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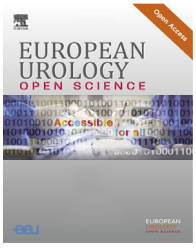

Renal Disease

Robotic Versus Open Kidney Transplantation from Deceased Donors: A Prospective Observational Study ☆

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Abstract

Background: While robot-assisted kidney transplantation (RAKT) from living donors has been shown to achieve favourable outcomes, there is a lack of evidence on the safety and efficacy of RAKT as compared with the gold standard open kidney transplantation (OKT) in the setting of deceased donors, who represent the source of most grafts worldwide.
Objective: To compare the intraoperative, perioperative, and midterm outcomes of RAKT versus OKT from donors after brain death (DBDs).
Design, setting, and participants: Data from consecutive patients undergoing RAKT or OKT from DBDs at a single academic centre between October 2017 and December 2020 were prospectively collected.
Intervention: RAKT or OKT.
Outcome measurements and statistical analysis: The primary outcomes were intraoperative adverse events, postoperative surgical complications, delayed graft function (DGF), and midterm functional outcomes. A multivariable logistic

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regression analysis assessed the independent predictors of DGF, trifecta, and suboptimal graft function (estimated glomerular filtration rate [eGFR] <45 ml/min/1.73 m^2) at the last follow-up.

Results and limitations: Overall, 138 patients were included (117 [84.7%] OKTs and 21 [15.3%] RAKTs). The yearly proportion of RAKT ranged between 10% and 18% during the study period. The OKT and RAKT cohorts were comparable regarding all graft-related characteristics, while they differed regarding a few donor- and recipient-related factors. The median second warm ischaemic time, ureterovesical anastomosis time, postoperative complication rate, and eGFR trajectories did not differ significantly between the groups. A higher proportion of patients undergoing OKT experienced DGF; yet, at a median follow-up of 31 mo (interquartile range 19–44), there was no difference between the groups regarding the dialysis-free and overall survival. At the multivariable analysis, donor- and/or recipient-related factors, but not the surgical approach, were independent predictors of DGF, trifecta, and suboptimal graft function at the last follow-up. The study is limited by its non-randomised nature and the small sample size.

Conclusions: Our study provides preliminary evidence supporting the noninferiority of RAKT from DBDs as compared with the gold standard OKT in carefully selected recipients.

Patient summary: Kidney transplantation using kidneys from deceased donors is still being performed with an open surgical approach in most transplant centres worldwide. In fact, no study has compared the outcomes of open and minimally invasive (robotic) kidney transplantation from deceased donors. In this study, we evaluated whether robotic kidney transplantation using grafts from deceased donors was not inferior to open kidney transplantation regarding the intraoperative, postoperative, and midterm functional outcomes. We found that, in experienced hands and provided that there was a time-efficient organisation of the transplantation pathway, robotic kidney transplantation from deceased donors was feasible and achieved noninferior outcomes as compared with open kidney transplantation.

1. Introduction

Open kidney transplantation (OKT) is the gold standard treatment for patients with end-stage renal disease, providing better survival and quality of life as compared with dialysis [1–3].

Elective robot-assisted kidney transplantation (RAKT) from living donors has been shown to achieve favourable outcomes [4–9] and to have the potential to minimise surgical morbidity as compared with OKT [10]. Nonetheless, RAKT is still controversial and underutilised in the setting of deceased donors, who represent the most frequent source of grafts in most countries worldwide [3].

While being more demanding for transplant teams from both technical and logistical standpoints [11], expanding the indications for RAKT to deceased donors is an unmet clinical need: a higher number of fragile and immunocompromised recipients could indeed benefit from minimally invasive surgery. In this regard, the feasibility and preliminary outcomes of RAKT from deceased donors has previously been reported by our group [11,12]. However, to date, there is a lack of evidence on the comparative effectiveness of RAKT versus OKT in this context.

To fill this gap, we sought to compare the intraoperative, perioperative, and midterm functional outcomes of RAKT versus OKT from donors after brain death (DBDs) over a 4-yr period.

2. Patients and methods

2.1. Patients and dataset

After ethical committee approval, data from consecutive patients undergoing RAKT or OKT from DBDs at our centre between October 2017 and December 2020 were prospectively collected in our institutional database. A comprehensive overview of the steps required to develop our RAKT programme is reported in previous publications [11,12]. Patients who underwent RAKT or OKT from living donors or from donors after circulatory death were excluded from this study (Supplementary Fig. 1).

DBDs were considered "expanded criteria donors" (ECDs) if they were aged >60 or 50–59 yr with two of the following features: history of hypertension, terminal serum creatinine ≥1.5 mg/dl, or death resulting from a cerebrovascular accident [3].

The Chronic Kidney Disease Epidemiology Collaboration formula was used to calculate estimated glomerular filtration rate (eGFR) in patients aged <70 yr [13], while the Berlin Initiative Study formula was used for patients aged ≥70 yr [14].

Cold ischaemia time (CIT) was defined as the time of cold storage, while second warm ischaemic time (SWIT) as the time needed during the construction of vascular anastomoses until revascularisation. For RAKT, SWIT (also defined as "rewarming time" [5]) was defined as the time between graft insertion in the abdominal cavity and revascularisation.

Intraoperative complications were reported according to the Intraoperative Adverse Incident Classification (EAUiaiC) by the European Association of Urology (EAU) ad hoc Complications Guidelines Panel [15],

while postoperative surgical complications were according to both the modified Clavien-Dindo system [16] and the Comprehensive Complication Index [17].

Delayed graft function (DGF) was defined as the need of dialysis in the first postoperative week [3]. *Trifecta* was defined as the contemporary achievement of the following outcomes: (1) no DGF, (2) no major (Clavien-Dindo grade ≥3) postoperative surgical complications, (3) eGFR ≥30 ml/min/1.73 m^2 at hospital discharge.

All recipients underwent computed tomography angiogram to assess their vascular anatomy and the potential presence of atherosclerotic plaques of iliac vessels.

Preoperative evaluation of donors, postoperative management of recipients, and follow-up after RAKT/OKT were performed by our multidisciplinary transplant team according to established guidelines and our institutional protocol [2,18].

