

1 **Robot-assisted kidney transplantation (RAKT): the 8-year European experience**

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ABSTRACT

Background and objective: Evidence regarding perioperative results and long-term functional outcomes of robotic-assisted kidney transplantation (RAKT) is limited. We evaluated perioperative surgical results and long-term functional outcomes of RAKT in patients receiving kidney transplants from living donors.

Methods: This retrospective analysis is based on a prospective multicenter cohort study conducted from July 2015 to October 2023 across 10 European centers. A total of 624 patients who underwent heterotopic RAKT from living donors were included, excluding those who received orthotopic RAKT. The primary outcomes measured were long-term renal function, perioperative complications, and survival rates. Renal function was assessed with the estimated glomerular filtration rate (eGFR). The Clavien-Dindo classification (CDC) was used to describe early (within 30 days) and late (from 31 to 90 days) postoperative complications. The probability of dialysis, graft nephrectomies and any-cause mortality during follow-up was reported in terms of 5-year cumulative incidence.

Key findings and limitations: A total of 624 patients with a median age of 35 years (IQR: 26-52) underwent RAKT. Preemptive RAKT was performed in 52% of cases, and the majority (84%) had the transplant in the right iliac fossa. The median operative time was 210 minutes (IQR: 180-262), with a rewarming time of 43 minutes (IQR: 38-50). Intraoperative complications were rare (1.1%), and postoperative graft nephrectomy occurred in 1.9% of patients. High-grade (CDC ≥ 3) early and late postoperative complications were observed in 7.7% and 2.3% of patients, respectively. Rates of incisional hernias, ureteral stenosis, and arterial stenosis were 1.4%, 1.1%, and 0.2%, respectively. Median eGFR values were 19 ml/min/1.73m², 52 ml/min/1.73m², and 53 ml/min/1.73m² on the 1st, 7th postoperative day, and at 6 months, respectively. Over a median follow-up of 23 months (IQR: 6-49), 17 patients received dialysis, 11 patients underwent graft nephrectomy, and 4 patients died. None of the deaths were due to RAKT. Main limitation is the absence of a comparator group.

Conclusions and clinical implications: With the largest experience worldwide on RAKT, we confirm the perioperative safety and excellent long-term functional outcomes of this procedure. Given the benefits of a minimally invasive robotic approach, these findings support the broader adoption of RAKT as a viable option for kidney transplantation.

Patient summary: For patients receiving a kidney transplant from a living donor, robotic-assisted kidney transplantation (RAKT) offers excellent long-term kidney function and a low risk of complications.

Introduction

Robot-assisted kidney transplantation (RAKT) has become a valid alternative to open kidney transplantation.[1] Since the description of the first completely robotic cases in 2015, the interest in RAKT has increased and multiple efforts have been made to expand the knowledge on this procedure and its indications. [2, 3] Various studies have confirmed that RAKT is a safe procedure, associated with good short-term functional outcomes, feasible in obese patients and in grafts with multiple vessels.[4–6] The advent of augmented reality has permitted to expand the indication of RAKT in selected patients with iliac artery atherosclerosis, while orthotopic RAKT has become an option in case of inaccessible iliac arteries.[7, 8] Increased trust and confidence in RAKT has resulted in an increased adoption of this surgical approach, constituting nowadays the technique of choice in about 46% of all renal transplantations from living donors in the ERUS-RAKT network.[9]

Nonetheless, the open approach is still regarded as the technique of choice for kidney transplantation by the current European Association of Urology guidelines, and it is still the preferred approach for kidney transplantations as shown by recent trends analysis.[10, 11] This is because only few retrospective and underpowered comparative studies have been published, while previous series on RAKT were characterized by limited sample sizes and short follow-up.[12, 13] However, growing evidence reports that postoperative complications rates (such as incisional hernias and surgical wound infections), pain and delayed graft function are significantly lower in patients undergoing RAKT.[12, 14] This is of particular relevance in a population of immunocompromised and often frail patients.

In order to further increase evidence on the safety of RAKT, herein we present an update of the largest and longest experience worldwide on RAKT, focusing on both long-term functional and surgical outcomes.

