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Can We Predict Kidney Graft Function and Graft Survival Using Hypothermic Machine Perfusion Parameters From Donors After Circulatory Death?

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Background. Hypothermic machine perfusion (HMP) reduces renal injury in donation after circulatory death donors with a high Kidney Donor Profile Index (KDPI). This study aims to characterize the correlation between KDPI, HMP parameters, and donor vitals during the withdrawal period in predicting short- and long-term graft outcomes. **Methods.** ANOVA with Tukey's honestly significant difference tests compared the relationship between average flow, average resistance, peak resistance, flow slope, and resistance slope on day 30, 1-y, and 3-y eGFR, and days of delayed graft function. Graft and recipient survival rates were assessed using Kaplan-Meier analysis. **Results.** The data for 72 grafts were suitable for analysis. Kidneys with KDPI >50% had a significantly higher day 30, and 1-y posttransplant eGFR, if HMP average flow was >150 mL/min, or the average resistance was <0.15 mm Hg/mL/min, compared with kidneys with also KDPI >50% but had not achieved the same pump parameters. There were no significant differences in the Kaplan-Meier analysis, considering recipient or graft survival, regardless of the KPDI score with 3- or 5-y outcomes. **Conclusions.** Use of average resistance and average flow from a HMP, in conjunction with KDPI, may be predictive of the short- and long-term function of donation after circulatory death kidney transplants.

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The use of kidneys from donors after brain death (DBD) has been well established in the literature with short- and long-term excellent results, but it does not supply all patients in need of a transplant. The comparison between DBDs and kidneys from donation after circulatory death (DCD) has been widely studied, even though the literature still needs to provide a better way to identify the quality of the grafts from DCDs. We know that with the demand for kidney transplants exceeding the number of available donors, extended criteria donors (ECDs) and DCDs provide an additional avenue for kidney donation.[1] The ECD definition has been replaced by the Kidney Donor Profile Index (KDPI), a numerical measure combining donor factors to provide a cumulative relative risk in a percentage scale to summarize the likelihood of graft failure after a deceased kidney transplant.[2-4]

The process of obtaining an organ from a DCD can be impacted by low blood pressure, lack of oxygenation, low heart rate, and mainly warm ischemic time. Therefore, the donor's vitals during the withdrawal process have been studied to correlate with the rate of delayed graft function (DGF) and long-term graft survival rate, but the literature has been inconsistent.[5-7] Hypothermic machine perfusion

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(HMP) has been shown to reduce renal injury and improve DGF compared with standard cold storage in DCD, mainly in those with KDPI >85%, which have a higher risk of graft failure.[8-11]

Pump parameters have been used to determine the useability of grafts and long-term transplant outcomes. Perfusion machine parameters may provide unique insight into interpatient graft variability. Previous work demonstrated an association between resistance >0.4 mL/min and the rate of DGF but have been inconsistent in showing a correlation with long-term graft survival.[12,13] Similarly, a recent 2022 study found that HMP parameters were predictive of early graft function, whereas donor demographic factors were more predictive of long-term function.[14] Other recent work suggested a correlation between KDPI and histopathologic findings, but without incorporation of HMP parameters.[15] A 2021 randomized controlled trial found no significant difference between HMP versus standard cold storage in terms of 1-y graft survival, DGF, or eGFR.[16] However, this study incorporated ECD criteria rather than KDPI and did not account for HMP parameters. There is limited work exploring the different components of these flow and resistance curves and examining their association with posttransplant outcomes. Identification of pump parameters that predict patient outcomes can guide patient care.

Thus, this study aims to characterize, for the first time, the intercorrelation between the pump parameters and KDPI in predicting the short- and long-term graft and recipient outcomes.

PATIENTS AND METHODS

Patients

This study received ethics approval from the London Health Sciences institutional review board (WREM-120252). We reviewed all adult patients who underwent kidney transplantation at our center from January 2016 to November 2019 to have a minimum follow-up of 3 y. All recipients were thoroughly assessed and independently cleared to undergo kidney transplantation by the nephrology and transplant surgery team. We had used the previous ECD criteria for allocation by the time these transplants happened. Still, to align our project with the literature, we calculated the KDPI retrospectively, using the cutoff of <50%, 50%–75%, and >75%. Grafts were procured from DCD, and all kidneys immediately after the procurement were continuously pumped in a hypothermic machine (LifePort from Organ Recovery system company) until being removed for the backtable. The time on the pump depended on the availability of an operating room in our center. Recipient and donor demographics, donor's withdrawal sheet containing the total time to arrest, time from the beginning of surgery until flush, and vital signs during the withdrawal period were collected. The pump parameters and postoperative outcomes were recorded and analyzed.

