Early, intermediate and late infectious complications after transcatheter or surgical aortic-valve replacement: a prospective cohort study

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Abstract

Transcatheter aortic valve implantation (TAVI) has been proposed to treat older surgical high-risk patients with severe symptomatic aortic stenosis. There are no data regarding short-term and long-term infectious complications in these patients. The objective of this study was to define the incidence, aetiology and outcome of early and late infectious complications following TAVI compared with patients >65 years old undergoing traditional surgical aortic replacement (SAR). This was a prospective observational study evaluating all consecutive patients who underwent TAVI or SAR. Follow up was performed up to 1 year after the procedure of valve implantation. Fifty-one patients underwent TAVI and were compared with 102 patients who underwent SAR. Compared with SAR patients, those who underwent TAVI had lower incidence of early post-operative (11.7% vs 26.4%, p 0.04), intermediate (5.9% vs 17.6%, p 0.01) and late (7.8% vs 11.7%, p 0.03) infections. Among SAR patients the most common infections were bloodstream infections, pneumonias, urinary tract infections and sternal wound infections. Patients who underwent TAVI had a longer survival without infection (358 days vs 312.9, p 0.006). There were no significant differences in 12-month crude survival between the two study populations. Despite a high frequency of coexisting illnesses, patients undergoing TAVI develop few infectious complications. TAVI appears to be a reasonable and safe option in high-risk patients with severe symptomatic aortic stenosis.

Keywords: Septic shock, severe aortic stenosis, staphylococcal infections, surgical valve replacement, transcatheter aortic valve implantation

Original Submission: 2 October 2013; **Revised Submission:** 19 November 2013; **Accepted:** 19 November 2013

Editor: Mical Paul

Article published online: 25 November 2013

Clin Microbiol Infect 2014; **20:** 758–763

10.1111/1469-0691.12470

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Introduction

Surgical aortic replacement (SAR) has been long considered the standard of treatment for patients with severe symptomatic aortic stenosis, and is associated with better prognosis and improvement in quality of life [1,2]. However, surgical valve replacement may result in severe complications, especially in elderly patients with multiple comorbidities. As a consequence, up to 30% of patients with severe symptomatic aortic stenosis do not undergo surgical intervention [3,4].

A novel approach, transcatheter aortic valve implantation (TAVI), has been proposed to treat older surgical high-risk patients with severe symptomatic aortic stenosis [5–7]. The Placement of Aortic Transcatheter Valves (PARTNER) trial was a randomized trial comparing TAVI with standard-of-care therapies in high-risk patients with aortic stenosis. One-year mortality outcomes from PARTNER found that TAVI was superior to standard therapy in patients who could not undergo surgery and not inferior to surgical replacement in high-risk patients [8]. No clinical studies have analysed the early and late infectious complications in patients undergoing TAVI, with the exception of a recent study that evaluated only

the post-operative infectious episodes during hospitalization [9]. The aim of our study was to define the incidence, aetiology and outcome of early and late (up to 1-year) infectious complications in a group of consecutive patients who underwent TAVI in our hospital, and to compare them with patients >65 years old undergoing traditional SAR.

Methods

Patient sample and definitions

This prospective observational study evaluated all consecutive patients who underwent TAVI from November 2009 to November 2012 in the Policlinico Umberto I of Rome, a 1100-bed teaching hospital. Patients were qualified for a TAVI procedure if they fulfilled the following criteria: presence of severe symptomatic aortic valve stenosis (valve area ≤ 1 cm^2), with or without aortic valve regurgitation and either (i) age ≥ 75 years and a logistic EuroScore $\geq 20\%$ or (ii) logistic EuroScore $<20\%$ and at least one of the following criteria: cirrhosis of liver, pulmonary insufficiency (FEV1 $\leq$ 1 L) or porcelain aorta. The patient was considered suitable to undergo a TAVI procedure if the inclusion criteria were met as confirmed by an interventional cardiologist, clinical cardiologist, cardiac anaesthesiologist and a cardiac surgeon (local heart team). Both currently commercially available devices, the Edwards SAPIEN XT balloon-expandable prosthesis (Edwards Lifesciences, Inc., Irvine, CA, USA; from January 2012) and the Medtronic Core-Valve self-expanding device (Medtronic, Minneapolis, MN, USA) were included. Only transfemoral procedures were analysed.

The following parameters were collected for each patient: demographics, clinical and laboratory findings, comorbidities, microbiological data, duration of intensive care unit stay and hospital stay, incidence of infections during hospitalization and 6 and 12 months after valve replacement, side-effects and outcome (overall mortality and mortality attributable to infection). To compare TAVI with SAR we included consecutive patients with an age ≥ 65 years undergoing SAR during the same study period, with a 1 : 2 ratio. Patients were excluded if they had an age <65 years or were lost to follow up. The selection of this population of patients was based on the need to create a homogeneous population to compare with patients undergoing TAVI. All patients were treated in the Heart Surgery Unit of our hospital. Intensive post-operative assistance was the same for both groups.

Bloodstream infections, respiratory infections, urinary tract infections and skin or soft tissue infections were defined according to the standard definitions of the Centers for Disease Control and Prevention (CDC) [10]. Bloodstream infections, including sepsis, severe sepsis and septic shock, were defined according to standard international criteria [11]. Bacteraemia was defined as the isolation of microorganisms from two or more separate blood cultures with clinical evidence of infection, and infective endocarditis was diagnosed according to the modified Duke criteria [12,13]. An infection was defined as: (i) *early post-operative* if the infection occurred within 1 month after the TAVI or surgical procedure, (ii) *intermediate* if the infections occurred between 1 month and 6 months after the procedure, and (iii) *late* if the infections occurred more than 6 months after valve replacement. All patients who underwent SAR received perioperative prophylaxis with intravenous cefazolin 2 g or acetyl-cefuroxime 2 g; patients with known methicillin-resistant *Staphylococcus aureus* (MRSA) colonization received intravenous prophylaxis with vancomycin 1 g. Screening for MRSA nasal colonization was performed before surgery, and colonized patients were treated with topical mupirocin.

Follow up was performed for all patients, by use of telephone interviews, evaluation during a new hospitalization, or ambulatory visits, when possible. Echocardiographic follow up was not mandatory, but was recommended at 1, 3, 6 and 12 months and then yearly. Data of all patients were entered in an electronic database. Written consent was obtained from the patient in all cases. The study was approved by the independent ethics committee or institutional review board of the participating centres.

Devices used

The Medtronic CoreValve prosthesis consists of a tri-leaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent frame. The profile size is 16–18 French with the current generation, three different device sizes are available for different annulus dimensions: the 26-mm prosthesis for aortic annulus sizes from 20 to 23.5 mm, the 29-mm prosthesis for annulus sizes from 23.5 to 27 mm and the 31-mm prosthesis for annulus sizes from 27 to 29 mm. The Edwards SAPIEN XT devices are balloon-expandable prostheses with a bovine pericardial tissue valve. Two device sizes were available at the time of enrolment, the 23-mm device for annulus sizes ranging between 18 and 21.5 mm and the 26-mm device for annulus sizes from 21.5 to 24 mm. The access options included only the transfemoral route. The profile size of the transfemoral vascular sheath was 16–20 Fr.

Statistical analysis

The results obtained were analysed using a commercially available statistical software package (SPSS, version 20.0; SPSS Inc., Chicago, IL, USA). To detect significant differences between groups, we used the chi-squared test or Fisher exact test for categorical variables, and the two-tailed *t* test or