
Luis Almenar, Javier Segovia, María G. Crespo-Leiro, Jesús Palomo, José M. Arizón, Francisco González-Vilchez, and Juan Delgado, on behalf of the Spanish Heart Transplantation Teams

*Director of the Registro Español de Trasplante Cardíaco, Sección de Insuficiencia Cardíaca y Trasplante Cardíaco, Sociedad Española de Cardiología, Madrid, Spain
Servicio de Cardiología, Hospital Universitario y Politécnico La Fe, Valencia, Spain
Servicio de Cardiología, Clínica Puerta de Hierro, Majadahonda, Madrid, Spain
Servicio de Cardiología, Hospital Universitario A Coruña, A Coruña, Spain
Servicio de Cardiología (Adultos), Hospital Gregorio Marañón, Madrid, Spain
Servicio de Cardiología, Hospital Reina Sofía, Córdoba, Spain
Servicio de Cardiología, Hospital Marqués de Valdecilla, Santander, Cantabria, Spain
Servicio de Cardiología, Hospital 12 de Octubre, Madrid, Spain

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Registry
Survival

A B S T R A C T

Introduction and objectives: The purpose of this article is to present the results obtained from heart transplantation since this therapeutic modality first began to be used in Spain in May 1984.
Methods: A descriptive analysis was performed of all heart transplantsations performed until 31 December 2011.
Results: The total number of transplantsations is 6528. The average clinical profile of the Spanish heart transplantation patient in 2011 was that of a 53-year-old male who had been diagnosed with nonrevascularizable ischemic heart disease accompanied by severely depressed ventricular function and poor functional status. The implanted heart was typically from a 38-year-old donor who had died from brain hemorrhage. The average waiting list time was 122 days. Mean survival time has progressively increased over the years. For the overall series, the probability of survival at 1, 5, 10, and 15 years was 77%, 66%, 53%, and 39%, respectively, whereas over the past 5 years the probability of survival at 1 and 5 years was 80% and 73%, respectively. The most frequent cause of death was acute graft failure (16%), followed by infection (15.6%), the combination of graft vascular disease and sudden death (14%), tumors (12.3%) and acute rejection (7.7%).
Conclusions: The survival rates obtained in Spain from heart transplantation, especially in recent years, place heart transplantation as the treatment of choice in irreversible heart failure patients without other established medical or surgical options.

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R E S U M E N

Introducción y objetivos: El propósito de este artículo es presentar los resultados del trasplante cardíaco desde que se inició esta modalidad terapéutica en España en mayo de 1984.
Métodos: Se ha realizado un análisis descriptivo de todos los trasplantes cardíacos realizados hasta el 31 de diciembre de 2011.
Resultados: El número total de trasplantes cardíacos es de 6.528. El perfil clínico medio del paciente que se trasplantó en España en 2011 fue el de un varón de 53 años, diagnosticado de cardiopatía isquémica no revascularizable con depresión grave de la función ventricular y situación funcional avanzada, al que se implantó un corazón de 38 años procedente de un donante fallecido por hemorragia cerebral y con un tiempo en lista de espera de 122 días. El tiempo medio de supervivencia se ha incrementado con los años. Así, mientras en la serie total la probabilidad de supervivencia tras 1, 5, 10 y 15 años es del 77, el 66, el 53 y el 30%, respectivamente, en los últimos 5 años la probabilidad de supervivencia tras 1 y 5 años es del 80 y el 73%, respectivamente. La causa más frecuente de fallecimiento es el fallo agudo del injerto (16%),

Palabras clave:
Trasplante cardíaco
Registro
Supervivencia

* Corresponding author: Hospital Universitario y Politécnico La Fe, Avda. Bulevar Sur s/n, 46026 Valencia, Spain.
E-mail address: lualmenar@gmail.com (L. Almenar).
○ Collaborators: Eulalia Roig, Ernesto Lage, Nicolás Manito, Gregorio Rábago, Félix Pérez-Villa, José L. Lambert, Manuela Camino, Domingo Pascual, María T. Blasco, Luis de La Fuente, Luis García-Guereta and Dimpna C. Albert.
Abbreviations

HT: heart transplantation

INTRODUCTION

This article is the annual update analysis, published since 1991, describing the results of heart transplantation (HT) activity conducted in Spain between the first such procedure, performed in May 1984, and December 31 of the year prior to publication.\textsuperscript{1-22}

This Registry includes data on all HTs performed by all teams at all centers in Spain (Appendix) through 2011. It is, therefore, an accurate account of the status of HT in our country. The report’s reliability is founded on the nationwide use of a single database constructed on mutually agreed principles, which standardizes variables and the possible responses.

