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Expanding the Donor Pool

REVIEW

SALEEM TORO, MD

KELLY H. SCHLENDORF, MD, MHS

*Author affiliations can be found in the back matter of this article

HOUSTON Methodist DEBAKEY HEART & VASCULAR CENTER

ABSTRACT

Given the aging population and despite advances in heart failure therapies, the number of patients with advanced heart failure in need of heart transplantation continues to increase, and the longstanding mismatch between organ demand and organ supply persists. In an effort to address this mismatch and expand the donor pool, a number of strategies are being pursued. This article reviews several of those strategies, including transplantation from hepatitis C virus-infected donors, transplantation from donors after circulatory death, the role of organ preservation technologies in facilitating transplantation of hearts that might otherwise be discarded, and the impact of public education and national donation policies.

CORRESPONDING AUTHOR:
Saleem Toro, MD

Vanderbilt Heart and Vascular Institute, Nashville, Tennessee, US

saleem.toro@vumc.org

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INTRODUCTION

By recent estimates, heart failure affects approximately 65 million adults worldwide, a number that continues to increase due to an aging population and improvements over time in evidence-based treatments.[1] Among patients with symptomatic heart failure, nearly 5% will progress to stage D heart failure, characterized by persistent symptoms and impaired quality of life despite optimal medical and device therapies. For these individuals, orthotopic heart transplantation remains the gold standard treatment, offering significant improvement in survival and functional status.[2]

In the United States (US), heart transplant rates have been increasing since 2015, reaching 122.5 transplants per 100 patient-years in 2022, an 81% increase relative to 2011. The increase in the number of transplants performed, however, has been accompanied by an increase in the number of candidates newly added to the waitlist, thereby perpetuating the longstanding mismatch between organ supply and demand. During 2022, for example, more than 7,000 candidates were waiting for a heart while only 4,169 heart transplants were performed,[3] and more than 400 patients on the waitlist either died or were removed from the waitlist for becoming too ill.[4] These numbers underscore the urgent need to explore ways to expand the donor pool.

Over the past decade, various strategies have emerged to help address this need. This article describes several of these strategies—including transplantation of hearts from hepatitis C-infected donors, transplantation of "extended criteria" hearts such as from donors after circulatory death (DCD), and utilization of novel organ preservation methods—that might otherwise be discarded due to long ischemic time or other factors.

TRANSPLANTATION FROM HEPATITIS C VIRUS-INFECTED DONORS

In the early 2000s, several studies demonstrated an association between donor hepatitis C virus (HCV) positivity and poor post-transplant outcomes. As a result, for nearly two decades, hearts from HCV-positive donors (defined at the time only by HCV antibody positivity) were routinely refused for transplantation. Beginning in 2014, however, the introduction of direct-acting antivirals (DAA) combined with donor HCV nucleic acid testing (NAT) prompted the transplant community to reexplore this potential donor pool, the population of which has grown dramatically due to the opioid epidemic.[5] In a single center study published in 2018, Schlendorf et al. showed that among a cohort of patients transplanted with HCV-positive donors and who developed HCV infection post-transplant, DAAs were well tolerated and highly effective in curing HCV; furthermore, waitlist candidates who consented to consider these donors had the potential for significant reductions in wait time.[6]

The largest single-center study to date, published by the same group, evaluated outcomes in 80 heart recipients of organs from HCV-positive donors, reporting 1-year survival of 90%, which is comparable to that of recipients of HCV-negative donor hearts transplanted during the same time frame. No cases of HCV transmission were reported from donors who were antibody-positive but NAT-negative.[7] More recently, a meta-analysis of 13 studies demonstrated that in the DAA era, heart transplant recipients from HCV-infected donors achieve a 100% HCV cure rate, with post-transplant survival of 95.6% and 92.9% at 6 and 12 months, respectively.[8] While two small studies have reported a higher incidence of cellular rejection in recipients of hearts from HCV-infected donors,[9,10] these findings have not been replicated elsewhere, nor have studies found any association in the current era with increased rates of allograft vasculopathy.[11,12] Larger, longer-term studies will be needed to further evaluate these and other outcomes.

