# Efficacy of portable and percutaneous cardiopulmonary bypass rewarming versus that of conventional internal rewarming for patients with accidental deep hypothermia*

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***Objective:*** **Since 2001, at our institution, a portable and percutaneous cardiopulmonary bypass system has been used for rewarming of patients with accidental deep hypothermia. Before 2001, a conventional internal rewarming technique was used. The aim of this research is to examine the efficacy of portable and percutaneous cardiopulmonary bypass for rewarming of patients with accidental severe hypothermia and compare it with that of conventional rewarming methods.**

***Design:*** **Historical study.**

***Setting:*** **The exclusive emergency medical center and trauma center level 1 in Western Kanagawa, Japan.**

***Patients:*** **From April 1992 to March 2009, 70 patients with accidental deep hypothermia (core temperature <28°C) were transferred to our hospital. Two patients presented with intracranial hemorrhage on initial head computed tomography scans. These two patients were excluded because each required an emergency operation. Therefore, 68 patients were included in this study. We compared patients' clinical characteristics and outcomes. The parameters included the following: sex, age, vital signs on arrival to our hospital (Glasgow coma Scale scores, systolic blood pressure, heart rate, respiratory rate, core temperature), electrocardiogram on arrival to our hospital, rewarming speed, time of rewarming until 34°C was reached, ventricular fibrillation occurrence rate during rewarming, cause of cold environmental exposure, Glasgow Outcome Scale scores, and mortality. In addition, we divided the conventional and portable and percutaneous cardiopulmonary bypass rewarming groups into two categories depending on whether cardiopulmonary arrest occurred on arrival to our hospital. We also compared the survival rate and average Glasgow Outcome Scale scores for each group.**

***Interventions:*** **None.**

***Measurements and Main Results:*** **Patients' clinical backgrounds did not differ significantly between the conventional and portable and percutaneous cardiopulmonary bypass rewarming groups. Glasgow Outcome Scale scores and survival rates of the portable and percutaneous cardiopulmonary bypass rewarming group patients, irrespective of whether cardiopulmonary arrest was experienced on arrival to our hospital, were significantly higher than those of the conventional rewarming group.**

***Conclusions:*** **Portable and percutaneous cardiopulmonary bypass rewarming can improve the mortality rates and Glasgow Outcome Scale scores of accidental deep hypothermia patients. (Crit Care Med 2011; 39:1064–1068)**

**KEY WORDS: accidental deep hypothermia; rewarming method; a portable and percutaneous cardiopulmonary bypass (PPCPB); conventional internal rewarming; Glasgow Outcome Scale (GOS); ventricular fibrillation (Vf); extracorporeal membrane oxygenation (ECMO)**

Accidental hypothermia is a critical condition; deep hypothermia (<28°C) in particular is very lethal (1–6). The standard therapy for deep hypothermia is internal active rewarming. The use of a traditional cardiopulmonary bypass (CPB) system is supported by many researchers because of its ability to rapidly rewarm patients, maintain a hemodynamic state, and maintain blood flow in the brain during the rewarming process (1, 2, 5–9). However, there are some related problems such as surgical technique, medical costs, invasiveness, and medical setting (3, 4). Therefore, the use of this rewarming method for patients with deep hypothermia, especially those with noncardiopulmonary arrest on arrival (nonCPAOA), is highly debatable. Our institution has used a portable and percutaneous cardiopulmonary bypass system (PPCPB) to rewarm patients with accidental deep hypothermia since 2001 (10). Before 2001, our institution used a conventional rewarming process including a heating blanket, intravenous administration of a warmed crystalloid, and infusion of warm fluid into the gastric or bladder cavities.

The aim of this research was to examine the efficacy of PPCPB rewarming for patients with accidental deep hypothermia. We accomplished this aim by comparing mortality rates and Glasgow Outcome Scale (GOS) scores of patients with deep hypothermia before and after introduction of the PPCPB.

