

Heart transplantation at the Peruvian National Heart Institute: One-decade single-center experience

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Abstract

Background: Heart transplantations are ideal for most patients with end-stage heart failure refractory to medical treatment. The transplantation program at the Peruvian National Heart Institute started with a 10-year-continuity in 2010. *Objective:* To report the results of a 10-year heart transplantation experience at the Peruvian National Heart Institute. *Methods:* We studied 83 patients who underwent orthotopic heart transplantation at a single center between January 2010 and December 2019. The recipients' profiles and survival were analyzed according to sex and age group, ensuring the information's confidentiality. *Results:* The recipients' mean age was 41.2 ± 17 years, 88% were adult, and 68.7% were male. The main indications for transplantation were idiopathic dilated cardiomyopathy. 85.5% of recipients were clinically categorized as INTERMACS Profile 1 to 3 before transplantation. There was a significant difference between sexes regarding the preoperative left ventricular ejection fraction and between age groups regarding the waiting time. The average ischemia time was 3.1 hours, operating time was 6.1 hours, cardiopulmonary bypass time was 3 hours, and aortic cross-clamp time was 1.7 hours. The principal early postoperative complications were hematological disorders and acute kidney failure. The principal late ones were kidney failure and severe anemia. The postoperative mortality was 15.9%, and the principal causes were infection and then acute rejection. The survival at one, five, and ten years was 87.5%, 79.8%, and 79.8%, respectively. The survival results were not influenced by sex or age group. *Conclusion:* Our patients' postoperative complications, mortality, and survival rates coincided with those reported by the ISHLT registry.

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ABSTRACT

Background: Heart transplantations are ideal for most patients with end-stage heart failure refractory to medical treatment. The transplantation program at the Peruvian National Heart Institute started with a 10-year-continuity in 2010.

Objective: To report the results of a 10-year heart transplantation experience at the Peruvian National Heart Institute.

Methods: We studied 83 patients who underwent orthotopic heart transplantation at a single center between January 2010 and December 2019. The recipients’ profiles and survival were analyzed according to sex and age group, ensuring the information’s confidentiality.

Results: The recipients’ mean age was 41.2 ± 17 years, 88% were adult, and 68.7% were male. The main indications for transplantation were idiopathic dilated cardiomyopathy. 85.5% of recipients were clinically categorized as INTERMACS Profile 1 to 3 before transplantation. There was a significant difference between sexes regarding the preoperative left ventricular ejection fraction and between age groups regarding the waiting time. The average ischemia time was 3.1 hours, operating time was 6.1 hours, cardiopulmonary bypass time was 3 hours, and aortic cross-clamp time was 1.7 hours. The principal early postoperative complications were hematological disorders and acute kidney failure. The principal late ones were kidney failure and severe anemia. The postoperative mortality was 15.9%, and the principal causes were infection and then acute rejection. The survival at one, five, and ten years was 87.5%, 79.8%, and 79.8%, respectively. The survival results were not influenced by sex or age group.

Conclusion: Our patients’ postoperative complications, mortality, and survival rates coincided with those reported by the ISHLT registry.

Keywords: Heart transplantation, heart failure, transplant recipients, cardiac surgery, survival.

Introduction

According to the International Society of Heart and Lung Transplantation (ISHLT), heart transplantations (HTx) are the ideal treatment for patients with end-stage heart failure (EHF) refractory to medical treatment (2). Currently, worldwide survival is favorable, 80% at one year and 60% at five years, mainly due to the development and improvement of immunosuppressive treatment, the strict selection of receptors, and the

early diagnosis of postoperative complications (3). Thus, approximately 124 700 HTx have been performed since Barnard's team performed the first successful HTx in 1967, with approximately 5 000 transplants per year to date (2,4).

These reports include mostly data from Europe and North America (5). However, the Latin American and Caribbean Transplantation Society reports a registry of 9 000 patients with HTx by 2016 in Latin America. In its registry, Peru shows around 97 HTx since 1993, considered one of the lowest regional rates (6). It was not until 1972 that the first HTx was carried out in Peru by Molina's team at Hospital Nacional Edgardo Rebagliati Martins. However, it was an isolated case, and it was until 1993 when the first Peruvian HTx National Program was created with Pacheco's team with some continuity (7). For a while since the late 1990s, HTxs were not carried out. It is impressive due to changes in government policy and sociocultural factors, as in other developing countries of the time, until the program was restarted at the Peruvian National Heart Institute (INCOR) in 2010 (2,8). Since then, it has been the only national reference center for HTx in Peru.