Methods

Study population

This was a retrospective analysis of a multicentre prospective cohort of patients undergoing RAKT between July 2015 and October 2023 at 10 European institutions participating in the ERUS-RAKT network. One surgeon per center performed RAKT over this period. The ERUS-RAKT network was established in 2015 to improve the standardization and investigate the outcomes of RAKT.[15] A web-based electronic data-management system (REDCap 14.2.2 - © 2024 Vanderbilt University) was created to prospectively collect data on patients undergoing RAKT [12]. Therefore, this dataset reports the whole experience of RAKT in the centers included. This dataset follows protection of personal data through patient identity codification, with each centre having its own user identification and password.

Eligibility criteria for RAKT have been previously described by Breda et al.[15] Briefly, contraindications for RAKT consisted in the presence of iliac artery atherosclerosis, malignancy, active infection, severe cardiovascular, pulmonary, or hepatic comorbidities, highly complex vascular anatomy (such as more than 3 arteries, more than 1 small accessory artery, or more than 2 veins) or simultaneous multiple organ transplantation. For this analysis, only patients undergoing living donor RAKT were selected, while patients undergoing orthotopic RAKT were excluded.

Demographic data for donors include age, sex, body mass index (BMI), blood group compatibility, side of kidney and complexity of the vascular anatomy. For recipients, we reported age, sex, BMI, Charlson Comorbidity Index (CCI), the American society of Anesthesiologists (ASA) score, history of abdominal surgery, preoperative estimated glomerular filtration rate (eGFR), and the preemptive status. Intraoperative data included: operative and console time; cold ischemia and rewarming time; arterial, venous and uretero-vesical anastomosis time; site of transplantation and intraoperative complications. Cold ischemia time is defined as the duration of cold storage (with or without perfusion with a storage solution) before graft introduction into the recipient, while rewarming time is defined as the period from the kidney's removal from cold storage to the beginning of reperfusion (during which ice slush is continuously added). Postoperative data referred to postoperative complications, length of hospital stay (LOS) and graft nephrectomy rate. Postoperative complications were classified according to the Clavien-Dindo Classification (CDC) and distinguished into early (within 30 days) and late (31-90 days) according to the timing of incidence from the day of surgery.

Surgical procedure

Patient and trocar positioning as well as surgical procedure have been previously described into details.[15] Despite minimal variations, a transperitoneal RAKT following the principles of the Vattikuti-Medanta technique was performed in all centres.[13, 16–18] Preoperative imaging to evaluate the vascular anatomy of recipients was performed in all cases to exclude calcifications of the iliac arteries, which represent a contraindication to RAKT in the iliac fossa. Stenting with a double-J catheter was performed during the bench surgery. The choice to leave an intraabdominal drain was taken on a case-by-case basis

at the end of the surgical procedure. All RAKT procedures have been performed with the da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, CA), either Si, X or Xi models.

Outcomes

Functional outcomes were described in terms of eGFR at 1st, 3rd and 7th postoperative days as well as at 6 months from surgery. Long terms functional outcomes consisted of need of dialysis, graft nephrectomy and any-cause mortality during follow-up. Surgical outcomes were described in terms of complication rates and graft nephrectomy rates; moreover, long-term incisional hernias, ureteral stenosis and arterial stenosis rates were collected.

Statistical considerations

Descriptive statistics for categorical variables were presented as frequencies and proportions. Continuous variables were described using either means and standard deviation (SD) or medians and interquartile ranges (IQR). Postoperative complications were as the proportion of patients experiencing a complication, considering the highest grade per term and reported separately segregated into early and late complications. The probability of dialysis, graft nephrectomies and any-cause mortality during follow-up was reported in terms of cumulative incidence. Statistical analyses were performed using R (R project, Vienna, Austria).

