Extended Criteria - Donor Hearts
Defining Criteria and Outcomes

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UT Health Science Center & Memorial Hermann Hospital

Center for Advanced Heart Failure
The HF Stats

- 5.8 million subjects (>20 y/o) in the USA have HF
- In 2030 > 8 million subjects in USA with HF
- > 910,000 patients diagnosed each year.
- 6.5 million hospital days each year.
- Annual number of hospitalizations
  - > 1 million as primary diagnosis
  - > 3 million as primary or secondary diagnosis.
- Re-hospitalization rates post-discharge
  - 25% within one month
  - 50% within 6 month
- The estimated direct and indirect cost of HF in the United States for 2012 was $30.7 billion
### Waiting list candidates as of today 5:33pm

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>121,445</td>
</tr>
<tr>
<td>Kidney</td>
<td>100,434</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1,037</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>1,940</td>
</tr>
<tr>
<td>Liver</td>
<td>14,758</td>
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<tr>
<td>Intestine</td>
<td>278</td>
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<tr>
<td><strong>Heart</strong></td>
<td><strong>4,164</strong></td>
</tr>
<tr>
<td>Lung</td>
<td>1,481</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>45</td>
</tr>
</tbody>
</table>

*All candidates will be less than the sum due to candidates waiting for multiple organs*
Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.
# HEART UTILIZATION

**Non-DCD donors younger than 55 years**

<table>
<thead>
<tr>
<th>Donor Recovery Date</th>
<th>N</th>
<th>% of donors</th>
<th>N</th>
<th>% of donors</th>
<th>N</th>
<th>% of donors</th>
<th>N</th>
<th>% of donors</th>
<th>N</th>
<th>% of donors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donors</strong></td>
<td>5190</td>
<td>100.0</td>
<td>5348</td>
<td>100.0</td>
<td>5425</td>
<td>100.0</td>
<td>5340</td>
<td>100.0</td>
<td>5260</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Donors with heart recovered</strong></td>
<td>2058</td>
<td>39.7</td>
<td>2247</td>
<td>42.0</td>
<td>2221</td>
<td>40.9</td>
<td>2148</td>
<td>40.2</td>
<td>2180</td>
<td>41.4</td>
</tr>
<tr>
<td><strong>Donors with heart transplanted</strong></td>
<td>2028</td>
<td>39.1</td>
<td>2223</td>
<td>41.6</td>
<td>2195</td>
<td>40.5</td>
<td>2133</td>
<td>39.9</td>
<td>2162</td>
<td>41.1</td>
</tr>
</tbody>
</table>

*OPTN*
Variability in donor utilization

- OPO performance
- Aggressiveness of transplant centers
- Donor age
The shortcoming in transplantation remains the relatively **stable organ supply** in the face of **rising organ demands**.

The lack of readily available organs in addition to increased scrutiny over quality and outcomes in health care, has led the Centers for Medicare and Medicaid Services (CMS) to **raise the standards** for individual institutional outcomes to match national mortality and graft survival outcomes.

*Kilic at al; J Thorac Dis 2014;6(8):1097-1104*
181 heart transplant pts
Divided into younger and older recipients, who received either optimal or ECD hearts
No differences in freedom from graft failure, RV failure, acute rejection, chronic rejection, neoplasia or CRF
### Traditional Donor Criteria

<table>
<thead>
<tr>
<th>Traditional cardiac donor selection criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> &lt;55 years old</td>
</tr>
<tr>
<td><strong>No history of chest trauma or cardiac disease</strong></td>
</tr>
<tr>
<td><strong>No prolonged hypotension or hypoxemia</strong></td>
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<tr>
<td><strong>Appropriate hemodynamics</strong></td>
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<tr>
<td>- Mean arterial pressure &gt; 60 mmHg</td>
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<tr>
<td>- Central venous pressure 8 to 12 mmHg</td>
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<tr>
<td><strong>Inotropic support less than 10 mg/kg/min (dopamine or dobutamine)</strong></td>
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<tr>
<td><strong>Normal electrocardiogram</strong></td>
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<tr>
<td><strong>Normal echocardiogram</strong></td>
</tr>
<tr>
<td><strong>Normal cardiac angiography (if indicated by donor age and history)</strong></td>
</tr>
<tr>
<td><strong>Negative serology (hepatitis B surface antigen, hepatitis C virus and human immunodeficiency virus)</strong></td>
</tr>
</tbody>
</table>
When accepting ECD

Appropriate donor selection and management has become paramount in maintaining and optimizing outcomes following heart transplantation.

