VCU Biopsy Study Data Collection

Figure S-1: REDCap Biopsy and Anatomy Data Collection Instrument

Record ID

OPTN Donor Id

* must provide value

Type initial letters to filter Donor ID dropdown

Confirm OPTN Donor Id

* must provide value

Kidney Laterality

* must provide value

Biopsy Information

Was a Biopsy Report found among the attachments?

* must provide value

- Yes
- No

reset

Type of Biopsy Sample:

* must provide value

- Needle / Core
- Wedge
- Other
- Unknown

reset

Other Biopsy Sample Type:

* must provide value

Expand

Biopsy Preparation Method:

* must provide value

- Frozen section
- Fixed/permanent (paraffin-embedded)
- Other
- Unknown

reset

Other Biopsy Sample Preparation Method:

* must provide value

Expand

Number of Glomeruli Observed:

Number of Glomeruli Sclerosed:

% Glomerulosclerosis (Calculated Field): View equation

% Glomerulosclerosis (Direct Entry of Percentage)

Interstitial Fibrosis*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (1-5%)
- Mild (6-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortex involved)
- Other
- Unknown

reset

You entered "Other" for Interstitial Fibrosis. Please describe.

* must provide value

Expand

Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% vascular narrowing)
- Other
- Unknown

reset

You entered "Other" for Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):. Please describe.

* must provide value

Expand

Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none
- Minimal
- Mild (at least one arteriole)
- Mild-moderate (more than one arteriole)
- Severe (multiple arterioles affected, circumferential)
- Other
- Unknown

reset

You entered "Other" for Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina). Please describe.

* must provide value

Expand

Tubular atrophy*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortical tubules involved)
- Other
- Unknown

reset

You entered "Other" for Tubular Atrophy. Please describe.

* must provide value

Expand

Interstitial inflammation*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- ○ Absent/none (0%)
- ○ Minimal (1-10%)
- ○ Mild (10-25%)
- ○ Mild-moderate (26-50%)
- ○ Severe (>50% of cortex involved)
- ○ Other
- ○ Unknown

reset

You entered "Other" for interstitial inflammation. Please describe.

* must provide value

Expand

Acute Tubular Injury (ATI) / Necrosis (ATN):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- ○ Absent
- ○ Minimal
- ○ Mild (epithelial flattening, tubule dilation, nuclear dropout, loss of brush border)
- ○ Mild-moderate (focal coagulative type necrosis)
- ○ Severe (infarction)
- ○ Other
- ○ Unknown

reset

You entered "Other" for Acute Tubular Injury (ATI) / Necrosis (ATN). Please describe.

* must provide value

Expand

Biopsy Comments

Expand

Was another Biopsy Report found among the attachments?

* must provide value

- ○ Yes
- ○ No

reset

Biopsy 2 Information

Type of Biopsy Sample:

* must provide value

- ○ Needle / Core
- ○ Wedge
- ○ Other
- ○ Unknown

reset

Other Biopsy Sample Type:

* must provide value

Expand

Biopsy Preparation Method:

* must provide value

- ○ Frozen section
- ○ Fixed/permanent (paraffin-embedded)
- ○ Other
- ○ Unknown

reset

Other Biopsy Sample Preparation Method:

* must provide value

Expand

Number of Glomeruli Observed:

Number of Glomeruli Sclerosed:

% Glomerulosclerosis (Calculated Field): View equation

% Glomerulosclerosis (Direct Entry of Percentage)

Interstitial Fibrosis*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (1-5%)
- Mild (6-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortex involved)
- Other
- Unknown

reset

You entered "Other" for Interstitial Fibrosis. Please describe.

* must provide value

Expand

Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% vascular narrowing)
- Other
- Unknown

reset

You entered "Other" for Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):. Please describe.

* must provide value

Expand

Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none
- Minimal
- Mild (at least one arteriole)
- Mild-moderate (more than one arteriole)
- Severe (multiple arterioles affected, circumferential)
- Other
- Unknown

reset

You entered "Other" for Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina). Please describe.

* must provide value

Expand

Tubular atrophy*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortical tubules involved)
- Other
- Unknown

reset

You entered "Other" for Tubular Atrophy. Please describe.
* must provide value

Expand

Interstitial inflammation*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)
* must provide value

- ○ Absent/none (0%)
- ○ Minimal (1-10%)
- ○ Mild (10-25%)
- ○ Mild-moderate (26-50%)
- ○ Severe (>50% of cortex involved)
- ○ Other
- ○ Unknown

reset

You entered "Other" for interstitial inflammation. Please describe.
* must provide value

Expand

Acute Tubular Injury (ATI) / Necrosis (ATN):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)
* must provide value

- ○ Absent
- ○ Minimal
- ○ Mild (epithelial flattening, tubule dilation, nuclear dropout, loss of brush border)
- ○ Mild-moderate (focal coagulative type necrosis)
- ○ Severe (infarction)
- ○ Other
- ○ Unknown

reset

You entered "Other" for Acute Tubular Injury (ATI) / Necrosis (ATN). Please describe.
* must provide value

Expand

Biopsy Comments

Expand

Was another Biopsy Report found among the attachments?
* must provide value

- ○ Yes
- ○ No

reset

Biopsy 3 Information

Type of Biopsy Sample:
* must provide value

- ○ Needle / Core
- ○ Wedge
- ○ Other
- ○ Unknown

reset

Other Biopsy Sample Type:
* must provide value

Expand

Biopsy Preparation Method:
* must provide value

- ○ Frozen section
- ○ Fixed/permanent (paraffin-embedded)
- ○ Other
- ○ Unknown

reset

Other Biopsy Sample Preparation Method:

* must provide value

Expand

Number of Glomeruli Observed:

Number of Glomeruli Sclerosed:

% Glomerulosclerosis (Calculated Field):

View equation

% Glomerulosclerosis (Direct Entry of Percentage)

Interstitial Fibrosis*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (1-5%)
- Mild (6-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortex involved)
- Other
- Unknown

reset

You entered "Other" for Interstitial Fibrosis. Please describe.

* must provide value

Expand

Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% vascular narrowing)
- Other
- Unknown

reset

You entered "Other" for Arterial intimal fibrosis (aka, arteriosclerosis or chronic vascular changes or vascular damage or vascular narrowing):. Please describe.

* must provide value

Expand

Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent/none
- Minimal
- Mild (at least one arteriole)
- Mild-moderate (more than one arteriole)
- Severe (multiple arterioles affected, circumferential)
- Other
- Unknown

reset

You entered "Other" for Arteriolar hyalinosis (strictly involves arterioles, the vessels without internal elastic lamina). Please describe.

* must provide value

Expand

Tubular atrophy*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (0%)
- Mild (1-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortical tubules involved)
- Other
- Unknown

reset

You entered "Other" for Tubular Atrophy. Please describe.

* must provide value

Expand

Interstitial inflammation*:

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not critical.)

* must provide value

- Absent/none (0%)
- Minimal (1-10%)
- Mild (10-25%)
- Mild-moderate (26-50%)
- Severe (>50% of cortex involved)
- Other
- Unknown

reset

You entered "Other" for interstitial inflammation. Please describe.

* must provide value

Expand

Acute Tubular Injury (ATI) / Necrosis (ATN):*

(* Note: absent and minimal will be grouped together for analysis, so the distinction is not important.)

* must provide value

- Absent
- Minimal
- Mild (epithelial flattening, tubule dilation, nuclear dropout, loss of brush border)
- Mild-moderate (focal coagulative type necrosis)
- Severe (infarction)
- Other
- Unknown

reset

You entered "Other" for Acute Tubular Injury (ATI) / Necrosis (ATN). Please describe.

* must provide value

Expand

Biopsy Comments

Expand

Anatomy Information

Was an Anatomy Report found among the attachments?

* must provide value

- Yes
- No

reset

Kidney Length (cm)

Kidney Width (cm)

Surgical Damage:

* must provide value

- Yes
- No
- Other
- Unknown

reset

You entered "[Surgical_Damage]" for Surgical Damage. Please describe.
* must provide value

Expand

Anatomical Abnormalities:
* must provide value

- Yes
- No
- Other
- Unknown

reset

You entered "[Anatomical_Abnormalities]" for Anatomical Abnormalities. Please describe.
* must provide value

Expand

Number of Arteries:
* must provide value

Number of Veins:
* must provide value

Ureter:
* must provide value

- Single
- Double
- Other
- Unknown

reset

Ureter 1 Length (cm):
* must provide value

Ureter 2 Length (cm):
* must provide value

You entered "[Ureter]" for Ureter. Please describe.
* must provide value

Expand

Aortic Plaque:
* must provide value

- Yes
- No
- Other
- Unknown

reset

Aortic Plaque Type:
* must provide value

- Soft
- Hard
- Unknown

Aortic Plaque Severity
* must provide value

- Mild
- Moderate
- Severe
- Unknown

reset

You entered "[Aortic_Plaque]" for Aortic Plaque. Please describe.
* must provide value

Expand

Arterial Plaque
* must provide value

- Yes
- No
- Other
- Unknown

reset

Arterial Plaque Type
* must provide value

- Soft
- Hard
- Unknown

Arterial Plaque Severity
* must provide value

- Mild
- Moderate
- Severe
- Unknown

reset

You entered "[Arterial_Plaque]" for Arterial Plaque. Please describe.
* must provide value

Expand

Infarcted Areas
* must provide value

- Yes
- No
- Other
- Unknown

reset

Number of Infarcted Areas
* must provide value

You entered "[Infarcted_Areas]" for Infarcted Areas. Please describe.
* must provide value

Expand

Capsular Tears
* must provide value

- Yes
- No
- Other
- Unknown

reset

You entered "Other" for Capsular Tears. Please describe.
* must provide value

Expand

Subcapsular Hematomas
* must provide value

- Yes
- No
- Other
- Unknown

reset

You entered "Other" for Subcapsular Hematomas. Please describe.
* must provide value

Expand

Cysts/Discoloration
* must provide value

- Yes
- No
- Other
- Unknown

reset

Number of Cysts

* must provide value

Mean Cyst Size (cm^3)

You entered "Other" for Cysts/Discoloration. Please describe.

* must provide value

Expand

Fat Removed

* must provide value

- Yes
- No
- Other
- Unknown

reset

You entered "Other" for Fat Removed. Please describe.

