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Letter to editor

Strength and pitfalls of the point of care testing: the central role of the laboratories for a successful goal

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To the Editor,

Point-of-care testing (POCT) is a well-known technology that ensures fast results close to the patient's bed site. For this reason, POCTs accelerate clinical decisions and could ameliorate patient outcomes. Nowadays, POCT technology has been improved by providing portable and easy-to-use devices for the quantitative determination of clinical chemistry analytes, coagulation, and cardiac biomarkers (e.g., high-sensitivity troponin assays). The advantages of POCT have improved the analysis time associated with delays due to transport in the laboratory thanks to the prompt execution of tests close to the patient and responding to the needs of emergency departments. Many POCTs ensure a lead time of less than 15 minutes for a complete panel of clinical chemistry, including electrolytes, ALT, AST, amylase, total bilirubin, calcium, albumin, creatinine, C-reactive protein (CRP) and glucose. An important effort has been made to develop POCT devices for Acute Myocardial Infarction (AMI) diagnosis. Considering cardiac injury biomarkers, in 2020, the European Society of Cardiology (ESC) coined the fourth definition of Acute Myocardial Infarction (AMI), defined as a clinical setting in the presence of cardio-myocyte necrosis with acute myocardial ischemia. The opportunity to use POCT technologies for quick and high-sensitivity measurements represents a fundamental improvement for AMI differentiated diagnosis in critical conditions. In fact, to make the diagnosis of AMI is required a combination of criteria between the use of high sensitivity cardiac troponin I or T (hs-TnI and hs-TnT) with at least one value above the 99th percentile of the higher reference limit (1). In 2021, Apple et al. validated the test for hs-TnI using the Atellica VTLi hs-cTnI immunoassay, with a TAT of 8 minutes (2), Atellica POCT requires a few drops of capillary blood or lithium heparin whole blood, meeting the criteria reported by ESC for AMI diagnosis. Apple et al. reported for Atellica VTLi hs-cTnI immunoassay an imprecision at the cardiac troponin (cTn) concentration of the lowest sex-specific 99th percentile upper reference limit ≤ 10% CV and the measured hs-cTn concentrations in ≥50% of healthy males and females, which exceeds the assay limit of detection (LoD) (3). Nowadays, POCT can be linked with the most adopted laboratory information system (LIS). Besides ensuring an automatic flow of results without manual data transcription, it permits the opportunity to have a laboratory remote control on all the analytical platforms deployed far from the hubs and to store all the patient results to guarantee their traceability over time. Although different points of strength, some considerations must be considered when POCT are available in our hospitals. Quality specifications for POCT testing should be the same as those for centralized laboratories. In particular, the advantages of sensitive assays of cTns in allowing early diagnosis and prompt treatment cannot be side-stepped by using POCT methods with a low analytical sensitivity. Lacking harmonization and traceability, these issues force us to carefully consider POCT results. Indeed,

