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# Ex vivo kidney resection in pharmacological cold ischemia followed by orthotopic autotransplantation

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***Introduction.*** *One of the priorities in oncology includes the development of alternative organoprotection treatments for renal cell carcinoma (RCC) of intraparenchymal and central tumour location.*

***Study objective*** *was to develop the method of extracorporeal kidney resection (ECKR) without ureter transection in conditions of pharmacological cold ischemia, followed by an orthotopic autotransplantation for RCC.*

***Materials and methods.*** *The study included 37 patients who had a morphologically confirmed RCC of stage pT1a-T3bN0M0-1G1-3 with intraparenchymal and central tumour location.*

***Results.*** *The mean duration of surgery was 413.97 ± 89.14 minutes. The mean cold and warm ischemia time for kidney was 151.41 ± 41.29 minutes, and 8.39 ± 4.75 minutes, respectively. Intraoperative complications made 8.1% (3), postoperative complication rate was 48.6% (18).*

***Conclusion.*** *Extracorporeal kidney resection without ureter transection in conditions of pharmacological cold ischemia, followed by an*

*orthotopic autotransplantation in RCC allows the resection of large tumours in any location in conditions of prolonged cold ischemia.*

**Keywords:** renal cell carcinoma, extracorporeal kidney resection, cold ischemia, custodiol.

## INTRODUCTION

The absolute number of patients first-ever diagnosed with malignant kidney neoplasm (MKN) in Russia in 2014 was 22,234. The increment in the disease incidence for previous 10 years turned out to be 29.4%. In 2014, the standardized incidence rate stood at 9.7 per 100,000 population, and the number of deaths was 8430. Thus, MKNs made 4% of all malignant neoplasms in the Russian population in 2014, ranking 10$^{th}$ in the structure of cancer incidence for both sexes [1, 2].

Despite the lack of randomized controlled trials comparing the efficacy of organ-saving therapy and radical nephrectomy for RCC, there are numerous retrospectively obtained data indicating a comparable efficacy of both treatment approaches with better parameters of renal function resulted from organ-saving treatment. Thus, given the numerous data on the development of renal failure after nephrectomy, and the increasing number of patients with early-stage RCC, the value of organ-saving treatment should not be underestimated [3-5].

Analyzing the results of the treatment of over one million patients in the US, A.S.Go found that a significant reduction of kidney function was associated with increased cardiovascular morbidity and mortality rates, and also with an increased rate of hospital admissions for various reasons. Historically, it was believed that since most kidney donors feel well for a long time after the organ donation, then nephrectomy does not represent any

danger in the patients either. Currently those views have very few or no advocates. Data obtained by P.Koenig have shown that patients with RCC have a higher risk of developing renal failure than healthy donors. In addition, J.McKiernan demonstrated the development of renal failure in one third of RCC patients prior to the treatment. In patients undergoing a long-term hemodialysis, the mortality from cardiovascular diseases was 10-30 times higher than in general population. The analysis of mortality from myocardial infarction demonstrated a significantly lower overall survival rate in patients on long-term dialysis compared to the patients without renal failure, or even those having concomitant diseases. According the United States Renal Data System (USRDS), the mortality in patients on dialysis makes 22% in the first 2 years, and 15% during the next 3 years. M.V.Rocco reported the need for hospitalization of over 50% of patients on chronic dialysis. About 20% of patients died. Furthermore, the high cost of the dialysis is worth mentioning: about $ 70,000 per patient have been allocated in the United States annually. According to up-to-date recommendations, the kidney transplantation for RCC can be performed only after 2 years of relapse-free period. And finally, even with obvious advances in transplantation, from 20% to 33% of the grafts function for no more than 5 years. Some studies have demonstrated a 5-year survival rate after transplantation being 75% only [6-14].

**The study objective** was to develop the ECKR technique under pharmacologically-induced cold ischemia without a ureteral transection, and followed by an orthotopic autotransplantation in patients with RCC.

## MATERIAL AND METHODS

The Urology Department of A.V. Vishnevsky Institute of Surgery developed an ECKR technique under a pharmacologically-induced ischemia in patients with MKN. The study included 37 patients treated in the period from 2012 to 2016 for morphologically confirmed RCC of pT1a-T3bN0M0-1G1-3 stage with an intraparenchymal or central tumour location. That number included 6 patients suffering from RCC of a solitary kidney and a single functioning kidney. The mean age of the patients was 55.32 ± 13.1 years (21-73 years) old. The male/female patient ratio was 75% (n=27)/27% (n=10), respectively.