Kilic at al; J Thorac Dis 2014;6(8):1097-1104
Clinical Investigation and Reports

Consensus Conference Report

Maximizing Use of Organs Recovered From the Cadaver Donor: Cardiac Recommendations: March 28–29, 2001, Crystal City, Va

Jonathan G. Zaroff, MD, Conference Co-Chair; Bruce R. Rosengard, MD, Conference Co-Chair; William F. Armstrong, MD; Wayne D. Babcock, BSN; Anthony D'Alessandro, MD; G. William Dec, MD; Niloo M. Edwards, MD; Robert S. Higgins, MD; Valluvan Jeevanandum, MD; Myron Kaufman, MD; James K. Kirklin, MD; Stephen R. Large, MD; Daniel Marelli, MD; Tammie S. Peterson, RN; W. Steves Ring, MD; Robert C. Robbins, MD; Stuart D. Russell, MD; David O. Taylor, MD; Adrian Van Bakel, MD; John Wallwork, MB; James B. Young, MD

Author Affiliations

Correspondence to Jonathan G. Zaroff, MD, UCSF Medical Center, 505 Parnassus Ave, Moffitt Suite 1176, San Francisco, CA 94143-0124. E-mail zaroff@medicine.ucsf.edu
Recommendations to Improve the Yield of Donor Evaluation

- Extracardiac Factors
  - Age
  - Size
  - Hep B+
- Structural Abnormalities
  - LVH
  - Valvular and Cong. Abn.
- CAOD
- Cardiac Enzymes
- ECHO Evaluations
- Improved Donor Mgt.
- Potentially creating an alternate recipient list
Extended Donor Criteria

- Age > 60
- ECHO abnormalities
- Prolonged ischemic time
- Donor / Recipient size mismatch > 30 %
- + Blood/Urine/Sputum cultures
- Hepatitis B and/or C
- Significant pressor/inotrope requirements
- Donor Substance abuse
- Long Standing DM
- CAOD
- Structural cardiac abnormalities
Age

- Early days < 35 y/o donors
- **Today - 50% Donors - age 18 -35**
- odds ratio for mortality based on donor age
  - 50-59 years old: OR 1.8 (1.4-2.0);
  - 40-49 years old: OR 1.7 (1.3-1.7);
  - 30-39 years old: OR 1.3 (1.1-1.5)
  all with P<0.05

Effect of Donor Age on Long-Term Survival Following Cardiac Transplantation

Veli K. Topkara, M.D., Faisal H. Cheema, M.D., Satish Kesavaramanujam, M.D., Michelle L. Mercando, B.A., Catherine S. Forster, B.A., Michael Argenziano, M.D., Barry C. Ersig, M.D., Mehmet C. Oz, M.D., and Yoshifumi Naka, M.D.

Department of Cardiothoracic Surgery, Columbia University College of Physicians and Surgeons, New York, New York

Abstract: Background and Aim: The current shortage of donor hearts has forced the criteria of organ procurement to be extended, leading to increased use of older donor hearts to bridge the gap between demand and availability. Our objective was to analyze the effect of donor age on outcomes after cardiac transplantation. Methods: We retrospectively studied 894 patients who underwent cardiac transplantation at New York Presbyterian Hospital–Columbia University between 1992 and 2002. Patients were divided into two groups: donor age < 40 years (Group A, n = 690) and donor age ≥ 40 years (Group B, n = 204). Results: Characteristics including gender, body mass index, and cytomegalovirus (CMV) status were significantly different between the two donor age groups. Race, CMV status, toxoplasmosis status, left ventricular assist device prior to transplant, diabetes mellitus, and retransplantation were similar in both the recipient groups, white age, gender, and BMI were different. Early mortality was lower in Group A, 5%, versus 0.5% in Group B. Multivariate analysis revealed recipient female gender (odds ratio (OR) = 1.71), retransplantation (OR = 1.93), and increased donor age (OR = 1.92) as significant predictors of poor survival in the recipient population. Actuarial survival at 1 year (86.7% vs 81.1%), 5 years (75% vs 65%), and 10 years (58% vs 42%) was significantly different as well as a log rank p = 0.002. Conclusions: These findings suggest that increased donor age is an independent predictor of long-term survival. However, the shortage of organs makes it difficult to follow strict guidelines when placing hearts. Therefore, decisions need to be made on a relative basis.

Orthotopic heart transplantation with donors greater than or equal to 60 years of age: a single-center experience

Giuseppe Bruschi*, Tiziano Colombo, Fabrizio Oliva, Nuccia Morici, Luca Botta, Aldo Cannata, Maria Frigerio, Luigi Martinelli

Cardiology & Cardio-Thoracic Surgery Department, Niguarda Ca' Granda Hospital, Milan, Italy

Received 30 August 2010, revised in revised form 2 February 2011, accepted 4 February 2011; available online 29 March 2011

