High – sensitivity Troponin T-clinical progress or just more noise?

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The 5th generation Troponin T assay, commonly referred to as "high sensitivity Troponin" or hs-cTnT, has been validated and used for several years in many countries, primarily in Europe and Australia, but was only recently approved by the FDA for use in the United States. It differs from "standard" or "4th generation" troponin assays in several important ways.

The sample size is increased from 15 to 50 microliters, increasing the chances of "recovery." Other modifications include signal amplification and genetic re-engineering of the chimeric antibody itself to improve precision and performance. Importantly, however, the assay detects the identical Troponin T epitopes as previous generations. As with other "high sensitivity assays" (such as hs-CRP), results are now reported in whole numbers per liter. For instance, a previous Troponin T value of 0.019 ng/ml would be reported at 19 ng/l. The new assay has a very low "limit of blank" – the level at which Troponin T can reliably be detected – and the limit of quantification is 6 ng/l.

New protocols for "rule out" of chest pain patients presenting to emergency departments (ED) have been developed. With such low levels of hs-cTnT detectable, patients can be ruled out (or in) for myocardial infarction (MI) much earlier, within one hour of presentation if chest pain has been present for at least three hours. A second hs-cTnT level is also drawn, generally at three hours post presentation. The "cut points" for positivity of this assay is based upon the 99th percentile of hs-cTnT in healthy individuals, which is 14 ng/l for women and 22 ng/l in men. Often, a "compromise" level of 19 ng/l has been used for both genders.

In the APACE study, a 1 hour "rule-in" level of 14ng/l was initially applied. A second analysis was performed using FDA approved levels: 6 ng/l for rule out and 19 ng/l for rule in. In the 3267 patients, MI was the final diagnosis in 15.8% of patients using 14 ng/l, and 15.5% using 19 ng/l. The negative predictive values and sensitivity of MI diagnosis were greater than 99% whether 5 or 6 ng/l was used as the rule out value. The positive predictive value and specificity of hs-cTnT for MI diagnosis were not as high, however, generally ranging from 50% to 75%.[1] Interestingly, in the sites participating in the APACE study, switching to the use of hs-cTnT increased the frequency of MI diagnosis (10% vs 14%), reduced the use of stress testing in ED chest patients (29% to 19%), and reduced the median time to discharge from the ED (by > 9 minutes). Mean total costs in these patients decreased by 20%, despite no change in the use of invasive coronary angiography (23% both before and after use of the new assay).[2]

In summary, use of the "generation 5", or high-sensitivity Troponin T presents a new, more efficient way to rule in or out the presence of myocardial necrosis in patients presenting with chest pain. If properly applied, costs and ED discharge times may decrease as well.

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