The RCC extent in the patients as assessed by TNM Cancer Staging System was as follows pT1a-T3bN0M0-1G1-3. Twenty patients (54.1%) were identified with RCC of stage pT1a, 12 (32.4%) patients had pT1b stage RCC, pT2 stage was identified in 2 (5.4%), and pT3 was identified in 3 (8.1%) patients. One patient with a solitary kidney RCC and intraluminal invasion had few minor hematogenous pulmonary metastases. Table 1 briefly presents the patients characteristics.

**Table 1. Brief characteristics of patients before surgery**

| Criterion | Group of patients (N=37) |
|---|---|
| Age, years | 55.32 ± 13.1 |
| Men, n (%) | 27 (73) |
| Women, n (%) | 10 (27) |
| Affected side, n (%)<br>right<br>left | <br>18 (48.6)<br>19 (51.4) |

| | |
|---|---|
| Tumour size, mm<br>1x<br>2x<br>3x | <br>46,9 ± 15,7<br>41,4 ± 14<br>42 ± 15.5 |
| Simultaneous RCC, n (%)<br>synchronous<br>metachronous | 3 (8.1)<br>2 (66.7)<br>1 (33.3) |
| Solitary kidney cancer, n (%) | 6 (16.2) |
| Tumour location, n (%)<br>central<br>peripheral | <br>21 (56.8)<br>16 (43.2) |
| T Category prevalence, n (%)<br>T1a<br>T1b<br>T2<br>T3 | <br>20 (54.1)<br>12 (32.4)<br>2 (5.4)<br>3 (8.1) |
| N Category prevalence, n (%)<br>N0 | <br>37 (100) |
| M Category prevalence, n (%)<br>M0<br>M1 | <br>36 (97.3)<br>1 (2.7) |
| * GFR, mL/min | 77.78 ± 18.4 |

Note: GFR stands for glomerular filtration rate

A vast majority of the patients (n = 31, or 83.8%) belonged to the group of a high R.E.N.A.L. nephrometry score. At the same time, the mean score was 10.32 ± 0.94 (Table. 2). **Table 2. Characteristics of R.E.N.A.L. Nephrometry Score (n=37)**

| Anatomical characteristics | Median | Range |
|---|---|---|
| Summarized Nephrometry Score | 10.32 ± 0.94 | 4-12 |
| R criterion | 2.0 ± 0.67 | 1-3 |

| | | |
|---|---|---|
| E criterion | 2.78 ± 0.42 | 1-3 |
| N criterion | 2.84 ± 0.37 | 1-3 |
| L criterion | 2.7 ± 0.62 | 1-3 |

Clear cell carcinoma was diagnosed histologically in 29 (78.4%) patients. Urothelial carcinoma G1 and G3 was identified in two cases (5.4%) (Table 3).

**Table 3. Histological types of tumours**

| Histological types of tumours | n (%) |
|---|---|
| Renal cell carcinoma:<br>Clear cell type<br>G1<br>G2<br>G3<br>Papillary type<br>G1<br>G2<br>G3<br>Chromophobe type, eosinophilic variant | 35 (94.6)<br>29 (78.4)<br>15 (51.8)<br>11 (37.9)<br>3 (10.3)<br>5 (13.5)<br>-<br>3 (60)<br>2 (40)<br>1 (2.7) |
| Urothelial cancer:<br>G1<br>G2<br>G3 | 2 (5.4)<br>1 (50)<br>-<br>1 (50) |

There was a single case of tumour thrombus (cava-renal form) in a RCC patient with a solitary (right) kidney. Thrombus extended antegrade for 48 mm from ostium of the right renal vein and had a diameter of 30 mm. Thrombectomy with the resection of the inferior vena cava and ECKR, thrombectomy from the central renal vessels with an orthotopic replantation

of vessels were performed in this patient simultaneously. Characteristic features of the surgical procedure are presented in Table. 4.

**Table 4. Characteristics of intraoperative manipulations**

| Criterion | Group of patients (n = 37) |
|---|---|
| The number of lymph nodes removed, n | 5.73 ± 4.13 |
| Multifocal tumour, n (%)<br>The average number of removed tumour nodules, n | 2 (5.4)<br>3 |
| Ureteral stenting, n (%) | 27 (72.9) |
| Tumour size as per histology study, mm<br>1x<br>2x<br>3x | <br>43.49 ± 17.28<br>38.08 ± 14.75<br>35.49 ± 12.89 |
| Resection and microvascular reconstruction of segmental arteries, n (%) | 8 (21.6) |
| Adrenalectomy, n (%) | 9 (24.3) |
| The mean temperature of cold nephroplegia, °C | 10.58 ± 0.66 |
| Renal artery prosthesis, n (%) | 12 (34.4) |
| Simultaneous surgery, n (%) | 2 (5.4) |
| Number of renal arteries, mean | 1.29 ± 0.62 |
| Number of renal veins, mean | 1.08 ± 0.28 |
| Solitary kidney, n (%) | 6 (16.2) |

The operative and anesthetic risk was assessed preoperatively by ASA Physical Status Classification System as Class I-II in 29 patients (78.4%), Class III-IV in 8 patients (21.6%).

