Catalan Heart Transplant Registry

1984-2011 Report





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Catalan Heart Transplant Registry. 1984-2011

Contents

Introduction	7
Some Remarks on Methodology	
Evolution of Heart Transplants	9
Recipient characteristics	11
Donor characteristics	
Transplant characteristics	
Retransplants	
Survival	
Mortality	
Waiting List	33
Heart Transplants in Children	

Catalan Heart Transplant Registry. 1984-2011

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 2011, 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 Kaplan-Meier 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 Log-rank test. 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).

Mortality rate at 30 days

Percentage of deaths occurring during the 30 days following the heart transplant.

Evolution of Heart Transplants

In the 1984-2011 period in Catalonia, 1038 heart transplants were performed: 1019 first transplants and 19 retransplants. These transplants were carried out on 1020 patients; one patient received the first transplant outside Catalonia. 1,4% (15) of the transplants were combined with another organ (Table 1).

	year activity init	n	
Heart – pancreas	1988	1	
Heart – kidney	1999	10	
Heart – lung	2006	1	
Heart – liver	2008	3	
Total combined transplants 15			

Table 1. Number of combined transplants. 1984-2011

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 2011, 54 transplants were performed (Figure 1).

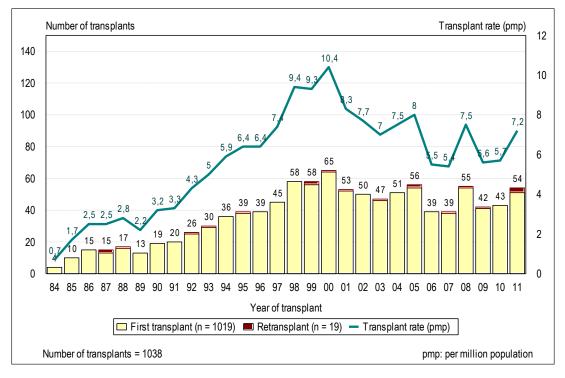
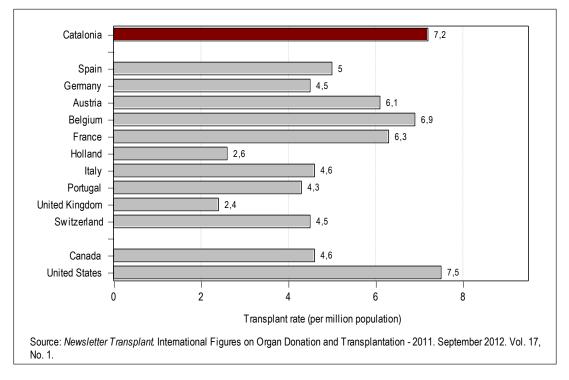


Figure 1. Annual evolution of the number of transplants and annual heart transplant rate. 1984-2011

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 2011, the transplant rate was 7.2 per million inhabitants, which was higher than the previous year (Figure 1).

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.).





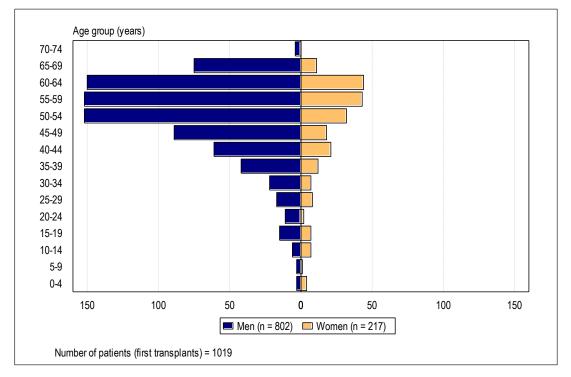
Recipient characteristics

• Sex and age

Of the 1019 patients who received transplants (first transplants) in the 1984-2011 period, 802 (78.7%) were men and 217 (21.3%) were women. In 2011, 35 (68.6%) patients were men and 16 (31.4%) were women.

The mean age of the patients who received their first heart transplant in the 1984-2011 period was 51 (51 for men and 48 for women), the median age was 54 with the range being from age 3 months to 71 (Figure 3).

Figure 3. Number of patients who received their first heart transplant, by age group and sex. 1984-2011



Over the years, the mean age has increased, going from 48 in 1997 to 50 in 2011 (Figure 4). In 2011, 6 transplants were performed on children under 16 years of age, which have reduced the mean age. Taking into account patients aged 16 or over, the mean age in 2011 was 55.

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 2011, 39.2% of the patients who received their first transplantation were between 50 and 60 and 33.3% were over 60. In 1997, these percentages were 33.3% and 20.0%, respectively (Figure 5).

Globally, 65.0% of patients were 50 or over when they received their first heart transplant. In fact, 52.3% of all patients were men aged 50 or more.

Figure 4. Annual evolution of the mean age of patients receiving their first heart transplant. 1992-2011

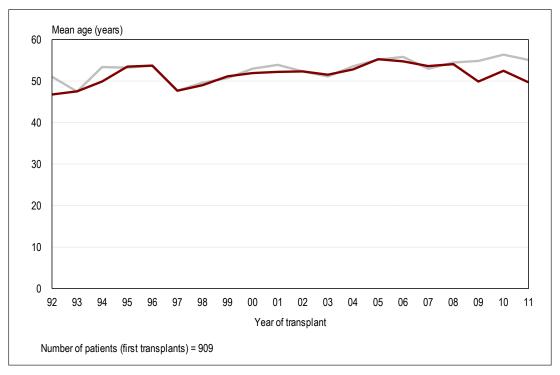
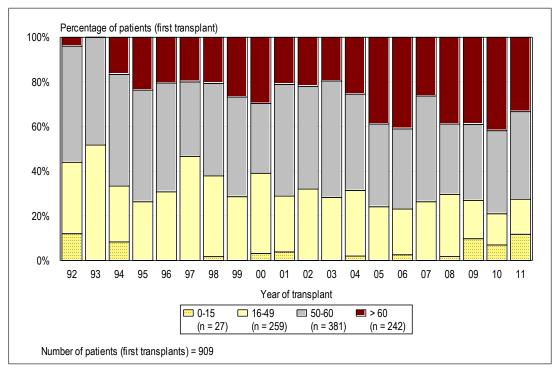