* must provide value

Expand

Anatomy Comments

Expand

Figure S-2. Bootstrapped Doubly Robust Regression Process Flow

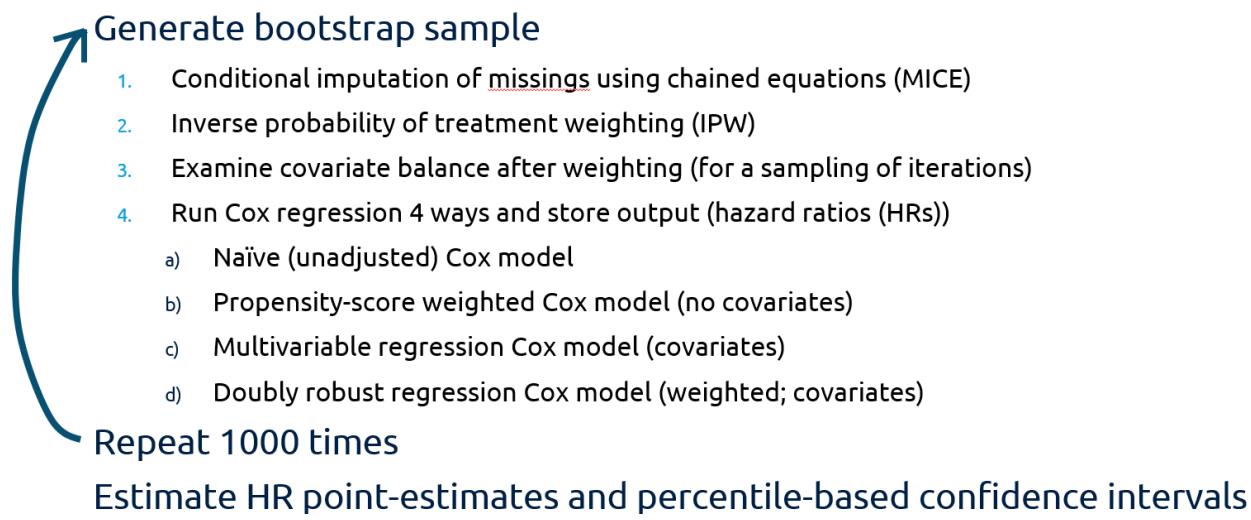


Figure S-3. Nominal vs. Empirical Bayes ("Shrinkage") Estimates of Glomerulosclerosis, by Number of Glomeruli Observed

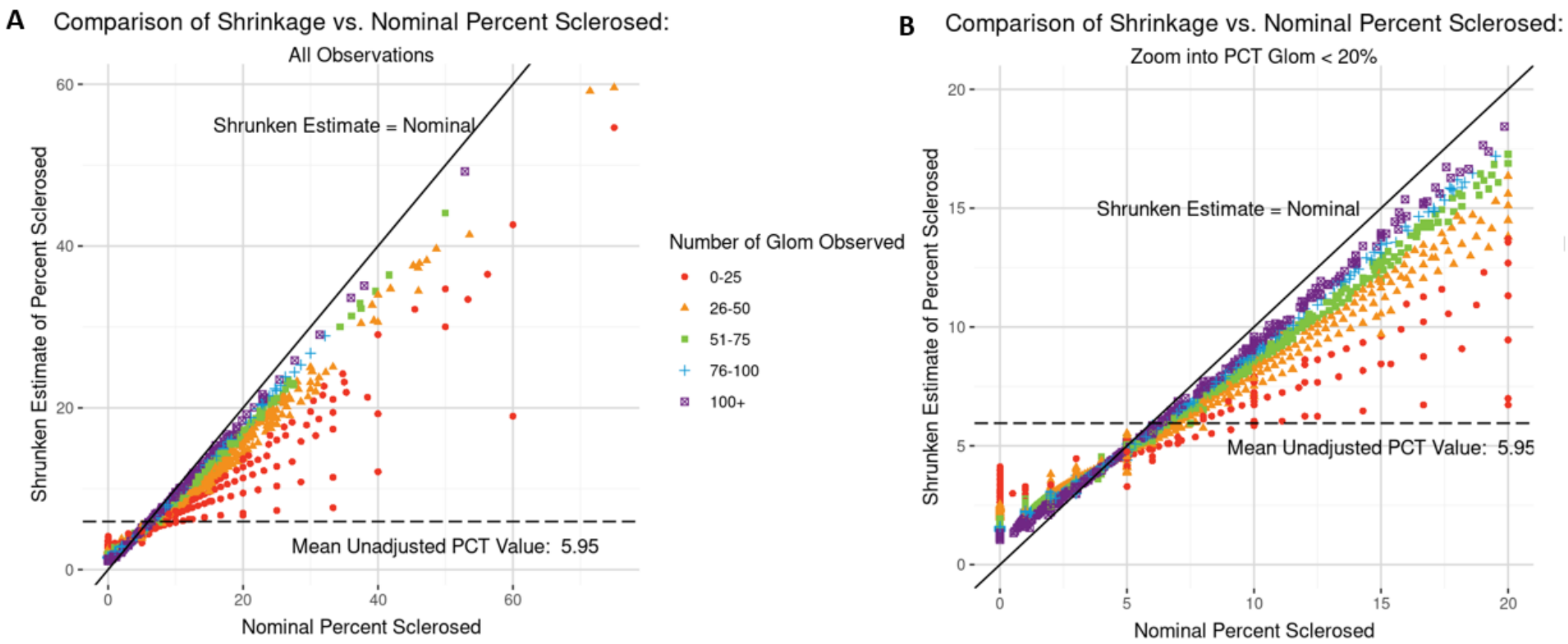


Figure S-4. Ten-Year Kaplan-Meier Death-Censored Graft Survival by 3-Level Glomerulosclerosis

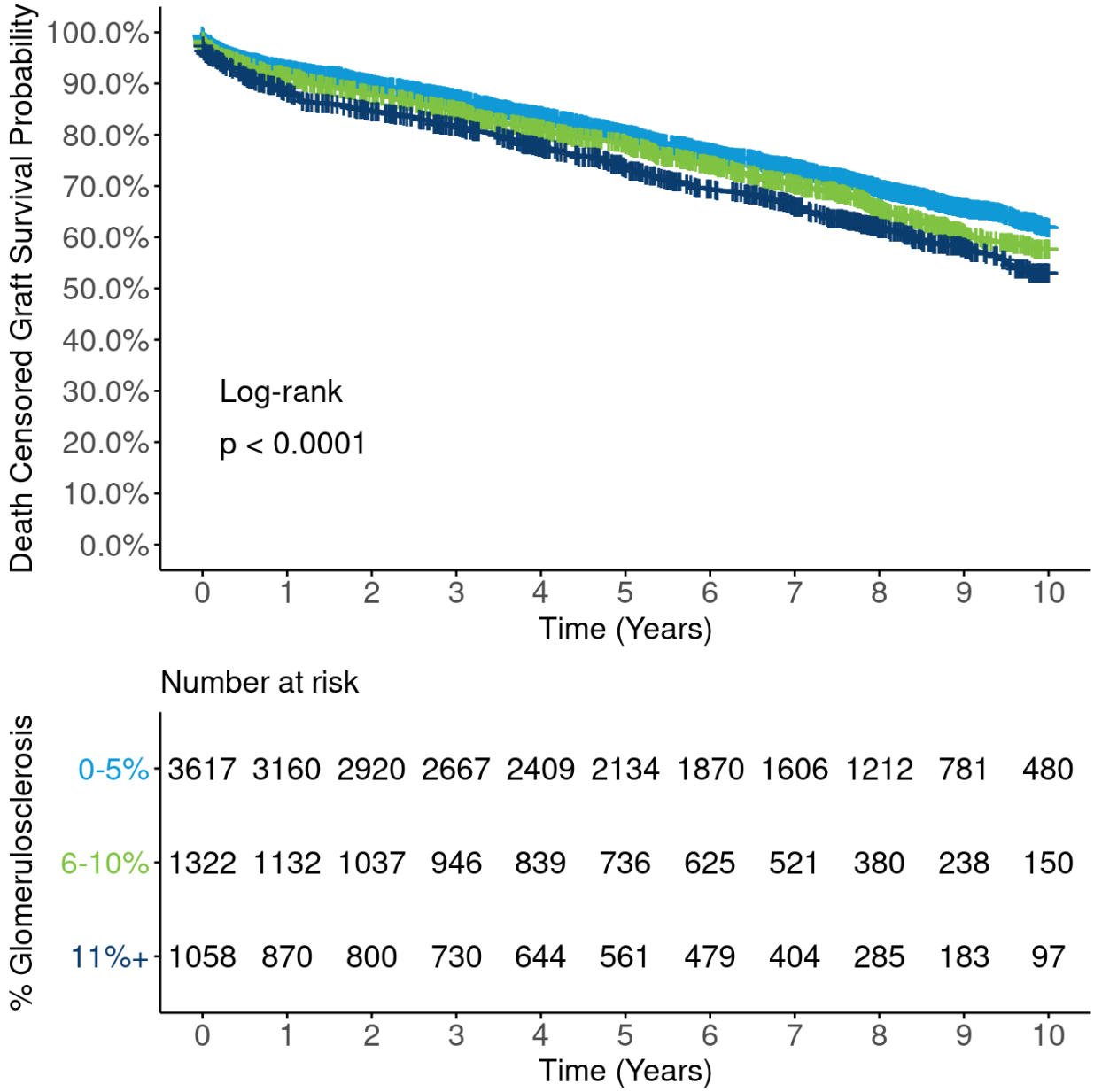


Figure S-5. Ten-Year Kaplan-Meier All-Cause Graft Survival by 5-Level Glomerulosclerosis

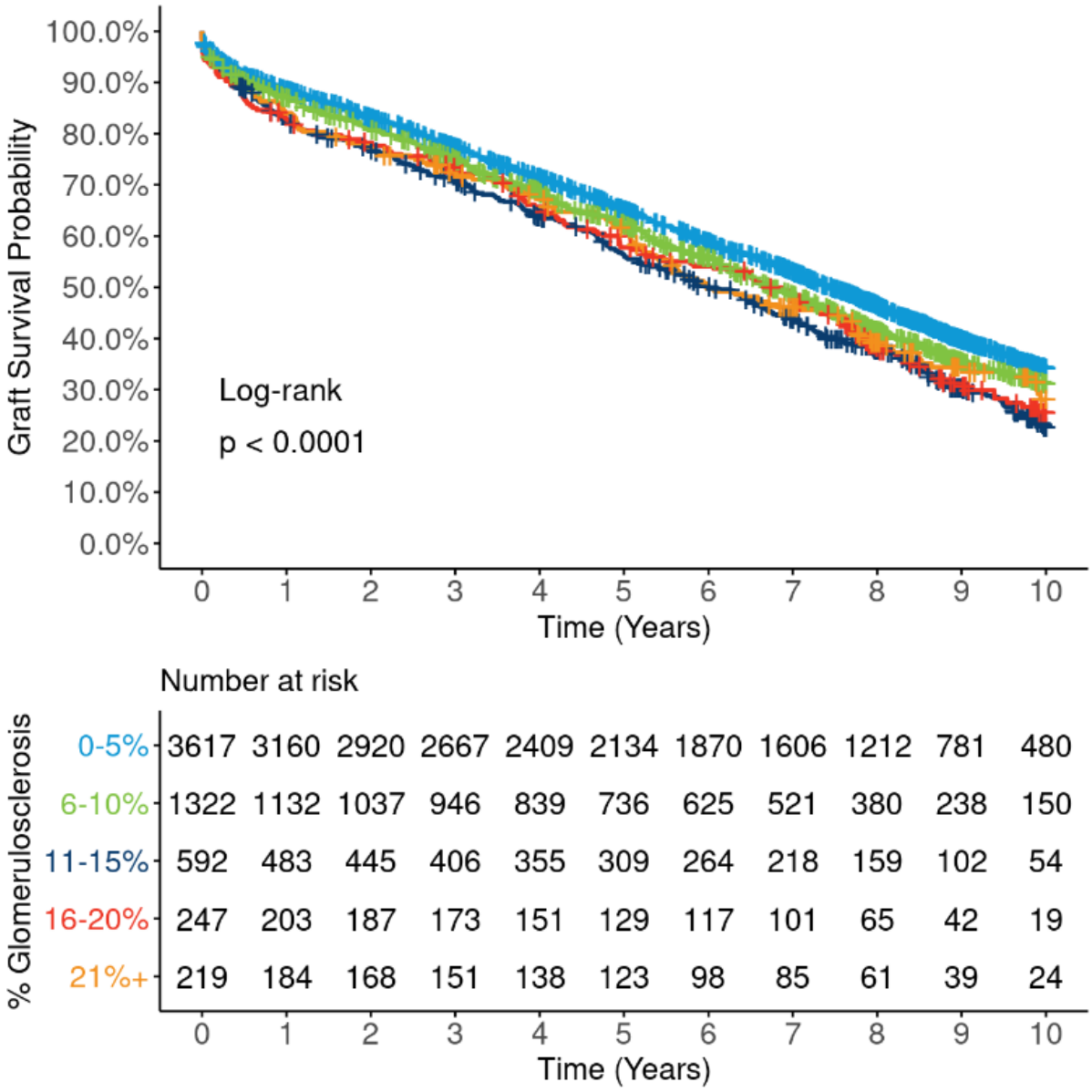


Figure S-6. Correlation between Kidney Donor Profile Index (KDPI) and Kidney Glomerulosclerosis