## PATIENTS AND METHODS

From April 1992 to March 2009, 70 patients with accidental deep hypothermia (core temperature <28°C) were transferred to Tokai University Hospital. After initial head computed tomography scans, two patients presented with intracranial hemorrhage that required emergency surgery, so they were excluded from the study. Therefore, 68 patients were included in this study; their clin-

***See also p. 1218.**

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Table 1. Characteristics of the 68 patients with accidental deep hypothermia

| | |
|---|---|
| Sex, male:female | 48:20 |
| Age, yrs | 67.8 ± 15.6 |
| Vital signs at arrival to our hospital | |
| GCS, points | 4.5 ± 2.1 |
| sBP, mm Hg | 50.8 ± 28.5 |
| HR, beats/min | 34.5 ± 18.9 |
| RR, breaths/min | 11.4 ± 6.4 |
| Core temperature, °C | 25.7 ± 1.5 |
| ECG | |
| Sinus rhythm | 34/68 (50.0%) |
| AF | 4/68 (5.9%) |
| A-V block | 7/68 (10.3%) |
| Ventricular rhythm | 10/68 (14.7%) |
| Vf | 1/68 (1.5%) |
| PEA | 3/68 (4.4%) |
| Asystole | 9/68 (13.2%) |
| Rewarming method | |
| Warmed crystalloid IV | 68/68 (100%) |
| Heat blanket | 68/68 (100%) |
| Gastric cavity | 26/68 (38.2%) |
| Bladder cavity | 30/68 (44.1%) |
| PPCPB | 38/68 (55.9%) |
| Rewarming speed, °C/hr | 4.4 ± 2.8 |
| Time of rewarming until 34°C | 3.1 ± 2.0 |
| Vf occurrence rate during rewarming | 18/68 (26.5%) |
| Cause of cold environmental exposure | |
| Alcohol | 15/68 (22.1%) |
| Cold submersion | 6/68 (8.8%) |
| Drug poisoning | 12/68 (17.6%) |
| Debility | 3/68 (4.4%) |
| Hypoglycemia | 8/68 (11.8%) |
| Sepsis | 8/68 (11.8%) |
| Severe burn | 1/68 (1.5%) |
| Unknown | 15/68 (22.1%) |
| GOS, points | 3.4 ± 1.8 |
| GOS of survivors, points (n = 46) | 4.6 ± 0.9 |
| Survival rate | 46/68 (67.6%) |

GCS, Glasgow Coma Scale; sBP, systolic blood pressure; HR, heart rate; RR, respiratory rate; ECG, electrocardiogram at arrival to our hospital; AF, atrial fibrillation; A-V block, atrioventricular block; Vf, ventricular fibrillation; PEA, pulseless electrical activities; Warmed crystalloid IV, intravenous administration of warmed crystalloid; Gastric cavity, infusion of warm fluid into the gastric cavity; Bladder cavity, infusion of warm fluid into the bladder cavity; PPCPB, portable and percutaneous cardiopulmonary bypass system; GOS, Glasgow Outcome Scale.

ical characteristics and outcomes are presented in Table 1.

Our institution has used the PPCPB system to rewarm patients with accidental deep hypothermia since 2001. Therefore, we divided the 68 study patients into two groups by period (from April 1992 to March 2001, conventional rewarming group [n = 30]; from April 2001 to March 2009, PPCPB rewarming group [n = 38]) and compared their clinical characteristics and outcome. Clinical characteristics and outcome included: sex, age, vital signs on arrival (Glasgow Coma Scale, systolic blood pressure, heart rate, respiratory rate, and core temperature), electrocardiogram on arrival, rewarming speed, time of rewarming for patient body temperature to reach 34°C, ventricular fibrillation (Vf) occurrence rate during rewarming, cause of cold environmental exposure, average GOS, average GOS of survivors, and mortality rate. Patients were categorized on the basis of their GOS scores as follows: death, 1; persistent vegetative state (minimally responsive), 2; severe disability (conscious but disabled, dependent on support for completing day-to-day activities), 3; moderate disability (disabled but can independently carry out day-to-day activities and can work in a sheltered setting), 4; and good recovery (able to resume normal activities despite minor deficiencies), 5.

In addition, we divided the conventional and PPCPB rewarming groups into two categories: with or without cardiopulmonary arrest on arrival (CPAOA) to our hospital. We also compared survival rates and average GOS scores of survivors. CPAOA was defined as Vf, pulseless electrical activity, and asystole. Our hospital's institutional ethics committee approved this study.

