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

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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.

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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

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