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ORIGINAL ARTICLE

Temporal trends and impact of willingness to accept organs from donors with hepatitis C virus

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SUMMARY

Direct-acting antivirals (DAA) transformed hepatitis C virus (HCV) treatment in 2014; however, their impact on transplant candidates' willingness to accept (CWTA) organs from HCV$^+$ donors remains uncertain. We retrospectively studied Organ Procurement and Transplantation Network data from 2008 to 2019, investigating CWTA different organs from HCV$^+$ donors over time, using segmented multivariable logistic regression, and how that influenced wait-time and deceased-donor transplantation (DDTx) probability, using multivariable logistic or linear regression. We found that DAA availability was associated with a marked increase in CWTA in all organs from HCV$^+$ donors except intestine. By December 2020, 40% of kidney, 33% of kidney-pancreas, 42% of pancreas, over 50% of liver, heart, lung, heart-lung, and 9% of intestine candidates waitlisted were CWTA an organ from HCV$^+$ donors. Compared with pre-DAA, yearly CWTA kidney from HCV$^+$ donors increased post-DAA $_{1.78}1.81_{1.83}$-fold, kidney–pancreas $_{2\cdot52}$ 2.78 $_{3.07}$-fold, pancreas $_{3.15}3.69$ $_{4.43}$-fold, liver $_{1.53}1.54_{1.56}$-fold, heart $_{1\cdot92}$ $2.0_{2\cdot08}$ -fold, and lung $_{2.00}2.1_{2\cdot20}$ -fold. CWTA kidney and liver from HCV$^+$ donors significantly increased DDTx probability post-DAA ($_{1.98}2.04_{2.1}$-fold and $_{1.24}1.29_{1.33}$-fold, respectively) and shortened kidney candidates' wait-time$_{78}90_{101}$ days (Mean with 95% CI). CWTA organs from HCV$^+$ donors rose significantly with DAA availability, benefitting kidney and liver candidates with increased DDTx rates and shortened kidney candidates' wait time. Further long-term outcomes investigation and standardized organ from HCV$^+$ donors' education could improve both provider and patient acceptance and utilization.

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Introduction

Transplantation has become the standard of care for most types of advanced organ failure. The demand for organ transplants has risen significantly faster than the pace of organ donation, leading to a persistent widening in the organ shortage gap. One strategy to expand organ supply is to increase the utilization of organs from HCV$^+$ donors, which are currently discarded at a high rate [1,2]. In 2011, the prevalence of organs from HCV$^+$

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donors was 3.5% among standard-risk potential organ donors and 18.2% among the Public Health Service increased risk donor [3]. Furthermore, the number of overdose death donors has increased, roughly 18% of whom are HCV+ with a median age of 31 years, and these organs provide comparable post-transplant outcomes to trauma-death donors [4].

The advent of direct-acting antiviral (DAA) medications in 2014 effectively changed the HCV treatment landscape and provided effective and reliable post-transplant HCV therapy without the risk of rejection and other side effects associated with interferon therapy [5]. In the DAA era, organs from HCV+ donors are reported to have equal or even better outcomes as compared to organs from HCV+ donors in kidney [1,6], liver [7], and heart transplantation[8]. During the initial clinical trials [9–11], the rate of HCV+ donor to HCV- recipient transplants increased more than 10-fold from 2016 to 2018.

Candidate's willingness to accept (CWTA) is defined as the candidate being identified on the waiting list as accepting organs from HCV+ deceased donors. Candidates and centers could change this designation any time after listing. A previous study reported that in the DAA era, initial listing CWTA kidney from HCV+ donors was significantly increased [1]. We posit that a candidates' initial CWTA, an organ from HCV+ donor, is dynamic and modifiable, either by the patients, independently, or via provider-generated educational initiatives in listing centers. The objective of this study was to report changes in CWTA organs from HCV+ donors over time. Another aim was to determine to what extent the choice to accept an organ from HCV+ donors affects a candidate's probability of receiving a deceased-donor transplant, as well as their waiting time. To answer these questions, we used national registry data to capture the change in a CWTA an organ from deceased HCV+ donors in the DAA era, and to further assess the effect of CWTA on the probability of, and the waiting time to receive an organ transplant.

