Follow-up donatore vivente

Linee guida ERBP 2013

No linee guida

KDIGO 2015

CHAPTER 18: POST-DONATION FOLLOW-UP CARE

18.1: Living kidney donors should be monitored long-term for hypertension, CKD, andoverall health status and well-being. Blood pressure, eGFR based on serum creatinine, and urine albumin testing are particularly important parameters to follow in kidney donors due to concerns for the impact of donation on long-term risk for development of hypertension and CKD. Assessment should include not only the absolute level of eGFR but also its trajectory over time. (Not Graded)

18.2: The following specific practices should be performed annually for each donor as part of post-donation follow-up care: (Not Graded)

- ✓ Blood pressure measurement
- ✓ Body mass index measurement
- ✓ Serum creatinine testing with estimation of GFR (eGFR)
- ✓ Evaluation for albuminuria
- ✓ Evidence of diabetes
- Review and promotion of healthy lifestyle practices including exercise, diet, avoidance of smoking
- ✓ Review of psychosocial health and well-being as it relates to their donation experience.

KDIGO 2015

CHAPTER 18: POST-DONATION FOLLOW-UP CARE

18.3: Follow-up information should be reported to national and/or regional registries to facilitate aggregation, assessment and dissemination of current donor outcomes data. (Not Graded)

18.4: Donors who develop hypertension or CKD should receive appropriate medical treatment for these conditions according to clinical practice guidelines for the conditions. (Not Graded)

18.5: Donors should receive age-appropriate healthcare maintenance according to clinical practice guidelines for the regional population. (Not Graded)

18.6: Metabolic conditions (e.g., diabetes), cardiovascular diseases (e.g., coronary artery disease, congestive heart failure), and cardiovascular risk factors (e.g., hyperlipidemia, obesity) or risk behaviors (e.g., smoking, sedentary lifestyle) should be evaluated during post-donation healthcare maintenance assessments and managed according to general population guidelines. (Not Graded)

18.7: Donor education provided prior to and at the time of donation should be reinforced by post-donation educational contacts from the transplant center such as newsletters, links to transplant center health recommendations or national guideline website documents to promote sustained healthy lifestyle choices and behaviors. (Not Graded)

18.8: When important new information becomes available on the long-term outcomes of living kidney donors that differs from what a donor was told prior to donation, the transplant program should use reasonable efforts to contact past donors and provide this information. (Not Graded)

Studi selezionati

Study

When Good Intentions Are Not Enough: Obtaining Follow-Up Data in Living Kidney Donors

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A Prospective Controlled Study of Kidney Donors: Baseline and 6-Month Follow-up

Bertram L. Kasiske, Teresa Anderson-Haag, Hassan N. Ibrahim, Todd E. Pesavento, Matthew R. Weir, Joseph M. Nogueira, Fernando G. Cosio, Edward S. Kraus, Hamid H. Rabb, Roberto S. Kalil, Andrew A. Posselt, Paul L. Kimmel, Michael W. Steffes Am J Kidney Dis. 2013;62(3):577-586

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<u>A Prospective Controlled Study of Living Kidney Donors: Three-Year Follow-up</u> Bertram L. Kasiske, Teresa Anderson-Haag, Ajay K. Israni, Roberto S. Kalil, Paul L. Kimmel, Edward S. Kraus, Rajiv Kumar, Andrew A. Posselt, Todd E. Pesavento, Hamid Rabb, Michael W. Steffes, Jon J. Snyder, Matthew R. Weir. Am J Kidney Dis.2015: 66(1):114-124.

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<u>Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate</u> MorganE. Grams, Yingying Sang, M.S., Andrew S. Levey, Kunihiro Matsushita, Shoshana Ballew, Alex R. Chang, EricK. H. Chow, M.Sc., Bertram L. Kasiske, CsabaP. Kovesdy, Girish N. Nadkarni, M.P.H., Varda Shalev, M.P.A., Dorry L. Segev, Ph.D., Josef Coresh, M.D., Ph.D., KristaL. Lentine, M.D., Ph.D., and AmitX. Garg, M.D., Ph.D., for the Chronic Kidney Disease Prognosis Consortium N Engl j med 2016

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Lifetime risk of renal replacement therapy in Europe: a population-based study using data from the ERA-EDTA Registry

Jan A.J.G. van den Brand¹, Maria Pippias², Vianda S. Stel², Fergus J. Caskey^{3,4}, Frederic Collart⁵, Partik Finne^{6,7}, James Heaf⁸, Jean-Philippe Jais⁹, Reinhard Kramar¹⁰, Ziad A. Massy^{11,12}, Johan De Meester¹³, Jamie P. Traynor¹⁴, Anna Varberg Reisæter¹⁵, Jack F.M. Wetzels¹ and Kitty J. Jager²



FIGURE 1: Cumulative incidence of RRT in Europe by age for women (left panel) and men (right panel), respectively.



FIGURE 2: Lifetime risk of RRT in Europe by index age for women (left panel) and men (right panel). The thick dotted l pooled lifetime risk of RRT. The country-specific estimates are indicated by the colour-coded abbreviations. Bel, Belgium France; Aut, Austria; NL, the Netherlands; Swe, Sweden; UK, the United Kingdom; Den, Denmark; Nor, Norway; Fin, Fi



In order to obtain a personalized lifetime ESRD risk estimate for a potential donor, one needs both a population reference for lifetime ESRD risk and information on his or her individual risk factors for ESRD.

Data from the European Renal Association– European Dialysis and Transplant Association (ERA-EDTA) Registry

Lifetime risk of RRT varied from 0.44% to .05% at age 20 years and from 0.17% to 1.59% at age 70 years across countries, and was twice as high in men as in women.

Lifetime RRT risk <u>decreased with age</u>, ranging from an average of 0.77% to 0.44% in 20- to- 70-year-old women, and from 1.45% to 0.96% in 20- to- 70-year-old men.

