Surgeons pilot expandable prosthetic valves for congenital heart disease

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(Medical Xpress)—Surgeons at Boston Children's Hospital have successfully implanted a modified version of an expandable prosthetic heart valve in several children with mitral valve disease. Unlike traditional prosthetic valves that have a fixed diameter, the expandable valve can be enlarged as a child grows, thus potentially avoiding the repeat valve replacement surgeries that are commonly required in a growing child. The new paradigm of expandable mitral valve replacement has potential to revolutionize care for infants and children with complex mitral valve disease.

The surgical team, led by Sitaram M. Emani, MD, and Pedro J. del Nido, MD, of the Department of Cardiac Surgery at Boston Children's, summarized their outcomes with two patients in the October 2012 edition of *Annals of Thoracic Surgery*.

The care of patients with disease of the mitral valve—which controls the flow of freshly oxygenated blood from the heart's left atrium to its left ventricle—can be very complicated. If a child needs a mitral valve replacement, there are only a limited number of options available, all of which have one limitation in common: they have a fixed diameter and cannot grow with a child.

Thus, children who undergo mitral valve replacement must undergo additional future surgeries to have new, larger valves implanted as they outgrow their replacements. However, once implanted, fixed-diameter valves restrict growth of the "annulus"—the backbone—of the mitral
valve. This limits the size of the valves that can be implanted in subsequent repeat replacement operations.

"We prefer to repair a child's mitral valve if we can, but patients who are not candidates for repair due to severe deformity of the valve must undergo replacement," said Emani, a pediatric cardiac surgeon who specializes in cardiovascular surgery for newborns and children with complex congenital heart disease. "One challenge that cardiac surgeons have not been able to overcome is the lack of a replacement valve small enough for mitral valve replacement in newborns, which forces us to perform suboptimal surgical repairs that mandate repeat operations until the child is old enough to get our smallest replacement valve. In addition, children often outgrow a prosthetic valve within months to years after implantation, requiring multiple replacements over time."

To provide a novel and more permanent option for children needing mitral valve replacement, Emani and his colleagues developed and surgically implanted a modified version of an expandable prosthetic valve available from Medtronic, Inc., called the Melody valve, in two infants with congenital heart disease. The Melody is approved by the US Food and Drug Administration for replacement of the heart's pulmonary valve, which controls blood flow from the heart to the lungs; this is the first instance of its use as a mitral valve replacement.

"We wanted to find a solution that would allow us to expand a valve as a child grows and avoid taking them back into the operating room," Emani explained. "This modified valve can be expanded within a patient via cardiac catheterization, potentially allowing us to leave the valve in place until a patient reaches adulthood and reducing the number of operations and the risk of lung swelling related to valve leakage. It opens up the opportunity to carry out mitral valve replacement in more children and at an earlier time point than has historically been possible."
One of the patients described in the paper, a nine-month-old baby, had a mitral valve that was deemed irreparable and which Emani’s team replaced with a modified Melody valve. Several months later, the team was able to successfully expand the replacement in a cardiac catheterization procedure. When compared to a major repeat chest operation, a cardiac catheterization – which involves insertion of a fine catheter into the heart through a vessel in the groin - is much less invasive and requires less recovery time.

"Since submitting this paper, we've carried the procedure out on an additional three patients, all of whom are doing well," Emani noted. "Two of our patients have already undergone their first growth-related valve dilations, and in both, the procedure went better than expected.

"The others have gone almost a year without the need for additional surgeries, which is remarkable given the level of surgical care small children with mitral valve disease usually need," he continued.

"This work illustrates perfectly the attitude of innovation that runs deep within our cardiac surgery team," said del Nido, who is the chief of cardiac surgery at Boston Children's. "We are striving to bring about better options in every aspect of pediatric cardiac care.

"Valve care is particularly complex, requiring a team approach involving providers from imaging, surgery, intensive care and other medical subspecialties to provide the best care," del Nido added. "It's rare for single institutions to have this combination of expertise necessary to bring a novel cardiac technology to pediatric patients."

Provided by Children's Hospital Boston

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