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Better Is the Enemy of Good: Ever-changing Heart Transplant Allocation

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Solid organ transplantation has been and likely always will be a scarce resource. In the absence of some technological breakthrough, the supply of organs will always be inadequate to meet the demand, particularly as the long-term survival associated with transplant continues to exceed most alternatives.¹ For heart transplantation, we have many issues, not the least of which are the complexities of determining donor quality, the complex acquisition process, and the need for immediate excellent function of cardiac allografts. In addition to these fixed issues, we have intense regulatory oversight which is a constant concern for programs in the United States.

In the beginning era of heart transplantation (starting in 1967), locating suitable donors for transplantation was mostly a local endeavor, but with the passage of the National Organ Transplant Act in 1984, a formal structure was implemented along with rules for organ allocation in the United States.² Heart transplant allocation has advanced over the years from a 2-tier system (in hospital versus home) to a 3- and now a 6-tiered system. The overriding goal has been to prioritize transplantation for the sickest patients and to reduce waitlist mortality while reducing or eliminating disparities (such as ones based on race, socioeconomic status, or geographic location).³

These are all very worthy goals, and each time the heart transplant allocation schema is changed, there is a period of great hope that finally the proper balance has been achieved and that waitlist mortality will be reduced and that waiting times will not be disproportionately affected. The most recent allocation change occurred after a lengthy period of study on October 18, 2018.³ Much has been written about

the outcomes since that time, with some showing worsening mortality as a result of preferentially transplanting the sickest patients and others showing no difference.⁴⁻¹⁹

In this issue of *Transplantation Direct*, Liu et al²⁰ share their experience with the new allocation system at a single US academic medical center. They describe 38 heart transplants performed before the change in allocation and 33 conducted in the year following the new rules. Their program is a microcosm of the activities of other centers around the United States. Before to the allocation change, 92% of their transplant patients were admitted from home, and were status 1B (stable ventricular assist device patients predominantly) or ventricular assist device (VAD) patients with complications but from home environment. These patients would be considered status 4 or possibly status 3 in the new allocation system.

There is no reason to think that the acuity of their patients significantly changed in October 2018, and yet, following the rule change, there were dramatic shifts. Fully 60% of the patients in the subsequent year were transplanted as status 2, with the majority receiving intra-aortic balloon pumps. The use of extracorporeal membrane oxygenation jumped as well increasing from no cases before the new allocation to 9% of the patients in the following year. Only 30% of the patients were admitted from home for their transplant. Despite all this, the survival was not statistically significantly different though there was a trend toward increased mortality occurring in VAD patients experiencing primary graft dysfunction posttransplant.

The lessons learned from the report of Liu et al are that clinicians will adapt to whatever the “rules of engagement” are. Several years ago, it is likely that the planners assumed (incorrectly) that therapies such as extracorporeal membrane oxygenation and intra-aortic balloon pump were so demanding and risky that certainly no patient would be supported with these modalities unless there was no alternative. Sadly, this is not true. Placement of intra-aortic balloon pumps can be done percutaneously via an axillary approach and patients will be able to walk and stay in good physical condition.²¹ In this scenario, the balloon is a “necessary evil” as opposed to inotropic therapy or a durable VAD which previously were the usual ways of managing a patient with end-stage heart failure. Even extracorporeal membrane oxygenation, which was reserved for the most unstable patients, has now been elevated to the ultimate escape hatch from the transplant list with such patients receiving nearly immediate transplantation as status 1.

The authors correctly point out that before 2018, durable VAD was a step on the serial journey to transplantation, but the new allocation puts the VAD recipient on a parallel pathway. The “bridge to transplant” is now an infinite loop

Received 12 October 2020. Revision received 15 October 2020.

Accepted 15 October 2020.

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The author declares the following conflicts of interest: Consulting for Abiomed, Getinge, Livanova, Procyon, Abbott. Speaker for Novartis and Pfizer. None are related to this manuscript. The author declares no funding.

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ISSN: 2373-8731

Transplantation Direct 2020;6: e645; doi: 10.1097/TXD.0000000000001089. Published online 15 December, 2020.

in the absence of serious complications of therapy which are less common with newer devices. It is ironic that now that we have vastly improved VADs with reduced thrombosis and stroke, the landscape has shifted and the bridge to transplant route has dropped substantially.²²⁻²⁴

Until we have a way of objectively assessing the illness of a patient that is independent of the therapies used to support them, we will be doomed to repeat the current cycle of rules changes, adaptation, and overcrowding of the highest priority status. However, a heart allocation score is many years in the future given the difficulty of generating the predictive models which are sufficiently validated to pass muster.²⁵

Some may disparage the current report as an example of clinicians “gaming” the system.²⁶ Each clinician prioritizes the well-being of the patients they are managing. The effect of the change in allocation was predictable since clinicians can choose between the balloon pump and inotrope. Both improve cardiac output, and there is a defined side effect profile for both. Given the markedly shorter waiting time, many patients are being treated with balloon pump placement, and this is certainly a direct effect of the allocation change despite safeguards built into the policy.

There will always be competition and crowding in the highest urgency tiers for transplantation, but in the United States in 2018, we simultaneously lost the counterbalance of donor service areas. Having a defined area where donors were preferentially offered allowed some less ill patients to receive transplant at lower statuses. Now, competition for donors extends 500 miles from each donor hospital, and therefore there are always a large and ever-changing number of recipients at high status who have priority for donors. The system prioritizes the “sick” to the clear detriment of the “well” patient who is dutifully waiting their turn for a transplant, just to find that the good donors are always out of reach.

In the old system, waiting times at 1A status were long, and centers would consider higher risk donors for those patients whose risk of dying on the transplant list was sufficiently high that there was a balance. Conversely, patients who were deemed stable “1B” candidates would wait for a “good” heart as the risk of dying on the waiting list was lower and therefore accepting higher risk hearts did not seem warranted. The current allocation model flips the paradigm 180°. Now the sickest patients get rapid access to the pick of the best hearts and the patients who are stable (such as VADs) are left with the donors not selected by a broad number of programs. Presumably, the majority of donors that reach status 4 candidates are those with small size, rare blood type, or some aspect which leads to widespread rejection such as left ventricular dysfunction. The most stable patients are now left with only the most questionable donors, and hence, there is an imbalance between urgency and donor quality.

Previous reports have demonstrated that transplant volume is modifiable with changes to donor acceptance criteria and tolerance for risk.²⁷⁻²⁹ For example, the group from Yale University recently reported dramatic increases in their program volume by accepting older donors, and by prioritizing temporary mechanical circulatory support.³⁰

The question is whether the new allocation has produced the desired outcome. Are we serving patients well with the new parallel pathways of VAD and transplant as opposed to the serial pathway that contributed to excellent outcomes? Will we find that we long for the days of local transplant allocation, and the 3-tier status 1A/1B/2 system? Is better truly the

enemy of good? Over the next years, we will find out whether we compromised waitlist survival, posttransplant survival, both or neither in the October 2018 allocation policy shift.

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