Given the lack of systematic reporting of experiences with regional programs, we sought to compare transplant recipients' profiles and survival from the Peruvian experience versus international benchmark results. Furthermore, contributing to the global understanding of these procedures' performance. Therefore, this study's objective was to report the results of a 10-year HTX experience at INCOR.

Materials and methods

IRB Approval: This manuscript had an ethics approval by the hospital Institutional Review Board.

Consent Statement: All research subjects signed and accepted the institutional informed consent to carry out research work.

Clinical trial registration: N/A

Population and Study Design

There were 86 records of patients who underwent human-to-human orthotopic HTx at INCOR's database from January 2010 to December 2019. We excluded three patients, two of whom were transplanted in other centers, and one medical record was unavailable at the study time. Therefore, we present 83 cases. There was no heart retransplantation, and none of the recipients had to undergo major cardiac surgery after the HTx. The profile of the recipients and their survival were analyzed according to sex and age group. The confidentiality of the data was ensured.

Surgical Procedure

The surgical technique currently performed at INCOR is the bicaval/unipulmonar described by Sarsam *et al.* (10).

Antibiotic Prophylaxis Protocol

Intravenous cefepime is included as antibiotic prophylaxis before transplantation. If cephalosporin allergy is present, vancomycin is chosen. It is prescribed at discharge oral trimethoprim/sulfamethoxazole once daily, oral nystatin three times daily, after meals, rinsing and swallowing, and topical clotrimazole twice daily. Oral valganciclovir is added on intermediate to high-risk patients once daily.

Immunosuppression Protocol

Our immunosuppressive protocol has been based on triple therapy: corticosteroids, a calcineurin inhibitor, and an antiproliferative agent. Induction therapy consisted of intravenous thymoglobulin (1.5 mg/kg/day) during the first five postoperative days and was preceded by acetaminophen, methylprednisolone, and chlorphenamine. Thymoglobulin dose was decreased (1 mg/kg/day) if leukocytes <3000 cells/mm³ or platelets <75000 cells/mm³, and discontinued if leukocytes <2000 cells/mm³ or platelets <50000 cells/mm³. Basiliximab (20 mg) is also administered, one drug regimen two hours preoperatively, and another on the fourth postoperative day. The corticosteroid regimen started with intravenous methylprednisolone (500 mg) in the

preoperative period and upon release of the aortic clamp, and 125 mg 3 times daily on the first postoperative day. Prednisone (1 mg/kg/day) was continued twice daily, with the dose being decreased 5 mg every three days until reaching approximately 0.2 mg/kg/day by the sixth week. After six months of treatment, it was tapered at 5 mg/day. Our institute currently employs oral tacrolimus (0.05 – 0.1 mg/kg/day) twice daily as a calcineurin inhibitor and adjusted according to renal function. It is titrated to achieve a serum level between 15 ng/mL and 20 ng/mL for the first month, between 10 ng/mL and 15 ng/mL from months one to nine, and between 5 ng/mL and 10 ng/mL after nine months from transplantation. Cyclosporine is only considered in the presence of tacrolimus intolerance. As an antiproliferative agent, we considered mycophenolate mofetil 1g pre-transplant if there was no induction therapy and 1g twice on the first day. Then it is tapered from 0.5g to 2g twice daily. Indications for discharge consisted of oral prednisone twice daily in descending doses of 5mg every three days until reaching 10 mg/day, oral tacrolimus twice daily with serum controls at regular time intervals, mycophenolate mofetil twice daily, and, eventually, everolimus. Endomyocardial biopsies were performed before discharge, in the second month, the third month, the sixth month, and one year after transplantation.

Statistical Analysis

Frequencies and percentages of qualitative variables were calculated, and arithmetic means and standard deviations of quantitative variables. Averages were compared using the Student's test for independent samples, verifying the variables' normality using the Shapiro-Wilk test. In the absence of normal distribution, the Mann-Whitney U test was used. The value of $p < 0.05$ was accepted to determine the significant differences in the statistical tests. Kaplan-Meier survival analysis was performed with the log-rank test to compare the survival distributions of the samples. The analysis was performed using SPSS Statistics 24.

