

## **Melody Valve in the Mitral and Tricuspid Position**

This multi-center, retrospective study will review the surgical histories of patients who have had a melody valve inserted into the mitral or tricuspid position. We will also review clinically indicated diagnostic tests for their ventricular and valvar function.

This study will help us to better understand the challenges and successes of treatment for this subpopulation of pediatric patients. Evaluating and identifying potential predictors of outcomes for our pediatric Melody valve population will help inform the treatment and management that could potentially improve patient outcomes.

**Specific Aim 1:            Evaluate the diagnosis, treatment and management of patient who have received a melody valve in the mitral and tricuspid position.**

## **1.0 Background:**

This multi-center, retrospective study will review the surgical histories of patients who have had a melody valve inserted into the mitral or tricuspid position. We will also review their clinically indicated diagnostics for their ventricular and valvar function. BCH will be the coordinating center and will receive de-identified data from outside institutions who have also used the Melody valve in the tricuspid or mitral position. The Melody valve has historically been used for pulmonary valve replacements, it has been more recently used in the mitral and tricuspid positions. We would like to review the durability of the valve in these new positions.

## **2.0 Rationale and Specific Aims**

This study will help us to better understand the challenges and successes of treatment for this subpopulation of pediatric patients. Evaluating and identifying potential predictors of outcomes for our pediatric Melody valve population will help inform the treatment and management that could potentially improve patient outcomes.

**Specific Aim 1: Evaluate the diagnosis, treatment and management of patient who have received a melody vale in the mitral and tricuspid position.**

## **3.0 Inclusion/Exclusion Criteria:**

Inclusion criteria:

- Children (under age of 17 at the time of melody valve placement)
- All patients who have received a melody valve at Monroe Carell Jr. Children's Hospital at Vanderbilt University (VCH)

Exclusion criteria:

- NA

## **4.0 Enrollment/randomization:**

This will be a retrospective study therefore screening and recruitment will be limited to a medical record search of all patients who have received a melody valve in the mitral or tricuspid position.

## **5.0 Study procedures:**

Patient health information, including demographic, decision to treat, radiographic, surgical services and clinical followup data, will be collected for each patient meeting inclusion criteria from the electronic medical record originally collected for non-research purposes. Data will then be evaluated for predictive value of clinical outcomes.

## **6.0 Adverse event reporting:**

As this study only involves the review of children previously receiving a melody valve at VCH, we do not anticipate any adverse events. A potential adverse event is a breach of confidentiality. However, we will notify the IRB and appropriate regulatory agencies in a timely manner as appropriate.

## **7.0 Study withdrawal/discontinuation:**

N/A

## **8.0 Statistical considerations:**

Statistical analysis will include descriptive statistics and logistic regression models to assess the impact of data collected on clinical outcomes. As we assume a cohort of 300 patients, we will assume a normal distribution and therefore parametric statistics will be used in the analysis. Statistical significance has been set a priori at  $p < 0.05$ .

#### **9.0 Privacy/confidentiality issues:**

There is minimal risk associated with this study as this is a retrospective review of patients who received a melody valve at VCH. The risk associated includes potential breach of confidentiality. To minimize this risk access to PHI will be limited to the PI and co-investigators participating in this study. All data will be de-identified for the purposes of analysis, publication/presentation and/or dissemination of results. Additionally, all data will be kept in secure locked computers that only the research team has access to.

The primary risk in this study involves the disclosure of protected health information. There are no direct benefits to patients in this study as this is a retrospective review of clinical decision making and outcomes. However, there is potential to improve care and overall patient health in the future and therefore future patients may benefit from the results of this study.

#### **10.0 Follow-up and Record Retention**

##### **Follow-up:**

As this is a retrospective study no additional follow up data will be collected.

##### **Record retention:**

Data will be maintained for at a minimum of three years from the date the research is closed with the VU IRB. De-identified data will be retained by the PI until such time as the results are disseminated the need for data verification is complete.