Results

Donors and recipients' baseline characteristics

Demographic data and baseline characteristics of 624 donors and recipients are described in **Table 1**. Median age at surgery for donors was 54 years (IQR: 46-61) and

196 (31%) donors were males. Blood group compatibility was present in 522 (83%) cases, while in 526 (84%) donors the left kidney was extracted for transplantation. Multiple arteries and multiple veins were present in 89 (14%) and 11 (1.8%) donors, respectively. Median age at surgery for recipients was 35 years (IQR: 26-52) and 400 (64%) recipients were males. Overall, 158 (25%) recipients had a CCI between 3 and 5, while 394 (63%) recipients had an ASA score of 3-4 at the time of surgery. Preemptive RAKT was done in 325 (52%) patients and 183 (29%) had a history of abdominal surgery.

Surgical data

Perioperative data are reported in **table 2**. Kidney transplantation was performed in the left iliac fossa in 98 (16%) recipients and in the right iliac fossa in 526 (84%). Median operative time was 210 (IQR: 180-262) minutes and rewarming time was 43 (IQR 38-50) minutes. Intraoperative complications were recorded in 7 (1.1%) cases. Median postoperative LOS was 8 (IQR: 7-11) days.

Postoperative complications

Graft nephrectomy was recorded in 12 recipients (1.9%). Eight (1.2%) of these were because of arterial thrombosis (n=4), venous thrombosis (n=3), and arterial kinking causing bad kidney perfusion (n=1); four cases were due to acute rejection.

Overall, complications were reported in 181 (29%) recipients, with high grade complications (CDC≥3) reported in 48 (7.7%) recipients in the early postoperative phase and in 14 (2.3%) in the late postoperative phase (**Table 3**). The most common early high-grade postoperative complication consisted of bleeding or hematomas requiring surgical reintervention (11/45 cases), followed by delayed graft function (5/45 cases),

symptomatic lymphoceles requiring drainage (4/45 cases), acute rejection (4/45) and graft arterial thrombosis (4/45 cases). The most common late high-grade postoperative complication consisted of symptomatic lymphoceles requiring drainage (4/15 cases). Over a median follow-up of 23 months (IQR: 6-49), a total of 9 (1.4%) incisional hernias, 7 (1.1%) ureteral stenosis and 1 (0.2%) arterial stenosis were recorded, respectively.

Functional outcomes and survival analysis

The global eGFR trend is displayed in **figure 1**. Median values of eGFR were 10 ml/min/1.73m² (IQR: 7-13), 19 ml/min/1.73m² (IQR: 13-26), 45 ml/min/1.73m² (IQR: 31-62.4), 52 ml/min/1.73m² (IQR: 40-66) and 53 ml/min/1.73m² (IQR: 41-64) before surgery, at 1st postoperative day, 3rd postoperative day, 7th postoperative day and at 6 months from surgery, respectively. In **figure 2** it is reported the 5-year cumulative incidence of dialysis, graft nephrectomies, and any-cause mortality. Over a median follow-up of 23 months (IQR: 6-49), 17 patients received dialysis, 11 patients underwent graft nephrectomy, and 4 patients died. None of the deaths were due to RAKT.

Discussion

Since its inception, the robotic approach for kidney transplantation has been introduced successfully in the surgical practice of many centers worldwide.[1] This has been possible through the standardization of the RAKT technique and the implementation of theoretical and practical courses in recognized training centers.[17, 19, 20] Moreover, different retrospective analysis have demonstrated the feasibility of RAKT in challenges cases, such as grafts with multiple vessels, obese recipients, deceased donor RAKTs, cases of iliac vessel calcifications and the pediatric population.[5–7, 21, 22] A comparative study

has shown that functional results tend to be similar with open kidney transplantation, both in terms of perioperative renal function and 3-years graft survival and overall survival.[23] Additionally, the biological evaluation of post-operative systemic inflammatory response syndrome after living-donor kidney transplant found no significant differences between OKT and RAKT, while short-term functional outcomes were similar.[24]

However, the adoption of the robotic approach for kidney transplantation is still slow.[11] In an effort to provide additional evidence on the safety of RAKT, we updated our prospective cohort of RAKT from living donors, presenting data on the largest cohort worldwide of 624 patients and with the longest follow-up. We demonstrated that eGFR at one week and 6 months from RAKT is comparable and that cumulative incidence of dialysis, graft nephrectomies, and any-cause mortality at 5-years from surgery were low. Furthermore, we highlighted that early postoperative high-grade complications are low (7.7%) and late ones are uncommon (2.3%). Specifically, graft arterial or venous thrombosis as well as arterial kinking made up to 1% of all causes of graft nephrectomy. Lastly, over the entire follow-up, cases of incisional hernias, ureteral stenosis and arterial stenosis were rare.