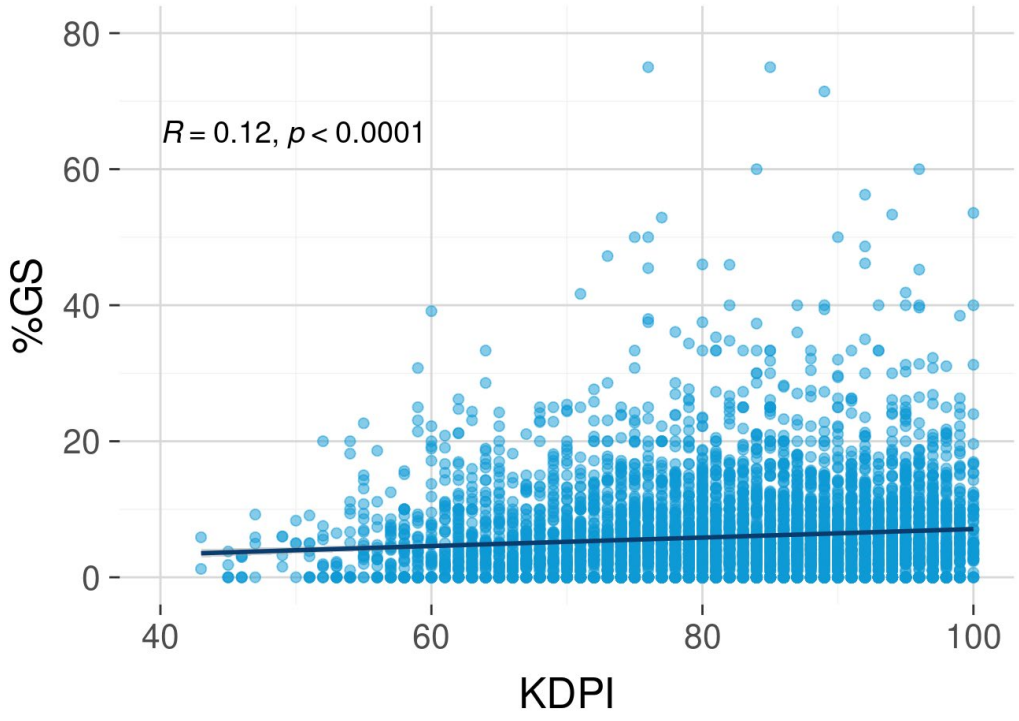


Figure S-7. Unadjusted and Adjusted Associations between Five-Level Glomerulosclerosis and 10-Year All-Cause Graft Failure Risk

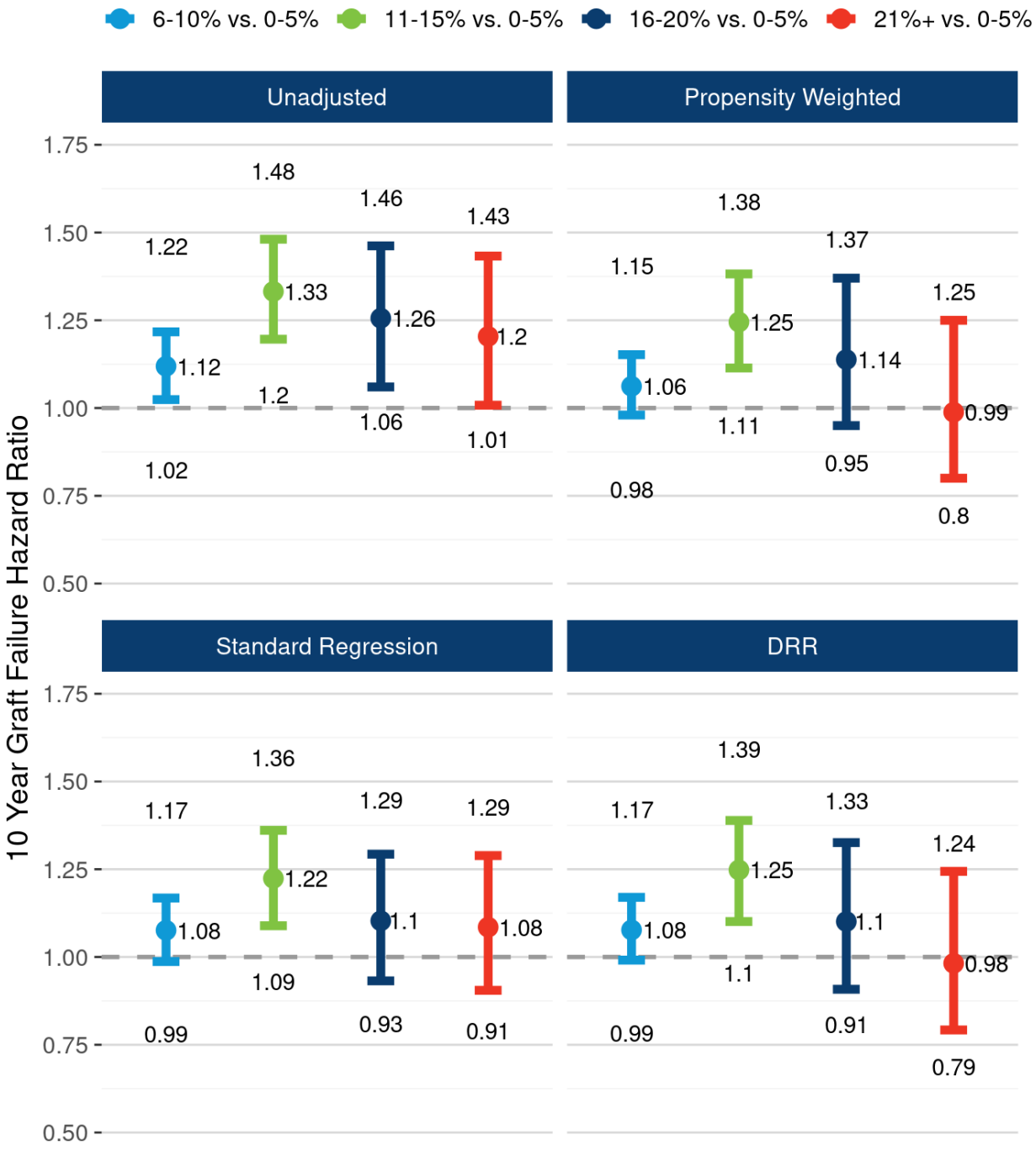


Figure S-8. Unadjusted and Adjusted Associations between Ten-Year All-Cause Graft Failure Risk and Empirical Bayes ("Shrunken") Estimate of Glomerulosclerosis, Modeled as a ~~Restricted Cubic Spline~~Nonlinear Function

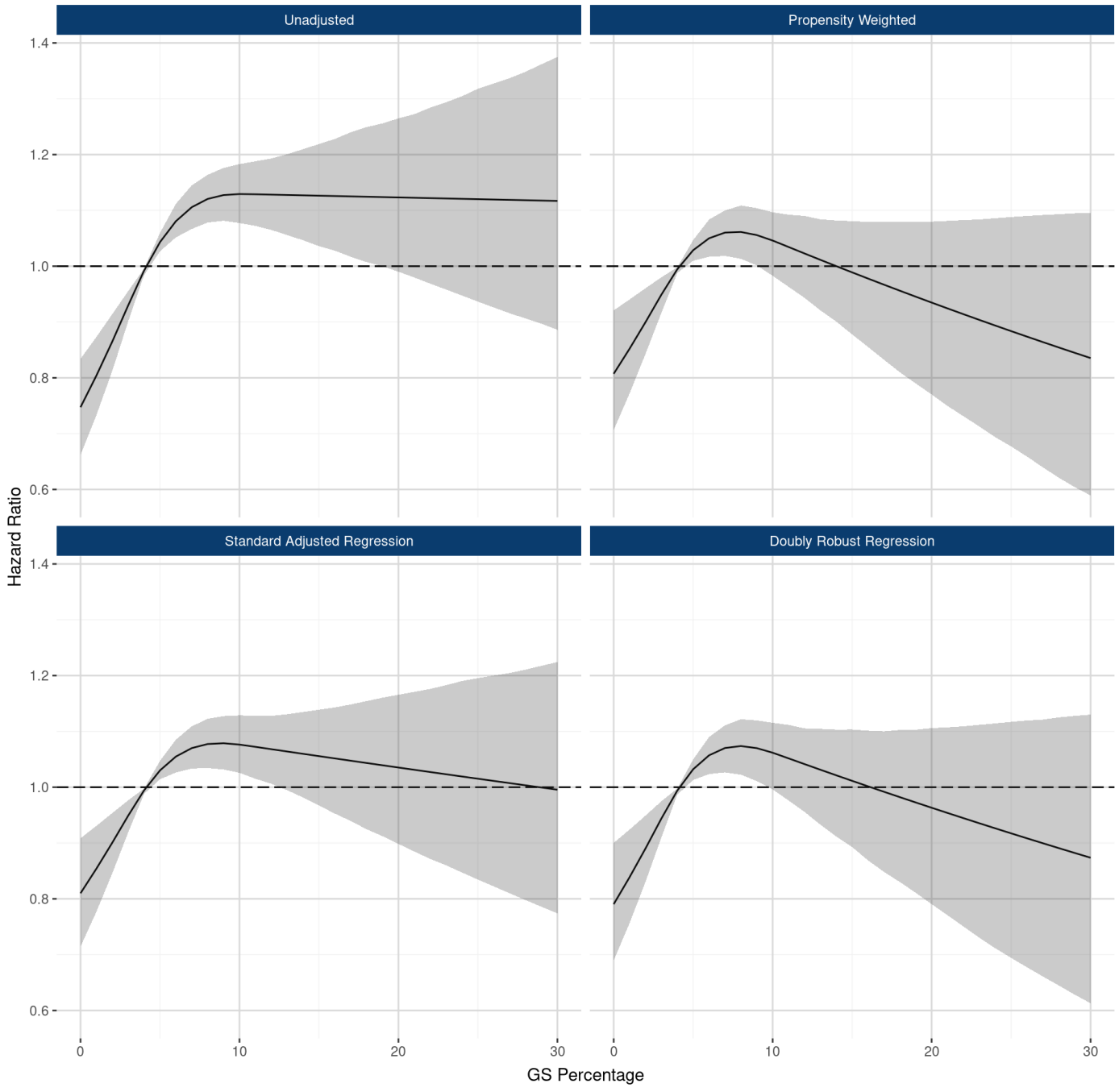


Figure S-9. Ten-Year Kaplan-Meier Death-Censored Graft Survival by Interstitial Fibrosis

