

Outcomes of Renal Transplants From Centers for Disease Control and Prevention High-Risk Donors With Prospective Recipient Viral Testing

A Single-Center Experience

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Hypothesis: The use of kidneys from deceased donors considered at increased infectious risk represents a strategy to increase the donor pool.

Design: Single-institution longitudinal observational study.

Setting: Tertiary care center.

Patients: Fifty patients who gave special informed consent to receive Centers for Disease Control and Prevention high-risk (CDCHR) donor kidneys were followed up by serial testing for viral transmission after transplantation. Nucleic acid testing for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus was performed on all high-risk donors before transplantation. Outcomes of CDCHR kidney recipients were compared with outcomes of non-high-risk (non-HR) kidney recipients.

Main Outcome Measures: New viral transmission, graft function, and waiting list time.

Results: No recipient seroconversion was detected during a median follow-up period of 11.3 months. Compared with non-HR donors, CDCHR donors were younger (mean [SD] age, 35 [11] vs 43 [18] years, $P = .01$), fewer were expanded criteria donors (2.0% vs 24.8%, $P < .001$), and fewer had a terminal creatinine level exceeding 2.5 mg/dL (4.0% vs 8.8%, $P = .002$). The median creatinine levels at 1 year after transplantation were 1.4 (interquartile range, 1.2-1.7) mg/dL for CDCHR recipients and 1.4 (interquartile range, 1.1-1.9) mg/dL for non-HR recipients ($P = .4$). Willingness to accept a CDCHR kidney significantly shortened the median waiting list time (274 vs 736 days, $P < .001$).

Conclusions: We show safe use of CDCHR donor kidneys and good 1-year graft function. With continued use of these organs and careful follow-up care, we will be better able to gauge donor risk and match it to recipient need to expand the donor pool and optimize patient benefit.

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AS THE NUMBER OF AMERICANS awaiting kidney transplantation has continued to grow, the disparity between organ demand and supply has increased.¹ Given the vast organ shortage, the well-established survival advantage of kidney transplantation over dialysis,^{2,3} and the high mortality among those awaiting transplantation, there has been pressure to expand the use of organs from nonideal donors. Despite shorter mean graft survival, the benefit of expanded criteria donors has been clearly demonstrated for certain recipient populations.^{4,5} Transplantation of kidneys from donors after cardiac death has also increased organ availability and has been shown to be beneficial in many recipient populations.⁶ The use of renal al-

lografts from donors designated by the Centers for Disease Control and Prevention (CDC) as being at increased viral infectious risk—yet another possible donor cohort from which to increase transplant volume—has been limited and continues to be controversial because primary data on actual risk are lacking.⁷⁻¹²

The CDC¹³ outlined several behaviors that were deemed high infectious risk for transmission of viral illnesses, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), from potential donors to recipients through organ transplantation. Organ procurement organizations (OPOs) are required to notify transplant surgeons when a donor meets these CDC high-risk (CDCHR) criteria, and United Network for Organ Sharing¹⁴ policy since 2008 man-

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dates the disclosure of this information to potential recipients by way of a special informed consent process. For potential recipients, the qualitative risks of CDCHR donors differ fundamentally from those of expanded criteria donors. For CDCHR recipients, the risk lies not in the prospect of receiving an organ with suboptimal long-term function but rather in the possibility of receiving a graft that, while physiologically ideal, may be the vehicle for transmission of a potentially life-threatening viral infection.

All OPOs perform antibody-based (enzyme-linked immunosorbent assay [ELISA]) testing for HIV, HBV, and HCV, but the reliability of this test is limited in donors infected shortly before death. The window period of detection (between the time of infection and the time at which antiviral antibodies can be detected in the serum) is as long as 66 days for HCV,¹⁵ and viral transmission from infected donors to transplant recipients has occurred as a consequence of false-negative ELISA testing.^{16,17} Nucleic acid testing (NAT) significantly shortens the window period for detection of these infections,¹⁶ but for many reasons, including increased cost, greater technical difficulty in performing the test, and a higher false-positive rate, NAT is neither required as a matter of policy nor is it performed by all OPOs. As of 2009, just over half of OPOs reported routinely performing NAT.^{12,18}

