# Extended Criteria - Donor Hearts

## *Defining Criteria and Outcomes*


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UT Health Science Center & Memorial Hermann Hospital

The University of Texas Medical School at Houston
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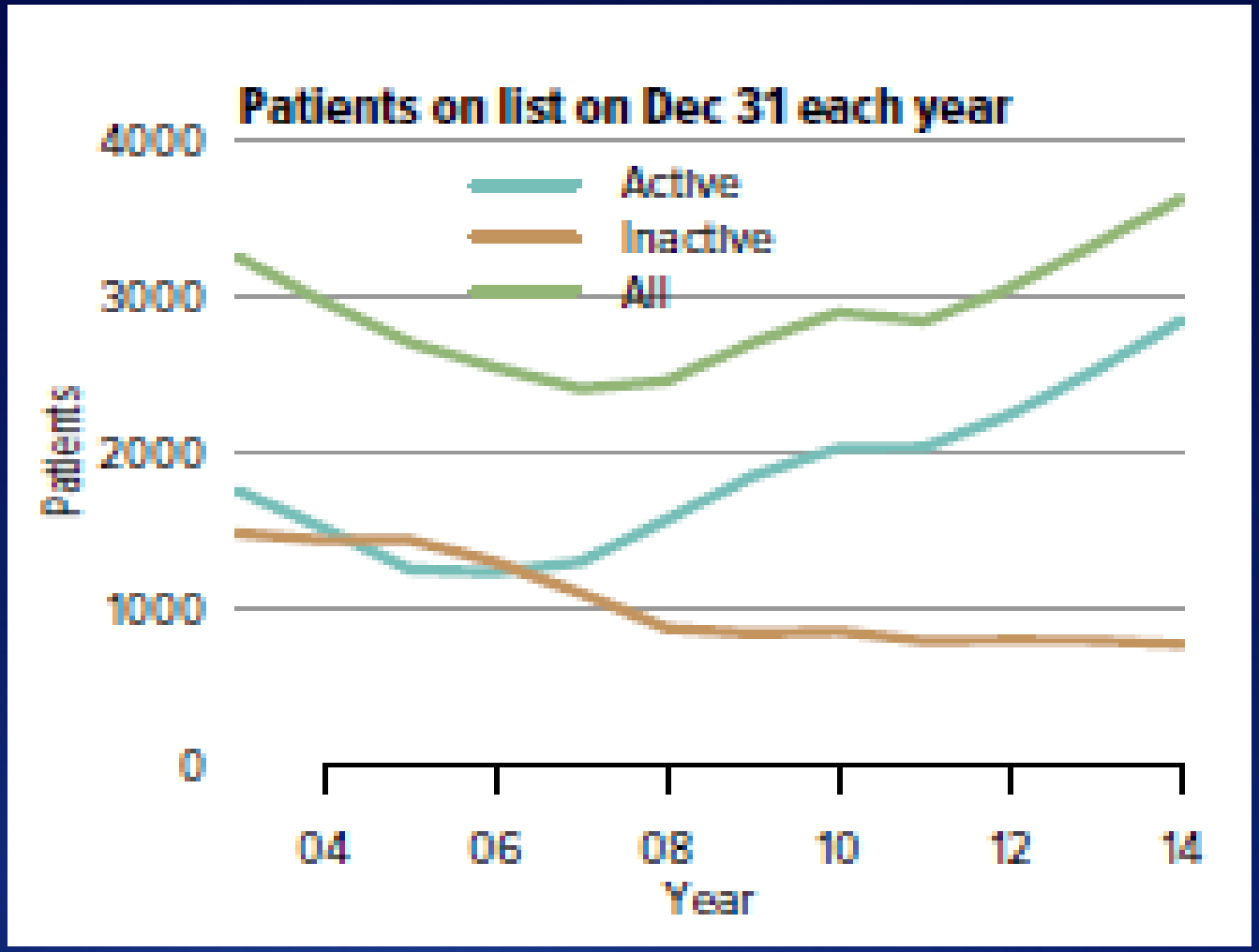
Center for Advanced Heart Failure

MEMORIAL HERMANN
Heart & Vascular Institute
Texas Medical Center

# The HF Stats

- **5.8 million subjects (> 20 y/o) in the USA have HF**
- **In y 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
  - > 3million 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

