

“Unintended” Consequences of Changes in Heart Transplant Allocation Policy: Impact on Practice Patterns

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The United Network of Organ Sharing (UNOS) implemented the new heart transplant (HTx) donor organ allocation policy in October 2018. One of the major changes of the new policy included prioritizing the patients on acute mechanical circulatory support (MCS) devices such as veno-arterial extracorporeal membrane oxygenation (VA ECMO), intraaortic balloon pump (IABP), and biventricular support on the HTx waiting list.¹ The policy changes also increased the radius in which the organ is offered to 500 miles eliminating the local first policy for the new priority criteria of acute MCS use (UNOS statuses 1 and 2). A recent review of the mortality as a result of the changes indicates an overall decrease in the 1 year survival after heart transplantation.² The aim of this report was to evaluate the characteristics of patients listed for HTx at the time of listing and transplant before and after the UNOS policy change.

The primary objectives of the study were as follows:

1. Use of VA ECMO and IABP at the time of listing and transplant before and after policy change.
2. Use of durable left ventricular assist device.
3. “Transplantability” before and after implementation of new policy (1, 3, 6 months).
4. Early post-transplant mortality before and after policy change (1, 3, 6 months).
5. Changes in wait times, ischemia times, and distance covered to procure donor organ.
6. Impact on monthly center volume.

Study Data and Patient Population

The UNOS thoracic transplant database was used to identify patients ≥ 18 years, listed and transplanted between January 2016 and March 2019.³ We divided the patients into study groups based on implementation date of the new policy (October 18, 2018); listed before new policy (transplanted before or after new policy); listed after the new policy. We used univariate nonparametric statistics such as rank-sum test (continuous variables) and χ^2 test (categorical variables) for analysis. All the tests were done using SAS 9.4 software at 95% confidence interval level. There were 12,368 patients listed during

the study period, of which 1,544 were listed after the new policy (Figure 1).

MCS Usage (ECMO, IABP, Left Ventricular Assist Device)

Patients listed for HTx with ECMO (1.8–2.7%; $p < 0.01$) or IABP (5.3–10.3%; $P < 0.01$) almost doubled following the new policy. Patients transplanted with ECMO increased from 1.2% to 7.6% and with IABP increased from 9% to 33% (both $P < 0.01$). The use of biventricular support devices at time of listing (1.3–2.1%; $P = 0.02$) and transplant (2.5–4.8%; $P < 0.01$) increased with new policy (Table 1).

The use of durable left ventricular assist devices (LVADs) at the time of listing (31% vs. 29%; $P = 0.07$) marginally decreased, whereas at the time of transplant, it significantly reduced (41% vs. 24%; $P < 0.01$).

Transplantability and Early Post-Transplant Outcomes Before and After Policy Change

We defined transplantability as the ability to receive transplant sooner after listing and calculated using Kaplan-Meier survival curves where transplant was treated as an event and time spent on waitlist was used as the time to transplant. The 1 and 3 months transplantability before policy change was 19% and 36%, respectively, which increased significantly to 30% and 42%, respectively, after the new policy ($P < 0.01$). However, the 6 month transplantability before and after the policy changes was comparable at 48% and 45% ($P = 0.02$). Compared with old policy, the 1, 3, and 6 months post-transplant mortality significantly increased with implementation of new

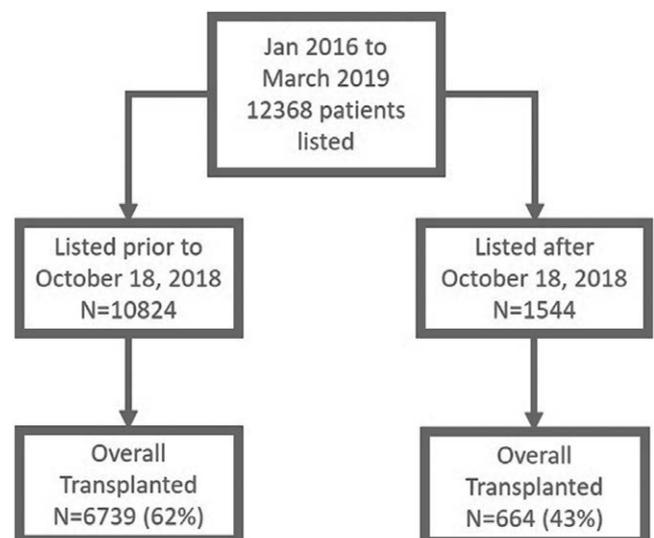


Figure 1. Study population.