**ECKR TECHNIQUE**

J(L)-shaped laparotomy is used. The line of Toldt is incised to get an access in the right (left) retroperitoneal space. The kidney together with perinephric fat is mobilized within the Gerota fascia. Fig. 1 shows MSCT scan of a resected kidney.

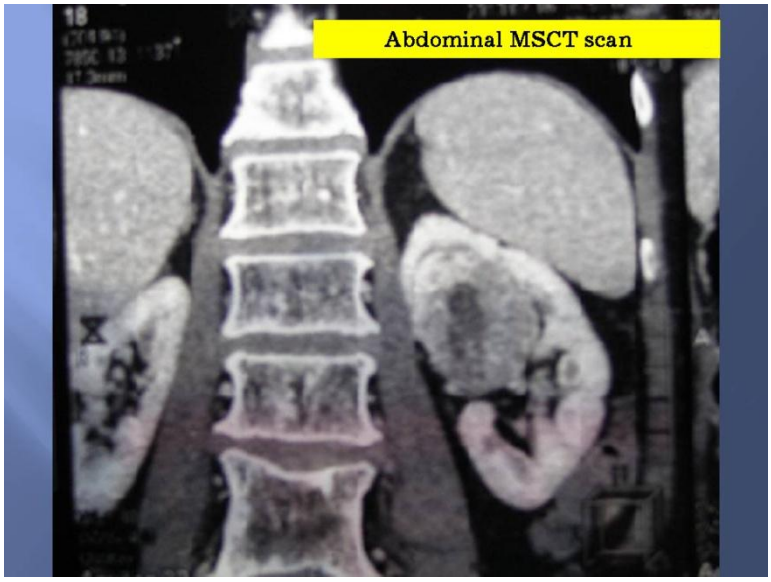


**Fig. 1. MSCT scan demonstrating the left kidney tumour in central location**

A regional lymphadenectomy is performed followed by the removal of the perirenal fat; and an intraoperative Doppler study of the kidney is performed. Aorta is mobilized in its supra-, intra- and infrarenal departments. The left (right) renal artery and renal vein are exposed along the whole length. One should note: when mobilizing the right renal artery,

the inferior vena cava is exposed, and the channel is formed beneath the inferior vena cava for passing the right renal artery when the reimplantation into the aorta is performed. A systemic heparinization is undertaken at a dose of 5000-7500 IU. Vascular clamps are placed on the renal artery proximally and distally, and an arteriotomy is performed at the ostium. The proximal stump is ligated and sutured. The renal vein with vascular clamps on is also transected at its ostium.

The kidney on the mobilized ureter is removed from the retroperitoneal space, and immersed in a pan with a crushed ice of isotonic sodium chloride solution ex vivo. Immediately, the system of kidney perfusion with Custodiol solution through the lumen of the transected renal artery is established (Fig. 2).

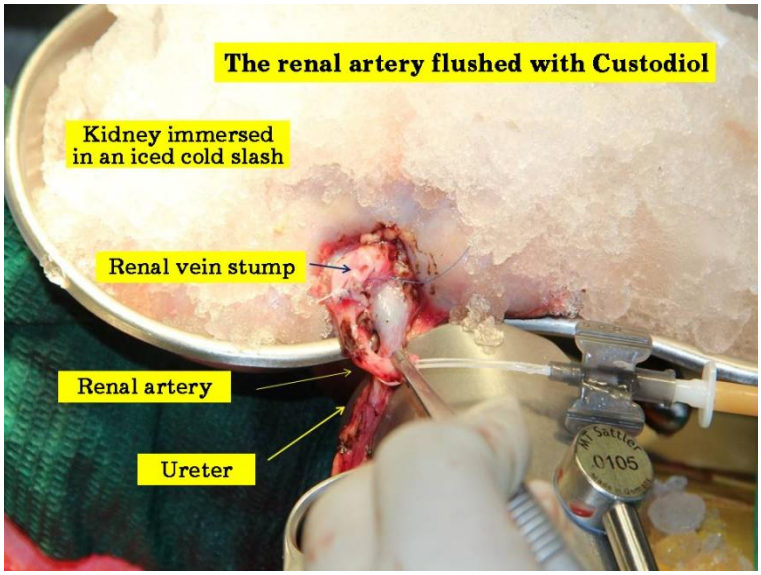


**Fig. 2. The stage of renal perfusion with cooled Custodiol solution**

Physical specifications of kidney cooling:

- Perfusion rate: 1.5 ml/min/g of kidney estimated weight (mean 150 g in an adult);

- Temperature of the solution: 5-8 °C;

- Perfusion time: at least 10.8 minutes (a homogeneous distribution of the solution in the extracellular space is ensured, including the interstitial tissue, and renal tubular system);

- The perfusion pressure measured at the site of the cannula introduction into the renal artery lumen: 90-110 mmHg (The container with the solution is located at a height of 120-140 cm above the kidney level);

- Guidelines: it is necessary to monitor the perfusion time and the solution container position at the kidney level; or to monitor the perfusion time and the perfusion pressure at the tip of renal cannula, in case the solution is delivered by a pump.

Throughout the entire resection period, the kidney is preserved in Custodiol solution cooled to 2-4° C. The kidney temperature is taken every 30 minutes. A strict compliance with the instructions of kidney cooling can ensure the organ protection from ischemic injury for up to 24 hours.

After the intraoperative sonography has been performed, the tumour is removed leaving the surrounding healthy tissue intact. Fig. 3 shows an extensive post-resection kidney wound.

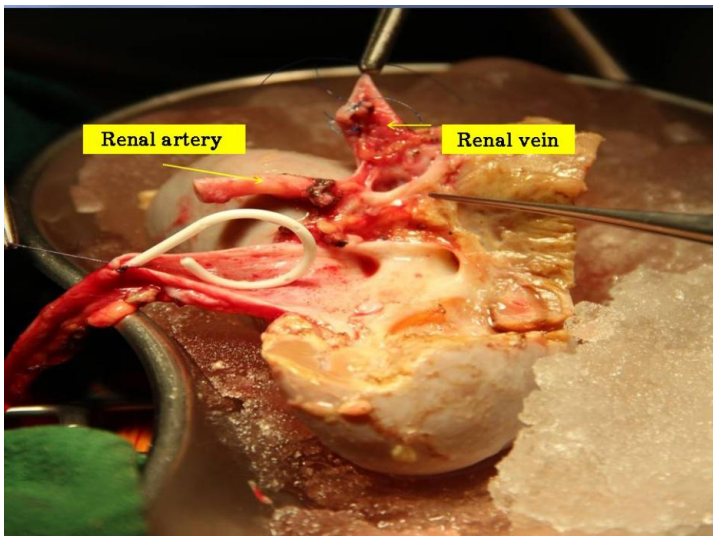


**Fig. 3. Kidney after tumour removal**

If an intraparenchymal injury (1-2 mm in diameter) of arteries and/or veins was observed at tumour removal, they were anastomosed, as possible, by making an oblique "end-to-end" anastomosis with a 8/0 polypropylene suture by using the microsurgical technique or were tightly sutured with the same type of filament. The suture competence was checked by an additional flush of Custodiol into the renal artery. Fig. 4 demonstrates a transected segmental artery.

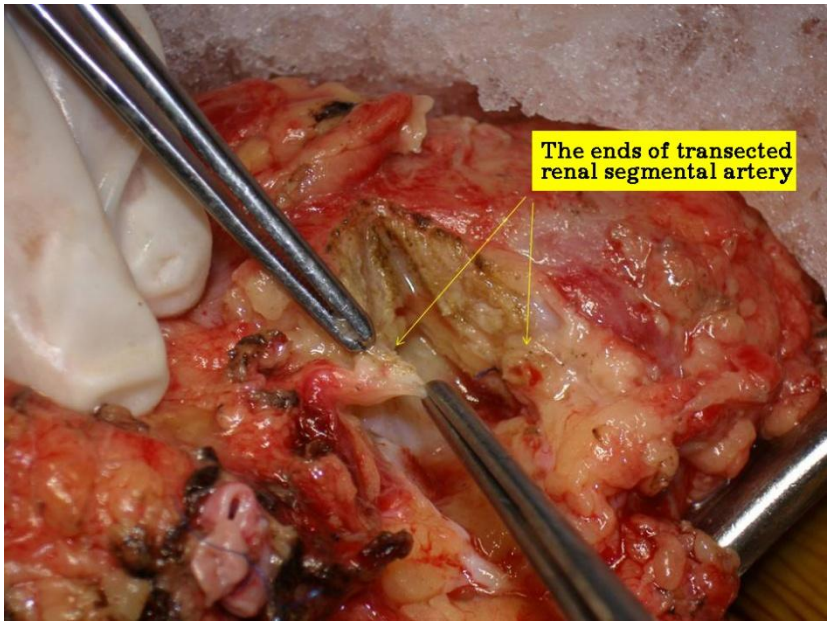


**Fig. 4. The proximal and distal segments of transected renal segmental artery**

Fig. 5 shows the stage of making arterial anastomosis in an "end-to-end" fashion.