In the wake of the aforementioned studies, the International Society for Heart and Lung Transplantation published an expert consensus statement in 2020 recommending that (1) hearts from HCV Ab+/NAT- donors should routinely be accepted for cardiothoracic transplantation given the negligible risk of HCV transmission, and (2) hearts from HCV NAT+ donors should be considered for waitlist candidates who have provided informed consent, particularly at transplant centers with established protocols, specialized multidisciplinary teams, and adequate resources to manage donor-derived HCV infection.[13] In 2024, nearly 10% of heart transplants performed in the US were from HCV-positive donors.[14]

TRANSPLANTATION FROM DONORS AFTER CIRCULATORY DEATH

While heart transplantation from HCV-infected donors has allowed for small but impactful increases in the donor pool, more impactful has been the recent adoption by many centers worldwide of DCD heart transplantation, a practice facilitated by novel strategies of organ recovery. Unlike hearts from donors who are brain dead (termed "DBD" hearts, the function of which can be visualized in situ prior

to organ recovery), DCD hearts have stopped beating and are subjected to a period of warm ischemia during which myocardial injury and cell death are known to occur.[15] Thus, although the first human heart transplants performed in the 1960s were indeed DCD, the majority of transplants performed from the 1980s onward—once brain death laws were in place—were DBD hearts.

Interest in DCD was revived following a case series in Australia and the United Kingdom describing successful DCD outcomes using an ex-vivo organ care platform called Organ Care System (OCS; TransMedics) for heart preservation.[16,17] This transportable machine maintains the excised heart in a warm, beating state using oxygenated donor blood and allows for serial measurements of aortic pressure, coronary flow, and arteriovenous lactate concentrations to assess cardiac function. The first DCD heart transplants performed in the US in the modern era utilized direct procurement followed by OCS. Schroder et al. reported that among a cohort of patients transplanted with this strategy, 6-month survival was non-inferior to that of patients transplanted using DBD hearts and standard cold storage.[17]

Since then, some centers (including ours) have elected to use normothermic regional perfusion (NRP) as an alternative to OCS for DCD heart recovery. During NRP, the heart is reanimated in situ following donor death using central extracorporeal membrane oxygenation. This allows for direct visualization of cardiac function prior to cardiectomy. In a single-center study that included 385 patients undergoing heart transplantation, 1-year survival among patients transplanted with DCD hearts (the majority of which were recovered using NRP) was similar to that of patients transplanted using DBD hearts during the same time period; additionally, there were no significant between-group differences in rates of primary graft dysfunction, rejection, or allograft vasculopathy at 1 year.[18] More recently, a meta-analysis that included 12 studies suggested that DCD heart transplantation is associated with a lower 1-year mortality rate compared with DBD. While differences in outcomes among DCD heart transplants by method of organ recovery remain to be fully elucidated, a recent United Network for Organ Sharing registry analysis found that DCD transplantation using NRP compared to direct procurement and machine perfusion was associated with improved short-term survival, even in propensity-matched cohorts.[19]

Over the past 4 years, DCD transplantation has continued to increase, accounting for nearly 18% of all US heart transplants performed in calendar year 2024.[4] By some estimates these donors may ultimately expand the US donor pool by as much as 30%.[20]

NOVEL PRESERVATION TECHNOLOGIES

In an effort to reduce allograft ischemic injury and motivate consideration of "extended criteria" hearts, several alternatives to traditional cold storage have been developed. One of these, ex-vivo machine perfusion with OCS, is previously described. In addition to facilitating DCD recovery, machine perfusion affords evaluation of hearts that might otherwise be discarded, including older donors or those with diabetes, mild luminal coronary irregularities, left ventricular hypertrophy, and other risk factors, especially in cases where the anticipated ischemic time is long. In the OCS Heart EXPAND trial, 173 extended criteria DBD hearts were perfused on OCS, including 150 hearts that were ultimately transplanted. Among transplanted hearts, patient survival was 93%, 89%, and 86% at 6, 12, and 24 months, respectively.[21]

