Robotic Radical Prostatectomy for Prostate Cancer in Renal Transplant Recipients: results from a multicenter series.

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Abbreviations

PCa= prostate cancer
RTR= renal transplant recipients
PLND= pelvic lumph node dissection
RCT=randomized controlled trials
OS=overall-survival
FC=focal cryotherapy
FS=free survival
RARP=robot assisted radical prostatectomy

Key Words:
Prostate cancer; renal transplant; treatment; robotic radical prostatectomy

Abstract (max 300 words)

Background: Despite an expected increase of PCa incidence in RTR in the near future, RARP has been poorly detailed in these patients. Whether results are comparable to RARP in non-RTR is not well understood.

Objective
To video-describe the surgical technique and report the results of our multi-institutional experience with RARP in RTR.

Design, setting, and participants
A retrospective review of the experience of four referral centers.

Surgical procedure
Transperitoneal RARP with PLND in selected patients.

Measurements
Patient, PCa and graft baseline features; intra- and post-operative features; complications, (Clavien classification); oncological and functional outcomes.

Results and limitations
We included 41 men. Median age, ASA score, pre-operative renal function and PSA were 60 (IQR 57-64) years, 2 (2-3), 45 mL/min (30-62) and 6.5ng/mL (5.2-10.2). Four men (9.8%) had biopsy Gleason Score >7. The majority (70.7%) did not undergo lymphadenectomy. Median operating time, hospital stay and catheterization time were 201 minutes (170-250), 4 days (2-6) and 10 days (7-13). At final pathology eleven men had extra-prostatic extension and seven had positive surgical margins.
At a median follow-up of 42 months (24-65) four men had BCR, including one case of local PCa persistence and one local recurrence. No metastases were recorded whilst two patients died for non-PCa related causes. Continence was preserved in 86.1% (p=NA) and erections in 64.7% (p=0.0633) of those continent/potent before the procedure. Renal function remained unchanged (p=0.08). No intraoperative and one major (Clavien 3a) complication were recorded.

Conclusions
RARP in RTR is safe and feasible. Overall operative, oncological and functional outcomes do comparable to those described for non-RTR with graft injury remaining undescribed. Further research is needed to confirm our findings.

Patient summary
Robotic prostatectomy is safe and feasible in RTR. Oncological and functional results and complications seem similar to those of non-RTR but warrant further research.

Take Home Message (max 40 words)
Robotic prostatectomy is safe and feasible in patients with renal transplant. Oncological and functional results and complications seem similar to those of non-RTR with no cases of graft injury being described.

Manuscript (Word count)

1. Introduction

Prostate cancer (**PCa**) remains the most frequent non-skin solid neoplasm in men with kidney transplants (**RTR**)[1,2]. In the next decades a rise of cases in RTR is to be expected. First, this is due to an overall increase in the number of transplants performed. Second, it is due to the changing features of RTR, who, in more than half of the cases are now older than 50, meaning approximately 10,000 kidney transplant surgeries performed yearly in the United Stated and Europe[3–5]. Thirdly, as technological and medical fields progressed considerably, we observe an increased life expectancy of these patients, now almost reaching 20 years for recipients in their fifties[3–5].

In this context, several issues remain unsolved including whether these patients are at risk of worse oncological and functional results and whether there is an optimal management for PCa[5–7]. Nonetheless, the number of PCa cases diagnosed and described in RTR is low[5,7].

Amongst PCa treatment options, robotic radical prostatectomy (**RARP**) gradually emerged in the last two decades and is now by far the most performed technique to surgically treat PCa[8]. However,

the paucity of reports on PCa cases for RTR is even more evident in this context. As highlighted by two recent systematic reviews, less than fifty robotic procedures have been described, mainly deriving from small single-center case series or case reports and using different approaches[5,7]. Despite outcomes being promising, there is thus an important lack of direct evidence to support the robotic approach in this context.