Based on the reported incidence of viral transmission through organ transplantation, studies^{7,9} have estimated the infectious risk via transplant, even from CDCHR donors, to be exceptionally low. In fact, the possibility of infection through transplantation may be less than the risk of acquiring these infections while receiving long-term hemodialysis.^{19,20} Physician reluctance to accept these organs may reflect that the perceived risk of transplant-mediated viral infection is far greater than the real risk.^{11,12} Nevertheless, for providers and potential recipients alike, making the most informed decision when presented a CDCHR organ offer requires an understanding of the actual risks and benefits.

In this study, we report the outcomes of 50 recipients of CDCHR kidneys transplanted since the implementation of a formalized special informed consent protocol at our institution. We hypothesized that the recipients of CDCHR kidneys would demonstrate equal, if not superior, graft function and have shorter waiting list times compared with those who elected to await a non-high-risk (non-HR) offer. Furthermore, with serial testing for viral transmission after transplantation, we have begun to quantify the actual infectious risk associated with the use of these organs.

METHODS

REGULATORY OVERSIGHT

Approval to collect and analyze data from the study population and the comparison population was obtained. The study was approved by the Johns Hopkins Medicine Institutional Review Boards.

STUDY POPULATION AND COMPARISON POPULATION

The study population (n = 50) comprised recipients of CDCHR donor kidneys who underwent transplantation at The Johns

Hopkins Hospital between September 1, 2008, and January 31, 2010. The comparison population (n = 125) comprised recipients of non-HR deceased donor kidneys who underwent transplantation at The Johns Hopkins Hospital during the same period. Pediatric (<18 years) recipients and recipients of simultaneous liver and kidney transplants were excluded from the analysis.

COUNSELING, INFORMED CONSENT, AND LONGITUDINAL STUDY DESIGN

Patients with end-stage renal disease referred to our institution for transplantation underwent standard evaluation. In addition, patients were counseled about the potential risks and benefits of CDCHR kidneys and were assessed for their potential willingness to consider CDCHR kidney offers. As part of our standard workup, all patients were screened by ELISA assay for HIV, HBV, and HCV. As organ offers for CDCHR kidneys were received, the donor details were discussed with potential recipients, and those interested in the offer were cross matched. At the time of transplantation, a special informed consent was obtained from those receiving a CDCHR kidney. In addition to the risks and benefits detailed in the traditional operative consent for kidney transplantation, the special informed consent specifically disclosed the high-risk nature of the kidney offer and the possible increased risk of viral transmission associated with the use of these organs. If not previously performed, all donors underwent NAT for HIV, HBV, and HCV by their local OPO or on import to our institution's OPO. Recipient baseline NAT for HIV, HBV, and HCV was obtained on the day of transplantation. Only HCV-positive recipients were offered HCV-positive organs. All recipients were considered for HBV NAT-negative and HBV core antibody-positive organs. After transplantation, in addition to standard follow-up care, recipients of CDCHR organs were tested by ELISA for HIV, HBV surface antigen, and HCV antibody and by NAT for HIV, HBV, and HCV. Testing was performed at 1, 3, 6, and 12 months after transplantation. The timing of testing was based on our institutional occupational exposure follow-up protocol. The primary outcome measure was new transmission of HIV, HBV, and HCV. Secondary outcome measures included short- and long-term graft function and patient and graft survival.

STATISTICAL ANALYSIS

Categorical values were compared using the χ^2 test; continuous variables were compared using the 2-tailed *t* test. Graft survival estimates were performed using the Kaplan-Meier method and were compared using log-rank test. Significance was set at $\alpha = .05$. All statistical analyses were performed using commercially available software (STATA 11.0; StataCorp LP, College Station, Texas).