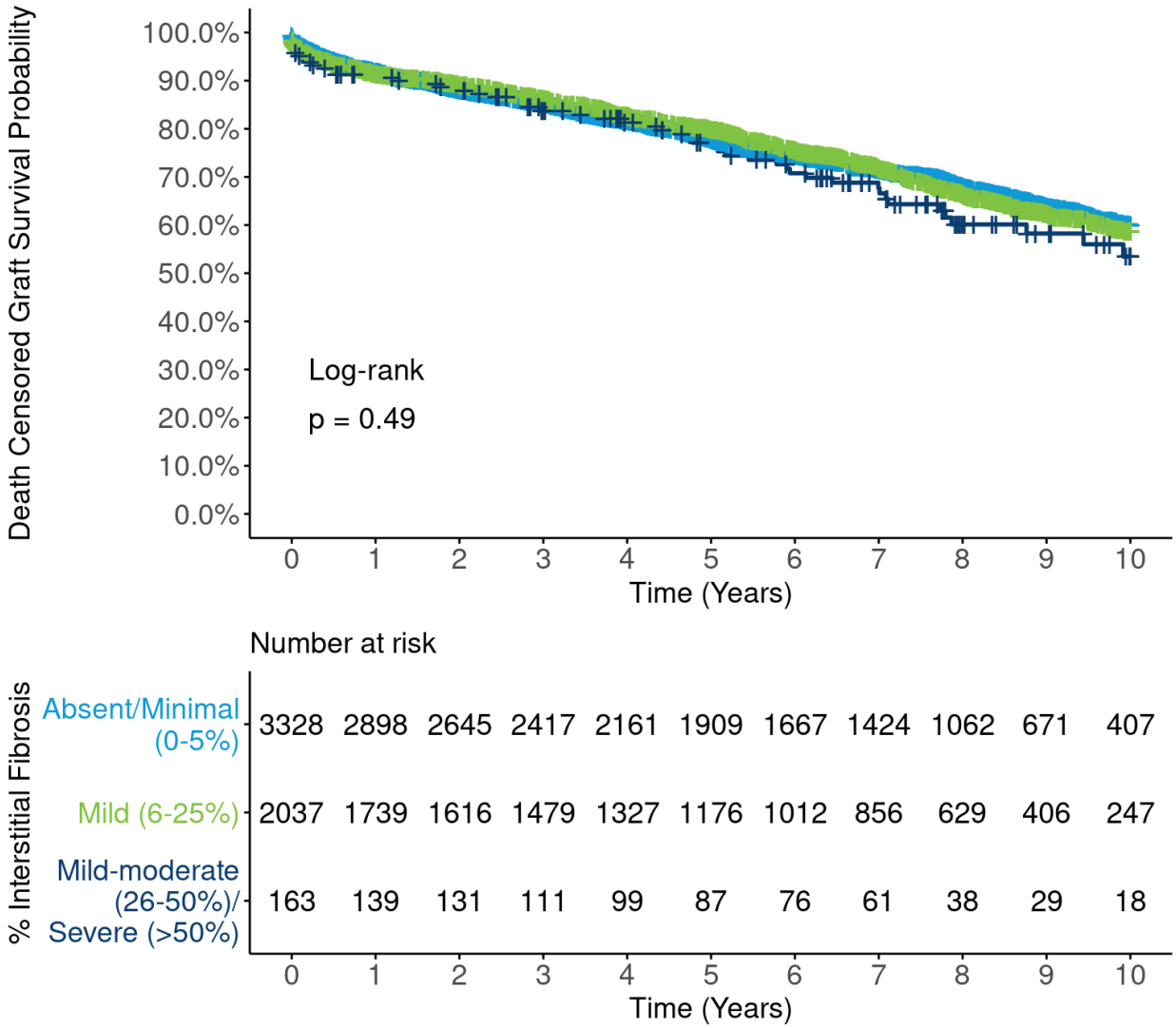


Figure S-10. Ten-Year Kaplan-Meier Death-Censored Graft Survival by Vascular Changes

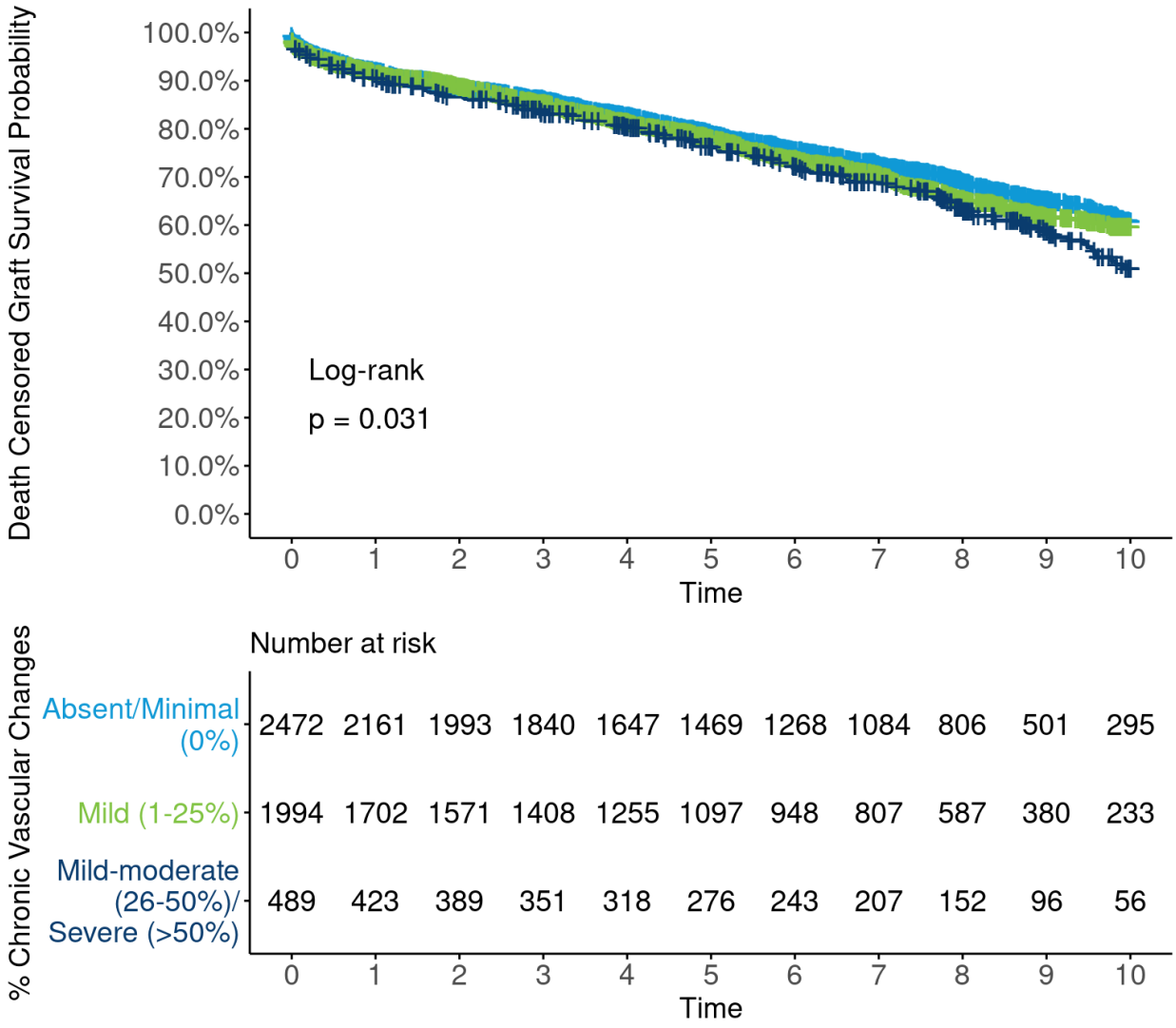


Figure S-11. Love Plot Showing Covariate Balance Across 3-Level Glomerulosclerosis after Propensity Score Inverse Probability Weighting

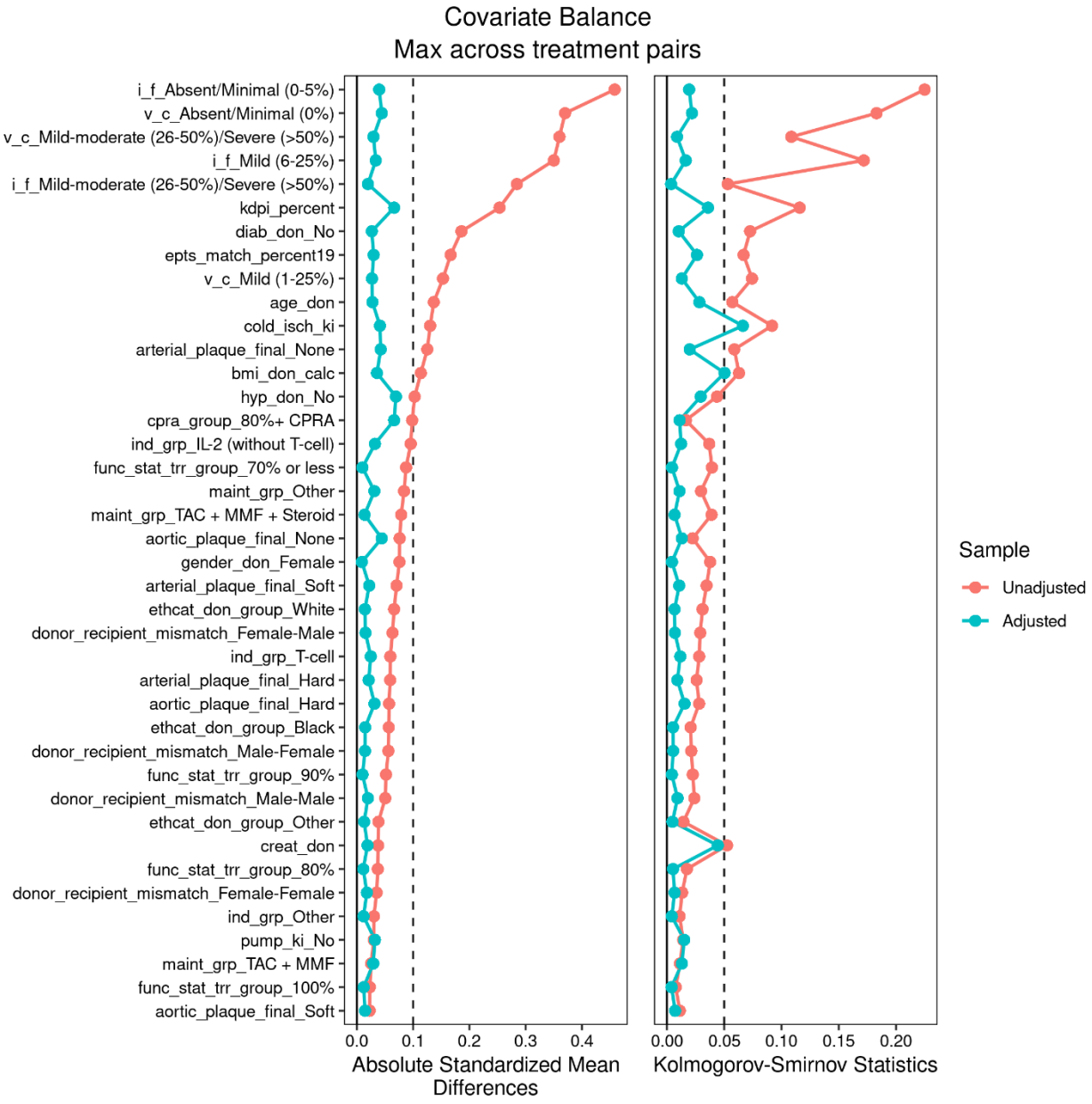


Figure S-12. Love Plot Showing Covariate Balance Across 3-Level Interstitial Fibrosis after Propensity Score Inverse Probability Weighting

