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ORIGINAL RESEARCH

Association Between Remote Monitoring and Interstage Morbidity and Death in Patients With Single-Ventricle Heart Disease Across Socioeconomic Groups

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BACKGROUND: Despite improvements in survival over time, the mortality rate for infants with single-ventricle heart disease remains high. Infants of low socioeconomic status (SES) are particularly vulnerable. We sought to determine whether use of a novel remote monitoring program, the Cardiac High Acuity Monitoring Program, mitigates differences in outcomes by SES.

METHODS AND RESULTS: Within the Cardiac High Acuity Monitoring Program, we identified 610 infants across 11 centers from 2014 to 2021. All enrolled families had access to a mobile application allowing for near-instantaneous transfer of patient information to the care team. Patients were divided into SES tertiles on the basis of 6 variables relating to SES. Hierarchical logistic regression, adjusted for potential confounding characteristics, was used to determine the association between SES and death or transplant listing during the interstage period. Of 610 infants, 39 (6.4%) died or were listed for transplant. In unadjusted analysis, the rate of reaching the primary outcome between SES tertiles was similar (P=0.24). Even after multivariable adjustment, the odds of death or transplant listing were no different for those in the middle (odds ratio, 1.7 [95% CI, 0.73–3.94) or highest (odds ratio, 0.997 [95% CI, 0.30, 3.36]) SES tertile compared with patients in the lowest (overall P value 0.4).

CONCLUSIONS: In a large multicenter cohort of infants with single-ventricle heart disease enrolled in a digital remote monitoring program during the interstage period, we found no difference in outcomes based on SES. Our study suggests that this novel technology could help mitigate differences in outcomes for this fragile population of patients.

Key Words: congenital heart disease ■ remote monitoring ■ socioeconomic status

Hypoplastic left heart syndrome (HLHS) and similar anatomic variants were once considered fatal diagnoses, with uniform death by 1 year of age.[1] The development of staged palliative surgeries, with subsequent improvements in surgical technique and perioperative management, has had a significant impact on survival.[2–4] Despite these advancements, the time between the first and second palliative surgery, the interstage period, remains a vulnerable time for patients with single-ventricle (SV) heart disease, with historical mortality rates as high as 10% to 20%.[5–8] Beyond anatomic issues and extracardiac comorbidities that are known risk factors for death, socioeconomic characteristics have also been associated with higher mortality rates during the interstage period.[5,8–12]

The precise factors contributing to worse outcomes for patients of lower socioeconomic status (SES) with SV heart disease are incompletely understood but

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RESEARCH PERSPECTIVE

What Is New?

- We found no disparities in outcomes among a large group of infants with single-ventricle heart disease from socioeconomically diverse backgrounds who were enrolled in a novel digital home monitoring program.
- The findings of our study suggest the potential that interventions in the home environment could have in reducing socioeconomic disparities for this fragile population of patients.

What Question Should Be Addressed Next?

- The findings of our study highlight the need for future observational studies or larger randomized controlled trials dedicated to confirming our study findings.

Nonstandard Abbreviations and Acronyms

CHAMP	Cardiac High Acuity Monitoring Program
HLHS	hypoplastic left heart syndrome
SES	socioeconomic status
SV	single-ventricle
SVR	Single Ventricle Reconstruction

could include lack of insurance, inability to purchase necessary medications or medical supplies, reduced likelihood of seeking medical attention for illnesses due to lack of education or community support, and less flexibility with employment-related leave time to attend follow-up visits.[13–15] Moreover, difficulty with transportation and lack of proximity or access to necessary follow-up care are also postulated as factors associated with worse outcomes for patients of lower SES with SV heart disease. Therefore, it seems plausible that interventions targeted at reducing barriers to accessing high-quality care may mitigate some of the differences in outcomes observed in patients with SV heart disease of lower SES.

The Cardiac High Acuity Monitoring Program (CHAMP) application is a novel digital platform designed specifically for monitoring of interstage patients.[16] It uses the standard metrics historically used for traditional home monitoring programs (ie, oxygen saturation, heart rate, and weight), with the addition of daily videos, which are optional. Instead of using a 3-ring binder and weekly phone calls with the care team, CHAMP allows caregivers to input patient clinical data into a device that allows electronic transfer of patient information to the medical team that is nearly instantaneous. CHAMP has now expanded from a single center to a multisite program that includes 12 pediatric cardiology sites across diverse US geographic regions. This presents a unique opportunity to study the outcomes of patients in the interstage period across a range of SES backgrounds. The goal of our study is to examine outcomes of infants with SV heart disease during the interstage period and to determine whether use of the CHAMP application mitigates differences in outcomes by SES. We hypothesized that there would be no difference in interstage outcomes across patients of differing SES tertiles and that the lack of difference in outcomes between SES tertiles may be related to use of CHAMP.

METHODS

Due to the sensitive nature of the data collected for this study, requests to access the data set are limited to only institutions participating in the collaborative multisite study.

