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Outcomes After Paravalvular Leak Closure

Transcatheter Versus Surgical Approaches

John A. Wells IV, BS, Jose F. Condado, MD, Norihiko Kamioka, MD, Andy Dong, Andrew Ritter, BS, Stamatios Lerakis, MD, Stephen Clements, MD, James Stewart, MD, Bradley Leshnower, MD, Robert Guyton, MD, Jessica Forcillo, MD, Ateet Patel, MD, Vinod H. Thourani, MD, Peter C. Block, MD, Vasilis Babaliaros, MD

ABSTRACT

OBJECTIVES The aim of this study was to compare outcomes of transcatheter intervention (TI) versus surgical intervention (SI) for paravalvular leak (PVL).

BACKGROUND Data comparing the treatment of PVL with TI and SI are limited.

METHODS A retrospective cohort study was conducted comparing baseline characteristics, procedural details, and 1-year survival in consecutive patients who underwent TI or SI for moderate or greater PVL from 2007 to 2016. The primary outcome was a composite of death, reintervention for PVL, or readmission for congestive heart failure–related symptoms at 1 year.

RESULTS Of 114 patients, 56 underwent TI and 58 underwent SI. PVL locations were mitral, aortic, and pulmonary in 69 (60.5%), 39 (34.2%), and 6 (5.3%) patients, respectively. At baseline, TI patients were older (age 71 vs. 62 years; $p = 0.010$) and had fewer cases of active endocarditis (0.0% vs. 25.9%, $p < 0.001$) than SI patients. The TI group had a shorter post-operative stay (4 vs. 8 days; $p < 0.001$), a shorter intensive care unit stay (0 vs. 3 days; $p < 0.001$), and fewer readmissions at 30 days (8.9% vs. 25.9%; $p = 0.017$). There were no differences in the primary endpoint (TI 33.9% vs. SI 39.7%; $p = 0.526$) or 1-year survival (TI 83.9% vs. SI 75.9%; $p = 0.283$) between groups.

CONCLUSIONS In this study, TI for PVL closure had comparable 1-year clinical outcomes with SI, even after adjusting for differences in baseline characteristics, with less in-hospital morbidity and 30-day rehospitalization. Although further study is needed, these findings support the increased implementation of TI for PVL closure at experienced institutions. (J Am Coll Cardiol Intv 2017;10:500–7) © 2017 by the American College of Cardiology Foundation.

Paravalvular leak (PVL) is a frequent and serious complication of both surgical and transcatheter valve replacement, occurring in 5% to 17% of surgical prosthetic valves and at even higher rates following transcatheter aortic valve replacement (TAVR) (1–3). Untreated PVL may lead to congestive heart failure and hemolytic anemia, and recent research has confirmed that PVL is associated with poor clinical outcomes (1,3–5). The PARTNER (Placement of Aortic Transcatheter Valves) II trial of TAVR in intermediate-risk patients found a significant relationship between moderate or greater PVL and late mortality after both surgical valve replacement and TAVR (3).

Until recently, surgical intervention (SI) with valve replacement or repair has been the standard approach to patients with PVL (4,6,7). SI has been successful for leak reduction, but many patients with PVL are high-

From the Division of Cardiology, Emory University School of Medicine, Atlanta, Georgia; and Division of Cardiothoracic Surgery, Emory University School of Medicine, Atlanta, Georgia. Dr. Block is a stockholder in Direct Flow Medical and a consultant for Medtronic and St. Jude Medical. Dr. Thourani is a consultant for Edwards Lifesciences, Maquet, St. Jude Medical, Sorin, and Direct Flow Medical; and is also a cofounder and stockholder of Apica. Dr. Babaliaros is a consultant for Direct Flow Medical and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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risk surgical candidates predisposed to perioperative morbidity (4,6-10), and complicated cardiac surgery has been associated with increased costs and high resource use (11,12). Transcatheter intervention (TI) for PVL closure is increasingly performed as an alternative to SI (13,14). Several descriptive series and meta-analyses have shown that TI can reduce the severity of PVL and its symptoms, with low rates of procedural complications and morbidity (10,15-18). Despite its growing application, there are limited data comparing the effectiveness of TI with that of SI (8,10,16).

