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Mortality and Kidney Transplantation Outcomes Among Hepatitis C Virus–Seropositive Maintenance Dialysis Patients: A Retrospective Cohort Study

Deirdre Sawinski, MD[1], **Kimberly A. Forde, MD, PhD**[2,3], **Vincent Lo Re III, MD, MSCE**[3,4], **David S. Goldberg, MD, MSCE**[2,3], **Jordana B. Cohen, MD, MSCE**[1], **Jayme E. Locke, MD, MPH**[5], **Roy D. Bloom, MD**[1], **Colleen Brensinger, MS**[3], **Joe Weldon, MBA**[6], **Justine Shults, PhD**[3,7], and **Peter P. Reese, MD, MSCE**[1,3]

[1.]Department of Medicine, Renal Electrolyte and Hypertension Division, University of Pennsylvania, Philadelphia PA

[2.]Department of Medicine, Division of Gastroenterology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

[3.]Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

[4.]Department of Medicine, Division of Infectious Diseases, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

[5.]Comprehensive Transplant Institute, University of Alabama at Birmingham, Birmingham AL

[6.]DaVita Clinical Research, Minneapolis, MN

[7.]Children's Hospital of Philadelphia, Philadelphia, PA

Abstract

Corresponding Author: Peter Reese, MD, MSCE, 917 Blockley Hall, 423 Guardian Drive, Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA 19104, peter.reese@uphs.upenn.edu, 215 900-3782.

Rationale & Objective: Hepatitis C virus (HCV) infection is common among maintenance dialysis patients. Few studies have examined both dialysis survival as well as transplantation outcomes for HCV-seropositive patients because registry datasets lack information on HCV serostatus.

Study design: Retrospective cohort study.

Setting and Participants: Adult long-term dialysis patients treated by a US national dialysis provider between 1/1/2004 – 12/31/2014.

Exposure: HCV antibody serostatus obtained as part of clinical data from a national dialysis provider.

Outcomes: Mortality on dialysis, entry onto the kidney transplant waiting list, kidney transplantation, and estimated survival benefit from kidney transplantation versus remaining on the waitlist.

Analytical approach: After linking clinical data with data from the Organ Procurement and Transplantation Network, Cox and cause-specific hazards regression were implemented to estimate the associations between HCV seropositivity and mortality as well as entry onto the kidney transplant waitlist. Cox regression was also used to estimate the survival benefit from transplantation versus dialysis among HCV-seropositive individuals.

Results: Among 442,171 dialysis patients, 31,624 (7.2%) were HCV seropositive. HCV seropositivity was associated with a small elevation in the rate of death (adjusted hazard ratio [aHR], 1.09; 95% CI, 1.07–1.11) and a substantially lower rate of entry onto the kidney transplant waitlist (sub-distribution hazard ratio [sHR], 0.67; 95% CI, 0.61 – 0.74). Once wait-listed, the kidney transplant rate was not different for HCV-seropositive (sHR 1.10; 95% CI, 0.96–1.27) versus HCV-seronegative patients. HCV-seropositive patients lived longer with transplantation (aHR at 3 years, 0.42; 95% CI, 0.27–0.63). Receiving an HCV-seropositive donor kidney provided a survival advantage at the 2-year post-transplantation timepoint compared to remaining on dialysis waiting for an HCV-negative kidney.

Limitations: No data on HCV viral load or liver biopsy.

Conclusions: HCV-seropositive patients experience reduced access to the kidney transplantation waitlist despite deriving a substantial survival benefit from transplantation. HCV-seropositive patients should consider foregoing HCV treatment while accepting kidneys from HCV-infected donors to facilitate transplant and prolong survival.

Introduction

Hepatitis C virus (HCV) prevalence in the general US population is approximately 1%,[1] while prevalence among hemodialysis patients is substantially higher, ranging between 3 –

14%.[2–4] In contemporary US practice, all dialysis patients are screened for HCV infection by testing for anti-HCV antibody and, more recently, HCV RNA, to confirm chronic infection. Historically, HCV infection has been associated with higher mortality rates in the dialysis population,[5,6] primarily due to an increased risk of hepatic decompensation[7] and cardiovascular disease.[8] Previous studies of dialysis patients with HCV infection have been limited by small sample sizes, limited comorbidity data, and/or an inability to account for transplantation events.

Transplantation is the ideal therapy for many patients with kidney failure but characterization of HCV-seropositive dialysis patients' outcomes on the kidney waitlist has been impeded by the fact that national registry data – including the Organ Procurement and Transplantation Network (OPTN) and the United States Renal Data Systems - do not include HCV serostatus for wait-listed patients. HCV-seropositive individuals undergo a more complex medical assessment that includes hepatology evaluation to be wait-listed; these additional steps may create barriers to transplantation.[9] If waiting-list registration challenges can be overcome, HCV-infected patients can reduce their time to transplantation by accepting kidneys from donors with HCV infection.[10] However, access to kidneys from HCV-infected donors is inconsistent because of geographic variations in HCV prevalence and center willingness to transplant these kidneys; in 2017, <50% of centers utilized HCV-infected kidneys.[11,12]

Irrespective of donor type, HCV-seropositive transplant recipients have diminished graft and post-transplantation survival compared to HCV-seronegative patients,[13] with higher rates of complications, including post-transplantation diabetes, glomerulonephritis, cirrhosis, and hepatocellular carcinoma. [14–17] While the availability of direct-acting antivirals (DAAs) has been hailed as a great advance for patients with HCV and emerging data[18] suggest a positive impact of DAAs on post-transplantation outcomes, clinical adoption has been slow; only 12.9% of kidney transplant recipients and 1.5% of dialysis patients have been treated for HCV, leaving most still at risk of infectious complications. Furthermore, economic decision analyses indicate that HCV treatment post-transplantation is preferred if HCV-infected kidneys are readily available.[19] Taken together, these data suggest that the majority of HCV-infected transplant candidates may remain untreated; understanding their barriers to transplantation and outcomes after wait-listing remain an important priority for the nephrology community.