On the one hand, RTR-specific factors, including immunosuppression, the anatomical situ of the graft in the iliac fossae and the potential pelvic tissues adhesions, may impact surgical outcomes[9,10]. On the other hand, also the risk of graft-related complications, from renal function decrease to graft rejection risk is not well acknowledged[5,7,11].

Hence, we aimed to describe our surgical approach to performing RARP in RTR and to report the initial results of our series, which to our knowledge is the largest available multicenter series.

2. Materials and methods

2.1 Data Collection

We retrospectively collected data of men undergoing RARP for histologically documented cN0M0 PCa after kidney transplant at four European tertiary referral centers between February 2009 and April 2019. All patients performed staging according to EAU guidelines (axial abdominal imaging – mpMRI and/or CT scan and bone scan). Three men also had pre-operative PET scan negative for extra-prostatic extension (choline n=1; PSMA n=2). Two physicians independently performed data quality review (G.M. and F.P.). Centers were re-contacted for data revision in case of uncertainty or missing information.

2.1 Surgical Technique

We performed transperitoneal RARP using the Da Vinci Xi (n=20) or the Si (n=21) platform. No relevant surgical and/or technical differences were acknowledged between the two platforms. When performing the procedure in RTR some steps need to be highlighted and kept in mind.

Trocar placement and Bladder Drop/Retzius Space development
Trocar scheme was the same as previously described for standard RARP using four robotic arms (10mm ports), and two ports for the assistant (12mm Air seal and 5mm port). Before placing lateral ports the graft site must be visualized and identified (**Figure 1A, B**). Its anatomical location remains key during bladder drop and the development of the Retzius space.

Homolateral Pelvic lymphadenectomy
When performing lymphadenectomy homolateral to the graft site, tissues can sometimes be fibrotic due to the previous transplant surgery. Also, the transplanted ureter route as well as the site of arterial anastomosis (either on the common or external iliac artery) must be kept in mind; in this phase, identification and isolation of the ureter are recommended (**Figure 1C**). Robotic magnified and 3-dimensional vision is in our view of help during this step.

Anterior dissection
A pre-operative excretory CT scan may help in locating the transplanted ureter during pre-operative planning. Depending on the previous transplant surgery, the transplanted ureter can be found

anterior to the bladder (**Figure 1D**) and also to the prostate. In case of an anteriorly located ureter, when dissection and isolation are performed, the ureter should not be skeletonized to minimize devascularization and the chance of related complications. When a uretero-pyelic anastomosis was performed for the transplant surgery of the native ureter, the ureter route was located in an orthotopic place.

Subsequent steps
The subsequent surgical steps do not vary compared to a conventional RARP approach [12].

2.2 Categorization of the variables

Continence was recorded considering the number of pads used/day and categorized as full continence (no pads), terminal dribbling, mild (1 pad/day), moderate (2 pads/day) and severe incontinence (≥3pads/day). Complications were graded using the Clavien-Dindo classification and adhering to the EAU guidelines on reporting complications, considering major complications those with a Clavien grade ≥3 [13]. Pre-operative comorbidity status was recorded using the ASA score. Biochemical persistence was defined as first post-operative PSA being >0.1ng/mL after at least 6 weeks from surgery; Biochemical recurrence (**BCR**) as a post-RARP undetectable PSA subsequently reaching >0.2ng/mL.

2.3 Outcomes

Primary outcome was to describe the surgical technique of RARP in kidney transplant recipients. Secondary outcomes were to assess: i) oncological results of sRP including positive surgical margin (**PSM**), BCR, Systemic progression, Cancer-Specific (**CSS**) and Overall Survival (**OS**); ii) functional outcomes; iii) complications, including graft-related complications.

2.4 Statistical analysis

Variables were reported as median and Interquartile ranges (continuous) or as number and percentages (categorical). To evaluate the possible differences between functional outcomes before and after RARP a univariate analysis was performed using the Kruskal Wallis test and the Bowker symmetry test for continuous and categorical variables respectively. Statistical analysis was conducted using SAS software version 9.4 (SAS Institute Inc, Cary, North Carolina).

