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Risk factors for refusing kidneys in Galicia. Is it possible to increase their use?

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SUMMARY

Introduction. *Demographic changes along with an increase in the demand of organs and an increase in the expertise of transplantation teams, lead to a constant modification of donors' characteristics and, accordingly, of the supply of the organs used and refused.*

Objective. *Analyze the use and refusal of kidneys generated in Galicia.*

Subjects and method. *A follow-up of kidney donors was carried out between 1996 and 2000, studying the reasons for non extraction and refusal of kidneys and analyzing the influence that donors' characteristics have on them. In order to evaluate the risk factors of not using grafts, multiple logistic regression patterns were made, assessing odds ratios with confidence intervals at 95%.*

Results. *836 kidneys were recovered from 433 donors, and 697 were implanted out of them. 17% of the organs extracted, a percentage approaching 25% in the two latest years, were discarded, due to the biopsy findings (27%), donor's previous conditions (22%), anatomical disorders (16%), prolonged cold ischemia (12%) or recipient not located or unsuitable (14%).*

The average age of refused grafts was significantly higher than that of implanted ones, in such a way that having more than 45 years old was an independent risk for refusing kidneys (OR = 1.76 and p = 0.05, for 45-59 years old; OR = 6.1 and p = 0.000, for older than 60 years old). The same happened with history of hypertension (OR = 1.59 and p = 0.044), high serum creatinine level (OR = 1.83 and p = 0.005) and positive serology for HCV (OR = 5.65 and p = 0.001) and anti-HBc (OR = 2.91 and p = 0.017).

Conclusions. *Elderly donors and donors with concomitant diseases enable us to increase the number of grafts, although they also lead to an increase in refusals, which nearly amounts to 20% of the ones generated. However, more than the half were refusede due to pontentially avoidable reasons and therefore these could have been valued for transplantation to limit recipients.*

Key words: ***Renal transplantation. Generated kidneys. Implanted kidneys. Rejected kidneys. Risk factors.***

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FACTORES DE RIESGO PARA LA DESESTIMACIÓN DE RIÑONES EN GALICIA. ¿ES POSIBLE INCREMENTAR SU UTILIZACIÓN?

RESUMEN

Los cambios demográficos, junto con el incremento de la demanda de órganos y de la experiencia de los equipos trasplantadores, conlleva una constante modificación de las características de los donantes y, en consecuencia, de la proporción de órganos utilizados y desestimados.

Pretendemos analizar la utilización y desestimación de riñones generados en Galicia, para lo cual hicimos un seguimiento de los donantes renales generados entre 1996 y 2000, estudiando las causas de no extracción y desestimación de riñones y analizando la influencia que sobre ellas ejercen las características de los donantes. Para evaluar factores de riesgo de no utilización de los injertos se elaboraron modelos de regresión logística múltiple, estimando odds ratios con intervalos de confianza al 95%.

Se extrajeron 836 riñones de 433 donantes, de los que se implantaron 697. El 17% de los órganos extraídos, porcentaje que en los dos últimos años se aproximó al 25%, se desestimaron, bien por resultados de las biopsias (27%), patologías previas del donante (22%), problemas anatómicos (16%), isquemia prolongada (12%) o ausencia de receptor (14%).

La edad media de los injertos desechados fue significativamente mayor que la de los implantados, de modo que superar los 45 años representó un factor de riesgo independiente para la desestimación de riñones (OR = 1,76 y p = 0,05, para edades entre 45 y 59 años; OR = 6,1 y p = 0,000, para mayores de 60 años), al igual que lo fueron los antecedentes de hipertensión arterial (OR = 1,59 y p = 0,044), los niveles elevados de creatinina sérica (OR = 1,83 y p = 0,005) y la presencia de anticuerpos frente al virus de la hepatitis C (OR = 5,65 y p = 0,001) y para el antígeno del core de la hepatitis B (OR = 2,91 y p = 0,017).