Surgical Technique

An extraperitoneal kidney transplantation in the iliac fossa was routine. We anastomosed in the external iliac artery and vein. We performed a core biopsy after reperfusion as a baseline. Lich-Gregoir with a ureteral stent was the technique for ureterovesical anastomosis. We routinely placed a surgical drain next to the kidney graft. We kept the urinary catheter in until postoperative day 4. A multidisciplinary team followed the patients postoperatively.

Immunosuppression, Anticoagulation, and Infection Prophylaxis

Our standard immunosuppression induction protocol for DCD kidney transplants included methylprednisolone (250 mg IV) and rabbit antithymocyte globulin at a dose of 1.5 mg/kg/d for a cumulative target dose of 5–6 mg/kg or Basiliximab 20 mg on induction and day 2 after the transplant, depending on cumulative reactive antibody panel, the patient's age, and comorbidities. Postoperative immunosuppression consisted of oral tacrolimus (once-daily dosing to a target level of 7–10 ng/mL), mycophenolic acid, and prednisone. The prophylactic antibiotic was Cefazolin. Recipients received a prophylactic treatment with valganciclovir for 6 mo if there was a cytomegalovirus mismatch between the donor and recipient.

Perfusion Parameters

The following perfusion parameters were obtained for each kidney graft: infusion time, resistance, and flow. Resistance and flow curves are depicted in Figure 1. We calculated the slope of the initial increase in flow using the following equation:

$$\text{Flow slope} = \frac{\text{Flow}_2 - \text{Flow}_1}{\text{Time}_2 - \text{Time}_1}$$

The slope of the initial decline in resistance was also calculated:

$$\text{Resistance slope} = \frac{\text{Resistance}_2 - \text{Resistance}_1}{\text{Time}_2 - \text{Time}_1}$$

After the flow and resistance curves plateaued, we also calculated the average flow and average resistance.

Postoperative Outcomes

Patients were followed daily postoperatively until the patient was discharged. Then, the patient was seen by a nephrologist and surgeon as an outpatient. Routinely, blood was withdrawn twice weekly for the first month or as necessary. We removed the urinary stent 4 wk after the transplant date. The surgical drain was removed when the output is <50 mL daily. DGF was defined as the use of dialysis within 7 d of the transplant.[17]

Statistical Analysis

Statistical analysis was conducted using R software (Version 1.1.463; Boston, MA). Pump parameters, such as the infusion time, flow, pressure, resistance, and temperature were plotted and demonstrated the predictable patterns in Figure 1. Four kidneys were excluded from the analysis due to their pump parameters demonstrating marked fluctuation without a return to a predictable pattern. Patient demographic data were summarized as mean ± SD. Unpaired *t* tests were conducted for continuous variables, and Fisher exact tests were conducted for categorical variables. Linear regression analysis was conducted to assess the association of different pump parameters to postoperative graft outcomes. One-way and 2-way ANOVA with Tukey's honestly

