Trends in pediatric donor heart discard rates and the potential use of unallocated hearts for allogeneic valve transplantation

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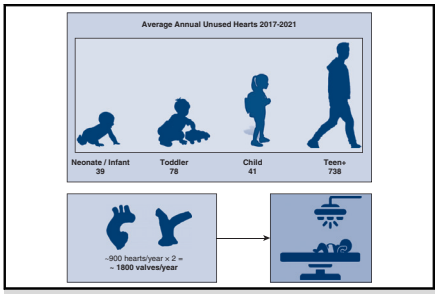
ABSTRACT

Objectives: Allogeneic valve transplantation is an emerging therapy that delivers a living valve from a donor heart. We reviewed the national discard rate of pediatric and young adult (aged 25 years or younger) donor grafts to estimate the number of hearts potentially available to source valve allotransplantation.

Methods: We queried the United Network for Organ Sharing database to identify pediatric and young adult heart donors from 1987 to 2022. Donor heart discard was defined as nontransplantation of the allograft.

Results: Of 72,460 pediatric/young adult heart donations, 41,065 (56.7%) were transplanted and 31,395 (43.3%) were unutilized. The average annual number of discarded hearts in era 1 (1987-2000), era 2 (2000-2010), and era 3 (2010-2022) was 791 (42.8%), 1035 (46.3%), and 843 (41.2%), respectively. From 2017 to 2021, the average annual number of discards by age was: 39 (31.8%) neonates/infants, 78 (38.0%) toddlers, 41 (49.4%) young children, 240 (38.0%) adolescents, and 498 (40.1%) young adults. High-volume procurement regions had the greatest proportion of nonutilization, with the national average discard rate ranging from 39% to 49%. The most frequently documented reasons for nonallocation were distribution to the heart valve industry (26.5%), presumably due to suboptimal graft function, poor organ function (22.7%), and logistical challenges (10.8%).

Conclusions: With ~900 pediatric/young adult donor hearts discarded annually, unutilized grafts represent a potential source of valves for allogeneic valve transplant to supplement current conduit and valve replacement surgery. The limited availability of neonatal and infant hearts may limit this technique in the youngest patients, for whom cryopreserved homografts or xenografts will likely remain the primary valve substitute. (JTCVS Open 2023;15:374-81)



The ~900 pediatric hearts discarded annually may source allogeneic valve transplantation.

CENTRAL MESSAGE

Unutilized pediatric and young adult deceased donor hearts are a feasible source of valves for allogeneic valve transplant to supplement conventional therapies.

PERSPECTIVE

A significant number of pediatric and young adult deceased donor hearts are discarded annually. Given the newfound interest in allogeneic valve transplant for young patients with unrepairable valve disease, we propose that valves from unutilized donor hearts may be used to expand the donor pool to address an important need in congenital cardiac surgery.

Pediatric patients with congenital heart disease and unrepairable valve malformations often require valve replacement. Unfortunately, outcomes following surgical valve replacement in neonates and infants remain dismal: The operative mortality for infants undergoing mitral valve replacement has been reported to be as high as 52%,[1] with age younger than 2 years at the time of surgery being a risk factor for early death.[2] Similarly, the early mortality of aortic valve replacement with a homograft ranges from 5% to 13% in children, with a 10-year freedom from reoperation of 50% to 60%.[3] Currently, there is no ideal valve substitute, and each has its associated risks and benefits. Mechanical prostheses yield excellent hemodynamics

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Abbreviations and Acronyms
OPTN = Organ Procurement and Transplant Network
UNOS = United Network for Organ Sharing

and durability, although the major drawback is mandatory long-term anticoagulation therapy. Furthermore, even the smallest-sized mechanical valve is too large for neonates and infants. Cryopreserved xenograft and homograft valves do not require anticoagulation therapy but are limited by accelerated structural degeneration and early valve failure. The fundamental problem with all current valve replacement options is the lack of somatic growth potential. As such, neonates, infants, and young children with valve disease will inevitably require serial reoperations within a short time frame to exchange the prostheses for increasingly larger sizes until they reach adulthood. This presents a major problem in terms of cumulative morbidity and mortality, in addition to having an enormous psychosocial impact on patients and their families.

