Medtronic's Transcatheter Offers Encouraging Results

Clinical trial results published in this week's *Journal of the American College of Cardiology (JACC)* describe six-month outcomes for patients using the Melody® Transcatheter Pulmonary Valve from Medtronic, Inc. The valve is implanted through a catheter procedure instead of open-heart surgery in patients with congenital heart disease affecting the function of their pulmonary valve.

The first-of-its kind device is currently under review by the U.S. Food and Drug Administration for approval of a humanitarian device exemption based on evidence of safety and probable benefit. "The Melody transcatheter valve is a viable procedural alternative designed to reduce the number of invasive surgeries and their associated risks," said Dr. Evan Zahn, director of cardiology at Miami Children's Hospital's Congenital Heart Institute and lead author of the published study. "It represents an exciting breakthrough for individuals who typically require numerous open-heart surgeries during the course of their lifetime."

The study is the first prospective, multi-center trial conducted to evaluate the implantation of the Melody valve. The JACC article reports procedural success in 97 percent of patients; encouraging immediate and six-month patient outcomes with improvements in heart and valve function; and overall acceptable study safety outcomes with no deaths or long-term procedure-related medical complications. "Our goal is to provide effective treatment options for patients with congenital heart disease, and the Melody Pulmonary Transcatheter Valve is an important part of our strategy to develop and deliver transcatheter therapies for diseased valves in all positions of the heart," said Dr. John Liddicoat, vice president and general manager of the Structural Heart division, part of the CardioVascular business at Medtronic.

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