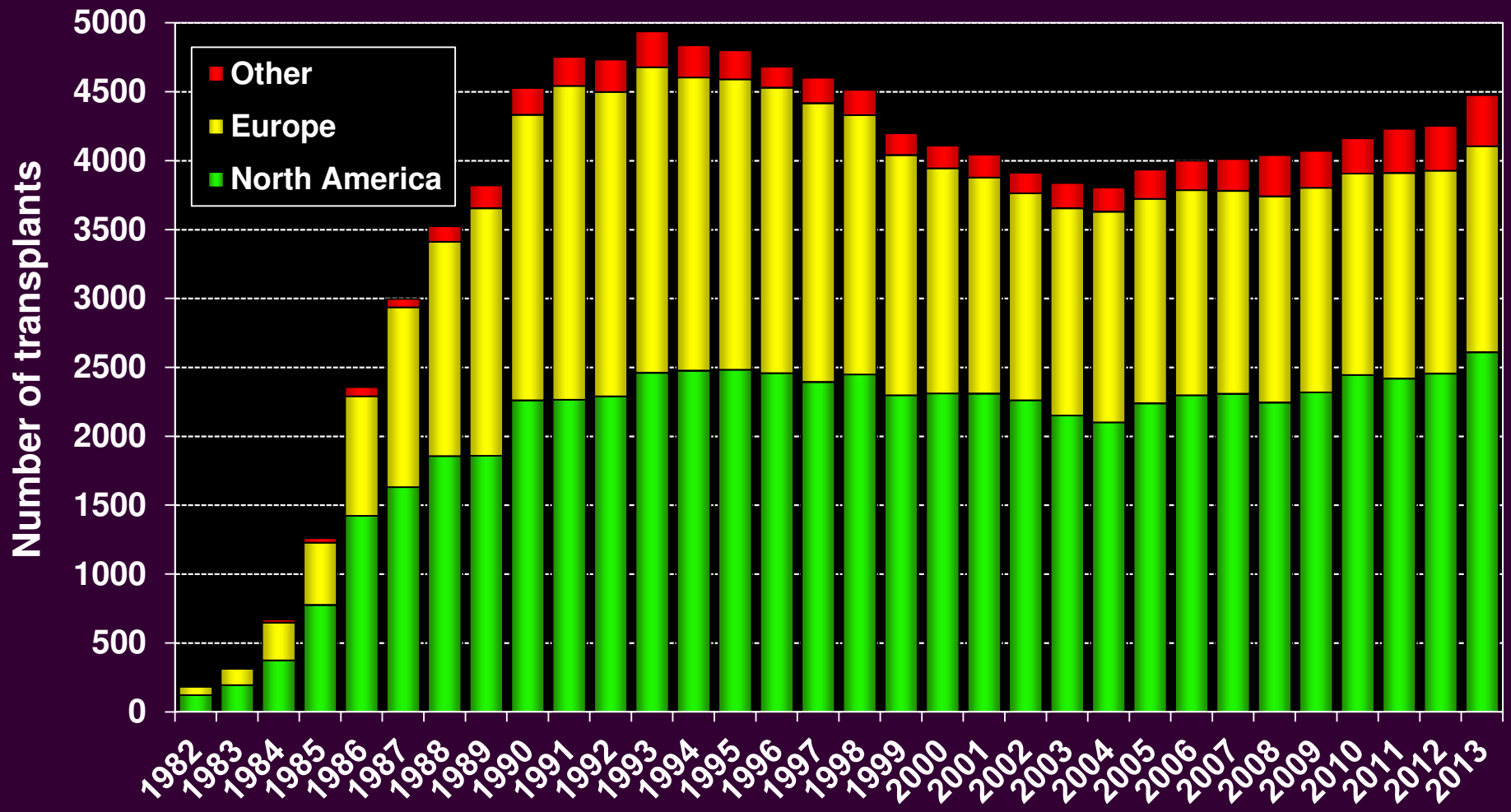

Patients on list on Dec 31 each year
4000
3000
2000
1000
0
Patients
Active
Inactive
All
04
06
08
10
12
14
Year

## Waiting list candidates as of today 5:33pm

| | |
|---|---|
| All ◆ | 121,445 |
| Kidney | 100,434 |
| Pancreas | 1,037 |
| Kidney/Pancreas | 1,940 |
| Liver | 14,758 |
| Intestine | 278 |
| Heart | 4,164 |
| Lung | 1,481 |
| Heart/Lung | 45 |

◆ 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.

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# HEART UTILIZATION

## Non-DCD donors younger than 55 years

| | Donor Recovery Date | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre-Policy Era -2: 7/12/04-7/11/05 | | Pre-Policy Era -1: 7/12/05-7/11/06 | | Post-Policy Era 1: 7/12/06-7/11/07 | | Post-Policy Era 2: 7/12/07-7/11/08 | | Post-Policy Era 3: 7/12/08-7/11/09 | | Post-Policy Era 4: 7/12/09-5/11/10 (Partial Year) | |
| | N | % of donors | N | % of donors | N | % of donors | N | % of donors | N | % of donors | N | % of donors |
| Donors | 5190 | 100.0 | 5348 | 100.0 | 5425 | 100.0 | 5340 | 100.0 | 5260 | 100.0 | 4239 | 100.0 |
| Donors with heart recovered | 2058 | 39.7 | 2247 | 42.0 | 2221 | 40.9 | 2148 | 40.2 | 2180 | 41.4 | 1853 | 43.7 |
| Donors with heart trans-planted | 2028 | 39.1 | 2223 | 41.6 | 2195 | 40.5 | 2133 | 39.9 | 2162 | 41.1 | 1845 | 43.5 |

OPTN

UNOS DONATE LIFE

# Variability in donor utilization

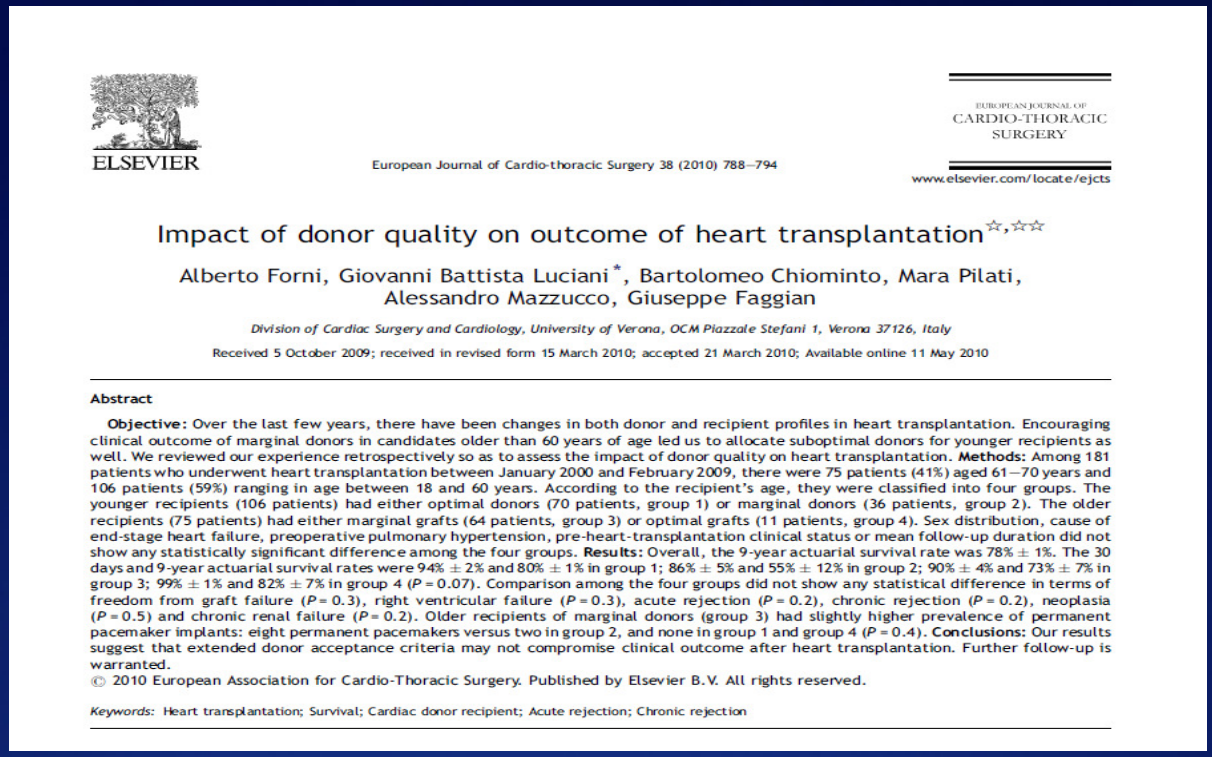
- **OPO performance**
- **Aggressiveness of transplant centers**
- **Donor age**

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



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EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

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# Impact of donor quality on outcome of heart transplantation☆,☆☆

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Received 5 October 2009; received in revised form 15 March 2010; accepted 21 March 2010; Available online 11 May 2010