Abstract

Objectives: Heart transplantation is the best therapeutic option for patients suffering from end-stage heart failure, but donor organ availability still represents a major problem. This had led to a drift toward extended donor criteria. The aim of the present study is to analyze the short- and long-term results of heart transplantation in patients with donor age ≥ 60 years. Methods: Since November 1985, 890 patients have been transplanted at our center. We consider, for the present study, only primary adult heart transplantsations performed after 1990, totaling 741 patients, mean age at transplantation 49.9 years, and 16% patients being male (81%). We compare the short- and long-term results of patients transplanted with donors younger than 60 years or ≥ 60 years. Results: Since 1990, at our center, 711 patients have been heart transplanted with a donor younger than 60 years, while 50 patients received a heart from a donor older than 60 years. No differences have been reported in the etiology of cardiomyopathy, previous surgery, or mean ischemic time. Patients transplanted with donors ≥ 60 years of age were significantly older compared to the younger donor group. Donor cause of death was a cerebrovascular accident in 62% of donors ≥ 60 years versus 41% in younger donors. Patients’ heart transplanted with donors ≥ 60 years had a higher incidence of acute graft failure with a hospital mortality of 32% (16 patients) significantly higher compared to 10.2% for the other group. No differences were noticed in the incidence of renal failure, acute rejection treated, coronary angiogram vasculopathy, and neoplasm during long-term follow-up. Conclusions: It was possible to expand the cardiac donor pool by accepting allografts from donors ≥ 60 years of age in selected cases by performing a coronary angiogram. A meticulous donor evaluation and a careful risk assessment between the risk of death on the waiting list and probable increased hospital mortality are needed.

Keywords: Heart transplantation; Donors ≥ 60 years
Adult Heart Transplants (2008-6/2013)
Risk Factors For 1 Year Mortality with 95% Confidence Limits

Donor Age

Donor Age

Hazard Ratio of 1 Year Mortality

p < 0.0001

(N = 10,904)
Adult Heart Transplants
Kaplan-Meier Survival by Donor Age Group
(Transplants: January 1982 – June 2013)

Median survival (years):
0-10=10.6; 11-39=11.2; 40-59=9.4; 60+=6.4

All pair-wise comparisons were significant at p < 0.05 except 0-10 vs. 11-39 and 0-10 vs. 40-59.
Adult and Pediatric Heart Transplants
Median Donor Age by Location

- **Europe**
- **North America**
- **Other**

<table>
<thead>
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<th>Year</th>
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<tr>
<td>2012</td>
<td>140</td>
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<tr>
<td>2013</td>
<td>145</td>
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</table>

*JHLT. 2014 Oct; 33(10): 996-1008*

*JHLT. 2015 Oct; 34(10): 1244-1254*
Donor Heart Function

- St/p CPR
- Head Trauma and low EF
- Thoracic Trauma
- High Inotropics/vasoactive support
- Nonspecific ST changes
- Elevated CPKK-MB or Troponin
ECHO

• Every door should have one!
• LVH
• Ventricular function
• Valve dysfunction
Outcome in Cardiac Recipients of Donor Hearts With Increased Left Ventricular Wall Thickness


*Department of Cardiovascular Surgery, Stanford University, Stanford, CA
#Department of Cardiovascular Surgery, Stanford University, Stanford, CA

The ongoing shortage of donors for cardiac transplantation has led to a trend toward acceptance of donor hearts with some structural abnormalities including left ventricular hypertrophy. To evaluate the outcome in recipients of donor hearts with increased left ventricular wall thickness (LVWT), we retrospectively analyzed data for 175 cardiac donors and respective recipients from January 2001 to December 2004. There were 47 recipients of donor heart with increased LVWT ≥ 1.2 cm, which constituted the study group and 110 recipients of a donor heart with normal LVWT < 1.2 cm that formed the control group. At 2–1.5 years, recipient survival was lower (50% vs. 82%, p < 0.0003) and incidence of allograft vasculopathy was higher (50% vs. 22%, p < 0.001) in recipients of donor heart with LVWT > 1.4 cm as compared to LVWT < 1.4 cm. Cox regression, donor LVWT > 1.4 cm (p < 0.001), recipient preoperative ventricular assist device (VAD) support (p < 0.04), and bypass time > 150 min (p < 0.05) were predictors of reduced survival. Our results suggest careful consideration of donor hearts with echocardiographic evidence of increased LVWT in the absence of hypovolemia, because they may be associated with poorer outcomes; such hearts should potentially be reserved only for the most desperately ill recipients.

Methods

Data analysis
We retrospectively analyzed data on the 175 consecutive cardiac transplant recipient and donor pairs for patients transplanted between January 2001 and December 2004 at Stanford University Medical Center and the UT Southwestern Medical Center.

