Post-approval study of transcatheter pulmonary valve completes one year

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The first post-FDA approval study of a non-surgically implanted replacement pulmonary valve showed strong short- and mid-term results for the device in a small sample of patients with certain congenital heart defects, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session.

This multi-center study of 100 patients consecutively implanted with the Melody transcatheter pulmonary valve between July 2010 and July 2012 assessed the effectiveness of the device at six and 12 months based on the percentage of patients who did not have stenosis, or narrowing, of the valve; valve leakage, known as regurgitation; or the need for additional procedures or surgeries for the valve. The study met its primary endpoint at six months, with 96.7 percent of 90 patients for whom data was available without stenosis and 100 percent without significant regurgitation or need for surgical or catheter-based intervention. Results were similar at 12 months with 94 percent (of the 87 patients for whom echo data were available and interpretable) without stenosis, significant regurgitation or need for additional intervention.

"This therapy may help to delay open heart surgery for patients," said Aimee Armstrong, M.D., associate director, University of Michigan C.S. Mott Children's Hospital Cardiac Catheterization Laboratories, and lead investigator of the study. "[Patients with certain congenital heart defects] typically require multiple open-heart surgeries throughout their lives, with each surgery resulting in greater scar tissue and higher risk for subsequent surgeries. Ultimately, delaying surgery will decrease the

number of lifetime open-heart surgeries needed, and reduce risk for these patients."

Patients were enrolled in 10 sites in a nonrandomized, prospective trial in order to test and confirm the valve's benefit to patients following FDA approval of the device in January 2010. All patients were diagnosed with dysfunctional right ventricular outflow tract conduits, which are surgically placed tubes between the right ventricle of the heart and the lungs. The FDA capped the total number of implants in the study at 100, and all patients eligible for the valve at the 10 study sites were initially included until that number was reached. Each site could implant up to 15 patients.

A total of 120 patients initially underwent cardiac catheterization for potential implantation of the valve; however, 19 could not be implanted for various reasons, such as risk for coronary compression, more extensive surgery requirements or no intervention was deemed necessary. The procedural success for the 101 implant attempts was 98 percent¬¬ (99 of 101). Of the two patients without a successful implant, one patient suffered a pulmonary hemorrhage during catheterization, and another had the valve surgically removed within 24 hours.

Of the 99 patients who were implanted with the device, nine patients did not have sufficient echocardiographic data collected at six months, and one patient withdrew from the study. Reported results for six months are based on the 90 patients and results at one year are based on 87 patients for whom echo data were available and interpretable.

Procedural adverse events were reported in 16 of the 120 patients (13 percent) who underwent cardiac catheterization for possible valve implantation and included issues such as conduit tears, vascular complications, fever, leak around the valve, arrhythmia and pulmonary edema. Within the first year of the study, there were eight adverse events

reported (8 percent): three cases of endocarditis (infection in the heart), two abnormal heart rhythm, and one each of bacterial infection, major stent fracture and blood clot in the lung.

Congenital heart defects are the most common type of birth defect in the United States, affecting an estimated one million adults and 800,000 children. Many of these defects involve the pulmonary valve, which sits between the right ventricle of the heart and the lungs.

The valve used in this study is made from a cow's jugular vein that is sewn into a metal stent. It is crimped onto a balloon catheter, which is inserted into the patient's leg and advanced to the heart. The balloon is then inflated, delivering the valve.

"At one year we are not seeing any more than mild leakage and very little narrowing of the valve," Armstrong said. "This study gives us more data – the results are comparable to those obtained in the initial U.S. investigational trial – but we will need additional follow up."

Interpretation of these results was limited due to missing or incomplete echocardiographic data for a subset of patients. Armstrong said long-term follow up is needed to determine the longevity of these valves and to better understand the incidence and cause of endocarditis in study patients. These patients will be followed for five years.

Provided by American College of Cardiology