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Overestimation of the Operative Risk by the EuroSCORE Also in High-Risk Patients Undergoing Aortic Valve Replacement with a Stentless Biological Prosthesis

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ABSTRACT

Background: The EuroSCORE generally overestimates the risk of standard aortic valve replacement (AVR). The predictive value of this risk algorithm for high-risk patients undergoing stentless AVR is unclear; therefore, we compared the EuroSCORE prediction with our results in this patient population.

Methods: One hundred thirty-two patients with a logistic EuroSCORE of at least 10 (mean, 25) underwent primary isolated AVR with a stentless bioprosthesis between January 2004 and December 2007. Seventy-one patients (54%) were octogenarians or nonagenarians, 62 (47%) had a reduced left ventricular ejection fraction, and 46 (35%) had an extracardiac arteriopathy.

Results: Maximum/mean pressure gradients for the implanted valve prostheses were 19/11 mm Hg, and the mean regurgitation grade was 0.06. Stroke occurred in 3% of the patients, and a permanent pacemaker was required in 3%. The 30-day mortality rate was 8%. Another 5% of the patients died after the 30th postoperative day but within the same hospital admission. The predicted mortality was almost 100% greater than the observed mortality.

Conclusion: We observed a mortality rate that was 50% lower than that predicted by the logistic EuroSCORE. Therefore, one should not hesitate to use stentless valves in high-risk patients because the EuroSCORE greatly overestimates their surgical risk.

INTRODUCTION

Surgical aortic valve replacement (AVR) has been an efficient therapy to treat aortic valve disease since its introduction in 1960 [Harken 1960]. It provides symptomatic relief and improves long-term survival [Bonow 1998]. Other treatment options, such as medical management [Bonow 1998] and balloon valvuloplasty [Liberman 1995], have been evaluated; however, these options have turned out to be associated with a poor prognosis and therefore have only a palliative character. Recently, transcatheter valve implantation has been developed as another alternative to standard AVR for high-risk patients. Patients selected in a study to gain clinical experience with this technique were chosen arbitrarily or on the basis of the logistic EuroSCORE [Cribier 2006; Marcheix 2007; Ye 2007]. It has been shown, however, that even these "high-risk" patients can successfully undergo standard AVR, and the predictive value of the logistic EuroSCORE for standard AVR in general has been doubted [Dewey 2008; Grossi 2008]. Stentless aortic bioprostheses offer superior hemodynamic results with excellent left ventricular mass regression, an important predictor of cardiovascular events [Borger 2005]; however, the implantation technique is more demanding, leading some surgeons to choose not to implant them, especially in high-risk patients. Therefore, we evaluated our institution's results with high-

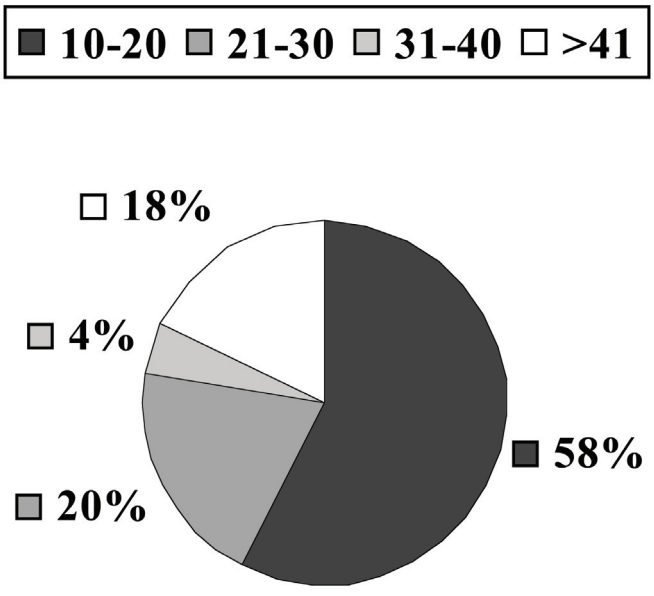

Figure 1. Diagram showing percentage of patients in classes of the logistic EuroSCORE.

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Table 1. Patient Characteristics according to EuroSCORE Criteria*

Characteristic	Patients (n = 132), n (%)
Age ≥80 y	71 (53.8)
Female sex	83 (62.9)
Extracardiac arteriopathy	46 (34.9)
COPD	28 (21.2)
Neurologic dysfunction	23 (17.4)
Critical preoperative state	16 (12.1)
Serum creatinine >200 μmol/L	13 (9.8)
Active endocarditis	14 (10.6)
LVEF	
30%-50%	49 (37.1)
<30%	13 (9.8)
Systolic PA pressure >60 mm Hg	22 (16.7)
Recent myocardial infarction	13 (9.8)
Unstable angina	0 (0.0)
Emergency	18 (13.6)

*COPD indicates chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; PA, pulmonary artery.

risk patients undergoing isolated, stentless AVR and compared the results with the EuroSCORE prediction.

