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Quality specifications in cardiac biomarkers assays: which updatings?

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The recommendations recently issued by clinical and biochemical Scientific Societies, about the measuring of biochemical markers of myocardial damage, underline again the relevance that such measurings hold in strategical clinical spheres for the outcome of the patients, particularly in diagnosis of acute coronary syndrome, in the evaluation of the efficacy of the therapy, in risk stratification and in prognosis with relevant consequences both on living quality and time of survival.

Therefore, it comes out that the quality of the results is always more critical both in reproducibility, accuracy, time to report results and evidence-based decisional limits. The evolution of biochemical knowledges should be added to all these considerations: in fact, nowadays, it is underlining unexpected preanalytical problems (development of autoantibodies against troponin I, glycosilation of circulating fragments of natriuretic peptides) which have relevant consequences on the accuracy of the results obtained with different methods commercially available. Therefore, it is to regard that, in spite of all the analytical problems which should be more considered and discussed (standardization of the methods to measure troponins and to assay the more recently studied natriuretic peptides as well as the new biochemical markers), the interest should be directed towards all the phases that concur to the production of a relevant biochemical information. The possibility, for example, of using in routine diagnosis of acute coronary syndrome some high-sensitive methods for troponins measurement, open an interesting debate on the presence of measurable troponins concentrations also in healthy subjects, that seems to be sex and age-dependent. Consequently, the criteria to select the healthy population in order to calculate the reference range as well as to evaluate the significant troponins change in different cardiac diseases should be updated.

The definition of quality specifications, according to the recent biochemical and physiopathological knowledges, should be both checked, following the actual standards, as well as improved considering the analytical performance, the specificity of new proposed methods, the informations which should be present in a laboratory report as well as the criteria to valute the results and the opportunity to provide a multimaker strategy using diagnostic algorithms.

These are the most important factors which concur to an efficient and useful biochemical information provided by laboratory medicine in several clinical fields, such as that of acute coronary syndrome, were the biochemical markers represent a validated and essential diagnostic support.

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