The American Journal of Surgery 220 (2020) 1278–1283

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Decreased graft loss following implementation of the kidney allocation score (KAS)

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ARTICLE INFO

Article history:
Received 18 February 2020
Received in revised form
19 April 2020
Accepted 25 June 2020

Keywords:
Kidney
Allocation
KDPI
Graft survival
Policy

ABSTRACT

Background: The Kidney Allocation System (KAS) was developed to improve equity and utility in organ allocation. We examine the effect of this change on kidney graft distribution and survival.
Methods: UNOS data was used to identify first-time adult recipients of a deceased donor kidney-alone transplant pre-KAS (Jan 2012–Dec 2014, n = 26,612) and post-KAS (Jan 2015–Dec 2017, n = 30,701), as well as grafts recovered Jan 2012–Jun 2019.
Results: Post-KAS, kidneys were more likely to experience cold ischemia time >24 h (20.0% vs. 18.8%, p < 0.001) and experienced more delayed graft function, though competing risks modeling demonstrated a lower hazard of graft loss post-KAS, HR 0.90 (95% CI 0.84–0.97, p = 0.007). Post-policy, KDPI >85% kidneys were more likely to be shared regionally (37% vs. 14%), and more likely to be discarded (60.6% vs. 54.9%) after the policy change. KDPI >85% graft and patient survival did not change.
Conclusions: Implementation of the KAS has increased sharing of high-KDPI kidneys and has decreased the hazard of graft loss without an impact on patient survival.

Introduction

The Kidney Allocation System (KAS) implemented on December 4, 2014 was designed to improve equity and utility of deceased donor kidney graft distribution. The KAS was comprised of a suite of changes including a) replacing the extended/standard criteria donor categorization with the kidney donor profile index (KDPI) which more fully captured donor kidney quality, b) including an expected post-transplant survival (EPTS, defined by age, time on dialysis, diabetes status, and prior organ transplants) into the matching criteria, to match the highest quality kidneys (as determined by KDPI) with the patients with the longest EPTS, c) increasing priority for patients who are sensitized as defined by calculated panel reactive antibody (CPRA, a measure of overall sensitization of a recipient to the pool of available), and d) allowing for all time on dialysis to be utilized as waiting time, regardless of the time of listing.[1] These changes were intended to increase the total number of life-years gained through transplantation, to reduce disparities in organ allocation, and to maximize organ use.

Since KAS implementation, there has been ongoing interest in evaluating the consequences of the change in kidney graft allocation. Generally, the KAS has made strides towards its goal of improving matching of donor and recipient, with the proportion of recipients greater than 30 years younger than the donor declining significantly.[2] Sensitized recipients have increased access to transplantation at most levels of CPRA.[3–5] Additionally, KAS has decreased racial disparities, with an increase in the proportion of African American recipients listed and transplanted[3,6,7]. Finally, though the KAS was intended to decrease organ discard rate, initial experience showed an increase in discard rate.[8]

We sought to examine the effects of the KAS on patient and graft survival five years after its implementation. Additionally, we sought to specifically address the effect of KAS on transplantation practice and outcomes of KDPI >85% kidneys.

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https://doi.org/10.1016/j.amjsurg.2020.06.061
0002-9610/

Table 1
Donor and recipient characteristics.