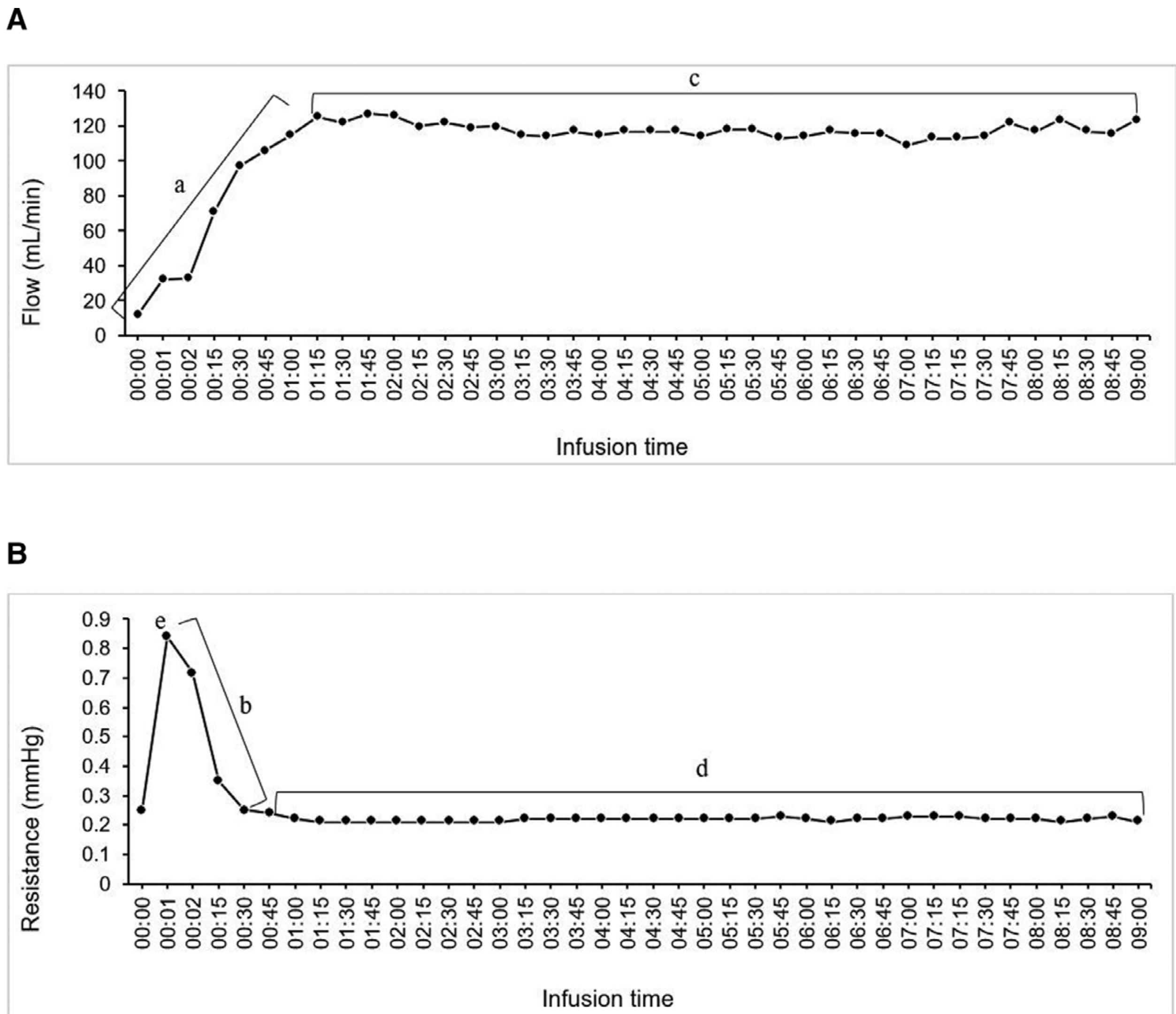

FIGURE 1. Perfusion machine parameters over time for a representative kidney graft. A, Flow and (B) resistance. The (a) flow slope, (b) resistance slope, (c) average flow, (d) average resistance, and (e) peak resistance were obtained.

significant difference tests were also conducted to compare the amplitude of pump parameters on postoperative outcomes. The cumulative graft and recipient survival rates were assessed using Kaplan-Meier analysis, and the log-rank test was used to compare the 2 groups statistically. Statistical significance was set at $P < 0.05$.

RESULTS

Between January 2016 and November 2019, we performed 86 kidney transplants from DCDs. The demographic information required to calculate the KDPI was only available for 72 donors, resulting in a N = 72 sample size for analysis involving KDPI. All kidneys were pumped using HMP (LifePort—kidney transporter machines) with Belzer MPS solution at 3–7 °C. The mean follow-up period posttransplant was 1734 d (± 389 d). Overall, early graft loss (first 90 d) occurred in 3.5% (3/86) of patients in our sample. None of these 3 graft losses were related to technical causes. Two of them had died secondary to sepsis from a pulmonary source, and 1 had a cardiac event after 1 mo of surgery. The all-cause mortality rate in this study was 13.5% (12/86) over the follow-up period. When examining the 72 recipients, 1.4% (1/72) experienced early graft loss, while all-cause mortality was 13.9% (10/72). The demographic characteristics between grafts with KDPI <50% and KDPI >50% are shown in Table 1.

Average flow and resistance were plotted against KDPI, and linear regression analysis demonstrated a significant association, with an increasing KDPI correlating with a decrease in average flow and an increase in average resistance (Figure 2A and B). We found that the average flow and resistance began to differ at a KDPI higher than 50%, as depicted in Figure 2. Although our analysis showed that kidneys with KDPI >50% had a lower average flow compared with kidneys with KDPI <50%, when kidneys with KDPI >50% were pumped for a period of time, and an average flow of 150 or more was reached, they had an excellent graft outcome at day 30, 1-y, and 3-y posttransplant, similar to the group with KDPI <50% (Figure 3A; Table 2). For grafts with a KDPI >50% and a low average flow of <75 mL/min, there was no significant difference in eGFR at 30 d or at 1-y when compared with grafts

TABLE 1.