Nephrol Dial Transplant (2017) 32: 348-355

FIGURE 3: Trends in lifetime risk of RRT in Europe between 2002 and 2011 by sex at index ages 20, 30, 40, 50, 60 and 70 year

Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate

Morgan E. Grams, M.D., Ph.D., Yingying Sang, M.S., Andrew S. Levey, M.D., Kunihiro Matsushita, M.D., Ph.D., Shoshana Ballew, Ph.D., Alex R. Chang, M.D.,

Eric K.H. Chow, M.Sc., Bertram L. Kasiske, M.D., Csaba P. Kovesdy, M.D.,

Girish N. Nadkarni, M.D., M.P.H., Varda Shalev, M.D., M.P.A., Dorry L. Segev, M.D., Ph.D., Josef Coresh, M.D., Ph.D.,

Krista L. Lentine, M.D., Ph.D., and Amit X. Garg, M.D., Ph.D.,

for the Chronic Kidney Disease Prognosis Consortium*



Figure 1. Projections of the Incidence of End-Stage Renal Disease (ESRD) in the United States According to Age, Race, and Sex for the Base-Case Scenario.

N Engl J Med. 2016 Feb 4;374(5):411-21

A total of <u>4,933,314</u> participants from seven cohorts were followed for a <u>median of 4 to 16 years</u>.

Table 3. Projected Incidence of ESRD in the United States among Hypothetical Donor Candidates in the Absence of Kidney Donation.*

Scenario	Age	Race	eGFR	Urinary Albumin: Creatinine Ratio†	Systolic Blood Pressure	Smoking Status	15-Yr Projection (95% CI)	Model-Based Lifetime Projection (95% CI)
	yr		ml/min/1.73 m²		mm Hg			
1	20	Black	115	4	130	Never	0.1 (0.1-0.1)	1.9 (1.2-2.5)
2	20	Black	115	4	130	Current	0.2 (0.1-0.2)	3.4 (2.0-4.8)
3	20	Black	115	4	140‡	Current	0.3 (0.1-0.4)	5.4 (2.9-8.5)
4	20	Black	115	30	140‡	Current	0.7 (0.2-1.5)	13.3 (4.8-27.0)
5	60	White	80	4	140	Never	0.2 (0.1-0.3)	0.4 (0.2-0.6)
6	60	White	60	4	140	Never	0.4 (0.2-0.6)	0.7 (0.3-1.2)
7	60	White	60	4	140‡	Never	0.5 (0.2-0.8)	1.0 (0.5-1.7)
8	60	White	60	30	140‡	Current	2.2 (1.1-3.6)	4.4 (2.1-7.0)

The 15-year projections of the risk of ESRD in the absence of donation varied according to race and sex; the risk was 0.24% among black men, 0.15% among black women, 0.06% among white men, and 0.04% among white women.

Risk projections were higher in the presence of a lower estimated glomerular filtration rate, higher albuminuria, hypertension, current or former smoking, diabetes, and obesity.

In the model-based lifetime projections, the risk of ESRD was highest among persons in the youngest age group, particularly among young blacks. The 15-year observed risks after donation among kidney donors in the United States were 3.5 to 5.3 times as high as the projected risks in the absence of donation

A Prospective Controlled Study of Kidney Donors: Baseline and 6-Month Follow-up

Bertram L. Kasiske, MD,¹ Teresa Anderson-Haag, PharmD, BCPS,¹ Hassan N. Ibrahim, MD,² Todd E. Pesavento, MD,³ Matthew R. Weir, MD,⁴ Joseph M. Nogueira, MD,⁴ Fernando G. Cosio, MD,⁵ Edward S. Kraus, MD,⁶ Hamid H. Rabb, MD,⁶ Roberto S. Kalil, MD,⁷ Andrew A. Posselt, MD,⁸ Paul L. Kimmel, MD,⁹ and Michael W. Steffes, MD¹⁰

Multicenter prospective study in which each living donor enrolled with an equally healthy control with 2 kidneys.

There were 201 donors and 198 controls who completed both baseline and 6-months visits

Compared with controls donors had:

- ✓ 28% lower glomerular filtration rates at 6 months (94.6±15.1 (SD) vs 67.6±10.1 mL/min/1.73 m2;P<0.001)
- ✓ **23% greater parathyroid hormone** (42.8±15.6 vs 52.7±20.9 pg/mL;P<0.001)
- ✓ **5.4% lower serum phosphate** (3.5±0.5 vs 3.3±0.5 mg/dL;P<0.001)
- ✓ **3.7% lower hemoglobin** (13.6±1.4 vs 13.1±1.2 g/dL;P<0.001)
- ✓ 8.2% greater uric acid (4.9±1.2vs 5.3±1.1 mg/dL;P<0.001)

A Prospective Controlled Study of Kidney Donors: Baseline and 6-Month Follow-up

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- ✓ 24 % greater homocysteine (1.2±0.3 vs 1.5±0.4 mg/L;P<0.001)
- ✓ 1.5% lower high-density lipoprotein cholesterol (54.9±16.4 vs 54.1±13.9 mg/dL;P<0.03) levels.

Three were no differences in albumin-creatinine ratios (5.0 [IQR, 4.0-6.6] vs 5.0 [IQR, 3.3-5.4] mg/g;P≤0.5), office bloodpressures, or glucose homeostas

	Baseli	ne Visit	6-mo	Visit		Pa	
Variable	Controls (n = 201)	Donors (n = 203)	Controls (n = 198)	Donors (n = 201)	Controls vs Donors ^b	Baseline vs 6 mo ^c	Inter- action ^d
Heart rate (beats/min)	68.0 ± 9.9	67.6 ± 10.5	66.2 ± 10.0	66.4 ± 10.2	0.6	0.003	0.5
	(n = 201)	(n = 194)	(n = 198)	(n = 200)			
Systolic blood pressure (mm Hg)	117 ± 13	117 ± 12	116 ± 12	115 ± 11	0.8	0.003	0.3
	(n = 201)	(n = 198)	(n = 198)	(n = 199)			
Diastolic blood pressure (mm Hg)	70.4 ± 9.0	70.3 ± 8.8	70.0 ± 8.5	70.3 ± 8.5	0.9	0.6	0.5
	(n = 201)	(n = 198)	(n = 198)	(n = 199)			
Body weight (kg)	77.7 ± 17.1	77.0 ± 14.8	78.0 ± 17.3	76.8 ± 15.2	0.6	0.6	0.06
	(n = 199)	(n = 199)	(n = 197)	(n = 199)			
Body mass index (kg/m ²)	26.9 ± 5.1	26.8 ± 4.2	27.0 ± 5.3	26.8 ± 4.3	0.8	0.3	0.3
	(n = 199)	(n = 199)	(n = 197)	(n = 199)			
Waist circumference (cm)	87.3 ± 12.8	88.0 ± 12.2	88.0 ± 13.6	87.2 ± 12.1	0.7	0.9	0.02
	(n = 181)	(n = 175)	(n = 179)	(n = 181)			

Note: Values are given as mean ± standard deviation (number analyzed). Numbers smaller than 202 reflect missing values.

