

Catalan Heart Transplant Registry

1984-2010 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 2010, 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 1984-2010 period in Catalonia, 984 heart transplants were performed on 968 patients (16 retransplants were performed). Of these, 14 were combined with another organ (Table 1).

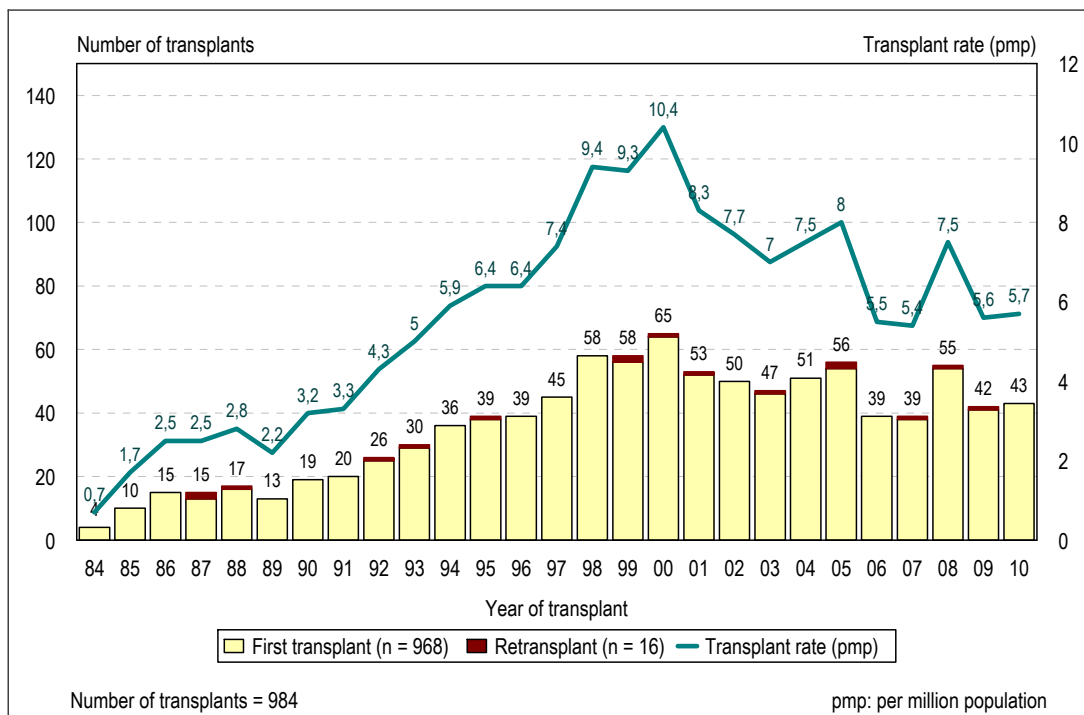
Table 1. Number of combined transplants. 1984-2010

	year activity init	n
Heart – pancreas	1988	1
Heart – kidney	1999	10
Heart – lung	2006	1
Heart – liver	2008	2
Total combined transplants		14

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 2010, 43 transplants were performed (Figure 1).

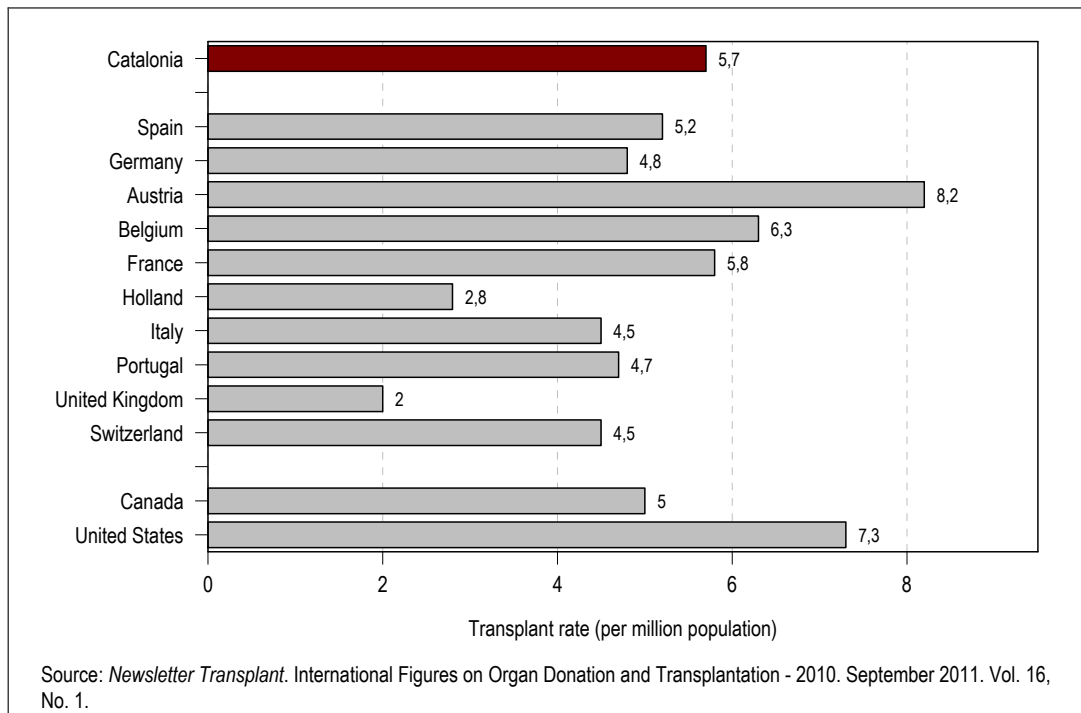
Because of these changes in trend, the annual rate of heart transplants was also affected and showed a clear upward trend in the 1992-2000 period, but has declined since then. In 2010, the transplant rate was 5.6 per million inhabitants, which was higher than the previous year (Figure 1).

Figure 1. Annual evolution of the number of transplants and annual heart transplant rate. 1984-2010



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. 2010



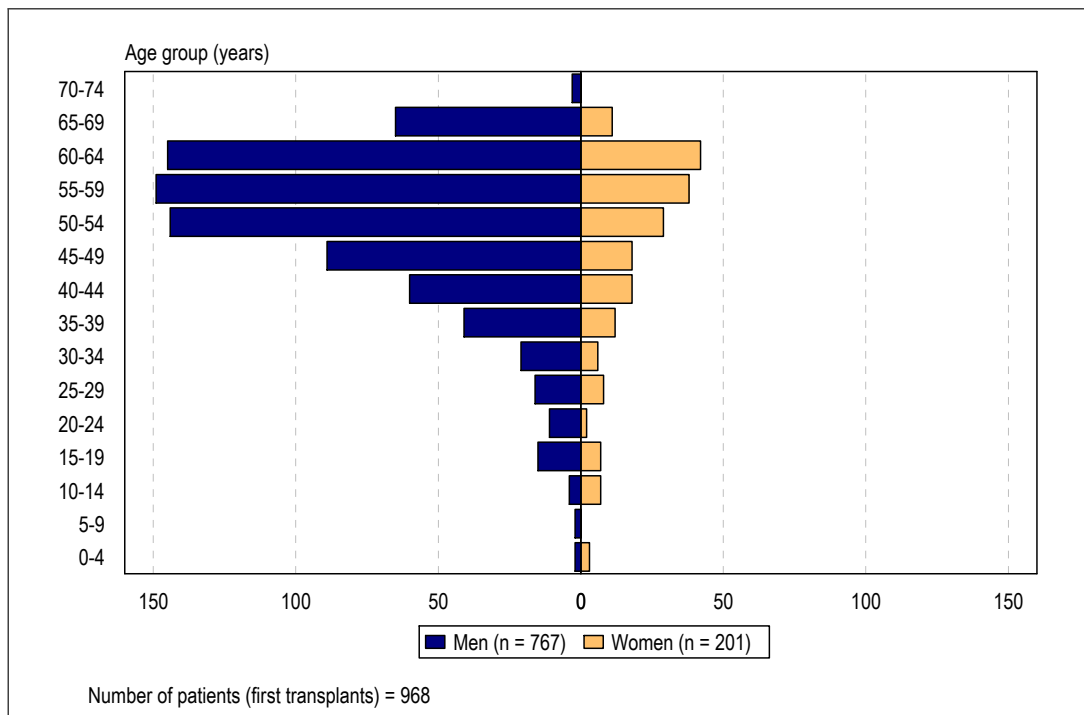
Recipient characteristics

◆ Sex and age

Of the 968 patients who received transplants (first transplants) in the 1984-2010 period, 767 (79.2%) were men and 201 (20.8%) were women. In 2010, 35 (81.4%) patients were men and 8 (18.6%) were women.

The mean age of the patients who received their first heart transplant in the 1984-2010 period was 51 (51 for men and 48 for women), the median age was 54 with the range being from age 5 months to 71 (Figure 3).

Figure 3. Number of patients who received their first heart transplant, by age group and sex. 1984-2010



Over the years, the mean age has increased, going from 48 in 1997 to 52 in 2010 (Figure 4). In 2010, 3 transplants were performed on children under 2 years of age, which have reduced the mean age. Taking into account patients aged 16 or over, the mean age in 2010 was 56,

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 2010, 37.2% of the patients who received their first transplantation were between 50 and 60 and 41.9% were over 60. In 1997, these percentages were 33.3% and 20.0%, respectively (Figure 5).

Globally, 64.7% 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. 1992-2010

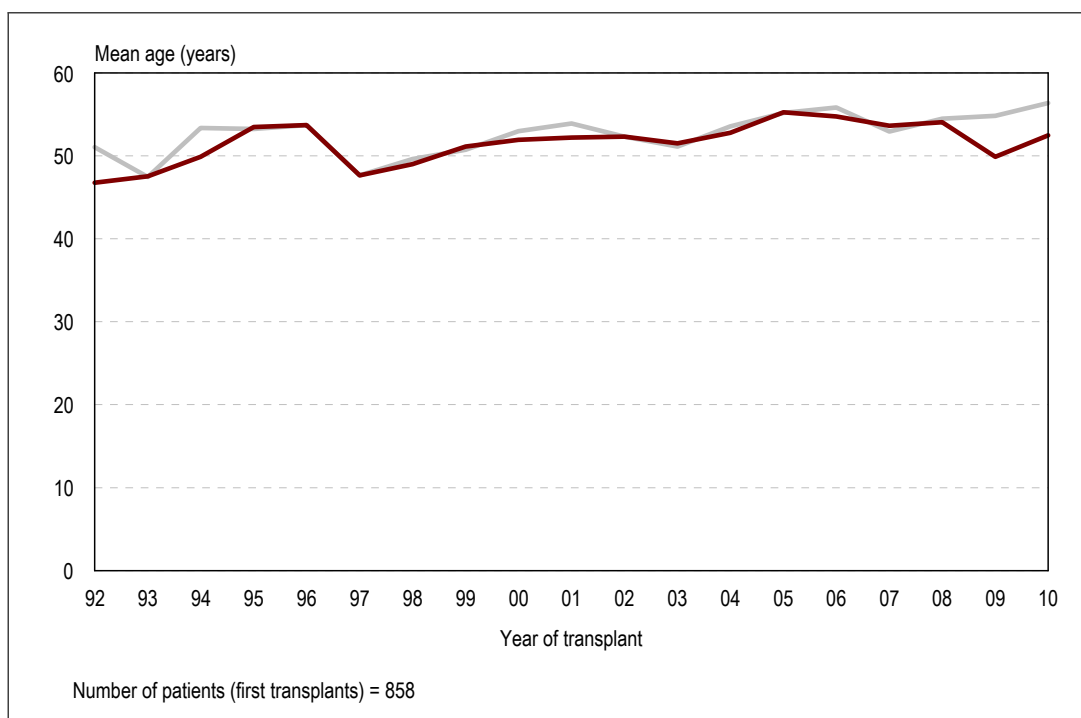
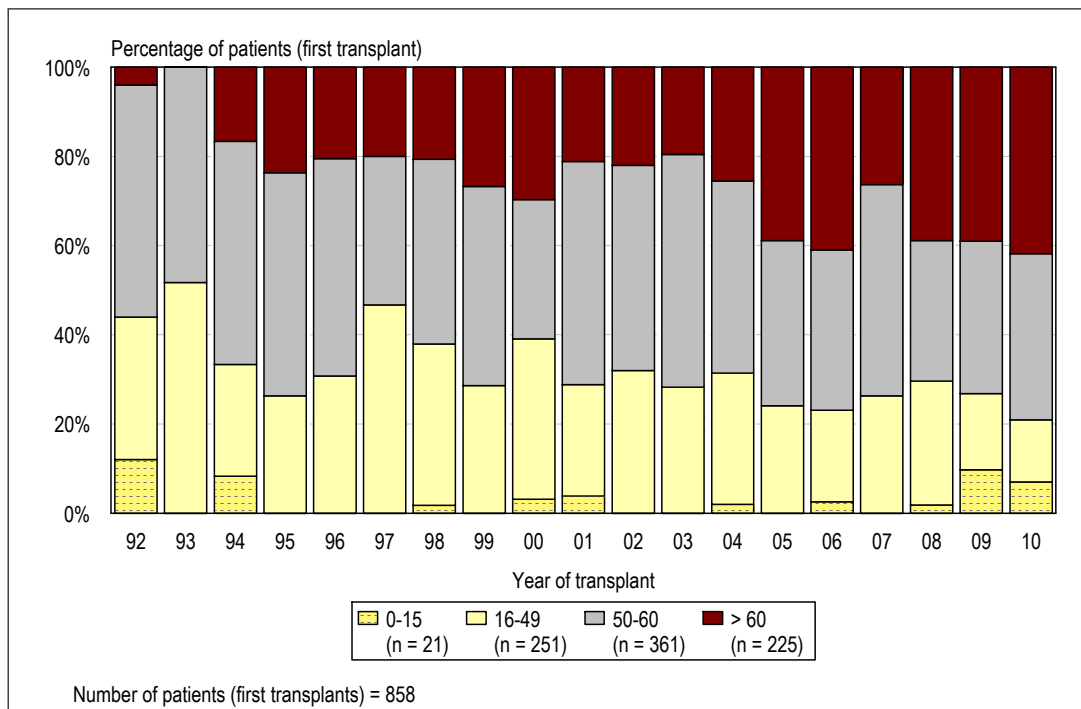


Figure 5. Annual evolution of the percentage of patients who received their first heart transplant, by age group. 1992-2010



◆ Place of residence

91.2% (n = 897) of patients receiving transplants were residents of Catalonia, 8.5% (n = 84) 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 = 44) or the autonomous community of Aragon (n = 15).