METHODS

Patients and Centers

Nineteen centers have supplied the registry with data (Table 1), although only 18 are currently carrying out transplantations.

In more than 25 years of transplantation activity, more than 6528 HTs have been performed. Of these, 94\% were isolated orthotopic transplants. Figure 1 displays the HT frequency distribution by year. Table 2 presents the distribution by type of HT procedure.

Design

The database includes 175 clinical variables with data on recipients, donors, surgery, immunosuppression, and follow-up. Each year, the centers send data to the Registry Director, who organizes the statistical methodology with the company hired to perform the analysis (currently ODDS, SL). An audit of the centers is organized periodically to verify registry data. The audit is carried out by an independent company which randomizes the centers and

![Figure 1. Number of transplants per year.](image-url)

Table 1

<table>
<thead>
<tr>
<th>Spanish Heart Transplantation Registry Collaborators 1984-2011 Participating Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hospital de la Santa Creu i Sant Pau, Barcelona</td>
</tr>
<tr>
<td>2. Clínica Universitaria de Navarra, Pamplona</td>
</tr>
<tr>
<td>3. Clínica Puerta de Hierro, Majadahonda, Madrid</td>
</tr>
<tr>
<td>4. Hospital Marqués de Valdecilla, Santander</td>
</tr>
<tr>
<td>5. Hospital Reina Sofia, Córdoba</td>
</tr>
<tr>
<td>6. Hospital Universitario y Politécnico La Fe, Valencia</td>
</tr>
<tr>
<td>7. Hospital Gregorio Marañón, Madrid</td>
</tr>
<tr>
<td>8. Fundación Jiménez Díaz, Madrid</td>
</tr>
<tr>
<td>9. Hospital Virgen del Rocío, Sevilla</td>
</tr>
<tr>
<td>10. Hospital 12 de Octubre, Madrid</td>
</tr>
<tr>
<td>11. Hospital Universitario A Coruña, A Coruña</td>
</tr>
<tr>
<td>12. Hospital de Bellvitge, L’Hospitala de Llobregat, Barcelona</td>
</tr>
<tr>
<td>13. Hospital La Paz, Madrid</td>
</tr>
<tr>
<td>14. Hospital Central de Asturias, Oviedo</td>
</tr>
<tr>
<td>15. Hospital Clinic, Barcelona</td>
</tr>
<tr>
<td>16. Hospital Virgen de la Arrixaca, El Palmar, Murcia</td>
</tr>
<tr>
<td>17. Hospital Miguel Sever, Zaragoza</td>
</tr>
<tr>
<td>18. Hospital Clínico, Valladolid</td>
</tr>
<tr>
<td>19. Hospital Vall d’Hebron, Barcelona</td>
</tr>
</tbody>
</table>

Ordered according to first transplantation.

Table 2

<table>
<thead>
<tr>
<th>Spanish Heart Transplantation Registry Collaborators 1984-2011 by Type of Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>De novo heart transplantations                              6202</td>
</tr>
<tr>
<td>Heart retransplantations                                     191</td>
</tr>
<tr>
<td>Combined transplants</td>
</tr>
<tr>
<td>Heart-lung                                                   77</td>
</tr>
<tr>
<td>Heart-kidney                                                 50</td>
</tr>
<tr>
<td>Heart-liver                                                  8</td>
</tr>
<tr>
<td>Total                                                        6528</td>
</tr>
</tbody>
</table>

The database includes 175 clinical variables with data on recipients, donors, surgery, immunosuppression, and follow-up. Each year, the centers send data to the Registry Director, who organizes the statistical methodology with the company hired to perform the analysis (currently ODDS, SL). An audit of the centers is organized periodically to verify registry data. The audit is carried out by an independent company which randomizes the centers and

![Figure 1. Number of transplants per year.](image-url)
the HTs, extracts a representative sample of information, and verifies the reliability of the data submitted.