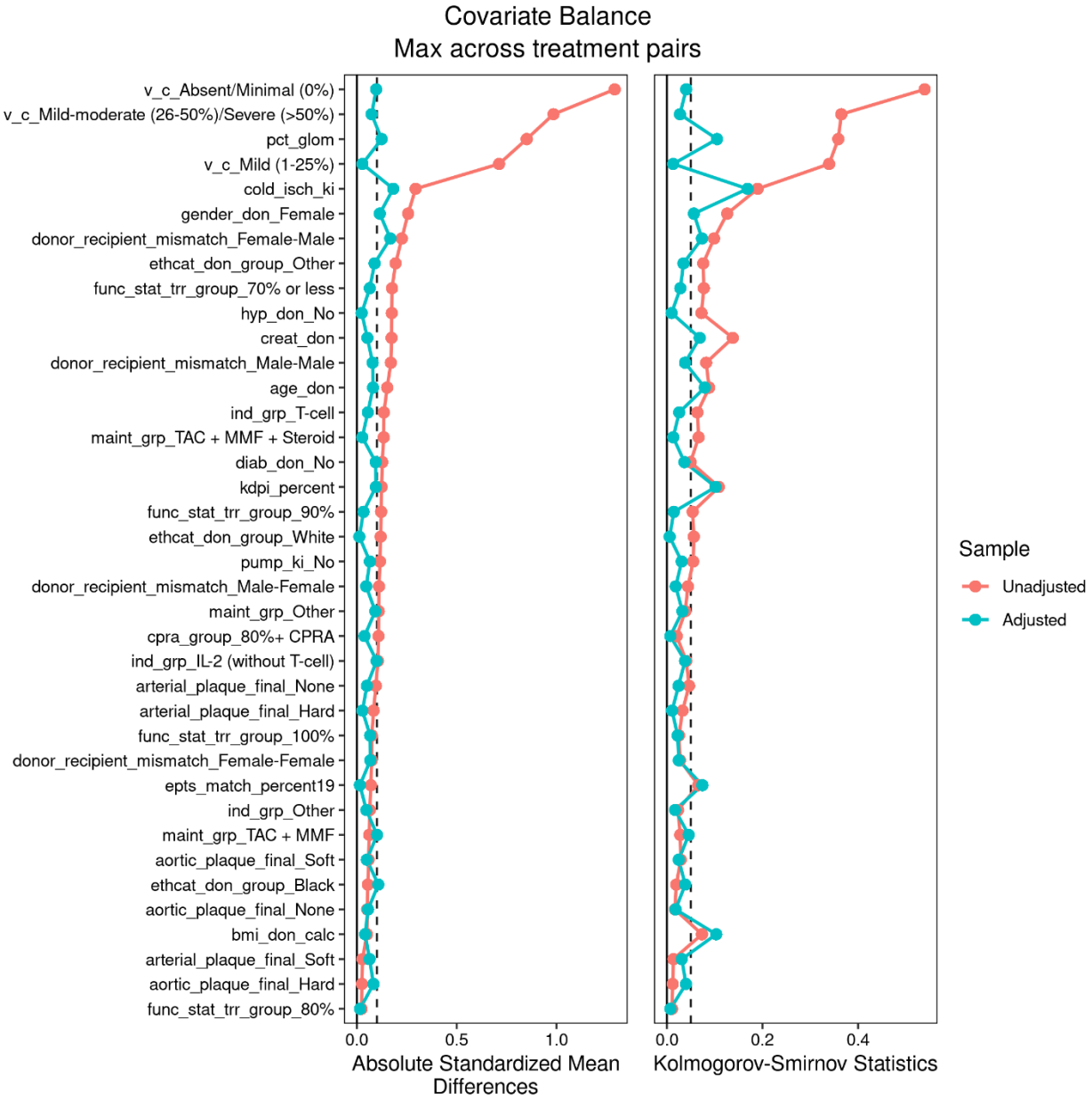


Figure S-13. Love Plot Showing Covariate Balance Across 3-Level Vascular Changes after Propensity Score Inverse Probability Weighting

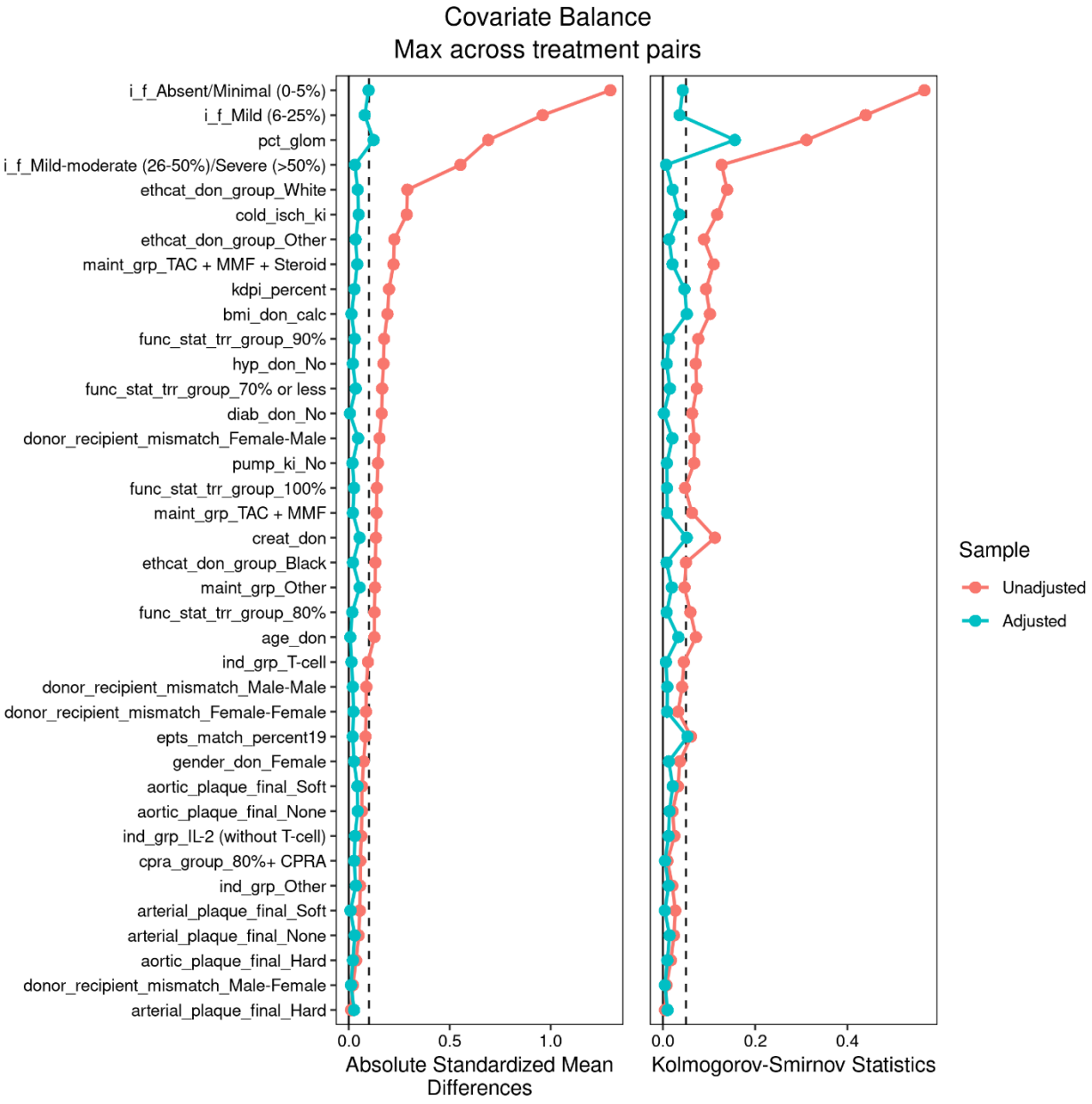
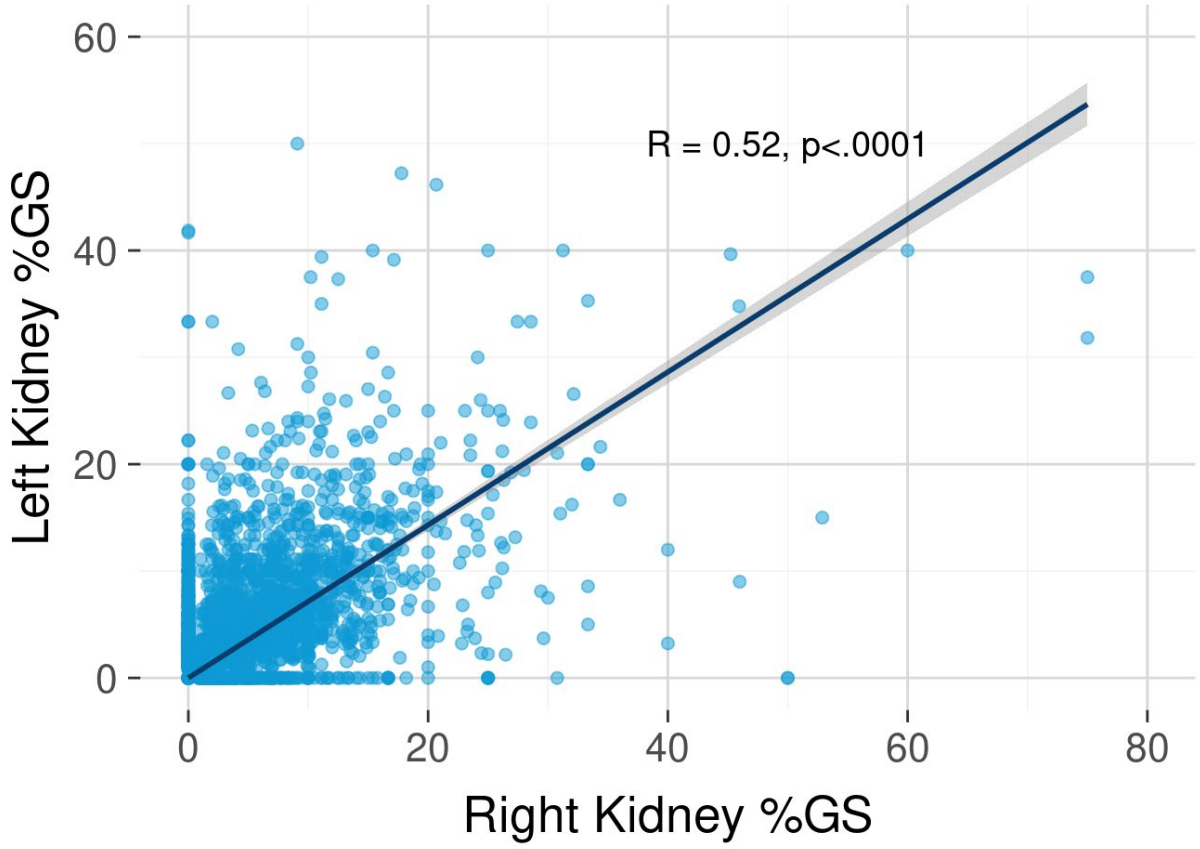
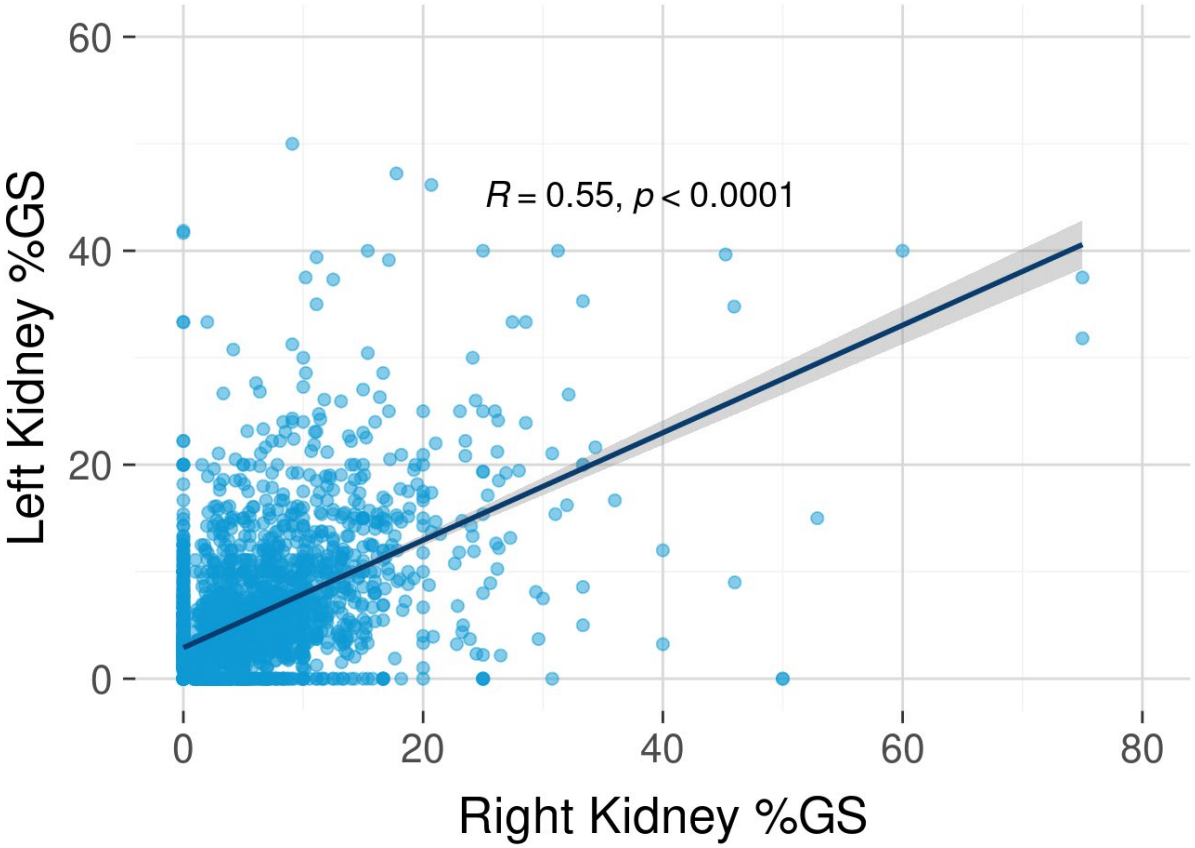


