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LETTER TO THE EDITOR

Analytical Performance of the VIDAS® High-Sensitivity Troponin I Assay and the Beckman Coulter Unicel® DXI AccuTnI+3 Assay in a Stat Laboratory

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SUMMARY

Background: **The aim of this study was to compare the validity of two different cTnI assay methodologies.**
Methods: **We collected 82 plasma samples from a stat laboratory. The plasma values of cTnI ranged from 0.012 to 29.715 ng/mL when tested on the Access® platform and from 4.5 to >40,000 ng/L when tested on the VIDAS platform. The patients included 34 females ranging in age from 49 to 100 years of age [76.7 ± 12 years] and 48 males ranging from 29 to 97 years of age [69.7 ± 12 years].**
Results: **Our results showed that the correlation between the two troponin results was $r^2 = 0.9836$ ($p < 0.001$). In this study, the kappa statistic (0.89) indicated a high degree of agreement between the VIDAS® High-sensitivity Troponin I assay and the Beckman Coulter Unicel® DXI AccuTnI+3 assay.**
Conclusions: **In summary, the VIDAS® High-sensitivity Troponin I assay is a reliable and feasible method for determining the levels of cTnI in plasma, but it requires manual operation, hands-on technical expertise, and time.**
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KEY WORDS

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TO THE EDITOR

Cardiovascular diseases are a major cause of mortality and morbidity worldwide [1,2]. The diagnosis and management of patients with an acute myocardial infarction (AMI) must be assessed immediately to identify life-threatening emergencies. Measuring blood levels of troponin has rapidly become an accepted method for detecting myocardial damage, with cardiac troponin assays regarded as the gold-standard for detecting AMI [3]. Moreover, the guidelines set out in 2014 by the American College of Cardiology and the American Heart Association for non-ST segment elevation acute coronary syndrome (NSTE-ACS) suggest that cardiac

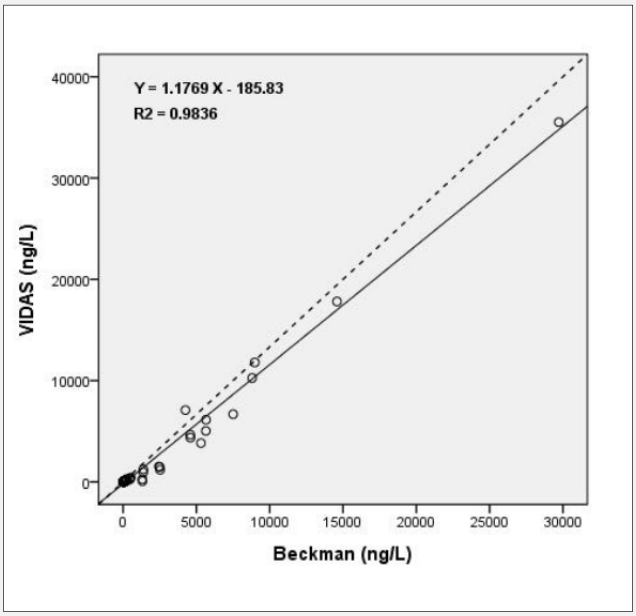

Figure 1. Comparisons of the two methods of cTnI measurement in patient plasma.

troponin I (cTnI) should be measured during the first assessment and then repeatedly 3 - 6 hours later [4]. Recently, highly sensitive cTnI assays have demonstrated an improved ability to detect and quantify cardiomyocyte injury more rapidly than the previous generations of cardiac troponin assays [5]. Moreover, these more sensitive assays may reduce the number of patients with undetected myocardial injuries. In this study, we compared the validity of two different cTnI methodologies. The levels of plasma cTnI were analyzed using the VIDAS® High-sensitivity Troponin I assay and the Beckman Coulter Unicel® DXI AccuTnI+3 assay, which reported range of 0.01 - 80 ng/mL and 1.5 - 40,000 ng/L, respectively. According to manufacturer specifications, the 99th percentile URL of the VIDAS® High-sensitivity Troponin I assay and the Beckman Coulter Unicel® DXI AccuTnI+3 assay is 19 ng/L and 0.04 ng/mL, respectively.

In this study, we collected 82 plasma samples from the stat laboratory of the Asia University Hospital and measured the plasma values of cTnI, which ranged from 0.012 to 29.715 ng/mL on the Access® assay and 4.5 to > 40,000 ng/L on the VIDAS assay. The patients from which these plasma samples were collected included 34 females ranging in age from 49 to 100 years [76.7 ± 12 years] and 48 males ranging in age from 29 to 97 years [69.7 ± 12 years]. Notably, our results showed that the 99th percentile URL CV% for the Access® and VIDAS assays is 1.47 - 3.20% and 5.41 - 8.80%, respectively. Analytical performance (CV%) showed that both assays satisfied the recommended guidelines for imprecision quality specification, with an increase in cardiac troponin levels exceeding the 99th percentile URL considered as clinically relevant and a cutoff for imprecision at ≤ 10 CV% [6]. The CV% of the VIDAS® High-sensitivity Troponin I assay is lower than that of the Beckman Coulter Unicel® DXI AccuTnI+3 assay. Figure 1 shows that the correlation between the troponin levels from the two assays which was $r^2 = 0.9836$ ($p < 0.001$). In this study, the kappa statistic (0.89) indicated a very high level of agreement between the VIDAS® High-sensitivity Troponin I and the Beckman Coulter Unicel® DXI AccuTnI+3 assays.

In the absence of myocardial ischemia and injury, elevated troponin levels can be caused by a variety of mechanisms, including vasculitis, drug abuse, myocarditis, pulmonary embolism, sepsis, and renal failure [7, 8]. In this study, we found that the two cTnI assays showed inconsistent results. The VIDAS® High-sensitivity Troponin I assay displayed negative results at 16.7 ng/L and < 1.5 ng/L, with a reference interval of < 19 ng/L, while the Beckman Coulter Unicel® DXI AccuTnI+3 assay displayed slightly positive results at 0.045 ng/mL and 0.054 ng/mL. Electrocardiography (ECG) identified sinus tachycardia and a 1st-degree AV block in the sinus rhythm. Moreover, the Beckman Coulter Unicel® DXI AccuTnI+3 assay showed negative results at 0.019 ng/L and 0.036 ng/L across the ref-

erence interval of < 0.04 ng/mL, while the VIDAS® High-sensitivity Troponin I assays showed slightly positive results at 21.6 ng/L and 22.6 ng/L. Abnormal readings on an ECG indicated a right bundle branch block as well as probable junctional tachycardia. These findings indicate the presence of false-positive results in this subset of patients without acute myocardial infarction. This study demonstrates that the VIDAS® High-sensitivity Troponin I assay is a reliable and effective approach to determine the plasma levels of cTnI. However, the VIDAS® High-sensitivity Troponin I assay is manually operated and requires hands-on technical expertise as well as time. The possible integration of the VIDAS® High-sensitivity Troponin I assay into an automated workflow remains a technical challenge that has yet to be overcome. The development of this automated workflow is essential, as laboratories with a high sample load require automation to achieve timely progress and acceptable turn-around times. Additionally, if the clinical data are not consistent with the elevated levels of cTnI, clinicians should consider other potential causes including false-positive results.

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Declaration of Interest:
There are no conflicts of interest associated with this paper.

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