PATIENTS AND METHODS

Between January 2004 and December 2006, 1305 patients underwent aortic valve operations with or without concomitant procedures at the Charité University Hospital, Berlin. Of these patients, 132 patients (10.1%) underwent primary isolated AVR and had a logistic EuroSCORE of at least 10 (mean, 25). Figure 1 shows the EuroSCORE distribution. The patient population had a mean age of 78 years; Table 1 summarizes other characteristics of the patient cohort. Notably, 71 (54%) of the patients were octogenarians or nonagenarians, and 62 (47%) had a reduced left ventricular ejection fraction. Operations were performed with median sternotomy, ascending aortic and right atrial cannulation, normothermic cardiopulmonary bypass, aortic cross-clamping, and intermittent antegrade warm blood cardioplegia. Pericardial and porcine stentless valves were used (see Table 2).

RESULTS

The mean times (±SD) of aortic cross-clamping and cardiopulmonary bypass were 59 ± 27 minutes and 79 ± 32 minutes, respectively. The mean blood loss was 405 ± 434 mL, and 77% of the patients were extubated within 24 h after the operation. The patients had a mean ventilation time of 10.1 ± 4.7 hours and stayed a mean of 4.1 ± 7.4 days in the intensive care unit and 13.2 ± 11.5 days in the cardiac surgical department. Maximum and mean pressure gradients of the

Table 2. Implanted Stentless Bioprosthesis

Prosthesis	Features	Patients, n (%)
3F Aortic Bioprosthesis (ATS Medical, Minneapolis, MN, USA)	Equine, pericardial	7 (5.3)
Pericarbon Freedom (Sorin Biomedica, Saluggia, Italy)	Bovine, pericardial	40 (30.3)
Freedom Solo (Sorin Biomedica, Saluggia, Italy)	Bovine, pericardial	44 (33.3)
Toronto SPV (St. Jude Medical, St. Paul, MN, USA)	Porcine	9 (6.8)
Elan (AorTech, Bellshill, Scotland, UK)	Porcine	15 (11.4)
Shelhigh (Shelhigh, Milburn, NJ, USA)	Porcine	17 (12.9)

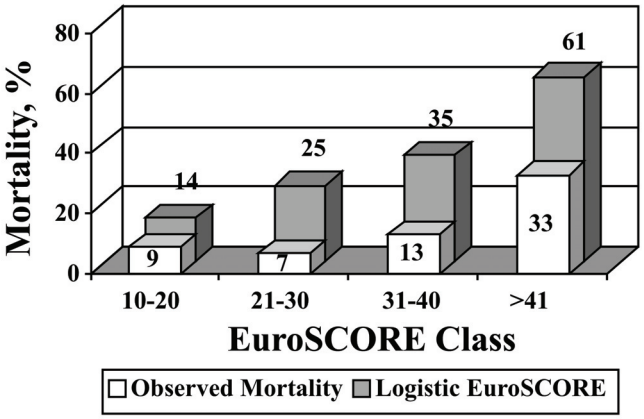

Figure 2. Predicted versus observed mortality of logistic EuroSCORE classes.

aortic valve prosthesis at discharge were 19.3 ± 8.4 mm Hg and 10.7 ± 4.8 mm Hg, respectively. The mean regurgitation grade was 0.06 ± 0.24, with a maximum of grade 1.0 to 2.0 observed in 1 patient (0.8%). No patient required reoperation for valve dysfunction. Stroke occurred in 4 patients (3.0%), and a permanent pacemaker was also required in 4 patients. One patient (0.8%) experienced myocardial infarction. There were no gastrointestinal complications. Table 3 lists all perioperative complications.

The 30-day mortality rate was 7.6% (10 deaths). Seven patients (5.3%) died after the first postoperative month but during the same hospital admission. Table 4 lists the causes of death. Thus, the observed combined mortality rate according to the EuroSCORE mortality definition was 12.9%. The predicted combined mortality rate according to the mean logistic EuroSCORE of the cohort was 25.3%. The logistic EuroSCORE also overestimated mortality in all EuroSCORE classes. A higher EuroSCORE class was associated with a greater absolute discrepancy between actual and predicted mortality (Figure 2).

