

Catalan Heart Transplant Registry

1984-2008 Report

Advisory Committee for the Catalan Heart Transplant Registry

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Introduction

In 1984, the first heart transplant carried out in Catalonia was performed at Hospital de la Santa Creu i Sant Pau. It was also the first successful heart transplant carried out in Spain. A few years later, in 1991, the Hospital Universitari de Bellvitge began working in this field, and was followed by the Hospital Clínic i Provincial de Barcelona in 1998. The Hospital Maternoinfantil Vall d'Hebron was authorized to perform heart and heart-lung transplants in 2006 for children and adolescents.

The Heart Transplant Registry was created in 1993 and contains data on the transplants done in Catalonia since 1984. The data on transplants carried out in the 1984-1993 period were gathered retrospectively, but, since 1994, the registry has systematically gathered data as they have become available.

Publishing the registry is one of the objectives of OCATT, as is managing the data of the Registry Advisory Committee, which responds to the information requirements on planning, resource management and the purchase of services of the Catalan Health Service and the Ministry of Health. The registry is also an information source that is accessible to external users, such as healthcare professionals, and responds to the needs of other sectors. In all cases, processing of and access to data is subject to regulations in force on the protection of personal data.

The main aim of this report is to provide information about the activity and characteristics of the heart transplants carried out in Catalonia in 2008, and to describe the evolution of the transplants carried out since 1984. This information is made available to professionals who are directly involved in this treatment, as well as members of the public administration working in the area of healthcare.

Some Remarks on Methodology

This report describes the evolution of heart transplants in Catalonia and analyses the characteristics of receivers, donors and transplants, as well as the results obtained.

The actuarial method was used to calculate the patient survival rate (time before death). The level of statistical significance of the different curves was evaluated using the Wilcoxon test (Gehan). The survival curves break off when the number of cases fell below 10.

The probability of receiving a transplantation was calculated bearing in mind the competitive risk model with three events of interest: transplantation, death and removal from the waiting list.

Description of indicators:

Annual transplant rate

The total number of heart transplants carried out during the year at authorized centres, regardless of the place of residence of the receiver, compared with the population of Catalonia (census of 1991, 1996 and, starting in 1997, annual census updates. National Statistics Institute). Expressed per million inhabitants (pmi).

Evolution of Heart Transplants

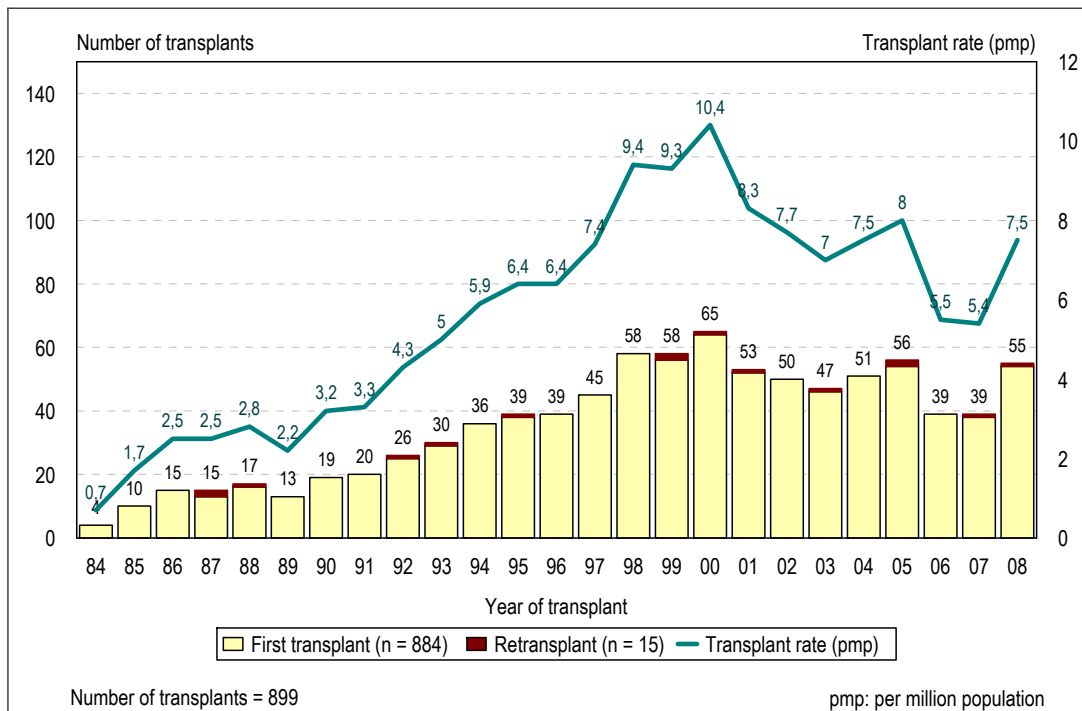
In the 1984-2008 period in Catalonia, 899 heart transplants were performed on 884 patients (15 retransplants were performed). In 2008, 55 transplants were performed on 54 patients (54 first transplants and one retransplantation).

The first combined heart-kidney transplant was performed in 1999 and 10 have been done since then, one of which was performed in 2008. In 1988 a combined heart-pancreas transplant was performed, in 2006, a heart-lung transplant was performed, and in 2008, a heart-liver transplant was performed.

The annual evolution of the number of heart transplants has varied over the years, showing upward trends in 1992 and 1997 (years in which new centres began activity) and until 2000, when the first changes in evolution were registered. In 2008, evolution showed an upward trend, going from 39 transplants to 55 (Figure 1).

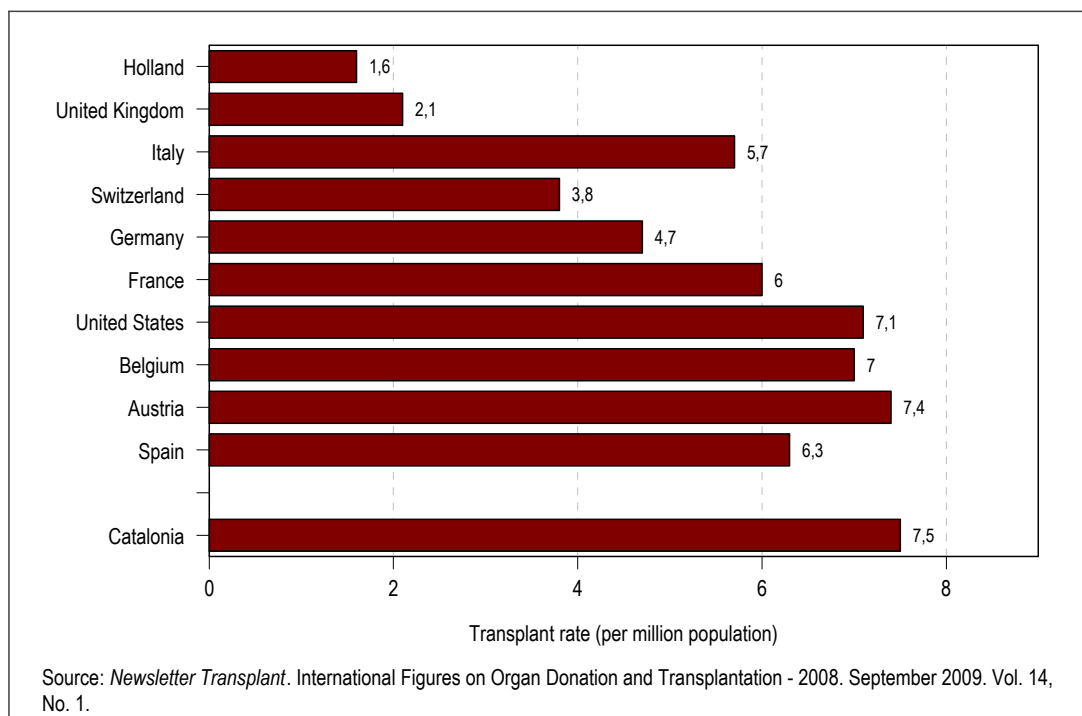
Because of these changes in trend, the annual rate of heart transplants was also affected and showed a clear upward trend in the 1992-2000 period, but has declined since then. In 2008, the transplant rate was 7.5 per million inhabitants, which was higher than the previous year (Figure 1).

Figure 1. Annual evolution of the number of transplants and annual heart transplant rate. 1984-2008



The annual heart transplant rate varies considerably between countries. Catalonia shows one of the highest rates of transplant activity (Figure 2). However, these data should be interpreted with caution, bearing in mind different factors that affect transplant activity in each country (the healthcare system, indication criteria, population structure, etc.).

Figure 2. Heart transplant rate in different countries. 2008



Recipient characteristics

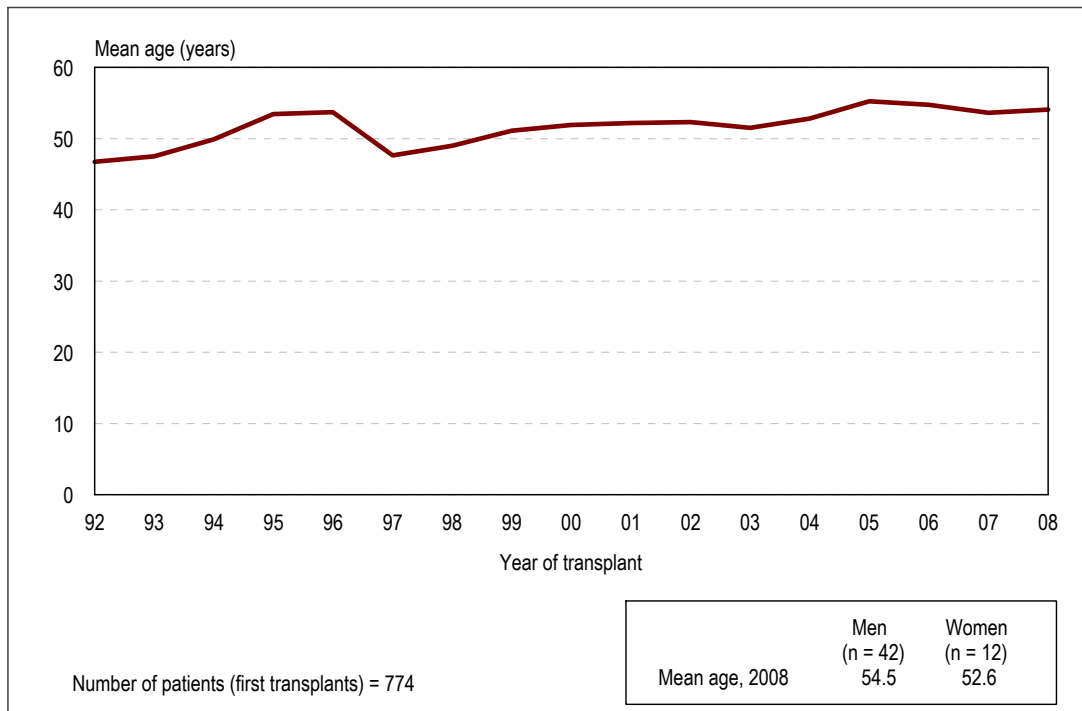
◆ Sex and age

Of the 884 patients who received transplants (first transplants) in the 1984-2008 period, 705 (79.8%) were men and 179 (20.2%) were women. These percentages remained stable in accordance with the year of the transplantation. In 2008, 42 (77.8%) patients were men and 12 (22.2%) were women.

The mean age of the patients who received their first heart transplant in the 1984-2008 period was 51 (51 for men and 49 for women), the median age was 53 and the range was from age 6 to 71.

Over the years, the mean age has increased, going from 48 in 1997 to 54 in 2008, though the highest mean age of 55 was reached in 2005 and 2006 (Figure 3).

Figure 3. Annual evolution of the mean age of patients receiving their first heart transplant. 1992-2008



The increase in mean age over the years is largely due to the gradual increase in transplants done on patients aged 50 or more.

In 2008, 31.5% of the patients who received their first transplantation were between 50 and 60 and 38.9% were over 60. In 1997, these percentages were 33.3% and 20.0%, respectively (Figure 4).

Globally, 63.6% of patients were 50 or over when they received their first heart transplant. In fact, 51.8% of all patients were men aged 50 or more (Figure 5).