^aAnalysis of variance with repeated measures. Each variable was analyzed separately and no adjustment was made for multiple comparisons.

^bControls versus donors *P* values test overall differences between donors and controls.

^cBaseline versus 6-month *P* values test overall differences between baseline (predonation) and 6-month visits. ^dInteraction *P* values test the interaction between donors versus controls and baseline versus 6-month visits. The short-term results of this study demonstrate that a number of physiologic changes associated with CKD are found in donors with mild declines in GFR.

However, a number of the reported changes wrought by CKD, such as increased blood pressure, were not found in kidney donors.

A Prospective Controlled Study of Living Kidney Donors: Three-Year Follow-up

Bertram L. Kasiske, MD,¹ Teresa Anderson-Haag, PharmD, BCPS,¹ Ajay K. Israni, MD,¹ Roberto S. Kalil, MD,² Paul L. Kimmel, MD,³ Edward S. Kraus, MD,⁴ Rajiv Kumar, MD,⁵ Andrew A. Posselt, MD,⁶ Todd E. Pesavento, MD,⁷ Hamid Rabb, MD,⁴ Michael W. Steffes, MD,⁸ Jon J. Snyder, PhD,⁹ and Matthew R. Weir, MD¹⁰

At 36 months, 182 of 203 (89.7%) original donors and 173 of 201 (86.1%) original controls continue to participate in follow-up visits.

Measurement	Follow-up Duration (mo)	Group	Rate of Change in Kidney Function	Pª
mGFR (mL/min per y)	12-36	Controls	-0.36 ± 7.55 (194)	0.005
		Donors	1.47 ± 5.02 (198)	
	36	Controls	-0.19 ± 5.31 (172)	0.002
		Donors	1.30 ± 3.49 (181)	
mGFR (mL/min/1.73 m ² per y)	12-36	Controls	-0.44 ± 7.35 (194)	0.01
		Donors	1.09 ± 4.28 (198)	
	36	Controls	-0.39 ± 4.81 (172)	0.004
		Donors	0.84 ± 3.09 (181)	
eGFR _{cr} (mL/min/1.73 m ² per y)	12-36	Controls	-1.04 ± 6.16 (196)	< 0.001
		Donors	1.82 ± 4.92 (200)	
	36	Controls	-0.46 ± 3.68 (173)	< 0.001
		Donors	1.60 ± 3.75 (182)	
eGFR _{cys} (mL/min/1.73 m ² per y)	12-36	Controls	-0.33 ± 7.36 (196)	0.003
		Donors	1.82 ± 6.76 (200)	
	36	Controls	0.16 ± 4.68 (173)	0.04
		Donors	1.21 ± 5.06 (182)	
eGFR _{cr-cys} (mL/min/1.73 m ² per y)	12-36	Controls	-0.73 ± 6.38 (196)	< 0.001
		Donors	1.89 ± 4.58 (200)	
	36	Controls	-0.07 ± 3.85 (173)	< 0.001
		Donors	1.49 ± 3.81 (182)	



Figure 1. Measured glomerular filtration rate (GFR) in controls (solid line) and donors (dashed line) before and 6, 12, 24, and 36 months after donation. Values are means and interquartile ranges.

The linear slope of the glomerular filtration rate measured by plasma iohexol clearance declined 0.3667.55 mL/min per year in 194 controls, but increased 1.4765.02 mL/min per year in 198 donors (P=0.005) between 6 and 36 months.

Kidney donors manifest several of the findings of mild chronic kidney disease. However, at 36months after donation, kidney function continues to improve in donors, whereas controls have expected age-related declines in function.

Long-term medical risks to the living kidney donor

Ngan N. Lam, Krista L. Lentine, Andrew S. Levey, Bertram L. Kasiske and Amit X. Garg

Nat. Rev. Nephrol. 11, 411-419 (2015)

Table 1 Studies that quantifie	ed long-term o	utcomes in livin	ng kidney donor	s compared with	th selected	healthy control	s	
Study	n		Median D	Donor age	Incid	ence (%)	HR (95% CI)	P value
	Living kidney donors	Healthy matched nondonors	donor follow-up time (years)	at donation (years)*	Donors	Nondonors		
End-stage renal disease		10.12	10 - 10 - 10 - 10 - 10 - 10 - 10 - 10 -			S 9		- 25 - 52
Mjøen et al. (2014) ³⁶	1,901	32,621‡	15.1	46 (11)	0.47	0.067	11.38 (4.37-29.63)	<0.001
Muzaale et al. (2014)37	96,217	96,217	7.6	40 (11)	0.10	0.037	NR	<0.001
Acute kidney injury treated with o	dialysis							
Lam et al. (2012)43	2,027	20,270	6.9	43 [34-50]	0.05	0.07	0.58 (0.08-4.47)	0.61
All-cause mortality								
Mjøen et al. (2014)36	1,901	32,621	15.1	46 (11)	11.8	7.4	1.30 (1.11–1.52)	0.001
Segev et al. (2010)12	80,347	80,347	6.3	NR	1.5	2.9	NR	<0.001
Reese et al. (2014)45	3,368	3,368	7.8	59 (NR)	3.4	4.5	0.90 (0.71-1.15)	0.21
Death or major cardiovascular ev	ent							
Reese et al. (2014)46	1,312	1,312	NR	NR	NR	NR	1.02 (0.87-1.20)	0.70
Garg et al. (2012)44	2,028	20,280	6.8	43 [34–50]	2.1	3.0	0.66 (0.48-0.90)	0.01
Major cardiovascular events								
Garg et al. (2012)44	2,028	20,280	6.8	43 [34–50]	1.3	1.4	0.85 (0.57-1.27)	0.43
Cardiovascular mortality								
Mjøen et al. (2014) ³⁶	1,901	32,621	15.1	46 (11)	3.6	2.1	1.40 (1.03–1.91)	0.03
Kidney stones with surgical interv	vention							
Thomas et al. (2013)48	2,019	20,190	8.8	43 [34-50]	0.79	0.89	0.85 (0.47-1.53)§	0.58
Major gastrointestinal bleeding								
Thomas et al. (2014)51	2,009	20,090	8.8	42 [34-50]	1.6	1.3	1.24 (0.85–1.81) [§]	0.26
Skeletal fractures								
Garg et al. (2012)56	2,015	20,150	6.9	43 [34-50]	1.2	1.3	0.88 (0.58-1.32)§	0.50
Gout								
Lam et al. (2015) ⁶⁰	1,988	19,880	8.8	43 [35-51]	3.4	2.0	1.6 (1.2-2.1)	<0.001
Gestational hypertension or pre-e	clampsia							
Garg et al. (2015)63	85	510	11.0	29 [26-32]	11.5	4.8	2.4 (1.2-5.0) [¶]	0.01

