Experimental heart-valve surgery bringing hope to many

By Josh Goldstein

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In 2008, Ralph Miller's heart was failing from a faulty valve. Walking upstairs left him gasping for air. The retired railroad worker from Chester County had run out of options and would likely die within two years.

On Wednesday, Miller, now 72, was back in his barn working on one of the lawn tractors he repairs and resells, thanks to an experimental surgery at the Hospital of the University of Pennsylvania.

Miller was among several hundred patients in a clinical trial at Penn and other medical centers focusing on valve patients who were too sick for traditional open-heart surgery. Instead, Miller and some others received experimental heart valves that significantly improved survival rates after a year. The results were published Thursday in the New England Journal of Medicine.

The valves were notable for the ease in which they were implanted. Typically, the devices are put in place during open-heart surgery after a team cracks open a patient's chest.

But for this study, the device was inserted through veins or, in Miller's case, via a small incision in his chest. The trial raises the prospect that new heart valves could soon be implanted almost as easily as stents, the thin tubes that prop open clogged blood vessels.

"This is a huge home run for these patients," said Howard C. Herrmann, an interventional cardiologist at Penn who led its arm of the study along with heart surgeon Joseph E. Bavaria. "I think it is a paradigm shift for how we are going to treat these high-risk patients."

At the same time, the device increased short-term side effects, and could be challenging for less experienced medical teams to implant.

Of the 358 patients in the trial, half got the new valve, and half received the standard treatment for inoperable cases - medications and having their aortic valves opened with a balloon when needed.

After a year, about 70 percent of those who got their new valves were still alive compared with about half of those getting standard care.

"There are few, if any, things in medicine that can reduce absolute mortality by 20 percent,"
Herrmann said.

Bavaria said that between 60,000 and 70,000 patients a year undergo aortic valve replacement and repair procedures, and an additional 20,000 to 35,000 are not even considered for surgery because they are deemed too sick to survive the operation.

That last group of patients - the sickest ones - would likely be those considered for the device, called a transcatheter aortic valve, which is made of cow tissue housed in a stent and collapsed around a balloon and guide wire.

The device's maker, Edwards Lifesciences Corp. of Irvine, Calif., is seeking approval from the Food and Drug Administration in a review that will likely take 11/2 years, Bavaria said. The device is already approved in Europe.

Called the Sapien device, it costs about $28,000 in Europe, five times the cost of surgically implanted valves.

As one of the 21 centers in the trial, Penn has access to a limited number of the devices for its patients through the FDA's continued access program. Bavaria said that the Penn program can implant only four to six of the valves per month, and "well over 100 patients" are on its waiting list.

If the new valve is approved, Bavaria hopes to treat more patients.

"We have a new kind of procedure that is pretty effective, certainly a lot better than doing nothing," he said.

But the treatment is not without risk, especially early on. The study reported that in the first 30 days after the devices were inserted, nine of the patients getting the valve died, compared with five patients in the standard care group.

Moreover, during that first month, 12 patients suffered strokes - nine of them major events - compared with three for the group that didn't get the new valve.

Those patients who got the valve were also more likely to have blood-vessel complications, such as punctures and nerve damage.

None of those findings were surprising, said Bavaria and Herrmann, since the patients underwent procedures to get the valves.

Still, the early dangers were important for patients and doctors to keep in mind.

"It is an impressive trial, and it is an impressive result," said Harlan Krumholz, a Yale University cardiologist and director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, who was not involved in the study.

Still, Krumholz said, before declaring total victory, it is important to note that the trial involved a very select group of patients who got the valves implanted by teams of top surgeons and cardiologists at elite academic medical centers.

"This data is certainly strong enough to say, 'Here is a good alternative' for patients who cannot undergo surgery," he said. The short-term complications and deaths in this group of patients suggest that there might be problems when this becomes more widely available, Krumholz said.
Penn's Bavaria said he hoped some of the concerns about choosing the right patients and which doctors implant the device will be addressed by the FDA and the Centers for Medicare and Medicaid Services by limiting payments to qualified medical teams.

Ralph Miller recommends it. Two years after he got his new valve, he is no longer so easily short of breath.

"I don't want to sit down and say I'm done," Miller said Wednesday. "I want to keep busy, because if I lay up and don't do anything, I won't live."

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