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An updated estimate of post-transplant survival after implementation of the new donor heart allocation policy

Kevin A. Lazenby, BE[1], **Nikhil Narang, MD**[2,3], **Kenley M. Pelzer, PhD**[4], **Gege Ran, BA**[1], **William F. Parker, MD, PhD**[4,5]

[1]Pritzker School of Medicine, University of Chicago, Chicago, Illinois

[2]Department of Medicine, University of Illinois-Chicago, Chicago, Illinois

[3]Advocate Heart Institute, Advocate Christ Medical Center, Oak Lawn, Illinois

[4]Department of Medicine, University of Chicago, Chicago, Illinois

[5]MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago, Illinois

Abstract

The Organ Procurement and Transplant Network (OPTN) implemented a new heart allocation policy on October 18, 2018. Published estimates of lower post-transplant survival under the new policy in cohorts with limited follow-up may be biased by informative censoring. Using the Scientific Registry of Transplant Recipients, we used the Kaplan-Meier method to estimate 1-year post-transplant survival for pre-policy (November 1, 2016, to October 31, 2017) and post-policy cohorts (November 1, 2018, to October 31, 2019) with follow-up through March 2, 2021. We adjusted for changes in recipient population over time with a multivariable Cox proportional hazards model. To demonstrate the effect of inadequate follow-up on post-policy survival estimates, we repeated the analysis but only included follow-up through October 31, 2019. Transplant programs transplanted 2594 patients in the pre-policy cohort and 2761 patients in the post-policy cohort. With follow-up through March 2, 2021, unadjusted 1-year post-transplant survival was 90.6% (89.5%–91.8%) in the pre-policy cohort and 90.8% (89.7%–91.9%) in the post-policy cohort (adjusted HR = 0.93 [0.77–1.12]). Ignoring follow-up after October 31, 2019, the post-policy estimate was biased downward (1-year: 82.2%). When estimated with adequate follow-up, 1-year post-transplant survival under the new heart allocation policy was not significantly different.

1 Introduction

The Organ Procurement and Transplantation Network (OPTN) implemented a new donor heart allocation policy on October 18, 2018. Studies evaluating the impact of this new policy on post-transplant survival contain discrepant findings.[1] Five reports found decreased

Corresponding author: William F. Parker, MD, PhD, wparker@uchicago.edu.

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Supporting Information

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post-transplant survival under the new policy,[2,3,4,5,6] and two reports found no difference in post-transplant survival.[7,8] Notably, the studies with lower estimates of post-transplant survival in the post-policy era have significantly fewer follow-up observations of post-policy recipients compared with the studies finding unchanged survival.

One proposed explanation for the conflicting results is informative censoring bias.[9] A fundamental assumption of the Kaplan-Meier survival estimator is that censoring is statistically independent of survival time.[10] If censored patients have longer survival times than non-censored patients, the Kaplan-Meier estimator can be biased downward. Transplant programs are required to report recipient deaths faster than routine follow-up appointments for healthy recipients.[11] If a study's data is heavily censored, this differential data submission requirement based on recipient survival status could lead to a lower Kaplan-Meier estimate than the true population survival rate. Studies that reported lower estimates of post-transplant survival in the post-policy era[2,3,4,5,6] have significantly more censoring in their post-policy cohorts than the studies finding unchanged survival.[7,8]

This study uses more complete recipient follow-up data to evaluate the hypothesis that informative censoring biased the estimates of lower post-transplant survival in the new heart allocation system.

2 Methods

2.1 Data source and study population

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. This study was approved by the University of Chicago Medical Center institutional review board. We identified adult (aged 18 or older at the time of listing), heart-only transplant recipients who underwent transplantation between November 1, 2015, and October 31, 2019. Recipients' date of listing for transplant was not an exclusion criterion, so the post-policy cohort includes recipients who were listed before implementation of the new policy.

2.2 Primary survival analysis

For the primary analysis, we selected recipients in two seasonally matched one-year cohorts, those transplanted from November 1, 2016, to October 31, 2017 (pre-policy) and November 1, 2018, to October 31, 2019 (post-policy). Cohorts were seasonally matched to control for known seasonal trends in deceased donor heart donation.[12,13] We selected a pre-policy cohort that ended one year before policy implementation to avoid contamination from any anticipatory practice changes in the final year of the pre-policy era.[14] We estimated survival for each cohort in the first year post-transplant using the Kaplan-Meier method with data through March 2, 2021. Survival data for recipients in both cohorts were administratively

censored at 1 year after transplant to prevent bias from differential length of follow-up between cohorts.

