JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
© 2016 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

VOL. 67, NO. 11, 2016
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2016.01.025

Procedural Success and Adverse Events in Pulmonary Artery Stenting

Insights From the NCDR

Matthew J. Lewis, MD, MPH,[a] Kevin F. Kennedy, MS,[b] Jonathan Ginns, MD,[a] Matthew A. Crystal, MD,[c] Alejandro Torres, MD,[c] Julie Vincent, MD,[c] Marlon S. Rosenbaum, MD[a]

ABSTRACT

BACKGROUND Risk factors associated with outcomes for pulmonary artery (PA) stenting remain poorly defined.

OBJECTIVES The goal of this study was to determine the effect of patient and procedural characteristics on rates of adverse events and procedural success.

METHODS Registry data were collected, and 2 definitions of procedural success were pre-specified for patients with biventricular circulation: 1) 20% reduction in right ventricular pressure or 50% increase in PA diameter; and 2) 25% reduction in right ventricular pressure or 50% decrease in PA gradient or post-procedure ratio of in-stent minimum to pre-stent distal diameter >80%. A separate definition of procedural success based on normalization of PA diameter was pre-specified for patients with single ventricle palliation.

RESULTS Between January 2011 and January 2014, a total of 1,183 PA stenting procedures were performed at 59 institutions across 1,001 admissions; 262 (22%) procedures were performed in patients with a single ventricle. The rate of procedural success was 76% for definition 1, 86% for definition 2, and 75% for single ventricle patients. In the multivariate analysis, ostial stenosis was significantly associated with procedural success for biventricular patients according to both definitions. The overall complication rate was 14%, with 9% of patients experiencing death or a major adverse event (MAE). According to multivariate analysis, weight <4 kg, having a single ventricle, and emergency status were significantly associated with death or MAEs.

CONCLUSIONS In our analysis, success was >75% across all definitions, and adverse events were relatively common. Biventricular patients with an ostial stenosis had a higher probability of a successful outcome. Patients who had a single ventricle, weight <4 kg, or who underwent an emergency procedure had a higher risk of death or MAE. These findings may help inform patient selection for PA stenting. (J Am Coll Cardiol 2016;67:1327–35) © 2016 by the American College of Cardiology Foundation.

Pulmonary artery (PA) stenosis is common in patients with congenital heart disease, and invasive PA procedures may account for up to 20% of all catheter-based interventions in this population (1-4). Despite the relative frequency of PA interventions, little is known about how often they yield a successful outcome. Although procedural success rates remain unclear, there is increasing evidence that adverse events may be common (3,5-8). In one of the few multicenter studies of PA interventions, 22% of patients experienced an adverse event and 10% experienced a high severity event (4). Given the high rates of procedural complications and poorly defined metrics of procedural success, additional data are needed to improve patient selection.

Listen to this manuscript's audio summary by *JACC* Editor-in-Chief Dr. Valentin Fuster.

From the [a]Division of Cardiology, Department of Medicine, Schneeweiss Adult Congenital Heart Center, Columbia University Medical Center, New York, New York; [b]Mid-America Heart Institute, Kansas City, Missouri; and the [c]Division of Pediatric Cardiology, Department of Pediatrics, Columbia University Medical Center, New York, New York. This research was supported by the American College of Cardiology's National Cardiovascular Data Registry. The authors have reported that they have no relationships relevant to the contents of this paper to disclose. The views expressed in this paper represent those of the authors and do not necessarily represent the official views of the National Cardiovascular Data Registry or its associated professional societies identified at www.CVQuality.ACC.org/NCDR.

Manuscript received November 17, 2015; revised manuscript received December 18, 2015, accepted January 5, 2016.