**Abstract**

**Objective:** Over the last few years, there have been changes in both donor and recipient profiles in heart transplantation. Encouraging clinical outcome of marginal donors in candidates older than 60 years of age led us to allocate suboptimal donors for younger recipients as well. We reviewed our experience retrospectively so as to assess the impact of donor quality on heart transplantation. **Methods:** Among 181 patients who underwent heart transplantation between January 2000 and February 2009, there were 75 patients (41%) aged 61–70 years and 106 patients (59%) ranging in age between 18 and 60 years. According to the recipient's age, they were classified into four groups. The younger recipients (106 patients) had either optimal donors (70 patients, group 1) or marginal donors (36 patients, group 2). The older recipients (75 patients) had either marginal grafts (64 patients, group 3) or optimal grafts (11 patients, group 4). Sex distribution, cause of end-stage heart failure, preoperative pulmonary hypertension, pre-heart-transplantation clinical status or mean follow-up duration did not show any statistically significant difference among the four groups. **Results:** Overall, the 9-year actuarial survival rate was 78% ± 1%. The 30 days and 9-year actuarial survival rates were 94% ± 2% and 80% ± 1% in group 1; 86% ± 5% and 55% ± 12% in group 2; 90% ± 4% and 73% ± 7% in group 3; 99% ± 1% and 82% ± 7% in group 4 ($P = 0.07$). Comparison among the four groups did not show any statistical difference in terms of freedom from graft failure ($P = 0.3$), right ventricular failure ($P = 0.3$), acute rejection ($P = 0.2$), chronic rejection ($P = 0.2$), neoplasia ($P = 0.5$) and chronic renal failure ($P = 0.2$). Older recipients of marginal donors (group 3) had slightly higher prevalence of permanent pacemaker implants: eight permanent pacemakers versus two in group 2, and none in group 1 and group 4 ($P = 0.4$). **Conclusions:** Our results suggest that extended donor acceptance criteria may not compromise clinical outcome after heart transplantation. Further follow-up is warranted.



*Keywords:* Heart transplantation; Survival; Cardiac donor recipient; Acute rejection; Chronic rejection

## 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 rejectic neoplasia or CRF

# Traditional Donor Criteria

**Table 2** Traditional cardiac donor selection criteria (adapted from Sabiston & Spencer surgery of the chest, 8th ed. Sellke FW, del Nido PJ, Swanson SJ, *et al.* eds. Philadelphia: Saunders Elsevier, 2010)

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

# 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

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## 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 Kauffman, 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

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# 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 $P<0.05$

Hong KN, Iribarne A, Worku B, et al. Predicting mortality after heart transplant using pretransplant donor and recipient risk factors. Ann Thorac Surg 2011;92:520-7; discussion 527.

# AGE



## 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. Esrig, 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 864 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 = 600) and donor age $\geq 40$ years (Group B, n = 264).** ***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, while age, gender, and BMI were different. Early mortality was lower in Group A, 5%, versus 9.5% in Group B. Multivariate analysis revealed recipient female gender (odd ratio (OR) = 1.71), retransplantation (OR = 1.63), and increased donor age (OR = 1.02) as significant predictors of poor survival in the recipient population. Actuarial survival at 1 year (86.7% vs 81%), 5 years (75% vs 65%), and 10 years (56% vs 42%) was significantly different as well with 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.** doi: 10.1111/j.1540-8191.2006.00189.x *(J Card Surg 2006;21:125-129)*

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European Journal of Cardio-thoracic Surgery 40 (2011) e55–e61

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

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

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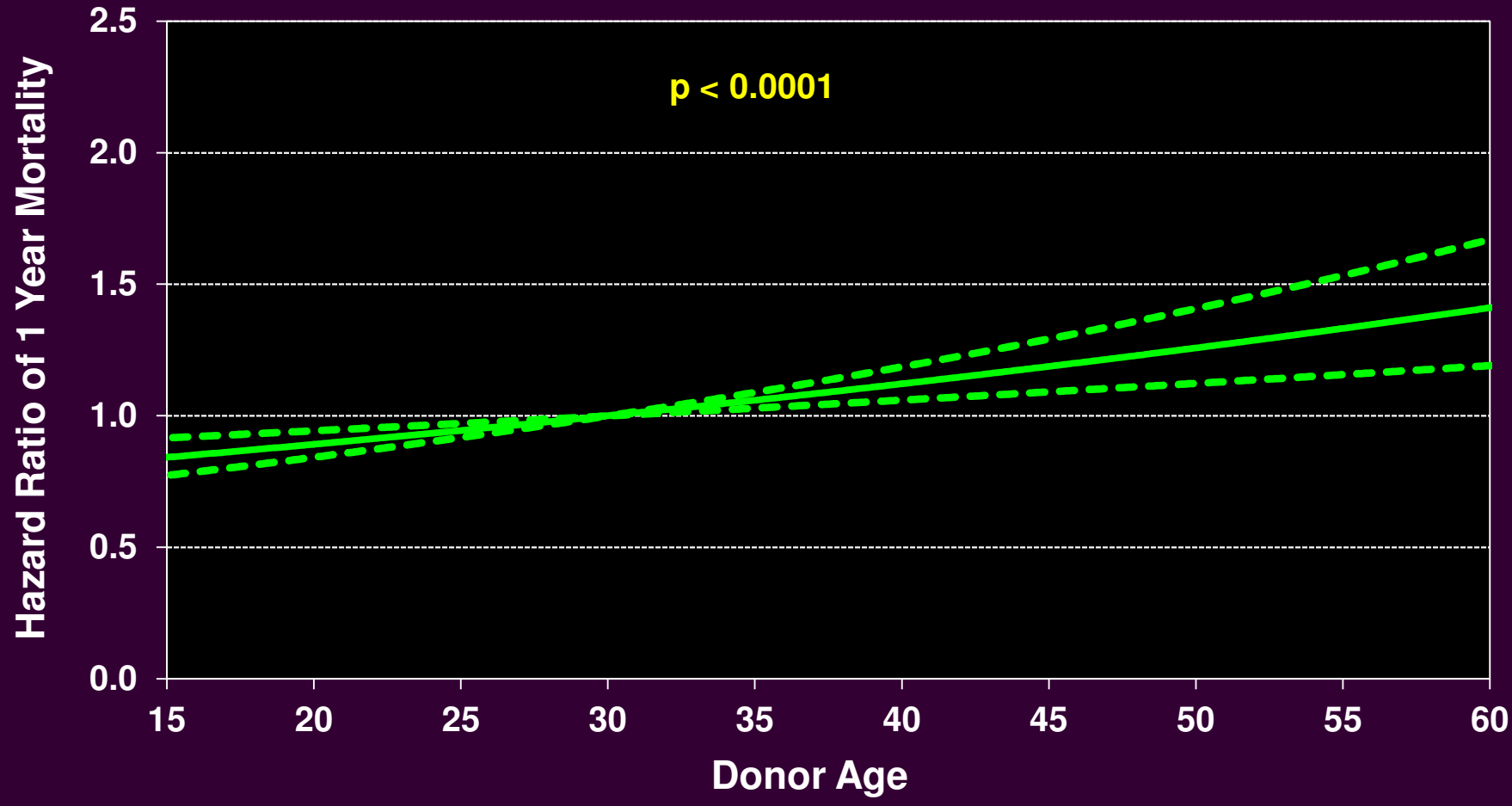
Received 30 August 2010; received in revised form 2 February 2011; accepted 4 February 2011; Available online 29 March 2011

**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 shift 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 transplantations performed after 1990, totaling 761 patients, mean age at transplantation 49.8 years, and 616 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 donors' group. Donor cause of death was a cerebrovascular accident in 82% 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 with 10.2% for the other group. No differences were noticed in the incidence of renal failure, acute rejection treated, coronary allograft 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 heart

