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An assessment of ST-segment measurement variability between two core electrocardiogram laboratories☆

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Abstract

Objectives: We evaluated inter-reader agreement of the ST-segment between two electrocardiogram (ECG) core laboratories.

Background: Accurate measurement of the ST-segment is key to diagnosis and management of acute coronary syndromes (ACS). Clinical trials also rely on adherence to the pre-specified ECG eligibility criteria.

Methods: 150 patients (100 ST-segment elevation (STE)-ACS, 50 non-STE-ACS) were selected. An experienced ECG reader from each laboratory measured ST-segment deviation on the baseline ECGs (nearest 0.1 mm).

Results: ∑ST-segment deviation showed excellent inter-reader agreement (R = 0.965, intraclass correlation coefficient (ICC) 0.949, 95% CI (0.930–0.963)). Similar agreement was observed when ∑ST-segment elevation (∑STE) and ∑ST-segment depression (∑STD) were assessed separately. Better agreement was evident in STE-ACS cohort (ICC (95% CI): 0.968 (0.953–0.978, 0.969 (0.954–0.979), 0.931 (0.899–0.953)) compared to NSTE-ACS patients (ICC (95% CI): 0.860 (0.768–0.917), 0.816 (0.699–0.890), 0.753 (0.605–0.851) across measurement of ∑ST-segment deviation, ∑STE, and ∑STD.

Conclusions: We demonstrated excellent agreement on ST-segment measurements between two experienced readers from two ECG core laboratories.

Keywords: Electrocardiogram; Reliability; Acute coronary syndromes

Introduction

ST-segment elevation (STE) represents the degree of ischemia in patients with ST-segment elevation myocardial infarction (STEMI), and is a fundamental metric in the diagnosis and response to therapy of these patients [1]. Prior studies have shown that clinicians vary widely regarding the position within the ST-segment they use to assess the extent of STE, which in turn influences the decision for reperfusion therapy [2–5]. Understandably this may not only lead to significant differences in the application of potential life saving therapy, but also in the assessment of successful reperfusion.

The importance of accurate STE measurement is not limited to its diagnostic and prognostic values in STEMI. Adherence to the pre-specified electrocardiogram (ECG) eligibility criteria is key to recruiting the right population and ultimate success of a clinical trial. The sources of the inter-reader variation and/or error in ECG interpretation are many and include reader experience, what complex(es) are chosen for analysis, baseline shifts, respiratory beat-to-beat variability, aberrant QRS patterns and variable ST-segment shape and slope [6].

Tjandrawidjaja et al. systematically evaluated the extent of adherence of the local investigators to ECG entry criteria in patient enrolment in a large multicenter clinical trial of acute STEMI, where ST-segment measurements were made at the J-point (Junction point): they found that 42% of

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inferior and 19% of non-inferior STEMI patients did not meet the ECG entry criteria. Moreover, those patients failing to meet the admission ECG criteria had lower event rates, thereby attenuating the power of the trial and potentially compromising the likelihood of achieving its primary goal [7]. Prior data from the ThRombin Inhibition in Myocardial infarction (TRIM) study also underscore the differences between on-site interpretation of ECG's in ACS patients and core laboratory variables attesting to the value of independent evaluation [8].

In addition to STE, accurate ST-segment depression (STD) measurement is also important. Willems et al demonstrated that not only STE but also reciprocal STD are useful for predicting the evolving infarct size from the baseline ECG. Patients with evolving anterior myocardial infarction (MI) and major ST-segment depression in the inferior leads (i.e., sum of ST-segment deviation in leads II, III, and aVF less than −2.0 mm) had a mortality more than twice that of patients in whom this sum was 2.0 mm or more [9]. Toma et al have also emphasized that ST-segment resolution after reperfusion is best assessed from the amount of total ST-segment deviation at baseline incorporating both STE and STD [10].