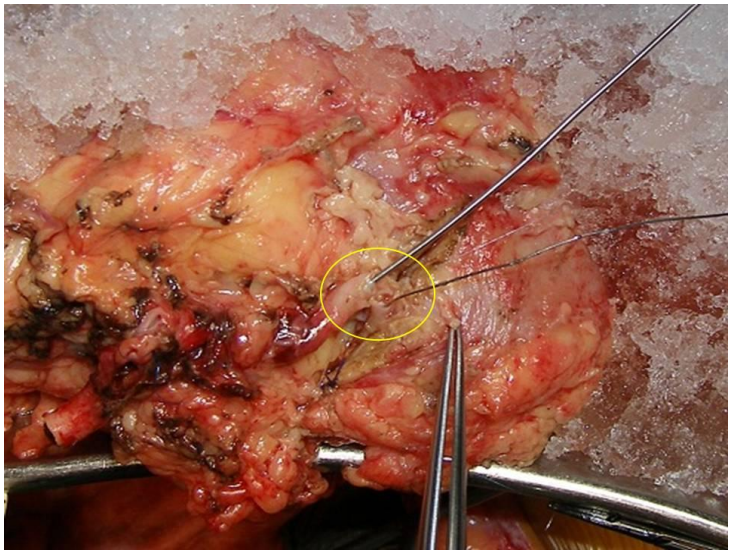

**Fig. 5. The stage of making arterial anastomosis in an "end-to-end" fashion with an 8/0 polypropylene suture.**

Fig. 6 demonstrates the final view at microvascular stage.

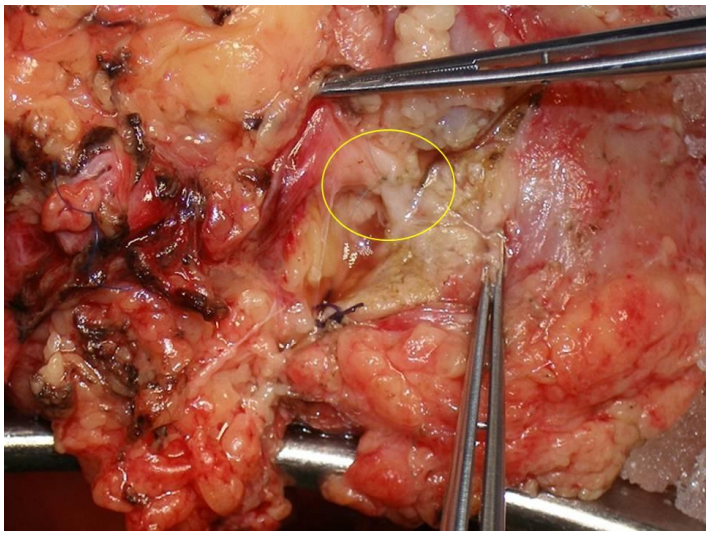

**Figure 6. The view of the completed arterial microvascular "end-to-end" anastomosis**

When indicated (in case of an extensively impaired hermiticity of renal pelvicalyceal system [PCS]), an antegrade ureteral stenting was

performed. A defect in PCS shall be repaired using a continuous 4/0 Vicryl suture. Gaping vessels are carefully stitched with Z-shaped 4-5/0 Vicryl sutures. The sutures are checked for competence. The renal parenchyma integrity is restored with 2-3-level single 1-2/0 Vicryl sutures, and then the kidney is transferred in the retroperitoneal space.

The next surgical step is the reconstruction of renal vessels and the kidney revascularization. The renal artery is flushed with an additional Custodiol solution dose of 100-300 ml. The kidney is placed orthotopically in the retroperitoneal space. In reimplantation of the left renal artery, the window of 5 cm in diameter is cut in the infrarenal aorta along the left side wall using aortic "punch", and the renal artery is implanted to the window in the "end-to-side" fashion with Polypropylene 6-7/0 continuous suture. In reimplantation of the right renal artery, the diastasis between the renal artery stump and the aorta is assessed. Fig. 7 demonstrates the surgical stage of the renal vascular reconstruction.