Remote Monitoring Program

CHAMP is a novel technology developed at Children's Mercy Kansas City in 2014. The rationale for development, technological aspects, and outcomes of initial patient enrollment have been previously described in detail.[16] In brief, the CHAMP application was originally a Windows-based tablet (more recently, also available as an application that works on both Android and iOS smartphones) that allows caregivers of infants with SV heart disease a mobile platform to input information about their child. The device has built-in cellular capability that is provided at no charge to the family. Caregivers are trained in the use of the application and instructed to obtain weight, heart rate, and oxygen saturation measurements consistent with their traditional home monitoring care teams' recommendations. To standardize introduction of CHAMP across sites, staff from Children's Mercy Kansas City train an administrator at each participating site, who then instructs families on use of the application. An instructional video and informational sheet are also provided to all participants. Each family is required to complete this standardized training and demonstrate appropriate use of the application before hospital discharge. After collecting their child's information, caregivers input data into the mobile device. Data are then transferred to a cloud-based web service, allowing the care team near instantaneous data access by logging on to a secure server. CHAMP was available to caregivers during the study time period in English, Spanish, Chinese, Korean, Filipino, Arabic, German, Vietnamese, and French.

Consistent with traditional home monitoring programs, data are reviewed daily and as needed by the care teams, and there is frequent communication with caregivers at home. CHAMP collects information on "red flag" events that align with national standards developed by the National Pediatric Cardiology Quality Improvement Collaborative.[17] Additionally, CHAMP has several events classified as "instant alerts" that result in automatic alerts (via hospital paging system) to the care team. The CHAMP application also has the capability to record and transmit video recordings of the infant to the care team. Although these videos are optional and used on a discretionary basis by the families and their care teams, prior work has demonstrated the utility of these videos in identifying infants at risk for clinical deterioration.[18]

Implementation of CHAMP monitoring began in 2014, and analysis of the first 31 infants enrolled in the program demonstrated no interstage deaths, significantly fewer unplanned intensive care unit days, shorter delays in care, lower resource use at readmissions, and lower incidence of interstage growth failure.[19] Since its development, CHAMP has expanded from a single center to a total of 12 pediatric cardiology programs across the United States. At the time of enrollment, patients and programs may consent to having their data available for use in research and quality improvement initiatives or included with a waiver of consent. This model formats a multicenter data set of patients monitored by CHAMP during the interstage period. Data from this multicenter data set were used for the present study. All participating sites have approved enrollment of patients into the CHAMP cardiac repository via a request to relay with the coordinating center or their local institutional review boards. The present study was reviewed by the institutional review board at Children's Mercy Kansas City and met criteria for exemption due to Health Insurance Portability and Accountability Act authorization being obtained at the time of enrollment in the CHAMP home monitoring program.

Patient Sample

All functionally univentricular patients discharged home during the interstage period who enrolled in CHAMP and consented to participation in research were evaluated for inclusion in the study. We chose to include all functionally univentricular lesions (ie, HLHS, tricuspid atresia, pulmonary atresia, unbalanced atrioventricular canal defect, double-inlet left ventricle, etc) for our study, because some home monitoring programs are not exclusive to patients with HLHS. Overall, 806 infants across 12 centers were enrolled in CHAMP from January 2014 to December 2021. Of these, we excluded patients actively using the device (n=70), those who ultimately underwent biventricular repair (n=75), those who initially enrolled in CHAMP but ultimately never discharged home interstage (n=12), those who transferred care to a different (non–CHAMP-participating) center (n=5), those with missing zip code or census data information (n=7), those with no data on ultimate treatment end point (n=5), those who were not candidates for Glenn palliation (second stage of SV palliation consisting of creation of a superior cavopulmonary anastomosis) or transplant (n=8), those who returned the device (n=12), and those who were lost to follow-up (n=2). Our final study cohort consisted of 610 patients from 11 centers (Figure 1).

Study Outcome

The primary outcome of interest was a composite end point of death or listing for heart transplant during the interstage period. As our primary focus was home monitoring, our study cohort did not include deaths

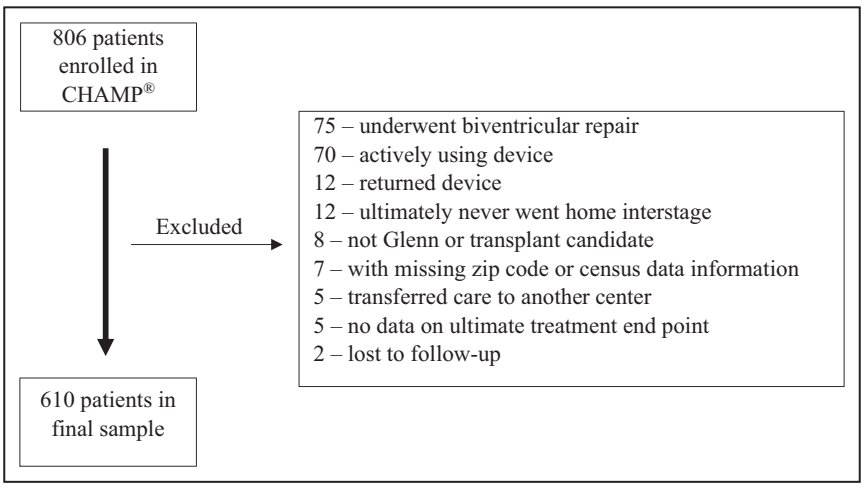

Figure 1. Flow diagram of patient sample.
Flowchart showing selection of patients for inclusion in the final study cohort.