En definitiva, los donantes añosos y con patología asociada permiten incrementar el número de injertos, aunque conllevan un incremento de los desestimados, que alcanzan casi el 20% de los generados; sin embargo, más de la mitad de los mismos se desecharon por causas potencialmente evitables, por lo que podrían haber sido valorados para implantar en receptores límites.

Palabras clave: ***Trasplante renal. Riñones utilizados. Riñones desechados. Factores de riesgo.***

INTRODUCTION

Far from that experimental surgery, and when fifty years have not yet gone since the first success in human beings,[1] renal transplantation currently represents the best therapeutic option for patients with chronic renal failure,[2] achieving now results really difficult to improve, with graft survival rates over 90% in the first year, and 70% within 5 years,[3] and with unquestionable benefits in relation to improvement of patients' quality of life.[4]

In this sense, it seems clear that the only limit to the transplantation race is the scant number of available donors. That is to say, the success of transplantation therapy created a new problem, the availability of organs enough to satisfy the demands, even in a country such as Spain, in which the highest rates of cadaver donations are reached worldwide.[5]

This disparity in the binomial donation-transplantation, together with population aging shared by all developed countries, and the greater experience of transplantation teams, entail a progressive modification of established criteria by these teams for organ acceptance, making them increasingly lax, so that donors' characteristics are cons-

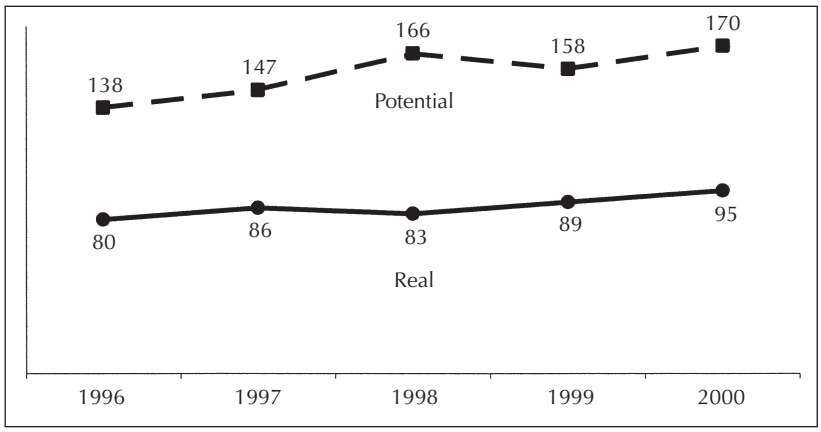

fig. 1.—Annual progression (1996-2000) of potential and real donors in Galicia.

tantly changing.[6-8] In this setting, it emerges the issue of establishing the barrier between the so-called *border-line donor* and the donor that should not be accepted. It seems clear the need of rejecting any graft that may pass on severe diseases to the recipient or that, due the status of his/her organs, could produce a life-threatening impairment to the recipient; nevertheless, it is important, as well, to prevent the loss of *border-line donors* that may safe the lives of potential recipients, because overestimating risk factors may lead to the loss of organs that could be valid.

Therefore, we aim at analyzing the influence of donor characteristics for the generation of kidneys, as well as in their use and final refusal, in the Autonomous Community of Galicia, in order to make possible studying and developing actions aimed at increasing grafts availability and, therefore, increasing the number of patients that may benefit from this type of replacement therapy.

SUBJECTS AND METHODS

The Autonomous Community of Galicia, located at the northwest of the Iberian Peninsula, has a surface area of 29,434 km^2, similar to Belgium, where 2,742,622 inhabitants reside, which represent 6.9% of the Spanish population.[9] The renal transplantation activity, initiated in the year 1981, is performed at two hospitals, the Juan Canalejo Hospital, at La Coruña, and the Clinic and University Hospital of Santiago; besides, six other public centers (Arquitecto Mercide of Ferrol, Xeral-Calde of Lugo, the Hospital Complexes of Orense and Pontevedra, and Xera-Cíes and Meixoeiro of Vigo) and two private centers (Povisa and Fátima, of Vigo) are accredited for organ extraction.

