Title

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Journal

New England Journal of Medicine, 391(15)

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Publication Date

2024-10-17

DOI

10.1056/NEJMoa2403733

Peer reviewed

Published in final edited form as:

N Engl J Med. 2024 October 17; 391(15): 1390–1401. doi:10.1056/NEJMoa2403733.

Safety of Kidney Transplantation from Donors with HIV under the HOPE Act

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Abstract

Background: Kidney transplantation (KT) from donors with HIV to recipients with HIV (HIV D+/R+) constitutes an emerging practice, performed in the United States since 2016 under the congressional HOPE Act. Currently approved for research only, Health and Human Services is considering expanding HIV D+/R+ to clinical practice; however, knowledge has been limited to small case-series without controls from donors-without-HIV (HIV D−/R+).

Methods: This observational study at 26 centers compared HIV D+/R+ to HIV D−/R+ deceased donor KT. The primary outcome was a composite of all-cause mortality, graft failure, serious adverse events (SAE), HIV-breakthrough, persistent HIV failure, opportunistic infection, compared in a noninferiority framework. Secondary endpoints included survival, graft survival, rejection, infection, cancer, and HIV superinfection.

Results: Between April 2018 and September 2021, 408 KT candidates enrolled; 198 underwent deceased donor KT. Comparing 99 HIV D+/R+ to 99 HIV D−/R+, transplant outcomes were similar-- one-year survival (94% vs. 95%), three-year survival (85% vs. 87%), one-year graft

survival (93% vs. 90%), three-year graft survival (84% vs. 80%), one-year rejection (13% vs. 21%), and three-year rejection (21% vs. 24%). The adjusted hazard ratio of the primary outcome was 1.0 (95% confidence interval [CI] 0.73–1.38), demonstrating noninferiority (prespecified margin 3.0). Incidence of SAEs, infections, surgical/vascular complications, and cancer was similar between groups. HIV-breakthrough was 3.14-fold higher in HIV D+/R+ (95%CI 1.02–9.63), with one potential HIV superinfection among 58 HIV D+/R+ with sequence data, and no persistent HIV failures.

Conclusions: In this multicenter observational study, HIV D+/R+ KT appeared noninferior to HIV D−/R+ KT. (Funded by the National Institute of Allergy and Infectious Diseases; ClinicalTrials.gov number NCT03500315)

Keywords

HIV; kidney transplantation; HIV Organ Policy Equity (HOPE) Act; opportunistic infection

Kidney transplantation (KT) provides a survival benefit for people with HIV (PWH) and end-stage kidney disease (ESKD),[1] but access is limited by an organ shortage. In particular, PWH on dialysis face a higher risk of death compared to people without HIV,[2,3] and less access to KT.[4,5]

KT from donors with HIV to recipients with HIV (HIV D+/R+) is a strategy that addresses the organ shortage and mitigates these disparities. Good outcomes from an HIV D+/R+ series in South Africa provided preliminary evidence to support this practice.[6,7] In the United States (US), HIV D+/R+ transplantation was historically banned but became legal as research only, following passage of the HIV Organ Policy Equity (HOPE) Act in 2013,[8–10] and publication of research guidance from the Department of Health and Human Services (HHS) in 2015,[11] with implementation of HIV D+/R+ KT since 2016.[12]

A HOPE pilot study including 25 HIV D+/R+ KT in the US demonstrated feasibility with encouraging short-term results.[13] However, that study was neither designed nor powered to determine noninferiority of HIV D+/R+ KT vs. KT from donors without HIV to recipients with HIV (HIV D−/R+ KT), considering potential risks of donor-derived HIV superinfection, opportunistic infections, and increased allograft rejection or dysfunction.[14] Such determination is critical, as the HHS Secretary is tasked by the HOPE Act with deciding whether HIV D+/R+ KT should move from research into clinical practice.[15]

The present study was designed to determine whether HIV D+/R+ KT was safe and noninferior compared with HIV D−/R+ KT in a larger, multicenter observational study, and to assess the risk of HIV-breakthrough, HIV superinfection, and post-transplant complications.

METHODS

Study Design and Oversight

Our observational, noninferiority study compared deceased donor HIV D+/R+ KT to HIV D−/R+ KT at 26 US transplant centers (Table S1). The study was designed by

the principal investigators and the National Institute of Allergy and Infectious Diseases (NIAID), Division of Allergy, Immunology and Transplantation (DAIT) project team. HHS HOPE Act Research Criteria were followed.[9] Institutional review boards at each center approved the study. All participants provided informed consent. The NIAID/DAIT Data Safety Monitoring Board (DSMB) reviewed annually. The protocol (available at NEJM.org) included pausing rules if rejection, graft loss, biopsy complications, or HIV-breakthrough exceeded pre-specified thresholds.

Data were managed by the Johns Hopkins Transplant Oncology Infectious Diseases Clinical Research Center and analyzed by the investigators and NIAID/DAIT team. The first author drafted the manuscript; all authors revised and approved the final manuscript. The first three authors vouch for the data accuracy and analysis.

Study Participants

Persons with HIV and end-stage kidney disease (ESKD) ≥18 years of age who met local KT criteria, and consented to consider kidneys from deceased HIV D+ were eligible. Participant criteria also included CD4 counts ≥ 200 cells/μL, active antiretroviral therapy (ART), and HIV RNA <50 copies/mL. Exclusion criteria included active opportunistic infections, prior progressive multifocal leukoencephalopathy, or central nervous system lymphoma.