Available among other efforts to enhance the cardiac donor pool, "extended" donor criteria have been proposed to allow utilization of donor hearts that do not meet standard criteria, such as hearts with reduced left ventricular ejection fraction (LVEF), coronary artery disease or left ventricular hypertrophy (LVH) [1-4]. Such proposals led to the creation of alternative recipient lists in some centers designed to match such "extended criteria" donors with "extended criteria" severely older recipients. In 1997, a higher incidence of early graft failure was reported in the recipients of donor hearts with LVH at one center [1]. However, other centers did not observe any decrease in survival in such recipients [2,3]. Although regression of donor heart ventricular hypertrophy has been noted in cardiac recipients [4-5], there remains a reluctance to accept donor hearts with LVH based on these studies. Over time, recipient factors such as hypertension and LVH and allograft rejection also contribute to the reduced survival of LVH hearts and may influence outcomes.

We conducted this retrospective study to compare mortality, occurrence of allograft vasculopathy and incidence of rejection in recipients of donor hearts with increased left ventricular wall thickness (LVWT) and those with normal LVWT at our institutions. We also wanted to define the severity of LVWT at which the unfavorable outcomes were observed and if there were any donor and recipient characteristics that also influenced the outcomes.

Conclusion

The results of our study suggest that LVWT > 1.2 cm is associated with decreased survival in cardiac transplant recipients. The occurrence of allograft vasculopathy and the incidence of rejection were also higher in recipients of donor hearts with LVWT > 1.4 cm. These findings highlight the importance of carefully considering donor hearts with increased LVWT and the need for alternative criteria to optimize outcomes in cardiac transplantation.

References

Cardiac function - Inotrops

- A multi-institutional retrospective study of 512 patients showed that the donor use of norepinephrine infusion did not negatively affect early survival (1).
- High doses of inotrops should be carefully evaluated in combination with other risk factors (such as older age and longer ischemic times) (2).

Although it is usually accepted not to use donors with multi-vessel coronary arterial disease for transplantation, several centers have reported with modest success in the use of single- or two-vessel-affected donor hearts (1-3).

Coronary atherosclerosis of the donor heart — impact on early graft failure

Onnen Grauhan*, Henryk Sniawski, Michael Dandel, Hans Lehmkuhl, Christoph Knosalla, Miralem Pasic, Yu-Guo Weng, Roland Hetzer

German Heart Institute, Berlin, Germany

Received 26 July 2006; received in revised form 28 June 2007; accepted 2 July 2007; Available online 15 August 2007

Abstract

Objective: Due to the shortage of donor hearts, the criteria for organ acceptability have been considerably extended and donor grafts with coronary atherosclerosis are among those offered. This study evaluated whether and to what degree pre-existing coronary atherosclerosis may be acceptable. Methods: A total of 1253 consecutive HTx recipients were investigated retrospectively for donor-transmitted coronary athero-
sclerosis (DCA). Donor-transmitted coronary atherosclerosis was defined as focal atherosclerosis with stenosis of at least 50%. Inclusion criteria were absence of pre-HTx angiogram but performance of angiogram or autopsy within 6 months after heart transplantation. Kaplan–Meier analysis and log-rank test were used. Results: Eighty-five out of 1253 (6.8%) cases were excluded, since coronary evaluation was not performed within 6 months (n = 45) or hearts had undergone pre-transplant angiography (n = 40). In 1096 patients no donor-transmitted coronary atherosclerosis was found (NDAS group) and in 82 patients (7%) donor-transmitted coronary atherosclerosis was diagnosed by angiography (n = 49) or autopsy (n = 33). Single-vessel donor-transmitted coronary atherosclerosis was found in 53/82 patients (DCA1 group) and double- or triple-vessel donor-transmitted coronary atherosclerosis in 26/82 patients (DCA2/3 group). Three of the 82 patients with donor-transmitted coronary atherosclerosis were excluded since the autopsy report was unclear regarding degree of atherosclerosis. Early after heart transplantation the 30-day mortality in the NDAS and DCA1 groups was 12.2% versus 13.2% whereas in the DCA2/3 group it was 61.5%. Beyond the first year the annual decrease with and without donor-transmitted coronary atherosclerosis (single-vessel disease) is comparable. Conclusions: Donor screening without coronary angiogram overlooks significant atherosclerotic lesions in a considerable number of cases (7.8%). Therefore, angiographic donor screening should be performed. Donor grafts with single-vessel coronary atherosclerosis may be accepted as marginal hearts, however, in our opinion, revascularisation (CABG, PTCA) should be considered. Grafts with two- or even three-vessel coronary atherosclerosis seem to have a serious risk for early graft failure. Beyond the first year the outcome of healthy grafts and grafts with donor-transmitted coronary atherosclerosis seems to be comparable.

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Donor Recipient Compatibility

• The downside of gender mismatch is observed more in male recipients from female donors and is correlated with both frequency and severity of graft rejection (1).

Adult Heart Transplants
Kaplan-Meier Survival by Donor/Recipient Gender
(Transplants: January 1982 – June 2013)

Median survival (years):
Male/Male=10.8; Male/Female=11.0;
Female/Male=9.6; Female/Female=11.4

All pair-wise comparisons with Female/Male were significant at p < 0.0001. No other pair-wise comparisons were significant at p < 0.05.
Donor Recipient Compatibility cont.