We assembled a large, national cohort of maintenance dialysis patients with information about HCV serostatus, wait-listing, and kidney transplantation. We aimed to determine the association between HCV serostatus, dialysis survival, and transplant access. Among HCV-seropositive patients, we aimed to determine whether kidney transplantation offered a survival benefit versus remaining on the waitlist. We examined the impact of transplantation with an HCV-seropositive donor kidney on survival compared to waiting for a kidney from an HCV-negative donor.

Methods

Study Design and Data Sources

We performed a retrospective cohort study of adult (18 years) incident and prevalent patients receiving outpatient maintenance dialysis between January 1, 2004 and December 31, 2014 (the last date of follow-up) at US facilities managed by a large national dialysis provider (DaVita). DaVita operates more than 2500 dialysis units in 47 states, providing a broad national sample of dialysis patients. DaVita data include detailed information about treatment modality, dialysis access, administrative claims related to comorbidities (ICD-9 codes), and laboratory measurements, including HCV serostatus.[20,21] We excluded patients with indeterminate HCV serostatus and/or with HIV infection (which adversely affects transplant access).

DaVita clinical data were linked to data from the OPTN[22] using five identifiers: Social Security Number, date of birth, first name, last name, and sex. The OPTN data system includes data on all donors, wait-listed candidates, and transplant recipients in the US, submitted by the members of the OPTN, The Health Resources and Services Administration (HRSA), US Department of Health and Human Services, provides oversight to the activities of the OPTN contractor. Analyses were performed using a de-identified dataset. The protocol was approved by the University of Pennsylvania Institutional Review Board (#822070) and informed consent was not required due to use of de-identified data.

Primary Exposure

The primary exposure was HCV antibody serostatus, which was assessed by dialysis provider protocol by either enzyme immunoassay or recombinant immunoblot assay. Results were reported as "positive," "negative," or "indeterminate.

Outcomes Assessment

The primary outcomes were: a) mortality on dialysis, b) wait-listing for kidney transplant, c) kidney transplantation, and d) estimated survival benefit from kidney transplantation versus remaining on the waitlist. Secondary outcomes included delisting (waitlist removal). Mortality was ascertained by either the dialysis provider or the OPTN, through linkage to the Social Security Master Death file (Item S1).[21] Wait-listing and kidney transplantation events were ascertained from the OPTN.

Covariate Assessment

For analyses of dialysis mortality and access to the waitlist, covariates were obtained from the DaVita dataset during the 6 months before the index date: HCV serostatus, age, sex, kidney failure cause, initial dialysis modality, pre-observation dialysis exposure (any/none), primary insurance type, body mass index (kg/m^2), and median household income (estimated using zip codes and US census data; additional methods description in Item S1). Cardiovascular disease, diabetes mellitus, severe liver disease, and chronic obstructive pulmonary disease (COPD) were determined with ICD-9 codes (Item S2).[23–25] We also collected laboratory data, including serum hemoglobin, platelets, and albumin.

For time to transplantation and survival benefit analyses, OPTN covariates were primarily used and supplemented with DaVita data (e.g. HCV serostatus, laboratory values, several comorbidities) only when not available in the OPTN dataset. OPTN covariates included blood group, panel-reactive antibody, donor HCV status, and donor service area (DSA).

Statistical Analyses

Descriptive statistics.—Analyses were performed using Stata 14.0 (StataCorp LP, College Station, TX). Descriptive statistics were generated to compare baseline clinical and demographic characteristics between patients with and without HCV seropositivity. Nonparametric continuous variables were compared between groups using Wilcoxon rank-sum. Categorical and binary variables were compared using the chi-square test.

Dialysis mortality by HCV serostatus.—The index date was the first day of dialysis in a DaVita facility. We used multivariable Cox regression to determine adjusted hazard ratios (aHRs) for mortality, with censoring on the date of transfer to a non-DaVita dialysis unit, kidney transplantation, or end of follow-up.

Time to wait-listing by HCV serostatus.—The index date was the first day of dialysis in a DaVita facility. We fit multivariable Cox regression models for the outcome of wait-listing for kidney transplantation. We used the Fine-Gray method[26] to estimate cause-specific sub-distribution hazard ratios (sHRs) and treated death as a competing risk. Both models clustered on DSA. These analyses excluded individuals listed for multi-organ transplant or wait-listed before their first DaVita dialysis treatment. When an individual had multiple waitlist registrations during the observation period, we selected the earliest episode.

Time to kidney transplantation by HCV serostatus.—The index date was the day of addition to the transplant waitlist. We fit multivariable Cox models for time to transplantation, censoring for death, de-listing, or living donor transplantation. Additionally, we fit models using the Fine-Gray method[26] that treated death as well as de-listing as competing risks for transplantation. Both models clustered on DSA.

Survival benefit from kidney transplantation versus dialysis among HCV-seropositive patients.—The index date was the day of addition to the transplant waitlist. We examined survival benefit from kidney transplantation only among HCV-seropositive patients using Cox regression with kidney transplantation as a time-updated covariate; we included an indicator variable for time post-transplantation.[27] The hazard ratio for each time indicator variable represents the hazard for death during that period post-transplantaion versus remaining on the waiting list. We also examined whether the strategy of accepting a kidney from an HCV-seropositive donor provided a survival benefit compared to the strategy of remaining wait-listed and/or accepting a kidney from a donor without HCV infection.[28,29] Patients were censored for de-listing.