To perform this study, we carried out a retrospective analysis of the 433 donors generated in Galicia from January 1st of 1996 and December 31st of 2000, collecting information from Transplantation Coordi-

Table I. Refused potential donors during the 1996-2000 period. Annual progression and distribution by reason for refusal

Year	MCI		FR		JP		Total	
	n	%	n	%	n	%	n	%
1996	20	34.5	38	65.5	0	0.0	58	42.0
1997	21	34.4	40	65.6	0	0.0	61	41.5
1998	35	42.2	47	56.6	1	1.2	83	50.0
1999	27	39.1	41	59.4	1	1.4	69	43.7
2000	24	32.0	50	66.7	1	1.3	75	44.1
1996-2000	**127**	**36.7**	**216**	**62.4**	**3**	**0.9**	**346**	**44.4**

MCI: medical contraindication. FR: family refusal. JP: judicial prohibition.

Table II. Non-extracted kidneys during the 1996-2000 period. Distribution by reasons

Reason	n	%
Pathological impairment	12	40.0
Family refusal	2	6.7
No recipient	2	6.7
Biological problems	6	20.0
Anatomical problems	1	3.3
Reanimation problems	2	6.7
Other	5	16.7
Total	**30**	**100**

Table III. Destination of kidneys generated in Galicia and exported during the 1996-2000 period

Community	n	%
Andalusia	2	1.9
Aragón	2	1.9
Asturias	15	13.9
Canary Isl.	1	0.9
Cantabria	13	12.0
Castile Leon	5	4.6
Catalonia	13	12.0
Extremadura	1	0.9
Madrid	46	42.6
Basque Country	9	8.3
Valencia	1	0.9
Total	**108**	**100**

nation Offices of the ten previously mentioned hospitals; this was made possible elaborating an information system using the DBMS (Data Base Management System) from Microsoft Access, version 2000, and registering the following variables: age, gender, cause of death, blood type, history of arterial hypertension and diabetes mellitus, viral markers (anti-HCV, anti-HBc, and HbsAg) and serum creatinine levels.

A complete follow-up of all kidneys was done, so that, in those not implanted, the causes for not collection or for later refusal for transplantation were studied, gathering also information about the reason for sending to another center. The influence of donor characteristics gathered in our study on usage or refusal of these organs was also analyzed.

For statistical analysis, SPSS software for Windows, version 6.0 was used.[10] Results of qualitative variables are expressed as absolute frequencies and in percentages, whereas those of quantitative variables are expressed as mean ± standard deviation. The Kolmogorov-Smirnov test was used to verify normal distributions, Pearson's Chi-squared to compare qualitative variables, and Student's t test to compare a continuous variable between two groups. In order to verify risk factors that may have an influence on refusal of previously assessed organs for transplantation, a multiple logistic regression model was created, estimating the odds ratio and the 95% confidence intervals; only differences with a probability of type I error lower than 5% were considered significant.

RESULTS

In the study period, 433 real donors were generated in Galicia, out of 779 potential donors, which represent mean annual indexes of 56.8 potential donors and 31.6 real donors per million population (pmp), keeping an up-wards trend year by year (fig. 1).

When analyzing the reasons for refusal of the 346 potential donors that did not finally donate (Table I), we observe that family refusal to donation represented 62% of the cases (32% of the interviews performed), and medical contraindications 37%, whe-

Table IV. Kidneys generated during the 1996-2000 period. Annual progression and distribution of refused and implanted

Year	Donors	Generated	Refused		Implanted	
			n	%	n	%
1996	80	152	22	14.5	130	85.5
1997	86	168	12	7.1	156	92.9
1998	83	161	21	13.0	140	87.0
1999	89	176	45	25.6	131	74.4
2000	95	179	39	21.8	140	78.2
1996-2000	**433**	**836**	**139**	**16.6**	**697**	**83.4**

