2.07, 95% CI = 1.21–3.62) and for those with cardioembolism (OR = 1.87, 95% CI = 1.01–3.49; table 3). As secondary outcomes, early hospital arrival within <3.0 h was independently predictive of an mRS score ≤1 at discharge (OR = 1.66, 95% CI = 1.21–2.28), but it was not predictive of in-hospital death (OR = 0.90, 95% CI = 0.53–1.52).

In the ICH patients, age ($p < 0.001$) and smoking habit ($p < 0.001$) differed among the 3 groups with different onset-to-arrival times (table 1). The initial NIHSS score ($p = 0.001$), the discharge mRS score ($p < 0.001$) and the in-hospital mortality rate ($p < 0.001$) decreased as the onset-to-arrival time increased. After multivariate adjustment, the earliest (<1.2 h) and the second (1.2–3.5 h) tertiles of onset-to-arrival time were inversely predictive of an mRS score ≤2 at discharge compared to arrival within ≥3.5 h as the reference (OR = 0.43, 95% CI = 0.30–0.63, and OR = 0.59, 95% = CI 0.40–0.86, respectively; table 2). Even when the ICH patients were divided into 3 groups using the same onset-to-arrival time points as for ischemic stroke, early arrival within <3.0 h (747 patients) was

Table 2. Effect of onset-to-arrival time on the primary and secondary outcomes

	mRS ≤2 at discharge			mRS ≤1 at discharge			In-hospital death		
	OR	95% CI	p value	OR	95% CI	p value	OR	95% CI	p value
Ischemic stroke									
<3	1.73	1.24–2.42	0.001	1.66	1.21–2.28	0.002	0.90	0.53–1.52	0.685
3–8 h	0.98	0.73–1.32	0.916	1.15	0.87–1.53	0.325	0.83	0.48–1.44	0.503
≥8 h	1.00	(reference)	–	1.00	(reference)	–	1.00	(reference)	–
ICH									
<1.2 h	0.43	0.30–0.63	<0.001	0.46	0.30–0.68	<0.001	2.41	1.62–3.64	<0.001
1.2–3.5 h	0.59	0.40–0.86	0.006	0.50	0.33–0.75	<0.001	1.59	1.05–2.43	0.030
≥3.5 h	1.00	(reference)	–	1.00	(reference)	–	1.00	(reference)	–

Adjusted for age, sex, hypertension, diabetes mellitus, hyperlipidemia, atrial fibrillation, initial NIHSS score, infratentorial infarction and stroke subtype (the latter 2 confounders were used for ischemic stroke patients only).

Table 3. Effect of onset-to-arrival time on the primary outcome (mRS ≤2 at discharge) for each ischemic stroke subtype

	Patients	OR	95% CI	p value
Large-artery atherosclerosis				
<3 h	189	2.07	1.21–3.62	0.009
3–8 h	210	0.81	0.50–1.31	0.389
≥8 h	196	1.00	(reference)	–
Cardioembolism				
<3 h	248	1.87	1.01–3.49	0.047
3–8 h	206	1.17	0.65–2.15	0.599
≥8 h	138	1.00	(reference)	–
Lacune				
<3 h	94	1.27	0.62–2.75	0.524
3–8 h	143	1.03	0.56–1.91	0.932
≥8 h	218	1.00	(reference)	–
Other				
<3 h	43	1.20	0.37–4.03	0.767
3–8 h	73	2.03	0.41–2.58	0.952
≥8 h	59	1.00	(reference)	–

Adjusted for age, sex, hypertension, diabetes mellitus, hyperlipidemia, atrial fibrillation and initial NIHSS score.

inversely predictive of an mRS score ≤2 compared to arrival within ≥8.0 h as the reference (149 patients, OR = 0.49, 95% CI = 0.31–0.78). As secondary outcomes, the earliest and second tertiles were inversely predictive of an mRS score ≤1 (OR = 0.46, 95% CI = 0.30–0.68, and OR = 0.50, 95% CI = 0.33–0.75, respectively) and positively predictive of in-hospital death (OR = 2.41, 95% CI = 1.62–3.64, and OR = 1.59, 95% CI = 1.05–2.43, respectively).

