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Coronary artery disease in patients undergoing transcatheter aortic valve implantation. A single center registry on prevalence, management and immediate clinical impact

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ABSTRACT

Introduction: Prevalence of coronary artery disease (CAD) ranges from 30% to 60% of all patients with aortic valve stenosis (AVS). At present, little is known about the best management of CAD in patients undergoing trans-catheter aortic valve implantation (TAVI). Aim of this study is to investigate the prevalence, management and the immediate clinical impact of CAD in this population, with a special focus on the feasibility and safety of a physiologically-guided revascularization strategy.

Methods and results: A total of 287 consecutive patients undergoing TAVI in our center were retrospectively included in the analysis. Those presenting CAD (123, 43%) were divided in three groups, according to the therapeutic strategy adopted by the operator: optimal medical therapy group (42 out of 123, 34%), preventive-PCI for angiographically significant coronary lesions (34 out of 123, 28%) and a physiologically-guided strategy (47 out of 123, 38%). The mean Logistic EuroSCORE was 31 ± 24% in the CAD population, with a higher risk profile in medical therapy group. TAVI procedural success in the overall population was 96%. Thirty-day clinical outcome showed a higher incidence of MACEs in the optimal medical therapy and the preventive PCI group (11.9% and 5.9% respectively), with no occurrence of adverse events in the FFR-guided group.

Conclusions: The best management of CAD in TAVI is still under investigation. Despite a relatively limited sample size, our findings demonstrate the feasibility and safety of a

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physiologically-guided revascularization strategy. Larger trials are needed to confirm our observations and to assess the long-term clinical impact.

Introduction

The prevalence of coronary artery disease (CAD) ranges from 30% to 60% of all patients with aortic valve stenosis (AVS) [1]. Observational studies reporting outcomes of patients undergoing trans-catheter aortic valve implantation (TAVI) revealed a prevalence of CAD in the range of 40–75% [2–4]. Current guidelines state that myocardial revascularization at the time of surgical aortic valve repair (SAVR) is a class-I recommendation in the presence of coronary stenosis ≥70%, and a class-IIa recommendation for angiographic stenosis 50–70% [5] while the best management of CAD in TAVI candidates is unclear [6]. At present, there is no evidence of increased survival or symptoms relief with a full revascularization strategy, thus raising concerns about the real functional meaning of coronary lesions incidentally found in this specific subset during the routine diagnostic workout. Furthermore, it is unknown whether percutaneous coronary interventions (PCI) should be performed before or after valve implantation, or even if a physiological assessment of lesion severity, by means of fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) should be adopted to guide myocardial revascularization. Recent studies from our institution have investigated the safety and feasibility of coronary angiography and intervention after TAVI [7], and a dedicated registry has more specifically explored the performance of FFR and iFR indexes before and after the percutaneous valve intervention [8].

The aim of the present analysis is to report the prevalence and clinical impact of CAD in a single center population of patients undergoing TAVI. Furthermore, the feasibility and safety of CAD management guided by FFR after TAVI was explored and compared to a conservative strategy of optimal medical therapy, and the percutaneous interventions indicated on the visual angiographic estimation of the coronary lesions.

Methods

All consecutive patients undergoing TAVI for severe aortic stenosis in our center have been included in the analysis. Severe symptomatic aortic stenosis was defined by the current ESC guidelines [9]. TAVI procedures were performed either by the percutaneous trans-femoral or by surgical trans-apical approach. As for the initial manufacturer's indications, vascular access was obtained with surgical approach in the first 20 patients and then percutaneous access was managed by pre-implantation of a Prostar closure device in the common femoral artery (Abbott Vascular, Santa Clara, CA, USA) in all trans-femoral cases. Cardiac surgeons managed access in trans-apical valve implantations. The choice of the aortic valve prosthesis was left to the operator's discretion. Both balloon-expandable Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA) and self-expandable Medtronic CoreValve (Medtronic Inc., Minneapolis, MN, USA) and Lotus Edge (Boston Scientific, Natick, MA, USA) prosthesis were implanted through the trans-femoral approach, while only the balloon-expandable device was adopted in the trans-apical group. Almost all patients underwent pre-TAVI imaging of the aortic root by means of contrast angiography and CT-scan. Coronary angiography was always performed before or during the TAVI procedure, at the operator's discretion. Patients presenting with CAD, defined as coronary obstruction ≥50% by visual estimation, have been further classified according to the therapeutic strategy adopted. Of note, myocardial revascularization has been consistently guided by functional assessment with FFR and iFR since January 2015, according to an internal research protocol whose features and results have been already published elsewhere [8]. Briefly, a pressure monitoring guide wire (PrimeWire, Volcano Therapeutics, Rancho Cordova, CA, USA) was advanced distally to the coronary artery stenosis after normalization; hyperemia was obtained after administration of intra-coronary bolus of 150–250 mg adenosine. An FFR value ≤0.80 was considered pathologic while an FFR value >0.80 was considered 'negative', i.e. unlikely to induce reversible myocardial ischemia according to current recommendation. iFR was measured online using the Volcano iFR computational algorithm. An iFR cut-off value of 0.90 was considered equivalent to the 0.80 FFR value for the determination of ischemia-provoking stenosis, according to recent recommendation; in case of discordance between the two techniques, revascularization was based on FFR.

Clinical outcome was obtained by consultation of our outpatient clinic data and by phone call when no documentation was available in our archives. The measured clinical endpoints were all-cause death, cardiac death, myocardial infarction (MI), ischemia-driven revascularization, stroke and the composite occurrence of these events at 30 days from the index procedure.

Statistical analysis

Summary descriptive statistics are reported as mean + standard deviation (SD), median (inter quartile range) or counts (%), as appropriate; 95% confidence intervals (CI) are added, as appropriate. Correlation among variables was determined by Pearson or Spearman correlation tests, as appropriate and expressed as *r*-value. Comparisons between continuous variables were performed using the Student's *t* test or Mann–Whitney *U* test, as appropriate. Comparisons between categorical variables were evaluated using the Fisher's exact test or the Pearson's chi-square test, as appropriate. A probability value of $p < 0.05$ was considered statistically significant. All analyses were performed with SPSS 21.0 (IBM Inc., New York, USA).