*Data presented as mean (standard deviation) or median [Interguartile range]. FLVing kidney donors were not matched to healthy nondonors in the comparison for end-stage renal disease risk. #Presented risk estimate is a rate ratio rather than a hazard ratio. Ilin 85 donors, there were 131 pregnancies in follow-up. Ib-Thesented risk estimate is an odds ratio rather than a hazard ratio. Abbreviations: CI, confidence interval; HB, hazard ratio; NR, not reported.

Long-term medical risks to the living kidney donor

Ngan N. Lam, Krista L. Lentine, Andrew S. Levey, Bertram L. Kasiske and Amit X. Garg

Studies have reported reassuringly safe and acceptable long-term outcomes for living kidney donors, although <u>limitations of these studies include:</u>

- ✓ Short follow-up durations (only a few studies have monitored a large number of donors for more than 20 years)
- ✓ high loss to follow-up
- ✓ limited racial diversity.

Most studies have compared donors with the <u>unscreened general population</u>; such comparisons are valid, but **a clear understanding of the limitations** of these comparisons relative to alternative study designs is critical for drawing inferences



Long-term risks for kidney donors

Geir Mjøen¹, Stein Hallan^{2,3}, Anders Hartmann¹, Aksel Foss¹, Karsten Midtvedt¹, Ole Øyen¹, Anna Reisæter¹, Per Pfeffer¹, Trond Jenssen¹, Torbjørn Leivestad⁴, Pål- Dag Line¹, Magnus Øvrehus², Dag Olav Dale¹, Hege Pihlstrøm¹, Ingar Holme⁵, Friedo W. Dekker⁶ and Hallvard Holdaas¹



Figure 1 | Flow chart showing inclusion and exclusion of kidney donors and controls. BMI, body mass index; BP, blood pressure;

Long-term risks for kidney donors

Geir Mjøen¹, Stein Hallan^{2,3}, Anders Hartmann¹, Aksel Foss¹, Karsten Midtvedt¹, Ole Øyen¹, Anna Reisæter¹, Per Pfeffer¹, Trond Jenssen¹, Torbjørn Leivestad⁴, Pål- Dag Line¹, Magnus Øvrehus², Dag Olav Dale¹, Hege Pihlstrøm¹, Ingar Holme⁵, Friedo W. Dekker⁶ and Hallvard Holdaas¹

	Unadiusted (n = 27,368-34,522)	Adjusted 1 ^a (n = 568/27.144)	Adjusted 2^{b} (<i>n</i> = 756/34,522)
	,	··· ·	
Kidney donation	3.18 (2.39-4.23, P<0.001)	1.52 (0.95–2.43, P = 0.08)	1.40 (1.03–1.91, P = 0.03)
Inclusion year	0.90 (0.87-0.94, P<0.001)	0.92 (0.87–0.98, P = 0.005)	0.95 (0.92–0.98, P = 0.004)
Age, years	1.13 (1.13–1.14, P<0.001)	1.13 (1.12–1.14, P<0.001)	1.13 (1.13–1.14, P<0.001)
Male	2.23 (1.92–2.60, P<0.001)	2.04 (1.71–2.44, P<0.001)	2.04 (1.75-2.38, P<0.001)
Systolic BP	1.05 (1.05–1.06, P<0.001)	1.01 (1.00–1.02, P = 0.15)	1.01 (1.00–1.02, P = 0.05)
Smoking	1.82 (1.55–2.14, P<0.001)	2.30 (1.94–2.72, P<0.001)	2.10 (1.75–2.51, P<0.001)
BMI	1.17 (1.14–1.21, P<0.001)	1.05 (1.01–1.08, P=0.006)	1.03 (1.00–1.07, P = 0.03)

Table 2b | Hazard ratio for cardiovascular death in kidney donors versus controls

Abbreviations: BMI, body mass index; BP, blood pressure.

^aAdjusted for age, gender, year of inclusion, systolic BP, smoking, and BMI.

^bAfter multiple imputation.

There was a corresponding increase in cardiovascular mortality (HR 1.40,95% CI 1.03–1.91,P=0.03)

Table 2c | Cox regression analysis for risk of end-stage renal disease in kidney donors versus controls

	Unadjusted (n = 25,063-35,222)	Adjusted 1 ^a (n = 31/34,522)	Adjusted 2 ^b (n = 31/34,522)
Kidney donation	18.99 (8.63-41.76, P<0.001)	11.42 (4.43–29.40, P<0.001)	11.38 (4.37–29.63, P<0.001)
Inclusion year	0.76 (0.70-0.83, P<0.001)	0.91 (0.83–1.00, P = 0.04)	0.90 (0.82–0.99, P = 0.03)
Age, years	1.04 (1.01–1.07, P = 0.003)	1.03 (1.00–1.06, P=0.04)	1.02 (0.99–1.05, P=0.13)
Male	0.94 (0.46–1.91, P = 0.86)	1.04 (0.51–2.11, P = 0.10)	0.90 (0.43–1.88, P=0.77)
Systolic BP	1.03 (1.00–1.07, P=0.14)	_	1.01 (1.00–1.06, P = 0.03)
Smoking	1.09 (0.48–2.46, P=0.83)	_	1.19 (0.51–2.76, P=0.68)
BMI	1.19 (1.02–1.38, P = 0.03)	_	1.13 (0.96–1.32, P=0.14)

Abbreviations: BMI, body mass index; BP, blood pressure.