Statistical analysis software (Dr SPSS II for Windows, 11.0.1J; SPSS Inc, Tokyo, Japan) was used for data analysis (Mann-Whitney *U* test, chi-square test, and Fisher's exact test). Data are represented as mean (SD). Statistical significance was defined as $p < .05$.

*Portable and Percutaneous Cardiopulmonary Bypass System.* As a result of recent technological advances, the CPB machine is now small and portable. A system that uses thin-walled percutaneously inserted cannulas was designed to provide rapid bypass, and it can safely be used at the bedside or in the emergency room for arterial and central venous cannulation to establish femoral arterial and venous CPB. The use of this system is now widespread for various diseases and in many situations. Various terms have been used for this system: extracorporeal membrane oxygenation (venovenous, venoarterial extracorporeal membrane oxygenation), PPCPB, portable extracorporeal circulation, and percutaneous cardiopulmonary support, which are all functionally similar. The use of different terms for the same system may be misleading to readers. Therefore, we will define our PPCPB system.

Our PPCPB device is a portable CPB machine that is used exclusively for percutaneous intervention (cannulation is performed through the femoral vein and artery [atrium–arterial bypass]); our PPCPB machine (Capiox; Terumo, Tokyo, Japan) had a closed circuit integrated oxygenator, centrifugal pump, and heat exchanger (Capiox Hepaface; Terumo).

Percutaneous cannulation was attempted using a modified Seldinger technique in the emergency room. After vessel puncture and guidewire placement, 15- and 16.5-Fr arterial and 18-, 19.5-, and 21-Fr venous cannulas were inserted after stepwise dilation of the femoral artery and vein. To prevent lower limb ischemia because of arterial cannulation, we routinely inserted a percutaneous 4-Fr sheath distally into the femoral artery for leg perfusion. If the percutaneous cannulation failed, a direct surgical cutdown to the femoral vessels was performed. Four of the 38 patients required this intervention. We did not observe any major complications directly related to PPCPB. Seven patients experienced minor bleeding at the cannulation site (puncture, three cases; surgical, four cases), which was easily controlled.

Anticoagulation therapy (sodium heparin) was administered and the activated coagulation time was maintained between 180 and 200 secs. If the patient did not achieve spontaneous circulation with 30 mins of resuscitation after PPCPB rewarming, PPCPB treatment was withdrawn.

*PPCPB Rewarming Group.* The subjects in the PPCPB group were rewarmed rapidly with PPCPB, a heating blanket, and warm infusion until their body temperature reached 34°C. From 34°C to normothermia, slow rewarming was performed with a heating blanket for 24–48 hrs.

PPCPB treatment was gradually withdrawn with or without the use of catecholamine after the following patient conditions were satisfied: core body temperature of >34°C, adequate oxygenation, and a stable hemodynamic status at an outflow rate of 0.5 L/min. However, patients who remained hemodynamically unstable despite rewarming continued to undergo bedside PPCPB.

*Conventional Rewarming Group.* A heating blanket and warm infusion were routinely used in all patients in the conventional rewarming group. In addition, patients were treated with warm fluid infusion into the gastric cavity, bladder cavity, or both until the body temperature reached 34°C. From 34°C until normothermia, slow rewarming was performed with a heating blanket for 24–48 hrs.

## RESULTS

The comparison study between the conventional and PPCPB rewarming groups is presented in Table 2. Sex, age, vital signs, and electrocardiogram on arrival and cause of cold environmental exposure were not significantly different between groups. The rewarming speed of the PPCPB group was significantly higher, and the time of rewarming to reach 34°C was significantly shorter than that of the conventional rewarming group. The rate of Vf occurrence during the rewarming protocol was high in the conventional rewarming group. The GOS scores (all patients and