- Do not undersize > 30 % in Pts w Pulm. HTN or F to M
- Not to oversize > 30 % in Pts w LVADs, recent AMI, Redo sternotomy
Ischemic Time

• ischemia time was shown to be an independent risk factor for survival with an Odds Ratio of 1.7 (1.0-2.8) in patients with an ischemic time >6 hours and an OR of 1.4 (1.3-1.6) in patients with an ischemic time between 4-6 hours (P<0.05 for both) (1).

Adult Heart Transplants (2008-6/2013)
Risk Factors For 1 Year Mortality with 95% Confidence Limits

Ischemia time

Hazard Ratio of 1 Year Mortality

Ischemia time (hours)

p = 0.0007

(N = 10,904)
Donor Predictors of Allograft Utilization and Recipient Outcomes after Heart Transplantation

Kiran K. Khush, MD, MAs1, Rebecca Menza, ACNP, MS2, John Nguyen, RN3, Jonathan G. Zaroff, MD3, and Benjamin A. Goldstein, PhD5

1Division of Cardiovascular Medicine, Department of Medicine, Stanford University School of Medicine, Palo Alto, CA 2Graduate School of Nursing, Midwifery, and Health, Victoria University of Wellington, New Zealand 3California Transplant Donor Network, Oakland, CA 5Kaiser Northern California Division of Research, Oakland, CA 6Quantitative Sciences Unit, Department of Medicine, Stanford University School of Medicine, Palo Alto, CA

Abstract

Background—Despite a national organ donor shortage and a growing population of patients with end-stage heart disease, the acceptance rate of donor hearts for transplantation is low. We sought to identify donor predictors of allograft non-utilization, and to determine whether these predictors are in fact associated with adverse recipient post-transplant outcomes.

Methods and Results—We studied a cohort of 1,872 potential organ donors managed by the California Transplant Donor Network from 2001–2008. Forty-five percent of available allografts were accepted for heart transplantation. Donor predictors of allograft non-utilization included age≥50 years, female sex, death due to cerebrovascular accident, hypertension, diabetes, a positive troponin assay, left ventricular dysfunction and regional wall motion abnormalities, and left ventricular hypertrophy. For hearts that were transplanted, only donor cause of death was associated with prolonged recipient hospitalization post-transplant, and only donor diabetes was predictive of increased recipient mortality.

Conclusions—While there are many donor predictors of allograft discard in the current era, these characteristics appear to have little effect on recipient outcomes when the hearts are transplanted. Our results suggest that more liberal use of cardiac allografts with relative contraindications may be warranted.
Reasons not to use the organs

- Age > 50
- Female sex
- CVA
- HTN, DM
- LV Disfunction
- Wall motion Abnormality
- Elevated Troponin
In 2004, the United Network for Organ Sharing (UNOS) added the label “high risk” for any organ donor who met the Center for Disease Control (CDC) criteria for high infectious risk behavior. It is our experience that this has led to the refusal of otherwise high quality grafts by families and medical professionals.

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**CDC “High Risk” Donor Status Does Not Significantly Effect Patient Outcome in Pediatric Heart Transplantation**

Hep “C” +

- OR 2.2 (1.1 – 4.0) for mortality  p < 0.05
- Centers abandon the use of high risk social behavior patients
  - Incarceration
  - Tatoos
  - Alternative lifestyle
  - Substance abuse
Cocaine use

- UNOS Database study
  - Cocaine use by Donor
    - Does not alter mortality
    - Does not increase incidence of Vasculopathy

Increased Troponin

Donor Cardiac Troponin I Levels Do Not Predict Recipient Survival After Cardiac Transplantation

Kiran K. Khush, MD, a Rebecca L. Menza, ACNP, MS, b Wayne D. Babcock, RN, b and Jonathan G. Zaroff, MD a

Background: Serum levels of cardiac troponin I (cTnI) are frequently measured in the evaluation of potential heart donors. However, the utility of cTnI levels for predicting recipient outcomes remains controversial. This study was performed to determine whether donor cardiac cTnI levels exceeding 1.0 μg/liter are associated with adverse recipient outcomes.

Methods: All donors managed by the California Transplant Donor Network between January 2001 and July 2002 with consent for donor evaluation and at least 1 measured cTnI level were included in the study if 1-year recipient mortality data were available. Each study subject was classified as having elevated cTnI if any level exceeded 1.0 μg/liter. Donor variables, recipient risk of 30-day and 1-year mortality, and recipient need for mechanical circulatory support were compared between the 2 groups.

