

## ORIGINAL ARTICLE

# Outcomes of kidney transplantation from uncontrolled donors after circulatory death vs. expanded-criteria or standard-criteria donors after brain death at an Italian Academic Center: a prospective observational study

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## ABSTRACT

**BACKGROUND:** The use of kidneys from “expanded criteria” donors after brain death (ECD) and uncontrolled donors after circulatory death (uDCD) has been warranted to increase the pool of donors for kidney transplantation (KT). However, there is lack of evidence on the feasibility and safety of KT from such donors in the Italian setting.

**METHODS:** We queried our prospectively KT database to select patients undergoing KT from deceased donors (uDCDs, ECDs, and standard-criteria donors [SCD] after brain death) from January 2017 to December 2020, comparing the peri-operative and mid-term functional outcomes.

**RESULTS:** Overall, 172 KTs were included. The donor’s profile was different among the study groups, while recipients’ characteristics were similar except for median age. Grafts from uDCDs and ECDs had longer median cold ischemia times as compared to grafts from SCDs. The proportion of patients experiencing DGF, the median hospitalization, as well as the overall and major complications rate, were significantly higher among recipients from uDCDs. The proportion of patients needing dialysis at last follow-up was significantly higher among recipients from uDCDs (33.3% vs. 8.5% vs. 5.4%,  $P < 0.001$ ). However, the median eGFR at the last follow-up was lower for recipients from ECDs compared to those from uDCDs and SCDs, respectively ( $P < 0.001$ ).

**CONCLUSIONS:** While “marginal” donors represent a relevant source of organs, KTs from uDCDs carry higher risks of major surgical complications, DGF, and worse graft survival as compared to KT from both ECDs and SCDs. As such, the use of grafts from uDCDs should be carefully assessed balancing the potential benefits with the risk of primary no function and the subsequent immunological sensitization.

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**KEY WORDS:** Kidney transplantation; Robotic surgical procedures; Kidney transplantation; Tissue donors.

During the last decades, end-stage renal disease has become a significant issue for national health systems worldwide, from both clinical and economic standpoints.<sup>1</sup> In this scenario, kidney transplantation (KT) represents the most cost-effective treatment, providing better survival and quality of life as compared to dialysis.<sup>1,2</sup> Unfortunately, the increased mismatch between the demand and the number of available kidneys has led to a progressive extension of waiting lists.<sup>1</sup> To fill this gap, a variety of strategies have been proposed and tested, such as the implementation of the living donation process (paired exchange KT, kidney donor chain, etc.) and the development of more efficient deceased donor programs.<sup>3,4</sup> Considering the relatively low proportions of KT from living donors in several countries worldwide, including Italy,<sup>5</sup> some health care systems have carried out organizational and economic efforts to optimize the quality and quantity of available kidneys in the deceased donor setting, using organs from both older/marginal donors after brain death (DBD) and donors after circulatory death (DCD).<sup>6</sup> The former category includes the so-called “expanded-criteria donors” (ECD) (defined as donors aged >60 or 50-59 year with two of the following features: history of hypertension, terminal serum creatinine  $\geq 1.5$  mg/dL, or death resulting from a cerebrovascular accident),<sup>4</sup> supported by the United Network for Organ Sharing (UNOS) as a potential additional source of grafts despite the expected worse outcomes.<sup>7</sup> The latter category includes both “controlled” and “uncontrolled” DCDs (*i.e.*, donors after cardio-respiratory arrest, previously defined as Nonheart-Beating Donors and currently classified into four categories according to the Modified Maastricht Classification).<sup>8</sup> Namely, type II (uncontrolled DCDs [uDCD]) donors are defined as patients with cardiovascular arrest and in whom cardiopulmonary resuscitation has been unsuccessful, while type III (controlled) donors as patients in whom withdrawal of life-sustaining therapies has been applied; these donors significantly differ regarding the overall donation process and logistical factors impacting the donation process.<sup>8</sup> In Europe, to date, KT programs from DCDs are active in some Countries, with heterogeneous jurisdictions, organizations, and applied procedures

for kidney harvesting;<sup>9,10</sup> yet, these donors could significantly contribute to the number of kidneys for KTs (*i.e.*, representing up to 29% of the KT activity in Spain).<sup>6</sup> Notably, however, KTs from uDCDs still represent a minority of KT from deceased donors globally,<sup>6,10</sup> their outcomes seem to be promising and comparable to standard-criteria donors in selected realities.<sup>11-14</sup> In Italy, while the Ministry of Health authorized organ procurement from uDCDs in 2007,<sup>15</sup> to the best of our knowledge no study has reported so far, the perioperative and functional outcomes of KT from such donors in the Italian setting. Of note, the Italian legal framework for organ donation from DCDs requires a “no-touch” period of 20 minutes to allow the donation process, that is significantly longer if compared to other European countries, like Spain or UK, where the no-touch period is only 5 minutes.<sup>10</sup> At our center, a standardized pathway for donation from uDCDs, involving several professional figures as well as a close collaboration between the out-of-hospital emergency services and the Accident and Emergency Department of the hospital, was initially conceptualized in 2012 and started in late 2016.<sup>16</sup> The aim of this study was to compare the outcomes of KT from uDCDs *vs.* ECDs *vs.* standard criteria donors (SCD) at a single referral Centre over a four-year period, focusing on postoperative surgical complications, delayed graft function and mid-term graft function.

## Materials and methods

### Patients and data set

After Ethical Committee approval (nP/903/217/2012), data from patients undergoing KT from deceased donors between January 2017 and December 2020 were identified in our Institutional prospectively maintained database. KTs were performed by expert surgeons using either an open or robotic minimally invasive approach.<sup>17-20</sup> The Chronic Kidney Disease Epidemiology Collaboration formula was used to calculate estimated glomerular filtration rate (eGFR) in patients aged <70 year, while the Berlin Initiative Study formula was used for patients aged  $\geq 70$  year. Cold ischemia time (CIT) was defined as the period from the start of perfusion with cold preservation fluid

after cessation of circulation, due to cardiac arrest or arterial clamping, until the start of the first vascular anastomosis at implantation, while second warm ischemic time (SWIT) as the time from the start of the vascular anastomosis until revascularization of the graft. Intraoperative complications were reported according to the Intraoperative Adverse Incident Classification (EAUiAiC) by the European Association of Urology (EAU) ad hoc Complications Guidelines Panel<sup>21</sup> while postoperative surgical complications were according to both the modified Clavien-Dindo system and the Comprehensive Complication Index.<sup>22, 23</sup> Delayed graft function (DGF) was defined as the need of dialysis in the first postoperative week.<sup>2</sup> All recipients underwent duplex ultrasound and/or computed tomography angiogram before KT to assess their vascular anatomy and the potential presence of atherosclerotic plaques of iliac ves-

sels. Preoperative evaluation of donors, postoperative management of recipients, and follow-up were performed by our multidisciplinary transplant team according to established guidelines and our institutional protocol.<sup>2, 24</sup>

