In which patients is transcatheter aortic valve replacement potentially better indicated than surgery for redo aortic valve disease? Long-term results of a 10-year surgical experience

Konstantinos Pechlivanidis, MD, Francesco Onorati, MD, PhD, Giuseppe Petrilli, MD, Francesco Santini, MD, Aldo Milano, MD, Salvatore Torre, MD, Daniele Calzaferri, MD, Alessandro Mazzucco, MD, and Giuseppe Faggian, MD

Background: Redo aortic valve replacement procedures have been reduced by the growing practice of trans-catheter aortic valve-in-valve procedures. We analyzed our long-term results of redo aortic valve replacement procedures during a 10-year period in an effort to define subgroups in which trans-catheter aortic valve-in-valve procedures may be better than surgery.

Methods: From 2002 to 2010, 131 redo aortic valve replacement procedures with at least 18 months of follow-up were prospectively enrolled. Hospital and follow-up outcome of the entire population and of high-risk subgroups were evaluated.

Results: Hospital mortality was 2.3%, major re-entry complications were seen in 1.5%, re-exploration for bleeding was seen in 9.2%, perioperative low cardiac output state (ie, low cardiac output syndrome) was seen in 9.9%, stroke was seen in 3.1%, prolonged ventilation was seen in 18.3%, pneumonia was seen in 4.6%, acute renal insufficiency was seen in 11.5%, intra-aortic counterpulsation (intra-aortic balloon pump) was seen in 9.2%, renal replacement therapy was seen in 4.6%, need for transfusions was seen in 60.3%, and permanent pacemaker implantation was seen in 2.3%. One hundred twenty-month actuarial survival, freedom from acute heart failure, reinterventions, stroke, and thromboembolisms were 61.5% $\pm$ 8.6%, 62.9% $\pm$ 6.9%, 97.8% $\pm$ 1.5%, 93.2% $\pm$ 3.0%, and 91.2% $\pm$ 3.2%, respectively. Patients aged >75 years had similar outcome to younger patients (nonsignificant P for all). Endocarditis resulted in higher hospital mortality ($P = .034$), low cardiac output state ($P < .0001$), intra-aortic balloon pump ($P < .0001$), prolonged ventilation ($P = .011$), pneumonia ($P = .049$), acute renal insufficiency ($P = .004$), lower actuarial survival (log-rank $P = .0001$), freedom from acute heart failure ($P = .002$), and re-intervention ($P = .003$). New York Heart Association functional class IV at admission resulted in a higher incidence of low cardiac output state ($P < .0001$), intra-aortic balloon pump ($P = .0001$), prolonged ventilation ($P < .0001$), pneumonia ($P = .015$), and a lower actuarial freedom from re-intervention ($P = .0001$). Higher need for permanent pacemaker implantation ($P = .015$) and lower freedom from acute heart failure ($P = .019$) emerged after urgencies/emergencies.

Conclusions: Redo aortic valve replacement procedures achieves good results, especially in nonendocarditic or elective cases, and young or New York Heart Association functional class I/II patients. Indeed, endocarditis significantly affects outcome. New York Heart Association functional class IV and nonelective procedures might benefit from trans-catheter aortic valve-in-valve procedures. (J Thorac Cardiovasc Surg 2014;148:500-8)

Supplemental material is available online.

Aortic valve replacement (AVR) is the most frequently employed cardiac valve operation, with more than 85,000 procedures performed yearly in the United States.[1] With the exponential growth of the geriatric population, the need for redo AVR (RAVR) is similarly growing.[2-4] Indeed, any redo cardiac surgery increases the risk of mortality and morbidity when compared with the corresponding first-time operation.[2-7] However, the extremely variable risk of mortality reported after RAVR has been attributed to different factors related to the risk profile of the enrolled population, the operator's skill, and the surgical volume of individual hospitals.[2-7] Furthermore, the very high mortality rate reported in some surgical experiences mandates identification of

From the Division of Cardiac Surgery, University of Verona Medical School, Verona, Italy.

Disclosures: Authors have nothing to disclose with regard to commercial support.
Received for publication Feb 26, 2013; revisions received Aug 1, 2013; accepted for publication Sept 10, 2013; available ahead of print Nov 1, 2013.

Address for reprints: Francesco Onorati, MD, PhD, Division of Cardiac Surgery, University of Verona Medical School, Piazzale Stefani, 1, 37126, Verona, Italy (E-mail: frankono@libero.it).

0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2013.09.031

Abbreviations and Acronymns

AVR = aortic valve replacement
EuroSCORE = European System for Cardiac Operative Risk Evaluation
NYHA = New York Heart Association
RAVR = redo aortic valve repair
TAVIV = transcatheter aortic valve-in-valve

peculiar very–high-risk subgroups.[2-7] On the other hand, the fragile profile of the geriatric population has led in past years to the widespread diffusion of transcatheter aortic valve-in-valve (TAVIV) procedures, given a reported relatively low risk of hospital mortality and morbidity.[8,9] However, midterm and late outcome of TAVIV are still unknown.[8,9]

Therefore, it was the aim of this study to analyze in-hospital and long-term results of a consecutive series of patients, and of specific high-risk subgroups, with at least 18 months of follow-up, undergoing RAVR during the past 10 years at our large-volume institution, to serve as benchmark for RAVR and to define subgroups in which TAVIV may be better than surgery or contraindicated.

