



Original article

## Activity and results of liver transplantation in Spain during 1984–2012. Analysis of the Spanish Liver Transplant Registry<sup>☆</sup>



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### ARTICLE INFO

#### Article history:

Received 30 May 2014

Accepted 7 July 2014

Available online 9 December 2015

#### Keywords:

Liver transplantation

Results

Survival

Cirrhosis

### ABSTRACT

**Background and objective:** Liver transplantation (LT) is a proven effective treatment of severe liver disease. The aim of this paper is to analyze the results of LT in Spain during the period 1984–2012.

**Patients and method:** We analyze the results of the database of Spanish Liver Transplant Registry.

**Results:** A total of 20,288 transplants were performed in 18,568 patients. The median age of the donor and recipient increased during the analysis period: 25 years (95% confidence interval [95% CI] 18–40) and 47 years (95% CI 34–55), respectively, in the period 1984–1994 compared to 59 years (95% CI 33–65;  $P < .05$ ) and 55 years (95% CI 48–61;  $P < .01$ ), respectively, in the period 2010–2012. The most frequent indications were liver cirrhosis (63.18%) and hepatocellular carcinoma (19.62%). The overall patient and graft survival was respectively 85.1 and 77.8% in the first year, 72.6 and 63.5% the fifth year and 62 and 52.6% in the tenth year. First year patients and graft survival increased respectively from 77.8 and 66.3% in the period 1984–1994 to 88.5 and 83% in 2010–2012 ( $P < .01$ ). Donor and recipient age, etiology of underlying disease, and hepatitis C virus serological status, were factors associated with decreased survival in univariate and multivariate analysis.

**Conclusions:** Results of LT improved significantly over the review period, despite a progressive increase in donor and recipient age.

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## Actividad y resultados del trasplante hepático durante el período 1984–2012. Análisis del Registro Español de Trasplante Hepático

### RESUMEN

**Fundamento y objetivo:** El trasplante hepático (TH) es un tratamiento de eficacia contrastada de la enfermedad hepática grave. El objetivo de este trabajo es analizar los resultados del TH en España durante el período 1984–2012.

**Pacientes y método:** Se analizó la base de datos del Registro Español de Trasplante Hepático.

**Resultados:** Se realizaron 20.288 trasplantes en 18.568 pacientes. La mediana de edad del donante y del receptor aumentó durante el período de análisis, desde 25 años (intervalo de confianza del 95% [IC 95%] 18–40) y 47 años (IC 95% 34–55), respectivamente, en el período 1984–1994, hasta 59 años (IC 95% 33–65;  $p < 0,05$ ) y 55 años (IC 95% 48–61;  $p < 0,01$ ), respectivamente, en el período 2010–2012. Las indicaciones más frecuentes fueron cirrosis hepática (63,18%) y hepatocarcinoma (19,62%). La supervivencia global

#### Palabras clave:

Trasplante hepático

Resultados

Supervivencia

Cirrosis

<sup>☆</sup> Please cite this article as: Cuervas-Mons V, de la Rosa G, Pardo F, San Juan F, Valdivieso A, en representación del Registro Español de Trasplante Hepático. Actividad y resultados del trasplante hepático durante el período 1984–2012. Análisis del Registro Español de Trasplante Hepático. Med Clin (Barc). 2015;144:337–347.

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<sup>◇</sup> Appendix 1 shows the teams of liver transplants participating in the Spanish Registry for Liver Transplants, the representatives of the Registry and the National Transplant Organisation.

del paciente y del injerto fueron, respectivamente, del 85,1 y 77,8% en el primer año, del 72,6 y 63,5% a los 5 años, y del 62 y 52,6% a los 10 años del TH. La supervivencia del paciente y del injerto al primer año aumentó, respectivamente, desde el 77,8 y 66,3% en el período 1984–1994 al 88,5 y 83% en el período 2010–2012 ( $p < 0,01$ ). La edad del donante y del receptor, la etiología de la enfermedad de base y la serología positiva para el virus de la hepatitis C del receptor se asociaron a menor supervivencia en los análisis univariados y multivariados.

**Conclusiones:** Los resultados del TH mejoraron significativamente a lo largo del período analizado, a pesar de un progresivo aumento en la edad del donante y del receptor.

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## Introduction

Liver transplantation is a treatment of proven effectiveness for severe, acute, or chronic liver disease. Its impact on severe hepatic disease is very important and has contributed to reduce mortality rates associated with hepatopathies.