Figure 5. Annual evolution of the percentage of patients who received their first heart transplant, by age group. 1992-2011



• Place of residence

91.4% (n = 932) of patients receiving transplants were residents of Catalonia, 8.3% (n = 85) 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 = 46) 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 43.4% and 38.9%, respectively, of all the heart transplants carried out in Catalonia since 1984 (Figure 6). In the case of men, 45.9% of patients suffered from ischemic cardiomyopathy and 40.3% from dilated cardiomyopathy. In the case of women, the most common indication (54.8%) was dilated cardiomyopathy (Figure 7).

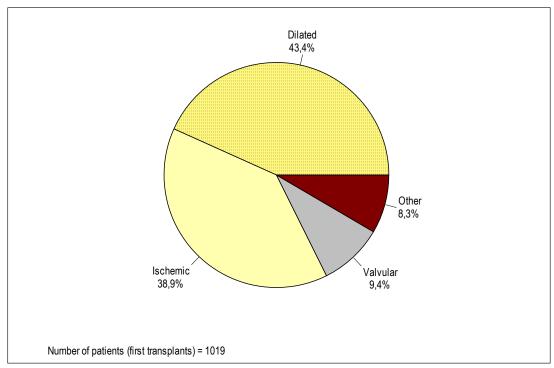


Figure 6. Percentage of patients who received their first heart transplant, by indication. 1984-2011

Table 2 provides a breakdown of the indications included in the "Other Indications" category.

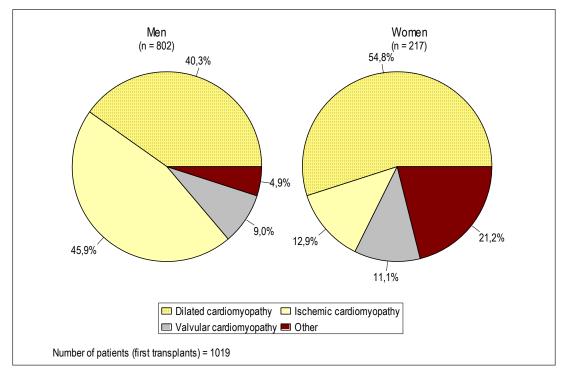


Figure 7. Percentage of patients who received their first heart transplant, by indication and sex. 1984-2011

	Men		Women		Total	
_	n %		n	%	n	%
Hypertrophic cardiomyopathy	14	35.9%	16	34.8%	30	35.3%
Restrictive cardiomyopathy	12	30.8%	15	32.6%	27	31.8%
Congenital disease	9	23.1%	12	26.1%	21	24.7%
Arrhythmogenic right ventricular dysplasia	4	10.3%	3	6.5%	7	8.2%
	39	100%	46	100%	85	100%

 Table 2. Indications included in the "Other Indications" category. 1984-2011

In 2011, 39.2% (n = 20) of the patients with ischemic cardiomyopathy, 31.4% (n = 16) with dilated cardiomyopathy, 5.9% (n = 3) with valvular cardiomyopathy and 23.5% (n = 12) with other indications (five patients with restrictive cardiomyopathy, four with hypertrophic cardiomyopathy, two with congenital disease and one case with arrhythmogenic right ventricular dysplasia).

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).

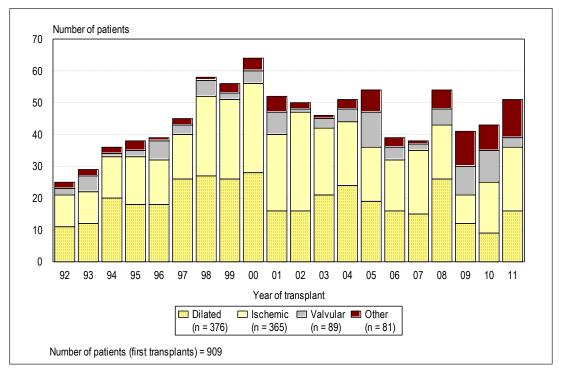
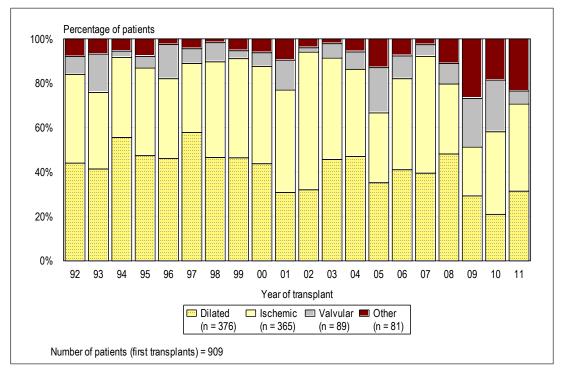


Figure 8. Annual evolution of the number of patients who received their first heart transplant, by indication. 1992-2011

Figure 9. Annual evolution of the percentage of patients who received their first heart transplant, by indication. 1992-2011



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 2011 were idiopathic dilated cardiomyopathy, ischemic cardiomyopathy and valvular cardiomyopathy (Figure 10).