Results

Recipients' Age and Sex

The mean age at HTx was 41.2 ± 17 years (5 - 69 years), 73 (88%) were adult, and 57 (68.7%) were male. The number of HTx performed according to the recipients' sex and age group per year is shown in Figure 1. It was observed an average of 8.3 HTx per year. A consecutive increase from 1 HTx in 2010 HTx to 13 in 2014. Then, it decreased to 5 by 2016, and a maximum of 14 in 2019. Recipients' characteristics at HTx are shown in Table 1.

Surgical Indications, Clinical Profile, and Comorbidities

The main indications for HTx included idiopathic dilated cardiomyopathy (DCM) in 55 (66.3%) patients and ischaemic cardiomyopathy in 15 (18.1%) patients. The other indications are also shown in Table 1.

The general preoperative left ventricular ejection fraction (LVEF) was $22.9 \pm 14.5\%$ (6 - 70%). In male, the LVEF was $19.9 \pm 10.6\%$ (6 - 67%), compared with $29.3 \pm 19.3\%$ (10 - 70%) in female. As for adults, the LVEF was $22.4 \pm 14.6\%$ (6 - 70%), compared with $26.2 \pm 13.6\%$ (10 - 57%) in pediatric patients. Overall, 74 (89.2%) patients had a reduced LVEF (<40%). There was a significant difference between sexes ($p = 0.04$) but not between age groups ($p = 0.19$) regarding the preoperative LVEF.

According to their clinical profile and condition, 61 recipients (73.5%) were clinically categorized as Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Profile 3 before transplantation (11). Thus, 45 (54.2%) were on intravenous inotropic support, of which 12 (14.5%) required mechanical assist device support: 5 of them with intra-aortic balloon pump (IABP), 4 had an implanted left ventricular assist device (VAD), and 3 had an implanted bi-VAD (Thoratec Corporation, CA, USA).

Among comorbidities, the most frequent were pulmonary hypertension (25.3%), hypothyroidism (19.3%), chronic kidney disease (15.7%), arterial hypertension (14.5%), and diabetes mellitus (8.4%).

Catheterization variables

From the recipients' preoperative catheterization evaluation, the averages of a mean pulmonary artery pressure (mPAP) of 35.2 ± 10.1 mmHg (13 - 55 mmHg), a pulmonary vascular resistance (PVR) of 3.2 ± 2.1 uW (0.3 - 11.1 uW), and a transpulmonary pressure gradient (TPG) of 10.7 ± 5.4 mmHg (1 - 25 mmHg). The differences in the means between sexes and age groups were not significant in mPAP ($p = 0.26$) ($p = 0.37$), PVR ($p = 0.19$) ($p = 0.90$), nor TPG ($p = 0.19$) ($p = 0.07$), respectively.

Surgical Procedure and Times

The most performed surgical technique was the bicaval/unipulmonar (96.4%); however, in 3 (3.6%) cases, biatrial surgery was performed before institutional surgical consensus. Thirteen patients (15.7%) had a previous sternotomy. An extension of the inferior vena cava with a bovine pericardial patch and another with a dacron tube had to be performed in 2 children. Two patients underwent combined simultaneous heart and kidney transplantation from the same donor. Three patients (3.6%) left the operating room with extracorporeal membrane oxygenation (ECMO) support.

Mean recipients' waiting time was 12.7 ± 28 weeks (0 - 232 weeks), mean ischemia time was 3.1 ± 1.2 hours (1.3 - 6.4 hours), mean operating time was 6.1 ± 1.9 hours (3.1 - 15.2 hours), mean cardiopulmonary bypass (CPB) time was 3 ± 1.5 hours (1.3 - 11.1 hours), and mean aortic cross-clamp time was 1.7 ± 0.8 hours (0.8 - 6.8 hours). Regarding the waiting time, there were no significant differences between sexes ($p = 0.57$) but there were between age groups ($p = 0.01$) with an average time in adults of 8.9 ± 13.2 weeks, compared with 40.6 ± 69.3 weeks in children. On the other hand, there were no significant differences between sexes and age groups of ischemia ($p = 0.18$) ($p = 0.12$), operating ($p = 0.41$) ($p = 0.94$), CPB ($p = 0.41$) ($p = 0.30$), nor aortic cross-clamp ($p = 0.42$) ($p = 0.52$) times, respectively.

Postoperative Complications and Times

The postoperative complications after HTx are shown in Table 2. The early complications were considered during the first 72 hours postoperative and the late after that period. During follow-up, three patients developed arterial hypertension, three diabetes mellitus, and 1 case of ascending aortic pseudoaneurysm in a child treated successfully with an endovascular stents placement (12). Neoplasms were not documented.