Figure 4. Annual evolution of the percentage of patients who received their first heart transplant, by age group. 1992-2008

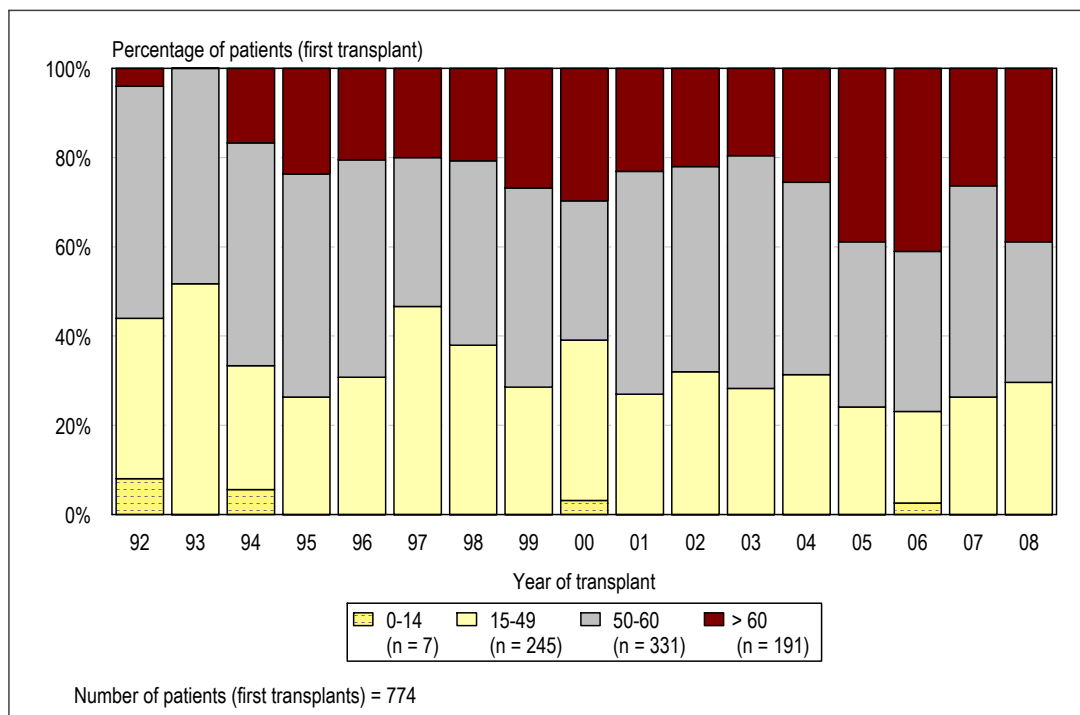
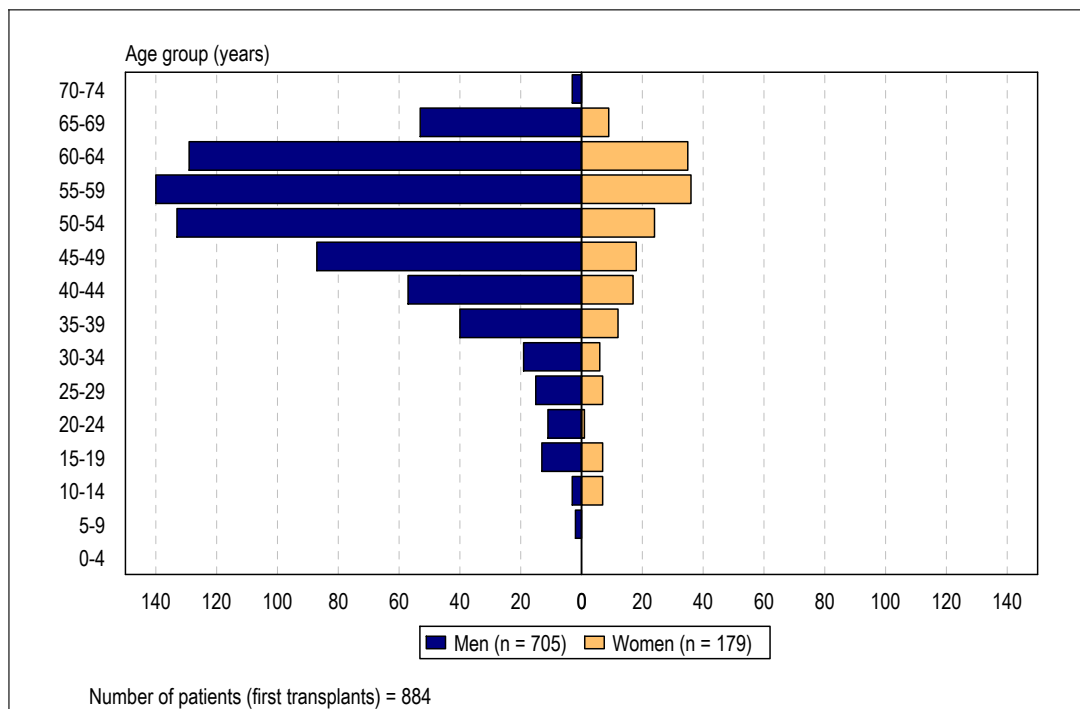


Figure 5. Number of patients who received their first heart transplant, by age group and sex. 1984-2008



◆ Place of residence

91.6% (n = 810) of patients receiving transplants were residents of Catalonia, 7.9% (n = 71) were residents of another part of Spain, and 0.3% (n = 3) were foreigners. In general, the patients who were not residents of Catalonia came from the Balearic Islands (n = 36) or the autonomous community of Aragon (n = 14).

◆ Indications

The diseases for which a heart transplant is indicated are arranged in four groups: dilated cardiomyopathy, ischemic cardiomyopathy, valvular cardiomyopathy and the “other” category, which includes restrictive cardiomyopathy, congenital cardiomyopathy and hypertrophic cardiomyopathy.

Dilated cardiomyopathy and ischemic cardiomyopathy have been the two most common indications and represent 45.9% and 39.4%, respectively, of all the heart transplants carried out in Catalonia since 1984 (Figure 6). In the case of men, 46.5% of patients suffered from ischemic cardiomyopathy and 42.0% from dilated cardiomyopathy. In the case of women, the most common indication (61.5%) was dilated cardiomyopathy (Figure 7).

Figure 6. Percentage of patients who received their first heart transplant, by indication. 1984-2008

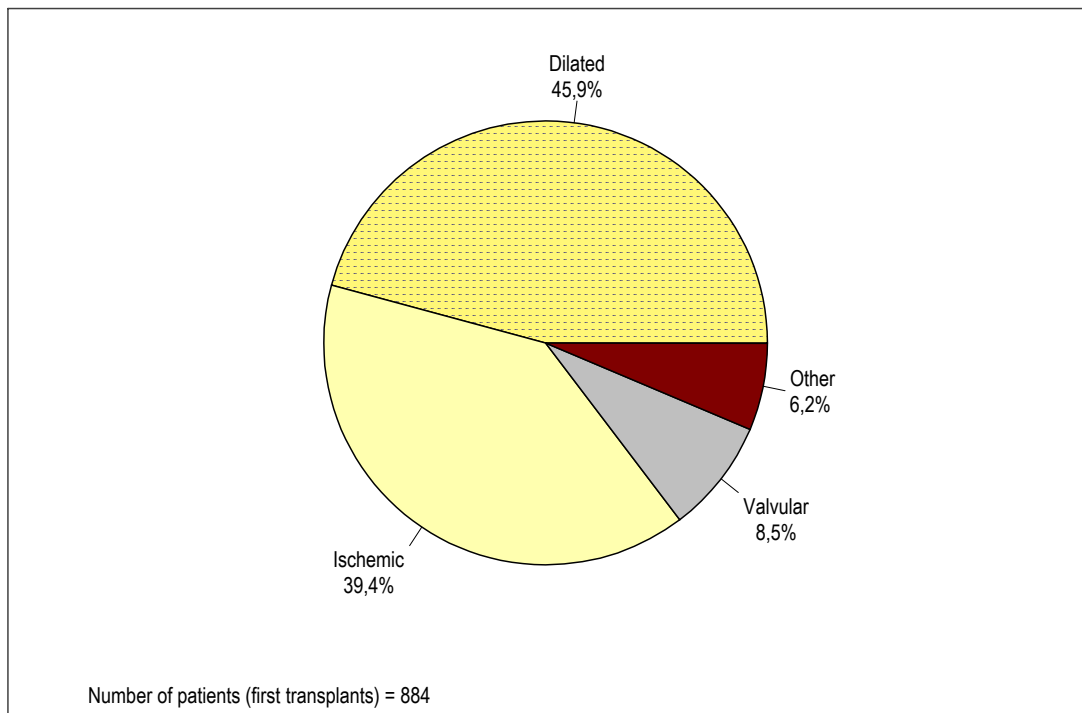
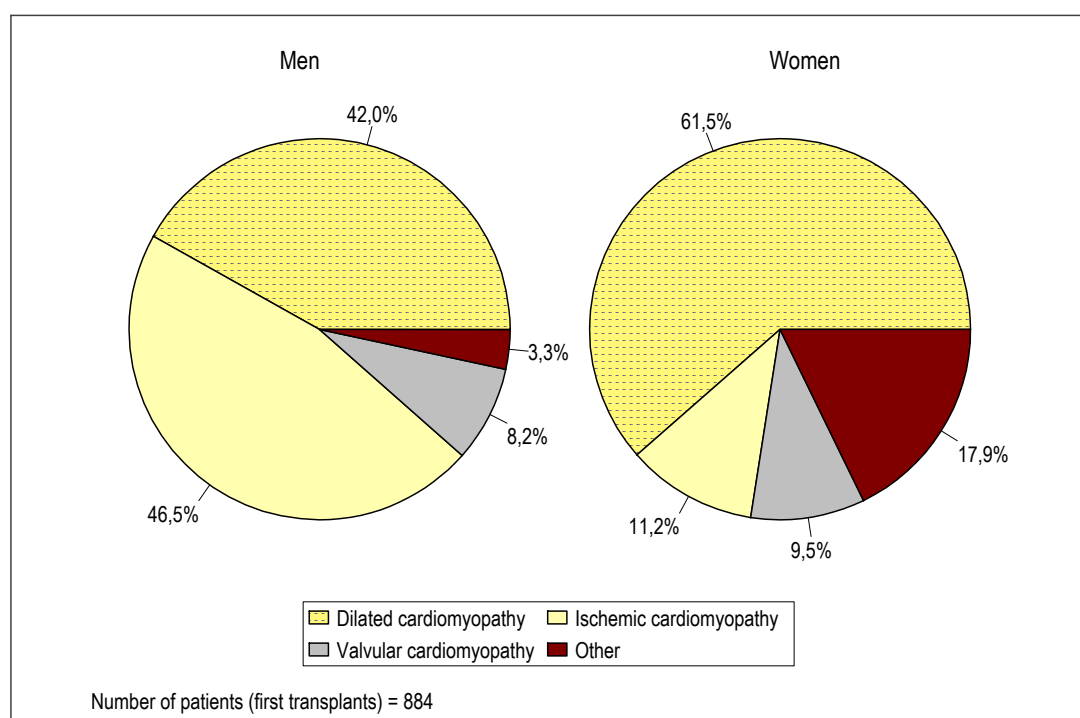


Table 1 provides a breakdown of the indications included in the “Other Indications” category.

Figure 7. Percentage of patients who received their first heart transplant, by indication and sex. 1984-2008**Table 1.** Indications included in the "Other Indications" category. 1984-2008

	Overall		Men		Women	
	n	%	n	%	n	%
Hypertrophic cardiomyopathy	21	38.2%	8	34.8%	13	40.6%
Restrictive cardiomyopathy	15	27.3%	7	30.4%	8	25.0%
Congenital disease	14	25.5%	6	26.1%	8	25.0%
Arrhythmogenic right ventricular dysplasia	4	7.3%	2	8.7%	2	6.3%
Myocardiotoxicity following chloroquine poisoning	1	1.8%	-	-	1	3.1%
	55	100%	23	100%	32	100%

In 2008, 48.1% (n = 26) of the patients presented with dilated cardiomyopathy and 31.5% (n = 17) with ischemic cardiomyopathy. The most common disease has changed over the years. Although dilated cardiomyopathy was the most frequent indication in the early years, the percentages of this disease are now much more similar to those of ischemic cardiomyopathy and in some years this indication was even the most frequent. At any rate, given the low number of transplants performed annually, it is difficult to assess the slight changes between one year and another (Figures 8 and 9).