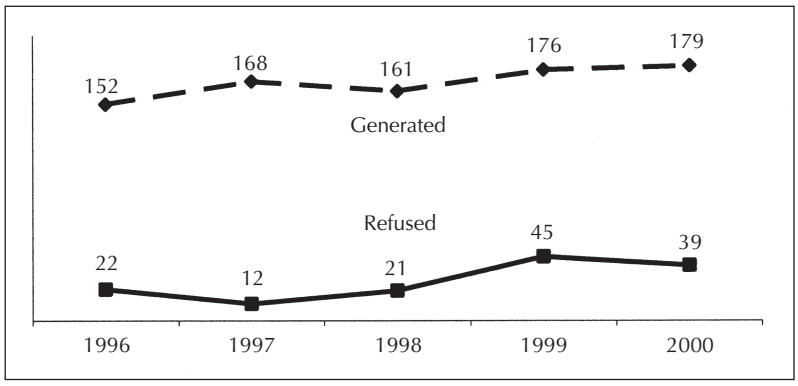

Fig. 2.—Annual progression (1996-2000) of generated and refused kidneys for transplantation.

reas judicial prohibition did not reach 1%, the interannual differences being insignificant.

Of the 866 kidneys that could have been generated, 30 were not extracted for the several reasons stated in table II, essentially for pathological impairments (40%), and for biological problems (20%) of donors, whereas in three cases, being single-kidney donors, only one organ could be extracted.

As a result, 836 kidneys were generated, of which 697 were implanted, 85% in the two Galician hospitals with renal transplantation program, and the remaining 108 were used in eleven other autonomous communities, to which they were sent, either because of not finding an appropriate recipient in Galicia or because of exchanges in the hyperimmunized or pediatric transplantation programs (table III).

Seventy percent of the generated grafts were refused for transplantation, a proportion that progressively increased, so that, in the last two years, it was near 25% (table IV) and fig. 2).

Table V summarizes the reasons for refusal of the 139 kidneys that were discarded after their extraction, among which stand out impairments detected in the correspondent histological examinations (27%) and previous donor pathologies (22%), such as positive serological tests, polycystic kidneys, history of hypertension or diabetes… Other reasons for not using the grafts were anatomical problems, essentially vascular problems, the unexpected prolongation of ischemia time, or not finding an appropriate receptor, that in many occasions overlaps with the previously mentioned prior pathologies of the donor.

Tabla V. Generated and refused kidneys during the 1996-2000 period. Distribution by causes

Cause	n	%
Previous pathology	31	22.3
Pathology	37	26.6
Prolonged ischemia	16	11.5
No recipient	19	13.7
Anatomical problems	23	16.5
Other	13	9.4
Total	**139**	**100**

The influence of donor characteristics on refusal of kidneys previously assessed for transplantation was studied (Table VI), observing that the mean age of refused organs was significantly higher than that for those implanted (58 ± 16 *vs* 43 ± 17, p = 0.000), whereas refused kidneys represented only 7% in donors younger than 45 years, and represented 35% in those older than 60.

Significant differences with regards to cause of death were also found, since 11% and 20% of the kidneys from subjects deceased by head trauma or by vascular cause, respectively, were refused; less than 79% of grafts from subjects deceased by asystolia were used.

33.8% of refused kidneys came from donors diagnosed with arterial hypertension, whereas this medical condition was present in only 16.5% of implanted grafts (p = 0.000). Similarly, the difference was significant in relation to donors with personal history of diabetes mellitus (4.3% in rejected kidneys and 1.4% in implanted ones), with positive anti-Hepatitis C antibodies (5.8% *vs* 1.4%, p = 0.001), and with anti-Hepatitis B core antigen antibodies (7.9% vs. 2.2%, p = 0.000).