Discussion

In the present study, we determined the effect of the time interval between stroke onset and hospital arrival on the outcome at discharge. The first major finding was that, after adjustment for confounders including the initial neurological severity, early hospital arrival was related to a favorable functional outcome corresponding to an mRS score ≤1 or ≤2 in the ischemic stroke patients, in particular among those with large-artery atherosclerosis and cardioembolism. The second major finding was that, after multivariate adjustment, early hospital arrival was related to an unfavorable functional outcome and in-hospital death in the ICH patients.

Ischemic stroke patients with severer initial disability have a tendency to visit hospitals earlier [5–12], and severe initial disability is a known predictor of a poor chronic outcome [17–21]. Thus, patients with earlier hospital arrival were reported to have a poorer outcome [5, 6], as was shown in the present unadjusted results. To minimize the influence of initial severity on the outcome, multivariate adjustment was incorporated into the analyses. Our adjusted results suggest that early hospital arrival contributes to better stroke recovery. A previous study using logistic regression analyses showed that early contact with a neurologist, but not early visit to the emergency department, after onset of stroke (mostly ischemic) was related to a good outcome on discharge [7]. This result suggests the limited acute stroke management capabilities of the emergency department when the study was conducted in the early 1990s.

Spontaneous or thrombolysis-induced improvement of the clinical features within minutes to hours of ischemic stroke onset is seen in some patients. In particular, a spontaneous dramatic improvement was called a spectacular shrinking deficit by Mohr and Barnett [22], and it was thought to be caused by rapid migration of an embolus initially lodged in a large artery to its distal branches [23]. In our previous studies, 12% of the ischemic stroke patients with an initial major hemispheric syndrome who did not receive thrombolysis showed spectacular shrinking deficit, and most of these patients visited our hospital within 4 h of stroke onset [24, 25]. Thus, this syndrome may be responsible for the association between early hospital arrival and a favorable outcome. Although IV rt-PA for hyperacute ischemic stroke can improve the patient outcome [2–4], this therapy might have affected our results less than previous studies from Western countries [5]. In Japan, IV rt-PA for stroke was approved just during the time of the present study (in October 2005); hence, the percentage of stroke patients receiving rt-PA during this period was not high. In fact, a postmarketing surveillance study estimated the rate to be approximately 2% between October 2005 and May 2007. In the present study, conventional management for ischemic stroke, including general supportive care, early initiation of oral aspirin and prevention of acute complications, may have contributed to the good outcome for the patients who arrived at the hospital early. In particular, the early initiation of management might be effective for atherothrombotic and cardioembolic strokes, which have a much higher risk of early clinical progression and recurrence than lacunar stroke [26–31].

Active bleeding of ICH is generally thought to cease within the first few hours; the Factor Seven for Acute Hemorrhagic Stroke Treatment trial indicated that little active bleeding occurs between the third and fourth hours after ICH onset [32]. The frequency of hematoma growth significantly decreased with time [33–36]. A previous study from our institute showed that the frequency was 36% when the initial CT was taken within 3 h from onset, 16% when the timing was 3–6 h, 15% when it was 6–12 h and 6% for 12–24 h [34]. In addition, hematoma growth is an established cause of clinical deterioration [34, 37, 38]. Thus, a potent reason for the poor outcome after ICH for early visitors after adjustment for initial severity appears to be that early hospital arrival increases the opportunity for continued active bleeding after arrival, which causes hematoma growth and clinical deterioration. The International Surgical Trial in Intracerebral Haemorrhage [39] failed to show an overall benefit from early surgery for ICH patients when compared with initial conservative treatment. These findings resulted in a relative increase in the role of medical therapies for acute ICH. Although the trial of efficacy and safety of recombinant activated factor VII for acute ICH failed [40], in the near future, new thrombostatic strategies may suppress active bleeding during the initial hours and be beneficial for early visitors.