2.2. Decision-making strategy regarding selection of open versus robotic surgical approach

Selection criteria for RAKT changed over time [11,12]. Nowadays, after the evaluation of graft suitability for transplantation by the Regional Transplant Authority and selection of the potential recipient, all the following criteria must be met to perform RAKT (Fig. 1): (1) absence of recipient-related contraindications for RAKT (currently represented by recipient age <18 yr, absolute contraindication for robotic surgery, multiple previous major abdominal surgeries, and severe atherosclerotic plaques at the level of iliac vessels), (2) availability of the robotic transplant team (mainly according to the surgeon on call; assistant surgeons and operating room staff are always available, if needed), (3) availability of the robotic operating room (during weekdays, nights, and weekends), (4) CIT <20 h to achieve graft reperfusion within a <24 h time frame, and (5) no graft-related contraindications for RAKT during bench surgery (mainly complex vascular anatomy requiring complex ex situ reconstruction and potentially multiple anastomoses).

2.3. Surgical team for OKT and RAKT

At our centre, OKTs were performed by four experienced urologic surgeons.

One of these surgeons (G.V.), experienced in both OKT and robotic urologic surgery (>1500 procedures), performed all RAKTs. At the beginning of his experience with RAKT from DBDs, the surgeon had already successfully performed six RAKTs [11].

Each of the four surgeons were on call for 1 d per week plus 1 weekend (Friday to Sunday) per month. As such, RAKT from DBDs was performed only if the kidney offer was made when the RAKT surgeon was on charge *and* all the above-mentioned criteria for RAKT (see Section 2.2) were met.

2.4. Surgical technique

A detailed step-by-step description of our surgical technique for RAKT from deceased donors is reported in previous publications [11,12] and graphically depicted in Figs. 2–4. During bench surgery, the graft is carefully prepared by the transplant surgeon and placed in a gauze jacket. In case of multiple vessels, the surgeon may use different techniques to

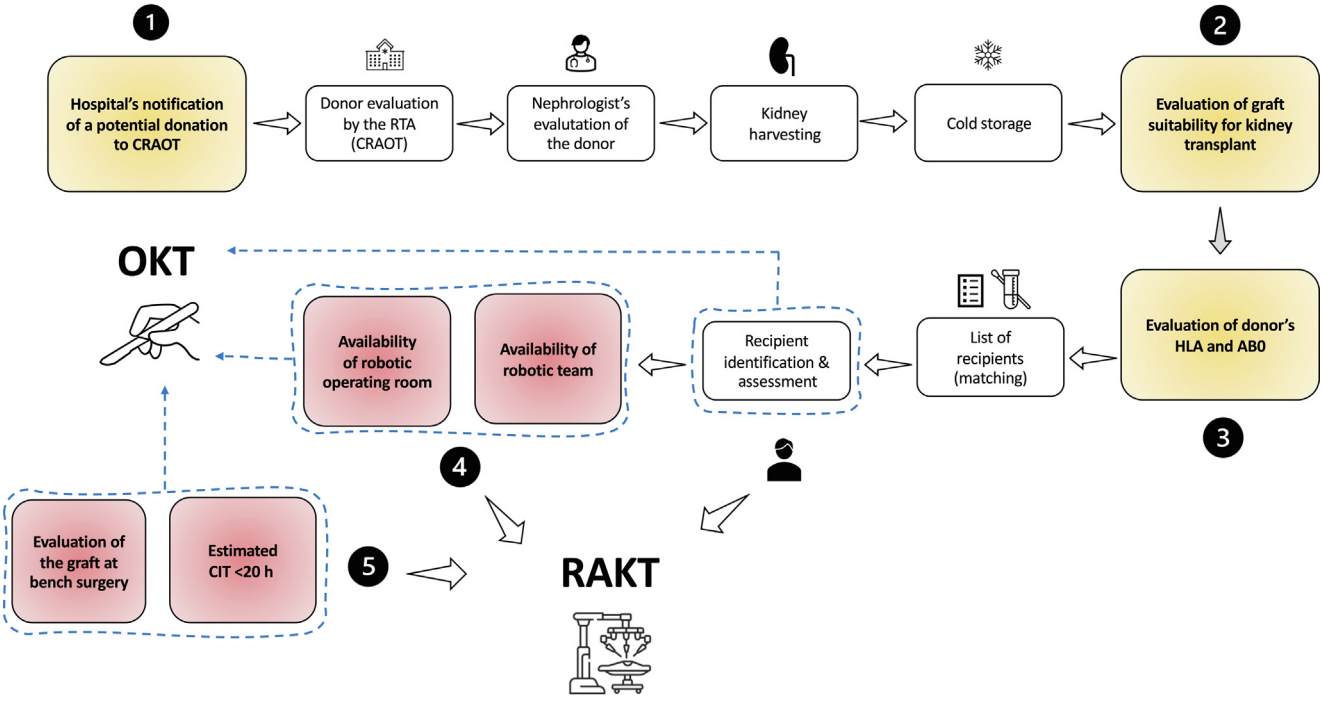

Fig. 1 – Flowchart showing the decision-making strategy regarding selection of the open versus robotic surgical approach for kidney transplantation from donors after brain death (DBDs) at our centre. Once the kidney offer has been received, the kidney has been evaluated for its suitability for transplantation by the Regional Transplant Authority (RTA; Centro Regionale Allocazione Organi e Tessuti [CRAOT]), and selection of the potential recipient has been finalised, specific criteria must be met to perform robot-assisted kidney transplantation (RAKT). If one or more criteria are not respected, then open kidney transplantation (OKT) is performed. In particular, there must be no recipient-related contraindications for RAKT (currently represented by recipient age <18 yr, absolute contraindication for robotic surgery, multiple previous major abdominal surgeries, and severe atherosclerotic plaques at the level of iliac vessels), the robotic transplant team and operating room staff must be available (even during the night or the weekends), the robotic operating room must be available, the cold ischaemia time (CIT) must be <20 h to allow a safe graft reperfusion within a <24 h time frame, and finally, no graft-related contraindications for RAKT must be seen at the time of bench surgery (ie, mainly complex vascular anatomy requiring complex ex situ reconstruction and potentially multiple anastomoses).