^aAdjusted for age, gender, and year of inclusion.

^bAfter multiple imputation and further adjustments for blood pressure, BMI, and smoking.

There was a significant increase in ESRD during long-term after kidney donation

End-stage renal disease risk in live kidney donors: what have we learned from two recent studies?

Ngan N. Lam^{a,b}, Krista L. Lentine^c, and Amit X. Garg^{a,b,d}

The American experience

Muzaale et al. reported on <u>96217 living kidney donors</u> from the United States who underwent donor nephrectomy between 1994 and 2011 [*median follow-up 7.6 years*, interquartile range (IQR) 3.9–11.5 years, maximum 15.0 years].

The comparison group consisted of 20 024 participants from the Third National Health and Nutrition Examination Survey (NHANES III) enrolled between 1988 and 1994. Nondonors could be selected more than once **resulting in a cohort of 96217 healthy matched** nondonors (*median follow-up 15.0 years*, IQR 13.7–15.0 years, maximum 15.0 years)

The estimated 15-year cumulative incidence of ESRD was higher in living kidney donors compared to healthy matched nondonors [30.8 per 10 000 persons (95% CI 24.3–38.5, approximately 1 in 320) vs. 3.9 per 10 000 persons (95% CI 0.8–8.9; approximately 1 in 2500); P < 0.001]

In subgroup analyses of the donors, the 15-year cumulative incidence of ESRD was higher in donors who were older (60 years) vs. younger (18–39 years) at the time of donation [70.2 per 10 000 persons (approximately 1 in 140) vs. 29.4 per 10 000 persons (approximately 1 in 340)] and amongst African American donors vs. Caucasian donors.

Curr Opin Nephrol Hypertens 2014, 23:592–596

End-stage renal disease risk in live kidney donors: what have we learned from two recent studies?

Ngan N. Lam^{a,b}, Krista L. Lentine^c, and Amit X. Garg^{a,b,d}

The Norwegian experience

Mjøen et al. reported on **1901 living kidney** donors who underwent donor nephrectomy from a single center in Norway **between 1963 and 2007** (median follow-up 15.1 years, range 1.5–43.9 years)

The **comparison control group** consisted of **32 621** individuals selected from a populationbased survey [Health Study of Nord-Trøndelag (HUNT)] conducted between 1984 and 1987 (median follow-up 24.9 years, range 0.1–26.0 years)

The risk of ESRD was higher in living kidney donors than healthy nondonors [adjusted hazard ratio 11.38, 95% confidence interval (CI) 4.37–29.63, P < 0.001].

There was also **an increased risk of all-cause mortality** (from the Kaplan–Meier curve, the cumulative incidence at 25 years was approximately 18% in donors vs. 13% in healthy nondonors matched to the donors on age, sex, SBP, BMI, and smoking status; adjusted hazard ratio 1.30, 95% CI 1.11–1.52, P < 0.001) **and cardiovascular mortality** (adjusted hazard ratio 1.40, 95% CI 1.03–1.91, P ¼ 0.03)

End-stage renal disease risk in live kidney donors: what have we learned from two recent studies?

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KEY POINTS

- Recent studies suggest that living kidney donors may be at a relatively higher risk of ESRD compared to a selected group of healthy nondonors; however, the absolute 15-year incidence of ESRD remains reassuringly low.
- We highly recommend that the lifetime risk of ESRD, along with any uncertainty in these estimates, be discussed with potential living kidney donors and their recipients as part of the informed consent process.
- A 1–3% lifetime incidence of ESRD after donation may exist for some individuals who are younger, of certain ethnicity, with certain pre-existing conditions, and biological susceptibility to kidney disease. Further research in this area is needed.

Mortality and Cardiovascular Disease among Older Live Kidney Donors

PP Reese^{1,2}, RD Bloom¹, HI Feldman^{1,2}, P Rosenbaum³, W Wang⁴, P Saynisch⁴, NM Tarsi⁴, N Mukherjee⁴, AX Garg⁵, A Mussell², J Shults², O Even-Shoshan⁴, RR Townsend¹, and JH Silber^{4,6}

✓ The lower glomerular filtration rate (GFR) associated with aging has raised concerns about the safety of living kidney donation by older adults. Further, given the strong associations between both older age and chronic kidney disease with cardiovascular disease (CVD), older live kidney donors could have an augmented risk of CVD attributable to nephrectomy.

✓ Data on live kidney donors from the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS).

During the period from 1996–2006, there were 5717 older donors (older than 55 years) in the United States. We matched **3368 donors 1:1 to older healthy non-donors**.

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Donors ≥60 years (right panel) versus Matched Healthy Older Individuals using the Kaplan-Meier Method**

In median follow-up of 7.8 years,

mortality was not different between donors and matched pairs (p=0.21).

Among donors with Medicare, the combined outcome of death/CVD (p=0.70) was also not different between donors and non-donors

Am J Transplant. 2014 August ; 14(8): 1853–1861

Kidney

Cardiovascular Effects of Unilateral Nephrectomy in Living Kidney Donors

William E. Moody, Charles J. Ferro, Nicola C. Edwards, Colin D. Chue, Erica Lai Sze Lin, Robin J. Taylor, Paul Cockwell, Richard P. Steeds, Jonathan N. Townend; on behalf of the CRIB-Donor Study Investigators

This was a multicenter, parallel group, blinded end point study of living kidney donors and healthy controls (n=124), conducted from March 2011 to August 2014

The primary outcome was a change in left ventricular mass assessed by magnetic resonance imaging (baseline to 12 months).



There were significant increases in left ventricular mass (+7±10 versus -3±8 g; P<0.001) and mass: volume ratio (+0.06±0.12 versus -0.01±0.09 g/mL; P<0.01),

Donors had greater risks of developing detectable highly sensitive troponin T (odds ratio, 16.2 [95% confidence interval, 2.6–100.1]; P<0.01) and microalbuminuria (odds ratio, 3.8 [95% confidence interval, 1.1–12.8]; P=0.04).

Change in GFR was independently associated with change in left ventricular mass ($R^2=0.28$; P=0.01). These findings suggest that reduced GFR should be regarded as an independent causative cardiovascular risk factor.