Demographic characteristics between KDPI <50% and KDPI >50%

Variables analyzed	KDPI <50% (n = 34), mean ± SD	KDPI >50% (n = 38), mean ± SD	*P*
Recipient characteristics			
Recipient age, y	49.38 ± 13.86	60.26 ± 8.67	<0.0001
Recipient incidence male, n (%)	20 (58.8)	24 (63.6)	0.81
Recipient dialysis, y	13.27 ± 18.99	24.08 ± 36.77	0.13
Donor characteristics			
KDPI	31.15 ± 11.91	69.97 ± 11.05	<0.0001
Donor age, y	38.18 ± 11.60	59.64 ± 5.48	<0.0001
Donor incidence male, n (%)	27 (79.4)	23 (60.5)	0.12
Donor creatinine	70.26 ± 49.22	60.69 ± 19.29	0.27
Donor terminal eGFR	132.16 ± 54.60	125.26 ± 37.83	0.53
Donor height, cm	174.54 ± 10.72	171.39 ± 9.57	0.19
Donor weight, kg	87.34 ± 32.34	84.35 ± 16.37	0.62
Donor ethnicity: White, n (%)	34 (100)	38 (100)	1.00
Donors with hypertension, n (%)	1 (2.9)	6 (15.8)	0.11
Donors with type 2 diabetes, n (%)	1 (2.9)	7 (18.4)	0.06
Donors with CVA death, n (%)	2 (5.9)	3 (7.9)	1.00
Donor HCV+, n (%)	2 (5.9)	0 (0.0)	0.22
Time to arrest, min	32.35 ± 34.92	25.34 ± 24.70	0.33
Graft characteristics			
Warm ischemia time when MAP <55, min	24.70 ± 11.64	24.77 ± 10.26	0.98
Cold ischemia time, min	441.62 ± 223.81	360.21 ± 213.30	0.12
Induction therapy, n (%)	n = 31	n = 34	
Basiliximab	9 (29.0)	5 (14.7)	0.23
Thymoglobulin	22 (71.0)	29 (85.3)	0.23

CVA, cerebral vascular accident; eGFR, estimated glomerular filtration rate; HCV, hepatitis C virus; KDPI, Kidney Donor Profile Index; MAP, mean arterial pressure.

with KDPI >50%. However, the 3-y eGFR was significantly lower for grafts with both a high KDPI >50% and a low flow of <75 mL/min (Table 2).

For kidneys with KDPI >50% that ended with an average resistance of 0.15 or less, the day 30 eGFR was equally good as kidneys with KDPI <50% (Figure 3B). However, if the average resistance ended at 0.4 or above, the day 30 eGFR was significantly lower compared with those with an average resistance of 0.15 or less. Therefore, donor kidneys with KDPI >50% with an average pump resistance of <0.15 or an average flow of 150 mL/min had 1-y outcomes similar to kidneys with KDPI <50%.

Furthermore, there were no significant associations—using 1-way ANOVA—between the flow slope, resistance slope or peak resistance, respectively, on any posttransplant parameters, such as day 30 eGFR and creatinine, 1-y eGFR and creatinine, DGF, and days of graft survival. When the data were divided by KDPI >50% and KDPI <50%, there were also no significant associations between the flow slope, resistance slope, or peak resistance on postoperative outcomes.

Kaplan-Meier analysis divided by KDPI <50% and >50% showed a cumulative recipient survival rate was 86.5% in the KDPI >50% group and 85.7% in the KDPI <50% group depicted in (Figure 4A) (*P* = 0.60). The cumulative graft survival rate was 97.3% in the KDPI >50% group and 100% in the KDPI <50% group (Figure 4B) (*P* = 0.30). A flow diagram depicting the primary outcomes is presented in Figure 5.

DISCUSSION

This study demonstrated that grafts with a KDPI >50% and a high average flow of 150 mL/min+ performed similarly, if not better, to low KDPI grafts in terms of 30-d, 1-y, and 3-y eGFR. Thus, a high KDPI graft may not necessary perform poorer than a low KDPI graft and use of HMP parameters may expand the use of high KDPI grafts. For grafts with a KDPI >50% but a low average flow/resistance, there was no significant difference in 30-d or 1-y eGFR compared with their KDPI <50% counterpart, However, 3-y eGFR was significantly lower in grafts with high KDPI and low average flow. There were also no significant differences in recipient or graft survival, regardless of the KPDI score with 3- or 5-y outcomes.

A recent systemic review and meta-analysis showed that kidneys from DCD could be safely used with outcomes similar to kidneys from DBD.[18] Nevertheless, DCD kidneys have a higher discard rate than brain death donors,[19] and this rate can be higher for those with higher KDPI. Finding reliable parameters for the decision-making process is fundamental.

Tingle et al[20,21] published a meta-analysis in 2019, proving the superiority of HMP compared with static solution. The rate of DGF, especially on DCD kidneys, was lower if the HMP was used with RR 0.75 (95% confidence interval, 0.64-0.87; *P* = 0.0002), with a higher graft survival rate compared with the static solution (93% versus 82%; *P* = 0.036). Jochmans et al[22] demonstrated the association of final resistance on the hypothermic perfusion machine with DGF and 1-y graft failure but with low positive predictive accuracy. Therefore, they did not recommend using it as a decision-making tool alone. The same authors suggested the multifactorial nature of DGF and overall graft function.