RESULTS

DONOR CHARACTERISTICS

Among patients who underwent transplantation at our hospital, CDCHR donors were significantly younger than non-HR donors (mean [SD] age, 35 [11] vs 43 [18] years; $P = .01$) (**Table 1**). The CDCHR and non-HR donors had similar body mass index (calculated as weight in kilograms divided by height in meters squared) and had comparable race/ethnicity distributions. Although differences in causes of death were not statistically significant,

Table 1. Donor and Recipient Demographics

Variable	CDCHR (n=50)	Non-HR (n=125)	P Value
Donors			
Demographics			
Age, mean (SD), y	35 (11)	43 (18)	.01
Female sex, %	34.0	46.4	.10
BMI, mean (SD)	25.2 (4.1)	26.9 (6.8)	.10
Race/ethnicity, %			
White	74.0	67.2	.60
Black	16.0	22.4	
Other	10.0	10.4	
Cause of death, %			
Head trauma	36.0	28.8	.20
Anoxia	34.0	24.8	
Cerebrovascular accident	30.0	44.8	
Other	0.0	1.6	
Share type, %			
Local	22.0	47.2	.005
Regional	4.0	5.6	
National	74.0	47.2	
Cold ischemia time, mean (SD), h	25.5 (12.0)	21.9 (12.7)	.10
Expanded criteria donor, %	2.0	24.8	<.001
Donor after cardiac death, %	10.0	20.0	.10
HBV core antibody positive, %	16.7	9.6	.20
HCV positive, %	18.0	7.2	.03
Terminal creatinine level			
Median (range), mg/dL	0.9 (0.8-1.1)	0.9 (0.6-1.2)	.50
>2.5 mg/dL, %	4.0	8.8	.002
Recipients			
Demographics			
Age, mean (SD), y	60 (12)	56 (13)	.02
Female sex, %	34.0	37.6	.70
Race/ethnicity, %			
White	38.0	40.0	>.99
Black	54.0	52.0	
Other	8.0	8.0	
ABO blood group, %			
A	36.0	36.0	.80
B	14.0	19.2	
O	40.0	40.0	
AB	10.0	4.8	
Diabetes mellitus	34.0	29.6	.10
BMI, mean (SD)	29.0 (5.0)	27.3 (5.2)	.04
Peak panel reactive antibody, mean (SD), %	12.3 (30.3)	16.1 (31.3)	.50
Previous kidney transplantation, %	10.0	9.6	.90
Preemptive kidney transplantation, %	25.0	13.7	.10
HCV positive, %	21.3	11.2	.10
HIV positive, %	8.0	0.0	.001
Waiting list time, median (range), d	274 (11-1855)	736 (325-1806)	<.001

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CDCHR, Centers for Disease Control and Prevention high risk; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; Non-HR, non-high risk.

SI conversion factor: To convert creatinine to micromoles per liter, multiply by 88.4.

head trauma was the most common cause of death among CDCHR donors (36.0%), while cerebrovascular accident was the most common cause of death among non-HR

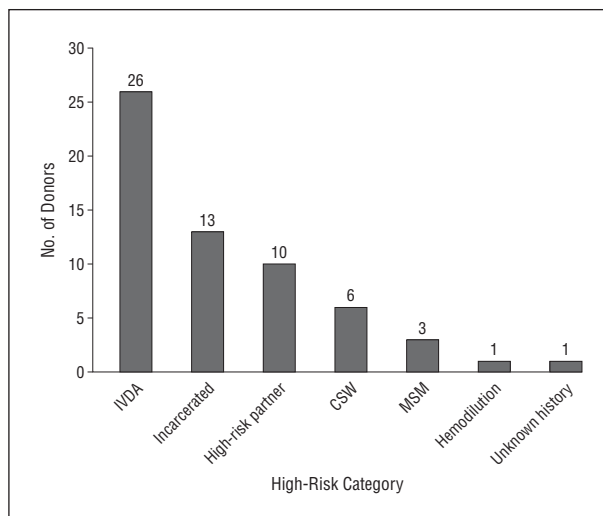


Figure 1. High-risk behaviors among donors. CSW indicates career sex worker; IVDA, intravenous drug abuse; and MSM, men who have had sex with men.

donors (44.8%). Most CDCHR donors were imported through national OPO sharing (74.0% vs 47.2% of non-HR donors, $P = .005$). Because our center routinely imports non-HR donor kidneys with lengthy cold ischemia times, the mean (SD) cold ischemia times were not significantly different between cohorts (25.5 [12.0] vs 21.9 [12.7] hours, $P = .1$), despite a higher percentage of nationally imported kidneys in the CDCHR group. The proportion of donors after cardiac death tended to be greater among non-HR donors (20.0% vs 10.0% of CDCHR donors, $P = .1$), and the proportion of expanded criteria donors was significantly greater among non-HR donors (24.8% vs 2.0% of CDCHR donors, $P < .001$).

