JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 7, NO. 5, 2014

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2014.01.159

STRUCTURAL
Clinical Research

The Learning Curve in Percutaneous Repair of Paravalvular Prosthetic Regurgitation

An Analysis of 200 Cases

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Objectives This study sought to assess the learning curve for percutaneous repair of paravalvular prosthetic regurgitation.

Background Percutaneous repair of prosthetic paravalvular regurgitation is a complex procedure. There is a paucity of data on the professional experience and tools needed to achieve optimal clinical outcomes.

Methods We examined the chronological experience of 200 patients (age 66 ± 13 years; 57% men) who underwent percutaneous closure of paravalvular prosthetic regurgitation at our institution. A sequence number of the patient was assigned as a continuous variable for analysis.

Results A total of 243 paravalvular defects (74% mitral; 26% aortic) were treated. Device delivery was successful in 92% with an average procedural time of 139 ± 47 min. The 30-day rate of major adverse cardiovascular events was 7%. With increased case experience and adoption of dedicated imaging and catheter techniques, there were decreases in procedural time, fluoroscopy time, contrast volume administered, length of hospital stay, and major adverse cardiovascular events. Procedural success remained unchanged throughout the experience. The predominant reason for procedural failure was prosthetic leaflet impingement, which accounted for 9 of 21 failed cases.

Conclusions In this single-center experience, there was evidence of a learning curve that occurred with the adoption of dedicated techniques for catheter delivery and echocardiographic imaging. In experienced operators, the potential for prosthetic leaflet impingement is the predominant limitation of the procedure. These data have implications for physician training and performance in complex structural heart disease interventions. (J Am Coll Cardiol Intv 2014;7:521–9) © 2014 by the American College of Cardiology Foundation

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Manuscript received December 11, 2013; accepted January 4, 2014.

Paravalvular regurgitation is a common complication of prosthetic valves with an estimated incidence of 3% to 6% among surgical implants (1–3). Patients can have minimal or no symptoms attributable to paravalvular regurgitation or can present with heart failure and/or hemolytic anemia. Percutaneous transcatheter methods for the treatment of paravalvular regurgitation have emerged. Data from a number of clinical registries have demonstrated the clinical efficacy of percutaneous repair, with success rates that approach 80% to 90% in selected patients (4–12). These data have led to an increasing number of patients undergoing the procedure, which can avoid the need for repeat sternotomy and the risks of open cardiac surgery (13–15).

The rapid growth of a variety of transcatheter structural heart disease interventions has spawned considerable interest in the expansion of interventional programs to address the need for physician training in this field of expertise (16). Percutaneous closure of paravalvular prosthetic regurgitation, although an efficacious therapy, is a notably complex procedure that entails a number of traditional and complex catheter techniques. Like other structural heart disease interventions, percutaneous closure requires expertise in techniques that are not commonly used in current physician training programs, leading either to the necessity of performing these cases at highly specialized centers or the need for ongoing on-site proctoring. Thus, for percutaneous closure of paravalvular prosthetic regurgitation and many structural heart disease interventions, the clinical experience required to optimize clinical outcomes remains unknown (16). To test the hypothesis that a substantial learning curve exists for this procedure and to gain insight into the professional experience needed for expertise in structural heart interventions, we examined the learning curve for percutaneous repair of prosthetic paravalvular regurgitation.

Abbreviations and Acronyms

MACE = major adverse cardiovascular event(s)

STS = Society of Thoracic Surgeons

Methods

Study population. The Mayo Clinic Institutional Review Board approved this study. Between February 1, 2004 and April 9, 2013, 203 patients were clinically evaluated and underwent percutaneous repair of paravalvular prosthetic regurgitation at the Mayo Clinic in Rochester, Minnesota. Patients with the following clinical criteria were considered for percutaneous repair: 1) severe symptoms of dyspnea or clinically significant hemolytic anemia; 2) moderately severe or severe paravalvular prosthetic regurgitation; 3) absence of active endocarditis; 4) regurgitation involving one-third or less of the circumference of the prosthetic annulus and absence of an unstable or rocking prosthesis; and 5) informed consent. Although computed tomography has been used for assessing paravalvular prosthetic regurgitation, echocardiography was the primary imaging modality for assessment in these patients. Regurgitation involving one-third of the circumference of the annulus was used as an empirical approximation. Informed consent entailed understanding the need for off-label use of approved devices, expected clinical efficacy, risks associated with the complex catheter techniques (e.g., transseptal access, apical puncture), and a detailed discussion of potential therapeutic options, including open cardiac surgery. Clinically significant hemolytic anemia was defined as anemia (typically hemoglobin <10 g/dl, usually transfusion dependent, with or without erythropoietin therapy) with laboratory evidence of intravascular hemolysis (i.e., abnormalities on peripheral smear or in serum levels of antiglobulin antibody, haptoglobin, lactate dehydrogenase, or reticulocyte count) associated with symptoms requiring blood transfusion.

Of the patients who underwent percutaneous repair, 3 declined use of their medical record for research. The remaining 200 patients provided consent to participate in the study in accordance with Minnesota statutes and form the cohort for analysis. The present cohort also includes the patients who were reported in our previous experience with this therapy (11,12).

Percutaneous repair. Our techniques for percutaneous repair of paravalvular prosthetic regurgitation have been described in detail previously (15). In brief, for patients with paramitral prosthetic regurgitation, standard transseptal access was obtained from the femoral vein with placement of a steerable sheath (e.g., 8.5- or 11-French Agilis catheter [St. Jude Medical, St. Paul, Minnesota]) in the left atrium. The deflectable tip of this catheter facilitates antegrade crossing of the defect using an angled-tip, exchange-length glide wire and placement of delivery catheters into the left ventricle, with guidance from fluoroscopy and transesophageal echocardiography. For para-aortic defects, a retrograde approach from the femoral artery typically is used, usually in conjunction with transthoracic or intracardiac echocardiography. The para-aortic defect is crossed with an angled-tip, exchange-length glide wire and steerable diagnostic coronary catheters (e.g., 6-French Amplatz Left 1). For both approaches, either a telescoped coronary guide catheter (e.g., 125-cm 5-French diagnostic inside a 100-cm 6-French Multipurpose) or a long delivery sheath (e.g., 8-French Cook shuttle [Cook Medical, Bloomington, Indiana]) can be advanced followed by placement of appropriately sized occluder device(s) (e.g., Amplatzer Vascular Plug II [St. Jude Medical]). For instances where increased support was needed to pass delivery catheters, a transcatheter rail was created. In this method, an exchange-length guidewire is snared in a chamber distal to the initial approach used for crossing the defect (e.g., snaring in the left ventricle or aorta for a wire passed antegrade from the left atrium) and exteriorized via the femoral