

Systematic donor selection review process improves cardiac transplant volumes and outcomes

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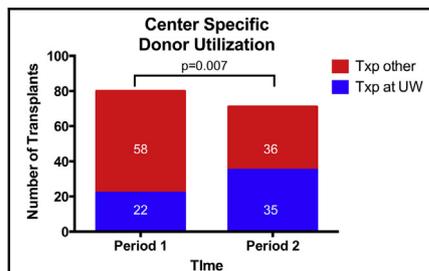
ABSTRACT

Background: Heart transplant remains the definitive therapy for advanced heart failure patients but is limited by organ availability. We identified a large number of donor hearts from our organ procurement organization (OPO) being exported to other regions.

Methods: We engaged a multidisciplinary team including transplant surgeons, cardiologists, and our OPO colleagues to identify opportunities to improve our center-specific organ utilization rate. We performed a retrospective analysis of donor offers before and after institution of a novel review process.

Results: Each donor offer made to our program was reviewed on a monthly basis from July 2013 to June 2014 and compared with the previous year. This review process resulted in a transplant utilization rate of 28% for period 1 versus 49% for period 2 ($P = .007$). Limiting the analysis to offers from our local OPO changed our utilization rate from 46% to 75% ($P = .02$). Transplant volume increased from 22 to 35 between the 2 study periods. Thirty-day and 1-year mortality were unchanged over the 2 periods. A total of 58 hearts were refused by our center and transplanted at other centers. During period 1, the 30-day and 1-year survival rates for recipients of those organs were 98% and 90%, respectively, comparable with our historical survival data.

Conclusions: The simple process of systematically reviewing donor turndown events as a group tended to reduce variability, increase confidence in expanded criteria for donors, and resulted in improved donor organ utilization and transplant volumes. (*J Thorac Cardiovasc Surg* 2016;151:238-43)



Graph showing an increase in heart utilization at our center despite a decrease in overall donors.

Central Message

Improving quality in donor selection can markedly increase transplant volume without compromising safety and quality.

Perspective

Heart transplant remains the gold standard treatment for end-stage heart failure, but is limited by donor availability, which has remained unchanged for 3 decades. We engaged in a donor selection review process to better understand our organ utilization and found that improving the consistency of donor selection improved our volumes and maintained outcomes, improving stewardship of a precious resource.

See Editorial Commentary page 243.

It is estimated that more than 6 million people in the United States suffer from heart failure, with 10 new diagnoses each year for every 1000 persons.¹ Orthotopic heart transplantation (OHT) remains the gold standard for end-stage heart failure in eligible patients.^{2,3} Transplant volumes in the US have remained static over the last 15 years at

approximately 2000 per year,⁴ largely due to decreasing rates of violent death, stricter seat belt and helmet legislation, improved airbag technology, and overall improvement in the trauma infrastructure.^{5,6} Owing to excellent long-term outcomes with OHT, many centers have proposed expanding the donor pool by considering organs from donors of older age, with increased infectious disease risk, with coronary artery disease, with left ventricular hypertrophy, with decreased ejection fraction, and others.⁷⁻¹⁰ Interestingly, however, despite this success, donor utilization rates have decreased nationwide.^{11,12} This decrease may be related to the increased use of left ventricular assist devices as a bridge to transplant, with these patients more stable than their inotrope-dependent counterparts.¹³ In addition, because of stable volumes, along with increased public scrutiny of outcomes, many centers may have evolved a risk-averse donor utilization scheme.

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Abbreviations and Acronyms

CDC	= Center for Disease Control
CDC-HR	= Centers for Disease Control and Prevention high-risk
OHT	= Orthotopic heart transplant(ion)
OPO	= Organ procurement organization
UNOS	= United Network for Organ Sharing

A review of the donor heart export rate in our organ procurement organization (OPO) found it higher than expected. In an effort to better understand organ utilization by our OPO and our center, we initiated a quality improvement initiative to examine this in detail. This study examines the donor utilization process at a single, moderate-volume center.

METHODS

The Institutional Review Board at the University of Washington granted approval for this study. A multidisciplinary group of transplant surgeons and cardiologists was assembled in collaboration with our local OPO. Retrospectively, all donor offers from July 2012 to June 2013 (period 1) were systematically reviewed. Along with demographic data, clinical parameters were captured from DonorNet, and refusal codes were collated. All organs refused by our center and subsequently transplanted elsewhere were analyzed to determine the presence of a potential candidate at our institution who was within a reasonable size range ($\pm 30\%$), devoid of unacceptable antigens, and in a position on the match run list to accept the organ.