Certain limitations need to be considered prior to the interpretation of the present study results. First, the data on acute therapies, including IV rt-PA, intra-arterial thrombolysis, antithrombotics, statins, surgery and the type of wards, were incomplete and could not be used for analysis. Second, unknown prehospital mortality might systematically bias the patient characteristics, especially in cases after ICH. Third, information on stroke recurrence or hematoma growth was not available. Fourth, the chronic outcome at 3 months was not evaluated. Although the outcome was assessed at hospital discharge, this timing might depend on the availability of secondary care facilities, such as rehabilitation centers or nursing homes. Fifth, we did not assess the data on NIHSS sub-items as an indicator for baseline neurological impairment.

In conclusion, early hospital arrival improved the patient outcome after ischemic stroke, even before rt-PA use had become routine. In Japan, given rt-PA approval in 2005, the setting for acute stroke management, including IV rt-PA and stroke care unit equipment, has been drastically improved. This improvement will further strengthen the clinical significance of early hospital arrival. Meanwhile, early hospital arrival was associated with a poorer outcome after ICH; this suggests the lack of efficient emergent management for ICH at this time point compared with ischemic stroke.

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Usefulness of Mobile Telemedicine System in Real-Time Transmission of Out-of-Hospital 12-Lead ECGs and Live-Images of Patients on Moving Ambulances

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Abstract : Mobile telemedicine system is a wireless communicating system between doctors at hospitals and emergency medical technicians on an ambulance. This system enables us to transmit a patient's live image and vital signs, such as 12-lead electrocardiogram (ECG), blood pressure, oxygen saturation, and respiratory rate to the hospitals in real time during the transportation using an ambulance by using mounted cameras and monitoring systems.

We collected all digital data in the cases using the mobile telemedicine from June 4 2008 to May 31 2009 and assessed the efficacy of this system in emergency system.

The mobile telemidicine system was utilized for 250 patients in one year. ECGs were transmitted in the 153 cases, including the 29 cases with 12-lead ECGs and the 124 cases with only the limb leads ECGs. For the 97 patients, only moving images through the camera were transmitted and 39 of them were the patients with trauma. The ECGs transmmision were mostly used for the patients with central nervous disease and cardiovascular disease.

By using the mobile telemedicine, we could make decisions on the treatment protocol and provide directions to emergency medical technicians on an ambulance about handling patients on the way to our hospital. In the meantime, it was possible to prepare the special treatments before admission to the hospital as soon as possible.

With these advantages in this system, the mobile telemedicine with live images and 12-leads ECG will be more popular in the emergency system.

Key Words : mobile telemedicine, 12-lead electrocardiogram, live image

1.Introduction

Mobile telemedicine is a wireless communicating system between moving ambulances and hospital physicians in emergency department, and enables us to transmit a patient's living body information, such as a seriese of 12-lead electrocardiogram (ECG), blood pressure, oxygen saturation, breathing rate, to a hospital in real time during an ambulance ride by using mounted cameras and monitoring systems. The guidelines recommend routine use of 12-lead electrocardiogram and advance notification to the emergency department for patients with ST-elevation myocardial infarction (STEMI)[1)]. However, transmission of out-of-hospital 12-lead ECG to emergency department is still not widely practiced and ECG interpretation before arrival at the emergency department is not established.

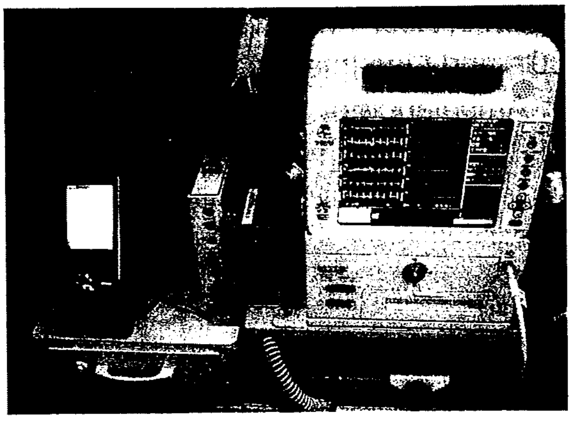
In the past, there used to be a variety of monitoring systems to observe patients during ambulance transfers; however, the information was sometimes not precise enough to assess cardiac patients [2)3)]. The novel mobile telemedicine system to transmit real-time 12-lead ECG data between moving ambulances and in-hospital physicians in cardiovascular emergency cases has been developed [4)-6)].