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

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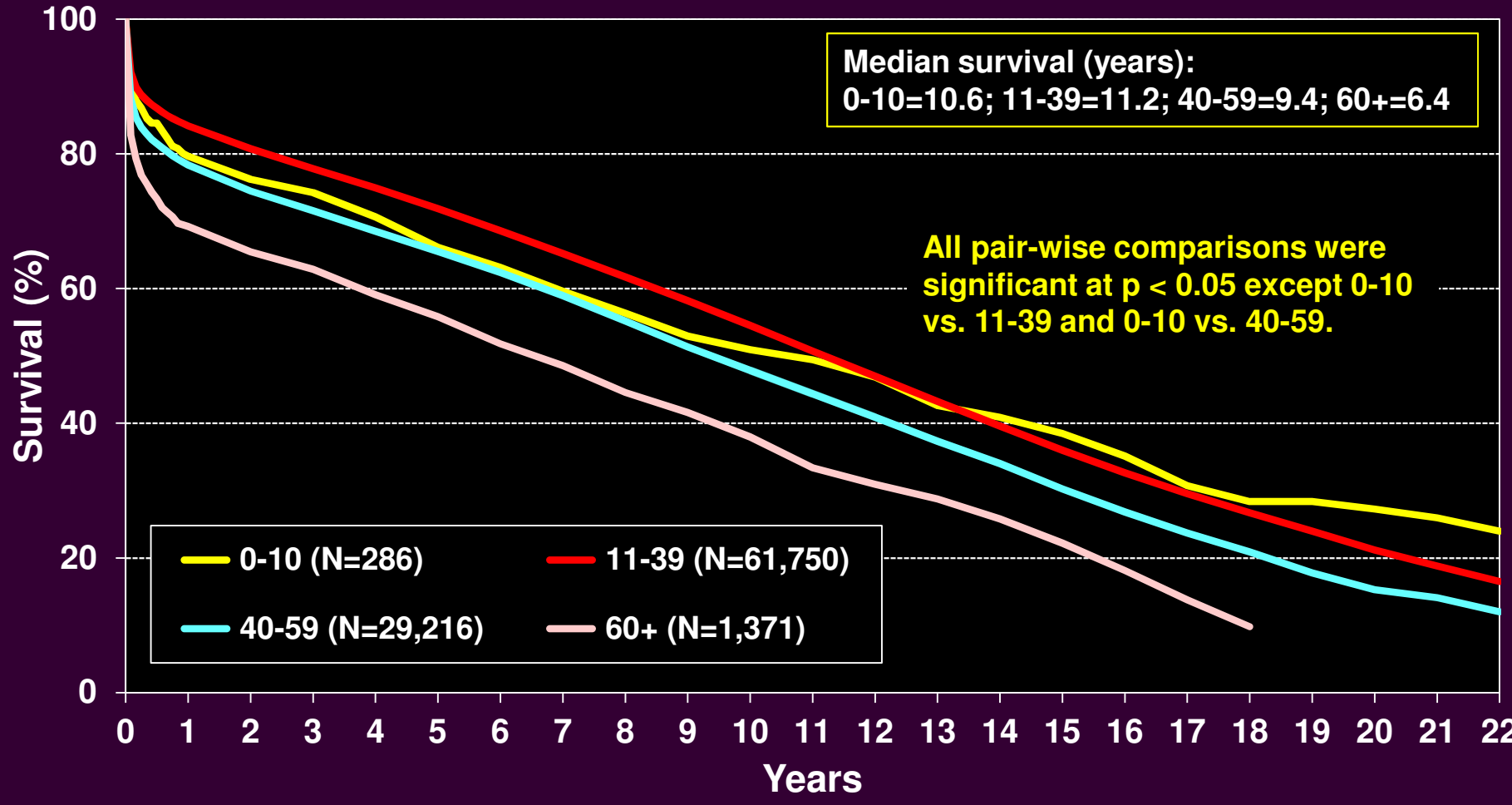
JHLT. 2015 Oct; 34(10): 1244-1254

(N = 10,904)

# Adult Heart Transplants
## Kaplan-Meier Survival by Donor Age Group
### (Transplants: January 1982 – June 2013)

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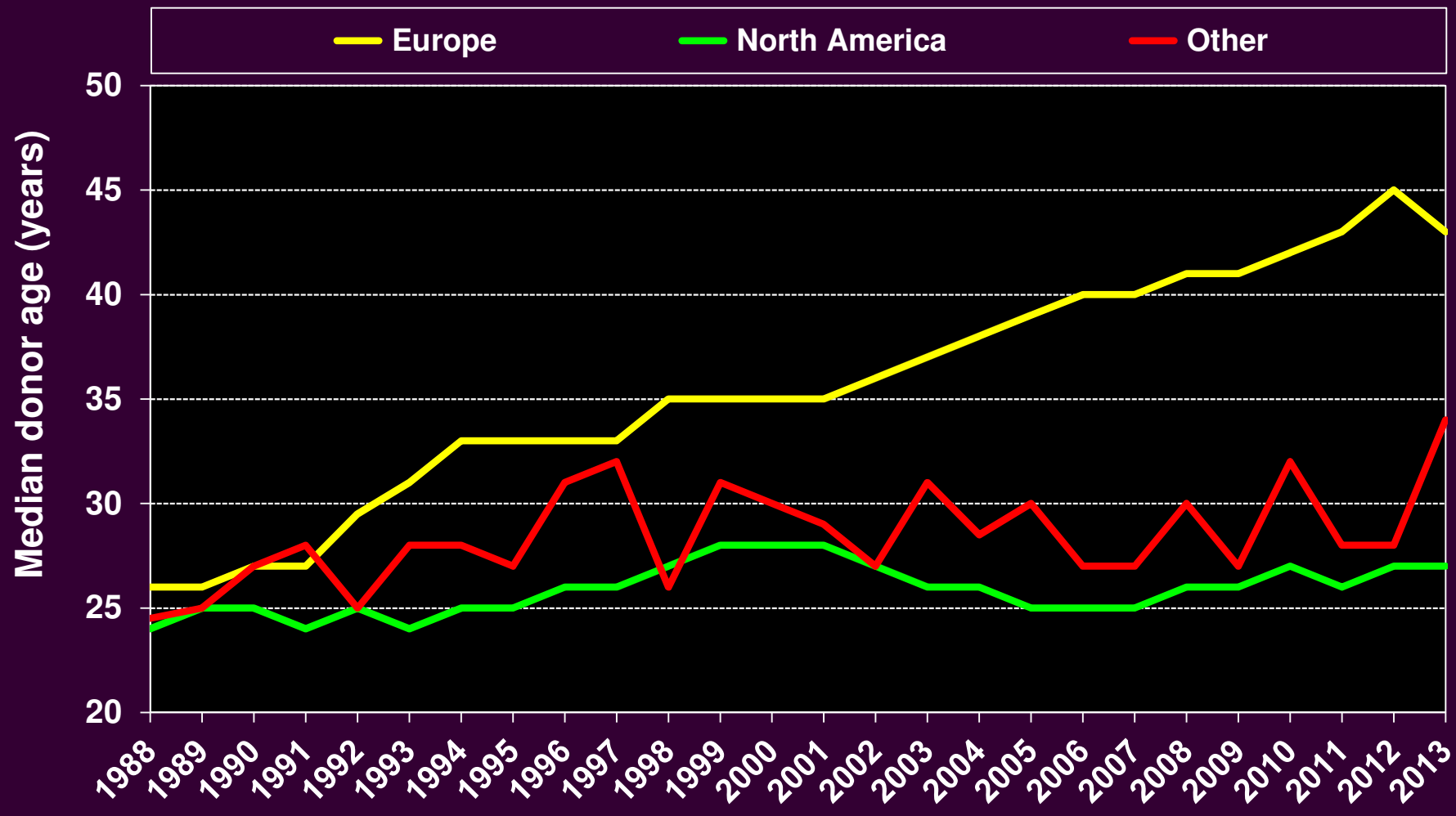
JHLT. 2015 Oct; 34(10): 1244-1254

