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The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

ORIGINAL CLINICAL SCIENCE

Incidence of temporary mechanical circulatory support before heart transplantation and impact on post-transplant outcomes

David Ouyang, MD,[a] Gunsagar Gulati, AB,[a] Richard Ha, MD,[b] and Dipanjan Banerjee, MD, MS[a]

From the [a]Division of Cardiovascular Medicine, Stanford University School of Medicine, Stanford, California; and the [b]Department of Cardiothoracic Surgery, Stanford University School of Medicine, Stanford, California.

KEYWORDS:
mechanical circulatory support;
orthotopic heart transplant;
UNOS allocation;
extracorporeal membrane oxygenation;
percutaneous ventricular assist device;
intra-aortic balloon pump

BACKGROUND: Proposed changes to the United Network for Organ Sharing heart transplant allocation protocol will prioritize patients receiving temporary mechanical circulatory support (tMCS), including extracorporeal membrane oxygenation (ECMO), percutaneous ventricular assist devices (PVADs), and intra-aortic balloon pumps (IABPs). We sought to evaluate contemporary trends in the incidence and outcomes of patients who required tMCS during the hospitalization before heart transplantation.

METHODS: Using the National Inpatient Sample from 1998 to 2014, we identified 6,892 patients who received an orthotopic heart transplant and classified them by pre-transplant ECMO, PVAD, or IABP placement or no pre-transplant tMCS. We compared baseline characteristics and in-hospital outcomes between patients who underwent pre-transplant ECMO, PVAD, or IABP and patients who did not receive tMCS before heart transplantation.

RESULTS: Of patients who underwent heart transplantation, 456 (6.6%) received tMCS before transplant. During the study period, the use of tMCS more than doubled, from 17 cases per year from 1998 to 2002 to 40 cases per year from 2012 to 2014 ($p < 0.001$ for trend). Of patients with tMCS, 341 (74.8%) were supported by IABP, 130 (28.5%) were supported by ECMO, and 21 (4.6%) were supported by PVAD. Before 2007, patients who required tMCS had higher in-hospital mortality than patients who did not require tMCS before transplant (14.3% vs 7.5%, $p = 0.05$). In the subsequent era (2007 to 2014), mortality was not significantly different (4.7% vs 5.1%, $p = 0.9$). Hospital mortality improved over time for all patients but most significantly in patients who required tMCS (9.6% absolute risk reduction). However, patients who received tMCS had increased lengths of stays and rates of acute renal, hepatic, and respiratory failure, sepsis, bleeding complications, and surgical reoperations.

CONCLUSIONS: The use of tMCS before cardiac transplantation is increasing, with no difference in in-patient post-transplant mortality in the recent era between patients who did and did not receive tMCS but with increased complication rates among those who received tMCS. These data support the use of tMCS before cardiac transplantation in appropriately selected patients. Clinicians should balance the above outcomes when making decisions to implant tMCS, given the impending changes to the United Network for Organ Sharing heart allocation protocol.

J Heart Lung Transplant ■■■■;■:■■■–■■■

Reprint requests: Dipanjan Banerjee, MD, MS, 300 Pasteur Dr, MC 5319, A260, Stanford, CA 94305. Telephone: +1 650 723 6459. Fax: +1 650 723 8392.
E-mail address: dipanjan@stanford.edu

1053-2498/
https://doi.org/10.1016/j.healun.2018.04.008

Congestive heart failure is a highly morbid, common disease affecting 5.7 million people and contributing to more than 300,000 deaths each year in the United States.[1,2] For patients who are symptomatic despite maximal medical therapy, cardiac transplantation serves a crucial role in the treatment of end-stage heart failure. Appropriate patient selection balances morbidity on the transplant waiting list with the desire to maximize survival and clinical outcomes after cardiac transplantation.

