

Condition CRITICAL

Is the right-heart catheter dangerous?

By KATHLEEN FACKELMANN

The scene: an intensive care unit in Anytown, USA. Doctors are inserting a device known as a right-heart catheter into a critically ill patient's pulmonary artery. The catheter gives doctors crucial information on how well the heart and lungs are working.

This scene is played out in hospitals every day. Yet a new study provides a chilling view of the practice. It suggests that each year, the right-heart catheter may play a role in the deaths of 23,000 people in the United States.

The American Heart Association's council on clinical cardiology says the report's conclusions appear "disturbing at first" but goes on to call the study "flawed." The report's authors acknowledge the study's design difficulties but contend that it is the best research to date on the right-heart catheter. Most researchers and doctors are calling for a randomized trial of the device. Such trials are expensive, however, and so far, no one has stepped forward to shoulder the bill.

Failure to undertake such a trial, warns an editorial accompanying the report in the Sept. 18 *JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA)*, raises the specter of an outright ban on the right-heart catheter, a move that would face heavy opposition from critical-care specialists.

Although many questions about the right-heart catheter remain unanswered, the study has clearly ignited a firestorm of debate.

Here's how a right-heart catheter works. First, a doctor exposes a vein in the neck or groin of a seriously ill patient. The physician inserts a plastic catheter into the vein and slowly guides the slender tube into the bloodstream. A tiny balloon on the tip of the catheter is inflated to float the device into the pulmonary artery, which leads from the heart to the lungs.

Once in place, the catheter relays information on blood pressure, blood flow, and oxygen concentrations in the blood. These data tell doctors whether

the heart is pumping effectively. Doctors use the information as a blueprint for therapy; for example, they may give the patient a drug that enhances the heart's pumping power. Doctors also use the catheter to monitor the patient's progress, sometimes leaving the device in place for several days.

Like many other medical products, the catheter was marketed before the Food and Drug Administration received its

and his team decided to design a study that would adjust for that bias.

The researchers began their inquiry by collecting data on 5,735 people who had been treated in an intensive care unit in one of five participating U.S. medical centers. The patients had been diagnosed with a serious illness such as heart or respiratory failure. Doctors had given 2,184 of the group a right-heart catheter.

The researchers tabulated information on each patient's age, education, income, insurance status, and sex. They also noted each patient's primary diagnosis, as well as any secondary illness. From the data, the team created a so-called propensity score, which rates each patient according to severity of illness.

Accounting for severity of illness made this study more powerful than the earlier ones. The

researchers could tell whether excess deaths in a group of patients were attributable to the treatment rather than to a more severe original disease.

Connors and his team would not have had to bother with a propensity score if they had conducted a large, randomized trial of the right-heart catheter. In such a study, researchers would have assigned half the participants to a group that got the catheter and half to a group that did not. That random sorting leads to groups with similar patients, on average. Thus, it would be unlikely that patients with the most severe illness would be concentrated in the group monitored with right-heart catheters.

Why didn't Connors and his colleagues conduct a randomized trial of the right-heart catheter? To date, U.S. physicians have refused to participate in such a trial because it would require them to withhold the catheter from some critically ill patients—a course they believe would be unethical.

So, like other researchers before them, Connors' team simply studied the data on each patient's progress after a physician had decided to use or not to use a right-heart catheter.

Still, the propensity score made Connors' work an observational study with a

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mandate to scrutinize new medical devices. Thus it has never been subjected to the rigorous testing that drugs must go through in order to gain approval. Indeed, there's no proof that the right-heart catheter offers patients any clear advantage. Nonetheless, critical-care specialists note that many people who receive a catheter do get better.

More than 1 million such catheters are sold in the United States. Annual costs associated with their use in intensive care units exceed \$2 billion.

Troubled by the lack of a definitive study on the safety and efficacy of the right-heart catheter, Alfred F. Connors Jr. of the University of Virginia School of Medicine in Charlottesville and his colleagues sought funding from the Robert Wood Johnson Foundation to begin the recently published *JAMA* study.

They knew that two previous studies had hinted at problems with the device. Both showed that people who had received a right-heart catheter risked dying sooner than similar patients who went without the device.

Those studies had been largely discounted because they had not adequately accounted for the fact that people who get the right-heart catheter tend to be sicker than those who don't. Connors

difference. The team's statistical analysis of the entire group of patients revealed that people who got the right-heart catheter ran a 21 percent greater risk of dying within 30 days than similar patients whose treatment did not include the catheter.

To make sure they were adjusting adequately for severity of illness, the team did a second computation. The researchers looked for matches between patients who received the right-heart catheter and peers who did not. For 1,008 of the patients with catheters, they found a nearly identical peer having the same type of disease and the same propensity score. When they ran a statistical analysis on the matched sets, they found that people who had received the right-heart catheter had a 24 percent greater risk of dying within 30 days than those who did not get the device.