Hypertension. 2016;67:368-377

OPEN

Patterns of End-Stage Renal Disease Caused by Diabetes, Hypertension, and Glomerulonephritis in Live Kidney Donors

S. Anjum, A. D. Muzaale, A. B. Massie, S. Bae, X. Luo, M. E. Grams, K. L. Lentine, A. X. Garg, D. L. Segev

125 427 donors were observed for a **median of 11.0 years** (interquartile range 5.3–15.7 years; maximum 25 years).

This study used data from the Scientific Registry of Transplant Recipients (SRTR)

The cumulative incidence of ESRD increased from 10 events per 10 000 at 10 years after donation to 85 events per 10 000 at 25 years after donation

Table 3:	Incidence	of late p	postdonation	ESRD	10–25 y	years foll	owing live	kidney	donation	compared	with early	y postdonati	on ESRD
0–9 years	s following	live kidr	ney donation	, United	States	s, Octobe	er 1, 1987,	to July	31, 2014	-			

	IRRs from cause-specific ESRD models ¹			
	Diabetes	Hypertension	Glomerulonephritis	
Timing of postdonation ESRD				
<10 years (early)	Reference	Reference	Reference	
10-25 years (late)	2.37.725.2	1.52.64.6	0.40.71.2	
Age, per 10-year increase ²	1.0 ^{1.3} 1.8	0.91.1 _{1.3}	0.60.81.1	
Race or ethnicity				
White or other	Reference	Reference	Reference	
Black	1.94.0 _{8.5}	2.3 ^{3.9} 6.7	4.17.3 _{12.8}	
Hispanic	0.20.83.4	1.02.14.1	0.20.82.6	
Sex				
Female	Reference	Reference	Reference	
Male	_{2.5} 5.0 _{10.0}	1.32.03.3	_{0.9} 1.7 _{2.5}	

American Journal of Transplantation 2016; 16: 3540-3547

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Late post-donation ESRD was more frequently reported as diabetic ESRD and hypertensive ESRD (IRR2.37.725.2and1.42.64.6, respectively). These time-dependent patterns were not seen with GN-ESRD (IRR0.40.71.2).



Figure 1: Hazard rates and cumulative incidence of cause-specific end-stage renal disease (ESRD) in live kidney donors, United States, October 1, 1987, to July 31, 2014. Kaplan–Meier curves (green, solid line) and generalized gamma models (orange,

Renal Function Profile in White Kidney Donors: The First 4 Decades

Hassan N. Ibrahim,* Robert N. Foley,* Scott A. Reule,* Richard Spong,* Aleksandra Kukla,* Naim Issa,* Danielle M. Berglund,[†] Gretchen K. Sieger,[†] and Arthur J. Matas[†]

We estimated the risk of proteinuria, reduced GFR, and ESRD in 3674 white kidney donors (mean follow-up 16.6±11.9 years, range 2-51), assessed the contribution of post-donation hypertension and diabetes to these outcomes, and developed a risk calculator

Clinical Outcome	Years Follow-up, Mean (SD)	Risk Factor	HR (95% CI)	P Value
Proteinuria(n=215)	16.6 (11.5)	BMI ^a	1.10 (1.06 to 1.13)	< 0.001
		Male gender	1.56 (1.18 to 2.05)	< 0.001
		Related to recipient	0.58 (0.36 to 0.96)	0.03
eGFR<60 ml/min per 1.73 m ² (n=1410)	9.5 (11.3)	Older age at donation*	1.05 (1.04 to 1.06)	< 0.001
		BMI ^a	1.03 (1.01 to 1.04)	< 0.001
		Systolic BP ^a	1.01 (1.00 to 1.01)	< 0.001
		Diastolic BP*	0.99 (0.98 to 1.00)	< 0.001
		Type 2 diabetes	1.52 (1.13 to 2.03)	< 0.001
		Related to recipient	0.56 (0.48 to 0.65)	< 0.001
		eGFR (CKD-EPI) "	0.98 (0.98 to 0.98)	< 0.001
eGFR<45 ml/min per 1.73 m ² (n=428)	11.0 (12.1)	Older age at donation*	1.07 (1.05 to 1.08)	< 0.001
		BMI*	1.03 (1.01 to 1.06)	< 0.001
		Systolic BP ^a	1.01 (1.01 to 1.02)	< 0.001
		Related to recipient	0.53 (0.39 to 0.71)	< 0.001
		eGFR (CKD-EPI)"	0.97 (0.96 to 0.97)	< 0.001
eGFR<30 ml/min per 1.73 m ² (n=101)	11.4 (12.4)	Older age at donation"	1.07 (1.05 to 1.10)	< 0.001
		BMI*	1.09 (1.04 to 1.14)	< 0.001
eGFR<30 ml/min per 1.73 m ² or ESRD(n=112)	15.5 (12)	Older age at donation"	1.07 (1.05 to 1.09)	< 0.001
		BMI ^a	1.08 (1.04 to 1.13)	< 0.001
		Systolic BP ^a	1.02 (1.00 to 1.04)	0.01
ESRD (n=28)	16.5 (11.9)	Systolic BP ^a	1.04 (1.01 to 1.07)	0.02

Table 2. Risk factors for adverse clinical outcomes

CKD-EPI, CKD Epidemiology Collaboration equation.

"Per increment of 1 unit—i.e., per year increment (for older age at donation), per kg/m² increment for BMI, per mmHg increment for BP, per ml/min per 1.73 m² increment for eGFR.

A higher BMI was the single predonation variable associated with every adverse postdonation outcome we studied, except for death; in fact, each increase of 1 unit in BMI was associated with a 3%–10% higher risk of proteinuria and reduced GFR. J

J Am Soc Nephrol 27: 2885–2893, 2016

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Figure 2. Cumulative risk of reduced GFR and proteinuria. Kaplan–Meier time to development of hypertension, proteinuria, eGFR<60ml/min per 1.73 m², eGFR<30ml/min per 1.73 m² or ESRD, and ESRD alone.