Donor Characteristics	Pre-KAS (n = 26612)	Post-KAS (n = 30701)	p-value
Age- median(IQR)	**41 (26–52)**	**39 (26–51)**	<0.001
Age – n%			<0.001
0–17	**2463 (9.5)**	**2754 (8.8)**	
18–34	**7624 (29.5)**	**10286 (33.0)**	
35–59	**13535 (52.3)**	**15792 (50.7)**	
> = 60	**2240(8.7)**	**2336 (7.5)**	
Diabetes-n (%)	2168 (8.2)	2171 (7.1)	<0.001
Hypertension-n (%)	7785 (29.3)	8621 (28.1)	0.002
Cause of Death-n (%)			<0.001
Anoxia	8632 (32.4)	12603 (41.1)	
Stroke	8251 (31.0)	7783 (25.4)	
Head Trauma	8872 (33)	9333 (30.4)	
CNS Tumor	134 (0.5)	116 (0.4)	
Other	723 (2.7)	866 (2.8)	
Serum creatinine- median (IQR)	**7.6 (5.6–10.1)**	**8.1 (5.9–10.6)**	<0.001
Creatinine > 1.5 mg/dL-n (%)	4646 (17.5)	6185 (21.2)	<0.001
BMI- median (IQR)	**26.8 (23.1–31.4)**	**26.9 (23.1–31.6)**	0.003
BMI≥35- n (%)	3627 (13.6)	4407 (14.4)	0.012
KDPI- median (IQR)	**0.46 (0.24–0.68)**	**0.44 (0.24–0.66)**	<0.001
KDPI – n(%)			<0.001
0–20%	**5407 (20.9)**	**6688 (21.5)**	
>20–50%	**8875 (34.3)**	**11031 (35.4)**	
>50–85%	**9326 (36.1)**	**11189 (35.9)**	
> 85%	**2254(8.7)**	**2260(7.3)**	
Extended Criteria Donor- n (%)	4328 (16.3)	4345 (14.2)	<0.001
Donation after Cardiac Death- n (%)	4730 (17.8)	6607 (21.5)	<0.001
Cold ischemic time- hours, median (IQR)	**16 (11–22)**	**16.7 (11.4–22.7)**	<0.0001
Cold ischemic time > 24h	5017 (18.9)	6156 (20.1)	0.0003
Machine perfusion- n (%)	12657 (47.6)	15098 (49.2)	0.0001
Distance Traveled- miles, median (IQR)	**44 (5–159)**	**65 (8–204)**	<0.0005
Sharing -n (%)			<0.001
Local	20262 (78.4)	22766 (73.0)	
Regional	2396 (9.3)	3911 (12.6)	
National	3203 (12.4)	4489 (14.4)	
Sharing, KDPI > 85%-n (%)			<0.001
Local	1593 (70.7)	1070 (47.4)	
Regional	316 (14.0)	835 (37.0)	
National	345 (15.3)	355 (15.7)	
Recipient Characteristics			
Age – median(IQR)	**57 (46–64)**	**55 (44–63)**	<0.0001
Age > 60-n (%)	9869 (37.1)	10462 (34.1)	<0.001
Female-n (%)	10451 (39.3)	12322 (40.1)	0.035
Ethnicity-n (%)			<0.0001
White	10897 (41.0)	10649 (36.7)	
Black	8739 (32.8)	11047 (36.0)	
Hispanic	4449 (16.7)	5930 (19.3)	
Asian	1987 (7.5)	2311 (7.5)	
Diabetes-n (%)	10433 (39.2)	11367 (37.0)	<0.0001
BMI-median (IQR)	**28.2 (24.6–32.2)**	**28.1 (24.4–32.2)**	0.0004
BMI≥35-n (%)	3371 (12.7)	3760 (12.3)	0.13
cPRA-Mean (SD)	16.9 (30.3)	19.5 (33.1)	<0.001
cPRA- median (IQR)	**0 (0–22)**	**0 (0–26)**	<0.001
cPRA > 80%-n (%)	2617 (9.8)	3640 (11.9)	<0.001

Methods

This study used data from the United Network for Organ Sharing (UNOS) STAR files. The STAR files contain data on all donors, waitlisted candidates, and transplant recipients in the United States. Data quality is monitored and enforced; timely and accurate submission is required for continued accreditation of transplant centers. The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services oversees the activities of the Organ Procurement and Transplantation Network (OPTN). This study was approved by the Duke University Institutional Review Board.

Data from the UNOS STAR files (retrieved June 2019) was used to identify first-time adult recipients of a deceased donor kidney-alone transplant pre-KAS (Jan 2012–Dec 2014) and post-KAS (Jan 2015–Dec 2017). Demographic variables were summarized and compared for donor and recipient, stratifying by era (pre- and post-KAS). Outcomes were tabulated and stratified by era and KDPI where appropriate. Comparisons were performed using Student's T-test for continuous variables, and Chi-square for categorical variables. Patient and graft survival were estimated using the Kaplan-Meier method and compared by the log-rank test. Cumulative incidence function was used to estimate the probability of graft loss with death as a competing event. The Fine and Gray subdistribution hazards model was used to evaluate the effect of pre-versus post-KAS era on the risk of graft loss. Hazard ratio and 95% confidence interval (CI) are provided as measures of strength of association and precision, respectively. We additionally performed competing risks modeling adjusted for donor age and KDPI. Follow-up was truncated to 24 months to account for the shortened duration of follow-up data available in the recent cohort.