that occurred following stage I palliation but before neonatal hospital discharge.

Patient Risk Factors

Detailed patient information (demographic data [sex, self-reported race, and ethnicity], birth characteristics, clinical and perioperative factors) are all obtained from each patient's chart when enrolling in CHAMP and input into the multicenter CHAMP data set. We considered a number of these characteristics for inclusion in our analysis. Variables were selected on the basis of those that are known to have potential association with outcomes in infants with SV heart disease based on clinical experience or prior literature.

Our primary predictor variable was neighborhood SES. We chose to use neighborhood SES rather than family SES, as this methodology allows for incorporation of several measures of SES rather than a single characteristic (ie, parental education, insurance status, etc). This methodology has been previously validated and described in detail and has been used in other studies evaluating the association of SES with outcomes in patients with SV heart disease.[10,20] In brief, individual patient zip codes were linked to publicly available data from the US Census Bureau. The value for 6 variables representing wealth and income (log of median household income; log of median value of housing units; percentage of households receiving interest, dividends, or net rental income), education (percentage of adults aged ≥25 years who completed high school and the percentage of adults aged ≥25 years who completed college), and occupation (percentage of employed people aged ≥16 years in management, business, science, and arts occupations) were identified for each patient's zip code. *Z* scores for each zip code were calculated for each variable, and the resultant sum of the *Z* scores was the neighborhood summary score. The summary scores were then arranged in ascending order and divided into tertiles (lower, middle, upper).

Adherence with input of data into the CHAMP application was evaluated to determine if there were systematic differences in use of the application by SES tertile. It is recommended that families input weight, oxygen saturation, and heart rate at least once daily into the application during the interstage period. Adherence was calculated for each patient by dividing the number of days these values were input in the application by the total number of interstage days (excluding any hospitalization days).

Statistical Analysis

Baseline characteristics across SES tertiles were compared using Kruskal–Wallis tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables. To evaluate for any associations between baseline characteristics and the primary end point, univariate analysis was performed with Wilcoxon rank-sum tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables.

To account for other patient characteristics that could confound the relationship between SES and mortality/transplant listing during the interstage period, we used multivariable hierarchical logistic regression, treating patient characteristics as fixed effects and center as a random effect. Hierarchical modeling accounts for the nested nature of the data (patients treated at different centers).[21] Variables included in the multivariable analysis were chosen on the basis of results of univariate analysis and characteristics known to be associated with the outcome on the basis of clinical experience. For all analyses, a *P* value of <0.05 was considered statistically significant. All study analyses were performed with SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

There were 610 infants across 11 centers discharged home during the interstage period enrolled in CHAMP and who met study inclusion criteria. Table 1 shows the sociodemographic and clinical characteristics of the patients stratified by SES tertile. Overall, the mean age at the time of newborn discharge of the study cohort was 42.7 days (SD=32.3), which was similar across the tertiles (*P*=0.14). Female infants comprised 36.3% of the cohort and male infants 63.7%. Less than 1.0% of the study population identified as either American Indian/Alaskan, Native Hawaiian/Pacific Islander, or multiracial. There were 1.8% of patients who identified as Asian, 9.7% Black/African American, 81.2% White, and 4.9% reported "other" race. Baseline characteristics across the tertiles were similar for many characteristics with similar distribution in terms of race and sex. Prenatal diagnosis was made for ≈4 of every 5 infants in the study cohort and was similar across tertiles (*P*=0.44). Similar frequency of HLHS existed across SES tertiles, ranging from 32.7% in the lowest tertile to 39.2% in the highest tertile (*P*=0.33). The mean gestational age of the study cohort was ≈38 weeks, with similar values across tertiles (*P*=0.29). The mean interstage duration was 156 days (SD=64.9), which was also similar across tertiles (*P*=0.12).