Figure S-14. Correlation between Left vs. Right Kidney Glomerulosclerosis in the Same Donor




60
40
20
0
Left Kidney %GS
R = 0.55, p < 0.0001
0
20
40
60
80
Right Kidney %GS

Supplementary Table S-1. Associations between Glomerulosclerosis and Modeled Covariates, 2008-2012 Biopsied ECD Kidney Transplants

	Glomerulosclerosis					
	0-5% (N=3617)	6-10% (N=1322)	11-15% (N=592)	16-20% (N=247)	21%+ (N=219)	p value
Donor Age						0.0007[1]
N	3617	1322	592	247	219	
Missing	0	0	0	0	0	
Mean (SD)	59.4 (5.8)	60.2 (6.1)	60.2 (6.2)	59.5 (6.0)	59.9 (6.3)	
KDPI						<0.0001[1]
N	3584	1308	585	242	218	
Missing	33	14	7	5	1	
Mean (SD)	80.7 (11.4)	82.7 (11.1)	83.9 (10.4)	82.7 (10.9)	83.7 (10.7)	
Donor BMI						0.0043[1]
N	3610	1320	592	247	219	
Missing	7	2	0	0	0	
Mean (SD)	28.9 (6.4)	29.2 (6.4)	29.3 (6.6)	30.3 (6.9)	29.7 (7.2)	
Donor Gender						0.1132[2]
Female	1648 (45.6%)	643 (48.6%)	297 (50.2%)	116 (47.0%)	109 (49.8%)	
Male	1969 (54.4%)	679 (51.4%)	295 (49.8%)	131 (53.0%)	110 (50.2%)	
Donor Terminal Creatinine						0.0391[1]
N	3617	1322	592	247	219	
Missing	0	0	0	0	0	
Mean (SD)	1.1 (0.9)	1.1 (0.6)	1.1 (0.5)	1.2 (0.6)	1.1 (0.5)	
Donor Race/Ethnicity						0.3327[2]
White	2468 (68.2%)	890 (67.3%)	370 (62.5%)	168 (68.0%)	151 (68.9%)	

	Glomerulosclerosis					
	0-5% (N=3617)	6-10% (N=1322)	11-15% (N=592)	16-20% (N=247)	21%+ (N=219)	p value
Black	562 (15.5%)	200 (15.1%)	111 (18.8%)	39 (15.8%)	32 (14.6%)	
Other	587 (16.2%)	232 (17.5%)	111 (18.8%)	40 (16.2%)	36 (16.4%)	
Donor History of Hypertension						0.0086[2]
Missing	13	8	4	4	0	
Yes	2691 (74.7%)	986 (75.0%)	455 (77.4%)	188 (77.4%)	186 (84.9%)	
No	913 (25.3%)	328 (25.0%)	133 (22.6%)	55 (22.6%)	33 (15.1%)	
Donor Diabetes						<0.0001[2]
Missing	27	11	3	3	1	
Yes	544 (15.2%)	251 (19.1%)	120 (20.4%)	56 (23.0%)	60 (27.5%)	
No	3046 (84.8%)	1060 (80.9%)	469 (79.6%)	188 (77.0%)	158 (72.5%)	
Interstitial Fibrosis						<0.0001[2]
Missing	325	108	51	18	17	
Absent/Minimal (0-5%)	2226 (67.6%)	655 (54.0%)	254 (47.0%)	96 (41.9%)	60 (29.7%)	
Mild (6-25%)	1013 (30.8%)	523 (43.1%)	257 (47.5%)	124 (54.1%)	110 (54.5%)	
Mild-moderate (26-50%)/Severe (>50%)	53 (1.6%)	36 (3.0%)	30 (5.5%)	9 (3.9%)	32 (15.8%)	
Chronic Vascular Changes						<0.0001[2]
Missing	688	217	93	52	30	
Absent/Minimal (0%)	1648 (56.3%)	487 (44.1%)	192 (38.5%)	57 (29.2%)	57 (30.2%)	
Mild (1-25%)	1096 (37.4%)	486 (44.0%)	225 (45.1%)	101 (51.8%)	82 (43.4%)	
Mild-moderate (26-50%)/Severe (>50%)	185 (6.3%)	132 (11.9%)	82 (16.4%)	37 (19.0%)	50 (26.5%)	
Arterial Plaque						0.0007[2]
Missing	620	208	84	37	39	
Hard	496 (16.5%)	230 (20.6%)	108 (21.3%)	41 (19.5%)	37 (20.6%)	
Soft	1208 (40.3%)	438 (39.3%)	230 (45.3%)	91 (43.3%)	75 (41.7%)	
None	1293 (43.1%)	446 (40.0%)	170 (33.5%)	78 (37.1%)	68 (37.8%)	
Aortic Plaque						0.1240[2]

	Glomerulosclerosis					
	0-5% (N=3617)	6-10% (N=1322)	11-15% (N=592)	16-20% (N=247)	21%+ (N=219)	p value
Missing	411	121	50	21	22	
Hard	1116 (34.8%)	461 (38.4%)	209 (38.6%)	85 (37.6%)	78 (39.6%)	
Soft	1694 (52.8%)	613 (51.0%)	286 (52.8%)	117 (51.8%)	98 (49.7%)	
None	396 (12.4%)	127 (10.6%)	47 (8.7%)	24 (10.6%)	21 (10.7%)	
Recipient EPTS						<0.0001[1]
N	3587	1313	585	246	216	
Missing	30	9	7	1	3	
Mean (SD)	64.3 (25.8)	66.4 (24.3)	67.9 (25.4)	69.8 (24.0)	69.9 (23.0)	
Recipient Functional Status						0.2073[2]
Missing	90	30	8	5	7	
100%	449 (12.7%)	172 (13.3%)	76 (13.0%)	22 (9.1%)	27 (12.7%)	
90%	878 (24.9%)	326 (25.2%)	157 (26.9%)	61 (25.2%)	66 (31.1%)	
80%	1168 (33.1%)	423 (32.7%)	195 (33.4%)	86 (35.5%)	78 (36.8%)	
70% or less	1032 (29.3%)	371 (28.7%)	156 (26.7%)	73 (30.2%)	41 (19.3%)	
Recipient CPRA						0.0376[2]
<80% CPRA	3482 (96.3%)	1283 (97.0%)	576 (97.3%)	242 (98.0%)	218 (99.5%)	
80%+ CPRA	135 (3.7%)	39 (3.0%)	16 (2.7%)	5 (2.0%)	1 (0.5%)	
Recipient Immunosuppression Regimen						0.0528[2]
TAC + MMF + Steroid	2124 (58.7%)	744 (56.3%)	337 (56.9%)	136 (55.1%)	107 (48.9%)	
TAC + MMF	1023 (28.3%)	371 (28.1%)	163 (27.5%)	73 (29.6%)	73 (33.3%)	
Other	470 (13.0%)	207 (15.7%)	92 (15.5%)	38 (15.4%)	39 (17.8%)	
Recipient Induction Therapy						0.4117[2]
T-cell	2339 (64.7%)	858 (64.9%)	400 (67.6%)	165 (66.8%)	149 (68.0%)	
IL-2 (without T-cell)	692 (19.1%)	260 (19.7%)	96 (16.2%)	43 (17.4%)	30 (13.7%)	
Other	586 (16.2%)	204 (15.4%)	96 (16.2%)	39 (15.8%)	40 (18.3%)	
Cold Ischemic Time						0.0006[1]

	Glomerulosclerosis					
	0-5% (N=3617)	6-10% (N=1322)	11-15% (N=592)	16-20% (N=247)	21%+ (N=219)	p value
N	3542	1296	584	241	214	
Missing	75	26	8	6	5	
Mean (SD)	19.1 (9.2)	19.5 (9.9)	20.3 (10.0)	21.0 (8.6)	20.2 (10.0)	
Pumped by OPO or TXC						0.4836[2]
Yes	2376 (65.7%)	887 (67.1%)	386 (65.2%)	172 (69.6%)	152 (69.4%)	
No	1241 (34.3%)	435 (32.9%)	206 (34.8%)	75 (30.4%)	67 (30.6%)	
Donor-Recipient Mismatch						0.3096[2]
Female-Female	615 (17.0%)	227 (17.2%)	102 (17.2%)	50 (20.2%)	42 (19.2%)	
Female-Male	1033 (28.6%)	416 (31.5%)	195 (32.9%)	66 (26.7%)	67 (30.6%)	
Male-Female	679 (18.8%)	220 (16.6%)	106 (17.9%)	46 (18.6%)	32 (14.6%)	
Male-Male	1290 (35.7%)	459 (34.7%)	189 (31.9%)	85 (34.4%)	78 (35.6%)	