Figure 8. Annual evolution of the number of patients who received their first heart transplant, by indication. 1992-2008

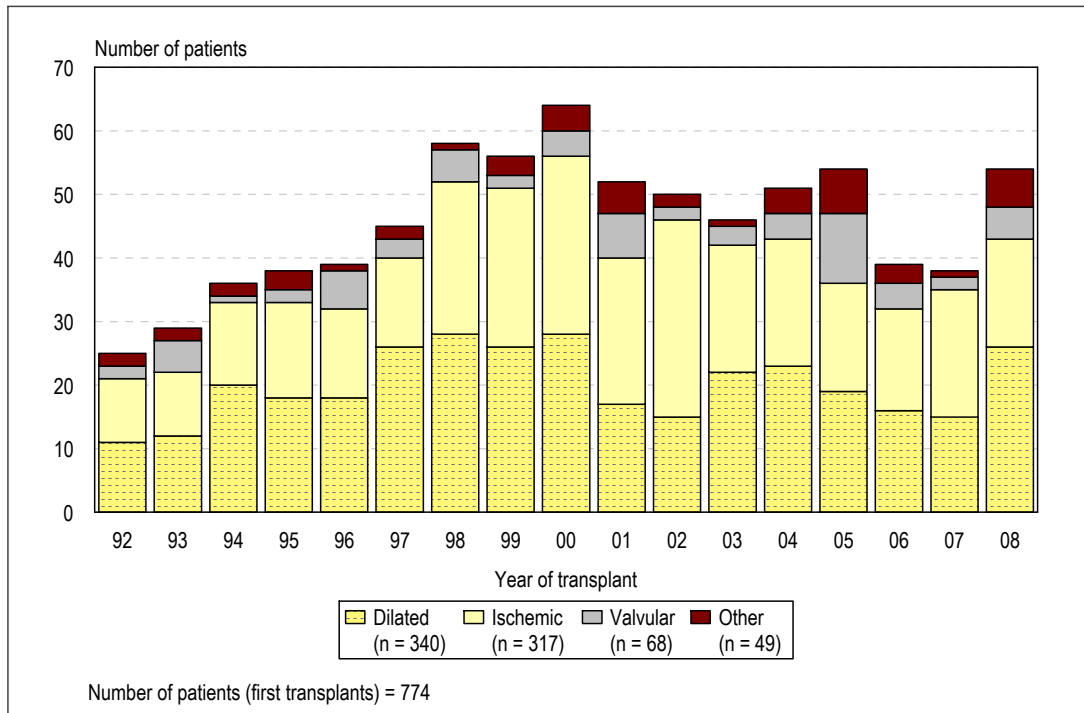
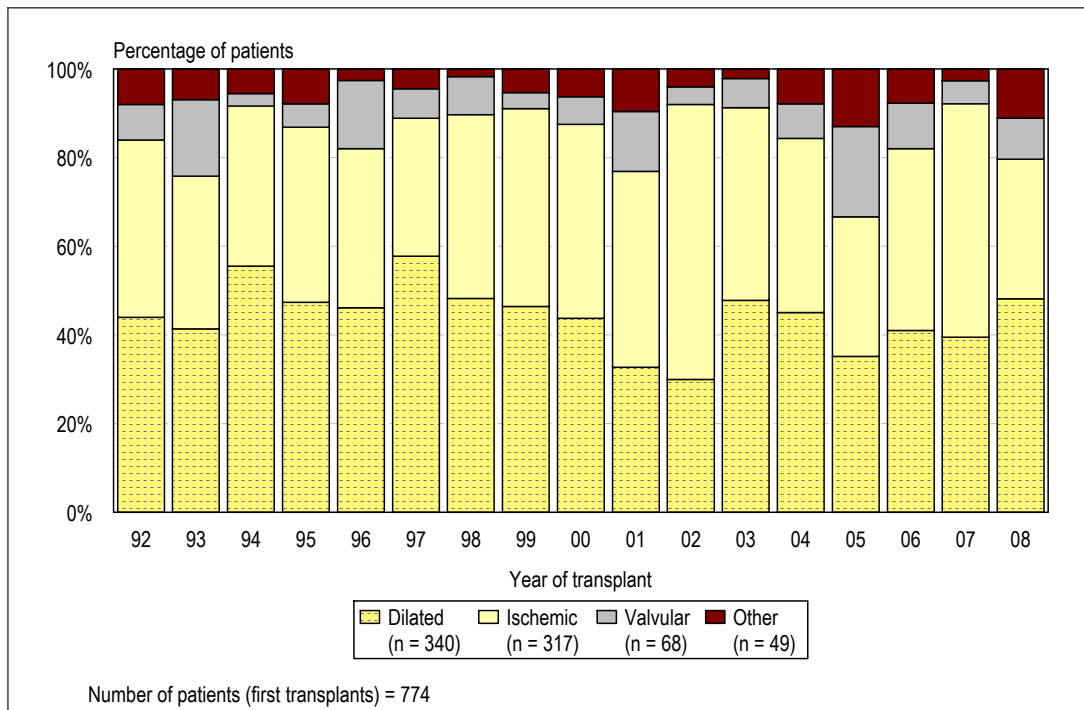
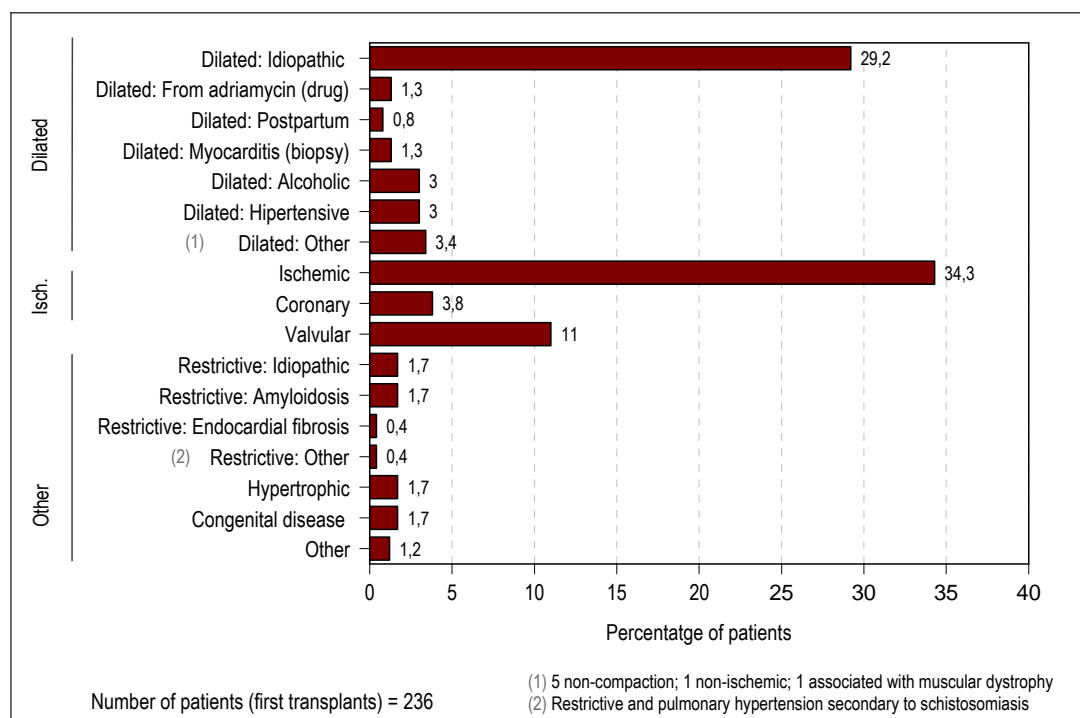


Figure 9. Annual evolution of the percentage of patients who received their first heart transplant, by indication. 1992-2008



In 2004, the registry started using a new system to classify indicated diseases so they could be accounted for more accurately. The most frequent indications in the years from 2004 to 2008 were idiopathic dilated cardiomyopathy, ischemic cardiomyopathy and valvular cardiomyopathy (Figure 10).

Figure 10. Percentage of patients who received their first heart transplant, by indication . 2004-2008



Statistically significant differences in mean age were observed between the four indications ($p < 0.0001$): the patients with ischemic cardiomyopathy or valvular cardiomyopathy were older than those who presented with dilated cardiomyopathy (Table 2). The differences between men and women when treated separately were also statistically significant (Table 3).

Table 2. Mean and confidence interval of age, by indication. 1984-2008

	n	Mean	95% CI
Dilated cardiomyopathy	406	49.0	47.7 – 50.4
Ischemic cardiomyopathy	348	54.2	53.4 – 55.0
Valvular cardiomyopathy	75	53.5	51.4 – 55.5
Other forms of cardiomyopathy	55	37.1	32.5 – 41.7
Total	884	50.7	49.9 – 51.5

Table 3. Mean and confidence interval of age, by indication and sex. 1984-2008

		n	Mean	95% CI
Dilated cardiomyopathy	Men	296	48.3	46.7 – 49.9
	Women	110	50.9	48.4 – 53.3
Ischemic cardiomyopathy	Men	328	54.3	53.4 – 55.1
	Women	20	53.2	49.4 – 57.1
Valvular cardiomyopathy	Men	58	53.7	51.4 – 55.9
	Women	17	52.7	47.2– 58.2
Other forms of cardiomyopathy	Men	23	39.2	31.7 – 46.7
	Women	32	35.6	29.6 – 41.7
Total	Men	705	51.2	50.4 – 52.1
	Women	179	48.6	46.5 – 50.7

Donor characteristics

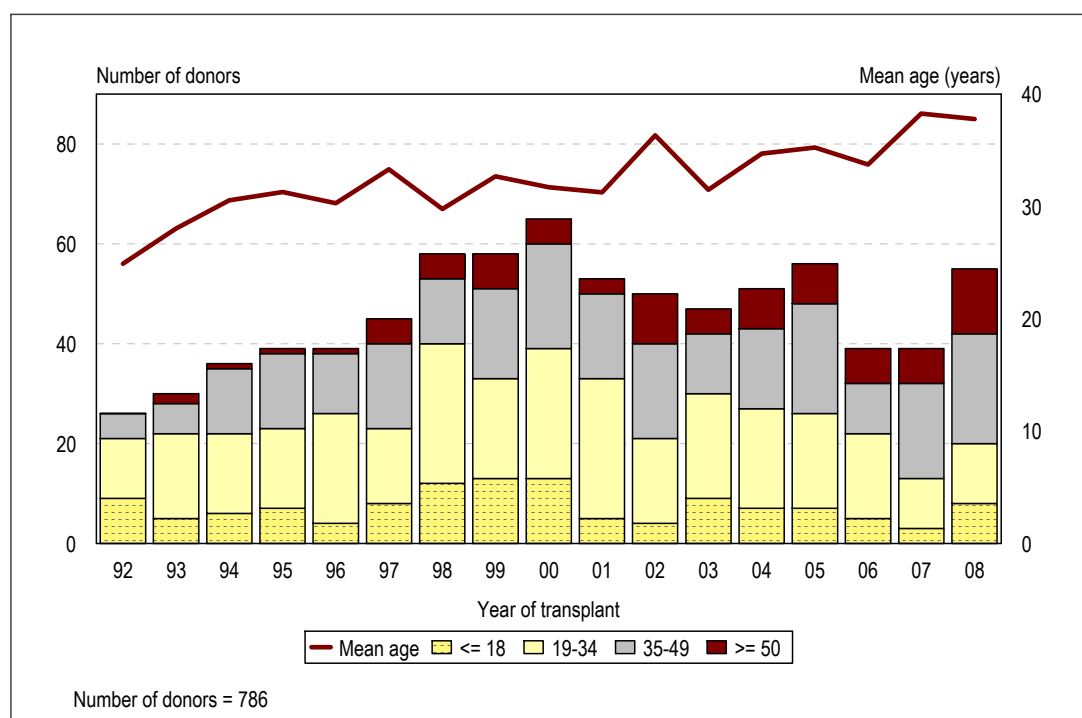
◆ Sex and age

Of the 786 transplants carried out in the 1984-2008 period, 71.1% of the donors were men (n = 559) and 28.9% were women (n = 227). In 2008, 70.9% were men and 29.1% were women.

The mean age of the donor over the 1984-2008 period was 32, the median age was 30 and the range was from age 5 to 64 (in the 1992-2008 period, the mean age of the donor was 33 and the median was 31). The mean age has increased over the years, going from 25 in 1992 to 38 in 2008 (Figure 11).

This increase has occurred because of older donors, given that in 2008, 23.6% of donors were age 50 and over, whereas there were no donors in this age group in the first years of the programme.