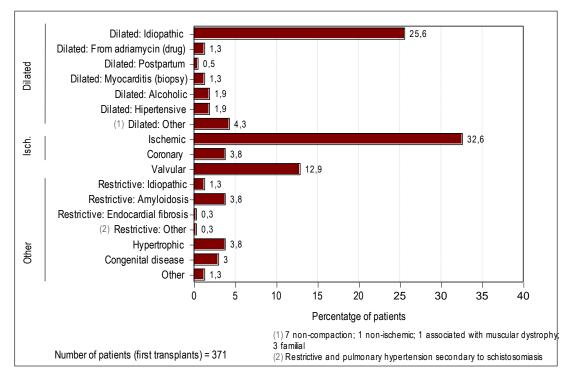
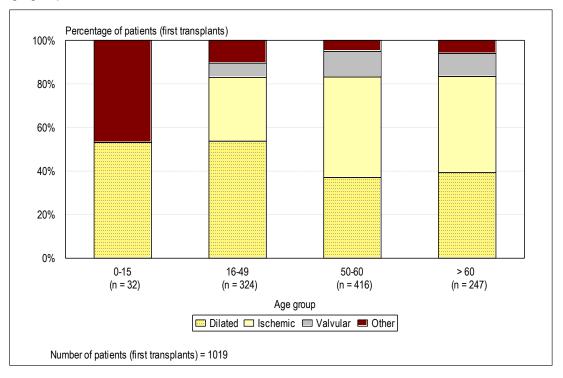


Figure 10. Percentage of patients who received their first heart transplant, by indication. 2004-2011

The most frequent indication in patients younger than 50 years is dilated cardiomyopathy. In patients over 50 years, the percentage of patients with ischemic cardiomyopathy is slightly higher than dilated cardiomyopathy (Figure 11).

Figure 11. Percentage of patients who received their first heart transplant, by indication and age group. 1984-2011



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 3). The differences between men and women when treated separately were also statistically significant (Table 4).

	n	mean	IC 95%	range
Dilated cardiomyopathy	442	48	47.0 - 49.7	1 – 71
Ischemic cardiomyopathy	396	55	53.8 - 55.4	28 – 70
Valvular cardiomyopathy	96	54	52.3 – 56.1	17 – 67
Other forms of cardiomyopathy	85	40	36.3 - 44.6	0 - 67
Total	1.019	51	49.9 – 51.5	0 – 71

Table 3. Mean and confidence interval of age, by indication. 1984-2011

Table 4. Mean and confidence interval of age, by indication and sex. 1984-2011

		n	mean	IC 95%	range
Dilated	Men	323	48	46.3 – 49.6	1 – 71
cardiomyopathy	Women	119	49	46.8 - 52.0	1 – 67
Ischemic	Men	368	55	53.9 – 55.6	28 – 70
cardiomyopathy	Women	28	53	49.8 - 56.0	34 – 62
Valvular cardiomyopathy	Men	72	54	51.4 – 55.9	17 – 67
	Women	24	56	52.1 – 59.9	28 – 65
Other forms of	Men	39	44	37.4 – 49.7	1 – 67
cardiomyopathy	Women	46	38	32.1 – 43.6	0 – 67
Total	Men	802	51	50.5 – 52.2	1 – 71
Total	Women	217	48	46.1 – 50.2	0 – 67

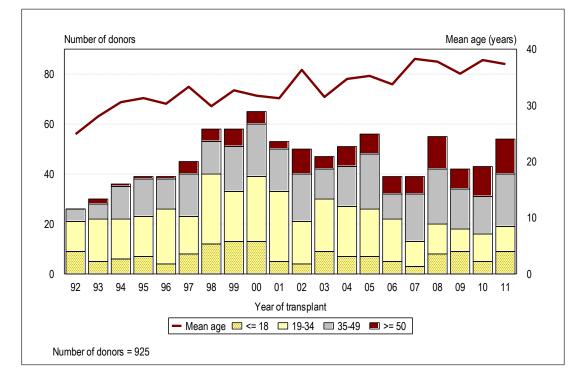
Donor characteristics

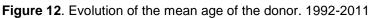
• Sex and age

Of the 925 transplants carried out in the 1992-2011 period, 69.7% (n = 645) of the donors were men and 30.3% (n = 280) were women. In 2011, 59.3% (n = 32) were men and 40.7% (n = 22) were women.

The mean age of the donor over the 1984-2011 period was 33, the median age was 31 and the range was from age 1 to 64 (in the 1992-2011 period, the mean age of the donor was 33 and the median was 33 too). The mean age has increased over the years, going from 25 in 1992 to 37 in 2011 (Figure 12).

This increase has occurred because of older donors, given that in 2011, 25.9% of donors were age 50 and over, whereas there were no donors in this age group in the first years of the programme.





Cause of death

The most frequent cause of death of the donor was head trauma (HT), which represented 54.1% (n = 562) of all causes, followed by cerebrovascular accident (CVA) / stroke, which represented 37.2% (n = 386). (In the 1992-2011 period, these percentages were 52.4% and 38.9%, respectively.)

In keeping with the increase in the age of donors, the number of donors who died from CVA / stroke also increased (Figure 13). In 2011, 35.2% (n = 19) of donors died from head trauma and 44.4% (n = 24) from CVA / stroke.

