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**TITLE:**

Death of recipients after kidney living donation triples donors' risk of dropping out from follow-up

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**AUTHORSHIP**

All authors contributed to designing the study, and writing the paper. Jordi Comas and Emma Arcos were in charge of collecting and analyzing data.

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## **RUNNING TITLE:**

Death of recipients and donors' risk of dropping out

## **KEYWORDS**

Donor Registries; Live Donors; Outcome; Follow-up; Recipient Death

## **ABBREVIATIONS:**

LKD: living kidney donors (LKD)

OPTN: Organ Procurement Transplant Network

RDVR: Living Kidney Donor Registry of Catalonia

RTU: Renal Transplant Units

UNOS: United Network for Organ Sharing

## DISCLOSURE

All authors declare no conflicts of interest.

## ABSTRACT

Although kidney transplantation from the donation of a living donor is a safe treatment for end-stage renal disease, inferences about safety of living kidney donors might be biased by an informative censoring caused by the non-inclusion of a substantial percentage of donors lost-to-follow-up.

With the aim of assessing the presence of a potential informative censoring in living kidney donation outcomes of Catalan donors for a period of 12 years, 573 donors followed and lost-to-follow-up were compared. Losses of follow-up over time were also assessed by univariate and multivariate survival analysis, along with Cox regression.

Younger and older ages, and the death of their recipient differentiated those donors who were lost-to-follow-up over time. The risk of dropping out from follow-up was more than twofold for the youngest and oldest donors, and almost threefold for those donors whose recipient died.

Results of studies on post-donation outcomes of Catalan living kidney donors might have overlooked older and younger cases, and, remarkably, a percentage of donors whose recipient died. If these donors showed a higher incidence of psychological problems, conclusions about living donors' safety might be compromised thus emphasizing the necessity of sustained surveillance of donors and prompt identification of these cases.

## INTRODUCTION

End-Stage Renal Disease is an ever-increasing problem. Kidney transplantation from the unselfish donation of a living donor has become not only an acceptable alternative to transplantation from deceased donors but also the best treatment available for end-stage renal disease.

Safety of living kidney donors (LKD) is attained partly by devoting considerable efforts and specialized human resources to select, through a thorough pre-donation assessment, those candidates with a low risk of developing medical complications or psychosocial problems after donation. Indeed, long-term studies suggest that LKD may be at a somewhat increased risk of medical complications and all-cause mortality (1-4). Moreover, only small percentage of LKD seems to develop psychological problems such as depression and anxiety disorders, or find that their health has worsened since donation (5-7).

Despite this low risk, assessment of long-term data on outcomes of LKD has been widely recommended and described as “an important responsibility of the transplant community” (8,9). Of specific importance is the identification of medical and psychosocial complications thus prompting early and appropriate interventions when needed. Nevertheless, several years ago it was already suggested that studies on LKD might be affected by an informative censoring caused by the non-inclusion of data from a substantial percentage of donors lost-to-follow-up. As a result, conclusions drawn from the results of these studies might be compromised (10). Certainly, if donors followed and lost-to-to-follow-up were different in variables such as their own health or the health status of their recipients, studies might be reporting results obtained mainly from donors free of medical or psychosocial adversities. On the other hand, if donors without complications post-donation were those who were

least likely to attend follow-up assessments, results obtained so far might not include a percentage of these healthiest donors and, consequently, could be even better than observed so far.

Confusion surrounding this type of informative censoring grows as the percentage of donors lost-to-follow-up increases. In most studies published until 2006, the percentage of loss-of-follow-up was above 20%, and in 30% of studies the status after donation of half of the living donors was unknown. Therefore, it was suggested that the encouraging results of these studies should be acknowledged with caution (10). The Organ Procurement Transplant Network/United Network for Organ Sharing (OPTN/UNOS) living donor data task force also reported data incompleteness which, they conclude, compromises data use for research or for drawing conclusions about living donors' safety (11).

Recent important studies report a follow-up assessment of some medical variables in 11.6% of all living donors contacted for examination (4), absence of yearly regular follow-up in 28% of donors (12), and non-response of post-donation surveys in 53% of living donors at two-year follow-up assessments of psychosocial outcomes (13). Prospective studies with best figures report a 10% of lost-to-follow-up donors at the third year of follow-up (14).