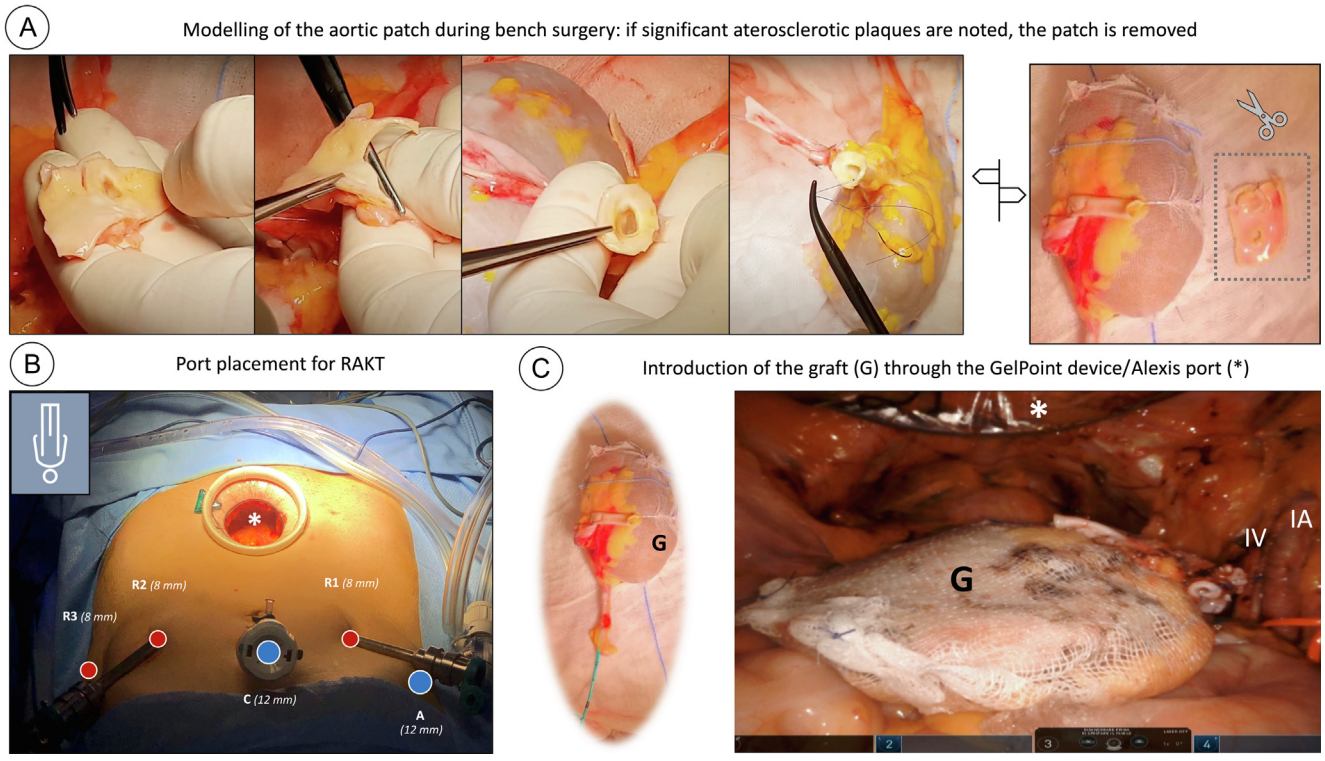

Fig. 2 – (A) Overview of the main steps of bench surgery, (B) port placement, and (C) introduction of the graft into the abdominal cavity according to the University of Florence technique for robot-assisted kidney transplantation (RAKT). (A) If severe atherosclerotic plaques are noted on the aortic patch at the level of the graft artery ostium, the surgeon may decide to remove it and perform the arterial anastomosis without the patch. (B) Port placement for RAKT from deceased donors. RAKT was performed following the principles of the Vattikuti-Medanta technique [4] using either the da Vinci Si or the Xi robotic platform in a four-arm configuration, with a 0° lens and a 20° Trendelenburg tilt. Pneumoperitoneum pressure was set at 8–10 mmHg and maintained constant through the use of the Airseal system. A Pfannenstiel incision is used to introduce the graft through the GelPoint device or the Alexis system. (C) External and intraoperative view of the graft before and after its introduction into the peritoneal cavity during RAKT. In this specific case, the aortic patch was removed by the surgeon during bench surgery. During bench surgery, the anterior margin of the graft vein is reshaped by cutting away a slice of venous tissue to improve visualisation of its posterior margin during the subsequent venous anastomosis. In case of right-sided grafts, an inferior vena cava patch is performed to increase the length of the graft renal vein. The graft is finally placed in a gauze jacket filled with ice, with the renal artery fixed to the gauze with a landmark stich. In case of RAKT, a double-J stent is routinely placed at the time of bench surgery to facilitate subsequent ureterovesical anastomosis. A = assistant port; C = camera port; G = graft; IA = (external) iliac artery; IV = (external) iliac vein; R = robotic port.

reconstruct the graft vessels aiming to perform a single anastomosis [19]. For RAKT, a double-J stent is routinely preplaced at the time of bench surgery. If severe atherosclerotic plaques are noted on the aortic patch at the level of the graft artery ostium, the surgeon may decide to remove it and perform the arterial anastomosis without the patch, mirroring RAKT from living donors (Fig. 2A).

OKT was performed following established principles [3], with a Gibson or fascial incision usually over the right iliac fossa. After creation of an extraperitoneal pouch, vascular anastomoses are completed in an end-to-side fashion between the graft and the external iliac vessels using two running, nonabsorbable, 5-0 or 6-0 polypropylene sutures. After completion of the anastomoses, the graft is placed in the extraperitoneal pouch and evaluated for adequate reperfusion (colour, turgor, and intraoperative ultrasound, if needed). The ureterovesical anastomosis is made with interrupted or running absorbable sutures according to a modified Lich-Gregoire technique over a double-J stent creating an antirefluxing mechanism.

RAKT was performed following the principles of the Vattikuti-Medanta technique [4] using either the da Vinci Si or the Xi robotic platform (Intuitive Surgical Inc., Sunnyvale, CA, USA) in a four-arm configuration, with a 0° lens and a 20° Trendelenburg tilt. Pneumoperitoneum pressure was set at 8–10 mmHg and maintained constant through the use of the Airseal system (Fig. 2 and 3).

Vascular anastomoses were completed in an end-to-side fashion to the external iliac vessels using a 5-0 or 6-0 GORE-TEX suture (Gore Medical, Flagstaff, AZ, USA) on a CV-6 TTc-9 needle.

Specific technical nuances were introduced by our group [11,12]. First, a Pfannenstiel incision is used to introduce the graft through the GelPoint device or the Alexis system (Fig. 2B). Second, two half running sutures using *two* (rather than one) threads are used for the arterial anastomosis. Lastly, intraoperative FireFly fluorescence vascular imaging with indocyanine green is employed to check for ureteral and graft reperfusion (if the da Vinci Xi robotic platform is used; Fig. 4) [20]. The ureterovesical anastomosis is completed with two running absorbable sutures according to a modified Lich-Gregoire technique over the preplaced double-J stent (Fig. 4).

