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THORACIC TRANSPLANTATION (J PATEL AND AM HOLM, SECTION EDITORS)

The New US Heart Allocation Scheme: Impact on Waitlist and Post-Transplant Survival

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Abstract

Purpose of Review In October 2018, the Organ Procurement and Transplantation Network (OPTN) revised the donor heart allocation system in an attempt to prioritize those patients with highest clinical urgency, reduce waitlist morality, and improve geographic equity in organ allocation. Our goal was to review the changes in the heart allocation policy and its impact on transplant characteristics and outcomes.

Recent Findings After the new 2018 donor heart allocation system became effective, there has been a trend toward increased use of temporary mechanical circulatory support. Also, initial reports suggested reduced post-transplant survival, although the initial analysis was limited by short follow-up and small sample size. Recent reports however illustrate survival outcomes similar to those of the previous allocation system.

Summary The new donor heart allocation policy has been associated with a change in management strategies for bridging patients to transplantation, with increased utilization of temporary mechanical circulatory support, with still uncertain effects on post-transplant survival.

Keywords Heart transplantation · Donor · Allocation scheme · Waitlist mortality · Temporary mechanical circulatory support

Introduction

Although the heart donor pool has recently expanded with the increased utilization of Public Health Service (PHS) increased-risk donors and hepatitis C virus (HCV)–positive donors [1], there is still a supply-demand mismatch between the number of patients with end-stage heart failure awaiting transplantation and donor availability [2]. The United States (US) donor heart allocation policy previously stratified patients waiting for orthotopic heart transplantation (OHT) by a 3-tiered system (status 1A, 1B, and 2), a system that was maintained by the United Network of Organ Sharing (UNOS) and originally implemented in 1999. Status 1A, the status representing highest urgency, included patients in cardiogenic shock hospitalized in the intensive care unit with continuous intravenous inotropes or temporary mechanical support in addition to patients with complications from a durable left ventricular assist device (LVAD). Status 1B was designated for patients at home on inotropic support or stable with a LVAD. Status 2 included patients stable on oral regimens and those with congenital heart disease or restrictive cardiomyopathies. The UNOS heart allocation policy was revised in 2006 to allow for regional donor sharing for statuses 1A and 1B prior to allocating hearts to patients listed status 2 in hopes of improving waitlist mortality without increasing post-transplant mortality. Following the 2006 algorithm change, Singh et al. illustrated that waitlist mortality decreased by 17% with no subsequent change in 1-year post-transplant mortality [3, 4].

Despite improvement in waitlist mortality after the 2006 revision to the adult heart allocation system, it became clear that there were too many candidates, with disparate clinical urgency, all grouped together in one status (1A). This system lacked clear stratification based on urgency, with a large number of patients meeting criteria for status

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1A, therefore increasing the median waiting time, despite improvement in waitlist mortality. There was also a noticeable increase in the use of mechanical circulatory support (MCS) with increased rates of associated complications. The geographic sharing scheme resulted in regional disparities and inequality of access to donor allografts [5]. In order to better risk stratify patients awaiting heart transplantation, further improve waitlist mortality, and reduce regional variability in waitlist time, the Organ Procurement and Transplantation Network (OPTN) revised the US adult heart allocation policy in October 2018.

New Allocation System

The new 6-tiered allocation system was implemented on October 18, 2018 (Table 1). The previous status 1A was subdivided into status 1, status 2, and status 3 in descending order of illness severity, with stratification based on clinical urgency and risk of waitlist mortality. The revised allocation scheme prioritizes patients on extracorporeal membrane oxygenation (ECMO), with status 1 including veno-arterial (VA) ECMO, non-dischargeable and surgically implanted biventricular support devices, and a mechanical circulatory support device (MCSD) with life-threatening arrhythmia. Status 2 includes patients with a non-dischargeable LVAD, intra-aortic balloon pump (IABP), percutaneous endovascular MCSD, MCSD with device malfunction or mechanical failure, and total artificial heart. Status 3 encompasses patients on multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring in place, dischargeable LVAD for 30 days, VA ECMO after 7 days, percutaneous endovascular circulatory device or IABP after 14 days, or MCS with device infection, hemolysis, pump thrombus, right heart failure, or bleeding.

The lower priority status 4 comprises patients with a durable LVAD following the discretionary 30-day post-implantation period. This status also includes patients on inotropic support without hemodynamic monitoring, patients with congenital heart disease, hypertrophic cardiomyopathy, restrictive cardiomyopathy, and amyloidosis. Statuses 5 and 6 include other patients with lower priority of urgency, with status 7 still representing those inactive on the list. Also, the new policy employed a broader distribution strategy, in which status 1 and status 2 were granted access to donors within 500 miles of the transplant center. As discussed, these modifications to the adult heart allocation system were meant to address deficiencies within the old system, prioritize the patients with the greatest risk of waitlist mortality, and address geographic disparities in the hope of establishing more geographic equity and to be in compliance with the Final Rule [6, 7].

