

Improvement in Strain Concordance between Two Major Vendors after the Strain Standardization Initiative

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Background: Disagreement of strain measurements among different vendors has provided an obstacle to the clinical use of strain. A joint standardization task force between professional societies and industry was initiated to reduce intervendor variability of strain. Although feedback from this process has been used in software upgrades, little is known about the effects of efforts to improve conformity. The aim of this study was to assess whether intervendor agreement for global longitudinal strain (GLS) has improved after standardization initiatives.

Methods: Eighty-two subjects (mean age, 52 ± 21 years; 55% men) prospectively underwent two sequential examinations using two most common ultrasound systems (Vivid E9 and iE33). GLS was calculated using proprietary software (EchoPAC-PC BT12 [E12] and BT13 [E13] vs QLAB version 8.0 [Q8], QLAB version 9.0 [Q9], and QLAB version 10.0 [Q10]). Agreements in GLS were evaluated with Bland-Altman plots. Coefficients of variation (CVs) were compared using the Friedman test and compared with CVs of left ventricular volumes and ejection fraction (LVEF).

Results: Median GLS using E12 was -19.2% (interquartile range [IQR], -15.2% to -23.2%), compared with -19.3% (IQR, -14.9% to -23.7%) for E13, -15.7% (IQR, -11.4% to -20%) for Q8, -19% (IQR, -15.7% to -22.3%) for Q9, and -18.7% (IQR, -15.7% to -21.7%) for Q10. The CVs of prestandardization GLS ($12 \pm 8\%$ [E12/Q8] and $14 \pm 8\%$ [E13/Q8]) were significantly larger than that of LVEF (5 ± 5) ($P < .001$). Since standardization, the CVs of GLS have shown improvement (6 ± 4 [E12/Q9], 7 ± 4 [E12/Q10], 6 ± 4 [E13/Q9], and 7 ± 4 [E13/Q10]) and are similar to those of LVEF.

Conclusions: Subsequent to the joint standardization task force, there has been improvement in between-vendor concordance in GLS between two leading ultrasound manufactures, the variability of which is now analogous to that of LVEF. The removal of concerns about measurement variability should allow wider use of GLS. (*J Am Soc Echocardiogr* 2015;28:642-8.)

Keywords: Strain, Ejection fraction, EACVI-ASE strain standardization, Concordance, Vendor difference

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Measurement of strain using two dimensional speckle-tracking echocardiography (STE) is a relatively new test for the assessment of cardiac function, especially for the quantitative evaluation of global and regional myocardial function.¹ STE has largely replaced tissue Doppler-derived strain because of reductions of angle and operator dependence, and STE has become an integrated application in most commercially available ultrasound systems. However, variations in proprietary software among vendors, causing poor intervendor agreement in measurements, have become a significant limitation to the implementation of STE.²⁻⁷ This limitation has raised concerns with regard to STE's becoming an acceptable mainstream methodology in daily clinical application, especially in laboratories with echocardiographic instruments from multiple vendors.

To achieve a consensus on methodology for the quantitative evaluation of cardiac mechanics, the European Association of Cardiovascular Imaging and the American Society of Echocardiography (ASE) invited vendors to participate in a concerted effort to reduce intervendor variability of strain measurement.^{1,8,9} Guidance has been provided on the steps necessary to

Abbreviations
ASE = American Society of Echocardiography
CV = Coefficient of variation
GLS = Global longitudinal strain
ICC = Intraclass correlation coefficient
IQR = Interquartile range
LOA = Limits of agreement
LV = Left ventricular
LVEDV = Left ventricular end-diastolic volume
LVEF = Left ventricular ejection fraction
LVESV = Left ventricular end-systolic volume
STE = Speckle-tracking echocardiography

reduce variability, and this information has been used in software upgrades, but little is known about the effects of this process. Thus, the aim of this study was to elucidate whether there has been an improvement in intervendor global strain (GLS) agreement using STE since the implementation of standardization initiatives. Despite variability of left ventricular (LV) volume and LV ejection fraction (LVEF) measurements, these are used clinically for serial evaluation, so variations in these parameters were used as a frame of reference to compare variations in GLS.

