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# Non-Inferiority of Dual Kidney Transplantation: A Retrospective Matched Study

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**Abstract: Background/Objectives:** Dual kidney transplantation is a potential technique to reduce the number of discarded kidneys from expanded-criteria donors. Due to allegedly poor outcomes, some centres have abandoned this technique. We aimed to compare dual versus single kidney transplantation. **Methods:** This retrospective, propensity score-matched, non-inferiority study compared dual kidney transplantation and single kidney transplantation results. Matching was performed based on key donor characteristics, including age, sex, serum creatinine levels, and cause of death due to cerebrovascular accident. The primary outcome was graft survival at ten years post-transplant. Secondary outcomes included overall survival and perioperative complications. Non-inferiority of dual kidney transplantation was defined as a difference in graft survival within a 10% margin. **Results:** After propensity score, 39 dual kidney transplant recipients were matched with 78 single kidney transplants. Five-year graft survival was 66.1% for dual kidney transplants and 81.3% for single kidney transplants ($p = 0.228$), and 9-year graft survival was 54.1% dual transplant and 60.8% for single transplant ($p = 0.961$). There was no significant difference in terms of 10-year overall survival ($p = 0.912$) either. Surgical times were greater during dual kidney transplants (199.31 ± 49.12 min vs. 129.37 ± 42.11 min, $p < 0.001$). There were more overall complications associated with dual kidney transplants (35.9% vs. 17.9%, $p < 0.05$). **Conclusions:** Dual kidney transplantation achieved non-inferiority for ten-year graft and overall survival, despite higher incidence of complications and longer surgical times. Dual kidney transplantation can be a viable alternative to single kidney transplantation and may increase the pool of potential donors, reducing renal transplant waiting lists.

**Keywords:** kidney transplantation; graft survival; intraoperative complications; postoperative complications; equivalence trial

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## 1. Introduction

End-stage kidney disease has become increasingly prevalent in recent years, leading to a subsequent rise in the number of patients on dialysis and kidney transplantation waiting lists [1]. In 2021, Portugal recorded the highest number of patients treated with renal replacement therapy (RRT) among European countries [2]. By 2022, the number of patients on waiting lists for transplantation had reached 2546, perpetuating the established upward pattern [1,2]. Kidney transplantation is considered the gold standard in RRT, offering greater patient survival, cost-effectiveness, and improved quality of life [3–5].

To overcome organ shortage, the concept of expanded-criteria donors (ECDs) was introduced, leading to a 10% increase in renal transplants. These broader criteria include donors aged over 60 years old or between 50 and 59 years old with two of the following conditions: serum creatinine levels above 1.5 mg/dL and a history of hypertension or cerebrovascular accident (CVA) as the cause of death, therefore carrying a higher risk of graft failure [6]. Nevertheless, these grafts can be optimized through dual kidney transplantation (DKT). Both kidneys from one donor are transplanted into a single recipient, so the renal function is improved by a significant increase of nephric mass [4]. The main DKT modalities are 'en bloc'—mostly used with paediatric donors—and dual ECD [7]. The surgical technique can be unilateral or bilateral with either an extra- or intraperitoneal approach, since no method has consistently demonstrated superior outcomes when compared to the others [7].

Some studies in DKT have demonstrated patient and graft survival rates comparable to those of single kidney transplantation (SKT), especially when the donors had similar characteristics [8–12]. Certain drawbacks have also been reported, including prolonged cold ischemia times with potential negative effects on renal function, doubling of surgical duration, and increased procedural complexity [4,7,8]. Additionally, several postoperative complications have been documented, including increased blood loss, graft thrombosis, and extended hospitalizations [4,7,8].

As a result, most centres prefer to utilize DKT in recipients with lower metabolic demands or reduced immunological risk, or in those who do not require the long-term durability of SKT, ultimately favouring old-to-old allocation strategies [8,12,13]. This lack of established criteria leaves the decision to the clinician, which often leads to the underuse of this procedure due to concerns about its potential underperformance [8,9,14,15].