Heart transplantation outcomes have continuously improved from 1-year survival of less than 50% to more than 90% in some cohorts.[3–5] Heart transplant volumes have increased slowly, but the large number of heart transplant waiting list candidates (3,928 in the United States in 2017)[6,7] means that 10% of patients on the waiting list die every year due to the lack of available organs.[8,9] Partly a result of the mismatch between the number of donor organs and the number of transplant candidates, candidates in the most urgent classification (1A) now make up most of eventual transplant recipients (67% of adult heart transplants in 2014).[6]

There is concern that 1A classification currently groups patients on the waiting list with significantly disparate life expectancies. Among status 1A candidates for heart transplantation, 6-month waiting list mortality ranges from 4.8% in those with durable mechanical circulatory support (MCS; e.g., a left ventricular assist device) complicated by infection to 35.7% in candidates supported by extracorporeal membrane oxygenation (ECMO).[6,10–14] Approximately 40% patients are now being bridged to cardiac transplantation with durable MCS, but fewer data are available on temporary MCS (tMCS) before cardiac transplantation. A variety of tMCS devices are available, including ECMO, percutaneous ventricular assist devices (PVADs), such as Impella (Abiomed Massachusetts, MA) and TandemHeart (Cardiac Assist Inc., LivaNova, London, United Kingdom), and intra-aortic balloon pumps (IABPs).

Given the significant variation in prognosis for waiting list candidates at 1A status, the Thoracic Organ Transplantation Committee of the Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS) proposed changes in 2016 to the adult heart allocation system to further stratify high-urgency patients.[6] By the proposed criteria, patients requiring support by ECMO or with temporary biventricular or right ventricular assist devices are given the highest priority, and the use of an IABP are among the criteria given the second highest priority, because these patients have the highest expected mortality on the waiting list.

There is some concern that this strategy could lead to worse outcomes after transplant. For patients undergoing ECMO support, for example, the 6-month mortality after heart transplant is 24.0%.[6] The desire to balance the needs of critically ill patients with long-term outcomes after the receipt of a limited resource suggests the need for further study of patients who require tMCS before transplantation. There is significant interest in the outcomes of these patients, but few studies have detailed their short-term or long-term outcomes. In this study, we used the largest national database of hospitalizations in the United States, the National Inpatient Sample (NIS), to assess the outcomes of patients who underwent tMCS before heart transplantation and compare their outcomes to patients who did not require tMCS.

We hypothesized that patients who underwent tMCS before heart transplantation would exhibit significantly higher morbidity and mortality after cardiac transplantation than those patients who did not require tMCS and that those outcomes would vary by type of support (ECMO vs PVAD vs IABP). We also sought to describe trends in the prevalence of tMCS before cardiac transplantation over time as well as changes in outcomes.

Methods

Data source and study design

The NIS, from the Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, is the largest database of all-payer inpatient discharge information, sampling approximately 20% of all non-federal United States hospitals and including approximately 9 million hospital admissions each year. It contains discharge data from more than 5,000 hospitals located across 45 states, of which approximately 1,200 hospitals are sampled each year to create a stratified sample of United States hospitals. The NIS is a stratified 2-stage cluster design with hospitals as clusters sampled at approximately 20% and discharges sampled at 100% for chosen hospitals. Each NIS entry includes all diagnosis and procedure codes of activity during the patient's hospitalization (including the date of each procedure), patient demographics, hospital characteristics, and short-term complications of the hospitalization. The person-level data are deidentified and thus exempt from Institutional Review Board approval.

We identified all patients who underwent heart transplantation in the NIS from 1998 to 2014. This population was further divided by whether each patient was supported pre-transplant with ECMO, PVAD, or IABP. Included in the study population were surgically implanted but non-durable MCS, such as TandemHeart devices, as well as centrally cannulated ECMO. Patients for whom the date of procedures was not available or the temporal relationship between temporary mechanical circulatory support and heart transplantation could not be established were excluded.

Comorbidities, including diabetes, ischemic heart disease, hypertension, renal dysfunction, obesity, peripheral vascular disease, and history of smoking, were identified by International Classification of Diseases, Ninth Edition code (Supplementary Table SA, available online at www.jhltonline.org). In-hospital complications, including acute renal failure, acute respiratory failure, redo sternotomy or reoperation, sepsis, bleeding complications, stroke, liver failure, and device failure were also identified by International Classification of Diseases, Ninth Edition code (Supplementary Table SB, online).