Transplantation of fresh valve allografts has been historically performed with good results, although this technique was eventually replaced by cryopreservation due to limited donor availability.[4] Given the need for a valve substitute with growth potential, allogeneic valve transplantation has recently been revisited with new enthusiasm and with the modification of adding immunosuppression and treating the overall process similarly to a standard orthotopic heart transplant. Although still in development, this is a promising strategy to deliver a living valve with growth potential to pediatric patients with unrepairable valve disease. To date, 2 infants with truncus arteriosus have successfully undergone an allogeneic valve transplant at a single institution.[5] In this approach, a size-matched donor heart is procured in the standard fashion; the valve is excised, placed under cold ischemia, and implanted within the usual time constraints of a conventional orthotopic heart transplant. Because it is not cryopreserved or fixed, the valve is theoretically fully viable and capable of growing with the developing child, just as cardiac allografts demonstrate somatic growth after transplant. Nonetheless, important factors such as the safety, durability, and growth potential of fresh valve allografts remain largely unknown.

Previous studies report a 40% to 50% annual discard rate of pediatric cardiac allografts[6]; therefore, a primary source of fresh valve allografts could theoretically be donor hearts deemed unsuitable for transplant. However, for allogenic valve transplantation to feasibly scale, we must first determine the potential number of valves that are available annually. We examined the annual discard rate of pediatric and young adult donor hearts in the United States to estimate the number of potentially usable valves for allogeneic valve transplants in current practice.

METHODS

Study Design and Patient Population

We performed a retrospective, observational study using data from the United Network for Organ Sharing (UNOS) database. UNOS is the regulatory agency responsible for overseeing all solid organ transplantation in the United States. Data are maintained on the characteristics of donors, recipients, and follow-up of all transplanted patients. We queried the UNOS database for all deceased pediatric and young adult solid organ donors (younger than age 25 years at the time of organ donation) from October 1987 to October 2022. Donors consented for heart donation after brain death were included in the study; donation after cardiac death donors were excluded. We stratified donors by the following age groups to best understand the matched available donor pool for prospective patients: neonates/infants (age 0-12 months), toddlers (age 1-4 years), young children (age 5-10 years), adolescents (age 10-18 years), and young adults (age 19-25 years). We assessed differences in cardiac allograft utilization over time across multiple eras: era 1 (1987-2000), era 2 (2000-2010), and era 3 (2010-2022), with a particular focus on the previous 5 years. We also analyzed the geographic distribution of unused donor hearts within Organ Procurement and Transplant Network (OPTN) regions 1 to 11. The study was approved by the Institutional Review Board of Columbia University Irving Medical Center with a waiver of consent (IRB AAAR3476, approved December 16, 2022).

Definitions

- Organ refusal: A center has declined the organ for transplantation; however, the organ may still be accepted and utilized by another center.
- Organ discard: A donor heart that is offered by an organ procurement organization to a center, but is ultimately not transplanted. Organs may be discarded for any of the following reasons:
  - Potential organ donors were not evaluated for organ donation or were evaluated without assessing the heart;
  - The donor heart was evaluated but the local center or organ procurement organization determined it unsuitable for donation and no offer was made;
  - The donor heart was accepted and procured, but not transplanted; or
  - The donor heart was offered, but not accepted by any center for procurement.

Statistical Analysis

All data were analyzed using STATA version 16 (StataCorp LLC). Categorical variables are presented as proportions and continuous variable are expressed as mean ± SD. Comparisons between the 2 groups were performed using Fisher exact test for categorical variables and the Mann-Whitney *U* test for continuous variables.

RESULTS

Overall Cardiac Allograft Utilization/Discard Rates

Between 1987 and 2022, a total 72,460 pediatric and young adult donors underwent procurement of at least 1 solid organ. Among these donors, 41,065 (56.7%) hearts were allocated and successfully transplanted, whereas 30,972 (42.7%) were considered unsuitable for transplant before or at the time of procurement. A remaining 423

TABLE 1. Pediatric and young adult donor cardiac allografts assessed for transplant

Variable	Transplanted	Unused	Total donors
Total donor hearts	41,065 (56.7)	31,395 (43.3)	72,460
Neonate/newborn infant, age 0-12 mo	2551 (67.3)	1237 (32.7)	3788
Toddler, age 1-4 y	3277 (44.7)	4059 (55.3)	7336
Young child, age 5-9 y	1425 (38.3)	2296 (61.7)	3721
Adolescent, age 10-18 y	12,111 (54.1)	10,269 (45.9)	22,380
Young adult, age 19-25 y	19,701 (59.3)	13,534 (40.7)	33,235
LVEF (%)	61.9 ± 8.1	47.3 ± 17.2*	
Fractional shortening (%)	33.9 ± 9.7	27.2 ± 12.3*	
Inotropic support	13,443 (32.4)	9087 (28.9)*	

Values are presented as n (%), mean ± SD, or n. *LVEF*, Left ventricular ejection fraction. *$P < .001$ when compared with transplanted cohort.

