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EDITORIAL COMMENT

Myocardial Recovery or Urgent Transplant

Mutually Exclusive Goals Under the Current UNOS Allocation System*

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It has been 3 years since the introduction of the revised United Network Organ Sharing (UNOS) heart allocation system. More than 50 papers have been published examining wait times and changes in patient care patterns and outcomes in the old vs new UNOS systems. In the analysis by Topkara et al[1] in this issue of the *Journal*, the outcomes of patients on temporary mechanical circulatory support (tMCS) listed as UNOS statuses 1 to 2 (current allocation system) vs status 1A (old system) for heart transplant were compared. Similar to prior reports,[2-5] patients listed status 1 to 2 in the new UNOS heart allocation system had greater use of tMCS, higher and quicker rates of transplantation, and lower waitlist mortality than patients listed as status 1A under the old system.[1]

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The novel results presented by Topkara et al[1] are that the frequencies of transplant delisting for myocardial recovery on tMCS are lower under the new allocation system. For waitlist candidates on extracorporeal membrane oxygenation (ECMO) or nondischargeable biventricular assist devices, delisting for myocardial recovery decreased from 7.9% under the old system to 1.5% in the new system. For status 2 patients on tMCS, recovery dropped from 1.6% to 0.2%.[1] Patients delisted for recovery were more likely to have a nonischemic diagnosis and lower pulmonary arterial pressures and were less likely to have implantable cardiac defibrillators, consistent with the characteristics of patients with acute (recoverable) heart failure as well as patients who have demonstrated recovery on durable left ventricular assist device (LVAD) support. The authors should be commended for their contributions, because their findings highlight the important need for providers to identify patients with recovery potential and to critically consider the risks and benefits of immediate status 1-2 transplant listing.

There are a few points worth considering, however, when interpreting the results. First, the intents of the UNOS allocation systems, in general, are to "increase the number of organs recovered and the number of transplants performed, and to ensure patients across the nation have equitable access to transplant."[6] Recovery is not an aim of UNOS transplant listing, and the new system should not be viewed as "hindering chances of myocardial recovery in select candidates." Rather, under the new policy's aim to expedite transplant for the sickest patients, a reduction in the frequency of delisting because of myocardial recovery in patients assigned to UNOS statuses 1-2 was completely foreseeable, appropriate, and in line with the new policy's intent.

Second, although the hazard ratios demonstrate reduced recovery for patients on tMCS under the new vs old allocation systems, the absolute number of patients delisted for transplant during the course of the entire analysis averaged only 9 candidates per year (80 recoveries within 2,925 patients studied over 10 years). In addition, myocardial recovery as defined

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by Topkara et al[1] occurred when candidates were delisted for "condition improved, transplant not needed." Delisting does not mean that heart function normalized, nor does it mean that patients had favorable outcomes after removal from the waitlist. Outcomes in these delisted patients are presently unknowable, because they are not tracked by UNOS.

Third, the variability in the types of patients listed in each era may affect the validity of the comparisons made. Listing patients with recovery potential under the old allocation system was likely conducted with a different set of patient considerations and expectations—expectations that were also heavily influenced by the different listing requirements and very different considerations for durable LVAD implant and anticipated time on the waitlist. For example, under the previous allocation system, status 1A wait times for patients on extracorporeal membrane oxygenation were much longer than in the present era (31 days for status 1A vs 5 days for status 1). Differences were also noted in the frequency of myocarditis diagnoses (3.1% of status 1 vs 7.2% of status 1A) in the urgent statuses.[1] Although it is possible that fewer patients had myocarditis in the new allocation era, it is more likely that practitioner expectations have evolved in response to the new system, and rather than abandoning recovery attempts, patients with recovery potential in the present UNOS era were either not listed or were listed at lower urgency statuses to avoid rapid transplant. Additionally, it is important to acknowledge that status 1A tMCS patient selection and management assumptions within the subpopulation of patients with recovery potential may not be transferable to today's status 2 patients. Although cardiogenic shock implies patient instability, the literature clearly demonstrates marked variability in shock phenotypes that goes beyond baseline characteristics and snapshot hemodynamics, the findings of which were the impetus behind the SCAI (Society for Cardiovascular Angiography & Interventions) shock categorizations.[7] Thus, it is possible that status 2 patients in the new UNOS era are of a sicker phenotype than tMCS 1A era patients. These potential differences in patient phenotypes and management strategies may make inferences on practitioner attempts at myocardial recovery through a comparison of recovery frequencies between UNOS eras potentially invalid.

Finally, the authors state that "shorter waitlist times may preclude the use and escalation of neurohormonal inhibitors and limit serial assessment of native cardiac function with imaging." We would argue that patients in cardiogenic shock with reliance on tMCS for organ perfusion will have little room for rapid titration of guideline-directed therapies. Hemodynamic stabilization to allow for medication titration for recovery takes time.

Despite the minor study limitations discussed, we believe that the data by Topkara et al[1] should force practitioners to pause when it comes to listing acute heart failure patients for status 1 to 2 transplant. As the decision to transplant is a point of no return, we agree that patients with acute heart failure with characteristics supportive of recovery may be better served by durable LVADs to allow time for clinical evolution of the patient's acute cardiomyopathy trajectory. Unfortunately, there are high costs to this strategy if recovery does not occur, because the pathway to transplant from durable LVAD is more difficult now under the current allocation system.

GAPS IN THE FIELD

This analysis highlights several current knowledge gaps.

- The field lacks a high level of evidence for using tMCS over inotropic support in patients listed for heart transplant who have early-stage shock.
- The rarity of recovery within this UNOS analysis,[1] other cohort analyses, and for patients on durable LVAD support leaves the field without an ability to accurately identify patients with acute heart failure and cardiogenic shock who will achieve sustained myocardial recovery.
- Finally, research within the field is hindered by a lack of linkage between the Intermacs, UNOS, and outside data sources (such as Medicare or insurance databases), preventing comparisons of management strategies (MCS, transplant, recovery) applied to similar heart failure populations. The field needs to abolish data silos and engage in collaborative research efforts across therapeutic offerings.

Filling these knowledge gaps will add much-needed evidence to team decision making as it relates specifically to myocardial recovery and (simultaneously) the overall application of advanced heart failure interventions that offer the best long-term outcomes for a given patient phenotype.

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Dr Cowger has served as a consultant/on the Advisory Board for Abbott Labs, BioVentrix, and Procyrion; is on the Steering Committee for Procyrion, Endotronix, and Abbott; and has served as a speaker for

Abbott, Zoll, and BioVentrix; and Henry Ford Hospital receives clinical trial funding from Abbott and Medtronic related to left ventricular assist devices. Dr Cogswell has served as a speaker/on the Advisory Board for Abbott Lab; has served on the Advisory Board for Medtronic; her spouse is an employee of Medtronic; and the University of Minnesota receives clinical trial funding from Abbott related to left ventricular assist device therapy.

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