**Table 2.** Comparison study of the conventional rewarming group and the portable and percutaneous cardiopulmonary bypass system rewarming group

| | Conventional Rewarming Group (n = 30) | PPCPB Rewarming Group (n = 38) | p |
|---|---|---|---|
| Sex, male:female | 23:7 | 25:13 | NS |
| Age, yrs | 68.0 ± 19.1 | 67.7 ± 12.5 | NS |
| Vital signs at arrival to our hospital | | | |
| GCS, points | 4.6 ± 2.1 | 4.3 ± 2.2 | NS |
| sBP, mm Hg | 49.5 ± 29.5 | 51.8 ± 28.0 | NS |
| HR, beats/min | 36.0 ± 21.2 | 33.3 ± 17.1 | NS |
| RR, breaths/min | 11.6 ± 6.9 | 11.3 ± 6.0 | NS |
| Core temperature, °C | 25.3 ± 1.4 | 26.0 ± 1.5 | NS |
| ECG | | | NS |
| Sinus rhythm | 14/30 (46.7%) | 20/38 (52.6%) | |
| AF | 2/30 (6.7%) | 2/38 (5.3%) | |
| A-V block | 3/30 (10.0%) | 4/38 (10.5%) | |
| Ventricular rhythm | 4/30 (13.3%) | 6/38 (15.8%) | |
| Vf | 0/30 (0%) | 1/38 (2.6%) | |
| PEA | 2/30 (3.7%) | 1/38 (2.6%) | |
| Asystole | 5/30 (16.7%) | 4/38 (10.5%) | |
| Rewarming speed, °C/hr | 2.0 ± 0.6 | 6.3 ± 2.3 | <.001 |
| Time of rewarming until 34°C, hrs | 4.8 ± 1.8 | 1.7 ± 0.5 | <.001 |
| Vf occurrence rate during rewarming | 14/30 (46.7%) | 4/38 (10.5%) | <.001 |
| Cause of cold environmental exposure | | | NS |
| Alcohol | 7/30 (23.3%) | 8/38 (21.1%) | |
| Cold submersion | 2/30 (6.7%) | 4/38 (10.5%) | |
| Drug poisoning | 5/30 (16.7%) | 7/38 (18.4%) | |
| Debility | 2/30 (6.7%) | 1/38 (4.4%) | |
| Hypoglycemia | 3/30 (10.0%) | 5/38 (13.2%) | |
| Sepsis | 3/30 (10.0%) | 5/38 (13.2%) | |
| Severe burn | 0/30 (0%) | 1/38 (2.6%) | |
| Unknown | 8/30 (26.7%) | 7/38 (18.4%) | |
| GOS, points | 2.4 ± 1.7 | 4.2 ± 1.5 | <.001 |
| GOS of survivors, points (14:32) | 4.1 ± 1.1 | 4.8 ± 0.6 | <.024 |
| Survival rate | 14/30 (46.7%) | 32/38 (84.2%) | .001 |

GCS, Glasgow Coma Scale; sBP, systolic blood pressure; HR, heart rate; RR, respiratory rate; ECG, electrocardiogram at arrival to our hospital; AF, atrial fibrillation; A-V block, atrioventricular block; Vf, ventricular fibrillation; PEA, pulseless electrical activities; PPCPB, portable and percutaneous cardiopulmonary bypass system; GOS, Glasgow Outcome Scale; NS, no significant difference.

**Table 3.** Comparison study of noncardiopulmonary arrest on arrival and cardiopulmonary arrest on arrival between the conventional rewarming group and the PPCPB rewarming group

| Group | Survival Rate (%) | Average of Survivors' GOS |
|---|---|---|
| Conventional rewarming group (n = 30) | | |
| NonCPAOA (n = 23) | 56.5% (13/23) | 4.2 |
| CPAOA (n = 7) | 14.3% (1/7) | 2.0 |
| PPCPB rewarming group (n = 38) | | |
| NonCPAOA (n = 32) | 84.4% (27/32)[a] | 4.9[c] |
| CPAOA (n = 6) | 83.3% (5/6)[b] | 3.8[d] |

PPCPB, portable and percutaneous cardiopulmonary bypass; GOS, Glasgow Outcome Scale; CPAOA, cardiopulmonary arrest on arrival.

[a]Versus survival rate (conventional rewarming group; nonCPAOA), $p < .05$; [b]vs. survival rate (conventional rewarming group; CPAOA), $p < .05$; [c]vs. Average survivor GOS score (conventional rewarming group; nonCPAOA), $p < .05$; [d]vs. average survivor GOS score (conventional rewarming group; CPAOA), could not be analyzed because there was only one CPAOA patient in the conventional rewarming group.

survivors) and survival rate of the PPCPB rewarming group were significantly higher than those of the conventional rewarming group.