Intervention

All participants consented for and were eligible for a D+ or D− kidney, receiving whichever was available first. Allocation could not be randomized due to constraints of the national Organ Procurement and Transplantation Network (OPTN) (e.g., blood type, HLA matching, geography). To account for potential over-enrollment of HIV D−/R+, a balancing rule randomized some HIV D−/R+ to a limited observational arm. Investigators were blinded to outcomes by group until study completion.

Per HOPE Research criteria, HIV D+ could not have active opportunistic infections or cancer. There were no donor HIV RNA or CD4 cell criteria; however, investigators had to anticipate and describe effective recipient ART post-transplant.[11] HIV D− were evaluated according to local criteria. As previously described, some donors had false-positive HIV tests.[16] Per OPTN, all donors in the US are screened for HIV with antibody and nucleic acid testing. Donors without known HIV with a single-positive HIV test were suspected false-positive donors, but were treated as HIV D+ during allocation. Subsequently, confirmatory testing was done by OPTN or the HOPE in Action Laboratory (Johns Hopkins, Baltimore, MD) with results within ≤7 days. In all suspected false-positive donors, confirmatory testing was negative; accordingly, recipients were assigned to the HIV D−/R+ group.

Measurements and Outcome Definitions

Participant visits occurred pre-transplant, at transplant, post-transplant week 1, 2, 3, 4, 13, 26, and every 6 months for a minimum of 1 year up to 4 years. Medications, hospitalizations, infections, and laboratory values were collected. Allograft biopsy was done at transplant, week 26, 52, and for clinical indications. Testing for donor-specific antibodies (DSA) was done pre-transplant, at week 52, and for clinical indications.

The primary outcome was time to a composite safety event: all-cause-mortality, graft failure, serious adverse event (SAE), HIV-breakthrough, persistent HIV failure, or opportunistic infection. Graft failure was defined as renal replacement therapy ≥90 days, graft nephrectomy, or re-transplant. SAE was defined by Division of AIDS Table for Grading SAEs.[17] HIV-breakthrough was defined as consecutive measurements of HIV RNA >200 copies/mL or one >1000 copies/mL. Persistent HIV failure was defined as HIV RNA >1000 copies/mL for >90 days. Opportunistic infections included AIDS-defining conditions per the Centers for Disease Control and Prevention (CDC).[18]

Secondary outcomes included survival, graft survival, SAEs, allograft rejection, graft function, HIV-breakthrough, persistent HIV failure, CD4 count, incidence of infections, surgical/vascular complications, cancer, and *de novo* DSA at week 52. Rejection was defined as clinically-suspected and treated, or biopsy-proven according to Banff classification.[19] Graft function was defined as the estimated glomerular filtration rate (eGFR) using the Chronic Kidney Disease Epidemiology 2021 equation, which omits race.[20] Infections were defined using CDC definitions for AIDS-defining conditions,[18] and Swiss Transplant Cohort Study definitions for other infections.[21] Kaposi's sarcoma-associated herpesvirus (KSHV) disease was considered an opportunistic infection and cancer. Induction therapy, maintenance immunosuppression, and infection prophylaxis (Table S2) were per local practice.

HIV Superinfection

HIV superinfection was defined as acquisition of a new, genetically distinct strain of HIV and was evaluated among HIV D+/R+ as previously described.[22] Genomic DNA was extracted from recipient and donor peripheral blood mononuclear cells (PBMCs). Site-directed next-generation sequencing for HIV pol and gp41 was performed (Illumina Inc, San Diego CA). Phylogenetic analyses were done to identify genetically distinct viral populations post-transplant, which were considered potential HIV superinfection/dual infections.

Statistical Analysis

The primary outcome was adjusted for factors potentially associated with transplant outcomes, including recipient hepatitis C viremia, anti-thymocyte globulin (ATG), and participation in a trial of CCR5 blockade (CT.gov, NCT02741323). The hazard ratio of the event was compared between groups using Cox regression in a noninferiority framework; margin of 3.0 was selected to be within the survival benefit of KT for PWH.[1] Pre-specified sensitivity analyses included the primary outcome adjusted for age, sex, race, CD4 count, years of renal replacement, subgroups of the composite, and opportunistic infections using a noninferiority framework (margin 3.0). Based on estimated event rates, 100 participants/group provided 96% power to satisfy noninferiority for the primary outcome with a two-sided alpha of 0.05.

For secondary outcomes, recurrent events and proportion with *de novo* DSA were quantified using Poisson regression. eGFR was analyzed using multilevel mixed-effects linear regression with a participant-level random intercept. No correction was made to

account for multiple comparisons. Missingness of longitudinal outcomes was assumed to be random; participants who died were censored for longitudinal outcomes.

To ensure completeness, data were linked to the Scientific Registry of Transplant Recipients (SRTR), which includes data on US donors, waitlist candidates, and recipients, submitted by the OPTN.[23] All analyses were two-tailed (α=0.05) and performed using Stata 17.0/MP (College Station, Texas).

RESULTS

Recipient and Donor Characteristics

From April 2018 through September 2021, 515 PWH consented; 408 were eligible for transplant and waitlisted (Figure S1). Of those, 209 received transplants; 2 withdrew on day of transplant and 9 HIV D−/R+ were randomized to limited observation, leaving 99 HIV D+/R+ and 99 HIV D−/R+ in the analytic group.