Table 1 Old versus new donor heart allocation system

Old allocation system	New allocation system	Description
Status 1A	Status 1	VA ECMO
		Non-dischargeable BiVAD
		MCSD with life-threatening arrhythmias
	Status 2	IABP
		Percutaneous endovascular MCS
		Sustained VT or VF
		Dischargeable BiVAD, TAH, RVAD
		MCSD with malfunction
	Status 3	Dischargeable LVAD for 30 days
		MCSD with complication (infection, pump thrombosis, etc.)
		IV inotrope infusion plus hemodynamic monitoring
Status 1B	Status 4	Inotropes without hemodynamic monitoring
		Stable LVAD
		Ischemia with intractable angina
		CHD
		Hypertrophic and restrictive cardiomyopathy
		Re-transplant
Status 2	Status 5	Combined organ transplants
	Status 6	Remaining active patients

VA ECMO, veno-arterial extracorporeal membrane oxygenation; *BiVAD*, biventricular assist device; *MCSD*, mechanical circulatory support device; *IABP*, intra-aortic balloon pump; *VT*, ventricular tachycardia; *VF*, ventricular fibrillation; *TAH*, total artificial heart; *LVAD*, left ventricular assist device; *RVAD*, right ventricular assist device; *CHD*, congenital heart disease

Outcomes with the New Allocation System

Since the implementation of the new donor heart allocation system, there has been ongoing assessment regarding outcome trends and consequences of the modifications. The OPTN Thoracic Committee focused its initial monitoring on the characteristics of transplanted patients, transplant outcomes, and mortality of patients on the waiting list. The initial early monitoring from OPTN revealed that the changes resulted in broader sharing with increased regional and national shares, with decreased median waiting times. The allocation change, not surprisingly, resulted in increased transit and ischemic times. The committee also found that there was an increase in transplantation amongst the candidates with the highest waitlist mortality. Prior to the allocation modifications, 67% of transplants occurred in status 1A patients; following October 2018, 75% of transplants occurred in patients listed status 1, status 2, and status 3 [8].

Temporary Mechanical Support

In January 2020, Dr. Cogswell and colleagues released an early investigation of outcomes with the new allocation system [9•]. This analysis included patients listed and transplanted in the three years prior to October 2018 compared with those listed and transplanted after October 18, 2018, until March 31, 2019. This study first highlighted the epidemiological shift in regard to bridging strategies, with patients now more likely to be supported with temporary mechanical circulatory support (MCS). Pre-transplant temporary MCS use increased from 10 to 41% after October 2018. The use of VA ECMO support was also noted to be four-fold greater than previously, 6.5% compared with 1.6% of those patients listed and transplanted [9•]. Although the use of ECMO increased, the overall numbers remain small, whereas the absolute number of patients supported with an IABP has increased significantly. Subsequent studies with additional patients and longer follow-up confirm the trend of increased temporary mechanical support, including Jawitz et al., who evaluated 6004 patients listed and transplanted in the old system compared with 1115 patients listed and transplanted in the new system, with follow-up through September 2019. Their results again demonstrated that candidates in the new system were four times more likely to be supported with temporary MCS, including IABP, ECMO, or temporary ventricular assist device (VAD) [10•]. Goff et al. also found an increase in IABP from 7.48% pre-allocation policy change to 27% ($p < 0.001$) after October 2018 in those patients who underwent transplantation [11]. It is important to highlight that pre-transplant ECMO continues to be identified as the highest independent risk factor for lower post-transplant survival, with an adjusted hazard ratio of 2.97 (95% CI: 2.06 to 4.28) [10•].

The increase in temporary MCS was seen in all patients on the waiting list, not just in those transplanted. IABP use at the time of listing increased from 3.9 to 8.9% pre- to post-policy change implementation [11]. Dr. Varshney et al. aimed to identify if the increase in temporary mechanical support reflected a true shift in the treatment of patients with cardiogenic shock versus an attempt to prioritize patients on the waitlist [12]. The authors utilized data from the Critical Care Cardiology Trials Network (CCCTN) Registry to identify 384 admissions for acute decompensated heart failure–related cardiogenic shock, with 248 to US transplant centers. Of those 248 admissions, 126 (51%) occurred prior to the allocation revision and 122 (49%) occurred after October 2018. This analysis from the CCCTN Registry found that there was an increase in temporary MCS noted in US transplant centers, but this increase was not replicated in non-transplant cardiac intensive care units (CICU) [12]. These results suggest that the increased use of temporary MCS reflects a management strategy shift of end-stage heart failure patients, with temporary MCS being utilized as a bridge to transplant and an attempt to increase a patient's priority.

