



# Renal transplantation in northwestern Spain. Activity analysis in the autonomous community of Galicia

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## SUMMARY

**Background:** Spain is the world leader in organ transplant rates, and the national average is maintained in the northwestern Spanish region of Galicia. However, there is no official registry recording transplantation results in this region. In this paper we report a study of patient and graft survival and risk factors among kidney transplant patients in Galicia between January 1996 and December 2000.

**Methods:** Patients receiving kidney transplants in Galicia in the above period were monitored up to the end of 2001, deaths and graft losses were recorded and analysed by actuarial and Kaplan-Meier methods, and possible risk factors for death and graft loss were evaluated using Cox's proportional hazards model.

**Results:** In the study period, 672 kidneys were transplanted, all from deceased donors. Graft and patient survival rates were respectively 80% and 94% after 1 year, and 67% and 83% after 5 years. Two-thirds of graft losses occurred within the first year and the most common cause was vascular thrombosis (44%). Independent risk factors for graft loss were donor asystole (relative risk [RR] = 3.41, 95% confidence interval [CI]: 1.73-6.73), donor age (RR = 1.54, CI: 1.05-2.27 for 40-60-year-olds, RR = 2.59, CI: 1.66-4.07 for over-60s, relative to under-40s), donation from outside the institution in which implant was performed (RR = 1.43, CI: 1.02-2.02), acute rejection (RR = 2.32, CI: 1.63-3.22), and retransplantation (RR = 1.56, CI: 1.03-2.37). The main causes of death were infections (38%), followed by cardiovascular pathologies (30%) and tumours (11%).

**Conclusions:** The kidney transplant rate varies excessively within Galicia; the global rate is 50 per million inhabitants per year. Patient survival is similar to those recorded in national registers, but graft survival is deficient, apparently due to a high incidence of vascular thrombosis.

Key words: **Mortality. Kidney transplantation. Risk factors. Survival. Galicia.**

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## TRASPLANTE RENAL EN EL NOROESTE ESPAÑOL. ANÁLISIS DE LA ACTIVIDAD EN LA COMUNIDAD AUTÓNOMA DE GALICIA

### RESUMEN

**Introducción:** España encabeza la actividad trasplantadora internacional y Galicia se sitúa en un nivel semejante; sin embargo, la ausencia de registros oficiales impide tener conocimiento de los resultados en esta Comunidad Autónoma. Por ello, analizamos el trasplante renal en Galicia en los últimos años, para determinar sus resultados en cuanto a supervivencia y factores de riesgo.

**Metodología:** Seguimiento, entre uno y seis años, de los trasplantes realizados en Galicia entre enero-1996 y diciembre-2000, analizando pérdidas de injertos y pacientes en función de distintas variables relacionadas con receptor y donante. Para estudiar la supervivencia se utilizaron los métodos actuarial y de Kaplan-Meier, y para evaluar factores de riesgo, el modelo de riesgos proporcionales de Cox.

**Resultados:** Se realizaron 672 trasplantes, todos procedentes de donante cadáver, siendo la supervivencia del injerto del 80% y 67% después de uno y cinco años; mientras que la del paciente fue del 94% y 83%. El 67% de las pérdidas de injerto se producen en los primeros doce meses, siendo la causa más frecuente la trombosis vascular (44%). Los factores de riesgo independientes para la pérdida del injerto fueron donación en asistolia (riesgo relativo [HR] = 3,41; intervalo de confianza al 95% [IC]: 1,73-6,73); edad del donante (RR = 1,54, IC: 1,05-2,27 entre 40-60 años; RR = 2,59, IC: 1,66-4,07 en mayores de 60; siempre en relación a los menores de 40); injerto generado en hospital no trasplantador (RR = 1,43; IC: 1,02-2,02); rechazo agudo (RR = 2,32; IC: 1,63-3,22) y retrasplante (RR = 1,56; CI: 1,03-2,37). Las infecciones fueron la principal causa de muerte (38%), seguidas de patologías cardiovasculares (30%) y tumores (11%).

**Conclusiones:** La tasa de trasplantes, aunque con significativas diferencias territoriales, es de 50 por millón de población y la supervivencia del paciente es comparable a la de cualquier registro internacional; sin embargo, la supervivencia del injerto, posiblemente debido a elevada incidencia de trombosis vascular, es manifiestamente mejorable.

