

Title: *Robotic Assisted Kidney Transplantation: Update from the ERUS series*

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Abbreviations

RAKT: Robotic assisted kidney transplantation

ERUS: European Robotic Urology Section

BMI: Body mass index

SD: standard deviation

DBD: donors after brain death

DCD: donors after circulatory death

ABOi: ABO-incompatible

eGFR: estimated glomerular filtration rate

DGF: delayed graft function

UNOS: United Network for Organ Sharing

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Abstract

Objective

To report the results of the robotic assisted kidney transplantation experience performed in 10 European centers members of the ERUS-RAKT group.

Materials & Methods

This is a multicenter prospective observational study of RAKT. Descriptive analysis of recipients and donor characteristics, surgical data, intra operative outcomes, complication rate and functional results were collected and analyzed.

Results

Between July 2015 and September 2019, 291 living donor RAKT were performed. Recipients were mostly male (189 (65%)), mean age 45.2 years (SD 13.35); mean BMI of 27.13 kg/m² (SD 19.28), and preemptive in 155 (53.8%) cases. Right and multiple arteries kidneys were used around 15.4%.

Mean total surgical and re-warming time was 244 min (SD 70.5), 53.16 min (SD 15.27) respectively.

Seventeen patients presented postoperative bleeding (5.7%). Five kidneys had delayed graft function; five (2%) were lost due to thrombosis and one for acute rejection. Two patients had arterial stenosis, three incision hernias, six ureteral stenosis and nine lymphocele.

Neither surgical time nor rewarming time showed correlation with post-operative serum creatinine levels ($p > 0.05$). Comparison of surgical data between the first 120 cases and the following 171 cases demonstrated a significantly shorter total surgical time in the second group (265 vs. 230 minutes, $p = 0.005$)

Conclusions

This is the largest European multicenter study on RAKT with good surgical and functional results competitive with open kidney transplant series, with a relatively short learning curve when performed in centers with a wide experience in open kidney transplantation and robotic surgery.

Key words

Kidney transplantation, robotics, minimal invasive surgery, living donor, Robotic assisted kidney transplantation

Introduction

Over the last 20 years surgery has experienced a revolution towards minimally invasive surgery. This revolution was not observed in the field of kidney transplantation, probably due to the challenges of performing vascular anastomosis using laparoscopic instruments and 2D vision. The introduction of robotics has filled the gap, enabling the intracorporeal vascular anastomosis required for kidney transplantation.

In this specific population that is usually fragile and under immunosuppressive treatment, minimally invasive surgery may be beneficial. A recent systematic review comparing open vs. minimally invasive operative recipient techniques showed, although with low level of evidence that minimally invasive techniques resulted in lower infection and incisional hernia rates, improved cosmetic result and postoperative recovery. Disadvantages included prolonged cold ischemia time, rewarming time and total operation time [1].

The first report on robot-assisted kidney transplantation (RAKT) in 2002 by Hoznek *et al.*, [2], demonstrated the feasibility of vascular anastomosis in a kidney transplant using an open approach but assisted by a robot. Eight years later, Giulianotti *et al.* and Boggi *et al.*, published their firsts pure RAKT performed in the USA and Europe respectively [3-4]. After this first experience, Menon *et al.*, standardized the transperitoneal approach with hypothermia maintenance during the rewarming time. Initial data demonstrated the safety and feasibility of the procedure [5,6].

In 2013, the first publication on RAKT in 39 obese patients with a mean Body mass index (BMI) of 42.6 showed good results [7]. Two years later, during the summer of 2015, three European centers performed a pure RAKT [8-10]. Since then, this technique is being increasingly used worldwide, and especially in many European centers. At the same time the extraperitoneal approach for RAKT has been introduced by Tsai *et al.*, with promising results [11].

With the introduction of robotics in kidney transplantation surgery, the European Association of Urology Robotic Urology Section (ERUS) has created a RAKT group with the aim of developing a common database to improve analysis of the results and confirm the feasibility and safety of this new procedure. So far, 10 centers have joined the group and currently more than 300 RAKTs has been performed.

The aim of our current paper is to report surgical results, complications rate and functional graft of the ERUS-RAKT series.