(0.6%) were discarded following recovery for various reasons, bringing the total number of unused pediatric and young adult hearts to 31,395 (43.3%). The overall proportions of discarded hearts since 1987, stratified by age group, are presented in Table 1. Since 1987, 32.7% of hearts from donors younger than age 1 year were not utilized. Notably, among toddler and young child donors, the proportion of discarded hearts exceeded those that were transplanted (toddler: 55.3% vs 44.7% and young child: 61.7% vs 38.3%). The proportions of discarded hearts from adolescents and young adults were 45.9% and 40.7%, respectively. Initial assessment of cardiac function revealed significantly decreased left ventricular ejection fraction (47.3% ± 17.2% vs 61.9% ± 8.1%; $P < .001$) and fractional shortening (27.2% ± 12.3% vs 33.9% ± 9.7%; $P < .001$) in hearts that were unused compared with those that were accepted for transplantation. At the time of organ assessment, there was greater utilization of inotropic support for donor hearts that were utilized compared with those that were discarded (n = 13,443 [32.4%] vs n = 9087 [28.9%]; $P < .001$) (Table 1).

Cardiac Allograft Discard Rate by Era

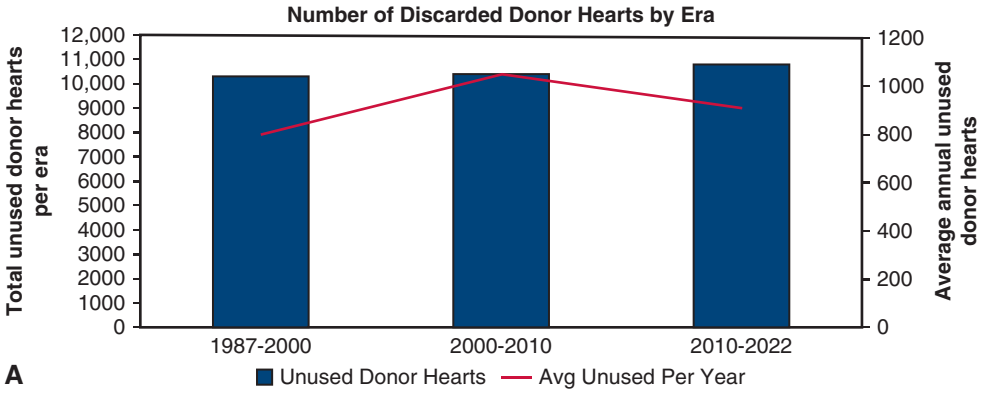
In era 1 (1987-2000), era 2 (2000-2010), and era 3 (2010-2022), the average annual number of unutilized hearts were 791 (42.8%), 1035 (46.3%), and 843 (41.2%), respectively (Figure 1, *A*). When we examined the pattern of unused hearts by donor age groups across eras (Table 2), the adolescent and young adult groups had the highest absolute number of discards across all 3 eras, although the proportion of discarded hearts was relatively low. Conversely, the toddler and young child groups had the highest proportion of discarded donor hearts across all eras; however, this number has been decreasing over time (toddlers: 66.5% > 63.6% > 43.3%; child: 68.9% > 62.6% > 49.7%). The proportion of discarded neonate/infant donor hearts has remained stable over time (35.0%, 29.7%, and 33.2% by era, respectively). The average annual number of discarded hearts in each donor age group, stratified by era, is illustrated in Figure 1, *B*.