METHODS

Study Population

Adult participants who underwent clinically indicated echocardiography were prospectively recruited in the outpatient clinics at Royal Hobart Hospital, Australia, and Takasaki General Medical Center, Japan, from June 2013 to November 2013. A group of adult healthy volunteers was also included in the study. We included patients >18 years of age, without atrial fibrillation or flutter. All subjects underwent two transthoracic echocardiographic studies using two ultrasound systems by the same experienced sonographers. The study protocol was approved by the relevant institutional review boards.¹⁰

Standard Echocardiography

Transthoracic echocardiography was performed using commercially available ultrasound systems from two vendors (S5-1 probe, iE33 [Philips Medical Systems, Andover, MA]; M5S probe, Vivid E9, and M4S probe, Vivid 7 Dimension [GE Medical Systems, Milwaukee, WI]). Each participant first underwent extensive standard assessments of cardiac anatomy and cardiac function according to clinical protocol with one ultrasound system. This was repeated using the other ultrasound system. Acquisition was obtained at the highest possible frame rate, with optimization of image depth and sector width. Multiple consecutive cardiac cycles of the three standard apical views (apical four-chamber, apical two-chamber, and apical long-axis views) were acquired and digitally stored as raw data for offline analysis. LV end-diastolic volume (LVEDV) and LV end-systolic volume (LVESV) were determined using the biplane method of disks.¹¹ The baseline assessment included standard two-dimensional, M-mode, color Doppler, pulsed-wave and continuous-wave Doppler, and Doppler tissue imaging modalities using standard parasternal, apical, subcostal, and suprasternal windows.

Measurement of Myocardial Strain

Measurement of GLS has been previously described.⁷ Briefly, two-dimensional images from three apical views (apical four-chamber, apical two-chamber, and apical long-axis views) were used. Readings

were obtained by averaging six segments in each view. GLS was determined from the average of all 18 segments. Figure 1 is a schematic description of image acquisition, strain analyses, and comparisons using the respective three generations of proprietary software packages from the two vendors. In the images acquired with the Vivid E9 (Figure 1A), speckle-tracking analyses were performed using proprietary software (EchoPAC-PC BT12 [E12], released March 2012, and BT13 [E13], released May 2013; GE Medical Systems). After tracing of the endocardial border, the region of interest was adjusted to include the entire myocardial thickness and avoid the pericardium. The software then selected stable speckles within the myocardium and performed speckle-tracking on a frame-to-frame basis throughout the entire cardiac cycle. The adequacy of tracking was verified manually. The cardiac cycle with the best tracking and visually most credible strain curves was selected for analysis. In segments with poor tracking, the border was readjusted manually until optimal tracking was achieved. After adjustment, segments with consistently poor tracking were excluded. Final GLS was calculated as the averaged value of GLS values from each apical view, using peak negative longitudinal strain during the cardiac cycle.

Because EchoPAC BT11 (E11; released May 2010) cannot analyze the images acquired using the current Vivid E9 system, because of a lack of compatibility with older versions of software, a separate group of normal volunteers were imaged using the Vivid 7 Dimension (mean frame rate, 72 ± 6 Hz) only for the comparison of E11 and E12 (Figure 1B). All offline measurements with E11, E12, and E13 were performed by a single observer (H.Y.).

Images acquired on the iE33 were analyzed using proprietary software from before the standardization initiative (QLAB version 8.0 [Q8], released April 2010; Philips Medical Systems) and after the standardization initiative (QLAB version 9.0 [Q9], released February 2012, and version 10.0 [Q10], released August 2013; Philips Medical Systems). For each view, endocardial and epicardial borders were manually traced in the end-systolic frame using three software versions with the same image view. All three software versions were used to trace the borders automatically frame by frame throughout the same cardiac cycle. Visual inspection of the tracking was carefully performed, and if automated tracking was unsatisfactory, manual point-to-point and frame-to-frame adjustments were carefully made until satisfactory tracking was achieved. Electrocardiographic tracing was used to estimate the timing of end-systole and early diastole. All offline measurement with QLAB was performed by the same observer (H.Y.). The analyses using QLAB were performed 4 weeks after analysis with EchoPAC, and the operator was blinded to the previous measurements.

Statistical Analysis

Continuous variables are presented as mean \pm SD. Categorical variables are expressed as percentages. Normality was evaluated using the Shapiro-Wilk *W* test. Because strain was not normally distributed, Spearman's ρ was used to express the correlation coefficient. The agreement between two vendors and with two software versions was studied using Bland-Altman analysis¹² to quantify a systemic difference (bias) between two techniques and the spread of differences of mean bias (limits of agreement [LOA]). Intraclass correlation coefficients (ICCs) were also used for the assessment of agreement. Coefficients of variation (CV) were calculated for all measurements. The difference of each set of paired variables was also assessed by percentage error. Percentage error was derived by dividing the LOA by the mean.¹³ The CVs of different systems

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