Mean postoperative intensive care unit (ICU) stay was 14.2 ± 14.1 days (1 - 84 days), mean postoperative hospital stay was 37.1 ± 26.3 days (1 - 165 days), and mean total hospital stay was 56.1 ± 41.7 days (3 - 178 days). In the evaluation of the postoperative ICU stay, the readmission cases were not considered. The postoperative hospital stay ranged from admission to the ICU until discharge, and the total hospital stays from admission to INCOR until discharge. There were no significant differences between sexes and age groups of postoperative ICU ($p = 0.15$) ($p = 0.53$), postoperative hospital ($p = 0.61$) ($p = 0.98$), nor total hospital ($p = 0.59$) ($p = 0.54$) stays, respectively.

Causes of Death

One patient died during surgery due to cardiogenic shock. In this case, the surgical indication was EHF due to Fontan failure, and it had 6.8 and 11.5 hours of ischemia and surgical time, respectively. There were 82 surviving recipients. The postoperative mortality was 15.9% (13 patients), and the principal causes of death were infection in 6 patients and acute rejection in 5. Hospital mortality was 7.3%; 2 died in the post-HTx 72-hours, one from cardiogenic shock, and one during reoperation due to revision of hemostasis. After the post-HTx 72-hours, three patients died from septic shock and one from acute humoral rejection. During the follow-up after hospital discharge, three patients died from cardiogenic shock due to 3R acute cellular rejection, two from septic shock, one from massive pulmonary thromboembolism, and one from septic and cardiogenic shock due to 3R acute cellular rejection. One of the recipients, who died from cardiogenic shock due to 3R acute cellular rejection, had blood type O- while the heart donor was O+. Causes of death after HTx are shown in Table 3.

Survival and the Influence of Recipients' Sex and Age Group

The global survival at one, five, and ten years was 87.5%, 79.8%, and 79.8%, respectively (Figure 2). Se-

parately, survival per recipient's sex at one, five, and ten years in male were 87.3%, 83.1%, and 83.1%, respectively, compared with 1-year's 87.9% and 5-year's 73.3%, in female ($p = 0.66$) (Figure 3). Besides, pediatric patients' survival was 100% in all years, and in adults, 85.% in 1-year and 77.4% in five and ten years ($p = 0.17$) (Figure 4).

Discussion

Through scientific development, ongoing training, and spreading program formation, HTx is now, to a greater extent, a better opportunity for the treatment of EHF patients around the world (5,13–16). However, only 102 countries report their numbers annually to the International Registry in Organ Donation and Transplantation (IRODaT) database (5). Given this development, some Latin American countries have reported their results, showing that HTx programs are feasible in developing countries (6–8). Approximately nine transplants were performed in Peru during the 1990s in different national centers in Lima (1,7). Although this initiative was bringing unhurried but worthy results, it declined due to the lack of funding and political interest (1). For this reason, it was not until 2010 that the INCOR's Program was reactivated without interruption until this study was carried out.

In this first decade, a total of 83 HTx were studied. Despite the program's effort, according to the IRODaT database in 2019, Peru is one of the countries with the lowest rate of HTx, with 14 HTx per year (5). The USA, France, Brazil, Spain, and Argentina led with 3587, 434, 381, 300, and 123 HTx per year, respectively (5). From another perspective, the average HTx frequency in these ten years in Peru was 8.3 HTx per year. In this regard, from 2013 to date, we reported a number greater than or equal to 9 HTx per year. According to Bocchi *et al.*, this frequency is sufficient not to be associated with an increased risk of death (19). Nevertheless, in 2016 only 5 HTx were performed in total due to institutional management changes. Additionally, Peru had a 0.5 HTx per million population (pmp) rate while the USA, Croatia, Spain, Uruguay, and Argentina had 10.9, 9.3, 6.5, 3.9, and 2.8 HTx pmp, respectively (5). This data also placed us as one of the countries with the lowest HTx pmp regionally and globally in 2019.

In our study, 68.7% were male. Although 76.9% of women had reduced LVEF, there was a significant difference between preoperative LVEF between the sexes. This could be related to the lower number of female recipients and the higher percentage (94.7%) of males with EHF with reduced LVEF. In addition, the low percentage of pediatric HTx is related to the lower rate of pediatric donors, and it is reflected in the significant difference regarding the waiting time, in which adults' average was 8.9 weeks, and children's, 40.9 weeks. This phenomenon is widely reported (15,16,18). In our experience, most of them have been children due to the lack of donors and the slowly growing number of HTx in developing countries, coinciding with regional experiences (17,20).