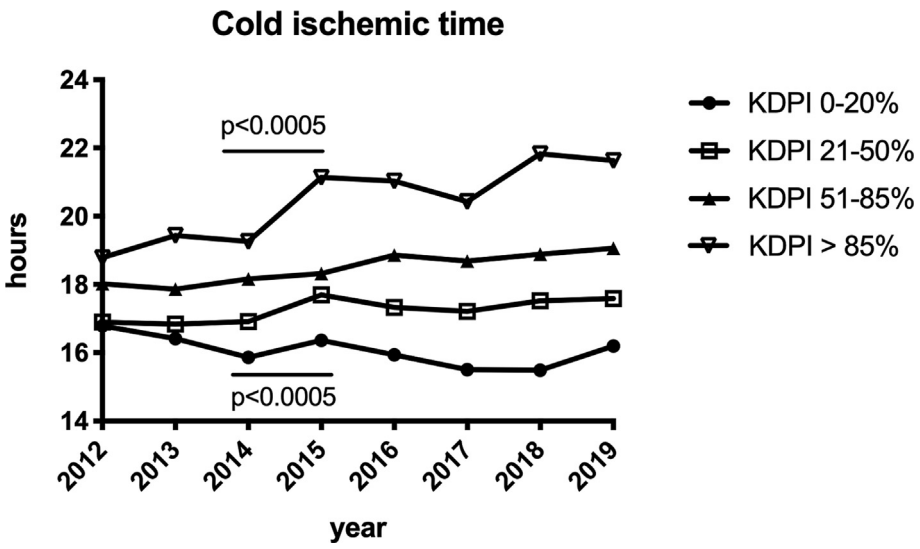

Fig. 1. Kidney graft cold ischemic time by transplant year, by categories of KDPI.

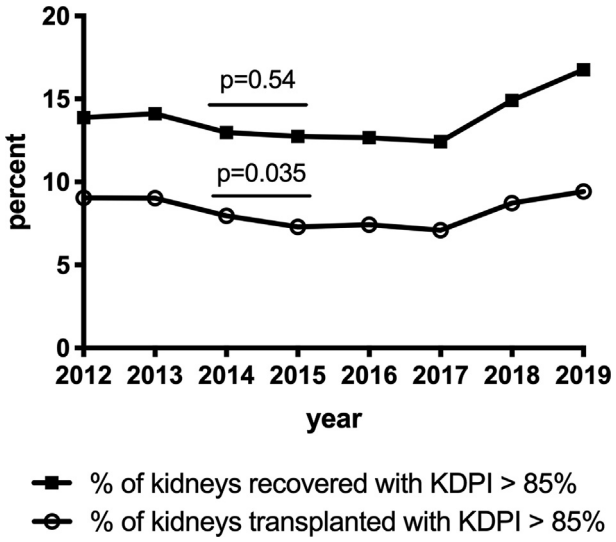

Fig. 2. Proportion of kidneys with KDPI >85% recovered and transplanted.

Kidney graft characteristics and discard rate were additionally described for the most recent available data, spanning Jan 2011–June 2019. Kidney discard rate was calculated by dividing the number of grafts procured and not transplanted per year by the number of kidney grafts procured.

Analysis was performed using STATA 15 (College Station, TX) and SAS (Cary, NC). P-value less than 0.05 was considered statistically significant. The data reported here have been supplied by the United Network for Organ Sharing as the contractor for the Organ Procurement and Transplantation Network. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government.

Results

Donor and recipient characteristics

There were 26,612 kidney transplants performed pre-KAS, and 30,701 post-KAS. Compared to pre-KAS, post-KAS donors were younger, less likely to have diabetes or hypertension, and more likely to die of anoxic brain injury. Compared to pre-KAS, post-KAS recipients were younger, less likely male or white, more likely to be diabetic, and had a higher CPRA and creatinine. (Table 1).

