

# International Fetal Cardiac Intervention Registry

## A Worldwide Collaborative Description and Preliminary Outcomes



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### ABSTRACT

**BACKGROUND** Invasive fetal cardiac intervention (FCI) has been reported in single-institution series, promoting technical and physiologic success.

**OBJECTIVES** This study describes the creation of an international registry of cases presenting for FCI, intended to compile technical and outcome data from a multicenter cohort.

**METHODS** For this initial analysis, the entire database of the International Fetal Cardiac Intervention Registry (IFCIR) was queried for details of diagnoses, procedures, and outcomes. Maternal-fetal dyads from January 2001 through June 2014 were included.

**RESULTS** Eighteen institutions submitted data by data harvest. Of 370 cases entered, 245 underwent FCI: 100 aortic valvuloplasties from a previous single-center report (excluded from additional reporting here), an additional 86 aortic and 16 pulmonary valvuloplasties, 37 atrial septal cases, and 6 unclassified cases. FCI did not appear to affect overall survival to hospital discharge. Among live-born infants with a fetal diagnosis of aortic stenosis/evolving hypoplastic left heart syndrome, more than twice as many were discharged with biventricular circulation after successful FCI versus those meeting institutional criteria but without any or successful FCI (42.8% vs. 19.4%, respectively). When fetal deaths were counted as treatment failures, the percentages were similar: biventricular circulation at discharge was 31.3% versus 18.5% for those discharged with univentricular palliation. Survival to discharge for live-born fetuses with atrial restriction was similar to that of those undergoing technically successful versus unsuccessful FCI (63.6% vs. 46.7%, respectively), although criteria for diagnosis were nonuniform.

**CONCLUSIONS** We describe the contents of the IFCIR and present post-natal data to suggest potential benefit to fetal therapy among pregnancies considered for possible intervention and support proposals for additional work. (J Am Coll Cardiol 2015;66:388-99) © 2015 by the American College of Cardiology Foundation.

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**C**ongenital heart disease, which occurs in approximately 6 of 1,000 live births (1), is the most common cause of infant death due to birth defect in the United States and other developed countries. The development of maternal-fetal surgery techniques and advances in ultrasonography technology have permitted treatment of some congenital defects during fetal life (2,3). From a historical perspective particular to cardiac intervention, in 1991 Maxwell et al. (4) published their first technically successful attempts to dilate the stenotic aortic valve in 2 mid trimester fetuses, using balloon valvuloplasty via a needle inserted in the left ventricle, aiming to prevent development of left heart hypoplasia. In 2004, a team from Boston showed feasibility and moderate success in a series of fetal balloon valvuloplasties for severe aortic stenosis (AS) (5). Other fetal cardiac interventions were subsequently described using a similar approach, specifically, balloon pulmonary valvuloplasty for severe pulmonary stenosis and pulmonary atresia with an intact ventricular septum (PS+PA/IVS) (6,7), and atrial septoplasty or stent placement for an intact or highly restrictive atrial septum in fetuses with hypoplastic left heart syndrome (HLHS) (8).

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Following this pioneering work, an increasing number of centers began offering fetal cardiac intervention (FCI), primarily for midgestation severe AS, which is thought, without intervention, to progress to HLHS by term (9). Given the rarity of suitable cases, prospective evaluation of outcomes with appropriate control groups may be extremely difficult. We therefore proposed initiation of an international registry of procedures performed to date, with options for both the retrospective and the prospective registration of candidates for fetal intervention (regardless of whether a procedure was performed). Our premise was that such a registry would allow for more rapid accumulation of combined experience with FCI than a single-center effort.

Thus, for this report, our main objective was to describe the development and introduction of a Research Electronic Data Capture (REDCap)

database of pregnant women, their fetuses, and infants evaluated at various international programs as FCI candidates. Our secondary objectives were to describe the content of the new International Fetal Cardiac Intervention Registry (IFCIR) after enrollment of most of the eligible sites and completion of their case entries and to compile data to support proposals for additional publications and trials in this area.

## METHODS

The present study is the initial report of data collected both retrospectively and prospectively in the IFCIR. It is a voluntary registry that collects pregnancy, perinatal, operative, and perioperative data for patients (maternal/fetal dyads and newborn infants) whom specialists believed would benefit from intervention based on fetal echocardiographic criteria, including those who eventually were not candidates because of other fetal noncardiac conditions or maternal conditions or preferences.

Collected data included basic demographic information, descriptive anatomic diagnoses, associated noncardiac or genetic anomalies, IFCIR-defined fetal procedures, pre-operative factors, maternal/fetal intraoperative details, FCI and post-natal surgical procedures performed, complications incurred at the time of or after fetal intervention through the remainder of pregnancy, technical success of the FCI procedure (defined as balloon dilation of the intended target structure or stent placement with patency and stable position at the conclusion of the procedure), and in-hospital neonatal/infant mortality (through to first discharge). Diagnoses and procedures were entered by clinicians and affiliated data managers. A complete list of data collected is available in the [Online Appendix](#). Procedures included periventricular fetal aortic valvuloplasty (FAV), periventricular fetal pulmonary valvuloplasty (FPV), and transatrial fetal atrial septoplasty and/or stent placement. Fetal pacemaker implantation and therapeutic hyperoxia were included in the database but were not included

## ABBREVIATIONS AND ACRONYMS

<b>AS</b>	= aortic stenosis
<b>FAV</b>	= fetal aortic valvuloplasty
<b>FCI</b>	= fetal cardiac intervention
<b>FPV</b>	= fetal pulmonary valvuloplasty
<b>HLHS</b>	= hypoplastic left heart syndrome
<b>PS+PA/IVS</b>	= severe pulmonary stenosis and pulmonary atresia with an intact ventricular septum
<b>REDCap</b>	= Research Electronic Data Capture

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