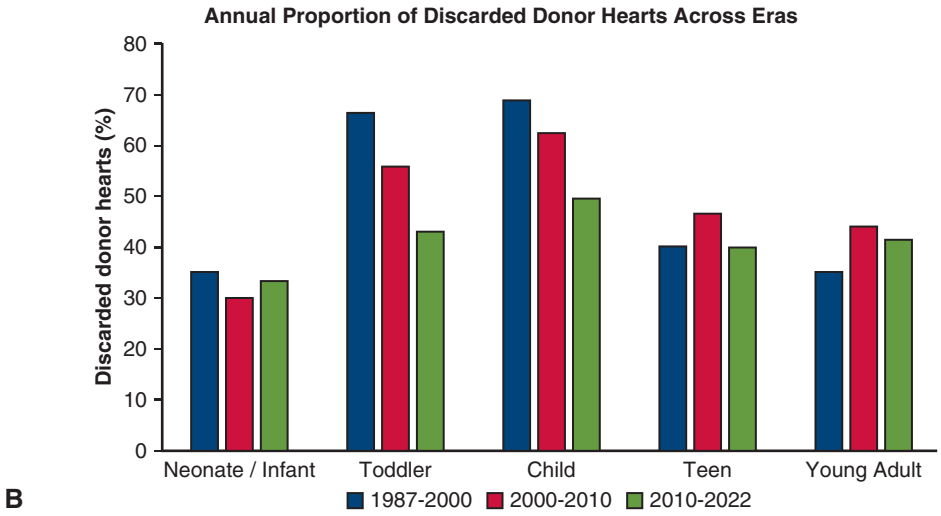
To understand the contemporary cardiac allograft utilization practice, particularly after the changes to the UNOS allocation system in 2016, we specifically focused on the number of discarded donor hearts from 2017 to 2021 (Table 2). We excluded 2022 because data for the months of October to December are incomplete in the UNOS registry. The overall proportion of unused donor hearts has remained stable since 2017. However, there has been a steady increase in the nonutilization rate of neonate/infant donor hearts during the recent years; after a low of 18.9% in 2018, the discard rate increased to 29.1% in 2019 and by 2021, had reached 43.7%. Meanwhile, the allograft nonutilization rate has remained fairly stable during recent years for all other age groups. From 2017 to 2021, the average annual number of discarded hearts in each donor age group was as follows: 39 (neonate/infant), 78 (toddler), 41 (young child), and 738 (adolescent and young adult) (Figure 1, *C*).

Geographic Variation of Donor Heart Nonutilization

Analysis of discard patterns by geographic location revealed large differences in the absolute number of discarded hearts across the 11 OPTN regions (Figure 2, *A*). Since 1987, regions 3 and 5 have had the greatest number of discarded hearts, with a total of 5256 (43.9%) and 4536 (41.1%), respectively, whereas regions 1 (n = 1073 [46.8%]) and 9 (n = 1288 [45.4%]) have had the fewest in number. In general, the number of hearts discarded in each OPTN region has remained relatively stable across all 3 eras, with the exception of regions 2, 4, 6, 8, and 11, which have seen a steady increase. The only region with a decrease in donor heart nonutilization was region 7 (Figure 2, *B*).

As expected, there was a direct correlation between OPTN heart procurement volume and the absolute number of discarded hearts; however, when evaluating the overall proportion of discarded allografts, there was little geographic variation with a national range of 39.3% to





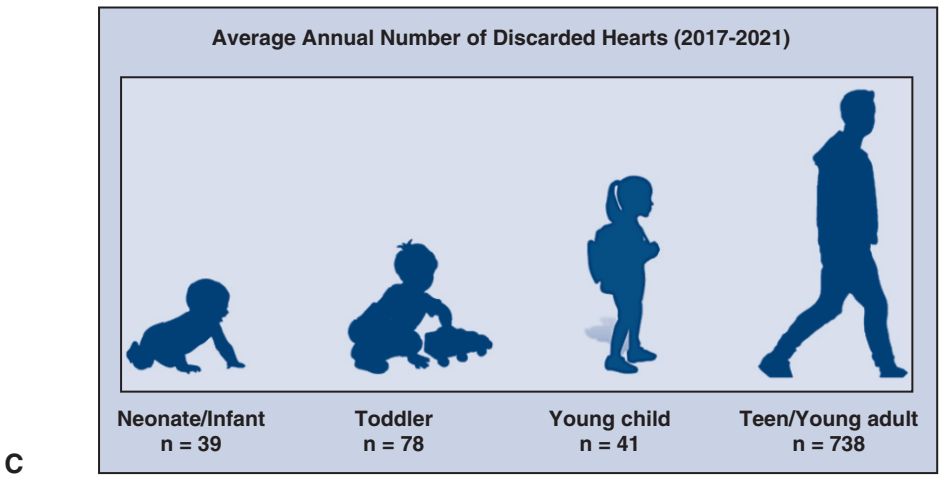


FIGURE 1. The frequency and distribution of discarded donor hearts by era. A, The total number of discarded donor hearts across 3 eras. The *green line* represents the average annual number of discarded hearts within each era. B, The proportion of discarded donor hearts by donor age group, stratified by era. C, The average annual number of unused hearts from 2017 to 2021.

49.0% (Figure 2, *C*). Lastly, the average annual number of discarded hearts across OPTN regions between 2017 and 2021 is shown in Figure 2, *D*. The discard trend in recent years seems to reflect that of the all-time discards, with regions 3 and 5 having the highest absolute number of discards and regions 1 and 9 having the lowest.