Methods

Study population

We performed analyses using data from all candidates on the waiting list from 2008 to 2019 for the descriptive analysis of change in CWTA organs from HCV+ donors (defined as acceptance of an HCV-antibody (Ab)-positive donor). We further performed two subgroup analyses: 1) all adult (age ≥18) candidates on the waiting list from 2008 to 2019 to analyze the association between CWTA organs from HCV+ donors and the probability of receiving a deceased-donor organ transplantation (DDTx) and 2) all adult kidney candidates who received DDTx from 2008 to 2019 to analyze the association between CWTA organs from HCV+ donors and waiting time to DDTx. Candidates with missing data regarding CWTA organs from HCV+ donors or age at listing were excluded.

OPTN registry

The Organ Procurement and Transplantation Network (OPTN) has collected data on all transplant recipients and waitlist registrants for solid organ transplantation, as well as all deceased and living organ donors since October 1, 1987. The OPTN data are linked to the Social Security Death Master File to augment ascertainment of candidate and recipient death. The CWTA organs from deceased donors with HCV were obtained from the waitlisted candidates and recorded whenever there was a change on this choice. We used data from the OPTN Analysis and Research file released in March 2021 based on data collected through March 5, 2021.

Definition of and change in CWTA organs from HCV+ donors

As briefly mentioned above, CWTA organs from HCV+ donors were defined as a variable in the OPTN database designated by the candidate's listing center to indicate provider and candidate's willingness to accept an organ from "an HCV-antibody positive donor". The OPTN collected data was available from the Analysis and Research file. Conversely, candidate acceptance of HCV nucleic acid testing (NAT)+ organs has only been documented in the OPTN database since February 2018, making HCV NAT+ acceptance data inadequate to investigate the DAA effect hypothesis on CWTA organs from HCV+ donors. We displayed the yearly distribution of candidates stratified by their CWTA organ from HCV+ donors at listing, and at most recent status. We also summarized the modification trends of their CWTA organ from HCV+ donors. We used a segmented multivariable logistic regression model to determine the yearly change in CWTA organs from HCV+ donors and compared the change in trends in the pre-DAA versus DAA era using January 1, 2014 as the cutoff date between the two eras. We adjusted for candidate's age, gender, ethnicity, insurance, organ failure diagnosis, and waiting time.

The candidate's probability to receive a deceased-donor organ

We used multivariable logistic regression to determine whether choosing to accept an organ from HCV$^+$ donors would affect the adult candidate's probability of receiving a deceased-donor organ transplant, adjusting for candidate's age, gender, ethnicity, insurance, organ primary diagnosis, waiting time, and DAA era.

The candidate's waiting time to receive a deceased-donor organ

We used multivariable linear regression to determine whether choosing to accept organ from HCV$^+$ donors would affect the adult kidney candidate's waiting time to receive a deceased-donor kidney transplant, adjusting for candidate's age, gender, ethnicity, insurance, organ failure diagnosis, dialysis times, last recorded current panel reaction antibody (CPRA), donation points, and DAA era.

Statistical analysis

Demographics and clinical characteristics were compared using chi-squared test or student's t-tests as appropriate. Estimates including odds ratio and slope were presented both in crude (without adjusting for any potential confounders) and in adjusted version. All analyses were performed using RStudio software, version 1.1.456 (R. RStudio, Inc., Boston, MA, USA). A *P*-value of <0.05 identified statistical significance, and all confidence intervals also used a 95% threshold.

Results

Change in the candidates' willingness to accept HCV$^+$ organs

We identified 551 957 candidates listed for kidney and/or pancreas, 162 988 candidates listed for liver, 84 824 candidates listed for heart and/or lung, and 2528 candidates listed for intestine from 2008 to 2019. Except for intestine, the number and proportion of candidates on the waiting list for other organs who were CWTA organ from HCV$^+$ donors at listing increased dramatically in the DAA era (Fig. 1). Of note, liver candidates' WTA organ from HCV$^+$ donors decreased from 2010 to 2016 and rapidly increased thereafter (Figure S1). After the introduction of DAA, we observed that the recovery of kidney, liver, heart, and lung from HCV$^+$ deceased donor increased significantly. The proportion of HCV$^+$ deceased donors who had two kidneys recovered, as well as those had two lungs recovered also increased in

