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RELIABILITY OF ECHOCARDIOGRAPHIC MEASUREMENTS OF LEFT VENTRICULAR SYSTOLIC FUNCTION IN POTENTIAL PEDIATRIC HEART TRANSPLANT DONORS

Sharon Chen¹, Elif Seda Selamet Tierney¹, Kiran K. Khush², John Nguyen³, Benjamin Goldstein⁴, Lindsay J. May¹, Seth A. Hollander¹, Beth D. Kaufman¹, and David N. Rosenthal¹

¹Pediatric Cardiology, Stanford University, Palo Alto, CA

²Cardiovascular Medicine, Stanford University, Palo Alto, CA

³California Transplant Donor Network, Oakland, CA

⁴Medicine, Stanford University, Palo Alto, CA

Abstract

Background—Echocardiogram reports, but not images, are usually available for the evaluation of potential donor hearts. To assess the reliability of local reports of potential pediatric heart donors, we compared echocardiographic measurements of left ventricular (LV) systolic function between local hospitals and a central echocardiography laboratory.

Methods—We identified all potential donors <18 years old managed by the California Transplant Donor Network from 2009–2013. Echocardiograms and reports were obtained from local hospitals. All studies were reviewed in a central laboratory by an experienced pediatric cardiologist blinded to local reports. Local and central measurements of fractional shortening (FS) were compared using the method of Bland and Altman (mean difference $\pm$ 2SD). LV function was categorized based on FS as normal or mild, moderately, or severely depressed.

Results—There were 70 studies from 59 donors with both local and central measurements of FS. The mean difference between local and central FS was 3.9 (SD 9.0). The limits of agreement ranged from –14.2 to 22. Twenty-five studies had discordant measurements of LV function, with 17 discordant by one category and eight by two or more categories. Of 55 studies categorized as normal by local measurement, six were moderately to severely depressed by central review. Of 15 studies categorized as depressed by local measurement, three were normal by central review.

Conclusion—Local and central measurements of LV systolic function were discordant in 36% of studies. Given such discordance, efforts to obtain and view actual echocardiographic images should be part of the standard evaluation of potential pediatric heart donors.

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Introduction

Over 500 children are added to the heart transplant waitlist in the US each year and nearly 20% will die while waiting for a suitable donor (1, 2). Identification of suitable donors includes evaluation of left ventricular (LV) systolic function in the donor heart, most commonly assessed by transthoracic echocardiography. In the US, echocardiography is typically performed at local hospitals where donors have been admitted. Echocardiography reports are then sent to a centralized database for review by potential transplant recipient centers. Uploading and viewing of actual echocardiogram images is not routinely done. The reliability of local hospital reports of LV systolic function in pediatric donor hearts has not been systematically studied.

Several studies in settings other than pediatric heart transplantation have examined the reliability of pediatric echocardiography performed at local sites and reviewed in a central laboratory. Investigators of the Pediatric Pulmonary and Cardiac Complications of Vertically Transmitted HIV Infection (P2C2) study reported a mean difference in fractional shortening (FS) of -0.97 (95% confidence interval: -10.2 to 8.3) between measurements made at local clinical sites and in a central echocardiography laboratory (3). While the mean difference was not clinically significant, the confidence interval was notably wide. Similarly, Project HeartBeat!, a study of healthy children and adolescents, reported a significant difference in LV end-diastolic dimension (0.19 ± 0.97 mm, $p=0.01$) between measurements made at local field centers and a central laboratory (4).

Based on these studies, we hypothesized that among potential pediatric heart donors, there would be a significant difference in the echocardiographic measurements of LV systolic function between local hospitals and a central echocardiography laboratory. Our objectives were to compare local and central measurements of LV systolic function, characterized by FS, and to determine whether donor or imaging factors, such as donor size or time of echocardiogram, contributed to the discordance noted between local and central measurements.