In 2008, the Registry was presented to and approved by the Committee for Biomedical Research Ethics of the Hospital Universitario La Fe, Valencia. On the other hand, the Registry is in the process of being registered in the Spanish Ministry of Health, Social Services and Equality to guarantee fulfillment of the Spanish Data Protection Law 15/1999. Furthermore, the database is expected to be available online by 2013.

Statistics

Variables are presented as the mean±the standard deviation and percentage. Survival curves have been calculated using the Kaplan-Meier test, and compared using the log rank test. The statistical significance is reached when P<.005. Survival data analysis has not included retransplantations or combined transplantsations.

RESULTS

Heart Transplant Patient Profile

The average clinical profile of HT recipients in Spain is that of a 53-year-old male diagnosed with ischemic heart disease or idiopathic dilated cardiomyopathy, with blood group A or O. Table 3 shows the clinical profile of HT recipients distributed by age. Replantation patients are analyzed independently.

Waiting List Mortality and Days Until Transplantation

In 2011, the mortality of patients in the waiting list was 5%. After being added to the waiting list, 20% of the patients were excluded from HT. Figure 2 represents the annual percentage of patients included on the waiting list who received HT, were excluded from the list, or passed away before receiving a transplantation.

The mean time recipients had to wait for HT in 2011 was 122 days. Figure 3 shows the evolution of the wait days throughout the last 20 years.

Cause of Death and Mean Donor Age

Most of the donor hearts come from individuals who died of cerebral hemorrhage. The mean age in 2011 was 38 years, as displayed in Figures 4 and 5.

Emergency Transplantation

The percentage of indicated emergency transplantsations in 2011 was 38%. Figure 6 shows the evolution of this HT option throughout the years.

Figure 2. Patient outcomes once included on heart transplant waiting list.
**Figure 3.** Year-by-year evolution of mean days on waiting list for heart transplantation recipients.

**Figure 4.** Year-by-year evolution of causes of heart transplant donor deaths. CH, cerebral hemorrhage; TBI, traumatic brain injury.

**Figure 5.** Year-by-year evolution of the mean age of heart transplant donors.

**Figure 6.** Year-by-year evolution of emergency transplantation percentage.
immunosuppressive
distribution
Ventricular
device,
MMF,
Immunosuppression
ventricular
increased
drug
The
Most
patients
who
received
HT
in
Spain
are
given
induction
immunosuppressive
treatment.
The
different
drugs
used
and
distribution
by
time
periods
are
displayed
in
Figure
8.

Ventricular
Assist
Devices
The
percentage
of
patients
transplanted
with
assist
devices
has
increased
over
time.
Within
the
last
7
years,
it
reached
24%.
The
distribution
by
time
periods,
as
well
as
by
type
of
ventricular
assist
device,
can
be
seen
in
Figure
7.

Immunosuppression
Most
patients
who
received
HT
in
Spain
are
given
induction
immunosuppressive
treatment.
The
different
drugs
used
and
distribution
by
time
periods
are
displayed
in
Figure
8.

De
novo
maintenance
immunosuppressive
treatment
and
changes
made
during
the
recipients’
evolution
appear
in
Figure
9.

Survival
Early
mortality
(within
30
days
from
HT)
was
19%
in
2011,
as
seen
in
Figure
10.
This
particular
mortality
is
slightly
higher
than
the
mean
of
the
previous
5
years
(17%).

After
incorporating
the
survival
data
from
2011
to
the
data
from
the
previous
years,
we
obtained
an
actuarial
survival
probability
of
87%
for
the
first
month.
For
1,
5,
10,
15,
and
20
years
we
obtained
actuarial
survival
probabilities
of
77%,
66%,
53%,
39%,
and
28%,
respectively
(Fig.
11).
Survival
per
time
period
improved
in
the
later
years,
with
a
survival
probability
of
80%
at
1
year
and
73%
after
5
years
(Fig.
12).

Survival
curves
varied
according
to
the
etiological
reason
for
HT
(Fig.
13).
The
degree
of
urgency
also
influenced
the
survival
probability
(Fig.
14).
Nonetheless,
there
were
no
differences
among
patients
urgently
transplanted
with
assistance,
whether
this
was
with
intra-aortic
balloon,
membrane
oxygenation,
or
ventricular
assist
device
or
without
it
(Fig.
15).