### Kidney harvesting and transplantation techniques

For uDCDs, after the determination of death through a 20-minute flat electrocardiogram (“no touch” period), normothermic regional perfusion (NRP) was used, as shown in Figure 1.<sup>25</sup> In this setting, following a dedicated protocol,<sup>16, 25</sup> when the kidney harvesting was completed, grafts were perfused through the hypothermic pulsatile perfusion machines (LifePort Kidney Transporter, Organ Recovery Systems, Itasca, IL, USA; or the WAVES machine, Institut Georges Lopez, Lissieu, France) (Figure 2, 3). Kidney harvesting for SCDs

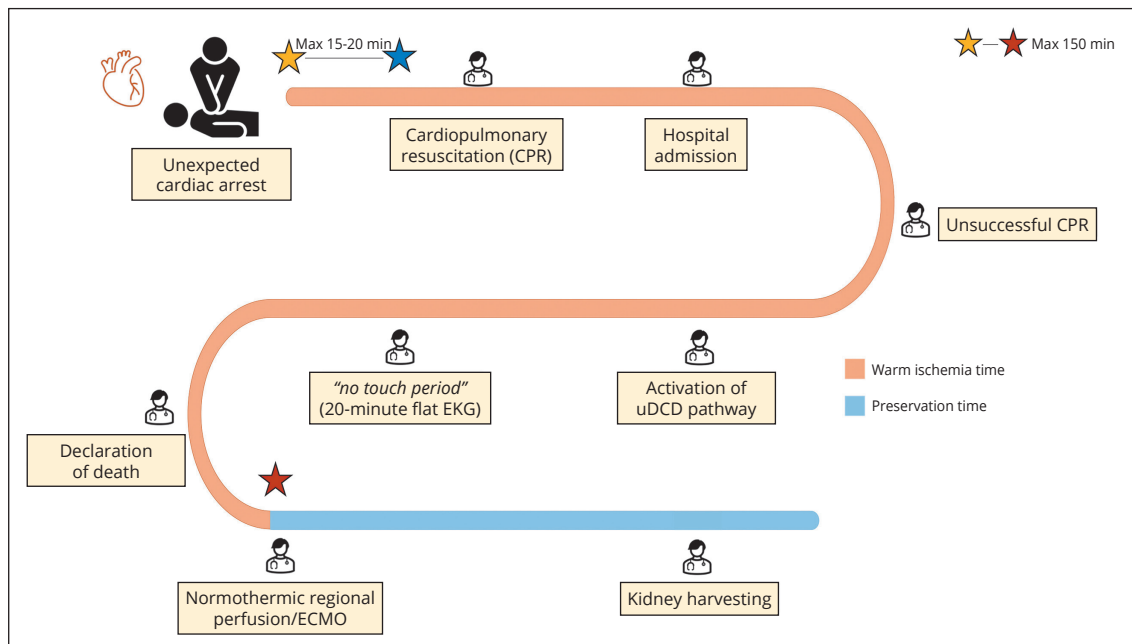


Figure 1.—Overview of our uncontrolled donor after cardiac death (uDCD) pathway.

The Emergency Medical System alerts the physician in charge at the Emergency Department in all cases of witnessed cardiac arrest with the aim of therapeutic fast track or donation path. A certified extracorporeal life support team is activated as well as contextually the procurement coordinator. At the Emergency Department, if irreversible circulatory death certification is declared, the local procurement coordination is alerted and if all the inclusion criteria are fulfilled, the patient is identified as a potential donor. To declare death, a 20-minute no-touch period is currently required by the Italian legislation, with continuous electrocardiographic recording to exclude the presence of any cardiac electrical activity. In this scenario, the no-touch period starts after the establishment of cardiac electrical silence, rather than after circulatory arrest (absence of pulse regardless of the cardiac rhythm). Then, the supradiaphragmatic aortic occlusion is achieved with the placement of an aortic balloon to allow the normothermic abdominal perfusion, maintaining a pump flow of >2 L/min. A continuous pressure of 60–65 mm Hg in the femoral arterial cannula is maintained, together with normothermic conditions. The procedure of veno-arterial ECMO cannulation (ECMO machine, Maquet, Rastatt, Germany) is performed under echocardiographic guidance.



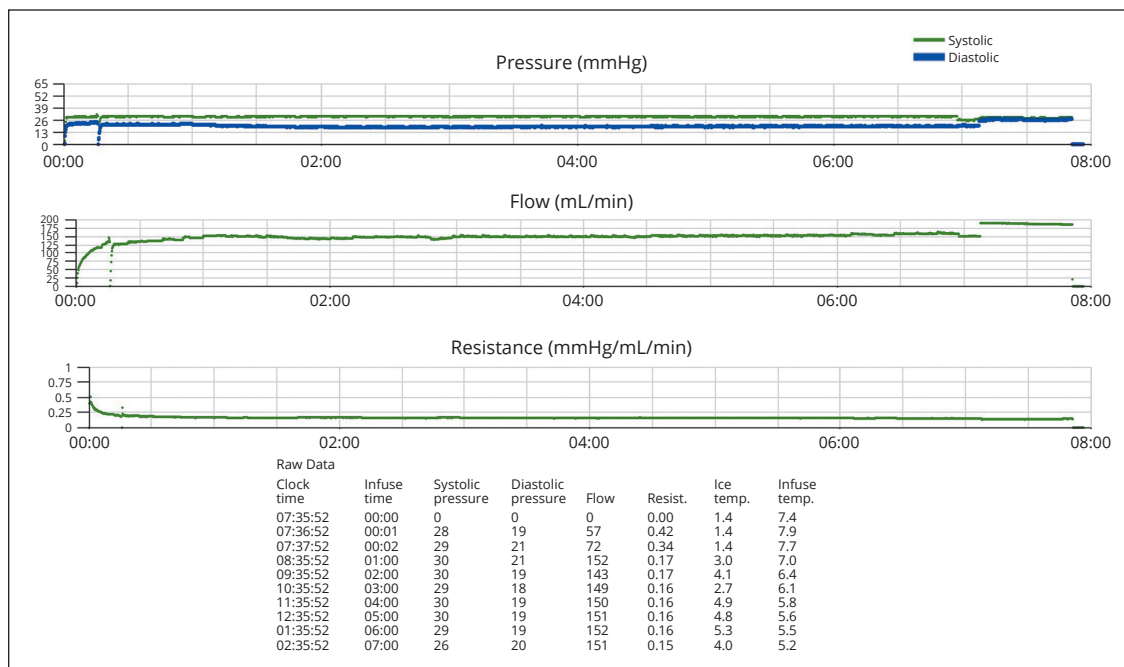


Figure 2.—Hypothermic pulsatile perfusion parameters monitoring for kidneys from uncontrolled donors after circulatory death (uDCD).

