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Quality control of regional wall motion analysis in stress Echo 2020

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Abbreviations: CAD1, coronary artery disease; RWMA, regional wall motion abnormalities; SE, stress echocardiography.

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ABSTRACT

Background: The trial "Stress Echo (SE) 2020" evaluates novel applications of SE beyond coronary artery disease. The aim of the study was control quality and harmonize reading criteria.
Methods: One reader from 78 centers of the SE 2020 network asked for credentials to read a set of 20 SE video-clips selected by the core lab. All aspiring centers met the pre-requisite of high-volume and the years of experience in SE ranged from 5 to 31 years (mean value 18 years). The diagnostic gold standard was a reading by the core lab. The a priori determined pass threshold was 18/20 (≥90%).
Results: Of the initial 78 who started, 57 completed the first attempt: individual readers' score on first attempt ranged from 07/20 to 20/20 (accuracy from 35% to 100%, mean 78.7 ± 13%) and 44 readers passed it. There was a very poor correlation between years of experience and the reader's score on first attempt ($r = -0.161$, $p = 0.231$). Of the 13 readers who failed the first attempt, 12 took it again after the web-based session and their accuracy improved (74% vs. 96%, $p < 0.001$). The kappa inter-observer agreement before and after web-based training was 0.59 on first attempt and rose to 0.91 on the last attempt.
Conclusions: In SE reading, the volume of activity or years of experience is not synonymous with diagnostic quality. Qualitative analysis and operator-dependence can become a limiting weakness in clinical practice, in the absence of strict pathways of learning, credentialing and audit.

1. Introduction

Like all proficiency tests in education, quality control in imaging reading is intended to provide a common measure for comparing the abilities of readers (cardiologists and sonographers) who come from a variety of educational backgrounds, in-field experience and institutions [1]. The problem of heterogeneity is magnified in echocardiography and especially in stress echocardiography (SE) reading of wall motion analysis, since wide inter-institutional variability exists even among highly experienced centers of undisputed reputation, and "under-readers" with a conservative attitude (and high diagnostic specificity) may coexist with "over-readers" with an aggressive attitude (and high diagnostic sensitivity) with comparable overall diagnostic accuracy [2]. The problem of selective accreditation for interpretation of regional wall motion abnormalities (RWMA) is therefore essential, since this parameter is probably the most valuable but also the most vulnerable to misinterpretation in the application of echocardiography in coronary artery disease (CAD). The problem is magnified when SE is used in a multi-center trial study, designed to provide effectiveness data, measuring the impact of the technique when deployed in the field with real doctors, real patients and real problems outside the virtual reality of academic centers studying only selected patients with highly specialized researchers using expensive and exclusive technologies [3]. In this setting, core lab reading would be prohibitive and makes no sense, since it would provide efficacy data under ideal conditions, but we need effectiveness data on what actually happens with the usual patients in the real world. The only feasible approach is to develop an upstream reading quality control for RWMA for prospective centers willing to enter the SE2020 study, as was done in the past for first-generation effectiveness studies on pharmacological SE [4,5]. The present report describes the rationale, method and results of the ongoing, permanent quality-control process within the SE2020 study platform to ensure consistent quality and harmonization of SE reading.

2. Methods

The core lab for stress echocardiography for the SE2020 study at IFC-CNR coordinated the quality control assessment for regional wall motion of all investigators who expressed their intention to participate in the study, which was publicly announced during the European Society of Cardiology meeting in Rome (August 29, 2016) in a session dedicated to stress echo. The candidate centers initially included 78 candidate centers (each with one certified reader) from 13 countries (Argentina, Brazil, Bulgaria, Costa Rica, Hungary, Italy, Kazakhstan, Lithuania, Poland, Russia, Serbia, UK, USA). The complete list of participants in the SE2020 consortium (as per March 20, 2017) is reported in the Appendix. The study protocol was reviewed and approved by the institutional ethics committee as a part of the SE 2020 study (1487-CE Lazio-1, July 20, 2016). The study was funded with institutional funding of the Italian National Research Council and with travel grants of the Italian Society of Cardiovascular Echography with dedicated sessions during national meetings. No support from industry was received.

An optional web-based educational platform was developed to facilitate the training process. Participating cardiologists were invited by email to join the platform, which was protected by user-specific passwords. The platform includes files and videos with detailed instructions on how to start the training and allows downloading and uploading of external files. The sequence of the certification process and web-based learning is shown in Fig. 1.The web-based training session was optional prior to the first attempt, and obligatory after failing the first attempt and prior to entering the last and final attempt.

2.1. Study population of readers

Seventy-eight readers from 78 different centers initially asked to enter the SE2020 study; of these, 9 dropped out when a strict quality control with standard procedures regulated by a computer scientist was proposed as mandatory, 11 dropped out during the first attempt (started but not completed) or after failing the first attempt with low scores (<15); 2 dropped out after failing the second, and final, attempt.

All participants were clinical cardiologists and expert echocardiographers with ongoing high volume (>100 tests per year) stress echo activity and the years of experience in SE ranged from 5 to 31 years (mean value 18 years). All were certified by national and/or international societies.

2.2. Reading sessions and pass threshold

We selected 20 cases in which the presence or absence of critical stenosis was documented by coronary angiography. The analysis of coronary angiogram was performed by visual analysis by an invasive cardiologist who performed the angiogram and was unaware of SE results. A diameter reduction ≥50% in a major coronary vessel was considered the cut-off for significant stenosis. The presence or absence of myocardial viability or scarring was documented by post-revascularization studies, and in which the interpretation by two independent experts of the core lab was concordant. The privacy of patients during acquisition, storage, and transmission of the SE study was protected. All images were anonymized, and the identity of patients was not disclosed at any time to the readers. Each SE study was structured in a single video-clip of 10–15 s, with resting images on the left and stress images on the right. The SE tests were scored according to a multiple-choice six-answer test as follows (only one response right per test): 1-Normal at rest and during stress; 2-Normal at rest and abnormal during stress on left anterior descending artery territory (ischemic response pattern); 3-Normal at rest and abnormal during stress on left circumflex/right coronary artery territory (ischemic response pattern); 4-Abnormal at rest, unchanged during stress (necrotic response pattern); 5-Abnormal at rest, improvement during stress (viability response pattern); 6-Abnormal at rest, worsening during stress (ischemic response and scar). The sequence of these six possible answers to multiple-choice questions differed from question to question.

The tests were selected to represent the garden variety of stress testing modes, responses, results and image quality. They came from seven different laboratories in four countries, and showed a wide spectrum of responses (normal, $n = 5$; ischemic on left anterior descending coronary artery territory, $n = 6$; ischemic on right coronary artery/left circumflex territory, $n = 3$; scar, $n = 1$; viability, n = 1; ischemia on scar = 4). All images were considered readable, with quality ranging from poor ($n = 2$), average-to-good ($n = 16$) to excellent (n = 2) in the assessment of the core lab. The stress employed was exercise in eight subjects, dobutamine in five, high dose accelerated (0.84 mg/kg over 6 min) dipyridamole in five and ergonovine in two (in the latter case, angiographic verification showed ergonovine-induced spasm in the coronary causing ischemia). The projection selected was an apical 4-chamber view in 12, apical 2-chamber in four, parasternal mid-papillary short-axis in three, and parasternal long-axis in one case.

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