For all multivariable models, variables were selected *a priori* for inclusion based on clinical relevance and prior studies.[30–34] We confirmed the proportional hazards assumption by visual inspection of log-log plots and examination of Schoenfeld residuals. Variables not meeting the proportional hazards assumption were refit as categorical variables

(hemoglobin, albumin, platelets) or with an interaction with time (waitlist year in survival benefit analyses). We generated Lowess plots for non-normally distributed continuous covariates (such as age) to identify appropriate cut-points; these variables were categorized based on identified cut-points.

Missing data.—For all models, we conducted a complete case analysis. All covariates were <5% missing, with the exception of BMI at the start of dialysis (14.2% missing); this covariate was only included in supplemental models restricted to hemodialysis patients. We used multiple imputation to address missing data in supplemental analyses (Item S1).

Sensitivity analyses.—In recognition of the fact that patients can spontaneously clear HCV infection, yet remain antibody-positive,[35–37] we performed secondary analyses in which we randomly reassigned 30% of the HCV-seropositive cohort as HCV-seronegative. When sufficient laboratory data were available, we calculated the Fibrosis-4 (FIB-4) index, which is highly associated with severity of liver fibrosis (Item S1).[38–40] We also fit models that accounted for patient acceptance of HCV-seropositive organs.

Results

Patient Characteristics

We identified 442,171 adult maintenance dialysis patients with a defined HCV serostatus (Figure S1), among whom 410,547 were HCV-seronegative and 31,624 were HCV-seropositive (Table 1). HCV-seropositive dialysis patients were younger (median 56 versus 64 years, $P<0.001$) and more likely to be male (65.9% versus 54.4%, $P<0.001$) and African American (54% versus 29.1%, <0.001) than HCV-seronegative patients. HCV-seropositive patients were twice as likely to have Medicaid as their primary insurance (7.4% versus 3.3%, $P<0.001$). The majority of the cohort received in-center hemodialysis, with central venous catheters most often used for vascular access. Median serum albumin and platelet counts were lower among HCV-seropositive versus HCV-negative patients, but differences were not clinically meaningful.

Mortality

HCV-seropositivity was associated with an increased risk of death on dialysis (aHR, 1.09; 95% CI, 1.07–1.11; Tables S1 and S2). Median follow-up was 652 (IQR, 232–1339) days. Results were similar in secondary analyses limited to hemodialysis patients or including the FIB-4 index (Tables S3 – S5). The most commonly reported causes of death were cardiovascular disease (33% HCV-seropositive vs. 35.8% HCV-seronegative) and infection (8.5% HCV-seropositive vs. 7.7% HCV-seronegative); patient death was attributed to liver disease in 3.3% of the HCV seropositive cohort, compared to 0.6% in seronegative patients ($P<0.001$).

Wait-listing

After exclusions, we analyzed 410,804 patients (29,263 HCV-seropositive; 381,541 HCV-negative). Median time to wait-listing was 354 (IQR, 173–716) days in the HCV-seronegative cohort and 473 (IQR, 222–970) days in the HCV-seropositive cohort ($P<0.001$).

HCV-seropositivity was associated with a lower likelihood of wait-listing for kidney transplant (aHR, 0.67; 95% CI, 0.61–0.74; Tables S6 and S2), which remained consistent in models that accounted for death as a competing risk for wait-listing (sHR 0.67; 95% CI, 0.61–0.74; Table 2 and Figure 1a) and in secondary analyses (Tables S7 – S9).

Kidney transplantation

Of the 51,625 patients wait-listed, 16,490 HCV-seronegative and 1117 HCV-seropositive patients underwent kidney transplantation. Overall time to transplantation was not significantly different between the groups (507 days [IQR, 178–1010] for HCV-seronegative; 433 days [IQR, 134–920] for HCV-seropositive; p=0.629), but was significantly shorter for recipients of HCV-seropositive kidneys (251 [IQR, 82–604] days, P<0.001). In unadjusted and adjusted analyses, patient HCV-seropositivity was not significantly associated with the rate of transplantation (aHR, 1.11; 95% CI, 0.97–1.28; Tables S10 and S3). Results were consistent in secondary analyses (Tables S11 – S14) and when death or delisting were considered as competing risks. The most common reported causes of death among wait-listed and transplanted patients, independent of HCV serostatus, were cardiovascular disease, infection, and malignancy. Depleting induction was more common in the HCV-seronegative group (77% vs. 73.4%). The majority of patients overall were discharged on a tacrolimus-based immunosuppression.

Transplantation survival benefit

Among HCV-seropositive patients, kidney transplantation was associated with a decreased risk of death, compared to remaining on the waitlist, and this benefit was achieved by 9 months after transplantation (Figure 2a). By 3 years, the adjusted hazard of death associated with transplantation compared to remaining on the waiting list was 0.42 (95% CI 0.27–0.63; Table S15). Of the 1117 HCV-seropositive recipients, 394 received kidneys from HCV-seropositive donors and survival benefit with transplantation was independent of donor HCV serostatus (aHR for death at 3 years, 0.42 [95% CI 0.25–0.72] for kidneys from HCV-seronegative donors vs 0.52 [95% CI 0.30–0.93] for kidneys from HCV-seropositive donors; Figure 2b; Table S16).

To assess the strategy of accepting a HCV-seropositive kidney versus waiting for a HCV-seronegative kidney, we compared the survival benefit associated with accepting an HCV-seropositive donor versus outcomes for individuals who remained wait-listed and/or received an HCV-seronegative kidney. Accepting an HCV-seropositive donor organ provided a survival advantage at the 2-year post-transplantation compared to waiting for a kidney offer from a donor without HCV (Figure 2b).