Our group has used kidneys from DCDs since the implementation in Canada in 2006. Nevertheless, due to the constant necessity to provide better evidence, we started to study different variables that could impact the quality of organs

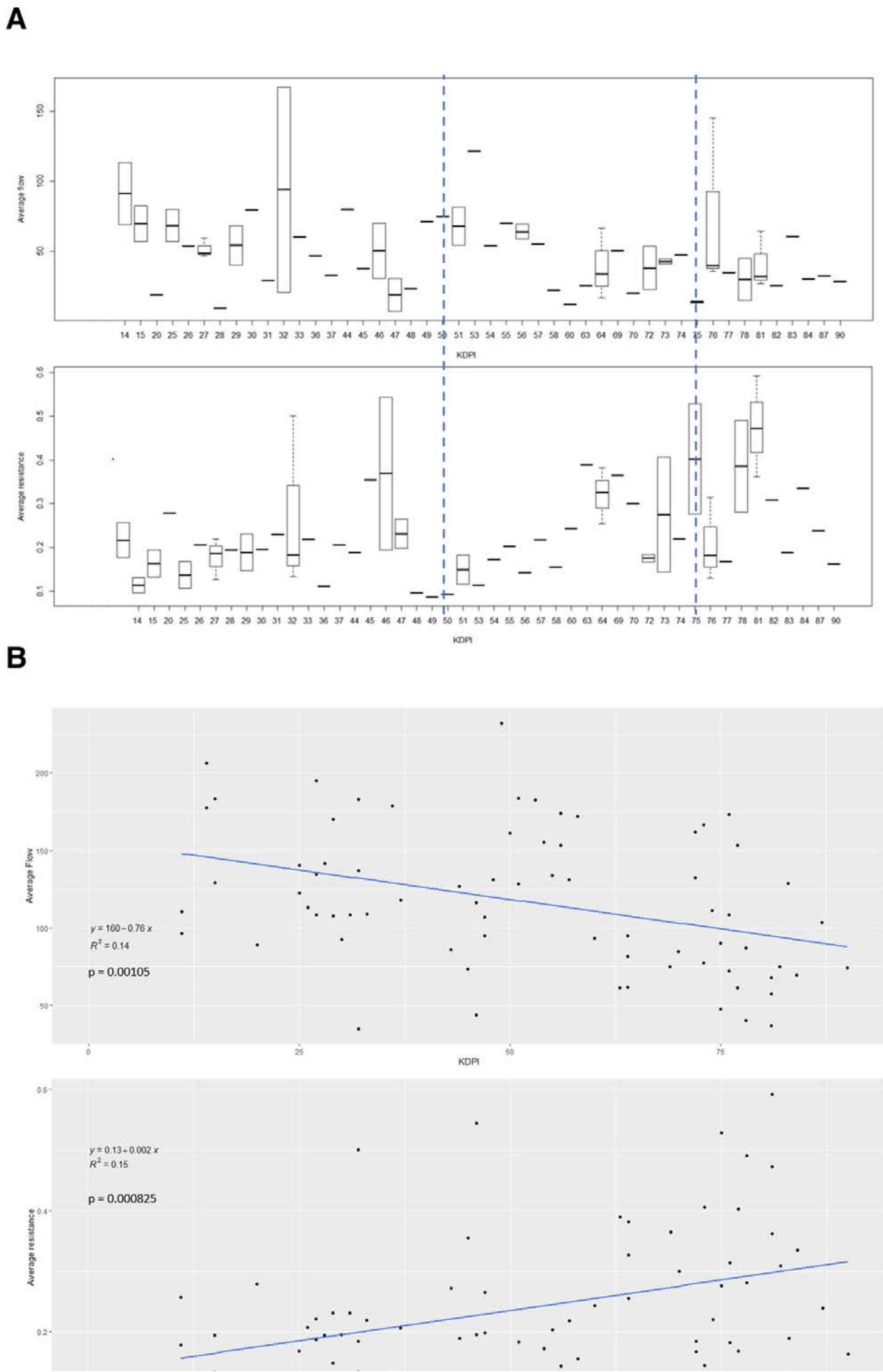

FIGURE 2. Relationship between average flow and resistance as KDPI increases. Average flow and average resistance with increasing KDPI, (A) visualized through boxplots, and (B) with linear regression analysis. KDPI, Kidney Donor Profile Index.

from DCDs. We analyzed donor information, initially allocated based on standard or expanded criteria characteristics. Moreover, we retrospectively calculated the KDPI and divided it into 3 cross-sections. After regression analysis, the cutoff was established as <50% or >50%. We understand that for the first time, an analysis is made crossing KDPI, pump parameters, and the donor's vital signs during the withdrawal period.