2.5. Study objectives

The primary objective of the study was to compare the perioperative and midterm results of RAKT versus OKT from DBDs. Specifically, the outcome measures evaluated were the following: (1) intraoperative adverse events; (2) early postoperative outcomes, including the length of hospitalisation (LOH), postoperative complications, and DGF; and (3) midterm outcomes, including patient and graft survival, reintervention rate, hospital readmission, and eGFR trajectories over time.

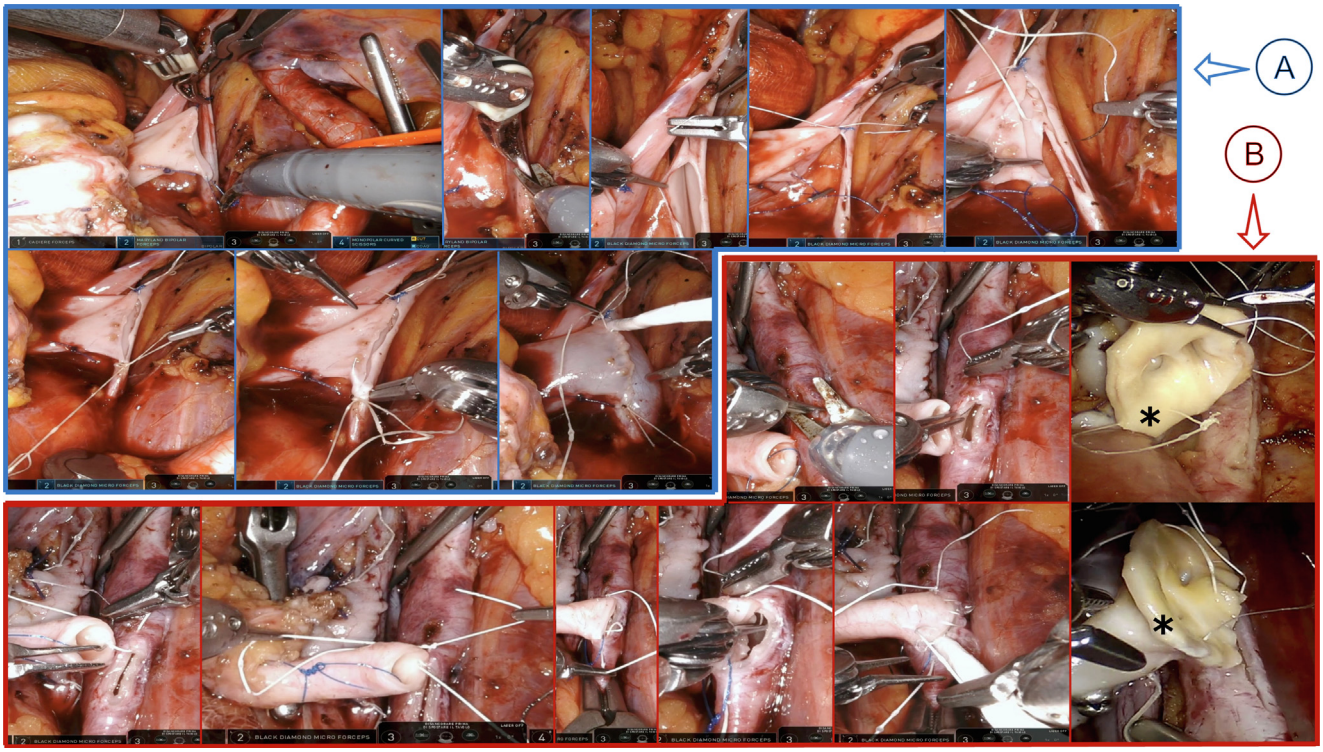

Fig. 3 – Intraoperative snapshots showing the main phases of the (A) venous and (B) arterial anastomoses during robot-assisted kidney transplantation from donors after brain death (Figs. 2 and 3). Vascular anastomoses are completed in an end-to-side fashion to the external iliac vessels using a 5-0 or 6-0 GORE-TEX suture (Gore Medical) on a CV-6 TTc-9 needle, as described previously [11,12]. For the arterial anastomosis, two half running sutures using two different threads are used, due to the thicker wall of both graft and recipient arteries. The arterial anastomosis may be performed without or with (*) the aortic Carrel's patch.

The secondary objective of the study was to assess the potential impact of surgical approach on DGF, trifecta, and optimal renal function (eGFR ≥45 ml/min/1.73 m^2) at the last follow-up.

2.6. Statistical analysis

Statistical analyses were performed and reported according to established guidelines [21].

Descriptive statistics were obtained reporting medians and interquartile ranges (IQRs) for continuous variables, awhile numbers and proportions were used for categorical variables.

The characteristics of the baseline donors, recipients, and grafts were compared between the OKT and the RAKT groups using the Kruskal-Wallis and chi-square tests, as appropriate.

Univariable and multivariable logistic regression analyses were performed to assess the independent predictors of the main study outcomes among donor-, graft-, recipient-, and surgery-related factors.

Statistical analyses were 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 $p < 0.05$.

3. Results

3.1. Characteristics of the study cohorts

Overall, 199 kidney transplantations were performed during the study period. Of these, 138 (69.3%) were from DBDs and were included in the analytic cohort (117 [84.7%)] OKTs and 21 [15.3%] RAKTs; Supplementary Fig. 1). The yearly proportion of RAKT from DBDs was 10% in 2017, which increased to 18% in 2018 and remained constant thereafter. The most frequent reason preventing the performance of RAKT was the unavailability of the robotic team (101/117 cases [86%]; Supplementary Fig. 1). The other reasons to perform OKT despite the availability of the RAKT team were as the learning curve of the RAKT surgeon (4%), potentially longer CIT (2%), unavailability of the robotic operating room (3%), and specific recipient- or graft-related contraindications (5%).