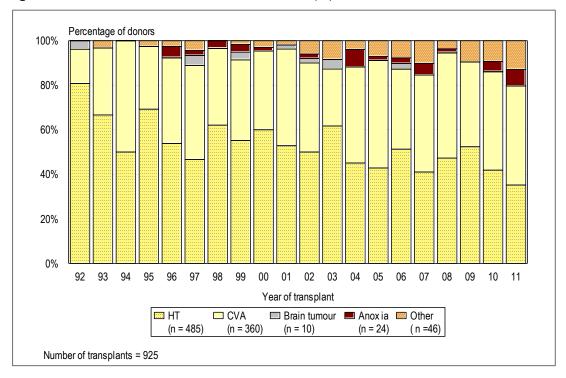


Figure 13. Evolution of the cause of death of donor (%). 1992-2011

Source of organs

In the 1984-2011 period, 21.5% (n = 223) of the transplanted organs came from the same hospital where the transplant was carried out, 44.5% (n = 462) from other hospitals in Catalonia, and 34.0% (n = 353) from hospitals outside Catalonia. In 2011, 11.1% (n = 6) of the organs came from the same hospital, 38.9% (n = 21) from Catalonia, and 50.0% (n = 27) from outside Catalonia (Figure 14).

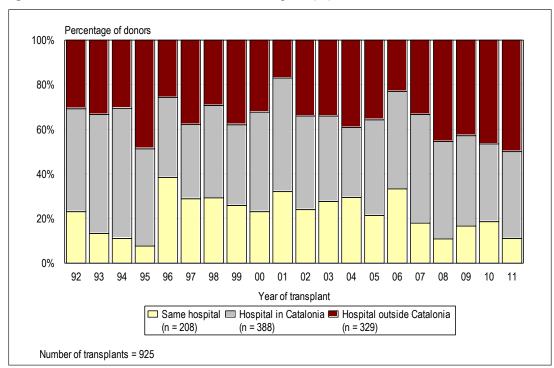


Figure 14. Annual evolution of the source of organs (%). 1992-2011

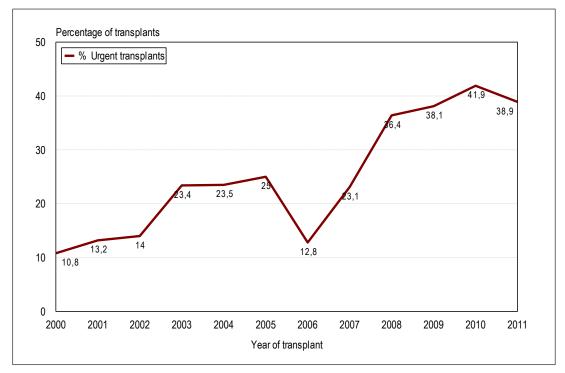
Transplant characteristics

• Emergency

Of the 1038 transplants carried out in the 1984-2011 period, 21.5% (223) were urgent.

38.9% (21) of the transplants carried out in 2011 were urgent, which is a lower percentage than in pervious years (Figure 15).

Figure 15. Annual evolution of the percentage of urgent transplants. 2000-2011



• Ischemia time

The mean ischemia time was 175 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 ischemia time was 80 minutes longer than when the organ came from a hospital in Catalonia (Table 5).

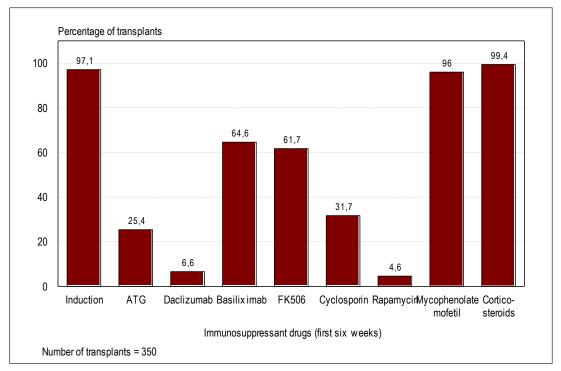
Immunosuppressors

The distribution of immunosuppressors used in the first six weeks after transplant is shown in Figure 16. The overwhelming majority of transplant patients underwent induction immunosuppressive treatment and basiliximab was the drug used most.

	Same Hospital (n = 223)	Hospital in Catalonia (n = 459)	Hospital outside Catalonia (n = 350)	Total (n = 1032)
Mean	132	156	229	175
Median	125	150	230	168
Range	60 – 238	64 - 369	87 – 360	60 – 369
95% CI	128 – 136	151 – 160	224 – 233	172 – 179

Table 5. Ischemia time, in minutes, in accordance with the source of the organ. 1984-2011

Figure 16. Immunosuppressant drugs used in the first six weeks after heart transplant. 2004-2011



Retransplants

A total of 19 of the 1038 heart transplants (1.8%) carried out in the 1984-2011 period have been retransplanted. One of these patients received the first transplant outside Catalonia.

The time between one transplantation and the other ranged from 0 to 13 years ¹. The mean was 5 years (the median was 6 years). Specifically, 4 patients (22.2%) received a second transplant within the first week after receiving the first, 3 (16.7%) between the first week and three months after receiving the first transplant, and eleven (61.1%) after the first year.

Tables 6 and 7 show the main characteristics of the retransplants.

	0 - 3 months (n = 7)	> 3 months (n = 11)	
Sex	. ,	· · · · · · · · · · · · · · · · · · ·	
Male	5 (71.4%)	8 (72.7%)	
Female	2 (28.6%)	3 (27.3%)	
Age (years)			
Mean	44	36	
Median	42	39	
Range	35 – 63	15 – 59	
Indications			
Dilated cardiomyopathy	2 (28.6%)	8 (72.7%)	
Ischemic cardiomyopathy	3 (42.9%)	3 (27.3%)	
Valvular cardiomyopathy	-	-	
Other forms of cardiomyopathy	2 (28.6%)	-	

Table 6. Characteristics of the patients who received a retransplantation, by the time elapsed since the first transplantation. 1984-2011

Of the 7 patients who received a retransplantation in the first three months after the first transplant, four had died (two by infection) at 31 December 2011. Of the 11 patients who received a retransplantation after the third month, 8 had died at 31 December 2011: 2 due to graft vascular disease, 2 due to primary dysfunction of the graft, 1 due to infection and 3 due to other causes.