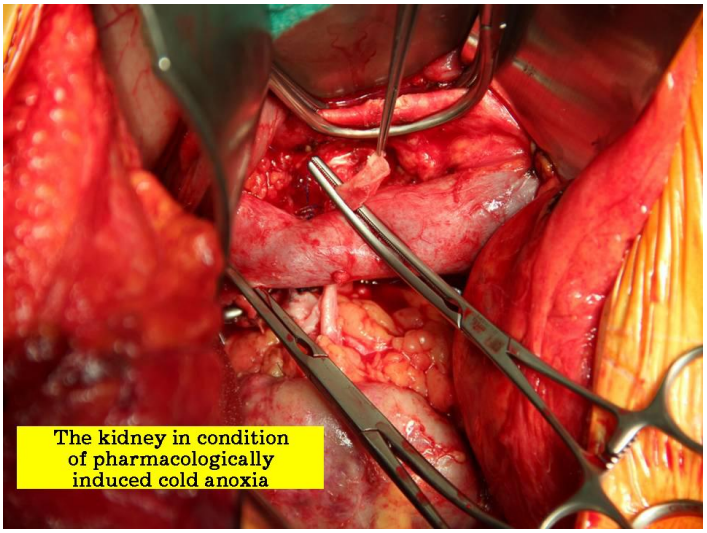


**Fig. 7. Pulling the aorta off and passing the right renal artery under the inferior vena cava**

The need for a prosthetic reconstruction of renal artery is considered. If it is not necessary, then the renal artery is passed to the aorta through the previously formed window under the inferior vena cava. Further, a window of 8-10 mm in diameter is cut out in the infrarenal aorta along the right side wall using the aortic "punch", and the renal artery is implanted to this window in the "end-to-side" fashion. The anastomosis is made in the "end-to-end" fashion between the proximal and distal stumps of the renal vein with a 5/0 polypropylene continuous blanket suture (using the "anastomosis expansion" technique to prevent its stenosis). The last stitch is not tightened till the start of the vein blood flow. Fig. 8 shows the stage of making the aortoarterial anastomosis.

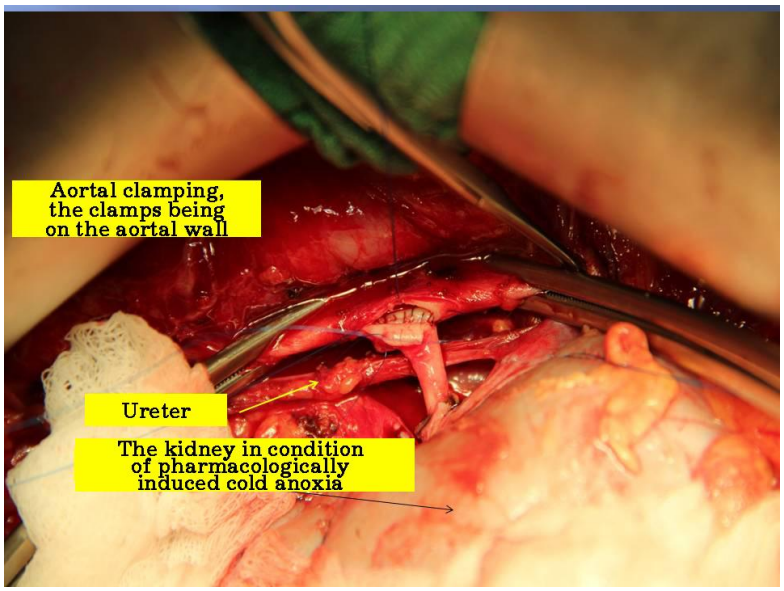


**Fig. 8. The stage of making the aortoarterial anastomosis**

When applying the last sutures, the blood flow is started (200-300 ml) to flush the Custodiol solution out of the renal parenchyma. Generally, any

neutralization of the remained heparin dose is not required. Fig. 9 presents the view of the surgical field after the start of blood flow.