3.Results

3.1 Baseline features

We included n=41 men. Baseline patients and kidney transplant features are displayed in **Table 1**. Median age and ASA score at surgery were 60 (IQR 57-64) and 2 (IQR 2-3) respectively. Median pre-operative renal function was 45 mL/min (IQR 30-62). Most frequent cause of renal failure was chronic glomerulonephritis (31.7%) with the majority having a single transplant (92.7%) mainly from single cadaver donor (70.7%).

Table 2 shows PCa features before RARP. Median time from transplant to PCa diagnosis and PSA were 118 months (IQR 57-184) and 6.5ng/mL (IQR 5.2-10.2) respectively. Only four men (9.8%) had

biopsy Gleason Score >7. Pre-operative mpMRI was performed in 83% with 4 patients (9.8 %) having suspicion of extracapsular extension.

3.2 Surgical and Pathological features

Intra-operative RARP features and RARP pathology are detailed in **Table 3**. The majority of men did not undergo lymphadenectomy (70.7%) whilst only two had bilateral lymphadenectomy which was less extended on the graft side (median contralateral nodes removed were 4.5 (IQR 3-7); ipsilateral removed nodes were n=2 and n=4 respectively). Median operating time, hospital stay and catheterization time were 201 minutes (IQR 170-250), 4 days (IQR 2-6) and 10 days (7-13). At final pathology four men had Gleason Score >7, eleven had extra-prostatic extension and seven had positive surgical margins.

3.3 Oncological outcomes

Median follow-up was 42 months (IQR 22-64). Overall four men underwent adjuvant radiotherapy at a median time of 6 months (IQR 4-6) after RARP. Two men experienced BCR and two experienced PSA persistence. One man had local disease persistence at 3 months (PSMA-PET) and one had local recurrence at 94 months (mpMRI and choline-PET). None of the patients had systemic progression. At last follow-up two patients died, both for non-PCa related causes. Thirty-six patients were alive with no evidence of PCa and three under androgen deprivation therapy.

High Risk PCa

Overall, thirteen patients had high-risk PCa due to initial PSA >20 ng/mL alone (n=1), initial PSA >20ng/mL and pT3 stage (n=1), Gleason score >7 alone (n=1), GS >7 and pT3 stage (n=3) or pT3 stage alone (n=7). Baseline and pathological features are presented in Supplementary Table 2. Three underwent adjuvant RT and ADT (n=1 due to positive margins). At an overall median follow-up of 36 (IQR 14-60) months, two had BCR (one with local recurrence at PSMA-PET) and have hormone sensitive non-metastatic disease under ADT, whilst the remaining are alive with no evidence of PCa.

3.4 Functional Outcomes and Morbidity

Functional outcomes and renal function variations are displayed in **Figure 2** and **in Supplementary material 1**. The majority of men had preserved continence (86.1%) after the procedure.
Twenty-seven men (81.2%) had stable erectile function - (n=11 potent before the procedure and n=16 with PGE-5 or no erections before surgery). Six men lost the erectile function (18.2%). Overall erectile function significantly decreased after the procedure (p=0.0143).
Renal function remained unchanged after the procedure (creatinine p=0.42; eGFR p=0.08).

No intra-operative complications were recorded. Three patients (7.3%) developed 4 complications. One man had post-operative hemorrhage requiring embolization 5 days PO (Clavien 3a) and blood transfusions and 14 days after the intervention experienced pyelonephritis, which was managed with IV antibiotics (Clavien 2). One man had UTI, managed with IV antibiotics (Clavien 2).
One man had renal insufficiency 10 days following the operation due to recurrence of glomerulonephritis requiring IV medical treatment (Clavien 2).

4. Discussion

In the current work we describe the most challenging surgical steps of RARP in RTR and, to our knowledge, we report the results of the largest series to date. Several findings are of interest.

