High-sensitivity troponin testing at the point of care for the diagnosis of myocardial infarction: a prospective emergency department clinical evaluation

In the ED, laboratory high-sensitivity cardiac troponin (hs-cTn) tests facilitate 'rule-out' of myocardial infarction (MI).[1] Contemporary point-of-care (POC) troponin tests have inferior analytical sensitivity,[2] preventing rapid 'rule-out' strategies in near-patient settings. The new Siemens Atellica VTLi POC test meets hs-cTn criteria.[3]

Between June and September 2022, adult ED patients (≥16 years) with symptoms suspicious for MI and no ST-segment elevation on ECG were eligible for inclusion if staff trained on the POC instrument were available. Simultaneously, blood was taken for near-patient testing with the VTLi POC hs-cTnI assay (limit of detection (LOD) of 1.2 ng/L, sex-specific 99th percentile upper reference limits (URLs) of 18 ng/L (female) and 27 ng/L (male), and an optimised 'rule-out' threshold of <4 ng/L)[3] and for laboratory testing with the Abbott Alinity hs-cTnI assay (LOD of 1.6 ng/L, URLs of 16 ng/L (female) and 34 ng/L (male), and an optimised 'rule-out' threshold of <5 ng/L),[4] the standard-of-care assay for this evaluation. Patients with no result for either assay or who presented ≤2 hours from symptom onset were excluded and POC results were not available to clinicians.

The end-point was an index presentation type 1 MI or cardiac death, independently adjudicated by two investigators (blinded to POC results) according to the fourth universal definition of MI.[5] Correlation of troponin concentrations was expressed using a Bland-Altman plot, and diagnostic metrics with 95% CIs (Wilson method) were calculated for performance at respective optimised rule-out thresholds. Time to result availability for each assay was also measured.

In total, 68 POC tests were performed on 59 patients (14 failures, 21%). Fifty patients (85%) met the inclusion criteria (mean age 63 years (SD 17), 68% male), of which 4 (8%) reached the primary outcome, all type 1 MI (online supplemental figure S1). A Bland-Altman plot of all 50 patients (online supplemental figure S2) was difficult to interpret due to three patients with high troponin concentrations, but one describing 47 patients with an average troponin concentration of <30 ng/L demonstrated very good correlation between the two assays, with the VTLi typically returning slightly higher values (figure 1). All four cases of type 1 MI were appropriately identified by both assays at respective rule-out thresholds. At <4 ng/L, the VTLi POC hs-cTnI test recognised less patients (10, 20%) as low risk than the Abbott Alinity hs-cTnI test, at <5 ng/L (33, 66%). The sensitivity for both assays was 100%, though the 95% CI extended down to 51%, and the NPV was 100% (95% CI 72% to 100%) for the POC test and 100% (95% CI 90% to 100%) for the laboratory test (table 1). Time from venepuncture to first POC result (including an 'invalid' result) was faster (mean 14 (SD 4), range 8–30 min) than to laboratory result (mean 65 (SD 24), range 37–156 min). The time difference between results varied between 14 and 146 (mean 52, SD 25) min.

In a prospective evaluation of 50 ED patients with suspected MI, we demonstrated very good correlation between the Atellica VTLi POC hs-cTnI and the Abbott Alinity laboratory hs-cTnI tests. At respective optimised rule-out thresholds, both assays demonstrated excellent sensitivity and NPV with respect to type 1 MI. Clinicians will have to consider the benefit of faster results (nearly an hour with POC testing) against identification of more low-risk patients (threefold in this evaluation) with a laboratory assay.

