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EDITORIAL COMMENT

Risk scores: Are these tools imperfect, or merely complex to use?☆

Scores de Risco: ferramentas imperfeitas ou apenas de utilização complexa?

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Developing therapeutic strategies guided by multiparametric criteria that go beyond merely clinical factors is a complex undertaking that in some cases fails to achieve its main objective, which is the identification of patient groups. The task is particularly important when the aim is to define risk groups.

Risk scores and risk tables are used extensively in cardiology to identify patients who have a better or worse prognosis for a given clinical condition at the time of observation and, on the basis of this classification, to decide on the appropriate treatment. A higher risk score often leads to a more aggressive approach, in an attempt to improve the initial prognosis.

Cardiac surgery also uses risk scores, but for a different purpose: they are mainly used to predict the mortality associated with a particular surgical intervention to be expected for a patient's specific clinical and anatomical characteristics. There are many cases when there is clearly a need for a surgical intervention, but the patient does not fulfill the conditions for it to be performed safely. The indication is there, but not the conditions.

The question of risk stratification has become increasingly pertinent in the case of aortic stenosis, in which a less aggressive but equally effective treatment is now available for patients at very high or prohibitive surgical risk: transcatheter aortic valve implantation (TAVI).

The first-line approach for patients with severe aortic stenosis and low to moderate surgical risk (except in specific anatomical conditions such as bicuspid valve) is surgery, TAVI being reserved for patients at very high or prohibitive surgical risk.

Opinions on the best score for selecting which of these approaches to adopt according to mortality risk, and hence which patients should be referred for TAVI, are currently divided between the European System for Cardiac Operative Risk Evaluation (EuroSCORE II)[1,2] and the Society of Thoracic Surgeons (STS) risk score.[3,4]

EuroSCORE II is derived from a database of more than 22 000 patients who underwent cardiac surgery at 154 hospitals in 43 countries between May and June 2010. It replaced the original EuroSCORE model for mortality risk assessment and proved to have superior discriminative ability, being less prone to overestimation of risk compared to its predecessor.[5] The STS published surgical risk scores from 1999 onward, based on data from patients who had undergone surgery using operative mortality as the only endpoint, and the final version was based on data from 101 661 procedures performed between January 1, 2002 and December

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31, 2006. This score is only to be used for isolated aortic valve replacement, isolated mitral valve repair or replacement, coronary artery bypass grafting (CABG), and CABG with aortic or mitral valve replacement (not double valve replacement).

Various articles have been published comparing the discriminative ability of these two scores to assess risk for therapeutic procedures in patients with aortic stenosis.[6,7] They have shown that correlation and agreement between EuroSCORE II and STS are weak. In a study by Arangalage et al.,[6] a EuroSCORE II $\geq$7% was observed in 51% of patients and provided the best diagnostic value (defined as the sum of sensitivity and specificity) to predict high surgical risk, compared with a logistic EuroSCORE of $\geq$20% (70% sensitivity and 75% specificity) and an STS score of $\geq$10% (69% sensitivity and 60% specificity). Using a value of $\geq$7% for EuroSCORE II, agreement with the logistic EuroSCORE was low, but it was even lower for the STS score. The algorithm for EuroSCORE II includes new parameters that may result in better performance than the other scores, including New York Heart Association (NYHA) and Canadian Cardiovascular Society classes, degree of renal impairment, left ventricular ejection fraction and pulmonary arterial systolic pressure, poor mobility, insulin-dependent diabetes, and degree of urgency. Probably due to the inclusion of these new parameters, EuroSCORE II has better calibration (ability to measure risk of operative mortality) and discriminative power (ability to differentiate between low and high risk) than the logistic EuroSCORE and the STS score. However, according to Arangalage et al.,[6] only half of patients reached the high-risk thresholds (EuroSCORE II $\geq$7% and STS $\geq$10%).[6] These results highlight the limitations of these scoring systems and the need for careful, evidence-based clinical judgment in addition to risk scores when deciding on the therapeutic approach.

These idealized risk scores, although imperfect, are able to identify patients who should be referred for TAVI on the basis of predicted surgical mortality. They have also been used to predict mortality in patients undergoing TAVI. In a 2013 article, Watanabe et al.[8] assessed the performance of EuroSCORE II in patients who underwent TAVI, comparing it to STS and logistic EuroSCORE. They concluded that EuroSCORE II predicted 30-day mortality better, albeit still poorly, than logistic EuroSCORE or STS. However, it was noticeably better in patients who underwent a transfemoral procedure.