The baseline donor-, recipient-, and graft-related characteristics in the RAKT and OKT cohorts are shown in Supplementary Table 1. The median donor age (55 vs 49 yr, $p = 0.2$), median donor body mass index (BMI; 25.1 vs 22.5, $p = 0.01$) and the proportion of expanded criteria donors (49.6% vs 28.6%, $p = 0.07$) were higher in the OKT cohort. While the study groups were comparable regarding recipients' median age, gender, and median BMI, the recipients' comorbidity burden was higher in the OKT group (median American Society of Anesthesiologists score 3 vs 2, $p < 0.001$). Nonetheless, the proportion of recipients with a higher comorbidity burden (Charlson Comorbidity Index ≥3) was similar across the two groups (17.1% vs 19.0%, $p = 0.8$). A significantly higher proportion of recipients receiving OKT had undergone previous major abdominal surgery (52.1% vs 28.6%, $p = 0.047$) or a previous kidney transplantation (12.8% vs 4.8%, $p = 0.3$). Lastly, recipients in the OKT group were less likely to be pre-emptive (5.1% vs 38.1%, $p < 0.001$) and had longer median times on dialysis (32 vs 9 mo, $p < 0.001$). The OKT and RAKT cohorts were comparable regarding all graft-related characteristics (Supplementary Table 1).

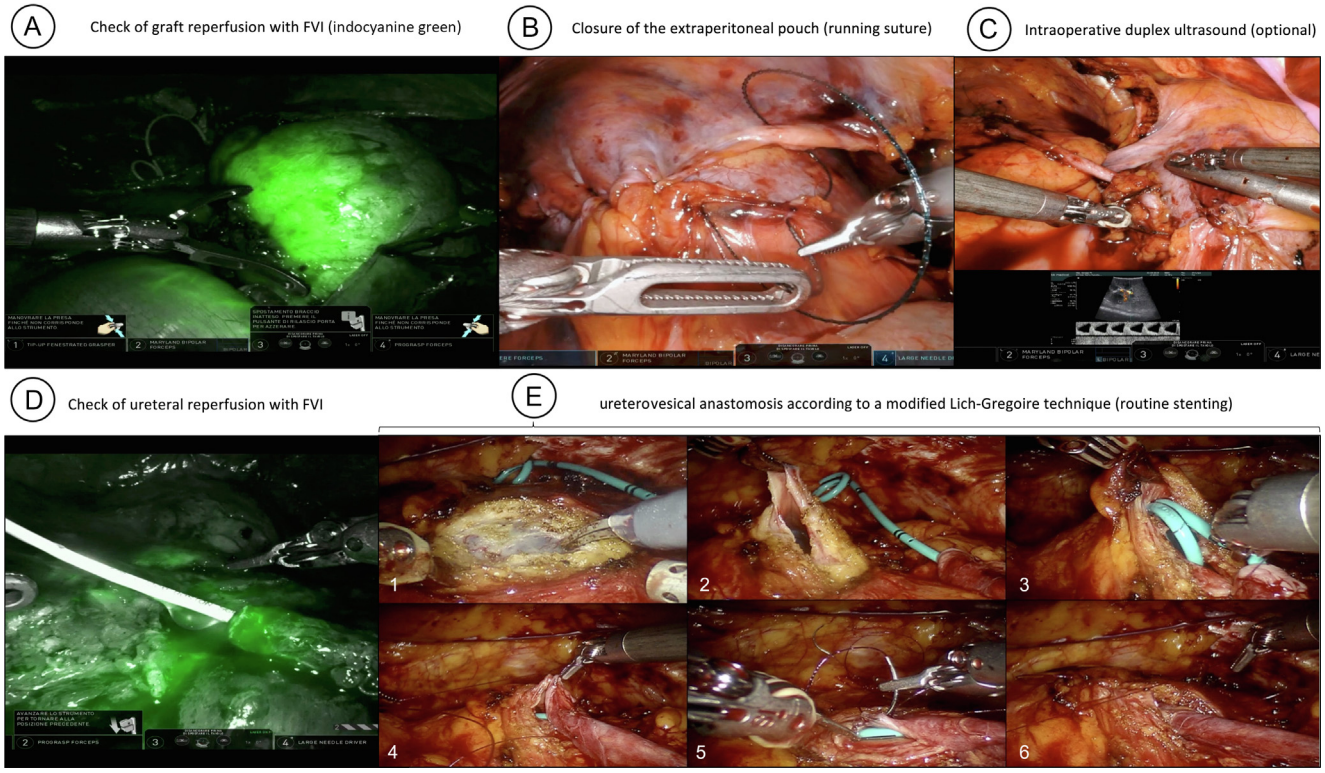

Fig. 4 – Intraoperative snapshots showing the last operative steps of robot-assisted kidney transplantation (RAKT) from donors after brain death (DBDs) according to the University of Florence technique. After completion of the vascular anastomosis, (A) the graft reperfusion is checked using intraoperative fluorescence vascular imaging with indocyanine green. Then, (B) the previously prepared extraperitoneal pouch is closed with a running suture. (C) Intraoperative duplex ultrasound may be used to further check graft reperfusion. (D) Before the ureterovesical anastomosis, the ureteral reperfusion is checked using intraoperative fluorescence vascular imaging with indocyanine green. Then, (E) the ureterovesical anastomosis is completed with two running absorbable sutures according to a modified Lich-Gregoire technique over the preplaced double-J stent (steps 1–6). FVI = fluorescence vascular imaging.

3.2. *Intraoperative outcomes*

All RAKTs were completed successfully, with no need of open conversion.

The median overall operative time (incision to closure), SWIT, and ureterovesical anastomosis time did not differ significantly between RAKT and OKT (210 vs 205 min, $p = 0.2$; 47 vs 48 min, $p = 0.2$; and 15 vs 18 min, $p = 0.2$, respectively).

Intraoperative adverse events were recorded in ten patients (7.2%), of whom nine underwent OKT and one RAKT (all EAUiaiC grade 0–1).

3.3. *Postoperative and early functional outcomes*

An overview of the early postoperative outcomes after RAKT versus OKT is provided in Table 1. There were no significant differences between RAKT and OKT regarding the overall and major postoperative complications rates, as well as the median Comprehensive Complication Index. The proportion of patients requiring perioperative blood transfusions was significantly lower in the RAKT cohort (14.3% vs 22.2%, $p = 0.008$), as well as the proportion of patients requiring opioids treatment for postoperative pain during hospitalisation (0% vs 7.7%).

Seven (5.0%) patients required graft nephrectomy during the early postoperative period (of whom six [5.1%] were in the OKT group and one [4.8%] in the RAKT group).

There was no significant difference between the study groups in the eGFR trajectories after transplantation, while a higher proportion of patients undergoing OKT experienced DGF (27.4% vs 9.5%, $p = 0.08$). Overall, the trifecta was achieved by 52.2% of patients (66.7% vs 49.6% in the RAKT vs OKT group, $p = 0.2$).