Graft utilization

Post-KAS, kidneys were more likely to be procured after cardiac death (21.5% vs. 17.8%, $p < 0.001$), to travel farther ($p < 0.0005$), and to experience cold ischemia time > 24 h (20.0% vs. 18.8%, $p < 0.001$) when compared to pre-KAS. Post-KAS, fewer KDPI >85% kidney grafts were transplanted (7.3% vs. 8.5%, $p < 0.0001$), though this trend demonstrated recovery in 2018 and 2019 (Fig. 2). Compared with low-KDPI kidneys, KDPI >85% kidneys were more likely to be shared regionally, and these grafts have experienced increasing cold ischemic time since 2014 (Fig. 1). Post-KAS grafts were also more likely to undergo machine perfusion.

The discard rate for kidneys with KDPI >85% was 54–58% per year pre-KAS, and increased by 6% post-KAS, while the proportion of KDPI >85% kidneys recovered did not change (13.0% in 2014 vs. 12.7% in 2015) (Fig. 3). Post-KAS, KDPI >85% kidneys were more likely to be discarded due to the recipient list being exhausted (43.7% vs. 28.0%, $p < 0.0001$), and less likely to be discarded due to biopsy findings (30.4% vs. 39.0%, $p < 0.0001$). The proportion of kidneys discarded for long cold ischemic time or pump time did not change (0.47% vs. 0.48%, $p = 0.80$).

Graft and patient outcomes

Post-KAS kidneys had greater delayed graft function (DGF), defined by requiring dialysis within the first week post-transplant (28.7% vs. 26.1%, $p < 0.001$ overall; 37.3 vs. 31.4%, $p < 0.001$ among KDPI >85%). DGF did not increase among kidneys with KDPI≤20% (data not shown). Patient survival did not change post-KAS globally (KM log rank $p = 0.51$), nor for kidneys with KDPI > 85% (KM log rank $p = 0.29$) (Fig. 4).

Competing risks modeling demonstrated a lower hazard of death-censored graft loss post-KAS, SHR 0.90 (95% CI 0.84–0.97, $p = 0.007$), and an unchanged hazard of graft loss for kidneys with KDPI > 85% (SHR 0.88 95% CI 0.70–1.10, $p = 0.27$). Cumulative incidence function of graft loss is presented in Fig. 5. The effect of KAS on graft loss persisted following adjustment for donor age and KDPI (SHR 0.90 95% CI 0.82–0.98, $p = 0.015$).

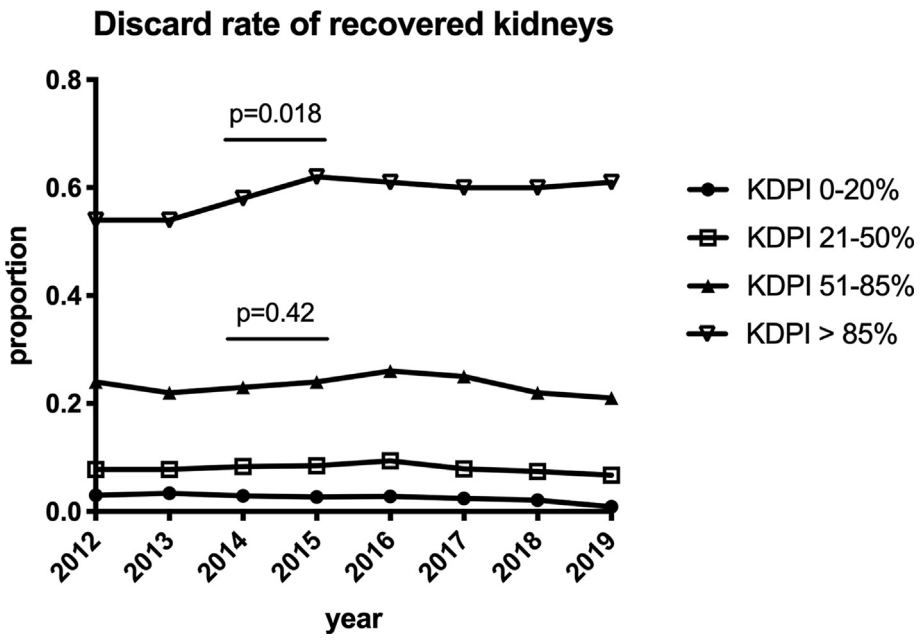

Fig. 3. Proportion of kidneys discarded over time, stratified by KDPI.

