Sensitivity and Specificity of Left Ventricular Ejection Fraction by Echocardiographic Automated Border Detection: Comparison with Radionuclide Ventriculography

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Summary

Background: Echocardiographic automated border detection (ABD) provides on-line, beat-to-beat estimation of left ventricular (LV) ejection fraction (EF). Sensitivity and specificity of using ABD-EF for diagnosing LV dysfunction in routine clinical situations have not been previously studied.

Hypothesis: Analysis of ABD-EF data based on receiver operating characteristic (ROC) should provide useful information about sensitivity and specificity for clinical diagnosis of LV function based on ABD-EF.

Methods: The study group included 50 consecutive patients with EF measured by both ABD and radionuclide ventriculography (RVG). ABD-EF was recorded for 25 consecutive heart beats in the apical four-chamber view. Data were analyzed statistically by linear regression, Bland-Altman plot, and ROC. In ROC analysis, abnormal LV function was defined $RVG-EF \leq 40\%$.

Results: ABD and RVG showed a moderate correlation in the EF measurements: slope = 0.93, intercept = 17%, $r = 0.79$ ($n = 50$). Interbeat variability in ABD was diminished by averaging consecutive beats; standard error of estimate (SEE) decreased from 15.6% without averaging to 12.5% with 25-beat averaging. Bland-Altman analysis indicated that ABD-EF compared unfavorably with RVG-EF, with limits of agreement from -11% to 39% . ABD-EF showed a systematic overestimation ($p < 0.005$), which was compensated by in-

creasing the threshold for abnormal ABD-EF to 56%. With the optimized threshold, ABD-EF provided 89% sensitivity and 89% specificity (85% overall diagnostic accuracy) for diagnosing abnormal LV function.

Conclusion: This study explored the limitations of on-line echocardiographic measurement of EF in a clinical setting and provided useful data for assessing interbeat variability, sensitivity, and specificity.

Key words: echocardiography, automated border detection, interbeat variability, sensitivity and specificity, Bland-Altman plot, receiver operating characteristic

Introduction

Assessment of left ventricular (LV) function has been systematically advanced over the last two decades.¹ It has been demonstrated that cross-sectional echocardiography can be applied to determining LV function whether subjectively or utilizing quantification methods.^{2,3} Recent research in ultrasonic tissue characterization⁴ has led to the development of real-time algorithms for tracking blood-tissue borders in the A lines of echocardiograms based on integrated backscatter signals. The studies by Perez *et al.*⁵ and Vandenberg *et al.*⁶ have further advanced the technique and utilization of automated border detection (ABD). The state-of-the-art echocardiographic systems routinely used in hospitals nowadays allow for on-line acoustic quantification of LV function on a beat-by-beat basis.

Radionuclide ventriculography (RVG) based on multiple uptake gated acquisition (MUGA) technique has been a standard clinical method for assessing LV function.⁷ Compared with nuclear cardiology, echocardiography is advantageous in terms of mobility, safety, promptness, and cost effectiveness. Improved echocardiographic techniques to quantify LV function have not yet been widely accepted for clinical applications because the methodology and reliability of acoustic quantification are not entirely defined. Numerous technical issues re-

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Received: April 25, 1997

Accepted with revision: September 2, 1997

main in regard to how ABD may be optimally applied to interpreting echocardiographic data in the clinical situation.⁸

In three recent studies,^{9–11} ABD was compared with RVG for determining LV ejection fraction (EF). These studies reported correlation coefficients in the range of 0.81–0.93. Although the correlations were reasonable, a significant portion (19–52%) of the patient group in these studies was excluded because of abnormal LV wall motions or technical difficulties. Furthermore, the results from these studies were not entirely consistent. Whereas Gorcsan *et al.*⁹ reported only slight (statistically insignificant) underestimation of EF by echocardiography, Lindower *et al.*¹⁰ reported significant underestimation and Yvorchuk *et al.*¹¹ reported significant overestimation. This variability may be attributed in part to the subjectivity in setting the sensitivity gain that affects positioning of blood-tissue borders in the ABD algorithm.¹²

We therefore undertook this study to assess the relationship of ABD-EF and RVG-EF obtained in the clinical situation. The applicability of ABD in the day-to-day operation was evaluated by collecting data from 50 consecutive patients without symptom-based prescreening and diagnosis-based postselection. In addition to determining the linear correlation between ABD and RVG data, we assessed the sensitivity and specificity for detecting abnormal EF by ABD. The study also addressed the issues of interbeat variability and systematic bias related to the gain sensitivity in ABD.