Methods

California Transplant Donor Network (CTDN) is the federally designated organ procurement organization for northern and central California and northern Nevada. We identified all potential heart transplant donors < 18 years old managed by CTDN from 2009 to 2013. Donor characteristics and echocardiogram results, including valvular insufficiency, wall motion abnormalities, FS and ejection fraction (EF), were collected from reports submitted by local hospitals to CTDN. For donor hearts that were transplanted, outcome of transplant recipients were also obtained from CTDN. Actual echocardiographic images were obtained from local hospitals and loaded onto a secure server in a central pediatric echocardiography laboratory, with study identifiers removed. This study was reviewed by our institution's Institution Review Board where it was determined that formal approval was not required as the research did not involve living subjects.

The central echocardiography laboratory is located in a pediatric heart center that performs over 10,000 echocardiograms and an average 17 transplants per year (5). An experienced pediatric cardiologist (ST) with training in pediatric echocardiography, blinded to local reports, reviewed all echocardiograms. All measurements were made at end-systole and end-diastole. LV dimensions (LVESD and LVEDD) were obtained at the level of the papillary muscle from either M-mode or 2-D images (depending on image quality). LV endocardial areas (LVAS and LVAD) were measured in the parasternal short axis view at the level of the papillary muscles. LV endocardial lengths (LVLS and LVLD) were measured from the four-chamber view in the plane of the mitral valve annulus. Wall motion abnormalities, intra-cardiac anomalies, and presence and degree of valvular regurgitation were noted. Prior to calculating FS and EF, a qualitative assessment of LV systolic function was assigned. FS was calculated as: $[(LVEDD - LVESD) / LVEDD] \times 100$. EF was calculated by the 5/6 area-length method as: $5/6 \times [(LVAD \times LVLD) - (LVAS \times LVLS)] / (LVAD \times LVLD) \times 100$ (6, 7). Categories of LV function based on FS and EF were assigned according to guidelines from the American Society of Echocardiography as normal (FS ≥ 28 and EF ≥ 55), mildly depressed (FS 22–27 and EF 45–54), moderately depressed (FS 17–21 and EF 30–44), or severely depressed (FS ≤ 16 and EF < 30) (8).

The date and time of each study was noted. Business hours were defined as Monday to Friday, 8:00am to 5:00pm. Characteristics of local hospitals were obtained from the American Hospital Association's Hospital Database, a web-based database that serves as a primary reference for the Centers for Disease Control and Prevention, Medicare and Medicaid Services (9). Certifications of local physicians interpreting the echocardiograms were verified with the American Board of Pediatrics and American Board of Internal Medicine (10, 11). Physicians were classified as pediatric or adult cardiologist, or unknown.

To assess intra-observer variability in the central laboratory, the primary reader (ST) read ten randomly selected studies twice in a blinded manner. To assess inter-observer variability, a second experienced pediatric cardiologist (DR) read another ten randomly selected studies that had also been read by the primary reader (ST). To ensure that our assessment of variability included studies with decreased LV function, three from each group of ten studies were selected from studies with local FS < 24 .

Variables were described as mean $\pm$ standard deviation and median (range). Concordances between local and central FS and EF were compared using the method of Bland and Altman. Mean differences were calculated as local minus central measurements. Limits of agreement were calculated as ± 2 standard deviations (12). Intra-class correlation coefficients (ICC) were calculated for intra- and inter-observer variability within the central laboratory. Student's paired t-test was used for comparisons between local and central measurements and between studies with depressed versus normal function. Wilcoxon rank-sum tests and ANOVA were used in the analysis by donor and imaging characteristics. Statistical analysis was performed on STATA/IC 13 (Texas, USA) and p-values ≤ 0.05 were considered significant.

Data were collected and managed using the Research Electronic Data Capture (REDCap) electronic data tool hosted at the Stanford Center for Clinical Informatics. REDCap is a secure, web-based application designed to support data capture for research studies (13).

Results

Between 2009 and 2013, 85 potential pediatric heart donors were managed by CTDN. One donor had a study that the local hospital could not locate. We obtained 100 echocardiographic studies on 84 donors from 32 local hospitals. Eight donors had studies that were in a format incompatible with the central server. The remaining 92 studies from 76 donors were reviewed in the central laboratory.

