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Letters to the Editor

Important Differences Between Manufacturers When Transitioning From a Contemporary Cardiac Troponin Assay to a High-Sensitivity Cardiac Troponin Assay

To the Editor:

Despite high-sensitivity cardiac troponin (hsTn) assays having superior analytical and clinical performance compared with contemporary cTn assays, there are still analytical issues that may necessitate that clinical laboratories institute additional testing and inform clinicians of errors when reporting hsTn results.[1-3] We have recently identified that the Ortho hsTnI assay misclassifies patients with myocardial injury (~10% false positives for injury at a hospital and cancer centre), compared with the Abbott hsTnI assay.[4] It is unclear what the impact would be for hospital sites transitioning from a contemporary cTn assay to Ortho's hsTnI assay and whether the increase in positivity would be evident at another hospital setting. Given this, we assessed the impact of transitioning from a contemporary cTnI assay (Siemens EXL cTnI normal < 0.06 ug/L) to the Ortho hsTnI (female normal: <10 ng/L; male normal: <14 ng/L) using the published 99th-percentile cutoffs on the percentage (%) of positive results at a community hospital with an emergency department (ED) (West Lincoln Memorial Hospital [~60 beds]).

Over the first 18 weeks after commencing Ortho hsTnI testing at this hospital, the % positive was higher (26%; 95% confidence interval [CI]: 25%–29%; n = 1914 total results; 87.0% results from ED in 2020) vs the Siemens cTnI assay in the corresponding timeframe in 2019 (13%; 95% CI: 11%-15%; n = 1628 total results, with 85.6% of results from ED). After the laboratory program instituted duplicate testing for the Ortho hsTnI assay (to mitigate analytical outliers) with any positive results reflexed for Abbott hsTnI, over 4 weeks, the Ortho hsTnI assay still yielded higher % positive results (29%; 95% CI: 24%-34%; n = 452 total results) compared with the Siemens cTnI (21%; 95% CI: 17%-26%; n = 417; total results in 2019; $P = 0.02$). The Abbott hsTnI assay yielded positivity estimates over these 4 weeks (23%; 95% CI: 19%-28%) similar to those from the Siemens cTnI assay ($P = 0.55$). The number of patients that were positive by Ortho hsTnI and negative by Abbott hsTnI over these 4 weeks was 15, or 6.4% (95% CI: 3.9%-10.4%) of the population with hsTnI measured. None of these 15 patients had a diagnosis of acute coronary syndrome with the discordant findings between Ortho hsTnI and Abbott hsTnI (Supplemental Table S1). Removal of the Ortho false positives and results with macrocomplexes (Fig. 1) yielded a higher correlation between Ortho hsTnI and Abbott hsTnI in this subgroup (rho = 0.94; 95% CI: 0.91-0.96; n = 91), with closer agreement to what has been observed in patients with symptoms suggestive of acute coronary syndrome.[4]

These data support suboptimal performance of Ortho hsTnI for the detection of myocardial injury in the community-hospital setting, with confirmation by another hsTnI assay helpful to prevent a misdiagnosis.

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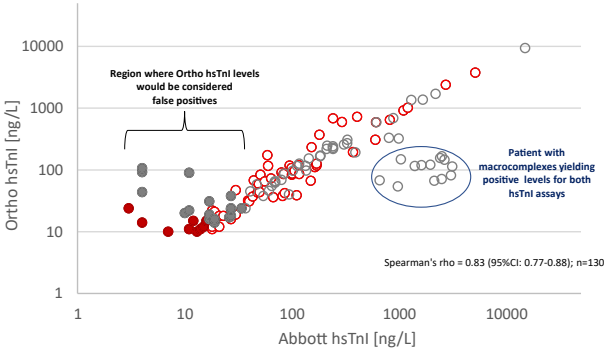

Figure 1. Comparison between Ortho high-sensitivity cardiac troponin (hsTn)I (y-axis) and Abbott hsTnI (x-axis) for patients at a community hospital who are positive with the Ortho hsTnI assay (red and grey filled circles are samples from females and males, respectively, who are positive for Ortho [upper reference limit (URL = 99th percentile); female URL < 10 ng/L; male URL < 14 ng/L]) and negative for Abbott hsTnI (ie, concentrations < sex-specific URLs).

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Disclosures

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The other authors have no conflicts of interest to disclose.

Ethics Statement

Ethics approval: HiREB 2179 as part of an on-going study on interferences in clinical chemistry and immunoassay tests.

References

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2021.01.017.