Causes
of
Death
The
most
frequent
cause
of
death
was
early
graft
failure
(16%),
followed
by
infection
(15.6%),
the
combination
of
graft
vascular
disease
and
sudden
death
(14%),
tumors
(12.3%),
and
acute
rejection
(7.7%)
(Fig.
16).

By
analyzing
the
causes
of
mortality
across
several
time
periods,
we
were
able
to
appreciate
that
they
vary.
In
the
first
month,
early
graft
failure
was
the
predominant
cause
of
death.
Between
the
first
month
and
the
first
year
the
main
causes
were
infection
and
transplantation
rejection.
Tumors
and
the
combination
of
chronic
rejection
with
sudden
death
were
the
predominant
causes
after
the
first
year.
In
Figure
17
we
can
observe
the
causes
of
death
distributed
by
time
periods.

DISCUSSION
After
almost
30
years
of
HT
development
in
Spain
and
with
more
than
6500
HT
performed,
we
are
able
to
say
that
this
therapeutic
modality
can
be
offered
to
all
the
population,
guaranteeing
levels
of
knowledge,
control,
quality
standards,
and survival similar or superior to those of other developed countries and the rest of the world. This can be confirmed if we compare our results with those of the annual publication of the International Society for Heart and Lung Transplantation Registry.\textsuperscript{23–26}

One of the greater advantages of the Spanish Registry of Heart Transplantation is that we have elaborated a homogeneous database among all the Spanish Transplantation teams, agreeing about all possible responses. Each year, all the teams update their database and send them to the registry director, who merges them and then forwards them to an independent statistical company for the appropriate analysis. This method is considered to provide reliable results and avoid errors, which are very common in nonhomogeneous databases. In 2007, the number of analyzed variables per patient reached 175. In addition, aiming for higher data quality and reliability, we mean to continue with the audit of centers through independent companies that guarantee the validity of the data.

Currently, 18 centers have transplanting activities. In Spain, transplantation teams are concerned because HT centers are being authorized without an adequate analysis of the necessary requirements. This is due to the clear decreasing trend of optimal donor numbers in Spain, which consequently causes the number of HTs/number of centers correlation to decrease. The reduced number of HTs performed causes, on one side, the underutilization of hospital resources that are prepared and available for multiple functions and, on the other, lengthens the learning process needed to achieve optimal results. The only benefit of the new centers to the patient is that he/she may stay in the same location, although

![Figure 10](https://www.revespcardiol.org/content/105-133/7/12/105914491_038.jpg)

**Figure 10.** Year-by-year percentage evolution of early deaths (first 30 days).

![Figure 11](https://www.revespcardiol.org/content/105-133/7/12/105914491_039.jpg)

**Figure 11.** Survival curve for the entire series. 95%CI, 95% confidence interval.

![Figure 12](https://www.revespcardiol.org/content/105-133/7/12/105914491_040.jpg)

**Figure 12.** Survival curve by time periods.

![Figure 13](https://www.revespcardiol.org/content/105-133/7/12/105914491_041.jpg)

**Figure 13.** Survival curves according to etiology indicating transplantation. iDCM, idiopathic dilated cardiomyopathy; IHD, ischemic heart disease; RHT, retransplantation.
Figures 14 and 15. Survival curves for different types of emergency. Statistical significance between urgent and non-urgent degree. No differences between types of emergency (with or without assistance). Assistance includes: intra-aortic balloon counterpulsation, extracorporeal membrane oxygenator, and pulsatile or continuous ventricular assistance. Assist, assistance.


Last year, the number of HTs performed decreased again due to the progressive trend of donor decrease (237 in 2011 compared to 243 in 2010). There is no single explanation for this decline, but it seems evident that lower mortality from traffic-related head injury along with better control and management of patients with multiple trauma units may be a cause. When the number of donors decreases, the possibilities of HTs decrease and the number of patients on the waiting list grows. Therefore, the proportion of patients with advanced heart failure who, once on the waiting list, cannot receive a transplant and are removed from the list (by death or deterioration) reaches 20%. Transplantation teams, aware of this problem, have attempted to expand the range of possible donors by expanding the donation criteria. Even so, the average age of donors shows very little variation (38 years in 2011 compared to 39 years in 2010).

