Research Project Description
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CRC Course

A. Study Purpose and Rationale

Transcatheter pulmonary valve implantation (TPVI) is a well-known, non-surgical therapeutic intervention for patients with right ventricle to pulmonary artery conduit failure as part of surgical management of Congenital Heart Disease (CHD). The Melody transcatheter pulmonary valve is authorized for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (greater than or equal to 16 mm in diameter when originally implanted). Hemodynamic and clinical improvement, low re-intervention rates, and good safety profiles have been seen on short and long-term follow up in patients with Melody Valve implantation.

Endocarditis secondary to bloodstream infection is a potentially lethal complication associated with prosthetic valve implantation. The incidence of endocarditis is rare, with reported rates of 1-2%. Endocarditis in surgical RV to PA conduits is a known and established complication. With more widespread use of the Melody valve, isolated reports of endocarditis have emerged in implanted patients. Few additional studies have been done to evaluate the incidence, risk factors, and outcomes in patients with endocarditis associated with Melody valve implantation. The aims of this study are to assess the incidence of endocarditis in our institution's large cohort of patients with Melody valve PPVI, and to evaluate the risk factors and outcomes associated with its occurrence.

B. Study Design and Statistical Analysis

Our clinical question focuses on determining the incidence, identifying the risk factors, and assessing the outcome of blood stream infection and endocarditis in our large cohort of patients who have undergone transcatheter pulmonary valve replacement with the Melody valve.

Hypothesis - While low in incidence, endocarditis associated with transcatheter Melody valve implantation is associated with prior endocarditis, long procedure time, higher RVOT median gradient at follow-up, and use of multiple stents in the RVOT.

Statistical Analysis:
Power Analysis: alpha = .05, power = .8. Expected N = 120 patients; can show significance with mean incidence of endocarditis < 3.2% or > 19%. Chi square and unpaired t-tests will be used to compare patients with endocarditis and those who do not to see what background and clinical factors are significant towards the development of endocarditis. Eventual covariate analysis, such as multivariate regression analysis, may be employed to compare significant variables.

C. Study Procedure

Retrospective review of prospectively enrolled patients in our institution's Investigational Device Exemption and Humanitarian Device Exemption protocols for Melody valve TPVI from 2007-2012 will be conducted. These patients underwent Melody valve TPVI for RVOT conduit or bioprosthetic valve dysfunction as outlined in previously reported studies.

Prospectively collected data included patient demographics, associated cardiac conditions, medical comorbidities, catheterization data at implantation, and pre and post-implantation studies such as imaging and electrocardiograms. Retrospective data from these patients' medical records that will be reviewed and analyzed include items from physician notes, and laboratory studies to determine rates of blood stream infection and endocarditis as defined by the Duke criteria. Electrocardiograms, echocardiograms, and chest x-rays obtained at routine follow-up visits conducted at 1 month, 3 months, 6 months, 1 year, and yearly thereafter will be reviewed. Cardiac catheterization reports will also be re-reviewed.

D. Study drugs

Not applicable

E. Medical device

Medtronic Melody Transcatheter Pulmonary Valve (Model PB10) and Medtronic Ensemble Transcatheter Valve Delivery System (NU10)

F. Study Questionnaires

Not applicable

G. Study Subjects

All patients implanted with a Melody valve from 2007 – present.

H. Recruitment of subjects

All patients were part of an HDE/IDE study conducted at Columbia University Medical Center.

I. Confidentiality of the study

During data collection the name and MRN of each patient will be available to the investigators. After data collection is complete all data will be de-identified.

J. Potential conflict of interest

None

K. Location of study

Columbia University Medical Center

M. Potential benefits

In identifying risk factors for endocarditis in patients with Melody valve implantation, further measures can be taken to reduce the incidence of bloodstream infections – including more stringent patient selection and procedural modifications.

N. Alternative therapies

Surgical repair of RV to PA conduit

O. Compensation of Subjects

Not applicable

P. Costs to Subjects

Not applicable

Q. Minors as Research Subjects

Chart review and data analysis of Melody valve implantation in children will be conducted. Little to no risk is imposed on the children involved in this study.

R. Radiation or Radioactive Substances

Not applicable

References:

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3. Romeih S, Kroft LJ, Bokenkamp R, Schalij MJ, Grotenhuis H, Hazekamp MG, Groenink M, de Roos A, Blom NA. Delayed improvement of right ventricular diastolic function and regression of right ventricular mass after percutaneous pulmonary valve implantation in patients with congenital heart disease. *Am Heart J*. 2009;158:40–46.
4. Lurz P, Coats L, Khambadkone S, et al. Percutaneous pulmonary valve implantation: impact of evolving technology and learning curve on clinical outcome. *Circulation* 2008;117:1964e72.
5. Buber J, Bergersen L, Lock JE, et al. Bloodstream Infections Occurring in Patients With Percutaneously Implanted Bioprosthetic Pulmonary Valve, A Single-center Experience. *Circ Cardiovasc Interv* 2013; 6(3):301-10.