For these reasons, our study aimed at assessing the presence of a potential informative censoring in living kidney donation outcomes of Catalan donors for a period of 12 years. Previous studies have shown that recipients' outcomes may influence donors' mental health or quality of life with, however, contradictory results showing either an adverse influence

(15-17) or no association between medical complications of recipients and donors' psychosocial outcomes (6,18,19). Therefore, status of the recipient was also considered a potentially important difference between donors followed and lost-to-follow-up and as such was included in the study.

## **MATERIALS AND METHODS**

### Participants

All LKD resident in Catalonia who donated during the period 2000-2011 were considered for selection. Donors were followed-up by several Renal Transplant Units (RTU) of Catalonia. Data until 12/31/2013 were obtained from the Living Kidney Donor Registry of Catalonia (RDVR), which is a mandatory population-based registry that collects information on all LKD in Catalonia since 2000. Data sent to the RDVR refers to the moment of nephrectomy and is updated at every follow-up available. Information is recorded by simple data entry or by electronic transfer depending on the RTU, and validated with every center and histocompatibility laboratory. Data are included in the RDVR at the beginning of every year to allow centers to complete nephrectomy and follow-up data.

Living kidney donors donating in 2012-2013 were excluded from the study so as to guarantee minimum of two years of follow-up, and thus allow a proper definition of losses-to-follow-up according to the requirement of the 2016 US OPTN of obtaining follow-up data for donors up to 24 months after donation (20). Follow-up of living donors not resident in Catalonia is not performed by Catalan RTU. Therefore, these donors were excluded to avoid an inflated imputation of losses at follow-up. Donors from one of the RTU were excluded due to underreporting of follow-up data to RDVR in 92% of cases. A final sample of 573 LKD was available for study (Figure 1).

Donors were considered lost-to-follow-up if: a) no follow-up register was available; b) if total follow-up time was less than one year; or c) if the last follow-up visit was undergone more than two years ago (i.e., no follow-up registers were available in the last two years). According to this definition, donors were considered either lost-to-follow-up or completers. Therefore, no donors changed their status from lost-to-follow-up to completer.

#### Statistical procedure

Donors followed and lost-to-follow-up were compared in gender, age at donation (both as a continuous and a categorical variable (9,11), donor-recipient relationship, period of donation, centre of follow-up (RTU), donor's health region of residence, history of hypertension, dislipemia, obesity, Body Mass Index, creatinine clearance at donation and in the last follow-up, nephrectomy technique, kidney localization, cold ischemia time and days of admission related to the nephrectomy. Recipient status was classified in three categories: a) Renal transplant still functioning at 31/12/2013, b) Renal transplant failed or c) Deceased recipient.

In a first step, donors were compared by Chi-square test for categorical variables and t-test or ANOVA for continuous variables. In a second step, losses of follow-up over time were assessed by univariate and multivariate survival analysis, along with Cox regression. The final Cox model was validated by the proportional hazard assumptions test based on the Schoenfeld residuals. To assess if the effect of recipient status on the rate of donor loss to follow up was differentially affected by follow up center, a 2-way interaction was incorporated in the Cox model.

Donors were also compared in: a) the complications observed in the nephrectomy or during follow-up and b) the status of the donor beyond the RTU data by linking our data with that of the Health Card Registry of Catalonia. The status of the donor could be: a) still active in Catalonia, b) deceased or c) moved from Catalonia. The low number of complications and changes in the status of donors only allowed a descriptive analysis.

Data were analyzed with statistical software package STATA, version 11.2.

## RESULTS

Of the 573 donors selected for the study, 388 (67.7%) were women with a mean (sd) age of 50.4 (10.6) years. Until 12/31/2013, 112 (19.6%) donors were lost-to-follow-up. Percentages of donors lost at one, 5 and 10 years from donation were 9.4%, 18.8%, and 30.4% respectively. Table 1 compares the characteristics of donors who completed the follow-up and those who were lost-to-follow-up.

Both youngest ( $\leq 34$  years) and oldest ( $\geq 65$  years) donors showed a lower percentage of follow-up over time ( $p=0.015$ ) compared to the 35-54 years and 55-64 years groups. Centre 1 reported the lowest percentage of losses of follow-up. Over time, however, non significant differences were observed among RTUs.