These data are important for several reasons. First, they demonstrate that postoperative kidney function is robust, consistent with previous investigations.[4, 13, 15] This is a critical aspect because, while the renal function of the initial cases described might have been influenced by strong selection bias,[13] RAKT is now applied to nearly half of kidney transplantations from living donors in the ERUS-RAKT network,[9] making our results more comparable with open kidney transplantation series. Additionally, the presence of good postoperative renal function in our series might be attributed to low

250 rewarming times, which are on average within the optimal threshold to avoid impairment
251 of renal function.[13, 15] In this regard, it is important to clarify the reason for the
252 difference in the total vascular anastomosis time and the rewarming time. The rewarming
253 time involves closing the Gel Point cap, docking the robotic arms, inserting and/or
254 changing the robotic instruments (e.g., grasper, scissors, forceps), positioning the kidney
255 appropriately to clamp the iliac vessels and perform the vascular anastomosis.
256 Furthermore, after completing each vascular anastomosis (between the renal and
257 external iliac vessels) and unclamping the iliac vessels (using a bulldog clamp placed at
258 the level of the renal vessels above the vascular suture), it is crucial to check for any
259 bleeding from the anastomosis before proceeding with graft reperfusion. In cases of
260 significant bleeding, an additional vascular stitch may be necessary; however, minor
261 bleeding can often be controlled with compression using hemostatic material (e.g.,
262 Surgicel). Once bleeding is adequately managed, graft reperfusion can be safely
263 achieved.

264 Second, we report excellent outcomes in terms of cumulative incidence of dialysis,
265 graft nephrectomies, and any-cause mortality during follow-up, which might be partly
266 attributed to the fact that most patients received a preemptive transplantation, were young
267 and with low comorbidity index.[25] In fact, it must be noted that the sole chronic kidney
268 disease conveys two points towards the CCI calculation. Taken together, these factors
269 may partially explain the lower rate of dialysis and mortality compared to some open
270 kidney transplantation series.[12, 26] In fact, it is unlikely that the difference in the two
271 surgical approaches reflects in different long-term functional outcomes, rather on
272 perioperative results.

Third, relatively low rates of high-grade perioperative complications and of ureteral and arterial stenosis reflect the safety of this procedure in experienced hands. Moreover, the rate of incisional hernias is lower than most series of open kidney transplantation.[27] Most importantly, the similar number of arterial and venous graft thrombosis in comparison with our last update on 291 cases, indicates that these complications mainly happen during the learning curve of RAKT.[13] This further supports the importance of an accurate training in the first part of the learning process of RAKT, with 35 cases being considered as the threshold to achieve reproducibility in terms of rewarming time, complications, and functional outcomes for experienced robotic surgeons with previous experience in kidney transplantation.[13, 28]

Fourth, all RAKT procedures have been performed with multiport da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, CA). The importance of this remark is fundamental, as new robots become slowly available on the market and might be increasingly applied to complex surgical cases.[29] Given that heterotopic RAKT involves iliac vessel clamping, the insertion of the kidney through a gel-point access, and relies on a smooth and responsive behavior of the robotic arms in order to proceed steady and keep rewarming time low, it is essential that new platforms will show adequate reliability, adaptability and safety profiles before being applied to RAKT. To our knowledge, only the Single-Port da Vinci® Surgical System has been tested as alternative to the multiport da Vinci® Surgical System, demonstrating safety and encouraging results.[30] We strongly support the adoption of the IDEAL framework for future applications of other robotic platforms to kidney transplantation, in order to ensure safety of surgical innovation (<https://www.ideal-collaboration.net/>).