Characteristics of the potential donors are shown in Table 1. The median age was 14 years old (7 days to 17 years). Head trauma was the most common cause of brain death (53%), followed by anoxia (37%). Seventy-six percent of potential donor hearts were transplanted. Two donor hearts were not offered, in both cases due to poor LV function on local report (one study was depressed by both local and central measurements, the other study did not have central interpretation of FS due to poor image quality). Thirteen donor hearts were not placed (offers made but not accepted for transplant). Table 2 shows LV function of the donor hearts that were not transplanted, as assessed by local and central measurements. Most echo studies were performed at hospitals with academic affiliations (76%) during business hours (59%), and were read by pediatric cardiologists (54%).

Analysis of LV function by FS

Of 83 studies with local FS reported, 13 (16%) were of inadequate quality for determination of FS in the central laboratory, leaving 70 studies from 59 donors who also had a central FS for comparison. The Bland-Altman plot for the difference between local and central FS is shown in Figure 1. The mean difference between local and central FS was 3.9 ± 9.0 (34.3 ± 9.5 local FS versus 30.4 ± 11.4 central FS, $p < 0.01$). The lower and upper limits of agreement were -14.2 and 22 , respectively, for an interval of 36.2 . The ICC for comparisons between local and central measurements of FS was 0.59 . Within the central laboratory, the ICCs for intra- and inter-observer variability for FS measurements were 0.88 and 0.79 , respectively.

Categories of LV systolic function by FS are shown in Table 4. Local and central measurements of FS were concordant in 45/70 (64%) studies. Of the 25 discordant studies, 17 were discordant by one category and eight by two or more categories. Of 55 studies considered normal by local FS, 15 (27%) were depressed by central FS. Of these 15 discordant studies, five were moderately depressed and one was severely depressed by central FS. All six of these donor hearts were transplanted. Conversely, of 15 studies considered depressed by local FS, three (20%) were normal by central FS. None of these three donor hearts were placed (offers made but not accepted). One of seven studies considered moderately to severely depressed by local FS was normal by central FS. These findings were similar when FS was analyzed as z-scores based on age (data not shown).

There was greater discordance between local and central measurements of LV function in studies with depressed function, defined as central FS < 28, than those with normal function, defined as central FS ≥ 28. Among 27 studies with central FS < 28, the mean difference between local and central FS was 8.9 ± 7.1 . Of 43 studies with central FS ≥ 28, the mean difference was 0.77 ± 8.8 (Figure 2, $p < 0.01$).

Discordance between local and central FS did not vary significantly when examined by donor age, donor heart outcome, use of inotropic support, qualification of local interpreting cardiologist, or time of study (Table 3). There was a significant difference in local and central FS between studies performed at academic versus community hospitals (mean FS difference 5.2 ± 9.6 versus 0.3 ± 6.1 , $p = 0.01$).

Analysis of LV function by EF

Of 91 studies with local EF reported, 27 (30%) were of inadequate quality for determination of EF in the central laboratory, leaving 64 studies from 53 donors who also had a central EF for comparison. Results of analyses by EF, shown in Figure 3 and Table 5, were similar to results by FS. The mean difference between local and central EF was 6.6 ± 12.3 (61.9 ± 13.1 local EF versus 55.3 ± 15 central EF, $p < 0.01$). The lower and upper limits of agreement were -17.9 and 31.2 , respectively, for an interval of 49.1 . Local and central measurements of EF were concordant in 41/64 (64%) studies. Of the 23 discordant studies, 13 were discordant by one category and 10 by two or more categories. The ICC for comparisons between local and central measurements of EF was 0.56. Within the central laboratory, the ICCs for intra- and inter-observer variability for EF measurements were 0.77 and 0.64, respectively.

Analysis of other echocardiographic findings

One study had a local report of severe mitral valve regurgitation; this was interpreted as mild regurgitation in the central laboratory. By local reports, 15 studies had LV regional wall motion abnormalities. Of these 15 studies, the central laboratory interpreted only two as having wall motion abnormalities (10 did not have wall motion abnormalities and three were indeterminate by central interpretation). An additional two studies were noted by the central laboratory, but not by local report, to have wall motion abnormalities. Seventeen studies had chamber enlargement by local report compared to seven by central review.

