

First randomised trial tests criteria used to diagnose heart attack

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Results of the first randomised trial testing the criteria used to diagnose heart attack are presented today in a Hot Line Session at ESC Congress 2018 and published in *The Lancet*.

Professor Nicholas Mills, principal investigator, University of Edinburgh, UK, said: "These results are controversial because they suggest that the Universal Definition of Myocardial Infarction needs to move away from binary thresholds to diagnose and treat [patients](#) with myocardial infarction. It is now up to the research community to find a superior approach."

Myocardial infarction is one of the leading causes of death worldwide. It is diagnosed with a combination of clinical history, electrocardiogram and a rise or fall in the concentration of cardiac [troponin](#), a protein released into the blood when the heart muscle is injured. The Universal Definition of Myocardial Infarction recommends that any increase in troponin above the 99th centile of a healthy reference population should be used as one of the diagnostic criteria.

The High-STEACS trial is the first randomised trial to evaluate whether the introduction of a high-sensitivity cardiac troponin I assay with a 99th centile diagnostic threshold would reduce subsequent myocardial infarction or [cardiovascular death](#) at one year in patients with suspected [acute coronary syndrome](#).

The trial included all patients presenting with suspected acute coronary syndrome to the emergency department at ten hospitals in Scotland, UK. All patients had measurements of cardiac troponin I using a contemporary assay as the standard of care and a high-sensitivity assay at presentation and six or 12 hours afterwards. During a six-month validation phase, clinical decisions were guided by the contemporary cardiac troponin I assay using the existing diagnostic threshold. Hospitals were then randomly

allocated to early or late implementation of the high-sensitivity assay to guide clinical decisions using the 99th centile. Registries were used to record the primary outcome of myocardial infarction or cardiovascular death at one year.

The rate of the primary outcome was compared in patients reclassified using the high-sensitivity assay (above the 99th centile but below the contemporary assay threshold) before and after implementation of the high-sensitivity assay for clinical decision making.

A total of 48,282 patients were enrolled. The average age was 61 years and 47% were women. Just over one-fifth (10,360; 22%) had high-sensitivity cardiac troponin I concentrations above the 99th centile. The high-sensitivity assay reclassified 1,771 (17%) patients with myocardial injury or infarction not identified by the standard assay. Of those, less than one third had a final diagnosis of myocardial infarction.

In those reclassified, the primary outcome occurred in 105 of 720 (14.6%) patients in the validation phase and 131 of 1,051 (12.5%) patients in the implementation phase. The adjusted odds ratio for the implementation versus validation phase was 1.10 (95% confidence interval 0.75-1.61, $p=0.620$).

Professor Mills said: "The trial found that implementation of a high-sensitivity cardiac troponin I assay using the 99th centile as the diagnostic threshold increased the frequency of diagnosing myocardial injury or infarction. However, use of this method to help diagnose and treat patients was not associated with lower rates of recurrent [myocardial infarction](#) or cardiovascular death at one year."

He continued: "The findings were surprising and initially disappointing. But it was encouraging that there was no evidence of misdiagnosis, inappropriate treatment, excess bleeding or harm.

Indeed, the length of stay across the trial population was reduced by almost a third suggesting that use of the high-sensitivity test increased the confidence of clinicians to rule out heart disease, with benefits for health service providers."

Professor Mills noted that the trial was embedded within routine clinical assessment with hospitals as the unit of randomisation. "It included every patient evaluated using the test, thereby avoiding selection bias and ensuring that the findings are generalisable," he said.

More information: Kristian Thygesen et al. Third universal definition of myocardial infarction, *European Heart Journal* (2012). DOI: [10.1093/eurheartj/ehs184](https://doi.org/10.1093/eurheartj/ehs184)

Kristian Thygesen et al. Fourth universal definition of myocardial infarction (2018), *European Heart Journal* (2018). DOI: [10.1093/eurheartj/ehy462](https://doi.org/10.1093/eurheartj/ehy462)

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