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Multi-centre evaluation of recent troponin assays for the diagnosis of NSTEMI

Camille Chenevier-Gobeaux[a,*], Louis Deweerdt[b], Anne-Valérie Cantero[c], Bertrand Renaud[d], Bruno Desmaizières[e], Sandrine Charpentier[f], Aline Leroy[g], Emmanuelle Adelaïde[h], Delphine Collin-Chavagnac[i], Eric Bonnefoy-Cudraz[j], Laurence Estepa[k], Akli Chekroune[l], Sylvie Basco[m], Stéphane Andrieu[n], Stéphane Bourgeois[o], Marie-Agnès Costa[p], Christine Vallejo[q], Tiphaine Robert[r], Siham Ouahabi[s], Bruno Baudin[t], Benedicte Beneteau-Burnat[t], Anne-Marie Gorce-Dupuy[u], Patrick Ray[v], Claire Gast[v], Monique Dehoux[r], Guillaume Lefèvre[s,w], for the Troponins Working Group of the Société Française de Biologie Clinique (SFBC), in collaboration with the Société Française de Médecine d'Urgence (SFMU) and the Société Française de Cardiologie (SFC)

[a] *Department of Automated Biological Diagnosis, Cochin Hospital, Hopitaux Universitaires Paris Centre (HUPC), Assistance Publique des Hôpitaux de Paris (APHP), 27 rue du Faubourg Saint-Jacques, 75679 Paris cedex 14, France*
[b] *Laboratoire de Biologie Médicale Groupe Biologic, Paray Le Monial, Labco, France*
[c] *Laboratoire de Biochimie, CHU Toulouse Rangueil, Toulouse, France*
[d] *Emergency Department, Cochin Hospital, Hopitaux Universitaires Paris Centre (HUPC), Assistance Publique des Hôpitaux de Paris (APHP), France*
[e] *Emergency Department, CH Paray Le Monial, Paray Le Monial, France*
[f] *Emergency Department, CHU Toulouse Rangueil, Toulouse, France*
[g] *Laboratoire de Biologie Médicale, Centre Hospitalier de Bourg-en-Bresse, Bourg-en-Bresse, France*
[h] *Emergency Department, Centre Hospitalier de Bourg-en-Bresse, Bourg-en-Bresse, France*
[i] *Groupement Hospitalier Sud Centre de Biologie et de Pathologie Sud, Hospices Civils de Lyon, 69495 Pierre Bénite, France*
[j] *Cardiology Department, Hospices Civils de Lyon, Lyon, France*
[k] *Laboratoire de Biologie, Hôpital de Blois, Blois, France*
[l] *Emergency Department, Hôpital de Blois, Blois, France*
[m] *Laboratoire de Biologie Médicale, Centre Hospitalier Henri Duffaut, Avignon, France*
[n] *Cardiology Department, Centre Hospitalier Henri Duffaut, Avignon, France*
[o] *Emergency Department, Centre Hospitalier Henri Duffaut, Avignon, France*
[p] *Laboratoire de Biochimie, Centre Hospitalier de Limoges, Limoges, France*
[q] *Emergency Department, Centre Hospitalier de Limoges, Limoges, France*
[r] *Laboratoire de Biochimie, Hôpital Bichat-Claude Bernard, Hôpitaux Universitaires Paris Nord Val de Seine, Assistance Publique des Hôpitaux de Paris (AP-HP), Paris, France*
[s] *Laboratoire de Biochimie et Hormonologie, Hôpital Tenon, Hôpitaux Universitaires Est Parisien, GRC-UPMC BIOSFAST Assistance Publique des Hôpitaux de Paris (AP-HP), Paris, France*
[t] *Laboratoire de Biochimie, Hôpital Saint-Antoine, Hôpitaux Universitaires Est Parisien, Assistance Publique des Hôpitaux de Paris (AP-HP), Paris, France*
[u] *Laboratoire de Biochimie et Hormonologie, Hôpital Lapeyronie, Montpellier, France*
[v] *Emergency Department, Hôpital Tenon, Hôpitaux Universitaires Est Parisien, Assistance Publique des Hôpitaux de Paris (AP-HP), Paris, France*
[w] *GRC-UPMC BIOSFAST, France*

[*] Corresponding author.
E-mail address: camille.gobeaux@aphp.fr (C. Chenevier-Gobeaux).