Hispanic ethnicity was more common in the lower SES tertile, with 41 (21.0%) Hispanic patients compared with 26 (12.6%) and 24 (12.2%) in the middle and upper tertiles, respectively (*P*=0.02). Patients in the lower tertile also tended to live further from their surgical center, with 98 (49.0%) patients in the lower tertile living >100 miles from their surgical center compared with 81 (38.8%) in the middle tertile and 60 (30.8%) in

Table 1. Baseline Characteristics of Study Cohort Stratified by SES

	Lower tertile (N=200)	Middle tertile (N=211)	Upper tertile (N=199)	*P* value
Demographic characteristics				
Sex,* n (%)				
Female	73 (36.7)	76 (36.0)	72 (36.2)	0.99
Male	126 (63.3)	135 (64.0)	127 (63.8)	
Race,† n (%)				
American Indian/Alaskan	1 (0.5)	1 (0.5)	2 (1.0)	0.67
Asian	3 (1.5)	5 (2.4)	3 (1.5)	
Black	24 (12.0)	19 (9.1)	16 (8.1)	
Multiracial	1 (0.5)	0 (0.0)	3 (1.5)	
Native Hawaiian/Pacific Islander	0 (0.0)	1 (0.5)	3 (1.5)	
Other	10 (5.0)	10 (4.8)	10 (5.1)	
White	161 (80.5)	172 (82.3)	160 (80.8)	
Ethnicity,‡ n (%)				
Hispanic/Latino	41 (21.0)	26 (12.6)	24 (12.2)	0.02
Non-Hispanic/Non-Latino	154 (79.0)	180 (87.4)	172 (87.8)	
Age at discharge, days, mean±SD	43.7±43.4	41.9±30.1	40.2±31.4	0.14
Educational attainment,§ n (%)	68 (44.5)	97 (64.3)	75 (70.7)	0.02
Surgical center distance,‖ n (%)	98 (49.0)	81 (38.8)	60 (30.8)	<0.001
Private insurance,# n (%)	54 (27.8)	95 (47.3)	112 (57.4)	<0.001
Neighborhood summary score (range)	−10.84 to −1.56	−1.55 to +1.21	+1.23 to +13.54	
Birth characteristics				
Prenatal diagnosis,¶ n (%)	164 (82.0)	173 (82.8)	172 (86.4)	0.44
Gestational age,** weeks, mean±SD	38.1±1.7	38.2±1.7	38.1±1.5	0.29
Birth weight,†† kg, mean±SD	3.2±0.6	3.1±0.6	3.2±0.5	0.53
Clinical characteristics				
Anatomy‡‡ – HLHS, n (%)	65 (32.7)	81 (38.6)	78 (39.2)	0.33
Genetic syndrome, n (%)	38 (19.0)	41 (19.4)	40 (20.1)	0.96
Other anomalies, n (%)	26 (13.0)	27 (12.8)	24 (12.1)	0.96
Predischarge AVVR,§§ n (%)	87 (43.5)	90 (42.6)	99 (50.0)	0.24
Predischarge function,‖‖ n (%)	12 (6.0)	13 (6.2)	15 (7.5)	0.91
Interstage period,## days, mean±SD	165.7±80.3	155.6±56.9	146.7±57.7	0.12
Readmission, days, mean±SD	13.5±20.7	12.6±18.9	15.3±28.3	0.86
Adherence,¶¶ %, mean±SD	55.0±30.0	65.0±29.0	62.0±29.0	0.003
Outcomes				
Glenn, n (%)	191 (95.5)	193 (91.5)	187 (94.0)	0.07
Death, n (%)	7 (3.5)	15 (7.1)	5 (2.5)	
Transplant listing, n (%)	2 (1.0)	3 (1.4)	7 (3.5)	

AVVR indicates atrioventricular valve regurgitation; HLHS, hypoplastic left heart syndrome; and SES, socioeconomic status.

*One patient (from lower tertile) with missing data.

†Three patients (2 from middle, 1 from upper tertile) with missing data. Two patients (1 from middle, 1 from upper) chose not to report race.

‡Thirteen patients (5 from lower, 5 from middle, 3 from upper tertile) with missing data.

§Educational attainment (of primary care giver): >12 y of schooling. Two hundred patients (47 from lower, 60 from middle, 93 from upper tertile) with missing data.

‖Surgical center distance=living >100 miles from surgical center. Six patients (2 from middle, 4 from upper tertile) with missing data.

#Twenty patients (6 from lower, 10 from middle, 4 from upper tertile) with missing data.

¶Two patients (from middle tertile) with missing data.

**Six patients (2 from each tertile) with missing data.

††Ten patients (2 from lower, 3 from middle, 5 from upper tertile) with missing data.

‡‡Two patients (1 from lower, 1 from middle tertile) with missing data.

§§Predischarge AVVR that was mild or greater at discharge. One patient (from upper tertile) with missing data.

‖‖Predischarge function=ventricular dysfunction that was mild or greater at discharge. Two patients (1 from lower, 1 from middle tertile) with missing data.

##One hundred twenty-four patients (39 from lower, 49 from middle, 36 from upper tertile) with missing data.