Methods

Data Acquisition

Echocardiographic imagery with ABD was obtained by using a 2.5 MHz ultrasonographic transducer and an HP SONOS 1500 system (Hewlett-Packard, Andover, Mass.). Echocardiograms in the apical four-chamber view were recorded with the patient in the supine position. Gain was adjusted as needed to accomplish border definition. Once a stable border pattern was achieved by the ABD algorithm, EF data were recorded for 25 consecutive beats during quiet respiration.

Technetium-99m sestamibi-labeled human serum albumin was injected intravenously at a dose of 20 mCi. MUGA scans were obtained in the left anterior oblique 30° and left lateral views by using a GE Starcam 4000 SPECT system (General Electric, Milwaukee, Wisc.). A region of interest was defined to identify the left ventricle. The EF was determined by using commercially available software with semi-automated edge detection.

Data were collected from 50 consecutive patients (both male and female) who agreed to participate in this study. Ejection fraction was determined by both the RVG and the ABD method within a 72-h period. To eliminate the interobserver variability in ABD-EF, all 50 echocardiographic studies were performed by an experienced and skilled echocardiographic technician. In the learning phase prior to the study, the technician had gained experience in using the ABD functions of the HP SONOS 1500 system in about 100 patients.

Statistical Analysis

Linear regression analysis and paired *t*-test were performed to compare ABD-EF with RVG-EF. The interbeat variability was evaluated based on the effect of beat averaging on the standard error of estimate (SEE) for ABD-EF. The averaging buffer began with the first beat of each 25-beat sequence with a length of 1 (no averaging), 5, 10, 15, 20, or 25 beats.

The Bland-Altman analysis¹³ was used to evaluate the agreement between ABD-EF and RVG-EF. In the Bland-Altman analysis, the difference was plotted versus the mean, where the difference was given by ABD-EF – RVG-EF and the mean by (ABD-EF + RVG-EF)/2. The mean and standard deviation (SD) of the differences were computed. The limits of agreement were mean $\pm$ 2 SD, which should include 95% of the samples from a Gaussian distribution.

An analysis based on the receiver operating characteristic (ROC) was conducted to determine sensitivity, specificity, and optimal threshold for abnormal ABD-EF. Positive samples included all patients with abnormal LV function defined by RVG-EF $\leq$ 40%; negative samples were defined by RVG-EF $>$ 40%. The 40% threshold was based on the criterion used in the multicenter study of Survival and Ventricular Enlargement (SAVE).¹⁴

The ROC analysis was conducted with the aid of a computer program that we had previously developed.¹⁵ The ABD-EF data were separated into two sets (i.e., positive and negative) based on the RVG-EF criterion described above. Each data set was fitted with a Gaussian probability density function. The goodness of fit was evaluated by use of the χ^2 test. The null hypothesis (H_0) was “the patient has normal LV function.” When H_0 was actually true but incorrectly rejected, a type I error or a false positive occurred. When H_0 was actually false but incorrectly accepted, a type II error or a false negative occurred. For a given ABD-EF threshold, the probability of making type I errors (α) and the probability of making type II errors (β) were determined from the probability density functions of positive and negative data, respectively. Sensitivity, or true positive rate, was determined by

$$\text{Sensitivity} = 1 - \alpha$$

Specificity, or true negative rate, was determined by

$$\text{Specificity} = 1 - \beta$$

The ROC curve was constructed by plotting sensitivity versus (1 – specificity) as the threshold for abnormal ABD-EF was systematically varied between 0 and 100%. To determine the optimal threshold for ABD-EF, the sensitivity and specificity were combined into a single performance index:

$$\text{Diagnostic accuracy} = 1 - \sqrt{\alpha^2 + \beta^2}$$

where $\sqrt{\alpha^2 + \beta^2}$ was the distance from the operating point on the ROC curve to the ideal point corresponding to 100% sensitivity and 100% specificity (the upper left corner of the

ROC plot panel). The optimal threshold was the one closest to the ideal point, yielding the maximum diagnostic accuracy. The area under the ROC curve (A_z) was also computed to assess the overall performance of the method, where $0 \leq A_z \leq 1$ with 1 being the ideal performance.