¹ Taking into account the patients who received the transplant and retransplant in Catalonia.

	0 - 3 months (n = 7)	> 3 months (n = 11)
Donor age (years)		
Mean	20	26
Median	23	21
Range	11 – 25	14 – 49
Cause of donor's death		
HT	6 (85.7%)	8 (72.7%)
CVA	-	2 (18.2%)
Other	1 (14.3%)	1 (9.1%)
Ischemia time (minutes)		
Mean	139	168
Median	115	146
Range	82 – 230	95 – 300

 Table 7. Characteristics of the donor and the transplantation (first transplant), by the time elapsed since the first transplantation. 1984-2011

Survival

The survival rate of patients receiving a first heart transplant in Catalonia in the 1984-2011 period was 85% in the first month, 77% in the first year, 72% in the third year, and 69% in the fifth year (Figure 17).

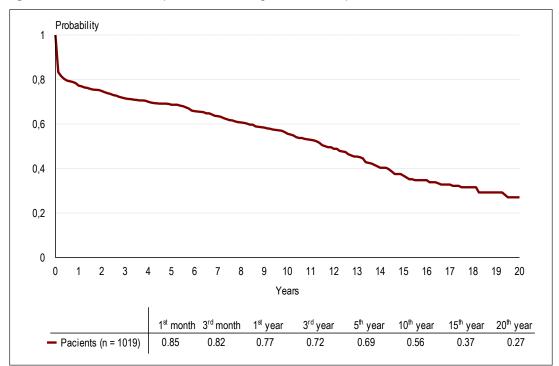


Figure 17. Survival rate of patients receiving a heart transplant. 1984-2011

The survival rate percentages were very similar to those of the Spanish and international registries (Table 8).

Table	8.	Graft	survival.	Data	comparing	the	Catalan	(RTCC),	Spanish	$(RETC)^2$	and
interna	tion	al regi	stries (IS⊢	$(LT)^3$.	1984-2011						

	RTCC (1984-2011)	RETC (1984-2011)	ISHLT (1982-6/2010)
1 st month	0,84	0,87	0,90
1 st year	0,76	0,77	0,81
5 th year	0,68	0,66	0,68
10 th year	0,54	0,53	0,51
15 th year	0,36	0,39	0,35

² Almenar Bonet, L. Registro Español de Trasplante Cardíaco. XXIII Informe Oficial de la Sección de Insuficiencia Cardíaca, Trasplante Cardíaco y otras Alternativas Terapéuticas de la Sociedad Española de Cardiología (1984-2011). Rev Esp Cardiol. 2012;65(11):1030-1038. ³ International Society for Heart and Lung Transplantation (available at: http://www.ishlt.org).

The overall patient survival rate in the 1984-2011 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, 2002-2006 and 2007-2011. Statistically significant differences were observed between the five periods (p = 0.003), but not between the last four (Figure 18).

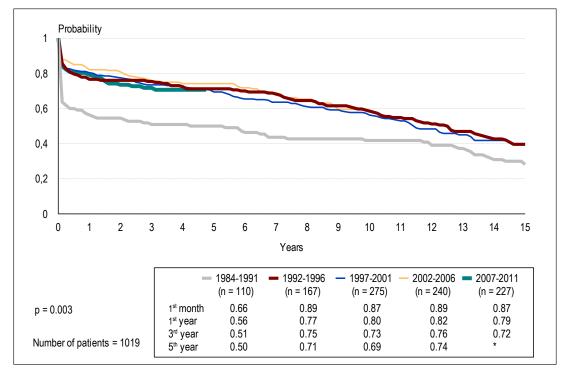


Figure 18. Survival rate of patients receiving a heart transplant, by period. 1984-2011

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 1997-2011 period, the patient survival rate was 87% in the first month, 81% in the first year, 74% in the third year, 71% in the fifth year, and 57% in the tenth year.

The long-term survival rate was slightly lower for men than women (Figure 19), though the differences were not statistically significant (p = 0.054).

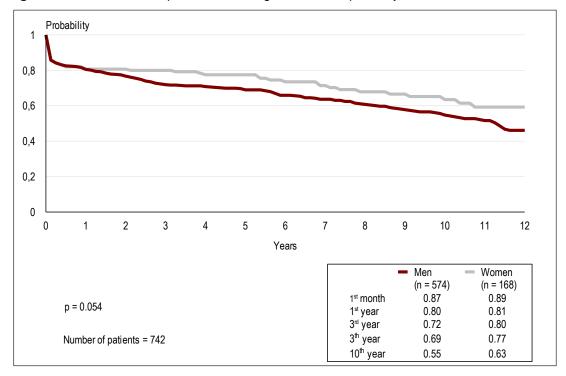
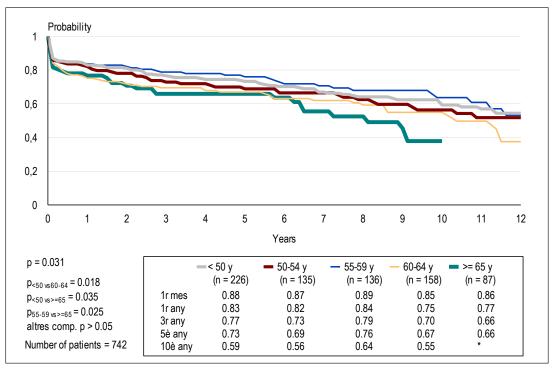


Figure 19. Survival rate of patients receiving a heart transplant, by sex. 1997-2011

Patients over the age of 60 have the lowest survival rate, with statistically significant differences (p = 0.031) (Figure 20).