Patients and Methods

Patients and Dataset

This is a multicenter prospective observational study of RAKT performed by members of the ERUS-RAKT group, created in 2015. A specific web-based dataset was created to prospectively collect data on patients undergoing RAKT [12]. This dataset follows protection of personal data through a patient identity codification. Every center has the own user identification and password. Currently the group

is consists of ten centers across Europe with previous wide experience in open kidney transplantation and robotic surgery.

Variables collected into the database include socio-demographic data, surgical and functional outcomes, early (30-day) postoperative complications, and 90-day readmission rate. . Warm ischemia time represents the time between clamping artery in the donor and ex-vivo perfusion and rewarming time is defined as the time between graft insertion in abdominal cavity until revascularization.

In this study we analyzed the data from RAKT recipients prospectively collected into the multi-institutional ERUS-RAKT common database between July 2015 and September 2019, after Ethical Committee approval and patient informed consent.

A comparison between surgical results between first 120 cases with the new cases will be done.

Surgical technique

Surgical technique for RAKT followed the principles of the Vattikuti-Medanta technique, using a transperitoneal approach with minimal inter-center variations [4,5].

A multidisciplinary team before surgery assessed donors and recipients. A Computed Tomography Angiography was performed for both donors and recipients, to optimize the surgical strategy and approach. Neither right kidney nor multiple donor vessels were a contraindication for kidney donation. Thanks to the growing experience with RAKT, an increasing number of recipients are eligible for this technique. Currently there are no guidelines on RAKT indications, but our group's experience decided that absolute contraindications for RAKT recipients are iliac artery atherosclerosis and prior bilateral kidney transplantation.

Statistical analysis

Variables recorded in the common database were exported in a SPSS database to perform statistical analysis. Statistical analysis was performed using SPSS version 23 (IBM SPSS 140 Statistics for Mac, Armonk, NY, IBM Corp). All tests were two-sided with a significance level set at $p < 0.05$. Descriptive statistics were obtained reporting means and standard deviation (SD) for continuous variables, and frequencies and proportions for categorical variables, as appropriate. Comparison of surgical times between first series reported and new cases was done using *T-student*.

Results

A total of 291 robotic assisted living donor kidney transplantations were analyzed. In most cases the donor nephrectomy was performed using conventional laparoscopy; in 16 (5.5%) cases, a laparoscopic assisted transvaginal approach was used (Barcelona and Toulouse); in 42 (14.4%) cases, the donor nephrectomy was performed robotically (Ghent, Florence and Saarland). All centers used organ solution preservation such as Celsior, IGL1 and Custodiol.

Donor and recipient characteristics are shown in Table 1. In our series, 51(17.5%) cases of the living donor group were ABO-incompatible. The desensitization protocol consisted of rituximab, plasma exchange or immunoadsorption, and immunoglobulins. Around half of recipients were in a preemptive condition.

As mentioned before, all cases were performed using the previously described technique [5,6.], a transperitoneal approach with minimal variations. The graft was introduced into the abdomen through an umbilical incision in 238 cases (81.7%) or Pfannenstiel incision in 48 cases (16.5%), using a GELPOINT® (Applied Medical) device. In five cases the vagina was used as a natural orifice for graft introduction. In case of an iliac vascular abnormality or occupied iliac fossa for previous kidney transplant, the donor kidney was transplanted in the left iliac fossa (18 cases (6.2%)). In three cases iliac vein was transposed to facilitate venous anastomosis and in one case an end-to-end ureter anastomosis was performed using the recipient ureter because bad vascular aspect of donor ureter.

The surgical data is summarized in table 2 , with special attention to surgical complications (Table 4-5). Forty five (15.4%) cases had multiple arteries (3 arteries in 4 cases) that required bench reconstruction in some cases before implantation and 44 (15.4%) cases of right donor kidneys.

Eight cases (2.7%), from different centers and at the beginning of the series, required immediate conversion to open surgery because of bleeding (3 cases) or bad perfusion of the kidney detected intra-operatively (5 cases). One case required re- perfusion and re-anastomoses, the others recover the perfusion spontaneously.

