

Numerous published biomarker prognostic models for heart failure exist, but none is officially recommended in clinical guidelines: a paradox or a research scandal/failure?

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Background/Introduction:

Heart failure (HF) is a major public health problem. Risk stratification along with tailored intensive therapy may alter HF patients' prognosis. Two decades of biomarker research highlighted the prognostic ability of certain markers, and encouraged the development of prognostic models. Despite numerous publications with a prognostic theme and ESC's recognition of the need for prognosis information, no such models have been adequately established in clinical practice.

Purpose:

To systematically assess the quality of published prognostic models and the evidence they present, for the first time. This is a complex time-constrained project with potential to advise on future HF prognostic model design and reporting, and contribute to improved HF research resources and clinical management.

Methods:

We applied Cochrane methodology for searching and assessing published studies on prognostic HF models. Using validated prognostic filters in a sensitive search, more than 40,500 titles with at least one HF-related biomarker and prognosis-related information were initially identified. Of these only 10% (4224) were relevant to HF biomarker prognostic models and factors. We used established tools of prognostic methodology to assess the eligible studies³.

Results:

Despite the extensive research on prognostic HF-biomarkers, only a maximum of 200 papers (5% of 4224 and only 0.5% of 40500) hinted on employing appropriate prognostic methodological processes, but less than 50 adequately reported their methods. As a preliminary result the adequately developed and validated models would not exceed 10.

In the vast majority of the papers there was a rather confusing marriage of HF-biomarker research and prognostic modelling methodology. Most were based on a simple logistic regression, which is merely explanatory of a causal or association hypothesis but doesn't qualify as a prognostic model on its own. Prediction research aims to provide an estimate of outcome probability to assist clinical management; it is independent of a causal hypothesis, and needs to be validated and if necessary, calibrated. The development and reporting of prognostic models was often misunderstood and/or misreported, while the adequate conduct and reporting of models' validation and calibration was usually absent.

Conclusions:

Our project is the first known attempt to assess systematically the evidence from HF prognostic models. We found largely inadequate use of prognostic methodology leading to multiple papers, with very little prognostic information for HF. This area of HF research would benefit from adopting REWARD alliance initiatives on avoiding research waste. Research teams should consider prognostic methodology training, before embarking on such projects. Responsibility also lies with the Journals for ensuring the quality of conduct of prognostic research through their peer review processes. Until such time use of prognostic models would be limited.