Our hypothermic dynamic perfusion machines allow a remote monitoring of the main parameters (pressure, flow, resistance). The figure shows perfusion data of a right kidney from a uDCD perfused for 7 hours using the hypothermic dynamic machine (overall cold ischemia time 15 hours). It was exposed to 140 minutes of warm ischemia. The recipient was a 46-year-old man, who experienced delayed graft function and anemia treated with blood transfusion. At the last follow-up, the creatinine was 1.56 mg/dL.

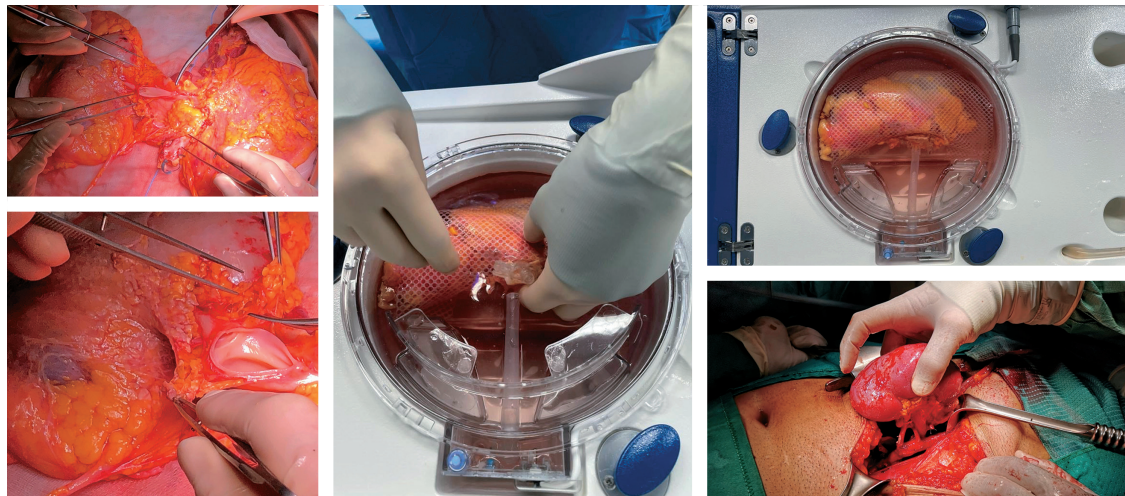


Figure 3.—Intraoperative snapshots showing the main phases of the kidney harvesting, its placement in the hypothermic pulsatile machine and the subsequent kidney transplantation.

and ECDs followed established surgical protocols.<sup>2,26</sup> A pre-KT inferior polar wedge biopsy was performed for all grafts from uDCDs and ECDs

according to our regional protocol, but only in selected cases for kidneys from SCDs according to a careful assessment of donor's characteristics,

risk factors, preoperative renal function. The histological characteristics of the graft at biopsy was assessed according to the Karpinsky Score.<sup>27</sup> A detailed step-by-step description of our surgical technique for open and robot assisted KT from deceased donors is reported in previous publications.<sup>17,18,24,28</sup> RAKT was performed following the principles of the Vattikuti-Medanta technique<sup>29</sup> using either the da Vinci Si or the Xi robotic platform (Intuitive Surgical Inc., Sunnyvale, CA, USA) in a four-arm configuration, with specific technical nuances<sup>30</sup> and new potential opportunities.<sup>31,32</sup>

**Study objectives**

The primary objective of the study was to compare the perioperative and midterm results of KT among different donor cohorts (SCD-DBDs vs. ECD-DBDs vs. uDCDs). Specifically, the outcome measures evaluated were the following: 1) intraoperative adverse events, including intraoperative surgical complications; 2) early postoperative outcomes, including the length of hospitalization (LOH), postoperative surgical complications, early functional outcomes and DGF; and 3) midterm outcomes, including patient and graft survival, reintervention rate, hospital readmission, and eGFR trajectories over time. The secondary objective of the study was

to evaluate the potential donor-, recipient-, graft- and surgery-related factors impacting on the risk of DGF, major (Clavien-Dindo grade 3-5) surgical complications, and eGFR at last follow-up.

**Statistical analysis**

Statistical analyses were performed and reported according to established guidelines.<sup>33</sup> Descriptive statistics were obtained reporting medians and interquartile ranges (IQRs) for continuous variables, while numbers and proportions were used for categorical variables. The characteristics of the baseline donors, recipients, and grafts were compared between the donor cohorts using the Kruskal-Wallis and chi-square tests, as appropriate. Univariable and multivariable logistic regression analyses were performed to assess the independent predictors of DGF and major surgical complications, while univariable and multivariable linear regression analysis were used to evaluate the independent predictors of eGFR at last follow-up. The development of multivariable models followed a stepwise approach, including evaluation of the results of univariable analysis, selection of clinical key variables to consider regardless from the results of univariable analysis, and careful assessment of collinearity between explanatory variables. Statistical analyses were