Transplant recipient outcomes

There were five recipient deaths among the 58 transplanted hearts in our study. Of these five deaths, one recipient had normal LV function by local measurement and severely depressed function by central measurement. Three recipients had normal local function but the central laboratory was unable to measure FS due to poor image quality. The remaining recipient who died had function that was normal by both local and central measurements.

Discussion

Our study showed that local and central measurements of LV systolic function in potential pediatric heart transplant donors were discordant in 36% of echocardiograms. In addition,

central interpretation of function was not possible due to image quality in 16–30% of cases, but local interpretation was performed and reported, providing an additional potential source of discordant interpretation. There are two potential outcomes when there is significant discordance between local and central measurements of LV function. One outcome is failure to accept potential donor hearts that have local reports of decreased function, but in central review, have normal function. In this study, 20% of echocardiograms with LV dysfunction by local measurements turned out to have normal function when measured in the central laboratory. These donor hearts were offered but not accepted for transplantation. While we do not have sufficient information to determine if reported LV dysfunction contributed to failure of placement, it has been shown that LV dysfunction impacts donor heart acceptance rates in adults (14). In light of the very limited pool of pediatric heart transplant donors, any possibility of preventing non-acceptance of donor hearts should be addressed.

The second outcome that may occur when there is significant discordance between local and central measurements of LV function is acceptance of donor hearts with normal reported function that have depressed function upon central interpretation. We found that 11% of echocardiograms with normal systolic function by local measurements had moderately to severely depressed function when measured in the central laboratory. The clinical importance of this discordance is not entirely clear, as there have been several studies in adults reporting favorable outcome after transplantation of donor hearts with LV dysfunction (15–18). A recent study in children also showed no significant difference in survival among pediatric heart transplant recipients of donors with normal or depressed function (19). However, it is notable that the one donor heart in our study with normal local function but severely depressed function by central measurement resulted in death of the transplant recipient.

Twenty-one percent of studies had LV dysfunction by local measurement compared to 38% by central measurement. We found that there was greater discordance among studies considered depressed by central review, but that discordance between local and central measurements was not influenced by donor or imaging characteristics such as donor age or time of study. Interestingly, studies performed at community hospitals were less likely to be discordant than studies performed in hospitals with academic affiliations. We did not collect sufficient information in this study to generate an explanation for this finding.

Overall, local hospitals reported better LV function than the central laboratory, with FS on average 3.9% higher. This difference is substantially higher than the mean difference reported in the P2C2 study (3). However, the P2C2 study was a much larger study performed under standardized research conditions. Over 700 children had echocardiograms performed at one of 10 designated clinical sites. All clinical sites followed a common echocardiographic protocol, as well as received training and regular site visits. While such rigorous circumstances may lessen the discordance between local and central measurements of LV function, such strict conditions are not feasible in the setting of donor heart evaluations.

Due to inadequate image quality, our central laboratory could not measure FS in 16% and EF in 30% of studies examined. Notably, three of the five recipient deaths in our study

cohort involved donor hearts with inadequate image quality, even though there were local reports of normal function in all three hearts. We also found discordance between local and central interpretations of wall motion abnormalities and chamber size. These findings lead us to emphasize the importance of reviewing actual echo images as part of donor heart evaluations.

This study was limited by its small sample size. We did not attempt to obtain echo studies dating prior to 2009 due to concern regarding availability of studies in a digitized format which was required for review in the central laboratory. We also limited our sampling to one organ procurement organization for ease of obtaining the studies. However, given the diversity of hospitals within the area served by CTDN, we believe that our results can be generalized to the larger pediatric heart transplant population.

In conclusion, we found discordance between local and central measurements of LV systolic function in over 30% of echocardiograms of potential pediatric donor hearts. There were both donor hearts with reportedly normal function re-measured as depressed and hearts with depressed function re-measured as normal. To maximize our utilization of an already limited pool of pediatric donor hearts, a critical evaluation of our assessment of LV function in potential donors is warranted. Given the widespread availability of digital images, reviewing actual echocardiographic images should be a component of every heart transplant donor evaluation.