◆ 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 43.8% and 38.8%, 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 40.4% from dilated cardiomyopathy. In the case of women, the most common indication (56.7%) was dilated cardiomyopathy (Figure 7).

Figure 6. Percentage of patients who received their first heart transplant, by indication. 1984-2010

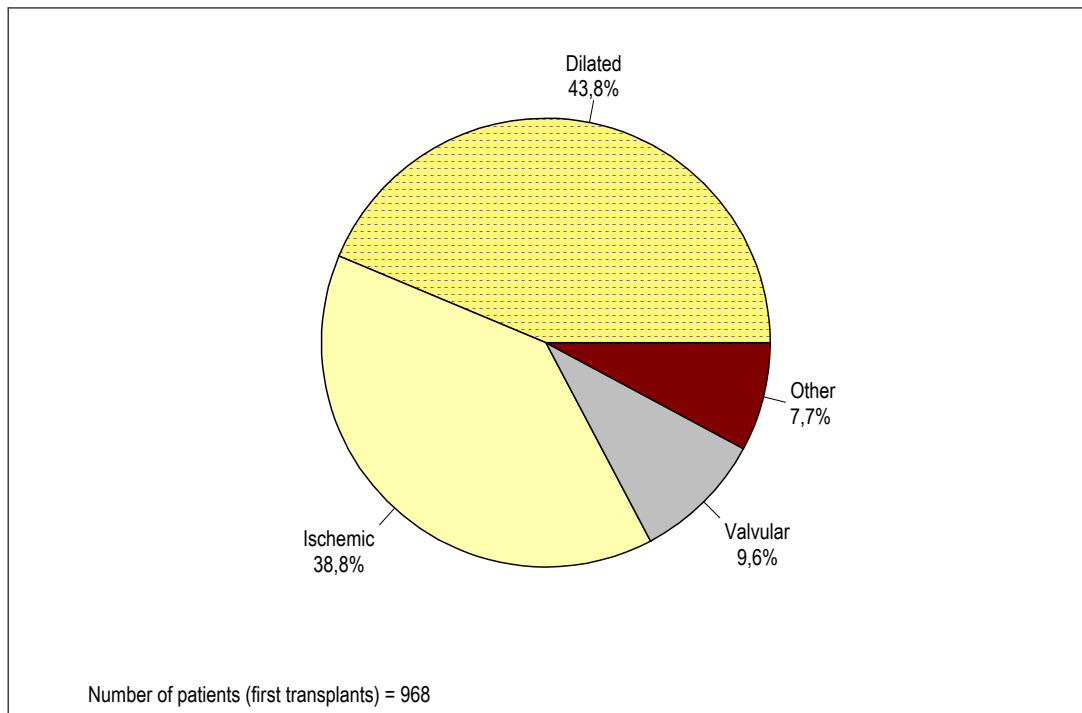
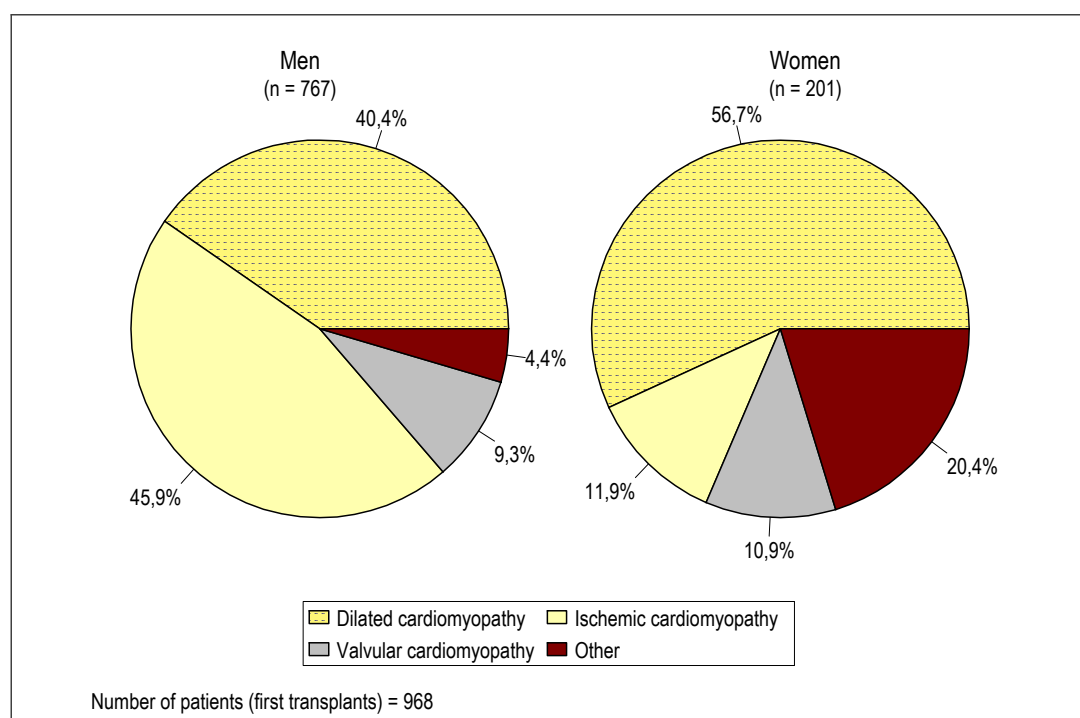


Table 2 provides a breakdown of the indications included in the “Other Indications” category.

Figure 7. Percentage of patients who received their first heart transplant, by indication and sex. 1984-2010**Table 2.** Indications included in the "Other Indications" category. 1984-2010

	Men		Women		Total	
	n	%	n	%	n	%
Hypertrophic cardiomyopathy	12	35.3%	13	31.7%	25	33.3%
Restrictive cardiomyopathy	9	26.5%	14	34.1%	23	30.7%
Congenital disease	9	26.5%	10	24.4%	19	25.3%
Arrhythmogenic right ventricular dysplasia	3	8.8%	3	7.3%	6	8.0%
Myocardiotoxicity following chloroquine poisoning	-	-	1	2.4%	1	1.3%
Becker's dystrophy	1	2.9%	-	-	1	1.3%
	34	100%	41	100%	75	100%

In 2010, 37.2% (n = 16) of the patients with ischemic cardiomyopathy, 23.3% (n = 10) with valvular cardiomyopathy, 20.9% (n = 8) with dilated cardiomyopathy and 18.6% (n = 8) with other indications (two patients with restrictive cardiomyopathy, one with hypertrophic cardiomyopathy, three with congenital disease and two cases 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. 1992-2010

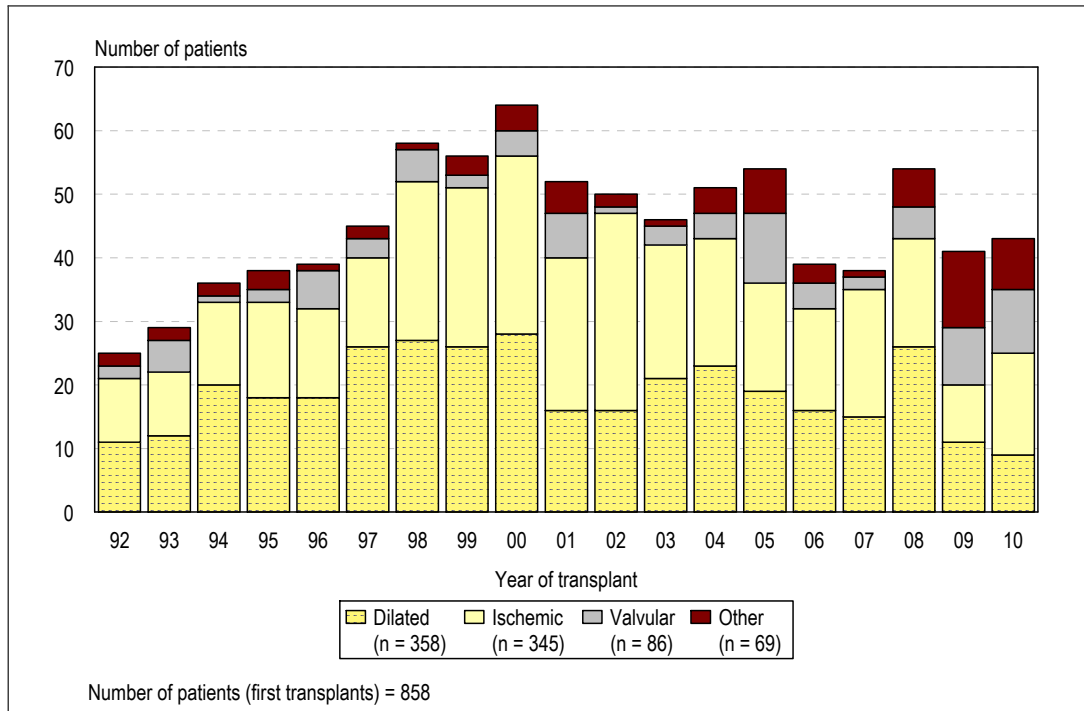
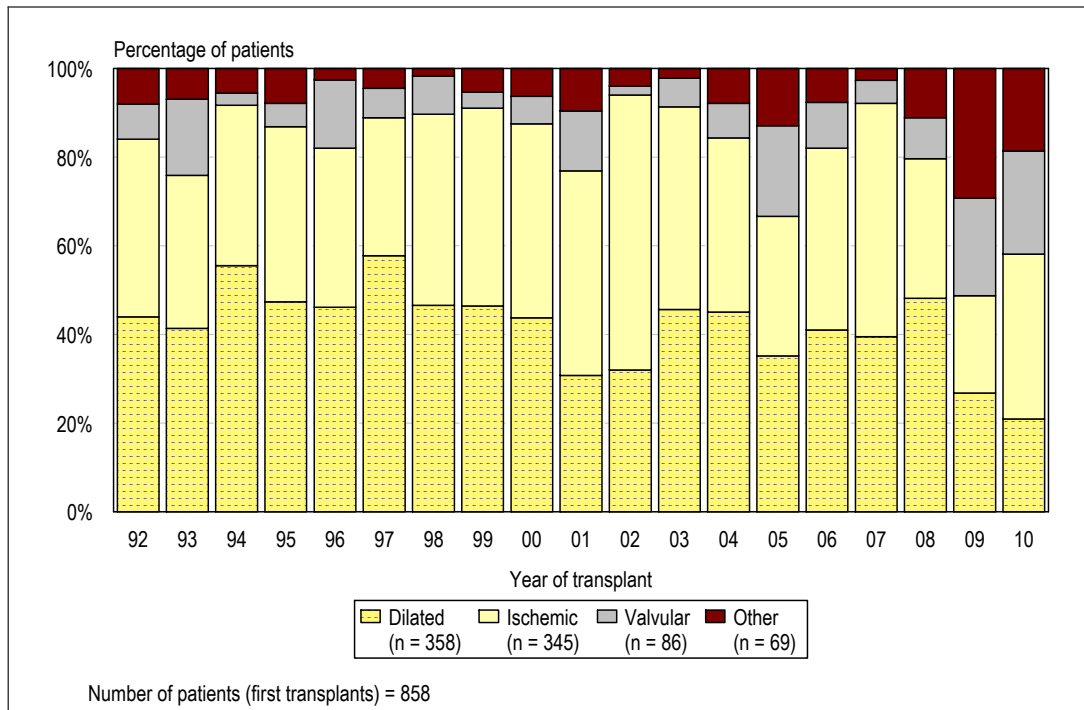