Outcome	Time-Dependent Covariate	HR (95% CI)	P Value
Death	Diabetes	0.74 (0.48 to 1.14)	0.17
	New-onset hypertension	3.82 (2.97 to 4.91)	< 0.001
	Proteinuria	2.25 (1.42 to 3.55)	< 0.001
	eGFR<60 ^a	4.62 (3.70 to 5.77)	< 0.001
	eGFR<30 ^a	2.99 (1.96 to 4.58)	< 0.001
	eGFR<30ª or ESRD	3.19 (2.20 to 4.62)	< 0.001
Proteinuria	Diabetes	4.92 (3.43 to 7.05)	< 0.001
	New-onset hypertension	3.9 (2.50 to 6.08)	< 0.001
	eGFR<60ª	3.94 (2.55 to 6.08)	< 0.001
	eGFR<30ª	6.45 (3.11 to 13.38)	< 0.001
	eGFR<30ª or ESRD	7.26 (3.63 to 14.48)	< 0.001
eGFR<30 ^a or ESRD	Diabetes	2.41 (1.42 to 4.09)	0.001
	New-onset hypertension	2.79 (1.55 to 5.03)	< 0.001
	Proteinuria	4.11 (2.04 to 8.26)	< 0.001
	eGFR<60ª	4.22 (2.65 to 6.71)	< 0.001
	eGFR<45ª	6.82 (4.19 to 11.11)	< 0.001

Table 4. Postdonation events and risk of death, proteinuria, and eGFR<30ml/min per 1.73 $\rm m^2$ or ESRD

Post-donation diabetes more than doubled the risk of GFR<30ml/min per 1.73 m² or ESRD (HR, 2.41; 95% CI, 1.42 to 4.09;P=0.001); post-donation hypertension produced a similar magnitude of increased risk of eGFR<30 ml/min per 1.73 m² or ESRD (HR, 2.79; 95% CI, 1.55 to 5.03;P<0.001). Developing proteinuria (HR, 4.11; 95% CI, 2.04 to 8.26;P<0.001) and an eGFR<60 ml/min per 1.73 m² (HR, 4.22; 95% CI, 2.65 to 6.71;P<0.001) post-donation were both associated with a fourfold increased risk of eGFR<30 ml/min per1.73 m² and ESRD. The development of postdonation hypertension, proteinuria, eGFR,60ml/min per 1.73 m², eGFR,30ml/min per 1.73 m²,and ESRD were all associated with a two-to five fold increased risk of death JAm Soc Nephrol 27: 2885–2893, 2016

Living-Donor Follow-Up Attitudes and Practices in U.S. Kidney and Liver Donor Programs

Amy D. Waterman,¹ Mary Amanda Dew,^{2,7} Connie L. Davis,³ Melanie McCabe,¹ Jennifer L. Wainright,⁴ Cynthia L. Forland,⁵ Lee Bolton,⁴ and Matthew Cooper⁶

The collection of follow-up information on donors' health status is crucial for understanding the risks and consequences of donation.

This information is important not only for the care of individual donors, who may require timely intervention should health problems be revealed during follow-up, but also for the education of potential donors so that they can make informed decisions about whether to donate

Living-donor programs must submit <u>living-donor follow-up (LDF) forms</u> to the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing(UNOS) **at hospital discharge or 6 weeks** after donation (whichever is earlier) as well as **at 6 months, 1 year, and 2years after donation.**

Medical data to be reported on these forms include **donor death**, **laboratory values** and **the development of specific medical conditions**.

Submitted forms often show that large percentages of donors (up to 100% in some programs) have been lost to follow-up

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Flow chart of study survey accrual and inclusion in final sample.

Respondents' opinions varied concerning how long adonor's health should ideally be monitored postdonation, with 31% of LKD respondents endorsing 5 years or more, 30% endorsing 2 years, 32% endorsing 1 year, and 8% en-dorsing 6 months or less.

TABLE 2. Medical and psychosocial data important to collect in follow-up with living donors				
	% Respondents			
General physical/psychosocial outcomes (n=147)				
Physical health status	94.1			
Psychologic well-being	66.7			
New temporary or permanent disability	59.3			
Donation regret	51.9			
Unanticipated change in donor-recipient relationship	28.1			
Insurance/employment issues (n=147)				
Donor's ability to return to work	68.1			
Difficulty obtaining health insurance	68.1			
Loss of insurance	54.1			
Unexpected out-of-pocket donation costs	53.3			
Insurance not covering donor expenses as expected	50.4			
Difficulty obtaining life insurance	48.9			
Iob loss	35.6			
Health parameters for kidney donors (n=147)				
Blood pressure	91.6			
Serum creatinine	95.4			
Development of hypertension	74.8			
Urine protein	67.9			
Urinalysis	62.6			
Weight	45.0			
Urine protein-creatinine	43.8			
New medications	42.0			
Fasting blood glucose	35.1			
Fasting lipid profile	9.2			
Waist circumference	3.8			
Health parameters for liver donors (n=36)				
Total bilirubin	93.3			
Alanine aminotransferase	90.0			
Aspartate aminotransferase	86.7			
Serum albumin	80.0			
International normalized ratio	76.7			
Blood pressure	56.7			
Serum creatinine	53.3			
Fasting lipid profile	30.0			
Fasting blood glucose	30.0			

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TABLE 3. Suggestions to improve living donor follow-up from open-ended questions	
	% Respondents (n=76)
Overcoming financial barriers	
Medicare should cover the 2 years of follow-up	32.9
Recipient's insurance should cover the 2 years of follow-up	30.3
Governmental agencies requiring follow-up should cover the 2 years of follow-up (e.g., HRSA and Centers for Med and Medicaid Services)	licare 10.5
Reimburse programs for follow-up (no funding source specified)	9.2
Donors should only be accepted if they have insurance	2.6
Programs should be reimbursed based on the completeness of their forms	2.6
Increasing donor cooperation	
Reimburse or incentivize donors for follow-up (e.g., tax deduction, coupon for required medical care, and paymen as in research studies)	t 19.7
Donors should complete surveys by mail	11.8
Donors should be better educated about why follow-up is important	11.8
Donors should self-report data using a national online system	10.5
Donors should be required to sign a contract mandating their compliance with follow-up	6.6
Donors should cooperate with programs for follow-up; it is for their own benefit	3.9
Improving accuracy of follow-up procedures	
Reduce data requirements to the basic tests, with extra tests required only if basic tests are abnormal	19.7
Patients' local primary care provider should conduct follow-up tests	15.8
A national organization should take responsibility for obtaining results of follow-up tests (e.g., UNOS and Nationa Living Donor Assistance Center)	l 9.2
Publish clearer information to physicians about what is required for follow-up and billing (e.g., correct tests to perform)	9.2
Reduce follow-up to 1 year; more is unnecessary	6.6
Stop penalizing for late/incomplete data	6.6
There should be designated staff for this task	5.3

HRSA, Health Resources and Services Administration; UNOS, United Network for Organ Sharing,

When Good Intentions Are Not Enough: Obtaining Follow-Up Data in Living Kidney Donors

E. S. Ommen, D. LaPointe Rudow, R. K. Medapalli, B. Schroppel and B. Murphy

RATIONALE FOR A LIVING DONOR FOLLOW-UP REGISTRY

We argue that a national donor follow-up registry is essential to ensure transparency in ascertaining long-term health outcomes among all living donors and in providing assessments of quality assurance within transplant programs.