First, the procedure was safe. No major events occurred intra-operatively and only one major post-operative complication was recorded. Other post-operative morbidities were mainly of low impact and rare, suggesting RARP does not have a higher risk of complications in RTR. Interestingly, half of these complications were of infectious type. Despite the overall numbers being low, this certainly requires further investigation to evaluate the clinical impact of immunosuppression regimen to prevent graft rejection, on the post-operative infectious. Finally, no graft or transplanted ureteral injuries were described. In our view, pre-operative planning with an excretory CT scan (if eGFR allows a venous contrast injection) to visualize the ureteral location and appropriate visualization and, when necessary, isolation during surgery, may be of value in avoiding graft injuries. Renal function did not seem influenced and remained overall stable after RARP.

Second, functional outcomes were also acceptable and did not seem hampered in RTR. In terms of continence the vast majority of patients achieved a pad/free status. As previously described for transplant patients, despite graft implantation improves erectile function compared to dialysis, only half were potent before surgery[14]. Nonetheless, almost two on three being potent before surgery preserved erectile function.

Third, lymphadenectomy homolateral to the graft was poorly performed in the present series. This does not seem surprising considering the theoretical risk-benefit ratio of the procedure. On the one hand, lymph node dissection does not seem to improve survival and oncological outcomes in the overall PCa scenario[15,16]. On the other hand, the proximity of vascular anastomosis and transplanted ureter increase the technical challenge. Furthermore, the impact of lymphadenectomy-related complications can be potentially devastating, as it may cause graft loss. This can happen directly, through vascular and urinary intra-procedural injuries, but also indirectly, through less common but equally graft-threatening complications, including vein thrombosis and hematomas/lymphoceles potentially compressing adjacent structures[5,17]. Nonetheless, these complications remain relatively rare and, when performed, homolateral lymphadenectomy was feasible in RTR. Similarly, no complications were detailed in most recent cases, which have not been included in the present series due to a short follow-up. In our view, correct identification and isolation of the ureter and graft vessels help in minimizing risks. Robotic magnified 3-dimensional vision may increase procedural precision and feasibility during this challenging step. Based on our preliminary experience, when in expert hands and indicated, lymphadenectomy should not be precluded upfront. Importantly, the possibility that PLND may hamper a subsequent homolateral graft due to secondary fibrotic adherence should be also kept in mind. Despite no ureteric injuries being described, in case of favorable PCa features and/or surgeon not willing to perform homolateral LAD, keeping intact the peritoneum on the side of the transplant may further minimize this risk.

Fourth, oncological control seems acceptable at a short- to intermediate-term follow-up. Positive surgical margins were relatively low, including men with high-risk PCa[20]. This finding is in line with the absence of anatomical and technical differences of the peri-prostatic part of the surgery. No patients experienced systemic progression and the vast majority remained free of disease. This is in

line with PCa being diagnosed mainly at a localized stage as per previous reports[5] and, possibly, to PSA screening being performed in our cohort at the time of first renal transplant and during periodical follow-up visits.

From a clinical perspective, when indicated, robotic surgery can be a valuable way to treat PCa in RTR. Our results mirror those of the majority of published series in terms of cancer control, functional outcomes and safety, overall suggesting the procedure does not differ much from RARP in conventional patients[5,7]. Nonetheless, a recently published robotic series described relevant morbidity of RARP in RTR, with high-grade and overall complications being experienced by 10.2% and 51.2% of men[18]. Further studies are thus needed to confirm our findings also in terms of morbidity.

From a research perspective, we increased available evidence on the feasibility of RARP. Importantly, in the context of the description of the surgical technique in RTR, the role of graft homolateral lymphadenectomy needs to be carefully weighted. As complications may have more relevant consequences in RTR compared to the general population, future research should better investigate the complication rate through larger series. Also, the risk cutoff we should use to favour homolateral lymphadenectomy in this setting may be different compared to the general population[15]. Finally, our view is based on a limited and preliminary experience which indeed requires further evidence to define feasibility, usefulness and optimal technique to perform homolateral lymphadenectomy in RTR.