¶¶Adherence=number of days families input data into the application divided by the total number of interstage days (excluding any hospitalization days).

the upper tertile (P<0.001). Patients in the upper tertile were more likely to have private insurance (57.4%), compared with those in the middle (47.3%) and lower tertiles (27.8%) (P<0.001) and were more likely to have completed at least 12 years of school (70.7% upper, 64.3% middle, 44.5% lower; P=0.02). The neighborhood summary score range was –10.84 to –1.56, –1.55 to +1.21, and +1.23 to +13.54 for the lower, middle, and upper tertiles, respectively. Adherence with the CHAMP application differed by tertile, with the highest percentage in the middle and upper tertiles (65.0% and 62.0%, respectively) compared with the lower tertile (55.0%) (P=0.003).

Overall, 39 (6.4%) patients reached the end point of death (27; 4.4%) or transplant listing (12; 2.0%) during the interstage period (Table 2). In univariate analysis, patients who died or were listed for transplant had higher incidence of mild ventricular dysfunction (18.0% versus 5.8%; P=0.01) and mild atrioventricular valve regurgitation (66.6% versus 43.9%; P=0.003) on predischarge

Table 2. Baseline Characteristics of Patients Experiencing and Not Experiencing Primary End Point

	Death/transplant listing N=39	Glenn N=571	*P* value
Sex,* n (%)			
Female	19 (50.0)	202 (35.4)	0.07
Male	19 (50.0)	369 (64.6)	
Race,† n (%)			
American Indian/Alaskan	0 (0.0)	4 (0.7)	0.77
Asian	0 (0.0)	11 (1.9)	
Black	4 (10.3)	55 (9.7)	
Multiracial	0 (0.0)	4 (0.7)	
Native Hawaiian/Pacific Islander	1 (2.6)	3 (0.5)	
Other	2 (5.1)	28 (4.9)	
White	32 (82.1)	461 (81.2)	
Ethnicity,‡ n (%)			
Hispanic/Latino	2 (5.1)	89 (15.9)	0.07
Non-Hispanic/Non-Latino	37 (94.9)	469 (84.1)	
Age at discharge, days, mean±SD	53.0±52.0	41.2±33.9	0.22
Educational attainment,§ n (%)	11 (52.4)	229 (58.8)	0.18
Surgical center distance,‖ n (%)	15 (38.5)	224 (39.6)	1.00
Private insurance,# n (%)	15 (40.5)	246 (44.5)	0.79
Prenatal diagnosis,¶ n (%)	31 (79.5)	478 (84.0)	0.46
Anatomy – HLHS,** n (%)	15 (38.5)	209 (36.7)	0.83
Genetic syndrome, n (%)	12 (30.8)	107 (18.7)	0.07
Predischarge weight,†† kg, mean±SD	4.0±1.02	3.7±0.72	0.03
Predischarge AVVR,‡‡ n (%)	26 (66.6)	250 (43.9)	0.003
Predischarge function,§§ n (%)	7 (18.0)	33 (5.8)	0.01
Oral feeding at discharge,‖‖ n (%)	10 (25.6)	231 (40.9)	0.02
Adherence,## %, mean±SD	63.0±31.0	60.0±29.0	0.48
Lower tertile, n (%)	9 (23.1)	191 (33.5)	0.24
Middle tertile, n (%)	18 (46.2)	193 (33.8)	
Upper tertile, n (%)	12 (30.8)	187 (32.7)	

AVVR indicates atrioventricular valve regurgitation; and HLHS, hypoplastic left heart syndrome.
*One patient (from primary outcome group) with missing data.
†Three patients (from Glenn group) with missing data. Two patients (from Glenn group) chose not to report race.
‡Thirteen patients (from Glenn group) with missing data.
§Educational attainment (of primary caregiver): >12 y of schooling. Two hundred patients (18 from primary outcome, 182 from Glenn group) with missing data.
‖Surgical center distance=living >100 miles from surgical center. Six patients (from Glenn group) with missing data.
#Twenty patients (2 from primary outcome, 18 from Glenn group) with missing data.
¶Two patients (from Glenn group) with missing data.
**Two patients (from Glenn group) with missing data.
††Two patients (from Glenn group) with missing data.
‡‡Predischarge AVVR=atrioventricular valve regurgitation that was mild or greater at discharge. One patient (from Glenn group) with missing data.
§§Predischarge function=ventricular dysfunction that was mild or greater at discharge. Two patients (from Glenn group) with missing data.
‖‖Six patients (from Glenn group) with missing data.
##Adherence=number of days families input data into the application divided by the total number of interstage days (excluding any hospitalization days).

echocardiogram, compared with those who achieved Glenn palliation. Patients who achieved Glenn palliation were more likely to weigh less on average at the time of neonatal discharge compared with those who died or were listed for transplant (3.7 kg versus 4.0 kg; *P*=0.03) and were also more likely to be exclusively orally fed at the time of discharge (40.9% versus 25.6%; *P*=0.02). Of the 39 patients who reached the primary outcome of death or transplant listing, 2 (5.1%) were Hispanic/Latino, compared with 89 (15.9%) of those who achieved Glenn palliation (*P*=0.07). Adherence with use of CHAMP was comparable between those who achieved Glenn compared with those who died or were listed for transplant (60.0% versus 63.0%, respectively; *P*=0.48).