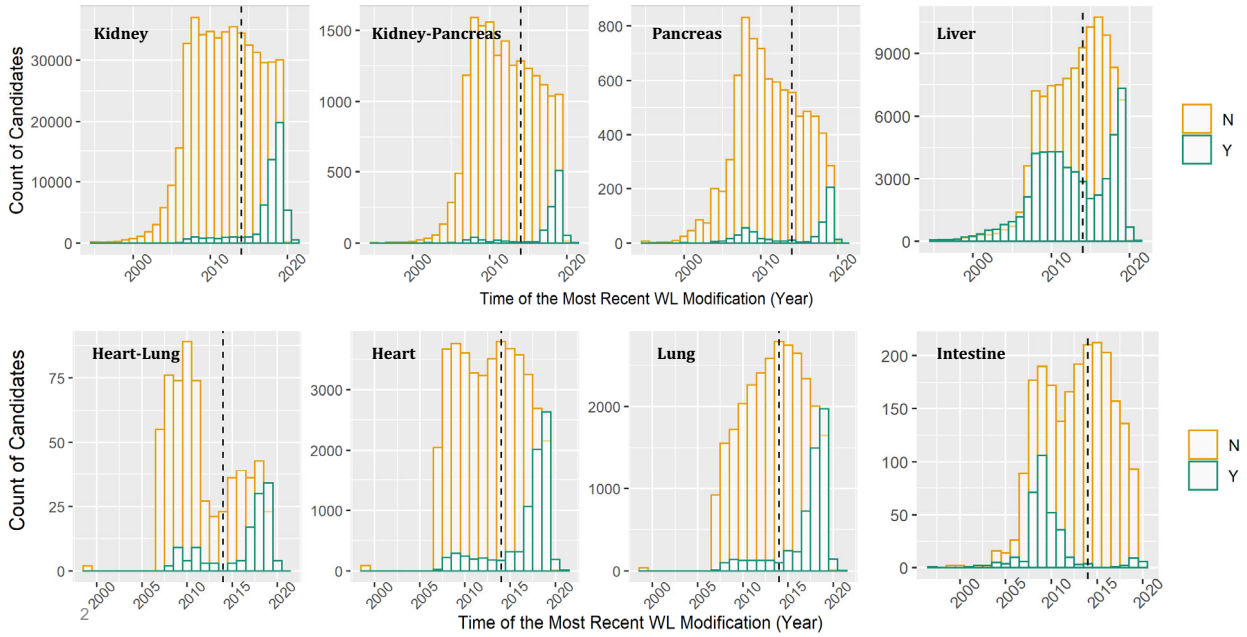

Figure 1 Most Recent Willingness to Accept organ from HCV$^+$ donors increased in the post-DAA era. Except for intestine, the number and proportion of candidates on the waiting list for other organs who were CWTA organ from HCV$^+$ donors at listing, increased dramatically in the DAA era.

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recent years. While the intestine and pancreas recovery remain low either from HCV- or from HCV+ deceased donor (Figure S2). We then summarized the trends of candidates' willingness modification by organ. In the DAA era, the number of candidates who changed their CWTA organ from HCV+ deceased donors from No to Yes increased, while that from Yes to No decreased, in most organ types except for intestine (Figure S3). These willingness modification trends resulted in a profound increase in the most recent CWTA organ from HCV+ donors' status in the DAA era (Fig. 1). By the end of 2020, 40% of kidney, 33% of kidney–pancreas, 42% of pancreas, over 50% of liver, heart, lung, and heart–lung, and 9% of intestine candidates who were listed from 2008 to 2019 chose to accept an organ from HCV+ donor.

After adjusting for the candidate's age, gender, ethnicity, insurance, organ failure diagnosis, and waiting time, we found a significant yearly increase in CWTA kidney from HCV+ donors (odds ratio (OR) 1.3 and 95% confidence intervals (CI) 1.28, 1.31 and decrease in the pancreas (OR 0.89 95% CI 0.83, 0.96) and liver (OR 0.91 95% CI 0.91, 0.91) candidates. Compared with that in the pre-DAA era, the yearly increase in CWTA organs from HCV+ donors in the DAA era was 1.81-fold higher for kidney (95% CI, 1.78, 1.83), 2.78-fold higher for kidney–pancreas (95% CI, 2.52, 3.07), 3.69-fold higher for pancreas (95% CI, 3.15, 4.43), 1.54-fold higher for liver (95% CI, 1.53, 1.56), 2.0-fold higher for heart (95% CI, 1.92, 2.08), and 2.10-fold higher for lung (95% CI, 2.00, 2.20) (Table 1). We further analyzed the yearly change in CWTA major organs (kidney, liver, heart, and lung) from HCV+ donors by centers. 67.2% kidney transplant centers (125/186), 50.4% liver centers (64/127), 82.5% heart centers (80/97), and 86.8% lung centers (79/91) had an increased trend of CWTA organs from HCV+ donors in the DAA era as compared with that in the pre-DAA era. A few centers (26 for kidney, 13 for liver, 49 for heart, and 54 for lung) even changed from having no candidate listed accepting organs from HCV+ donors to at least one of their candidates' accepting organs from HCV+ donors.