Mean serum creatinine levels were 1.0 ± 0.4 mg/dL for donors of implanted kidneys, whereas it was 1.3 ± 0.6 mg/dL in donors of refused kidneys (p = 0.000). Thirty-seven percent of refused kidneys came from donors with creatinine levels higher than 1.2 mg/dL, refusing from these donors twice as much

Table VI. Influence of the several donor characteristics on refusal of kidneys during the 1996-2000 period

Donor characteristics		Implanted		Refused		p
		n	%	n	%	
Gender	Male	466	84,4	86	15,6	0,257
	Female	231	81.3	53	18.7	
Age	Mean ± SD	43.2 ± 17.5		57.6 ± 15.9		0.000
	< 45	358	93.0	27	7.0	
	45-59	193	86.2	31	13.8	0.000
	≥ 60	146	64.3	81	35.7	
Cause of death	Trauma	288	89.4	34	10.6	
	Vascular	336	80.0	84	20.0	0.003
	Other	40	76.9	12	23.1	
	Asystolia	33	78.6	9	21.4	
Blood type	A	351	81.6	79	18.4	
	0	286	85.6	48	14.4	0.383
	B	42	80.8	10	19.2	
	AB	18	90.0	2	10.0	
Viral markers	anti-HCV	10	1.4	8	5.8	0.001
	anti-HBc	15	2.2	11	7.9	0.000
	HbsAg	2	0.3	2	1.4	0.072
Associated pathology	AHT	115	16.5	47	33.8	0.000
	DM	10	1.4	6	4.3	0.024
Creatinine	Mean ± SD	1.0 ± 0.4		1.3 ± 0.6		0.000
	≤ 1.2 mg/dl	549	86.3	87	13.7	
	> 1.2 mg/dl	148	74.0	52	26.0	0.000

DM: diabetes mellitus. AHT: arterial hypertension; Mean ± SD: mean ± standard deviation.

(in percentages) kidneys than from donors with creatinine levels within normal values, a difference that also was statistically significant.

With the multivariate analysis, including the donor characteristics analyzed, the variables that reached statistical significance, that is to say, that represented an independent risk factor for refusal of kidneys that had been previously assessed for transplantation, were: age, a history of arterial hypertension, elevated serum creatinine levels, and the presence of anti-Hepatitis C antibodies and anti-Hepatitis B core antigen antibodies (table VII).

DISCUSSION

In the last decade, approximately 130 kidney transplantations are performed in Galicia each year[11-13], which represents an approximate index of 50 pmp, similar to the Spanish mean, which in turn is the highest worldwide with regards to transplantations from cadaver donors.[5] However, the stagnation in the number of interventions does not match with the increasing rate in incidence of patients on renal replacement therapy,[11,12] so that the waiting list for renal transplantation keeps on increasing and is nowadays of around 130 pmp.

Although mortality of patients on dialysis treatment is near 20%,[12] the percentage of deceased patients while on the waiting list is considerable lower, since it always includes the *best patients*;[2] but, in any case, what patients do loose for the time they wait to have access to transplantation is quality of life.[4] As a result, it seems evident that kidney demands is constantly increasing, which obliges to widen the donor selection criteria.

As in the rest of Spain,[7] there is the verification in Galicia from recent years of a clear modification in donor characteristics,[8] becoming more important aged donors, those deceased by cerebrovascular

Table VII. Multivariate analysis of refusal of kidneys by donor characteristics (*)

Donor characteristics		Odds ratio	IC 95%	p
Age	< 45	1		
	45-59	1.76	1.0-3.1	0.050
	≥ 60	6.10	3.7-10.1	0.000
Hypertension	No	1		
	Yes	1.59	1.0-2.5	0.044
Creatinine	≤ 1.2	1		
	> 1.2	1.83	1.2-2.8	0.005
anti-HBc	Neg	1		
	Pos	2.91	1.2-7.0	0.017
anti-HCV	Neg	1		
	Pos	5.65	2.0-16.0	0.001

(*) In the analysis, besides varibles that were statistically significant, also were included gender, cause of death, and donor blood type, and history of diabetes mellitus and presence of HbsAg.

cause, and those that have an associated medical condition, at the same time that the percentage of multi-organ donors also increases, which allowed for increasing by 20% kidney generation between 1996 and 2000; but simultaneously, the number of grafts refused for transplantation doubled, which represented 17% of all initially considered for transplantation.