This study aimed to evaluate graft survival (GS) and overall survival (OS) in DKT compared to SKT, as well as to assess the perioperative complications associated with these procedures at a tertiary referral centre. This research seeks to determine whether DKT could be widely adopted, thereby reducing kidney discard rates and consequently decreasing waiting list times.

## 2. Materials and Methods

The present study was approved by the institutional ethical committee (CE-113/2024). This was a retrospective non-inferiority cohort study. Patients included underwent renal transplant in Coimbra University Hospital's Renal Transplantation Unit between June 1980 and March 2024. We selected patients who received organs from ECD, including both SKT and DKT procedures. Patients younger than 18 years, adults without legal capacity, pregnant women, and recipients of 'en bloc' DKT from paediatric donors were excluded from this study.

Data extracted from the institutional prospective database included age, sex, transplantation date, operating and cold ischemia times, urinary anastomosis, delayed graft function, length of hospitalisation, complications (urinary fistulae, urinary stenosis, venous thrombosis, arterial stenosis, abscess, abdominal wall haematoma, lymphocele, graft haemorrhage, graft rejection), graft loss, and death date. Serum creatinine levels at 1, 3, and 6 months and 1, 2, 3, 5, and 10 years post-transplant were also recorded. Data extracted from the donors included age, sex, serum creatinine levels, and cause of death (specifically CVA).

The indication for DKT was made on a case-by-case basis, taking into account the characteristics of the donor and recipient. Generally, ECD kidneys considered not valid for simple transplantation were selected, namely with Remuzzi score 4 on biopsy. Histologic criteria have an important role in assessing the viability of combining both kidneys in order to grant sufficient function of the graft. For DKT, moderate Remuzzi scores (4–6) are an indication for dual kidney transplantation, while biopsies that have a severe Remuzzi score (7–12) should be discarded [16].

In all cases, due to its more favourable anatomy, with a more superficial and anterior artery, the two kidneys were placed in the right iliac fossa. Briefly, the left kidney is first implanted (given its longer vein) positioned more superior and lateral, performing the anastomoses to the common iliac vessels. After reperfusion of this kidney, the second graft is implanted in a more inferior and medial position (partially overlapping the first), with the anastomoses made to the external iliac vessels. Finally, separate ureteral anastomoses are performed with a JJ stent.

The same immunosuppression regimen was applied in both groups, except for selected patients with higher immunologic risk, where induction therapy included anti-thymocyte globulin.

### 2.1. Primary and Secondary Endpoints

The primary endpoint of our study evaluated graft survival, defined as the time between kidney transplant and graft loss. The secondary endpoint assessed overall survival, defined as the time between transplant and patient death from any cause. Follow-up was censured at last medical assessment or patient death with a functioning graft. The maximum period of follow-up was 10 years. Complications, operation and cold ischemia times, and delayed graft function were also assessed.

### 2.2. Sample Size and Propensity Score Matching

We calculated a sample size for non-inferiority with the SampSize online application, with an alpha of 0.05 and power of 90%. The calculated total sample size required for the analysis was 78 patients. The non-inferiority margin was set at 10% for five-year GS and OS, supported by previous meta-analyses showing a 78.4% survival rate for ECD kidneys against 86.4% from standard-criteria donors [17,18]. Patients who received DKT were matched to those who received SKT using propensity score matching (PSM) in a 1:2 ratio, which allowed the creation of two groups balanced in terms of potential cofounding baseline variables. The propensity score was estimated by multivariable logistic regression analysis based on donor covariates: age, sex, serum creatinine levels, and dead from CVA. Variables used on PSM were used to select ECDs suitable for transplant. Matching was performed by finding the two SKT propensity scores that were closest to the DKT propensity score, ensuring comparability between the groups for subsequent analyses.

### 2.3. Statistical Analysis

The statistical analysis was performed using SPSS (version 29.0, IBM Corp., Armonk, NY, USA). Statistical significance was considered when $p < 0.05$ for all analyses. Continuous variables are presented using means along with standard deviations and categorical variables are described using proportions. To compare the two groups, Student's *t* test or chi-squared tests were applied. GS and OS were evaluated through the construction of Kaplan–Meier curves, and the log-rank test was applied for survival differences.