Following the allocation change, there was also a noticeable decrease in patients bridged to transplant with a durable LVAD. Twenty-three percent of patients listed and transplanted in the new system have a LVAD at the time of transplant, compared with 42% in the prior system [9•]. Given the revision aimed to decrease waitlist mortality by prioritizing patients with temporary MCS, the inevitable consequence was that stable outpatients with LVADs were listed at a lower urgency status. After the discretionary 30 days, patients with a durable LVAD are listed status 4. Even with LVAD complications such as right heart failure, the strict criteria limit most upgrades in priority to status 3, with status 2 being reserved only for device malfunction or mechanical failure. The Society of Thoracic Surgeons (STS) Intermacs 2019 annual report highlighted this dramatic alteration in implant strategies. This report illustrated that before 2018, 25% of patients received a LVAD as bridge to candidacy (BTC), 25% as bridge to transplantation (BTT), and half as destination therapy (DT). Following October 2018, less than 10% of LVAD implants were BTT and over 70% were implanted as DT [13].

Improved Waitlist Mortality

The implemented changes aimed to improve waitlist mortality, and from initial analyses, this goal was achieved. Survival on the waitlist at 180 days in the old allocation system was 95%, and Cogswell et al. demonstrated that survival at 180 days in the new system was 96.1%. A competing risk analysis, adjusted for recipient age, presence of durable LVAD or temporary support, and diabetes mellitus, was performed and did show that the new allocation system was protective against waitlist mortality (adjusted hazard ratio [HR]

0.43, 95% CI: 0.31–0.60, $p < 0.001$) [9•]. Hanff et al. recalculated the waitlist mortality utilizing more recent UNOS registry data and also illustrated a decrease in 180-day waitlist mortality from 3.9% to 2.3% associated with the new allocation scheme (HR: 0.56, 95% CI: 0.39–0.81, $p = 0.002$) [14]. Although these initial studies revealed small improvements in waitlist mortality, more recent results demonstrate that the overall waiting list mortality was unchanged in the new system. However, it does appear that the new system more effectively stratified patients into the correct status based on mortality risk, with status 1 candidates having significantly higher waiting list morality than other statuses [11]. New allocation system transplant recipients also were found to have a shorter amount of time on the waitlist compared with the old system (median 15 versus 68 days; $p < 0.001$) [10•].

Worse Survival Outcomes

Although waitlist mortality has largely remained unchanged, there was initial concern regarding data demonstrating worse short-term mortality and overall worse outcomes post-transplant. Dr. Cogswell's initial analysis illustrated a 180-day survival estimate of 77.9% and a higher unadjusted hazard ratio for death or re-transplantation (HR: 2.1, 95% CI: 1.5–3.0, $p < 0.001$) in the new system compared with a 180-day survival estimate of 93.4% in the prior system [9•]. This increase in post-transplant mortality from 6.6 to 22.1% was alarming, but the sample size is small with widened confidence intervals and limited follow-up [15]. Hanff et al. replicated this analysis with additional UNOS data follow-up through September 27, 2019, and found an estimated 180-day survival of 91.5% in the new system [14]. Jawitz et al. also found that short-term post-transplant survival in the new system was comparable to post-transplant survival in the previous allocation system. However, their unadjusted analysis continued to illustrate minimally decreased survival, albeit not statistically significant, amongst heart transplant recipients in the new allocation system [10•].

Jawitz et al. also performed a propensity score matching sensitivity analysis to compare a subgroup of transplant recipients in the new system with recipients prior to allocation change who had similar baseline clinical characteristics. They found no change in survival outcomes between the two groups. However, this analysis is difficult to interpret given that the demographic and baseline characteristics of transplant recipients have changed as a result of the allocation change itself. Cogswell et al. illustrated a higher level of acuity for patients listed and transplanted, with significantly higher mean pulmonary capillary wedge pressures, higher pulmonary vascular resistance, and lower cardiac output [9•]. However, despite the increased acuity of patients and the increased use of temporary MCS, Goff et al., in their analysis of the OPTN data up to February 21, 2020, also found that the 6-month post-transplant survival estimate post allocation change was 92.8% compared with 93.6%, with no statistically significant change in survival pre- and post-change [11]. Yet Kilic et al. performed a similar analysis of 6-month survival outcomes of 2371 first-time primary isolated heart transplant recipients prior to the allocation policy change compared with 1311 recipients in the new system and found that the 6-month post-transplant survival was worse after the policy change, 88.2% versus 93.9% ($p < 0.001$) [16]. With these discrepant findings regarding transplant survival outcomes, the true impact of the allocation policy change on post-transplant survival is yet to be determined.