Statistical analysis

Python 2.7 (Python Software Foundation, www.python.org) and R 2.13 (R Foundation, www.r-project.org) software used for statistical analysis. The R packages ggplot2, plyr, stringr, survey, and survival were used for data processing and statistical analysis. Stratified *t*-tests and analysis of variance were used to calculate *p*-values, with significance thresholds of 0.05. Logistic regression was performed for the multivariable analysis, which included the number of comorbid conditions but not individual diagnoses. Patients who received heart-kidney transplants were excluded from our analysis of renal failure. To determine the effect of time on

outcomes in this cohort, we divided the cohort into two eras: 1998 to 2006 and 2007 to 2014 (the modern era). In addition, univariate analysis for trend over time was performed for mortality rates. We followed the latest published research guidelines with regard to analysis using the NIS data set,[15] including identifying observations as hospitalization events rather than unique patients, not performing state-, physician-, or hospital-level analyses, avoiding use of nonspecific secondary diagnosis codes to infer in-hospital events, using survey-specific analysis methods that account for clustering, stratification, and weighting (the R survey package above), and accounting for data changes in trend analyses spanning major transition periods in the data set by using trend analysis using the TRENDWT variable.

Results

Baseline patient characteristics

Between 1998 and 2014, 6,892 patients underwent cardiac transplantation in the NIS (Table 1). The patients were predominantly male (72.0%) and white (57.0%) and were a mean age of 46.5 (standard deviation, 19.0) years. Most patients were hospitalized at large, urban, academic hospitals, and the median day of heart transplant was hospital Day 17 (interquartile range, Day 2–36). Mechanical support was initiated a median of 18 days before transplantation (interquartile range, 7–45 days). There was no statistically significant difference between eras in the time from initiation of mechanical support to transplantation. Consistent with the demographics of congestive heart failure overall, patients had a high proportion of ischemic heart disease (42.9%), hypertension (29.7%), diabetes (19.5%), and pre-existing renal dysfunction (33.2%). Patients receiving ECMO and PVAD were younger than patients receiving IABP, but otherwise these 3 cohorts did not substantially differ (Supplemental Table S1, online).

Temporal trends

Between 1998 and 2014, the use of tMCS before cardiac transplantation increased over time, from 5.9% of

Table 1 Baseline Characteristics of Cardiac Transplant Recipients From 1998 to 2014, Stratified by Use of Temporary Mechanical Circulatory Support Before Transplantation

Characteristic	Total (n = 6,892)	Acute circulatory support (n = 456)	None (n = 6,436)	p-value[a]
Age, year	46.5 ± 19.0	47.1 ± 17.5	46.5 ± 19.1	0.60
Length of stay, days	43.1 ± 49.9	69.7 ± 51.6	41.3 ± 49.2	0.95
Length of stay after OHT, days	19.8 ± 19.4	23.4 ± 22.0	19.5 ± 19.1	0.36
Length of time on ACS, days	18 (IQR 7-45)	18 (IQR 7-45)	NA	
Sex				0.24
Male	4,960 (72.0)	339 (74.3)	4,621 (71.8)	
Female	1,931 (28.0)	117 (25.7)	1,814 (28.2)	
Race				0.61
White	3,927 (57.0)	272 (59.6)	3,655 (56.8)	
Black	969 (14.1)	75 (16.4)	894 (13.9)	
Hispanic	531 (7.8)	40 (8.8)	501 (7.8)	
Asian/Pacific Islander	180 (2.6)	17 (3.7)	163 (2.5)	
Native American	22 (0.3)	0 (0.0)	22 (0.3)	
Other or unknown	1,253 (16.1)	52 (11.4)	1,101 (18.7)	
Median household income				0.36
$1–$24,999	1,195 (17.3)	84 (18.4)	1,111 (17.3)	
$25,000–$34,999	1,621 (23.5)	113 (24.7)	1,508 (23.4)	
$35,000–$44,999	1,793 (26.0)	114 (25.0)	1,679 (26.1)	
≥$45,000	2,122 (30.8)	137 (30.0)	1,985 (30.8)	
Unknown	161 (2.3)	8 (1.8)	153 (2.3)	
Hospital bed size				0.40
Small	522 (7.6)	43 (9.4)	479 (7.4)	
Medium	1,099 (15.9)	75 (16.4)	1,024 (15.9)	
Large	5,271 (76.5)	338 (74.1)	4,933 (76.6)	
Comorbidities				
Diabetes	1,347 (19.5)	69 (15.1)	1,278 (19.9)	<0.01
Ischemic heart disease	2,954 (42.9)	194 (42.5)	2,760 (42.9)	0.88
Hypertension	2,049 (29.7)	106 (23.2)	1,943 (30.2)	<0.01
Pre-existing renal dysfunction	2,288 (33.2)	119 (26.1)	2,169 (33.7)	<0.01
Peripheral vascular disease	111 (1.6)	8 (1.8)	103 (1.6)	0.78
History of smoking	370 (5.4)	16 (3.5)	354 (5.5)	0.02
Body mass index ≥30 kg/m^2	203 (3.0)	11 (2.4)	192 (3.0)	0.40

ACS, acute circulatory support; NA, not applicable; OHT, orthotopic heart transplantation.
Continuous data are shown as mean ± standard deviation and categoric data as number (%).
[a]Stratified t-test or analysis of variance.