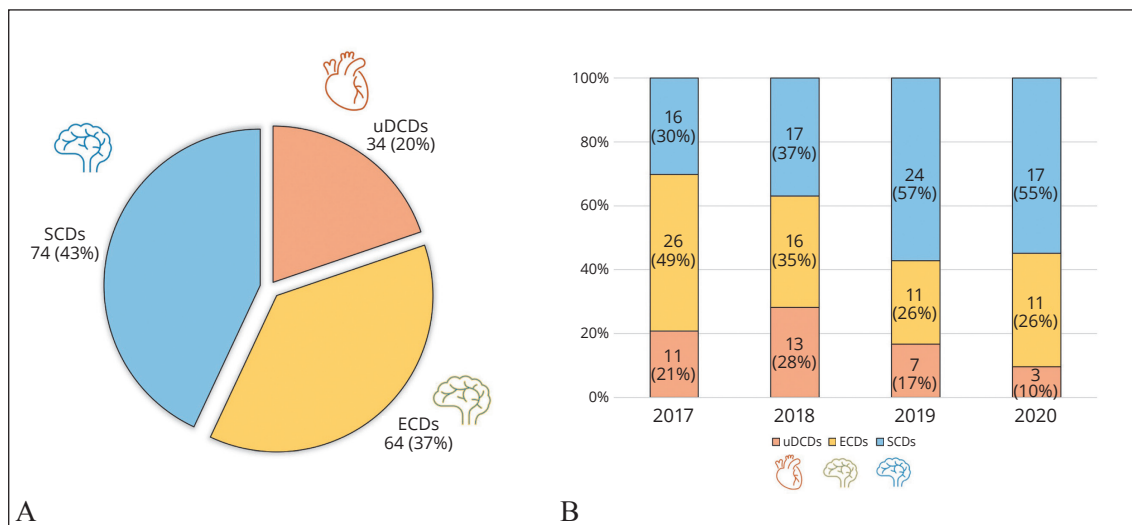


Figure 4.—Study flowchart. A) Proportion of kidney transplantations performed at our center during the study period, classified according to the donor type (expanded criteria donors [ECDs], standard criteria donors [SCDs] and uncontrolled donor after circulatory death [uDCD]). B) Proportion of kidney transplantations per year during the study period (2017-2020), stratified by the donor type.

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performed using SPSS v.26 (IBM SPSS Statistics for Mac; IBM Corp., Armonk, NY, USA). All tests were two sided, with a significance set at P<0.05.

### Results

Overall, 172 KTs from deceased donors were performed during the study period. Of these, 34 (20%) were from uDCDs, 64 (37%) from ECDs, and 74 (43%) from SCDs (Figure 4A, B). Pre-

operative donors' and recipients' characteristics were reported in Table I; uDCDs, ECD-DBDs and SCD-DBDs significantly differed regarding donor's median age, gender, BMI, cause of death and history of hypertension. Recipients from uDCDs and SCDs were younger (median age 47 years [IQR 40-54] and 43 years [IQR 33-49] vs. 57 years [IQR 48-63], respectively; P<0.001) and had a lower median Charlson Comorbidity Index (2 vs. 2 vs. 3, respectively;

TABLE I.—Comparison of the donor-, recipient- and graft-related preoperative characteristics classified according to the donor type.

Variables	Overall (N.=172)	uDCD (N.=34)	ECD(N.=64)	SCD (N.=74)	P value
<b>Donor characteristics</b>					
Cause of death (N., %)					<0.01*
Ischemic/hemorrhagic stroke	81 (47.1)	0 (0.0)	47 (73.4)	34 (45.9)	
Cardiac arrest	18 (10.5)	18 (52.9)	0 (0.0)	0 (0.0)	
Trauma	30 (17.4)	0 (0.0)	11 (17.2)	19 (25.7)	
Other	43 (25)	16 (47.1)	6 (9.4)	21 (28.4)	
Age (year) (median, IQR)	54 (44-61)	51 (40-55)	62 (57-71)	45 (35-52)	<0.01*
Body Mass Index (kg/m <sup>2</sup> ) (median, IQR)	25.3 (22.7-27.7)	27.7 (25.4-29.4)	25.2 (22.7-27.7)	24.6 (22.3-27.1)	<0.01*
Male sex (N., %)	101 (58.7)	27 (79.4)	29 (45.3)	45 (60.8)	<0.01*
History of Hypertension (N., %)	44 (25.6)	5 (14.7)	31 (48.4)	8 (10.8)	<0.01*
Creatinine (mg/dL) (median, IQR)	0.88 (0.67-1.27)	1.34 (1.02-1.62)	0.75 (0.63-1.08)	0.80 (0.67-1.06)	<0.01*
eGFR (mL/min/1.73 m <sup>2</sup> ) (median, IQR)	91 (62-104)	62 (53-87)	94 (60-99)	103 (73-114)	<0.01*
<b>Recipient characteristics</b>					
Age (year, (median, IQR)	48 (41-58)	47 (40-54)	57 (48-63)	43 (33-49)	<0.01*
Male gender (N., %)	105 (61.0)	24 (70.6)	39 (60.9)	42 (56.8)	0.4
Body Mass Index (kg/m <sup>2</sup> ) (median, IQR)	23.5 (21.6-26.5)	23.9 (21.8-25.3)	24.3 (22.1-27.8)	23.2 (21.1-26.0)	0.2
Diabetes Mellitus (N., %)	21 (12.2)	3 (8.8)	10 (15.6)	8 (10.8)	0.5
ASA Physical status classification (median, IQR)	3 (2-3)	3 (2-3)	3 (2-3)	3 (2-3)	0.5
Recipient Charlson Comorbidity Index (no age adjusted) >2 (N., %)	29 (16.9)	5 (14.7)	15 (23.4)	9 (12.2)	0.2
Native nephrectomy (N., %)	6 (3.5)	3 (8.8)	2 (3.1)	1 (1.4)	0.1
Major previous abdominal surgery (N., %)	79 (45.9)	12 (35.3)	35 (54.7)	32 (43.2)	0.1
Previous kidney transplantation (N., %)	17 (9.9)	1 (2.9)	9 (14.1)	7 (9.5)	0.2
Antiplatelet/anticoagulant therapy at surgery (N., %)					0.8
Antiplatelet	23 (13.4)	4 (11.8)	10 (15.6)	9 (12.2)	
Anticoagulant	5 (2.9)	1 (2.9)	1 (1.6)	3 (4.1)	
Antiplatelet and anticoagulant	1 (0.6)	0 (0.0)	1 (1.6)	0 (0.0)	
Preemptive status (N., %)	15 (8.7)	1 (2.9)	7 (10.9)	7 (9.5)	0.4
Type of dialysis (if not pre-emptive) (N., %)					0.6
Peritoneal dialysis	43 (27.3)	8 (24.2)	14 (24.6)	18 (26.9)	
Hemodialysis	114 (72.6)	25 (75.8)	43 (75.4)	46 (68.7)	
Duration of dialysis (if not pre-emptive) (months) (median, IQR)	27 (13-50)	25 (12-46)	32 (15-48)	25 (13-54)	0.8
<b>Graft characteristics</b>					
Warm ischemia time (WIT) (minutes) (median, IQR)	1 (1-4)	149 (143-160)	1 (1-2)	1 (1-2)	<0.01*
Cold Ischemia Time (CIT) (hours) (median, IQR)	16 (13-19)	18 (16-19)	17 (15-19)	15 (12-18)	<0.01*
Right-sided graft (N., %)	88 (51.2)	17 (50.0)	29 (45.3)	42 (56.8)	0.4
Karpinsky Score (at biopsy) (median, IQR)	4 (3-4)	3 (2-4)	4 (3-4)	3 (2-4)	<0.01*
Graft with multiple arteries (N., %)	41 (23.8)	8 (23.5)	18 (28.1)	15 (20.3)	0.5
Graft with multiple veins (N., %)	6 (3.5)	1 (2.9)	3 (4.7)	2 (2.7)	0.8