We compared the baseline characteristics between those candidates who chose to accept an organ from HCV+ donors and those who did not. We found that candidates listed for kidney and / or pancreas who chose to accept an organ from HCV+ donors were older, more likely to be African American, and had less waiting time, while the liver candidates who chose to accept an organ from HCV+ donors had longer waiting time compared with those not willing to accept these organs (Table 2a,b).

After adjusting for the candidate's age, gender, ethnicity, insurance, organ failure diagnosis, and waiting time, we found that only kidney and liver candidates' WTA organ from HCV+ donors significantly increased their probability of receiving a deceased-donor organ in the post-DAA era. The adjusted odds ratio was 2.04 (95% CI, 1.98, 2.1) for kidney and 1.29(95% CI, 1.24, 1.33) for liver candidates (Fig. 2).

Table 1. Change in willingness to accept organ from HCV+ donors.

	Yearly Increase		Difference in Slope (post-DAA vs. pre-DAA)	
	OR	95% CI	OR	95% CI
Kidney	1.3	(1.28, 1.31)	1.81	(1.78, 1.83)
Kidney–pancreas	1.04	(0.97, 1.11)	2.78	(2.52, 3.07)
Pancreas	0.89	(0.83, 0.96)	3.69	(3.15, 4.32)
Liver	0.91	(0.91, 0.91)	1.54	(1.53, 1.56)
Heart	1.04	(1.01, 1.07)	2.00	(1.92, 2.08)
Lung	1.01	(0.97, 1.04)	2.10	(2.00, 2.20)

DAA, direct-acting antivirals.

The association between CWTA organ from HCV+ donors and the candidate's waiting time to receive a deceased-donor organ

Finally, we evaluated the association between CWTA kidneys from HCV+ donors and waiting time to DDTx, given that waiting time is the most significant factor in kidney allocation; its influence on other organs allocation is considerably less. We found that choosing to accept an organ from HCV+ donors shortened the waiting time to transplantation by 205 days (95% CI, 193, 218). After adjusting for candidate age, gender, ethnicity, insurance, organ failure diagnosis, dialysis times, CPRA, and donation points, CWTA organs from HCV+ donors still shortened the waiting time by 90 days (95% CI, 78, 101) $P < 0.001$ (Fig. 3).

Discussion

Candidates' willingness to receive a novel therapy reflects the understanding of the risk–benefit ratio related to that specific therapy. The excellent outcomes of organs from HCV+ donors in the DAA era have attracted more candidates to accept them. However, it

Table 2. (a) Characteristics of candidates listed for kidney and/or pancreas, (b) Characteristics of candidates listed for liver.

CWTA Organ from HCV$^+$ donors	Kidney			Kidney–pancreas			Pancreas		
	No	Yes	*P*-value	No	Yes	*P*-value	No	Yes	*P*-value
n	456 149	55 075		17 780	1078		7650	445	
Age at listing (median [IQR])	53.0 [42.0, 62.0]	55.0 [45.0, 62.0]	<0.001	41.0 [34.0, 48.0]	42.0 [34.0, 49.0]	0.082	42.0 [35.0, 49.0]	42.0 [34.0, 50.0]	0.871
Male gender (%)	275 922 (60.5)	35 409 (64.3)	<0.001	10 388 (58.4)	607 (56.3)	0.181	3945 (51.6)	213 (47.9)	0.141
Race (%)			<0.001			<0.001			<0.001
White	201 009 (44.1)	23 337 (42.4)		10 837 (61.0)	561 (52.0)		5889 (77.0)	273 (61.3)	
African American	131 813 (28.9)	20 534 (37.3)		3937 (22.1)	305 (28.3)		916 (12.0)	101 (22.7)	
Hispanic	81 072 (17.8)	7431 (13.5)		2311 (13.0)	157 (14.6)		680 (8.9)	54 (12.1)	
CPRA (mean (SD))	1.66 (10.84)	0.41 (5.51)	<0.001	1.81 (11.04)	0.74 (7.36)	0.002	2.28 (12.32)	0.92 (8.12)	0.022
Waitlist Days (median [IQR])	804.0 [334.0, 1469.0]	734.0 [368.0, 1324.0]	<0.001	355.0 [128.0, 782.3]	415.5 [120.3, 765.3]	0.622	479.50 [134.0, 1156.75]	409.0 [104.0, 711.0]	<0.001
Diagnosis (%)			<0.001			<0.001			<0.001
Diabetes	151 797 (33.3)	18 712 (34.0)		16 084 (90.5)	998 (92.6)		1202 (15.7)	184 (41.3)	
Hypertension	94 066 (20.6)	11 847 (21.5)		723 (4.1)	15 (1.4)		53 (0.7)	4 (0.9)	
Non-private Insurance (%)	260 168 (57.0)	31 708 (57.6)	0.016	9276 (52.2)	543 (50.4)	0.264	3263 (42.7)	241 (54.2)	<0.001

