THE CHANGING SCENARIO FOR ORGAN DONATION

Elisabeth Coll Torres MD PhD
Organización Nacional de Trasplantes, Spain
DECREASE OF RELEVANT MORTALITY FOR THE DONATION OF ORGANS IN MOST COUNTRIES OF THE EUROPEAN UNION

SDR, motor vehicle traffic accidents, all ages, per 100 000

SDR, cerebrovascular diseases, all ages, per 100 000

© World Health Organization 2015

...and Spain is here
Decrease in Potential for Brain Death Donation in Spain

De la Rosa et al. Am J Transplant 2012; 12:2507
The second concept is based on the principle of non-maleficience and justice. The treating physician is not obliged to perform or continue with futile treatments, these being those which do not achieve their expected objective.

In this sense, continuing futile treatments is considered a bad clinical practice since it is not respectful with human dignity; on the other hand, the unnecessary use of health care resources is against the principle of distributive justice.'
OBJECTIVE: Donor rate 40 pmp

- DBD Optimization
- DCD
- Living Donation
- Expanded criteria/ NSR donors
- Donation in minorities
- Special Surgical Techniques
Donor Pool

Living donation

Brain Death optimization

Donation after circulatory death

Donation in minorities

Old donors

Special surgical techniques (liver split and domino, double kidney)

Expanded criteria, Non standard risk donors

Transmissible diseases
- Neoplasias
- Infections

Other pathologies:
- HTA, DM
- Intoxications
- Rare diseases...

OBJECTIVE: Donor rate 40 pmp

40 pmp DONOR PLAN
Benchmarking project in the donation after brain death

**QUANTITATIVE PHASE**

**INDICATORS**

1. REFERRAL OF POTENTIAL DONORS TO CU
2. MANAGEMENT OF POTENTIAL DONORS INSIDE CU
3. OBTAINING CONSENT TO ORGAN DONATION

**QUALITATIVE PHASE**

**VISIT TO BPH**

- STRUCTURED INTERVIEW
- TRANSPLANT COORDINATORS
- OPENED QUESTIONS

**WHO IS THE BEST?**

**IDENTIFICATION OF BEST PERFORMER HOSPITALS (BPH)**

**HOW DO THEY DO IT?**

**IDENTIFICATION AND DESCRIPTION OF BEST PRACTICES**

Monthly evolution of the interannual number of deceased organ donors in Spain

Number of donors within the 12 previous months at a given date

http://www.ont.es/publicaciones/Paginas/Publicaciones.aspx

THE LANCET

Matesanz R et al. Lancet 2012
Involvement Emergencies health professionals in donation process

TRAINING PROGRAMMES
ONT–SEMES

215 COURSES ALL AROUND SPAIN:
>7000 emergency professionals trained during the last eight years

COMMON RESEARCH PROJECTS

ANÁLISIS DEL POTENCIAL DE DONACIÓN EN LOS SERVICIOS DE URGENCIAS HOSPITALARIAS

PROYECTO COLABORATIVO ONT_SEMES

RECOMMENDATIONS/ DOCUMENTS

Available at http://www.ont.es
Involvement of Intensive Care Professionals in donation process

From 2008, collaboration agreement with Spanish Intensive Care Society (SEMICYUC)

- Training Programme (+ 1000 young intensivists trained)
- Research projects
- Recommendations

## Involvement of Intensive Care Professionals in donation process - Quality Indicators  SEMICYUC

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>SD</th>
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<tr>
<td><strong>ORGAN DONATION</strong></td>
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<tr>
<td>Nº Donors</td>
<td>60%</td>
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<tr>
<td>Nº BD people in CU</td>
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<td>---------------------------------------------------------------------------------------------</td>
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<tr>
<td>Nº people in BD correctly monitored</td>
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<td>Nº CU Deaths</td>
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**ACCORD Spain** - small interventions in deceased donation through PDSA cycles in 40 donor hospitals

- Proactive follow-up system for patients with catastrophic brain injuries – ICD-10 codified mortality, neuroimages, etc. – discussion with treating physicians.
- Notification criteria with supporting material
- New systems of notification
- Protocols on Elective Non Therapeutic Intensive Care to facilitate organ donation
- Daily review of deaths
- Training sessions and feedback activities
1 out of 4 actual donors in Spain have been admitted to the ICU to enable organ donation