Ischemic Time

Although further follow-up is needed before more definitive conclusions can be made regarding post-transplant survival outcomes in the new allocation system, it is important to consider independent risk factors that are associated with worse survival. The new allocation system has seen an increase in ischemic time. There has been an increase in distances between donor and recipient centers, and the median distance traveled has increased from 83 nautical miles (NM) (IQR: 13 to 248) prior to the allocation change to a median of 216 NM (IQR: 65, 400) ($p < 0.001$). The average ischemic time has increased to 3.4 h in the new system from 3 h in the old system ($p < 0.001$) [11]. The increase in ischemic time, which significantly increases the risk of primary graft dysfunction, is important to consider in regard to worse mortality rates as well. Jawitz et al. found that increasing graft ischemic time was an independent risk factor for worse post-transplant survival, with an estimated adjusted hazard ratio of 1.20 per hour; (95% CI: 1.12 to 1.28) [10•]. However, ex vivo perfusion systems, such as the portable Organ Care System (OCS™), may serve as a way to reduce ischemic times in the future [17].

Cost Analysis

The new allocation system is aimed at addressing regional disparities and focusing on broader sharing, and there has been a statistically significant change in distribution of share types. However, it is important to consider the economic consequences of broader sharing. Increased transit times and further distance between donor and recipient centers not only result in increased graft ischemic times but also lead to increased cost, particularly related to travel cost and the increased utilization of air travel that is necessary with broader regional sharing. However, given the shorter amount of time on the waiting list, one would expect less time in the intensive care units (ICUs). Will the decreased ICU costs balance the increased cost of transportation necessary to continue broader regional sharing? This is also yet to be determined.

Future Perspectives

Following the publication of the Cogswell et al. article, there was substantial concern that post-transplant survival was reduced after the implementation of the new allocation system. However, there is discrepancy regarding survival outcomes, with later data using more complete follow-up demonstrating comparable post-transplant mortality rates before and after the allocation change. Further follow-up and evidence are needed before drawing clear conclusions regarding the impact of the allocation change on post-transplant survival outcomes.

However, it is important to at least acknowledge the emerging trends. There is substantial evidence of increasing use of temporary mechanical circulatory support compared with BTT LVADs, illustrating a change in bridging practices. The new allocation system prioritizes patients with highest urgency, so has this incentivized transplant centers to use more temporary support? Are we transplanting patients that are too critically ill rather than delaying transplant by utilizing a durable support BTT LVAD to allow for end-organ recovery and better survival? Although there are criteria for extending higher priority listing to avoid overuse of temporary mechanical support, the trends are hard to ignore. It is difficult to believe that the 400% increase in ECMO and 200% increase in IABP are not related specifically to programmatic attempts at prioritizing patients for transplant. Given that patients with durable LVADs are listed status 4 after the initial 30-day discretionary period, there is concern that these patients will not be transplanted or at least have a lower likelihood of transplant. So are we allowing sick patients to become sicker in an attempt to avoid "VAD purgatory"? [18] Are stable LVAD patients being disenfranchised by the change in allocation, relegating them to status 4 until they have a LVAD complication, that increases their priority status, without hopefully jeopardizing their transplant candidacy? Does the new allocation system further disadvantage certain patient subgroups, such as those who are highly sensitized, have blood type O, or have a higher BMI, in whom a BTT LVAD may be the only option? Will future implementation of the continuous distribution policy help to re-prioritize patients with BTT LVADs and consider post-transplant survival in the allocation scoring system?

The allocation changes were made in an attempt to decrease waitlist mortality and prioritize the most critically ill patients to the highest urgency. However, did the pendulum swing too far? In an effort to get a patient transplanted, are centers avoiding BTT LVADs and over-utilizing ECMO and other temporary mechanical support such as IABPs, which provide hemodynamic support but are not benign therapies? Will the BTT LVAD become a thing of the past; and if so, is that the best thing for our patients? With an increase in donor hearts allocated to more critically ill patients, a rise in post-transplant mortality would not be unexpected. Further data needs to be analyzed before clear conclusions can be made about the new allocation system.

Conclusion

The new allocation system has altered the management strategies of patients awaiting transplantation, with more patients being bridged with ECMO and temporary mechanical circulatory support devices and less patients receiving durable BTT LVADs. Further follow-up is needed to determine the true impact on survival outcomes and waitlist mortality.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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