The researchers found no subgroup—by symptoms, sex, or age—that appeared to benefit from the catheter.

"It wasn't what I expected to find," Connors says. He goes on to say, though, that further study may very well uncover such people.

The research also demonstrated that people who were treated with the catheter incurred greater expenses than their peers. The average cost per hospital stay was \$49,300 for people who got the right-heart catheter and \$35,700 for those who did not.

If the study's conclusions are correct, what's behind the increased death rate? The study itself doesn't answer that question; however, the researchers point to several possibilities.

The first is that the catheter itself heightens a critically ill patient's chance of dying. One possible complication is the risk of bacterial infection of the catheter. Previous studies have shown that of 1,000 people who get a right-heart catheter, about 60 develop such an infection, and 18 die as a result.

Nobody denies that hazard. Many doctors simply believe that the benefits of the right-heart catheter outweigh such risks. The JAMA study calls that risk-benefit equation into question.

The second possibility is that the right-heart catheter is a marker for a more aggressive style of practicing medicine. It may not be the right-heart catheter but other procedures that go along with it that boost the death rate. Doctors who are likely to rely on the catheter, for example, may submit their patients to other invasive, and risky, procedures.

"The question really is—is doing more always good for the patient?" Connors asks. "I can't answer that from this analysis. But one possible explanation is that

it isn't."

Finally, the researchers point to a third possibility. Doctors rely on the right-heart catheter to guide their choice of therapy, but the therapy selected may not work. For example, when the catheter identifies a low cardiac output in a patient, doctors respond by giving drugs that boost the heart's pumping ability. But is that the right approach?

"It may be that increasing [cardiac output] inappropriately may cause harm," says James E. Dalen, a cardiologist at the University of Arizona Health Sciences Center in Tucson and an author of the editorial in JAMA. "Now that's just a potential," he says, though noting that it is a frightening possibility.

Despite the study's strength, almost everyone agrees that it cannot take the place of a randomized trial. "This is a well-done study," says Bart

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Chernow, president of the American College of Chest Physicians and a critical-care specialist at Johns Hopkins Medical Institutions in Baltimore. Yet the observational design may lead to false conclusions, he cautions.

"There's no substitute for a randomized trial," agrees David H. Spodick at the University of Massachusetts Medical School in Worcester. In 1980, Spodick had called for a randomized trial of the right-heart catheter. "I've been in this fight for years," he says.

The JAMA editorial concurs: "We believe that it is imperative to determine if [right-heart] catheterization benefits or harms critically ill patients." It urges the National Heart, Lung, and Blood Institute (NHLBI) in Bethesda, Md., to fund immediately a randomized, controlled trial of the right-heart catheter.

Claude Lenfant, director of NHLBI, acknowledges the importance of a randomized trial, but he told SCIENCE NEWS that his agency won't fund one. Instead, he says, the organizations representing critical-care doctors should undertake such a study.

Even a randomized trial may not go far enough, adds Joanne Lynn, director of the Center to Improve Care of the Dying at George Washington University in Washington, D.C. It would prove difficult to randomize styles of practice, says

Lynn, a coauthor of the JAMA study.

She advocates setting up teams that would visit intensive care units across the country. Through a painstaking process of observation and data entry, such teams might identify practices that would make the catheter safer. Such knowledge could then be disseminated to the field, she says.

The JAMA study has put the right-heart catheter on the critical list.

Indeed, the American College of Chest Physicians is so concerned, it convened a blue-ribbon panel to study the issues raised in the JAMA report. Several sessions at the group's recent annual meeting in San Francisco were devoted to discussions of the right-heart catheter, Chernow says.

Connors hopes such attention will spur physicians to participate in a randomized trial of the catheter. Indeed, a team of Canadian researchers has successfully randomized its use in an ongoing study of surgical patients. That trial has yet to be completed, lead researcher J. Dean Sandham of the University of Calgary in Alberta told SCIENCE NEWS.

Without definite answers to the questions raised by the JAMA report, critical-care physicians must remain in limbo.

Neal V. Dawson of Case Western Reserve University in Cleveland and a coauthor of the JAMA report points out that the data the right-heart catheter offers are available no other way. "It's believed to be information you can trust," he says.

Indeed, Spodick, who is semiretired, says, "I haven't pushed a catheter in a long time. But I tell you, when you do, you have the feeling: I'm getting something here."

There is no universal standard for the use of the right-heart catheter, yet many critical-care specialists are trained to use it as a matter of course, Dawson says. "From a clinical point of view, the catheter is something that people literally depend on every day." He adds, "Whether that dependence is appropriate or not is really the question we're trying to address."

What if the right-heart catheter is doing harm?

The answer to that question may leave critical-care specialists with the monumental task of reinventing their approach to care.

Connors, a critical-care specialist himself, says he understands the current confusion in the field. He has used the right-heart catheter because he believed that it was the best treatment for his patients.

"But I know in my heart that we haven't proven that benefit," he says. □