Recipient and transplant characteristics were similar between groups (Tables 1 and S3). There were 146 donors: 64 HIV D+ and 82 HIV D−, of whom 27 had had false-positive HIV tests. Donor characteristics were similar between groups, except more HIV D+ were Black, had a lower Kidney Donor Profile Index, and higher seropositivity of hepatitis B, and CMV (Tables 1 and S3).

Primary Outcome

Median follow-up time was 2.19 years (IQR 1.77–3.11) for HIV D+/R+ and 2.25 years (IQR 1.45–3.24) for HIV D−/R+. Comparing time to the composite event (all-cause-mortality, graft failure, SAE, HIV-breakthrough, persistent HIV failure, or opportunistic infection) in HIV D+/R− vs. HIV D−/R+, the adjusted hazard ratio (aHR) was 1.00 (95% confidence interval [CI] 0.73–1.38), meeting noninferiority (Figure 1A). Pre-specified sensitivity analyses are shown in Figure 1B.

Secondary Outcomes

Comparing opportunistic infections in HIV D+/R− vs. HIV D−/R+, the adjusted incidence rate ratio (IRR) was 1.28 (95%CI 0.51–3.18); noninferiority was not demonstrated, as the 95%CI upper bound exceeded 3.0 (Figure 1B).

Patient survival was 94% in HIV D+/R+ vs. 95% HIV D−/R+ at 1 year, and 85% in HIV D+/R+ vs. 87% in HIV D−/R+ at 3 years (Figure 2A, Table S4). All-cause graft survival was 93% in HIV D+/R+ vs. 90% HIV D−/R+ at 1 year, and 84% in HIV D+/R+ vs. 80% in HIV D−/R+ at 3 years (Figure 2B, Table S5).

Rejection incidence was 13% in HIV D+/R+ vs. 21% HIV D−/R+ at 1 year, and 21% in HIV D+/R+ vs. 24% in HIV D−/R+ at 3 years (Figure 3C, Table S6). Survival, graft survival, and rejection for the HIV D−/R+ observational group are reported in Table S7. Comparing HIV D+/R+ vs. HIV D−/R+, the IRR of rejection was 0.65 (0.38–1.14) (Table 2). Median eGFR was 49 (37–60) ml/min/1.73m^2 in HIV D+/R+ vs. 48 (36–60) ml/min/1.73m^2 HIV D−/R+ at

1 year and 41 (26–60) ml/min/1.73m^2 in HIV D+/R+ vs. 48 (33–69) ml/min/1.73m^2 in HIV D−/R+ at 3 years (Figures S3 and S4).

There was no evidence of a difference in incidence of SAEs, infections, infections requiring hospitalization, opportunistic infections, surgical/vascular complications, or cancer (Tables 2 and S8, S9). There were 17 HIV-breakthroughs, 13 in HIV D+/R+ and 4 in HIV D−/R+; the incidence rate ratio (IRR) was 3.14 (95%CI 1.02–9.63) (Tables 2 and S10). The most common reason for breakthrough was ART nonadherence (11/17); in all cases, HIV RNA decreased to <200 copies/mL at a median of 26 days later.

HIV Superinfection

Among 99 HIV D+/R+ KT, 71 had HIV pol and/or gp41 sequences amplified from pre-transplant and ≥1 post-transplant timepoint. Of these, 58 had successful amplification of the same region at both timepoints, allowing longitudinal phylogenetic analysis. In 1/58, a genetically distinct viral population was identified post-transplant (Figure S5); HIV sequence amplification from donor PBMCs was unsuccessful in this case, therefore this was categorized as a potential HIV superinfection (Table S11).

DISCUSSION

In this multicenter, noninferiority, observational study, HIV D+/R+ KT was noninferior to HIV D−/R+ KT by the primary safety outcome (all-cause-mortality, graft failure, SAE, HIV-breakthrough, persistent HIV failure, or opportunistic infection). There was no evidence of difference in survival, graft survival, or rejection between groups. Furthermore, incidence of SAEs, infections, surgical and vascular complications, and cancer were similar between groups, although, noninferiority was not demonstrated for opportunistic infection incidence. HIV-breakthrough was three-fold higher in HIV D+/R+, primarily due to ART nonadherence. Importantly, all participants re-achieved viral suppression. There was a single case of potential HIV superinfection/dual infection without clinical consequences. Taken together, these outcomes support expansion of HIV D+/R+ KT from research to clinical care.

Over 500 PWH consented for this study with age, sex, and race/ethnicity generally similar to what has been reported among PWH and ESRD in the United States (Table S12).[24,25] At study close, there were 141 participants remaining on the KT waitlist; most subsequently joined a follow-up HIV D+/R+ study (IRB00270533), highlighting the need for KT in PWH.[4,5] Although the annual number of D+ has not yet reached projected potential,[9,26–28] it has been increasing over time,[29] and a substantial wait time advantage exists for those who are willing to accept D+ kidneys.[30]

Overall survival in HIV D+/R+ KT in the present study was slightly lower (1-year 94%) than in the HOPE KT pilot study (1 year 100%).[13] This may be due to the COVID-19 pandemic, which occurred after the pilot study, with 8/23 COVID-19 deaths in this study. Nonetheless, survival in 99 HIV D+/R+ KT in this study (1-year 94%, 3-year 85%) was comparable to survival in 51 HIV D+/R+ KT in South Africa (1-year 87%, 3-year 87%)[31] and in 150 HIV D−/R+ KT in the US NIH Transplant Recipient (NIH-TR) cohort (1-year