[1]Kruskal Wallis [2]Chi-Square

(report generated on 29APR2021)

Supplementary Table S-2. Associations between Interstitial Fibrosis and Modeled Covariates, 2008-2012 Biopsied ECD Kidney Transplants

	Interstitial Fibrosis			
	Absent/Minimal (0-5%) (N=3328)	Mild (6-25%) (N=2037)	Mild-moderate (26-50%)/Severe (>50%) (N=163)	p value
Donor Age				0.2348[1]
N	3328	2037	163	
Missing	0	0	0	
Mean (SD)	59.7 (6.0)	59.8 (5.9)	59.0 (5.2)	
KDPI				0.0205[1]
N	3289	2018	163	
Missing	39	19	0	
Mean (SD)	81.4 (11.4)	82.3 (11.0)	82.7 (9.7)	
Donor BMI				0.9589[1]
N	3323	2033	163	
Missing	5	4	0	
Mean (SD)	29.1 (6.5)	29.0 (6.4)	28.7 (6.1)	
Donor Gender				<0.0001[2]
Female	1645 (49.4%)	866 (42.5%)	60 (36.8%)	
Male	1683 (50.6%)	1171 (57.5%)	103 (63.2%)	
Donor Terminal Creatinine				<0.0001[1]
N	3328	2037	163	
Missing	0	0	0	
Mean (SD)	1.1 (0.6)	1.2 (0.7)	1.2 (0.5)	
Donor Race/Ethnicity				<0.0001[2]
White	2311 (69.4%)	1305 (64.1%)	104 (63.8%)	
Black	535 (16.1%)	308 (15.1%)	23 (14.1%)	
Other	482 (14.5%)	424 (20.8%)	36 (22.1%)	
Donor History of Hypertension				0.0844[2]

	Interstitial Fibrosis			
	Absent/Minimal (0-5%) (N=3328)	Mild (6-25%) (N=2037)	Mild-moderate (26-50%)/Severe (>50%) (N=163)	p value
Missing	16	13	0	
Yes	2484 (75.0%)	1543 (76.2%)	134 (82.2%)	
No	828 (25.0%)	481 (23.8%)	29 (17.8%)	
Donor Diabetes				0.2486[2]
Missing	33	10	0	
Yes	561 (17.0%)	351 (17.3%)	36 (22.1%)	
No	2734 (83.0%)	1676 (82.7%)	127 (77.9%)	
Percent Glomerulosclerosis				<0.0001[1]
N	3291	2027	160	
Missing	37	10	3	
Mean (SD)	4.7 (5.8)	7.6 (7.7)	11.6 (9.9)	
Chronic Vascular Changes				<0.0001[2]
Missing	585	168	14	
Absent/Minimal (0%)	1901 (69.3%)	445 (23.8%)	24 (16.1%)	
Mild (1-25%)	733 (26.7%)	1129 (60.4%)	62 (41.6%)	
Mild-moderate (26-50%)/Severe (>50%)	109 (4.0%)	295 (15.8%)	63 (42.3%)	
Arterial Plaque				0.1600[2]
Missing	537	363	21	
Hard	488 (17.5%)	322 (19.2%)	31 (21.8%)	
Soft	1122 (40.2%)	700 (41.8%)	55 (38.7%)	
None	1181 (42.3%)	652 (38.9%)	56 (39.4%)	
Aortic Plaque				0.5097[2]
Missing	361	175	20	
Hard	1072 (36.1%)	663 (35.6%)	57 (39.9%)	
Soft	1540 (51.9%)	997 (53.5%)	68 (47.6%)	
None	355 (12.0%)	202 (10.8%)	18 (12.6%)	

	Interstitial Fibrosis			
	Absent/Minimal (0-5%) (N=3328)	Mild (6-25%) (N=2037)	Mild-moderate (26-50%)/Severe (>50%) (N=163)	p value
Recipient EPTS				0.0277[1]
N	3295	2026	162	
Missing	33	11	1	
Mean (SD)	64.9 (25.4)	66.8 (24.9)	65.7 (25.5)	
Recipient Functional Status				<0.0001[2]
Missing	83	34	0	
100%	378 (11.6%)	286 (14.3%)	23 (14.1%)	
90%	763 (23.5%)	583 (29.1%)	47 (28.8%)	
80%	1086 (33.5%)	666 (33.3%)	53 (32.5%)	
70% or less	1018 (31.4%)	468 (23.4%)	40 (24.5%)	
Recipient CPRA				0.2002[2]
<80% CPRA	3210 (96.5%)	1979 (97.2%)	155 (95.1%)	
80%+ CPRA	118 (3.5%)	58 (2.8%)	8 (4.9%)	
Recipient Immunosuppresion Regimen				<0.0001[2]
TAC + MMF + Steroid	1982 (59.6%)	1078 (52.9%)	93 (57.1%)	
TAC + MMF	925 (27.8%)	623 (30.6%)	46 (28.2%)	
Other	421 (12.7%)	336 (16.5%)	24 (14.7%)	
Recipient Induction Therapy				0.0310[2]
T-cell	2204 (66.2%)	1282 (62.9%)	113 (69.3%)	
IL-2 (without T-cell)	578 (17.4%)	420 (20.6%)	27 (16.6%)	
Other	546 (16.4%)	335 (16.4%)	23 (14.1%)	
Cold Ischemic Time				<0.0001[1]
N	3252	2009	157	
Missing	76	28	6	
Mean (SD)	18.6 (8.5)	20.3 (9.5)	21.1 (8.8)	
Pumped by OPO or TXC				0.3461[2]

	Interstitial Fibrosis			
	Absent/Minimal (0-5%) (N=3328)	Mild (6-25%) (N=2037)	Mild-moderate (26-50%)/Severe (>50%) (N=163)	p value
Yes	2225 (66.9%)	1358 (66.7%)	100 (61.3%)	
No	1103 (33.1%)	679 (33.3%)	63 (38.7%)	
Donor-Recipient Mismatch				<0.0001[2]
Female-Female	602 (18.1%)	333 (16.3%)	25 (15.3%)	
Female-Male	1043 (31.3%)	533 (26.2%)	35 (21.5%)	
Male-Female	568 (17.1%)	415 (20.4%)	35 (21.5%)	
Male-Male	1115 (33.5%)	756 (37.1%)	68 (41.7%)	

(report generated on 29APR2021)
[1]Kruskal Wallis [2]Chi-Square

Supplementary Table S-3. Associations between Vascular Changes and Modeled Covariates, 2008-2012 Biopsied ECD Kidney Transplants

	Chronic Vascular Changes			
	Absent/Minimal (0%) (N=2472)	Mild (1-25%) (N=1994)	Mild-moderate (26-50%)/Severe (>50%) (N=489)	p value
Donor Age				0.0038[1]
N	2472	1994	489	
Missing	0	0	0	
Mean (SD)	59.4 (5.9)	59.9 (5.9)	59.2 (6.0)	
KDPI				<0.0001[1]
N	2440	1970	487	
Missing	32	24	2	
Mean (SD)	80.7 (11.5)	82.8 (10.9)	83.0 (11.0)	
Donor BMI				0.0009[1]
N	2466	1991	489	
Missing	6	3	0	
Mean (SD)	28.8 (6.2)	29.0 (6.4)	30.1 (7.1)	
Donor Gender				0.0814[2]
Female	1198 (48.5%)	906 (45.4%)	219 (44.8%)	
Male	1274 (51.5%)	1088 (54.6%)	270 (55.2%)	
Donor Terminal Creatinine				<0.0001[1]
N	2472	1994	489	
Missing	0	0	0	
Mean (SD)	1.1 (0.6)	1.2 (0.8)	1.2 (0.5)	
Donor Race/Ethnicity				<0.0001[2]
White	1724 (69.7%)	1261 (63.2%)	273 (55.8%)	
Black	377 (15.3%)	338 (17.0%)	99 (20.2%)	
Other	371 (15.0%)	395 (19.8%)	117 (23.9%)	
Donor History of Hypertension				0.0038[2]

Chronic Vascular Changes				
	Absent/Minimal (0%) (N=2472)	Mild (1-25%) (N=1994)	Mild-moderate (26-50%)/Severe (>50%) (N=489)	p value
Missing	15 (.%)	12 (.%)	1 (.%)	
Yes	1846 (75.1%)	1510 (76.2%)	401 (82.2%)	
No	611 (24.9%)	472 (23.8%)	87 (17.8%)	
Donor Diabetes				0.0007[2]
Missing	22 (.%)	18 (.%)	1 (.%)	
Yes	382 (15.6%)	364 (18.4%)	108 (22.1%)	
No	2068 (84.4%)	1612 (81.6%)	380 (77.9%)	
Percent Glomerulosclerosis				<0.0001[1]
N	2441	1990	486	
Missing	31	4	3	
Mean (SD)	4.8 (6.0)	6.7 (6.7)	9.9 (9.1)	
Interstitial Fibrosis				<0.0001[2]
Missing	102 (.%)	70 (.%)	22 (.%)	
Absent/Minimal (0-5%)	1901 (80.2%)	733 (38.1%)	109 (23.3%)	
Mild (6-25%)	445 (18.8%)	1129 (58.7%)	295 (63.2%)	
Mild-moderate (26-50%)/Severe (>50%)	24 (1.0%)	62 (3.2%)	63 (13.5%)	
Arterial Plaque				0.6849[2]
Missing	298 (.%)	422 (.%)	77 (.%)	
Hard	399 (18.4%)	291 (18.5%)	77 (18.7%)	
Soft	900 (41.4%)	637 (40.5%)	182 (44.2%)	
None	875 (40.2%)	644 (41.0%)	153 (37.1%)	
Aortic Plaque				0.2800[2]
Missing	233 (.%)	193 (.%)	42 (.%)	
Hard	807 (36.0%)	645 (35.8%)	155 (34.7%)	
Soft	1145 (51.1%)	963 (53.5%)	239 (53.5%)	
None	287 (12.8%)	193 (10.7%)	53 (11.9%)	

	Chronic Vascular Changes			
	Absent/Minimal (0%) (N=2472)	Mild (1-25%) (N=1994)	Mild-moderate (26-50%)/Severe (>50%) (N=489)	p value
Recipient EPTS				0.0181[1]
N	2451	1976	488	
Missing	21	18	1	
Mean (SD)	64.9 (25.4)	66.9 (25.1)	65.2 (25.0)	
Recipient Functional Status				<0.0001[2]
Missing	54 (.%)	34 (.%)	7 (.%)	
100%	266 (11.0%)	284 (14.5%)	76 (15.8%)	
90%	514 (21.3%)	576 (29.4%)	135 (28.0%)	
80%	878 (36.3%)	589 (30.1%)	155 (32.2%)	
70% or less	760 (31.4%)	511 (26.1%)	116 (24.1%)	
Recipient CPRA				0.1549[2]
<80% CPRA	2387 (96.6%)	1945 (97.5%)	473 (96.7%)	
80%+ CPRA	85 (3.4%)	49 (2.5%)	16 (3.3%)	
Recipient Immunosuppresion Regimen				<0.0001[2]
TAC + MMF + Steroid	1480 (59.9%)	1078 (54.1%)	239 (48.9%)	
TAC + MMF	653 (26.4%)	628 (31.5%)	160 (32.7%)	
Other	339 (13.7%)	288 (14.4%)	90 (18.4%)	
Recipient Induction Therapy				0.4226[2]
T-cell	1634 (66.1%)	1294 (64.9%)	301 (61.6%)	
IL-2 (without T-cell)	479 (19.4%)	396 (19.9%)	107 (21.9%)	
Other	359 (14.5%)	304 (15.2%)	81 (16.6%)	
Cold Ischemic Time				<0.0001[1]
N	2409	1959	483	
Missing	63	35	6	
Mean (SD)	18.7 (8.9)	20.7 (9.7)	21.6 (10.8)	
Pumped by OPO or TXC				<0.0001[2]

