

True 99th centile of high sensitivity cardiac troponin for hospital patients: prospective, observational cohort study.

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Abstract

OBJECTIVE: To determine the distribution, and specifically the true 99th centile, of high sensitivity cardiac troponin I (hs-cTnI) for a whole hospital population by applying the hs-cTnI assay currently used routinely at a large teaching hospital.

DESIGN: Prospective, observational cohort study.

SETTING: University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom, between 29 June 2017 and 24 August 2017.

PARTICIPANTS: 20 000 consecutive inpatients and outpatients undergoing blood tests for any clinical reason. Hs-cTnI concentrations were measured in all study participants and nested for analysis except when the supervising doctor had requested hs-cTnI for clinical reasons.

MAIN OUTCOME MEASURES: Distribution of hs-cTnI concentrations of all study participants and specifically the 99th centile.

RESULTS: The 99th centile of hs-cTnI for the whole population was 296 ng/L compared with the manufacturer's quoted level of 40 ng/L (currently used clinically as the upper limit of normal; ULN). Hs-cTnI concentrations were greater than 40 ng/L in one in 20 (5.4%, n=1080) of the total population. After excluding participants diagnosed as having acute myocardial infarction (n=122) and those in whom hs-cTnI was requested for clinical reasons (n=1707), the 99th centile was 189 ng/L for the remainder (n=18 171). The 99th centile was 563 ng/L for inpatients (n=4759) and 65 ng/L for outpatients (n=9280). Patients from the emergency department (n=3706) had a 99th centile of 215 ng/L, with 6.07% (n=225) greater than the recommended ULN. 39.02% (n=48) of all patients from the critical care units (n=123) and 14.16% (n=67) of all medical inpatients had an hs-cTnI concentration greater than the recommended ULN.

CONCLUSIONS: Of 20 000 consecutive patients undergoing a blood test for any clinical reason at our hospital, one in 20 had an hs-cTnI greater than the recommended ULN. These data highlight the need for clinical staff to interpret hs-cTnI concentrations carefully, particularly when applying the recommended ULN to diagnose acute myocardial infarction, in order to avoid misdiagnosis in the absence of an appropriate clinical presentation.

TRIAL REGISTRATION: Clinicaltrials.gov [NCT03047785](https://clinicaltrials.gov/ct2/show/study/NCT03047785).