Figure 20. Survival rate of patients age 15 and older receiving their first heart transplant, by age group. 1997-2011



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 21). The differences between the four diagnostic groups were not statistically significant (p = 0.064).

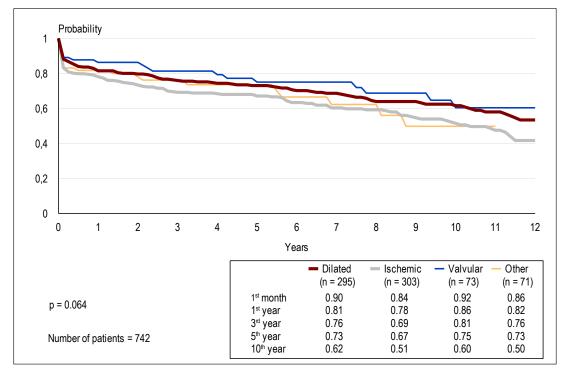


Figure 21. Survival rate of patients receiving a heart transplant, by indication. 1997-2011

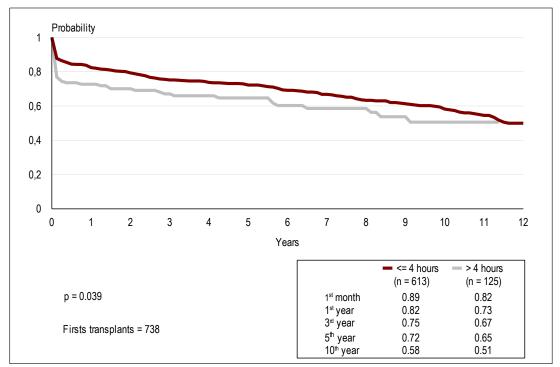


Figure 22. Survival rate of patients receiving a heart transplant, by ischemia time. 1997-2011

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 ischemia time was less than or equal to four hours (p = 0.039) (Figure 22).

There are statistically significant differences (p = 0.006) in survival rates of patients depending on whether the transplant was an emergency or elective (Figure 23).

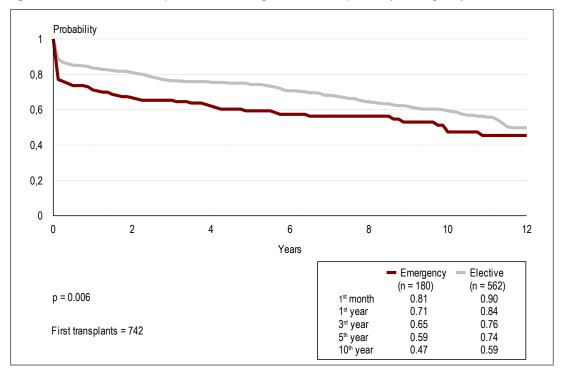


Figure 23. Survival rate of patients receiving a heart transplant, by emergency. 1997-2011

Mortality

Of the 1020 patients receiving a transplant in the 1984-2011 period, 487 (47.7%) had died at 31 December 2011, 523 (51.3%) remained alive, and monitoring could not be continued on 10 (1.0%).

The most common causes of death were infection (21.0%) and primary dysfunction of the graft (18.4%), followed by neoplasm (13.0%) and severe rejection (9.9%). The first two causes alone accounted for more than 40% of all deaths (Figure 24).

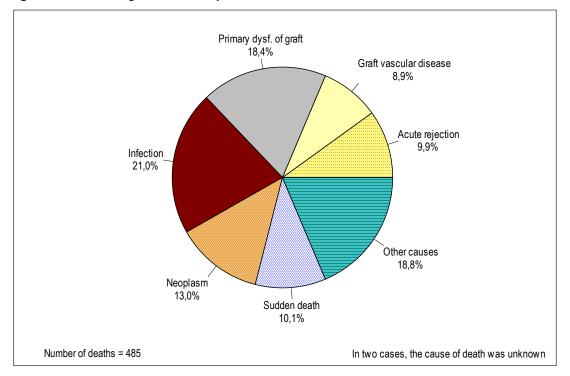


Figure 24. Percentage of deaths, by cause of death. 1984-2011

When the sex of the patient was considered, these four causes of death were the same, though the percentages for each sex varied (Figure 25).

In 30.4% of cases, death occurred in the first month after transplantation (Figure 26) and the main cause of death was primary dysfunction of the graft (Figure 27).

The mortality rate at 30 days is 15.0% (12.9% in 1997-2011 period). In 2011, the mortality rate at 30 days was 18.5%, upper than the year before (Figure 28).

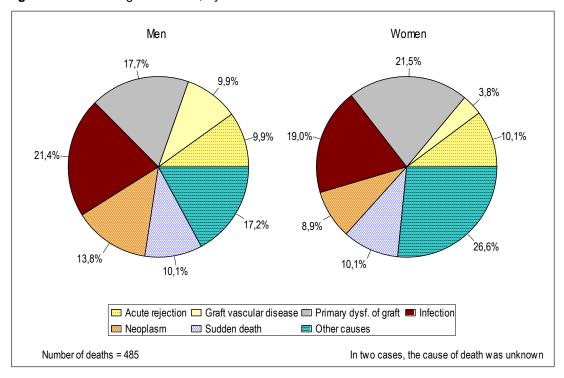
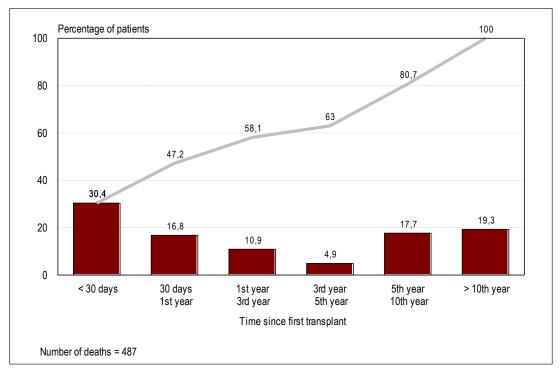


