Trauma Resuscitation Study to Test Hypothermia

BY PATRICE WENDLING

CHANDLER, ARIZ. — The idea of using suspended animation in trauma care was unthinkable just 5 years ago, but surgeons now stand at the cusp of the first clinical trial in humans.

The nonrandomized, phase II trial will use emergency preservation and resuscitation (EPR), as it is now called, to buy surgeons time for victims of blunt or penetrating trauma who have exsanguinated to the point of cardiac arrest.

Hypothermia is achieved via a flush of ice-cold saline pumped into the aorta until the brain is cooled to a tympanic membrane temperature of less than 10° C. Patients can then undergo surgical interventions to control bleeding, followed by rewarming and resuscitation with cardiopulmonary bypass, principal investigator Dr. Samuel Tisherman explained at the annual meeting of the Eastern Association for the Surgery of Trauma.

Patients in the Emergency Preservation and Resuscitation for Cardiac Arrest from Trauma (EPR-CAT) trial must have at least one sign of life present within the 5-minute period prior to ED arrival or in the ED, and have no response to open-chest cardiopulmonary resuscitation with clamping the aorta or remain pulseless for 5 minutes despite aggressive resuscitative efforts.

Informed consent is impossible, said Dr. Tisherman, professor of critical care medicine and surgery and associate director of the Safar Center for Resuscitation Research at the University of Pittsburgh. "Why do it? Because we know our outcomes are so bad. These patients have almost no chance of survival with current therapy," he said.

Standard resuscitation for patients in cardiac arrest from blunt or penetrating injuries includes emergency department thoracotomy (EDT), open cardiac massage, and fluid resuscitation. A recent analysis of 283 consecutive penetrating injury cases showed that patients with multiple cardiac or great-vessel gunshot wounds, regardless of ED signs of life, were "nearly unsalvageable"; only 1 patient survived EDT (J. Trauma 2009;67:1250-7).

Hypothermia is commonly used in elective pediatric and neurologic surgery, and is effective for cardiac arrest. In trauma care, however, hypothermia has been considered unfeasible because of three hurdles, coinvestigator Dr. Hasan B. Alam said at the meeting. The procedure is performed in a chaotic environment on patients who are typically in shock; it is technically challenging to cool the patient in less than 5 minutes, as opposed to the slow hypothermia induced in elective cases; and hypothermia has long been thought to exacerbate bleeding and coagulopathy in trauma patients.

Active rewarming can actually reverse coagulopathy, and although trauma patients may bleed more during hypothermic arrest, some systems allow for blood to be recirculated back into the patient, said Dr. Alam of Massachusetts General Hospital and Harvard University, both in Boston.

Why use suspended animation in trauma patients who are in cardiac arrest? 'Because we know our outcomes are so bad. These patients have almost no chance of survival with current therapy.'

The goal of the multicenter trial is to limit EPR to less than 60 minutes. The hypothesis is that aortic arch flush can be initiated within 5 minutes of pulselessness, decreasing the tympanic membrane temperature to less than 20° C in 15 minutes.

A meeting attendee commented that death isn't the worst or most expensive outcome in these patients, noting the trial's potential for extremely poor outcomes. Data have shown that encephalopathy can begin 4 minutes after the cessation of blood flow in normothermic patients.

"The cheapest thing is a quick death," Dr. Alam replied. "It's expensive if the heart comes back but the brain does not. But if we don't do this, we won't push ahead."

The primary end point of the EPR-CAT trial is survival to hospital discharge without major disability, with the secondary outcome being neurologic function at 6 months.

Despite many medical and ethical questions, the trial is moving ahead; medical protocols have been submitted at two of the eight participating centers. Researchers expect to treat the first patient sometime in the second half of 2010, Dr. Tisherman said. The Food and Drug Administration will keep a close eye on the trial. ■

Disclosures: *The trial is sponsored by the University of Pittsburgh. Dr. Tisherman disclosed no financial conflicts of interest.*

Analysis Shows That Trauma Center Care Is Cost Effective, Saves QALYs

BY KERRI WACHTER

PITTSBURGH — Treatment at trauma centers was associated with 70 additional life-years per 100 patients, compared with care at nontrauma centers in a large, multistate study.