To replicate previous results which were potentially biased downward by informative censoring, we repeated the primary analysis while ignoring follow-up observations that occurred after October 31, 2019. To determine the amount of follow-up required for an unbiased estimate of one-year survival, we repeated this process of truncating follow-up for each day from November 1, 2019, to March 2, 2021.

To control for changes in recipient demographics over time, we estimated the effect of the policy using a multivariable Cox proportional hazards regression controlling for the components of the Index for Mortality Prediction After Cardiac Transplantation (IMPACT) score using the entire study data range.[15] Because treatment practices have changed since the new policy was implemented,[16,17] we also estimated post-transplant survival before and after policy implementation by treatment support at the time of transplantation. For these subgroup analyses, high-dose inotrope support was defined by OPTN policies as "multiple inotropes or a single high-dose inotrope and has hemodynamic monitoring" (e.g., dobutamine at greater than or equal to 7.5 mcg/kg/min).[11] Low-dose inotrope support is inotropic support without continuous hemodynamic monitoring. See Supporting Information for required minimum doses for each drug and category. Additionally, the pre-policy cohort was expanded to include recipients transplanted between November 1, 2015, and October 17, 2018, because of low treatment utilizations in the pre-policy era.

2.3 Sensitivity analyses and statistical analysis

We performed sensitivity analyses with different seasonally matched pre-policy cohorts to ensure our results were robust to the chosen year. These cohorts spanned from November 1, 2015, to October 31, 2016; November 1, 2017, to October 17, 2018; and November 1, 2015, to October 17, 2018. Categorical variables were compared using the chi-square test. Continuous variables were compared using the Wilcoxon rank sum test. All analyses were performed using R version 4.0.4 and RStudio (RStudio Team, 2021. RStudio: Integrated Development for R. RStudio, PBC, Boston, MA). See the Supplemental Material for access to all analysis code. All statistical tests were two-sided, and $p < 0.05$ was considered significant.

3 Results

3.1 Recipient characteristics

Of the 10466 heart transplant recipients in the full study period, there were 2594 in the pre-policy cohort and 2761 in the post-policy cohort (Table 1). The post-policy cohort was more likely to be treated in the ICU (28.6% pre-policy vs. 51.9% post-policy, $P < 0.001$) with mechanical ventilation (0.9% pre-policy vs. 2.6% post-policy, $P < 0.001$), extracorporeal membrane oxygenation (1.0% pre-policy vs. 5.5% post-policy, $P < 0.001$), and intra-aortic balloon pumps (8.3% pre-policy vs. 28.4% post-policy, $P < 0.001$). Recipients transplanted while supported with only low-dose inotropes (10.6% pre-policy vs. 4.3% post-policy) or high-dose inotropes (16.0% pre-policy vs. 6.2% post-policy) decreased under the new

allocation policy. Bridging with left ventricular assist devices (49.2% pre-policy vs. 32.3% post-policy, $P < 0.001$), and median wait-list time (112 days [IQR: 30–324] pre-policy vs. 39 days [10–195] post-policy, $P < 0.001$) decreased after policy implementation.

3.2 Post-transplant survival with complete follow-up

With follow-up through March 2, 2021, estimated 1-year post-transplant survival was not significantly different before (90.6%, 95% CI: 89.5%–91.8%) and after (90.8%, 95% CI: 89.7%–91.9%) policy implementation (log-rank $P = 0.8$) (Figure 1). In multivariable Cox proportional hazards regression controlling for IMPACT score risk factors, receiving a transplant after policy implementation was not associated with difference in survival (hazard ratio 0.93; 95% CI: 0.77 – 1.12, y; $P = 0.45$) (Table S1).

3.3 Post-transplant survival estimates with limited follow-up

When ignoring observations after October 31, 2019, the median time at risk in the post-policy cohort decreased from 366 days (IQR: 335–396) to 154 days (IQR: 71–182). Repeating survival analysis on the same cohorts with truncated follow-up resulted in lower 1-year post-transplant survival in the post-policy cohort (90.6% [95% CI: 89.5%–91.8%] pre-policy vs. 82.2% [95% CI: 74.9%–90.2%] post-policy) (Figure 2). In contrast, the hazard ratio of transplant after policy implementation from an unadjusted Cox proportional hazards model was not significantly increased with incomplete follow-up (Figure S1). Cox hazard ratios are listed with follow-up truncated at November 1, 2019 (unadjusted HR = 1.04 [0.85–1.28]), May 1, 2020 (unadjusted HR = 1.04 [0.87–1.25]), November 1, 2020 (unadjusted HR = 0.99 [0.83–1.18]), and March 2, 2021 (unadjusted HR = 0.98 [0.82–1.17]).

