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RESEARCH LETTER

Changes in Type of Temporary Mechanical Support Device Use Under the New Heart Allocation Policy

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On October 18, 2018, the Organ Procurement and Transplantation Network implemented a new heart allocation policy in an effort to promote equitable distribution of organs.[1] The policy instituted sweeping changes in listing criteria to better risk stratify patients. Under this new system, patients requiring the greatest levels of temporary mechanical circulatory support (MCS) are assigned higher priority status. Patients supported by venoarterial extracorporeal membrane oxygenation (VA-ECMO) are listed as status 1; patients with nondischargeable, surgically implanted ventricular assist devices (VADs) (e.g., Impella) or intra-aortic balloon pumps (IABPs) as status 2. Recent studies demonstrate an expected rise in MCS use broadly and ECMO specifically before transplantation.[2] However, national data on trends in specific types of temporary MCS used are lacking. This is important because some devices, like IABPs, are more easily placed than others, raising concerns that transplant programs are incentivized to insert IABPs[3] when lesser forms of support may be adequate. We evaluated the specific types of temporary MCS used at transplantation before and after the new policy implementation.

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), US Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. This analysis was exempt from institutional review board review.

We included US patients ≥18 years of age who underwent a single-organ heart transplant between January 1, 2017, and January 31, 2020 (excluding Puerto Rico). Patients transplanted in October 2018 were excluded (n=236) because the policy was implemented that month. We evaluated trends in temporary MCS use before (January 1, 2017, through September 30, 2018) and after (November 1, 2018, through January 31, 2020) the policy change, stratified by gender. We defined temporary MCS as VA-ECMO, left and right-sided VADs (Cardiac Assist Tandem Heart and Protek Duo; Impella Recover 2.5 and 5.0/CP/RP; CentriMag [Thoratec/Levitronix]; and Maquet Jostra Rotaflow), and IABPs. Data were missing on the presence of VADs for 86 patients and VAD type for 3 patients, all of whom were excluded; no data were missing on IABPs or ECMO. Use of MCS by policy period and gender (including their interaction effect) was compared using logistic regression models. A 2-sided α=0.05 was used to establish significance. All analyses used SAS version 9.4 (SAS Institute).

During the study period, 7923 adults underwent heart transplantation at 124 centers with 3300 (41.7%) transplanted after the policy change. Under the old policy, 7.6% of patients were transplanted with an IABP, 1.8% with

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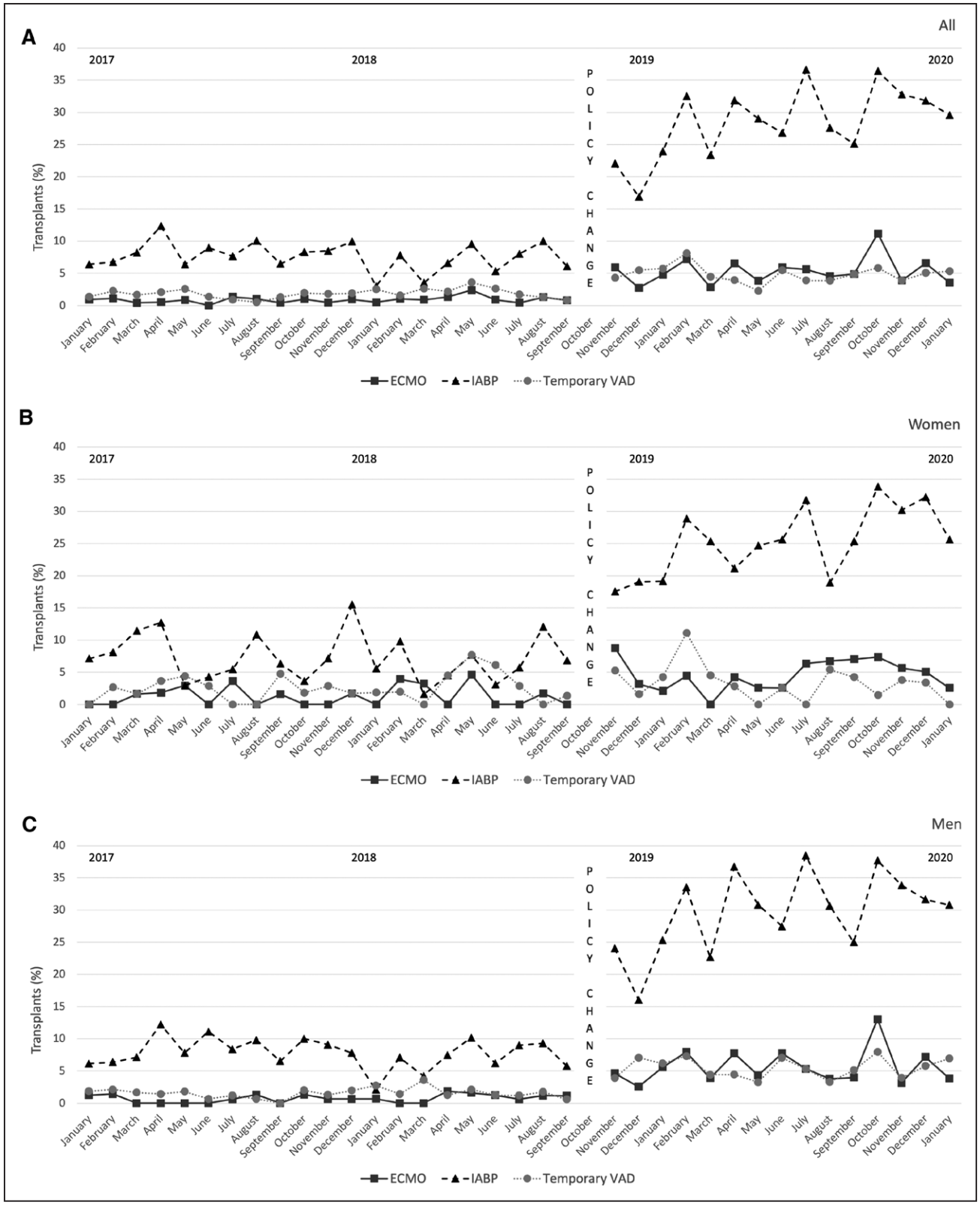