CWTA Organ from HCV$^+$ donors	No	Yes	p-value
n	101 784	51 409	
Age at listing (median [IQR])	56.0 [50.0, 62.0]	56.0 [49.0, 62.0]	<0.001
Gender = M (%)	64 890 (63.8)	32 543 (63.3)	0.085
Race (%)			0.888
White	71 570 (70.3)	36 080(70.2)	
African American	8617 (8.5)	4393 (8.5)	
Hispanic	15 572 (15.3)	7914 (15.4)	
Waiting days (median [IQR])	207.0 [41.0, 623.0]	224.0 [44.0, 695.0]	<0.001
Organ failure diagnosis (%)			0.077
Biliary disease	7494 (7.4)	3873 (7.5)	
Liver disease	74 813 (73.5)	37 763 (73.5)	
Metabolic	1746 (1.7)	841 (1.6)	
Tumor	11 502 (11.3)	5661 (11)	
Non-private Insurance (%)	45 156 (44.4)	22 501 (43.8)	0.027

CWTA, candidate's willingness to accept; CPRA, current panel reaction antibody; IQR, interquartile range.

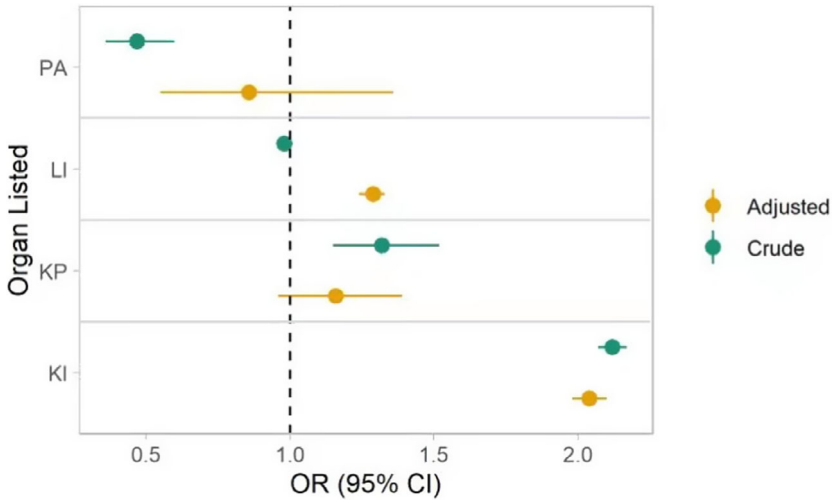

Figure 2 Listed as willing to accept organ from HCV+ donors, increased their probability to receive a deceased-donor organ Tx in the post-DAA era. (Crude means overall results and without any adjustment.) Only kidney and liver candidates' WTA organ from HCV+ donors significantly increased their probability of receiving a deceased-donor organ in the post-DAA era. The adjusted odds ratio was 2.04(95% CI, 1.98, 2.1) for kidney, and 1.29(95% CI, 1.24, 1.33) for liver candidates.