METHODS

Scope and Data Collection

It was the aim of our study to evaluate the outcome of isolated RAVR or RAVR plus cardiopulmonary artery bypass graft in patients considered potentially eligible—in the current era—for TAVIV. Therefore, patients with concomitant root or mitral valve disease were not enrolled in the study. Accordingly, given the possibility for concomitant percutaneous coronary intervention during TAVIV, patients undergoing RAVR with concomitant coronary artery bypass graft were considered eligible for enrollment. Accordingly, 131 consecutive RAVR (with or without concomitant coronary artery bypass graft) patients admitted to our institution from January 2002 to June 2011, with at least 18 months of follow-up, were enrolled.

The choice to start enrollment from 2002 was done to avoid potential biases related to differences in perioperative management and care, as well as to have a picture of current RAVR practice at our institution. Follow-up was closed on December 30, 2012; therefore, the choice to truncate the enrollment at June 2011 was dictated by the intention to evaluate at least midterm outcome at 18 months. No patient was lost during follow-up, which was therefore 100% complete.

High-risk subgroups were chosen based on traditional risk factors for hospital mortality according to the European System for Cardiac Operative Risk Evaluation (EuroSCORE) score, as well as to worldwide accepted literature data,[1-4,10] provided that an acceptable sample size was at least detected for each risk group in our population. Therefore, elderly patients (aged >75 years), patients admitted in New York Heart Association (NYHA) functional class IV, urgent/emergent procedures, and endocarditic etiology were specifically analyzed. On the other hand, to define patients at potential very–low-risk after RAVR, subgroups of young patients (aged <65 years) and those admitted in NYHA functional class I or II were specifically investigated in terms of long-term outcome.

All data were collected prospectively in the institutional database and hospital charts but retrospectively analyzed. It was our institution's policy to discharge all patients to rehabilitation clinics; thus, follow-up started at our outpatient clinic at the end of the rehabilitation program, where patients were followed-up with at least once. Events that occurred during rehabilitation were collected from rehabilitation hospital charts and follow-up was then continued by cardiac surgeons at the outpatient clinic by the referral cardiologist or by the patient's general practitioner after the first surgical control. Follow-up data collection was based on patient charts of our outpatient clinic, on telephone contacts with cardiologists or general practitioners, and finally—in the absence of recent data—by direct telephone contact with the patient. Institutional review board approval and individual patient consent were waived due to the observational nature of the study.

Surgery

The choice for mechanical or biological prosthesis was left to patient preference after discussion and evaluation with a surgeon regarding the risks and benefits of each choice. Anesthesia, surgery, and cardiopulmonary bypass were standardized and reported elsewhere.[11] Preoperative chest computed tomography was performed in all patients per institutional policy, to correctly plan surgical re-entry. Surgical access consisted in a median full re-sternotomy in all patients, and no ministernotomy or alternative accesses were ever used during the study period. Peripheral cannulation was chosen when surgical re-entry via median re-sternotomy was considered high risk, but no percutaneous peripheral cannulation was employed during the study period. Postoperative care was similarly standardized and already reported.[11]

Definitions and Endpoints

Primary endpoints of the study were hospital mortality, which was defined as all-cause mortality during the index hospitalization, and follow-up mortality. The secondary endpoints were rate of hospital complications, and follow-up freedom from acute heart failure, reoperation, stroke, and thromboembolisms.[11,12]

The following hospital complications were collected: major cardiovascular re-entry complications, defined as any severe and/or life-threatening (ie, requiring reanimation and/or immediate changing of the surgical plan and/or massive transfusions >4 red packed cells) injury of major vessels or cardiac structures, occurred during surgical re-entry; revision for bleeding, defined as any reoperation during the index hospitalization, due to postoperative bleeding; need for permanent pacemaker implantation; low cardiac output syndrome, defined as hemodynamic instability for >1 hour during the intensive care unit stay, with peripheral signs of hypoperfusion despite inotropic support and adequate correction of preload, afterload, and all electrolyte and blood gas abnormalities[11]; need for intraoperative/postoperative intra-aortic balloon pump; prolonged intubation, defined as the need for prolonged (>48 hours) mechanical ventilation or acute respiratory insufficiency after extubation with need for reintubation or need for noninvasive ventilation lasting >48 hours[11]; pneumonia, defined as evidence of bacterial growth in the lung with at least 1 positive bronchoalveolar fluid lavage culture, together with new alveolar infiltrates at chest roentgenogram, irrespective of the presence of fever or leukocytosis, or as evidence of new alveolar infiltrates with leukocytosis and purulent sputum, confirmed by computed tomography scan and/or by consultation of an independent infectivologist or pneumologist[11]; stroke, defined per current guidelines[12]; and acute renal insufficiency, defined as a >50% increase over the preoperative serum creatinine value.[11] Other perioperative collected variables considered as surrogates of the quality of clinical outcome were length of intubation (expressed in hours), need for transfusions (regardless of red packed cells, fresh frozen plasma, or platelets), and length of hospitalization (expressed in days, starting from the day of surgery).

Apart from survival, other outcome variables collected during follow-up were acute heart failure, defined as any episode of acute congestive heart failure requiring hospitalization and/or optimization of medical therapy; reintervention, defined as any reoperation on the aortic valve prosthesis