Results: A total of 263 potential donors were evaluated, and 98 had elevated cTnI levels. Of these potential donors, 139 were accepted for transplantation. The cTnI levels were normal in 96 and elevated in 43. Most donors (77%) with elevated cTnI levels had levels of less than 10 μg/liter. Donor cardiopulmonary resuscitation was associated with cTnI elevations. Donors with elevated cTnI levels did not require higher doses of inotropic drugs before transplantation and had similar hemodynamic profiles compared with donors with normal cTnI levels. Although there was a trend towards longer post-transplant hospitalization in recipients of grafts from donors with elevated cTnI levels (17 days vs 15 days, p = 0.044), there was no significant difference in the recipient need for mechanical circulatory support or 30-day and 1-year mortality between the 2 groups.

Conclusions: In this study, a modestly elevated donor cTnI was not associated with a higher risk of recipient mortality or need for post-transplant mechanical circulatory support. A potential donor heart should not be discarded solely because the troponin level is elevated. J Heart Lung Transplant 2007;26: 1048–53. Copyright © 2007 by the International Society for Heart and Lung Transplantation.

263 donors
139 accepted for Tx
43 with elevated troponin - most (77%) with levels < 10 micro g/liter
Trend for longer LOS, however
No diff. in need for MS or 30 day and 1 yr mortality
Compromised LV Function

- Needs optimization of pre TX management
- Stress ECHO
- Awaiting - to improved function if feasible

Stunned Donor’s heart

Research Article

Donor Heart Utilization following Cardiopulmonary Arrest and Resuscitation: Influence of Donor Characteristics and Wait Times in Transplant Regions

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Department of Cardiothoracic Surgery, Virginia Commonwealth University, Richmond, VA 23298, USA

Correspondence should be addressed to Mohammed Quader; mquader@mcvh-vcu.edu

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Background. Procurement of hearts from cardiopulmonary arrest and resuscitated (CPR) donors for transplantation is suboptimal. We studied the influences of donor factors and regional wait times on CPR donor heart utilization. Methods. From UNOS database (1998 to 2012), we identified 44,744 heart donors, of which 4,964 (11%) received CPR. Based on procurement of heart for transplantation, CPR donors were divided into hearts procured (HP) and hearts not procured (HNHP) groups. Logistic regression analysis was used to identify predictors of heart procurement. Results. Of the 4,964 CPR donors, 1,427 (28.8%) were in the HP group. Donor characteristics that favored heart procurement include younger age (25.5 ± 12 yrs versus 39 ± 18 yrs, P ≤ 0.0001), male gender (34% versus 23%, P ≤ 0.0001), shorter CPR duration (<30 min versus >30 min, P ≤ 0.0001), and head trauma (50% versus 15%). Among the 11 UNOS regions, the highest procurement was in Region 1 (37%) and the lowest in Region 3 (24%). Regional transplant volumes and median waiting times did not influence heart procurement rates. Conclusions. Only 28.8% of CPR donor hearts were procured for transplantation. Factors favoring heart procurement include younger age, male gender, shorter CPR duration, and traumatic head injury. Heart procurement varied by region but not by transplant volumes or wait times.
Transplant of stunned donor hearts rescued by pharmacological stress echocardiography: a “proof of concept” report

Tonino Bombardini1†, Sonia Gherardi1, Ornella Leone1, Rosa Siani1 and Eugenio Piana1

Abstract

Background: Due to the shortage of donor hearts, the criteria for acceptance have been considerably expanded. Hearts with regional or global left ventricular dysfunction are excluded from donation, but stress echo might be useful to identify patients with reversible wall motion abnormalities, potentially eligible for donation.

Methods: Six marginal candidate donors (mean age, 40 ± 13 years; three men) were enrolled. Resting echocardiography showed in all subjects a LV ejection fraction ≥ 45% (mean 51 ± 5%), but multiple risk factors were present. All donors had either global or discrete wall motion abnormalities. Wall Motion Score Index (WMSI) rest = 1.33 ± 0.25. Stress echocardiography was performed with the dipyridamole high dose of 0.84 mg/kg given over 6 min.

Results: The stress echo results were abnormal in three donors (WMSI rest = 1.51 ± 0.19 vs peak = 1.41 ± 0.30). These hearts were excluded from donation and cardiac pathology verification was available in two cases of confirmed LV myocardial fibrosis and/or severe coronary stenosis. The remaining three hearts improved during stress (WMSI rest = 1.15 ± 0.13 vs peak = 1.04 ± 0.09) and were transplanted uneventfully. Recipients (three male, mean age 53 ± 4 years) underwent post-TX coronary angiography, IVUS and endomyocardial biopsies. No recipient had primary graft failure, and all showed normal coronary angiography and normal LV function. EF = 57 ± 6%; WMSI = 1 ± 0) at 1-month post-TX. The recipients were alive at 12-month median follow-ups.