All donors tested negative for HIV by NAT. Among CDCHR donors, 18.0% were HCV positive compared with 7.2% of non-HR donors ($P = .03$) (Table 1). All HCV-positive organs were transplanted into HCV-positive recipients who specifically gave consent to accept an HCV-positive kidney. Among CDCHR donors, 16.7% were HBV core antibody positive compared with 9.6% of non-HR donors ($P = .2$). All recipients of kidneys from HBV core antibody-positive donors specifically consented to accept these organs. Overall, the median terminal creatinine level did not differ between CDCHR and non-HR donors (0.9 mg/dL for both groups) (to convert creatinine level to micromoles per liter, multiply by 88.4). However, a greater proportion of non-HR donors had a high terminal creatinine level exceeding 2.5 mg/dL (8.8% vs 4.0% of CDCHR donors, $P = .002$).

The distribution of high-risk behaviors among CDCHR donors is shown in **Figure 1**. Intravenous drug abuse was the most common high-risk behavior among these donors and was reported in 26 of 50 donors. Thirteen donors were inmates of correctional facilities at the time of death, 10 had a history of having had sex with a high-risk partner, 6 were career sex workers, 3 were men with a history of having had sex with other men, 1 was characterized as high risk for a history of massive transfusion and hemodilution at the time of death and at the time of NAT, and 1 was characterized as high risk be-

Table 2. Outcomes After Renal Transplantation

Variable	CDCHR Recipients (n=50)	Non-HR Recipients (n=125)	P Value
Follow-up period, median (IQR), mo	13.8 (9.6-15.7)	10.7 (7.1-14.1)	.04
Deaths, No.	1	1	.50
Graft losses, No.	2	5	>.99
Delayed graft function, %	22.0	24.0	.80
1 mo After transplantation			
Creatinine level, median (IQR), mg/dL	1.4 (1.1-1.9)	1.5 (1.2-1.9)	.20
No. with follow-up data	50	125	...
3 mo After transplantation			
Creatinine level, median (IQR), mg/dL	1.2 (1.0-1.6)	1.4 (1.1-1.8)	.07
No. with follow-up data	50	112	...
12 mo After transplantation			
Creatinine level, median (IQR), mg/dL	1.4 (1.2-1.7)	1.4 (1.1-1.9)	.40
No. with follow-up data	33	57	...

Abbreviations: CDCHR, Centers for Disease Control and Prevention high-risk; IQR, interquartile range; Non-HR, non-high-risk. SI conversion factor: To convert creatinine to micromoles per liter, multiply by 88.4.

cause no family could be contacted at the time of death to confirm or deny any high-risk behavior. High-risk behaviors were not mutually exclusive, and some donors exhibited more than 1 high-risk behavior.

RECIPIENT CHARACTERISTICS

Recipients of CDCHR kidneys were older than recipients of non-HR kidneys (mean [SD] age, 60 [12] vs 56 [13] years, $P=.02$) (Table 1). A greater proportion of CDCHR recipients had diabetes mellitus, but this difference was not statistically significant (34.0% vs 29.6% of non-HR recipients, $P=.10$). The CDCHR recipients had slightly higher body mass index compared with non-HR recipients (29.0 [5.0] vs 27.3 [5.2], $P=.04$). The mean (SD) peak panel reactive antibody values were similar between CDCHR vs non-HR recipients (12.3% [30.3%] vs 16.1% [31.3%], $P=.50$), as was the proportion with a history of a previous kidney transplantation (10.0% vs 9.6%, $P=.90$). There was a trend toward a greater proportion of CDCHR recipients who underwent transplantation preemptively, although this difference did not achieve statistical significance (25.0% vs 13.7% of non-HR recipients, $P=.10$). A greater proportion of CDCHR recipients were HCV positive before transplantation, although the difference was not statistically significant for this sample size (21.3% vs 11.2% of non-HR recipients, $P=.10$). At transplantation, no non-HR recipients were HIV positive, while 8.0% of CDCHR recipients were HIV positive ($P=.001$). Most important, recipients of CDCHR kidneys had a significantly shorter median waiting list time compared with recipients of non-HR kidneys (274 vs 736 days, $P<.001$).