Another newer preservation technique is controlled hypothermia, whereby the cardiac allograft is preserved at carefully controlled temperatures during transport from donor to recipient hospital. The SherpaPak Cardiac Transport System (Paragonix) utilizes a sterile insulated canister filled with preservation solution to maintain a controlled hypothermic environment between 4°C and 8°C. In an analysis of the Guardian Heart Registry, which included transplants performed using this method, investigators found that 2-year post-transplant survival was superior to that of patients whose hearts were preserved using standard cold storage; this was due in part to significantly reduced rates of primary graft dysfunction (6.6% versus 10.4%; $P = .039$).[22] Like SherpaPak, the XVIVO Heart Assist Transport Device (XHAT, XVIVO) preserves the resting heart during transport at a controlled temperature of 8°C; unlike SherpaPak, it also uses oxygenated perfusion, theoretically extending the time the heart can be outside the body. In the Hope (hypothermic oxygenated perfusion) trial performed in New Zealand and Australia, investigators found 100% patient survival at 30 days and only one case of primary graft dysfunction among 36 recipients whose hearts were preserved using XHAT for up to 8 hours and 47 minutes.[23] A US trial using this (still investigational) device is not yet completed.

The advancement of these and other organ preservation technologies has paved the way for the use of marginal donor hearts or those located at extended distances from the transplant center that were previously considered unsuitable for transplantation. By one analysis, the use of extended criteria hearts between 2015 and 2022 could have potentially added 5,396 donor hearts to the transplant pool, a 43% increase in the number of hearts available for transplantation.[24]

PUBLIC POLICY AND EDUCATION AROUND ORGAN DONATION

Perhaps equally if not more influential than any of the aforementioned strategies for expanding the donor pool is the impact of ongoing policy efforts and public education on the life-saving role of organ donation. Worldwide, there are three main policies for organ donation: opt-in, opt-out, and reciprocity. Based on the opt-in policy, any individual who wants to be an organ donor should register as such. Usually, this takes place while obtaining a driver's license. Alternatively, organ donation could proceed following death and after obtaining consent from the donor's family.[25] In opt-out systems, such as those implemented in Belgium and France, a person is considered an organ donor unless he or she states otherwise.[26] Lastly, the reciprocity model, such as the one implemented in Israel, prioritizes organ donation to those who consent to be donors, encouraging a culture of reciprocity within the society.[27]

While each of these policies has distinct frameworks, their impact in increasing the donor pools remains a subject of debate. In 2003, many European countries adopted the opt-out strategy based on data showing a striking disparity in consent rates between opt-in countries (42%) and opt-out countries (82%).[28] However, more recent evidence suggests that presumed consent alone does not fully account for variations in organ donation rates across countries. For example, Spain, which is known to have the highest deceased organ donation rates, saw significant increases only after implementing a national transplant coordination network, which included appointing specialized transplant coordinators to identify potential donors, manage cases, and communicate effectively with bereaved families.[29] Moreover, a recent longitudinal analysis of five countries that transitioned from opt-in to opt-out systems showed similar trends, with improvement in organ donation rates increasing after pairing the opt-out framework with investment on the public policy level, spreading awareness and addressing family concerns about transplantation.[30] This underscores the multifactorial nature of increasing organ supply and the importance of implementing a comprehensive approach.

Cultural values also play a pivotal role in shaping the effectiveness of donation policies. For instance, adopting an opt-out system in a society that prioritizes individual autonomy, such as the US, might backfire and lead to counterproductive results. On the contrary, such a policy could be better suited for a utilitarian society that adopts social contract ethics.[31] Addressing cultural sensitivities is particularly relevant in the US since obtaining family consent remains a significant factor in the organ donation process. According to data from 2013, approximately 25% of families refused to consent to organ donation.[32] Reasons for refusal often include cultural or religious beliefs and inadequate communication between procurement organizations and families.

Utilization of NRP during DCD transplantation has introduced yet another layer of complexity to organ donation and recovery. From an ethical standpoint, the question is whether in situ reanimation of the heart violates the dead donor rule and whether ligating the cerebral arteries, as is routinely done at the commencement of NRP, causes brain death. Professional societies have expressed differing opinions. The American College of Physicians has strongly condemned NRP and called for a pause on this practice, arguing that circulatory criteria for determining death consist of irreversible cessation of circulatory and respiratory function regardless of the intention.[33] The American Society of Transplant Surgeons, on the other hand, has fully endorsed the use of NRP, noting its utility in procuring organs and emphasizing the importance of respecting the donor's and families' autonomy in the ethical assessment.[33]

Ongoing and transparent education about the donation process, brain death, and associated policies is critical to the maintenance and ongoing expansion of the donor pool.[34] Building trust with families, understanding diverse cultural and religious perspectives toward transplantation, and addressing families' concerns with empathy are all essential strategies.[35]

OTHER STRATEGIES

While the strategies described above have had the greatest impact in expanding the heart donor pool in recent years, other strategies have had smaller but nonetheless impactful influences (Table 1). These strategies include transplantation of hearts from SARS-CoV-2-positive donors and, for waitlisted candidates with human immunodeficiency virus (HIV), transplantation of hearts from HIV-infected donors under the HIV Organ Equity Policy (HOPE) Act.