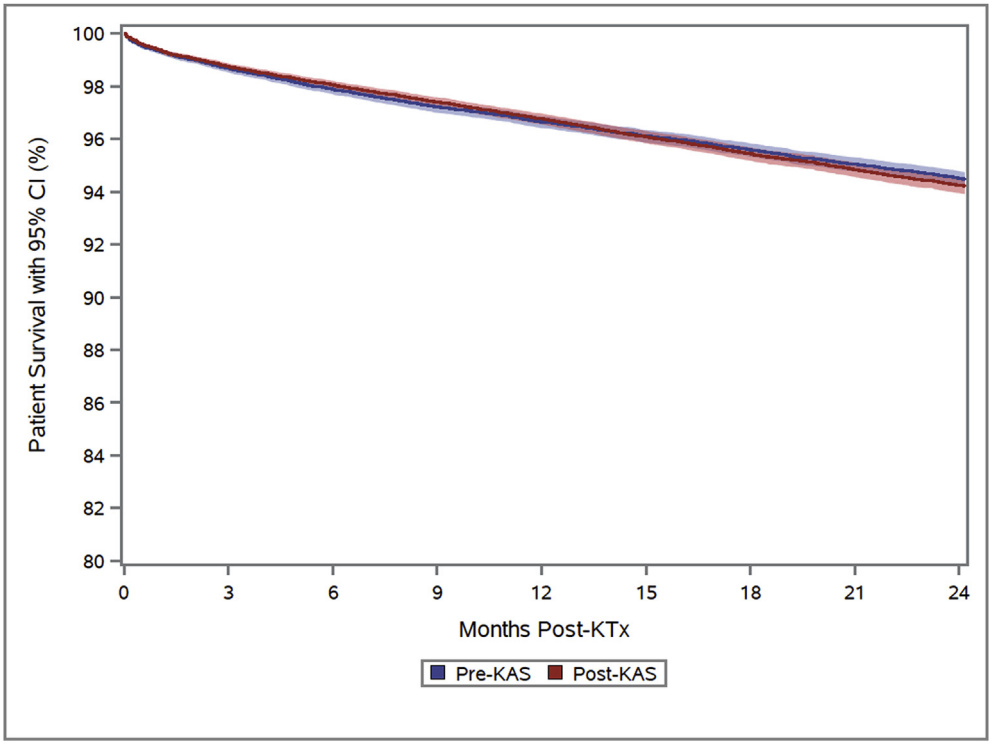

Fig. 4. Kaplan-Meier curves of patient survival, stratified by implementation of the Kidney Allocation System. Follow-up truncated at two years.

Discussion

The implementation of the Kidney Allocation System in late 2014 aimed to improve allocation, utilization, and longevity of kidney grafts. Though successful by many measures, the system has had the unintended consequence of greater discard rate of KDPI >85% kidneys.

We use the UNOS dataset to investigate the change in kidney graft utilization and outcomes after implementation of the policy. We find that discard of KDPI >85% kidneys increased following KAS, with a rate of 61% in 2019. KDPI >85% kidneys were more broadly shared and experienced longer cold ischemic time, but their use did not reduce patient or graft survival at 2 years. Globally, cumulative incidence of graft failure decreased by 10% following KAS.

Early post-KAS analyses found an initial decrease in survival, though were limited by short available duration of follow-up.[9] Others found no difference in patient or graft survival as failures are infrequent in the first year post transplant.[8,10] Our study has the