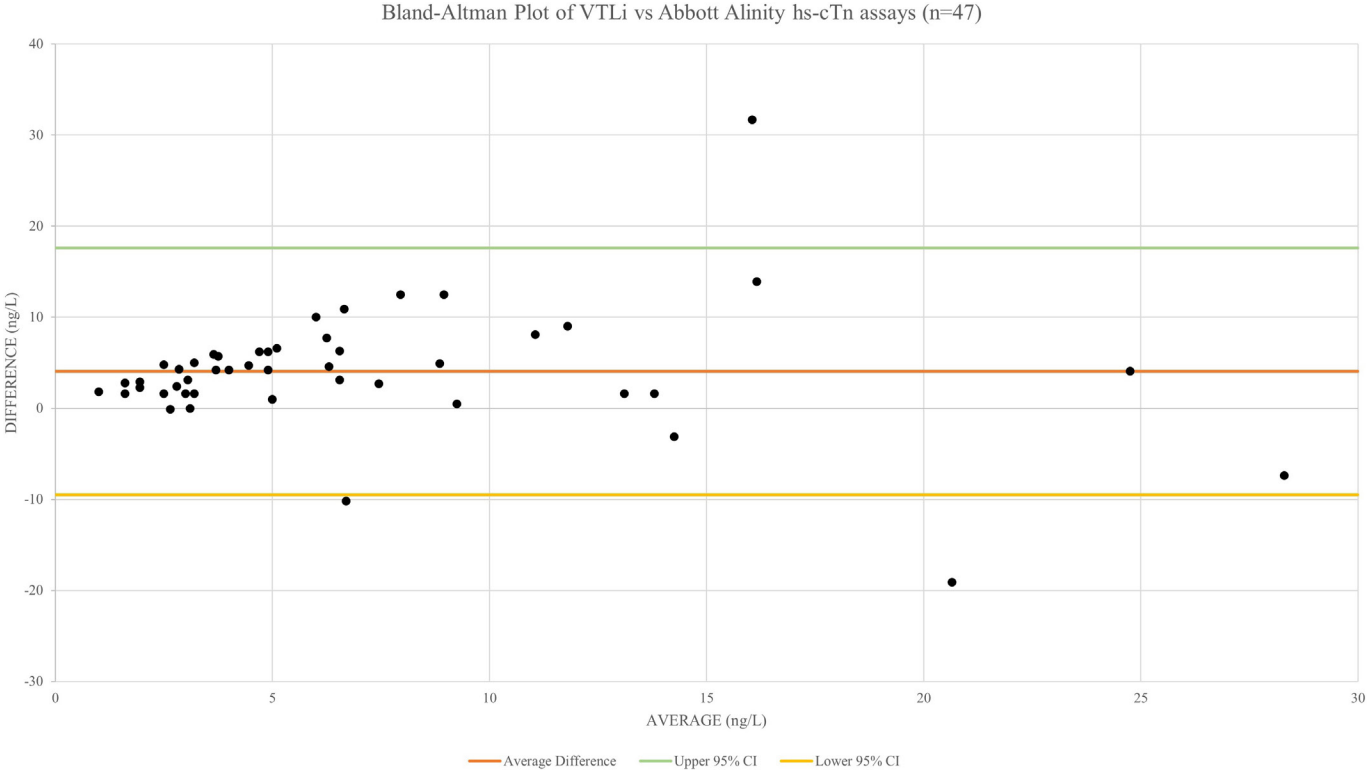

Figure 1 Bland-Altman plot of the results of the Siemens Atellica VTLi POC hs-cTnI test vs the Abbott Alinity laboratory hs-cTnI assay in 47 patients in whom the mean troponin concentration was <30 ng/L. hs-cTn, high-sensitivity cardiac troponin; POC, point of care.

Table 1 The diagnostic performance of the Siemens Atellica VTLi POC hs-cTnI assay (at an optimised rule-out threshold of <4 ng/L) and the Abbott Alinity laboratory hs-cTnI assays (at an optimised rule-out threshold of <5 ng/L) to predict the primary outcome of index type 1 MI or cardiac death

Cardiac troponin assay	Optimised 'rule-out' threshold	Number (%) low risk	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Siemens VTLi POC hs-cTnI	<4 ng/L	10 (20%)	100% (51% to 100%)	22% (12% to 36%)	10% (4% to 23%)	100% (72% to 100%)
Abbott Alinity hs-cTnI	<5 ng/L	33 (66%)	100% (51% to 100%)	72% (58% to 83%)	24% (10% to 47%)	100% (90% to 100%)

hs-cTn, high-sensitivity cardiac troponin; MI, myocardial infarction; NPV, negative predictive value; POC, point of care; PPV, positive predictive value.

The high failure rate was subsequently determined, in conjunction with the manufacturer, to predominantly result from blood collection into heparin containing gas syringes before transfer to the VTLi cartridge. This method was accepted by Siemens, but cartridges are now validated only for capillary whole blood samples or venous lithium heparin whole blood or plasma samples.

We acknowledge the limitations of our small sample size, the possibility of verification bias (since low-risk allocation in clinical practice was determined by an Abbott Alinity hs-cTnI result <5 ng/L) and the exploratory nature of our evaluation, but hope it will inform future research in this area.