Medical variables did not show statistically significant differences between donors. A higher percentage of donors lost-to-follow-up required 5-8 admission days after nephrectomy. However, number of admission days showed no statistical significance either when assessed as a continuous variable or in the survival analysis.

Donors whose recipients died showed the highest percentage of losses-of-follow-up. The survival analysis confirmed these cross-sectional differences: at 10 years after donation



55.1% of donors whose recipient died, 34.4% of donors whose recipient lost the graft and 25.5% of donors of a still functioning graft had been lost-to-follow-up (Figure 2). Donors lost at follow-up whose recipient lost the graft (n=12), underwent their last follow-up visit mainly post graft failure (66.7%), while the majority of donors lost-to-follow-up whose recipient died (n=18) came to their last follow-up visit before their recipients' death (72.2%).

Cox regression analysis showed a risk 2.60-fold (95%CI 1.33-5.07) for donors  $\leq$  34 years and 2.69-fold (95%CI 1.38-5.24) for donors  $\geq$ 65 years compared to donors between 55-64 years. Donors with a deceased recipient showed an increased risk of 2.98-fold (95%CI 1.73-5.11) of becoming lost-to-follow-up (Table 2).

Centres 3 and 5 did not report enough cases of recipients' death or graft failure to be included in the analyses of the differential effect of recipient status on the rate of donor loss to follow up by centre. For the rest of the centres, graft failure increased the risk of becoming lost-to-follow-up in Centre 6 (Hazard ratio=3.20 [95%CI 1.49 to 6.85]; p=0.003), but not in Centres 1 and 4. Recipients' death still increased the Donors' risk of becoming lost-to-follow-up in all centres (Hazard ratios=18.9 [95%CI: 3.39 to 105.29]; p=0.001 to 2.23 [95%CI: 1.00 to 5.00]; p=0.05).

None of the 112 donors lost-to-follow-up suffered medical complications during nephrectomy, and only 2 of them (1.8%) presented some complication at follow-up. For the 461 donors who remained at follow-up, 9 (2.0%) presented complications during nephrectomy (evisceration, eventration or hemoperitoneum) and 16 (3.5%) presented complications during the follow-up (hernia, eventration, lithiasis or prerenal acute kidney

injury). Among donors who completed follow-up, 1 (0.2%) died and 7 (1.5%) moved from Catalonia, while among the 112 donors lost-to-follow-up 2 (1.8%) died and 20 (17.9%) moved from Catalonia.

## **DISCUSSION**

The results of our study suggest that Catalan LKDs lost-to-follow-up are different in health characteristics from those who remained in regular assessment. Cross-sectional comparisons of donors are at risk of not considering that the likelihood of being lost-to-follow-up may change over time (21). For this reason, a survival analysis aimed at defining which particular circumstances or characteristics influence the probability of being lost-to-follow-up seems more advisable. Survival analysis showed that only age and death of the recipient differentiated those donors who completed or were lost-to-follow-up over time. Cox regression showed that the risk of dropping out from follow-up was more than twofold for donors younger than 34 and older than 65 years, and almost threefold for those donors whose recipient died.

Age has been related to the risk of missing data at follow-up. Younger donors seem more likely to have missing clinical and laboratory follow-up data compared to donors older than 65 years. This finding has been tentatively associated with a lower proclivity to seek medical care and better health among younger donors (9). However, at least one study suggests that younger donors may show more difficulties to completely recover their quality of life at one-year follow-up (22). Even in the case that younger donors were healthier and less inclined to seek medical attention, this justification would not explain our finding that older donors also

showed a higher percentage of losses-of-follow-up. In late adolescence it has been shown that dysfunctional beliefs promote maladaptive health-behavior (23). An alternative explanation could be, then, that it was donors' health beliefs rather than their age, which influenced the assistance to follow-up appointments. To the best of our knowledge, this issue has not been assessed in kidney living donation. If similar dysfunctional beliefs were observed in donors lost-to-follow-up regardless of their age, strategies aimed at modifying these beliefs could improve their compliance with regular assessments. Preliminary results have already shown that such a treatment is able to improve health-related behavior (24,25). Number of admission days showed no statistical significance in the survival analysis. However, a higher percentage of donors lost-to-follow-up required more admission days after nephrectomy. A recent study shows that adverse postdonation outcomes among donors (namely ESRD) was related to an increase of graft loss and mortality among their recipients, regardless of the donor/recipient relationship (34). Therefore, it seems advisable to assess in future studies the direction of causality or even the presence of bidirectional relationships between adverse postdonation outcomes in recipients and donors.