At the multivariable analysis (Table 2), donor BMI (odds ratio [OR]: 1.21; 95% confidence interval [CI]: 1.07–1.37, $p = 0.002$) and time of pretransplantation dialysis (OR: 1.09; 95% CI: 1.03–1.16, $p = 0.003$) were the only significant predictors of DGF in our cohort. Similarly, type of DBDs (OR for standard donor vs ECD: 2.14; 95% CI: 1.10–5.00, $p = 0.038$) and time of pretransplantation dialysis (OR: 0.93; 95% CI: 0.87–0.98, $p = 0.011$) were the only independent predictors of trifecta achievement.

The median LOH was 13 d in both groups. At the multivariable analysis, the only independent predictors of LOH $\geq$2 wk ($n = 70/138$ patients; 50.7%) were the need for postoperative blood transfusions, occurrence of major surgical complications, and DGF (Supplementary Table 2).

There was no statistically significant difference in the proportion of patients experiencing major (Clavien-Dindo grade $\geq$3) surgical complications and/or DGF between the open ($n = 42/117$, 35.9%) and robotic ($n = 5/21$, 23.8%) groups ($p = 0.2$).

There was no difference in median LOH between OKT and RAKT both in the cohort of patients *not* experiencing major

Table 1 – Intraoperative, postoperative, and midterm functional outcomes after robot-assisted kidney transplantation (RAKT) versus open kidney transplantation (OKT) in our study

	Overall cohort (n = 138)	OKT (n = 117)	RAKT (n = 21)	p value
Intraoperative outcomes				
Intraoperative complications, n (%)	10 (7.2)	9 (7.6)	1 (4.8)	0.2
EAUiaiC grade 0	5	5	0	
EAUiaiC grade 1	5	4	1	
Operative time (incision to closure; min), median (IQR)	208 (180–240)	205 (180–230)	210 (185–241)	0.2
Console time (for RAKT; min), median (IQR)	–	–	180 (150–202)	–
Arterial anastomosis time (min), median (IQR)	21 (17–26)	22 (17–29)	18 (15–21)	**0.008**
Vein anastomosis time (min), median (IQR)	23 (18–28)	24 (18–32)	18 (16–22)	**0.007**
Ureterovesical anastomosis (min), median (IQR)	18 (15–20)	18 (15–20)	15 (12–21)	0.2
Second warm ischaemic time (min), median (IQR)	48 (42–55)	48 (43–55)	47 (41–52)	0.2
Early postoperative outcomes (during hospitalisation)				
Overall length of hospitalisation (d), median (IQR)	13 (11–18)	13 (11–18)	13 (10–18)	0.5
Highest grade postoperative surgical complication (according to the Clavien-Dindo classification), n (%)				0.6
Grade 0	46 (33.3)	40 (34.2)	6 (28.6)	
Grade 1	4 (2.9)	4 (3.4)	0 (0.0)	
Grade 2	65 (47.1)	53 (45.3)	12 (57.1)	
Grade 3a	9 (6.5)	7 (6.0)	2 (9.5)	
Grade 3b				
Overall	11 (8.0)	10 (8.5)	1 (4.8)	
Graft nephrectomy (thrombosis)	6 (4.3)	5 (4.3) (3 venous thrombosis) (2 arterial thrombosis)	1 (4.8) (venous thrombosis)	
Graft nephrectomy (haemorrhagic complications)	1 (0.7)	1 (0.8)	0 (0)	
Endoscopic reintervention (double-J stent misplacement)	1 (0.7)	1 (0.8)	0 (0)	
Endoscopic placement of a double-J stent for urinary fistula	1 (0.7)	1 (0.8)	0 (0)	
Reintervention for bleeding causing graft compression	2 (1.4)	2 (1.7)	0 (0)	
Grade 4a	2 (1.4)	1 (0.9)	1 (4.8)	
Grade 4b	0 (0.0)	0 (0.0)	0 (0.0)	
Grade 5	1 (0.7)	1 (0.9) (sepsis with multiorgan failure)	0 (0.0)	
Patients requiring perioperative blood transfusions, n (%)	29 (21.0)	26 (22.2)	3 (14.3)	**0.008**
Major postoperative surgical complication (highest grade ≥3 according to the Clavien-Dindo classification), n (%)	23 (16.6)	20 (17.1)	3 (14.3)	0.7
Comprehensive Complication Index, median (IQR)	20.9 (0.0–29.6)	20.9 (0.0–29.6)	20.9 (0.0–29.6)	0.8
Patients requiring opioid treatment for postoperative pain, n (%)	9 (6.5)	9 (7.7)	0 (0)	0.1
Early functional outcomes (during hospitalisation)				
Delayed graft function, n (%)	34 (24.6)	32 (27.4)	2 (9.5)	0.08
eGFR (ml/min/1.73 m^2), median (IQR)				
POD 1	7.5 (6–10)	7.2 (5.7–9)	8.5 (7.5–14)	0.7
POD 3	10.2 (7.1–24)	10.6 (6.8–23.4)	10 (8–35)	0.6
POD 7	25.3 (11–48.1)	25 (11–48.6)	28.2 (12.7–40.4)	0.7
At hospital discharge	39.7 (23.5–56.6)	39.4 (22.7–56)	41 (29.8–59.2)	0.3
Trifecta, n (%)	72 (52.2)	58 (49.6)	14 (66.7)	0.2
Follow-up outcomes				
Follow-up (mo), median (IQR)	31 (19–44)	31 (20–44)	27 (16–42)	0.5
Graft nephrectomy, n (%)	8 (5.8)	7 (6.0) Causes detailed above (n = 6) + chronic rejection (n = 1)	1 (5.0) Cause detailed above	0.8
Patients alive at last follow-up, n (%)	133 (96.4)	113 (96.6)	20 (95.2)	0.7
Patients who were alive and dialysis free (n = 133), n (%)	124 (93.2)	105 (93.0)	19 (95.0)	0.7
Hospital readmission (at least one episode) after KT, n (%)	71 (51.4)	61 (52.1)	10 (47.6)	0.7
KT-related reinterventions, n (%)	9 (6.5)	6 (5.1)	2 (9.5)	0.6
TRAS requiring PTCA + stenting	5	3	2	
Lymphoceles requiring percutaneous drainage	2	2	0	
Ureteral reimplantation	1	1	0	
Ureteral stenting	1	1	0	
eGFR at last follow-up (ml/min/1.73 m^2), median (IQR)	53.5 (38.0–68.0)	51.0 (37.5–64.3)	68.7 (46.0–81.0)	**0.042**

EAUiaiC = Intraoperative Adverse Incident Classification by the European Association of Urology; eGFR = estimated glomerular filtration rate; IQR = interquartile range; KT = kidney transplantation; POD = = postoperative day; PTCA = percutaneous transluminal coronary angioplasty; TRAS = transplant renal artery stenosis.

surgical complications and/or DGF (12 d [IQR 10–16] vs 13 d [IQR 9–15], p = 0.9) and in the cohort of patients experiencing major surgical complications and/or DGF (35.9% of patients in the OKT group and 23.8% of patients in the RAKT group, p = 0.2; 17 d [IQR 14–23] vs 18 d [IQR 16–22], p = 0.9).

