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ALSIUS
A NEW DEGREE OF CARE

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Kevin Everett's Spinal Cord Injury: Why There is Hope in His Future

On September 9, 2007, Buffalo Bills' tight end, Kevin Everett, seriously injured his spinal cord during a tackle. Once Everett was taken off of the field, therapeutic hypothermia had begun immediately. He was brought to Millard Fillmore Hospital, in Buffalo, NY, and tests that evening showed he was quadriplegic. The Bills' team orthopedist, Dr. Andrew Cappuccino, described Everett's condition as, "potentially catastrophic." After four hours of surgery, Everett was placed on the Alsius CoolGard 3000® for hypothermia treatment and was kept at 33.5°C for 24 hours. He was slowly rewarmed and continued to maintain normothermia on the Alsius CoolGard 3000 until he was transferred to rehab. A few days after the injury he was taken off of a respirator. That same day, Everett was able to wiggle his toes, move his ankles, extend his elbows, kick out a leg, and slightly flex his biceps. Five weeks after his injury, Everett himself announced his astonishing progress, "This week, with the assistance of a walker, I was able to take steps, and I have been able to move in my wheelchair, both of which are great triumphs for me." The doctors who treated Everett knew this was a life threatening injury and believed he would be quadraplegic indefinitely. With Everett's positive attitude and encouragement from family, friends, and fans, he continues to show improvement with his rehabilitation at Memorial Hermann in Houston, TX.

The neuroprotective qualities of hypothermia in animal experimental models of neurotrauma and ischemia have been well established. There is ample experimental evidence to show that hypothermia can mitigate secondary injury mechanisms such as excitotoxicity, BBB breakdown, free radical production, inflammation, etc. In the last fifteen years, attempts have been made to use mild to moderate hypothermia during the early and late post-injury period to improve long term functional outcomes in patients who have suffered Traumatic Brain Injury (TBI). Hypothermia in patients with neurological injury is being implemented more frequently throughout the United States and internationally.

The effects of hypothermia in patients with spinal cord injury, however, have yet to be evaluated properly. After encouraging results in the first group of patients with Alsius CoolGard 3000, surgeons at the department of Neurological Surgery from the University of Miami are currently undergoing a study to examine the effect of hypothermia in patients with spinal cord injury. The prospective study is looking at long-term functional outcomes by assessing motor and sensory function as well as overall function in daily living. The results will help determine if hypothermia provides important neuroprotective benefits in patients with new spinal cord injury.

*Please see page two for references.

SPINAL CORD INJURY Q&A

Q: What is spinal cord injury?

Spinal cord injury (SCI) is damage to the nerves within the spinal canal. Most SCI's are caused by trauma to the vertebral column, thereby affecting the spinal cord's ability to send and receive messages from the brain to the body's systems that control sensory, motor and autonomic function below the level of injury.

Q: How common are spinal cord injuries?

Approximately 450,000 people in the United States have sustained traumatic spinal cord injuries, with more than 10,000 new cases of para- and quadriplegia emerging in the U.S. every year. There are also 100,000 new cases of partial paralysis. Males account for 82% of all SCI's and females for 18%.

Q: What are the leading causes of traumatic spinal cord injuries?

Motor vehicle collisions (54.7%), other medical conditions and sports injuries (27.6%), and falls (17.7%).

Q: What are the outcomes for spinal cord injury victims?

85% of SCI patients who survive the first 24 hours following injury are alive 10 years later. Most are quadriplegic or paraplegic, both of which have a huge impact on families and society as a whole.

Q: What causes secondary injuries in spinal cord injuries?

Swelling and reduced blood flow causes secondary injuries because it cuts off the supply of oxygen to the cells, therefore causing the cells to die. Therapeutic hypothermia prevents cells from dying by not allowing swelling to take place and reduced blood flow to occur.