Perhaps the main finding of our study is that recipients' death almost tripled the risk of the donor becoming lost-to-follow-up. Recipient's death has been related to negative outcomes in donors such as reduced motivation and activity, guilt and regretting donation (7, 26-28). Less severe complications such as recipient re-hospitalizations have been also related to the increase of psychological distress in donors (15). Even donors' subjective perception of worsening of their recipients' health may increase the risk of suffering psychological problems (16,17). Therefore, results of studies on post-donation outcomes of Catalan LKD might have overlooked a percentage of cases with a possibly higher incidence of distress

and emotional problems. If these findings were confirmed, and as previously stated in other contexts (10,11), conclusions of these studies about living donors' safety should be also acknowledged with caution.

It could be plausible that these donors decided that follow-up after their recipients' death was no longer necessary. However, most of them came to their last visit before their recipients' decease. Still, considering that two cases of suicide by donors following the death of their recipients were already reported some years ago (29), it seems advisable to ascertain if these donors suffered a clinically significant negative impact secondary to their recipients' death. This information could help: a) defining the necessity of an early, and maybe mandatory, identification of these cases to assess their overall psychological state and prevent the development of depression and suicidal ideation; b) improving education about the importance of completing regular assessments; and c) setting strategies to prevent donor's inability to accept a potential death of their recipient.

Follow-up of LKDs has improved but still requires further efforts to avoid missing donors (9). This necessity seems reinforced by our finding that Catalan donors lost-to-follow-up show a higher percentage of deaths among their recipients. These donors might be at an increased risk of developing not only distress and worsening of their quality of life, but also a worse impression and regretting of the living donation.

Nonetheless, a rigid requirement of donor follow-up might disturb those who are in good health and feel that a sustained follow-up is unneeded. However, in 28% of centers, losses-

Accepted Article

of-follow-up seem to be related solely to the health professionals' consideration that follow-up is unnecessary because donors' health is good (30). These data contrast with suggestions that some donors may feel somewhat ignored after surgery (31), and that 25% of recipients believe that donors' healthcare after nephrectomy was insufficient (32).

#### Limitations

One of the limitations of this study might be the absence of several follow-up data which were thus not included in the analyses. However, other follow-up data such as the creatinine clearance at the last follow-up available, or medical complications at follow-up showed non-relevant for the donors' risk of dropping out.

Data from an RTU were not included. Although only the results of 50 (8%) out of 623 donors were excluded, we do not know if this exclusion compromises the generalization of results. Also, differences in percentages of losses-to-follow-up among RTUs, probably due to differences in follow-up procedures, although non-relevant in the survival analysis, might also affect the generalization of results. Unlike what was observed in the multivariate analysis including all centres, recipients' graft failure increased the donors' risk of becoming lost-to-follow-up in a single centre. Also, 2 out of 5 centres did not observe enough cases of recipients' death or graft failure to be included in the analysis of the differential effect of recipient status by centre on the rate of donor loss to follow up. For these reasons, a further assessment of the centers' characteristics potentially influencing the rate of donors' losses to follow-up is needed.

Donor's death was not included in the definition of losses-to-follow-up. However, only three out of 573 donors died at follow-up. A follow-up assessment two months before her death was available for one of these donors and, hence, she was not considered lost-to-follow-up. One donor died two years later than her last follow-up visit and as such was considered lost-to-follow-up before decease. One donor out of 573 could have been defined as deceased instead of lost-to-follow-up and thus excluded from the analysis. We may not be certain that the exclusion of this donor had substantially changed our results.

Several variables previously related to a higher probability of being lost-to-follow-up include context-related factors such as being uninsured, which hardly apply to the Catalan and European Health Systems. Others, such as smoking, are quite independent from cultural issues and have not been assessed in our study (13).

Several variables showed a high percentage of missing cases. Especially important might be the 56.4% of missing cases in admission days considering that significant differences were observed between categories in the percentage of donors lost-to-follow-up. A homogenization of the protocols for collecting data could help to solve this limitation in future studies.