The time that patients must wait for a compatible heart increased significantly, from 99 days in 2010 to 122 days in 2011. In previous years the wait had decreased due to the higher numbers of emergency transplantations. However, given that the time it takes to find a compatible organ for emergency transplantations is increasing, it is very likely that the waiting time will increase progressively in the next years.

The clinical profile of patients has not changed in the last few years. The patients have been divided in three groups (pediatrics, adults, and retransplantations), given that they have different clinical characteristics. Thus, pediatric patients receive transplantations due to congenital heart disease or idiopathic dilated cardiomyopathy; they have higher pulmonary resistance and absence of cardiovascular risk factors. Retransplantations are usually caused by graft vascular disease, with more organ deterioration and more risk factors. This, rather than the fact that it is a second transplantation, may contribute to a worse prognosis.

Emergency HT is subject to controversy because certain characteristics (recipients in worse clinical condition, not ideal donors, and longer ischemic times) of these interventions bring forth a worse prognosis that when the HT can be programmed. In these last years, the number of emergency transplantations also increased (38% in 2011 compared to 34% in 2010). The percentage of patients that are counted as urgent differs from area to area and changes noticeably through the years. The reasons for these changes or for the geographical distribution are unclear, although we suspect that a low number of donors and better maintenance of critical patients (ventricular assist) increase the odds of emergency transplantations being performed. The necessity of an emergency transplantation has been questioned given that the results are clearly not good. However,
transplantation teams consider that the option must exist, if in a controlled manner. As recommended by the recent European guidelines on heart failure, in order to guarantee the survival of the patient we must keep in mind that the patient must be stabilized before HT is indicated. Also, HT should not be considered treatment for acute unstable heart failure because it takes too long to find a donor even with this degree of emergency, among other reasons.

The number of patients that reach HT with some form of ventricular assistance has increased significantly, especially in the last 5 years. The intra-aortic counterpulsation balloon is still the most widely used, although its use has not increased in the last 5 years. The use of extracorporeal membrane oxygenators and pulsatile devices have significantly increased. More than half of the emergency transplantation patients in the last 5 years carried some sort of ventricular assistance previous to transplantation. These devices are crucial for the maintenance and stabilization of patients with chronic heart failure. Therefore, it is advised that all transplantation teams have access to them to be used on the most critical patients. Furthermore, they are of great utility in case of a fatal graft failure immediately after transplantation. This complication is becoming more frequent because of worsened conditions of recipients, nonoptimal donors, and the longer ischemic times that come with the degree of emergency and the distance to the organ.

In the majority of HTs, immunosuppression induction has been used. The most-used treatment since the beginning has been antilymphocyte antibodies, OKT3. However, the most widely used in the last 5 years are interleukin-2 antagonists, which represent 85% of the transplantations performed. The maintenance immunosuppressive therapy used is called triple association: tacrolimus versus cyclosporine, azathioprine versus mycophenolate, and mofetil versus steroids. However, while the patient progresses it is usual to introduce other immunosuppressive drugs such as rapamycin, everolimus, mycophenolic acid, and more recently, sustained-release tacrolimus. The administration of everolimus has increased the most. It is administered to 2.8% of patients at the start of transplantation but is included in up to 12.6% of transplantations when renal dysfunction, tumors, or graft vascular disease concur.

Early mortality rose from 18% in 2010 to 19% in 2011. Over the last 4 years this trend has been increasing. The increase may be related to a greater number of emergency transplantations and to the use of ventricular assists, with which the patients reach HT in even more critical condition. The early period after transplantation is the most important when it comes to increasing survival. The survival curve stabilizes during the first months after HT.

General survival reveals a clear trend towards improvement. Nevertheless, as expected, the number of patients incorporated to the registry every year represents a number lower than the total, and thus the probability of big changes in a year is very unlikely. This makes the analysis of survival by time periods a better display. In the last few years, survival has increased significantly as compared to previous years. Nonetheless, there is an "inactivity" in the survival curve that has been attributed to the worsened clinical situation of recipients and to the fact that organs are less optimal and have longer ischemic time. However, even in high-risk HT groups the survival is much greater than in patients with advanced heart failure without transplantation.

