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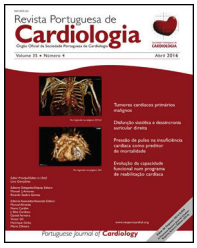

RECOMMENDED ARTICLE OF THE MONTH

Comment on "Development and Validation of a Risk Prediction Model for In-Hospital Mortality After Transcatheter Aortic Valve Replacement"

Comentário a «Desenvolvimento e validação de um modelo de predição de risco para mortalidade intra-hospitalar em doentes submetidos a implantação transcateter da válvula aórtica»

Fred H. Edwards, MD; David J. Cohen, MD; Sean M. O'Brien, PhD; Eric D. Peterson, MD, MPH; Michael J. Mack, MD; David M. Shahian, MD; Frederick L. Grover, MD; E. Murat Tuzcu, MD; Vinod H. Thourani, MD; John Carroll, MD; J. Matthew Brennan, MD, MPH; Ralph G. Brindis, MD, MPH; John Rumsfeld, MD, PhD; David R. Holmes Jr, MD; for the Steering Committee of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. JAMA Cardiol. 2016;1(1):46-52. doi:10.1001/jamacardio.2015.0326

Abstract

Importance: Patient selection for transcatheter aortic valve replacement (TAVR) should include assessment of the risks of TAVR compared with surgical aortic valve replacement (SAVR). Existing SAVR risk models accurately predict the risks for the population undergoing SAVR, but comparable models to predict risk for patients undergoing TAVR are currently not available and should be derived from a population that underwent TAVR.

Objective: To use a national population of patients undergoing TAVR to develop a statistical model that will predict in-hospital mortality after TAVR.

Design, Setting, and Participants: Patient data were obtained from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry. The model was developed from 13718 consecutive US patients undergoing TAVR in centers participating in the STS/ACC TVT Registry from November 1, 2011, to February 28, 2014. Validation was conducted using 6868 records of consecutive patients undergoing TAVR from March 1 to October 8, 2014. Covariates were selected through a process of expert opinion and statistical analysis. The association between in-hospital mortality and baseline covariates was estimated using logistic regression. The final set of predictors was selected via stepwise variable selection. Data were collected and analyzed from November 1, 2011, to February 28, 2014.

Main Outcomes and Measures: In-hospital TAVR mortality.

Results: The development sample included 13718 patient records from 265 participant sites (of 13 672 with data available, 6680 men [48.9%]; 6992 women [51.1%]; mean [SD] age, 82.1 [8.3] years). The final validation cohort included 6868 patients from 314 participating centers (3554 men [51.7%]; 3314 women [48.3%]; mean [SD] age, 81.6 [8.8] years). In-hospital mortality occurred in 730 patients (5.3%). The c statistic for discrimination was 0.67 (95% CI, 0.65-0.69) in the development group and 0.66 (95% CI, 0.62-0.69) in the validation group. The final model covariates (reported as odds ratios; 95% CIs) were age (1.13; 1.06-1.20), glomerular filtration rate per 5-U increments (0.93; 0.91-0.95), hemodialysis (3.25; 2.42-4.37), New York Heart Association functional class IV (1.25; 1.03-1.52), severe chronic lung disease (1.67; 1.35-2.05), nonfemoral access site (1.96; 1.65- 2.33), and procedural acuity categories 2 (1.57; 1.20-2.05), 3 (2.70; 2.05-3.55), and 4 (3.34; 1.59-7.02). Calibration analysis demonstrated no significant difference between the model (predicted vs observed) calibration line (−0.18 and 0.97 for intercept and slope, respectively) compared with the ideal calibration line.

Conclusions and Relevance: Data from the STS/ACC TVT Registry have been used to develop a predictive model of in-hospital mortality for patients undergoing TAVR. Validation based on a population of patient records not used in model development demonstrates discrimination and calibration indices that are more favorable than other models used in populations with TAVR. This model should be a valuable adjunct for patient counseling, local quality improvement, and national monitoring for appropriateness of selection of patients for TAVR.

Comment

Na edição de abril de 2016 do *JAMA Cardiology*, Edwards e associados[1] publicam um estudo que teve como objetivo construir um modelo de predição de risco para mortalidade intra-hospitalar na população norte-americana submetida a implantação transcateter da válvula aórtica (TAVI).

Os dados dos doentes incluídos no estudo provieram do registo nacional norte-americano «*The STS-ACC Transcatheter Valve Therapy National Registry*». O modelo foi desenvolvido com dados de 13 718 doentes submetidos consecutivamente a TAVI entre novembro de 2011 e fevereiro de 2014; a validação do modelo foi realizada em 6868 doentes tratados entre março e outubro de 2014. De entre um conjunto de 39 variáveis pré-operatórias existentes na base de dados, 14 foram selecionadas para análise *via expert consensus*, e, finalmente, nove destas variáveis foram retidas no modelo final utilizando metodologia estatística analítica. O poder discriminatório do modelo é ligeiro (a área abaixo da curva ROC foi de 0,67 no grupo de desenvolvimento e de 0,66 no grupo de validação). Estes resultados atestam a limitada capacidade discriminativa neste grupo de doentes. Mesmo os «melhores» modelos de risco disponíveis explicam apenas uma pequena proporção da variabilidade dos resultados. É por esta razão que as mais recentes recomendações enfatizam que a avaliação do risco deve apoiar-se essencialmente na avaliação clínica[2,3].

Um conjunto de limitações ao estudo merece reflexão. Algumas são elencadas pelos autores, nomeadamente: dados em falta, um processo de auditoria incompleto, ausência de indicadores de fragilidade e de qualidade de vida e o facto de terem restringido a um período temporal muito curto a análise da mortalidade. Penso que, a esta lista deveriam ter sido adicionados outros aspetos tais como: ausência de informação relativamente a complicações *major*, quer cardíaca quer não cardíaca, bem como informação adicional clarificadora relativamente ao modo como as variáveis foram selecionadas para análise *via expert consensus*.

Conflicts of interest

The author has no conflicts of interest to declare.

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