ABBREVIATIONS AND ACRONYMS

CI = confidence interval

MAE = major adverse event

PA = pulmonary artery

RR = risk ratio

TOF = tetralogy of Fallot

Optimizing patient selection for PA stenting is obscured by a lack of a standardized definition of procedural success, the plurality of indications, and the paucity of multi-institutional studies. Although previous studies have classified successful outcomes of PA stenosis treatment as a >50% increase in PA diameter post-procedure and/or >20% decrease in the ratio of subpulmonic to aortic pressure, this definition has never been validated and may not apply to patients with a single ventricle (9). The heterogeneity of indications also complicates comparisons between patients, especially in the setting of small, single-center studies in which lesion location and morphological severity are not standardized. As a result, it remains challenging to define the patient parameters that provide the greatest probability of a successful outcome while minimizing the risk of complication.

SEE PAGE 1336

The IMPACT (Improving Pediatric and Adult Congenital Treatment) Registry is a multi-institutional initiative to develop performance and quality metrics for patients with congenital heart disease undergoing diagnostic catheterizations and catheter-based interventions (10). In participation with the IMPACT Registry, the goal of the present study was to determine the rate of procedural success and adverse events for PA stenting according to indication and procedural characteristic.

METHODS

Data for this study were obtained from the National Cardiovascular Data Registry-IMPACT Registry, which comprises data on pediatric and adult congenital heart disease catheterizations obtained from centers that have agreed to enrollment. Specific details regarding the registry have been published previously (10,11). Definitions for exposures and outcomes of interest were pre-specified and collected in accordance with a strict quality program previously described for the National Cardiovascular Data Registry (12). For the purposes of the present study, all pertinent data related to PA procedures were reviewed before formulation of the analytic plan. Endpoints were pre-specified as defined later.

STUDY POPULATION AND EXPOSURES OF INTEREST. The study assessed IMPACT data collected during cardiac catheterizations for PA stenting in patients enrolled from January 2011 to January 2014. All patients who underwent PA stenting were eligible for inclusion. Demographic, procedural, and historical data were available for each visit. Procedure status was defined to indicate if a procedure was performed emergently, urgently, electively, or as a salvage procedure. Patients were grouped into 1 of 5 diagnostic categories. Group 1 included all patients with tetralogy of Fallot (TOF) and TOF-like anatomy (including patients with pulmonary atresia, "hemitruncus," or a TOF-type double outlet right ventricle); group 2 comprised all patients with a primary PA abnormality; group 3 included all nongroup 1 patients with a conotruncal abnormality; group 4 comprised all patients with a single ventricle; and group 5 included all other patients. Procedural indication was defined by each patient's treating physician and included PA gradient, PA flow discrepancy, right ventricular hypertension/dysfunction, angiographic narrowing, and pulmonary insufficiency. Procedure-specific data, including defect location and type, pre- and post-procedure proximal and distal PA systolic pressures, and pre- and postprocedure PA diameter, were also collected. Data pertaining to stent type were not standardized and incomplete, and they were not used in the analysis. Data on adverse events, including mortality, were collected per admission and subdivided into major adverse events (MAEs) based on severity (Table 1).

OUTCOMES AND DEFINITIONS OF PROCEDURAL SUCCESS. Given the lack of a standardized definition for PA stenting procedural success, 2 definitions were pre-specified for patients with biventricular hearts, and a separate definition was pre-specified for patients with a single ventricle (Table 2). The first definition for patients with a biventricular heart was extracted from previous studies; it represented a historical definition of procedural success and consisted of improvements in subpulmonic ventricular pressure and PA diameter.

A second definition of procedural success was created and implemented to account for potential deficits in the historical definition. In addition to metrics based on changes in ventricular pressure and PA size, definition 2 also included a >50% gradient

TABLE 1 Adverse Events Considered "Major"

• Cardiac arrest
• Unplanned surgery
• Major bleeding event
• Device embolization
• Cardiac tamponade
• Event requiring left ventricular assist device/extracorporeal membrane oxygenation (nonelective)
• Embolic stroke
• Air embolus
• Airway event requiring intubation