Results

The age for the 50 patients in this study was 65 ± 11 (mean $\pm$ SD), ranging from 47 to 87 years. RVG-EF was $47 \pm 17\%$, ranging from 12 to 76%. The patient group consisted of 20 subjects with normal cardiovascular function, 24 with coronary artery disease, 3 with cardiomyopathy, 2 with hypertension, and 1 with sarcoidosis. Wall motion abnormality (WMA) was identified by angiography in 14 of the 24 patients with coronary artery disease.

Automated border detection-EF for each averaging buffer length was compared with RVG-EF by linear regression. In Table I, the linear regression result is summarized in terms of slope and intercept of regression line, correlation coefficient (r), and SEE. The interbeat variability was diminished by beat averaging, as evidenced by the progressive improvement in correlation and reduction in SEE with increasing average buffer length. In Figure 1, ABD-EFs from single beat and with 25-beat average, respectively, are plotted versus RVG-EFs. By comparing the two plots, the effect of averaging 25 beats was related to the reduction of scatter about the regression line. With a 25-beat average, the ABD method showed a systematic overestimation of the EF as evidenced by the distribution of the points above the line of identity. The one-tailed paired t -test showed that ABD-EF $>$ RVG-EF with $p < 0.005$.

The linear regression analysis was also conducted with a 36-patient group obtained by excluding the 14 patients with WMA. The 25-beat average was applied. By excluding patients with WMA, the SEE of ABD-EF decreased from 12.5

TABLE I Linear regression analysis between ABD-EF and RVG-EF

	Slope	Intercept (%)	r^a	SEE (%)
Single-beat	0.86	19	0.69	15.6
5-beat average	0.94	17	0.77	13.4
10-beat average	0.93	18	0.78	13.0
15-beat average	0.93	19	0.78	12.8
20-beat average	0.92	18	0.78	12.7
25-beat average	0.93	17	0.79	12.5

^a $p < 0.005$, $n = 50$ for all cases.

Abbreviations: ABD = automated border detection, EF = ejection fraction, RVG = radionuclide ventriculography, SEE = standard error of estimate.

to 9.5%. The correlation coefficient actually decreased from 0.79 (50 patients) to 0.73 (36 patients). However, caution should be taken in interpreting the correlation coefficient because the reduction in sample size itself could cause a decrease in correlation coefficient.

In Figure 2, the Bland-Altman plots were generated for single-beat and 25-beat average ABD-EFs, respectively. Again, the effect of averaging 25 beats on reducing scatter of the differences was evident. The limits of agreement between ABD-EF and RVG-EF were from -18 to 44% with single-beat and from -11 to 39% with 25-beat average. The mean of the differences was 16% with single-beat and 14% with 25-beat average, confirming the systematic overestimation of EF by the ABD method.

In Table II, the result from ROC analysis for single-beat and 25-beat average ABD-EFs is summarized. The fit of the Gaussian probability density function was acceptable for both positive and negative data sets. The χ^2 value was less than the critical value with $p < 0.05$ in all cases. In Figure 3, the ROC curves for single-beat and 25-beat average ABD-EFs are

FIG. 1 Linear regression analysis between ABD-EF and RVG-EF with single-beat ABD-EF (A) and 25-beat average ABD-EF (B). Regression line (solid) and line of identity (dashed) are shown. ABD = automated border detection, EF = ejection fraction, RVG = radionuclide ventriculography.

FIG. 2 Bland-Altman plot for assessing agreement between ABD-EF and RVG-EF with single-beat ABD-EF (A) and 25-beat average ABD-EF (B). SD = standard deviation. Other abbreviations as in Figure 1.

plotted in the same panel for comparison. The advantage to averaging 25 beats was evident by the shift of the ROC curve toward the upper left (ideal) corner. With 25-beat average, the optimal threshold for ABD-EF was at 56%, yielding 89% sensitivity, 89% specificity, and 85% diagnostic accuracy.