uDCD: uncontrolled donor after circulatory death; ECD: extended criteria donor after brain death; SCD: standard criteria donor after brain death; eGFR: estimated glomerular filtration rate.

\*Statistically significant.

P<0.001) as compared to those from ECDs. The proportion of patients receiving a second/third KT was higher among recipients from ECDs and SCDs as compared to uDCDs (14.1% vs. 9.5% vs. 2.9%, respectively, P=0.2). All other recipient-related characteristics were comparable between the study cohorts. The median warm ischemia time among uDCDs was 149 min (IQR 143-160). A higher median cold ischemia time was recorded for uDCDs and ECDs

(as compared to SCD, 18 vs. 17 vs. 15 h, respectively, P=0.002); however, all grafts procured from uDCDs were perfused in hypothermic pulsatile machines before KT (an overview of the perfusion parameters is detailed in Supplementary Digital Material 1: Supplementary Table I). At biopsy, the median Karpinsky Score was 3 (IQR 2-4) for grafts from both uDCDs and SCDs, while 4 (IQR 3-4) for grafts from ECDs (P=0.002). As shown in Table II, no differences

TABLE II.—Comparison of intra- and postoperative outcomes after kidney transplantation classified according to the donor type.

Variables	Overall (N.=172)	uDC (N.=34)	ECD-DBD (N.=64)	SC-DBD (N.=74)	P value
<b>Intraoperative outcomes</b>					
Surgical approach (N., %)					0.2
Open	146 (84.9)	29 (85.3)	58 (90.6)	59 (79.7)	
Robot-assisted	26 (15.1)	5 (14.7)	6 (9.4)	15 (20.3)	
Intraoperative complications (N., %)	12 (7.0)	2 (5.9)	6 (9.4)	4 (9.4)	0.6
<b>Intraoperative complications classification (EAUiaiC) (N., %)</b>					
0	6 (3.4)	1 (2.9)	4 (6.2)	1 (1.3)	0.4
1	6 (3.4)	1 (2.9)	2 (3.1)	3 (4.0)	
Overall operative time (minutes) (median, IQR)	205 (180-240)	205 (180-240)	200 (180-231)	210 (180-240)	0.8
Second warm ischemic time (minutes) (median, IQR)	50 (44-55)	52 (47-57)	49 (43-56)	48 (42-57)	0.6
<b>Early postoperative outcomes</b>					
Overall length of hospitalization (days) (median, IQR)	15 (11-22)	23 (18-33)	15 (11-21)	13 (11-17)	<0.01
Patients with multiple postoperative complications (N., %)	60 (43.9)	20 (58.8)	25 (39.1)	15 (20.3)	<0.01
<b>Highest grade postoperative surgical complication (according to the Clavien-Dindo classification) (N., %)</b>					
Grade 0	52 (30.2)	4 (11.8)	15 (23.4)	33 (44.6)	0.01
Grade 1	4 (2.3)	0 (0.0)	2 (3.1)	2 (2.7)	
<b>Grade 2</b>					
Overall	83 (48.3)	18 (52.9)	36 (56.3)	29 (39.2)	
Transfusion	35 (20.3)	9 (26.5)	14 (21.9)	12 (16.2)	
<b>Grade 3A</b>					
Overall	10 (5.8)	3 (8.8)	5 (7.8)	2 (2.7)	
<b>Grade 3B</b>					
Overall	19 (11.0)	7 (20.6)	6 (9.4)	6 (8.1)	
Graft nephrectomy	11 (6.4)	4 (11.8), 1 (vein thrombosis, 1 (arterial thrombosis), 2 primary non function)	3 (4.6), 2 venous thrombosis), 1 (arterial thrombosis)	4 (5.4), 2 venous thrombosis), 1 (arterial thrombosis), 1 primary non function)	
Grade 4A	2 (1.2)	0 (0.0)	0 (0.0)	2 (3.1) 1 generalized tonic-clonic seizure, 1 respiratory failure	
Grade 4B	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Grade 5	2 (1.2)	1 (2.9), (sepsis with multiorgan failure)	1 (1.6), (septic shock)	0 (0.0)	

(To be continued)



TABLE II.—Comparison of intra- and postoperative outcomes after kidney transplantation classified according to the donor type (continues).