95%, 3-year 88%).[32] Moreover, graft survival in this study (1-year 93%, 3-year 84%) was higher than observed in the South Africa cohort (1-year 75%, 3-year 61%)[31] and the NIH-TR cohort (1-year 90%, 3-year 74%).[32] These data may reflect improvements in post-transplant management of PWH over time,[33] or the impact of curative treatment for hepatitis C virus (HCV), a common comorbidity among PWH, associated with lower graft survival.[32,34] In our study, most recipients with HCV were cured pre-transplant, with only 7 recipients HCV-viremic at transplant.

In prior studies, rejection was recognized as an increased risk for KT recipients with HIV.[32,35] Multiple contributing factors have been proposed including lower overall exposure to immunosuppressants due to interactions with ART,[32,36] and/or immune dysregulation from HIV. Observed rejection rates vary by type of immunosuppression, with lower rejection with receipt of ATG (vs. non-lymphocyte depleting) induction,[35,37] and tacrolimus (vs. cyclosporine) for maintenance.[32,38] In the present study, rejection in HIV D+/R+ (1-year 13%, 3-year 21%) was lower than observed in the HOPE KT pilot study (1-year 50%).[13] One explanation is that 65% of participants received ATG in this study vs. 33% in the pilot. Rejection was also lower than observed in the South Africa HIV D+/R+ cohort (1-year 25%, 3-year 39%).[31] In that cohort, 100% received ATG, however 24% were on protease-inhibitor ART (which interacts with maintenance immunosuppression), compared to only 6% in this study. Rejection was also lower than observed in the NIH-TR HIV D−/R+ cohort (1-year 31%, 3-year 41%); there, only 32% received ATG induction, 66% tacrolimus maintenance, and 42% protease-inhibitors.

Our study participants had 19 opportunistic infections (11 in HIV D+/R+ vs. 8 in HIV D−/R+), a lower rate than observed in the HOPE kidney pilot.[13] The adjusted IRR was 1.28 for HIV D+/R+; although this was not statistically significantly different than the IRR among HIV D−/R+, noninferiority was not demonstrated due to a wide confidence interval, likely resulting from a lower than expected infection rate. Herpesvirus infections, which are more prevalent among HIV D+,[29] were most common, followed by candida esophagitis. Reassuringly, infections requiring hospitalization were similar between groups and all infections resolved.

Donor-derived HIV superinfection is a theoretical risk of HIV D+/R+ transplantation which could contribute to HIV-breakthrough or persistent HIV failure. In the present study, there were 17 HIV-breakthroughs, with a 3-fold higher rate in HIV D+/R+. This primarily occurred due to ART nonadherence, with rare cases attributed to medication interactions or lab error. In all cases, HIV RNA re-suppressed to <200 copies/mL without ART resistance. Using phylogenetic analysis, one HIV D+/R+ had potential HIV superinfection/dual infection, without HIV-breakthrough. In the HOPE kidney pilot, no HIV superinfections were detected among 14 HIV D+/R+ recipients.[22] In the South Africa HIV D+/R+ cohort, donor virus was transiently detected in 8/24 recipients at the earliest post-KT timepoints, with one case of a donor-derived minor variant at 12 weeks post-KT, that was not sustained.[31] Similarly, in a US case report of HIV D+/R+ KT, in-depth viral analysis revealed transient donor HIV detection in recipient urine and renal cells, that was not sustained.[39] Taken together, these data suggest HIV superinfection is rare and without clear clinical ramifications.

Our study has certain limitations. True randomization of D+ vs. D− organ type was not possible, due to OPTN allocation constraints (e.g., blood-type, HLA matching, geography). However, participants were equally eligible for a D+ or D− kidney; group assignment was determined by whichever organ was available first. Furthermore, there was an HIV D−/R+ control group, including 27 donors with false-positive HIV tests, treated as D+ during allocation, representing an ideal counterfactual. Immunosuppression and prophylaxis were heterogenous; however, these factors were balanced between groups and reflect real-world practice, increasing generalizability.

In conclusion, this multicenter observational study demonstrated that HIV D+/R+ KT appeared noninferior to HIV D−/R+ KT with excellent post-transplant outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

At Johns Hopkins University School of Medicine: Grace Link Barnes, Nadine Brown, Jill Kessler, Bahati Kuffar, and Quinten Stearns. At Mount Sinai Hospital, Recanati-Miller Transplantation Institute: the medical, surgical and research teams.

Funding/Support

This work was supported in part by the Division of Intramural Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health (Redd), by the by National Institute of Health grant numbers R01AI120938 and R01DK131926 (Tobian), U01 AI134591, U01AI138897, and U01AI177211 (Durand/Segev), and R01DK101677 (Massie). SRTR data was supplied by Hennepin Healthcare Research Institute. The analyses described here are the responsibility of the authors alone and do not necessarily reflect the views or policies of the Department of Health and Human Services or the SRTR, nor does mention of trade names, commercial products or organizations imply endorsement by the U.S. Government.