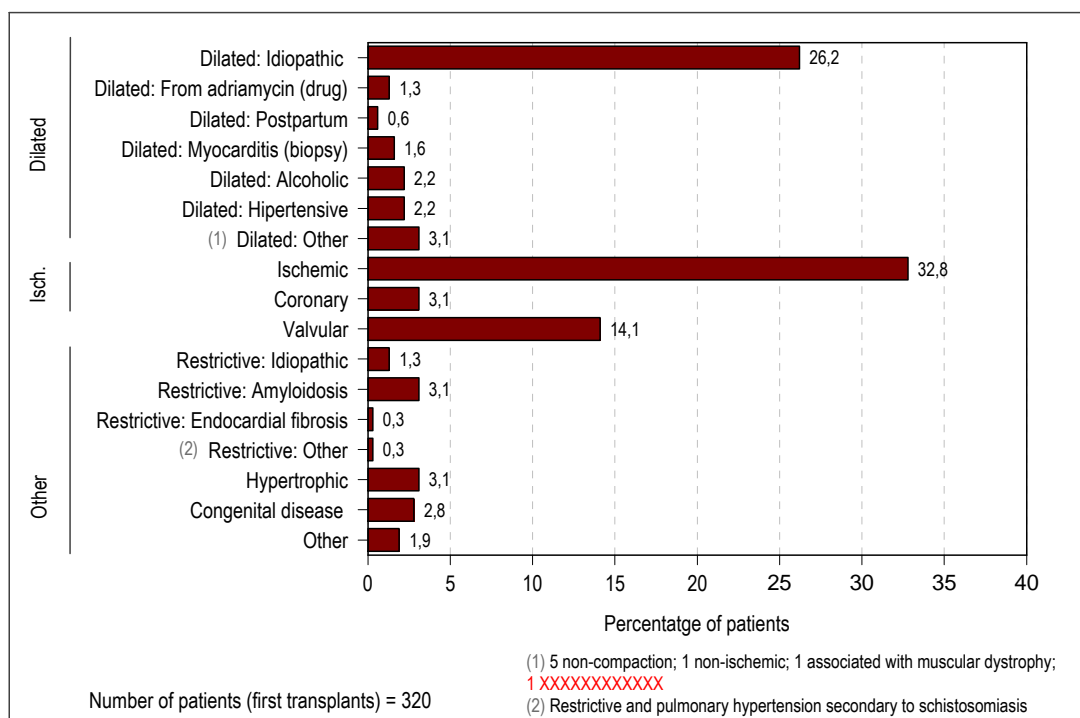
Figure 9. Annual evolution of the percentage of patients who received their first heart transplant, by indication. 1992-2010



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

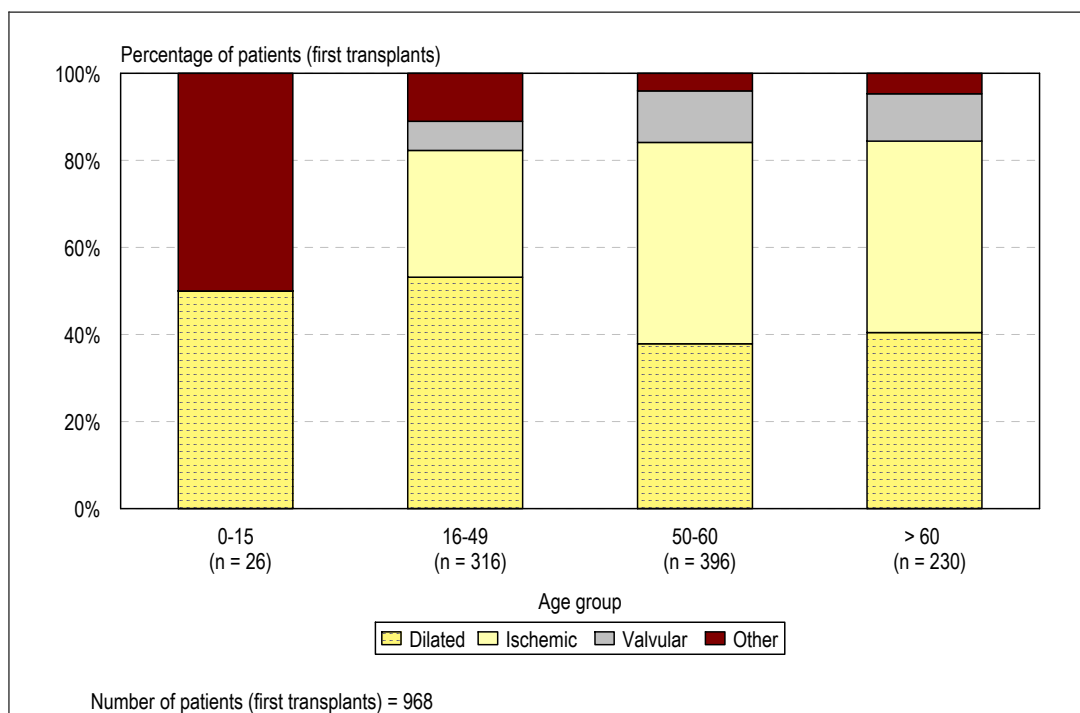
years from 2004 to 2010 were idiopathic dilated cardiomyopathy, ischemic cardiomyopathy and valvular cardiomyopathy (Figure 10).

Figure 10. Percentage of patients who received their first heart transplant, by indication. 2004-2010



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. 1984-2010



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).

Table 3. Mean and confidence interval of age, by indication. 1984-2010

	n	mean	IC 95%	range
Dilated cardiomyopathy	424	49	47.4 – 50.1	1 – 71
Ischemic cardiomyopathy	376	54	53.7 – 55.3	28 – 70
Valvular cardiomyopathy	93	54	52.1 – 56.0	17 – 67
Other forms of cardiomyopathy	75	39	34.8 – 43.3	0 – 67
Total	968	51	49.9 – 51.5	0 – 71

Table 4. Mean and confidence interval of age, by indication and sex. 1984-2010

		n	mean	IC 95%	range
Dilated cardiomyopathy	Men	310	48	46.6 – 49.9	1 – 71
	Women	114	50	47.6 – 52.7	1 – 67
Ischemic cardiomyopathy	Men	352	54	53.7 – 55.4	28 – 70
	Women	24	54	50.6 – 57.2	34 – 62
Valvular cardiomyopathy	Men	71	53	51.2 – 55.7	17 – 67
	Women	22	56	51.5 – 60.1	28 – 65
Other forms of cardiomyopathy	Men	34	43	36.2 – 49.1	1 – 67
	Women	41	36	30.3 – 41.9	0 – 67
Total	Men	767	51	50.5 – 52.2	1 – 71
	Women	201	48	46.2 – 50.5	0 – 67

Donor characteristics

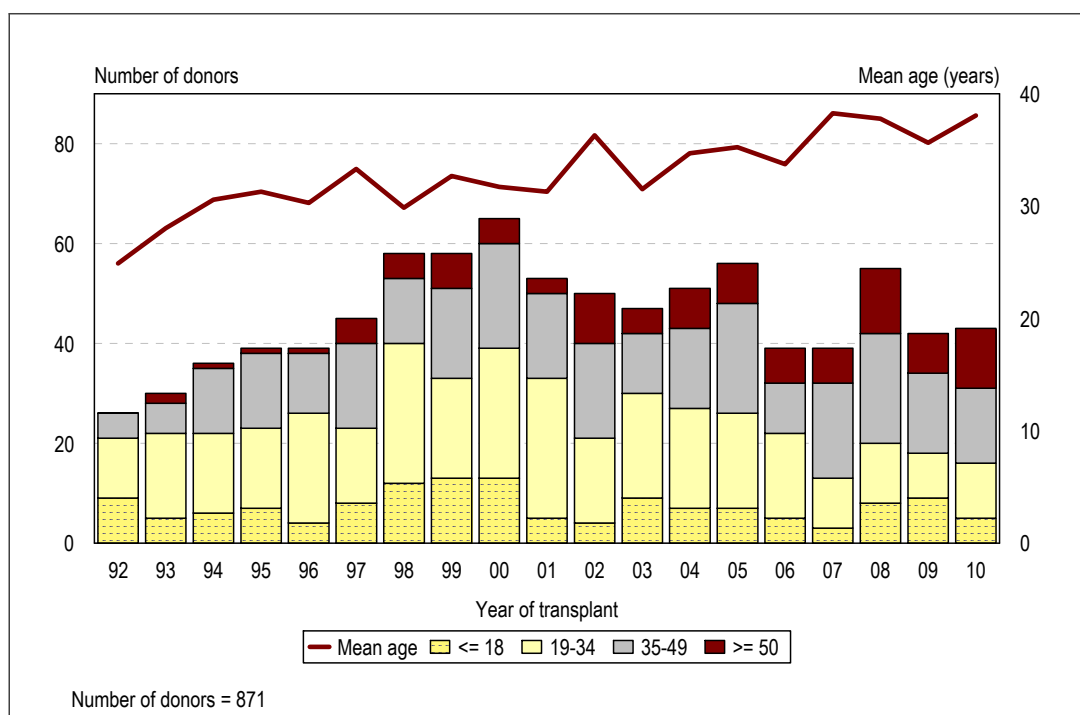
◆ Sex and age

Of the 871 transplants carried out in the 1984-2010 period, 70.4% of the donors were men and 29.6% were women. In 2010, 67.4% (n = 29) were men and 32.6% (n = 14) were women.

The mean age of the donor over the 1984-2010 period was 32, the median age was 31 and the range was from age 1 to 64 (in the 1992-2010 period, the mean age of the donor was 33 and the median was 32). The mean age has increased over the years, going from 25 in 1992 to 38 in 2010 (Figure 12).

This increase has occurred because of older donors, given that in 2010, 27.9% of donors were age 50 and over, whereas there were no donors in this age group in the first years of the programme.

Figure 12. Evolution of the mean age of the donor. 1992-2010

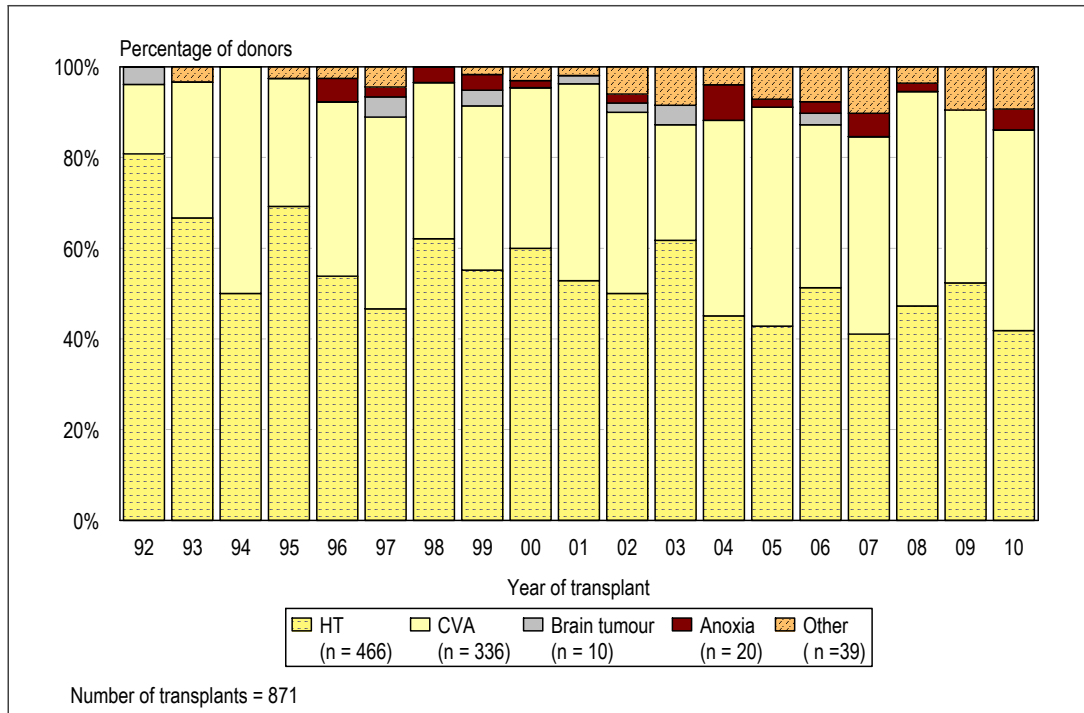


◆ Cause of death

The most frequent cause of death of the donor was head trauma (HT), which represented 55.2% of all causes, followed by cerebrovascular accident (CVA) / stroke, which represented 36.8%. (In the 1992-2010 period, these percentages were 53.5% and 38.6%, 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 2010, 41.9% of donors died from head trauma and 44.2% from CVA / stroke.