GRAFT FUNCTION AND PATIENT AND GRAFT SURVIVAL

Recipients of CDCHR donor kidneys had a median follow-up period of 13.8 (interquartile range [IQR], 9.6-15.7) months compared with 10.7 (IQR, 7.1-14.1) months among recipients of non-HR donor kidneys (Table 2). The incidence of delayed graft function was similar among

CDCHR recipients vs non-HR recipients (22.0% vs 24.0%, $P=.80$). At 1, 3, and 12 months after transplantation, the median serum creatinine levels were similar between CDCHR recipients and non-HR recipients. The death-censored graft survival at 12 months was similar between CDCHR recipients vs non-HR recipients (95.0% vs 93.6%, $P=.9$) (Figure 2). Among CDCHR recipients, 1 patient developed a treatment-refractory posttransplantation lymphoproliferative disorder, which necessitated transplant nephrectomy at 10 months, despite normal renal function. A second graft among CDCHR recipients was lost owing to acute cellular rejection. Among non-HR recipients, 1 graft displayed primary nonfunction, 1 was lost because of renal vein thrombosis, 2 were lost due to acute cellular rejection, and 1 was lost owing to antibody-mediated rejection in a highly sensitized patient.

Two patient deaths occurred. One CDCHR recipient died of pneumonia at 7 months after transplantation, and 1 non-HR recipient sustained a cardiopulmonary arrest at home at 6 months after transplantation. Both patients died with functioning renal allografts.

VIRAL TRANSMISSION

NAT performed over a median follow-up period of 11.3 (IQR, 6.0-13.1) months among recipients of CDCHR donor kidneys revealed no donor-related transmission of HBV, HCV, or HCV. No needlesticks or other occupational exposures of health providers occurred associated with the use of these organs.

COMMENT

In this study, we prospectively followed up the first 50 consecutive recipients of CDCHR kidneys since the establishment of a formal special informed consent process for the use of these organs at our institution. The objectives of this study were to evaluate the outcomes of these recipients vs recipients of non-HR kidneys and to begin to quantify the risks of viral transmission by serially assaying for new viral transmission following trans-

plantation. NAT testing of all CDCHR donors and ongoing NAT assessment of recipients were performed, and no new transmission of HIV, HBV, or HCV was identified over the follow-up period to date. Furthermore, recipients willing to accept CDCHR organs demonstrated graft function equivalent to that of recipients of non-HR kidneys and experienced significantly shorter waiting times for transplantation.

Given the significant mortality among those on the waiting list, the most obvious benefit to accepting a CDCHR kidney in our cohort was the dramatic reduction in waiting time. Patients willing to accept a CDCHR kidney waited half as long as those receiving non-HR allografts. Because only patients who received specific counseling about CDCHR kidneys in clinic were offered these organs, patients evaluated before the initiation of this protocol were initially excluded until they could be appropriately educated. Therefore, these patients had longer waiting times, and this contributed to the vast difference in waiting times we observed. However, waiting list registrants at the top of the list frequently refused CDCHR offers given their perceived likelihood of receiving a non-HR offer in a short period. In contrast, registrants at the bottom of the list were frequently eager to accept these organs, as this offered them the possibility of receiving a transplant years before they had anticipated. The concern raised most frequently by patients about CDCHR organs pertained not to what their infectious risk was but rather to whether the social behaviors of the donors would affect the function of the kidneys.