Figure 11. Evolution of the mean age of the donor. 1992-2008

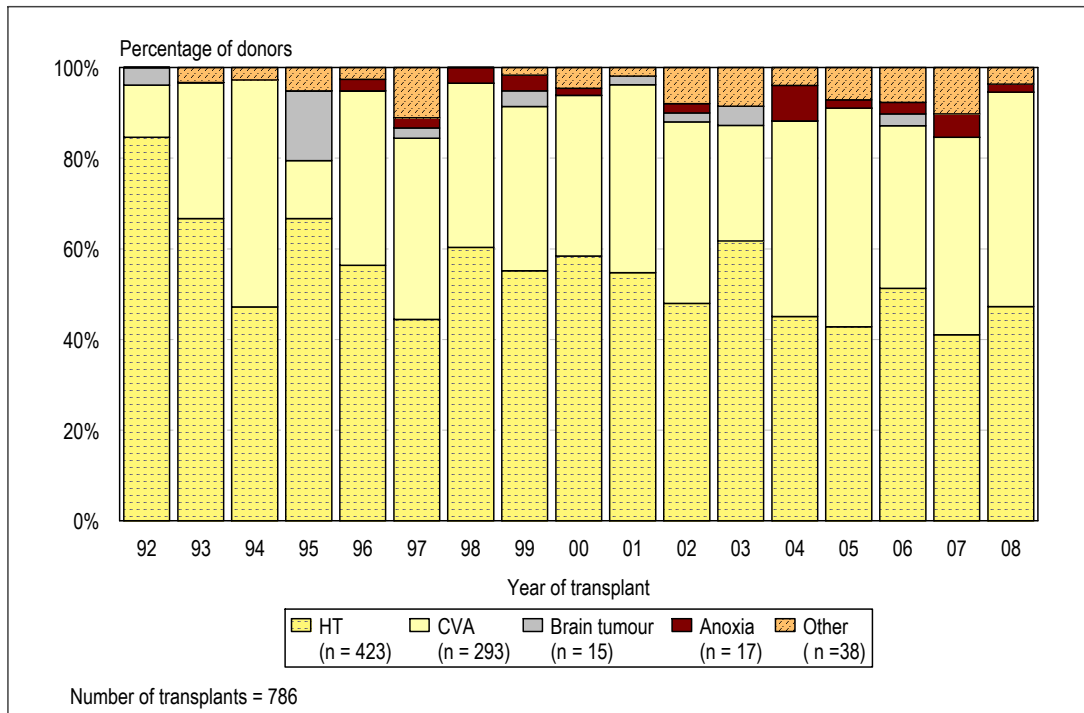


◆ Cause of death

The most frequent cause of death of the donor was head trauma (HT), which represented 55.7% of all causes, followed by cerebrovascular accident (CVA) / stroke, which represented 35.6%. (In the 1992-2008 period, these percentages were 53.8% and 37.4%, respectively.)

In keeping with the increase in the age of donors, the number of donors who died from CVA / stroke also increased (Figure 12). In 2008, 47.3% of donors died from head trauma and 47.3% from CVA / stroke.

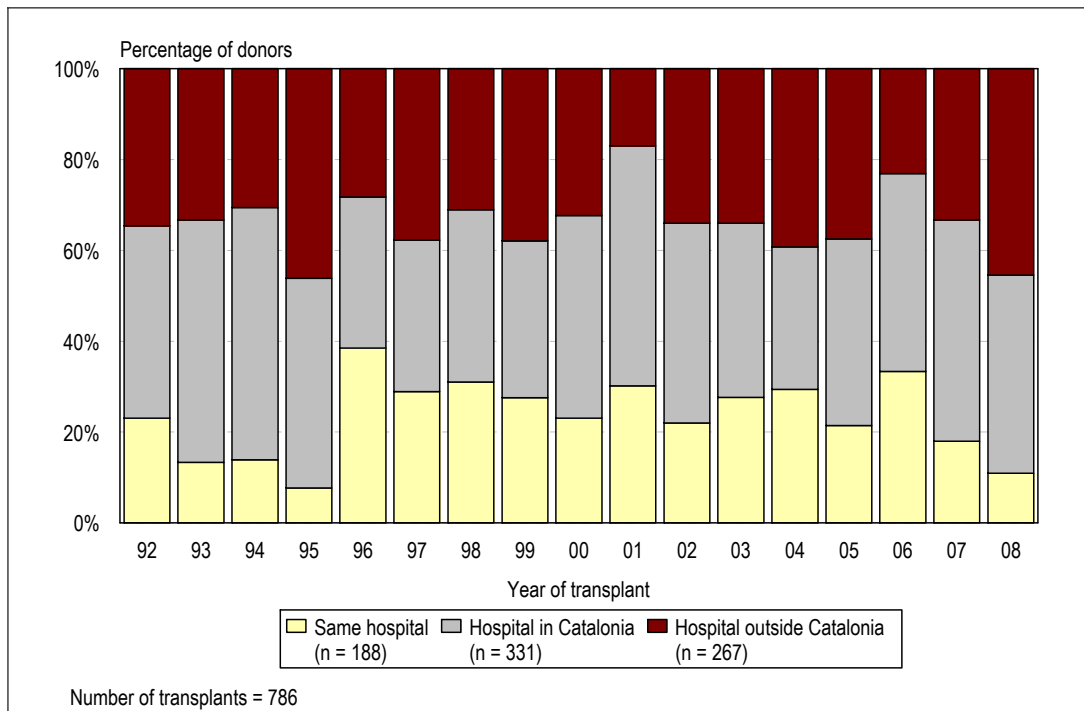
Figure 12. Evolution of the cause of death of donor (%). 1992-2008



◆ **Source of organs**

In the 1984-2008 period, 22.6% (203) of the transplanted organs came from the same hospital where the transplant was carried out, 45.1% (405) from other hospitals in Catalonia, and 32.4% (291) from hospitals outside Catalonia. In 2008, 10.9% of the organs came from the same hospital, 43.6% from Catalonia, and 45.5% from outside Catalonia (Figure 13).

Figure 13. Annual evolution of the source of organs (%). 1992-2008



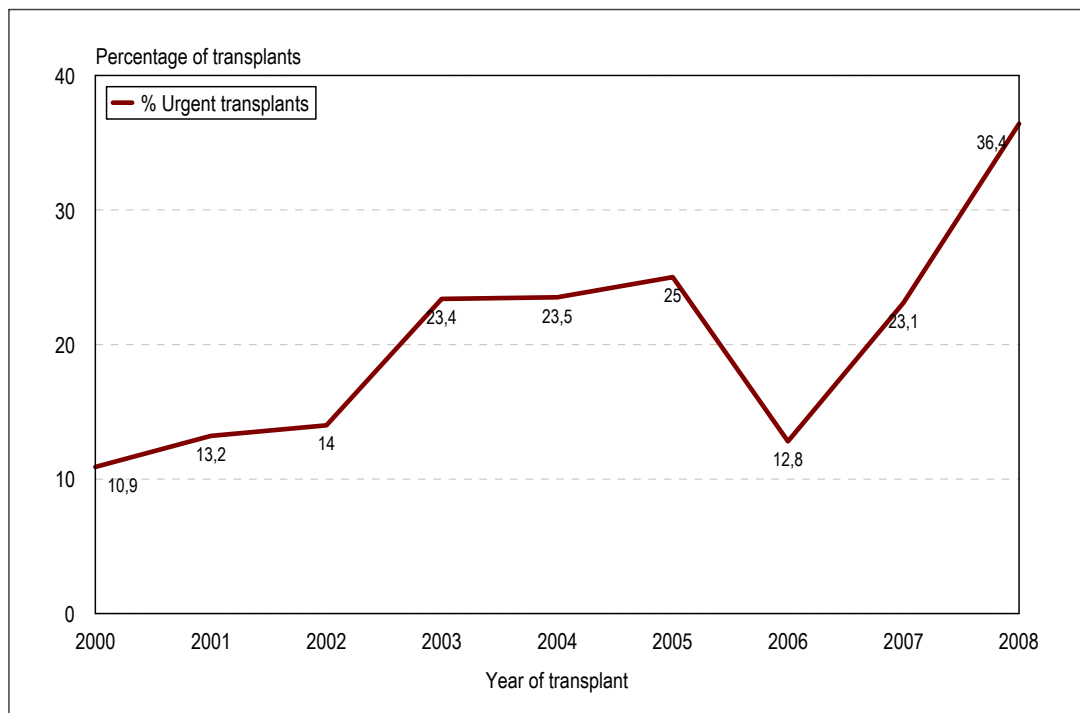
Transplant characteristics

◆ Urgency

Of the 455 transplants carried out in the 2000-2008 period, 20.2% (92) were urgent.

36.4% (20) of the transplants carried out in 2008 were urgent, which is a higher percentage than in previous years (Figure 14).

Figure 14. Annual evolution of the percentage of urgent transplants. 2000-2008



◆ Cold ischemia time

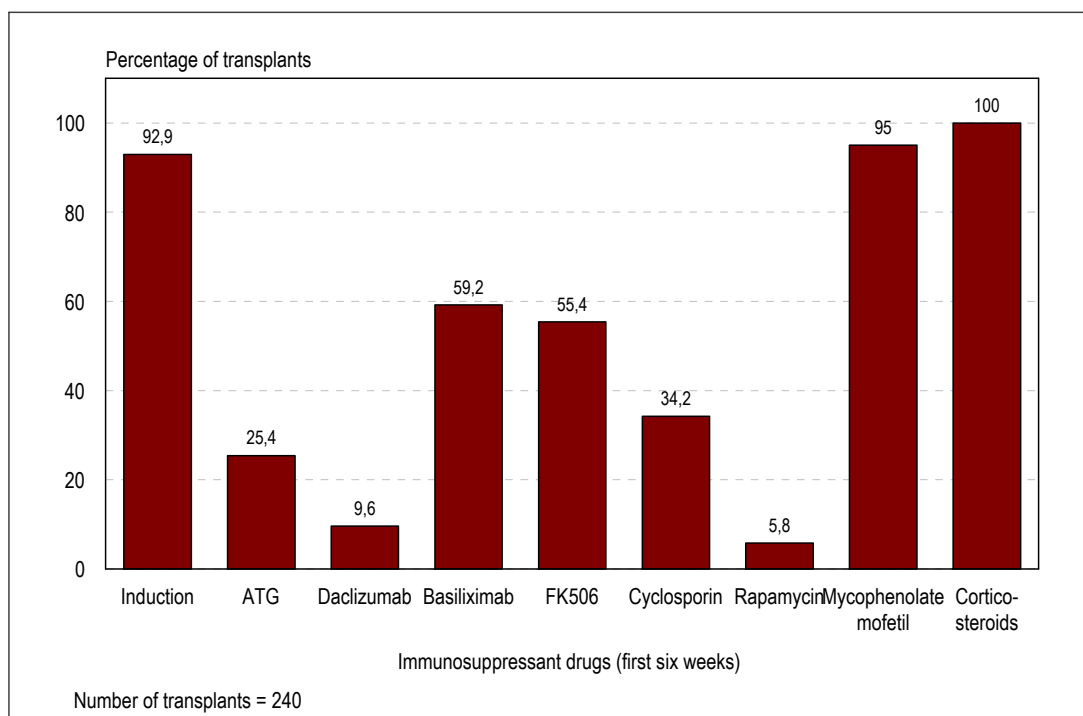
The mean cold ischemia time was 171 minutes. Bearing in mind the source of the organ, the differences observed were statistically significant ($p < 0.0001$). When the organ came from a hospital outside Catalonia, the mean cold ischemia time was 75 minutes longer than when the organ came from a hospital in Catalonia (Table 4).

◆ Immunosuppressors

The distribution of immunosuppressors used in the first six weeks after transplant is shown in Figure 15. The overwhelming majority of transplant patients underwent induction immunosuppressive treatment and basiliximab was the drug used most.

Table 4. Cold ischemia time, in minutes, in accordance with the source of the organ. 1984-2008

	Same Hospital (n = 200)	Hospital in Catalonia (n = 399)	Hospital outside Catalonia (n = 285)	Total (n = 884)
Mean	130	153	226	171
Median	125	148	228	162
Range	60 – 230	64 – 369	105 – 360	60 – 369
95% CI	126 – 135	148 – 157	221 – 231	167 – 175

Figure 15. Immunosuppressant drugs used in the first six weeks after heart transplant. 2004-2008

Retransplants

Of the 805 transplants carried in the 1984-2008 period, 15 were retransplants.