Like ISHLT reports, our main indications were idiopathic DCM in 66.3% of HTx and ischaemic cardiomyopathy in 18.1% (21). Although Chagas disease continues to be a Latin American public health problem, we have no indications for HTx due to Chagas cardiomyopathy (7,22). We consider that this is related to the underreporting of cases, and this local factor should be reevaluated since we are still a Chagas endemic country (23). Regarding pretransplant clinical status, 85.5% had an INTERMACS Profile 1 to 3, similar to ISHLT reports (24). It is a progressive increase of urgent HTx from 36.2% to 46.8% in the last decade in Spain; in our program, the average was 54.2% due to longer waiting times (15). On the contrary, 54.2% of recipients required inotropic support pretransplant, lower than ISHLT's (24). Since the REMATCH trial, it is well-known that mechanical circulatory support potentially reduces mortality, increases survival, and improves the quality of life of transplanted recipients (25). Consequently, the ISHLT reports a gradual increase in VADs as bridge-to-transplant in 23% by 2005 and 50.3% by 2019 (24). Likewise, Gonzales *et al.* describe an inverse relationship in the use of IABPs and VADs (15). Our program utilized mechanical support in 14.5% of patients: 6% with IABP and 9.6% with VADs.

Even though having elevated catheterization values and pulmonary hypertension in 25.3% of cases, reversibility of these values was achieved through pretransplant pharmacological and mechanical support avoiding high incidences of graft failure (18). Furthermore, the world's average waiting time is 10 weeks; our recipients

expected an adequate average of 12.7 weeks compared to 25, 22.6, and 4.1 weeks in the USA, Australia-New Zealand, and Chile, respectively (8,26,27). The optimal ischemia time is a maximum of 4 to 6 hours, and we had a mean of 3.1 hours (28). We associate this result with the speed of the system when the National Donor Alert is activated.

Our mean postoperative stays in ICU and hospital were higher than reported in the USA, Brazil, and Chile (8,14,28). Consistent with most reports, infection was the first cause of death after HTx; however, the second cause was acute rejection, unlike other series, which was primary graft failure (2,13,15). Our overall survival rate was slightly higher than that described by the ISHLT at one, five, and ten years after HTx, and the analysis by age group was also higher, especially in children, as they still have a 100% survival (3). Consistently, we neither found significant differences in survival rates between the sexes. These results are subject to a limited number of HTx performed and a still short follow-up, especially in children, so future analyses are required. Although the ISHLT describes significant differences between the survival rates of adults recipients by sex, we did not find them, but a notable decrease in the females' from 87.9% at one year to 73.3% at five years, while in males, the difference was minor from 87.3% to 83.1% (3). Indeed, Bocchi *et al.* describe female recipients, in experimental models, may require increased immunosuppression due to higher frequency of rejection, and this may not be related to sex as such but to a previous pregnancy, a variable not considered in this study (19).

The study's limitations include the lack of data in the clinical histories on the profile of the donors and the short follow-up time concerning the appearance of complications. We agree and suggest that with well-selected donors, a careful evaluation of recipients, and a strict follow-up by a multidisciplinary team, suitable results can be reached in developing countries (18,28).

Conclusion

In summary, HTx remains the treatment of choice for most EHF patients. Our patients' postoperative complications, mortality, and survival rates coincided with those reported by the ISHLT registry. However, no survival adjustment was made according to postoperative complications or multivariate analysis of the profiles. The careful receptor and donor selection, advancement in immunosuppression protocol, and the early detection of postoperative complications have allowed us to perform HTx in our institution with acceptable results compared to others worldwide.

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Conflict of Interest: None

Data Availability Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

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Figures

Figure 1. Number of heart transplantations performed per year. **A**, According to the recipients’ sex. **B**, According to the recipients’ age group.

Figure 2. Kaplan-Meier survival curve after heart transplantations.