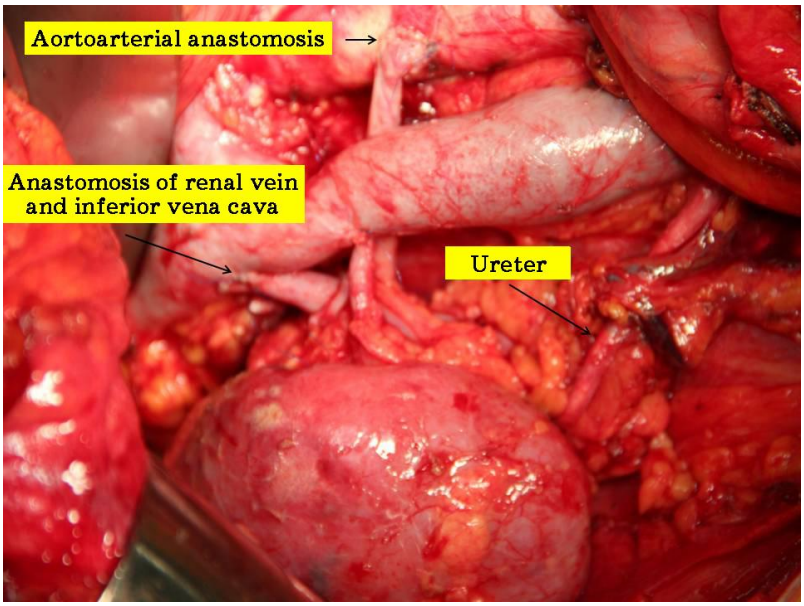


**Fig. 9. The view of the surgical field after the start of blood flow**

In case the renal artery is deficient in length, its prosthetic reconstruction is made. We used the *GoreTex* polytetrafluoroethylene prosthesis of 8 mm in diameter for all the cases. First, the anastomosis is applied between the renal artery and the prosthesis ex vivo, and then between the prosthesis and aorta in orthotopic kidney position. Fig. 10 shows the renal artery prosthetic reconstruction stage.

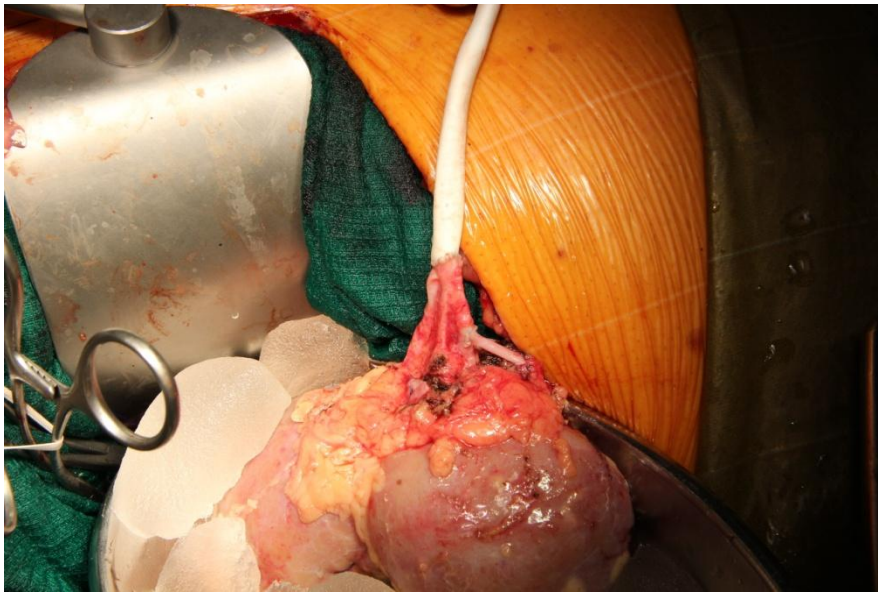

**Fig. 10. The renal artery prosthetic reconstruction stage**

## RESULTS AND DISCUSSION

The mean surgery duration was 413.97 ± 89.14 minutes (from 280 to 730 minutes), the total duration of anesthesia was 485.95 ± 98.8 min. The mean warm and cold ischemia times were 8.39 ± 4.75 minutes, and 151.41 ± 41.29 minutes, respectively, the cold ischemia time varying from 70 to 240 minutes. The volume of blood loss made 729.03 ± 481.4 ml. We should note that the duration of the first five operations was longer than 500 min that was associated with mastering and refining the surgical technique. The mean surgery duration for the following 32 operations was shorter making 388.8 ± 58.2 min that was comparable with published data on ECKR with ureteral transection and kidney autotransplantation into the iliac area [15] (Table 5).

**Table 5. Data on the duration of surgery, anesthesia, and the ischemia time**

| Surgery characteristics | Median |
|---|---|
| Surgery duration, min | 413.97 ± 89.14 |
| Anesthesia duration, min | 485.95 ± 98.8 |
| Warm ischemia time, min | 8.39 ± 4.75 |
| Cold ischemia time, min | 151.41 ± 41.29 |
| Blood loss, ml | 729.03 ± 481.4 |

Intraoperative complications were identified in 3 patients (8.1%). There was no intrarenal blood flow in two cases with normally functioning major vessels. After a failed attempt to restore the intrarenal blood flow by conservative therapy in both cases, the kidney was declared non-viable, and, therefore, a radical nephrectomy was performed for the kidney removal. In another case, the prosthetic renal artery thrombosis occurred after starting the blood flow.