# Adult and Pediatric Heart Transplants
## Median Donor Age by Location

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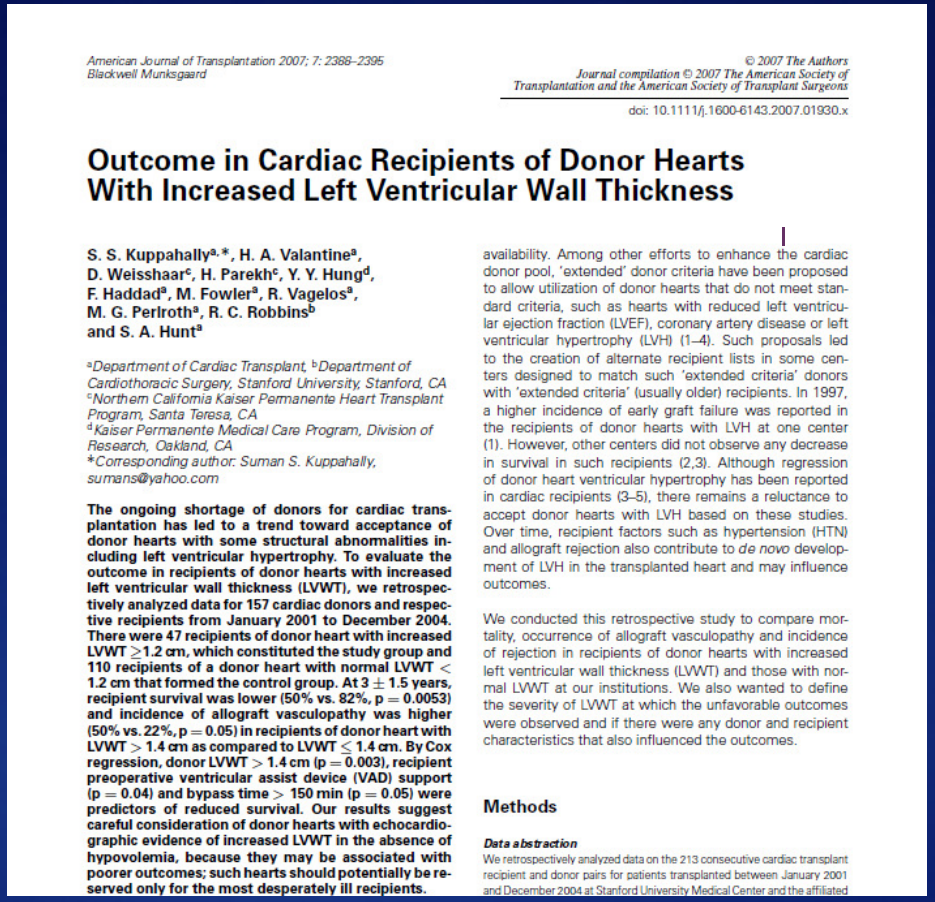
# Donor Heart Function

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

# ECHO

- Every door should have one !
- LVH
- Ventricular function
- Valve dysfunction

# Wall Thickness



American Journal of Transplantation 2007; 7: 2388–2395
Blackwell Munksgaard



doi: 10.1111/j.1600-6143.2007.01930.x

## Outcome in Cardiac Recipients of Donor Hearts With Increased Left Ventricular Wall Thickness

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**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 157 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 3 ± 1.5 years, recipient survival was lower (50% vs. 82%, p = 0.0053) and incidence of allograft vasculopathy was higher (50% vs. 22%, p = 0.05) in recipients of donor heart with LVWT > 1.4 cm as compared to LVWT ≤ 1.4 cm. By Cox regression, donor LVWT > 1.4 cm (p = 0.003), 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.**

availability. 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 alternate recipient lists in some centers designed to match such 'extended criteria' donors with 'extended criteria' (usually 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 reported in cardiac recipients (3–5), there remains a reluctance to accept donor hearts with LVH based on these studies. Over time, recipient factors such as hypertension (HTN) and allograft rejection also contribute to *de novo* development of LVH in the transplanted heart 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.

### Methods

***Data abstraction***

We retrospectively analyzed data on the 213 consecutive cardiac transplant recipient and donor pairs for patients transplanted between January 2001 and December 2004 at Stanford University Medical Center and the affiliated

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# 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).

1 ) Fiorelli AI, Branco JN, Dinkhuysen JJ, et al. Risk factor analysis of late survival after heart transplantation according to donor profile: a multi-institutional retrospective study of 512 transplants. Transplant Proc 2012;44:2469-72.
2 ) Stoica SC, Satchithananda DK, Charman S, et al. Swan-Ganz catheter assessment of donor hearts: outcome of organs with borderline hemodynamics. J Heart Lung Transplant 2002;21:615-22.

# CAOD

- 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).

1) Pinto CS, Prieto D, Antunes MJ. Coronary artery bypass graft surgery during heart transplantation. Interact Cardiovasc Thorac Surg 2013;16:224-5.

2) Grauhan O, Siniawski H, Dandel M, et al. Coronary atherosclerosis of the donor heart--impact on early graft failure. Eur J Cardiothorac Surg 2007;32:634-8.

3) Marelli D, Laks H, Bresson S, et al. Results after transplantation using donor hearts with preexisting coronary artery disease. J Thorac Cardiovasc Surg 2003;126:821-5.

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European Journal of Cardio-thoracic Surgery 32 (2007) 634–638

CARDIO-THORACIC SURGERY

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

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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 atherosclerosis (DCAS). 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 1086 patients no donor-transmitted coronary atherosclerosis was found (NDCAS 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 (DCAS1 group) and double- or triple-vessel donor-transmitted coronary atherosclerosis in 26/82 patients (DCAS2/3 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 NDCAS and DCAS1 groups was 12.2% versus 13.2% whereas in the DCAS2/3 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 (7.0%). 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.