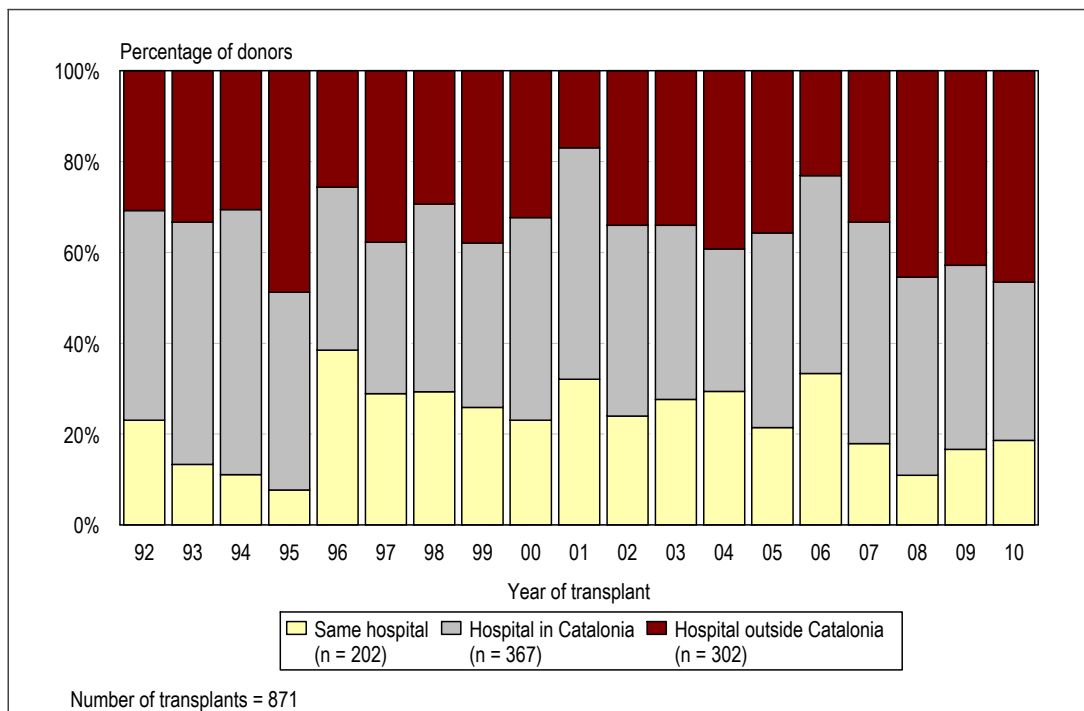
Figure 13. Evolution of the cause of death of donor (%). 1992-2010



◆ **Source of organs**

In the 1984-2010 period, 22.1% of the transplanted organs came from the same hospital where the transplant was carried out, 44.8% from other hospitals in Catalonia, and 33.1% from hospitals outside Catalonia. In 2010, 18.6% of the organs came from the same hospital, 34.9% from Catalonia, and 46.5% from outside Catalonia (Figure 14).

Figure 14. Annual evolution of the source of organs (%). 1992-2010



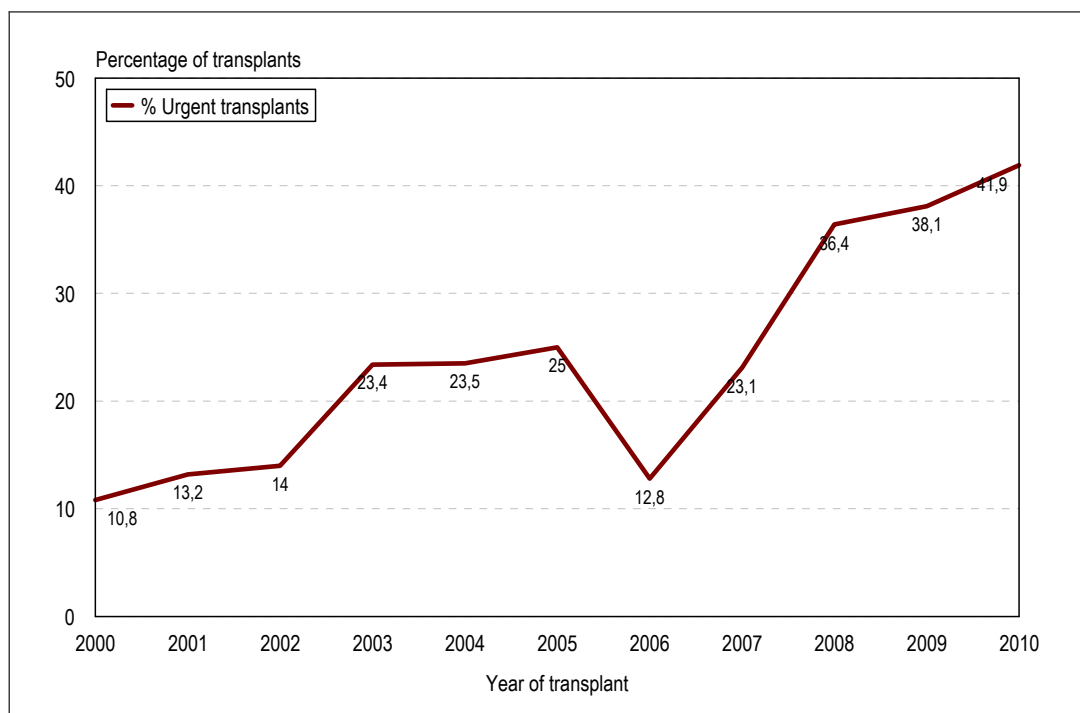
Transplant characteristics

◆ Emergency

Of the 984 transplants carried out in the 1984-2010 period, 20.5% (202) were urgent.

41.9% (18) of the transplants carried out in 2010 were urgent, which is a higher percentage than in previous years (Figure 15).

Figure 15. Annual evolution of the percentage of urgent transplants. 2000-2010



◆ Cold ischemia time

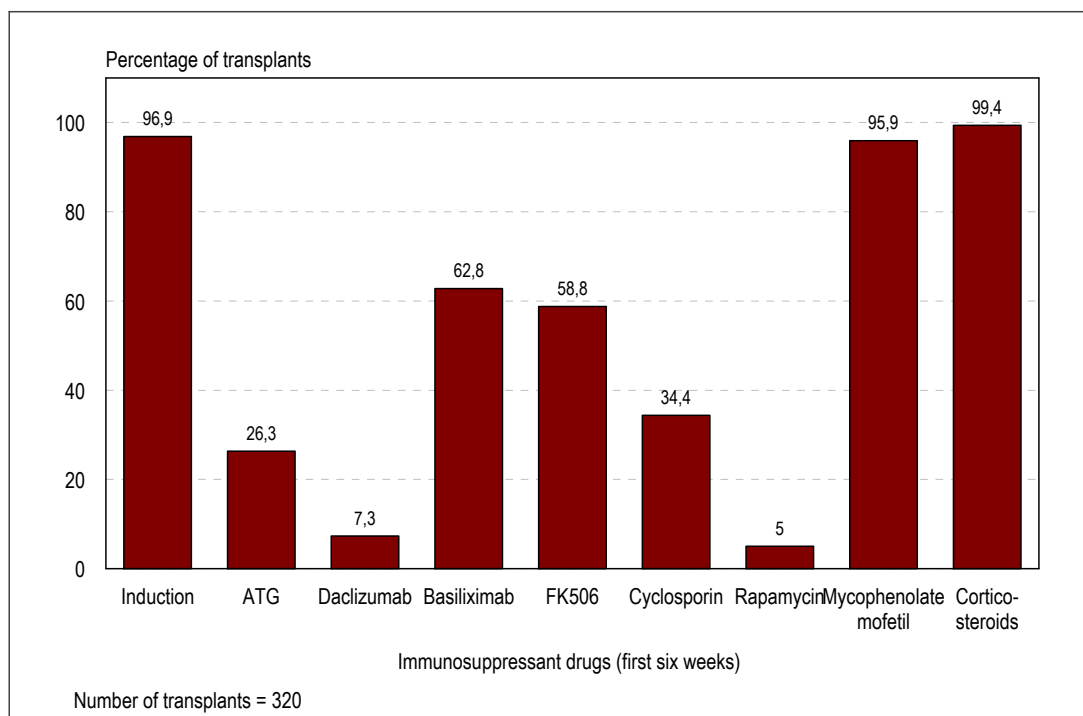
The mean cold ischemia time was 174 minutes. Bearing in mind the source of the organ, the differences observed were statistically significant ($p < 0.0001$). When the organ came from a hospital outside Catalonia, the mean cold ischemia time was 75 minutes longer than when the organ came from a hospital in Catalonia (Table 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.

Table 5. Cold ischemia time, in minutes, in accordance with the source of the organ. 1984-2010

	Same Hospital (n = 217)	Hospital in Catalonia (n = 438)	Hospital outside Catalonia (n = 323)	Total (n = 978)
Mean	133	155	227	174
Median	126	150	230	165
Range	60 – 238	64 – 369	87 – 360	60 – 369
95% CI	128 – 137	151 – 159	222 – 232	170 – 177

Figure 16. Immunosuppressant drugs used in the first six weeks after heart transplant. 2004-2010

Retransplants

Of the 984 transplants carried in the 1984-2010 period, 16 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 4 years). Specifically, 4 patients (25.0%) received a second transplant within the first week after receiving the first, 3 (18.8%) between the first week and three months after receiving the first transplant, and nine (56.3%) after the first year.

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

Table 6. Characteristics of the patients who received a retransplantation, by the time elapsed since the first transplantation. 1984-2010

	0 - 3 months (n = 7)	> 3 months (n = 9)
Sex		
Male	5 (71.4%)	6 (66.7%)
Female	2 (28.6%)	3 (33.3%)
Age (years)		
Mean	44	36
Median	42	39
Range	35 – 63	15 – 59
Indications		
Dilated cardiomyopathy	2 (28.6%)	7 (77.8%)
Ischemic cardiomyopathy	3 (42.9%)	2 (22.2%)
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, four had died (two by infection) at 31 December 2010. Of the 9 patients who received a retransplantation after the third month, 7 had died at 31 December 2010: 2 due to graft vascular disease, 2 due to primary dysfunction of the graft and 3 due to other causes.

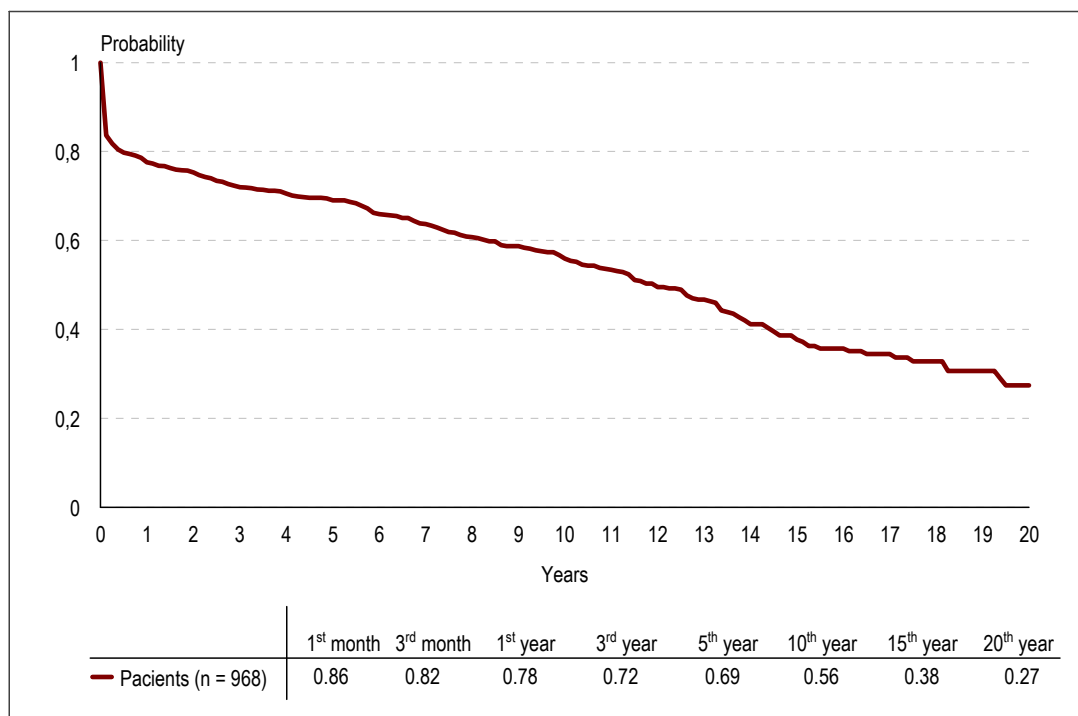
Table 7. Characteristics of the donor and the transplantation (first transplant), by the time elapsed since the first transplantation. 1984-2010

	0 - 3 months (n = 7)	> 3 months (n = 9)
Donor age (years)		
Mean	20	25
Median	23	21
Range	11 – 25	14 – 49
Cause of donor's death		
HT	6 (85,7%)	6 (66,7%)
CVA	-	2 (22,2%)
Other	1 (14,3%)	1 (11,1%)
Ischemia time (minutes)		
Mean	139	150
Median	115	140
Range	82 – 230	95 – 300

Survival

The survival rate of patients receiving a first heart transplant in Catalonia in the 1984-2010 period was 86% in the first month, 78% 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. 1984-2010



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)¹ and international registries (ISHLT)². 1984-2010

	RTCC (1984-2010)	RETC (1984-2009)	ISHLT (1982-6/2008)
1 st month	0.85	0.88	0.90
1 st year	0.77	0.78	0.81
5 th year	0.68	0.67	0.68
10 th year	0.55	0.54	0.50
15 th year	0.37	0.41	0.33