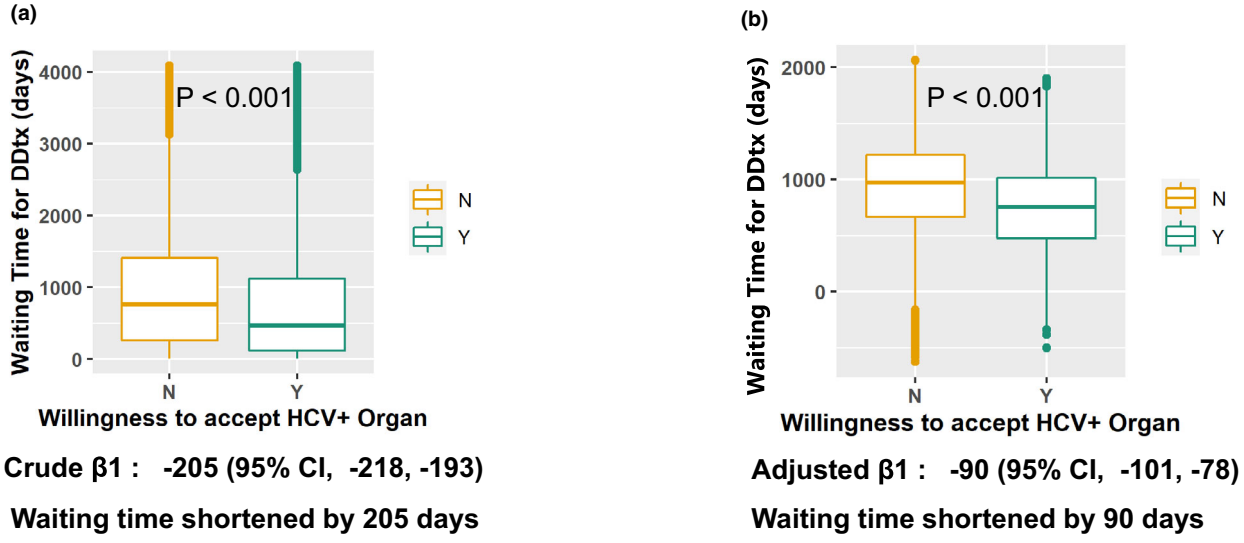

Figure 3 Listed as willing to accept organ from HCV+ donors, shorten kidney candidate's waiting time to receive a deceased-donor organ. (a) Crude, (b) Adjusted. (β1 is the slope of waiting time change in the linear regression model). Choosing to accept an organ from HCV+ donors shortened the waiting time to transplantation by 205 days (95% CI, 193, 218). After adjusting for candidate age, gender, ethnicity, insurance, organ failure diagnosis, dialysis times, CPRA, and donation points, CWTA organs from HCV+ donors still shortened the waiting time by 90 days (95% CI, 78, 101).

is common to have some lag in acceptance of new organ transplant practices because of the lack of awareness and verification of the advantage of those organs, and the need to educate not only patients to these benefits but also their care providers as well. Specifically, certain centers universally choose not to accept certain types of organs for transplantation and candidates listed at these centers are not even provided the option to make the decision. Consequently, this will hinder the change in candidates' willingness to adopt new innovations in clinical transplantation, in this case, accepting organs from HCV+ donors. In this study, we found a marked increase in the CWTA an organ from HCV+ donors in the DAA era in all organ types except intestine, at listing, during modification, and at most recent status. Probably because of the relatively sufficient

supply of intestine grafts from deceased donor, only a low proportion choose to accept HCV^+ donor. Our findings were consistent with the trends reported in the "OPTN/SRTR 2018 Annual Data Report: Hepatitis C from 2018" [12]. This increase in CWTA correlates with the ability to treat donor transmitted HCV in recipients with DAA, and subsequent clinical trials demonstrating successful transplantation of different organs from HCV^+ donors [9,11,13,14].

We observed organ-specific differences in the effect of the candidates' willingness on transplant probability and waiting time. CWTA organ from HCV^+ donors significantly improved the kidney and liver candidates' probability of receiving DDTx and further reduced the kidney candidates' waiting time. This was not significant in candidates listed for other organs. Potential causes for this phenomenon include differences across organs in urgency for transplantation, organ-specific demand and supply, and differences in organ-specific allocation algorithms. End-stage renal disease patients' urgency for transplantation is inherently less as compared to liver, heart, and lung candidates because of the availability and reliability of renal replacement therapy. There are more patients on the kidney wait list than any other organ type, with long wait times and the largest supply–demand imbalance, so that prompt organ availability will impact wait times more significantly than for any other organ. The trials demonstrating successful DAA therapy in HCV NAT^+ donor to NAT^- recipients in kidney transplantation may also attribute to explain the organ-specific difference, as kidney in general took place 1-2 years before thoracic studies [9,11]. Indeed, when using the same registry data one year prior, we can only find significantly improved probability of receiving DDTx in kidney but not liver candidates. Also, the advantage (decrease) in waiting time for DDTx resulted from CWTA, a kidney from HCV^+ donors, was much greater than now, which was 291 days (95% CI, 278, 305). This change further indicated the lag in other organs as compared with kidney, and that the trends and impact of CWTA organs from HCV^+ donors were temporal.