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Table 1. The UNOS Policy and Its Impact on Listing and Transplant Characteristics

Patient Characteristics	Listed Before October 2018	Listed After October 2018	<i>p</i>
ECMO at listing	1.8%	2.7%	0.02
IABP at listing	5.3%	10.3%	<0.01
ECMO at Tx	1.2%	7.6%	<0.01
IABP at Tx	9.4%	32.8%	<0.01
LVAD at listing	31%	29%	0.07
LVAD at Tx	41%	24%	<0.01
Biventricular support @ listing	1.3%	2.1%	0.02
Biventricular support at Tx	2.5%	4.8%	<0.01
Ischemia time (hr)*	3.0 (2.3–3.7)	3.4 (2.8–4.0)	<0.01
Distance (miles)*	82 (13–261)	243 (72–443)	<0.01
Wait time (days) for Txed patients*	73 (24–189)	14 (6–35)	<0.01
Transplantability† at (months)			
1	19%	31%	<0.01
3	36%	42%	<0.01
6	48%	45%	0.02
Post-Tx mortality (months)			
1	4%	5%	0.3
3	6%	15%	<0.01
6	7%	23%	<0.01

*Presented as median (interquartile range).

†Transplantability defined as the ability to get transplanted sooner and was calculated as the actuarial rate of transplant (Kaplan-Meier).

ECMO, extracorporeal membrane oxygenation; IABP, intraaortic balloon pump; LVAD, left ventricular assist device; Tx, transplant; UNOS, The United Network of Organ Sharing.

policy (respectively 4% vs. 5%, $P = 0.3$, 6% vs. 15%, $P < 0.01$, 7% vs. 23%; $P < .01$, **Figure 2**).

3.4 hours; $P < 0.01$) and distance (82 vs. 243 miles; $P < 0.01$) traveled increased.

Waiting Time, Ischemia Time, and Distance

The median waiting time of patients receiving transplant significantly reduced after the policy change from 73 to 14 days ($P < 0.01$), whereas the median ischemia time (3.0 vs.

Impact on Center Volume

Irrespective of the listing period, 137 centers performed 10,454 HTx between years 2016 and 2019 (March), of which 9,166 were before policy change and 1,288 were after policy