	Chronic Vascular Changes			
	Absent/Minimal (0%) (N=2472)	Mild (1-25%) (N=1994)	Mild-moderate (26-50%)/Severe (>50%) (N=489)	p value
Yes	1574 (63.7%)	1405 (70.5%)	323 (66.1%)	
No	898 (36.3%)	589 (29.5%)	166 (33.9%)	
Donor-Recipient Mismatch				0.0135[2]
Female-Female	428 (17.3%)	342 (17.2%)	100 (20.4%)	
Female-Male	770 (31.1%)	564 (28.3%)	119 (24.3%)	
Male-Female	462 (18.7%)	357 (17.9%)	89 (18.2%)	
Male-Male	812 (32.8%)	731 (36.7%)	181 (37.0%)	

(report generated on 29APR2021)
[1]Kruskal Wallis [2]Chi-Square

Supplementary Table S-4. Association between Left vs. Right Kidney Interstitial Fibrosis in the Same Donor

	Right Kidney Interstitial Fibrosis		
Left Kidney Interstitial Fibrosis	**Absent/Minimal (0-5%)**	**Mild (6-25%)**	**Mild-moderate (26-50%)/Severe (>50%)**
Absent/Minimal (0-5%)	1315 (57.2%)	80 (3.5%)	3 (0.1%)
Mild (6-25%)	114 (5.0%)	704 (30.6%)	16 (0.7%)
Mild-moderate (26-50%)/Severe (>50%)	6 (0.3%)	27 (1.2%)	35 (1.5%)

Supplementary Table S-5. Association between Left vs. Right Kidney Vascular Changes in the Same Donor

	Right Kidney Chronic Vascular Changes		
Left Kidney Chronic Vascular Changes	**Absent/Minimal (0%)**	**Mild (1-25%)**	**Mild-moderate (26-50%)/Severe (>50%)**
Absent/Minimal (0%)	950 (46.7%)	73 (3.6%)	10 (0.5%)
Mild (1-25%)	88 (4.3%)	669 (32.9%)	42 (2.1%)
Mild-moderate (26-50%)/Severe (>50%)	11 (0.5%)	65 (3.2%)	128 (6.3%)

Supplementary Table S-6. Mate Kidney Analysis: Biopsy Finding Comparison for Transplanted vs. Discarded Kidneys from the Same Donor

	Transplanted Kidney %GS				
Discarded Kidney %GS	0-5%	6-10%	11-15%	16-20%	21%+
0-5%	248 (31.0%)	44 (5.5%)	17 (2.1%)	11 (1.4%)	6 (0.8%)
6-10%	67 (8.4%)	63 (7.9%)	25 (3.1%)	9 (1.1%)	6 (0.8%)
11-15%	25 (3.1%)	48 (6.0%)	17 (2.1%)	11 (1.4%)	7 (0.9%)
16-20%	16 (2.0%)	18 (2.2%)	19 (2.4%)	9 (1.1%)	2 (0.2%)
21%+	29 (3.6%)	36 (4.5%)	28 (3.5%)	17 (2.1%)	22 (2.8%)

Kappa Statistic: z=10.328, p<0.001

	Transplanted Kidney Interstitial Fibrosis		
Discarded Kidney Interstitial Fibrosis	Absent/Minimal (0-5%)	Mild (6-25%)	Mild-moderate (26-50%)/Severe (>50%)
Absent/Minimal (0-5%)	312 (43.5%)	32 (4.5%)	2 (0.3%)
Mild (6-25%)	54 (7.5%)	244 (34.0%)	11 (1.5%)
Mild-moderate (26-50%)/Severe (>50%)	9 (1.3%)	34 (4.7%)	20 (2.8%)

Kappa Statistic: z=19.464, p<0.001

	Transplanted Kidney Chronic Vascular Changes		
Discarded Kidney Chronic Vascular Changes	Absent/Minimal (0%)	Mild (1-25%)	Mild-moderate (26-50%)/Severe (>50%)
Absent/Minimal (0%)	239 (37.1%)	27 (4.2%)	4 (0.6%)
Mild (1-25%)	31 (4.8%)	221 (34.3%)	15 (2.3%)
Mild-moderate (26-50%)/Severe (>50%)	9 (1.4%)	34 (5.3%)	64 (9.9%)

Kappa Statistic: z=22.382, p<0.001

Supplementary Table S-7. Number of Glomeruli Observed and Glomerulosclerosis by Biopsy Sample Type

	Number of Glomeruli Observed				
	0-24	25-49	50-74	75-100	100+
Needle / Core	227 (28.2%)	343 (42.6%)	164 (20.4%)	53 (6.6%)	18 (2.2%)
Unknown	642 (18.8%)	1301 (38.1%)	855 (25.0%)	332 (9.7%)	271 (7.9%)
Wedge	247 (13.9%)	557 (31.4%)	504 (28.4%)	240 (13.5%)	223 (12.6%)

	Glomerulosclerosis				
	0-5%	6-10%	11-15%	16-20%	21%+
Needle / Core	454 (56.4%)	167 (20.7%)	88 (10.9%)	46 (5.7%)	50 (6.2%)
Unknown	2151 (62.9%)	734 (21.5%)	308 (9.0%)	119 (3.5%)	106 (3.1%)
Wedge	1012 (57.0%)	421 (23.7%)	196 (11.0%)	82 (4.6%)	63 (3.6%)

The 20 cases with GS reported but not the number of glomeruli were excluded from the top table.

Modified STROBE Statement—checklist of items that should be included in reports of observational studies (Cohort/Cross-sectional and case-control studies)

	Item No	Recommendation	Authors' Statement
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	(abstract) "we applied causal inference methods in a Cox regression framework"
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	(abstract) Hazard ratios and confidence intervals are provided, "after adjusting for potentially confounding donor and recipient variables"
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Intro describes conflicting findings in the literature relative to our specific objectives
Objectives	3	State specific objectives, including any prespecified hypotheses	(intro) "this study seeks to estimate the degree to which the three central biopsy compartments (glomerulosclerosis, interstitial fibrosis, and vascular changes) are independently associated with long term outcomes above and beyond standard clinical and demographic factors."
Methods			
Study design	4	Present key elements of study design early in the paper	The intro articulates our rationale for applying advanced causal inference methods instead of relying on the traditional multivariable regression approach.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	U.S., kidneys recovered for transplant 2000-2012, recipients followed for up to 10 years, as explained in Methods.

Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Cohort study, as described in Methods, CONSORT diagram (figure 1), and follow-up summary (Table 1).
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	All-cause and death-censored graft survival, as detailed in methods. Three exposure variables (GS, IF, VC) clearly called out. Potential confounders evaluated explained in Methods; confounders adjusted for shown in Tables S-1, S-2, and S-3. The study conserved sample size/power for main effect estimation; effect modification was out of scope.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement).	The OPTN database is well characterized. Two citations are provided with further details about this widely used registry.
Bias	9	Describe any efforts to address potential sources of bias	Efforts to reduce selection bias associated with the decision to perform a "for-cause" biopsy, vis-à-vis a routine biopsy, are extensively explained. Other potential sources of bias, such as selection bias due to decisions to accept vs discard kidneys and unmeasured confounding, are also explained as limitations.
Study size	10	Explain how the study size was arrived at (if applicable)	100% of ECD transplants from 2008-2012 with biopsy data were included. This cohort was chosen to allow

			approximately 10 years of follow-up. Transplants prior to 2008 were not included due, in part, to lower rates of biopsy data completeness, as well as manual data entry budgetary considerations.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	The parameterization of glomerulosclerosis, as both a continuous and categorical variable, is explained extensively.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	The intro and methods sections articulate our rationale for applying advanced causal inference methods instead of relying on the traditional multivariable regression approach, which relies on stronger assumptions in a way that is often underappreciated by researchers.
		(*b*) Describe any methods used to examine subgroups and interactions	The study conserved sample size/power for main effect estimation; effect modification was out of scope and of limited potentially utility, due to incomplete reporting of variables such as sample type (wedge vs. needle).
		(*c*) Explain how missing data were addressed	Conditional imputation using MICE is explained in Methods and shown in the statistical process flow (Figure S-2). If statistical inference were to be based on imputation methods, we would have used multiple imputation. However, since we used the bootstrap procedure to characterize statistical uncertainty in the entire analytical process, we used single imputation instead.
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	We found median follow-up times among non-failed transplants to exceed 8 years, and the reverse Kaplan-Meier estimates of median censoring time (the

		Case-control study—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	analytically preferred approach for quantifying length of follow-up) to exceed 9 years, suggesting minimal loss-to-follow-up in our study, with respect to our aim of estimating survival up to 10 years post-transplant.
		(*e*) Describe any sensitivity analyses	The main sensitivity analysis conducted and reported in the paper involves using Empirical Bayes ("shrinkage") estimation for more stable estimates of the % glomerulosclerosis. Results were similar to the primary analysis and are explained extensively in the paper and supplement. Also, our use of the E-value, a relatively new measure, provides a type of sensitivity analysis to help assess how much of a concern unmeasured confounding may or may not be in this particular study. Results suggest that
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	See CONSORT diagram (Figure 1).
		(c) **Use of a flow diagram**	CONSORT diagram (Figure 1) and statistical method process flow (Figure S-2).
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Tables S-1, S-2, and S-3 include summary statistics of both exposures and confounders, and show the degree to which they are associated.

		(b) Indicate number of participants with missing data for each variable of interest	Included in Tables S-1, S-2, and S-3.
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Included in Table 1.
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Included in Table 1.
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*n/a*
		Cross-sectional study—Report numbers of outcome events or summary measures	*n/a*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Both unadjusted and adjusted (using 3 different methods) are provided for comparison, along with confidence intervals. Variables included for adjustment, as well as uncorrelated variables evaluated but ultimately not included, are described in detail.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Sensitivity analysis extensively described. Subgroup analysis and interaction effects were considered, and may be included in future work, but were out of scope at present.
Discussion			
Key results	18	Summarise key results with reference to study objectives	Description of results aligns with stated objective of estimating independent effects of the three biopsy exposure variables.

Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Limitations, including sample sizes, different types of bias, and unmeasured confounding, are discussed extensively. Our use of the E-value, a relatively new measure, aids in assessing the likelihood of unmeasured confounding materially affecting the study's key findings.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Caution is weaved into the discussion and limitations, particularly surrounding potential findings related to vascular changes that are hampered by small sample sizes at the most extreme level.
Generalisability	21	Discuss the generalisability (external validity) of the study results	Results are clearly framed as being generalizable only to transplants using kidneys from older, marginal donors. These are the kidneys that tend to be routinely biopsied and for which debate continues on whether, and how, biopsy results could possibly help improve utilization decisions, not harm them. Further research would be needed to assess generalizability to higher quality kidneys, which are biopsied sporadically and often "for-cause" in the U.S.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.