Multiple-Hospital Survey of Ejection-Fraction Variability Using a Cardiac Phantom

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A dynamic cardiac phantom was used to provide identical input data at 11 different nuclear medicine laboratories throughout the Philadelphia area, and the variability in the resulting calculations of ejection fraction (EF) was assessed. The variability observed between different operators using the same computer system averaged 3 EF units, which was similar to that between different observers using different types of computers. In the range of low ejection fractions, however, there was a suggestion that EFs calculated with an MDS computer were slightly lower than those from a DEC computer.

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The ejection fraction is the most commonly determined parameter of left-ventricular (LV) function (*1*). There are many nuclear medicine computer systems available for performing and analyzing a gated equilibrium cardiac study, and each of these gives results that correlate well with those from cardiac catheterization. The comparability of results obtained with different computers, however, has not been established. Such an evaluation requires the same input data to each computer. We used a dynamic cardiac phantom to perform a survey of 11 computer systems in the Philadelphia area. We analyzed (a) the variability implicit in an observer analyzing the same data on one computer, (b) the variability between different observers using the same computer system, and (c) the difference between computer systems.

METHODS

Phantom

A dynamic cardiac phantom* was used to provide identical data at each of 11 nuclear medicine laboratories in the Philadelphia area. The phantom (Fig. 1) consists of two compartments, one of which is fixed and simulates the background areas (right ventricle, lung field, and descending aorta). The other compartment, which simulates the left ventricle and atrium, is a double oval in configuration and is mounted on a turntable that rotates at a speed selected by the operator. Both compartments are filled with technetium-99m. Also on the turntable is a lead attenuator that passes between the oval left-ventricle chamber and the gamma camera once during each rotation and causes a drop in the observed counting rate, which mimics systolic contraction. Three attenuators are provided with the phantom to result in high, medium, and low simulated ejection fractions. Data collection is synchronized to the rotation of the turntable by an electrical output to the R-wave trigger. Figure 2 shows the "left ventricular" time-activity curve, and Fig. 3 shows the "end-diastolic" and "end-systolic" images. All hospitals imaged the phantom in the "upright" position since the phantom was not designed to be turned on its side.

Data collection

Computers. At four hospitals, the data were collected using a DEC Gamma-11 computer systems. One hospital used a ADAC computer, and six had MDS A^2 computers.

Data collection. Simulated "heart rates" of 60, 120, and 180 bpm were provided at each laboratory, using each of the three attenuators. At each institution the number of frames per cardiac cycle was kept constant for all nine collections, but varied slightly between institutions (mean 18, range 16 to 20). Total counts per frame averaged 150,000 in all data collections.

Ejection fraction calculation. The studies were analyzed in each hospital by the person who usually performs the analysis at that site. No advice was given regarding the method of analysis (e.g., spatial or temporal smoothing, selection of

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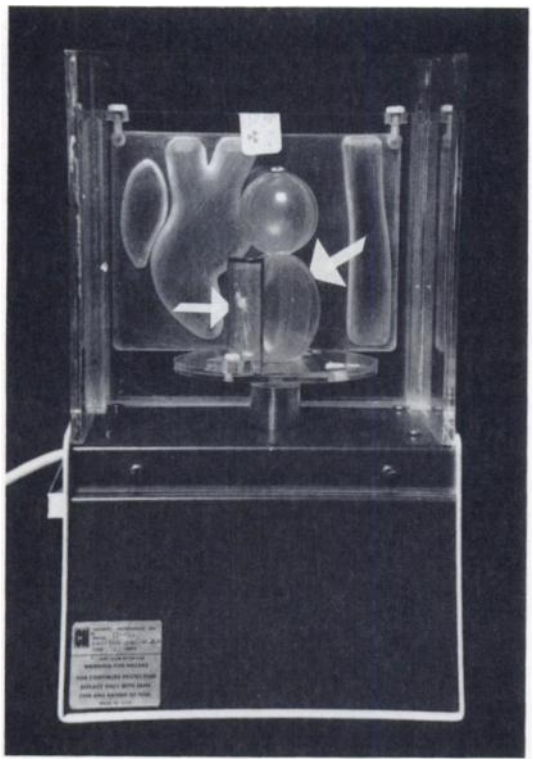

FIGURE 1
Dynamic cardiac phantom. Large arrow identifies oval compartment representing "left ventricle," and small arrow indicates lead attenuator that controls observed "LV" counting rate

background region, etc.), but all sites used the variable-ROI technique. Analyses involved operator identification of the left ventricle in the first data frame. For each frame of the study, the computer then displayed its estimate of the LV border, which estimate could be accepted or modified by the operator. In practice, operator intervention was necessary only occasionally and in the high-EF collections. The computer also selected a background region of interest over the left lung. The selected region was displayed to the operator, who had the option of accepting the ROI or manually drawing his own (if the selected ROI was overlaying a focus of increased activity area such as the "aorta").