## 3. Results

At our centre, 3757 patients underwent renal transplantation from June 1980 to March 2024, with a total of 1247 transplants from ECDs (33%). Of the ECD recipients, 39 underwent DKT and 1208 underwent SKT. After propensity score matching, our sample included 117 patients with a mean follow-up of six years and two months (Figure 1).

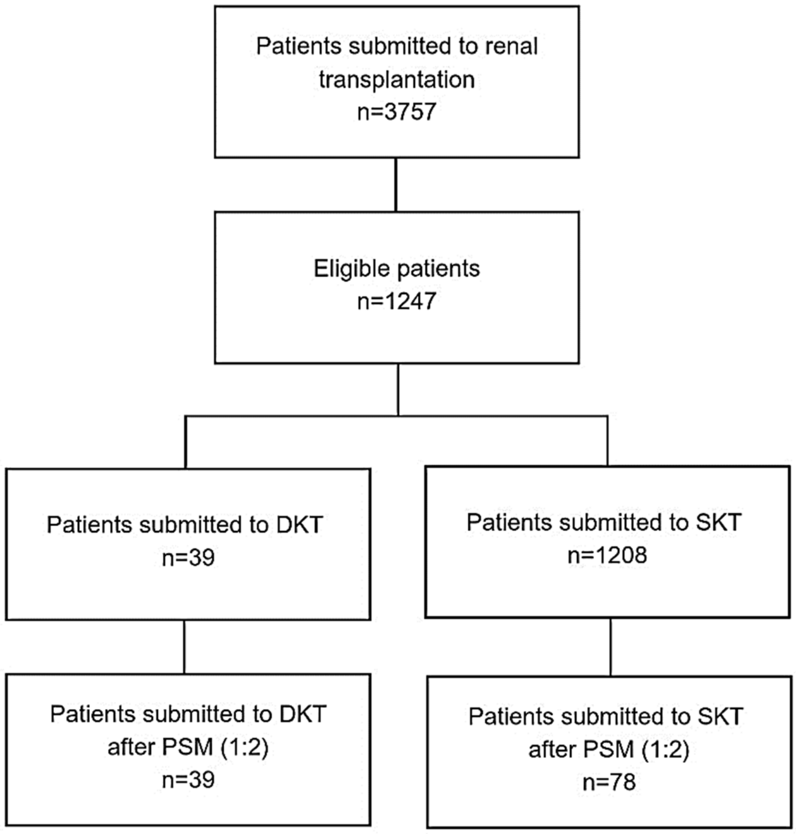


**Figure 1.** Flow diagram of patient selection and propensity score matching.

Donors' characteristics are summarized in Tables 1 and 2. The mean age of donors was 70 years, and most were female. The most common cause of death was CVA. After applying PSM, there were no statistically significant differences among matched variables: age, sex, donor serum creatinine, and cause of death.

**Table 1.** Baseline characteristics of donors.

| **Characteristic** | |
|---|---|
| Age ± SD, years | 69.95 ± 7.63 |
| Male, *n* (%) | 54 (46.2%) |
| Female, *n* (%) | 63 (53.8%) |
| Serum creatinine ± SD, mg/dL | 0.82 ± 0.32 |
| Dead from CVA, *n* (%) | 96 (82.1%) |

SD—standard deviation; *n*—number of cases.

**Table 2.** Comparison of donors' characteristics after propensity score matching.

| **Characteristic** | **Type of Transplantation** | | ***p*-Value** |
|---|---|---|---|
| | **DKT** | **SKT** | |
| Age ± SD, years | 70.00 ± 7.53 | 69.92 ± 7.73 | 0.959 |
| Male, *n* (%) | 14 (35.9%) | 40 (51.3%) | 0.168 |
| Female, *n* (%) | 25 (64.1%) | 38 (48.7%) | 0.168 |
| Serum creatinine ± SD, mg/dL | 0.83 ± 0.33 | 0.82 ± 0.31 | 0.835 |
| Dead from CVA, *n* (%) | 37 (94.4%) | 71 (91%) | 0.234 |

DKT—dual kidney transplantation; SKT—single kidney transplantation; SD—standard deviation; *n*—number of cases.