Our work is not without limitations. Its retrospective nature and, in spite of its being the largest available series, its relatively small number of patients, with a limited follow-up, may have caused underestimation of short- and long-term complications. Multiple surgeons with different degrees of experience performed the procedure. Whilst this strengthens the reproducibility of the results, indications to perform lymphadenectomy and procedural steps may have suffered from slight variability across different centers. Also, despite reports are currently limited for RTR, other robotic techniques may be of interest[21], including the Retzius-sparing approach, which decreases vicinity with the graft by sparing its anatomical site compared to the standard approach. This may potentially further increase the safety of the procedure and results are eagerly awaited.

As the quality of the present and of available studies remains low, prospective data are warranted to confirm our findings and the possible impact of immunosuppression on complications, morbidity and cancer control. Prospective comparison with RARP in conventional cohorts and with other surgical[19] and non-surgical approaches in RTR should also be performed.

5. Conclusions

RARP in RTR is safe and feasible. Attention should be paid to some key surgical steps. Overall operative, oncological and functional outcomes do seem comparable to those described for non-RTR with graft injury remaining undescribed. Further research is needed to confirm our findings.

Conflict of Interest: none to declare.

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Ethics: All included patients underwent robotic radical prostatectomy and provided written informed consent. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Author contributions
Study concept and design: Marra, Agnello, Biancone, Gontero
Analysis and interpretation of data: Marra, Agnello, Giordano, Oderda, Biancone, Gontero
Statistical analysis: Marra, Soria
Manuscript Draft: Marra, Soria, Oderda, Gontero
Critical revision of the manuscript: All authors

Tables and Figures Legend

Figure 1. Critical steps when performing Robot-assisted radical prostatectomy in renal transplant recipients. **A)** Trocar placement and extra-corporeal graft site location in a patient with two previous kidney transplants; **B)** Graft identification before placing the lateral ports in a patient with two previous transplants; **C)** Identification and isolation of the graft ureter **D)** Excretory CT phase showing a transplanted ureter located anteriorly close to the prostate gland.