3.4 Post-transplant survival by treatment

Post-transplant survival increased after policy implementation for recipients bridged with ECMO (1-year: 69.3% [59.6%–80.6%] pre-policy vs. 87.2% [81.8%–93.0%] post-policy, log-rank $P < 0.001$) and mechanical ventilation (68.2% [57.8%–80.4%] pre-policy vs. 82.9% [74.5%–92.2%] post-policy, log-rank $P = 0.03$) but was not significantly different for patients treated with IABP (log-rank $P = 0.6$) and durable LVAD (log-rank $P = 0.3$) (Figure 3). Post-transplant survival estimates were also not significantly different for patients treated with high- and low-dose inotropes, other mechanical circulatory support (MCS), and no MCS (Figure S2).

3.5 Sensitivity analyses

The estimated 1-year post-transplant survival was not significantly different for recipients transplanted November 1, 2015, to October 31, 2016 (91.8%, 95% CI: 90.7%–92.8%); November 1, 2017, to October 17, 2018 (91.8%, 95% CI: 90.8%–92.9%); and the entire pre-policy period November 1, 2015, to October 17, 2018 (91.4%, 95% CI: 90.8%–92.0%) (Tables S2 **and** S3).

4 Discussion

In this registry cohort study of 10,466 heart transplant recipients with median follow-up over one year, one-year post-transplant survival was not significantly different after implementation of the new heart allocation policy. Estimating post-policy recipient survival with limited follow-up biased the Kaplan-Meier estimate downwards. With adequate follow-up, one-year post-transplant survival increased for patients treated with ECMO and mechanical ventilation, and was unchanged for other treatment types.

Our findings confirm that previous reports of decreased post-transplant survival using limited follow-up were biased by informative censoring. The Kaplan-Meier survival estimator assumes that censoring is statistically independent of survival time,[10] but different data submission requirements for recipient follow-up and recipient deaths can bias survival estimates when recipient follow-up is extremely limited. Transplant hospitals are required to notify the OPTN within 14 days of a recipient's death or graft failure; in contrast, programs have until 30 days after the six-month and one-year anniversaries of a recipient's transplant date to report survival.[11] This systematic difference in post-transplant data submission leads to a downward bias on survival without adequate follow-up. These data submission requirements apply to all organ allocation systems governed by OPTN policies, so these results are potentially relevant for all evaluations of U.S. organ allocation policy changes. Our findings suggest that informative censoring bias should be considered in any cohort study with a similar design that analyzes national transplant registry data from the United States.

Differences in study design explain why some studies have found unchanged recipient survival while others have reported decreased survival after policy implementation. Studies that found decreased post-transplant survival post-policy defined the end of the post-policy cohort near or at the end of available follow-up data, creating heavy censoring. For example, the Cogswell et al. estimate of 90-day survival had follow-up beyond 50 days in less than a quarter (125 out of 539) of their post-policy cohort,[3] and the Kilic et al. estimate of 1-year survival only had follow-up beyond 6 months in less than half (976 out of 2455) of the post-policy cohort.[2]

In contrast, Goff et al. and Hanff et al. designed their post-policy cohort end date to allow sufficient time for follow-up data to accumulate for post-policy recipients and found no significant difference in Kaplan-Meier estimated post-transplant survival.[7,8] For example, Hanff et al. had follow-up beyond 100 days for 90 percent (355 out of 398) of post-policy recipients and found no significant difference in Kaplan-Meier estimated survival at 180 days. Our study provided 16 months between the end of the post-policy cohort and the last available follow-up, with follow-up through six months for nearly 90 percent (2436 out of 2761) of the post-policy cohort.

Our results show how just a few death events that occur in the context of heavy censoring can create large changes in the Kaplan-Meier survival curve estimate of a new policy change. However, when combined with administrative censoring at one year post-transplantation, we found that the hazard ratio estimate of the policy effect was not

significantly different. This result can be explained by the relatively small contribution of these few events to the Cox proportional hazard model likelihood function. Our results suggest that a Cox proportional hazards model run on data administratively censored by calendar date may better evaluate early impacts of new allocation policy on post-transplant survival than Kaplan-Meier generated point estimates of specific survival times.