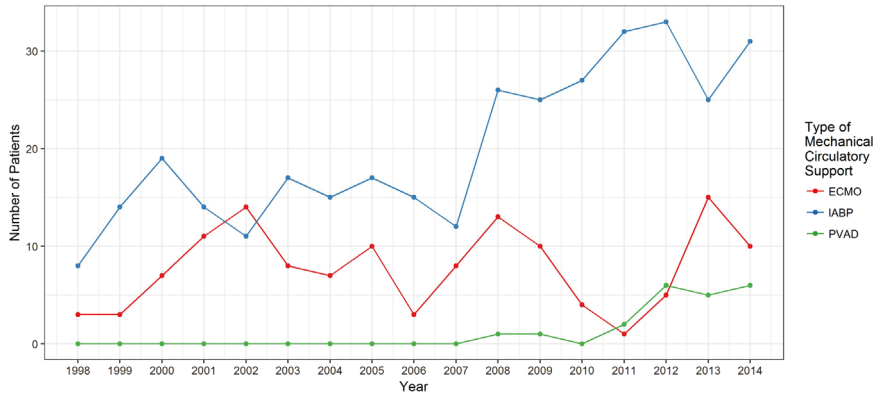

Figure 1 Number of heart transplant patients between 1998 and 2014 who received temporary mechanical circulatory support by extracorporeal membrane oxygenation (ECMO), percutaneous ventricular assist devices (PVADs), and intra-aortic balloon pumps (IABPs).

transplants from 1998 to 2006 to 8.2% from 2007 to 2014 ($p < 0.001$ for pairwise comparison). In this cohort, 456 transplant recipients required tMCS before heart transplantation (Figure 1), of which 341 patients had an IABP placed, 130 patients were started on ECMO, and 21 patients underwent PVAD placement. Twenty-seven patients had both IABP and ECMO, 9 patients had both IABP and subsequent PVAD, and 3 patients had both PVAD and ECMO. Patients requiring tMCS were of similar age, sex, and average household income compared with patients who did not require tMCS. For patients requiring tMCS, there was a decreased rate of diabetes, hypertension, and pre-existing renal dysfunction but similar rates of ischemic heart disease, peripheral vascular disease, obesity, and history of smoking (Table 1).

Transplant outcomes

A summary of post-transplant outcomes is reported in Table 2.

Mortality

In-hospital mortality in the entire cohort decreased over time from 7.9% from 1998 to 2006 to 5.1% from 2007 to 2014. In-hospital mortality decreased for patients who required tMCS ($p < 0.001$ for trend) as well as for patients who did not require tMCS ($p = 0.012$ for trend), although the decline in mortality was more pronounced in patients who required tMCS (Figure 2). In the earlier era, patients who received tMCS before transplant had increased mortality compared with those who did not (14.3% vs 7.5%, $p = 0.05$). In the modern era, patients who received tMCS before transplant had similar mortality to those who did not (4.7% vs 5.1%, $p = 0.90$).

In a multivariable analysis of predictors of mortality, increasing number of comorbid conditions was associated with increased mortality, whereas transplantation during the modern era and PVAD support appeared protective (Table 3). Duration of tMCS support did not independently affect mortality.

Table 2 Mortality, Length of Stay, and Complications in Patients Who Underwent Cardiac Transplant From 1998 to 2014, by Transplantation Era