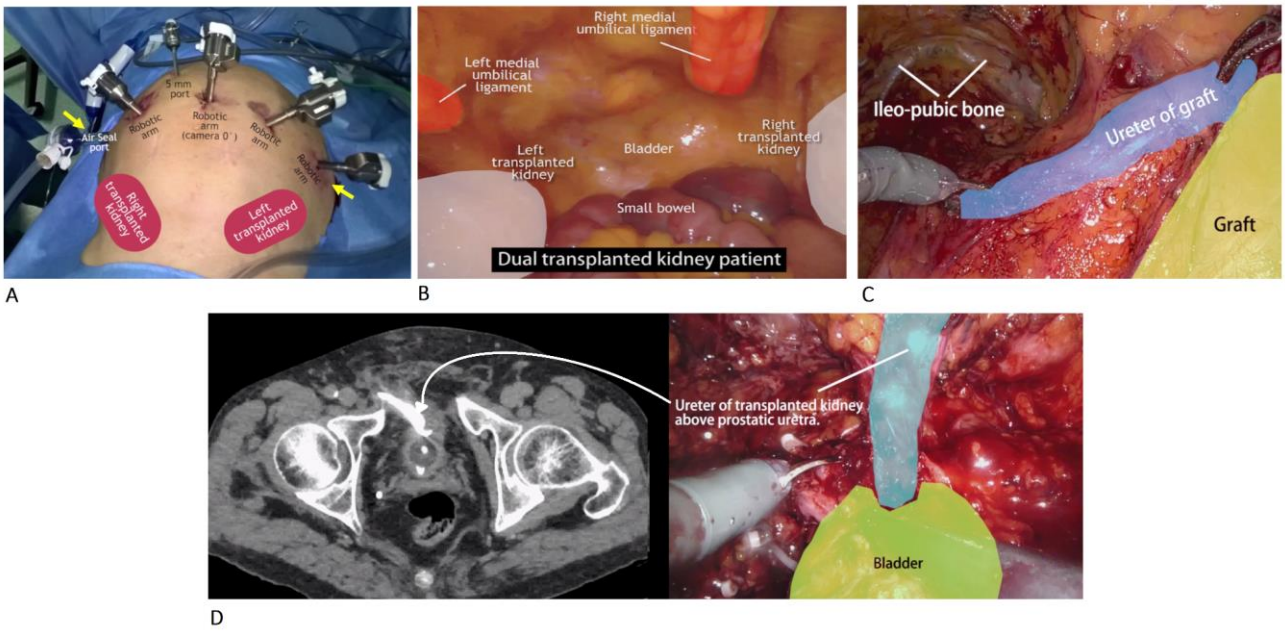

Figure 2. Renal function and functional outcomes variations.

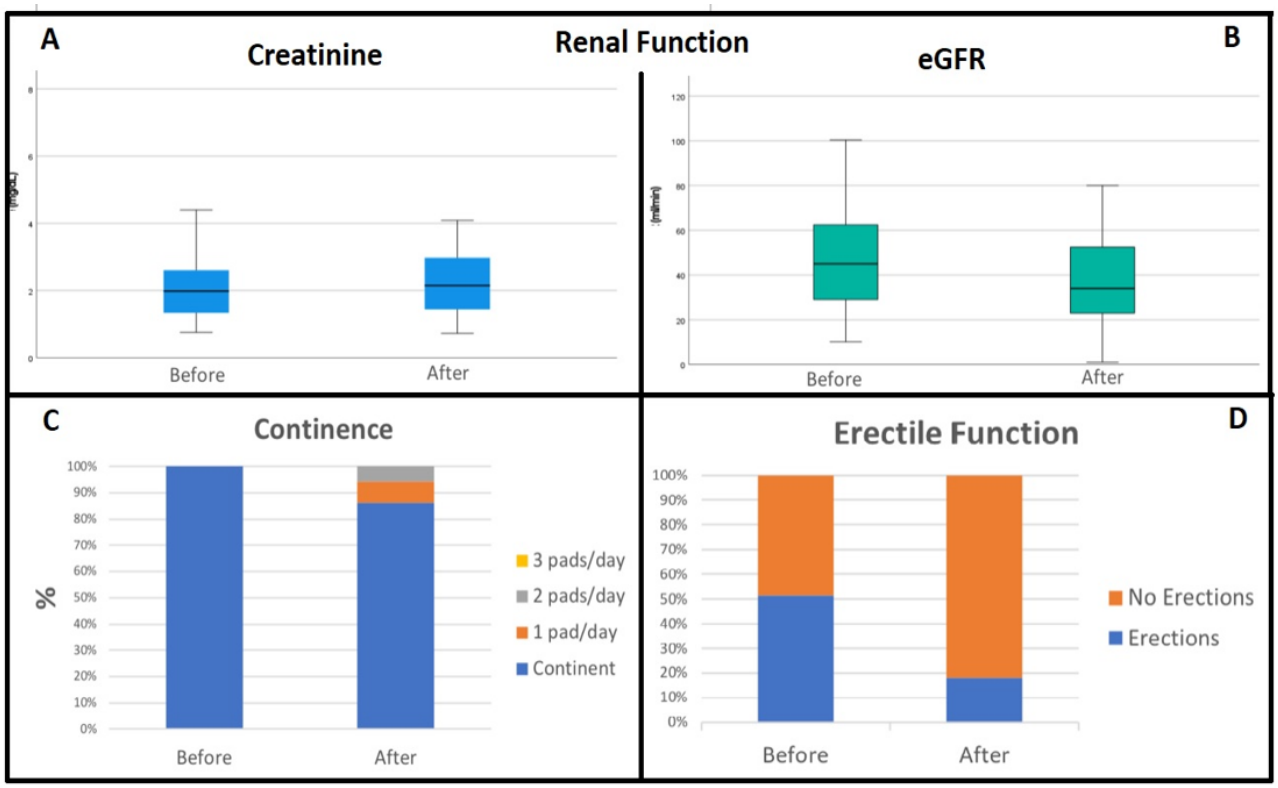

Table 1. Patients and kidney transplant baseline features.