Palabras clave: **Mortalidad. Trasplante renal. Factores de riesgo. Supervivencia.**

### INTRODUCCIÓN

Nowadays, renal transplantation is the best therapeutic alternative for most of the patients with chronic renal failure.<sup>1</sup> It is not still the real panacea but the outcomes achieved are certainly difficult to surpass, so that in those centers with more stringent selection criteria no more than 10% of grafts are lost within the first year, even less if grafts come from a living donor, and more than 80% still remain functioning within three years;<sup>2</sup> besides, we cannot let aside the unquestionable benefits that transplantation represents for patients as regard to quality of life improvement.

Although this treatment has some limitations as to availability of necessary organs to satisfy all the de-

mands, there is no doubt that in Spain, where we have the highest donation rates from cadaver donor worldwide,<sup>3</sup> there are more and more patients that benefit from it; in fact, since the beginning of the 1990s, Spain is the country that leads the international arena on performance of renal transplantations per million population (pmp).<sup>3</sup> In this sense, the Autonomous Community of Galicia ranks at the same level of activity as the national average, of around 50 interventions pmp per year. However, the real absence of official registries precludes having detailed and accurate information of this activity and its outcomes.<sup>4</sup>

So for, in this work we pretended to describe the renal transplantation activity in Galicia, studying recipient and donor characteristics, and

analyzing graft and recipient survivals, as well the causes for losing the grafts, since although the results should not be different from those in nearby populations,<sup>5</sup> it is convenient to have a precise knowledge of our own activity in order to being able of evaluating the whole process and implementing the appropriate measures to improve it and, thus, making possible that the citizenship may benefit more and better from this type of renal replacement therapy.

## SUBJECTS AND METHODS

The Autonomous Community of Galicia has a surface area of 29,434 km<sup>2</sup> and 2,742,622 inhabitants that are administratively distributed in four provinces (A Coruña, Lugo, Ourense, and Pontevedra) and account for 6.9% of the Spanish population. Renal transplantation activity, initiated in 1981, is performed at two hospitals, Juan Canalejo Hospital of A Coruña and the University Clinic Hospital of Santiago.

To carry out this study, we undertook a retrospective analysis on 672 renal transplantations performed in Galicia to 645 patients between January 1<sup>st</sup> of 1996 and December 31<sup>st</sup> of 2000, with a follow-up period of grafts and patients until December 31<sup>st</sup> of 2001. However, trying to avoid bias due to their different features, we excluded from the survival analysis combined transplantations (21), pediatric patients (2), and those lost to follow-up for any reason before the end of the study period (2), consequently analyzing 647 grafts and 621 patients.

Data were gathered from both transplantation centers, reviewing the clinical charts from the hospital files, and in the case of patients returning to dialysis therapy after losing their graft, from the files in the corresponding dialysis units. For that, an information system was created, using the Database Management System (DBMS) from Microsoft Access<sup>®</sup>, version 2000, recording the following variables:

- a) Age, gender, cause and type of donor's death, and center of origin
- b) Recipient's age, gender, place of living, primary renal disease, and previous dialysis duration.
- c) Center of transplantation, previous transplantations, and type of transplantation (single or combined).
- d) Existence or absence of acute rejection episodes, date and cause of graft loss, date of re-transplantation, date and cause of patient's death (with or without functioning graft).

## Statistical analysis

To verify the association between variables, we have used the Chi-squared and Student's t tests, whereas for survival analysis the actuarial method, Kaplan-Meier curves, the log-rank test, and Cox's proportional hazards model were used. To assess risk proportionality the method proposed by Grambsch and Therneau was used. Relative risks (RR) and 95% confidence intervals (CI) were calculated from regression analysis coefficients.

## RESULTS

Six hundred and seventy-two grafts were implanted, all of them from cadaver donor, into 645 patients that account for 68% of the patients in the waiting list during the analyzed period. The annual rate progression remains steady being close to 50 pmp.

Sixty-three percent of transplantations were done in male patients, and mean age of patients was 47.3 ± 13.7 years, range 8-72 years, with 22% of patients being older than 60 years. There were statistically significant differences ( $p < 0.001$ ) by patients' origin, since 61% resided in the provinces of A Coruña and Ourense (53% of the population) and only 39% were from Pontevedra or Lugo (47% of the population). A similar thing occurred with those patients residing in urban areas (51% of transplantations for 46% of the population) as compared to those in rural areas (49% of transplantations for 54% of the population) ( $p = 0.0165$ ).