TABLE 2. Average number of discarded hearts per era

Era/Year	Overall	Neonate/infant	Toddler	Young child	Adolescent	Young adult
Era 1, 1987-2000	791 (42.8)	30 (35.0)	133 (66.5)	85 (68.9)	300 (40.2)	241 (35.1)
Era 2, 2000-2010	1035 (46.3)	34 (29.7)	122 (63.6)	66 (62.6)	351 (46,7)	460 (44.2)
Era 3, 2010-2022	843 (41.2)	39 (33.2)	85 (43.3)	40 (49.7)	223 (40.0)	453 (41.7)
2017	920 (39.9)	41 (33.3)	71 (36.0)	47 (58.8)	251 (38.5)	510 (40.8)
2018	858 (38.7)	20 (18.9)	91 (40.3)	36 (45.0)	216 (35.9)	495 (41.2)
2019	882 (38.5)	39 (29.1)	82 (39.4)	38 (38.4)	237 (36.9)	486 (40.3)
2020	894 (39.0)	41 (33.9)	64 (34.4)	43 (53.1)	241 (39.0)	505 (39.3)
2021	937 (39.9)	55 (43.7)	86 (40.0)	42 (51.9)	258 (39.9)	496 (38.7)

Values are presented as n (%).

Reasons for Donor Heart Nonutilization

Overall, the most commonly cited reason for discard of a donor heart was distribution to the heart valve industry (26.5%). Although the original reason for discard is unclear, these allografts were likely unallocated due to suboptimal function. Other common reasons for donor allograft discard across all donor age groups included poor organ function (22.7%), family beliefs/requests (4.5%), and donor history (3.5%). Less than 1% of hearts were discarded secondary to an anatomic abnormality, although specific details are unavailable. Logistical barriers, including time constraints, lack of a local procurement team, and inability to identify a suitable recipient, were cited as the rationale for discard of 10.8% of hearts across all donor age groups. Such transplant/procurement logistical issues were particularly apparent in the younger cohort because 18.0% of neonate/infant, 18.0% of toddler, and 17.7% of young child donor hearts were unable to be allocated for this reason. Additional reasons for donor heart nonutilization are listed in Table 3.

DISCUSSION

Although not yet an established therapy, allogeneic valve transplantation is a promising strategy to deliver a living