Overall sample characteristics were evaluated before matching. At the time the transplant was performed, recipients' mean age was 60.8 ± 7.82 years, and 67.5% were male. The mean cold ischemia time was 15.63 h. Most patients had immediate function (78.4%), and primary dysfunction was seen in eight patients (6.8%). In the selected patients, 24% had complications (any) after transplant, such as urinary fistulae, urinary stenosis, venous thrombosis, arterial stenosis, graft haemorrhage/haematoma, abscess, abdominal wall haematoma, lymphocele, and graft rejection. Mean serum creatinine at 6 months and 5 years was 1.64 mg/dL and 1.61 mg/dL, respectively.

The characteristics and outcomes of the two groups, SKT and DKT, are shown in Table 3. When comparing age and sex, variables were not considered statistically different. No differences were identified in cold ischemia times. Surgical times were greater during DKT when compared to SKT (199.31 ± 49.12 min vs. 129.37 ± 42.11 min, $p < 0.001$).

**Table 3.** Comparison of recipients' characteristics and outcomes after SKT or DKT.

| | **Type of Transplantation** | | ***p*-Value** |
|---|---|---|---|
| | **DKT** | **SKT** | |
| Age ± SD, years | 60.85 ± 7.09 | 60.87 ± 8.21 | 0.987 |
| Sex, *n* (%) | | | |
| Male | 23 (59.0%) | 56 (71.8%) | 0.209 |
| Female | 16 (41.0%) | 22 (28.2%) | 0.209 |
| Cold ischemia time ± SD, hours | 16.63 ± 4.95 | 15.13 ± 6.95 | 0.234 |
| Surgical time ± SD, minutes | 199.31 ± 49.12 | 129.37 ± 42.11 | <0.001 |
| Urinary Anastomosis, *n* (%) | | | |
| Lich–Gregoir | 32 (82.1%) | 65 (83.3%) | 0.420 |
| Taguchi | 7 (17.9%) | 12 (15.4%) | 0.420 |
| Uretero-ureterostomy | - | 1 (1.3%) | <0.05 |
| Renal Function, *n* (%) | | | |
| Immediate function | 31 (78.4%) | 60 (77.9%) | 0.759 |
| Late function | 5 (12.8%) | 13 (16.9%) | 0.759 |
| Primary dysfunction | 3 (7.7%) | 4 (5.2%) | 0.759 |
| Complications, *n* (%) | 14 (35.9%) | 14 (17.9%) | <0.05 |
| Length of hospitalization ± SD, days | 10.7 ± 5.5 | 10.00 ± 3.4 | 0.759 |
| Type of graft loss, *n* (%) | | | |
| Acute rejection | 1 (2.6%) | 1 (1.4%) | 0.889 |
| Chronical rejection | 1 (2.6%) | 6 (8.5%) | 0.889 |
| Serum creatinine ± SD, mg/dL | | | |
| 1 month | 1.68 ± 0.99 | 2.08 ± 1.15 | 0.070 |
| 3 months | 1.29 ± 0.37 | 1.81 ± 0.75 | <0.001 |
| 6 months | 1.51 ± 0.87 | 1.71 ± 0.53 | 0.525 |
| 1 year | 1.45 ± 0.84 | 1.69 ± 0.62 | 0.504 |
| 5 years | 1.25 ± 0.52 | 2 years | 0.414 |
| 10 years | 1.39 ± 0.74 | 1.87 ± 0.91 | 0.375 |

DKT—dual kidney transplantation; SKT—single kidney transplantation; SD—standard deviation; *n*—number of cases.