Conclusions: Dipyridamole stress echo performed in brain-dead potential donors with LV resting global or discrete wall motion abnormalities identifies hearts with severe morphologic abnormalities excluded from donation (wit fixed response during stress echo) from hearts eligible for donation, showing improvement in regional wall motion during stress feasibility and normal function and coronary anatomy following transplantation.

Keywords: Heart transplant, Heart donor shortage, Stress echocardiography, Reversible wall motion abnormalities, Early graft failure

Heart transplantation outcomes from cardiac arrest–resuscitated donors

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BACKGROUND: The aim of this study was to compare the outcomes of heart transplantation from cardiopulmonary-resuscitation donors (CPR) to those who received hearts from donors who did not require cardiopulmonary resuscitation (CPR).

METHODS: This investigation was a retrospective analysis of UNOS adult heart transplantation donor and recipient data from May 1994 through July 2012. Continuous variables were compared using the chi-square test. Continuous variables were compared using the t-test. Patient and graft survival rates were calculated using the actuarial method and compared using Wilcoxon's test.

RESULTS: Of the 79,342 adult heart transplants performed in USA during the study period, 497 patients (6.16%) received hearts from CPR donors. The patients in the CPR+ group were younger (23.5 ± 15 years vs 26.5 ± 14 years; p < 0.0001) and more likely to be female (51% vs 27%; p = 0.001). Mean duration of CPR in these donors was 20 minutes. UNOS listing status at the time of transplantation was Status IA for 54.3% of those in the CPR+ group and 46.9% in the CPR− group (p < 0.0001). More recipients were hospitalized and were in the intensive care unit at transplantation in the CPR+ group (56% vs 51%; p = 0.0001). Recipient survival at 30 days, 1 year and 5 years was 95.2%, 88.2% and 72.9% in the CPR+ group, and 94.7%, 78.7% and 74.4% in the CPR− group, respectively. Similarly, graft survival at 30 days, 1 year and 5 years was 94.7%, 87.6% and 71.9% in the CPR+ donor hearts, and 94.8%, 85.3% and 73.2% in the CPR− donor hearts, respectively.

CONCLUSIONS: This large, multicenter adult heart transplant database from across the USA did not show inferior outcomes in recipients of heart transplantation from selected CPR+ donors. Recipient and graft survival were similar over 5 years of follow-up.

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A cardioprotective preservation strategy employing ex vivo heart perfusion facilitates successful transplant of donor hearts after cardioplegic death

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Keywords: Ex vivo heart perfusion; Heart transplantation; Donor heart after cardioplegic death; Ex vivo.

Background: Ex vivo heart perfusion (EVP) has been proposed as a promising strategy for improving organ preservation. However, the clinical application of this technology has been limited due to technical challenges. We aimed to evaluate the feasibility and safety of using EVP for heart transplantation.

Methods: EVP was performed on ex vivo donor hearts by perfusing cold University of Wisconsin solution through the coronary arteries and the heart was preserved for 4 hours before reimplantation.

Results: EVP did not significantly affect the oxygenation of the donor hearts, and the hearts reperfused well after transplantation. The surviving donor hearts were functional and had a similar left ventricular ejection fraction to the native hearts.

Conclusions: EVP appears to be a viable strategy for improving organ preservation and may be a promising tool for heart transplantation.

Ex vivo heart perfusion: current clinical experience and the future

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Keywords: Ex vivo heart perfusion; Heart transplantation.

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Conclusions: EVP appears to be a viable strategy for improving organ preservation and may be a promising tool for heart transplantation.
International EXPAND Heart Pivotal Trial (EXPANDHeart)

This study is currently recruiting participants. (see Contacts and Locations)

Verified October 2015 by TransMedics

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Purpose

To evaluate the effectiveness of the OCS™ Heart to recruit, preserve and assess donor hearts that may not meet current standard donor heart acceptance criteria (as identified above) for transplantation to potentially improve donor heart utilization for transplantation

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tr>
<td>Heart Transplant</td>
<td>Device: Preservation of Hearts for Transplantation</td>
<td>Phase 3</td>
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Study Type: Interventional
Study Design:
- Endpoint Classification: Efficacy Study
  - Intervention Model: Single Group Assignment
  - Masking: Open Label
  - Primary Purpose: Treatment

Official Title: International Trial to Evaluate the Safety and Effectiveness of The Portable Organ Care System (OCS™) Heart For Preserving and Assessing Expanded Criteria Donor Hearts for Transplantation (EXPAND Heart Trial)

Resource links provided by NLM:
- MedlinePlus related topics: Heart Transplantation

Further study details as provided by TransMedics:
Case report - Transplantation

Intentional and successful use of a marginal donor heart with surgically-corrected interventricular communication

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Received 8 April 2010; received in revised form 13 June 2010; accepted 15 June 2010

Abstract

We describe a case of heart transplantation (HTx) performed using a heart from a 29-year-old donor who underwent surgical closure of a ventricular septal defect during childhood. Our 29-year-old patient was successfully discharged to a rehabilitation centre on day 20 post-transplantation. To our knowledge, this is the first report of an HTx performed with a “redo” donor heart with previous surgical correction of a congenital heart defect. The widespread use of HTx as a therapeutic option is currently limited by the increase in number of patients listed annually for this procedure. The concomitant lack of organ donors has led to the concept of ‘marginal donors’ to broaden the classic standard criteria of donor suitability, but these extended criteria do not consider the possibility of using hearts that have undergone surgical correction of simple congenital heart defects. There has been a considerable increase in the grown-up congenital heart disease population over the past 20 years. We discuss the feasibility of using these hearts for transplantation and consider the limitations and precautions of such practice.

