

ORIGINAL INVESTIGATIONS

# Procedural Results and Safety of Common Interventional Procedures in Congenital Heart Disease



## Initial Report From the National Cardiovascular Data Registry

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### ABSTRACT

**BACKGROUND** The National Cardiovascular Data Registry (NCDR) launched the IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry in 2010. By 2013, its patient enrollment exceeded that of other current and historical congenital catheterization registries.

**OBJECTIVES** This study sought to describe procedural results and safety of 6 common congenital interventions performed in patients enrolled during the IMPACT Registry's initial periods.

**METHODS** With specified exclusions, we compiled registry data from patients enrolled in the IMPACT Registry from January 2011 through March 2013 who underwent 1 of the following isolated procedures: device closure of atrial septal defect (ASD); device closure of patent ductus arteriosus (PDA); pulmonary valvuloplasty; aortic valvuloplasty; coarctation of the aorta angioplasty and stenting; and pulmonary artery stenting. Patient data, procedural data and results, and adverse events (AEs) were reviewed and described.

**RESULTS** In 4,152 catheterizations, 1 isolated procedure was reported. There were 1,286 single-ASD procedures, 1,375 PDA procedures, 270 "typical" pulmonary valve procedures, 305 aortic valve procedures, 671 aortic procedures, and 245 pulmonary artery procedures. The reported procedure was performed in >95% of catheterizations. Stated outcomes were accomplished in >98% of ASD and PDA procedures, but less commonly in the others, with coarctation angioplasty procedures being the least successful (51%). Reported major AE rates ranged from 0% to 3.3%; total AE rates ranged from 5.3% to 24.3%.

**CONCLUSIONS** Contemporary community practice, procedural outcomes, and safety for 6 common congenital interventional procedures are reported. These benchmarks may be compared with individual center results and historical single-center and multicenter results. (J Am Coll Cardiol 2014;64:2439-51) © 2014 by the American College of Cardiology Foundation.

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## ABBREVIATIONS AND ACRONYMS

<b>ADO</b>	= Amplatzer duct occluder
<b>AE</b>	= adverse event(s)
<b>ASD</b>	= atrial septal defect
<b>ASO</b>	= Amplatzer septal occluder
<b>AV</b>	= aortic valvuloplasty
<b>Coarct</b>	= coarctation of the aorta
<b>FDA</b>	= U.S. Food and Drug Administration
<b>MAE</b>	= major adverse event(s)
<b>NCDR</b>	= National Cardiovascular Data Registry
<b>PA</b>	= pulmonary artery
<b>PDA</b>	= patent ductus arteriosus
<b>PV</b>	= pulmonary valvuloplasty
<b>Qp/Qs</b>	= pulmonary flow/systemic flow

Most previous reports of interventional procedures in congenital heart disease have been single-center or single-device studies. Although there have been some registry-based studies, historically, congenital catheterization registries have been physician initiated and limited. The Michigan and the European PDA Coil Registries (1,2) and the VACA (Valvuloplasty and Angioplasty of Congenital Anomalies) Registry (3) closed decades ago and reported on procedures using somewhat dated technologies. The MAGIC (Mid-Atlantic Group of Interventional Cardiology) Registry (3) and the Congenital Cardiovascular Interventional Study Consortium (CCISC) (4) are active, but have limited scopes. The C3PO (Congenital Cardiac Catheterization Project on Outcomes) Registry (5), which generated several groundbreaking studies, involves a relatively limited number of study centers.

The IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry, 1 registry in the National Cardiovascular Data Registry (NCDR), was launched in 2010 (6). As of October 2013, the IMPACT Registry had 81 participating centers and enrolled >26,000 catheterization episodes of care. Because of wide congenital heart center participation, the IMPACT Registry has the potential to define community practice and contemporary practice benchmarks. Moreover, its sophistication, size, and scope give IMPACT Registry the potential to support better powered, more nuanced reviews and analyses than previous studies.

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In this report, we describe the procedural results and safety of 6 common congenital interventions performed in patients enrolled in the IMPACT Registry during its initial periods. These procedures are device closure of an atrial septal defect (ASD), device closure of patent ductus arteriosus (PDA), pulmonary valvuloplasty (PV), aortic valvuloplasty (AV), coarctation of the aorta (Coarct) angioplasty and stenting, and pulmonary artery (PA) stenting.

## METHODS

**NATIONAL CARDIOVASCULAR DATA REGISTRY.** The IMPACT Registry is an initiative of the American College of Cardiology Foundation and was previously described (7). The Registry collects data for use in development of performance and quality metrics, quality improvement programs, and peer-reviewed outcomes research focused on patients with congenital heart disease undergoing cardiac catheterizations. Demographic, clinical, procedural, and institutional data elements are collected at participating centers, entered via a Web-based platform, and collected in a secure, centralized database. A description of IMPACT Registry data elements and definitions is available online (8). When not pre-specified, definition of other aspects of data elements was left to the discretion of participating centers.

The IMPACT Registry has a data quality program consistent with that described for the NCDR (9). The program ensures data completeness, consistency, and accuracy. In this study, all reported data met Registry criteria for completeness and consistency. During data collection for this study, IMPACT Registry auditing procedures were under development. Therefore, data accuracy was not verified by audits. Patient consent forms of centers enrolled in the IMPACT Registry include the provision that parties agree to allow use of clinical data in deidentified quality review. Because patient information is collected anonymously and without unique patient identifiers, the IMPACT Registry research studies meet the definition of research not requiring specific informed consent.

**THIS STUDY.** This study focuses on describing IMPACT Registry data pertaining to procedural elements and results in patients who underwent 1 of the following procedures: device closure of ASD, device closure of PDA, PV, AV, Coarct angioplasty and stenting, and PA stenting. Data from January 2011 to March 2013 were collected from a total of 4,152 catheterization laboratory visits that included 1 of the aforementioned procedures.

Only patients who had “isolated” procedures were eligible for inclusion; patients undergoing more than

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