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ABSTRACT

Objectives: We aimed to compare the use of nine different cardiac troponin (cTn) assays (2 cTnT and 7 cTnI) for the diagnosis of NSTEMI in a single multi-centre population.
Design and methods: One hundred and fifty-eight patients were included (mean age 60 years, SD 17 years), including 23 patients (14%) with NSTEMI.
Results: The analytical comparison highlighted a large heterogeneity of cTn assays, as reflected by percentages of patients with detectable cTn, correlation coefficients, Passing-Bablok comparisons and concordance coefficients. Correlations within cTnI assays were good and correlation within cTnT assays was excellent. Diagnostic performances demonstrated that each cTn assay has specific threshold values. Furthermore, some assays (HS-cTnI and T, cTnI-Pathfast and cTnI-Centaur) indicated high sensitivity and negative predictive value using the limit of detection (LoD) diagnostic strategy. For the latter assays, a significant increase in specificity was found when using the 99th percentile or the H0-H3 strategies, in comparison to the LoD strategy. When applying the European Society of Cardiology H0-H3 algorithm, comparable diagnostic performances were obtained.
Conclusion: All 9 cTn assays indicated overall good diagnostic performances for the diagnosis of NSTEMI in emergency departments when the recommended algorithm based on the variation of cTn value between two measurements at admission and 3 h later was used.

1. Introduction

Since the European Society of Cardiology (ESC) recommendations about myocardial infarction in 2012 and 2015, the main role of cardiac troponin (cTn) results has been confirmed in the diagnosis of non-ST elevation acute myocardial infarction (NSTEMI) [1,2]. In 2012, Thygesen et al. recommended a way in which to use high-sensitive cTn (HS-cTn) assays, based on two blood samples (one at admission or H0, and one 3 h later or H3), and the use of a specific delta change (either relative or absolute) between H0 and H3 [3]. Recently, this H0-H3 strategy was confirmed as a 'universal' algorithm for rule-in or rule-out of NSTEMI, for all cTn assays [2]; however, the delta change value was not specifically indicated for each cTn assay. Recent guidelines further suggest the use of a rule-out rapid algorithm, based on a single cTn measurement at admission (H0) and using low threshold values (the limit of detection (LoD) of the assay) [2]. However, this rapid exclusion algorithm is not recommended for all cTn assays [2].

In hospital laboratories and in point-of-care testing, cardiac troponin measurements are achieved by various assays, including "contemporary", "sensitive" and "highly-sensitive" assays [4]. Briefly, the adjectives "contemporary", "sensitive" and "highly-sensitive" are used when the analytical precision of the assay (calculated as the coefficient of variation [CV]) at the 99th percentile value is above, equal to or less than 10%, respectively. Due to the absence of standardisation, troponin results cannot be transferred from one assay to another, and individual cut-offs must be strictly used in the context of the troponin assay for which they were determined [4]. Few studies indicate delta change values for cTn assays in a single population, but most are reported for HS-cTn methods [3,5–7].

We thus aimed to compare, from both an analytical and a clinical view, the use of different cTn assays in a routine setting for the diagnosis of NSTEMI in emergency departments, in a single multi-centre population, in order to determine the diagnostic characteristics of each cTn assay following the recommended algorithms.

2. Materials and methods

2.1. Study population

The study was conducted in 13 French hospitals: 9 centres were involved in patient inclusion and sample collection, with 4 additional centres involved in the measurement of troponin only. Inclusions were performed between April 2014 and November 2015.

Our study complied with all of the relevant national regulations and institutional policies, was in accordance with the tenets of the Helsinki Declaration, and was approved by the local ethics committee (Comité de Protection des Personnes [CPP] Ile-de-France III: study reference SC-3122; Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé [CCTIRS], from the Direction Générale pour la Recherche et l'Innovation [DGRI]: study reference DGRI CCTIRS MG/CP 2014.297). All patients gave informed consent.

We followed the recommendations on reporting diagnostic studies set forth by the Standards for Reporting of Diagnostic Accuracy (STARD) initiative [8]. We enrolled consecutive patients (> 18 years of age) who presented to the ED with chest pain suggestive of AMI with the onset or peak occurring within the previous 6 h. Patients with ST elevation myocardial infarction (STEMI) and patients with acute or chronic kidney failure requiring dialysis were excluded, but no upper age limit was applied. Patients without 2 cardiac troponin measurements (on admission, H0, and 3-h later, H3) were excluded. Patients with haemolysed plasma samples were also not included (sample haemolysis evaluation was performed routinely by the instrument concomitant with cTn measurements).