Data evaluation

Nine EFs were calculated at each site: three different attenuators at each of three heart rates. Because there was no significant effect of heart rate (see Results), the three calculations with each attenuator could be used to determine the intraobserver variability. The results from institutions having the same computer system were used to assess interobserver variability. Finally, the variability between DEC and MDS computer systems (independent of the operator variability) was assessed by comparing the observed difference to the variability implicit in each system. The single ADAC site was not included in the analysis.

Statistical analysis

Data are expressed as the mean ±1 s.d. The effects of heart rate and EF level (with regard to computer system) were analyzed using two-way analysis of variance with repeated measures design. The effects of heart rate, EF level, and computer system were similarly analyzed, eliminating data from the single ADAC site. Differences between means were analyzed using the two-tailed t-test. The Mann-Whitney Rank Sum test was used to compare subgroup data.

RESULTS

The nine "ejection fraction" determinations from each of the 11 sites are given in Table 1. Listed for each hospital is the computer system and the calculated EF for each attenuator at each rotation rate, with the mean and s.d. of all collections with a given attenuator and rotation rate. There was no significant difference in the calculated EFs attributable to different heart rates, and for subsequent analysis the EFs with a given attenuator were treated as repeated measurements.

Table 2(A) lists, for each institution and at each EF level, the mean "ejection fraction" and its associated s.d. Inspection of the standard deviations shows that they are quite small although they are larger for the higher EFs. The variability observed when different computer operators analyze the same

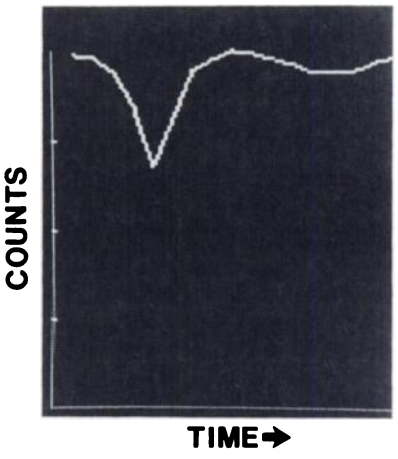

FIGURE 2
Observed time-activity curve from "left ventricle"

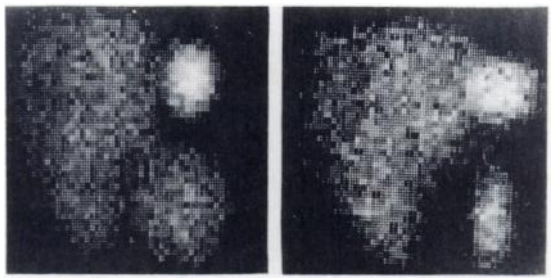

FIGURE 3
"End-diastolic" and "end-systolic" frames from phantom study. "Atrium" appears brighter than "Ventricle"; this is nonphysiologic, but will not affect calculations of LVEF because analysis programs all involve manual identification of LV and verification of LV boundaries

TABLE 1
"Ejection Fraction" Determinations

Hospital	Computer	Low "EF" Rotation rate 60	Low "EF" Rotation rate 120	Low "EF" Rotation rate 180	Mid "EF" Rotation rate 60	Mid "EF" Rotation rate 120	Mid "EF" Rotation rate 180	High "EF" Rotation rate 60	High "EF" Rotation rate 120	High "EF" Rotation rate 180
1	DEC	0.40	0.38	0.37	0.57	0.59	0.58	0.86	0.85	0.87
2	DEC	0.40	0.35	0.37	0.52	0.54	0.56	0.84	0.83	0.84
3	DEC	0.39	0.39	0.39	0.51	0.52	0.53	0.79	0.81	0.82
4	DEC	0.42	0.41	0.38	0.55	0.50	0.56	0.82	0.73	0.82
5	ADAC	0.41	0.41	0.37	0.58	0.56	0.49	0.89	0.85	0.79
6	MDS	0.39	0.38	0.39	0.54	0.54	0.49	0.75	0.74	0.76
7	MDS	0.33	0.33	0.33	0.49	0.48	0.50	0.76	0.78	0.79
8	MDS	0.36	0.36	0.34	0.50	0.51	0.50	0.78	0.79	0.83
9	MDS	0.37	0.38	0.37	0.53	0.51	0.53	0.82	0.81	0.81
10	MDS	0.34	0.36	0.35	0.55	0.53	0.52	0.89	0.91	0.92
11	MDS	0.35	0.35	0.37	0.50	0.50	0.51	0.78	0.78	0.79
Mean value		0.378	0.373	0.366	0.531	0.525	0.525	0.816	0.807	0.821
Standard deviation		0.030	0.025	0.019	0.030	0.030	0.031	0.047	0.052	0.044

data is given in Table 2(B). The values obtained with the ADAC system were closely comparable to those obtained with the DEC systems, but the MDS results were slightly lower (Fig. 4). The difference between the results of the MDS and DEC systems was not statistically significant for all measurements ($p = 0.077$), but it was if the data for the low and mid EF ranges were taken in isolation ($p \leq 0.05$). When there have been multiple measurements, it may not be valid to analyze a subset of the data, so we feel there is a suggestion, not certain, that the MDS analysis may report a lower EF than DEC in some EF ranges.