As a research project supported by the grant from the Ministry of Health, Labour and Welfare, the mobile telemedicine system in Kumamoto city has started between Kumamoto Medical Center and Kumamoto City Fire Bureau since June 4, 2008.

2.Materials and Methods

This system (Mobile telemedicine system® NTT COMWARE) can continuously monitor the patient's condition such as real-time 12-lead ECG and vital signs, and transmit live video. The data is sent to the hospital with a third generation cellular phone through a micro server connected to the bedside monitor, which displays 12-lead ECG (Radacirc® Dainippon Sumitomo Pharma Co., Ltd.) and vital signs, and through the network cameras, which monitor the patient's condition, in the ambulance. The data transmitted in real time is received with a commercial personal computer using a standard Internet protocol. Moreover, the data transmitted by two or more physicians remotely can serve as a telephone-conferencing system.

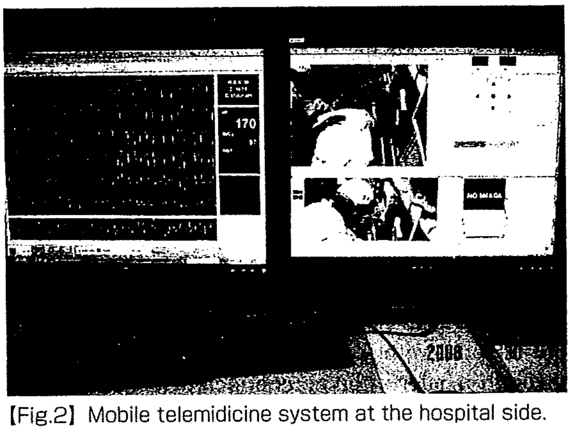
The mobile telemedicine system in the ambulance is shown in the [Fig.1] . The implementation of open-standard medical waveform encoding rule with motion noise-reduction system is used in the system to minimize the motion noise[7)]. A camera is set above the back door and images from a patient's



[Fig.1] Mobile telemidicine system on an ambulance side.

feet side. It can be controlled from a hospital side through the internet, so we can focus on wherever we want to see, from the patient's head to toe. Moreover, blood pressure, oxygen saturation and breathing rate are transmitted using the third-generation digital mobile phone (FOMA) by only 1 second delay to the hospital side[7].

Figure 2 shows the mobile telemedicine system set at the hospital. The left monitor shows 12-leads ECG, oxygen saturation and breathing rate, and images appear on the right monitor. We can control the camera angle by touching the arrow buttons on the right monitor. Furthermore, one more image, for example, an image from coronary care unit can be set in the monitor at the same time, and we can have a three-way discussion.



[Fig.2] Mobile telemidicine system at the hospital side.

We collected all the digital data in the cases sent via the mobile telemedicine during a year from June 4, 2008 to May 31, 2009 and examined the efficacies of this system.

The institutional review board approved the study protocol.

3.Result

Mobile telemidicine system was utilized for 250 patients, 39 % of the patients the EMTs transffered during the year, and their images and vital signs were transmitted.

[Table 1] The patients' symptoms whose ECGs were transmitted.