Statistically significant differences were not observed when it came to renal function, length of hospitalization, graft loss, or acute or chronic rejection. There was no difference between the serum creatinine levels of the two groups, except for the values measured at 3 months post-transplantation, where SKT showed worse results, due to the larger nephric mass transplanted in DKT (1.81 ± 0.75 mg/dL vs. 1.29 ± 0.37 mg/dL, $p < 0.001$). There were more overall complications associated with DKT (35.9% vs. 17.9%, $p < 0.05$), Urinary stenosis, abscess formation, lymphocele, and arteriovenous complications were observed more frequently in DKT. The complications listed did not show statistical significance regarding graft loss. Other complications included poor patient compliance and issues related to the recipient's underlying diseases. Table 4 provides a summary of all complications and graft loss by complication.

**Table 4.** Comparison of recipients' graft loss for each type of complication after SKT or DKT.

| Complications | Type of Transplantation | | *p*-Value | Graft Loss | *p*-Value |
|---|---|---|---|---|---|
| | DKT | SKT | | | |
| Urinary fistula, *n* (%) | 1 (2.6%) | 1 (1.3%) | 0.614 | - | - |
| Urinary stenosis, *n* (%) | 2 (5.1%) | - | <0.05 | 2 (100%) | 0.057 |
| Venous thrombosis, *n* (%) | 1 (2,6%) | 1 (1.3%) | 0.614 | 2 (100%) | 0.057 |
| Abscess, *n* (%) | 2 (5.1%) | - | <0.05 | 1 (50.0%) | 0.675 |
| Abdominal wall haematoma, *n* (%) | 1 (2.6%) | - | 0.156 | - | - |
| Lymphocele, *n* (%) | 1 (2.6%) | - | <0.05 | 1 (100%) | 0.180 |
| Incisional hernia, *n* (%) | - | 1 (1.3%) | 0.478 | - | - |
| Graft infection, *n* (%) | - | 4 (5.1%) | 0.150 | 2 (50.0%) | 0.550 |
| Arteriovenous fistula, *n* (%) | 2 (5.1%) | - | <0.05 | 1 (50.0%) | 0.675 |
| Graft haemorrhage, *n* (%) | 1 (2.6%) | 1 (1.3%) | 0.614 | 1 (50.0%) | 0.675 |
| Primary graft failure, *n* (%) | - | 2 (2.6%) | 0.313 | 2 (100.0%) | 0.057 |
| Others, *n* (%) | 1 (2.6%) | 2 (2.6%) | 1.000 | 2 (66.7%) | 0.260 |

DKT—dual kidney transplantation; SKT—single kidney transplantation; *n*—number of cases.

*Graft Survival and Overall Survival*

At five years post-transplant, GS was 81.3% (95%CI: 76.8–85.8%) for SKT and 66.1% (95%CI: 56.9–75.3%) for DKT (Figure 2). The difference between GS curves was not statistically significant ($p = 0.228$).