3.4. Follow-up outcomes

At a median follow-up of 31 mo (IQR 19–44), patient survival and dialysis-free survival were comparable between the RAKT and OKT groups (Table 1). Similarly, the readmis-

Table 2 – Univariable and multivariable logistic regression models assessing the independent predictors of delayed graft function (DGF), trifecta, and optimal graft function (estimated glomerular filtration rate ≥45 ml/min/1.73 m^2) at last follow-up among donor-, recipient-, graft-, and surgery-related factors

	Delayed graft function			Trifecta			eGFR ≥45 ml/min/73 m^2 at last follow-up		
	Univariable a. OR (95% CI)	Multivariable a. OR (95% CI)	*p* value	Univariable a. OR (95% CI)	Multivariable a. OR (95% CI)	*p* value	Univariable a. OR (95% CI)	Multivariable a. OR (95% CI)	*p* value
Donor characteristics									
Age (yr)	1.02 (0.99–1.05)	–	–	0.97 (0.95–0.99)	–	–	0.96 (0.93–0.99)	–	–
BMI (kg/m^2)	1.20 (1.08–1.35)	**1.21 (1.07–1.37)**	**0.002**	0.92 (0.84–1.00)	0.93(0.85–1.02)	0.1	0.94 (0.86–1.02)	–	–
Gender (male vs female)	0.96 (0.44–2.09)	–	–	1.12 (0.62–2.37)	–	–	0.88 (0.41–1.87)	–	–
No history of hypertension	0.45 (0.20–1.02)	–	–	1.92 (0.90–4.07)	–	–	1.73 (0.75–4.04)	–	–
SCD vs ECD	0.51 (0.23–1.13)	0.67 (0.26–1.68)	0.4	2.82 (1.41–5.64)	**2.14(1.10–5.00)**	**0.038**	3.10 (1.42–6.79)	**2.54 (1.09–6.52)**	**0.04**
eGFR (ml/min/1.73 m^2)	0.99 (0.97–1.01)	0.98 (0.97–1.01)	0.2	1.00 (0.99–1.01)	–	–	1.00 (0.99–1.01)	–	–
Recipient characteristics									
Recipient age (yr)	1.02 (0.98–1.05)	–	–	0.96 (0.94–0.99)	0.98(0.94–1.02)	0.4	**0.97 (0.93–0.99)**	0.99 (0.95–1.03)	0.6
Gender (male vs female)	1.18 (0.53–2.62)	–	–	0.83 (0.42–1.67)	–	–	1.31 (0.61–2.73)	–	–
Recipient BMI (kg/m^2)	0.99 (0.98–1.01)	–	–	1.00 (0.99–1.01)	–	–	1.00 (0.98–1.03)	–	–
No diabetes mellitus	0.83 (0.27–2.52)	–	–	0.51 (0.18–1.44)	–	–	1.34 (0.41–4.39)	–	–
ASA score (continuous)	1.68 (0.83–3.40)	–	–	0.87 (0.50–1.49)	–	–	0.73 (0.39–1.36)	–	–
No previous KT	0.67 (0.22–2.13)	–	–	1.49 (0.52–4.26)	–	–	2.26 (0.68–7.53)	–	–
Recipient CCI (continuous)	1.24 (0.72–2.12)			1.07 (0.65–1.77)	–	–	0.85 (0.49–1.84)	–	–
Pre-emptive recipient	NA*	–	–	14.10 (1.79–111.13)	–	–	3.21 (0.68–15.09)	–	–
Duration of dialysis (6 mo)	1.08 (1.02–1.14)	**1.09 (1.03–1.16)**	**0.003**	0.92 (0.87–0.98)	**0.93 (0.87–0.98)**	**0.011**	0.95 (0.90–1.02)	0.96 (0.90–1.03)	0.3
Graft characteristics									
Cold ischaemia time (h)	1.01 (0.93–1.09)	0.97 (0.88–1.07)	0.6	0.95 (0.87–1.01)	0.97(0.89–1.05)	0.5	0.99 (0.91–1.07)	1.01 (0.93–1.10)	0.8
Right- vs left-sided graft	0.92 (0.43–2.01)	–	–	1.08 (0.55–2.12)	–	–	0.68 (0.32–1.47)	–	–
Karpinsky score (at biopsy)	1.20 (0.72–2.00)	–	–	1.12 (0.71–1.73)	–	–	1–09 (0.68–1.72)	–	–
No multiple graft vessels	0.80 (0.33–1.89)	–	–	0.98 (0.46–2.11)	–	–	1.27 (0.54–3.02)	–	–
Surgery-related factors									
Open vs robotic approach	3.57 (0.78–16.23)	2.12 (0.39–11.56)	0.4	0.50 (0.18–1.32)	0.84(0.28–2.49)	0.7	0.50 (0.16–1.63)	0.74 (0.21–2.57)	0.6
Second warm ischaemic time (min)	0.97 (0.92–1.04)	–	–	1.06 (0.92–1.07)	–	–	0.99 (0.95–1.03)	–	–
Overall operative time (min)	1.01 (0.99–1.01)	–	–	0.99 (0.98–1.02)	–	–	1.00 (0.99–1.01)	–	–
Postoperative factors									
No delayed graft function	–			–			2.90 (1.20–6.98)	2.25 (0.89–5.67)	0.08

a. = analysis; ASA = American Society of Anesthesiologists; BMI = body mass index; CCI = Charlson Comorbidity Index; CI = confidence interval; ECD = expanded criteria donor; eGFR = estimated glomerular filtration rate; KT = kidney transplantation; NA = not available; OR = odds ratio; SCD = standard criteria donor.

sion and reintervention rates were comparable. The median eGFR at the last follow-up was significantly higher among RAKT recipients (68.7 vs 51.0 ml/min/1.73 m^2, p = 0.042).