These results make it clear, although changes to EuroSCORE II have been proposed to improve its performance, including frailty (identified by weight loss, exhaustion, low energy, slowness and weakness),[9] that other tools are needed to predict mortality after TAVI.

The 2011-12 pilot European Sentinel Registry of Transcatheter Aortic Valve Implantation, published in 2013,[10] observed in-hospital mortality in 7.4% of patients, stroke in 1.8%, myocardial infarction in 0.9% and major vascular complications in 3.1%. The low rate of complications was associated with greater operator experience and improvements in catheters and valves. Multivariate analysis identified advanced age, high pre-procedural logistic EuroSCORE, pre-procedural grade $\geq$2 mitral valve regurgitation and valve deployment failure as predictors of higher mortality. Although this study helps to identify the factors associated with poor prognosis after TAVI, it does not meet what is becoming an urgent need in an era of rapid growth in the use of TAVI: the ability to predict mortality after the procedure, i.e. to develop a risk score specific to TAVI.

The group headed by Bernard Iung[11] set out to develop an easy-to-use multiparametric score to predict the risk of patients undergoing TAVI on the basis of data from the FRench Aortic National CoreValve and Edwards (FRANCE-2) Registry. A population of 3833 consecutive patients was divided into two cohorts comprising 2552 and 1281 patients, used respectively to develop and validate a scoring system predicting 30-day or in-hospital mortality.

In-hospital and 30-day mortality was 10%. A multivariate logistic model identified the following predictive factors of early mortality: age $\geq$90 years, body mass index <30 kg/m^2, NYHA class IV, pulmonary hypertension, critical hemodynamic state, $\geq$2 pulmonary edemas during the last year, respiratory insufficiency, dialysis and transapical or other approaches (not transfemoral). The last four were the most important predictors. Each of these factors was weighted and integrated into a 21-point risk score, with an expected mortality of <5% in patients with the lowest score and >40% with the highest.

The authors described the score's discrimination as ''moderate'' (C-index of 0.67 in the development cohort and 0.59 in the validation cohort), which indicates that it may not be suitable for very high-risk patients. According to Ribeiro et al.,[12] there are three main reasons for this result. The first is the size of the patient cohort, which although large, was much smaller than those used for most surgical risk scores. The second relates to the characteristics of the population, which was very old and had a high comorbidity burden; the lack of functional as well as frailty parameters may have reduced the predictive power of the model. Third is the high mortality after TAVI ($\sim$10% at 30 days and 14% within the months after the procedure), in contrast to the very low mortality in the same period following surgical valve replacement.

Another point raised by Ribeiro et al. is the lack of improvement in quality of life or functional status after TAVI in some patients. This should be borne in mind in future studies for the development of risk scores for this complex group of patients. Nevertheless, procedural complications have decreased as centers and teams have gained more experience, which has played an important part in the low 30-day mortality associated with TAVI and should be taken into consideration in decision-making and incorporated into the rationale of risk scores.

The article by Carmo et al. published in this issue of the *Journal*[13] follows the publication of the FRANCE-2 risk score and aims to compare multiparametric risk scores to predict early mortality after TAVI. Through a retrospective analysis of 240 patients from a prospective study who underwent TAVI between January 2008 and December 2015, the authors assessed the discrimination and calibration of three scores, EuroSCORE II, STS and FRANCE-2. They concluded that all three scores had only a modest ability to predict early mortality after TAVI and that in their study population FRANCE-2, despite being derived from a TAVI population, was no better than the surgical risk scores. The discriminative capacity of EuroSCORE II (C-index 0.67) and STS (C-index 0.67) was

better than that of FRANCE-2 (C-index 0.53), although this difference was not statistically significant.

These results demonstrate that the ideal tools for predicting mortality in either surgical or percutaneous treatment of aortic valve disease are still not available, and that the lack of standardized risk models makes it difficult to identify patients who would be the best candidates for a less aggressive approach.

As the number of patients undergoing TAVI increases, the size of patient groups that can be analyzed for the development of risk scores can also be expected to increase. This may overcome some of the limitations that have been responsible for the weakness of risk models to date.

Conflicts of interest

The author has no conflicts of interest to declare.

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