- A: Active treatment in the ICU until brain death (n=539)
- B: Active treatment in the ICU until the patient suffers an unexpected CA from which the patient cannot be resuscitated (n=92)
- C: Admission to ICU to incorporate the option of organ donation into end-of-life (n=200)
- D: Active treatment in the ICU until the decision is made to WLST (n=370)
- E: Not admitted into ICU (n=769)

N=1970 possible donors aged ≤85
11/1/2014-4/30/2015

Domínguez-Gil B, et al. Transplantation 2017
Patients dead as a result of a devastating brain injury (possible donors) ≤ 85 years
68 hospitals
1\textsuperscript{st} November 2014 – 30\textsuperscript{th} April 2015

1970 Possible donors

769 Not admitted into the ICU (39%)

Mean age 78 years

342 NEVER REFERRED TO THE DONOR COORDINATOR

427 No medical contraindications (56%)

49 Intubated—39 dead ≤ 3 days
378 Not intubated—226 dead ≤ 3 days
Intensive Care to facilitate Organ Donation - ICOD

- Legal, deontological and ethical framework
- Identification of possible donors
- Research of the will of donation. Care and communication with the family of the possible donor
- Critical Unit management
- Recommendation to implement a ICOD program
- Outcomes evaluation

EXTERNAL REVIEW PHASE
Donor Pool

Living donation

Brain Death optimization

Donation in minorities

Donation after circulatory death

Special surgical techniques (liver split and domino. double kidney)

Old donors

Expanded criteria Non standard risk donors

Transmissible diseases
- Neoplasias
- Infections

Other pathologies:
- HTA. DM
- Intoxications
- Rare diseases…
Spanish program to promote DCD

AIMS

1. Creation of new DCD programs – uDCD & cDCD
2. Increase the effectiveness of DCD - utilization rate and number of organs recovered & transplanted per donor
3. Evaluate post-transplant outcomes with organs from DCD-strategies for improvement
1. Introduction
2. Glossary & classification of DCD
3. Determination of death by circulatory criteria
4. Uncontrolled DCD
   a. Out-of-hospital logistics. Donor selection criteria
   b. In-hospital logistics. Donor selection criteria
   c. Preservation. recovery and organ viability
   d. Family approach
5. Controlled DCD
   a. Donor selection criteria
   b. WLST
   c. Family approach
   d. Extubation. cardiac arrest and death determination
   e. Preservation. recovery and organ viability
   f. Requisites for starting a controlled DCD program
6. Recipient selection criteria & peritransplant management. Information to the potential recipient
7. Communication with the media
8. Ethical & legal aspects

DCD in Spain: state of the art and recommendations

National Consensus Document 2012
Additional measures

• **Training courses**

  Controlled and uncontrolled DCD
  New scenarios for family interview
  Normothermic Abdominal Perfusion

• **Annual Report DCD activity in Spain**

  Description of procedures and trends
  Outcomes: organ recovery, transplantation and post transplant results

• **National protocols on:**

  Liver Donation and Transplantation (2015)
  Lung Donation and Transplantation (2017)
IN 2015, SPAIN WAS THE 3rd COUNTRY IN ABSOLUT NUMBERS, AFTER USA AND UK
DCD TRANSPLANTS IN SPAIN

From 24 to 838 tx / year

+ 3500 from the beginning
Donor Pool

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Brain Death optimization

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Expanded criteria
Non standard risk donors
CHANGES IN THE PROFILE OF POTENTIAL ORGAN DONORS

PROGRESSIVE CHANGE IN ELEGIBILITY CRITERIA FOR ORGAN DONATION

DECLINE IN MORTALITY RELEVANT TO ORGAN DONATION

IMPROVEMENTS IN THE CARE OF NEUROCRITICAL PATIENTS

Information on the quality and safety of transplants performed with organs from these donors is **ESSENTIAL** to guide risk-benefit assessments in the future.
Donors with an increased risk of donor related disease in the recipient, assumed before transplantation.

- All NSRD since 01/01/2013
- Utilization NSRD
- Follow-up recipients
Infections:

- CNS infections
- TBC
- Emerging infections
- Bacteriemies
- Endocarditis

Malignancies:

Prior or present history of malignancy

Poisoning:

- Cocaine
- Ecstasy
- Hydrocarbons
- Mushrooms
- Organophosphates
- Ethylene glycol Methanol
- Rodenticide
- Other

Other diseases:

- Myeloproliferative disorders
- Amyotrophic lateral sclerosis
- Systemic lupus erythematosus
- Multiple Sclerosis
- Other (rare diseases)
NSRD REPORT 2013-2014

176 actual donors

155 utilized donors

430 transplants

No Graft loss/Patient death attributable to NSRD

*cardiac recipient HCV

1 Transmission*/Related problem

84% follow-up

INFORME ANUAL
DONANTES DE RIESGO NO ESTÁNDAR (DRNE)
España 2013-2014

TRANSPLANT RESULTS
# Age Evolution of Donors

## Graph

The graph shows the age distribution of donors over the years from 2000 to 2016. The percentage of donors in each age group is represented by different colors and shades.