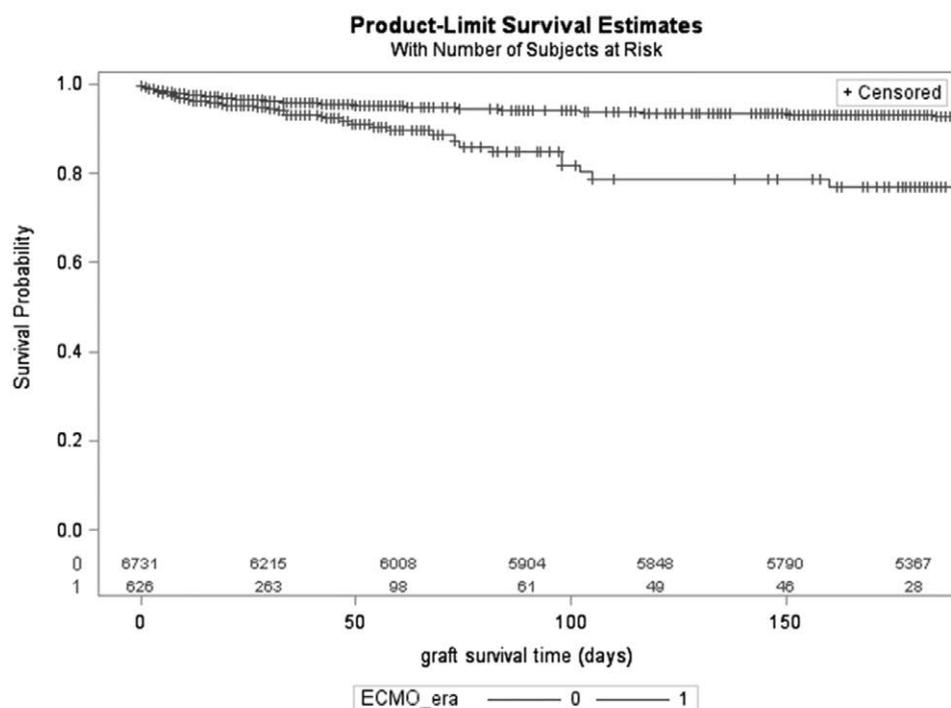


Figure 2. Post-transplant survival before and after policy change. ECMO, extracorporeal membrane oxygenation.

change (some may be listed before policy change). The mean transplant rate per center per month before the new policy was 1.96 and after the new policy was 1.88 which is a marginal decline. During the old policy, 43 centers (low volume) did ≤ 1 transplant per month, 44 centers (mid volume) performed >1 but ≤ 2 transplants per month and 50 centers (high volume) performed >2 transplants a month. Per month transplant volume was calculated for each center before and after the policy change. Of all, 71 programs substantially increased the use of acute MCS, which correlated to an increased monthly volume of 29 (41%) programs, whereas 17 (24%) programs had no change in the monthly volume and 25 (35%) programs had a decline in monthly volume. The remaining 66 programs did not increase the acute MCS use of which 46 (70%) had decreased monthly volume, whereas 12 (30%) programs either increased or had no change in monthly volume. With the new policy, 65% of low volume centers (≤ 1) had decreased monthly transplant volume with 19 centers not performing any transplants between October 2018 and March 2019 (end of study period). Forty-three percentage mid (1–2) and 48% high (>2) volume centers had decreased monthly transplant volume, whereas rest of the centers either increased or had no change in their monthly transplant volume. Of the 66 non-MCS programs, 37 were low volume, among which 27 (73%) had a decline in the monthly volume after policy change, whereas six programs adopted the MCS policy of which only one (16%) had a decline in their monthly volume.

Comment

With the implementation of new UNOS policy, there is a substantial alteration in the practice of listing and transplanting advanced heart failure patients requiring HTx. Use of acute MCS devices such as ECMO and IABP which increases the priority level (status 1, 2, or 3) of waitlist patients has significantly increased, whereas use of durable LVADs has marginally declined. With the change in heart allocation radius policy (500 miles), the median distance traveled to procure the organ and the ischemia times have significantly increased. The most immediate and positive impact of the new policy is reduction of waiting time and increased “transplantability,” that is, more patients are able to receive a donor heart faster compared with the old policy.

However, the early post-transplant mortality after the new policy has also significantly increased.² One of the reasons for this could be increased use of acute mechanical support pre-transplant which may not allow the patient to stabilize before transplant resulting in a higher risk of early mortality. Previous

studies have shown poor post-transplant survival with the use of ECMO.⁴ Use of LVADs have not only reduced the waiting list mortality but are associated with comparable post-transplant survival to non-LVAD patients; however, this study indicates a decline in its use in favor temporary/acute MCS devices.^{5,6} The decline in LVAD use may deny some patients an opportunity to be stable on waiting list until a suitable donor heart is available. The primary objective of the new policy was to reduce the waitlist mortality without affecting the post-transplant survival; however, the changes in the practice patterns and compartment of the programs toward increased use of acute MCS devices was not one of the intended outcomes.

The other major drawback of the new policy is on the low volume transplant centers, as 65% of these centers had a reduction in their monthly transplant volume. Further subanalysis showed that 71 programs substantially increased the use of acute MCS and 66 programs did not increase the acute MCS use. Of the 66 nonadopter programs, 37 were low volume, among which 27 (73%) had a decline in the monthly volume after policy change.

In summary, the UNOS policy change has significantly increased the number of patients listed and transplanted with acute MCS resulting in reduced waiting time for transplanted patients while increasing the distance traveled to procure a donor heart, increasing the donor ischemic time and also increased early post-transplant mortality. In addition, a significant number of low volume programs had a reduction in the number of patients transplanted which over a longer period of time may result in limiting access.

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