It is our opinion that the main limitation of this study is that the hypothesis that Catalan donors whose recipient died at follow-up might be at an increased risk of developing psychological problems has not been assessed. Future studies combining data from different national registries might help answering this issue.

## Conclusions

The reduction of the risk of an informative censoring to improve conclusions about the long-term outcome of LKD seems to need an increased attention to older and younger donors, and particularly those donors whose recipient died. Assessment of donors' dysfunctional health beliefs along with matching data from different sources could add to the extensively reviewed measures (11,33) to improve the sustained surveillance and guarantee of living kidney donors' health.

## ACKNOWLEDGMENTS

## FIGURE LEGENDS

Figure 1. Flow diagram showing donors' selection

Figure 2. Survival analysis of donor's lost-to-follow up event

Figure 3. Cumulative probability of loss to follow-up

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- Accepted Article
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Table 1. Characteristics of the donors and relationship with the loss-of-follow-up

Variable (% missing data)		By donor follow-up				
		Followed-up		Lost to follow-up		p
		n	% (row)	n	% (row)	
Sex (0%)	Female	317	81.7	71	18.3	0.276
	Male	144	77.8	41	22.2	
Age (0%)	<=34	31	68.9	14	31.1	0.020
	35-54	245	80.6	59	19.4	
	55-64	151	85.8	25	14.2	
	>=65	34	70.8	14	29.2	
	<i>Mean and SD</i>	<i>50.8</i>	<i>10.0</i>	<i>48.8</i>	<i>12.5</i>	
Relationship donor-recipient (0%)	Parents	143	79.9	36	20.1	0.299
	Brother/Sister	105	80.2	26	19.9	
	Husband/wife	181	82.7	38	17.4	
	Other relatives	20	76.9	6	23.1	
	Not related	9	60.0	6	40.0	
Donation period (0%)	2000-2007	175	75.8	56	24.2	0.020
	2008-2011	286	83.6	56	16.4	
Follow-up centre <sup>1</sup> (0%)	Centre 1	73	91.3	7	8.8	0.037
	Centre 3	25	78.1	7	21.9	
	Centre 4	184	82.1	40	17.9	
	Centre 5	18	78.3	5	21.7	

	Centre 6	161	75.2	53	24.8	
Hypertension history (0%)	No	422	80.4	103	19.6	0.884
	Yes	39	81.3	9	18.8	
Creatinine clearance (CKD-EPI) at the donation (6.8%)	<=79	134	79.8	34	20.2	0.778
	80-99	148	79.6	38	20.4	
	>=100	148	82.2	32	17.8	
	<i>Mean and SD</i>	<i>88.9</i>	<i>19.0</i>	<i>88.0</i>	<i>18.4</i>	<i>0.663</i>
Creatinine clearance (CKD-EPI) at the last follow-up (0.9%)	<=79	402	81.2	93	18.8	0.640
	80-99	52	82.5	11	17.5	
	>=100	7	70.0	3	30.0	
	<i>Mean and SD</i>	<i>62.5</i>	<i>15.2</i>	<i>59.9</i>	<i>17.2</i>	<i>0.117</i>
Admission days (56.4%)	0-4	56	88.9	7	11.1	0.045
	5-8	106	74.7	36	25.4	
	>=9	38	84.4	7	15.6	
	<i>Mean and SD</i>	<i>6.4</i>	<i>2.6</i>	<i>6.5</i>	<i>2.2</i>	<i>0.756</i>
Recipient status <sup>2</sup> (0%)	Functioning graft	405	83.3	81	16.7	<0.001
	Graft lost	33	73.3	12	26.7	
	Deceased	21	53.9	18	46.2	

<sup>1</sup>One of the follow-up centers was excluded due to the high percentage of unreported data.

<sup>2</sup>There are three donors with a recipient outside of Catalonia that couldn't be evaluated.

