Development of an International Congenital Heart Disease Cardiac Catheterization Database to Measure Long Term Outcomes

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Over the past 20 years, cardiac catheterization of patients with congenital heart disease (1 in 1000 live births/year, > 1,000,000 adults with congenital heart disease, in the US) has moved from the realm of diagnosis to therapy. > 70% of cardiac catheterizations for congenital heart disease are now therapeutic. However, there presently exists no means, at a broad international level, to analyze the number and outcomes of these therapeutic procedures in children and adults. Existing large databases, such as the one managed by the American College of Cardiology, do not address patients with congenital heart disease. As a result, our therapeutic decision making in the care of children and adults with congenital heart disease is guided by relatively small numbers of patients from single institutions rather than by evidence-based approaches.

There are significant obstacles to the development of outcome studies for catheter based techniques. One is the physical requirement of data entry. The mechanics of data submission - adding data to forms and then submitting the information in the context of a busy clinical program - doom the collection process to non-compliance and failure. Also, most of the catheter-based therapy in the US is delivered by medium-sized clinical programs (200-500 cases/year). To understand outcomes in the "real world," results from these centers have to be included. Another problem is how to empower clinicians at such programs to design and conduct clinical research through collaboration with other centers. It is important that methods are devised to minimize or remove these obstacles and facilitate the collection of cardiac catheterization data for the future of the field.

To address these problems, we took advantage of an existing congenital heart disease cardiac catheterization database used by centers around the world, PedCath™. Working with the developer, we modified PedCath™ to function as a catheterization data submission tool and developed a database to house the data at Johns Hopkins. The primary goal in the design was that very little extra data entry would be required. This is possible because PedCath™ already contains patient demographics, hemodynamic data, calculations, diagnosis, procedure and billing codes. The only supplementary data is whatever the investigators for a clinical study require. The secondary goal was to design the system so that long term follow up data (such as Echo results, etc.) for patients in a study could also be added in PedCath™.

To pilot this system, we developed the **M**id-**A**tlantic **G**roup of **I**nterventional **C**ardiology (MAGIC), a consortium of Johns Hopkins (Allen Everett and Richard Ringel), University of Virginia (Scott Lim), Duke University (John Rhodes) and Vanderbilt University (Tom Doyle) investigators. We developed data panels in PedCath™ to collect limited supplemental data, such as in a registry, and more detailed supplemental data, as in a specific clinical study, on interventions for coarctation, atrial septal defect closure and pulmonary and aortic valve stenosis. Data panels were also developed to collect follow up data for each of the studies. Once data is entered into the panel with the click of a button (red heart in Figure 1), the data is stripped of

HIPAA identifiers and immediately transferred by FTP (file transfer protocol) to the data warehouse at Johns Hopkins for storage and analysis by the investigators. The database at Johns Hopkins performs automated queries, with summary data analysis of each study emailed weekly to all investigators for review.

MAGIC's mission is to determine the long term outcomes of therapeutic interventions in the cardiac catheterization laboratory. To address this mission, MAGIC was designed as an open consortium with study proposals initiated by individual investigators, with approval by an Oversight Committee composed of representatives of all the participating institutions. Our goal is to add as many additional US and International Centers as wish to participate and have participating centers submit new protocols for study.

The significance of efforts such as MAGIC and the CCISC Project, spearheaded by Tom Forbes to study coarctation of the aorta, is that they allow comparison of present and future therapies. This information is important at many levels, from facilitating FDA approval of new devices to defining the best approach/device for therapy with the lowest complication rate.

In summary we have developed a facilitated process for collaborative research on the outcomes of therapeutic cardiac catheterization interventions. Based on the estimates from the current participants in MAGIC, if 50 centers were members, we could study the outcomes of more than 6,000 therapeutic interventions a year. That's some really BIG MAGIC.

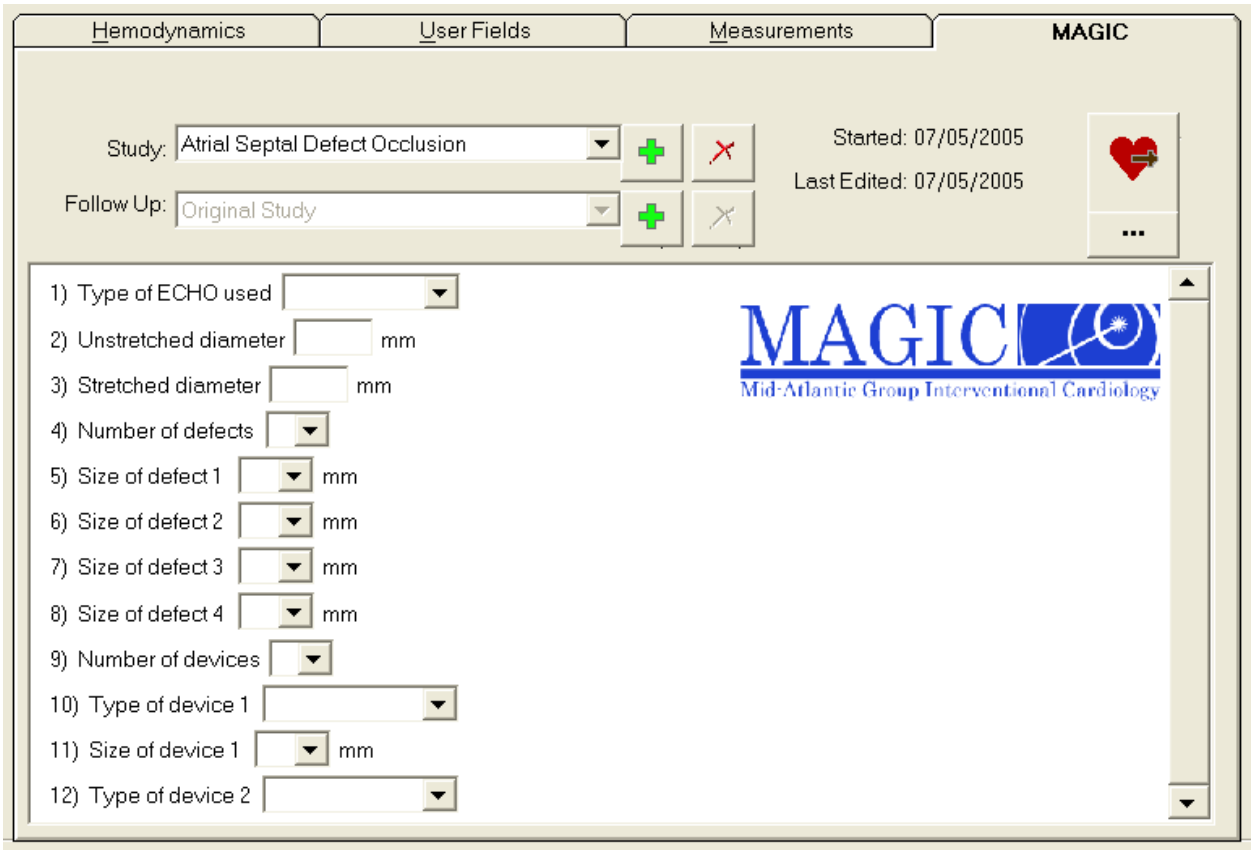

Figure 1. Supplemental data entry panel in PedCath™ for the MAGIC ASD closure study. 12 of 20 ASD study questions are shown. Once data is entered, a mouse click on the heart and arrow button on the top right transmits the data to the database. Follow up data is entered in the same panel for each case by a mouse click on the green plus sign next to follow up and then transmitted to the database in the same manner.