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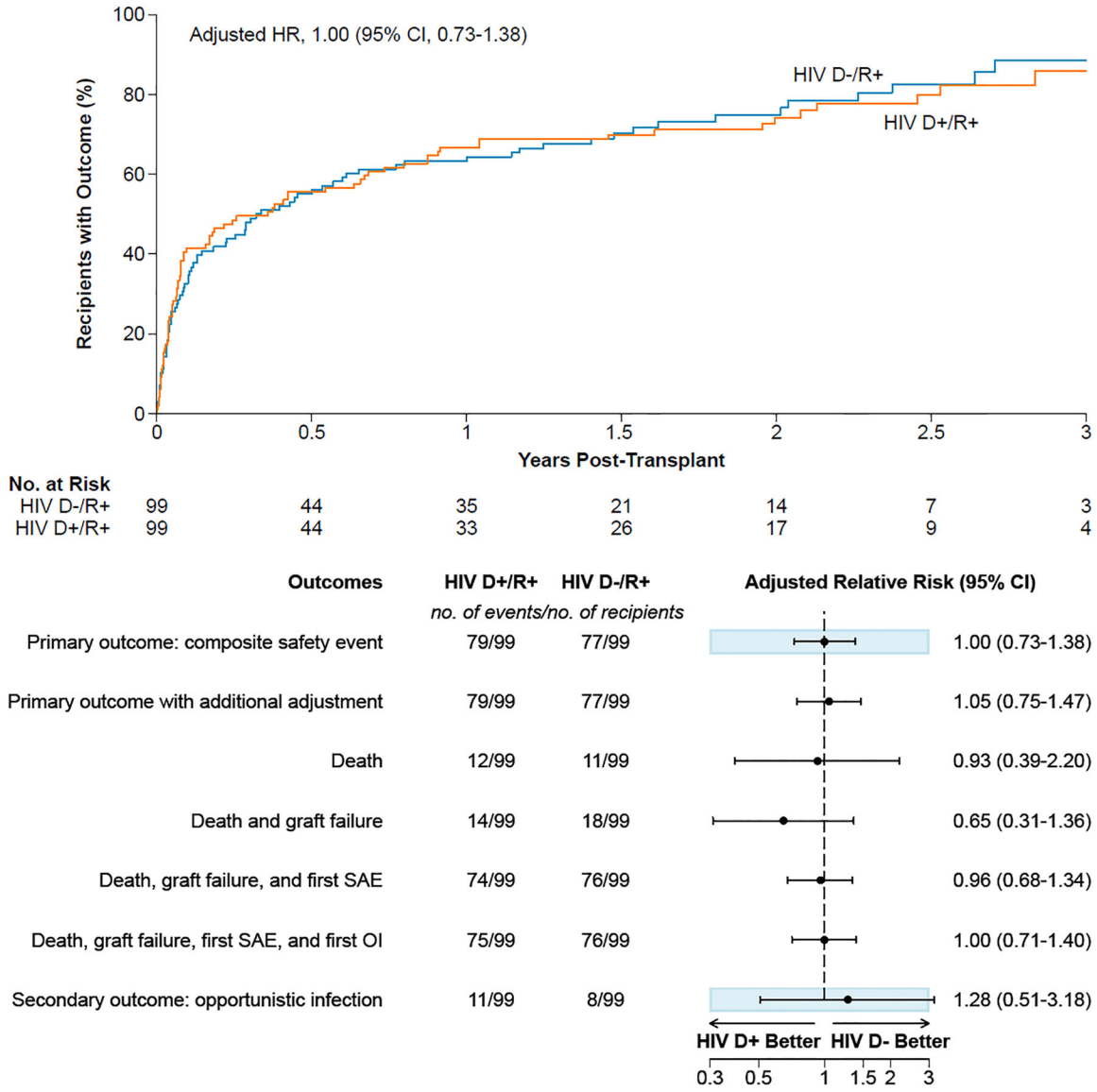