	1998–2006			2007–2014		
Variable	Acute circulatory support ($n = 182$)	None ($n = 3,114$)	*p*-value	Acute circulatory support ($n = 274$)	None ($n = 3,322$)	*p*-value
Length of stay, days	70.8 ± 52.4	43.4 ± 52.6	0.52	68.9 ± 51.1	39.2 ± 45.7	0.82
Length of stay after OHT, days	24.6 ± 27.9	18.3 ± 17.5	0.70	22.6 ± 17.1	20.6 ± 20.4	0.37
Mortality	26 (14.3)	233 (7.5)	0.05	13 (4.7)	169 (5.1)	0.90
Post-transplant circulatory support	1 (0.6)	31 (1.0)	0.48	3 (1.1)	59 (1.8)	0.25
Acute failure						
Renal	78 (42.9)	837 (26.9)	<0.001[b]	175 (64.3)	1,478 (44.5)	<0.001[a]
Liver	12 (6.6)	50 (1.6)	0.005[b]	41 (15.1)	148 (4.5)	<0.001[a]
Respiratory	40 (22.0)	223 (7.2)	<0.001[b]	85 (31.0)	433 (13.0)	<0.001[a]
Cardiac complications	28 (15.4)	367 (11.8)	0.32	48 (17.6)	452 (13.6)	0.09
Sepsis	8 (4.4)	57 (1.8)	0.16	44 (16.1)	275 (8.3)	<0.001[a]
Stroke	1 (0.5)	50 (1.6)	0.03[b]	19 (7.0)	101 (3.0)	0.009[a]
Complication requiring reoperation	41 (22.5)	407 (13.1)	0.002[b]	88 (32.1)	581 (17.5)	<0.001[a]
Bleeding complication	60 (33.0)	549 (17.6)	<0.001[b]	85 (31.0)	630 (19.0)	0.002[a]

Continuous data are shown as mean ± standard deviation and categoric data as number (%).
[a]Statistically significant ($p < .05$) by stratified *t*-test or analysis of variance.

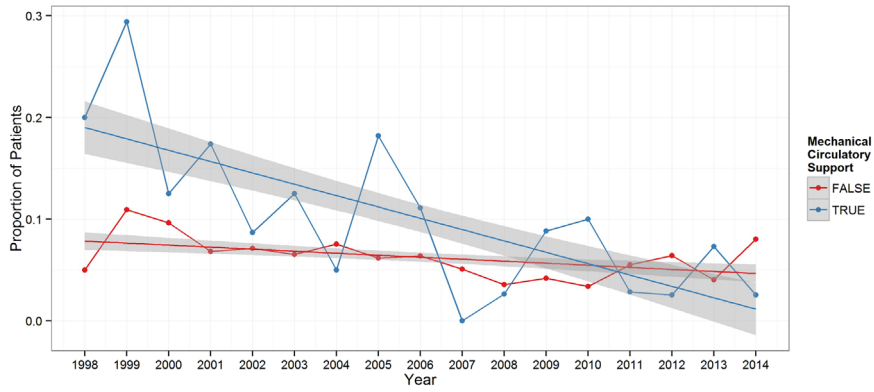

Figure 2 Time trend of mortality rate by presence of temporary mechanical circulatory support before transplantation between 1998 and 2014. The shaded area shows the 95% confidence interval.

In-hospital complications

In the entire study cohort, in-hospital complications were more common in patients who required tMCS, with an increased risk of acute renal failure (55.5% vs 36.0%, $p < 0.001$), acute liver failure (11.6% vs 3.1%, $p < 0.001$), and acute respiratory failure (27.4% vs 10.2%, $p < 0.001$), as well as bleeding complications (31.8% vs 18.3%, $p < 0.001$), surgical complications requiring reoperation (28.3% vs 15.4%, $p < 0.001$), and sepsis (11.4% vs 5.2%, $p < 0.001$).

The frequency of strokes in both groups increased over time in general, with the rate of stroke increasing from 0.5% to 7% in those requiring tMCS and from 1.6% to 3% in those without tMCS (Figure 3). In multivariable analysis, female gender and increasing number of comorbid conditions were associated with increased risk of stroke (Table 4). Increasing age was statistically associated with stroke but not at a clinically significantly level (relative risk [RR], 0.99; $p < 0.001$). There was no independent risk of stroke based on the type of tMCS received.

Multivariable analysis showed female gender, increasing age, and increasing number of comorbid conditions were associated with an increased risk of renal failure (Table 5). In comparing the 3 types of tMCS, pre-transplant ECMO (RR, 1.12; $p = 0.01$) and IABP (RR, 1.13; $p < 0.001$) placement conferred a statistically significant risk of renal failure. PVAD placement conferred a similar risk by odds ratio but was likely underpowered to show effect (RR, 1.16; $p = 0.15$).