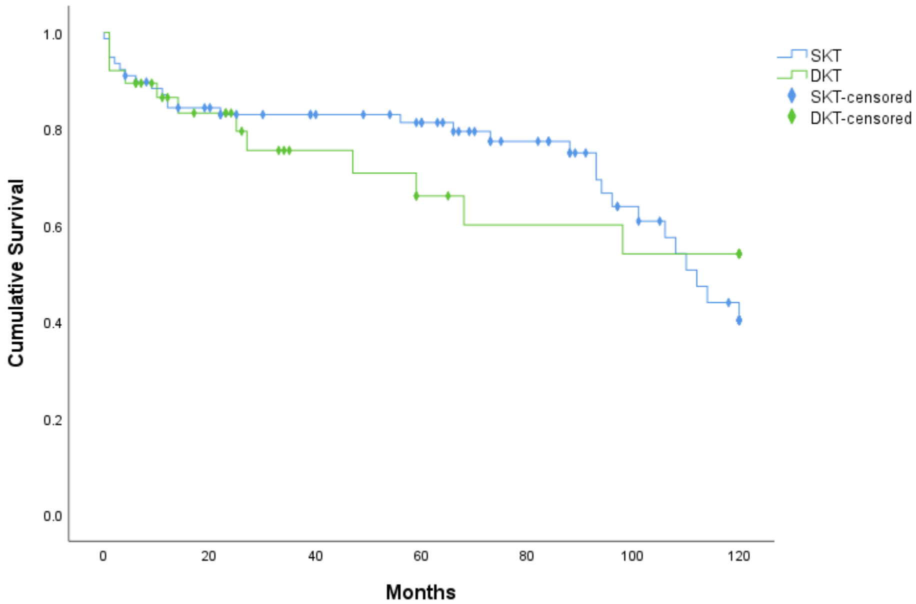


**Figure 2.** Ten-year graft survival Kaplan–Meier analysis.

There was no statistically significant difference between 10-years GS between the two groups ($p = 0.961$) either. At 9-year follow-up, where the last data were censured, GS was 60.8% (95%CI: 53.6–68.0%) for SKT and 54.1% (95%CI: 43.3–64.4%) for DKT (Figure 2).

In terms of overall survival, there was no significant difference between the procedures. The 10-year OS was 71.1% (95%CI: 64.1–78.1%) for SKT and 81.0% (95%CI: 73.7–88.3%) for DKT (Figure 3).

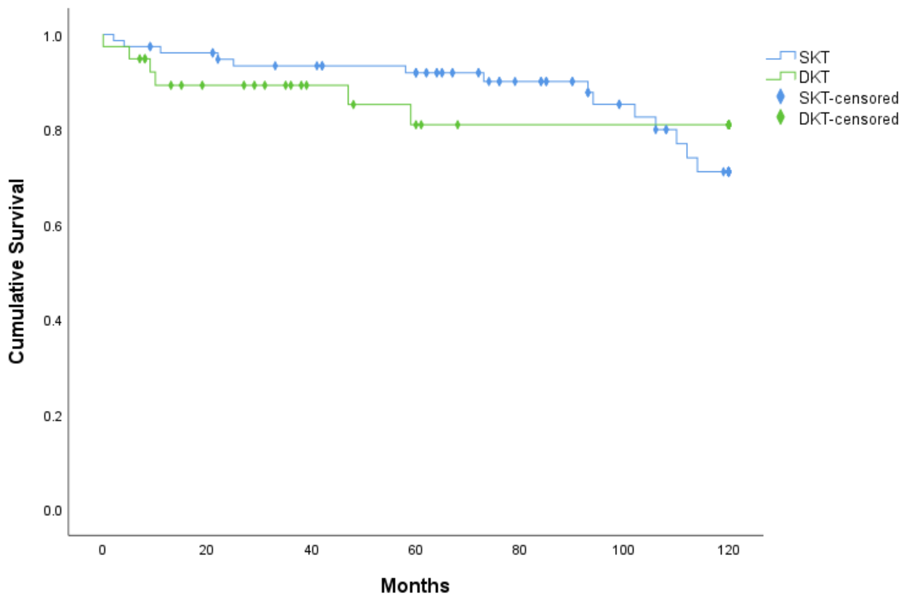


**Figure 3.** Ten-year overall survival Kaplan–Meier analysis.

## 4. Discussion

Our study endorses the non-inferiority of DKT when compared to SKT in the extended-criteria donor population, both in terms of graft and overall survival. These results confirm what prior studies have shown in terms of DKT survival rates, supporting the validity of this procedure [4,9,11,16,19,20]. In contrast to previous studies, we directly compared DKT with a matched control group of SKT recipients.

The ten-year GS of DKT was similar to that of SKT, as previously reported [19,20]. Interestingly, when looking at five-year GS, the predefined non-inferiority margin was exceeded, with a 15% higher GS in the SKT group. However, this difference was not statistically significant in the survival analysis and did not persist at the 10-year cut-off. Although no clear explanation was given, these findings are most likely to be interpreted in the light of the higher percentage of complications, primary dysfunction, and acute rejection.

