The interobserver reliability of a novel qualitative point of care assay for heart-type fatty acid binding protein

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Rapid triage of patients admitted to the Emergency Department (ED) with chest pain is time-consuming and a diagnostic challenge. Heart-type fatty acid–binding protein (h-FABP may help to improve the early diagnosis of acute coronary syndromes (ACS) in patients presenting to the Emergency Department (ED) with chest pain. It has been shown to be a more effective biological marker than myoglobin for the very early detection of AMI. H-FABP being detected within 20 min of cardiac injury and peak levels are achieved 6 to 8 hours after the onset of AMI, and they return to normal values within 24 to 36 hours. A novel qualitative point of care H-FABP lateral flow immunoassay could enable results to be available to clinicians within 5 minutes; this rapid result is of significant benefit in emergency situations where time is critical for facilitates rapid decisions. The performance of a diagnostic test is dependent upon the ability of the observer to reliably and predictably assess the presence or absence of a positive result. Given the qualitative nature of this test, we aimed to determine interobserver reliability in a pragmatic study. Methods: In a nested prospective cohort study, we included consenting patients who presented to the ED with suspected cardiac chest pain within 12 hours of symptom onset. Venous blood was drawn on arrival and 3 hours later. Fresh whole blood samples were then immediately tested for H-FABP using a qualitative lateral flow immunoassay (calibrated to provide a positive result at 4ng/ml). After 5 minutes, tests interpreted by two independent observers including clinical research nurses; emergency physicians; and a medical technologist, each of whom had been previously instructed on how to interpret the test result. The observers were blinded to each other’s interpretation and recorded their interpretation on separate case report forms. We determined interobserver reliability by calculating the kappa score and 95% confidence intervals in SPSS version 20.0. We calculated that a sample of 44 patients would achieve the required level of precision. Results A total of 43 test results were interpreted by each of two independent investigators for this study. The tests were drawn from a total of 31 patients (12 of whom had tests on arrival and 3 hours later interpreted by two investigators). A total of 10 observers interpreted H-FABP results in this study, including four doctors (emergency physicians), five nurses and one medical technologist. Absolute agreement between investigators was 93.0% with a kappa of 0.81 (95% CI 0.6 – 1.0), indicating near perfect agreement. In total there were three (7.0%) disagreements. In each case one investigator reported a ‘weak positive’ result while the other interpreted the result as ‘negative’. Conclusions These findings demonstrate the reliability of a qualitative point of care H-FABP assay. Further work (which is on-going) must evaluate diagnostic accuracy and determine the clinical implications of the small rate of disagreement, including whether an automated reader may add value.