As for primary disease, 25% were of unknown origin, 22% had glomerulopathies, and 17% had interstitial nephritis; 88% of the patients were diabetics. One hundred and twenty-two (18%) out of 672 operations were re-transplantations, accounting for the second cause of transplantation; of them, 102 were a second transplantation, 18 a third one, and 2 the fourth one. Mean age of these patients was significantly lower than that of those operated for the first time (43.1 vs. 48.2 years;  $p = 0.000$ ).

Mean time duration on dialysis for recipients of a first graft was 16.8 months, and 61% were for less than one year, whereas only 19% were longer than two years. Twenty-six preventive transplantations were performed, with no previous dialysis.

As for donors, their characteristics have changed over time, so that their mean age increased from 40.7 ± 17.2 years in 1996 to 46.0 ± 15.9 in 2000; besides, the number of kidneys from donors older than 60 years also increased from 14.8% in 1996 to 23.1% in 2000 (fig. 1). A similar thing occurred with

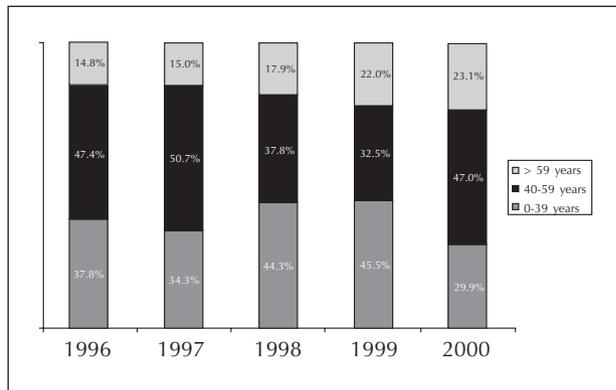


Fig. 1.—Age of donors. Percent annual distribution.

organs from donors died from a vascular cause (39% vs. 56%), whereas those coming from traumatic death were reduced (48% vs. 36%). Kidneys obtained in asystolia accounted for 5.2% of implanted grafts. Forty-eight percent of the grafts were generated at the same transplantation center, and 12% were imported from other Autonomous Communities, these being significantly older ( $p = 0.001$ ) and a greater proportion of donors dying from vascular causes ( $p = 0.018$ ).

It could be observed that 16.8% of implants had some acute rejection episode within the first year post-transplantation, during which period 19.8% of grafts were lost, 3.4% because of recipient's death and the remaining 16.4% because of renal function failure. Table I shows that the most frequent loss cause within the first year was vascular thrombosis (43.7%), whereas from then on, 46.8% were lost because of patient's death.

Whole survival of the 647 grafts was 80.2%, 71.3%, and 67.1% within one, three, and five years, respectively, although if losses due to patient's death with functioning graft are censored, survival reaches

**Table I.** Cause of graft loss. Distribution by loss within the first year or within the following years

Cause of loss	1 <sup>st</sup> year n (%)	Following years n (%)
No primary function	17 (13.3)	0 (0)
Acute rejection	8 (6.3)	0 (0)
Vascular thrombosis	56 (43.7)	1 (1.6)
Infection	6 (4.7)	1 (1.6)
Chronic dysfunction	8 (6.3)	25 (40.3)
Others	11 (8.6)	6 (9.7)
Exitus	22 (17.2)	29 (46.8)
Total	128 (100)	62 (100)

83.5% within the first year and 75.9% within five years.

When analyzing survival in relation to recipient's characteristics, we evidence that it is lower in patients older than 60 years than in those younger than 40 (relative risk [RR = 1.73; 95% confidence interval [CI] = 1.18-2.55), but this differences is no longer statistically significant in the multivariate analysis in which, after including all studied variables, the following were independent risk factors for graft loss: the presence of acute rejection episodes within the first year, re-transplantation, donor's age, donation in asystolia, and grafts generated at a different hospital than the one performing the transplantation (table II).

When we analyzed the outcomes by donor's and recipient's age, setting the cut-off point between young and elder patients at 60 years, we observed that the highest survival is achieved when the donor and the recipient are young, whereas in the remaining situations survival is balanced for the first two years but thereafter it worsens in those cases where donor is old, independently of recipient's age (fig. 2).

