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Predictive mortality estimation in older patients undergoing TAVI

Comparison of the Logistic EuroSCORE, EuroSCORE II and STS score

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Abstract

Background

Older people with aortic valve stenosis are often denied surgical aortic valve replacement. Transcatheter aortic valve implantation (TAVI) is proven to be a less invasive alternative. At present we rely on the judgment of the Heart Team and the calculation of surgical risk scores to select TAVI candidates. Our aim is to compare the predictive value for early (procedural) and late (2 year) mortality of these surgical risk scores in TAVI patients.

Material and methods

A retrospective single center study including all patients who underwent TAVI. The Logistic EuroSCORE, EuroSCORE II, and Society of Thoracic Surgeons score were calculated for each patient. Each score was divided into low-, medium- and high risk according to their definition. The actual procedural and 2 year mortality was then compared to the predicted mortality.

Results

One hundred fifty seven patients were included. LES, ES II and STS score ranked respectively 20%, 38% and 27% as low risk, respectively 45%, 44%, 57% as medium risk and respectively 35%, 18% and 16% as high risk. The median predicted procedural mortality of the LES, ES II and STS score were 16.2%, 5.3% and 5.4% respectively. The actual procedural mortality was 8.2%. Only the STS score predicted the highest 2 year mortality in the high risk group (53%, p=0.001).

Conclusion

None of the surgical risk scores provide predictive value to estimate procedural risk and 2 year mortality in TAVI patients. Therefore, the need for a specific TAVI risk score imposes itself.

Key-words

Cardiac surgical risk scores, predictive mortality estimation, TAVI, older people

Text

Introduction

Aortic valve stenosis is the most common acquired valvular heart disorder in older people. Despite advances in cardiac surgery and low mortality rates after surgical aortic valve replacement (SAVR), up to one third of patients with symptomatic aortic stenosis are not considered for SAVR, often due to frailty or co-morbidities [1]. Transcatheter aortic valve implantation (TAVI) enables treatment of aortic valve stenosis without open heart surgery. Recently, TAVI using the balloon-expandable SAPIEN valve (Edwards LifeSciences, Irvine, CA, USA) or the self-expanding CoreValve bioprosthesis (Medtronic, Inc., Minneapolis, MN, USA) has been shown to be superior to standard medical therapy for inoperable patients and to be at least non-inferior to SAVR in (very) high-risk patients with severe symptomatic aortic stenosis [2, 3].

At present surgical risk is mainly estimated by clinical judgment of the Heart Team and by classic surgical risk scores due to lack of specific TAVI scores. Risk modeling is suggested to predict outcomes of procedures based upon patient preoperative characteristics with possible impact [4]. The three most common used risk models for SAVR are the logistic EuroSCORE (LES), the EuroSCORE II (ESII) and the Society of Thoracic Surgeons (STS) score (Table 1). The *LES* is the subsequent scoring system of the additive EuroSCORE to provide greater precision in higher-risk patients [5]. The latter was developed using operative outcomes in 14.871 patients from 128 centers in eight European countries performing cardiac surgery between September and November 1995. Subsequently, the LES has been developed in 2003 to improve risk stratification and to correct risk-overestimation. Fourteen covariates are identified to predict aortic valve mortality. Although validated for coronary artery bypass

grafting (CABG), several studies show an overrating in patients with high risk for valvular heart surgery by a factor of 3 [4].

ES II is an update of the LES to reflect better current cardiac surgical practice [6]. Outcome data on 22 381 consecutive patients undergoing major cardiac surgery in 154 hospitals in 43 countries over a 12-week period (May–July 2010) were collected.

The *STS score* is based on a 67.292 population undergoing isolated SAVR between 2002 and 2006 in 800 centers in the United States. It includes 24 covariates [7]. All three scores estimate procedural mortality, though with slightly different definitions. For the LES and STS score this means death within 30 days from operation or later than 30 days if still in hospital [8, http://riskcalc.sts.org/About%20the%20STS%20Risk%20Calculator%20v2.73.pdf]. The ES II defines mortality as death in hospital where the operation took place [6].

There is evidence that these scores are inaccurate in predicting mortality in patients undergoing TAVI [9,10].

The purpose of this study is to compare the predictive value for early and late mortality of the different risk scores (LES, ES II and STS score) in a single center TAVI population.