The comparison study of noncardiopulmonary arrest on arrival and cardiopulmonary arrest on arrival between the conventional rewarming group and the PPCPB rewarming group is presented in Table 3. The conventional rewarming group (n = 30) had 23 nonCPAOA patients and seven CPAOA patients. Their survival rates and average survivor GOS scores were 56.5% and 4.2 14.3% and 2.0, respectively. The PPCPB rewarming group (n = 38) had 32 nonCPAOA patients and six CPAOA patients. Their survival rates and average survivor GOS scores were 84.4% and 4.9 and 83.3% and 3.8, respectively. The survival rates of both nonCPAOA and CPAOA patients were significantly higher in the PPCPB rewarming group. The average GOS score of the nonCPAOA survivors in the PPCPB rewarming group was significantly higher than that of the nonCPAOA survivors in the conventional rewarming group. The average GOS of survivors in the CPAOA group could not be analyzed because there was only one survivor with CPAOA (GOS; 2 points) in the conventional rewarming group. However, the average GOS score of survivors in the PPCPB rewarming group was comparatively high (average, 3.8 points; 5, 4, 4, 4, and 2 points).

## DISCUSSION

Recently, PPCPB has been successfully used for cardiogenic shock treatment, resuscitation of patients in cardiopulmonary arrest, treatment of traumatized patients, and for many other medical conditions in the emergency room (11–15). The merits of PPCPB compared with traditional CPB are its low cost, less invasive nature, short setup time, and ability to use this system continuously in both the emergency room and at a patient's bedside (3, 10). Traditional CPB requires median sternotomy or surgical exposure of the great vessels, which can be time-consuming and difficult, particularly during an emergency. Additionally, the setup time required for traditional CPB is 106–134 mins (1,2, 16). In contrast, PPCPB can be performed percutaneously and can therefore be used safely and quickly. We previously reported the efficacy of PPCPB rewarming for 24 patients with accidental deep hypothermia with nonCPAOA (these 24 patients are included in this study) (10). In the present study, we found that their survival rate was 87.5%. In addition, the average time of initiation of PPCPB after arriving to our hospital was 42.0 ± 7.9 mins. No major direct PPCPB-related complications were noted. Some researchers have reported successful rewarming of hypothermia patients, emphasizing that this system does not warrant the use of any special surgical techniques and could be safely and rapidly used at the bedside or in the emergency room (16, 17).

The Seldinger technique enables physicians who are not specialists in surgical techniques to safely perform cannulation. However, if cannulation fails, a direct surgical cutdown is required. In our study, four of the 38 PPCPB rewarming patients required this intervention. In this situation, a skilled and experienced surgeon must be consulted. Therefore, institutions that do not have resident surgeons might face difficulties in this regard. Some complications such as bleeding at the cannulation site, vessel perforation, arterial dissection, distal ischemia, and incorrect location were reported. However, no significant direct PPCPB-related complications were noted in our patients. In our hospital, physicians with expertise in the use of PPCPB treatment provide training to emergency department physicians and nurses twice a year, which may have contributed to the low complication rate and short setup time observed in our study.

Selection of a rewarming method for patients with deep hypothermia can vary (3, 4). In the initial treatment approach to rewarming, the type of rewarming to be used (ie, passive external, active external, or internal rewarming) needs to be analyzed; passive rewarming is not generally preferred for patients with deep hypothermia. In addition, one of the risks of performing only active external rewarming is the inevitable drop in core body temperature after the procedure concludes, which occurs when the extremities and trunk are simultaneously warmed. Furthermore, removal of the patient from the cold environment results in peripheral vasodilation, which potentially contributes to precipitous hypotension, inadequate coronary perfusion, and Vf (18). Prolonged hypotension and occurrence of Vf during rewarming affect the patient's brain function and mortality.

