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Predictors and Impact of Myocardial Injury After Transcatheter Aortic Valve Replacement

A Multicenter Registry

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ABSTRACT

BACKGROUND Cardiac biomarker release signifying myocardial injury post-transcatheter aortic valve replacement (TAVR) is common, yet its clinical impact within a large TAVR cohort receiving differing types of valve and procedural approaches is unknown.

OBJECTIVES This study sought to determine the incidence, clinical impact, and factors associated with cardiac biomarker elevation post TAVR.

METHODS This multicenter study included 1,131 consecutive patients undergoing TAVR with balloon-expandable (58%) or self-expandable (42%) valves. Transfemoral and transapical (TA) approaches were selected in 73.1% and 20.3% of patients, respectively. Creatine kinase-myocardial band (CK-MB) measurements were obtained at baseline and at several time points within the initial 72 h post TAVR. Echocardiography was performed at baseline and at 6- to 12-month follow-up.

RESULTS Overall, 66% of the TAVR population demonstrated some degree of myocardial injury as determined by a rise in CK-MB levels (peak value: 1.6-fold [interquartile range (IQR): 0.9 to 2.8-fold]). A TA approach and major procedural complications were independently associated with higher peak of CK-MB levels ($p < 0.01$ for all), which translated into impaired systolic left ventricular function at 6 to 12 months post TAVR ($p < 0.01$). A greater rise in CK-MB levels independently associated with an increased 30-day, late (median of 21 [IQR: 8 to 36] months) overall and cardiovascular mortality ($p < 0.001$ for all). Any increase in CK-MB levels was associated with poorer clinical outcomes, and there was a stepwise rise in late mortality according to the various degrees of CK-MB increase after TAVR ($p < 0.001$).

CONCLUSIONS Some degree of myocardial injury was detected in two-thirds of patients post TAVR, especially in those undergoing TA-TAVR or presenting with major procedural complications. A greater rise in CK-MB levels associated with greater acute and late mortality, imparting a negative impact on left ventricular function.
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ABBREVIATIONS AND ACRONYMS

CK-MB = creatinine kinase-myocardial band

LVEF = left ventricular ejection fraction

NYHA = New York Heart Association

TA = transapical

TAVR = transcatheter aortic valve replacement

TF = transfemoral

VARC = Valve Academic Research Consortium

Transcatheter aortic valve replacement (TAVR) has emerged as a therapeutic alternative to surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis (AS) at high or prohibitive perioperative risk (1). Compared with conventional open-heart surgery, TAVR procedures are less invasive due to the avoidance of aortic cross-clamping and cardioplegia. However, TAVR systematically associates with some degree of myocardial injury, defined biochemically by variable increases in cardiac biomarkers (2–4). A negative clinical impact associated with a higher degree of myocardial injury post TAVR has also been suggested (2,5), and the recent Valve Academic Research Consortium (VARC-2) consensus on TAVR has established specific biomarkers cut-off values for defining clinically significant myocardial infarction post TAVR (2,6). However, a validation of these VARC definitions upon clinically relevant myocardial infarction post TAVR is still lacking.

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Prior studies evaluating myocardial injury post TAVR included limited numbers of patients and duration of follow-up, with a paucity of cardiovascular outcomes data (2–4). Also, a single transcatheter valve system (balloon- or self-expandable) and/or delivery approach were used in most previous studies (2–4). Thus, a comprehensive understanding of the factors associated with myocardial injury post TAVR in a real-world all-comers population, incorporating the true clinical impact of varying degrees of myocardial injury detected biochemically, is currently lacking. Finally, most previous studies had focused on troponin levels as a biomarker of myocardial injury, yet there are limited data regarding the impact of creatinine kinase-myocardial band (CK-MB) levels, which has undergone a more robust validation for defining periprocedural myocardial infarction in the cardiac surgery and percutaneous coronary intervention fields (7). The objectives of the present study were to evaluate the incidence, prognostic significance and factors associated with myocardial injury as determined by CK-MB elevation (including validation of the VARC-2 proposed cut-off for myocardial infarction) in a large multicenter cohort of patients undergoing TAVR with differing valve types and approaches.

METHODS

STUDY POPULATION. This was a multicenter study including 1,172 patients who underwent TAVR from March 2007 until December 2014, in different centers across North America, South America, and Europe. A total of 41 patients were excluded due to procedural death (within the first 24 h after the procedure), precluding the collection of at least one blood sample for cardiac biomarker measurements post procedure. Therefore, the final study population consisted of 1,131 patients, 486 patients (43.0%) from 3 centers in North America, 123 patients (10.9%) from 4 centers in South America and 522 patients (46.1%) from 6 centers in Europe. A balloon-expandable valve was used in 658 patients, being an Edwards-Sapien (Edwards Lifesciences Inc., Irvine, California) in 261 (23.1%), Sapien XT (Edwards Lifesciences Inc.) in 380 (33.6%), Sapien 3 (Edwards Lifesciences Inc.) in 14 (1.2%), and Inovare (Braile Biomedical, São Paulo, Brazil) in 2 patients (0.2%). Also, a self-expandable valve was used in 473 patients, being a CoreValve (Medtronic, Minneapolis, Minnesota) in 458 (40.5%), Portico (St. Jude Medical, Minneapolis, Minnesota) in 13 (1.1%), and Lotus (Boston Scientific SciMed Inc., Maple Grove, Minnesota) in 1 (0.1%). Indications for TAVR, device type and approach were based on the assessment recommendation of the heart team at each center. Data were prospectively collected in a dedicated database at each center. The first one-half of patients treated at each center were considered as early TAVR experience. Clinical outcomes for the

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