Sonnenday et al[23] showed the importance of donor information associated with pump parameters.[20] The same authors also suggested a threshold of 0.4 mm Hg/mL/min as the cutoff to use the organ. In our study, we used an average flow and resistance instead of the final flow and resistance. The decision for average resistance and flow was based on the idea of having a complete picture of the behavior of that kidney during the whole period on a pump, which could bring additional information.

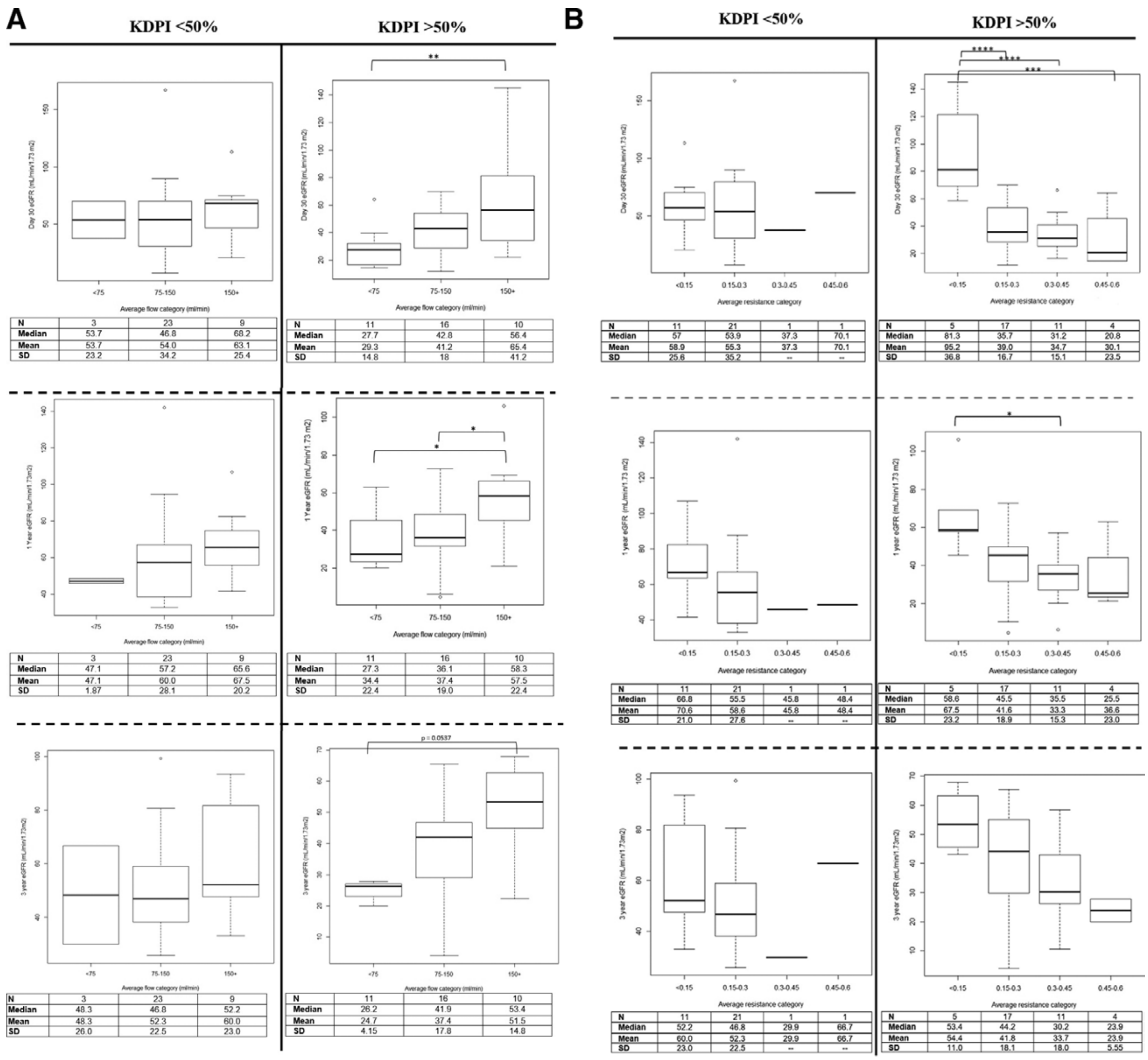

FIGURE 3. Box plots demonstrating the relationship between average flow or resistance and eGFR at day 30, 1 y and 3 y. A, Association of average flow to day 30, 1-y, and 3-y eGFR for donors with KDPI <50% and KDPI >50%. B, Association of average resistance to day 30, 1-y, and 3-y creatinine for donors with KDPI <50% and KDPI >50%. One-way ANOVA with Tukey tests were conducted. **P* < 0.05, ***P* < 0.01, ****P* < 0.001, *****P* < 0.0001. eGFR, estimated glomerular filtration rate; KDPI, Kidney Donor Profile Index.