The precise location at which STE measurement should be undertaken is also uncertain. According to the "Third Universal Definition of Myocardial Infarction" from the Joint European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation Task Force and also the American Heart Association/American College of Cardiology Foundation/Heart Rhythm Society recommendations for standardization and interpretation of the ECG, the J-point should be used to determine the magnitude of the ST-segment shift [11–13]. The J-point is the first inflexion on the upstroke of the S-wave [2] and by definition, the ST-segment begins here. However in many prior studies, investigators have estimated STE 20 ms after J-point to ensure that the measurement is located within the ST-segment and not during the QRS complex [14–16]. Still others have used 40, 60 and 80 ms after J-point as the reference point for STE measurements in an attempt to avoid underestimating STE [9]. This approach may be problematic however, since the point of measurement may coincide with the upslope of the ascending limb of T-wave, especially if tachycardia is present.

Moreover, the sums of ST-segment deviation at J and J plus 60 ms significantly differ, especially in anterior infarction [17], and little is known about their relative prognostic value. Since the latter approach requires incorporation of two measurement points the potential for error increases. Importantly, no clinical validation has been performed to establish a uniform point optimal for quantitatively determining STE. Because of the recognized inter-reader variability in identifying the extent of STE, core ECG laboratories have been established to provide a more reliable and consistent measurement of ECG parameters such as STE [18]. However, the inter-laboratory agreement on the measurement of STE has not been well studied.

The main objectives of the present study were to assess the inter-reader variation of ST- segment measurements between two experienced ECG core laboratories, and their agreement on the diagnosis of STEMI according to the third Universal MI definition [11].

Methods

An experienced ECG reader from each core laboratory (Canadian VIGOUR Centre, Edmonton, Alberta, Canada; St. Louis University ECG Core Laboratory, St. Louis, MO, USA) assessed the ST-segment deviation on the baseline ECGs at the J-point. The J point was identified as the inflection point where the QRS complex meets the ST segment and the slope change is most rapid [19]. The decision to measure at this location was the result of a pilot inter-laboratory evaluation of 100 STEMI patients designed to establish the optimum point of STE measurement among J, J + 20 and J + 60 ms, and to account for variations according to MI location, heart rate, and confounding factors such as RBBB. In brief, a subset of 100 STEMI patients was chosen for the pilot study, consisting of 35 inferior and 65 non-inferior MIs selected from the Assessment of PEXelizumab in Acute Myocardial Infarction (APEX-AMI) trial [20]. Also 15% of the ECGs were pre-specified to have a heart rate of ≥100 beats per minute at baseline ECG, and 10% to have RBBB. Each patient had a baseline and a 30-min post-percutaneous coronary intervention (PCI) ECG. All baseline and post-PCI ECGs were assessed, and the worst lead STE (i.e., the lead with maximal ST-segment elevation) was identified, and a single complex in the same lead was marked by an independent ECG reader. The worst lead of post-PCI ECG could be either the same as that of the baseline ECG or a different lead. An experienced ECG reader from each of the two core laboratories participating in this study read the STE at three separate points in the ST-segment i.e. J-point, J + 20 ms and J + 60 ms using the TP segment as the isoelectric baseline.

For the main study a total of 150 patients with baseline ECGs were randomly selected from a contemporary ACS clinical trial, PLATelet inhibition and patient Outcomes (PLATO): 100 patients from STE-ACS cohort and 50 non-STE-ACS patients (as identified by the local investigator). The PLATO trial design, rationale, and primary results have been published [21,22]. The selected patients had ECGs reporting a heart rate between 60 and 100 beats per minute; patients with confounding factors including left bundle branch block (LBBB), right bundle branch block (RBBB) or left ventricular hypertrophy were excluded.

All 12 leads of each qualifying ECG were visually assessed using a calibrated magnified coding loupe and the ST-segment deviation measurements were recorded. Readers expressed ST- segment deviation measurements to the nearest 0.1 mm or 0.01 mV. The overall baseline ∑ST-segment deviation, as well as ∑ST-segment depression and ∑ST-segment elevation separately, was calculated across all leads except aVR and compared between the two core laboratories.

To assess the readers' agreement on diagnosis of MI among the 150 ACS patients, the updated ECG criteria from the third Universal MI definition were applied, i.e., new ST-