Eighty-seven percent of the 621 analyzed patients remained alive at the end of the study, therefore the crude mortality rate was 13%, and among those deceased, 61% died with a functioning kidney and 39% did so after having lost their grafts. The whole patients' actuarial survival was 93.7%, 88.3%, and 82.5% within one, three, and five years, respectively; however, if only patients living longer than the first 12 months are analyzed, survival improves up to 97% within two years and 88% within five years. A high percentage of deaths occurs within the first year of the operation, as it can be observed in the survival table created by the actuarial method (Table 3), which shows that the likelihood of dying within the

**Table II.** Predictive variables of graft loss in a proportional hazard model<sup>a</sup>

Variables	RR (95% CI) <sup>b</sup>
Num. transplantation (1st/following)	1.56 (1.03-2.37)
Acute rejection (no / yes)	2.32 (1.63-3.22)
Donor's age < 45 years	1
45-59 years	1.54 (1.05-2.27)
≥ 60 years	2.59 (1.66-4.07)
Donor's death (brain/asystolia)	3.41 (1.73-6.73)
Donor's origin (hospital/another center)	1.43 (1.02-2.02)

<sup>a</sup>The table shows those variables that were statistically significant but were also included in the model were: age, gender, recipient's residence area, as well as year and center of transplantation, primary renal disease, time on dialysis, and donor's age and cause of death.

<sup>b</sup>RR: relative risk calculated for the indicated category in each variable; 95% CI: 95% confidence interval.

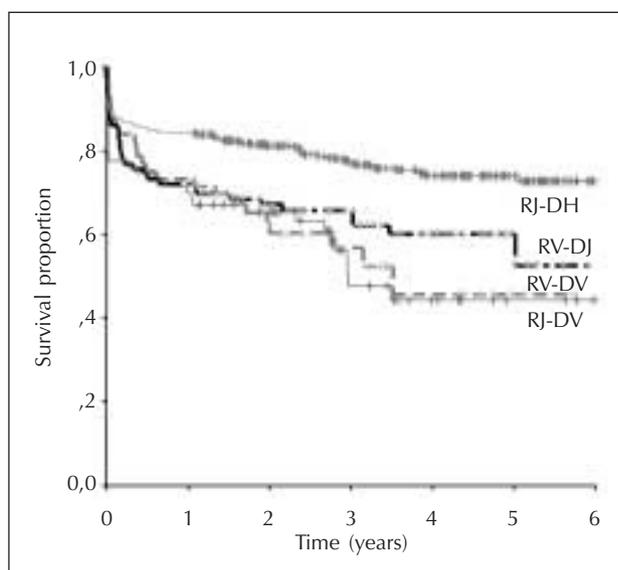


Fig. 2.—Graft survival analysis (Kaplan-Meier curves) after renal transplantation by age of donors and recipients. RJ: recipient younger than 60 years; RV: recipient older than 60 years; DJ: donor younger than 60 years; DV: donor older than 60 years. RR: relative risk; CI: confidence interval. The reference group is RJ-DJ.

first year is 5.5%, being thereafter between 1-2% per semester.

Although diabetes mellitus presence as primary renal disease (RR = 2.18; CI = 1.18-4.05), graft failure (RR = 2.44; CI = 1.54-3.85), donor's age older than 40 years (RR = 2.08, IC = 1.16-3.74 for 40-59 years; RR = 3.93, IC = 2.13-7.27), and donor's death for vascular cause (RR = 1.64; IC = 1.01-2.65) all worsen patient's survival, when we performed a multivariate analysis that included all studied variables, the only independent risk factors were recipient's age

older than 60 years, the presence of any acute rejection episode, and the lack of primary function of the kidney (table 4).

Table 5 shows that infections were the main death cause (38%), accounting for up to 60% of the deaths within the first 12 months post-transplantation; cardiovascular disease, which cause 30% of total deaths, represent the first death cause after the first year post-transplantation.

When we analyzed the first-year mortality by age groups and calculating the standard mortality index (table 6), we observed that transplanted patients have, during that period, a mortality rate five fold higher than that of Galician population, and it increases up to 23-fold for those younger than 40 years.