Data from a retrospective analysis of the United Network for Organ Sharing database revealed no differences in 30-day graft failure or mortality among 1,241 recipients of transplanted organs (including 106 heart recipients) from SARS-CoV-2 NAT+ donors.[36] However, one longer-term follow-up study showed that while recipients of hearts from donors with recently resolved COVID-19 infection had

Donation after circulatory death
Normothermic regional perfusion
Machine perfusion
Controlled hypothermia for organ preservation
Hepatitis C virus-infected donors
Public policy & education
HIV- and COVID-infected donors
Xenotransplantation
Bioengineered hearts

Table 1 Current and evolving strategies to expand the donor pool.

similar outcomes to those transplanted with non-COVID donors, recipients of hearts from donors with active COVID infection experienced higher 6-month (HR, 1.74; 95% CI, 1.02-2.96; *P* = .043) and 1-year (HR, 1.98; 95% CI, 1.22-3.22; *P* = .006) mortality.[37] As the SARS-CoV-2 epidemic lingers indefinitely, further work is needed to elucidate the long-term safety of transplanting hearts from these potential donors.

The HOPE Act, enacted in 2015, allows organs from HIV-positive donors to be transplanted into recipients who also have HIV with the stipulation that ongoing research investigates the safety and feasibility of this strategy. In July 2024, the third heart transplant performed under the HOPE Act took place. As more transplant centers choose to participate under this law, the hope is that it will allow more individuals with HIV to become organ donors and expand the donor pool for HIV-positive waitlisted candidates.

Finally, while still very much investigational, strategies such as xenotransplantation and bioengineered hearts may someday hold promise for further expansion of the donor pool.[38,39] Over the past 3 years, genetically modified porcine hearts have been transplanted into two humans at the University of Maryland, one of whom survived for 60 days and the other of whom survived just over 5 weeks. While these cases confirmed the technical feasibility of using xenografts, much remains to be clarified and understood about the risks (ie, xenozoonoses), costs, and ethics of this approach.[40]

SUMMARY

While heart transplantation continues to be the gold standard treatment for end-stage heart failure, the longstanding mismatch between organ demand and organ supply persists. However, several key strategies adopted and developed just in the past decade have afforded significant expansion of the heart donor pool. Ongoing studies evaluating the long-term safety of these strategies are needed, as are additional strategies that facilitate transplantation of hearts that might otherwise be discarded. In the background of these strategies, public policy and education about organ donation continue to play important roles.

KEY POINTS

- Given the increasing number of patients with advanced heart failure who need heart transplantation and the ongoing mismatch between organ demand and organ supply, there is a pressing need to expand the donor pool.
- Several strategies are being considered to expand the donor pool, including transplantation of hearts from hepatitis C-infected donors, transplantation of "extended criteria" hearts such as from donors after circulatory death, and utilization of novel organ preservation methods.
- Transplantation using donors after circulatory death has increased in the past 4 years, accounting for nearly 18% of all US heart transplants performed in calendar year 2024; this donor group is estimated to expand the US donor pool by as much as 30%.
- Novel organ preservation technologies have paved the way for use of marginal donor hearts or those located at extended distances from the transplant center, which could greatly increase the number of hearts available for transplantation.
- Ongoing and transparent education about the donation process, brain death, and associated policies is critical to maintaining and expanding the donor pool.

COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR AFFILIATIONS

Saleem Toro, MD orcid.org/0000-0002-3654-7118
Vanderbilt Heart and Vascular Institute, Nashville, Tennessee, US
Kelly H. Schlendorf, MD, MHS orcid.org/0000-0002-8811-1957
Vanderbilt Heart and Vascular Institute, Nashville, Tennessee, US

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