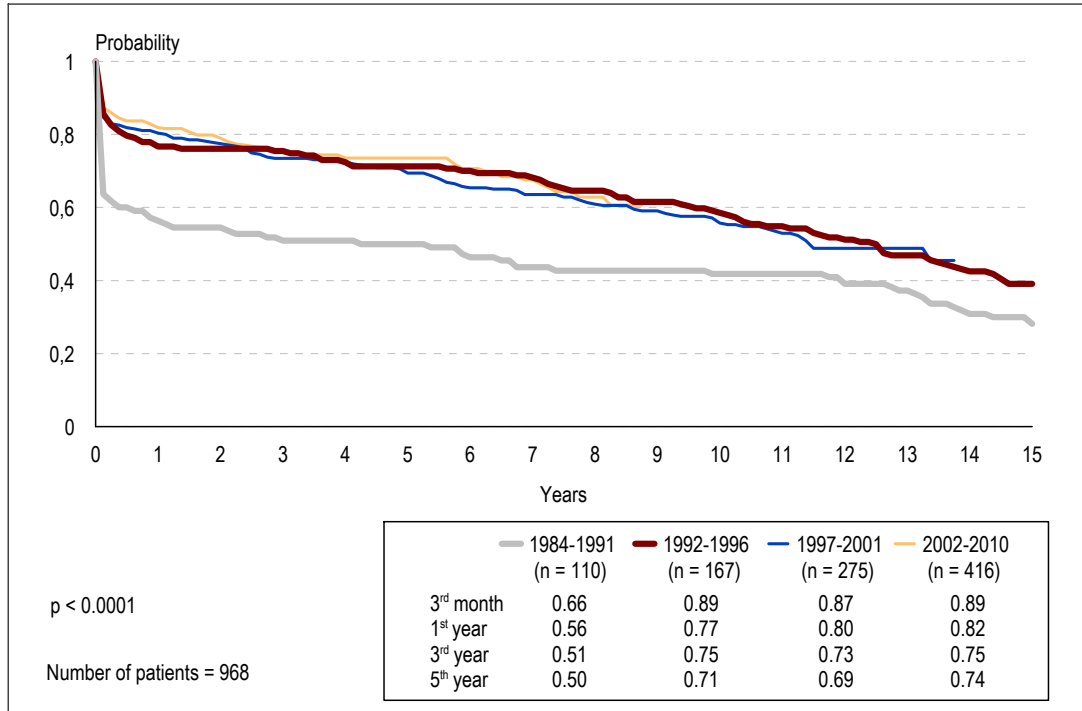
¹ Almenar Bonet, L. Registro Español de Trasplante Cardíaco. XXI Informe Oficial de la Sección de Insuficiencia Cardíaca, Trasplante Cardíaco y otras Alternativas Terapéuticas de la Sociedad Española de Cardiología (1984-2009). Rev Esp Cardiol. 2010;63(11):1317-28.

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

The overall patient survival rate in the 1984-2010 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 2002-2010. Statistically significant differences were observed between the four periods ($p < 0.0001$), but not between the last three (Figure 18).

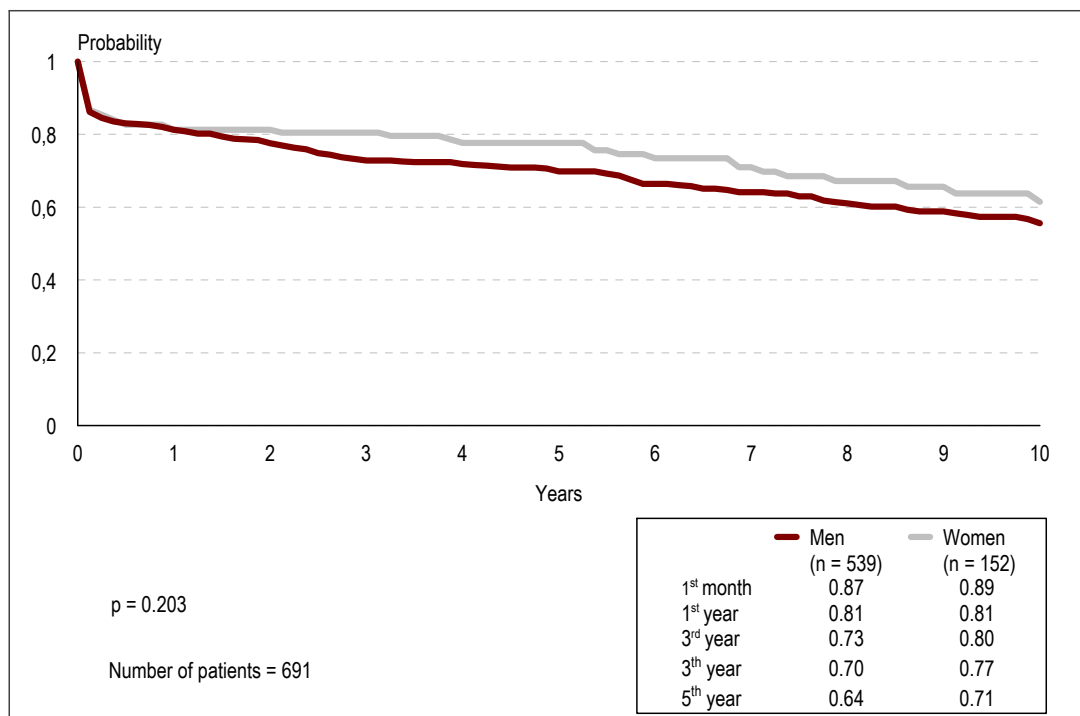
Figure 18. Survival rate of patients receiving a heart transplant, by period. 1984-2010



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 1997-2010 period, the patient survival rate was 88% in the first month, 81% in the first year, 74% in the third year, 71% in the fifth year, and 66% in the seventh year.

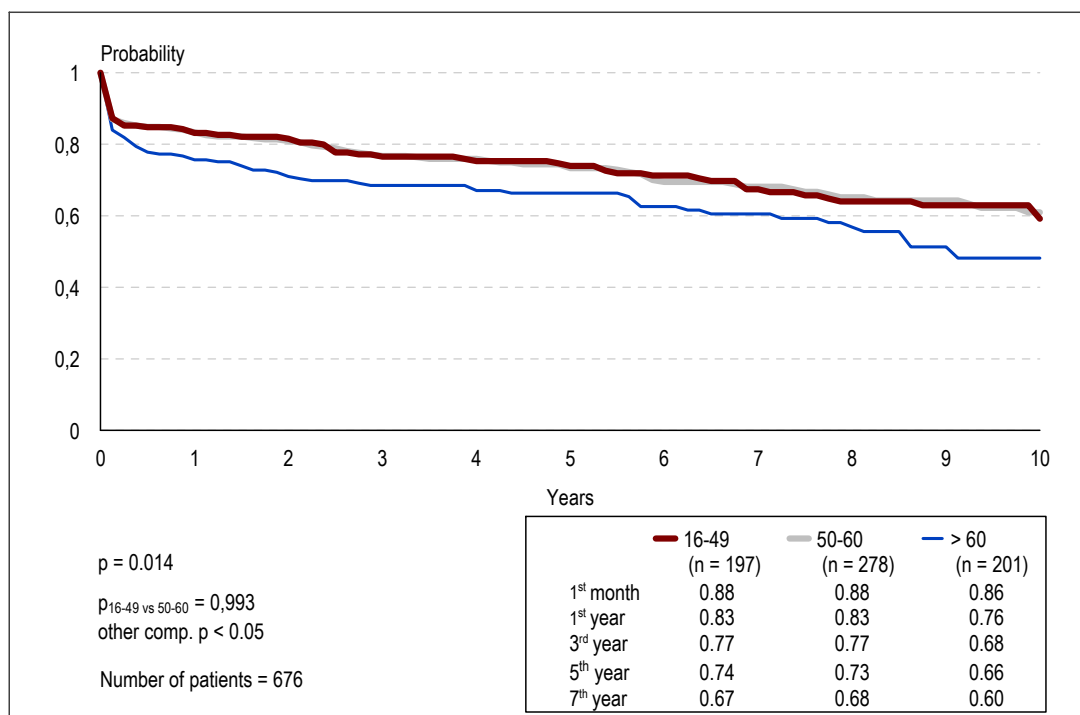
The long-term survival rate was slightly lower for men than women (Figure 19), though the differences were not statistically significant ($p = 0.203$).

Figure 19. Survival rate of patients receiving a heart transplant, by sex. 1997-2010



Patients over the age of 60 have the lowest survival rate, with statistically significant differences ($p = 0.014$) (Figure 20).

Figure 20. Survival rate of patients age 15 and older receiving their first heart transplant, by age group. 1997-2010



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 ($p = 0.132$), nor were the differences between the two most represented diagnostic categories ($p = 0.070$).

Figure 21. Survival rate of patients receiving a heart transplant, by indication. 1997-2010

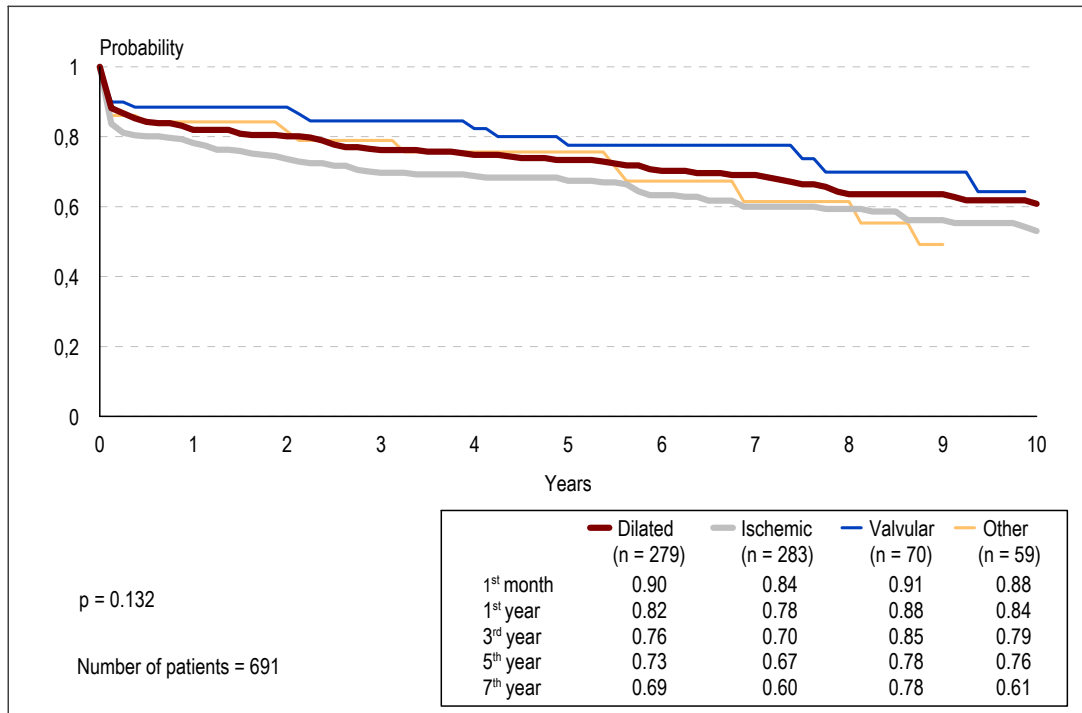
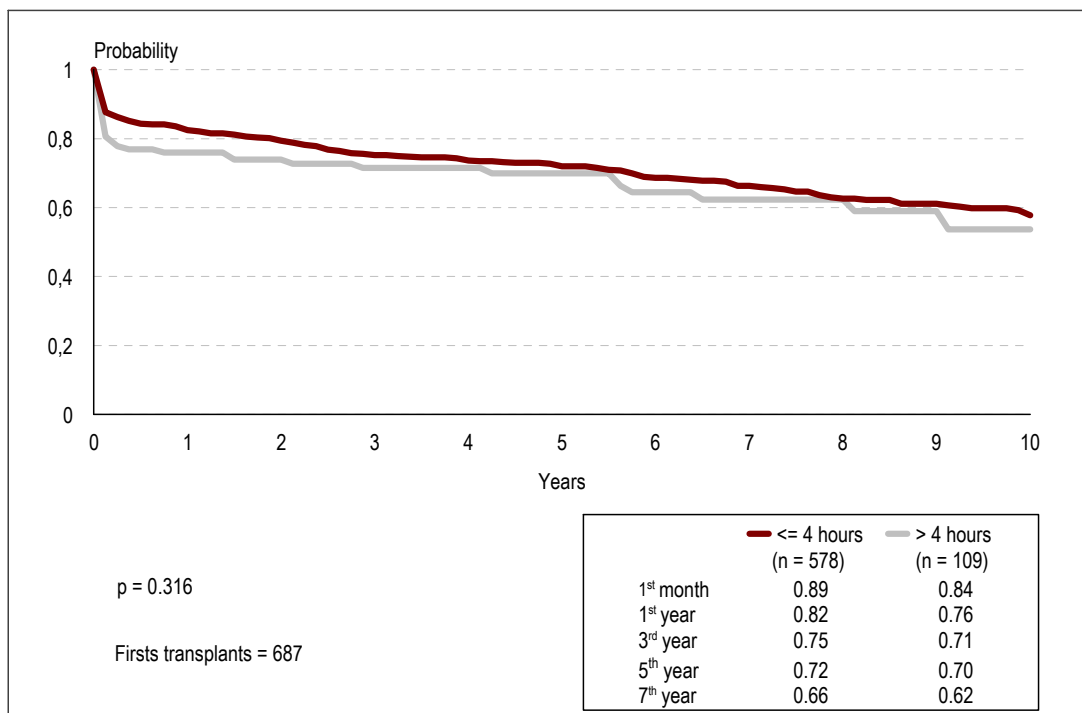