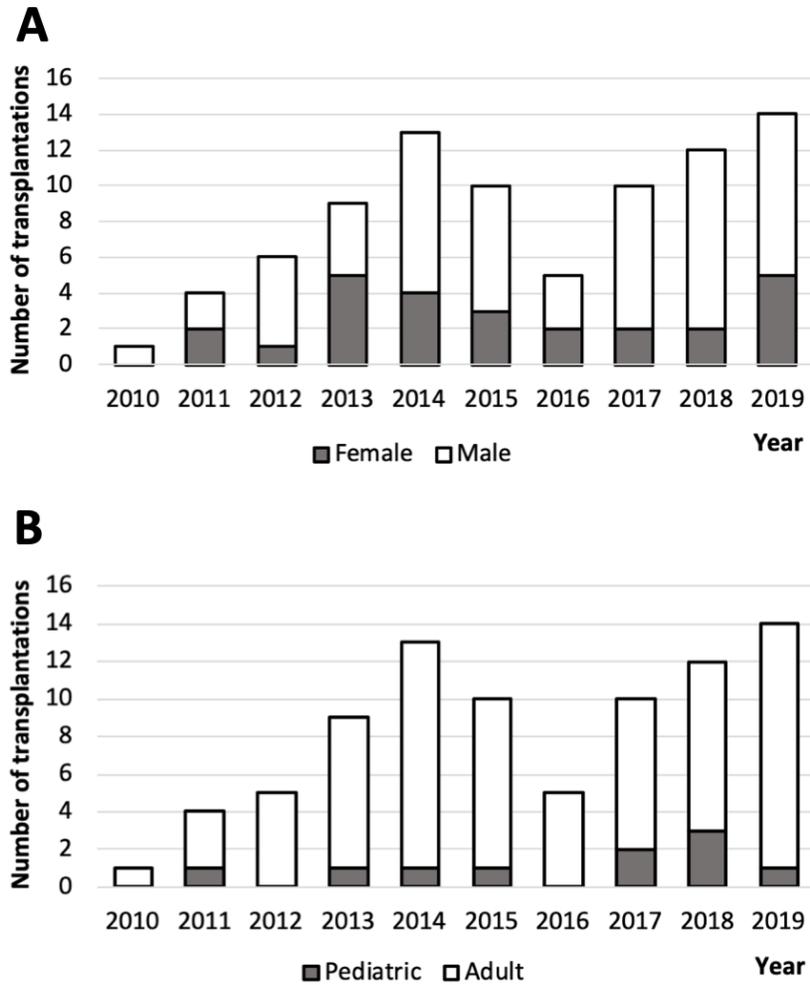
Figure 3. Kaplan-Meier survival curve after heart transplantations according to the recipients’ sex.