## DISCUSSION

About 50 transplantations pmp are performed in Galicia each year, a rate similar to the Spanish ave-

Table IV. Predictive variables of mortality in a proportional hazard model<sup>a</sup>

Variables	RR (95% CI) <sup>b</sup>
Recipient's age < 45 years	1
45-59 years	2.05 (0.99-4.25)
≥ 60 years	4.78 (2.28-9.98)
Acute rejection (no / yes)	1.72 (1.01-2.94)
Graft function (fyes / never functioned)	9.09 (4.17-20.0)

<sup>a</sup>The table shows variables that were statistically significant but also included were: recipient's gender and residence area, year and center of transplantation, primary renal disease, time on dialysis, and donor's age, gender, origin, cause and type of death.

<sup>b</sup>RR: relative risk calculated for the indicated category in each variable; 95% CI: 95% confidence interval.

Table III. Life table renal transplanted patients by an actuarial method

Time (months)	Num. of patients	Num. exposed	Num. of exitus	Proportion of exitus (%)	Proportion of survivors (%)	SE of prop. of surv.
0-6	621	621.0	34	5.5	94.5	0.9
6-12	587	587.0	5	0.9	93.7	1.0
12-18	582	556.0	9	1.6	92.2	1.0
18-24	521	491.5	7	1.4	90.9	1.2
24-30	455	424.0	5	1.2	89.8	1.3
30-36	388	368.5	6	1.6	88.4	1.4
36-42	343	310.5	7	2.2	86.4	1.5
42-48	271	249.5	3	1.2	85.3	1.6
48-54	225	195.0	2	1.0	84.5	1.7
54-60	163	135.0	3	2.2	82.6	2.0
60-66	104	79.0	0	0.0	82.6	2.0
66-72	54	27.0	0	0.0	82.6	2.0

SE: standard error of the survival proportion.

**Table V.** Cause of death in transplanted patients

Cause of death	n (%)
Cardiac pathology	17 (21.0)
Vascular pathology	7 (8.6)
Infections	31 (38.3)
Neoplasms	9 (11.1)
Unknown	7 (8.6)
Others	10 (12.4)
Total	81 (100)

**Table VI.** Standardized mortality index within the first year of renal transplantation. Distribution by age groups

Age	Observed deaths	Expected deaths	SMI (od/ed)
15-39 years	5	0.2	22.7
40-59 years	13	1.3	10.0
≥ 60 years	21	5.0	4.2
Global ≥ 15 years	39	7.6	5.2

SMI: standardized mortality index / od: observed deaths / ed: expected deaths.

rage, which in turn is the highest worldwide;<sup>3</sup> however, stagnation in number of procedures does not parallels the increasing incidence rate of patients in renal replacement therapy,<sup>6</sup> so that the transplantation waiting list still grows and is close to 130 pmp. This increase in demands of kidneys has lead to expand donor selection criteria. Recent studies<sup>7</sup> quantify the contribution of donor's characteristics on graft's function variability in 40%, and the ideal donor would be younger than 50 years and deceased from traumatism; however, similarly to what happens in the other regions of Spain, we also observe in Galicia a clear change in donor's characteristics,<sup>8</sup> with increasing numbers of older people deceased from cerebrovascular death and those with comorbid conditions.

Although graft survival seems to be significantly shorter when donors' age is beyond 55-60 years,<sup>9,10</sup> there are also large studies in which these differences are not so clear-cut.<sup>11</sup> In our series, 23% of the donors were older than 60 years, and there were highly significant differences in graft survival according to donor's age, the latter being a clear risk factor, so that the risk of graft loss when donor's age is greater than 60 years is almost three fold higher than when donor's age is less than 40. Also, when com-

paring the group of elder donors (> 60) in young recipients (> 60) with the group of young donors and recipients, the results were conclusive with 5-year graft survival less than 45% in the former group and reaching up to 73% in the latter group; these results are similar to that found nearby.<sup>5</sup>

Besides, the above-mentioned scarcity of donors led to the use of kidneys from donors in asystolia. A high number of studies published on this issue have reported good outcomes when using this type of grafts, so that there do not represent a significant difference in the intermediate and long terms, although they may represent a high risk for delay in onset of graft function.<sup>10,12</sup> In our experience, however, and probably due to a small sample size of only 34 implants coming from asystolic donors, differences in graft survival were highly significant, so that the risk of graft loss increases three fold as compared to grafts from donors with brain death. However, this difference mainly occurs within the first year post-transplantation because when we analyzed those grafts that go beyond the first 12 months, we found out that survivals leveled.