Discussion

While radionuclide ventriculogram remains the standard, acoustic quantification has emerged as a useful method for determining LV function. Off-line analysis of cross-sectional echocardiography using hand-traced LV borders and a volume model such as area-length and Simpson's rule has been previously defined.² On-line echocardiographic analysis based on the ABD technique allows for intraoperative assessment of LV function and decreases the likelihood of significant interob-

server variability.^{5,6} However, applications of on-line acoustic quantification techniques in the day-to-day clinical situation demand further improvements of the ABD-based technique.⁸ The present study has addressed the following issues: (1) comparison between acoustic quantification and radionuclide ventriculogram for determining EF in the clinical situation, (2) reduction of interbeat variability of ABD-EF by beat averaging, (3) compensation of systematic bias by use of the ROC analysis for optimizing the ABD-EF threshold, and (4) sensitivity and specificity for diagnosing abnormal LV function based on ABD-EF.

Our result showed a moderate correlation ($r = 0.79$, $SEE = 12.5\%$, $n = 50$) between ABD-EF and RVG-EF. We compared our study with three previous studies⁹⁻¹¹ that were chosen because they provided data for comparing ABD-EF and RVG-EF. Table III summarizes these results in terms of view plane, number of beats averaged, total number of patients,

TABLE II Results of fitting Gaussian probability density functions to positive and negative samples and ROC analysis for single-beat and 25-beat average ABD-EFs

	Single-beat average		25-beat average	
	Positive RVG-EF $\leq 40\%$	Negative RVG-EF $> 40\%$	Positive RVG-EF $\leq 40\%$	Negative RVG-EF $> 40\%$
No. of samples	16	34	16	34
ABD-EF mean (%)	40	69	40	71
ABD-EF SD (%)	14	14	13	12
χ^2	0.48	1.35	0.01	2.96
χ^2 Critical value	3.84	3.84	3.84	3.84
ABD-EF threshold (%)	55		56	
Sensitivity	0.85		0.89	
Specificity	0.84		0.89	
Diagnostic accuracy	0.78		0.85	
A_z of ROC curve	0.92		0.96	

Abbreviations: SD = standard deviation, ROC = receiver operating characteristic. Other abbreviations as in Table I.

FIG. 3 Receiver operating characteristic (ROC) curves for single-beat (dashed) and 25-beat average (solid) ABD-EF. Cross shows optimal threshold for abnormal ABD-EF. Abbreviations as in Figure 1.

number of patients included in study, correlation coefficient, slope, intercept, and SEE. Compared with the previously reported data ($r = 0.81$ – 0.93 , $SEE = 7.5$ – 9.2% , $n = 26$ – 69), the correlation in the present study was comparable but slightly lower. The lower correlation was expected considering the fact that all 50 consecutive patients were included in our analysis, whereas between 19 and 52% of the patients in these previous studies were excluded.

The beat-to-beat variation of ABD-EF may be caused by a variety of factors including nongeometric shape of mitral valve, mitral annular calcification, effect of respiration, patient motion, transducer motion, and physiologic beat-to-beat variation in stroke volume. As demonstrated in this study, ABD-EF from single beat showed a poorer correlation with RVG-EF ($r = 0.69$, $SEE = 15.6\%$). Increasing the average buffer length resulted in an asymptotic improvement of the correlation (see Table I); the improvement leveled off as the averaging buffer length increased to 20–25 beats. This result suggested that, in order to diminish the interbeat variability, the averaging buffer should include about 25 consecutive beats.

The Bland-Altman analysis also indicated the benefit of 25-beat average in narrowing the limits of agreement. However, even with 25-beat average the ABD method compared unfavorably with the RVG method. The limits of agreement in EF measurement was from -11 to 39% . The agreement was insufficient for the current ABD method to replace the RVG method for clinical determination of LVEF.