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Keywords: Heart transplantation; Marginal donor; Congenital heart defect; Surgical correction
10 year Experience with ECD

454 patient transplanted
84 patients received heart from ECD
Pts were older (66.6 y/o vs 53.2 y/o)
Had more frequent DM (46.4% vs 24.6%)
and CKD
At 1 year:
Standard criteria Tx was 89% vs ECD was 86%
At 5 yrs 77% vs 66% respectively

Original Article

Ten-Year Experience With Extended Criteria Cardiac Transplantation

Marc D. Samsky, MD; Chetan B. Patel, MD; Ashley Owen, MD; Phillip J. Schulte, PhD; Jacob Jenster, MD; Paul B. Rosenbarg, MD; G. Michael Felker, MD, MHS; Carmelo A. Milano, MD; Adrian F. Hernandez, MD, MHS; Joseph G. Rogers, MD

Background—Extended criteria cardiac transplant (ECC) programs expand the transplant pool by matching donors and recipients typically excluded from the transplant process because of age or comorbidity. There is a paucity of data examining long-term outcomes with this strategy.

Methods and Results—Between January 2000 and December 2009, adult patients undergoing isolated heart transplant were prospectively classified as ECC based on prespecified criteria. Baseline characteristics and outcomes were compared between ECC and standard criteria cardiac transplant recipients. Two Cox proportional hazards models were developed. The first to identify clinical variables contributing to survival between the 2 groups, and the second to determine the additional risk associated with assignment to ECC. Among the 454 patients who underwent heart transplant, 84 (18.5%) were ECC. Compared with the patients who underwent standard criteria cardiac transplant, ECC patients were older (median, 66.6 years versus 53.2 years; P<0.001), with higher frequency of diabetes mellitus (46.4% versus 24.6%; P<0.001) and chronic kidney disease (median estimated glomerular filtration ratio, 55 versus 61.6 mL/min; P=0.001). After adjustment for baseline characteristics, standard criteria cardiac transplant survival was higher than ECC at 1 (89% versus 86%; P=0.18) and 5 (77% versus 66%; P=0.035) years. In a multivariate model that included listing criteria, creatinine (hazard ratio, 1.05 per 0.1 mg/dL; 95% confidence interval, 1.02–1.09; P=0.001) was a significant predictor of post-transplant mortality.

Conclusions—ECC is an acceptable alternative for advanced heart failure therapy in select patients. Age and renal dysfunction are important determinants of long-term survival and post-transplant morbidity. (Circ Heart Fail. 2013;6:1236–1248.)

Key Words: heart failure ■ survival ■ transplantation
Cardiac transplantation: the alternate list and expansion of the donor pool.

Patel J¹, Kobashigawa JA.

Abstract

PURPOSE OF REVIEW: Advances in immunosuppression and surgical techniques have allowed cardiac transplantation to become a viable option and the treatment of choice for select patients with end-stage heart failure. The success of the procedure has, however, led to a discrepancy between the number of donors available and the number of patients awaiting cardiac transplantation. As wait times for heart transplant recipients increase, nonstandard donor hearts are increasingly being used for higher risk recipients and critically ill (Status I) patients. We review the development of two recipient lists as a way to provide cardiac transplantation as an option to recipients who would be otherwise ineligible, and determine its impact on expanding the donor pool. Other methods of expanding the donor pool are also reviewed.

RECENT FINDINGS: The alternate list appears to be successful in offering transplantation to patients (mostly older patients) who would not normally be eligible for this life-saving procedure. The alternate list (by changing donor organ acceptance criteria) and ongoing programs to increase organ donation have helped to expand the donor pool.

SUMMARY: The donor organ shortage will continue as an increasingly older population develops end-stage organ disease. Expanding the donor pool by a variety of methods will be essential to extend the lives of these patients.
Conclusion

• ECD is an acceptable alternative for advanced heart failure therapy in select patients.

• Age and renal dysfunction are important determinants of long-term survival and post-transplant morbidity
No easy answers to improving and increasing donor heart availability

Requires continued concerted effort by all stakeholders
- Policy makers
- OPOs
- Donor hospitals
- Transplant centers
- General public
Thank You