

4 out of 106 heart replacement valves from pig hearts failed

June 29 2009

Pig heart valves used to replace defective aortic valves in human patients failed much earlier and more often than expected, says a report from cardiac surgeons at Washington University School of Medicine in St. Louis. This is the first report to demonstrate this potential problem, the researchers say.

Between 2001 and 2005, four out of 106 patients with the pig valves implanted in the aortic position developed severe impairment after less than four years, and the patients required surgery to replace the valves. The findings are published in the June issue of the *Journal of Thoracic and Cardiovascular Surgery*.

Lead author Jennifer S. Lawton, M.D., a Washington University cardiothoracic surgeon at Barnes-Jewish Hospital, notes that the valves are expected to last 10 to 15 years in patients over 70. All four patients who needed a "redo" operation were over 70.

"We noticed an increased incidence of this complication," says Lawton, associate professor of surgery. "We were very concerned, and we believe it is important for others to know about it. A four percent failure rate may not sound like a lot, but we would not expect that many of the valves to fail in such a short period of time."

In the four patients affected, the pig valves failed after 3, 14, 19 and 44 months. Each patient underwent a second operation to replace the defective valve with a valve made from cow heart tissue. No patient died

as a direct consequence of the pig heart valve impairment.

The pig [heart valves](#) that failed early were Medtronic Mosaic porcine valves produced by Medtronic Inc. The company indicated that the four valves that failed were not from the same production lot, the researchers report.

Pathologists at the University and at the valve manufacturer examined the failed pig heart valves. The valves' leaflets had thickened and stiffened making them much less mobile than normal, which would interfere with blood leaving the heart through the [aorta](#). The leaflets were covered with numerous bumps, but the exact nature of these tissue growths couldn't be determined. No specific cause for the valve failure was identified. The cause of early valve failure, whether it is related to patient factors or valve factors, remains unclear, the researchers say.

Estimates are that one in eight people age 75 or older in the United States have at least moderate heart valve disease, and more than 100,000 heart valve procedures are performed each year. These include procedures to either repair defective heart valves or replace them with mechanical valves or with tissue replacement valves — usually pig heart valves or valves formed from the pericardial sac of cow hearts. In general, mechanical valves tend to last longer than tissue valves, but patients who receive them have an increased risk of blood clots and must take anticoagulants.

"After valve replacement surgery, patients typically get an echocardiogram to check valve structure at three, six and twelve months and then yearly after that," Lawton says. "If symptoms such as shortness of breath, chest pain or lightheadedness occur, more frequent exams may be conducted. If patients have had a pig valve implanted, I would tell them that most likely they will be fine, but if they have symptoms they need to see their cardiologist and get an echocardiogram."

Lawton first realized there might be a problem when one of her patients developed symptoms of valve impairment and needed a new valve after about a year. That prompted her to examine the records to see if other such cases had occurred.

Cardiovascular surgeons prefer not to operate again on these patients soon after their first replacement surgery because redo operations are more difficult. Patients also often have atrial fibrillation, a history of coronary artery disease and are elderly.

"At Barnes-Jewish Hospital and Washington University, we are no longer implanting this valve, and we are waiting for further data about it," Lawton says. "We have alternatives available for our patients."

More information: Lawton JS, Moazami N, Pasque MK, Moon MR, Damiano RJ. Early stenosis of Medtronic Mosaic porcine valves in the aortic position. *Journal of Thoracic and Cardiovascular Surgery*. 2009 Jun;137(6):1556-7.

Source: Washington University School of Medicine ([news](#) : [web](#))

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