We hypothesized that outcomes of TI would be similar to those of SI, and thus we compared 1-year outcomes in patients undergoing TI or SI for PVL at a single U.S. academic center.

SEE PAGE 508

METHODS

We reviewed all patients who underwent either TI or SI for clinically significant PVL at our institution between January 2007 and June 2016. Clinically significant PVL was defined as moderate or greater PVL with symptoms of heart failure and/or hemolysis (3,7,18). Standard definitions for grading PVL severity were applied (19-21). Hemolytic anemia was defined by clinical documentation of symptoms in conjunction with laboratory evidence of anemia (hemoglobin <15 mg/dl in men and <13 mg/dl in women) and hemolysis (lactate dehydrogenase >500 U/l or haptoglobin <20 mg/dl) (18). The Society of Thoracic Surgeons (STS) Predicted Risk of Mortality (PROM) score is reported for valve replacement directly from the STS online risk calculator (22). Other patient factors and outcomes were defined according to the STS Adult Cardiac Surgery Database Data Specifications, version 2.81, and the Valve Academic Research Consortium 2 consensus document, as appropriate (23,24).

For patients with multiple PVL interventions, the first intervention within the study period was counted as the index procedure. For all cases, baseline characteristics, procedural details, and procedural outcomes up to 1 year were collected from the electronic medical record. Patients were contacted by telephone follow-up for data not in the electronic medical record.

The study's primary endpoint was the composite of all-cause mortality, readmission for congestive heart failure, and reintervention for PVL at 1 year. Secondary endpoints included 30-day clinical success, post-operative complications, length of hospital stay, length of intensive care unit stay, and major morbidity. Clinical success was defined as mild or less PVL on echocardiography at the time of 1-month follow-up and 30-day hospital-free survival (18). If 1-month echocardiographic data were unavailable,

ABBREVIATIONS AND ACRONYMS

PROM = Predicted Risk of Mortality

PVL = paravalvular leak

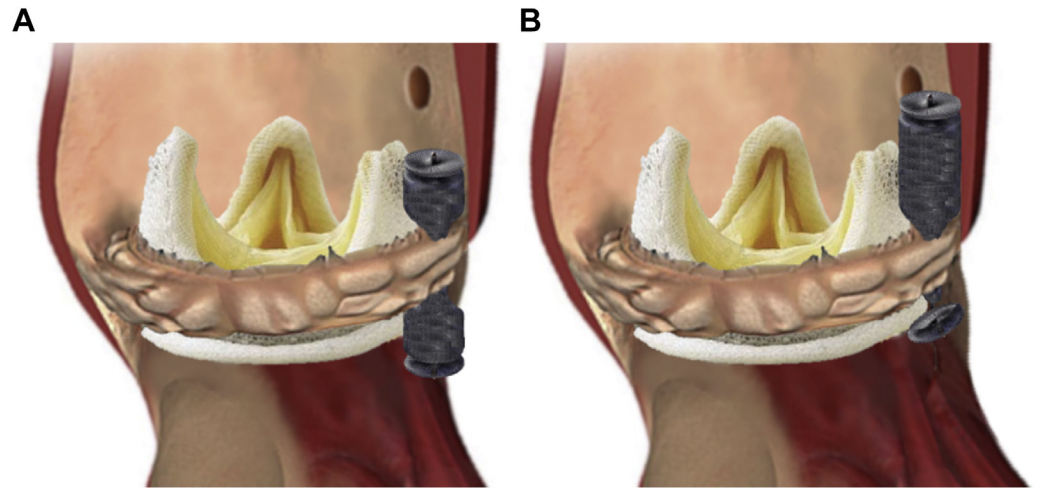
SI = surgical intervention

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

TI = transcatheter intervention

FIGURE 1 Illustrations of the Transcatheter Techniques of Paravalvular Leak Closure



(A) Waist technique, demonstrating the body of an Amplatzer Vascular Plug II device in the space between the sewing ring and the wall of the aorta. **(B)** Cap technique, demonstrating the disk of the device covering the leak space.