Left ventricular ejection fraction is computed from systolic and diastolic LV volumes. The accuracy of estimating LVEF is therefore dictated by the accuracy of estimating LV volumes. The estimation errors of systolic and diastolic LV volumes are not necessarily correlated. For example, Marcus *et al.* observed that an on-line backscatter system overestimated end-systolic LV area but underestimated end-diastolic LV area.¹⁶ Thus, errors in systolic and diastolic volumes are not likely to cancel each other out when the ratio is formed for calculation of EF. In this study we focused on LVEF because (1) errors in the estimation of absolute LV volumes should be reflected in the estimation of LVEF, and (2) LVEF is a major, if not the most important, determinant of LV function and strongly correlates with the prognosis of patients with coronary artery disease¹⁷ and acute myocardial infarction.¹⁸

Because LVEF has been used routinely in making treatment-related decisions in the clinical situation, it is important to assess ABD-EF in terms of sensitivity and specificity for diagnosing LV function in addition to its linear correlation with RVG-EF. This study showed that ABD identified abnormal LV function, defined by $RVG-EF \leq 40\%$, with 89% sensitivity and 89% specificity (85% all diagnostic accuracy). This, however, was achieved by using the 56% optimal threshold for ABD-EF that was identified by the ROC analysis.

In allowing for proper endocardial border detection, it is often necessary to adjust the overall instrument gain as well as the lateral gain that compensates for the weaker backscatter signals from blood–tissue interfaces not perpendicular to the ultrasound beams.¹⁹ Whereas insufficient gain results in misdetection of endocardial borders, excessive gain causes encroachment of borders into LV cavity. As pointed out by Martin,¹² standardization of the gain-sensitive nature of ABD remains to be an important area for future instrumental development. The subjectivity of gain adjustment is likely to be the cause of this inconsistency in the systematic bias of the ABD-EF reported in literature.^{9–11} As demonstrated in this study,

TABLE III Summary of comparison between ABD-EF and RVG-EF in present and other previous studies

Study/(Ref. no.)	View plane	No. of beats averaged	Total no. of patients	No. of patients included (%)	Correlation coefficient (r)	Slope	Intercept (%)	SEE (%)
Gorcsan <i>et al.</i> (9)	Short-axis/apical	5–10	88	69 (78)	0.89	0.96	–4	9
	Short-axis ($\times 3$)	5–10	88	66 (75)	0.91	0.89	0.8	8
Lindower <i>et al.</i> (10)	Short-axis	3	46	27 (59)	0.93	1.2	–3.2	9.2
Yvorchuk <i>et al.</i> (11)	4-Chamber	5	54	44 (81)	0.81	0.66	10.6	7.5
	2-Chamber	5	54	26 (48)	0.83	0.79	7.9	8.3
Present study	4-Chamber	25	50	50 (100)	0.79	0.93	17	12.5

Abbreviations as in Table I.

the ROC analysis can be used to identify the optimal threshold for abnormal ABD-EF and achieve maximum diagnostic accuracy. However, this retrospective optimization can be extended prospectively only if the systematic bias is consistent and reproducible.

Study Limitations

A number of technical factors intrinsic to the echocardiographic system may affect the determination of EF by echocardiographic ABD. The current study is limited in that EF, which is a volumetric phenomenon, cannot be precisely determined by analysis of a single plane. The accuracy of the ABD technique is dependent on the maintenance of an appropriate imaging plane to obtain an easily reproducible and delineated interface between endocardium and blood pool cavity.²⁰ Wall motion abnormalities at different levels in the heart may occur and may not be in the imaging plane, resulting in a falsely high EF. Small ventricular size and inclusion of intracavity LV thrombus within the region of interest may result in a falsely high EF as well. Utilizing biplane echocardiograms may improve the situation; however, it is not without limitations.²¹ Observer bias and manipulation in the image acquisition process may attribute to additional errors and variabilities in acoustic quantification.

Conclusion

A moderate correlation ($r = 0.79$, SEE = 12.5%) was observed between ABD-EF and RVG-EF in 50 consecutive patients. The limits of agreement between ABD-EF and RVG-EF were from -11% to 39% as determined by the Bland-Altman analysis. Interbeat variability in ABD-EF was diminished by averaging 25 consecutive beats. Receiver operating characteristic analysis showed that the optimal threshold for abnormal ABD-EF was 56%. With the optimal ABD-EF threshold, abnormal LV function (defined by RVG-EF $\leq 40\%$) was diagnosed with 89% sensitivity and 89% specificity.

Acknowledgments

The authors wish to thank Sylvia Collins for her skillful assistance in the echocardiographic studies.

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