TABLE 2.

Comparison of eGFR between the 3 average flow categories for KDPI >50% and KDPI <50%

eGFR over time	Average flow, mL/min	n	KDPI <50%	n	KDPI >50%	*P*
Day 30 eGFR	<75	3	53.7 ± 23.2	11	29.3 ± 14.8	0.70
	75–150	23	54.0 ± 34.2	16	41.2 ± 18	0.18
	150+	9	63.1 ± 25.4	10	65.4 ± 41.2	0.89
1-y eGFR	<75	3	47.1 ± 1.87	11	34.4 ± 22.4	0.36
	75–150	23	60.0 ± 28.1	16	37.4 ± 19.0	<0.01 (0.0081)
	150+	9	67.5 ± 20.2	10	57.5 ± 22.4	0.32
3-y eGFR	<75	3	48.3 ± 26.0	11	24.7 ± 4.15	<0.01 (0.0074)
	75–150	23	52.3 ± 22.5	16	37.4 ± 17.8	<0.05 (0.0335)
	150+	9	60.0 ± 23.0	10	51.5 ± 14.8	0.35

Numbers are derived from Figure 3. Unpaired *t* tests were conducted comparing the mean ± SD eGFR between KDPI <50% and KDPI >50%.
eGFR, estimated glomerular filtration rate; KDPI, Kidney Donor Profile Index.