From July 2013 through June 2014 (period 2), the multidisciplinary group implemented our quality improvement analysis of donor utilization. Using similar methodology, demographic data, clinical parameters, and refusal codes were analyzed. In addition, real-time rationales were captured at the time of organ refusal. The multidisciplinary group reviewed all organ refusals on a quarterly basis in a nonconfrontational setting. All of the refused organs that were ultimately transplanted and met the foregoing criteria were brought to a full quorum for open discussion. The review process was then continued as a regular element in our transplant program quality assessment program. The review process was facilitated to provide a constructive environment to encourage the development of best practices and consistency. Specific attention was given to pertinent literature to support decision making, and short-term outcomes on declined organs were obtained from the United Network for Organ Sharing report on organs offered to our center but transplanted elsewhere.

Statistical Analysis

All data were analyzed using the Prism 6 statistical software package (GraphPad Software, La Jolla, Calif). Continuous variables were recorded as means and compared using an unpaired Student *t* test. categorical variables were compared using Fisher's exact test, owing to the small sample sizes. A *P* value $\leq .05$ was used to determine the level of statistical significance. All reported *P* values are 2-sided.

RESULTS

Donor Characteristics

Over the period of review, 6 cardiac surgeons and 8 transplant cardiologists actively participated in donor selection. During period 1, there were 293 total heart offers, and 132

hearts were transplanted at any center. During period 2, there were 279 total heart offers, and 129 were transplanted at any center. Donor demographics and clinical parameters are presented in Table 1. Donor characteristics were similar in hearts transplanted at our institution and those transplanted at other institutions after our refusal across both time periods. Only 2 donor characteristics were statistically significantly different between the 2 groups: donor height was greater in our group (174-177 cm vs 169-170 cm; *P* = .04 for period 1, and *P* = .003 for period 2), and there was a higher incidence of gunshot wounds as an etiology of donor death in organs accepted at our institution versus those accepted elsewhere during period 1 (*P* = .03).

Donor Utilization

During period 1, of the 132 transplanted hearts, 80 were available to recipients at our institution with no provisional acceptance, with an appropriate size match, and without unacceptable antigens. Twenty-two transplants were performed by our center, yielding a center specific donor utilization rate of 28%. In period 2, 71 of the 129 transplanted hearts were available to recipients at our institution with similar characteristics. Thirty-five transplants were performed, yielding a significantly higher donor utilization rate of 49% (*P* = .007) (Figure 1). This increase in volume was sustained over the next year, July 2014 to June 2015, with volumes increasing again to 43 transplants. Survival data are not yet available for this time period. Over this same later period, the total number of offers declined again, to 222. Of those hearts, 132 were ultimately transplanted at some institution, and of those 71 were available to our institution based on the foregoing criteria. This yielded a center utilization rate of 61%. The vast majority of hearts transplanted at our institution originated within our OPO.

There was a statistically significant decrease in the rate of organ export over the 2 time periods. A total of 21 exports and 18 hearts were accepted and transplanted at our institution during period 1, compared with 9 and 27, respectively, during period 2. This represents an improvement in center-specific, OPO-limited utilization rate from 46% in period 1 to 75% in period 2 (*P* = .02) (Figure 2).

From the OPO perspective, in period 1 there were 77 heart offers and 45 were accepted for transplant, for an OPO utilization rate of 58.4%. During period 2, there were 61 heart offers and 40 acceptances, for an OPO utilization rate of 65.6% (*P* = .40).

Refusal Codes

We attempted to assess the variation in utilization of refusal codes. Although there was no statistical difference between the 2 periods in the use of refusal codes, there was a trend toward decreased use of codes for donor age/quality, from 39% to 32% (*P* = .15) and donor social history, from 8% to 5%. From period 1 to period 2, there was a