Table 2. Multivariate Cox analysis with variables related to living kidney donor loss-of-follow-up

Variable		HR	CI95%
Sex	Male (reference)	1	
	Female	0.83	(0.56-1.23)
Age group in the nephrectomy (in years)	55-64 (reference)	1	
	<=34	2.60*	(1.33-5.07)
	35-54	1.58	(0.98-2.55)
	>=65	2.69*	(1.38-5.24)
Period of donation	2000-2007 (reference)	1	
	2008-2011	1.75*	(1.10-2.76)
Follow-up centre	Centre 1 (reference)	1	
	Centre 3	3.33*	(1.15-9.65)
	Centre 4	2.35*	(1.04-5.32)
	Centre 5	3.49*	(1.10-11.11)
	Centre 6	3.08*	(1.36-6.93)
Recipient status	Functioning graft	1	

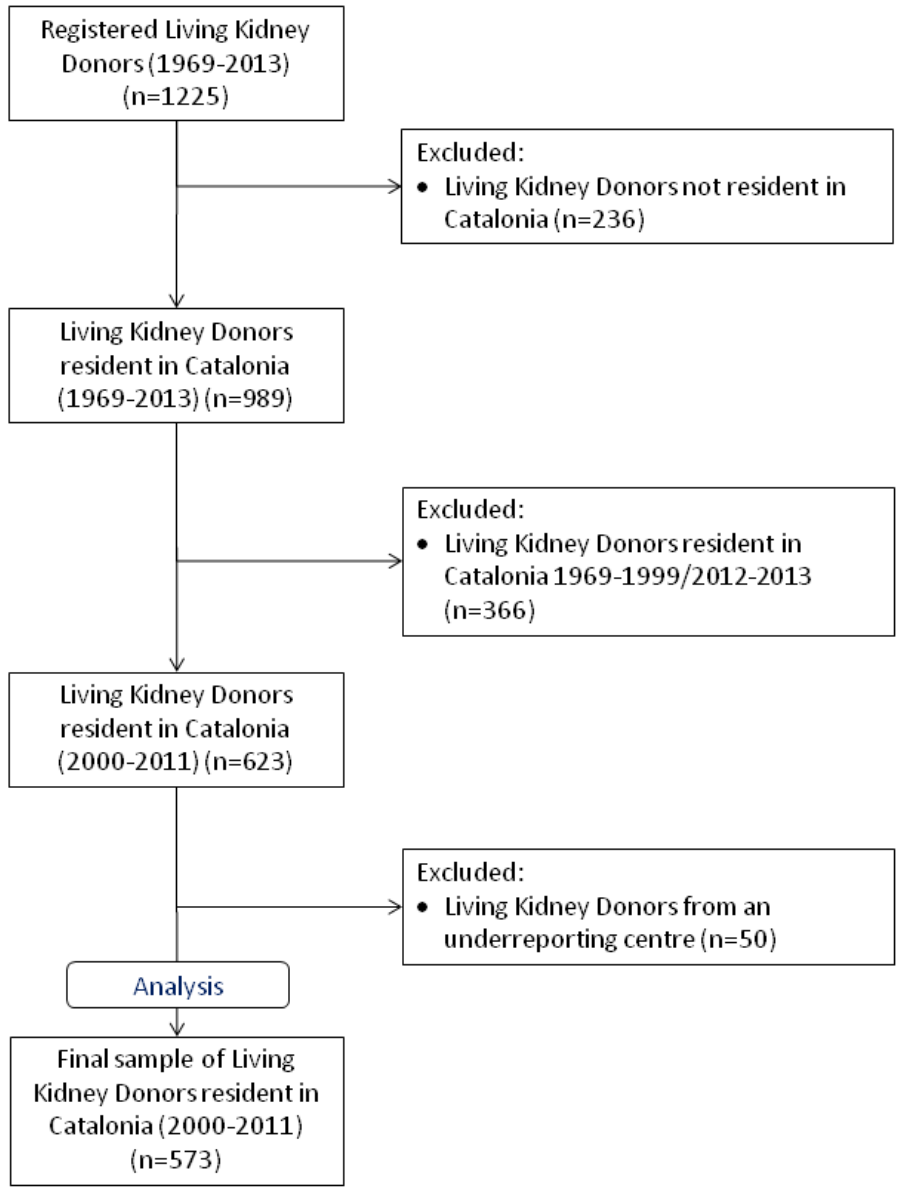
(reference)

Lost graft 1.59 (0.85-2.97)

Deceased recipient 2.98\* (1.73-5.11)

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\*p<0.05





Cum Survival