Secondary analyses

Our results were confirmed in models using multiple imputation to account for missing data (Tables S17 – S19).

Discussion

In this national cohort, HCV-seropositive patients experienced a modest elevation in their risk of death on dialysis, but were 33% less likely to gain access to the kidney transplantation waiting list. However, among HCV-seropositive patients who were wait-listed, transplantation rates were similar to HCV-seronegative individuals, and kidney transplantation was associated with a lower risk of death compared to remaining wait-listed. For HCV-seropositive transplant candidates, accepting a kidney from an HCV-seropositive donor provided a survival advantage versus waiting for an uninfected organ.

HCV was only associated with a 9% increase in dialysis mortality. This finding is consistent with a contemporary report from the international Dialysis Outcomes and Practice Patterns Study (DOPPS) cohort,[7] but lower in magnitude than the hazard of death reported in older studies of US dialysis populations;[5,41] this difference may be due in part to improvements in dialysis care over time. In the DOPPS cohort, HCV-seropositive patients had only a modestly higher adjusted risk of hospitalization (HR, 1.09; 95% CI, 1.04–1.13) versus seronegative patients. However, this persistently elevated mortality for HCV-seropositive patients in our study and others should concern nephrologists, as these patients were younger and had fewer comorbid conditions than their HCV-seronegative counterparts, and would have been expected to have equivalent or better outcomes. Taken together, these findings highlight the need for interventions to improve the health of patients with HCV.

The fate of HCV-seropositive patients on the waitlist has been previously impossible to study on a national level due to limitations inherent in registry data. Our finding that HCV-seropositive patients in the US were much less likely to be wait-listed is a novel and troubling insight, especially since these patients were almost a decade younger than their HCV-seronegative counterparts. This finding is consistent with a study from France[42] that demonstrated that patients with "hepatic disease" were less likely to be wait-listed for transplantation (aHR, 0.34), but the authors did not specify if this population was limited to patients with HCV or included others with Hepatitis B virus. The reasons for this disparity are unclear. It is possible that HCV-seropositive patients are less likely to be referred for transplantation or wait-listed because providers overestimate the deleterious health effects of HCV, assuming it will undermine the usual benefits of transplantation. Rigorous performance oversight for transplant centers may also cause physicians to be reluctant to waitlist patients considered "high risk,"[43,44] such as those with HCV. At the patient level, the medical evaluation for transplant is complex. Patients with HCV have to contend with additional steps, including an assessment of liver fibrosis and potentially consideration of simultaneous liver-kidney transplantation.[9] Importantly, HCV-seropositive patients in our cohort were more likely to be African-American and had lower median household income; thus, merely curing their HCV infection may be insufficient to reverse their diminished access to transplantation. Candidates from racial/ethnic minorities or who have limited financial resources face challenges completing the transplant evaluation process, and HCV infection may exacerbate this disparity.[45,46] These findings should motivate efforts to identify and overcome the sources of these disparities in transplant access. HCV-seropositive patients may benefit from enhanced support in navigating the medical workup. Providers may also need education about post-transplantation outcomes for HCV-seropositive patients.

Despite the challenges in getting wait-listed, our study provides evidence for the survival benefit associated with kidney transplantation for HCV-seropositive individuals. Studies from the US and Canada[47–50] have reported a survival benefit beyond 6 months post-transplantation for HCV-seropositive patients, but these were limited by the relatively small number of patients, dependence on single center/organ procurement organization data and an inability to address the impact of HCV-infected donors. Our study extends their work by assessing outcomes on a national level and specifically addressing the contribution of donor HCV serology to outcomes. Demonstration of a survival benefit with transplantation for HCV-seropositive recipients is important in light of the decreased access to transplantation that they currently face; these results should motivate efforts to facilitate their listing.

Previous studies of the impact of donor HCV status on transplant outcomes have yielded conflicting results; registry data[51–54] suggest a negative impact on patient and allograft survival, while single and multi-center reports[55,9] found no differences. This study provides new evidence that transplantation with kidneys from HCV-infected donors is advantageous to HCV-seropositive patients.[51] Recipients of HCV-seropositive donor kidneys experienced shorter waiting times, and use of these kidneys was associated with better survival than remaining on dialysis to wait for a seronegative kidney. While this finding is similar to what has been shown with expanded criteria, high Kidney Donor Profile Index, and kidneys from donors with diabetes, the decision that we studied -- acceptance of HCV-infected kidneys -- is crucial for patients with HCV.[28,56,57] The opioid abuse epidemic has led to a dramatic increase in HCV-infected donors, and recent data suggest that outcomes using HCV-infected organs are excellent, yet not all centers transplant these organs.[12,58,59] Our findings should encourage all centers to utilize organs from HCV-infected donors to maximize the benefit for their listed HCV-seropositive patients. Furthermore, in light of the availability of HCV treatment regimens that can be administered to patients with ESRD, these data provide a clear rationale for providers and patients to forego HCV treatment while on dialysis in order to preserve the option of accepting an HCV-infected organ and accelerating transplantation (provided that HCV-infected organs are readily available in that area).[19,60]

This study advances the understanding of outcomes for HCV-seropositive patients with ESRD by leveraging a dataset from a large dialysis provider providing care in all 50 states and with linkage to the transplant registry, permitting for an analysis of their outcomes from dialysis through waitlisting and transplantation. These data demonstrate a clear disparity in access to the waiting list and provide a compelling clinical rationale, rather than an economic argument, for patients to postpone HCV therapy in the hopes of sooner transplantation with an HCV-infected organ.[19]

