Very Early Diagnosis Of Chest Pain By Point Of Care Testing; Comparison of the Diagnostic Efficiency Of a Panel of Cardiac Biomarkers Compared to Troponin Measurement Alone In The Randomised Assessment Of Panel Assay of Cardiac Markers (RATPAC) Trial.

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ABSTRACT

Introduction. A prospective randomised trial of troponin marker testing by point of care testing (POCT) the Randomised Assessment of treatment Panel Assay of Cardiac Markers (RATPAC) trial was performed to assess any impact of POCT faster testing on time to diagnosis of acute coronary syndrome (ACS) resulting in major adverse outcome (MAO) in the emergency department (ED). Patients 16 or older presenting with acute chest pain to the emergency department (ED) of a participating hospitals with suspected acute coronary syndrome (ACS) were enrolled. 1125 patients were randomised to POCT measurement of the triple marker cTnI, CK-MB and myoglobin(renal origin was excluded) or to laboratory standards. Time to diagnosis was defined as the time from patient arrival to the ED to the time of any POCT triad measurement by the laboratory staff. Measurements were performed using the Stratus CS (Siemens Healthcare Diagnostics). The analytical characteristics of this assay were as follows: cTnI detection limit 0.05 µg/L, analytical range 0.05-10 µg/L, inter assay CV 4.0% b<0.07 (0.03-0.54 µg/L). The 99th percentile of the assay is 0.07 µg/L. CK-MB: detection limit 1.0 µg/L, analytical range 1-1000 µg/L, inter assay CV 1.9-3.5% (for 360 µg/L), reference interval, males 20-180 µg/L; females 11-150 µg/L. Myoglobin: detection limit 0.05 µg/L, analytical range 0.05-100 µg/L, reference interval, males 40-400 µg/L; females 40-110 µg/L. For all three assays the sample was sent in the same manner to the local laboratory for cardiac troponin measurement. The RATPAC trial was funded by the National Institute for Health Research Health Technology Assessment programme (no 06/302/19) and sponsored by the University of Sheffield. The study funders had no role in study design, in the collection, analysis and interpretation of data, in the writing of the report or in the decision to submit the paper for publication. The researchers were independent of the study funders. All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

METHODS

Ethical permission for the study was obtained from the Leeds East Research Ethics Committee (7/07/D032/07) and the study was performed in accordance with the declaration of Helsinki. The RATPAC trial (ISRCTN76270528) (3) randomised five low risk patients presenting with chest pain to diagnostic assessment where a cardiac panel was measured by POCT to diagnosis when biomarker measurement was based on central laboratory testing (CLT). As these data was not part of the patient case notes, and follow up investigations plus troponin measurement, utilizing laboratory derived values wherever possible. The following diagnostic strategies were compared: individual marker values (cTnI > 99th percentile, CK-MB > 5 µg/L, and myoglobin > 40 µg/L), and the combination of presentation or 90 minute value plus delta value. In the admission sample measurement of cTnI was the most diagnostically efficient with areas under the ROC curve of 0.91 for cTnI, 0.87 for CK-MB and 0.75 for myoglobin. For the rule in diagnosis of AMI cTnI was superior to both CK-MB or myoglobin (respectively 0.91 vs. 0.86 vs. 0.78) or Delta cTnI v Delta CK-MB. For accuracy in the overall final classification into AMI or non-AMI groups, cTnI measurement was superior to CK-MB (0.85) or myoglobin (0.78) or Delta CK-MB v Delta myoglobin (0.69). With ethnicity this was significantly different only from delta myoglobin (p = 0.003) and delta cTnI (p = 0.004).

RESULTS

Receiver operator characteristic curves for biomarker data for the diagnosis of acute myocardial infarction on admission (left) and 90 minutes from admission (right).

Conclusions


CONCLUSION

The measurement of cTnI alone is sufficient for diagnosis of AMI. Measurement of a marker panel does not facilitate diagnosis.

Conflict of interest: None

References