## Table

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### Color Legend
- ≥80
- 70-79
- 60-69
- 45-59
- 30-44
- 15-29
- 0-14

>50% 

- Indicates percentages greater than 50%
‘(...)the number of donors >70 years increased from 3.8 to 8.8 pmp (a 132% increase) in Spain and they now constitute 25.4% of all Spanish organ donors.

In contrast, the number of US donors >70 years increased from 1.0 to 1.3 pmp, and they constitute only 4.4% of total deceased donors’.

Halldorson J et al, . Liver Transplant 2013; 19
MAXIMUM DONOR AGE
(PER ORGAN TRANSPLANTED)
Patient and graft outcomes from deceased kidney donors age 70 years and older: an analysis of the Organ Procurement Transplant Network/United Network of Organ Sharing database.

Chelvalidhamma D, O'Hir, A, Talanowod S, Madhira BR, Cho YY, Shah T, Bhanvadati S

Abstract

BACKGROUND: The organ shortage has resulted in more use of older deceased donor kidneys. Data are limited on the impact of donor aged 76 years and older on transplant outcomes. We examined patient and graft outcomes of renal transplant from expanded criteria donors (ECDS) aged 70 years and older, using the Organ Procurement Transplant Network/United Network of Organ Sharing database.

METHODS: We identified 601 deceased donor transplants from donors older than 70 years from 2000 to 2005. The follow-up time was until May 2007. Allograft and patient survival were compared between recipients of transplants from older ECDS (age ≥ 70) and younger ECDS (age 60–69). The relative risk of graft loss and patient death was assessed by Cox proportional hazards regression.

RESULTS: The adjusted relative risks of graft loss (hazard ratio 1.10; 95% CI 1.01–1.20) and patient death (hazard ratio 1.20; 95% CI 1.01–1.42) were higher for recipients of transplants from older ECDS compared with recipients of transplants from younger ECDS. The relative risk of patient death was lower in older than younger donors (age 60–69).

CONCLUSIONS: Transplants from older ECDS are associated with earlier graft loss and higher mortality compared with younger ECDS. The relative risk of patient death was lower in older donors (age 60–69).

A systematic review of kidney transplantation from expanded criteria donors.

Patel VJ, Ponce V, Pichs E

Abstract

BACKGROUND: During the past few years, there has been renewed interest in the use of expanded criteria donors (ECD) for kidney transplantation to increase the numbers of deceased donor kidneys available. More kidney transplants would result in shorter waiting times and delay the morbidity and mortality associated with long-term dialysis therapy.

STUDY DESIGN: Systematic review of the literature.

SETTING & POPULATION: Kidney transplantation population.

SELECTION CRITERIA FOR STUDIES: Studies were identified by using a comprehensive search through MEDLINE and EMBASE databases. Inclusion criteria were case series, cohort studies, and randomized controlled trials assessing kidney transplantation in adult recipients using ECDs.

PREDICTOR: A special focus was given to studies comparing the evolution of kidney transplantation between standard criteria donors (defined as a donor who does not meet criteria for donation after cardiac death or ECD and ECDs defined as any brain-dead donor aged ≥ 60 years or a donor aged > 60 years with at least two of the following conditions: history of hypertension, terminal serum creatinine level > 1.5 mg/dL, or death resulting from a cerebrovascular accident).

OUTCOMES: Criteria used to define and select ECDs, practice patterns, long-term outcomes, early complications, and some patient issues, such as selection criteria and immunosuppressive management.

RESULTS: ECD kidneys have worse long-term survival than standard criteria donor kidneys. The optimal ECD kidney for donation depends on adequate glomerular filtration rate and acceptable donor kidney histological characteristics, albeit the usefulness of biopsy is debated.

LIMITATIONS: This review is based mainly on data from observational studies, and varying amounts of bias could be present. We did not attempt to quantitatively analyze the effect of ECD kidneys on kidney transplantation because of the huge heterogeneity found in study designs and definitions of ECD.