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Contributors JGC and BLC conceived the study and its design. JMC, AM, SMW, BLC and JGC acquired the data, JMC and JGC performed the analysis and JMC, BLC and JGC interpreted the data. JMC and JGC drafted the manuscript and all authors reviewed the manuscript critically for intellectually important content and provided their final approval of the version to be submitted. All authors are accountable for the work.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by After Institutional Research Governance review this project was registered as a service evaluation (ID 5721). Caldicott Guardian approval obtained (CG/2023/166). See answers above—service evaluation.

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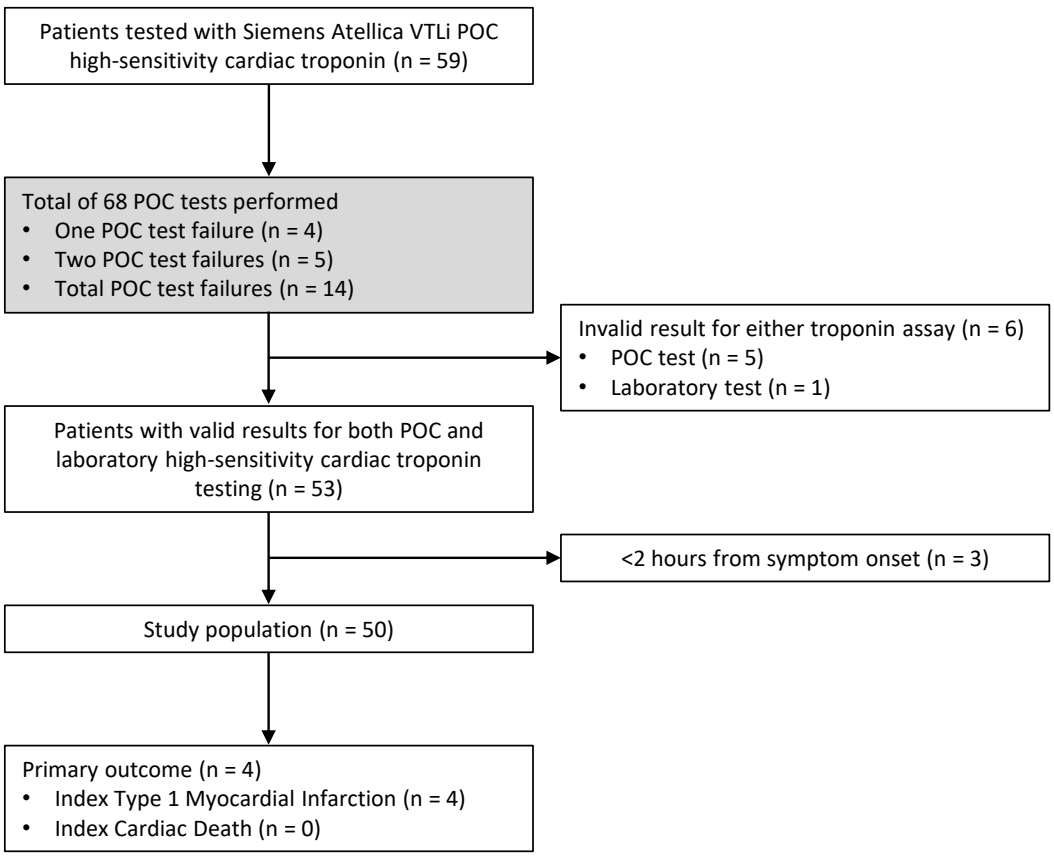
Patients tested with Siemens Atellica VTLi POC high-sensitivity cardiac troponin (n = 59)
Total of 68 POC tests performed
• One POC test failure (n = 4)
• Two POC test failures (n = 5)
• Total POC test failures (n = 14)
Invalid result for either troponin assay (n = 6)
• POC test (n = 5)
• Laboratory test (n = 1)
Patients with valid results for both POC and laboratory high-sensitivity cardiac troponin testing (n = 53)
<2 hours from symptom onset (n = 3)
Study population (n = 50)
Primary outcome (n = 4)
• Index Type 1 Myocardial Infarction (n = 4)
• Index Cardiac Death (n = 0)