30 Day Mortality :

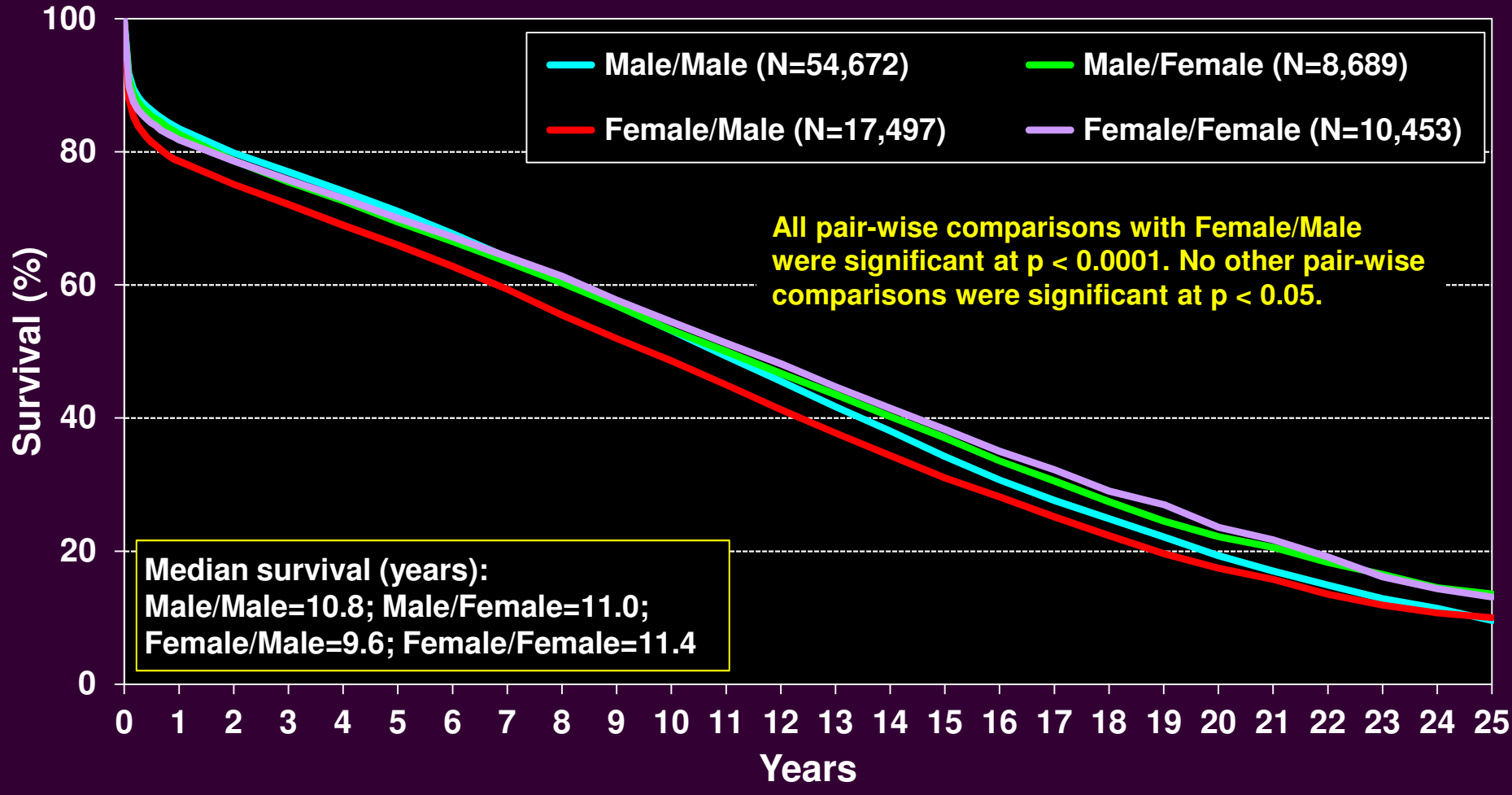
NDCAS and DCAS1 :
12.2% and 13.2%
DCAS 2/3 :
61%

# 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).

1) Welp H, Spieker T, Erren M, et al. Sex mismatch in heart transplantation is associated with increased number of severe rejection episodes and shorter long-term survival Transplant Proc 2009;41:2579-84.

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

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# Donor Recipient Compatibility cont.

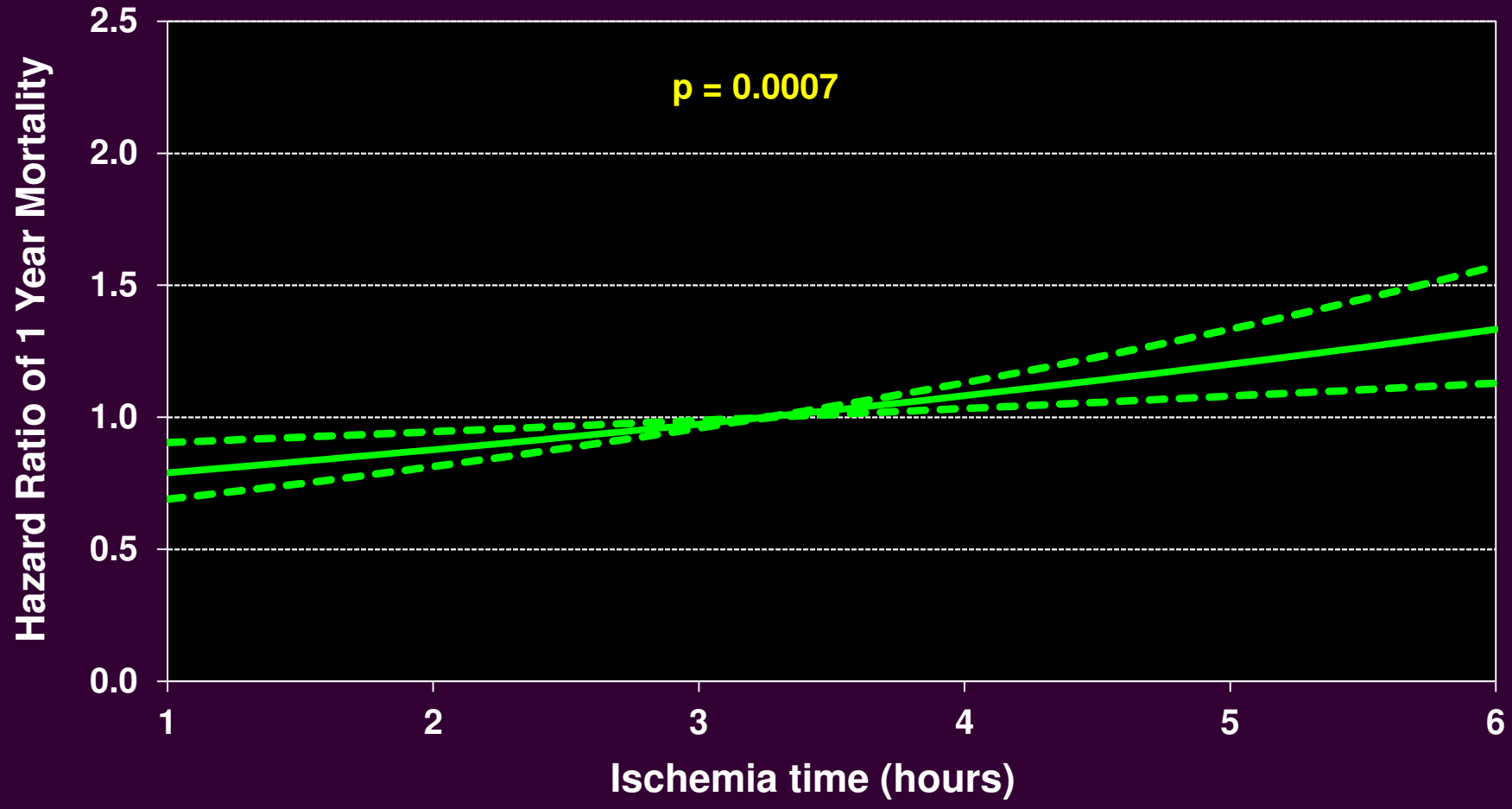
- Do not undersize > 30 %in Pts w Pulm. HTN or F to M
- Not to oversize > 30 % in Pts w LVADs, recent AMI, Redo sternotomy