When we assessed the influence on graft survival of receiving a graft generated at the same hospital or at a different hospital from the one performing the transplantation, we observed that almost half (48%) of transplanted kidneys were generated at the same center and their survival was significantly higher than that of grafts coming from other centers, which is likely related to increase in ischemia times of imported kidneys.<sup>13</sup>

On the other hand, in recent years, modification of recipient's characteristics was as much as changes in type of donors. Half of the patients starting on renal replacement therapy are older than 60 years,<sup>6</sup> which makes that recipient's age progressively increases; thus, in our series, in frank agreement with other registries,<sup>5</sup> mean age at the time of transplantation is close to 50 years, and even the largest numbers are found from that age and on.

In this regard, although recipient's age greater than 65 years still is a relative contraindication to renal transplantation, the publication of studies that question that premise<sup>14</sup> and the evidence of quality of life improvement make that year by year more and more elder patients are being transplanted, as it happens in our series in which almost 10% of operated patients are older than 65 years; also, although in our series we observe a lower graft survival in the univariate analysis in patients older than 60, this difference vanishes off once all variables have been added to the model. However, when analyzing patient's survival, we observe that the risk in patients older than 60 increases five-fold as compared to that

in those younger than 40, which is in agreement to what has been largely reported in the literature.<sup>5,10,15</sup>

Acute rejection has been described as a determinant factor of long-term graft course, being the main reason of early graft failure, and representing an independent risk factor for both graft and recipient survival,<sup>5,10,16</sup> so that in our series the risk was twice in both cases.

Although advances in immunosuppressive drug therapy allowed for a dramatic reduction in acute rejection incidence, the first post-transplantation year still is the most critical one with regards to renal function loss. In our transplantation series, we obtained a 80% global graft survival within the first year and 67% within five years, but when exclusively analyzing those kidneys going beyond the first 12 months, 90% are still functioning within 3 years, and 84% within 5 years. In this regard, our results within the first year do not reach those reported by other registries in our setting, but they do are comparable later on.<sup>5</sup>

In this sense, we may point out that although patient's death is currently reported as the main cause of graft loss during the first year,<sup>5,17</sup> in our series exitus within that same period accounted for only 17% of graft losses, whereas 44% are lost due to vascular thrombosis. Anyhow, we should be cautious when interpreting these data since it is difficult to determine whether it is primary thrombosis or it is due to an episode of acute rejection, so that the two causes for graft loss would be overlapping. Therefore, we believe there is a need for additional studies for correctly analyzing these data, so that it would be appropriate and urgent creating and consolidating a Galician registry that would allow for continuous analysis of the progression of transplantation activity.

As for patient's survival, the outcomes were also remarkably increased in recent times; our analysis shows results indicating 94% and 83% survival rates within one and five years, respectively, which favorably compare with those reported by North American registries.<sup>2</sup> In two thirds of deceased patients the graft was still functioning, so that it would be interesting to know to what extent the exitus may be attributed to the consequences of renal transplantation or to the same conditions that lead to death in the general population. In this sense, there are studies indicating that mortality rate within the first year may be 14-fold higher than that in the general population,<sup>18</sup> whereas in our analysis it was 5-fold higher than that of Galician population.

Most of the deaths (38%) were due to infectious conditions, getting close to 60% within the first year, which is in contrast with several studies,<sup>5,17,19</sup> in

which the first death cause is cardiovascular pathology. However, we believe that our outcomes, which are similar to those reported in series similar to ours,<sup>20</sup> are conditioned by the short follow-up of patients, which was no longer than 6 months in any case, so that the logical thinking would be that with longer follow-up times the ratios of infectious and cardiovascular mortalities would reverse.

Finally, we would like to point out that patients residing in the province of A Coruña, because of its proximity to the transplantation center, and Ourense, may due to an optimal use of resources, as well as those residing in urban areas, are more likely to receive a transplantation, which suggests the existence of regional differences for Galician citizens in accessibility to this type of treatment, which requires studying and implementing the appropriate correction measures.

Definitely, the outcomes obtained from our work confirm that transplantation rate in the Autonomous Community of Galicia ranks among the best worldwide, although with important regional differences, and as for results, patient survival rates reaches the best levels of any international registry, where as graft survival rates, especially within the first year, is susceptible to improve, presumably at the expense of the high incidence of vascular thrombosis.

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