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REVIEW

High-sensitivity cardiac troponin assays: Answers to frequently asked questions



Troponine dosée avec un test de haute sensibilité : éléments de réponse aux questions fréquemment posées

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Abbreviations: ACS, acute coronary syndrome; AMI, acute myocardial infarction; cTn, cardiac troponin; cTnI, cardiac troponin I; cTnT, cardiac troponin T; CV, coefficient of variation; ECG, electrocardiogram; ESC, European Society of Cardiology; HAMA, heterophilic human antimouse antibody; hs-cTn, high-sensitivity cardiac troponin; LBBB, left bundle branch block; LoB, Limit of Blank; LoD, Limit of Detection; LoQ, Limit of Quantitation; NSTEMI, non-ST-segment elevation myocardial infarction; RCV, reference change value; ROC, receiver operator curve; SFBC, Société française de biologie clinique; SFC, Société française de cardiologie; SFMU, Société française de médecine d'urgence; STEMI, ST-segment elevation myocardial infarction; URL, upper reference limit.

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Acute coronary
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Chest pain

Summary Cardiac troponin (cTn) assays have quickly gained in analytical sensitivity to become what are termed 'high-sensitivity cardiac troponin' (hs-cTn) assays, bringing a flurry of dense yet incomplete literature data. The net result is that cTn assays are not yet standardized and there are still no consensus-built data on how to use and interpret cTn assay results. To address these issues, the authors take cues and clues from multiple disciplines to bring responses to frequently asked questions. In brief, the effective use of hs-cTn hinges on knowing: specific assay characteristics, particularly precision at the 99th percentile of a reference population; factors of variation at the 99th percentile value; and the high-individuality of hs-cTn assays, for which the notion of individual kinetics is more informative than straight reference to 'normal' values. The significance of patterns of change between two assay measurements has not yet been documented for every hs-cTn assay. Clinicians need to work hand-in-hand with medical biologists to better understand how to use hs-cTn assays in routine practice.

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MOTS CLÉS

Troponine ;
Haute sensibilité ;
Infarctus du
myocarde ;
Syndrome coronarien
aigu ;
Douleur thoracique

Résumé L'évolution rapide des méthodes de dosage des troponines cardiaques (cTn) vers une meilleure sensibilité analytique (cTn de haute sensibilité, ou cTn HS) s'accompagne de nombreuses données de la littérature mais encore incomplètes. En l'absence de standardisation des cTn et de données consensuelles sur l'utilisation et l'interprétation des résultats, les auteurs de cette revue proposent, à partir d'une revue de la littérature, et de façon multidisciplinaire, des éléments de réponses aux questions fréquemment posées. En conclusion, le bon usage des cTn HS repose sur la connaissance : des caractéristiques propres de la méthode utilisée, en particulier de la précision obtenue au 99^e percentile d'une population de référence ; des facteurs de variation de la valeur du 99^e percentile ; de la forte individualité des dosages de cTn HS, pour lesquels la notion de cinétique individuelle est plus informative que la simple référence à des valeurs usuelles. La significativité des variations entre deux dosages, n'est pas encore documentée pour toutes les méthodes HS. La collaboration entre cliniciens et biologistes est nécessaire à une meilleure utilisation des troponines au quotidien.

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Background

International guidelines on myocardial infarction (MI) diagnosis recommend running a cardiac troponin (cTn) assay in suspected MI patients unless they present ST-segment elevation (suspected lone-event non-ST-segment elevation MI [NSTEMI]). The need to observe an increase in troponin over the 99th percentile of a reference population together with the significant assay-to-assay variation make it necessary to use what are dubbed sensitive or hypersensitive cTn assays. cTn assays are rapidly gaining in analytical sensitivity. Published data on this latest generation of more sensitive assays are dense, but are still incomplete. Furthermore, cTn assays are not yet standardized and there are still no consensus-built data on how to use and interpret high-sensitivity cTn (hs-cTn) assay results.

Given this context, three French academic societies – the Société française de médecine d'urgence (SFMU) for emergency medicine, the Société française de cardiologie (SFC) for cardiology and the Société française de biologie clinique (SFBC) for clinical biology – have joined forces to co-propose an integrated French-language document that, through a review of the literature, tackles the issue of how to use troponin assays properly. The document adopts a

'Question and Answer' format to connect with grass-roots practitioners, and is written to provide clinicians and biologists with the most routine-relevant conclusions possible, including a series of boxes headed 'In practice/takeaways', which recap the key messages.

Terms and definitions

What does assay sensitivity mean?

An assay that qualifies as sensitive or hypersensitive (qualifiers arbitrarily grouped under the term 'high-sensitivity' in this paper) is an assay that demonstrates greater analytical sensitivity and precision than the conventional method it is built on. The word 'sensitive' refers to the assay, not to the biomarker itself.

From an analytical standpoint, analytical sensitivity is the smallest measurable analyte concentration above the limit of detection. Here, sensitivity is determined by the slope of the calibration curve. Higher sensitivity increases the possibility of getting low variations between two assays, as their respective signals will be significantly different (Fig. 1).

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