Table 3 Multivariable Analysis of Risk Factors for Mortality[a]

Variable	OR	2.5%	97.5%	*p*-value
Decade of age	1.00	0.9996	1.0004	0.99
Not white	1.01	1.00	1.02	0.18
Female	1.00	0.99	1.03	0.39
Before transplant				
ECMO	1.04	0.99	1.10	0.13
IABP	0.99	0.93	1.05	0.74
PVAD	0.94	0.92	0.97	<0.001[b]
Modern era	0.95	0.93	0.97	<0.001[b]
No. of Comorbidities	1.01	1.00	1.01	<0.001[b]

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; OR, odds ratio; PVAD, percutaneous ventricular assist device.

[a]Logistic regression model: death, age, race, sex, type of temporary mechanical circulatory support, era, number of comorbidities

[b]Statistically significant ($p < 0.05$).

Length of stay

In both the earlier and modern eras, patients who received tMCS before transplant had an increased length of stay (71 vs 43 days and 69 vs 39 days, respectively), but this was not statistically significant given the significant variance in length of stay in both groups. Similarly, the length of stay after heart transplantation was longer for patients who required tMCS (70 vs 41 days), but again, this difference was not statistically significant.

Outcomes by type of tMCS

The rate of complications and mortality did not differ significantly by type of tMCS apart from overall length of stay being longer in the ECMO group vs IABP group (89 vs 63 days, $p < 0.0001$); length of stay after transplant was similar (Supplemental Table S2, online). The multivariable analyses of the effect of type of tMCS on these outcomes are reported above.

Discussion

In this cohort of heart transplant patients identified in the NIS, in-hospital mortality decreased over time, and this trend in decreasing mortality persisted despite an increasingly elderly patient population, patients with more comorbidities, and increased use of tMCS before heart transplantation.

This trend held true for patients who received tMCS before transplantation and patients who did not. In fact, the most significant improvement in hospital mortality over time was in the cohort who received tMCS. Although not statistically significant, there was a modest trend in the modern era toward decreased mortality in the tMCS cohort.

During this period, the use of tMCS before transplant increased, more than doubling from 2002 to 2014. Mortality

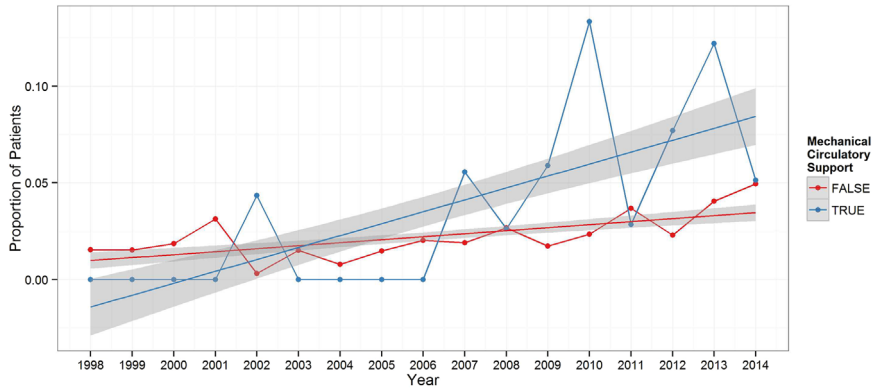

Figure 3 Time trend of stroke rate by presence of temporary mechanical circulatory support before transplantation between 1998 and 2014. The shaded area shows the 95% confidence interval.

rates became similar between the 2 cohorts, but the rate of post-transplant complications remained significantly higher in patients who received tMCS before transplantation, and the rates of important complications, such as stroke and renal failure, increased over time.

The question of when and whether patients are "too sick" for heart transplantation is not explicitly described in the UNOS heart allocation proposal. Given the reduction over time of mortality for patients who received tMCS, our data suggest the proposed changes may be justified. However, based on the proposed changes, there could be an acceleration of the number of patients who receive tMCS before transplantation. This could shift the overall transplant candidate population toward sicker patients before transplantation and lead to longer waiting times for other patients on the transplant list, while also increasing post-transplant morbidity, mortality, and overall cost to the health care system.

The question of when patients are "too sick" also depends on the state of the art peri-operative treatment of patients undergoing transplantation, which has changed over time. If, as we found, the in-hospital mortality rates of transplant patients who require tMCS converges with the mortality rate of patients who do not require tMCS, advances in circulatory support might allow more patients to overcome critical cardiac failure and become transplant candidates. Patients who would otherwise die waiting on the transplant list could instead receive a transplant and have good outcomes.