The overall variabilities of the analyses with each attenuator are given in Table 2(C) and the standard deviations at the three "ejection fraction" levels are 0.025, 0.029 and 0.047, respec-

TABLE 2
Mean "Ejection Fraction" and s.d. (A) and Observed Variability (B)

Hospital	Low "EF" Mean	Low "EF" s.d.	Mid "EF" Mean	Mid "EF" s.d.	High "EF" Mean	High "EF" s.d.
(A)						
1	0.383	0.015	0.580	0.010	0.860	0.010
2	0.373	0.025	0.540	0.020	0.837	0.006
3	0.390	0.000	0.520	0.010	0.807	0.015
4	0.403	0.021	0.537	0.032	0.790	0.052
5	0.397	0.023	0.543	0.047	0.843	0.050
6	0.387	0.006	0.523	0.029	0.750	0.010
7	0.330	0.000	0.490	0.010	0.777	0.015
8	0.353	0.012	0.503	0.006	0.800	0.027
9	0.373	0.006	0.523	0.012	0.813	0.006
10	0.350	0.010	0.533	0.015	0.907	0.015
11	0.357	0.012	0.503	0.006	0.783	0.006
(B)						
DEC	0.388	0.013	0.544	0.025	0.823	0.031
ADAC	0.397	—	0.543	—	0.843	—
MDS	0.358	0.020	0.513	0.016	0.805	0.054
(C)						
Total	0.372	0.025	0.524	0.029	0.815	0.047

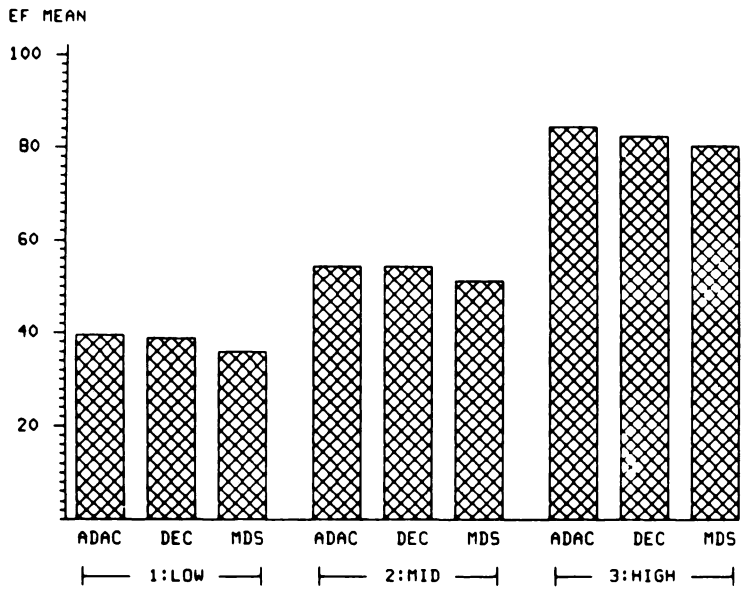

FIGURE 4
Average "ejection fractions" for each computer system with each of three attenuators. ADAC and DEC results are virtually indentical. Although MDS results are slightly lower (specially in low EF range), overall difference is not statistically significant (see text for details)

tively. These are all ~6% of the mean EF at the corresponding level.

DISCUSSION

Cardiac patients are often evaluated at various times in the course of the disease. When serial measurements of ventricular function are obtained, there is a minimum change that must be observed before it is clear that cardic function is altered. This minimum change is based, in part, on the variability in the calculations of EF (*1*), and also may reflect short-term changes in myocardial function (*2,3*). The variability at single institutions has been examined, and changes in the observed EF of ~5 EF units are required before they can be considered statistically significant (*1-3*).

Clinical experience shows that as the LVEF rises the variability in the results becomes larger (*3*). A similar pattern was also found in the present study, in which the variability in the three EF ranges were 0.025, 0.029, 0.047, respectively. The reason for this is not certain, but it may be because the end-diastolic and end-systolic boundaries are similar at low ejection fractions and become increasingly disparate at higher EFs.

When results from different institutions are compared, there are potentially two new variables: the different approaches taken by the operators at each institution and, if different computers are used, the algorithms by which various computers calculate the EF.

The intraobserver reproducibility at a single institution is easily determined by reanalyzing the same data—but it is difficult to compare institutions because it is not easy to provide the same data for analysis at various locations (especially if the institutions have different computer systems, precluding exchange of patient data). For this reason we used a cardiac phantom to provide identical data to a series of hospitals in our area. Note that this study could not have been performed by labeling the blood pool of an individual patient and having him travel around the city, because there are variations in an individual's EF over the course of hours (*1*) and days (*2*).

Our findings show that, throughout a metropolitan area, the results at several hospitals were consistent, although there was a suggestion that the MDS may give a slightly lower EF value than the DEC computer in the lower EF ranges. Our survey thus shows that when EF results from different institutions are compared, the operator is at least as great a source of variability as is the computer system on which the data are analyzed, although both of these sources of variability are less than the potential physiologic variation in an individual patient.

FOOTNOTE

* Capintec, Inc., Pittsburgh, PA.

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