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# Acute Success of Balloon Aortic Valvuloplasty in the Current Era

## A National Cardiovascular Data Registry Study

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## ABSTRACT

**OBJECTIVES** The aim of this study was to evaluate practice patterns and outcomes of a contemporary group of patients undergoing balloon aortic valvuloplasty (BAV) for congenital aortic stenosis (AS).

**BACKGROUND** BAV is the most common treatment for isolated congenital AS.

**METHODS** Within the IMPACT (Improving Pediatric and Adult Congenital Treatments) Registry, all BAV procedures performed between January 2011 and March 2015 were identified. Procedures were separated into those performed for critical versus noncritical AS. Outcomes were stratified into optimal, adequate, and inadequate, with optimal and adequate outcomes defining "successful" procedures. Multivariate logistic regression was used to identify patient and procedural characteristics associated with unsuccessful BAV. Mortality and adverse events rates were compared across patient cohorts.

**RESULTS** Of the 1,026 isolated BAV procedures captured in IMPACT, 718 (70%) were "successful." Success rates were 70.9% for noncritical AS (n = 916) and 62.7% for critical AS (n = 110). Multivariate analysis revealed that prior cardiac catheterization, mixed valve disease, baseline aortic valve gradient >60 mm Hg, baseline aortic insufficiency greater than mild, presence of a trainee, and multiple balloon inflations were associated with unsuccessful BAV in the noncritical AS cohort. There were no factors associated with unsuccessful procedures in the critical AS group. No procedural deaths occurred, but 2.4% of patients did not survive to hospital discharge. Adverse events occurred in 15.8% of all cases and were more frequent in procedures performed for critical AS (30.0% vs. 14.1%; $p < 0.001$).

**CONCLUSIONS** BAV is an effective treatment for congenital AS with low rates of mortality and adverse events. Patients with critical AS have a higher risk for procedure-related adverse events. (J Am Coll Cardiol Intv 2017;10:1717–26)


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**ABBREVIATIONS AND ACRONYMS**

**AI** = aortic insufficiency

**AS** = aortic stenosis

**BAV** = balloon aortic valvuloplasty

**PSEG** = peak systolic ejection gradient

Transcatheter balloon aortic valvuloplasty (BAV) is considered the first-line palliative therapy for congenital aortic stenosis (AS) at most centers. The procedure has been shown to avoid or delay aortic valve surgery in long-term follow-up studies (1–5). Technical factors of the procedure and associated outcomes have been studied since the inception of BAV in the 1980s. These early studies identified balloon-to-aortic annulus ratio >1, younger age, and unicuspid or thickened valve morphology as risk factors for worse outcomes (6–11). Additionally, higher rates of mortality and complications were documented in procedures performed for neonatal "critical" AS (12,13).

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Despite several early studies documenting the risk factors and outcomes for BAV, current procedural outcomes are less understood. Although 2 recent studies reported on the acute success of BAV, these studies were somewhat limited in their sample sizes (14,15). Given the significant improvement in catheter-based equipment (e.g., low-profile balloons, smaller sheaths) and techniques (e.g., rapid ventricular pacing, balloon-to-aortic valve annulus ratio <1) over the past few decades (14,16–18), an understanding of contemporary practice patterns and outcomes is important.

Since 2011, the IMPACT Registry has been collecting multicenter prospective data on congenital cardiac catheterizations, including BAV procedures. This registry contains the largest available dataset of patients undergoing catheterization for congenital heart disease and presents a unique opportunity to study outcomes of patients undergoing BAV. The aim of this study was to describe practices and acute outcomes of BAV in the current era, using the IMPACT Registry. In addition, we sought to evaluate factors associated with acute outcomes and complications.

## METHODS

**STUDY POPULATION.** The IMPACT Registry, part of the National Cardiovascular Data Registry, is an initiative of the American College of Cardiology Foundation and is focused on patients with congenital heart disease who undergo cardiac catheterization (19). Demographic, clinical, procedural, and institutional data variables are voluntarily entered by participating centers using a Web-based portal, and data are then collected in a secure, centralized database. Data entered in version 1.0.1 of the IMPACT Registry were used for this study. A complete description of data variables captured by the IMPACT Registry version 1.0.1 can be found at https://www.ncdr.com/WebNCDR/docs/default-source/public-data-collection-documents/impact_v1_datacollectionform_1-0-1.pdf?sfvrsn=2. This study was performed using deidentified data from the IMPACT Registry and thus meets criteria for research not requiring specific informed consent. The collected data are subject to rigorous quality assurance standards set by the Data Quality Program for all National Cardiovascular Data Registry registries, and auditing procedures were developed during the study time frame (20,21).

Standardized and pre-specified procedural information collected for BAV procedures within the IMPACT Registry were included in the study. The technical aspects of BAV have been previously described (8,9,12). Each procedure was performed at the discretion of the operator. Echocardiographic imaging is most commonly used to evaluate AS in the clinical setting, and BAV is performed under fluoroscopic guidance with angiography used to evaluate immediate outcomes (22). Data were collected from January 2011 through March 2015. Only data meeting pre-specified criteria by the National Cardiovascular Data Registry for completeness and accuracy are included in analytic datasets and used for quality reporting back to participating sites (19). Procedures with missing data fields for study outcomes were excluded from analysis. In an effort to describe the outcomes attributed to BAV, patients were excluded if another catheter-based intervention was performed in concert. Patients were also excluded from the study if they were diagnosed with single-ventricle disease or were receiving extracorporeal membrane oxygenation support at the start of the procedure.

The patient population was subdivided by diagnosis into either critical AS or noncritical AS. Critical AS was defined by patients who were <1 month of age at the time of the procedure and receiving prostaglandin infusion within 1 day of the catheterization date. Procedural data for BAV collected by the IMPACT Registry include the catheter-measured peak systolic ejection gradient (PSEG) across the aortic valve and the degree of angiographic aortic insufficiency (AI) as graded by the operator (14,15,23,24):

- none
- 1+ (mild), a small amount of contrast enters the left ventricle in diastole
- 2+ (moderate), faint opacification of the entire chamber occurs
- 3+ (moderately severe), the left ventricular chamber is well opacified and equal in density with the ascending aorta