The time between one transplantation and the other ranged from 0 to 13 years. The mean was 4.5 years (the median was 2 years). Specifically, 4 patients (26.7%) received a second transplant within the first week after receiving the first, 3 (20.0%) between the first week and three months after receiving the first transplant, and 8 (53.3%) after the first year.

Tables 5 and 6 show the main characteristics of the retransplants.

Table 5. Characteristics of the patients who received a retransplantation, by the time elapsed since the first transplantation. 1984-2008

	0 - 3 months	> 3 months
Sex		
Male	5 (71.4%)	6 (75.0%)
Female	2 (28.6%)	2 (25.0%)
Age (years)		
Mean	44	33
Median	42	38.5
Range	35 – 63	15 – 43
Indications		
Dilated cardiomyopathy	2 (28.6%)	6 (75.0%)
Ischemic cardiomyopathy	3 (42.9%)	2 (25.0%)
Valvular cardiomyopathy	-	-
Other forms of cardiomyopathy	2 (28.6%)	-

Of the 7 patients who received a retransplantation in the first three months after the first transplant, three had died (two by infection) at 31 December 2008. Of the 8 patients who received a retransplantation after the third month, 5 had died at 31 December 2008: 1 due to graft vascular disease, 2 due to primary dysfunction of the graft and 1 due to other causes.

Table 6. Characteristics of the donor and the transplantation (first transplant), by the time elapsed since the first transplantation. 1984-2008

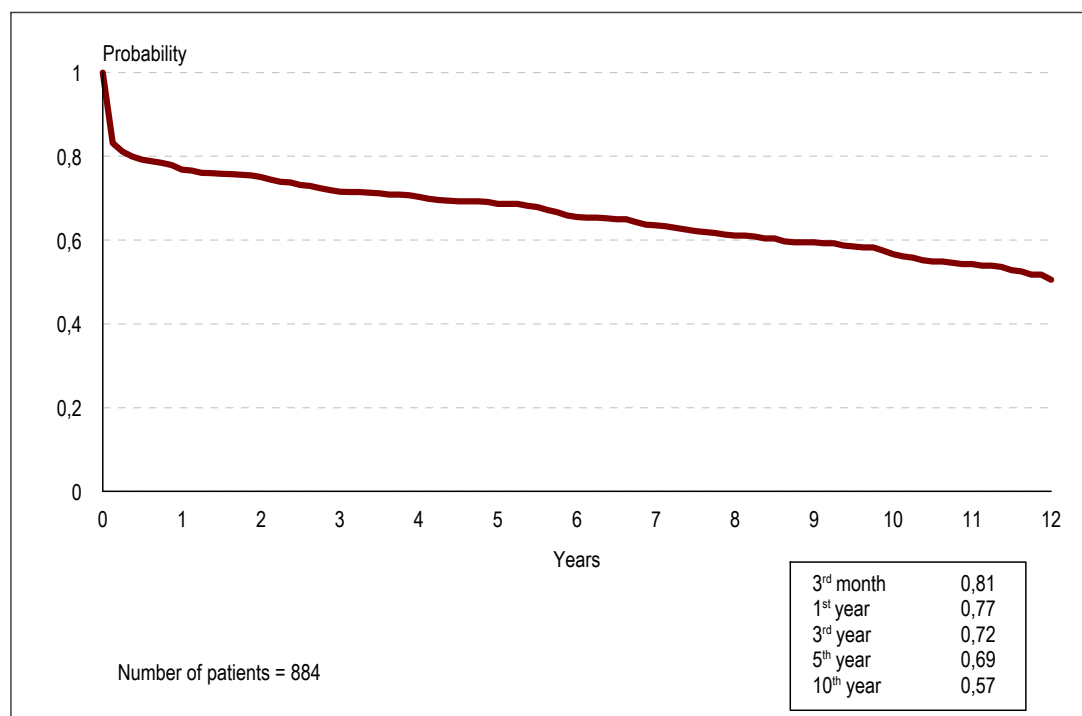
	0 - 3 months ¹	> 3 months
Donor age (years)		
Mean	21	26
Median	23	22.5
Range	11 – 25	14 – 49
Cause of donor's death		
HT	6 (85.7%)	6 (75.0%)
CVA	-	2 (25.0%)
Other	1 (14.3%)	-
Ischemia time (minutes)		
Mean	148	148.0
Median	137.5	131.5
Range	82 – 230	95 – 300

¹ In one case, the ischemia time was not available.

Survival

The survival rate of patients receiving a first heart transplant in Catalonia in the 1984-2008 period was 81% in the first three months, 77% in the first year, 72% in the third year, and 69% in the fifth year (Figure 16).

Figure 16. Survival rate of patients receiving a heart transplant. 1984-2008



The survival rate percentages were very similar to those of the Spanish and international registries (Table 7).

Table 7. Graft survival. Data comparing the Catalan (RTCC), Spanish (RETC)¹ and international registries (ISHLT).² 1984-2008

	RTCC (1984-2008)	RETC (1984-2008)	ISHLT (1982-6/2007)
1 st year	0,76	0,77	0,82
5 th year	0,68	0,66	0,69
10 th year	0,56	0,53	0,51
15 th year	0,36	0,40	0,34

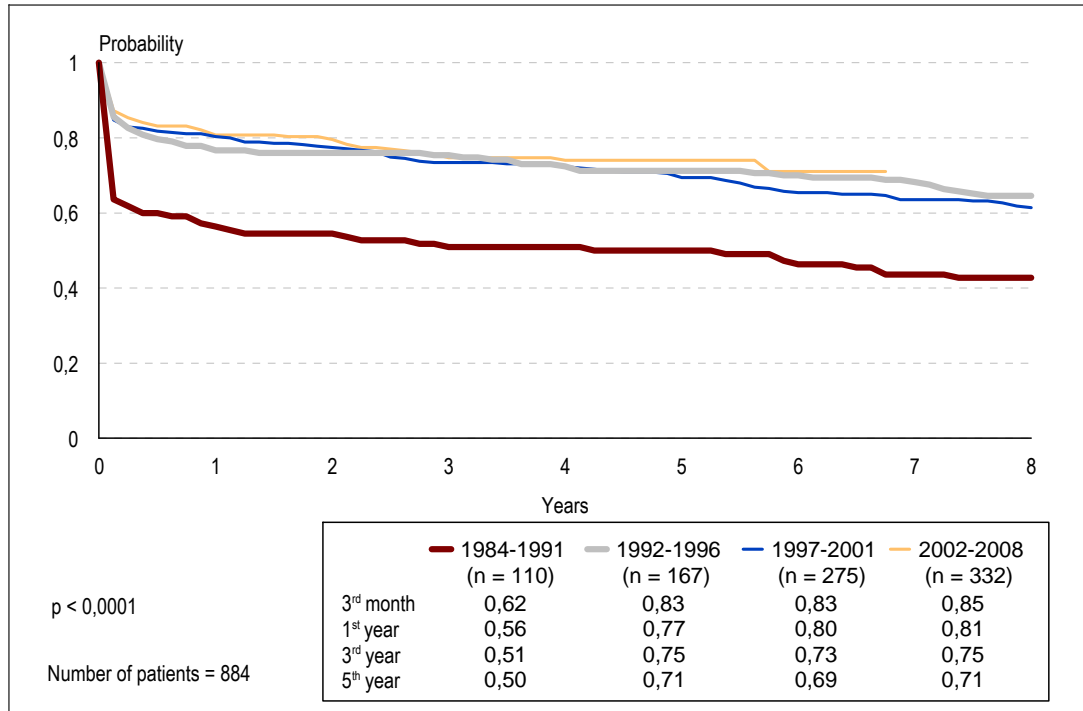
¹ Almenar Bonet, L. Registro Español de Trasplante Cardíaco. XIX Informe Oficial de la Sección de Insuficiencia Cardíaca, Trasplante Cardíaco y otras Alternativas Terapéuticas de la Sociedad Española de Cardiología (1984-2008). Rev Esp Cardiol. 2009;62(11):1286-90.

² International Society for Heart and Lung Transplantation (available at: <http://www.isHLT.org>).

The overall patient survival rate in the 1984-2008 period was affected by the characteristics of the transplants carried out in the first few years (low number of cases, learning period) and by the factors of the transplants carried out in subsequent years (the inclusion of older patients and patients with a more negative prognosis).

The study by period was divided into four time intervals: 1984-1991, 1992-1996, 1997-2001 and 2002-2008. Statistically significant differences were observed between the four periods ($p < 0.0001$), but not between the last three (Figure 17).

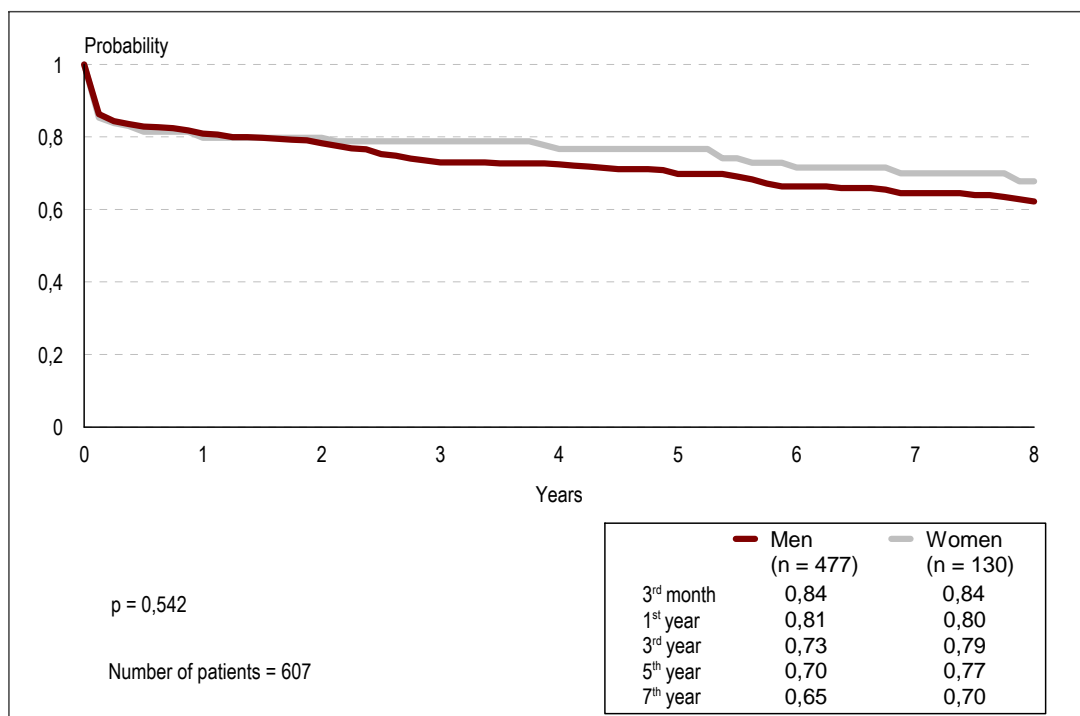
Figure 17. Survival rate of patients receiving a heart transplant, by period. 1984-2008



In order to gain a more up-to-date look at the results, survival rates were prepared with data on the transplants carried out since 1997. In the 1997-2008 period, the patient survival rate was 84% in the third month, 81% in the first year, 74% in the third year, 71% in the fifth year, and 66% in the seventh year.