Our study has limitations. We only had HCV-antibody data and lacked information on HCV viral loads; therefore, we were unable to assess which patients spontaneously cleared their HCV infection or were treated. We cannot assess if any HCV infections were nosocomially acquired. However, because interferon-based therapy for HCV has limited effectiveness in this population and direct-acting antivirals were only approved in the year 2013 and not widely adopted in ESRD populations by 2014, it is very unlikely many patients were treated. [7] Sensitivity analyses that randomly reassigned 30% of the HCV-seropositive cohort to HCV-seronegative and revealed similar outcomes to the main analysis. We were also unable

to assess which patients may have had HBV co-infection, but our dialysis mortality estimates were similar to those reported in studies adjusting for HBV.[7] Another limitation is incomplete information regarding liver disease severity. Among individuals with sufficient data, we calculated the FIB-4 index, which predicts liver injury; results were consistent with the main analysis. Additionally, there are also center-level differences in the selection of patients for kidney-alone versus simultaneous liver-kidney transplantation; because we lack liver biopsy data we are unable to assess the specific impact of advanced liver disease on wait-listing rates, however inclusion of the FIB-4 index as a surrogate marker did not significantly alter our results. We excluded patients who were listed for simultaneous liver-kidney transplant as the selection practices for these patients are significantly different from kidney-alone transplant, which limits generalizability of our findings. We also acknowledge that decreased access to transplantation may be due to residual confounding – for example, some HCV-seropositive patients may have lower education or health literacy on average than other patients. We adjusted for socioeconomic status and insurance, but were unable to adjust for other factors such as medication nonadherence or substance abuse, which can jeopardize acceptance onto the transplant waitlist. Finally, as with any observational study, causation cannot be inferred.

In conclusion, this study provides important and comprehensive insights into outcomes for HCV-seropositive patients with ESRD on the spectrum from maintenance dialysis through kidney transplantation. HCV-seropositive patients are younger yet experience a slightly higher adjusted rate of death on dialysis. They have diminished access to the transplant waiting list, but those who are transplanted rapidly achieve a significant survival benefit. The survival benefit from kidney transplantation among HCV-seropositive patients suggests that removing barriers to wait-listing for this patient group should be a priority for providers. The benefit in accepting a HCV-infected organ over waiting for a HCV negative one should encourage patients to carefully consider post-transplantation HCV treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements:

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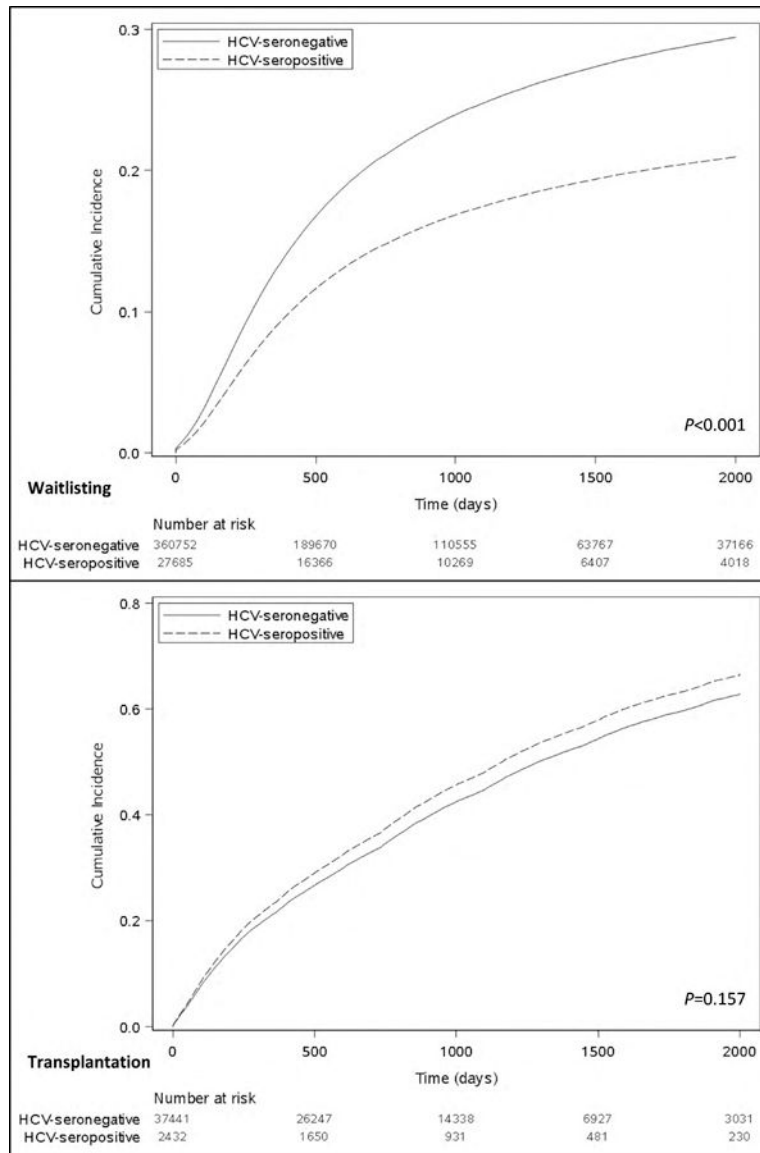
Figure 1a and 1b.
Cumulative incidence of a) waitlisting and b) transplantation, treating death as a competing risk in each case.
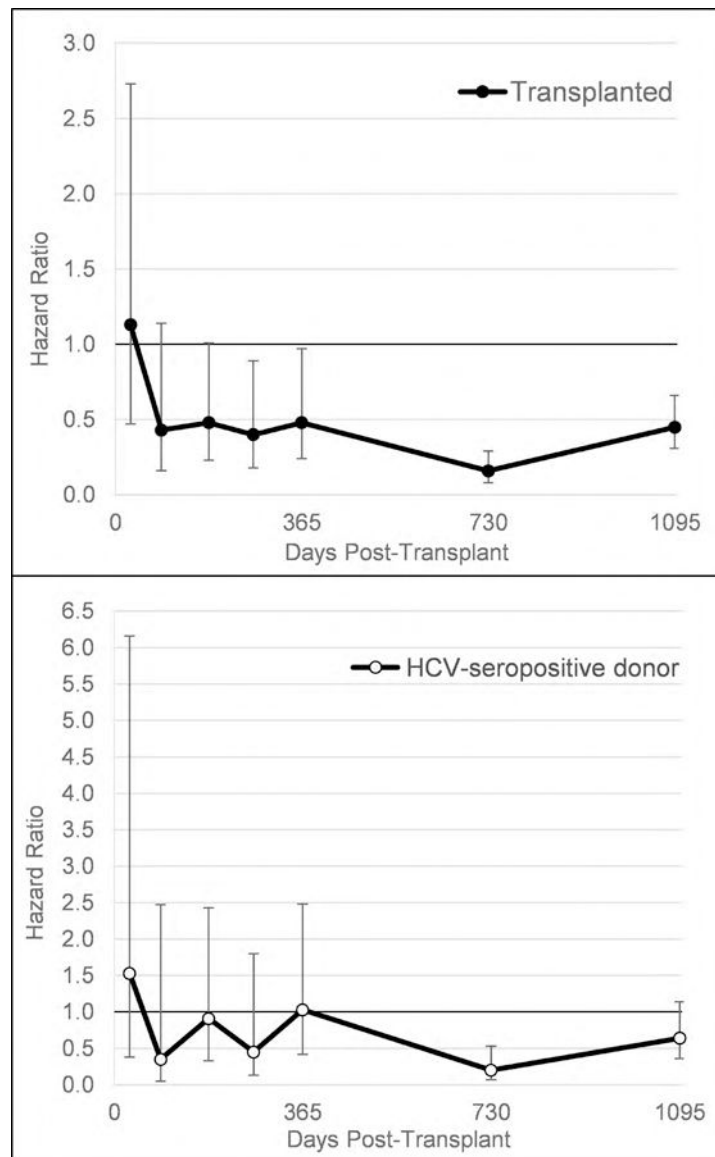
Figure 2a and 2b.
Hazard ratio for death among HCV-seropositive candidates associated with a) kidney transplantation compared to remaining on the waiting list, b) kidney transplantation with a HCV-seropositive kidney compared to the strategy of remaining on the waitlist and/or accepting a HCV-negative kidney*
* Models were time updated for transplantation and included age, gender, race, diabetes, cardiovascular disease, severe liver disease, insurance, income, panel reactive antibody, dialysis vintage, prior kidney transplant, body mass index, dialysis modality, year of waitlisting interacted with time, hemoglobin, platelets, and albumin.