Although care at a trauma center was found to be more expensive than care at a nontrauma hospital, trauma center costs were well within widely accepted benchmarks used to judge cost-effectiveness, Ellen MacKenzie, Ph.D., said at the annual meeting of the American Association for the Surgery of Trauma.

The cohort of 5,043 severely injured adult trauma patients received care in 69 hospitals in 14 states. In all, 1,085 patients died. All patients who were discharged were contacted by phone at 3 and 12 months to determine their use of health services and assess their functional status. Medical records, claims data from the Centers for Medicare and Medicaid Services, hospital bills, and patient interviews were used to calculate costs.

The researchers estimated cost-effectiveness using three standard methods: cost per life saved, cost per life-year gained, and cost per quality-adjusted life-year (QALY) gained. Using data from the National Study for Cost and Outcomes in Trauma database, they included patients who died or who sustained an injury with an Abbreviated Injury Score of at least 3.

To estimate incremental life years gained, the researchers assumed that a survivor benefit from trauma center care does not extend beyond 1 year post injury. They also discounted future life-years by the standard value of 3%. This analysis found 70 additional life-years per 100 patients in trauma versus nontrauma centers.

QALYs were calculated using adjusted values on the Short Form-16 at 3 and 12 months, together with assumptions about how function declines with age. To estimate costs, the researchers derived estimates of 1-year treatment costs using previous data, then projected lifetime costs, making some assumptions about life expectancy and ongoing medical expenditures for survivors.

The added cost of treatment in a trauma center versus a non–trauma center was found to be $36,319 per life-year gained ($790,931 per life saved) and $36,961 per QALY gained—well within the cost-effectiveness ratios of $50,000 to $100,000 per life-year gain deemed acceptable in the literature. The higher price tag associated with treatment at a trauma center is attributable largely to costs incurred during initial hospitalization.

The difference between the two types of facilities in per-lifetime patient costs was estimated to be $20,000, said Dr. MacKenzie, chair of the department of health policy and management at the Johns Hopkins University's Bloomberg School of Public Health.

The study "provides data that is likely to be critical in our efforts to persuade legislators and the public to invest in trauma systems infrastructure," said the invited discussant for the paper, Dr. Robert C. Mackersie, professor of surgery and director of trauma services at San Francisco General Hospital. ■

Disclosures: *Dr. MacKenzie reported that she has no relevant financial relationships.*

CDC Will Track Adverse Events From Transfusions

Officials at the Centers for Disease Control and Prevention are asking U.S. hospitals to enroll in a new national surveillance system for monitoring adverse events in patients receiving blood transfusions.

The voluntary Hemovigilance Module is the latest addition to the CDC's National Healthcare Safety Network, which allows health care providers to securely submit data on heath care–associated infections via the Internet. Through the network, the CDC provides hospitals with risk-adjusted data to be used for internal comparisons and local quality-improvement activities.

"Health care facilities that join the Hemovigilance Module will now have a yardstick by which to measure their current safety initiatives and their future efforts," Dr. Dan Pollock, chief of the branch that leads the CDC safety network, said in a statement. "Through this system, health care facilities can also see how their performance stacks up to similar facilities nationwide, with a goal of designing the best processes to protect patients' health and reduce health care costs."

Previously, hospitals have been left to monitor transfusion-related adverse events on their own, according to the CDC. Hospitals that opt into the new system can submit data confidentially; the CDC, along with some private partners, will use the national data to identify potential strategies to improve transfusion safety.

The CDC is offering the module, training, and user support free of charge.

The module was developed by the CDC and the AABB, an international association representing organizations involved in transfusion and cellular therapies.

The AABB called the launch of the surveillance system an important step forward. "The U.S. is the only developed country that does not have an established method to track and monitor adverse events associated with blood transfusion on a national level," AABB's CEO Karen Shoos Lipton said in a statement.

More information on the Hemovigilance Module is available online at www.cdc.gov/nhsn/bio.html.

—Mary Ellen Schneider