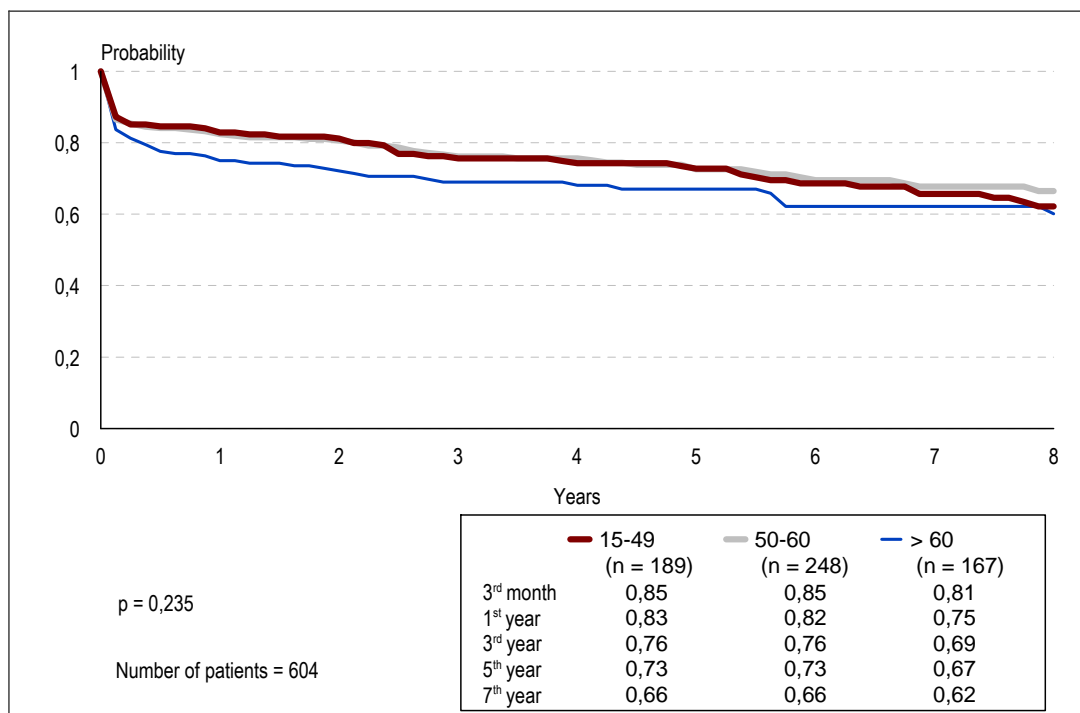
The long-term survival rate was slightly lower for men than women (Figure 18), though the differences were not statistically significant ($p = 0.542$).

Figure 18. Survival rate of patients receiving a heart transplant, by sex. 1997-2008



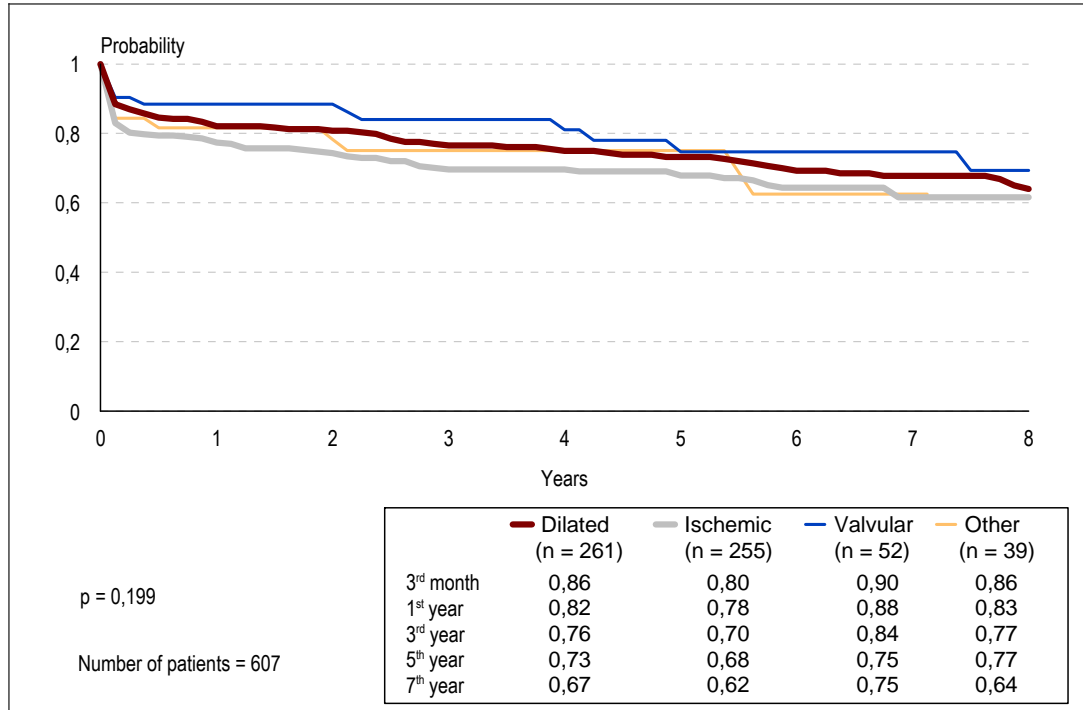
The differences in the survival rates of different age groups (except for patients under age 15 when they received their first transplant) were not statistically significant (Figure 19).

Figure 19. Survival rate of patients age 15 and older receiving their first heart transplant, by age group. 1997-2008



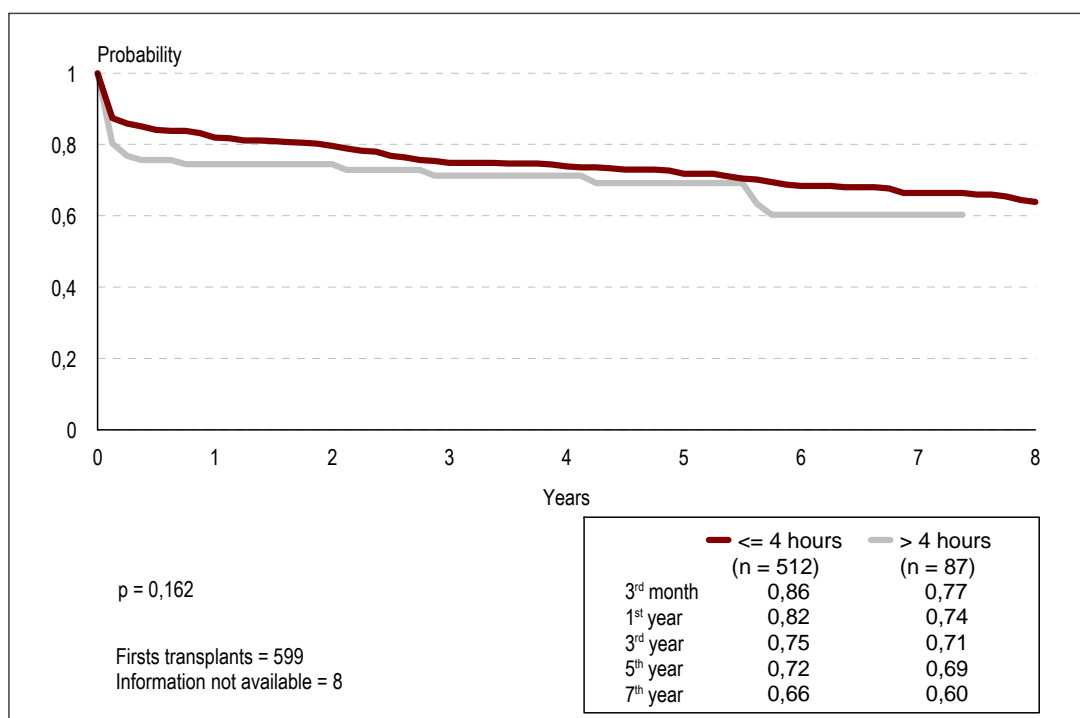
Bearing in mind the indicated disease, the patients with valvular cardiomyopathy showed a higher survival rate than patients with ischemic cardiomyopathy, who had the lowest survival rate (Figure 20). The differences between the four diagnostic groups were not statistically significant ($p = 0.199$), nor were the differences between the two most represented diagnostic categories ($p = 0.096$).

Figure 20. Survival rate of patients receiving a heart transplant, by indication. 1997-2008



When the survival rate was analysed based on the time elapsed between the extraction of the organ and the time of the transplant, it was observed that the probability of survival was greater when the cold ischemia time was less than or equal to four hours, though the differences were not statistically significant ($p = 0.162$) (Figure 21). The greatest differences were seen over the short term.

Figure 21. Survival rate of patients receiving a heart transplant, by cold ischemia time. 1997-2008

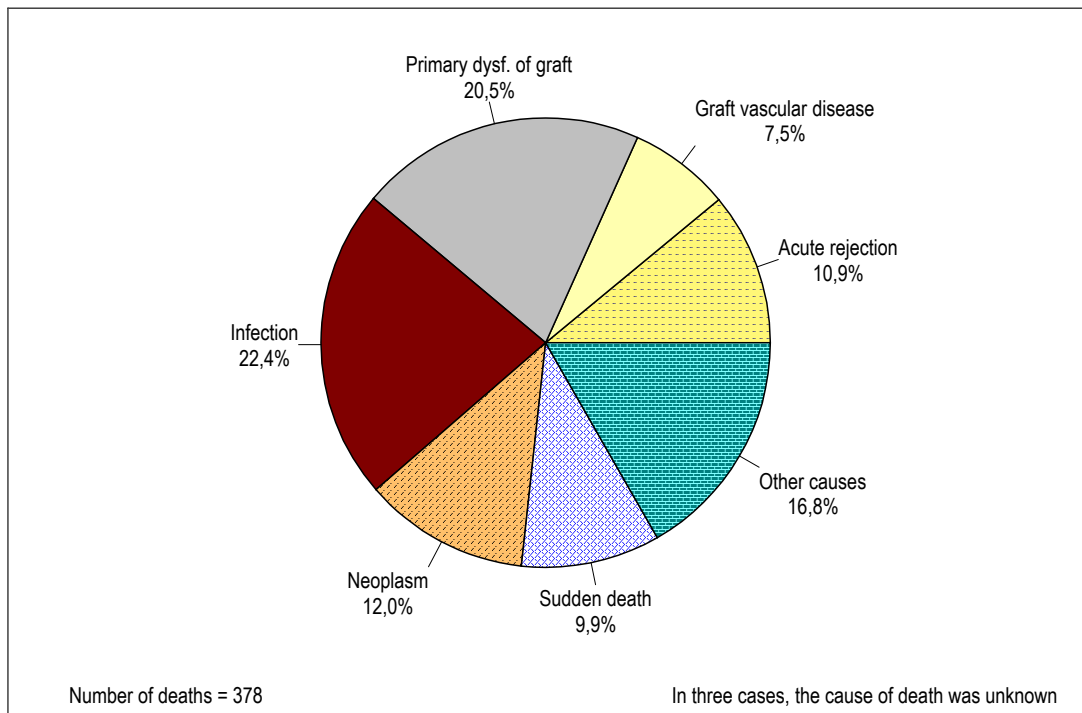


Mortality

Of the 884 patients receiving a transplant in the 1984-2008 period, 378 (42.8%) had died at 31 December 2008, 504 (57.0%) remained alive, and monitoring could not be continued on 2 (0.2%).

The most common causes of death were infection (22.4%) and primary dysfunction of the graft (20.5%), followed by neoplasm (12.0%) and severe rejection (10.9%). The first two causes alone accounted for more than 40% of all deaths (Figure 22).

Figure 22. Percentage of deaths, by cause of death. 1984-2008



When the sex of the patient was considered, these four causes of death were the same, though the percentages for each sex varied (Figure 23).

Mortality was analysed in terms of percentage (per 100 people/year) in relation to the period (year of death). The 1984-1991 period was clearly the one with the highest mortality rate (18.06%), whereas in subsequent periods the mortality rate was less than half the rate of the first period (1992-1996: 7.12%; 1997-2001: 6.25%; 2002-2008: 5.51%). Figure 24 shows the distribution of the cause of death by period, and reflects the drop in mortality due to primary dysfunction of the graft and severe rejection.