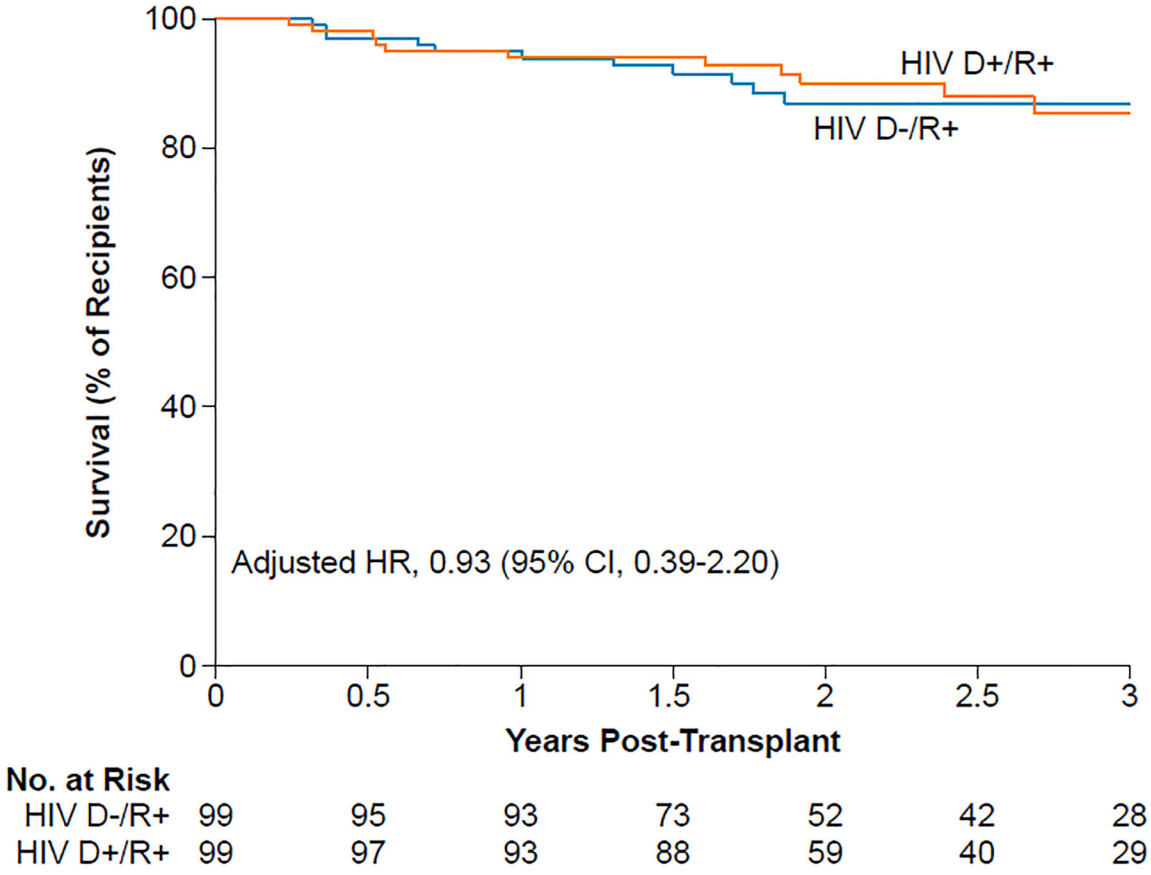
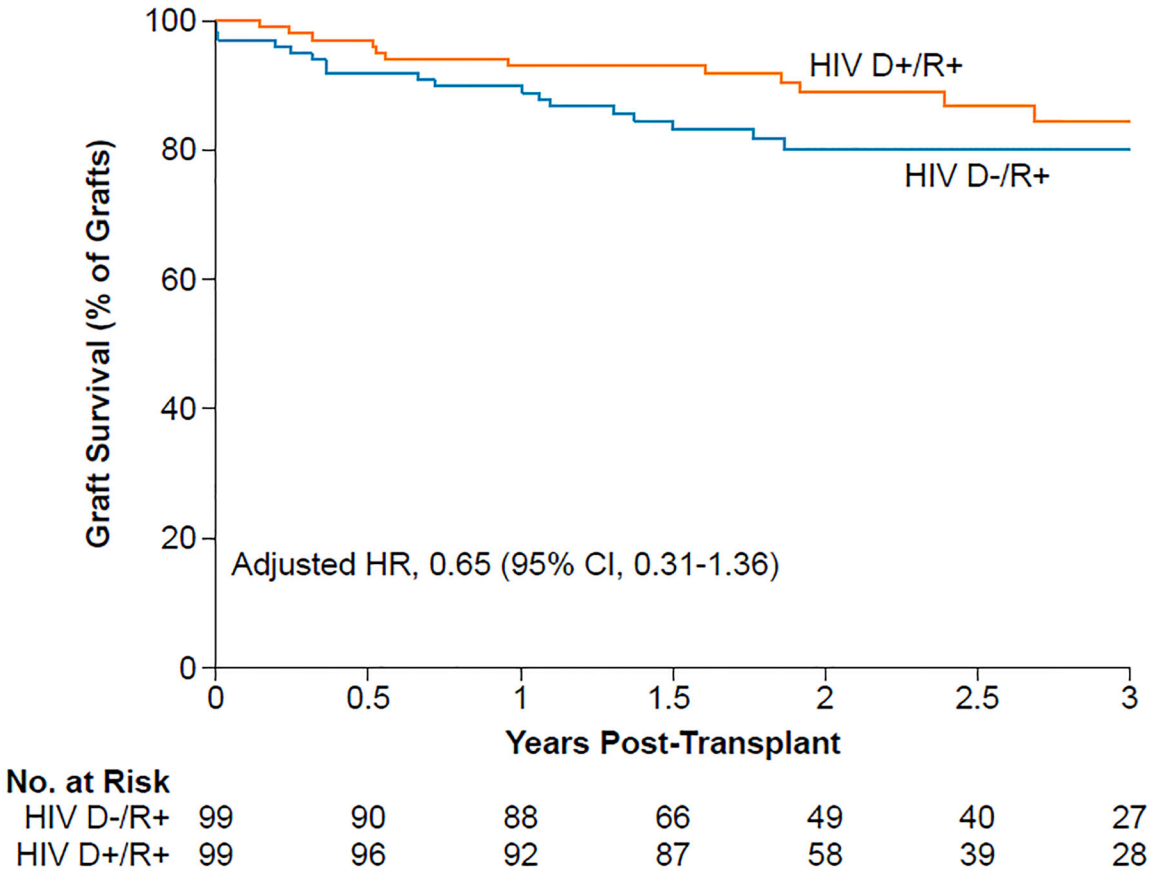