The first liver transplant in Europe was performed in 1968 and up until December 2012, according to data from the European Liver Transplant Registry (ELTR), 113 627 transplants were performed on 102 442 patients at 153 centres in 28 European countries.<sup>1</sup> In Spain, the first liver transplant was performed in 1984 at the Hospital de Bellvitge (Barcelona). Since then, and up until December 2012, more than 20 000 transplants had been performed, which makes Spain the second most active European country after France.<sup>1</sup>

The purpose of the present article is to analyse the historical evolution and overall results of liver transplantations performed in Spain until December 31, 2012.

## Patients and methods

We analysed the Spanish Liver Transplant Registry (*Registro Español de Trasplante Hepático*, RETH) database, which gathers data on liver transplants in Spain. Although participation in the RETH is voluntary, all the liver transplant units include their data in this national registry. The upkeep and scientific analysis of the RETH is the result of cooperation between the Spanish Society of Liver Transplantation (*Sociedad Española de Trasplante Hepático*, SETH) and the National Transplant Organization (*Organización Nacional de Trasplantes*, ONT). The database is managed by the ONT. The RETH complies with requirements established by the Spanish Data Protection Act 15/1999. The RETH database is registered with the Spanish Data Protection Agency under registry number 2100491806, published in the Official State Bulletin, issue 3, of 04/01/2010, under ONT resolution of 16/12/2009.

The RETH database includes clinical variables with information about the recipient, donor, surgery, immunosuppression and the evolution of the patient and of the implant, and it is updated annually. Initially, the RETH database was constructed by copying the structure of the ELTR. Later, new variables of scientific interest were added, maintaining its compatibility with the ELTR, to which an updated RETH database is sent annually.

In each liver transplantation unit the person responsible for the registry sends the ONT updated data from the centre annually. The ONT verifies the thoroughness and internal consistency of the data and compares the information with the ONT donor database. A refined database is sent back to the centres, to continue recording new cases. Four centres are chosen at random for annual audit. During the audit, a representative sample of the transplants from each centre is examined and the quality of the information, security and confidentiality of the data are analysed.

The ONT representative responsible for records performs a statistical analysis and prepares the annual RETH results report. A scientific committee comprised of professionals from the SETH and the ONT checks the design and content of the annual results

report once a year. It is then distributed to all the participating hospitals. The annual report contains an overall analysis section, which professionals who are interested can access through the SETH<sup>2</sup> and ONT<sup>3</sup> websites.

## Statistical analysis

Categorical variables are expressed as frequency distributions. Quantitative variables are expressed as mean and SD, or median and interquartile range, as applicable, with their frequency distribution after have been stratified in age groups. Survival curves are calculated using the Kaplan–Meier test, and the curve comparison is carried out using the log-rank test. To compare variables with more than 2 categories, we used the Cox proportional hazards model. Multivariate analysis was performed using the Cox proportional hazards regression analysis. The multivariate analysis results are expressed as hazard ratio, with their corresponding 95% confidence interval (95% CI) and  $p$ -value. Differences are considered significant if the  $p$ -value is  $< 0.05$ .

## Results

### Liver transplant activity

Prior to December 31, 2012, a total of 20 423 liver transplants had been performed in Spain in the 26 hospitals authorised to perform the procedure in adults (25 centres) or children (5 centres). Of the 20 423 transplants, 20 288 (99.31%) are included in the RETH database and constitute the population under study.

The number of liver transplantations performed annually gradually increased between 1984 and 2002 and then stabilised, with minimal fluctuations, at around 1000 transplants per year (Fig. 1). The year 2012 saw 1084 transplants, which represents a rate of 22.9 per million inhabitants. The number of transplants performed varied from centre to centre. The quartile with most activity encompasses 6 of the 26 centres, which are responsible for 9038 (44.54%) transplants, whereas the 6 centres with the least activity account for 1521 (7.49%) RETH transplants.

The 20 288 liver transplants were performed in 18 568 patients (70.45% were male). Of these, 17 475 patients (94.05%) were adults (age 16 or older; 71.66% were male) and the other 1103 (5.95%) were children (under the age of 16; 51.40% were male).

Of the 20 288 transplants, 1720 (8.47%) were retransplants (1556 were first retransplants, 153 were second retransplants and 11 were third retransplants). Fig. 1 shows the evolution over time in the number of transplants and retransplants performed annually. The percentage of patients needing a retransplant was significantly higher in paediatric transplants ( $n = 185$ ; 16.77%) than adult transplants ( $n = 1371$ ; 7.85%) ( $p < 0.01$ ).

### Emergency and elective transplants

Overall, 18 399 (90.68%) of the transplants were elective procedures and the other 1889 (9.31%) were code zero or national priority

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