Figure. Use of temporary mechanical circulatory support before and after policy change.
Use of intra-aortic balloon pumps (IABPs), temporary ventricular assist devices (VADs), and venoarterial extracorporeal membrane oxygenation (VA-ECMO) before and after policy change in all cardiac transplant recipients (**A**), women (**B**), and men (**C**). While on VA-ECMO, 69 patients had additional forms of temporary support (IABP or temporary VAD; 10 before and 59 after policy change) and 14 had both an IABP and temporary VAD at transplant (4 before and 10 after policy change).

a temporary VAD, and 0.9% with VA-ECMO, with stable rates over time (Figure A). After implementation of the new policy, 28.3% of patients were transplanted with an IABP, 4.8% with a temporary VAD, and 5.3% with VA-ECMO (Figure A; $P<0.001$ for all comparisons). After the policy change, men were more likely to have an IABP ($P=0.01$) or temporary VAD ($P=0.01$) compared with women, with 29.6% of men and 25.2% of women having an IABP at transplant (Figure B and C). Interaction effects suggested a similar rise in the likelihood of having an IABP among men and women ($P=0.45$) but a greater increase in the likelihood of receiving a temporary VAD ($P<0.001$) or ECMO ($P=0.046$) for men than women after the policy change.

We found an increase in temporary MCS use after the new heart allocation policy, with more than one-fourth of patients having an IABP at transplant. This is consistent with a recent smaller study showing a rise in IABP use from 19.8% to 25.4%, although these percentages show clear differences between our national cohort and those 7 select centers.[4] The abrupt and sustained increase in MCS use after the policy change raises the question of whether this is an appropriate change, reflecting transplantation of more critically ill patients, or is driven by nonclinical factors including "gaming."[5] Although hemodynamic criteria were put in place under the new policy for listing patients at the highest statuses, patients with chronic heart failure can meet these criteria without markers of malperfusion denoting cardiogenic shock and may not dissuade providers from using disproportionate forms of support than is necessary to stabilize patients. To determine whether our findings represent "gaming" or better care requires additional research and potentially monitored use of these devices. Whereas temporary MCS use increased for both genders, there was significantly greater use in men under the new policy. Further study is necessary to determine whether gender differences persist and exacerbate disparities in heart transplantation. Limitations include the study's retrospective design, short time period, and potential for confounding. Because the Scientific Registry of Transplant Recipients includes data on all transplants in the United States, it provides important insights into potential unintended consequences of the new heart allocation criteria across the nation.

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Disclosures

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