Early (30-day) complications were noticed in 54 (18.5%) cases. The most frequent complication was postoperative bleeding, seen in 17 (5.8%) cases. Six patients required blood transfusion; six patients required surgical revision to evacuate the hematoma and two patients needed selective embolization for active bleeding (from a capsular renal artery and a hypogastric artery). The remaining 3 patients were observed.

Six (2%) kidneys were lost due to arterial thrombosis (2 cases), venous thrombosis (3 cases), and acute rejection (1 case) during the first week; all were treated by transplantectomy, none of the kidneys were tersed. This complication occurred at different centers and during the first cases. During follow-up 13 more cases developed some grade of graft rejection treated with specific medical treatment with a good end result. During the immediate post-operative period six (2%) patients developed paralytic ileus, in two cases surgical exploration was required without any abnormal finding. During the first 30-day period only one wound infection was reported.

Functional outcomes are assessed by serum creatinine and estimated glomerular filtration rate (eGFR). Figures 1 and 2 reflect serum creatinine and eGFR of recipients, demonstrating a progressive improvement in renal function. Delayed graft function (DGF), considered as the need for dialysis during the first week post transplantation, and was seen in five patients (1.7%), all of them reported in the dialysis group patients. Table 3 shows early complications according to the Clavien-Dindo classification.

Late complications were defined after 90 days of kidney transplantation. After this period of time two arterial stenoses (0.6%) were diagnosed, in one case an angioplasty was carried out and the other one did not require treatment. Three patients (1%) required surgery for umbilical incision hernia repair

and six patients (2.1%) developed ureteral stenosis, two were treated conservatively, two required ureteral reimplantation and the other two were treated endoscopically with balloon dilatation.

Nine lymphoceles (3%) were diagnosed during follow up; five required laparoscopic marsupialization and two were drained percutaneously. Table 4 shows late complications according to the Clavien-Dindo classification. One patient died due to pulmonary thromboembolism four months after surgery, not related to surgery.

Neither surgical time nor rewarming time showed any correlation with post-operative serum creatinine levels at 7 days, 30 days, and one year follow up ($p>0.05$) (table 5). Mean follow up was 24.7 months (SD 12.6).

We compared the surgical data between the first cases previously described (July 2015 – May 2017) [13] and the cases performed between June 2017 and September 2019. Although surgical times were shorter in the second group, only the total surgical time was significantly shorter (Table 6).

Discussion

Kidney transplantation is the treatment of choice for patients with end stage renal disease because of improved survival and quality of life compared with dialysis [13]. The application of minimally invasive techniques such as laparoscopy and robotic surgery offer the possibility of reducing the morbidity in these immunocompromised patients by obtaining faster recovery periods, reduced wound infections and better cosmetic results. This benefit should be even higher for obese patients, in whom a larger incision is required for kidney transplant surgery.

Following the first European experience and after consolidation by the ERUS-RAKT group [12-14], RAKT has experienced an important expansion in many centers in Europe and around the world. Concretely, our group has performed more than 300 cases in the last four years. The construction of a unique prospective online database has permitted the analysis of a higher number of cases. Our series is characterized by the use of the same transabdominal technique with minimal center variations and mainly from living donors.

In line with the first published results [12], this study confirms that expert surgeons in robotics and kidney transplantation can perform RAKT safely. Cadaveric RAKT courses and mentor's assistance during the first cases may reduce the learning curve. The RAKT group has permitted a forum for doubts and improvements, obtaining better results over time.

Regarding donor and recipient characteristics, we have noticed an increasing number of kidneys with multiple vessels and recipients with previous kidney transplantation. In the recent analysis, there were 45 kidneys with multiple arteries compared to 7 patients in the first report. We noticed an exponential increase in the number of cases with complex vascular anatomy in the last 100 cases. A more detailed description of the first 21 cases of multiple arteries kidneys from our group has recently been published and the final conclusion is that surgical and functional results using those grafts were the same as using simple vessel grafts, with a similar complication rate [15]. Right kidneys were used at the same percentage in both periods (15%), probably this reflects the previous wide experience in laparoscopic living donor kidney transplantation from all centers. In the literature, initial experience with laparoscopically harvested right kidneys was characterized by more renal vein thrombosis [16]. Nonetheless, recent studies have shown similar results using left or right kidneys [17-18]. In two cases an iliac vein transposition was carried out to facilitate venous anastomosis in right kidneys. Ciudin *et al.*, described this technique in 2012 that allows for a reduction in the space between vein anastomosis. At that time 43 right laparoscopic living donor kidneys were transplanted using this technique. Neither vein thrombosis nor lymphoceles were seen [19].