Previous reports proposed that observed decreases in post-transplant survival in the post-policy era were due to higher transplantation rates among high-acuity candidates.[18,19] However, with adequate follow-up, we found that post-transplant survival has increased for recipients on ECMO and mechanical ventilation. More transplantation of urgent candidates with preserved post-transplant survival suggests a higher survival benefit of transplant under the new policy.[20]

4.1 Limitations

Though our study used more complete follow-up data than previous studies, there may have been residual informative censoring in the post-policy cohort. Even with 16 months of follow-up data after the last transplant in the post-policy cohort, 36.7% of post-policy recipients were censored prior to 1 year compared to 0.7% of recipients in the pre-policy cohort. Post-policy survival estimates may be even higher when more one-year follow-up appointments for post-policy recipients enter the SRTR dataset.

5 Conclusion

With adequate follow-up, 1-year post-transplant survival is not significantly different under the new heart allocation policy. Informative censoring can bias attempts to estimate policy effects on post-transplant survival.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Availability Statement

The data that support the findings of this study are available from the Scientific Registry of Transplant Recipients (SRTR). Restrictions apply to the availability of these data, which were used under license for this study.

Abbreviations:

ECMO	extracorporeal membrane oxygenation
IABP	intra-aortic balloon pump
IMPACT	Index for Mortality Prediction After Cardiac Transplantation
LVAD	left ventricular assist device
MCS	mechanical circulatory support
OPTN	Organ Procurement and Transplant Network
SRTR	Scientific Registry of Transplant Recipients
UNOS	United Network for Organ Sharing

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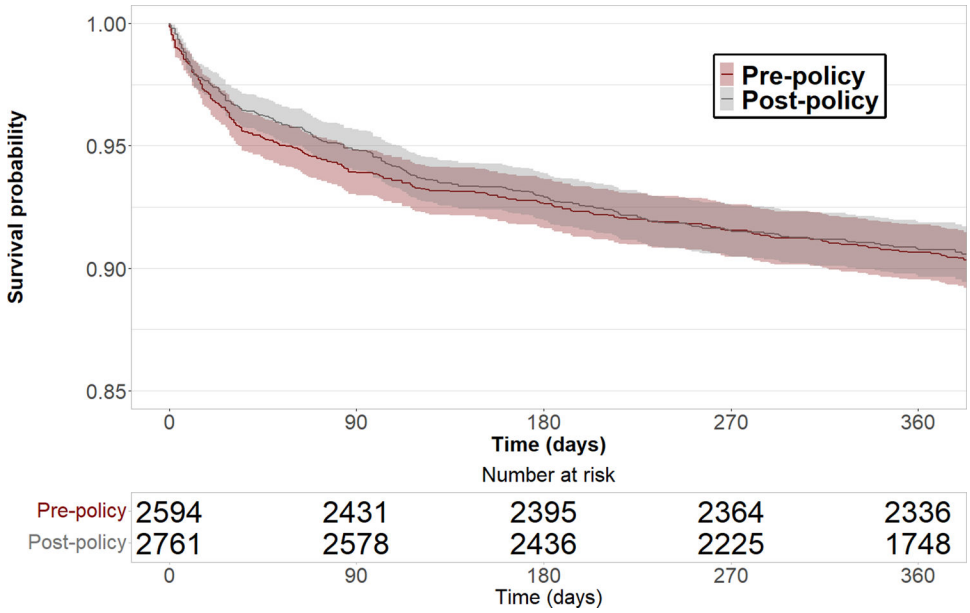

Figure 1: Survival of heart transplant recipients before and after implementation of the new heart allocation policy

1-year post-transplant survival was not significantly different since implementation of the new heart allocation policy. Shaded regions indicate 95% confidence intervals.