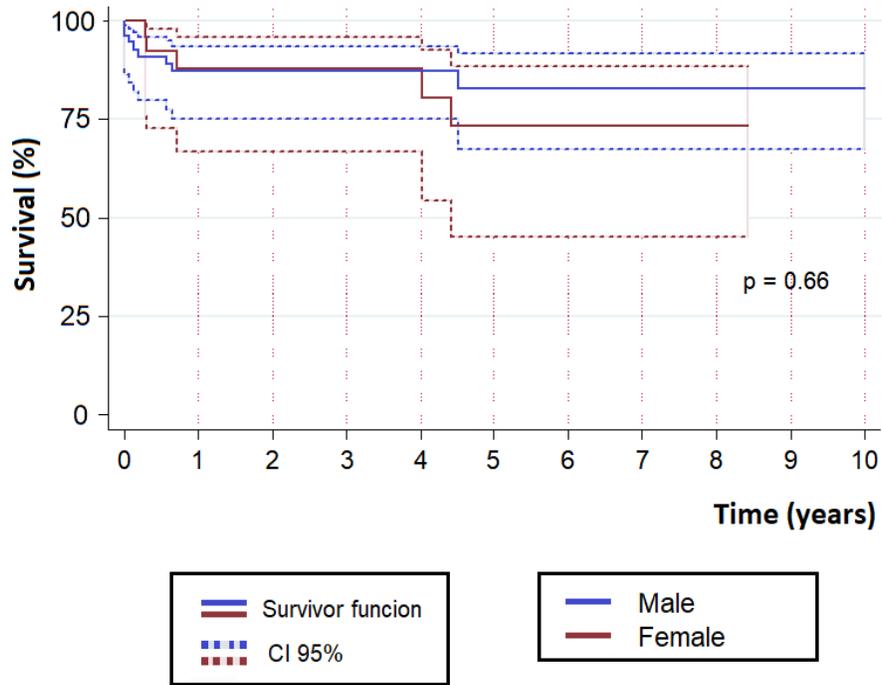
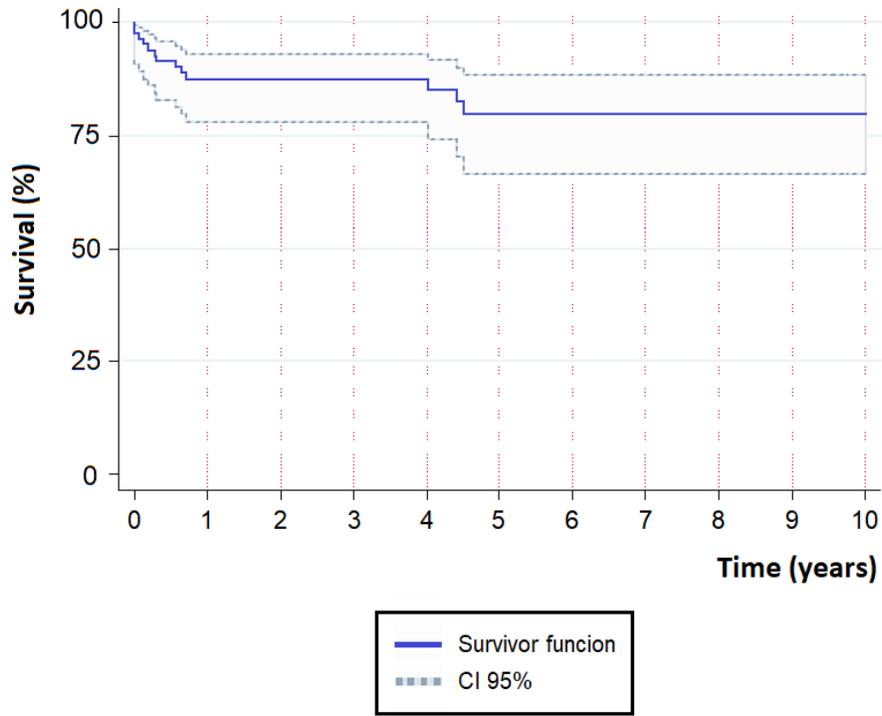
Figure 4. Kaplan-Meier survival curve after heart transplantations according to the recipients’ age group.

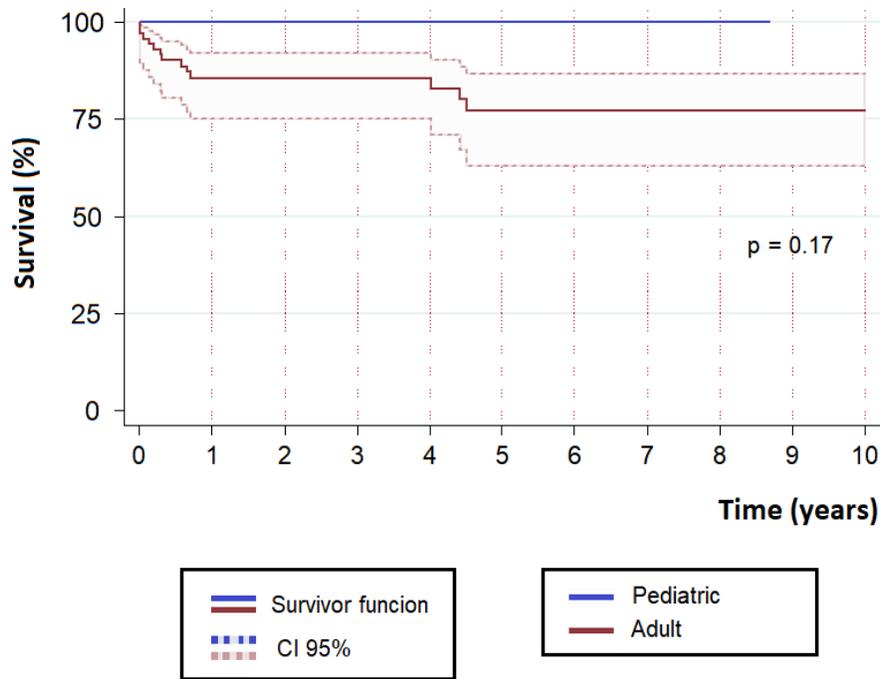
Tables

Table 1. Recipients' characteristics at heart transplantation.

Table 2. Causes of death after heart transplantation.







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