# 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).

1) Hong KN, Iribarne A, Worku B, et al. Who is the high risk recipient? Predicting mortality after heart transplant using pretransplant donor and recipient risk factors. Ann Thorac Surg 2011;92:520-7; discussion 527.

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

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(N = 10,904)

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# Donor Predictors of Allograft Utilization and Recipient Outcomes after Heart Transplantation

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## 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

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Circ Heart Fail. 2013 Mar;6(2):300-9. doi: 10.1161/CIRCHEARTFAILURE.112.000165. Epub 2013 Feb 7.
**Donor predictors of allograft use and recipient outcomes after heart transplantation.**
Khush KK[1], Menza R, Nguyen J, Zaroff JG, Goldstein BA

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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**

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# 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

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Circ Heart Fail. 2013 Mar;6(2):300-9. doi: 10.1161/CIRCHEARTFAILURE.112.000165. Epub 2013 Feb 7.
**Donor predictors of allograft use and recipient outcomes after heart transplantation.**
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# Cocaine use

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



- Brieke A, Krishnamani R, Rocha MJ, et al. Influence of donor cocaine use on outcome after cardiac transplantation: analysis of the United Network for Organ Sharing Thoracic Registry. J Heart Lung Transplant 2008;27:1350-2.

# 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. 

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



Kono T, Nishina T, Morita H, et al. Usefulness of low-dose dobutamine stress echocardiography for evaluating reversibility of brain death-induced myocardial dysfunction. Am J Cardiol 1999;84:578-82.

# 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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*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 (HNP) 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 ($25.5 \pm 15$ yrs versus $39 \pm 18$ yrs, $P \leq 0.0001$), male gender (34% versus 23%, $P \leq 0.0001$), shorter CPR duration (<15 min versus >30 min, $P \leq 0.0001$), and head trauma (60% 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, short CPR duration, and traumatic head injury. Heart procurement varied by region but not by transplant volumes or wait times.

Bombardini et al. Cardiovascular Ultrasound 2013, 11:27
http://www.cardiovascularultrasound.com/content/11/1/27

CARDIOVASCULAR ULTRASOUND

RESEARCH Open Access

# Transplant of stunned donor hearts rescued by pharmacological stress echocardiography: a "proof of concept" report

Tonino Bombardini[1*], Sonia Gherardi[2], Ornella Leone[3], Rosa Sicari[1] and Eugenio Picano[1]

**Abstract**

**Background:** Due to the shortage of donor hearts, the criteria for acceptance have been considerably expande 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 (WMS rest = 1.33 ± 0.25. Stress echocardiography was performed with the dipyridamole high dose of 0.84 mg/kg give 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 ± 0.06) and were transplanted uneventfully. Recipients (three mal mean age 53 ± 4 years) underwent post-TX coronary angiography, IVUS and endomyocardial biopsies. No recipi 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-up.

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

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

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The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

# Heart transplantation outcomes from cardiac arrest–resuscitated donors

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**KEYWORDS:**
heart transplantation;
cardiopulmonary resuscitation;
donor selection;
recipient survival;
risk factor;
ischemic preconditioning

**BACKGROUND:** The aim of this study was to compare the outcomes of heart transplantation from cardiopulmonary-resuscitated 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. Discrete 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 29,242 adult heart transplantations performed in USA during the study period, 1,396 patients (4.7%) received hearts from $CPR^+$ donors. The patients in the $CPR^+$ group were younger (25.5 ± 15 years vs 28.5 ± 14 years; $p < 0.0001$) and more likely to be female (31% 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 1A 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%; $p = 0.0008$). Recipient survival at 30 days, 1 year and 5 years was 95.2%, 88.2% and 72.9% in $CPR^+$ group, and 94.7%, 87.7% 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 94.4%, 87.3% 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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# Ex vivo heart Perfusion

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ORIGINAL PRE-CLINICAL SCIENCE

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

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*From the [a]Cardiac Sciences Program, University of Manitoba, St. Boniface Hospital, Winnipeg, M Cardiovascular Sciences, St. Boniface Hospital, Winnipeg, Manitoba, Canada; [c]Papworth Hospital, Research Council Institute for Biodiagnostics, University of Manitoba, Winnipeg, Manitoba, Canad University of Manitoba, Winnipeg, Manitoba, Canada.*

**KEYWORDS:**
*Ex vivo* heart perfusion;
heart transplantation;
donation after cardiocirculatory death;
DCD;
ischemia-reperfusion injury;
adenosine-lidocaine cardioplegia

**BACKGROUND:** Ex vivo heart perfusion (EVHP) has been propose of donor hearts after cardiocirculatory death (DCD) and increase the to clinical EVHP may exacerbate myocardial injury and impair func to determine if a cardioprotective EVHP strategy that eliminates my kalemia cardioplegia and minimizes cold ischemia could facilitate **METHODS:** Anesthetized pigs sustained a hypoxic cardiac ar standoff period. Strategy 1 hearts (S1, $n = 9$) underwent initial cardioplegia, normothermic EVHP, and transplantation after a (current EVHP strategy). Strategy 2 hearts (S2, $n = 8$) unde adenosine-lidocaine cardioplegia, normothermic EVHP, and tran perfusion (cardioprotective EVHP strategy).
**RESULTS:** At completion of EVHP, S2 hearts exhibited less wei [S1] g/hour, $p = 0.008$) and less troponin-I release into the con $6.3 \pm 1.5$ [S1] ng/ml; $p = 0.014$). Mass spectrometry analysis o transplant myocardium revealed less oxidative stress in S2 hearts. pulmonary bypass, post-transplant systolic (pre-load recruitable s 10.9 [S1], $p = 0.043$) and diastolic (isovolumic relaxation constar $p = 0.020$) function were superior in S2 hearts.
**CONCLUSION:** In this experimental model of DCD, an EVHP stra adenosine-lidocaine cardioplegia and continuous myocardial perf improves short-term post-transplant function compared with t hyperkalemic cardioplegia before organ procurement and transpla