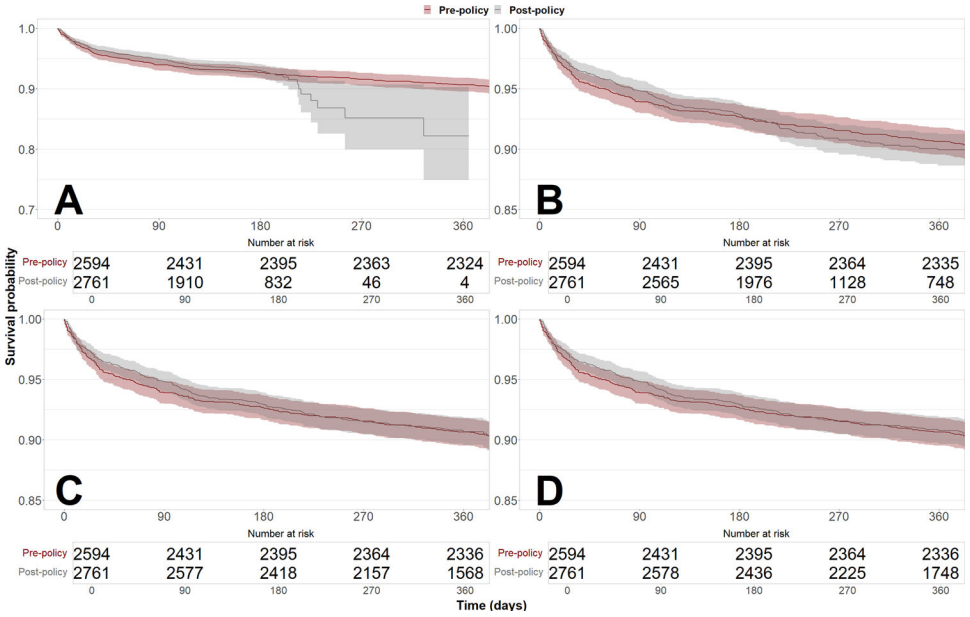

Figure 2: Survival of heart transplant recipients before and after implementation of the new heart allocation policy with increasing follow-up

Estimates of 1-year post-transplant survival were biased downward by informative censoring with artificially truncated follow-up. However, the hazard ratio of transplant after policy implementation from an unadjusted Cox proportional hazards model was not significantly increased with truncated follow-up. Follow-up was truncated at November 1, 2019 (Panel A, log-rank $P = 0.7$, unadjusted HR = 1.04 [0.85–1.28]), May 1, 2020 (Panel B, log-rank $P = 0.6$, unadjusted HR = 1.04 [0.87–1.25]), and November 1, 2020 (Panel C, log-rank $P = 0.9$, unadjusted HR = 0.99 [0.83–1.18]). Panel D shows survival curves with full follow-up through March 2, 2021 (log-rank $P = 0.8$, unadjusted HR = 0.98 [0.82–1.17]).

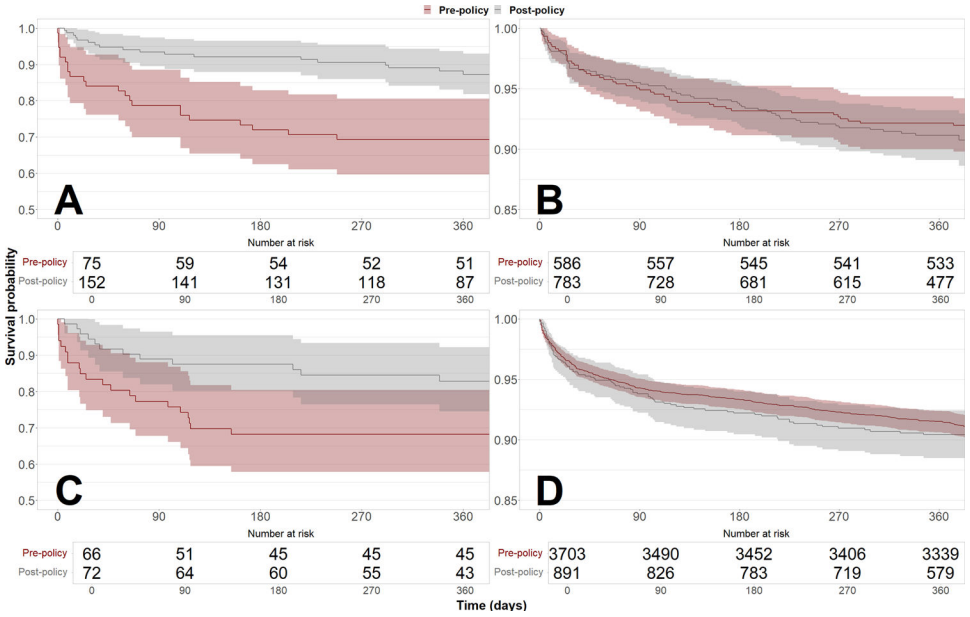

Figure 3. Survival of heart transplant recipients before and after implementation of the new heart allocation policy by treatment type