The cause of transplantations is obviously related to survival. Patients diagnosed with idiopathic dilated cardiomyopathy have a higher survival than those transplanted for other causes, due to their younger age and lower prevalence of cardiovascular risk factors.

The most frequent cause of death was early graft failure (16%), followed by infection (15.6%), the combination of graft vascular disease and sudden death (14%), tumors (12.3%), and acute rejection (7.7%). However, the actual cause of death is usually related to time from the HT, so that for the first month the most common cause of death is graft failure. From the first month until the first year, the main causes are infection and rejection. In subsequent periods, the most common cause of death is sudden death combined with chronic rejection and tumors. The observed distribution of causes of death has not changed in recent years, and should make us reflect on the need to achieve a "balance" in administering immunosuppression because death due to failure in preventing rejection is 7.7%, while death directly related to excessive immunosuppression (infection and tumors) is 28.2% of mortality cases.

CONCLUSIONS

Transplantation teams must consider donors with expanded criteria in order to offer this treatment to most patients with advanced heart failure and to prevent their poor prognosis.

Survival rates of the Spanish Heart Transplantation Registry are similar to other records. However, efforts should be increased to improve the likelihood of survival during the early period, which will result in significant overall improvement.

Ventricular assistance has boomed. These devices allow recipients to maintain appropriate conditions until the availability of a compatible organ. However, because sometimes the wait time can be weeks, it becomes necessary to have medium- and long-term ventricular assist devices available to prevent further deterioration of the patient and to keep him or her in optimal condition for transplantation.

There is still a large imbalance between the complications that immunosuppression prevents (rejection) and the ones that it favors (tumors, infection). In the coming years these problems must be addressed and immunosuppression must be customized to certain patient characteristics.

ACKNOWLEDGEMENTS

This year, elections will take place to choose a new Director of the Spanish Heart Transplantation Registry, an office that I have held since 1997. Throughout this time, I have attempted to perform the duties of this position with pride and honor. I wish to express my gratitude for all I have learned but, above all, for the enormous satisfaction of seeing that all the Spanish heart transplant teams have confided in me, sending me, year after year, the data concerning their transplantation procedures. Thank you all very much! (in words of the first author, Luis Almenar).

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CONFLICTS OF INTEREST

None declared.
APPENDIX. SPANISH HEART TRANSPLANTATION REGISTRY COLLABORATORS 1984-2011

Clinica Puerta de Hierro Majadahonda, Madrid

Hospital Universitario y Politécnico La Fe, Valencia
Luis Martínez-Dolz, Ignacio Sánchez-Lázaro, Mónica Cebrián

Hospital Universitario A Coruña, A Coruña
María J. Panagua-Martín, Eduard Barge-Caballería, Raquel Marzoa-Rivas, Zulaida Grille-Cancela

Hospital Gregorio Marañón (adults), Madrid
Juan Fernández-Yáñez, Adolfo Villa, Yago Sousa, Iria González, Manuel Martínez-Sellés

Hospital Reina Sofía, Córdoba
Amador López-Granados, Juan Carlos Castillo

Hospital Marqués de Valdecilla, Santander
José Antonio Vázquez de Prada, Manuel Cobo

Hospital 12 de Octubre, Madrid
María J. Ruiz, Pilar Escribano, Miguel A. Gómez, Marta Paradina

Hospital Virgen del Rocío, Sevilla
José Manuel Sobrino, Alejandro Adsuara

Hospital de Bellvitge, L'Hospitalet de Llobregat, Barcelona
Josep Roca, José González-Costello

Clínica Universitaria de Navarra, Pamplona
Beltrán Levy, Rafael Hernández

Hospital Clinic, Barcelona
Montserrat Cardona, Marta Farrero, M. Ángeles Castel

Hospital Central de Asturias, Oviedo
Beatriz Díaz

Hospital Gregorio Marañón (children), Madrid
Enrique Maroto, Constancio Medrano

Hospital Virgen de la Arrixaca, El Palmar, Murcia
Irís Garrido

Hospital Miguel Servet, Zaragoza
María L. Sanz, Ana Portalés

Hospital Clínico, Valladolid
Javier López-Díaz, Amada Recio

Hospital La Paz, Madrid
Daniel Borches, Luz Polo, Carlos Labrador, Lucía Deiros

Hospital Vall d’Hebron, Barcelona
Ferran Gran, Raül Abella


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