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# Association Between Remote Monitoring and Interstage Morbidity and Mortality in Single Ventricle Patients Across Socioeconomic Groups

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# The Association Between Remote Monitoring and Interstage Morbidity and Mortality in Single Ventricle Patients Across Socioeconomic Groups

Bianca Cherestal, MD











## Background

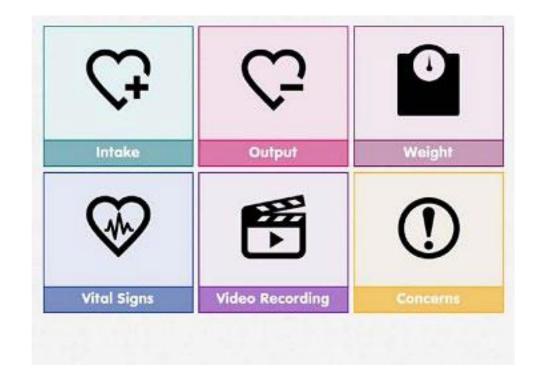
 Despite improving outcomes, morbidity and mortality for single ventricle (SV) infants remains high.

• Infants of low socioeconomic status (SES) are known to be particularly vulnerable following stage 1 palliation.

Interventional strategies to target this population are lacking.

## Background

- CHAMP® (Cardiac High Acuity Monitoring Program)
  - Enrollees download the CHAMP app or are provided a device.
  - Parents obtain daily weight, heart rate and oxygen saturation.
  - Data input into the app is transferred via cloud-based web service.
  - Process allows for near instantaneous transfer of data to the care team.



## Background

• Aim: To investigate whether use of a novel remote monitoring program, CHAMP <sup>®</sup> (Cardiac High Acuity Monitoring Program), mitigates the known disparate outcomes for lower SES SV infants during the interstage period (ISP) by providing more direct access to the care team

• **Hypothesis:** Among a large cohort of CHAMP <sup>®</sup> participants, there will be no difference in outcomes by SES.



## Methods

- Data Source: CHAMP®
  - CHAMP® enrollment has expanded from CMH to 12 sites across the U.S.
- Inclusion criteria:
  - Functionally univentricular patients discharged home during the IS period.
  - Consented to research.
- Exclusion criteria:
  - Currently using/returned device.
  - Underwent biventricular repair.
  - Missing/incomplete data.
  - Not Glenn or transplant candidate.
  - Transferred care to another center.



## **Methods: Predictor Variable**

#### **Neighborhood Socioeconomic Status**

Log of median household income

Log of Median value of housing units

Percentage of households with interest, dividend, or rental income

Percentage of adult residents who completed high school

Percentage of adult residents who completed college

Percentage of employed residents with executive, managerial, or professional occupations



## Methods

- Outcome Variable: Death or transplant listing during the interstage period.
- Covariates:
  - Sex
  - Race/Ethnicity
  - Prenatal diagnosis
  - Hypoplastic Left Heart Syndrome
  - Gestational Age
  - Birth Weight
  - Genetic Syndrome
  - Presence of AV-valve regurgitation prior to discharge
  - Ventricular dysfunction prior to discharge
  - Adherence with CHAMP ® app



## **Methods: Statistical Analysis**

- Comparison of baseline characteristics by SES tertile:
  - Kruskal-Wallis tests for continuous variables and  $\chi 2$  or Fisher's exact tests for categorical variables.
- Comparing characteristics of patients reaching the primary outcome vs. those who did not:
  - Wilcoxon rank-sum tests for continuous variables and  $\chi 2$  or Fisher's exact tests for categorical variables.
- Multivariable hierarchical logistic regression to adjust for potential confounding variables.



# Results



## **Study Population**

806 patients enrolled in **CHAMP** 75 – underwent biventricular repair 70 – actively using device 12 – returned device 12 – ultimately never went home interstage 8 – not candidate for Glenn or transplant Excluded 7 – with missing zip code or census data information 5 – transferred care to another center 5 – no data on ultimate treatment end point 2 – lost to follow up 610 patients in final sample