Variables	Overall (N.=172)	uDC (N.=34)	ECD-DBD (N.=64)	SC-DBD (N.=74)	P value
Comprehensive Complication Index (median, IQR)	20.9 (8.7-29.6)	29.6 (22.6-33.7)	22.6 (20.9-29.6)	20.9 (0.0-22.6)	<0.01*
Highest grade postoperative surgical complication ≥ 3 (N., %)	33 (19.2)	12 (35.3)	11 (17.2)	10 (13.5)	0.01*
Delayed graft function (N., %)	62 (36.0)	28 (82.4)	20 (31.3)	14 (18.9)	<0.01*
Acute rejection (N., %)	7 (4.1)	2 (5.9)	4 (6.3)	1 (1.4)	0.3
eGFR (mL/min/1.73m <sup>2</sup> ) (median, IQR)					
POD 1	7.1 (5.7-9.1)	6.0 (5.1-7.6)	7.1 (5.6-8.6)	8.0 (6.0-11.0)	<0.01*
POD 3	9.0 (6.2-18.0)	6.6 (5.1-8.4)	8.5 (6.2-14.9)	15 (8.0-39.0)	<0.01*
POD 7	17.0 (9.0-40.4)	8.3 (6.3-10.2)	17.0 (9.6-29.5)	34.8 (14.0-67.0)	<0.01*
At hospital discharge	36.1 (20.4-52.1)	21.8 (13.4-34.2)	28.3 (19.7-43.3)	43.0 (34.2-61.8)	<0.01*
Follow-up outcomes					
Follow-up (months) (median, IQR)	32 (20-43)	37 (28-43)	36 (24-45)	27 (17-42)	0.18
Death (N., %)	6 (3.5)	1 (2.9)	5 (7.8)	0 (0.0)	0.04*
Graft nephrectomy at last follow-up (n, %) (N.=166)	13 (7.8)	5 (15.2)	4 (6.8)	4 (5.4)	0.2
		Causes detailed above (N.=4) + graft with complex cyst (N.=1)	Causes detailed above (N.=3) + chronic rejection (N.=1)	Causes detailed above (N.=4)	
Patients undergoing surgery for postoperative KT-related complications (N., %) (N.=166)	12 (6.2)	3 (9.0)	5 (8.5)	4 (5.4)	0.4
TRAS requiring PTCA + stenting	6 (3.6)	1 (3.0)	2 (3.1)	3 (4.0)	
Lymphocele drainage procedure	3 (1.8)	1 (3.0)	1 (1.5)	1 (1.3)	
Ureteral Reimplantation	1 (0.6)	0 (0.0)	1 (1.5)	0 (0.0)	
Ureteral stenting	1 (0.6)	0 (0.0)	1 (1.5)	0 (0.0)	
Nephrostomy placement for JJ stent removal	1 (0.6)	1 (3.0)	0 (0.0)	0 (0.0)	
Re-admission (at least one episode) after KT (N., %) (N.=166)	92 (55.4)	21 (63.6)	39 (66.1)	32 (43.2)	0.02*
Dialysis at last follow-up (N., %) (N.=166)	20 (12.0)	11 (33.3)	5 (8.5)	4 (5.4)	<0.01*
		5 graft nephrectomy, 6 loss of function)	4 graft nephrectomy, 1 loss of function)	4 graft nephrectomy	
eGFR at last follow-up (mL/min/1.73m <sup>2</sup> ) (median, IQR)	53.7 (38.0-66.6)	56.6 (40.0-65.0)	45.2 (32.3-58.0)	59.0 (47.0-75.0)	<0.01*

eGFR: estimated glomerular filtration rate.

\*Statistically significant.

were found between the study groups regarding surgical approach (open vs. robotic KT), intraoperative complications, and median second warm ischemic time. A higher proportion of patients experiencing early graft nephrectomy and major postoperative complications was observed in patients undergoing KT from uDCDs compared to those from ECDs and SCDs (11.8% vs. 4.6% vs. 5.4%, P=0.3 and 35.3% vs. 17.2% vs. 13.5%, P=0.002, respectively). Similarly, the proportion of patients experiencing multiple surgical complications was higher among recipients from uDCDs and ECDs as compared to SCDs (58.8% vs. 39.1% vs. 20.3%, P<0.001). KTs from uDCDs were also associated with a significantly longer median length of hospitalization

compared to those from ECDs and SCDs (23 vs. 15 vs. 13 days, P<0.001). Regarding functional outcomes, recipients from uDCDs experienced a significantly higher rate of DGF as compared to those from ECDs and SCDs (82.4% vs. 31.3% vs. 18.9%, P>0.001); moreover, the eGFR trajectories after KT were significantly worse for recipients from uDCDs at all time points evaluated (Table II). At a median follow-up of 32 months (IQR 20-43), 6 (3.5%) patients died and 20 (12%) required dialysis (33.3% vs. 8.5% vs. 5.4% among recipients from uDCDs, ECDs and SCDs, respectively, P<0.001). Among patients not requiring dialysis at last follow-up, the median eGFR was significantly higher for recipients from uDCDs and SCDs as compared



to ECDs (56.6 mL/min/1.72m<sup>2</sup> vs. 59.0 mL/min/1.72m<sup>2</sup> vs. 45.2 mL/min/1.72m<sup>2</sup>, respectively, P<0.001). At multivariable analysis, the type of donor (uDCD and ECD vs. SCD) and the need for dialysis before KT (non-preemptive

status) were independent predictors of DGF (Table III). Similarly, uDCDs were independent predictors of the risk to develop major surgical complications in the early postoperative period, as recipient BMI and overall operative time (Ta-

TABLE III.—Univariable and multivariable analysis for predictors of delayed graft function and high-grade postoperative complications.

Variables	Delayed graft function				Highgrade postoperative complications (Clavien-Dindo grade 3-5)		
	Univariable analysis		Multivariable analysis		Univariable analysis		Multivariable analysis
	OR (95% CI)	P value	OR (95% CI)	OR (95% CI)	P value	OR (95% CI)	
Donor	SCD	Ref.	§	Ref.	Ref.	§	Ref.
	ECD	1.94 (1.05-4.22)	0.04**	2.02 (1.11-4.48) <sup>a</sup>	1.39 (0.52-3.37)	0.55	1.20 (0.44-3.23)
	uDCD	20.00 (6.95-57.51)	<0.01**	19.81 (6.75-58.16) <sup>a</sup>	3.49 (1.32-9.20)	0.01**	3.75 (1.34-10.51) <sup>a</sup>
	Age (y) (continuous)	1.00 (0.98-1.03)	0.71	§	1.00 (0.98-1.03)	0.55	§
	Male (vs. female)	1.46 (0.77-2.77)	0.25	§	1.29 (0.59-2.83)	0.52	§
	Body Mass Index (kg/m <sup>2</sup> ) (continuous)	1.23 (1.11-1.35)	<0.01**	*	1.09 (1.01-1.18)	0.02**	*
	eGFR mL/min/1.73m <sup>2</sup> (continuous)	0.98 (0.97-0.99)	<0.01**	*	0.99 (0.98-1.01)	0.53	§
Graft	First warm ischemia time (minutes) (continuous)	1.02 (1.01-1.02)	<0.01**	*	1.00 (1.00-1.01)	<0.01**	*
	Cold ischemia time (hours) (continuous)	1.07 (0.99-1.15)	0.09	§	1.06 (0.97-1.17)	0.16	§
Recipient	No preemptive status (vs. preemptive)	8.90 (1.14-69.38)	0.04**	8.40 (1.12-75.23) <sup>a</sup>	3.59 (0.45-28.27)	0.23	§
	Age (years) (continuous)	1.00 (0.97-1.03)	0.97	§	1.00 (0.97-1.04)	0.68	§
	Male (vs. female)	1.57 (0.82-3.01)	0.19	§	1.35 (0.61-3.00)	0.46	§
	Body Mass Index (kg/m <sup>2</sup> ) (continuous)	1.06 (0.99-1.14)	0.08	§	1.08 (1.00-1.18)	0.04**	1.10 (1.00-1.21) <sup>a</sup>
	Charlson Comorbidity Index >2 (vs. ≤2)	1.10 (0.48-2.51)	0.82	§	0.86 (0.30-2.44)	0.77	§
Surgery	Open approach (vs. robot-assisted)	1.64 (0.65-4.15)	0.30	§	1.36 (0.44-4.26)	0.59	§
	Operative time per 10 minutes (continuous)	1.03 (0.98-1.09)	0.19	§	1.08 (1.02-1.15)	<0.01**	1.09 (1.02-1.16) <sup>a</sup>
	Second warm ischemia time (minutes) (continuous)	1.00 (0.96-1.04)	0.83	§	0.99 (0.95-1.04)	0.87	§
	Intraoperative complication (vs. no)	2.67 (0.81-8.81)	0.10	§	2.26 (0.64-8.01)	0.21	§