The patients willing to receive CDCHR organs also tended to be those whose prognosis on the waiting list was generally poor, namely, older patients, patients with diabetes, and those already infected with HIV or HCV. Although this study was not designed to evaluate survival benefit of earlier transplantation in these patients, it is conceivable that these particularly vulnerable patient populations derive a survival benefit from their willingness to accept a CDCHR kidney, as the benefits of earlier transplantation with a high-quality organ will likely outweigh the small risk of viral transmission from a CDCHR donor. In fact, as we continue to quantify the risk of transplant-mediated infection, we may find the actual risk to be so low as to suggest the benefit of transplanting these organs in almost all recipients.

Regardless of the perceived risk of viral transmission through the use of CDCHR organs, this study and other evidence support the notion that the real risk is likely to be very low. Among our small group of recipients, the incidence of new transmission was zero. Although the real risk is certainly not zero, it will be measurable only when multiple transplant centers prospectively screen for new viral transmission from CDCHR organs, as we have done herein, and this information is assimilated over a much larger sample size than a single center could generate.

At least for our patient population, the benefits of accepting a CDCHR organ offer were multiple. Recipients of CDCHR kidneys enjoyed graft function equivalent to that of recipients of non-HR organs. The quality of CDCHR kidneys was high, as these donors were younger, they were less likely to be expanded criteria donors or donors after cardiac death, and fewer had a high termi-

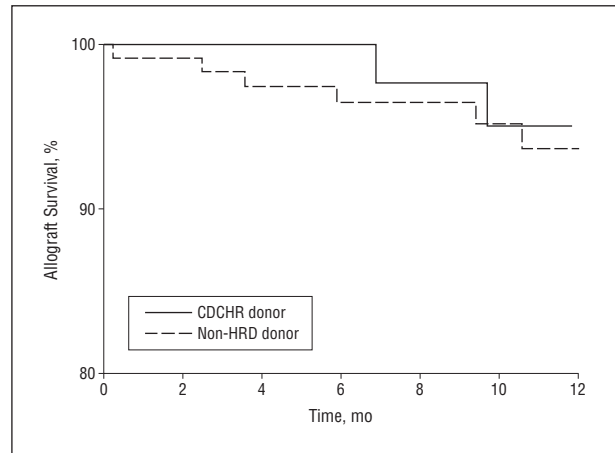


Figure 2. Death-censored renal allograft survival among recipients of Centers for Disease Control and Prevention high-risk (CDCHR) donor kidneys compared with recipients of non-high-risk (non-HR) donor kidneys. Death-censored graft survival at 12 months was 95.0% for CDCHR recipients vs 93.6% for non-HR recipients ($P=.9$).

nal creatinine level compared with non-HR donors. Given the younger age of CDCHR donors, it is possible that these grafts will ultimately demonstrate more durable function relative to that of older non-HR donor grafts. To assess this possibility, it will be important to gather long-term follow-up data for these patients.

Reluctance on the part of providers to use these organs is implied by our observation that a far greater proportion of CDCHR kidneys were imported from other OPOs compared with non-HR kidneys. As providers and patients alike realize that the actual risk of viral transmission from these organs is low, it is possible that the number of patients willing to accept them will grow. This will attenuate some of the potential benefit to the more vulnerable patients who are now willing to accept them. Demonstrating that the infectious risks of these organs are low will likely lead to more CDCHR organs used, fewer CDCHR organs discarded, and an overall increase in the donor pool, which will ultimately benefit all patients on the waiting list.

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Author Contributions: Dr Singer had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Lonze, Dagher, Kucirka, Montgomery, Segev, and Singer. *Acquisition of data:* Lonze, Dagher, Liu, Segev, and Singer. *Analysis and interpretation of data:* Lonze, Dagher, Kucirka, Simpkins, Locke, Desai, Cameron, Montgomery, Segev, and Singer. *Drafting of the manuscript:* Lonze, Dagher, Segev, and Singer. *Critical revision of the manuscript for important intellectual content:* Lonze, Liu, Kucirka, Simpkins, Locke, Desai, Cameron, Montgomery, Segev, and Singer. *Statistical analysis:* Kucirka and Segev.

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