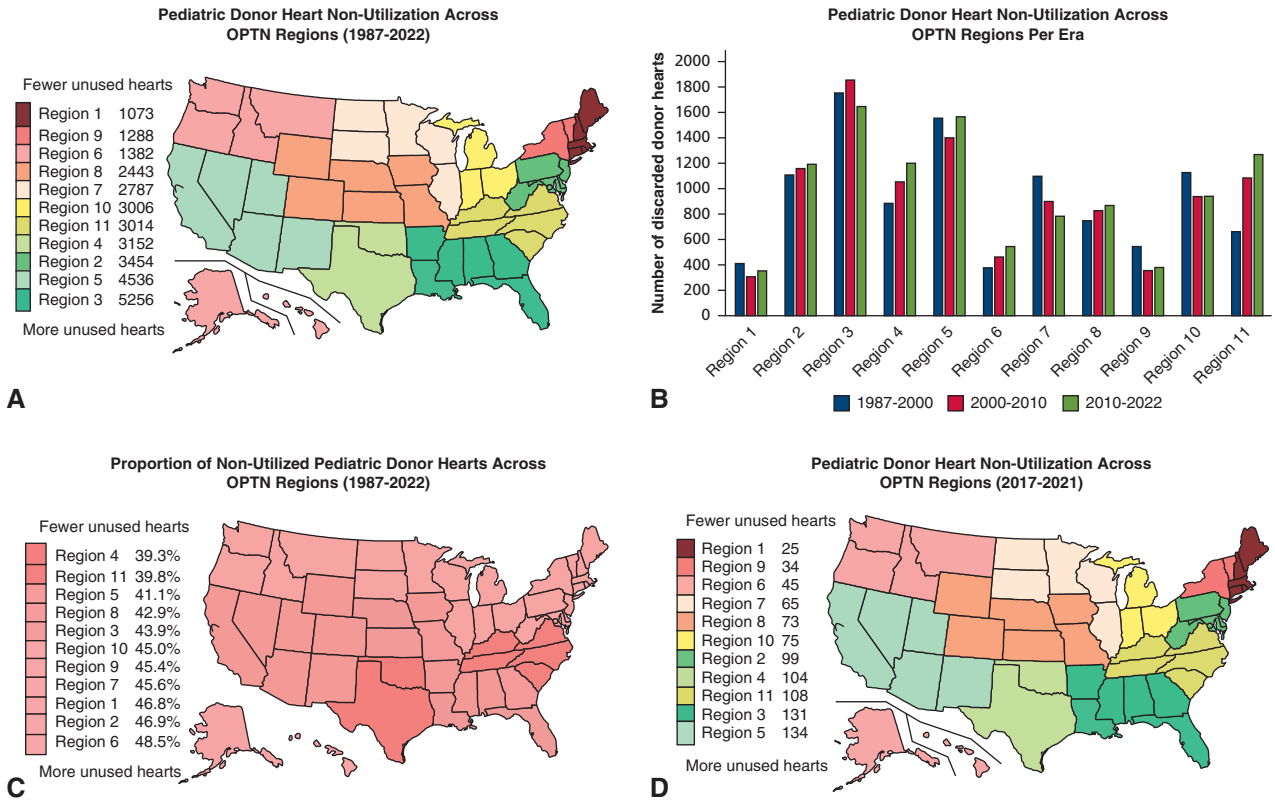


FIGURE 2. Geographic variation in pediatric donor heart nonutilization. A, Absolute number of discarded donor hearts across the 11 Organ Procurement and Transplant Network (*OPTN*) regions. B, Absolute number of discarded donor heart across the OPTN regions, stratified by era. C, Proportion of discarded donor hearts across the OPTN regions from 1987 to 2022. D, Average annual number of discarded donor hearts across the OPTN regions from 2017 to 2021.

TABLE 3. Documented reasons for cardiac allograft discard upon organ evaluation

Reason	Overall	Neonate/infant	Toddler	Young child	Adolescent/young adult
Total	31,395 (100)	1237 (100)	4059 (100)	2296 (100)	23,803 (100)
Sent for heart valves	8313 (26.5)	317 (25.6)	1283 (31.6)	858 (37.4)	5855 (24.6)
Poor organ function	7119 (22.7)	169 (13.7)	801 (19.7)	388 (16.9)	5761 (24.2)
No recipient located	1704 (5.4)	138 (11.2)	466 (11.5)	258 (11.2)	842 (3.5)
Family beliefs/emotions	1403 (4.5)	65 (5.3)	154 (3.8)	89 (3.9)	1095 (4.6)
Organ refused by all programs	1206 (3.8)	59 (4.8)	216 (5.3)	130 (5.7)	801 (3.4)
Research	1114 (3.6)	29 (2.3)	85 (2.1)	47 (2.1)	953 (4.0)
Donor history	1094 (3.5)	40 (3.2)	100 (2.5)	61 (2.7)	893 (3.8)
Prior cardiac disease	947 (3.0)	25 (2.0)	90 (2.2)	40 (1.7)	792 (3.3)
Unstable hemodynamics	900 (2.9)	16 (1.3)	77 (1.9)	39 (1.7)	768 (3.2)
Discarded after evaluation	744 (2.4)	24 (1.9)	44 (1.1)	19 (0.8)	657 (2.8)
Nonbeating donor	580 (1.9)	30 (2.4)	48 (1.2)	13 (0.6)	489 (2.1)
Time constraints	463 (1.5)	24 (1.9)	43 (1.1)	15 (0.7)	381 (1.6)
Medical examiner restriction	454 (1.5)	51 (4.1)	87 (2.1)	18 (0.8)	298 (1.3)
Infection/serology positive	410 (1.3)	8 (0.7)	14 (0.3)	14 (0.6)	374 (1.6)
Anatomic abnormality	182 (0.6)	13 (1.1)	14 (0.3)	11 (0.5)	144 (0.6)
Trauma to heart	164 (0.5)	1 (0.08)	3 (0.1)	12 (0.5)	148 (0.6)
Vascular damage	64 (0.2)	3 (0.2)	7 (0.17)	2 (0.1)	52 (0.2)
Donor age	50 (0.2)	26 (2.1)	15 (0.4)	1 (0.04)	8 (0.03)
Prior cardiac surgery	29 (0.1)	5 (0.4)	6 (0.2)	3 (0.1)	15 (0.1)
Po_2 <200 on challenge	4 (0.01)	1 (0.08)	0 (0.00)	0 (0.00)	3 (0.01)
Biopsy findings	4 (0.01)	1 (0.08)	1 (0.02)	0 (0.00)	2 (0.01)
Donor ABO	2 (0.01)	1 (0.08)	1 (0.02)	0 (0.00)	0 (0.00)
Surgical damage	23 (0.07)	0 (0.00)	0 (0.00)	1 (0.04)	22 (0.1)
No local recovery team	19 (0.06)	1 (0.08)	3 (0.1)	3 (0.1)	12 (0.1)
Other	4428 (14.1)	191 (15.4)	503 (12.4)	273 (11.8)	3461 (14.5)