If we take a look at surgical times, the new cases are less time consuming, becoming competitive with open procedures. We have seen a statistically significant difference between the first 120 cases and the following 171 cases in operative time, confirming improvement over time. We noticed a reduction of operative time during this second period, even taking into account the new centers with few cases. This is achieved thanks to the transmission of knowledge within the RAKT working group.

During this period other European centers performed RAKT using an extraperitoneal approach. Michiels *et al.*, in 2017 reported the first European case using this approach. The authors concluded that using this approach might minimize difficulties encountered in obese patients with a potentially difficult dissection of the pelvic vessels, because the bowel is contained by the peritoneum, reducing possible complications [20]. More recently the group of Bruyere *et al.*, published eight cases using the extraperitoneal approach with a four-centimeter incision in the iliac fossa to place the Alexis port for kidney introduction. The median hospital stay was 14 days. They described one conversion for bleeding; a laparotomy for bowel injury suspicion and two patients had delayed graft function [21].

The outcomes of our RAKT series are promising and in line with other RAKT series [4-22] and should be considered as an alternative to the open approach in urologic centers with experience in robotic surgery and kidney transplantation. Six kidneys were lost due to arterial or venous thrombosis during the first cases in different centers, probably related to the technical mistakes early in the learning curve. All these patients required transplantectomy.

A typical complication in kidney transplantation is lymphocele formation due to iliac vessel dissection. In our series, only 3% of patients developed this complication and active treatment was required in 7 cases. This low percentage could be explained by the transperitoneal approach, that allows natural lymph drainage to the peritoneal cavity.

Animal studies demonstrated a reduction in renal perfusion caused by pneumoperitoneum in laparoscopic living donor nephrectomies without repercussion on kidney function when a correct hydration of the donor was performed [23]. Likewise, RAKT could also have an incremental effect on the perfusion of these laparoscopically harvested kidneys. Usually we work at 12mmHg, but some centers use 6-10 mmHg during RAKT to reduce the potential consequences of pneumoperitoneum on graft function and this is probably most important once the kidney is revascularized. The use of the Airseal system can help to maintain a stable working environment with very low pneumoperitoneum. In our series five patients (1.7%) presented DGF. This percentage is equivalent to that described by Redfield *et al.*, from a review of 64024 living donor transplantations from the United Network for Organ Sharing (UNOS) dataset. In their analysis, the authors also described multiple factors (right kidney, BMI, ...) associated with DGF and the impact on graft survival [24]. In our series different organ preservation fluids were used with good creatinine normalization over time. In this series we could not find any possible deleterious issue of surgical time or rewarming time on kidney function measured by serum creatinine level and eGFR (table 4).

Only eight cases (2.7%) presented with late complications: two arterial stenoses with one treated by angioplasty, three incision hernia repair and four ureteral stenoses treated by balloon dilatation or reimplantation.

The limitations of this study are the retrospective analysis of a prospectively collected database with some risk of detection bias and underreporting of (low-grade) complications. This is not a single-

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surgeon experience; many surgeons (one or two per center) were involved, with different backgrounds and experience. However, all surgeons had experience in both open kidney transplantation and robotic urologic surgery and were trained before and performed the first cases under mentor guidance.

There could also be a selection bias, especially at the beginning of the series, where the best candidates for robotic surgery were selected: preemptive, without atheromatosis, first kidney transplantation, and single vessel.