CONCLUSIONS: Based on the available evidence, we conclude that patients younger than 40 years or scheduled for kidney retransplantation should not receive an ECD kidney. Patients 40 years or older, especially with diabetic nephropathy or nondiabetic disease, but with a long expected waiting time for kidney transplantation, show better survival receiving an ECD kidney than remaining on dialysis therapy.
Donor age is not the only relevant factor in the outcome of LT, however, surgical factors such as IT or hemodynamic instability during surgery, and recipient factors, such as MELD score are also essential. Therefore, avoiding these factors as much as possible in LT performed with elderly donors may lead to outcomes similar to those with transplants performed with younger donors.

### Table 1: Studies that analyze impact of donor age on liver transplant outcomes

<table>
<thead>
<tr>
<th>Ref.</th>
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<th>No. of patients</th>
<th>Outcomes</th>
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<td>Adam et al.</td>
<td>Multiple age groups</td>
<td>&lt; 65 years</td>
<td>95</td>
<td>Lower death rates in younger age group</td>
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<tr>
<td>Cuebas et al.</td>
<td>Multiple age groups</td>
<td>&lt; 70 years</td>
<td>200</td>
<td>Increased survival rates in younger donors</td>
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**Actual Risk of Using Very Aged Donors for Unselected Liver Transplant Candidates: A European Single-center Experience in the MELD Era.**

#### Abstract

**Objective:** To evaluate the whole experience of liver transplantation (LT) with donors >70 years in a single center not applying specific donor/recipient matching criteria.

**Background:** LT with very old donors has historically been associated with poorer outcomes. With the increasing average donor age and the advent of Model for End-stage Liver Disease (MELD) score-based allocation criteria, an optimal donor/recipient matching is often unsuitable.

**Methods:** Outcomes of all types of LTs were compared according to 4 study groups: patients transplanted between 1998 and 2003 with donors <70 (group 1, n=196) or ≥70 years (group 2, n=118), patients transplanted between 2004 and 2010 with donors <70 (group 3, n=199), or ≥70 years (group 4, n=140). From 2003, graft histology was routinely available before cross-clamping, and MELD-driven allocation was adopted.

**Results:** Groups 1 and 2 were at a lower rate of moderate-to-severe acute graft failure, median donor age, recipient age, decreased. Five-year graft survival (P=0.129). Transplants performed treatments were independently as.

**Conclusions:** Even without specific donor/recipient matching criteria, LT with donors >70 years may lead to outcomes similar to those with transplants performed with younger donors.

### Octogenarian Donors in Liver Transplantation.

#### Abstract

**Introduction:** Due to the disparity between the number of patients on the waitlist for liver transplantation and the availability of organs, the use of older donors has become necessary. The aim of this study was to investigate the outcomes of liver transplantation using octogenarian donors.

**Methods:** From December 2003 to February 2016, 777 liver transplantations were performed at our institution. 33 of them (4.2%) with donors 80 years old and above. Our policy for the acceptance of these donors is based on preoperative liver function tests, donor hemodynamic stability, and intraoperative normal gross aspect. Octogenarian grafts were deliberately not assigned to retransplantations or to recipients with multiple previous surgical procedures or extensive portal thrombosis.

**Results:** Mean donor age was 82.7 ± 2.1 years with a range between 80 and 88. Only 12.1% suffered hemodynamic instability during the intensive care unit stay. Three donors (9.1%) had a history of diabetes mellitus. The mean Model for End-Stage Liver Disease score at the time of recipient recruitment was 14.7 ± 5.6. Mean cold ischemia time was 302 ± 61 minutes. After a median follow-up of 18.6 months (range 7.6 to 47.6), no graft developed primary nonfunction. We observed hepatectomy failure in 1 patient (3%) and biliary complications in 4 patients (12.5%). There was 1 case of ischemic-type biliary leak, although it was related to hepatic artery thrombosis. Patient survival at 1 and 3 years was 92.3% and 85.4%, respectively.

**Conclusions:** Excellent midterm results can be obtained after liver transplantation with octogenarian donors with strict donor selection and adequate graft allocation.
RECIPIENT SELECTION

Lung Transplantation With Lungs From Older Donors: Recipient and Surgical Factors Affect Outcomes


Abstract

Background: A shortage of donors has compelled the use of extended-criteria donor lungs in lung transplantation. The purpose of this study was to evaluate the impact of older donors on outcomes after lung transplantation using current protocols.