Yet, even if mortality remains similar between patients who receive tMCS before transplant and those who do not, our finding of increased complication rates in patients receiving tMCS gives one pause. As the field of MCS advances, the focus on improving outcomes has broadened beyond mortality to other complications that negatively affect quality of life and cost. We thus need ways to reduce complication rates, whether by improved management of these patients or improved technology. The new UNOS allocation scheme does suggest the use of serial hemodynamic evaluations to determine whether a patient can remain a candidate for cardiac transplantation while on tMCS, and these and other measures could further refine our evaluation of patients' candidacy while on the waiting list, potentially improving morbidity rates after transplantation in patients receiving tMCS. For example, if tMCS devices were implanted in patients earlier in their hospital course, the rates of complications could decline. The type of tMCS may also be important, as we found that PVAD support significantly reduced post-transplant mortality, but this finding can only be hypothesis generating.

Table 4 Multivariable Analysis of Risk Factors for Renal Failure[a]

Variable	OR	2.5%	97.5%	*p*-value
Decade of age	0.999	0.9991	0.9996	<0.001[b]
Not white	0.99	0.987	1.002	0.16
Female	1.01	1.001	1.02	0.03[b]
Before transplant				
ECMO	1.02	0.98	1.06	0.31
IABP	1.01	0.99	1.02	0.49
PVAD	1.05	0.92	1.20	0.46
Modern era	1.01	0.998	1.014	0.16
No. of comorbidities	1.003	1.002	1.005	<0.001[b]

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; OR, odds ratio; PVAD, percutaneous ventricular assist device.

[a]Logistic regression model: stroke, age, race, sex, type of temporary mechanical circulatory support, era, and number of comorbidities.

[b]Statistically significant ($p < 0.05$).

Table 5 Multivariable Analysis of Risk Factors for Stroke[a]

Variable	OR	2.5%	97.5%	*p*-value
Decade of age	1.003	1.002	1.004	<0.001[b]
Not white	1.01	0.99	1.04	0.38
Female	0.97	0.94	0.99	0.01[b]
Before transplant				
ECMO	1.12	1.02	1.21	0.01[b]
IABP	1.13	1.08	1.19	<0.001[b]
PVAD	1.16	0.95	1.43	0.15
Modern era	1.04	0.99	1.09	0.13
No. of comorbidities	1.04	1.03	1.04	<0.001[b]

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; OR, odds ratio; PVAD, percutaneous ventricular assist device.

[a]Logistic regression model: renal failure, age, race, sex, type of temporary mechanical circulatory support, era, and number of comorbidities.

[b]Statistically significant ($p < 0.05$).

Our study has a few limitations based on the design of the NIS. We are not able to explicitly determine the priority of the patients in our cohort or the time on the transplant waiting list. Given the use of tMCS, we can assume that patients were status 1A before transplantation.

As a retrospective cohort, we are not able to ascertain why tMCS was initiated and the discussion around which modality of circulatory support was chosen. The lack of hemodynamic data in the NIS means we cannot assess changes in patient's clinical condition before transplantation.

In addition, the NIS also only lists same hospitalization complications and mortality and does not have information of follow-up after hospital discharge. Given the increased length of stay and the high rates of complications while hospitalized, it is possible these patients would have a more challenging post-hospitalization course.

Although the number of comorbid conditions was associated with worse outcomes in our multivariable model, the nature of the NIS data set prevented us from precisely examining the effect of clinical factors such as renal function, blood pressure, and serum glucose levels on outcomes. The NIS data set contains instead diagnoses such as chronic kidney disease, hypertension, and diabetes. Hemodynamic data or contemporaneous data on end-organ function at time of implant would provide incremental benefit to our analysis. These data would also potentially aid in patient selection for tMCS, defining to some extent patients who should and should not receive tMCS before transplantation (e.g., because the latter would have poor outcomes after cardiac transplantation).

In conclusion, we found that although overall morbidity after heart transplantation increased over time in patients who received tMCS, in-hospital mortality rates did not significantly differ in more recent years between patients who received tMCS before cardiac transplantation and those who did not. These data support the use of tMCS before cardiac transplantation in appropriately selected patients, and if the use of tMCS before heart transplantation continues to increase over time, further refinement of patient management and selection may be required to improve outcomes.

Disclosure statement

None of the authors has a financial relationship with a commercial entity that has an interest in the subject of the presented manuscript or other conflicts of interest to disclose.

Appendix A. Supporting information

Supplementary data are available in the online version of this article at www.jhltonline.org.

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