Table 3. Frequencies of Postoperative Complications

Complication	Patients, n (%)
Renal failure	15 (11.4)
Pneumonia	14 (10.6)
Sepsis	12 (9.1)
Rethoracotomy for bleeding/tamponade	6 (4.5)
Low cardiac output	5 (3.8)
Stroke	4 (3.0)
Atrioventricular block III	4 (3.0)
Mediastinitis	3 (2.3)
Myocardial infarction	1 (0.08)

Table 4. Time and Causes of Death

Cause	Patients, n	Postoperative Day
Multiorgan failure	7	10, 13, 27, 29, 41, 54, 64
Pneumonia	3	41, 42, 186
Heart rhythm disturbance	2	14, 17
Myocardial infarction	1	3
Sepsis	1	1
Destructive endocarditis	1	0
Stroke	1	28
Brain tumor	1	81

COMMENT

The logistic EuroSCORE overestimated the actual mortality by 100% in our group of high-risk patients who underwent isolated AVR with a stentless bioprosthesis. This result further calls into question the predictive value of this risk algorithm for patients undergoing AVR. It is important to know that the EuroSCORE risk-stratification model was developed from a database of cardiac patients who underwent various surgical procedures, but primarily isolated coronary artery bypass grafting (65%) [Roques 1999]. Therefore, the EuroSCORE proved to be most accurate in cohorts of similar patients [Geissler 2000]. Only 17% of the EuroSCORE patients underwent aortic valve surgery, and the number of high-risk aortic valve patients was probably much lower. Improvements in surgical technology as well as in perioperative critical care since the introduction of the EuroSCORE system more than a decade ago also contribute to these results. This consideration could explain the great discrepancy between the actual mortality rate and that predicted by the EuroSCORE for such patients, not only for those observed in our study but for patients in other studies as well. Several other groups have noticed actual mortality rates that were <50% of the logistic EuroSCORE in "high-risk" aortic valve patients [Dewey 2008; Grossi 2008]; however, the present study is the first to focus on the operative risk of implanting a stentless bioprosthesis in high-risk patients. Stentless aortic bioprostheses offer superior hemodynamic results with excellent left ventricular mass regression, an important predictor of cardiovascular events [Borger 2005]. The implantation technique is more demanding, however, leading some surgeons to choose not to implant them, especially in the high-risk patient. We believe that modern stentless valves can as be as safe and as quickly implanted as stented biological or mechanical valves. We are encouraged by the presented results and do not hesitate to use this technique, even in high-risk patients with strongly elevated EuroSCOREs.

When standard surgical AVR is problematic, as in the case of a porcelain aorta or open coronary artery bypass grafts, a left ventricular apico-aortic conduit should be considered. It can be performed on the beating heart without cardiopulmonary bypass and with an acceptable risk [Gammie 2006]. In contrast, percutaneous aortic valve implantation (PAVI) and transapical aortic valve implantation (TAP-AVI) are frequently performed in arguably "prohibitive" patients, and until now the advantages of these approaches have not been convincing. Moreover, if the EuroSCORE risk is consistently overestimated, then judging the safety of new AVR technologies (eg, PAVI, TAP-AVI) by comparing the observed outcomes with the predicted EuroSCORE mortality rate may lack scientific validity. The actual mortality rate after PAVI was reported to be in the range of the logistic EuroSCORE, and complication rates were unacceptably high (eg, 20% stroke) [Marcheix 2007]. If the outcomes observed for PAVI are similar to the EuroSCORE predictions for high-risk patients, then surgical AVR is, statistically speaking, still a lower-risk treatment, even with stentless valves in this patient population. The functional outcomes of PAVI are dubious because of reports of regurgitation of at least grade 2 in most of the surviving patients [Cribier 2006]. The performance of TAP-AVI seems to be better than for PAVI, according to recently published data by Walther et al [2008]; however, the results are not better than those of standard AVR: There was a 30-day mortality rate of 8% in a cohort with a logistic EuroSCORE of 27. That is exactly what we observed in our patients. We prefer a safe replacement under direct vision, which is, by the way, much more cost-effective.

In summary, the data we have presented indicate that surgical AVR with a stentless bioprosthesis can also be performed in high-risk patients with results that are much better than expected. The EuroSCORE greatly overestimates the surgical risk of implanting such a valve substitute. We conclude that despite an elevated EuroSCORE, one should not hesitate to use stentless valves in high-risk patients.

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