Only a national donor follow-up registry can serve the vital tasks of:

- 1. ascertaining long-term health outcomes among all living donors and in particular subgroups of donors
- 2. providing assessments of quality assurance within transplant programs
- 3. maintaining transparency in the performance of these tasks.

APPROACH TO A LIVING DONOR FOLLOW-UP REGISTRY

"Any registry proposal must be realistic and, therefore simple; its implementation must be feasible"

The European Union nations have national health care systems that ensure health care for all living donors and protection of donors on an individual level.

When Good Intentions Are Not Enough: Obtaining Follow-Up Data in Living Kidney Donors

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We therefore propose the following:

- 1. Requirement that transplant centers provide meaningful data for 75% of all donor follow-up forms for 2 years, with escalating penalties for center noncompliance.
- 1. Enforcement of measures to encourage follow-up and limit disincentives on the part of living donors.
 - ✓ The impact of donor inconvenience is augmented by donors' perception of risksto their health
 - The second and third most commonly cited barriers to donor follow-up are direct and indirect costs to donors
- 1. Lifelong reporting of donor follow-up data by primary care providers
 - ✓ Follow-up data beyond 2 years is essential to meet the goals of a donor follow-up registry and the only way to achieve this follow-up is to create a system for donors to submit this data.

Long-term Safety of Living Kidney Donation in an Emerging Economy

S. Adibul Hasan Rizvi, FRCS,¹ Mirza Naqi Zafar, PhD,² Fatema Jawad, FRCP,³ Tahir Aziz, MD,⁴ Zafar Hussain, MS, Altaf Hashmi, MS,¹ Manzoor Hussain, MS,¹ Fazal Akhtar, FRCP,⁴ Ejaz Ahmed, FRCP,⁴ Rubina Naqvi, MD,⁴ and S A Anwar Naqvi, MBBS, MHPE¹

Reports on donor safety from developed countries may not be applicable to donors in emerging economies because paucity of healthcare facilities and economic constraints prevent follow-up care.

Follow-Up Protocol:

Between 6 and 12 months after nephrectomy and there after annually or when intercurrent medical problems occurred.

Each visit included: a complete **medical history, psychological assessment**, physical **examination** (including height, weight, and blood pressure), and **laboratory investigations complete** blood picture, renal function, urea, electrolytes, creatinine, liver functions, serum proteins, lipid profile, diabetes screening by fasting blood glucose, bone profile, uric acid and 24-hour urine collection for protein excretion, estimation of glomerular filtrationrate (GFR) by CrCl.

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Therapeutic Interventions Diagnosed:

Hypertension: lifestyle changes followed by angiotensin-converting enzyme (ACE) inhibitor, calcium channelblockers, and βblockers

Proteinuria: lifestyle changes and ACE inhibitor.

Hyperlipidemia: lifestyle changes, plus statin for hyper-cholesterolemia, and fibrates for hypertriglyceridemia

Diabetes: lifestyle changes, sulphanylurea, biguanide, dipeptidyl peptidase 4 inhibition, or insulin

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	Donors n = 90	Nondonors n = 90	<u>Р</u> <
Age, y	37.7 ± 11	37.7 ± 11	1.0
Male (%)	63 (70%)	63 (70%)	1.0
BMI	25.3 ± 4.6	25.3 ± 4.8	1.0
Follow-up period, y	5.8 ± 4.4	5.2 ± 5.1	0.4
Blood glucose, mg/dL	86 ± 15	96 ± 15	0.001
Cholesterol, mg/dL	174 ± 42	179 ± 33	0.4
Cholesterol > 200 mg/dL	18 (20%)	24 (27%)	0.4
Triglyceride, mg/dL	129 ± 69	137 ± 75	0.5
Triglyceride >150 mg/dL	25 (28%)	30 (33%)	0.6
Serum creatinine, mg/dL	1.12 ± 0.25	0.99 ± 0.27	0.005
Predonation CrCl, mL/min per 1.73 m ²	109.8 ± 22	109.5 ± 20	0.92
CrCl, mL/min per 1.73 m ²	84 ± 24	96 ± 26	0.02
24 h urine volume	2117 ± 1008	2092 ± 900	0.85
$CrCl < 60 mL/min per 1.73 m^2$	10 (11.1%)	7 (7.8%)	0.5
Protein excretion (median), mg/24 hr	75	71	0.66
Protein >300 mg/24 hr	4 (4.4%)	5 (5.5%)	0.8
Hypertension	13 (14%)	26 (29%)	0.05
Systolic BP, mm Hg	122 ± 11	123 ± 17	0.88
Diastolic BP	81 ± 9	84 ± 11	0.08
Diabetes mellitus	2 (2.2%)	3 (3.3%)	0.7
Ischemia heart disease	1 (1.1%)	1 (1.1%)	1.0

Intervention at regular intervals for hypertension, diabetes, proteinuria, and increased BMI allowed us to modify the risk factors and thus reducing risk of chronic kidney disease or ESRD.

This also perhaps is reflected by better health parameters in donors as compared with nondonors' siblings who did not have similar follow-up care

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

Xavier Torres, Jordi Comasb, Emma Arcosb, Jaume Tortb, Fritz Diekmann Transplant International 2017

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

All LKD resident in Catalonia who donated during the period 2000-2011 were considered for selection; 573 donors were selected for the study, 112 donors were lost to follow-up



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.

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