Materials and methods

Patients

This retrospective single center study included all patients with severe symptomatic aortic stenosis who were selected for TAVI at the University Hospital of Antwerp in Belgium from December 2007 through April 2013. All patients underwent TAVI using the self-expanding CoreValve bioprosthesis (Medtronic, Inc., Minneapolis, MN).

Assessment

The LES, ES II and STS score were calculated for each patient. Low risk was defined as <10%, <4% and <4%, medium risk as 10-20%, 4-10% and 4-10% and high risk as >20%,

>10%, >10% by LES, ES II and STS score respectively [11,12]. Survival of the patients was followed up for two years after TAVI.

Statistics

Categorical variables are presented as frequencies. Continuous variables are presented as mean (± standard deviation) or as median (Q1-Q3), depending on the distribution of the data. Survival was determined with the use of Kaplan Meier curves and differences of survival (24 months) between low, medium and high risk profile were tested based on the log rank test. All data were processed using the Statistical Package for Social Science (SPSS), version 20.0 (IBM Corporation, New York).

Results

One hundred fifty seven patients with severe symptomatic aortic stenosis were included. Median age was 82 (77-86) years old and 46% were male. The mean aortic valve area was 0.62 cm^2 (normal range: 3-4 cm^2) with a mean gradient of 43.0 mmHg (normal: < 5mmHg). Eighty four patients had associated coronary artery disease. Moreover, 48 patients underwent previous CABG and 44 patients underwent percutaneous coronary intervention in the past (Table 2).

The median predicted procedural mortality of the LES, ES II and STS score were 16.2%, 5.3% and 5.4% respectively. The procedural mortality of this TAVI population, according to the 3 definitions of the risk scores, was 8.2%. When the median predicted procedural scores of the survivors (n=144) were compared to the median predicted procedural scores of the deceased group (n=13) no significant differences were found between the LES (16.08% vs. 16.45%, p = 0.960), ES II (5.18% vs. 7.06%, p=0.430) and STS scores (5.32% vs. 5.61%, p = 0.430).

Progressive mortality over time in this TAVI population is summarized in Table 3. The 2 year mortality was 26.8%.

The LES ranked 32 patients (20%) as low risk, 71 patients (45%) as medium risk and 54 patients (35%) as high risk. The procedural mortality was respectively 6.2%, 8.5%, 7.4% (p=0.924) and the 2 year mortality was respectively 18.7%, 30.6% and 26.3% (p=0.523, Fig 1A). The ES II ranked 59 patients (38%) as low risk, 69 patients (44%) as medium risk and 29 patients (18%) as high risk. The procedural mortality was respectively 6.8%, 8.7%, 6.9% (p=0.908) and the 2 year mortality was respectively 32.7%, 24% and 21.4% (p=0.515, Fig 1B). ES II also predicted better survival in the high risk group. The STS score defined 43 patients (27%) as low risk, 89 patients (57%) as medium risk and 25 (16%) as high risk. The procedural mortality was 4.7%, 6.7%, 16% (p=0.210) and the 2 year mortality was 14 %, 25.1% and 53%, respectively. For the 2 year survival, only the STS score significantly predicted the worst survival in the high risk group (p=0.001, Fig 1C).

Factors that played a significant role in predicting mortality within 30 days in this TAVI population were peak gradient (odds ratio: 0.968 (0.939-0.998), p = 0.039) and mean gradient (odds ratio: 0.948 (0.908-0.990), p = 0.017). Other factors such as age, sex, aortic valve area, peripheral vascular disease, history of acute myocardial infarction, percutaneous coronary intervention and coronary bypass surgery were not significantly related to early mortality. None of the listed predictive factors were significantly related to long term mortality (24 months), except STS score (hazard ratio: 1.118 (1.049-1.192), p = 0.001) and baseline creatinine level (hazard ratio: 1.003 (1.001-1.006), p = 0.010).

Discussion

TAVI was considered in patients with severe symptomatic aortic stenosis who were unsuitable for SAVR. This decision was until now based on the multidisciplinary heart team

discussion, taking into account the clinical assessment, next to detailed imaging of the aortic valve, aortic root, descending and abdominal aorta and peripheral vasculature [13].

