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Organ allocation in adults with congenital heart disease listed for heart transplant: Impact of ventricular assist devices

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BACKGROUND: Adults with congenital heart disease (CHD) listed for heart transplantation are rarely supported by ventricular assist devices (VADs). This may be a disadvantage to their priority for organ allocation. We sought to determine the relationship between VAD implantation and successful transplantation among patients listed for heart transplant.

METHODS: Adults with CHD patients ($N = 1,250$) were identified from the United Network for Organ Sharing (UNOS) database from 1985 to 2010 and compared to patients without congenital etiology for heart failure ($N = 59,606$). VAD use at listing, listing status, status upgrades and reasons for upgrade prior to transplant were trended at 5-year intervals and appropriate statistical comparisons were made between groups.

RESULTS: Since 1985, VAD use prior to transplant has increased significantly in patients without CHD, but not in CHD patients (17% vs 3% in 2006 to 2010, $p < 0.0001$). CHD patients were more likely to be listed as Status 2, compared to those without (66% vs 40%, $p < 0.001$ for 2006 to 2010), and less likely to be upgraded to Status 1 after listing (43% vs 55%, $p = 0.03$). Among those upgraded to Status 1, CHD patients were less likely to have a VAD at transplant than those without (3% vs 18%, $p = 0.005$). VAD use was more likely to result in death in CHD patients.

CONCLUSIONS: VAD use is less common in CHD patients than in patients without CHD, both at the time of listing and transplantation. Reduced VAD use appears to contribute to lower listing status and organ allocation. These differences have grown more disparate over time. Separate criteria for organ allocation for CHD patients may be justified.

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Adult congenital heart disease (CHD) patients are growing more numerous because of improved survivorship through childhood. They remain vulnerable to myocardial dysfunction and clinical heart failure,[1] a major cause of death in these individuals.[2,3] Thus, adult CHD patients are increasingly referred for heart transplantation.[4] Despite the anatomic and physiologic challenges,[5] favorable long-term transplant outcomes have been reported.[6,7]

Use of ventricular assist devices (VADs) as a bridge to transplant has become more commonplace, particularly since the introduction of continuous-flow pumps.[8,9] Extension of this practice to CHD patients, however, has been slower. Data from the United Network for Organ Sharing (UNOS) standard transplant and research data set has demonstrated that, compared to those without CHD, listed CHD patients are less likely to have a VAD or other

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mechanical support, as well as longer wait times in Status 2.[10,11] Consequently, cardiovascular mortality on the heart transplant waiting list is higher in CHD patients.

In 2006, a universal policy change was made in U.S. organ allocation, such that Status 1 patients outside the local referral area were offered organs before local Status 2 patients. This change has decreased the number of overall transplants for Status 2 patients.[4,12,13] Because VAD implantation is a qualification for Status 1 listing, lower VAD implantation rates in listed patients with CHD may result in lower priority status and reduced organ allocation for these patients.[12] We sought to determine the impact of VAD utilization on listing and heart allocation for CHD heart transplant candidates by following trends over time.

Methods

Patient population

Patient-level data were obtained from UNOS, a U.S. registry of transplant listing, organ allocation, and outcomes maintained continuously since 1985. Our institutional review board approved use of these deidentified data, and the requirement for individual consent was waived. We excluded patients who were <18 years old at the time of listing, listed for double organ transplantation, or listed for re-transplantation. The remaining patients were classified as CHD or without CHD based on the stated etiology of their heart failure.

Variables obtained included age, gender, listing status, inotrope use and VAD implant at the time of listing. Patients who were Status 2 at listing, but Status 1 (1, 1A, or 1B) at the time of organ offering were considered to have had a status upgrade. Patients in whom inotropic support was provided at time of transplant but not at listing were considered upgraded on the basis of inotrope use. Similarly, patients in whom VAD was present at transplant but not at listing were considered upgraded on the basis of VAD placement. Both were expressed as a percentage of patients upgraded. These were not mutually exclusive, nor did they account for all upgrades. All VADs were included together regardless of designation as "right" or "left," given the potential incongruity of nomenclature for systemic vs sub-pulmonic ventricles. Missing values for VAD fields were assumed to indicate no VAD support was present.

Data were analyzed by 5-year incremental eras starting from 1985 and were based on the listing date. Groups were compared using SPSS (version 18) for Macintosh using chi-square testing for categorical variables, and Student's *t*-test for continuous variables. $p < 0.05$ was considered statistically significant.

Results

Of 78,470 individuals in the database, 40,785 were excluded (including 13,177 pediatric patients, 4,068 listed for multiple organs simultaneously, 2,389 listed for re-do transplant, not mutually exclusive), leaving a study population of 60,856. From these, we identified 1,250 CHD patients (36% female), and 59,606 without CHD (22% female). CHD patients were, in general, younger at listing (33.5 ± 12.5 years vs 51.4 ± 11.2 years, $p < 0.001$), as expected from previous studies.[10,11] Peak VO_2 was not significantly different (12.6 ± 3.2 vs 11.6 ± 3.5 ml/kg/min). The majority of CHD patients were classified as "CHD with unknown surgery" ($N = 828$), with 372 identified as "CHD with surgery" and 47 as "CHD without surgery."

Numbers of adults listed for transplantation for both groups are given by era (Table 1). The percentage of listed patients transplanted has declined over time, with a larger drop in CHD patients to 50% (95% CI 45% to 56%) vs 62% (95% CI 61% to 63%) of patients without CHD for the most recent era ($p < 0.001$).

The percentage of patients initially listed as Status 2 has not changed in the CHD group for the past 3 eras (Figure 1). However, this percentage has gradually dropped for those without CHD to 40% in the most recent era (95% CI 39% to 41%, $p < 0.001$ vs CHD). The number of patients transplanted after initial listing in Status 1 has not changed significantly over time for either group. Yet there has been a decline in transplantation from Status 2 since 2006 for both groups (Figure 2). Currently, the proportion of patients transplanted from Status 2 is 33% (95% CI 24% to 42%) for CHD, and 41% (95% CI 39% to 44%) for those without CHD ($p < 0.0001$ for both compared with prior era).

For patients without CHD, VAD use rose steadily to 17% (95% CI 16% to 17%) at listing and to 17% (95% CI 16.5% to 17.8%) at transplant over the study period ($p < 0.001$ for change from 1985 to 1990 for both listing and transplant; Figure 3). Strikingly, there has not been a significant change in VAD utilization in CHD patients over this same time period.

The frequency of status upgrades while listed is shown for both groups (Figure 4). A similar percentage of patients were upgraded from Status 2 at listing to Status 1 at transplant for both CHD vs those without CHD during all eras except 2006 to 2010, when there was a significantly higher percentage upgraded among patients without CHD (55%, 95% CI 53% to 56%) compared with the CHD group (43%, 95% CI 36% to 51%, $p = 0.003$ vs no CHD).

Table 1 Adults Listed for Heart Transplantation by Era

Era	CHD listed (*N*)	CHD transplanted (%)	95% CI	Without CHD listed (*N*)	Without CHD transplanted (%)	95% CI
1985–1990	69	100	(100–100)	6,712	85	(85–86)
1991–1995	204	77	(71–82)	14,004	70	(69–71)
1996–2000	293	57	(52–63)	15,414	61	(60–62)
2001–2005	366	67	(62–72)	11,825	67	(66–67)
2006–2010	318	50	(45–56)	11,651	62[a]	(61–63)

Number of adults listed for transplantation by era, together with percent transplanted (with 95% confidence interval), for adults with congenital heart patients (CHD) vs those without CHD.

[a] $p < 0.001$ for CHD vs no CHD.