Lastly, the environmental impact of robotic surgery should be considered. While the carbon footprint of RAKT has not yet been tested, robotic procedures have demonstrated to produce higher CO² emissions than laparoscopic surgery and open surgery.[31] Given that high carbon footprint depends principally on disposables, future efforts should be directed towards reducing waste of surgical material and developing reusable materials.

The retrospective design with its inherent biases represents the main limitation of this study. Specifically, in the case of kidney transplantation, nonadherence to follow-up programs has been associated with worse graft survival or function, thus potentially altering the results of our analysis.[32] Second, while all centers followed the Vattikuti-Medanta technique, slight modifications in terms of trocar positioning or incision for graft insertion might have been applied but were not captured in our database. Third, multiple surgeons and table-side assistants with different levels of experience in robotic surgery and of exposure to kidney transplantation have been involved. Fourth, despite a previous publication showed that RAKT is slowly becoming the technique of choice for kidney transplantation,[9] we did not collect reasons other than patients' factors, such as of economical or organizational nature, that might influence the decision to plan a patient for the robotic or the open approach. This type of decision might in fact be related to specific hospital scenarios or settings of the health care system.

Conclusions

In the largest multicenter experience on RAKT, we confirm the safety of this procedure from both a surgical and a functional standpoint. At five years from surgery, the cumulative incidence of dialysis, graft nephrectomies, and any-cause mortality was low. Backed by the existing evidence supporting improved surgical outcomes from RAKT in comparison

319 with open kidney transplantation, our study reasserts and further supports the aim to
320 spread the adoption of this surgical modality for kidney transplantation.

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Table 1 – Donors and recipients demographic characteristics.

Variables	Donors (n=624, 100%)	Recipients (n=624, 100%)
Age, years, median (IQR)	54 (46-61)	35 (26-52)
Male sex, n (%)	196 (31)	400 (64)
BMI, kg/m², mean (SD)	25.8 (3.7)	25.8 (4.9)
Charlson comorbidity index		
0-2	-	290 (47)
3-5	-	158 (25)
6-10	-	13 (2)
Missing	-	163 (26)
ASA score		
1-2	-	102 (16)
3-4	-	394 (63)
Missing	-	128 (21)
History of abdominal surgery, n (%)	-	183 (29)
Preoperative eGFR, ml/min/1.73m², mean (SD)	-	10.6 (5.5)
Preemptive kidney transplantation, n (%)	-	325 (52)
Previous kidney transplantation, n (%)	-	42 (6.7)
Reason for kidney renal failure, n (%)		
Amyloidosis	-	2 (0.3)
Anephria	-	2 (0.3)
Autosomal dominant polycystic kidney disease (ADPKD)	-	93 (14.9)
Autosomal dominant tubulointerstitial kidney disease	-	1 (0.2)
Congenital nephropathy	-	21 (3.4)
Contrast-induced glomerulonephritis	-	1 (0.2)
Cystic fibrosis	-	2 (0.3)
DM nephropathy	-	34 (5.4)
Drug-related nephropathy	-	3 (0.5)
Fabry disease	-	1 (0.2)
Focal segmental glomerulosclerosis (FSGS)	-	37 (5.9)
Goodpasture syndrome	-	3 (0.5)
Hemolytic uremic syndrome	-	7 (1.1)
Hypertensive nephropathy	-	23 (3.7)
IgA nephropathy (Berger)	-	87 (13.9)
Kidney atrophy	-	7 (1.1)
Lupus nephritis	-	12 (1.9)
Membranoproliferative glomerulonephritis (MPGN)	-	15 (2.4)
Membranous glomerulonephritis (MGN)	-	32 (5.1)
Mesangial glomerulonephritis	-	2 (0.3)
Microscopic polyangiitis	-	3 (0.5)
Minimal change nephropathy	-	1 (0.2)
Myeloperoxidase-specific vasculitis	-	1 (0.2)
Nephroangiosclerosis	-	4 (0.6)
Nephronophthisis	-	4 (0.6)