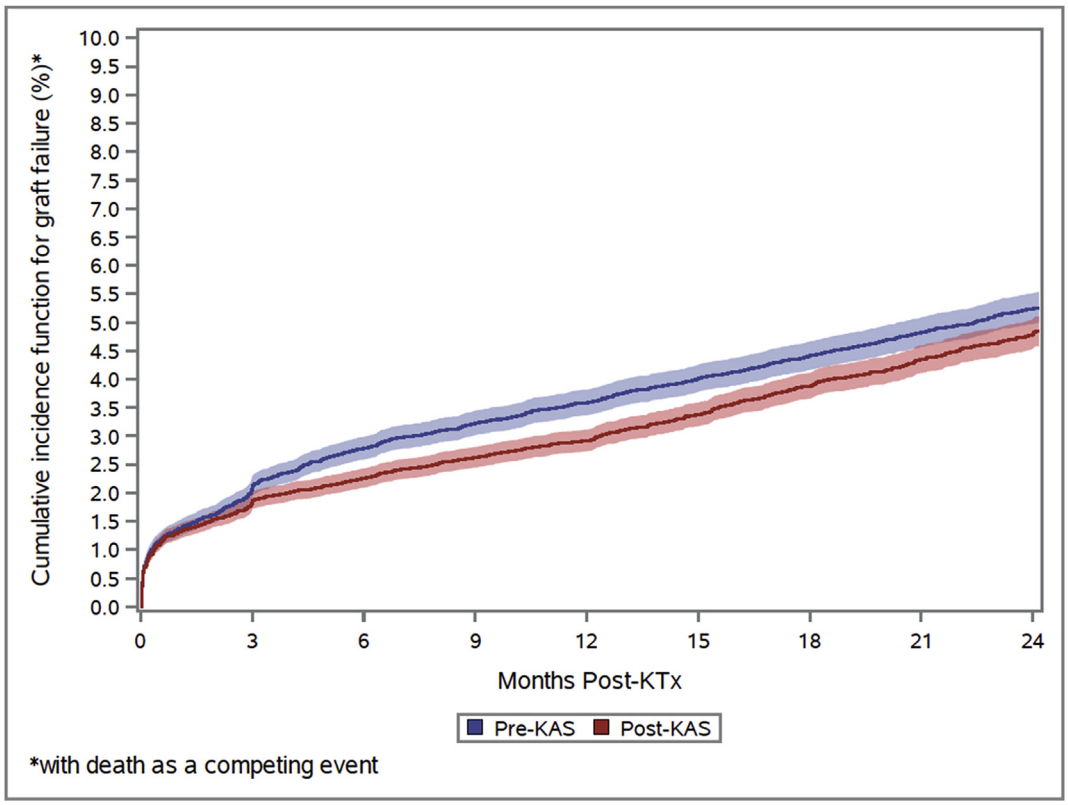

Fig. 5. Cumulative incidence function for graft loss, with death as competing risk, stratified by implementation of the Kidney Allocation System. (Gray's test: p = 0.009).

advantage of longer follow-up. Our findings of increased DGF after KAS is consistent with prior reports.[11] This is of particular concern as DGF represents a risk factor for worse post-transplant outcomes broadly[12] and has been implicated in a more rapid graft failure and return to dialysis.[13] While our analysis demonstrating a decrease in graft failure post-KAS despite an increase in DGF may signify improved donor-recipient matching, longer follow-up is needed to more accurately assess the long-term consequences of this intermediate outcome.

The high discard rate of high-KDPI kidneys after KAS was initially reported by Bae et al.[14] We have found that this effect persists, with a discard rate of 61% for KDPI >85% kidneys in 2019. We also found that 43.7% of KDPI >85% kidneys are now discarded due to exhaustion of the list, with no suitable recipient found. The new Kidney Allocation System now requires clinicians to set a maximum acceptable KDPI for each recipient, which may lead to automatic rejection of otherwise suitable kidneys. Previous rejections of high KDPI kidneys may also generate cognitive biases that contribute to discard.[15] Bae et al.[14] additionally demonstrated a survival advantage to high-KDPI transplant when compared to remaining on the waiting list for a better quality kidney. In the context of a growing kidney transplant waiting list, more judicious use of high-KDPI kidneys may beneficial, and research that investigates the reasons for declining high-KDPI kidney grafts is warranted.

This analysis is limited by the use of a historical comparator group, which may introduce era bias. Due to the relative recency of the policy implementation, we are unable to ascertain longer-term outcomes. We additionally cannot comment on the clinical reasoning leading to the high discard rate of KDPI >85% kidneys. The discard categories of "list exhausted" and "biopsy findings" may not be mutually exclusive. Stewart et al.[16] analyzed graft distribution during a period of erroneously high KDPI values in 2016, and found that while KDPI influenced discard rate, the increase in discard rate did not match the false increase in KDPI. We additionally cannot comment on metrics other than KDPI that centers and clinicians use for kidney acceptance and discard due to limited granularity of the available data.

Conclusions

Implementation of the KAS improved global kidney graft survival, and has increased sharing of high-KDPI kidneys without adversely affecting graft or patient survival. It has also resulted in an increase and persistently high discard rates for kidneys with KDPI >85%. More attention is needed to the reasons behind discard of high-KDPI kidneys and the effects of discard rate on waiting list mortality, when utilization of these organs could otherwise provide a survival advantage.

Declaration of competing interest

The authors have no conflicts of interest to disclose.

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