Conventional internal active rewarming such as intravenous administration of a warmed crystalloid; circulation of warm humidified air through the airway through a facial mask or an endotracheal tube; infusion of warm fluid in the gastric, colonic, pleural, peritoneal, or pericardial cavities; and other techniques have been reported to have rewarming speeds of 1.0–2.5°C/hr (7, 19–22). When patients with deep hypothermia are treated by conventional internal rewarming, more than a few hours are required for normothermia to be achieved. For patients with cardiopulmonary arrest in particular, physicians should continue chest compressions for a long time. Prolonged resuscitation in an emergency carries the concomitant risk of inadequate resuscitation and iatrogenic chest injury as a result of extended chest compressions. Extracorporeal blood rewarming using venovenous bypass is another internal active rewarming method that has been reported (23). Although this method can rewarm a patient rapidly (2–3°C/hr) compared with other conventional internal active methods, it is not able to maintain a hemodynamic state during rewarming. Hypothermic hearts may be unresponsive to cardiovascular drugs, pacemaker stimulation, and defibrillation; therefore, we believe that rapid active rewarming is a life-saving procedure for patients with deep hypothermia. CPB clearly offers an opportunity to promptly and effectively stabilize the hemodynamic state (1–3).

Traditional CPB is considered the gold standard in the treatment of patients with accidental deep hypothermia with cardiopulmonary arrest. However, treatment of these patients who are not in cardiopulmonary arrest remains controversial. Since the first report of the use of percutaneous CPB rewarming for hypothermic patient by Laub et al (16), recent literature has reported the successful use of the PPCPB system for rewarming of patients with accidental deep hypothermia whether in cardiopulmonary arrest or not (10, 24). However, most studies could not evaluate efficacy because of the limited sample size or case report (10, 16). Ruttmann and coworkers (24) showed that PPCPB improved survival of patients with accidental deep hypothermia with cardiopulmonary arrest compared with traditional CPB using multivariate logistic regression analysis. They concluded that the cause of improvement was that PPCPB allowed prolonged cardiorespiratory support after initial resuscitation.

PPCPB is the same as CPB in its ability to rapidly rewarm patients, maintain a hemodynamic state, and maintain brain blood flow during the rewarming process. Our study showed four advantages of PPCPB compared with other internal active rewarming methods. First, it can rapidly rewarm patients to 34°C because of its high rewarming speed. Although it is questionable whether rapid active rewarming positively impacts a patient's neurologic outcome, our study showed significantly higher GOS scores in the PPCPB rewarming group vs. the conventional rewarming group. Second, the Vf occurrence rate during rewarming was significantly lower in the PPCPB rewarming group compared with the conventional rewarming group (PPCPB 10.5% vs. conventional 46.7%; $p < .001$). Although the mechanism of the low Vf occurrence rate during rewarming is not clear, we hypothesize that it may be the result of PPCPB decreasing the myocardial workload. Third, survival rates between the two groups were significantly different (PPCPB 84.2% vs. conventional 46.7%; $p = .001$). In addition, patients in the PPCPB rewarming group (regardless of CPAOA or nonCPAOA at arrival) had significantly higher survival rates than those of the conventional rewarming group. Fourth, GOS scores of survivors in the PPCPB rewarming group were significantly higher than those of the conventional rewarming group (PPCPB 4.8 vs. conventional 4.1; $p < .024$). In addition, GOS scores of surviving patients in the PPCPB rewarming group who were non-CPAOA on arrival were significantly higher. The significance of intergroup differences in GOS scores of surviving patients who were CPAOA on arrival to our hospital could not be analyzed because there was only one patient in the conventional rewarming group who met these criteria. However, the average GOS of the PPCPB rewarming group's survivors was 3.8 points. Based on these data, we believe that PPCPB is an equal or more successful treatment than traditional CPB for patients with accidental deep hypothermia.

Many studies of accidental deep hypothermia in the literature discuss mortality rates. Although prevention of death is obviously the most important medical goal, the ability to perform daily activities is important for both the survivor and the survivor's family.

## CONCLUSION

This kind of study cannot be performed as a randomized controlled trial because use of CPB to rewarm patients with accidental deep hypothermia, especially those in CPAOA, has already been proven. Therefore, we retrospectively compared the efficacy of PPCPB vs. conventional rewarming. This study showed that use of PPCPB can improve mortality rates and survivor GOS scores of patients with accidental deep hypothermia.

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