Imprecision and clinical performance of a whole blood high sensitivity point of care troponin I: the first prospective real-time study in suspected acute coronary syndrome

A. Dakshi[1], J. Hatherley[2], PO. Collinson[3], S. Phillips[2], L. Bailey[2], A. Hassan[2], M. Shaw[4] , G. Miller[5], A. Khand[1].
[1]University of Liverpool, Liverpool, UK [2]Royal Liverpool University Hospital, Liverpool, UK [3]St George's University Hospital NHS Foundation Trust, London, UK [4]Liverpool Heart and Chest Hospital, Liverpool, [5]UK Aintree University Hospital, Liverpool, UK

BACKGROUND

Implementation of accelerated diagnostic protocols (ADP) for suspected acute coronary syndrome (ACS), with resultant improvement in patient flow, will be facilitated by the use of point of care (POC) testing. To date there has been no published data on the use of a whole blood POC high sensitive troponin (hstn) in real time in a clinical environment.

OBJECTIVE

Independent evaluation of the analytical and clinical performance of the Quidel TriagetrueTM hs-TnI assay on whole blood and plasma.

METHODS

In a nested sub-study of a pragmatic randomised control trial, consecutive patients with suspected ACS and Chest pain <12 hours duration, underwent sampling for central lab hs-TnT Roche elecsys, Quidel TriageTrue POC hstnI whole blood and plasma and NICE approved central lab hstn I Siemens Attellica. (Figure 1-2).

Assay imprecision:

Assay imprecision was assessed by three operators (one expert, two non-expert) using duplicate analysis of whole blood samples at three levels: (low, near 10% CV5-10ng/l),(medium-approximating 99th percentile, 15-25 ng/L) and 3-5 times the 99th percentile (high, 60-100 ng/L).

Clinical performance:

Final diagnosis for Type 1 MI was adjudicated based on all relevant clinical and imaging data together with hstn T (Roche, elecsys) using the 4th universal definition of MI.

RESULTS

Figure 1. MACROS trial design

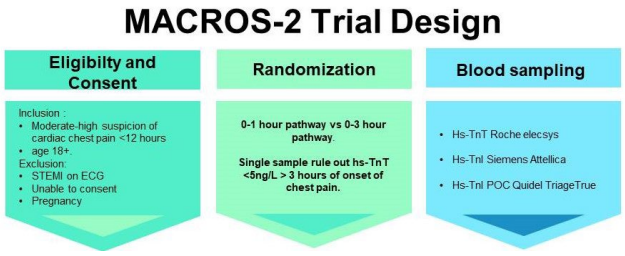


Figure 2. Demographics

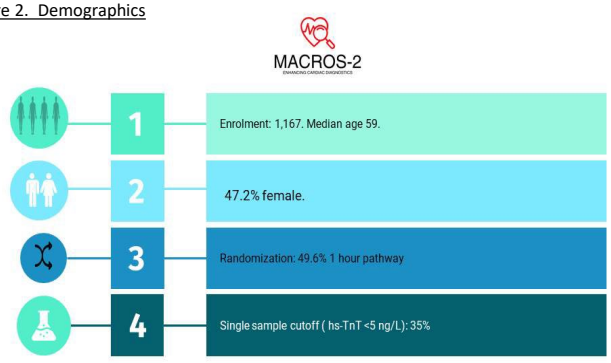
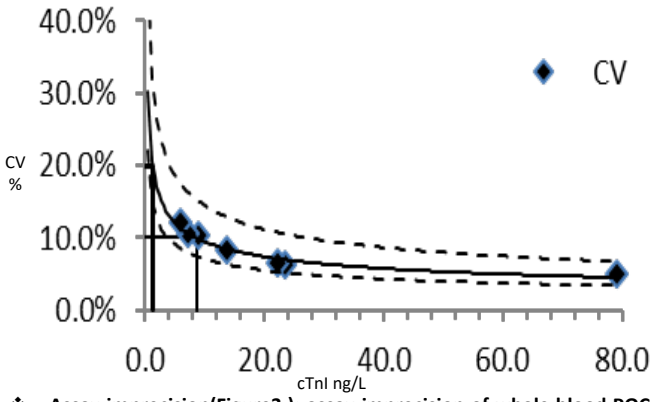
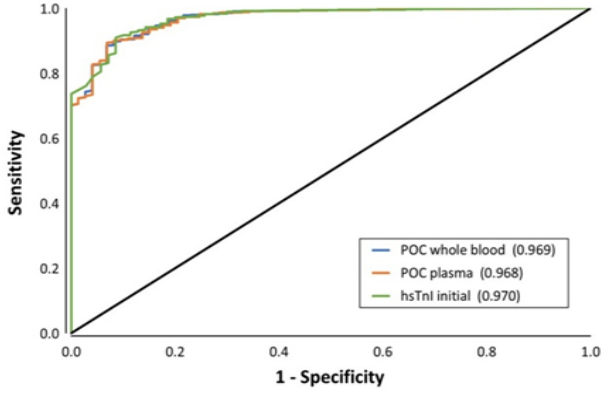


Figure 3. Total imprecision curve for whole blood measurements



❖ **Assay imprecision(Figure3.): assay imprecision of whole blood POC Quidel triage true revealed 10% CV at 8.6 ng/L, (>50% lower level than 99th percentile [20.4ng/l]) and a 20% CV at 1.2 ng/l).**

Figure 4.Comparison of Receiver Operating Characteristic curves.



❖ **Clinical Performance (Figure 4.): There was excellent overall agreement between laboratory hsTnI method and whole blood poc cTnI [Quidel triage true = 1.28, cTnI Attelica +1.3].**

CONCLUSION

The POC whole blood Quidel triage true demonstrates imprecision levels consistent with high sensitivity characteristics. The Quidel TriageTrueTM POC hs-TnI clinical performance is equivalent to an established and well validated laboratory hstn I. This is the first clinical validation of whole blood POC hstn assay studied real-time in a clinical environment.