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HIGH-SENSITIVITY CARDIAC TROPONIN I ASSAY TO REPLACE CURRENT TROPONIN ASSAY IN THE REGIONAL CENTERS

Gene Shaw, M.D., Sarah Bissonnette, Ph.D.

Effective July 27th, 2020 the Marshfield Clinic Health System regional centers will convert to the recently FDA-approved Siemens LOCI high-sensitivity cardiac troponin I assay. Compared with the current assay, the high-sensitivity assay offers greater precision especially at the low end of the measurable range. Significantly more patients will now have a reportable value rather than the < 16 ng/L often reported currently. Additionally, the new assay facilitates more rapid and accurate assessment of chest pain for timelier patient triage.

Figure 1 below shows the proposed algorithm for use with this assay. This is essentially the same algorithm validated by a multi-national European study of 1755 patients using a Siemens high sensitivity troponin assay, published in Clinical Chemistry[1]. It should only be applied after ST-elevated myocardial infarction has been ruled out by ECG and should always be used in conjunction with all other clinical information, a detailed history of the chest pain characteristics, and physical examination. To ensure best practice, providers should strictly abide to the draw times: at presentation and two hours later. Patients that RULE OUT based on the algorithm have a very low risk of acute myocardial injury (negative predictive value of 99%). Additional high-sensitivity troponin I testing after two hours may be especially helpful in patients not meeting either the rule-in or rule-out criteria.

In the usual emergency department setting, a slight majority of patients can be ruled out for acute myocardial injury within two hours using this algorithm. They can usually be safely discharged to home if there are no other acute medical problems requiring hospitalization. Conversely, about 15% of patients will rule in for acute myocardial injury (most meeting criteria for a non-ST-elevation or NSTEMI). These patients are at significantly higher risk for major adverse cardiac events or death within 30 days and will likely benefit from interventions such as antiplatelet therapy, use of a statin (or other lipid – lowering agent), and potentially revascularization (depending on angiographic findings). A residual approximately 30% of patients will fall into an observation (gray-zone) category. For this subgroup repeat testing will likely be needed along with ongoing clinical assessment. Perhaps 15% of patients in this

BEYOND numbers

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subgroup will eventually meet criteria for NSTEMI.

Obtaining a single high-sensitivity troponin I value is discouraged in the acute care setting. A low value may seem reassuring, but the onset of symptoms and/or ischemia can be difficult to pin down. Conversely, some patients with chronic cardiac conditions (e.g. congestive heart failure) can have stable mild elevations in troponin I; this should not be confused with acute coronary syndrome (ACS). Thus, getting a second value to calculate the delta is critical in assessing patients with potential ACS. In some clinical situations, ordering a single high-sensitivity troponin I value is appropriate; e.g. monitoring congestive heart failure or checking for drug-induced cardiotoxicity. The interested reader is referred to the published Fourth Universal Definition of Myocardial Infarction article in Circulation available on line for further discussion on how high sensitivity troponin assays should be used in other settings such as re-infarction or procedure-related myocardial infarction[2].

Clinical and technical questions or concerns:

Gene R. Shaw, MD; Sarah Bissonnette, PhD.
Phone number: 1-800-222-5835

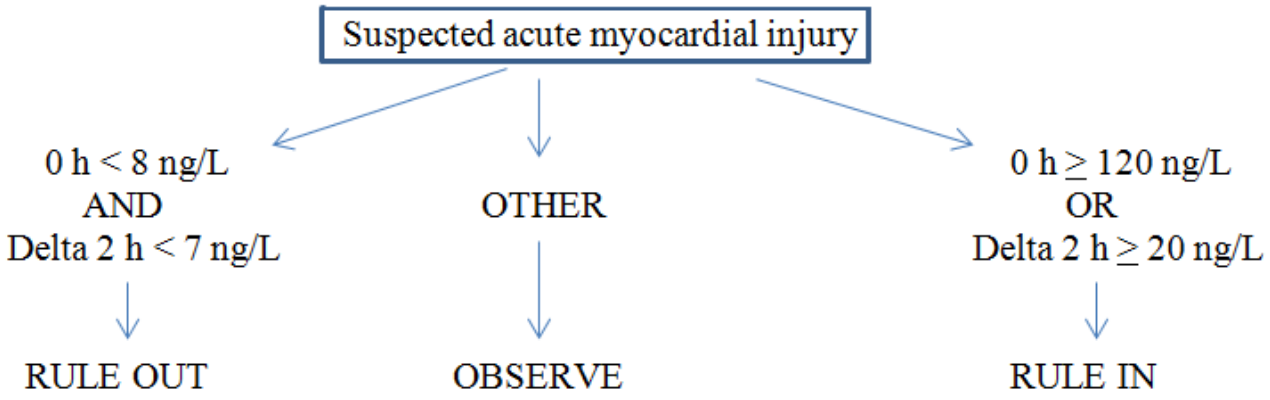
Interpretive comments:

Normal population 99th percentiles: ≤ 51 ng/L women; ≤ 76 ng/L men.
Values greater than these cutoffs will be flagged as high.

Sample type:

Preferred: plasma (lithium-heparin). No clotting time required.
Acceptable: serum. Requires longer turn-around time to allow for clotting prior to centrifugation.

Figure 1:



References:

1. Boeddinghaus J, et al. Clinical Validation of a Novel High-Sensitivity Cardiac Troponin I Assay for Early Diagnosis of Acute Myocardial Infarction. Clin Chem. 64:1347-1360. 2018.

2. Thygesen K, et al. Fourth Universal Definition Myocardial Infarction (2018). Circulation. Online. 2018.