TABLE 1. Donor characteristics

Donor characteristic	Donors accepted for transplant			Donors available to our center but refused			P value, I vs III	P value, II vs IV
	I	II	P value, I vs II	III	IV	P value, III vs IV		
	Period 1 (n = 22)	Period 2 (n = 35)		Period 1 (n = 58)	Period 2 (n = 36)			
Age, y, mean	32.5	28.7	.22	35.2	33.9	.66	.39	.10
Male sex, n (%)	15 (68)	28 (80)	.36	34 (59)	21 (58)	1.00	.61	.07
Height, cm, mean	174	177	.28	169	170	.67	.04	.003
Weight, kg, mean	78.9	85.3	.14	76.8	84.6	.11	.66	.89
Body mass index, mean	25.9	27.3	.33	26.9	29.4	.13	.51	.24
ABO class, n (%)								
O	12 (54)	18 (51)	1.00	30 (52)	15 (42)	.40	1.00	.48
A	7 (32)	14 (40)	.58	16 (28)	16 (44)	.12	.78	.81
B	3 (14)	3 (9)	.67	12 (20)	5 (14)	.58	.54	.71
AB	0	0	—	0	0	—	—	—
Cause of death, n (%)								
Intracranial hemorrhage	2 (9)	3 (9)	1.00	13 (22)	10 (28)	.62	.22	.06
Closed head injury	9 (41)	12 (34)	.78	15 (26)	7 (20)	.62	.27	.19
Gunshot wound	9 (41)	6 (17)	.07	9 (16)	3 (8)	.36	.03	.33
Asphyxiation	1 (4.5)	7 (20)	.13	4 (7)	3 (8)	1.00	1.00	.19
Drug intoxication	1 (4.5)	5 (14)	.39	11 (19)	4 (11)	.39	.16	.74
Other	0	2 (6)	.52	6 (10)	9 (25)	.08	.18	.05
Ejection fraction, %, mean	64.5	62.3	.11	63.3	62.8	.70	.36	.76
CPR performed, n (%)	7 (32)	18 (51)	.18	25 (43)	21 (58)	.39	.44	.64
CDC-HR, n (%)	3 (14)	6 (17)	1.00	9 (16)	7 (19)	.78	1.00	1.00

CPR, Cardiopulmonary resuscitation; CDC-HR, Centers for Disease Control and Prevention high-risk.

nonsignificant increase in donors with a Centers for Disease Control and Prevention (CDC) high-risk designation (CDC-HR) transplanted at our institution (3 vs 6; $P = 1.0$). There was also a trend toward increased utilization of donors who underwent cardiopulmonary resuscitation, from 32% of the donors in period 1 to 51% in period 2 ($P = .18$). At the same time, there was an increase in use of the donor/recipient size mismatch code and the code for “other,” with an option to write in reasons during the second period.

Transplant Outcomes

A review of our transplant outcomes over the duration of the study revealed no significant difference in 30-day or 1-year mortality between period 1 and period 2 ($P = .38$ and $.67$, respectively) (Table 2). Using the United Network for Organ Sharing (UNOS) report, we were able to ascertain the function of organs that we refused but were ultimately transplanted elsewhere. We found follow-up data on 46 of the 58 hearts that were refused. The 30-day mortality was

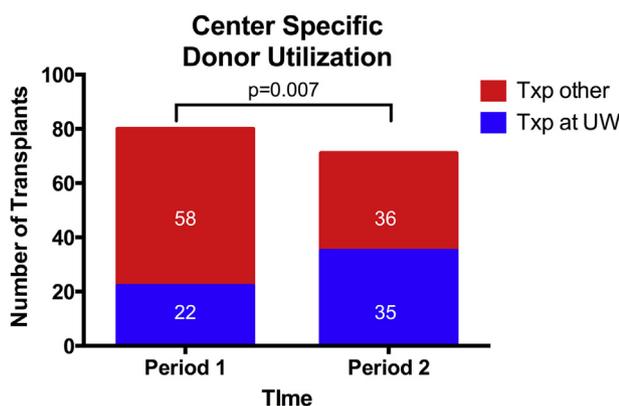


FIGURE 1. Center-specific donor utilization in periods 1 and 2, showing increasing utilization of available donor organs despite decreasing numbers of overall donors. UW, University of Washington.

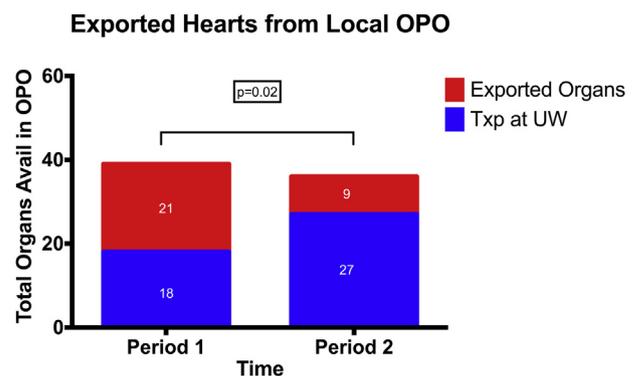


FIGURE 2. A reduction in the number of exported hearts from our local region from 21 to 9 accounted for most of the increased transplant volume at our center. UW, University of Washington; OPO, organ procurement organization.

