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New Intra-Arrest Cooling Method May Save More Brains During Cardiac Arrest

Study Unveiled at AHA Late Breaking 'Best of Best' Presentation Shows Survival Benefit

ORLANDO, Fla., Nov. 15 /PRNewswire/ -- The first randomized intra-arrest cooling study performed using a novel intra-nasal cooling method showed much faster and earlier cooling in treated patients and significantly higher neurologically intact survival - to - discharge rate in many patients. The Pre-Resuscitation Intra-Nasal Cooling Effectiveness (PRINCE) study involved 200 patients and was conducted by 15 Emergency Medical Systems (EMS) in Belgium, Germany, Italy, Czech Republic and Sweden. The aim was to determine safety and efficacy of intra-nasal cooling during ongoing resuscitation of cardiac arrest patients even before the return of circulation (ROSC).

The study was conducted using the RhinoChill™ IntraNasal Cooling System, a non-invasive nasal catheter that sprays a rapidly evaporating coolant liquid into the nasal cavity. This large cavity is a heat exchanger and lies right under the brain.

The trial was designed to determine the safety and effectiveness of early cooling initiated at the site of the arrest. The RhinoChill System enabled cooling to start much earlier than is possible with conventional methods used in a hospital setting and focuses on the brain. "The brain is the organ that dies first so the closer to the time of arrest the brain is cooled, the more of it is rescued," said Denise Barbut, M.D, founder and CEO of BeneChill, the company that makes the RhinoChill System. "The brain is the organ that controls the heart, much like a puppet on a string," she added.

Additional endpoints included cooling rates, time to achieve target temperature, ease of use in the field, ROSC rates, survival and neurologically intact survival. EMS personnel recruited adults over 18 years old who were in cardiac arrest and not hospitalized during resuscitation. All patients who were deemed eligible for advance cardiac life support (ACLS) were included as long as the arrest was witnessed and cardiopulmonary resuscitation (CPR) was initiated within 20 minutes of collapse.

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The results of the study included:

- Cooling was initiated 23 minutes following arrest and lowered brain temperature (tympanic) (34.2 degrees C vs. 35.5 degrees C) and body (core) temperature (35.1 degrees C vs. 35.8 degrees C) significantly by ER arrival.
- Time to target tympanic temperature of 34 degrees was three hours faster and time to target core temperature was two hours faster in patients cooled intra-nasally in the field compared to those receiving hospital cooling alone.
- Survival to discharge was higher in treated patients admitted to hospital (46.7% vs 31%) and significantly higher in those in whom CPR was initiated within 10 minutes of collapse, irrespective of rhythm (59.1% vs 29.4%).
- Neurologically intact survival to discharge was higher in treated patients admitted to the hospital (36.7% vs 21.4%) and significantly higher in those in whom CPR was initiated within 10 minutes of collapse, irrespective of rhythm (45.5% vs 17.6%).
- Intra-nasal cooling with the RhinoChill™ IntraNasal Cooling System was feasible and safe during an arrest. Nasal discoloration was the most commonly reported adverse event occurring in 13 patients. This resolved spontaneously in all patients who were successfully resuscitated.

Maaret Castren, M.D, Ph.D of the Department of Clinical Science and Education, Karolinska Institute, Stockholm, Sweden and the Department of Emergency Medicine, Sodersjukhuset and PRINCE lead investigator noted, "In this study, early cooling of the brain combined with early CPR favorably affected outcomes, irrespective of rhythm. We believe that this study demonstrates that making every attempt to initiate both CPR and intra-arrest cooling as early as possible in the resuscitation process should be adopted."

The EMS teams also noted that the portability of the device and ease of use meant that cooling could be administered in the field by non-specialized medical personnel. This also is useful in the hospital setting where the patient can be transported around with on-going cooling.

Dr. Castren presented the findings in Orlando, FL on Sunday, November 15 during the American Heart Association's Resuscitation Science Symposium "Best of the Best" presentations.

The sponsor of the study is BeneChill, a privately held medical device company which develops novel, rapid cooling systems to improve survival and brain function after cardiac arrest and other forms of brain ischemia. Its lead product, the RhinoChill

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Intranasal Cooling System, which was used in the PRINCE study, can be administered quickly and close to the brain using a nasal catheter that delivers a rapidly evaporating coolant. The RhinoChill System will be marketed in Europe in early 2010 and currently is not available in the US.

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