Figure 1.

Panel A shows the cumulative incidence of recipients with the primary outcome composite event of all-cause-mortality, graft failure, serious adverse event (SAE), HIV-breakthrough, persistent HIV failure, or opportunistic infection. 79/99 recipients in HIV D+/R+ had the primary outcome composite event, with 71 attributed to SAEs, 6 HIV-breakthroughs, 1 opportunistic infection, and 1 death. 77/99 recipients in HIV D−/R+ had the primary outcome composite event, with 70 attributed to SAEs, 3 graft failures, 2 HIV-breakthroughs, and 2 opportunistic infections. Median outcome-free time was 0.36 years (IQR, 0.05–2.08) in HIV D+/R+ and 0.34 years (IQR, 0.05–2.02) in HIV D−/R+. Panel B shows the adjusted relative risk (hazard ratio or incidence rate ratio) for each outcome. The shaded area indicates the pre-specified noninferiority margin of 3.0. Kaplan-Meier estimates of the subcomponents are shown in the Figure S2.





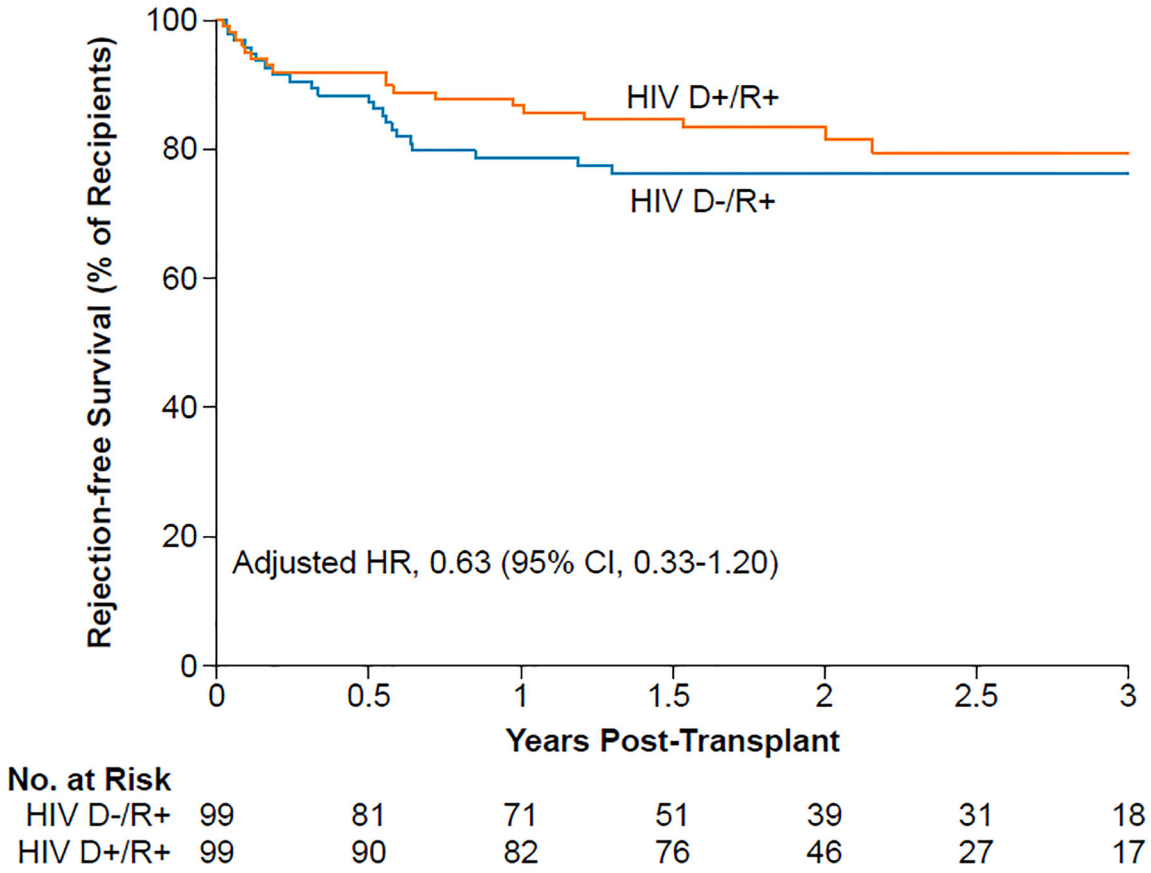


Figure 2.

Shown are the Kaplan-Meier estimates of patient survival (Panel A), all-cause graft survival (Panel B), and rejection-free survival (Panel C). Patient survival was 94% (95% CI, 87–97) in HIV D+/R+ vs. 95% (95% CI, 88–98) HIV D−/R+ at 1 year, and 85% (95% CI, 74–92) in HIV D+/R+ vs. 87% (95% CI, 77–93) in HIV D−/R+ at 3 years. 12 deaths were observed in HIV D+/R+ and 11 in HIV D−/R+. All-cause graft survival was 93% (95% CI, 86–97) in HIV D+/R+ vs. 90% (95% CI, 82–94) HIV D−/R+ at 1 year, and 84% (95% CI, 73–91) in HIV D+/R+ vs. 80% (95% CI, 70–87) in HIV D−/R+ at 3 years. Rejection was 13% (95% CI, 8–22) in HIV D+/R+ vs. 21% (95% CI, 14–31) HIV D−/R+ at 1 year, and 21% (95% CI, 13–31) in HIV D+/R+ vs. 24% (95% CI, 16–34) in HIV D−/R+ at 3 years.