Obstruction	-	3 (0.5)
Oligomeganephronia	-	1 (0.2)
Other renal syndromes*	--	8 (1.3)
Post infectious glomerulonephritis	-	6 (1.0)
Pregnancy-related (HELLP** syndrome)	-	3 (0.5)
Schönlein-Henoch purpura	-	7 (1.1)
Tubulointerstitial nephritis	-	24 (3.8)
Unspecified glomerulonephritis	-	32 (5.1)
Unspecified nephropathy	-	110 (17.6)
Vascular nephropathy	-	14 (2.2)
Vesico-ureteral reflux nephropathy	-	16 (2.6)
Wegener's Granulomatosis	-	1 (0.2)
Blood group compatibility, n (%)	522 (84)	-
Left kidney, n (%)	526 (84)	-
Vascular anatomy, n (%)		
Multiple arteries	89 (14)	-
Multiple veins	11 (1.8)	-

Abbreviations: IQR= interquartile ranges; SD = standard deviation; BMI = body mass index; eGFR = estimated glomerular filtration rate. * Alport, cardiorenal, Galloway-Mowat; ** HELLP = syndrome of hemolysis, elevated liver enzymes and low platelet count

Table 2 – Perioperative data of recipients.

Variables	Overall (n=624, 100%)
<i>Intraoperative data</i>	
Transplantation site: right iliac fossa, n (%)	526 (84)
Operative time, min, median (IQR)	210 (180-262)
Console time, min, median (IQR)	165 (130-200)
Cold ischemia time, min, median (IQR)	1 (1-3)
Rewarming time, min, median (IQR)	43 (38-50)
Arterial anastomosis time, min, median (IQR)	16 (13-20)
Vein anastomosis time, min, median (IQR)	17 (13-20)
Uretero-vesical anastomosis time, min, median (IQR)	19 (15-24)
Conversion to open surgery, n (%)	15 (2.4)
<i>Reasons</i>	
Active bleeding	2 (12)
Venous thrombosis	1 (6.2)
Altered perfusion of the graft	8 (12)
Arterial anastomosis issue	2 (12)
Vein anastomosis issue	1 (6.2)
Bleeding during clamping (atherosclerotic plaques)	1 (6.2)
Intraoperative complications, n (%)	7 (1.1)
<i>Postoperative data</i>	
Postoperative complications, n (%)	184 (28)
Length of hospital stay, days, median (IQR)	8 (7-11)
Graft nephrectomy, n (%)	
<i>Overall</i>	12 (1.9)
Acute rejection	4 (0.6)
Arterial thrombosis	4 (0.6)
Venous thrombosis	3 (0.5)
Arterial kinking	1 (0.2)
Deaths, n (%)	
<i>Overall</i>	7 (1.1)
Cancer-related death	2 (0.3)
Covid-19 infection	3 (0.5)
Not reported	2 (0.3)

Abbreviations: SD = standard deviation; BMI = body mass index; eGFR = estimated glomerular filtration rate

Table 3 – Early (within 30 days) and late (31-90 days) complications according to the Clavien-Dindo Classification (CDC).

Variable	Early complications n (%)	Late complications n (%)
Max. grade of CDC		
0 (no complications)	467 (74.8)	595 (95.3)
1-2	117 (18.5)	15 (2.4)
≥3	48 (7.7)	14 (2.3)
CDC grade ≥3*	48 (100)	14 (100)
<i>Infective</i>		
Urinary tract infection	1 (2.1)	0
Septic shock	1 (2.1)	1 (7.1)
Graft abscess	0	1 (7.1)
Wound dehiscence	2 (4.2)	0
<i>Gastrointestinal</i>		
Ileus	2 (4.2)	0
<i>Respiratory</i>		
Respiratory failure	2 (4.2)	0
<i>Surgical</i>		
Bleeding/hematoma	11 (22.9)	2 (14.2)
Incisional hernia	0	2 (14.2)
DJ dislocation (requiring nephrostomy)	1 (2.1)	1 (7.1)
Ureteric stenosis	0	2 (14.2)
Anastomotic swelling (nephrostomy)	1 (2.1)	0
Uretero-vesical anastomotic leak (nephrostomy)	1 (2.1)	0
Uretero-vesical anastomotic leak (ureteric reimplantation)	0	1 (7.1)
Lymphocele (drainage)	4 (8.3)	4 (28.6)
<i>Vascular</i>		
Deep vein thrombosis	1 (2.1)	0
Graft arterial thrombosis (graft nephrectomy)	4 (8.3)	0
Graft venous thrombosis (graft nephrectomy)	3 (6.2)	0
Arterial kinking (graft nephrectomy)	1 (2.1)	0
Arterial kinking (kidney repositioning)	2 (4.2)	0
<i>Functional complications</i>		
Acute rejection (graft nephrectomy)	4 (8.3)	0
Acute rejection (graft biopsy)	2 (4.2)	0
DGF (need for dialysis)	5 (10.4)	0