Figure 25. Percentage of deaths, by cause of death and sex. 1984-2011

Figure 26. Time elapsed between the transplantation and death. 1984-2011



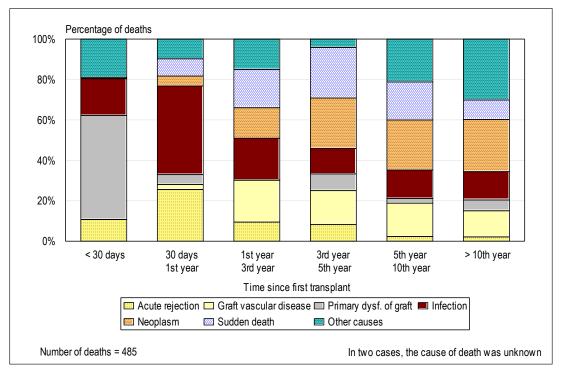


Figure 27. Percentage of deaths by cause of death and time elapsed since the transplantation. 1984-2011

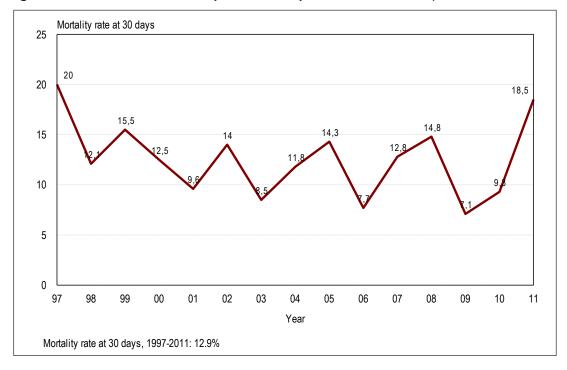
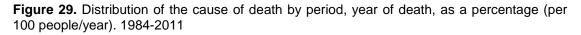
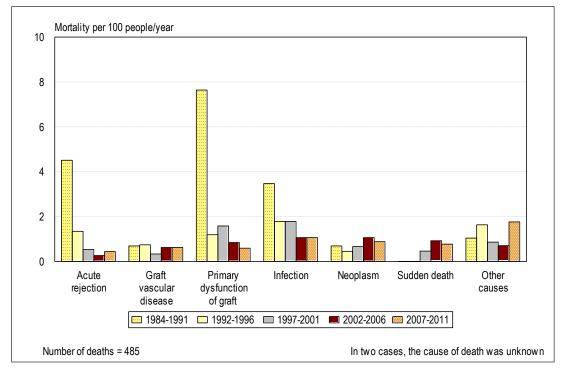


Figure 28. Evolution of the mortality rate at 30 days after the heart transplant. 1997-2011

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%; 2002-2006: 5.45%; 2007-2011: 6,17%). Figure 29 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.





Waiting List

The number of patients on the waiting list at the end of 2011 was upper than in previous years, going from 18 to 21 (Figure 30).

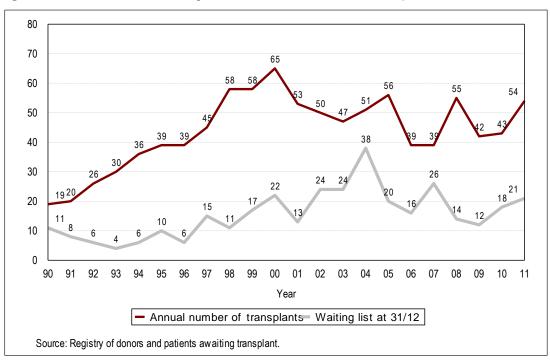


Figure 30. Evolution of the waiting list and the number of heart transplants. 1990-2011

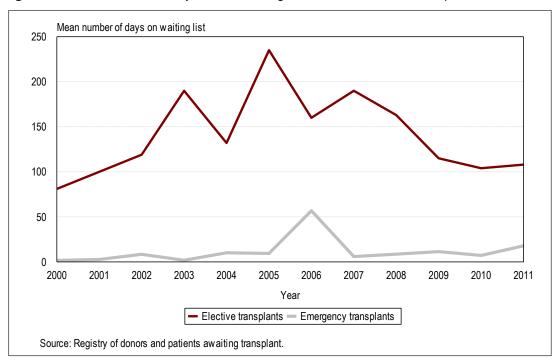


Figure 31. Mean number of days on the waiting list to receive a heart transplant. 2000-2011

In 2011, the mean number of days that a patient was on the waiting list for a heart transplant was 89; 108 days in elective transplants and 18 days in emergency transplants (Figure 31).

In 2011, 79 patients were added to the waiting list. Of the patients taken off the list, 2 were removed because their health improved and 7 were removed because their health worsened. The mortality rate of the patients on the waiting list was 1.1%. Because of the low number of cases in recent years, the major fluctuations observed should be evaluated with caution (Figure 32).