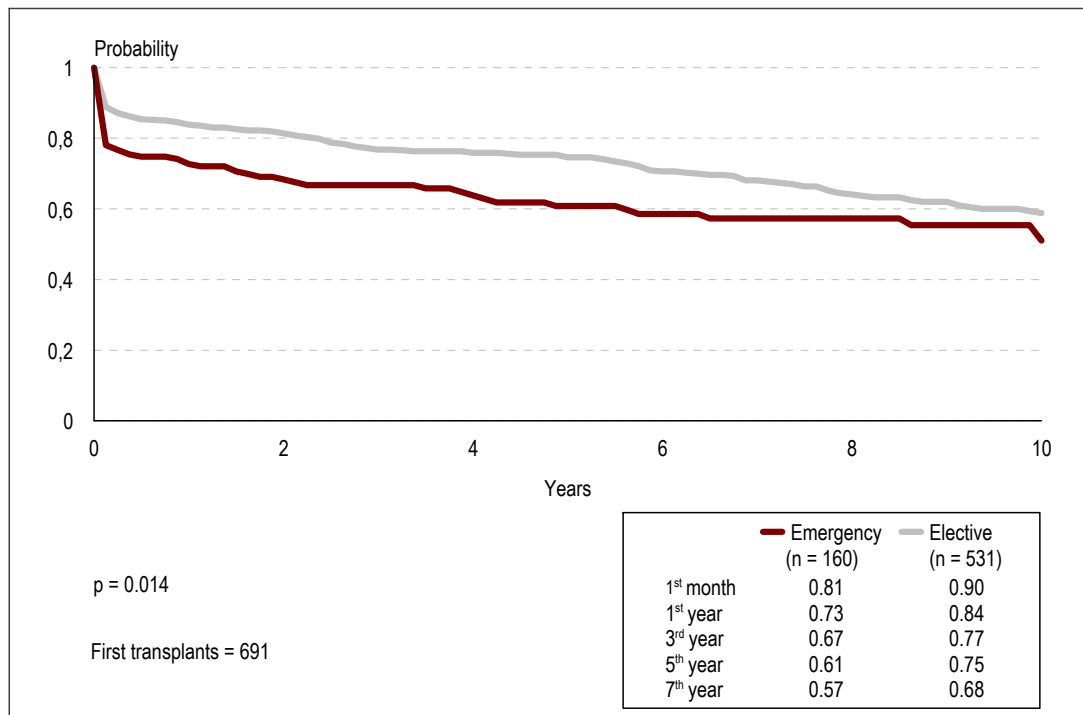
Figure 22. Survival rate of patients receiving a heart transplant, by cold ischemia time. 1997-2010



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 ($p = 0.316$) (Figure 22). The greatest differences were seen over the short term.

There are statistically significant differences ($p = 0.014$) 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. 1997-2010

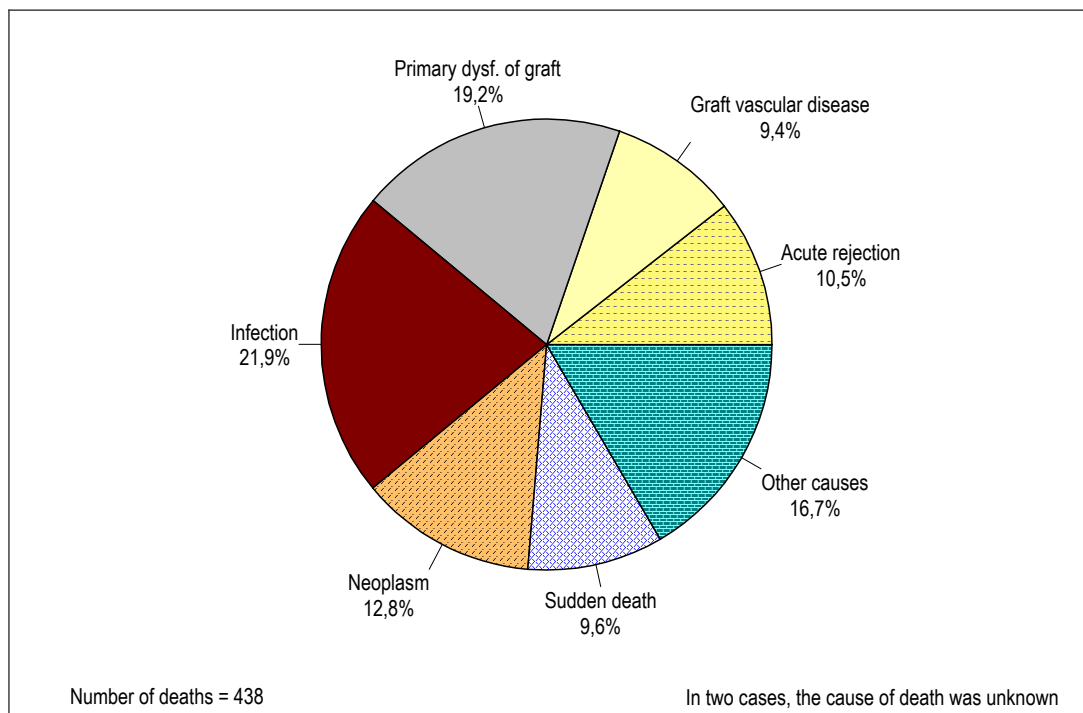


Mortality

Of the 968 patients receiving a transplant in the 1984-2010 period, 440 (45.5%) had died at 31 December 2010, 517 (53.4%) remained alive, and monitoring could not be continued on 11 (1.1%).

The most common causes of death were infection (21.9%) and primary dysfunction of the graft (19.2%), followed by neoplasm (12.8%) and severe rejection (10.5%). The first two causes alone accounted for more than 40% of all deaths (Figure 24).

Figure 24. Percentage of deaths, by cause of death. 1984-2010



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 31.6% 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 14.8% (12.4% in 1997-2010 period). In 2010, the mortality rate at 30 days was 9.3%, upper than the year before (Figure 28).

Figure 25. Percentage of deaths, by cause of death and sex. 1984-2010

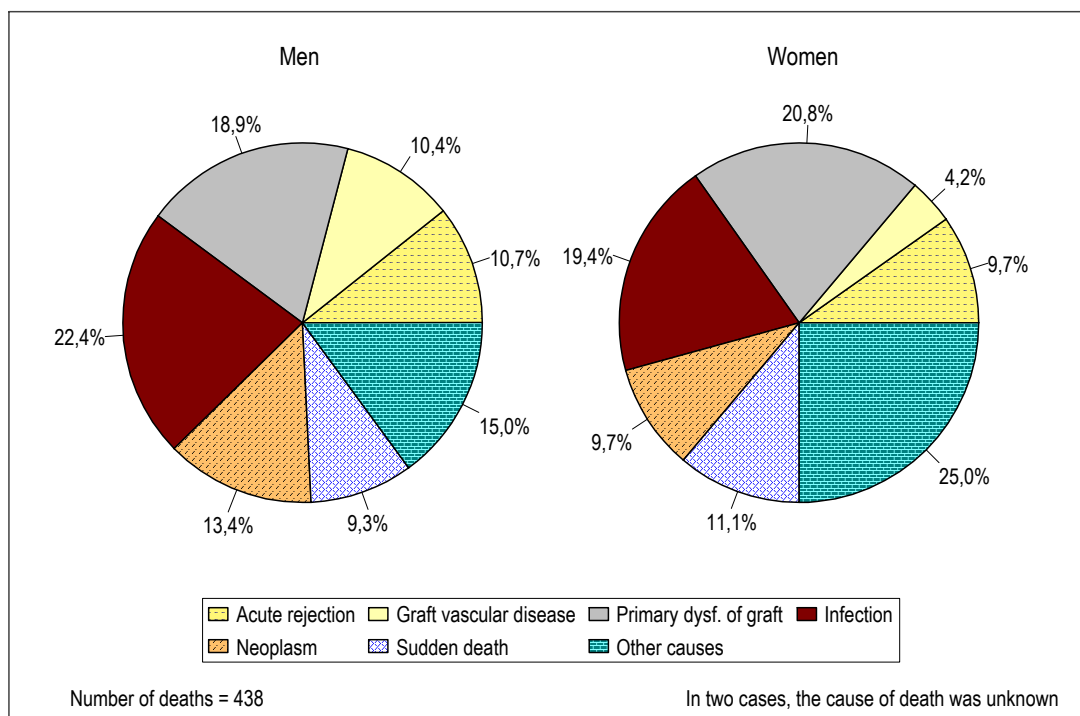


Figure 26. Time elapsed between the transplantation and death. 1984-2010

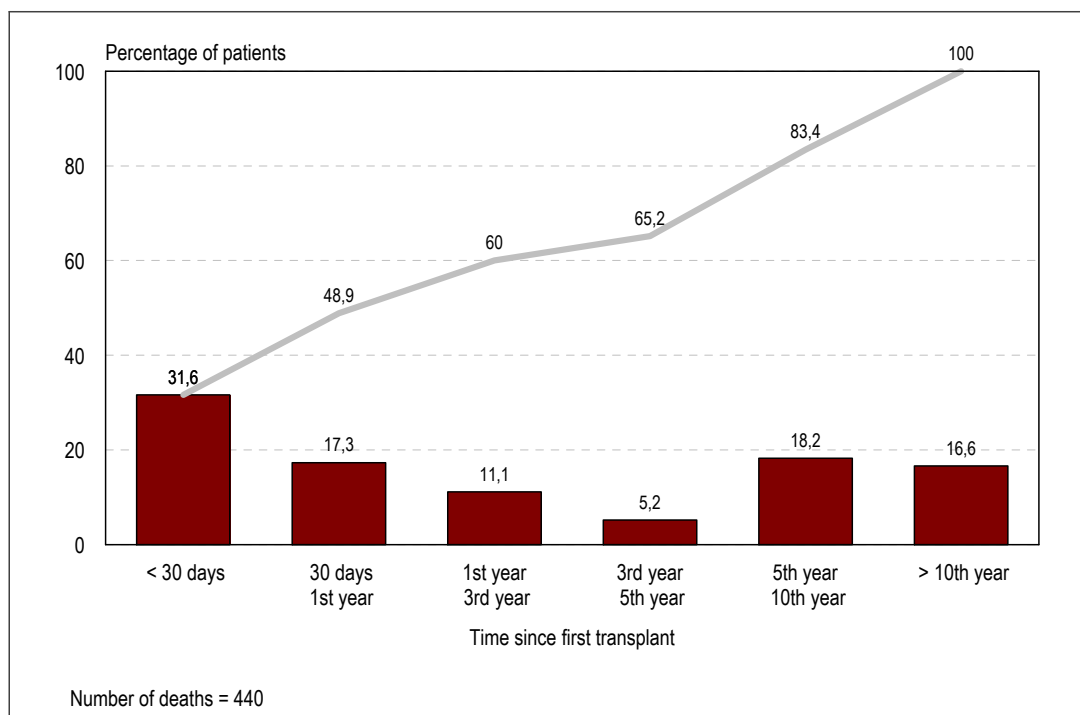


Figure 27. Percentage of deaths by cause of death and time elapsed since the transplantation. 1984-2010