At the multivariable analysis, surgical approach did not influence the risk of suboptimal graft function at the last follow-up: donor type (OR for standard donor vs ECD: 2.54; 95% CI: 1.09–6.52, p = 0.04) was the only significant predictor of eGFR ≥45 ml/min/1.73 m^2 at the last follow-up (Table 2).

4. Discussion

During the past decade, minimally invasive surgery has increasingly permeated several fields, especially urology [22]. The widespread adoption of robotics worldwide has led to an increasing body of evidence supporting its noninferiority to open surgery and its benefits for both surgeons and patients for selected interventions [23,24].

The transplantation community has been rather resistant to such change, and OKT still remains the gold standard approach at most centres worldwide [2,3].

Notably, in recent years, several groups have developed and standardised the technique of RAKT, aiming to reduce the morbidity of kidney transplantation [4–6,8–12,25]. Yet, a vast majority of RAKTs are elective procedures from living donors, performed at a few referral centres in selected countries [26]. Therefore, there is a lack of evidence on the safety and outcomes of RAKT in the broader and much more complex scenario of *deceased* donors, who represent the predominant source of grafts worldwide. Of note, RAKT from deceased donors can be referred as an urgent robotic procedure, increasing the challenges for transplant teams from both technical and logistical standpoints [11].

To the best of our knowledge, this is the first study that provides preliminary evidence supporting the noninferiority of RAKT as compared with OKT from deceased donors using standardised outcome metrics. Our findings provide key clinical messages for urologists and transplant surgeons.

First, our study confirms that, despite the higher logistical complexity, RAKT from DBDs can be performed successfully, as reported previously [11,12].

Second, our study showed that RAKT from DBDs can achieve noninferior intraoperative, perioperative, and mid-term functional outcomes as compared with OKT in well-selected recipients. Following established surgical principles [4–6], no major intraoperative adverse events were recorded during RAKT, and both median CIT and SWIT were comparable with those of the OKT counterpart. The postoperative morbidity profiles of RAKT and OKT from DBDs were also similar in our preliminary experience. Moreover, the minimally invasive approach of RAKT led to a lower proportion of recipients requiring perioperative blood transfusions or treatment with opioids for postoperative pain (Table 1). Confirming previous prospective data in the setting of living donation [5,6,10], we did not record any case of symptomatic lymphocele requiring percutaneous drainage and wound complication among patients undergoing RAKT from DBDs. Notably, the median LOH after kidney transplantation in our study (comparable with the average LOH reported in other European countries [27,28]) was similar between RAKT and OKT. This finding should be interpreted in light of several factors as well as our hospital policies. As in France and Spain [27,28], the characteristics of the Italian public health system, greater acceptance of older/comorbid recipients, increasing proportion of ECDs, and absence of ambulatory facilities may explain the longer LOH at our centre than that in other countries such as the USA [29]. Moreover, the early hospital readmission rate is a significant quality metric at our centre, leading to cautious early hospital discharge. Lastly, as in other European countries [27,28], nephrologists are responsible for postoperative care of recipients at our transplant centre and take decisions regarding hospital discharge. Further research is needed to assess the differential impact of surgical approach, provider-related factors, healthcare context, and enhanced recovery after surgery protocols on LOH, unplanned readmissions, and costs of kidney transplantation [30].

At the multivariable analysis (Table 2), surgical approach was not found to be an independent predictor of DGF, trifecta, and "favourable" graft function (eGFR ≥45 ml/min) at a median follow-up of >2 yr; these outcomes were influenced only by specific donor- and/or recipient-related characteristics.

Despite their novelty, our findings need to be interpreted with caution. In fact, several caveats and limitations could have influenced the study results. First, this is a prospective *nonrandomised* study with a relatively small sample size: as such, the risk of selection bias and residual confounding cannot be ruled out. Of note, the OKT and RAKT cohorts were comparable regarding all graft-related characteristics, but a few important clinical variables were not balanced between the study groups (Supplementary Table 1). Moreover, although the primary reason to perform OKT was the unavailability of the robotic surgical team, even when potentially feasible, a careful patient selection was pursued (Supplementary Fig. 1). For instance, patients with moderate-to-severe atheromatosis of the aortoiliac axis might have been more likely to undergo OKT despite the logistical feasibility for RAKT. Unfortunately, our dataset lacked granular information on aortoiliac atheromatosis, precluding any analysis on its impact on recipient selection for RAKT versus OKT.

Taken together, the differences in baseline donor- and-recipient related characteristics could explain the worse functional outcomes observed after OKT, ultimately making our findings hypothesis generating. While propensity-score matching techniques might have at least partially overcome this limitation, they could not be employed given the small sample size of our analytic cohort. Second, OKT was performed by four different surgeons, and the results of RAKT might still be sensitive to a learning curve effect [8]; yet, due to the limited sample size, we could not formally evaluate the extent to which a surgeon's experience and skills might have modulated intra- and postoperative outcomes.

Lastly, our study is limited by a relatively short follow-up and a lack of data on patient-reported outcomes as well as the cost effectiveness of RAKT versus OKT. Considering the need for time-efficient logistics and previous experience in RAKT, whether our findings could be generalisable to other transplant centres remains unknown.

Acknowledging these limitations and recognising the challenges for conducting randomised-controlled trials in this field [31], our study adds significant novel data to the kidney transplantation literature and provides key insights into foster clinical implementation of RAKT in the setting of deceased donors as well as a foundation for significant further research.

Larger multicentre prospective studies are indeed warranted to (1) confirm the feasibility and safety of RAKT from DBDs in other healthcare contexts, (2) define the best indications and limits of RAKT from deceased donors, (3) establish RAKT-specific modular training curricula to increase the number of surgical teams that may offer minimally invasive kidney transplantation, and (4) develop a framework to promote RAKT at a higher number of transplant centres worldwide.

5. Conclusions

Our study provides preliminary evidence supporting the noninferiority of RAKT from deceased donors as compared with the gold standard OKT in carefully selected recipients. Larger multicentre studies with longer follow-up are needed to confirm our findings and to define the best indications and limits of robotics in this clinical scenario.

***Author contributions*:** Riccardo Campi had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Appendix A. Supplementary data

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