* Percentages refer to the number of ≥3 CDC complications.

Figure 1 – Estimated glomerular function rate (eGFR) over time in 624 patients receiving robot-assisted kidney transplantation (RAKT). The error bars refer to the 25th and 75th interquartile ranges.

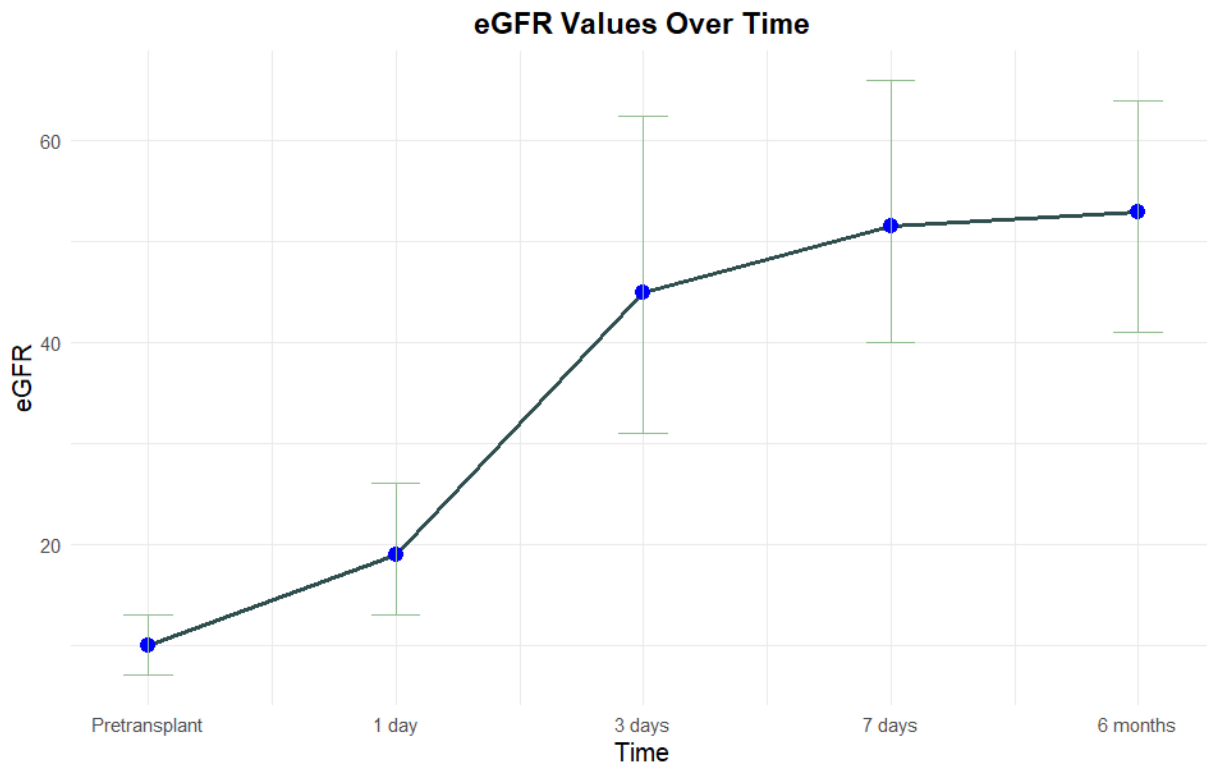


Figure 2 – Plots reporting the cumulative incidence of dialysis, graft-nephrectomies and death during follow-up.