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Figure 1.
Bland-Altman Plot for Fractional Shortening

* p < 0.01

Figure 2.
Difference between local and central FS by LV function
* p < 0.01

Figure 3.
Bland-Altman Plot for Ejection Fraction

Table 1

Donor and imaging characteristics (n = 76 donors)

	Median (range) or n (%)
Age	14 years (7 days to 17 years)
Gender (M:F)	1.4:1
Wt (kg)	56.3 (3 to 264)
BSA (m ²)	1.46 (0.12 to 3.75)
Cause of death	
Head trauma	40 (53)
Anoxia	28 (37)
CVA/Stroke	4 (5)
Tumor	1 (1)
Other	3 (4)
Disposition of donor heart	
Transplanted	58 (76)
Not offered	2 (3)
Allocated, not recovered	3 (4)
Not placed	13 (17)
On inotropic support	47 (76)
Hospital	
Community	18 (24)
Academic affiliation	58 (76)
Echo during business hrs (M-F 8-5) *	54 (59)
Echo read by pediatric cardiologist *	50 (54)

* n = 90 echocardiographic studies

Table 2

LV function of donor hearts not transplanted

Donor	Donor heart disposition	Function by local FS	Function by central FS
1	Not offered	Mildly depressed	Severely depressed
2	Not offered	Severely depressed	Unable to assess
3	Allocated, not recovered	Normal	Normal
4	Allocated, not recovered	Normal	Mildly depressed
5	Allocated, not recovered	Mildly depressed	Moderately depressed
6	Not placed	Normal	Normal
7	Not placed	Normal	Normal
8	Not placed	Normal	Normal
9	Not placed	Normal	Normal
10	Not placed	Normal	Normal
11	Not placed	Normal	Normal
12	Not placed	Normal	Mildly depressed
13	Not placed	Normal	Mildly depressed
14	Not placed	Moderately depressed	Normal
15	Not placed	Moderately depressed	Severely depressed
16	Not placed	Moderately depressed	Severely depressed
17	Not placed	Severely depressed	Severely depressed
18	Not placed	Not reported	Moderately depressed

Table 3

Difference between local and central FS by donor and imaging characteristics*

	N	FS difference (mean±SD)	p-value
Age			0.16
0 to < 12 months	7	3.4 ± 11.9	
12 months to < 5 years	8	9.7 ± 7.5	
5 years to < 18 years	55	3.1 ± 8.7	
Transplanted			0.90
Yes	47	40 ± 10	
No	23	3.8 ± 7	
Inotropic support			0.14
Yes	17	5.1 ± 11.9	
No	40	2.9 ± 8.2	
Hospital type			0.01
Academic	52	5.2 ± 9.6	
Community	18	0.3 ± 6.1	
Local MD			0.09
Pediatric	39	4.8 ± 10.6	
Adult	25	1.8 ± 6.8	
Time of study			0.55
Business hrs	42	4.5 ± 9.9	
Non-business hrs	28	3.0 ± 7.8	

*
n = 70 studies

Table 4

Categories of LV function by central versus local FS

Central FS							n (%)
		Normal		Depressed		Severe	
		FS 28	FS 22 to 27	FS 16 to 21	FS < 16		
Local FS	Normal	40	9	5	1	55 (79%)	
	Mild	2	2	3	1	8 (11%)	
	Depressed	1	0	0	3	4 (6%)	
	Severe	0	0	0	3	3 (4%)	
	n (%)	43 (62%)	11 (16%)	8 (11%)	8 (11%)	70	

Table 5

Categories of LV function by central versus local EF

		Central EF				n(%)
		Normal	Mild	Depressed Moderate	Severe	
		EF 55	EF 45 to 54	EF 30 to 44	EF < 30	
Local EF	Normal	35	9	5	3	52 (81%)
	Mild	0	2	4	1	7 (11%)
	Depressed	1	0	2	0	3 (5%)
	Severe	0	0	0	2	2 (3%)
	n (%)	36 (57%)	11 (17%)	11 (17%)	6 (9%)	64