Values are presented as n (%). ABO refers to patient blood type.

valve from a deceased donor heart that grows with the child; however, the critical donor organ shortage remains a limiting factor.[7] Our analysis of the UNOS registry revealed a significant proportion of unused hearts across multiple age groups and geographical regions that has persisted over time. Between 2017 and 2021, the average number of discarded hearts per year was 920 (40.0%), 858 (38.7%), 882 (38.5%), 894 (39.0%), and 937 (38.9%), respectively. When stratified by donor age group, the average annual number of discarded donor hearts in the modern era was as follows: 39 (31.8%) neonate/infant, 78 (38.0%) toddler, 41 (49.4%) young child, 240 (38.0%) adolescent (age 10-18 years), and 498 (40.1%) young adult. We estimate that this represents an adequate number of valve allografts to initially supplement conventional valve and conduit replacement surgeries in children, including repair of truncus arteriosus, tetralogy of Fallot with pulmonary atresia, or any other lesion requiring outflow tract reconstruction with a conduit (Figure 3). However, in neonates and infants with valve disease, for whom allogeneic valve transplant would provide the largest benefit, the small annual number of donor hearts from this age group limits the scalability of this therapy. As such, cryopreserved homografts or xenografts will likely remain the primary source of valve or conduit replacement in these cases. In adolescents and young adults—for whom there is the greatest availability of donor hearts—the growth potential of the allograft is less important and many other valve replacement options exist. Nonetheless, allogeneic valve transplant is a valid option, although the risks of immunosuppression should be weighed against factors such as anticoagulation, structural valve degeneration, and reoperation.

Our analysis is likely an underestimate of the number of potentially available valves, as we believe explanted hearts of recipients undergoing an orthotopic heart transplant may also be a source of fresh valve allografts. This practice was previously carried out in the 1980s to early 1990s, whereby

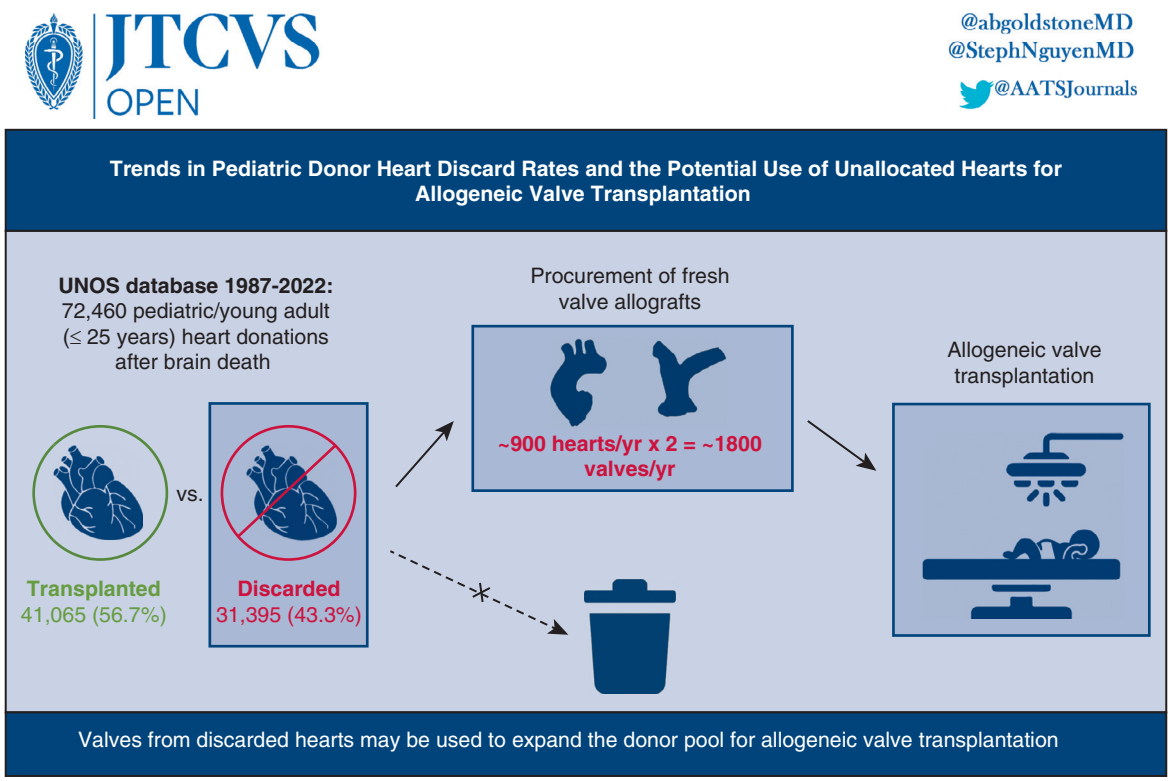


FIGURE 3. Trends in pediatric donor discard rates and the potential use of unallocated hearts for allogeneic valve transplantation. *UNOS*, United Network for Organ Sharing.