uDCD: uncontrolled donor after circulatory death; ECD: extended criteria donor after brain death; SCD: standard criteria donor after brain death; eGFR: estimated glomerular filtration rate.

§Non-significant at univariable analysis or excluded by multivariable analysis; <sup>a</sup>P<0.05; \*excluded for significant collinearity with an included variable according to Spearman's Rho for continuous variables or  $\chi^2$  test for association for categorical variables (P<0.05); \*\*statistically significant.

TABLE IV.—Simple and multiple logistic regression analysis for estimated glomerular filtration rate (eGFR) at last follow-up.

Variables	Outcomes					
	Simple linear regression			Multiple linear regression model		
	Unstandardized β (95% CI)	P value	Adjusted R <sup>2</sup>	Unstandardized β (95% CI)	P value	
Donor	Donor type					
	SCD	Ref.	§	§	§	§
	ECD	-15.11 (-22.40 to -7.83)	<0.01**	0.105	-14.34 (-21.61 to -7.06) <sup>a</sup>	<0.01**
	uDCD	-7.11 (-16.94 to 2.72)	0.15		-6.15 (-15.95 to 3.65)	0.22
	Age (years)	-0.53 (-0.76 to -0.30)	<0.01**	0.13	*	§
	Male sex	Ref.	§	§	§	§
	Female sex	-0.04 (-9.03 to 5.21)	0.60	0.01	§	§
	Body Mass Index (kg/m <sup>2</sup> )	-0.5 (-1.08 to -0.54)	0.51	0.003	§	§
	Last eGFR mL/min/1.73m <sup>2</sup>	0.08 (-0.06 to 0.22)	0.25	0.003	§	§
Graft	First warm ischemia time (minutes)	0.001 (-0.006 to 0.006)	0.98	-0.01	§	§
	Cold ischemia time (hours)	-0.49 (-1.28 to 0.30)	0.22	0.004	§	§
Recipient	No preemptive status	Ref.	§	§	§	§
	Preemptive status	3.54 (-8.36 to 15.43)	0.57	-0.005	§	§
	Age (y)	-0.51 (-0.79 to -0.23)	<0.01**	0.07	*	§
	Male sex	Ref.	§	§	§	§
	Female sex	-3.83 (-10.95 to 3.28)	0.29	0.008	§	§
	Body Mass Index (kg/m <sup>2</sup> )	-0.81 (-1.67 to 0.05)	0.06	0.020	§	§
	CCI age adjusted ≤2	Ref.	§	§	§	§
	CCI age adjusted >2	0.69 (-9.30 to 10.68)	0.89	0.000	§	§
	No preoperative diabetes	Ref.	§	§	§	§
	Preoperative diabetes	0.99 (-10.55 to 12.54)	0.86	0.000	§	§
Surgery	Open approach	Ref.	§	§	§	§
	Robotic approach	10.80 (1.16-20.44)	0.03**	0.03**	-8.73 (-18.04 to 0.58)	0.06
	Operative time per 10 minutes	-0.04 (-0.68 to 0.61)	0.91	0.000	§	§
	Second warm ischemia time (minutes)	0.12 (-0.36 to 0.60)	0.62	0.005	§	§
Postoperative period	No delayed graft function	Ref.	§	§	§	§
	Delayed graft function	-4.10 (-11.76 to 3.56)	0.29	0.008	§	§

uDCD: uncontrolled donor after circulatory death; ECD: extended criteria donor after brain death; SCD: standard criteria donor after brain death; eGFR: estimated glomerular filtration rate.

§Non-significant at simple univariable regression analysis or excluded by multivariable analysis; <sup>a</sup>P<0.05; \*excluded for significant collinearity with an included variable according to Spearman's Rho for continuous variables or  $\chi^2$  test for association for categorical variables (P<0.05); \*\*statistically significant.

ble III). On the contrary, ECDs (but not uDCDs) were independent predictors of lower eGFR at last follow-up (Table IV).

### Discussion

The increased mismatch between the demand and the offer of kidneys for KT worldwide has led to an increased use of “sub-optimal” grafts, including those from older/comorbid donors after brain death, donors after circulatory death, and kidneys with small renal masses.<sup>34, 35</sup> Yet, such donors carry higher risks of adverse events, worse functional outcomes as compared to the standard donors, but a better quality of life and survival as compared to dialysis.<sup>1</sup> In this scenar-

io, allocating the “right” graft to the “right” recipient is becoming increasingly relevant, given the variety of clinical, logistical, and economic implications for patients and clinicians.<sup>36</sup> While variation exists in the use of kidneys from ECDs and DCDs across European Countries,<sup>6</sup> the number of KTs from uDCDs still represents a minority even at high-volume transplant Centres,<sup>6, 14</sup> despite the incidence of out of hospital cardiac arrest.<sup>37</sup> In fact, even in Spain most KTs are obtained from deceased donors and DCD contribute to 29% of the overall KT activity, only 2% of all KTs are performed from uDCDs.<sup>6</sup> This is due to several differences between cDCD and uDCD regarding the clinical and logistical factors impacting the donation process.<sup>8</sup> From a

