

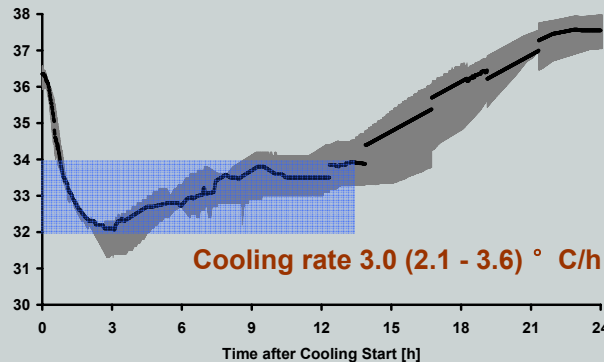
# Efficacy and Safety of a Novel Rapid Non-invasive Surface Cooling Device for Induction of Therapeutic Hypothermia in Patients after Cardiac Arrest

Michael Holzer M.D., Andreas Janata M.D., Moritz Haugk M.D., Danica Krizanac M.D., Fritz Sterz M.D.

Department of Emergency Medicine, Medical University of Vienna, Austria

## Purpose of the study

Therapeutic hypothermia after cardiac arrest improves neurologic recovery and mortality. Rapid induction of therapeutic hypothermia might further improve neurologic outcome after cardiac arrest. The safety and effectiveness of the ThermoSuit® System was assessed in survivors of cardiac arrest.



The patients stayed 6 (4 – 11) days at the intensive care unit. Eight patients (80%) were successfully discharged from the hospital after 22 (9 – 33) days. The NIH stroke scale at discharge was 0 (0 - 3) and the Mini Mental score was 29.5 (27.5 - 30). A total of 7 serious adverse events (asystole, ventricular fibrillation, sepsis, aphasia and in-stent thrombosis) and 10 adverse events occurred in the 10 patients. None of the adverse events was related to the cooling device.

## Results

The patients were 63 (48 – 69) years old, there were 9 men and the body mass index was 26.3 (24.8 – 27.8) kg/m<sup>2</sup>. The cardiac arrest was witnessed in 7 patients, all patients had ventricular fibrillation. The no-flow time was 3 (0 – 6) min, the time until return of spontaneous circulation 17 (15 – 21) min and the epinephrine dose 1 (0 – 2) mg. Percutaneous coronary intervention was performed in 9 patients. The esophageal temperature immediately before start of cooling was 36.2 (35.5 - 36.8). At 93 (76 – 121) min after return of spontaneous circulation and 50 (36 – 71) min after admission the patients were cooled with the device for 36 (27 - 47) min and a temperature of 34° C was reached after 44 (32 - 56) min. This led to a cooling rate of 3.0 (2.1 - 3.6)°C/h. The temperature dropped slightly below the target temperature of 32 – 34°C. The median lowest temperature was 31.7 (31.1 – 32.1)°C, The deepest temperature that was reached was 29.9°C. In 6 patients additional warming and in 5 patients additional cooling was needed during the maintenance phase. The temperature at start of rewarming was 33.5 (33.3 – 34.3) °C, the rewarming rate 0.3 (0.2 – 0.4) °C/h.

## Materials and Methods

Ten patients who have been successfully resuscitated from cardiac arrest were included in a prospective observational case series at an emergency department of a tertiary care university hospital. Patients were surface cooled with ice cold water circulating in the device (ThermoSuit® System, Life Recovery Systems, Kinnelon, USA) until a target esophageal temperature of 34.5°C was achieved. Further they were kept at a temperature between 32 and 34°C for 12 hours by external surface cooling or warming and were then passively rewarmed. Results are presented with median and interquartile range.

## Cerebral Performance Category

CPC 1	●●●●●
CPC 2	●
CPC 3	●
CPC 4	
CPC 5 or dead	●●

## CONCLUSIONS

The ThermoSuit® System was safe and highly effective in inducing therapeutic hypothermia in patients after cardiac arrest. The vast majority of the survivors had excellent neurologic performance scores at hospital discharge.

FDA-Cleared Indication: Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients. PN 51012, Ver. A