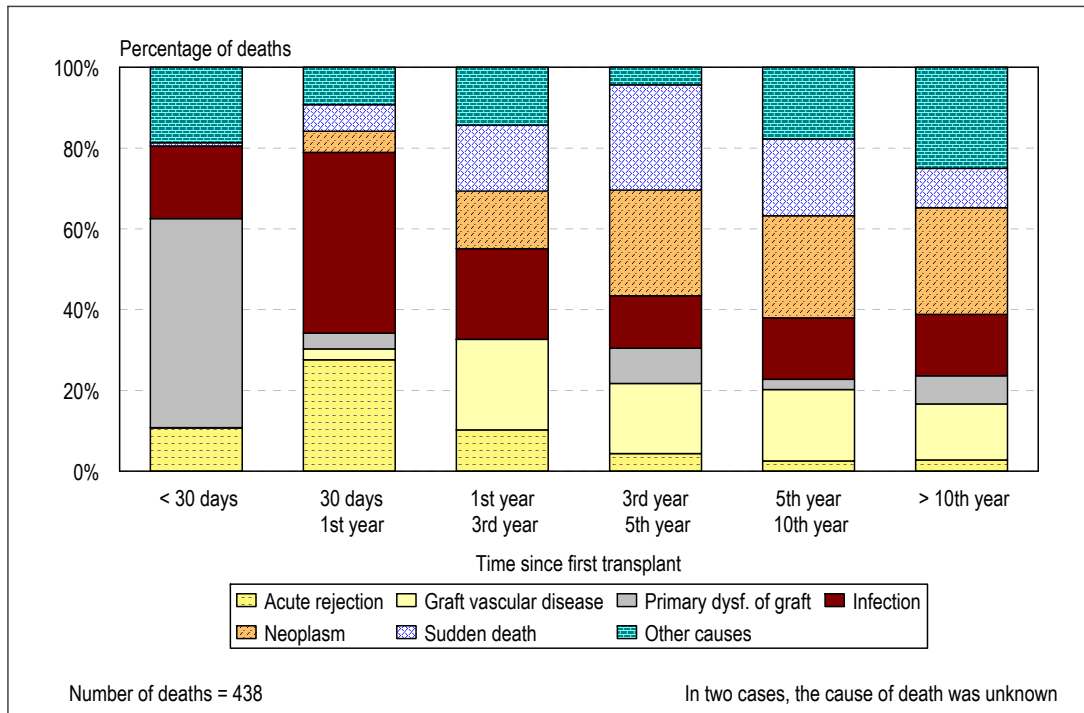
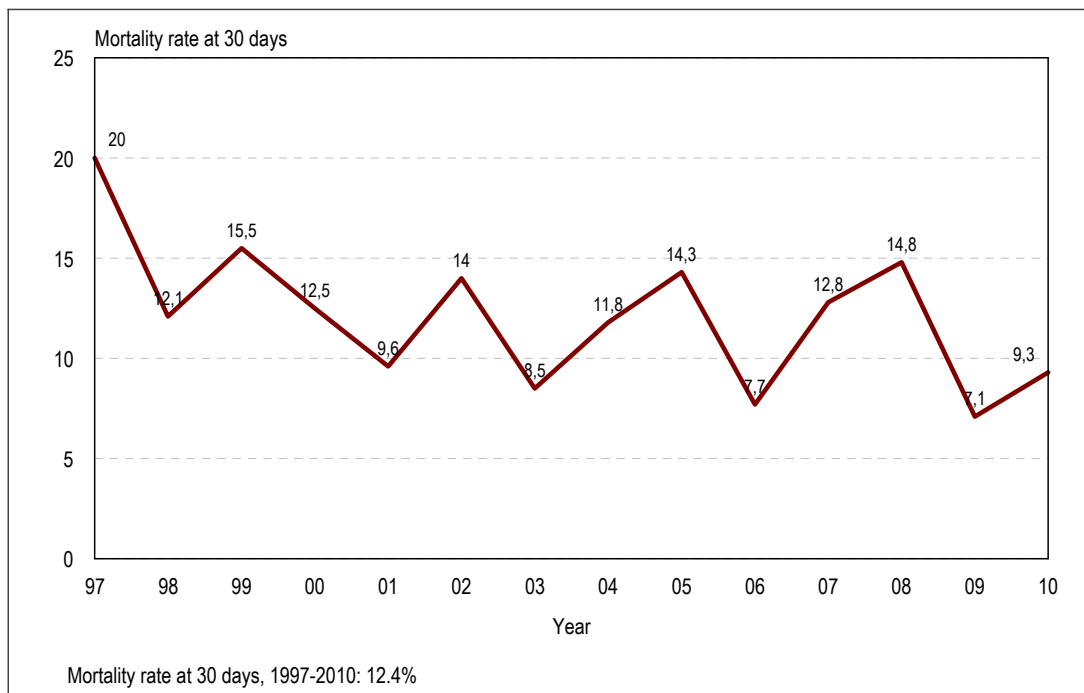


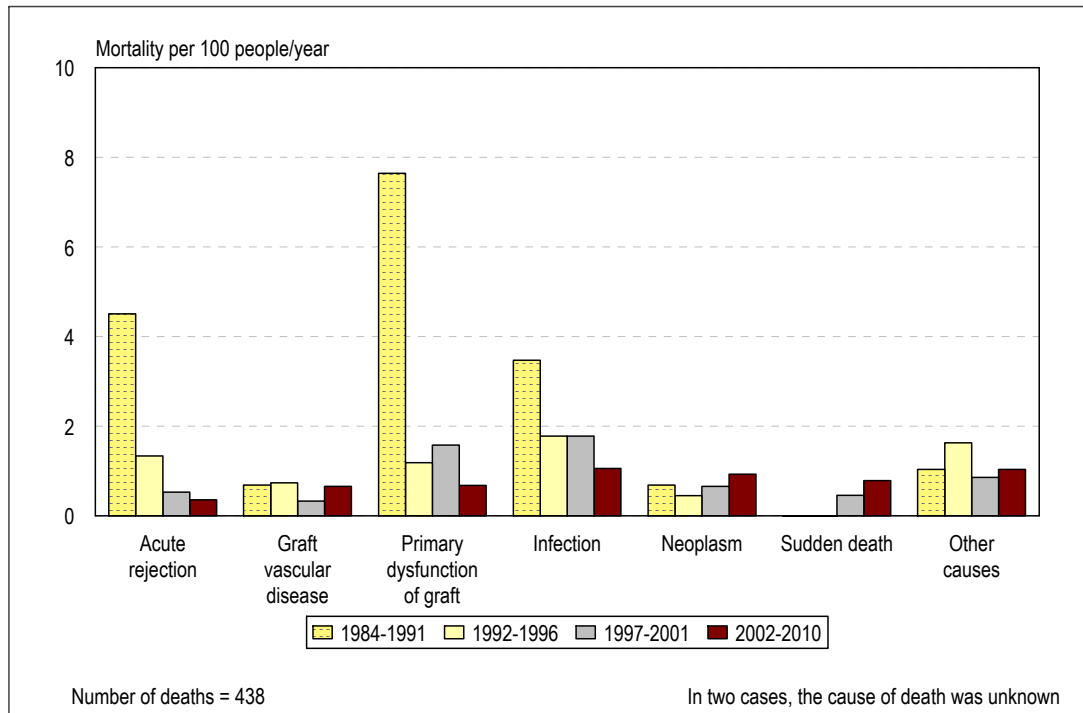
Figure 28. Evolution of the mortality rate at 30 days after the heart transplant. 1997-2010



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%; 2002-2010: 5.54%). 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.

Figure 29. Distribution of the cause of death by period, year of death, as a percentage (per 100 people/year). 1984-2010



Waiting List

The number of patients on the waiting list at the end of 2010 was upper than in previous years, going from 12 to 18 (Figure 30).

Figure 30. Evolution of the waiting list and the number of heart transplants. 1990-2010

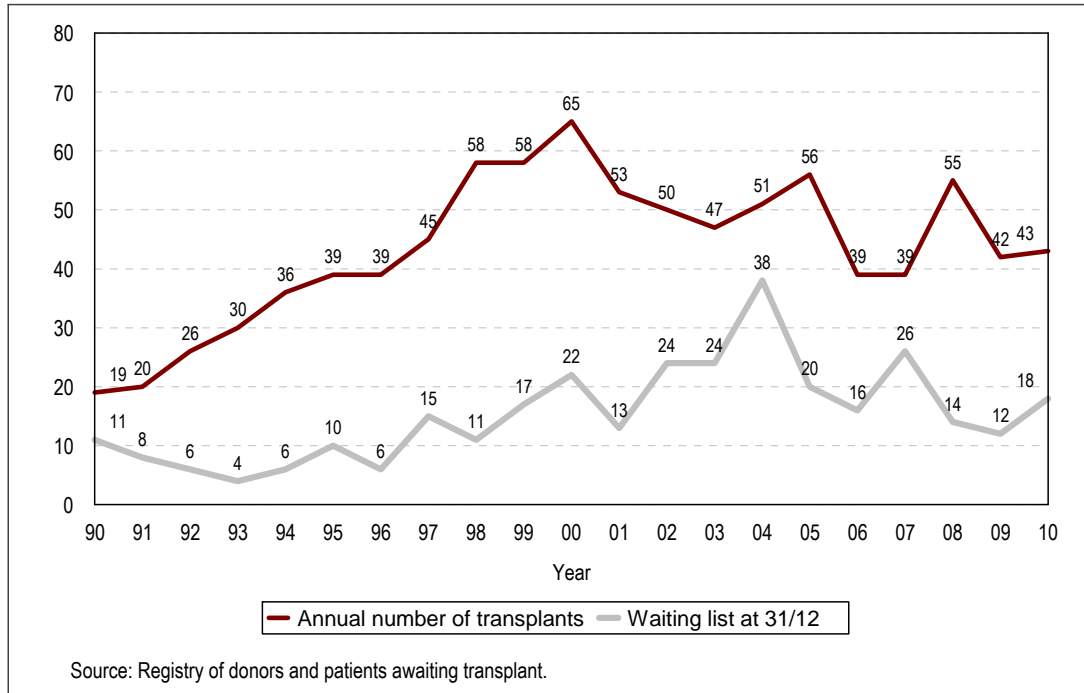
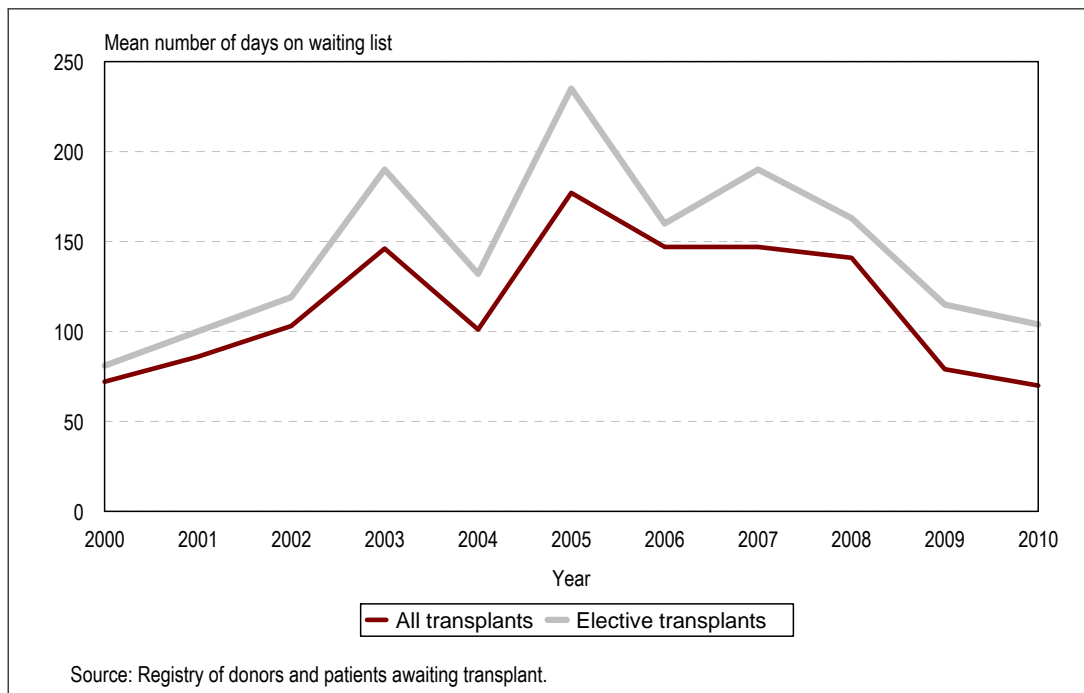


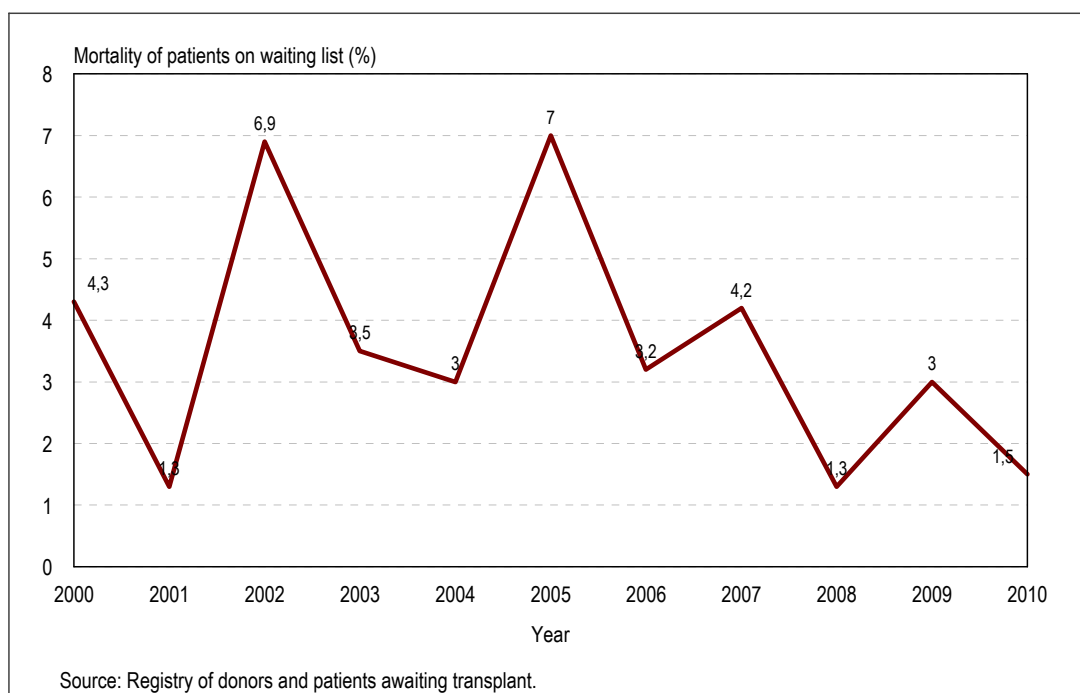
Figure 31. Mean number of days on the waiting list to receive a heart transplant. 2000-2010



In 2010, the mean number of days a patient was on the waiting list for a heart transplant was 70; if urgent transplants are excluded, the mean number of days went up to 104 (Figure 31).