J Heart Lung Transplant 2013;32:734–743
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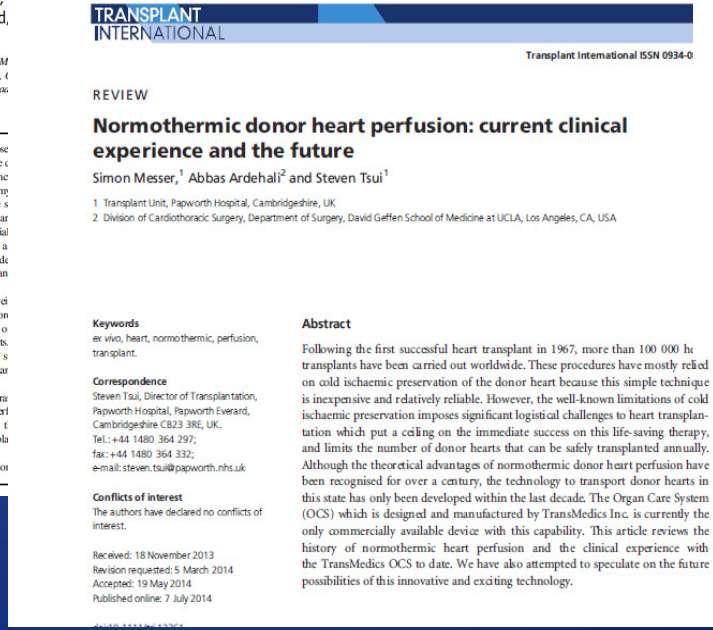

TRANSPLANT INTERNATIONAL

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REVIEW

**Normothermic donor heart perfusion: current clinical experience and the future**

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**Keywords**
ex vivo, heart, normothermic, perfusion, transplant.

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**Conflicts of interest**
The authors have declared no conflicts of interest.

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**Abstract**

Following the first successful heart transplant in 1967, more than 100 000 he transplants have been carried out worldwide. These procedures have mostly relied on cold ischaemic preservation of the donor heart because this simple technique is inexpensive and relatively reliable. However, the well-known limitations of cold ischaemic preservation imposes significant logistical challenges to heart transplantation which put a ceiling on the immediate success on this life-saving therapy, and limits the number of donor hearts that can be safely transplanted annually. Although the theoretical advantages of normothermic donor heart perfusion have been recognised for over a century, the technology to transport donor hearts in this state has only been developed within the last decade. The Organ Care System (OCS) which is designed and manufactured by TransMedics Inc. is currently the only commercially available device with this capability. This article reviews the history of normothermic heart perfusion and the clinical experience with the TransMedics OCS to date. We have also attempted to speculate on the future possibilities of this innovative and exciting technology.

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European Journal of Cardio-thoracic Surgery 34 (2008) 318–325

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Review

**Preserving and evaluating hearts with ex vivo machine perfusion: an avenue to improve early graft performance and expand the donor pool☆**

Michael J. Collins, Sina L. Moainie, Bartley P. Griffith, Robert S. Poston*

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Received 14 September 2007; received in revised form 4 March 2008; accepted 6 March 2008; Available online 6 June 2008

**Summary**

Cardiac transplantation remains the first choice for the surgical treatment of end stage heart failure. An inadequate supply of donor grafts that meet existing criteria has limited the application of this therapy to suitable candidates and increased interest in extended criteria donors. Although cold storage (CS) is a time-tested method for the preservation of hearts during the ex vivo transport interval, its disadvantages are highlighted in hearts from the extended criteria donor. In contrast, transport of high-risk hearts using hypothermic machine perfusion (MP) provides continuous support of aerobic metabolism and ongoing washout of metabolic byproducts. Perhaps more importantly, monitoring the organ's response to this intervention provides insight into the viability of a heart initially deemed as extended criteria. Obviously, ex vivo MP introduces challenges, such as ensuring homogeneous tissue perfusion and avoiding myocardial edema. Though numerous groups have experimented with this technology, the best perfusate and perfusion parameters needed to achieve optimal results remain unclear. In the present review, we outline the benefits of ex vivo MP with particular attention to how the challenges can be addressed in order to achieve the most consistent results in a large animal model of the ideal heart donor. We provide evidence that MP can be used to resuscitate and evaluate hearts from animal and human extended criteria donors, including the non-heart beating donor, which we feel is the most compelling argument for why this technology is likely to impact the donor pool.



*Keywords:* Non-heart beating donor; Myocardial viability; Machine perfusion; Heart transplantation; Myocardial preservation

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**ClinicalTrials.gov**
A service of the U.S. National Institutes of Health

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Home > Find Studies > Study Record Detail

## International EXPAND Heart Pivotal Trial (EXPANDHeart)

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

*Verified October 2015 by TransMedics*

**Sponsor:**
TransMedics

**Information provided by (Responsible Party):**
TransMedics

**ClinicalTrials.gov Identifier:**
NCT02323321

First received: December 18, 2014
Last updated: October 15, 2015
Last verified: October 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

### 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

| Condition | Intervention | Phase |
|---|---|---|
| Heart Transplant | Device: Preservation of Hearts for Transplantation | Phase 3 |

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

U.S. FDA Resources

**Further study details as provided by TransMedics:**

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# Corrected Structural Defects in Cardiac Donors

doi:10.1510/icvts.2010.240168

INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY

Interactive CardioVascular and Thoracic Surgery 11 (2010) 501-502

www.icvts.org

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 20-year-old donor who underwent surgical closure of a ventricular septal defect during childhood. Our 26-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 donor' 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.



*Keywords:* Heart transplantation; Marginal donor; Congenital heart defect; Surgical correction

# 10 year Experience with ECD

**Original Article**

## Ten-Year Experience With Extended Criteria Cardiac Transplantation

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

***Background***—Extended criteria cardiac transplant (ECCT) 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 ECCT based on prespecified criteria. Baseline characteristics and outcomes were compared between ECCT 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 ECCT. Among the 454 patients who underwent heart transplant, 84 (18.5%) were ECCT. Compared with the patients who underwent standard criteria cardiac transplant, ECCT 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 rate, 55 versus 61.6 mL/min; $P=0.001$). After adjustment for baseline characteristics, standard criteria cardiac transplant survival was higher than ECCT 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***—ECCT 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;6:1230-1238.**)

**Key Words:** heart failure ■ survival ■ transplantation

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

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# Alternate list

Curr Opin Cardiol. 2004 Mar;19(2):162-5.

## Cardiac transplantation: the alternate list and expansion of the donor pool.

Patel J[1], Kobashigawa JA.

Author information

**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



Marc D. Samsky (Circ Heart Fail. 2013;6:1230-1238.)

# Conclusion cont..d

**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*