Table 1.

Baseline characteristics of the cohort

	All Dialysis Patients			All Wait-listed Patients		
	HCV− (n=410,547)	HCV+ (n=31,624)	P value	HCV− (n=31,944)	HCV+ (n=2074)	P value
Age, y	64 (52–74)	56 (50–63)	<0.001	53 (42–62)	55 (49–60)	<0.001
Male sex	22,862 (54.4)	20,847 (65.9)	<0.001	19,492 (61)	1444 (69.6)	<0.001
Race			<0.001			<0.001
Caucasian	195,687 (47.7)	8732 (27.6)		11,471 (35.9)	517 (24.9)	
African-American	119,325 (29.1)	17,092 (54)		11,627 (36.4)	1171 (56.5)	
Asian	14,548 (3.5)	629 (1.9)		2183 (6.8)	59 (2.8)	
Latino	60,002 (14.6)	3853 (12.2)		5942 (18.6)	290 (14)	
Other	18,547 (4.5)	1161 (3.6)		721 (2.3)	37 (1.8)	
Missing	2438 (0.6)	157 (0.7)		0	0	
Cause of ESRD			<0.001			<0.001
DM	179,190 (43.6)	12,601 (39.9)		13,751 (43)	803 (38.7)	
HTN	111,782 (27.2)	10,175 (32.3)		8509 (26.6)	674 (32.5)	
GN	39,687 (9.7)	3307 (10.4)		4489 (14.1)	262 (12.6)	
PKD	7215 (1.7)	310 (0.9)		909 (2.8)	27 (1.3)	
Other	40,379 (9.8)	2837 (8.9)		2722 (8.5)	185 (8.9)	
Missing	32,294 (8)	2394 (7.6)		1564 (4.9)	123 (5.9)	
Any preobservation dialysis	348,637 (84.9)	27,913 (88.3)	<0.001	-	-	
Preobservation dialysis days	11 (5–173)	15 (6–465)	<0.001	-	-	
CVD	69,560 (16.9)	4580 (14.5)	<0.001	3863 (12.1)	238 (11.5)	0.4
DM	262,680 (64)	19,684 (62.2)	<0.001	19,617 (61.4)	1255 (60.5)	0.4
Liver disease	5003 (1.2)	2440 (7.7)	<0.001	351 (1.1)	150 (7.2)	<0.001
COPD	11,575 (2.8)	817 (2.6)	<0.001	604 (1.9)	35 (1.7)	0.5
BMI (kg/m^2)	27.2 (23.3–32.6)	25.5 (22.2–30.1)	<0.001	28.3 924.4–32.8)	26.9 (23.6–30.8)	<0.001
Insurance						
Medicare	245,292 (59.7)	18,093 (57.2)	<0.001	14,938 (46.7)	1104 (53.2)	<0.001
Medicaid	13,378 (3.3)	2326 (7.4)		1051 (3.3)	96 (4.6)	
Private	151,143 (36.8)	11,145 (35.2)		15,917 (49.9)	874 (42.1)	
Missing	734 (0.2)	60 (0.2)		50 (0.1)	1 (0.1)	
Initial access type						
AVF/AVG	174,492 (42.5)	14,684 (46.4)	<0.001	13,580 (42.5)	1021 (49.2)	<0.001
CVC	197,872 (48.2)	14,872 (47)		13,507 (42.3)	825 (39.8)	
PD catheter	31,366 (7.6)	1543 (4.9)		4367 (13.7)	194 (9.4)	
Other	4539 (1.2)	348 (1.1)		0	0	
Missing	2278 (0.5)	177 (0.6)		490 (1.5)	34 (1.6)	
Initial modality						

