Fixing Complex Problems Without Open-Heart Surgery

The pediatric cardiac team at Oregon Health & Science University Doernbecher Children's Hospital is the first in the region and one of a handful in the nation to implant a pulmonary heart valve without open-heart surgery. To date, four patients have received the valve in the OHSU Pediatric and Adult Congenital Cardiac Catheterization Lab. All reported immediate improvement in their energy level and stamina.

The FDA-approved device, called the Medtronic Melody® Transcatheter Pulmonary Valve, is used to replace a narrow or leaky pulmonary valve "conduit" — a tube connecting the heart to the lungs — in children and adults who previously have undergone surgery to correct a congenital heart defect. Until now, pulmonary valve replacements have required open-heart surgery. The Melody valve is inserted into a tiny opening in the leg and guided by a catheter through blood vessels into the heart. Once the valve is correctly positioned, a balloon on the end of the catheter is inflated, delivering the valve and immediately correcting blood flow.

"Children born with blocked or leaky heart valves can undergo as many as four open-heart surgeries before reaching adulthood to replace conduits that have worn out or that they've outgrown, and each time the risk goes up," said Grant Burch, M.D., director of the OHSU Pediatric and Adult Congenital Cardiac Catheterization Lab. "The Melody extends the useful life of an implanted valve conduit and is very likely to reduce the number of open-heart operations a patient might require over a lifetime. This device is not going to abolish the need for open-heart surgery, but it does provide a safe and effective alternative to surgery for many children and young adults with congenital heart disease," explained Burch.

"The remarkable thing about this procedure is that the valve is placed into the beating heart through a vein in the patient's leg. After the procedure, patients spend a night on the hospital ward and are discharged the following morning," said Laurie Armsby, M.D., associate professor of pediatric cardiology at OHSU and Burch's partner. "This device brings us closer to the goal of providing children less invasive alternatives to surgery for the treatment of congenital heart disease."

More than 1,700 patients have been implanted worldwide since the valve was approved for commercial use in Europe in 2006. According to the FDA, an estimated 1,000 U.S. children and adults with congenital heart disease will qualify for the new valve annually. Drs. Burch and Armsby are the only pediatric cardiologists in Oregon with advanced training in interventional cardiology. Together they perform more than 300 cardiac catheterizations in newborns, children, and adults with congenital heart disease each year.

The FDA approved the Melody valve under the Humanitarian Device Exemption provision, which allows for the use of devices determined to be safe and whose benefits to health outweigh the risk of injury or illness. A Humanitarian Use Device (HUD) is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The exemption is only given when there are no comparable devices available to treat or diagnose the disease or condition.

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