In a study by Stratta *et al.*[14] on more than 30,000 kidneys extracted in the USA between 1996 and 1998, the refusal percentage does not exceed 10%; however, the ration found in our study is very similar to that registered for the whole country, Spain, and has the same upwards trend,[7] so that, currently, only 3 out of 4 generated kidneys are transplanted.

Almost 60% of refused kidneys came from donors older than 60 years, so that the risk for refusal was six-fold higher in these donors than in those younger than 45; similarly, 60% had died from cerebrovascular attack, although the cause of death, as a risk factor for refusal, lost statistical significance when it was integrated in the multivariate analysis. On the other hand, a history of arterial hypertension, elevated serum creatinine levels, or positive serological tests for hepatitis B and C virus were also prognostic factors for kidney refusal; however, by contrast with Stratta's study,[14] the gender had not an influence.

Thus, it seems clear that kidney refusal is clearly related with the increase in the number of the so-called *borderline donors*; however, the transplantation community assumes that age, cause of death, or associated medical conditions, by themselves, should not represent a barrier to donation.[15,16]

There are recent analyses that quantify as 40% the contribution of donor characteristics to graft function variability;[17] however, although graft survival seems to be significantly lower when donor's age is over 60 years,[18] there are also large studies that conclude that the outcomes of transplantation of kidneys from elder donors are perfectly acceptable.[19,20] Moreover, the risk that the vascular cause of death represents for graft survival is usually associated to the fact that frequently these patients have older age, a history of arterial hypertension, and atherosclerosis.[21] On the other hand, kidneys from donors with asystolia do not involve significant differences in their intermediate and long term survival, although they present a high risk for delay in onset of graft function.[22,23]

Anyhow, although the characteristics of the border-line donor may lead a shorter graft survival, as compared to optimal donors, it is evident that they also may allow improving quality of life, to certain elderly recipients with a difficult access to renal transplantation, and even increasing their survival as compare to continue on dialysis.[24,25] Besides, when donors are very old and/or important percentages of glomerulosclerosis, an option may be to implant both kidneys in the same recipient with the aim of gaining some nephron mass, obtaining excellent results.[26,27] Moreover, treating these donors with corticosteroids, immunogenicity of marginal grafts may be reduced and functional outcomes improved.[28]

Definitely, there are kidneys, as those in which a previous pathology is detected (renal failure, tumors, etc.) or that present anatomical problems, essentially vascular, that must be refused because of evident safety criteria; however, there is an important proportion of refused kidneys that might be implanted in *borderline recipients*. We are referring to a proportion of those kidneys that were refused because of an unexpected dilation of ischemia time, for technical problems during extraction or even by logistic errors, and also to those that were lost because of lack of an appropriate recipient, basically in cases of positive serological tests; all these reasons should be reduced to naught. On the other hand, there are also kidneys refused because of glomerulosclerosis, some vascular pathology, or even polycystic renal disease,[29] which may be

useful in patients that, due to their age, will have never access to transplantation and that, with their lower metabolic requirements, their lower immune reactivity, and their lower life expectancy, may compensate their expected shorter functioning duration.

In our casuistic, these kidneys represent more than 50% of refused ones, and considering those that were never extracted because of lack of recipient, an exclusively renal family refusal, or simply donor's age, the total 80 grafts that could have likely been implanted.

In summary, we can conclude that renal transplantation indexes reach high levels, waiting lists keep on increasing year by year in Galicia, and spite of the big effort done by transplantation coordination offices, not implanted kidneys for potentially preventable reasons represent almost 12% of the transplanted patients during the time period of our study; thus, we consider that with an optimal graft assessment and a thorough selection of appropriate recipients a better exploitation of existent donors could be achieved.

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