Looking at the overall survival analysis, 80% of patients in the DKT were alive at ten years, proving to be an option for RRT, especially when compared to the five-year life expectancy for patients on dialysis, which is estimated at 40% [21,22].

Surgical and cold ischemia times were longer for DKT recipients, although the difference was relatively small. Post-transplant complications were indeed more common in the DKT group, particularly urinary fistula, urinary stenosis, venous thrombosis, arteriovenous fistula, graft haemorrhage, and graft rejection. These outcomes were expected [7,8], and were considered a consequence of the procedural complexity [9,16], but also of the poorer quality of the grafts. DKT requires more anastomosis of both vessels and ureters and a larger dissection, therefore having a higher risk of complications [9,23].

Renal function and serum creatinine levels did not unveil substantial differences between whether the transplant was SKT or DKT. These results are aligned with previous studies [16], suggesting that it is possible to achieve comparable post-transplant renal function outcomes.

Given our results, DKT is an option when discussing RRT with potential recipients. Patients must be informed of the good GS results and the potentially higher risk of graft loss in the first five years and the increased risk of post-transplant complications. We endorse the acceptance of DKT, particularly in old-to-old strategies, as it seems to be the most common approach [8]. However, it is worth noting that the establishment of criteria could boost the use and outcomes of this technique [15].

A notable strength of this research was the employment of PSM, which represented an important asset to effectively control confounding factors. Another advantage of this retrospective study was the use of our institutional prospective database, which allowed us to analyse a larger cohort of patients within a reasonable timeframe.

This study had key limitations that should be taken in consideration. Although the retrospective design favoured a considerable pool of data, there was a chance of selection bias that cannot be eliminated through PSM. Even so, the study had a small sample, including only 39 DKTs. This limited number is primarily due to the study being a single-centre experience, as well as previous concerns regarding the use of this technique. The uncertainty of its potential complications, particularly in elderly patients because of the old-to-old allocation strategy, and the requirement for a healthy vascular bed to implant both kidneys—more challenging to meet in older patients, especially with severe atherosclerosis—leads to greater underuse of DKT.

Additionally, biopsy scores were not available for all SKT donors, which could have been beneficial for inclusion in the PSM to ensure that the renal mass quality was comparable between the two groups [24]. However, it is worth noting that several limitations of the Remuzzi score can be identified, such as interobserver variability, limited value in predicting long-term outcomes, and overestimation of renal impairment. Therefore, the Remuzzi score is not universally used in all transplant centres [25].

Furthermore, patient-reported outcomes, such as quality of life, were not considered. Nevertheless, despite the mentioned limitations, we hope that future prospective studies will further enhance this observation.

Our group will also conduct a study using renal scintigraphy to analyse whether both kidney masses are functioning to determine if the graft function is the result of both kidney units. A prospective, multicenter study with well-defined inclusion criteria for DKT would help eliminate selection bias, assess the reproducibility of the technique, and enhance the generalizability of DKT outcomes.

## 5. Conclusions

Dual kidney transplantation has demonstrated non-inferiority to standard procedures in the extended-criteria donor population, despite a higher incidence of complications. Therefore, DKT is a viable and effective alternative in the management of patients with end-stage renal disease and an option to reduce transplant waiting lists. Patients need to be informed of the non-inferiority of DKT, with the potential risk of increased complications and graft loss in the first five years.

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**Institutional Review Board Statement:** The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of the Faculty of Medicine of the University of Coimbra (CE-113/2024, 13 June 2024).

**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** Data that support the findings of this study can be obtained from the corresponding authors upon reasonable request.

**Conflicts of Interest:** The authors declare no conflicts of interest.

## Abbreviations

The following abbreviations are used in this manuscript:

| | |
|---|---|
| CVA | cerebrovascular accident |
| DKT | dual kidney transplant |
| ECD | extended criteria donors |
| GS | graft survival |
| OS | overall survival |
| PSM | propensity score matching |
| RRT | renal replacement therapy |
| SD | standard deviation |
| SKT | single kidney transplantation |

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