Symptoms	n
Consciousness Disturbance	70
Chest Pain	26
Dyspnea	14
Palpitation	8
Abdominal Pain	6
Vertigo	5
Psychotic Disorder	5
Trauma	5
Sick	5
Cardio-pulmonary Arrest	4
Miscellaneous	3
total	153

[Table 2] Thefinal diagnosis in the patients with ECG transmission

Diseases	n
Central-nervous Disorder	60
Cardio-vascular disease	39
Psychiatric Disorder	15
Digestive Disorder	13
Respiratory Disorder	10
Metabolic Disorder	8
Trauma	5
Urinary tract Disorder	3
total	153

[Table 3] The details in the central nervous disorder

Central-nervous Disorder	n
Syncope	15
Epilepsy	11
Cerebral Infarction	9
Cerebral Hemorrhage	5
Transient Ischemic Attack	5
Vertigo Syndrome	5
Subarachnoid Hemorrhage	4
Miscellaneous	6
total	60

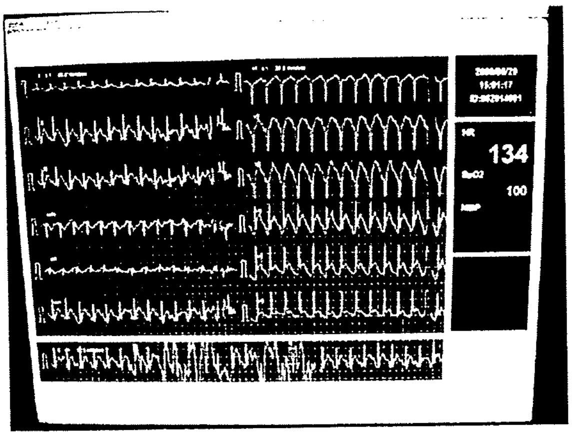
[Fig.3] This patient called an ambulance due to sudden onset of right hemi-plegia, showing Bàrre,s sign in right arm.

ECGs in the 153 cases (61% of 250 patients) were transmitted, including 29 cases with 12-lead ECGs and 124 cases with only the limb leads ECGs.

Table 1 shows the symptoms of 153 patients on which emergency medical technicians (EMTs) made a decision to transmit ECGs. Table 2 is the final diagnoses for the 153 patients after admission. Table 3 lists detail diagnoses for 60 central-nervous disorder patients.

Figure 3 shows a woman on an ambulance with sudden onset of right hemi-plegia during shopping. Examinig the transmitted images, right sided paralysis was seen, and ECG indicated atrial fibrillation. Judging from these results, we assumed there was possibility of cardio embolic brain infarction.

Table 4 shows detail diagnoses for 39 patients with cardio vascular diseas. The ECGs transmitted via this system oviously shows ST changes [Fig.4]. This is very useful, specially for acute myocardial infarction cases. Since ST-elevation is clearly identified by checking the transmitted 12-ECG during the transfer, specialists can prepare the special treatments, such as emergency coronary angiography before admission to the hospital. This system is also useful to diagnose heart deseases because it can keep all the records during transfer, such as ST changes and arrhythmia which are sometimes normalized on arrival.



[Fig.4] Real time trannsmitted 12-leads ECG image from moving ambulance. This showes ST elevations in many leads indicating AMI.

[Table 4] The detail diseases of cardio vascular disease patients.

Cardio-vascular Diseases	n
Acute Myocardial Infarction	8
Unstable Angina Pectoris	8
Arrhythmia	5
Cardio-Pulmonary Arrest	4
Dissection of Aorta	3
Heart Failure	2
Abdominal Aorta Aneurysm Rupture	1
Miscellaneous	8
total	39

Figure 5 shows an image of a patient with cardio pulmonary arrest (CPA) in the Doctor Car. In case of transferring CPA patients, it is very difficult to describe the on-the-spot situation constantly and in detail by only using the phone. On the other hand, using a mobile telemedicine makes it possible for EMTs to send real-time images and ECG throughout the transfer. During that time, EMTs can concentrate on treatment; moreover, doctors at a hospital are also able to give directions for tracheal intubation or adrenaline administration when they are needed. In these points, this system is very effective on establishing on-line medical control systems.