**Please see page two for references.

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Comparison of different cooling methods to induce and maintain normo-and hypothermia in ICU patients: a prospective intervention study

Although methods of temperature management are used frequently, little is known about the optimal cooling methods for inducing and maintaining controlled normo-and hypothermia in the ICU. This study compared the efficacy of several devices for temperature management in various neurologically injured patients in the ICU. Fifty adult patients were consecutively assigned to groups: conventional cooling, cooling with water circulating blankets, air circulating blankets, water circulating gel-coated pads, or intravascular heat exchange system.

Cooling rates were higher with intravascular cooling compared to conventional cooling and air circulating blankets. After target temperature was met, the intravascular cooling device kept patients closer to target temperature than all other methods examined. The Alsius intravascular cooling system proved to be the most accurate to maintain a stable target temperature.

| | ALSIUS CoolGard & ICY Catheter | Medivance Arctic Sun | Cincinnati Subzero Blanketrol II | Medeco Caircooler | Conventional |
|--|--------------------------------|--------------------------|----------------------------------|-------------------------------|---------------------------|
| Cooling Method | Intravascular Heat Exchange | External Gel-coated Pads | External Water Circulating Pads | External Air Circulating Pads | Cold Saline Ice Bags, etc |
| Cooling Rate in Hypothermia Group (°C/hr) | 1.46 | 1.04 | 1.33 | 0.18 | 0.32 |
| Cooling Rate in Normothermia Group (°C/hr) | 1.02 | 1.02 | 1.12 | 0.15 | 0.06 |
| % of time patient temperature was > 0.2°C (+/-) from target (Hypothermia Group) | 3.2 | 44.2 | 50.5 | 74.1 | 69.8 |
| % of time patient temperature was > 0.2°C (+/-) from target (Normothermia Group) | 4.2 | 40.2 | 74.8 | 53.6 | 97.4 |

Cornelia W. Hoedemaekers, Mustapha Ezzahiti, Aico Gerritsen and Johannes G. van der Hoeven. Department of Intensive Care. Radboud University Nijmegen Medical Centre, The Netherlands, Critical Care 2007, 11:R91 (doi:10.1186/cc6104)

New from Alsius: IV Fluid Cooler/Warmer Unit

Introducing a simple solution that gives Emergency Medical Teams the ability to quickly and easily manage core temperature any time it's needed!

The latest trends in emergency medicine indicate a significant advantage to initiate cooling or warming therapies by temperature controlled IV fluid infusion. Many more emergency patients could benefit from fast and efficient cooling or warming if this technology were available in the field.



ALSIUS IV fluid bag coolers and warmers provide a simple, straightforward method of maintaining therapeutically effective saline bag temperatures. Unlike external methods of temperature control, such as cooling/warming blankets or ice packs, ALSIUS enables you to regulate core body temperature internally. With ALSIUS IV Fluid Cooler/Warmer unit, therapy is immediately initiated right in the field and is great for prepping patients for in-hospital temperature management.

Three models are available. Two 14 quart units, that can hold six 1L bags of saline. One cools only and the other cools or warms. A 22 quart unit, that cools and can hold thirteen 1L saline bags, is ideal for in hospital and emergency department use.

*Everett, Kevin, Message from Kevin Everett, Memorial Hermann, 10/17/07, <http://www.memorialhermann.org/newsroom/101707.htm>
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 The Project 2007, Clinical Trials Initiative Moves Forward
 **2002-2007 Spinal Cord Injury Information Pages <http://www.sci-info-pages.com/faq.html>
 2007 NeurosurgeryToday.org <http://www.neurosurgerytoday.org/media/fact/spinal.asp>
 Davis, Henry, Is injured Bill Kevin Everett's progress good luck or a minor miracle? 9/15/07 <http://www.buffalonews.com/home/story/163188.html>

Alsius wishes you and your family a safe and happy holiday season!

Please visit www.alsius.com or contact us at 1-877-2ALSIUS (877-225-7487)