Table 1. Patients and transplant features.	n (%) / median (IQR)	
n	41	(100.0)
Patent baseline features		
Age	60	(57-64)
Race		
Caucasian	37	(90.2)
Afro-american	2	(4.9)
Asiatic	2	(4.9)
BMI	26	(24-28)
Smoking status		
Active	1	(2.4)
Former	5	(12.2)
Diabetes	7	(17.1)
ASA score	2	(2-3)
Transplant and Kidney Failure features		
Pre-operative renal function		
Creatinine (mg/dL)	**2.0**	(1.36-2.6)
eGFR (mL/min)	**45**	(29.7-61.8)
Renal Failure		
Chronic	40	(97.6)
Acute	1	(2.4)
Cause of renal Failure		
Chronic glomerulonephritis	13	(31.7)
APKD	8	(19.5)
Diabetic nephropathy	3	(7.3)
Nephrosclerosis	3	(7.3)
Vesicoureteral reflux	2	(4.9)
Chronic pyelonephritis	1	(2.4)
Others	10	(2.4)
Previous Dialisis	32	(78.0)
Number of kidney transplants		
1	38	(92.7)
2	3	(7.3)
Type of first transplant		
Single Cadaver	29	(70.7)
Singe Living donor	11	(26.8)
Double Cadaver	0	0
Site		
Left iliac fossa	15	(36.6)
Right iliac fossa	24	(58.5)
Immunosuppression		
mTOR inhibitors	1	(2.4)
Antiproliferative Agents	2	(4.9)
Calineurin Inhibitors	31	(75.6)
Steroids	12	(29.2)
Time from IS to treatment (mo)	130	(64-202)

Table 2. PCa baseline features

Table 2. PCa baseline features.	n (%) / median (IQR)	
Patent PCa features		
Time transplant to PCa diagnosis (mo)	118	(57-184)
PCa familiarity	0	(0.0)
PSA (ng/mL)	6.5	(5.2-10.2)
DRE suspicious	32	(78.0)
Gleason Score		
3+3	9	(21.9)
3+4	24	(58.5)
4+3	4	(9.7)
4+4	2	(4.9)
4+5	2	(4.9)
Biopsy Cores		
Taken	14	(12-24)
Positive	5	(3-8)
Max PCa length (mm)	9.5	(6-12.75)
pre-op mpMRI	2	(2-3)
No	7	(17.0)
Yes	34	(83.0)
with contrast	32	(94.1)
without contrast	2	(5.9)
Negative	1	(2.9)
Positive (1 index lesion)	28	(82.4)
Positive (>1 lesion)	5	(14.7)
ECE	4	(12.5)
SVI	1	(3.1)

Table 3. Robotic radical prostatectomy intra-operative features and pathological results.

Table 3. RARP features	n (%) / median (IQR)	
RARP intraoperative features		
Lymphadenectomy		
No	29	(70.7)
Contralateral	10	(24.4)
Contralateral + homolateral limited	2	(4.9)
Nerve Sparing		
No	20	(48.8)
Unilateral	5	(12.2)
Bilateral	13	(31.7)
Operating Time (min)	210	(170-250)
Estimated Blood Loss (mL)	300	(200-400)
Intraoperative Blood Transfusions	2	(4.8)
Hospital Stay (dys)	4	(2-6)
Cateter Removal (dys)	10	(7-13)
Surgeon Experience		
0-50	4	(9.7)
50-100	2	(4.9)
100-500	31	(75.6)
>500	4	(9.7)
RARP post-operative pathology		
Gleason score		
3+3	11	(26.8)
3+4	20	(48.8)
4+3	4	(9.8)
4+4	3	(7.3)
4+5	1	(2.4)
pT stage		
2	29	(70.7)
3	11	(26.8)
pN stage		
x	29	(70.7)
0	12	(29.2)
1	0	(0.0)
Nodes removed	6	(4-7)
Positive Margins	7	(17.1)