In 2010, 70 patients were added to the waiting list. Of the patients taken off the list, 4 were removed because their health improved and 3 were removed because their health worsened. The mortality rate of the patients on the waiting list was 1.5%. 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 (%). 2000-2010



In the 2000-2010 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 70% (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. 2000-2010

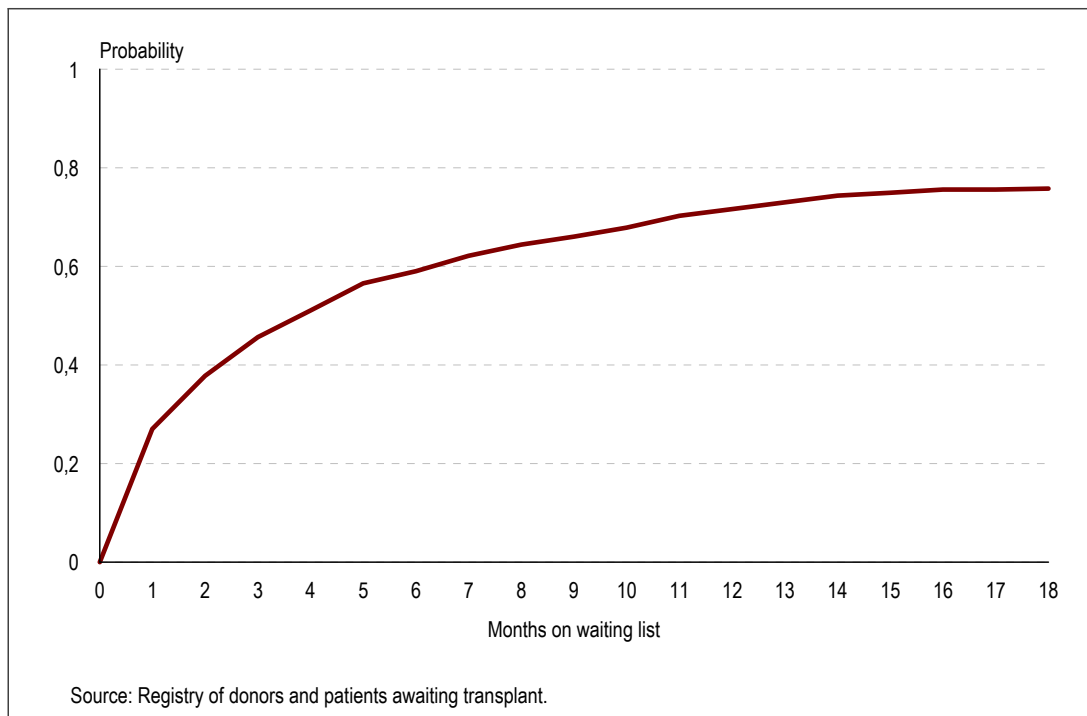
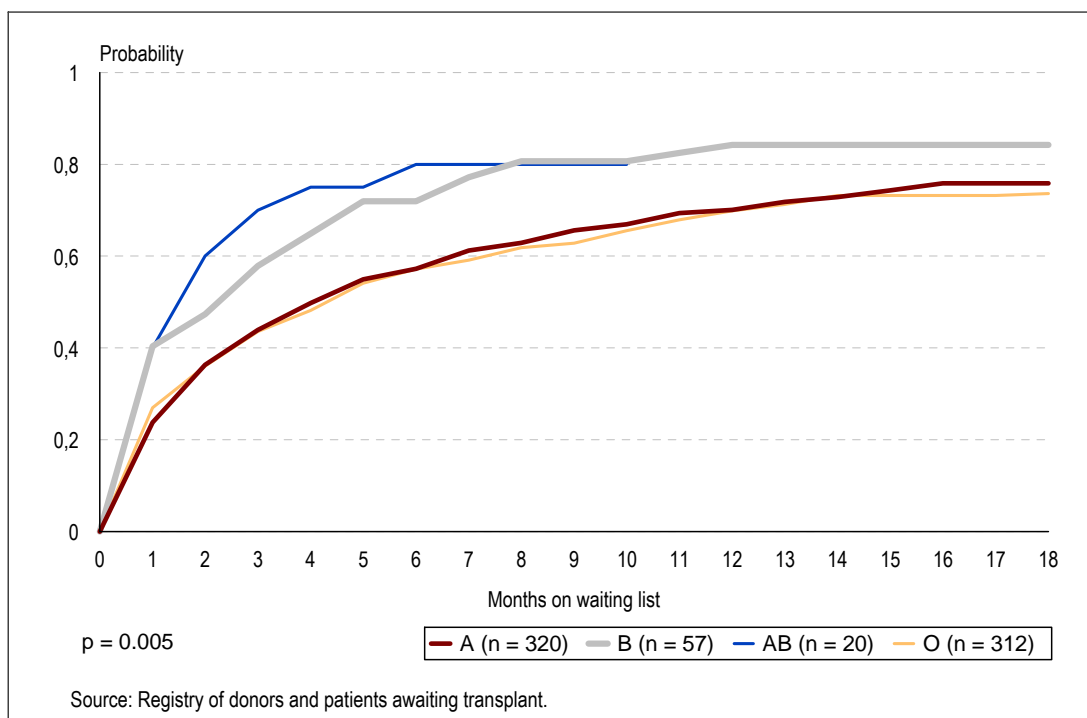


Figure 34. Probability of receiving a heart transplant, by blood type. 2000-2010



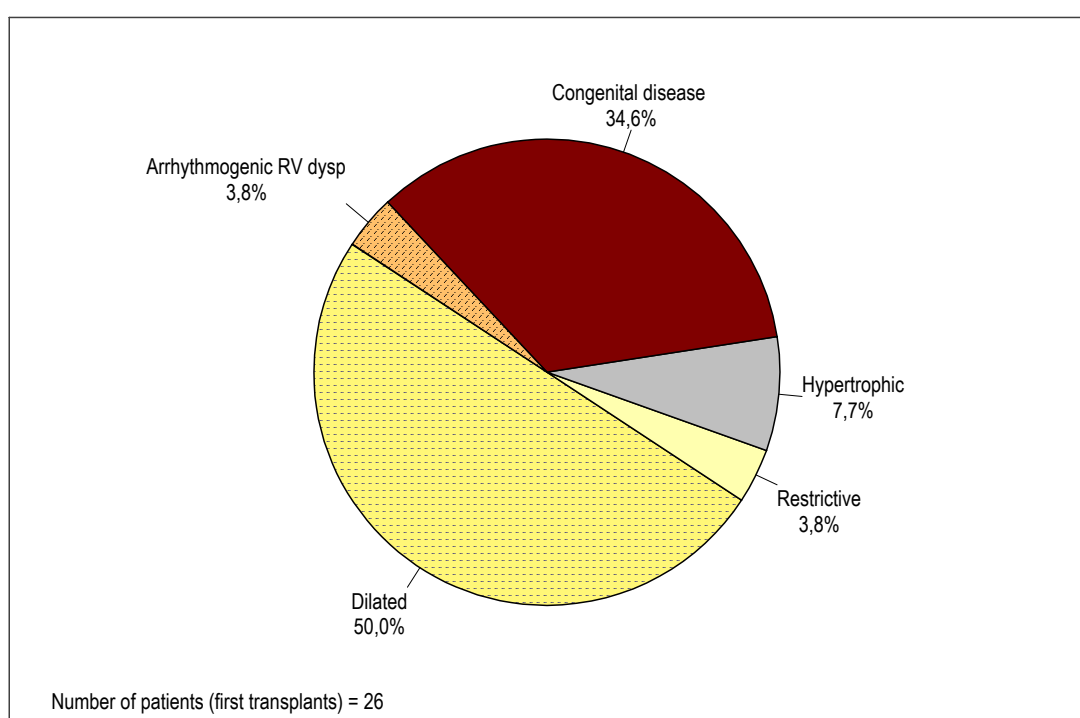
Heart Transplants in Children

Of the 984 transplants carried out in Catalonia in the 1984-2010 period, 26 were performed on children under 16 years of age, and one of the patients received a heart-lung transplant. In 2010, 3 transplants were performed.

Of the 26 patients who received heart transplants, 53.8% (14) were men and 46,2% (12) women. The mean age was 11 (median = 13.5, range = 5 month – 15 years), although 69.2% (18) of patients were 12-15 years.

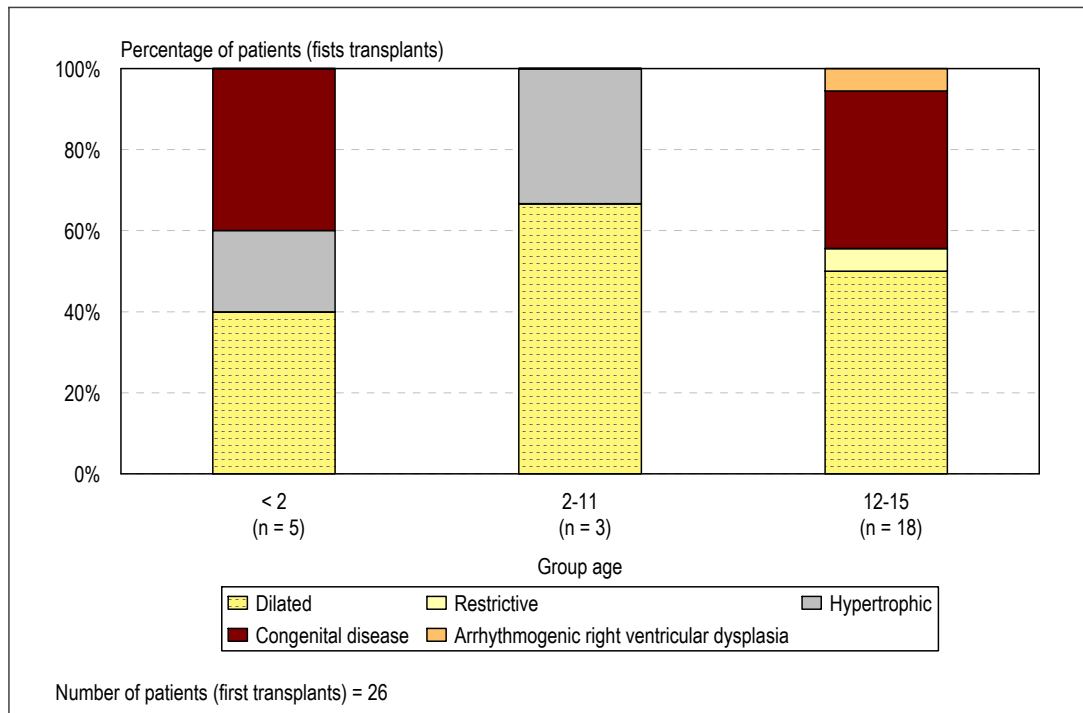
The two most frequent indications are dilated cardiomyopathy and congenital disease (Figure 35 and 36).

Figure 35. Indications in patients receiving transplants as children (under 16 years of age). 1984-2010



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

Of the 26 patients (under 16 years of age), one needed a retransplant and eleven had died at 31 December 2010.

Figure 36. Indications in patients receiving transplants as children (under 16 years of age) by age group. 1984-2010**Table 9.** Characteristics of donors in patients receiving transplants as children (under 16 years of age). 1984-2010

Sex of donor	
Male	11 (42.3%)
Female	14 (53.8%)
Information unavailable	1 (3.8%)
Age of donor	
Mean (\pm SD)	18 (\pm 12.8)
Median	17.50
Range	1 – 56
Cause of donor's death	
HT	18 (69.2%)
CVA	4 (15.4%)
Other	4 (15.4%)
Source of organ	
Same hospital	7 (26.9%)
Hospital in Catalonia	6 (23.1%)
Hospital outside Catalonia	13 (50.0%)

Table 10. Characteristics of transplants in patients receiving transplants as children (under 16 years of age). 1984-2010

Emergency	
Urgent	10 (38.5%)
Elective	16 (61.5%)
Cold ischemia time (minutes)	
Mean (\pm SD)	188 (\pm 61.8)
Median	188
Range	60 – 300