Surgical risk scores (LES, ES II, STS score) could be helpful in the discussion. In this study, three scores were compared to evaluate their predictive accuracy for mortality in a TAVI population. First, our results show that none of the three risk scores could predict actual procedural mortality, although the median ES II and the STS score in this single center TAVI population come close to the actual procedural mortality. Moreover the median LES overestimates the actual procedural mortality by a factor 2. Silaschi M et al also compared LES, ES II, STS score and 2 other risk scores (Ambler and Parsonnet scores) and found that no risk evaluation system provided acceptable predictive ability [14]. Second, if the scoring systems were divided into categories according to degree of risk patients, who were ranked as high risk with the LES and ES II, tended to have a better long-term survival. As risk scoring systems have been developed to predict expected mortality, one would expect that the higher the risk score, the higher the observed mortality. The STS score, however, correlates best with two year mortality of the high risk group in this TAVI population. On the other hand, there is no difference in survival between the low and medium risk group. Therefore, the STS score is not a good risk stratification tool for two year mortality. All three risk scores lack predictive value for two year mortality. Hemmann et al reported that the STS-score was the only independent predictor of one-year mortality in comparison with LES and ES II [15]. Moreover, the apical approach with the Edwards Sapien device was associated with a higher risk of death periprocedural due to pre-existing co-morbidities in comparison with the transfemoral approach. The long-term prognosis was comparable for both accesses. Unbehaun et al also showed that ES II and STS score aren't strong predictors for short-term survival [16]. On the other hand, Stähli et al concluded that ES II performed best in predicting short- and long-term mortality compared to LES and STS score [17].

These risk scores have some limitations. First, all three were based on data from cardiac surgery. They did not take TAVI-related risk factors into account and consequently, they were in general not accurate enough to predict prognosis after TAVI. Second, all three scores were meant to predict procedural mortality and not long-term mortality. Third, the population used to validate the risk scores was not a frail geriatric sample who suffers most commonly from severe, symptomatic aortic stenosis. In such patients the presence of geriatric syndromes (falling, dementia, malnutrition) and 'frailty', need to be considered. Frailty is not included in the present cardiovascular risk scores. When frail patients are exposed to a stressor, they are at increased risk for functional decline, developing disability or even increased mortality [18]. Therefore, risk prediction can be improved by adding simple screening tests for frailty such as the 'Frail Questionnaire' and the 'Clinical Frailty Scale' [19]. In a recent study of Kamga et al the SHERPA score was indicated as a quick and simple test for the prediction of one year survival after transfemoral TAVI with the balloon-expandable SAPIEN valve (Edwards LifeSciences, Irvine, CA) [20]. SHERPA assessed the risk of functional decline after hospitalization, which has been linked to frailty. Unfortunately, this screening tool is not yet implemented in daily practice. Therefore it is important to emphasize the participation of a geriatrician in the heart team, to improve general patient assessment.

Conclusion

Although the STS score seems to be a more reliable score index in predicting two year mortality than LES and ES II in (very) high risk patients who underwent TAVI in this study, none of the surgical risk scores provide predictive value to estimate procedural risk and 2 year mortality in TAVI patients. Therefore, the need for a specific TAVI risk score imposes itself.

Disclosure of interest

Prof Johan Bosmans is a consultant for Medtronic.

Tables and their legends

Table 1:

Variables included in cardiac surgery risk scores

STS: Society of Thoracic Surgeons score; LES: Logistic EuroSCORE; ES II: EuroSCORE II, NYHA classification: New York Heart Association; CABG: coronary arterial bypass grafting; PCI: percutaneous coronary intervention

Table 2:
Patients characteristics

Categorical data are presented as frequencies N and percentage between brackets, continuous variables as mean ± SD or as median (Q1-Q3)

BMI: Body Mass Index; LES: Logistic EuroSCORE; STS: Society of Thoracic Surgeons; AVA: aortic valve area; CABG: coronary arterial bypass grafting; TIA: transient ischemic attack; COPD: chronic obstructive pulmonary disease

Table 3:
Progressive 2 year mortality in 157 patient undergoing TAVI

TAVI: Transcatheter aortic valve implantation

Legends of figures
Fig 1:

Actual survival according to LES (A), ES II (B) and STS score (C) categorized by low, medium and high risk.

LES: logistic EuroSCORE; ES II: EuroSCORE II; STS score: Society of Thoracic Surgeons score, cum survival: cumulative survival.

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