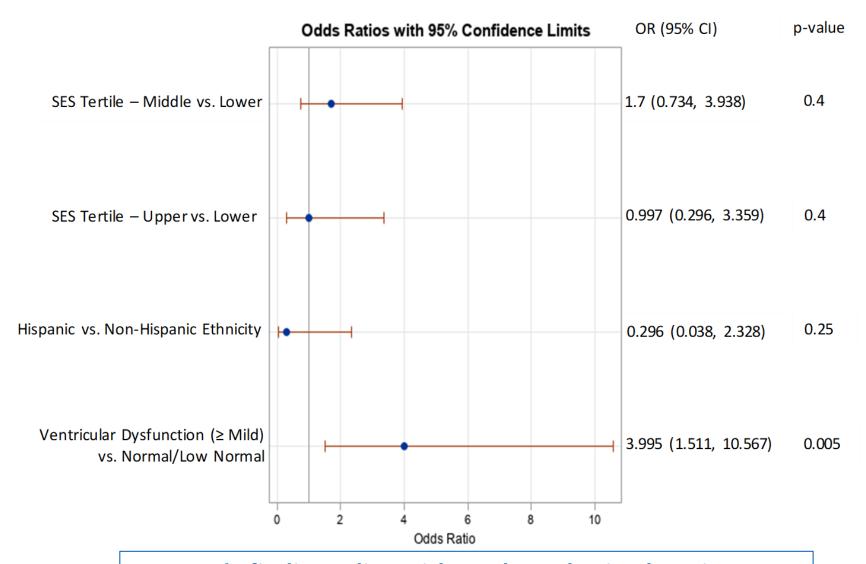
	Lower Tertile N = 200	Middle Tertile N = 211	Upper Tertile N = 199	P value
Demographic characteristics				
Female, n (%)	73 (36.7)	76 (36)	72 (36.2)	0.99
Non-White Race, n (%)	39 (19.5)	39 (18.5)	39 (19.6)	0.95
Hispanic/Latino. n (%)	41 (21)	26 (12.6)	24 (12.2)	0.023
Age at Discharge (days), mean ± SD	45.5±35.5	42.3±29.9	40.4±31.3	0.32
Educational Attainment*, n (%)	74 (48.4)	104 (68.9)	79 (74.5)	<0.001
Surgical Center Distance*. n (%)	98 (49)	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	0.61
Birth characteristics				
Prenatal diagnosis. n (%)	164 (82)	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
Birthweight (kg), mean ± SD	3.2±0.57	3.1±0.55	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 (%)	162 (81)	170 (80.6)	159 (79.9)	0.96
Other Anomalies, n (%)	174 (87)	184 (87.2)	175 (87.9)	0.96
Bypass Time (min), mean ± SD	145.7±60.4	150.1±55.4	144±51.4	0.85
Cross Clamp Time (min), mean ± SD	66.7±40.5	69.2±38.1	74.2±41.5	0.25
Pre-Discharge AVVR*, n (%)	93 (46.5)	96 (45.5)	106 (53.5)	0.64
Pre-Discharge Function* – normal, n (%)	186 (93.5)	196 (93.3)	183 (92)	0.94
Interstage Period (days), mean + SD	165 7+80 3	155 6+56 9	146 7+57 7	0.12
Adherence (%)*, mean ± SD	55±30	65±29	62±29	0.003
Outcomes				
Glenn, n (%)	191 (95.5)	193 (91.6)	187 (93.9)	
Death, n (%)	7 (3.5)	15 (7.1)	5 (2.5)	0.07
Transplant Listing, n (%)	2 (1)	3 (1.4)	7 (3.5)	

Adherence = (# days weight, oxygen saturation & heart rate entered in app)/(total # IS days – hospitalization days).



	Death/Transplant Listing N=39	Glenn N=571	p-value
Female, n (%)	19 (5)	202 (35.4)	0.07
Non-White Race, n (%)	7 (17.9)	110 (19.3)	0.84
Hispanic/Latino, n (%)	2 (5.1)	89 (15.9)	0.07
Educational Attainment*, n (%)	11 (52.4)	229 (58.8)	0.83
Surgical Center Distance*, n (%)	15 (38.5)	224 (39.6)	0.65
Private Insurance, n (%)	15 (40.5)	246 (44.5)	0.79
Prenatal Diagnosis, n (%)	31 (79.5)	478 (84)	0.46
Anatomy – HLHS, n (%)	15 (38.5)	209 (36.7)	0.83
Genetic Syndrome, n (%)	27 (69.2)	464 (81.3)	0.07
Pre-Discharge weight (kg), mean± SD	4.0±1.02	3.7±0.72	0.03
Pre-Discharge AVVR*, m (%)	27 (66.6)	250 (43.8)	<0.001
Pre-Discharge Function*, n (%)	7 (17.9)	33 (5.8)	0.02
Oral Feeding at Discharge, n (%)	10 (25.6)	231 (40.9)	0.02
Adherence, mean (%)	60±31	60±29	0.58
Lower Tertile, n (%)	9 (23.1)	191 (33.5)	
Middle Tertile, n (%)	18 (46.2)	193 (33.8)	0.24
Upper Tertile, n (%)	12 (30.8)	187 (32.7)	





Study findings align with our hypothesis: there is no significant difference in outcomes by socioeconomic status.



## Limitations

• Sample size.

• Low event rate limited ability to adjust for potential confounders in multivariable analysis.

No comparison group.



## Conclusion

 In this large cohort of SV infants enrolled in a digital remote monitoring program during the ISP, we found no difference in outcomes based upon SES.

• These findings differ from prior studies showing worse outcomes for SV patients of lower SES.

• Our study suggests this novel technology could help mitigate differences in outcomes for this fragile population of patients.



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# Questions?