[Fig.5] An emeregency physician was perfoming chest compression to a CPA patient on a moving ambulance. His ECG showed pulseless electrical activity with chest compression wave.

Only live-images through the camera were transmitted in the 97 patients. Table 5 shows the symptoms and signs of the patients.

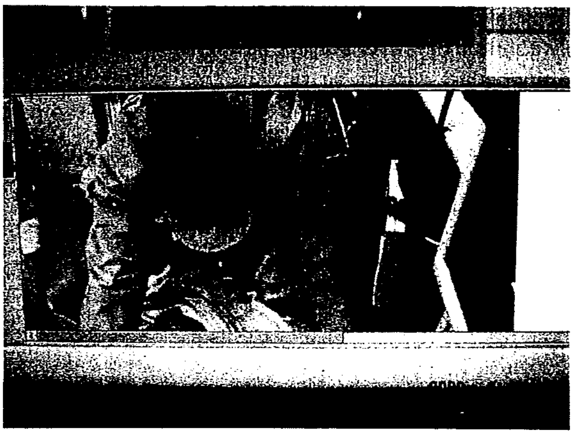
Transmitted images were also very useful for traumatic patients [Fig.6]. It is rather difficult to imagine the patients' condition, such as how deep the injury is, over the phone call only. However, with observing patients through the monitor images, it helps to be better prepared to treat the patients before they arrive at a hospital.

[Table 5] The symptoms of the 97 patients.

Symptoms	n
Trauma	39
Consciousness Disturbance	27
Abdominal Pain	8
Dyspnea	7
Vertigo	6
Burn	2
Miscellaneous	5
total	97

[Fig.6] Monitor images are very useful to specify the regions and degree of injuries

In patients with psychiatric disorder, it is also difficutl to describe the situation only over the phone. Using the live-video, the situations for those patients were easily understood [Fig.7].



[Fig.7] In the case of a patient with psychiatric disorder, struggling in the patient and holding down the patient by a medical staff were easily understood.

4.Discussion

Previously, ECG transmission from the ambulance is used only ventricular fibrillation to permit for the defibrillation. However, emergency medical technicians have become eligible to perform defibrillation without sending the data; thus, those transmitters are not used any more.

At present, ECG, especially only one-limb lead is commonly used in the ambulances in Japan. EMTs use them to observe patients' condition during the transfer. Unfortunately, however, in cases of acute myocardial infarction, only limb leads induce sometimes failure to catch the ST changes. AHA/ACC guidelines recommend routine use of 12-lead ECG and advance notification for patients with acute coronary syndrome 1. However, transmission of out-of-hospital 12-lead ECG to emergency department is still not spread and ECG interpretation on the prehospital and emergency department is not established. Setting 12-leads ECG on an ambulance and transmitting a patient's living body information to a hospital during the transfer enable both doctors at the hospital and staff on the ambulance to see the data at the same time. This means doctors can diagnose acute myocardial infarction before his/her arrival and make a decision on the treatment protocol and provide directions to the ambulance's medical staff about handling the patient on the way to the hospital. In the meantime, the staff at the hospital makes full preparation to receive the patient as soon as possible. With these advantages, 12-leads ECG will become more popular for ambulance use. Moreover, for the other diseases including cerebrovascular diseases or trauma, the live-images are useful in the transmission before admission.

5.Conclusion

Mobile Telemedicine System, such as real-time transmission of out-of-hospital 12-lead ECG and live-videos of patients on moving ambulances, is very useful for emergency medicine. Using this System, we can make up all ambulances and helicopters as virtual-doctor mobiles in future.