Eighteen patients (48.6%) developed postoperative complications as defined per Clavien-Dindo International Classification of Surgical Complications. In 15 of them (40.5%), the ultrasonography, MSCT, or Magnetic Resonance Imaging (MRI) performed in the postoperative period revealed hematoma in the resection area. A US-guided puncture drainage of hematoma was required in 5 cases. The remaining 10 patients were treated conservatively under sonography monitoring. The high incidence of complications could be attributed to a considerable technical difficulty of the surgery, the kidney surgical trauma due to an ex vivo resection, and intraoperative heparinization. Hematomas in all cases resolved successfully,

without repeated open surgical interventions. Grade II, III, and IV complications included rare cases of acute pyelonephritis, eventration, acute renal failure, intra-abdominal bleeding, and acute pancreatitis. One death (2.7%) was caused by mesenteric thrombosis that occurred on the 4$^{th}$ postoperative day and was followed by the development of multiple organ failure. All the cases of Grade 1 complications were represented with hematoma at the resection site requiring no surgical intervention (Table 6) [16].

**Table 6. Postoperative complications graded by their severity according to Clavien-Dindo Classification of Surgical Complications**

| Complication severity per Clavien-Dindo Classification | Incidence | |
|---|---|---|
| | abs. | % |
| Grade I | 7 | 38.8 |
| Grade II | 1 | 5.6 |
| Grade IIIa<br>Grade IIIb | 4<br>4 | 22.2<br>22.2 |
| Grade IVa<br>Grade IVb | 1<br>- | 5.6<br>- |
| Grade V | 1 | 5.6 |

The tumour size and location, the prevalence of tumour T criterion, and the cold ischemia time were found to pose no impact on the incidence of postoperative bleeding and hematoma. When compared to our personal experience of kidney resection in situ in the Urology Clinic of the Institute of Surgery, a significantly increased incidence of those complications was noted after ex vivo surgical operations (2.3% vs. 43%, respectively). Gender,

age, the affected side, the tumour size, location, and T category had no impact on the risk of a decreased kidney function in the early and long-term postoperative period. The second functioning kidney available significantly reduced the risk of a transient increase in the level of nitrogenous wastes. The incidence and type of complications correlated with the parameters of the R.E.N.A.L. nephrometry scoring system. We assessed the relationship between the patient's having a high R.E.N.A.L. nephrometry score and the incidence of hematoma at the resection site.

A planned histological examination detected no tumour cells at the resection edges in any of the cases. A follow-up period was from 3 to 41 months (21.4 ± 7.3). No data on tumour recurrence or malignancy progression were seen in any of the patients. The gromerular filtration rate (GFR) was 77.78 ± 18.4 ml/min before surgery, and 63 ± 26.06 ml/min after surgery. None of the patients was in a renoprival state at discharge.

## CONCLUSIONS

1. ECKR performed under conditions of pharmacologically induced cold ischemia without a ureteral transection, followed by orthotopic autotransplantation is an efficient and safe organ-preserving treatment technique for patients with RCC. Meanwhile, about 40% of all developed complications are assessed as Grade I by their severity and carry no vital risk.

2. This surgical technique makes the nephrectomy feasible in the cases of intraparenchimal and central tumour location, with the involvement of kidney segmental arteries and veins in the process, when the tumour size exceeds 40 mm.

3. The kidney return to the orthotopic position in the retroperitoneal space, avoiding the resection on the ureter and its recovery phase, significantly reduces the surgery duration and minimizes surgical trauma when compared to autotransplantation into iliac area.

4. The compliance with all oncological principles while making this surgical intervention (a radical removal of the tumour, a histological control over the edges of nephrectomy both in the renal parenchyma and in the kidney collecting system, the implementation of an adequate extended para-aortic lymphadenectomy, the removal of perirenal fat) yields favourable immediate and long-term cancer outcomes (the median of follow-up makes 21.4 ± 7.3 months).

5. ECKR allows a thorough visual inspection of the resection edges, a precise exposure of intraparenchimal renal vessels with their subsequent reconstruction (with a prosthesis, when necessary), the monitoring of the resection bed for achieving an adequate hemostasis, and placing microsurgical sutures on the structures of the renal sinus (using a zoom magnifying glass or a microscope).

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