In univariate analysis, there was no difference in rates of death or transplant listing by SES tertile. There were 9 (23.1%), 18 (46.2%), and 12 (30.8%) patients who died or were listed for transplant in the lower, middle, and upper tertiles, respectively (*P*=0.24). For multivariable analysis, the list of candidate variables was a priori narrowed to avoid model overfitting.[22] After multivariable adjustment for ethnicity and presence of ventricular dysfunction, the association between SES and death/transplant listing remained nonsignificant. Compared with those in the lower tertile, the odds of death or transplant listing was not different for those in the middle (odds ratio, 1.7 [95% CI, 0.734–3.938] or upper (odds ratio, 1.0 [95% CI, 0.30–3.36]) SES tertile (overall *P* value 0.42; Figure 2).

DISCUSSION

In this large cohort of infants with SV heart disease enrolled in a digital remote monitoring program during the interstage period, we found no significant differences in death or transplant listing based on SES. Even after adjusting for other clinically relevant patient characteristics, outcomes across SES groups were similar. Our study highlights the potential of novel technology like CHAMP to decrease the mortality rate and mitigate differences in outcomes by SES and highlights the need for further randomized controlled trials or focused observational studies assessing the utility of CHAMP.

Several prior studies have identified lower SES as a risk factor for worse outcomes among infants with SV heart disease. In a large study of infants enrolled in the SVR (Single Ventricle Reconstruction) trial, the authors examined the association between neighborhood SES and postoperative outcomes.[10,23] In their analysis, patients in the highest SES tertile had a 42%

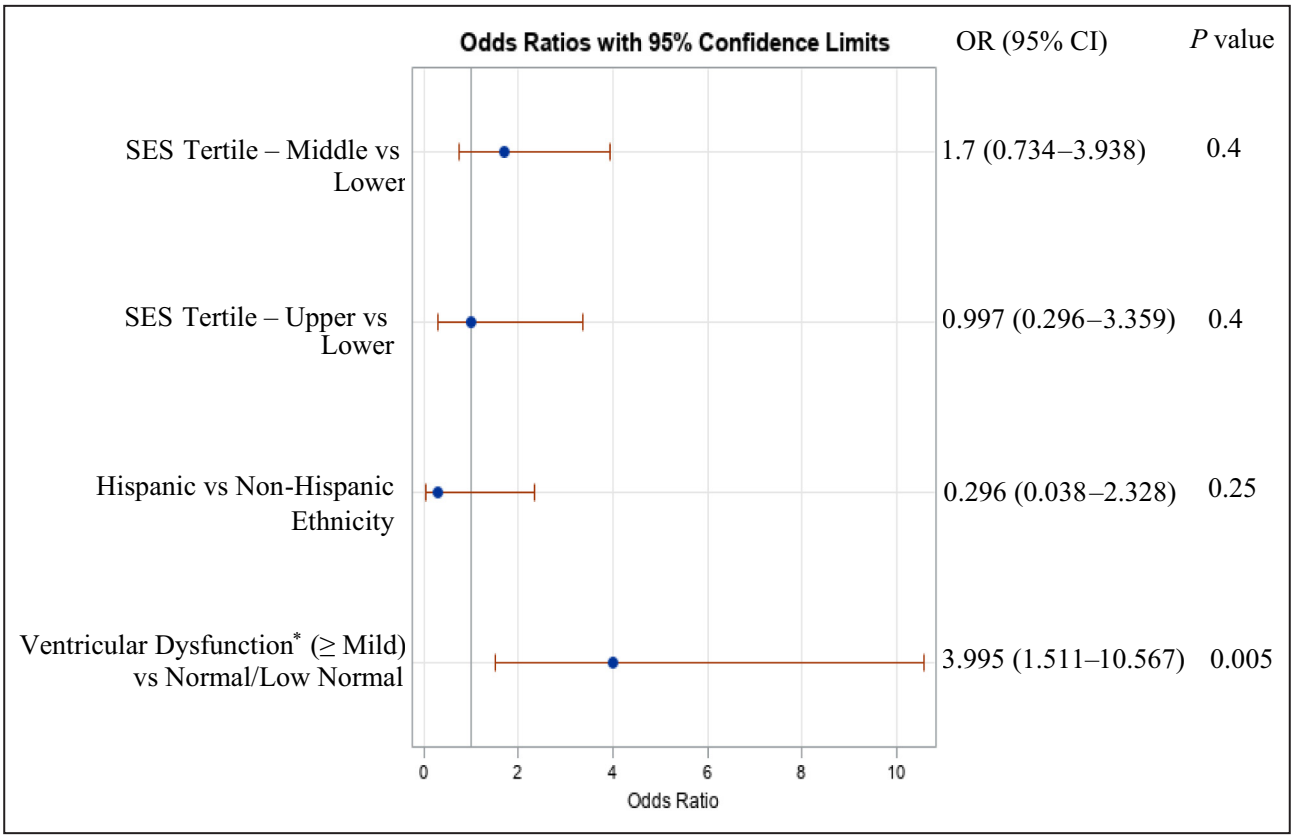

Figure 2. Association between SES tertile and interstage death/transplant listing.
Forest plot showing odds of mortality or transplant listing by SES tertile for CHAMP infants during the interstage period. *Ventricular dysfunction that was mild or greater on predischarge echocardiogram. OR indicates odds ratio; and SES, socioeconomic status.