Figure 23. Percentage of deaths, by cause of death and sex. 1984-2008

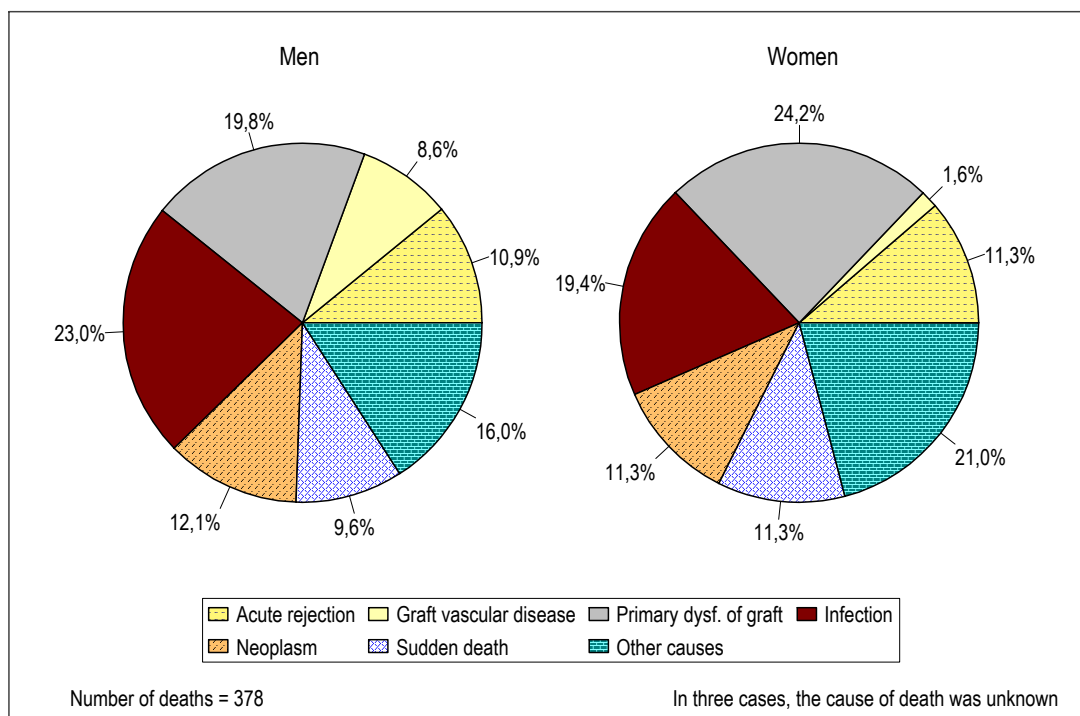
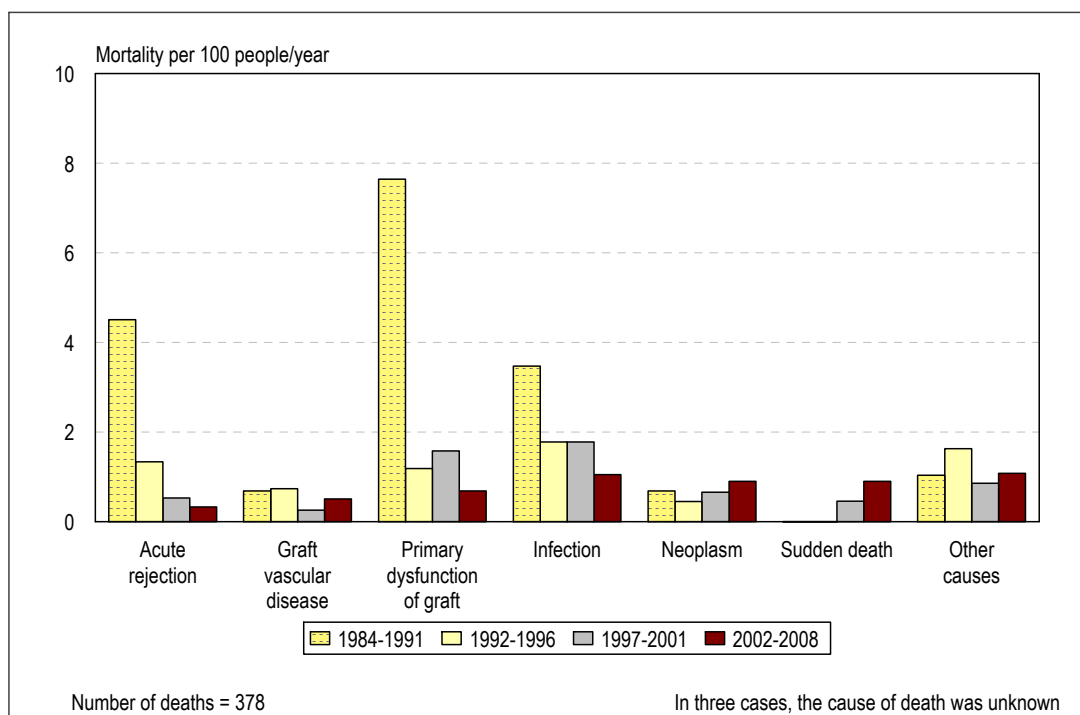


Figure 24. Distribution of the cause of death by period, year of death, as a percentage (per 100 people/year). 1984-2008



In 34.9% (132) of cases, death occurred in the first month after transplantation (Figure 25) and the main cause of death was primary dysfunction of the graft (Figure 26).

Figure 25. Time elapsed between the transplantation and death. 1984-2008

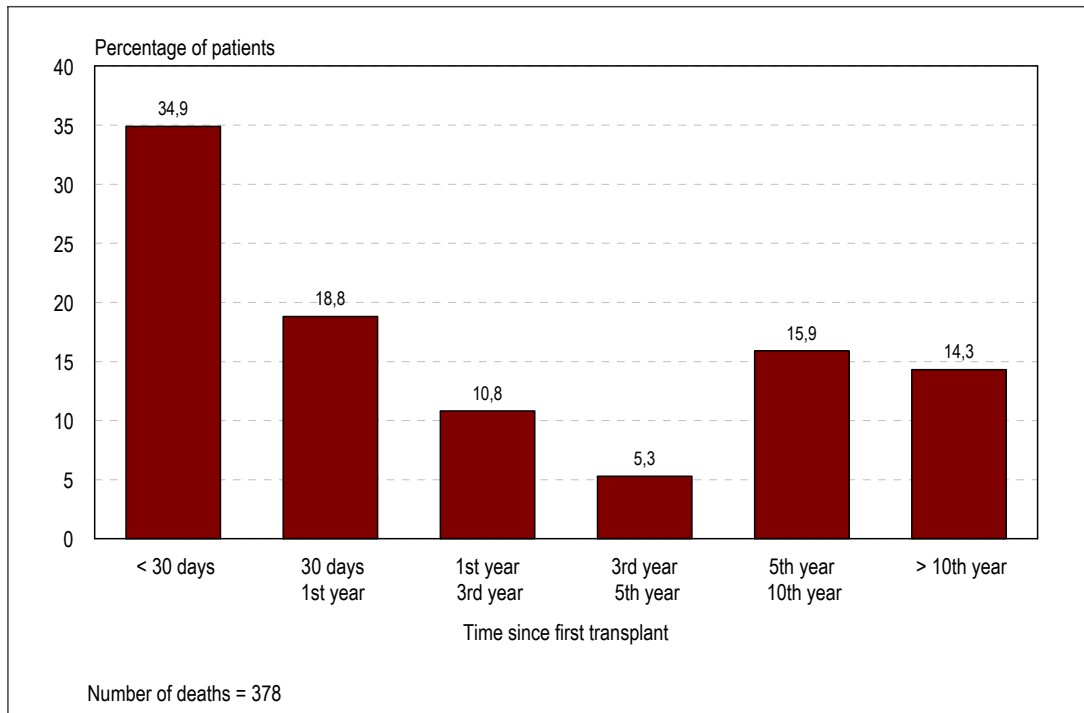
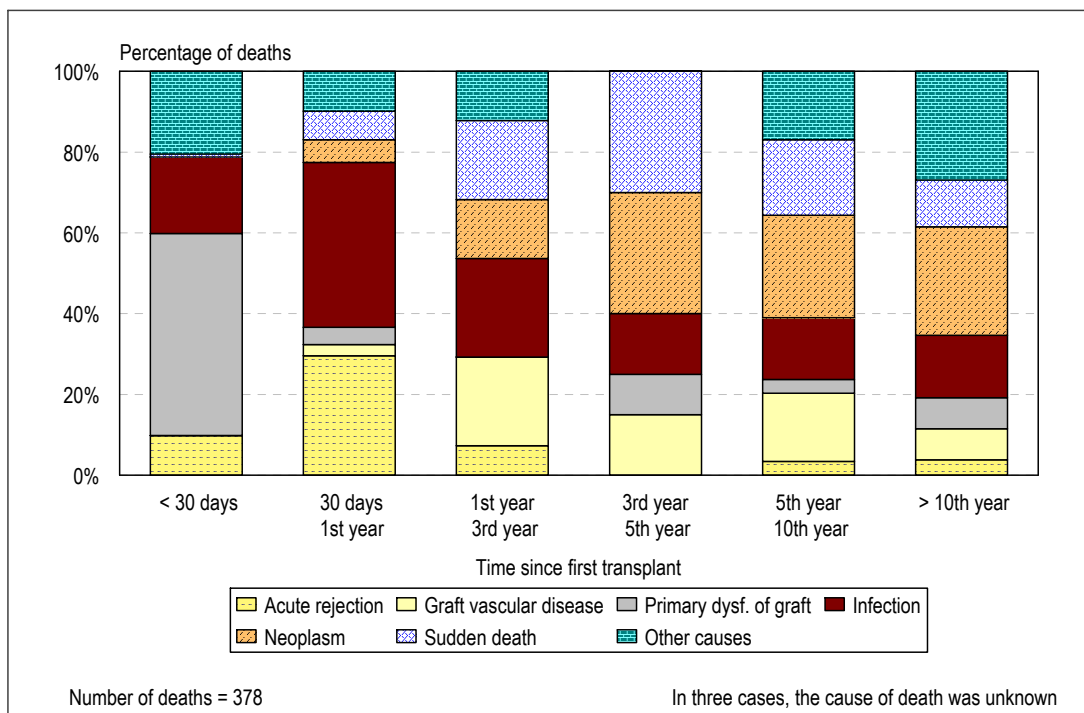


Figure 26. Percentage of deaths by cause of death and time elapsed since the transplantation. 1984-2008



Waiting List

The number of patients on the waiting list at the end of 2008 was lower than in previous years, going from 26 to 14 (Figure 27).

Figure 27. Evolution of the waiting list and the number of heart transplants. 1990-2008

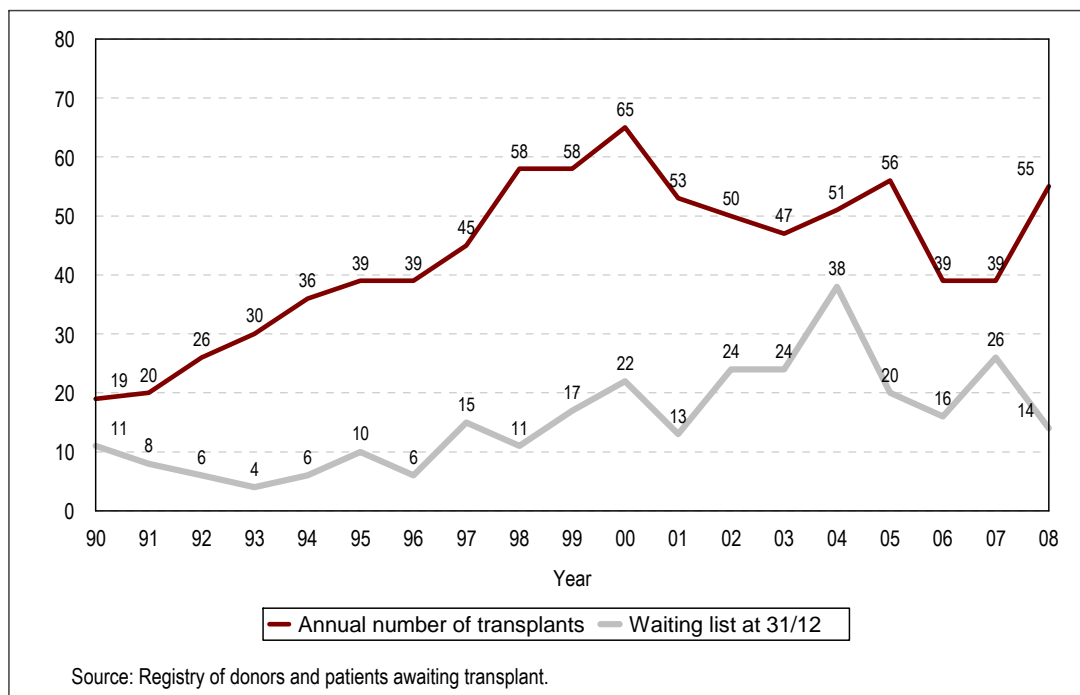
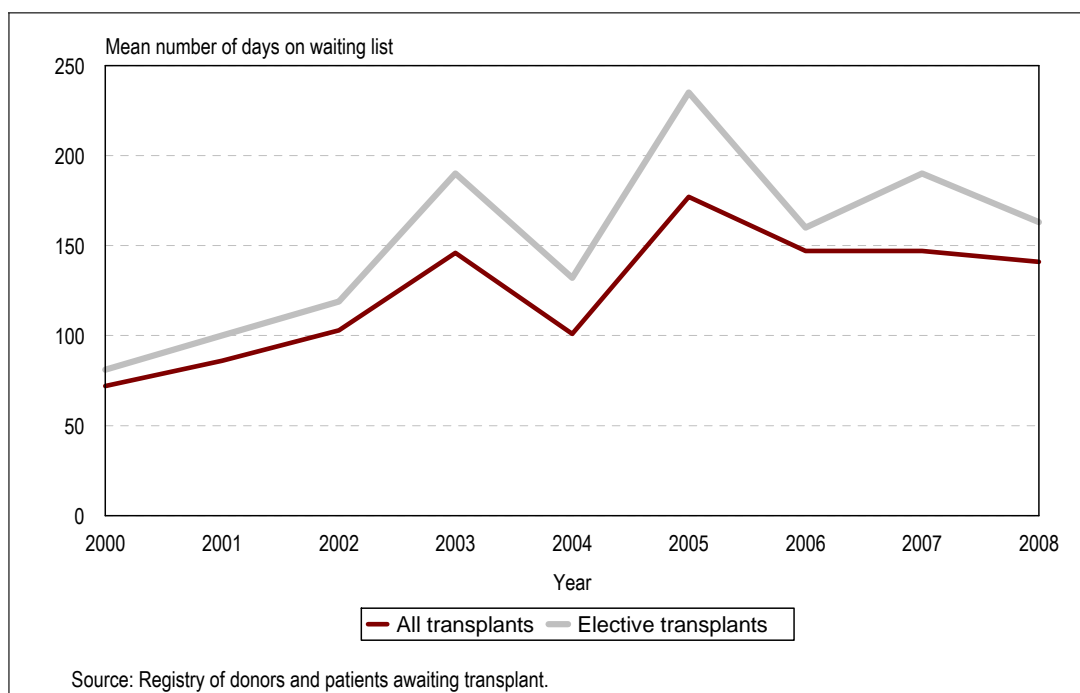