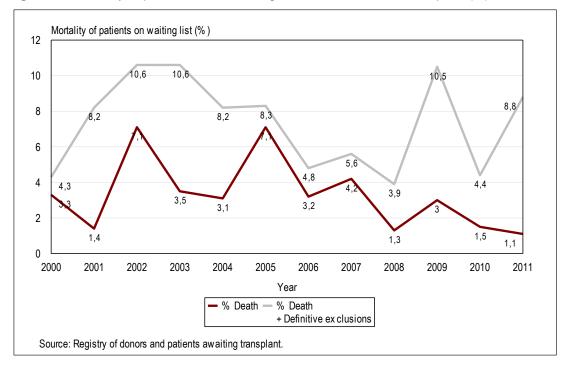


Figure 32. Mortality of patients on the waiting list to receive a heart transplant (%). 2000-2011

In the 2000-2011 period, the probability of receiving a heart transplant in the first six months on the waiting list was 59%; in the first year, it was 71% (Figure 33).

When the probability of receiving a transplant was analysed bearing in mind the patient's blood type, it was observed that patients with blood type A or O have the same probabilities (57% in the first six months and 70% 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 34).

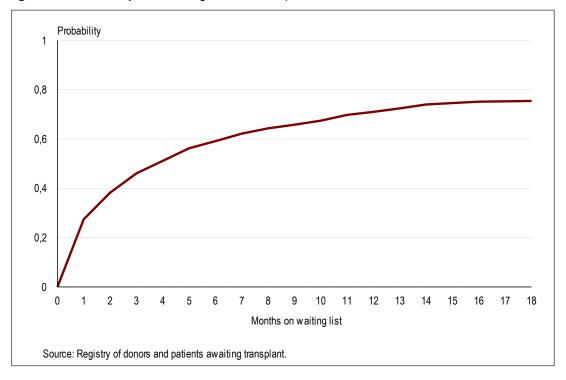
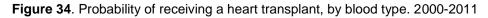
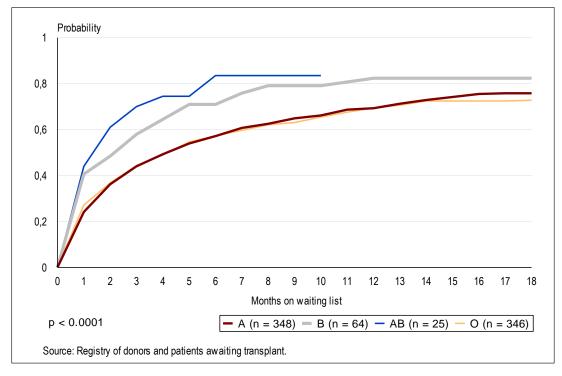


Figure 33. Probability of receiving a heart transplant. 2000-2011





Heart Transplants in Children

Of the 1038 transplants carried out in Catalonia in the 1984-2011 period, 33 were performed on children under 16 years of age (32 first transplants and one retransplant). In 2011, 7 transplants were performed.

Of the 32 patients who received heart transplants, 50% (16) were men and 50% (16) women. The mean age was 10 (median = 12.5, range = 3 month - 15 years), although 59.4% (19) of patients were 12-15 years.

The two most frequent indications are dilated cardiomyopathy and congenital disease (Figure 35 and 36).

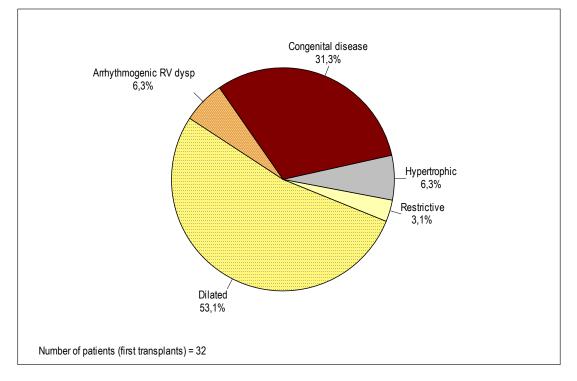


Figure 35. Indications in patients receiving transplants as children (under 16 years of age). 1984-2011

Tables 9 and 10 show the characteristics of the donor and the transplants carried out on children.

Of the 32 patients (under 16 years of age), one needed a retransplant and thirteen had died at 31 December 2011.

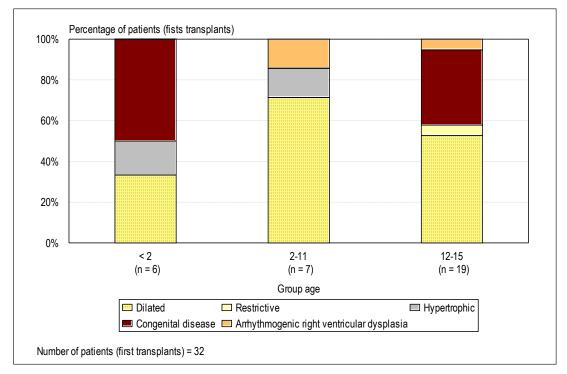


Figure 36. Indications in patients receiving transplants as children (under 16 years of age) by age group. 1984-2011

Table 9. Characteristics of donors in patients receiving transplants as children (under 16 years of age). 1984-2011

Sex of donor				
Male	15 (46.9%)			
Female	16 (50.0%)			
Information unavailable	1 (3.1%)			
Age of donor				
Mean (± SD)	17 (± 12.7)			
Median	17			
Range	0 – 56			
Cause of donor's death				
HT	19 (59.4%)			
CVA	4 (12.5%)			
Other	9 (28.1%)			
Source of organ				
Same hospital 7 (21.9%				
Hospital in Catalonia 6 (18.8%)				
Hospital outside Catalonia	19 (59.4%)			

Emergency	
Urgent	13 (40.6%)
Elective	19 (59.4%)
Ischemia time (minutes)	
Mean (± SD)	200 (± 63.7)
Median	208
Range	60 - 340

Table 10. Characteristics of transplants in patients receiving transplants as children (under 16 years of age).1984-2011