The benefit of choosing to accept a kidney from HCV^+ donors is more likely to be augmented by the newly implemented kidney allocation system (KAS) in 2014 [15]. KAS prioritizes allocation by the Kidney Donor Risk Index (KDRI) algorithm, which factors in the donor HCV infection status and in fact, assigns the largest coefficient among the dichotomous donor factors to HCV positivity in the donor [16]. In addition, KDRI likely underestimates the longevity of kidneys from HCV^+ donors in the DAA era, excluding high-quality kidneys from HCV^+ donors from those declining kidney offers based on KDRI beyond a certain threshold. These kidneys then become available for those who choose to accept kidneys from HCV^+ donors based on their individual benefit–risk assessment. However, clinical practice evolves as more data emerge, and when the perceived risks decrease with the accumulation of experience or breakthroughs in treatment, allocation should self-adjust to guarantee justice in the large population, with the caveat that disparity in organ allocation and selection is always a concern the transplant community should address, especially with novel therapies and approaches. Therefore, we postulate that as we acquire more long-term outcomes with kidneys from HCV^+ donors, the benefit to kidney candidates from being CWTA kidneys from HCV^+ donors will gradually vanish.

There are several limitations to our study. First, the OPTN data for CWTA an organ from HCV^+ donors did not differentiate NAT or Ab acceptance status prior to February 2018, nor did they record the candidates' own HCV status, which makes it impossible to trace the exact intent of those candidates: do they only want a NAT^- but Ab^+ organ, or also a NAT^+ one. Despite this ambiguity, we believe that because candidates' willingness was made under the same definition of HCV positivity of donor (by Ab rather than NAT) during the entire time period of our study, the trends could be summarized to estimate its association with some exposure (e.g. DAA eras). Second, we used the available relevant candidates' factors to adjust for baseline differences when estimating the extent of yearly change in CWTA, the probability of receiving a DDTx, and waiting time. There may be other unmeasured potential factors that were not recorded, or variables that were not accurately captured (e.g. the missing data on willingness to accept) in the registry data, which may bias our estimation. Third, the willingness recorded in the database could be a mixture of the listing center's style of practice and the patient's choice. To differentiate between the two is beyond the scope of this study and the available data. Lastly, we did not account for multiple listing across centers, which could also bias our estimation of the change in willingness.

Conclusion

Candidate's willingness to accept organs from HCV^+ donors increased in the post-DAA era, which benefited kidney and liver candidates by increasing their rate of DDTx and shortened the waiting time for kidney candidates. This study is the first to capture candidates' willingness to accept various organs from HCV^+ donors.

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Future studies should continue to investigate the long-term outcomes of transplanted organs from HCV+ donors, especially unforeseen morbidity associated with HCV infection transmission. Discard rates of organs from HCV+ donors and reasons for discard should continue to be collected. The data accrued thus far on HCV+ to HCV naïve recipients suggest that this is a safe, robust, but underutilized source of donor organs, especially as regards kidney transplantation. The data beg for wider adoption and utilization of this scarce resource.

Authorship

Qing Yuan and Nahel Elias designed research and study, and wrote the paper. Qing Yuan, Hanwen Cui, Shanjuan Hong, Greg A Leya, and Eve M Roth performed research and study. Nahel Elias collected data. Qing Yuan, Shanjuan Hong, and Hanwen Cui analyzed data. Qing Yuan, Hanwen Cui, Meghan E Sise, Emily D Bethea, Heidi Yeh, Winfred W Williams, and Nahel Elias reviewed and edited the paper.

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Conflicts of interest

The authors have declared no conflicts of interest.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Initial Willingness to Accept organ from HCV+ donors increased in the post-DAA era.

Figure S2. The yearly change in deceased donor stratified by organ and HCV ab status.

Figure S3. Willingness Modification: Increased from N to Y, Decreased from Y to N.

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