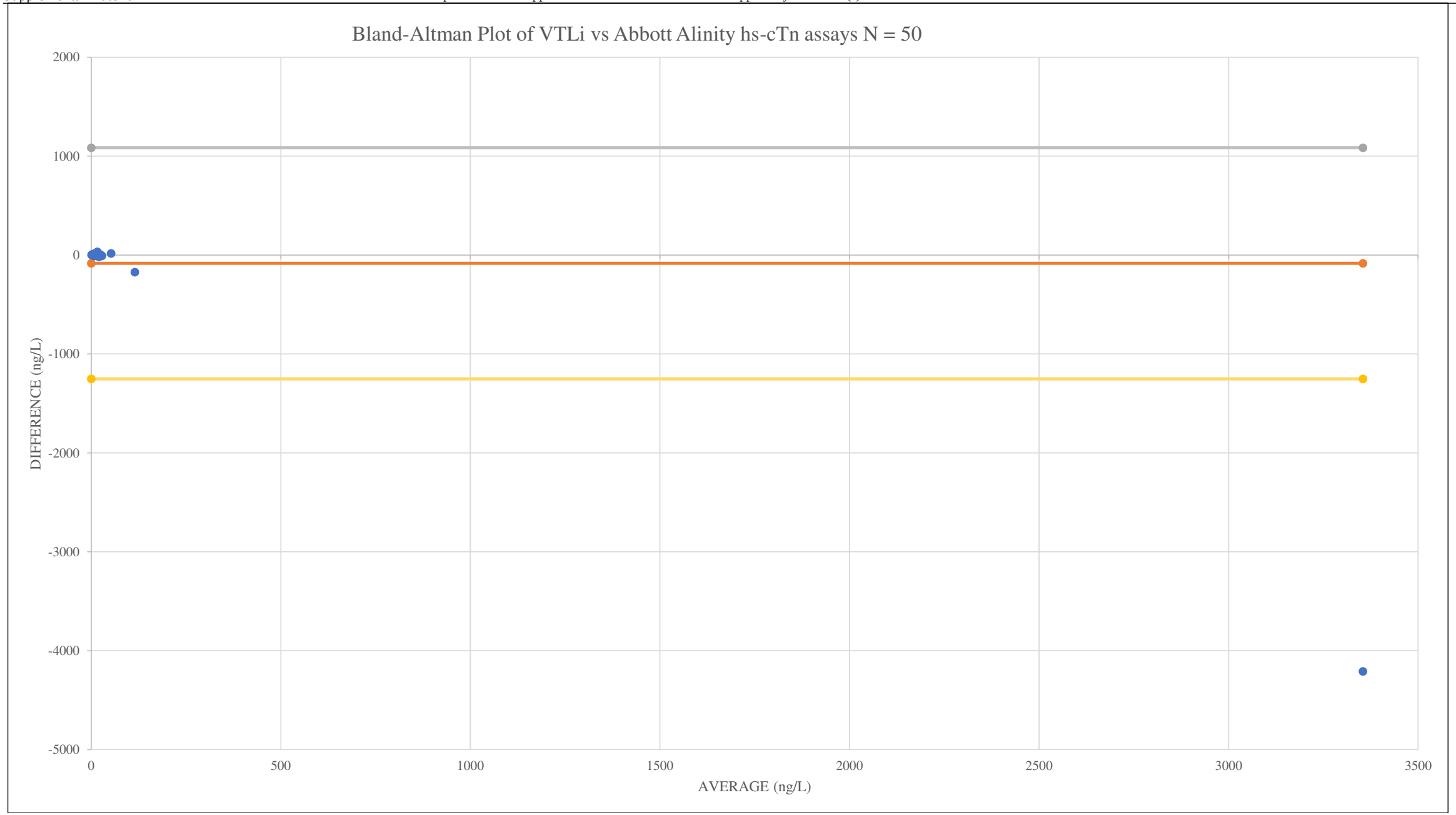
Bland-Altman Plot of VTLi vs Abbott Alinity hs-cTn assays N = 50
DIFFERENCE (ng/L)
AVERAGE (ng/L)
2000
1000
0
-1000
-2000
-3000
-4000
-5000
0
500
1000
1500
2000
2500
3000
3500

Figure S1.

Patient flow diagram.

Figure S2.

Bland-Altman Plot of the results of the Siemens Atellica VTLi POC hs-cTnI test versus the Abbott

Alinity laboratory hs-cTnI assay in all 50 patients.

Abbreviations: CI = confidence interval; hs-cTn = high sensitivity cardiac troponin; POC = point-of-care.