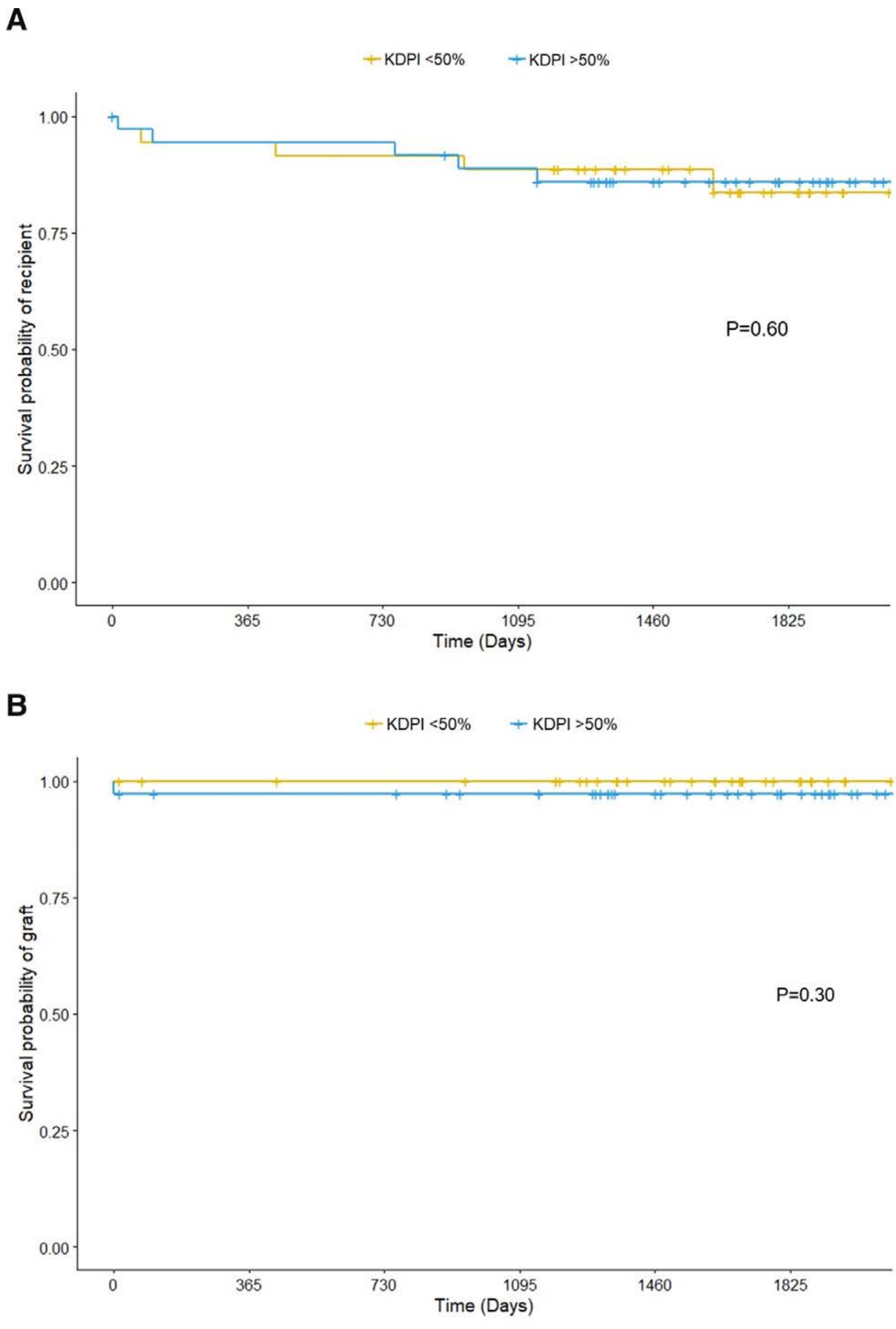

FIGURE 4. Recipient and graft survival rates for grafts with KDPI <50% and >50%. Kaplan-Meier curves depicting (A) recipient and (B) graft survival. The cumulative graft and recipient survival rates were assessed using log-rank tests. KDPI, Kidney Donor Profile Index.

We showed the impact of HMP in kidneys with KDPI >50%, considering a multivariable analysis of pump parameters. Grafts with KDPI >50% performed similarly to kidneys with a KDPI <50% when the pump parameters achieved the expected average resistance of <0.15 and an average flow >150. On the other hand, kidneys with KDPI >50% had worse kidney function on day 30, with a trend to have a worse overall outcome on the 1- and 3-y posttransplant if it had an average resistance higher than 0.45, confirming what Sonnenday et al[23] published in 2003.

We want to encourage the use of kidneys from DCDs, considering the shortage of organs and the number of patients with chronic kidney disease in renal replacement therapy are expected to double in 2030 compared with 2010.[24] Previous research showed that patients on dialysis for >10 y had significantly higher rates of DGF, graft loss, and patient death within 30 d.[25] Thus, the use of DCD kidneys offsets the number of patients on renal replacement therapy, which may improve posttransplant outcomes. Although our data showed a correlation between pump parameters and kidney function in the short term, we advocate using the provided data to inform patients of what to expect of the follow-up period, knowing that the kidney can change the patient survival rate compared with staying on dialysis, even for those kidneys with KDPI >50% and average resistance higher than 0.45.

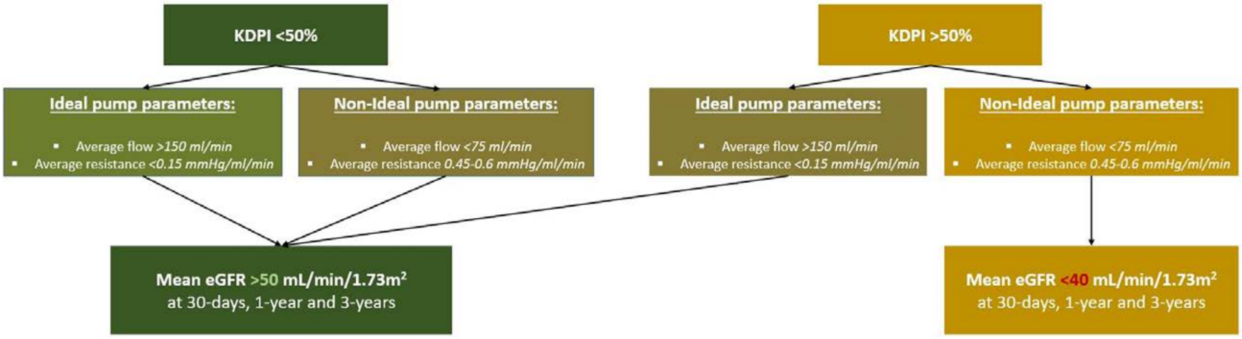

FIGURE 5. Flow diagram depicting the primary findings of this study. eGFR, estimated glomerular filtration rate; KDPI, Kidney Donor Profile Index.

This study has some limitations. The small sample size tempers our findings, which were from a single center and using in a retrospective study design. As mentioned above, we have yet to analyze the long-term outcomes. Moreover, the sample size of kidneys ending with an average resistance >0.45 or an average flow less the 75 cmHg was small, which could create a positive or negative confounding error. The final average resistance and flow could be calculated only after the kidney was removed from the pump, which was difficult to obtain because the information had to be immediately downloaded. Incorporating this data may provide better information compared with the final resistance or flow alone. Despite these limitations, our results support future prospective, multicenter, and randomized studies, which compare posttransplant outcomes for patients receiving grafts of the same KDPI but different HMP parameters.

CONCLUSIONS

Average resistance and flow can be used as a tool to understand better the behavior of DCD kidneys pumped on a hypothermic perfusion machine. Our data suggest that pump parameters can be used to predict day 30, 1-, and 3-y graft function if the average resistance is 0.15 or less and or the average flow is 150 or more. Our findings may help match the appropriate recipient to a specific kidney or contribute to the creation of a stronger predictive tool, while incorporating multiple parameters which are already available. A multicenter study is warranted to address this question definitively.

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