pathophysiologic view, the ischemia-reperfusion injury is the main challenge affecting organ quality. In Italy, the complexity of the uDCD donation pathway is further challenged by the specific medico-legal framework requiring a 20-min “no-touch” period (one of the longest worldwide) which significantly increases the overall warm ischemic time, making it complex to compare the outcomes of KT from uDCDs in Italy vs. other countries. To the best of our knowledge, this is the first study comparing the perioperative and functional outcomes of KT from uDCD vs. ECDs vs. SCDs in the Italian setting. Our study provides several key findings to contextualize the potential benefits and harms of using kidneys from uDCDs, as compared to both older/marginal donors after brain death and standard-criteria donors. A first key finding of our study is that uDCDs and ECDs contributed significantly to the amount of KTs performed at our Centre during the last four years (Figure 4A, B). In fact, more than 50% of deceased-donor KTs were performed using grafts from such categories. Most recipient characteristics were comparable between uDCDs, ECDs and SCDs (Table I); however, recipients from ECDs were older, more comorbid and with a longer median pre-KT dialysis period as compared to both recipients from SCDs and uDCDs. These findings suggest that current donation schemes at our Centre favour the allocation of kidneys from uDCDs to younger/less comorbid recipients (with clinical characteristics which are almost comparable to those of recipients from SCDs) rather than more “fragile” recipients (such as those from ECDs). While the allocation strategy for kidneys from uDCDs is likely heterogeneous across European Countries and KT Centres,<sup>6</sup> it should be noted that the analysis of the cost-effectiveness of KT from such donors is inherently related to the recipient profile. A second key finding of our study is that, while no significant differences were found between uDCDs, ECDs and SCDs regarding surgical and intraoperative outcomes, KTs from uDCDs carried a significantly higher risk of perioperative adverse events, DGF and graft loss (Table II). This finding could be explained by the specific caveats of the uDCD donation process (including the longer warm ischemic times);<sup>8</sup>

yet, the specific legal framework mandating a longer no-touch period in Italy might have relevantly played a role. A such, reducing the length of the “no-touch” period in Italy could significantly reduce the overall warm ischemic time for uDCDs, aligning it to the median times reported in other European Countries.<sup>6</sup> The implications of the worse outcomes experienced by recipients from uDCDs are clinically relevant. First, a higher proportion of DFG (82.4% vs. 31.3% and 18.9% of ECDs and SCDs, respectively) leads to longer median hospitalization periods (23 days vs. 15 and 13, respectively) and thus higher costs of care. Second, the non-negligible higher rate of graft loss in the early postoperative period (11.8% vs. 4.6% and 5.4%, respectively) forces again recipients to dialysis, increasing the complexity and challenges of a subsequent KT from both immunological and surgical standpoints. In fact, at multivariable analysis, uDCDs were found to be independent predictors of both DGF and major surgical complications after KT (Table III), while no other graft-related factor was significantly associated with such outcomes. Despite the relatively low quantity and quality of the evidence assessing the comparative effectiveness of KT from uDCDs vs. SCDs, the higher risk of DGF and worse graft survival reported for uDCDs in our study are in line with previous publications.<sup>38</sup> A third key finding of our study is that, at a median follow-up of 32 months, despite the significantly lower dialysis-free survival as compared to ECDs and SCDs (66.7% vs. 91.5% vs. 94.6%, respectively), the graft function after KT from uDCDs was comparable to that after KT from SCDs (median eGFR 56.6 mL/min/1.73m<sup>2</sup> vs. 59.0 mL/min/1.73m<sup>2</sup>) (Table II) and higher than that after KT from ECDs (median eGFR 45.2 mL/min/1.73m<sup>2</sup>). Notably, at multivariable analysis, ECDs (but not uDCD) were the only independent risk factor for worse functional outcomes at a mid-term follow-up (Table IV). While it should be interpreted with caution, this finding suggests that kidneys from uDCDs do have the potential to recover after the early perioperative period (regardless of the transient need for dialysis after surgery), providing favourable functional outcomes in two out of three patients at a mid-term follow-up.

### Limitations of the study

Our study has several limitations. First, this is a non-randomized single-Centre observational study including a low number of KTs from uDCDs, limiting the generalizability of our findings. Unfortunately, we could not evaluate the outcomes of KT from uDCDs vs. ECDs vs. SCDs using survival analyses due to lack of granular information on time-to-events in our dataset. Second, the follow-up period might be still insufficient to capture the long-term benefits and harms of KT from uDCDs as compared to ECDs or SCDs. Third, our study involved multiple surgeons, potentially increasing the risk of bias and residual confounders when analyzing the impact of donor type on the risk of perioperative complications after KT. Finally, preoperative KT-biopsy was performed only in kidneys from ECD and uDCD, potentially increasing the risk of postoperative complications. Acknowledged these limitations, our prospective study provides for the first time an overview of the outcomes of uDCDs vs. ECDs vs. SCDs in Italy and offers clinicians and patients insights to offer “the right kidney” to the “right recipient.” This aim could be ideally reached by fostering novel legal frameworks in Italy mirroring the best European practices (including the implementation of KT from cDCDs)<sup>8</sup> and/or by optimizing our contemporary allocation schemes. Namely, kidneys from uDCDs could be best offered to more fragile recipients, who could accept the higher risks of perioperative adverse events and worse functional outcomes instead of continuing the dialysis treatment. Further research is warranted to confirm our findings in larger European cohorts, assess the outcomes of KT from uDCDs in the long-term follow-up, improve the pre-KT strategy to evaluate the quality of available grafts,<sup>39, 40</sup> explore the incremental value and cost-effectiveness of KT from uDCDs as compared to both KT from other donors and dialysis, and lastly to define the modifiable predictors of adverse events after KT from “sub-optimal” donors/DCDs among the graft-, recipient- and surgery-related characteristics.

### Conclusions

In conclusion, uncontrolled donors after circulatory death and older/marginal donors after brain

death represent a non-negligible source of grafts in our contemporary KT practice. While no significant differences were found between uDCDs, ECDs and SCDs regarding surgical and intra-operative outcomes, KTs from uDCDs carried a significantly higher risk of perioperative adverse events, longer hospitalization periods, DGF and graft loss. However, at a mid-term follow-up, selected recipients from uDCDs had favorable functional outcomes, that were comparable to those of recipients from SCDs. Our study provides insights on the benefits and harms of KT from uDCDs, aiming to refine current graft allocation schemes and ultimately recipient outcomes.

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