lower unadjusted hazard of 1-year death or transplant compared with patients in the lowest SES tertile. This difference persisted even after adjusting for patient demographics, birth characteristics, and anatomy.[10] In another study evaluating risk factors for intermediate-term death and cardiac transplantation using data from the SVR trial, the authors found a 1.28 times increased risk of death for every 5-point decrease in SES score during the first year following Norwood palliation.[24]

Despite an understanding that infants with SV heart disease and lower SES are at higher risk of poor outcomes, studies evaluating potential interventional strategies are limited. In 2016, Castellanos and colleagues[9] investigated the impact of a home monitoring program on interstage death in patients with SV heart disease with high-risk sociodemographic factors. In this single-center retrospective study, the authors studied patients living in neighborhoods with >5% of families living below the poverty line. Compared with historical controls treated before the initiation of a home monitoring program, there was an 80% relative reduction in interstage death in the home monitoring group.[9] These improvements with home monitoring suggest that patients of low SES may benefit from interventions in the home environment, a notion that is supported by our current study.

There are several potential reasons why interventions like CHAMP have the potential to improve outcomes for those of low SES. Patients of low SES may have more transportation barriers and less flexibility with employment-related leave time. While more direct access to the medical care team is likely to benefit all patients, this may be particularly germane to those patients with the most barriers to seeking care. In our study, a greater proportion of patients in the lower SES tertile lived >100 miles from the surgical center, compared with those in the middle and upper tertiles. Prior work has demonstrated that proximity to a specialized pediatric cardiac center is associated with lower rates of infant death in patients with congenital heart disease. Compared with those living in close proximity to a pediatric cardiac center, infants whose mothers did not live in close proximity had a 28% greater adjusted risk of death.[25] Interventions such as CHAMP may allow for proactive communication by the health care team and quicker triage of patients. This may be particularly beneficial to patients of lower SES living at a distance from their pediatric cardiac center and could result in eliminating the disparities in outcomes noted in prior studies.

We found no difference in outcomes by SES for patients enrolled in CHAMP. While encouraging regarding the potential use of this novel technology, it would be difficult to definitively conclude, based only on our study results, that CHAMP was the sole driver of these findings. Ideally, such a study would be conducted using a randomized controlled trial design. In 2018, Bingler et al[19] performed a randomized crossover study using the first 31 patients enrolled in CHAMP. They found no interstage deaths, fewer unplanned intensive care unit stays, shorter delays in care, and less interstage growth failure, and CHAMP was preferred over the traditional 3-ring binder approach. Enrollment stopped early due to patient safety concerns. Thus, future studies using a randomized controlled trial design for CHAMP patients were not pursued due to concerns regarding clinical equipoise. For our current study, the majority of patients at CHAMP participating sites chose to enroll in CHAMP, so we did not have a "control" group to which we could compare the outcomes. However, given the resources and expenses that widespread implementation of such a program would entail, the findings of our study should be confirmed in future observational studies or as part of larger randomized controlled trials.

Research evaluating parental use of mobile health technology for infants with SV heart disease defines adherence as "the degree to which parents' transfer of [mobile] health data for their infant meets health care providers' recommendations for symptom home monitoring."[26] In our study, the overall adherence with use of CHAMP was 61% (SD=29). To date, there is not a recommended level of adherence for monitoring of infants with SV heart disease; however, the degree of adherence in our study aligns with prior studies.[27,28] Jackson et al[28] reviewed adherence with mobile health monitoring of infants with SV heart disease at their institution during the interstage period. They defined high adherence as >50%, which was achieved in only 61% of their cohort, and found no association with adherence and interstage death. In our CHAMP cohort, there was >50% adherence in each tertile, and although adherence was statistically different across tertiles, it was not significant by outcome. There are various sociodemographic factors that have been found to correlate with adherence using mobile monitoring systems, and CHAMP addresses some of these with its availability in multiple languages and the built-in cellular capability of the device when provided. While improving adherence with use of CHAMP is a target for future quality improvement, even using the CHAMP application 61% of the time during the interstage period is likely to benefit patients. Although not all patients may input data with the recommended frequency, the application provides more direct access to the care team and can be used by caregivers to input data if and whenever they have a concern regarding their child.