Table 1.

Characteristics of Kidney Transplant Recipients and Donors According to Donor HIV Status, Abridged.

Characteristics	HIV D+/R+	HIV D−/R+	SMD
Recipients	**N=99**	**N=99**	
Age, years — median (IQR)	53 (45–60)	57 (50–63)	0.264
Female sex — no./total no. (%)	16/99 (16)	19/99 (19)	0.080
Race /ethnicity — no./total no. (%)			0.296
Black	72/99 (73)	69/99 (70)	
White, non-Hispanic	10/99 (10)	13/99 (13)	
Hispanic or Latino	10/99 (10)	15/99 (15)	
Other	7/99 (7)	2/99 (2)	
Hepatitis C antibody positive — no./total no. (%)	9/99 (9)	17/99 (17)	0.241
Among those, hepatitis C NAT positive — no./total no. (%)	1/9 (11)	6/17 (35)	0.598
HIV RNA < 200 copies/mL at transplant — no./total no. (%)‡	98/99 (99)	98/99 (99)	0
CD4+ cells, count — median (IQR)	511 (375–652)	492 (362–686)	0.021
Antiretroviral therapy (ART) — no./total no. (%)			
PI or cobicistat-containing ART	6/99 (6)	6/99 (6)	0
INSTI-containing ART	98/99 (99)	95/99 (96)	0.194
Cause of kidney failure — no./total no. (%)			0.092
HIV-associated nephropathy	34/99 (34)	36/99 (36)	
Diabetes	23/99 (23)	25/99 (25)	
Hypertension	20/99 (20)	17/99 (17)	
Years of renal replacement therapy — median (IQR)	4.1 (2.6–6.1)	4.8 (2.6–7.6)	0.359
Induction immunosuppression — no./total no. (%)			0.187
ATG/ATGAM	61/99 (62)	63/99 (64)	0.042
Basiliximab	34/99 (34)	33/99 (32)	0.021
Maintenance Immunosuppression — no./total no. (%)			
Tacrolimus	96/99 (97)	98/99 (99)	0.144
Mycophenolate Mofetil/Mycophenolic acid	96/99 (97)	95/99 (96)	0.054
Steroids	77/99 (78)	82/99 (83)	0.127
Participation in CCR5 trial (NCT02741323)	30/99 (30)	23/99 (23)	0.160
Donors	**N=64**	**N=82**	
Age, yr. — median (IQR)	36 (28–45)	40 (30–49)	0.305
Female sex — no./total no. (%)	18/64 (28)	26/82 (32)	0.078
Race/ethnicity — no. /total no. (%)			0.480
Black	25/64 (39)	17/82 (21)	
White, non-Hispanic	30/64 (47)	47/82 (57)	
Hispanic/Latino	9/64 (14)	15/82 (18)	
Other	0/64 (0)	3/82 (4)	
Kidney donor profile index — median (IQR)	38 (26–54)	53 (35–69)	0.407
Hepatitis C antibody positive — no./total no. (%)	3/64 (5)	10/82 (12)	0.273
Hepatitis C RNA detectable — no./total no. (%)	2/64 (3)	8/82 (10)	0.273

False positive HIV test — no./total no. (%)	N/A	27/82 (33)	N/A

ATG indicates rabbit anti-thymocyte globulin, ATGAM equine anti-thymocyte globulin, IQR interquartile range, SMD (absolute) standardized mean difference.

[≠]1 HIV D+/R+ with HIV RNA 423 copies/mL at transplant, day 9 post-transplant HIV RNA <20 copies/mL. 1 in HIV D−/R+ with HIV RNA 38679 copies/mL at transplant, day 30 post-transplant HIV RNA <40 copies/mL.

An unabridged version of this table may be found in the Supplementary Appendix, Table S3

Table 2.

Post-Transplant Events According to Donor HIV Status

Outcomes	HIV D+/R+ (n=99)		HIV D–/R+ (n=99)		Crude Incidence Rate Ratio (95% CI)
	Recipients with event — no./total no. (%)	*Total no. of event*	*Recipients with event — no./total no. (%)*	*Total no. of event*	
Serious adverse event	74/99 (75)	206	76/99 (77)	222	0.90 (0.74–1.08)
Allograft rejection	18/99 (18)	21	22/99 (22)	32	0.63 (0.37–1.10)
One-year allograft rejection	13/99 (13)	13	20/99 (20)	25	0.52 (0.26–1.01)
HIV-breakthrough	10/99 (10)	13	4/99 (4)	4	3.14 (1.02–9.63)
Persistent HIV failure	0/99 (0)	0	0/99 (0)	0	N/A
Any infection	81/99 (82)	273	71/99 (72)	229	1.15 (0.97–1.37)
Opportunistic infection	8/99 (8)	11	7/99 (7)	8	1.33 (0.53–3.30)
Any infection with hospitalization	43/99 (43)	94	43/99 (43)	97	0.94 (0.70–1.24)
Surgical or vascular complication	12/99 (12)	17	19/99 (19)	23	0.71 (0.38–1.34)
Cancer	8/99 (8)	9	6/99 (6)	6	1.45 (0.52–4.07)
De novo DSA at one year*	9/67 (13)	9	13/59 (22)	13	0.61 (0.28–1.33)

*32 participants in HIV D+/R+ group and 40 in HIV D−/R+ group had no DSA data at either Day 0 or one year.