Supplementary Material 1. Renal function and functional outcome changes before and after the surgical procedure. *calculated on n=36 subjects with pre- and post-operative values available; ^n=34; **n=33; ***n=36.

Renal Function and Functional Outcomes before and after RARP					
	n (%)				
	Before		After		p
	Continence				
Continent	40	(100.0)	31	(86.1)	na***
Incontinent					
1 pad/day	-	-	3	(8.3)	
2 pads/day	-	-	2	(5.6)	
3 pads/day	-	-	0	(0.0)	
	Erectile function				
Potent/PDE-5	17	(51.5)	11	(32.3)	0.0143**
PGE	12	(36.4)	9	(26.5)	
Complete Dysfunction	4	(12.1)	14	(41.2)	
	Renal Function				
Creatinine (mg/dL)	1.98	(1.34-2.61)	2.15	(1.44-2.98)	0.4235*
eGFR (mL/min)	24.03	(29-62)	34	(23-52)	0.0799^

Supplementary Material 2. Features the subgroup of renal transplant patients undergoing robot-assisted radical prostatectomy with high risk prostate cancer according to the final pathology.

Supplementary Material 2.	n (%) / median (IQR)	
n	13	(100.0)
Baseline features		
Age	58	(57-62)
Race		
Caucasian	12	(92.3)
Asiatic	1	(7.7)
ASA score	2	(2-3)
Transplant and Kidney Failure features		
Renal Failure		
Chronic	13	(100.0)
Acute	0	(0.0)
Previous Dialisis	10	(76.9)
Number of kidney transplants		
1	11	(84.6)
2	2	(15.4)
Type of first transplant		
Single Cadaver	10	(76.9)
Singe Living donor	3	(23.1)
Double Cadaver	0	(0.0)
Immunosuppression		
mTOR inhibitors	1	(7.7)
Antiproliferative Agents	6	(46.1)
Calineurin Inhibitors	8	(61.5)
Steroids	3	(23.1)
Time from IS to treatment (mo)	126	(99-243)
PCa features		
Time transplant to PCa diagnosis (mo)	118	(57-184)
PCa familiarity	0	(0.0)
PSA (ng/mL)	6.8	(5.2-14)
DRE suspicious	11	(84.6)
Gleason Score		
3+3	2	(15.4)
3+4	6	(46.1)
4+3	1	(7.7)
4+4	2	(15.4)
4+5	2	(15.4)
Biopsy Cores		
Taken	14	(12-20)
Positive	5	(4-7)
Max PCa length (mm)	10.5	(5.75-12.0)
pre-op mpMRI		
No	1	(7.7)
Yes	12	(92.3)
ECE	2	(15.4)
SVI	0	(0.0)
RARP intraoperative features		
Lymphadenectomy		
No	9	(69.2)
Contralateral	2	(15.4)
Contralateral + homolateral limited	2	(15.4)
Operating Time (min)	242.5	(180-250)
Estimated Blood Loss (mL)	300	(262.5-337.5)
Intraoperative Blood Transfusions	1	(7.7)
Hospital Stay (dys)	3	(1-5.25)
Cateter Removal (dys)	10	(9-13)
RARP post-operative pathology		
Gleason score		
3+3	2	(15.4)
3+4	6	(46.1)
4+3	1	(7.7)
4+4	3	(23.1)
4+5	1	(7.7)
pT stage		
2	2	(15.4)
3	11	(84.6)
Positive Margins	2	(15.4)

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