Our findings are still limited, as this is a multicenter experience coming from referral urologic Centers with longstanding experience in both urologic robotic surgery and open kidney transplant. However, these results encourage the maintenance of the minimally invasive procedure and even expand the indication to deceased donors and kidneys with more complex vascular pedicle. Moreover, we are increasing the number of patients that may benefit the most from RAKT, the obese recipients. Currently there is no a cost analysis study comparing open versus robotic kidney transplantation. In radical cystectomy studies, robotics has showed a higher cost compared to open procedures, but the final cost is reduced by reducing complications rate and blood loss [25]. Cost analysis study in RAKT is warranted to ensure this question.

This is the largest European multicenter study on RAKT. When performed by surgeons with previous experience in open kidney transplantation and robotic surgery, the surgical and functional results are acceptable. The RAKT working group permitted the gathering of a higher number of RAKT cases and a better knowledge transmission of this specific technique to new centers facilitating the learning curve.

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Conflicts of Interest

Dr. Musquera has nothing to disclose.

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Table 1. Patient and living donor characteristics (n=291)	
Variable	Results
Donor characteristics	
Donor sex (male/female) n (%)	97(38)/155(62)
Donor Age (mean, SD)	50.8(10.8)
Donor BMI (mean, SD)	25.5(3.6)
Donor Side, (left/right) n (%)	241(84.6)/44(15.4)
Recipient Characteristics	
Recipient Sex (Male/female) n (%)	189 (65)/102(35)
Preemptive Yes/no n (%)	155(53.8)/133(47.2)
Mean recipient age at surgery, yr (SD)	45.2(13.35)
Median BMI (SD)	27.13(19.28)
Vascular anatomy n (%)	
Multiple arteries	45(15.4)
Multiple veins	4(1.3)

Table 2. Surgical Data (n=291).	
Variable	Mean (SD)
Operative time (min)	244.38 (70.5)
Console time (min)	164.88 (56.2)
Warm ischemia time (min)	2.9 (2.2)
Rewarming time (min)	53.16 (15.27)
Arterial anastomosis Time (min)	18.71 (6.1)
Vein anastomosis time (min)	20.54 (7.2)
Ureterovesical anastomosis time (min)	23.5 (8.8)
Estimated blood loss (cm3)	153 (118)

Table 3. Early Complications graded according Clavien Dindo

Complications	n%
Grade I	
Wound infection	1 (0.3)
Bleeding (observation)	3 (1)
ileus	4 (1.4)
Pielonephritis	1(0,3)
Grade II	
Deep venous trombooses	1 (0.3)
Bleeding with transfusion	6 (2)
Grade IIIa	
Embolization	2 (0.7)
DGF	5 (1.7)
Grade IIIb	
Transplantectomy for Arterial thromobosis	3(1)
Transplantectomy for vein thrombosis	3(1)
Bleeding requiring surgical exploration	6(2)
Ileus requirig surgical exploration	2(0.7)
Transplantectomy for acute rejection	1(0.3)
Grade IV	0
Grade V	0

Table 4. Late complications graded according to Clavien Dindo

Grade I	
Lymphocele	2(0.7)
Ureteral stenosis (conservatively)	2(0.7)
Grade II	
0	
Grade IIIa	
Lymphocele	2(0.7)
Angioplasty	1(0.3)
Ureteral stenosis (endoscopically)	2(0.7)
Grade IIIb	
Lymphocele	5(1.7)
Hernia repair	3(1)
Ureteral stenosis (re-anastomosis)	2(0.7)
Grade IV	
0	
Grade V	
1	

Table 5 . Correlation between operative time and rewarming time with creatinine

	Operating time		Rewarming time	
	r	p value	r	p value
POD7				
creatinine(micromol/l)	0.10	0.08	0.10	0.08
POD30				
creatinine(micromol/l)	0.08	0.17	0.05	0.38
One year				
creatinine(micromol/l)	0.06	0.39	0.005	0.94

Table 6. Comparison between periods on Surgical times

Time (min)(mean(SD))	Initial(n=120)	New (n=171)	p
Total Surgery	250(80)	230(71)	<0.005
Rewarming	50,26(11,5)	52.5(15.4)	0.4
Arterial anastomoses	19,26(6.5)	18,3(6,7)	0.2
Vein anastomoses	20,36(6.5)	19.9 (7.5)	0.12
Uretrovesical anastomoses	21,01(9,6)	23.2 (8.3)	0.47