Recipients who were treated with ECMO before transplant (Panel A) experienced significantly increased 1-year survival in the post-policy cohort (69.3% [59.6%–80.6%] pre-policy vs. 87.2% [81.8%–93.0%] post-policy, log-rank $P < 0.001$). Recipients who were treated with IABP before transplant (Panel B) showed no significant difference in 1-year survival (92.1% [90.0%–94.3%] pre-policy vs. 91.1% [89.1%–93.2%] post-policy, log-rank $P = 0.6$). Recipients who were treated with mechanical ventilation before transplant (Panel C) experienced significantly increased 1-year survival in the post-policy cohort (68.2% [57.8%–80.4%] pre-policy vs. 82.9% [74.5%–92.2%] post-policy, log-rank $P = 0.03$). Recipients who were treated with durable LVAD before transplant (Panel D) showed no significant difference in 1-year survival (91.5% [90.6%–92.4%] pre-policy vs. 90.4% [88.5%–92.4%] post-policy, log-rank $P = 0.3$).

Table 1.

Recipient characteristics at the time of transplant before and after implementation of the new heart allocation policy

	Pre-policy (n = 2594)	Post-policy (n = 2761)	*P* value
Male	1909 (73.6)	1978 (71.6)	0.116
Age	57 (46–63)	56 (45–63)	0.128
BMI	27.5 (24–31.5)	27.5 (23.9–31.4)	0.448
Race/Ethnicity			
White	1661 (64)	1780 (64.5)	0.782
Black	595 (22.9)	605 (21.9)	
Hispanic	223 (8.6)	245 (8.9)	
Asian	90 (3.5)	108 (3.9)	
Other	25 (1)	23 (0.8)	
Recipient history			
Diabetes	732 (28.2)	745 (27)	0.327
Malignancy	254 (9.8)	247 (8.9)	0.31
Cerebrovascular disease	161 (6.2)	187 (6.8)	0.435
Heart failure etiology			
Nonischemic dilated cardiomyopathy	1489 (57.4)	1543 (55.9)	<0.001
Ischemic cardiomyopathy	690 (26.6)	707 (25.6)	
Congenital heart disease	59 (2.3)	104 (3.8)	
Restrictive cardiomyopathy	79 (3)	123 (4.5)	
Valvular heart disease	31 (1.2)	21 (0.8)	
Hypertrophic cardiomyopathy	69 (2.7)	93 (3.4)	
Failure of primary transplant	50 (1.9)	73 (2.6)	
Other etiology	127 (4.9)	97 (3.5)	
Total bilirubin (mg/dL)	0.7 (0.4–1)	0.7 (0.5–1.1)	0.082
Serum creatinine (mg/dL)	1.16 (0.95–1.42)	1.13 (0.9–1.4)	0.016
Pretransplant hospitalization status			
In ICU	743 (28.6)	1434 (51.9)	<0.001
Hospitalized, not in ICU	381 (14.7)	397 (14.4)	
Not hospitalized	1470 (56.7)	930 (33.7)	
Blood type			
A	1051 (40.5)	1121 (40.6)	0.68
B	370 (14.3)	422 (15.3)	
AB	135 (5.2)	143 (5.2)	
O	1037 (40)	1068 (38.7)	
Pretransplant medical therapy			
IV antibiotics in 2 weeks before transplant	227 (8.8)	288 (10.4)	0.042
High dose IV inotropes	414 (16)	170 (6.2)	<0.001

	Pre-policy (n = 2594)	Post-policy (n = 2761)	*P* value
Low dose IV inotropes	274 (10.6)	119 (4.3)	<0.001
Mechanical ventilation	23 (0.9)	72 (2.6)	<0.001
IABP	216 (8.3)	783 (28.4)	<0.001
ECMO	25 (1)	152 (5.5)	<0.001
Durable LVAD	1276 (49.2)	891 (32.3)	<0.001
Other MCS	71 (2.7)	178 (6.4)	<0.001
No MCS	1022 (39.4)	854 (30.9)	<0.001
Days on wait list	112 (30–324)	39 (10–195)	<0.001
Wait-list status at transplant			
Old Status 1A	1706 (65.8)	–	–
Old Status 1B	825 (31.8)	–	
Old Status 2	63 (2.4)	–	
New Status 1	–	244 (8.8)	
New Status 2	–	1251 (45.3)	
New Status 3	–	636 (23)	
New Status 4	–	506 (18.3)	
New Status 6	–	122 (4.4)	

[a]Values are n (%) or median (IQR)

[b]BMI = body mass index; ICU = intensive care unit; IV = intravenous; IABP = intra-aortic balloon pump; ECMO = extracorporeal membrane oxygenation; LVAD = left ventricular assist device; MCS = mechanical circulatory support