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For Patients with Severe Lung Injury, Less Is More

Study Answers Long-Debated Questions on Fluid Management in Critical Care

Results from the largest controlled clinical trial of fluid management methods in patients with severe lung injury provide important new information on the risks and benefits of patient care strategies currently used in the intensive care unit. The two studies that comprised the trial showed that for patients with acute lung injury or its more severe form, acute respiratory distress syndrome, less fluid is better than more, and a shorter, less invasive catheter is as helpful as and safer than a longer catheter for monitoring patients. The trial was conducted by scientists from the Acute Respiratory Distress Syndrome Clinical Research Network of the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health.

Investigators from the Fluid and Catheter Treatment Trial (FACTT) presented the findings May 21 at the American Thoracic Society (ATS) International Conference in San Diego. The results were also published early online concurrently by the *New England Journal of Medicine (NEJM)*. The study comparing the use of the longer pulmonary artery catheter to the shorter central venous catheter for managing patients will be published in the May 25 print issue of *NEJM*; the study evaluating fluid management strategies will appear in the June 15 print issue of *NEJM*.

Acute lung injury (ALI) and Acute Respiratory Distress Syndrome (ARDS) are life-threatening lung conditions that affect more than 190,000 people in the United States each year, based on an estimate published in the October 20, 2005, *NEJM*. Thirty percent to 60 percent of cases result in death. ALI/ARDS develops in patients who are critically ill with other diseases such as pneumonia or sepsis (severe and widespread bacterial infection), or who have sustained major injuries. Fluid builds up in the lungs, and as a result, breathing is difficult, and other organs such as kidneys, liver, heart or brain fail if they do not get enough oxygen from the blood. There is no specific drug treatment for ALI/ARDS. Patients are placed in the intensive care unit (ICU) and supported with mechanical ventilators (breathing machines) and intravenous fluids such as saline (salt water), blood, or drugs such as dobutamine to improve heart function or diuretics to increase fluid output.

"A key focus of caring for these critically ill patients is management of fluids," said NHLBI Director Elizabeth G. Nabel, MD. "Fluid management in patients with ALI/ARDS has been the subject of intense debate for decades. We now have answers to two important questions to help guide critical care specialists on the best ways to support patients with severe lung injury."

FACTT was designed to clarify: Is it better to give ALI/ARDS patients more fluids (liberal fluid management) or smaller amounts of fluids (conservative fluid management)? Is a pulmonary artery catheter (PAC) superior to a central venous catheter (CVC) for monitoring these patients? The two studies were conducted simultaneously at 20 clinical centers, with 1,000 participants randomized to receive either of the two fluid management strategies with either of the two catheters.

For the fluid management component of the study, approximately one-half (503) of the participants were assigned to receive a conservative fluid strategy and the other half (497) received liberal fluid management for 7 days. Patients were monitored continuously, and treatment was adjusted according to the study protocol based on the status of key factors measured at least every four hours. Composition of the fluids and treatments for patients in shock were left to the judgment of the physician.

At 60 days, FACTT researchers did not detect a difference in the numbers of deaths between patients receiving conservative fluid management compared to those on a liberal fluid management strategy. However, compared to the liberal fluid management approach, the conservative fluid strategy improved lung function and shortened the time that patients needed mechanical ventilation and intensive care, without increasing the risk of organ failure, the researchers report.

"Based on these results, we recommend that a conservative fluid management approach be used in patients with ALI or ARDS," said Herbert P. Wiedemann, M.D., chairman of the Department of Pulmonary, Allergy and Critical Care Medicine at Cleveland Clinic, and lead author of the fluid management paper. "Less time on the ventilator and fewer days in the ICU could translate into cost savings and lower risk for patients."