in many cases, POCT uses a biological matrix that is not the common one used on automated laboratory analysers (ALA), giving hardly comparable results. For instance, Piccolo Express® AmLyte 13 required lithium heparin whole blood instead of serum, referring to different reference intervals. Moreover, the ALT and AST methods present on Piccolo Express® AmLyte13 do not include P-5'-P as the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) recommended for transaminase determination. Regarding hs-Tn the importance of the matrix is once more pivotal. Regarding cardiac biomarkers, the comparability between POCT hs-TnI and hs-TnI obtained with a laboratory automated immunoassay must be evaluated before allowing the use of POCT results since most laboratories in Italy use lithium heparin plasma or serum with the possibility of not comparable results. The traceability of hs-TnI methods is still lacking. Thus, every laboratory must validate its 99th percentile to establish its own cut-off for AMI rule-out. Hs-TnI POCT could be present in the emergency department and could be employed for the 0/1-hour protocol to exclude AMI, but how about the follow-up determinations? If the first determination was performed with POCT, would the result be comparable to that of the central laboratory? It is very important to know if these two analytical platforms are harmonized to guarantee the opportunity to establish serial measurements as in evaluating the degree of myocardial damage. Serial troponin measurement after AMI diagnosis is also important as a prognostic value for the evaluation of the reserve ejection fraction presented by the patient. Therefore, it is pivotal for every laboratory to know the eventual bias between POCT and central laboratory instrumentation to decide whether it is acceptable or not, giving accurate instruction to the physician for a correct interpretation. Central laboratory instruments must be checked before starting the routine analysis, respecting the imprecision and bias declared by the producers. Moreover, as we know, external proficiency tests are mandatory for public clinical laboratories in Italy. Regarding POCT, ISO22870 lists specific requirements for the quality and competence of point-of-care testing (POCT) which are intended for medical laboratories in conjunction with ISO15189. Rampoldi et al. highlighted once more that clinical governance, connectivity, the role of the laboratory director and staff, quality control (QC), education, risk management and the role of the in vitro diagnostic companies are extremely crucial for the correct use and implementation of POCT (4, 5). In many cases, POCT includes an internal quality control provided by the producer with known low and high concentrations of analytes intended to be measured. Third-party quality control is strongly advised exactly as for central laboratory instrumentation. In 2022 Emilia Romagna region (Italy) published a document giving indications for the laboratories working on its territory to harmonize the installation and application of these platforms (5, 6). Our concern is high when we are informed that POCT could be available in private clinics without a laboratory's connectivity. As POCTs are user-friendly, they could also be "error-friendly," especially if the QC protocols and performances are not verified. POCT should not be used to perform the test when even just one QC level fails. Finally, the strength of POCTs is represented by their usefulness in emergency contexts to guarantee timely clinical choices for better patient management. Once more, the network between the central laboratory and the POCT is necessary to achieve quality standards, so it is mandatory for the POCTs to be integrated with the central laboratory thanks to the support of connectivity. New clinical governance framework may be based on an integrated diagnostic structure, where POCT and central laboratory data are fully combined with all patient data to allow not only traditional policy, programme of quality assurance, risk management, and technology assessment but also integrated for shared the patient management.

Considering these issues, the role of laboratory is pivotal as a governance of POCT technologies used inside or outside the hospitals. Good procedures shared with emergency departments, a strict supervising of quality control, and continuous training of users are the way to pursuit if we want to permit an accurate use and interpretation of results in clinical practice.

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References

1. Collet JP, Thiele H, Barbato E, et al. ESC Scientific Document Group. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J. 2021 Apr 7;42(14):1289-1367. doi: 10.1093/eurheartj/ehaa575. Erratum in: Eur Heart J. 2021 May 14;42(19):1908. Erratum in: Eur Heart J. 2021 May 14;42(19):1925. Erratum in: Eur Heart J. 2021 May 13.
2. Apple FS, Schulz K, Schmidt CW, Van Domburg TSY, Fonville JM, de Theije FK. Determination of sex-specific 99th percentile upper reference limits for a point of care high sensitivity cardiac troponin I assay. Clin Chem Lab Med 2021;59:1574–8. Doi: 10.1515/cclm-2021-0262.
3. Wu AHB, Christenson RH, Greene DN, et al. Clinical laboratory practice recommendations for the use of cardiac troponin in acute coronary syndrome: expert opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry and Laboratory Medicine. Clin Chem 2018;64:645–55. Doi: 10.1373/clinchem.2017.277186.
4. Oliver P, Fernandez-Calle P, Buno A. POCT Accreditation ISO 15189 and ISO 22870: Making the Point. EJIFCC. 2021 Jun 29;32(2):131-139.
5. Rampoldi E, Patrucco G, Casati M, Morelli B, Carraro P. Principi per l'implementazione e la gestione del point-of-care-testing (POCT): indicazioni essenziali. Biochimica Clinica 2021-vol. 45, n. 3. doi: 10.19186/BC_2021.032
6. Allegato 1: Dispositivi Point of Care Testing (PoCT) Indicazioni Regionali in merito all'organizzazione, all'utilizzo ed all'accesso in regime SSN. Regione Emilia Romagna 28/04/2022.

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