Sources of Funding

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Usefulness of Varying ST changes in transmitted 12-lead electrocardiogram from a moving ambulance with the Mobile Telemedicine System in a patient with acute myocardial infarction

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Abstract : Mobile telemedicine is a wireless communicating system between doctors at a hospital and Emergency Medical Technicians on an ambulance, and enables us to transmit a patient's living body information, such as 12-Lead electrocardiogram, (ECG), blood pressure, oxygen saturation, breathing rate, and so on to a hospital in real time during an ambulance ride by using mounted cameras and monitoring systems. The patient was a 71-year-old man having severe chest pain. His initial ECG transmitted from the ambulance showed ST elevation in the II III aVF and precardial leads indicating ST elevated myocardial infarction. Though, his final ECG on arrival did not show any ST elevations but the chest pain continued. We therefore performed immediate coronary arteriography and carried out interventions to segment 6 and 13. Using 12-Lead ECG before admission, we were able to diagnose ST elevation acute coronary syndrome during the transfer and useful for preparation for acceptance. This may be the first report of live-ECGs showing the usefulness of varying ST changes transmitted from a moving ambulance.

Key Words : Mobile telemedicine, 12-Lead electrocardiogram, acute myocardial infarction

1. Introduction

In the past, there used to be a variety of monitoring systems to observe patients during ambulance transfers; however, the information was sometimes not precise enough to assess cardiac patients[1)2)]. Recently, the quality of transmitted images has remarkably improved.

Mobile telemedicine is a wireless communicating system introduced by the National Cardiovascular Center, Japan [3)-5)]. The system provides a wireless link between physicians at a hospital and paramedics on an ambulance and enables us to transmit a patient's vital signs information, such as 12 lead electrocardiogram (ECG), blood pressure, oxygen saturation, breathing rate, and so on to a hospital in real time during an ambulance ride by using mounted cameras and monitoring systems.

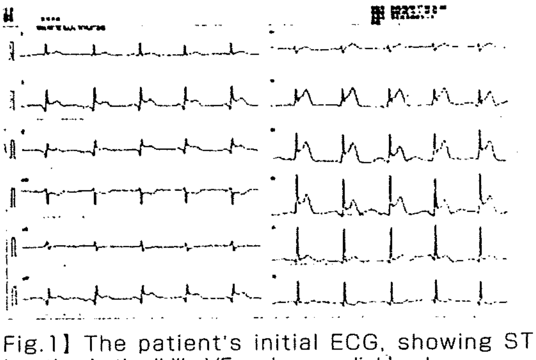
2. Case

The attached figures show live ECGs taken on a moving ambulance and transmitted to our emergency and critical care center via the Mobile telemedicine system. The patient was a 71-year-old man, with a very long history of irregular chest pain. One day he had a severe chest pain while walking and called for an ambulance.

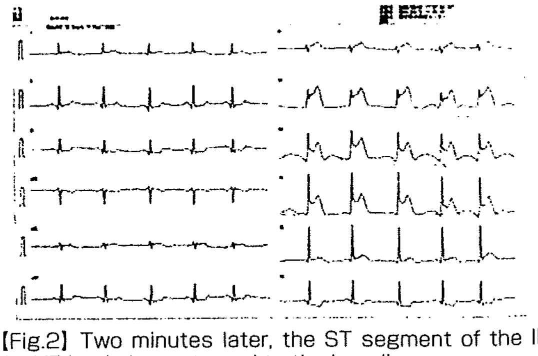
His initial ECG showing ST elevation in the II III aVF and precardial leads indicating ST elevated myocardial infarction [Fig.1] .

On his way to our hospital, his ST segment showed some fluctuations [Fig.2-4] . His final ECG on arrival did not show any ST elevations but the chest pain continued [Fig.5] .

We therefore performed emergency coronary angiography and carried out interventions to left anterior descending artery and left circumflex artery using coronary stenting right after thrombo absorbsion [Fig.6] . Max Creatinine kinase was elevated to 1394 IU/L. ECG on chronic state showed no Q waves.



[Fig.1] The patient's initial ECG, showing ST elevation in the II III aVF and precardial leads.



[Fig.2] Two minutes later, the ST segment of the II III aVF leads has returned to the baseline.

3. Discusion

Although there had been ST elevation during the transfer in real-time fashion, we didn't see any ST elevation at his arrival. Before admission, we prepared the emergency catheterization due to the information of ST elevation ECG. As thrombus and