Methods: From January 2003 to August 2009, 593 lung transplants were performed at our institution. We compared 87 patients (14.7%) who received lungs from donors aged 55 years or older with 506 patients who received lungs from donors less than 55 years old. We examined risk factors for mortality in recipients of lungs from older donors.

Results: The incidence of major complications including severe primary graft dysfunction and early mortality rates were similar between the groups. However, transplant mismatch peak FIO2 was lower in the patients who received lungs from older donors (71.2% vs. 80.8%, \(P < 0.005\)). In multivariate analysis, recipient pulmonary hypertension (transmural pulmonary pressure gradient > 20 mm Hg) and prolonged respiratory support were significant risk factors for mortality in the recipients of lungs from older donors.

Conclusions: This large, single-center experience demonstrated that transplanting lungs from donors older than 55 years of age did not yield worse short- or long-term outcomes as compared to transplanting lungs from younger donors. However, transplanting lungs from older donors into recipients with pulmonary hypertension or recipients who required prolonged cardiopulmonary bypass increased the risk for mortality. Although lungs from older donors should not be excluded because of donor age alone, surgeons should carefully consider their patient selection criteria and surgical plans when transplanting lungs from older donors.

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Background: A shortage of donors has compelled the use of extended-criteria donor lungs in lung transplantation. The purpose of this study was to evaluate the impact of older donors on outcomes after lung transplantation using current protocols.

Methods: From January 2003 to August 2009, 593 lung transplants were performed at our institution. We compared 87 patients (14.7%) who received lungs from donors aged 55 years or older with 506 patients who received lungs from donors less than 55 years old. We examined risk factors for mortality in recipients of lungs from older donors.

Results: The incidence of major complications including severe primary graft dysfunction and early mortality rates were similar between the groups. However, transplant mismatch peak FIO2 was lower in the patients who received lungs from older donors (71.2% vs. 80.8%, \(P < 0.005\)). In multivariate analysis, recipient pulmonary hypertension (transmural pulmonary pressure gradient > 20 mm Hg) and prolonged respiratory support were significant risk factors for mortality in the recipients of lungs from older donors.

Conclusions: This large, single-center experience demonstrated that transplanting lungs from donors older than 55 years of age did not yield worse short- or long-term outcomes as compared to transplanting lungs from younger donors. However, transplanting lungs from older donors into recipients with pulmonary hypertension or recipients who required prolonged cardiopulmonary bypass increased the risk for mortality. Although lungs from older donors should not be excluded because of donor age alone, surgeons should carefully consider their patient selection criteria and surgical plans when transplanting lungs from older donors.

Lung Transplantation With Lungs From Older Donors: Recipient and Surgical Factors Affect Outcomes

Donor Pool

Living donation

Brain Death optimization

Donation in minorities

Donation after circulatory death

Special surgical techniques (liver split and domino, double kidney)

Old donors

Expanded criteria
Non standard risk donors

Transmissible diseases
- Neoplasias
- Infections

Other pathologies:
- HTA, DM
- Intoxications
- Rare diseases...

- Information program to patients
- Information and training professionals
- Expand living donors pool: Crossover-Donor Kidney program, good samaritan
OBJECTIVE: > 10-15% KIDNEY TRANSPLANTS
KIDNEY TX EVOLUTION IN SPAIN
ACCORDING TO DONOR TYPE

Living donor  DCD  DBD

Living Donor

BRAIN DEATH


Living
DCD
OBJECTIVE: FULL INTEGRATION OF IMMIGRANTS AND MINORITIES TO DONATION AND TRANSPLANTATION

POBLATIONAL SURVEY: ATTITUDES OF IMMIGRANT POPULATION TOWARDS ORGAN DONATION

(in collaboration with Faculty of Psychology, Universidad Autónoma de Madrid)

- Lack of information on donation and transplantation
- Family interview is essential
- Three collectives reluctant to donation:
  - North Africa
  - Sub-Saharan Africa
  - Asia

  Specially for religious reasons - Muslims with strong religious beliefs.
STRATEGIES

✓ Information and awareness of donation and transplantation: *Donación sin fronteras* campaign, *En el lado de lado de la vida* (silent short film)

✓ Enhance collaboration between transplant network and cultural mediators (Symposium, workshops)

✓ Strengthen relations with the most representative social organizations of the different groups
  - Muslims
  - Gypsies
The difficulty of changing "Because it has always been done like this" is a challenge.

'To improve is to change; to be perfect is to change often' — Winston Churchill

‘Nothing happens until something moves’ — Albert Einstein