	All Dialysis Patients			**All Wait-listed Patients**		
	HCV− (n=410,547)	**HCV+ (n=31,624)**	**P value**	**HCV− (n=31,944)**	**HCV+ (n=2074)**	***P* value**
HD	381,142 (92.8)	30,159 (95.3)	<0.001	28,056 (87.8)	1878 (90.5)	0.002
Home HD	1306 (0.3)	86 (0.2)		132 (0.4)	10 (0.5)	
Nocturnal	575 (0.1)	42 (0.1)		90 (0.3)	5 (0.2)	
PD	27,421 (6.7)	1331 (4.3)		3663 (11.5)	181 (8.7)	
Missing	103 (0.1)	6 (0.1)				
annual income (US$)	47,625 (37,529–63,065)	45,835 (35,717–60,157)	<0.001	48,697 (38,052–64,234)	46,059 (35,134–60,230)	<0.001
FIB-4 Index						
Low	136,378 (33.2)	6650 (21)	<0.001	11,515 (36)	225 (10.8)	<0.001
Intermediate	74,968 (18.2)	5445 (17.2)		2680 (8.3)	128 (6.2)	
High	16,238 (3.9)	2253 (7.1)		213 (0.6)	30 (1.4)	
Missing	182,963 (44.7)	17,276 (54.7)		17,536 (55.1)	1691 (81.6)	
Albumin (g/dL)	3.6 (3.2–3.9)	3.5 (3–3.9)	<0.001	4 (3.7–4.2)	3.9 (3.6–4.1)	<0.001
Hb (g/dL)	10.4 (9.4–11.5)	10.5 (9.4–11.7)	<0.001	11.3 (10.5–12.2)	11.7 (10.8–12.5)	<0.001
Platelets x10^3/mm^3	233 (180–298)	218 (162–286)	<0.001	232 (188–287)	214 (168–269)	<0.001
PRA>80%	-	-	-	4669 (15)	293 (14.5)	0.8
Blood group						0.006
O	-	-	-	16,760 (52.5)	1076 (51.9)	
A	-	-	-	9164 (28.7)	538 (25.9)	
B	-	-	-	5117 (16)	385 (18.6)	
AB	-	-	-	903 (2.8)	75 (3.6)	

Continuous data given as median [interquartile range]; categorical data as count (percentage).

Abbreviations: HCV−, Hepatitis C virus seronegative; HCV+, HCV seropositive; IQR – Interquartile range; ESRD - end-stage renal disease; DM – Diabetes mellitus; HTN – hypertension; GN – glomerulonephritis; PKD – polycystic kidney disease; CVD – cardiovascular disease; COPD – chronic obstructive pulmonary disease; BMI – body mass index; AVF – arteriovenous fistula; AVG – arteriovenous graft; CVC – central venous catheter; PD – peritoneal dialysis; FIB-4 – Fibrosis-4 Index; PRA – panel reactive antibody; Hb, hemoglobin

Table 2.

Association of HCV serostatus with the outcome of wait-listing for kidney transplantation, in a multivariable model with clustering on donor service area

Characteristic	Death Censored (n=388,437)		Death as a Competing Risk (n=388,437)	
HCV-seropositive	0.67 (0.61–0.74)		0.67	0.61–0.74
Age				
<40 y	1.00 (reference)		1.00 (reference)	
40–70 y	0.56	0.53–0.59	0.51	0.48–0.54
>70 y	0.06	0.05–0.07	0.05	0.04–0.06
Male sex	1.33	1.30–1.37	1.33	1.30–1.37
Race				
Caucasian	1.00 (reference)		ref	ref
African American	0.85	0.79–0.92	0.96	0.89–1.03
Asian	1.30	1.06–1.59	1.49	1.25–1.78
Latino	0.80	0.62–1.02	0.92	0.73–1.16
Other	1.01	0.90–1.13	1.13	1.01–1.26
Dialysis Modality				
Hemodialysis	ref	ref	ref	ref
Home Hemodialysis	1.35	1.16–1.56	1.39	1.17–1.64
Nocturnal	1.45	1.22–1.72	1.45	1.25–1.69
Peritoneal dialysis	1.71	1.59–1.84	1.78	1.66–1.92
Insurance				
Medicare	ref	ref	ref	ref
Medicaid	0.75	0.69–0.82	0.73	0.67–0.80
Private	1.49	1.32–1.70	1.49	1.32–1.68
Cardiovascular disease	0.79	0.75–0.83	0.78	0.74–0.82
Diabetes mellitus	0.78	0.74–0.82	0.77	0.73–0.81
Liver disease	1.00	0.90–1.11	0.94	0.84–1.05
COPD	0.46	0.42–0.52	0.43	0.38–0.48
Income quintile				
$8,993–35,363	ref	ref	ref	ref
$35,370–43,265	1.09	1.01–1.17	1.08	0.99–1.16
$43,331–52,143	1.18	1.04–1.33	1.16	1.04–1.31
$52,173–67,316	1.31	1.18–1.45	1.31	1.19–1.44
$67,331–180,120	1.45	1.27–1.66	1.45	1.27–1.66
Albumin < 3.5 g/dl	0.86	0.84–0.89	0.75	0.73–0.78
Hemoglobin				
<10 g/dL	1.35	1.29–1.41	1.27	1.22–1.33
10–12 g/dL	1.16	1.13–1.20	1.11	1.08–1.14