TABLE 2. Transplant outcomes for recipients who underwent transplantation at our institution demonstrating that outcomes by these measures were unchanged despite increasing utilization

Measure	Period 1	Period 2	P value
Number	22	35	.22
Total ischemic time, min, mean	244.7	244.9	.99
Mechanical circulatory support, n (%)	2 (9)	5 (14)	.69
30-d mortality, n (%)	3 (14)	2 (6)	.38
1 year mortality, n (%)	3 (14)	3 (9)	.67

2%, and 1-year mortality was 10% (Figure 3). Owing to the delay in reporting outcomes with the UNOS offer report, we were able to obtain follow-up only for the recipients from other centers from period 1. The outcomes of patients on the waiting list at our center were also reviewed and we found a 17.2% mortality during period 1 and 12.0% mortality for period 2 ($P = .50$).

DISCUSSION

Because of the scarcity of donor organs, there is a worldwide imperative to maximize the utilization of suitable donors. The assessment of donor quality for heart transplantation remains an area of controversy and investigation.^{9,14} Programs have examined a multitude of donor factors in an attempt to expand the donor pool.^{9,15} Average donor age has increased over the last 20 years from a mean of 29 years to a peak of 33, followed by a drop to the current 31 years.¹² This is driven in part by an increase in the acceptable upper limit of donor age from 40 years to 50 years and even into the mid-60s in some aggressive centers.¹⁶⁻¹⁹ The use of CDC-HR donors has also been championed owing to the low risk of transmission with contemporary testing methods.²⁰ Studies of donor use of illicit drugs has also been investigated revealing that both remote and current narcotic use has no effect on transplant outcomes.²⁰ The use of methamphetamine- and cocaine-positive donors historically has been more controversial, but an emerging body of work affirms the safety of using carefully selected donors who are users of these substances.²¹⁻²³ Cardiopulmonary resuscitation in donors with return to normal function has not demonstrated adverse outcomes, and longer total ischemic time may be more acceptable than previously thought.²⁴⁻²⁶ The impact of left ventricular hypertrophy on donor quality is also facing scrutiny, and may be less restrictive than historically assumed.²⁷

Although the changes in the use of donor organs with each of these individual high-risk donor characteristics were not statistically significant at our center, the vector of change was in the direction of using more of these organs, which we feel accounts for the behavioral adaptation that has led to increased transplant volumes. There is a dedicated body of literature testifying to potential expansion

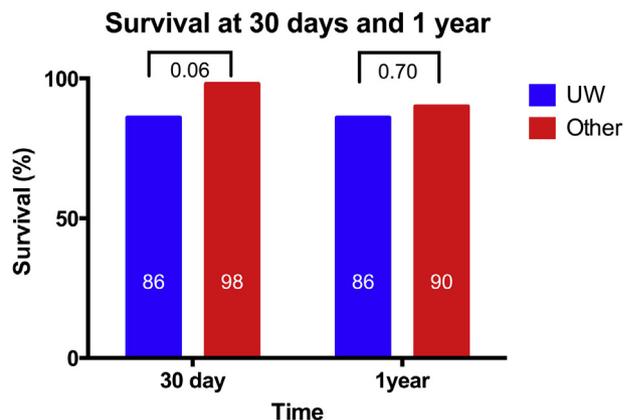


FIGURE 3. Survival at 30-days and at 1-year for our patients in period 1 compared with patients who received hearts that we refused over the same time frame. Only period 1 is reviewed to have sufficient follow-up for 1-year survival. UW, University of Washington.

of the donor pool and increasing our use of this precious resource. With that in mind, it remains somewhat surprising that no global increase in the donor pool has been seen in more than 3 decades.³ Some of that lack of growth is related to the decreasing numbers of high-quality donors from public health initiatives, as well as to improved acute neurologic care that may prevent progression to brain death.²⁸

The individual decision to use or discard a donor organ is one of the most challenging aspects of transplant medicine. It requires balancing donor risks against the exigencies of the recipient. We found a large number of hearts being exported from our OPO. By engaging in a systematic, proactive quality improvement process to examine this specific aspect, we were able to increase our use of hearts within our area from 46% to 75%, thereby increasing our transplant volume despite the fact that there were fewer total donor offers in period 2 of our study. Moreover, the use of organs from our local OPO increased over the study period, from 58.4% in period 1 to 65.6% in period 2. Although this was not a statistically significant increase, larger study numbers may bear out this trend.

