Biomarker-Led Predictive Modelling and Risk Classification in Personalized Medicine

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Abstract

Background: Identifying predictive and prognostic factors is becoming pivotal in medical research, especially as scientific discoveries have led to an in-depth understanding of diseases and genetics, resulting in personalized therapy. As we gain a better understanding of aspects involved in disease processes, biomarkers of disease are identified, investigated either to predict the occurrence of an event (i.e. the occurrence of a complication, death or, conversely, positive outcomes including healing, improvement of symptoms, etc.), or to serve as targets for new therapeutic measures. *Methods*: The use of biomarkers in medical research aided the refinement of prediction models and the identification of how these biomarkers could improve the prediction model. The question remains how do we assess whether or how much a biomarker improves prediction of the event? *Results*: The important point to note is that a biomarker may be significantly associated with a disease outcome, but this does not necessarily imply that it improves the risk prediction of an event to occur or reclassifies patients into different risk categories. The objective of the present research study is to develop an improved predictive modelling and risk stratification tool to support clinical decision-making by integrating clinical variables and biomarkers. At the same time, the incremental prognostic value of each candidate biomarker in addition to clinical characteristics were evaluated. The performance of the prediction model developed based on risk scores was compared and the design validation, testing and implementation of predictive analysis algorithms were performed. *Conclusions*: The predictive performance was based on the evaluation of two characteristics: calibration and discrimination. With an increase in data complexity brought about by constant technological advancements, statistical methods play an increasingly important role in medical research and healthcare. A clear specification of the main scientific objectives is required to identify the most appropriate analysis methods to address the questions of interest.

Keywords: Predictive modelling; Risk classification; Biomarker; Personalized medicine.