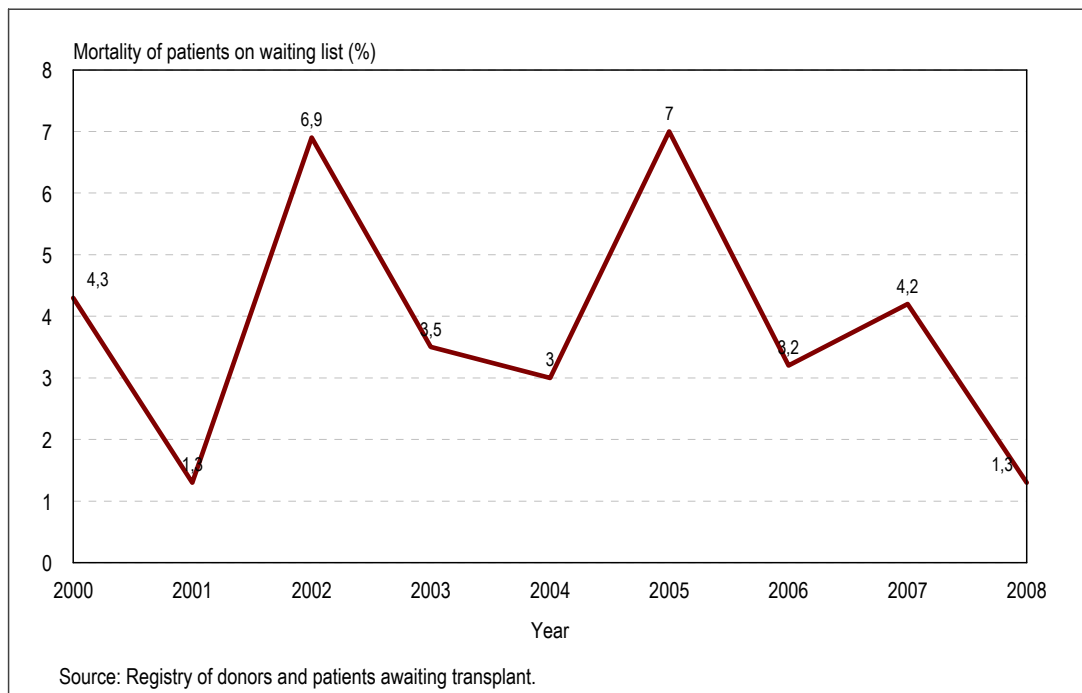
Figure 28. Mean number of days on the waiting list to receive a heart transplant. 2000-2008



In 2008, the mean number of days a patient was on the waiting list for a heart transplant was 141; if urgent transplants are excluded, the mean number of days went up to 163 (Figure 28).

In 2008, 70 patients were added to the waiting list. Of the patients taken off the list, 2 were removed because their health improved and 18 were removed because their health worsened. The mortality rate of the patients on the waiting list was 1.3%, which was lower than in previous years. Because of the low number of cases in recent years, the major fluctuations observed should be evaluated with caution (Figure 29).

Figure 29. Mortality of patients on the waiting list to receive a heart transplant (%). 2000-2008



In the 2000-2008 period, the probability of receiving a heart transplant in the first six months on the waiting list was 58%; in the first year, it was 71% (Figure 30).

When the probability of receiving a transplant was analysed bearing in mind the patient's blood type, it was observed that for patients with blood type A, the probability (56% in the first six months and 70% in the first year) was slightly higher than patients with blood type O (56% in the first six months and 69% in the first year). Patients with blood type B and AB had higher probabilities, but these probabilities were unstable due to the low number of cases (Figure 31).

Figure 30. Probability of receiving a heart transplant. 2000-2008

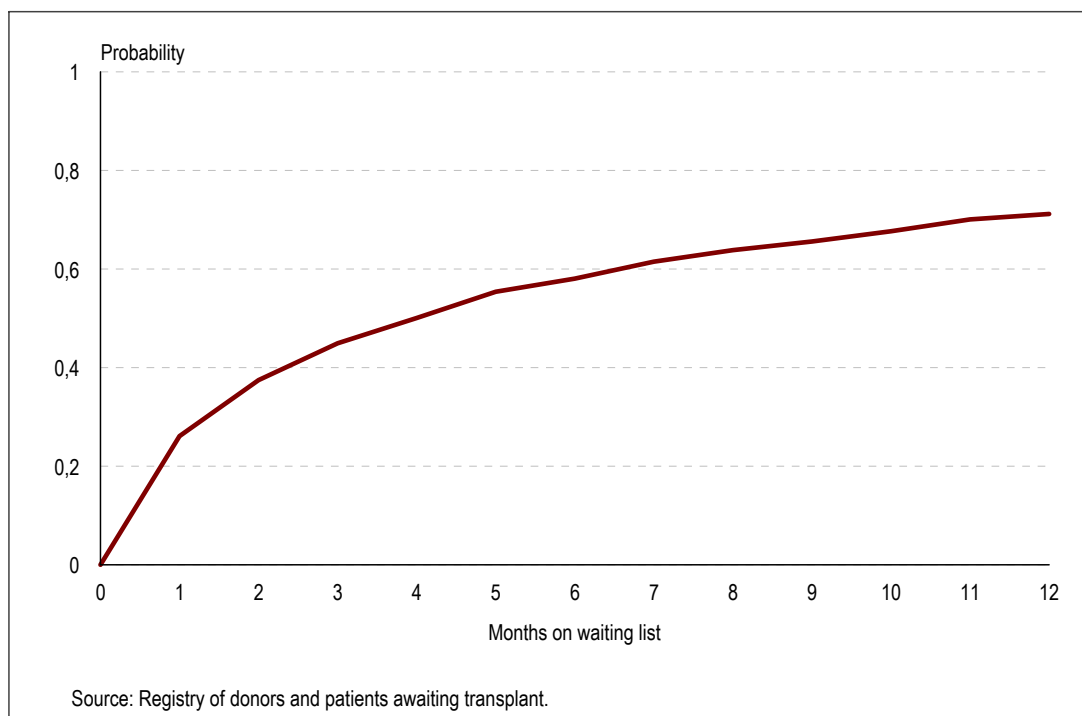
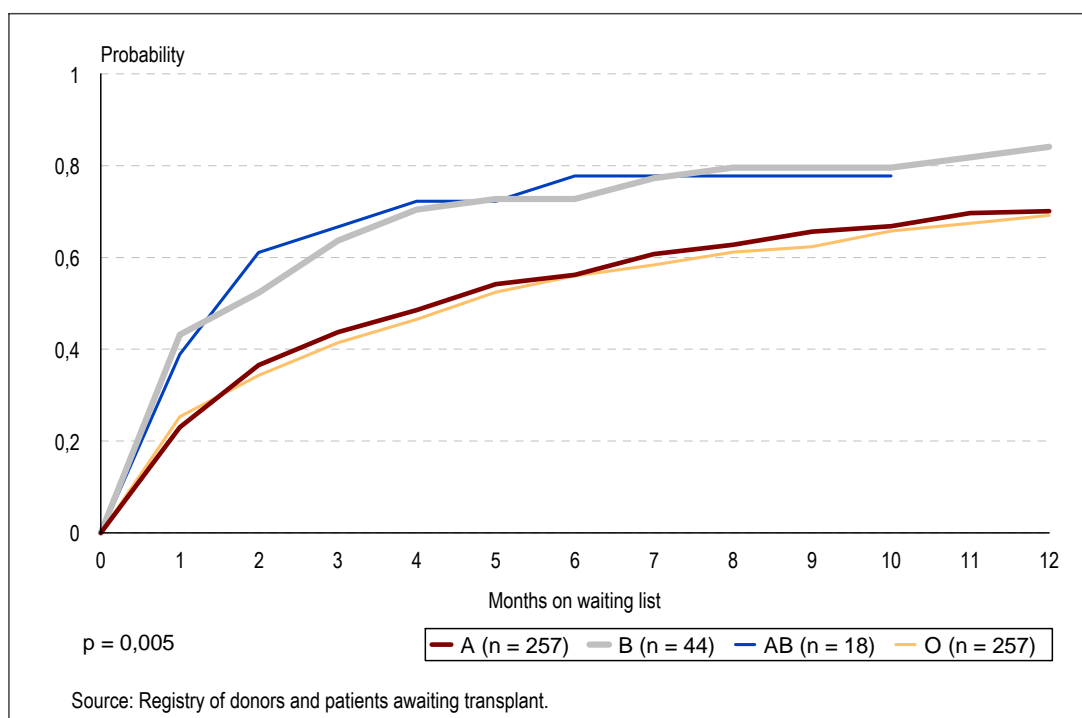


Figure 31. Probability of receiving a heart transplant, by blood type. 2000-2008



Heart Transplants in Children

Of the 830 patients receiving a transplant, 12 received their first transplant as children (up to age 15).

Six of the patients presented with dilated cardiomyopathy and the other six with other kinds of cardiomyopathy that were neither ischemic nor valvular. Specifically, three suffered from congenital cardiomyopathy, one from hypertrophic cardiomyopathy, one from arrhythmogenic right ventricular dysplasia, and the last from restrictive cardiomyopathy (Table 8). One of the patients received a heart-lung transplant.

Table 8. Characteristics of patients receiving their first transplant as children (up to age 15). 1984-2008

Sex	
Male	5 (41.7%)
Female	7 (58.3%)
Age	
Mean (\pm SD)	12 (\pm 2.6)
Median	13
Range	6 – 14
Indications	
Dilated cardiomyopathy	6 (50.0%)
Ischemic cardiomyopathy	-
Valvular cardiomyopathy	-
Other forms of cardiomyopathy	6 (50.0%)

At 31 December 2008, five of these patients had died. Two of them died in the first month after the transplant.

None of these patients received a second transplant, either as children or adults.

Table 9 shows the characteristics of the donor and the transplants carried out on children.

Table 9. Characteristics of donors and transplants in patients receiving transplants as children (up to age 15). 1984-2008

Sex of donor	
Male	2 (16.7%)
Female	3 (25.0%)
Information unavailable	7 (58.3%)
Age of donor	
Mean (\pm SD)	19 (\pm 7.5)
Median	18
Range	5 – 30
Cause of donor's death	
HT	10 (83.3%)
CVA	1 (8.3%)
Other	1 (8.3%)
Source of organ	
Same hospital	4 (33.3%)
Hospital in Catalonia	3 (25.0%)
Hospital outside Catalonia	5 (41.7%)
Cold ischemia time (minutes)	
Mean (\pm SD)	151 (\pm 48.6)
Median	160
Range	60 – 216