In our study, we found no statistically significant difference in outcomes between the SES tertiles. However, the crude mortality rates were highest in those in the middle tertile, and the point estimate in

our multivariable analysis was also higher in the middle compared with the lower tertile. Although not a universal finding, other studies have also demonstrated worse outcomes among patients with SV heart disease closer to an "average" SES compared with those at the extremes. Using SVR data, Ghanayem and colleagues[12] found that patients in communities with 5.4% to 13% of inhabitants living below the federal poverty level had a greater risk of interstage death compared with subjects in more destitute and affluent communities. De Loizaga et al[29] found that in the first year of life, patients with SV heart disease living at the mean of the community deprivation index had higher hazard of 1 year death compared with those at the extremes. These findings underscore the complexity of socioeconomic factors and how they relate to outcomes. While intuitively it may seem that a relationship between SES and outcomes would be linear, it is likely that this association is nuanced and possible that patients who are closer to an "average" SES face unique challenges compared with those at the extremes. This finding highlights the importance of continued research dedicated to understanding the social determinants of health that are unique to individual patients and populations and how we can tailor our medical care to best meet these unique needs.

In our analysis, we chose a comprehensive measure of neighborhood SES rather than a single measure of family SES (ie, payer, caregiver education level). We chose to do analysis in this way as one marker of patient SES may not be sufficient to capture the complex interplay between SES and health outcomes. For example, in a large study from the Pediatric Health Information System database, data were linked to estimates of neighborhood household income (by zip code), obtained from the US Census Bureau. The authors found that children from the lowest-income neighborhoods who were undergoing cardiac surgery had 1.18 times the odds of death even after accounting for differences in race, payer, and center.[30] For this reason, we chose to measure neighborhood SES for the purposes of our analysis. However, we recognize the challenges with using zip code as the only surrogate for SES. For example, prior work looking at mortality rates in non-Hispanic White adults has shown that patients of lower SES who live in higher SES neighborhoods have worse outcomes.[31] This suggests that if a patient/family is of lower SES but resides in a high-income neighborhood, they may not universally benefit from the higher-quality resources available to them in a higher SES neighborhood. For example, access to social services that are more prevalent in lower-income areas may not be available to them. Moreover, issues of transportation, work inflexibility, insurance, and ability to purchase medication/equipment impacts patients of lower SES regardless of neighborhood income. Additionally, patient/family SES may have associations with adherence to mobile monitoring programs like CHAMP, as has been previously noted, and in ways that may not be captured by neighborhood SES. This highlights the need for measures of SES that address both individual- and neighborhood-level factors.

We found that patients in the upper SES tertile had a higher incidence of transplant listing at 3.5%, compared with the middle (1.4%) and lower tertiles (1.0%). While the absolute number of patients listed for transplant was very small and limits the ability to draw definitive conclusions about this association, the finding is worth noting. This higher incidence may be attributed to the increased means, educational status, and insurance status of patients in the higher SES tertile. However, a recently published study that surveyed providers from the Pediatric Heart Transplant Society suggests that racial and socioeconomic biases may also affect decisions regarding transplant listing. Providers from the Pediatric Heart Transplant Society were surveyed and given race and SES implicit association tests. Their results showed an implicit preference for White individuals and people of higher SES, and a strong explicit preference for people with higher education.[32] Findings of studies like this highlight the need for further bias education and training within the health care system.

Our study is subject to the following potential limitations. First, as noted above, our analysis ideally would have included a comparison of outcomes between patients using and not using CHAMP, and we cannot definitively conclude that the absence of differences between SES tertiles is solely attributable to CHAMP. Nonetheless, our study highlights the need for additional focused studies regarding the impact of programs like CHAMP on reducing health care disparities. Second, despite our relatively large sample size, it is possible that we were underpowered to detect associations between SES tertile and the outcome of interest. Our relatively low event rate also limited our ability for more robust multivariable adjustment. Our study is also subject to the same limitations as other observational studies including issues related to human errors with data input and the potential for unmeasured confounding. Moreover, our study was designed to evaluate for differences in outcomes for infants with SV heart disease on the basis of SES and did not incorporate any measures of cost effectiveness. Given the costs of CHAMP with respect to maintaining the technology, data storage, and providing access at no charge to families, evaluating programmatic costs needs to be considered before considering more widespread dissemination. Finally, unlike some prior studies relating SES to outcomes that included only patients with HLHS, our study comprised all functionally univentricular patients. While it is possible that this impacted our

study findings, we found no significant differences in frequency of HLHS among the SES tertiles.

CONCLUSIONS

In summary, in a large cohort of infants with SV heart disease enrolled in a novel, digital home monitoring program, we found no statistically significant difference in outcomes based on SES. Although CHAMP was not created as an intervention to address disparities in health care outcomes, this study suggests that programs providing more direct access to the health care team could help in mitigating differences in outcomes for this vulnerable population of patients.

ARTICLE INFORMATION

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