valves were harvested from the native heart of transplant recipients or brain dead donors and stored in nutrient medium at 4 °C on the order of hours to months before being transplanted.[4,8,9] The largest experience with these fresh homograft valves belongs to Yacoub and colleagues[4] who reported the use of 224 aortic valves harvested from the explanted native hearts of transplant recipients from 1980 to 1993. The homografts were implanted using either the freehand (subcoronary) technique or as a freestanding root replacement. The original cardiac disease included ischemic heart disease, cardiomyopathy, and congenital heart disease. Although the authors do not provide echocardiographic data on the function of the explanted valves, we presume that they were free from significant valvulopathy despite severe myocardial dysfunction or other intracardiac abnormalities. Long-term durability was excellent, with actuarial rates for freedom from degenerative valve failure of 94% ± 2% and 89% ± 3% at 5 and 10 years, respectively. Furthermore, freedom from valve-related complications (ie, reintervention, degeneration, endocarditis, and thromboembolism) was 92% ± 2% and 80% ± 5% at 5 and 10 years, respectively. Similarly acceptable outcomes were reported in smaller series.[8,9] Despite good durability, such homovital valves fell out of favor with the introduction of modern cryopreservation techniques that allow for prolonged storage and greater availability.[10] Nonetheless, the past success of this abandoned procedure validates the use of explanted native hearts without valve pathology to source allogeneic valve transplants.

The primary reason for nonutilization was poor organ quality, which presumably refers to ventricular dysfunction. In such cases, semilunar valve function was likely preserved, hence the significant number distributed to the heart valve industry for cryopreservation. In general, specific reasons for donor organ refusal and/or discard are poorly captured by network registry data. With newfound interest in allogeneic valve transplantation and to inform future organ allocation practices, we propose that all donor hearts deemed nontransplantable should be evaluated for procurement of fresh valves for allotransplantation using standardized assessment criteria, as for commercially prepared valves. A major drawback would be the tradeoff between fresh valves and cryopreserved homografts, which currently have limited availability in certain sizes.

Other common reasons for nonutilization of donor hearts were transplant or procurement logistical barriers, such as timing constraints, unavailability of a procurement team, or lack of a suitable recipient. Such issues are particularly pertinent to heart transplantation due to the stringent limitations on organ ischemic times. In contrast, procurement of isolated heart valves would be considerably

more flexible. Kwon and colleagues' investigation of aortic valve allograft viability with prolonged cold storage at 4 °C revealed preserved structural integrity, no increased level of apoptosis, and unchanged cellular metabolic activity for up to 48 hours, unlike hearts, which demonstrate cell death and myocardial necrosis after 6 hours of cold ischemia.[11] The longer permissible window of cold ischemia has multiple clinical implications. First, it may allow for an extended travel radius for donor harvests and organ sharing between OPTN regions to alleviate disparities in use. Second, this may have a substantial economic and environmental impact because entire procurement teams would not need to travel to and from the donor hospital in a private aircraft or vehicle. Instead, existing local procurement teams could harvest the valve and deliver it to the recipient hospital by commercial courier services, as is routinely done for kidney transplants.

There are several important limitations to this study. The retrospective nature of the study, compounded by analysis of a large database, limits the completeness and granularity of clinical data. As such, we were unable to determine the presence or severity of valve pathology or other clinical factors that may contraindicate valve harvest for allogeneic valve transplant in many donors. Additionally, we do not yet know the number of pediatric valve replacement surgeries performed annually to determine the exact supply and demand relationship.

CONCLUSIONS

Our study demonstrates that the annual number of discarded donor hearts represents a feasible source of valves for allogeneic valve transplant to become a valve replacement option nationwide. To further expand the donor pool, we propose that donor hearts turned down for transplant should be systematically evaluated for isolated valve donation. Also, explanted native hearts of heart transplant recipients may be another potential source of valve allografts. This redirects well-functioning valves to meet an important clinical need in congenital cardiac surgery.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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