The amount of fluid in the body must be carefully monitored and adjusted to maximize lung and heart function. A conservative fluid approach limits the amount of fluids patients are given in an attempt to decrease the amount of fluid in the lungs. However, limiting fluids can strain the heart and further limit oxygen delivery to kidneys and other organs. Conversely, a more liberal use of fluids might help keep blood and oxygen flowing to other organs, but could further damage lungs by adding to the amount of fluid build-up.

"Fluid management is a complex issue, and, until now, it was not clear whether providing more or less fluids was more beneficial," noted Gordon Bernard, MD, director of the Division of Allergy, Pulmonary and Critical Care Medicine at Vanderbilt University in Nashville, and chair of the NHLBI ARDS Clinical Research Network Steering Committee. "Current trends in usual care appear to more closely resemble the liberal fluid management arm of this study — the study arm with worse outcomes. This suggests that changing usual practice and adapting more conservative fluid management would better serve ALI and ARDS patients."

In a separate but interrelated component of FACTT, investigators evaluated the safety and efficacy of a PAC compared to a CVC to guide management of patients with ALI and ARDS. Both types of catheters are used to deliver fluids to the patient and to assess heart and lung function by measuring pressures in specific blood vessels. With a CVC, a short tube is placed in a large vein. A PAC provides additional information on heart and lung function, such as the pressures in the lung and cardiac output, because the catheter passes through the heart and into a large artery in the lung. Because the PAC is more invasive, concerns had been raised about whether increased risks for other complications outweigh the benefits of the device.

In FACTT, PAC-guided therapy did not improve survival or organ function compared to CVC. After 28 days in the study, the numbers of ventilator-free days and ICU-free days also were similar between the two groups. However, participants in the PAC group had twice as many complications related to catheters compared to those in the CVC group.

"The PAC did not provide any additional benefit over CVC to patients with acute lung injury," noted Arthur P. Wheeler, MD, Associate Professor of Medicine, Vanderbilt University Medical Center, and lead author of the FACTT catheter study. "Patients managed with pulmonary-artery catheters are more likely to have complications such as disturbances in their heart rhythms, so we do not recommend routine use of PACs to manage patients with acute lung injury."

FACTT investigators also reported that they found no interaction between the type of catheter used and the fluid management strategy.

"The fluid management and catheter treatment study represents another key finding concerning the importance of supportive care for patients with ALI/ARDS," said Andrea Harabin, PhD, NHLBI project officer for the NHLBI ARDS Clinical Research Network. "FACTT was a large randomized clinical trial with a highly defined protocol followed under rigorous monitoring. These results are relevant to ALI patients and clinicians nationwide."

FACTT is one of six clinical trials conducted by the NHLBI ARDS Clinical Research Network, which was formed in 1994 to hasten the development of effective therapies for ALI and ARDS by evaluating new treatments and management practices. The network's first clinical trial, a ventilator management study, was stopped early in 1999 when data showed that death rates were lowered by approximately 25 percent among patients receiving small breaths of air from the mechanical ventilator compared to patients receiving large breaths of air, which were the standard of care at that time. The results have been heralded as signaling a new era of research and management of the critically ill. Recently published results from another ARDS Network study showed that corticosteroids do not improve survival and may increase complications in patients with late-stage ARDS.

For more information:

Acute Respiratory Distress Syndrome (for patients and the public)
http://www.nhlbi.nih.gov/health/dci/Diseases/Ards/Ards_WhatIs.html

ARDS Clinical Research Network
<http://www.ardsnet.org/index.php>

To interview Dr. Harabin about this study, please contact the NHLBI Communications Office, (301) 496-4236 or nhlbi_news@nhlbi.nih.gov. To reach Dr. Wiedemann, please contact Kate Nagel at Cleveland Clinic's Department of Media Relations at 216-445-6472 or nagelk@ccf.org. To reach Dr. Bernard or Dr. Wheeler, please contact John Howser at the Vanderbilt University Medical School Public Affairs Office at (615) 322-4747.

Part of the National Institutes of Health, the National Heart, Lung, and Blood Institute (NHLBI) plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep

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