Characteristic	Death Censored (n=388,437)		Death as a Competing Risk (n=388,437)	
>12 g/dl	ref	ref	ref	ref
Platelets <150 × 10^3/mm^3	0.79	0.77–0.83	0.69	0.66–0.72

Values shown are adjusted hazard ratio (95% confidence interval).

Abbreviations: COPD – chronic obstructive pulmonary disease; BMI – body mass index; AVF – arteriovenous fistula; AVG – arteriovenous graft; CVC – central venous catheter; PD – peritoneal dialysis; PRA – panel reactive antibody

Table 3.

Multivariable regression analysis of the association of HCV serostatus with the outcome of kidney transplantation, clustering on donor service area[*]

Characteristic	Adjusted HR (95% CI)					
	Death Censored N=39,873		Death as a Competing Risk N=39,873		Death or Delisting as a Competing Risk N=39,873	
HCV-seropositive	1.11 (0.97–1.28)		1.10	0.96–1.27	1.12	0.99–1.28
Age 40years	0.83	0.78–0.88	0.77	0.73–0.82	0.82	0.77–0.87
Male sex	1.01	0.97–1.06	1.00	0.96–1.05	0.99	0.95–1.04
Race						
Caucasian	ref		ref		ref	
African American	0.61	0.55–0.66	0.66	0.61–0.72	0.71	0.66–0.77
Latino	0.66	0.54–0.80	0.73	0.61–0.88	0.80	0.67–0.95
Asian	0.51	0.38–0.68	0.56	0.43–0.75	0.61	0.46–0.81
Other	0.68	0.56–0.81	0.75	0.63–0.90	0.80	0.67–0.96
BMI[*]						
18.5–30 kg/m^2	ref		ref		ref	
<18.5 kg/m^2	1.06	0.92–1.22	1.04	0.91–1.18	1.05	0.92–1.20
30–40 kg/m^2	0.82	0.79–0.86	0.85	0.82–0.89	0.88	0.84–0.92
>40 kg/m^2	0.50	0.42–0.60	0.54	0.49–0.64	0.59	0.50–0.70
PRA>80%	0.74	0.66–0.83	0.73	0.65–0.82	0.73	0.65–0.82
Blood group						
O	ref		ref		ref	
A	1.69	1.60–1.79	0.64	1.55–1.73	1.57	1.49–0.66
B	1.07	1.00–1.13	1.05	1.00–1.11	1.04	0.99–1.10
AB	2.60	2.32–2.91	2.45	2.20–2.72	2.28	2.04–2.54
Pre-WL dialysis, per 1-d longer	1.00	1.00–1.00	1.00	1.00–1.00	1.00	1.00–1.00
Diabetes mellitus	0.80	0.76–0.84	0.74	0.71–0.78	0.72	0.68–0.76
Liver disease	0.98	0.84–1.14	0.97	0.83–1.14	0.96	0.83–1.12
CVD	0.91	0.84–0.99	0.89	0.82–0.96	0.88	0.83–1.12
Income quintile ($US)						
$8,993–35,363	ref		ref		ref	
$35,370–43,265	1.00	0.91–1.11	1.00	0.91–1.10	0.99	0.90–1.09
$43,331–52,143	0.94	0.78–1.13	0.93	0.78–1.11	0.93	0.80–1.09
$52,173–67,316	0.90	0.75–1.07	0.89	0.75–1.07	0.90	0.76–1.06
$67,331–180,120	0.89	0.74–1.07	0.89	0.74–1.07	0.88	0.74–1.05
Insurance						
Medicare	ref		ref		ref	
Medicaid	0.99	0.87–1.13	1.02	0.89–1.15	1.04	0.92–1.18

Characteristic	Adjusted HR (95% CI)					
	Death Censored N=39,873		Death as a Competing Risk N=39,873		Death or Delisting as a Competing Risk N=39,873	
Private	1.20	1.14–1.26	1.23	1.17–1.29	1.20	1.14–1.26
Albumin <3.5 g/dL	0.81	0.74–0.88	0.72	0.66–0.79	0.73	0.67–0.80
Hemoglobin						
<10 g/dL	0.82	0.77–0.89	0.79	0.74–0.86	0.75	0.70–0.81
10–12 g/dL	0.88	0.84–0.93	0.87	0.83–0.92	0.84	0.80–0.89
>12 g/dL	ref		ref		ref	
Platelets <150 × 10³/mm³	0.99	0.93–1.04	0.94	0.89–1.00	0.95	0.89–1.00

Values shown are adjusted hazard ratio (95% confidence interval).

*Body mass index from the day of wait-listing for kidney transplantation, as reported to the OPTN

Abbreviations: HR – Hazard ratio; CI – Confidence Interval; HCV – Hepatitis C virus; BMI – body mass index; PRA – panel reactive antibody; WL – Waitlist; CVD – cardiovascular disease; COPD – chronic obstructive pulmonary disease;