This finding suggests that the local OPO continues to identify high-quality donor organs, and that our volume increase is related to a higher utilization rate rather than to an increase in supply. Our waitlist mortality decreased from 17% to 12% over the course of the study, which, although not statistically significant, does indicate that increasing use of organs that may be outside of the usual pattern is associated with a trend toward improved waitlist survival and needs to be considered when assessing donor hearts. As transplant lists continue to grow in the face of stagnating availability of donor organs, other technologies have sought to make inroads to meet the growing demand. Until ventricular assist devices begin to approach the long-term survival of OHT, we need to continue to carefully assess every available heart.²⁹

This quality improvement process was born out of a close collaboration between cardiology and cardiac surgery programs. We were able to conduct these reviews in an open and collegial manner that ignited excitement about the potential expansion of our program and providing a service to an ever-growing patient population. We also found the sessions to be educationally rich for trainees, who prompted a heart failure journal club to review transplant- and donor-related literature. This collegial atmosphere is essential to the success of this type of initiative and reflects common practice in many advanced heart failure programs.

Moving forward, our center continues to deliberately evaluate each heart offer. Although our donor utilization has increased dramatically, opportunities for further growth remain. We took more care when considering hearts refused by multiple centers, which we ultimately accepted and successfully transplanted. Further investigations into gender and size matching may be worthwhile, and increased consideration of older donors may be reasonable. Finally, there was a significant number of hearts not ultimately transplanted by any center. This represents a large, untapped pool of potential donor hearts that might add to the net number of transplants performed nationally and not merely redistribute organs. A better understanding of the reasons why these hearts are refused for transplantation may allow us to identify opportunities to rescue some of these discarded organs. We plan to continue this effort by examining discarded organs in our region and evaluating factors or technologies that might help differentiate between unusable organs and those available for transplant.

CONCLUSIONS

We systematically examined our center's donor utilization practices using a nonconfrontational, proactive multidisciplinary approach. Through judicious use of relevant literature and frank discussion regarding individual and group bias, we were able to successfully reduce variability and increase our center-specific donor utilization. This resulted in increased transplant volumes at our program despite a decreasing donor pool and with no increase in perioperative morbidity or mortality.

Conflict of Interest Statement

Dr Smith is a consultant for Thoratec and is a primary site investigator for the EXPAND Trial sponsored by TransMedics. Dr Dardas is supported by the American College of Cardiology/Daiichi Sankyo Career Development Award. Dr Pal reports grant support from Tenax. Dr Levy is a consultant for HeartWare, Novartis, GE Healthcare, Pharmin, and Biotronik. Dr Mahr is a consultant for Thoratec, HeartWare, and Abiomed. Dr Mokadam is a consultant for Thoratec, HeartWare, Syncardia, and St Jude Medical, and is the recipient of research grants from Thoratec,

HeartWare, and Syncardia. All other authors have nothing to disclose with regard to commercial support.

We would like to credit the collaborative efforts of our organ procurement organization, LifeCenter Northwest, Bellevue, Washington. All staff members at LifeCenter Northwest have demonstrated their dedication to improving organ transplant in our region. Kevin O'Connor and Candy Wells deserve special mention for their instrumental role in accessing the data to help our center develop the quality improvement process that led to the increased utilization of donor organs in our region.

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Key Words: heart transplant, cardiac donor selection, organ utilization, transplant stewardship

EDITORIAL COMMENTARY

Saying yes or saying no!

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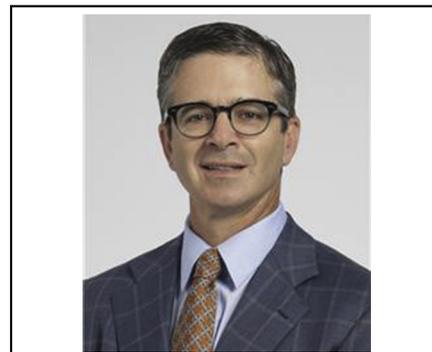
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In their article in this issue of the *Journal*, Smith and colleagues¹ from the University of Washington in Seattle demonstrate an impressive increase in donor heart use at both the transplant center and the local organ procurement organization through a multidisciplinary retrospective review of organ use practices. In the course of 3 years, their acceptance rate of offered hearts increased from 28% to 60%, doubling the transplant volume without an increase in transplant-associated mortality. Whereas intercenter organ use is a zero-sum game, if each organ procurement organization could increase the organ use by 7% annually, an additional 150 hearts could be transplanted in the United States each year.

The readers are challenged to ascertain how Smith and colleagues made such dramatic changes. Smith and colleagues refer somewhat euphemistically to “behavioral

adaptation” and “frank discussions” regarding “individual and group bias” as explanations, but understanding exactly how this is accomplished is not easy.

In his number one best seller *Thinking, Fast and Slow*, Daniel Kahneman,² (Nobel Prize in Economics in 2002)



Nicholas G. Smedira, MD

Central Message

Decision making with incomplete information is challenging. Multidisciplinary involvement reduces biases and increases organ use.

See Article page 238.