

Can a single-layer of renorrhaphy be applied with hemostatic agent in robot-assisted laparoscopic nephron-sparing surgery applied to complex renal tumors?

Kompleks renal tümörlerde uygulanan robot yardımcı laparoskopik nefron koruyucu cerrahide hemostatik ajan eşliğinde tek kat renorrafisi uygulanabilir mi?

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Özet

Amaç: Kompleks renal tümör nedenli robotik parsiyel nefrektomi uygulanan hastalarda hemostatik ajan eşliğinde tek kat renorrafisi ile çift kat renorrafisi kullanımı sonuçlarının karşılaştırılması amaçlanmıştır.

Gereç ve Yöntemler: Ağustos 2017-Şubat 2021 tarihleri arasında kompleks renal tümör (PADUA skoru \geq 10) nedenli robotik parsiyel nefrektomi uygulanan 51 hasta retrospektif olarak çalışmaya dahil edilmiştir. 36 hastada çift kat renorrafisi (Grup 1), 15 hastada FloSeal® (Baxter Medical, Fremont, CA) hemostatik ajan eşliğinde tek kat renorrafisi (Grup 2) uygulanmıştır. Pre- ve post-operatif serum kreatinin, glomerüler filtrasyon hızı ve hemoglobin düzeyleri, cerrahi ve sıcak iskemik süreleri, dren ve hastanede kalış süreleri, komplikasyonlar değerlendirildi.

Bulgular: Hastaların ortalama yaşı 50 olup kadın/erkek oranı 18/33'dü. Grup 1 ve Grup 2 ortalama PADUA skorları sırasıyla 11 ve 10.47 hesaplandı. Pre-, post-operatif 1.gün ve 6.ay ortalama serum kreatinin değerleri Grup 1'de sırasıyla 1.02, 1.15 ve 1.09 mg/dL olup Grup 2'de 0.93, 1.02 ve 0.90 mg/dL idi. Pre-, post-operatif 1.gün ve 6.ay ortalama GFR değerleri Grup 1 'de sırasıyla 91.47, 77.31 ve 81.90 mL/dk/1.73m² olup Grup 2'de 92.07, 84.93 ve 90.73 mL/dk/1.73m² idi. Pre- ve post-operatif hemoglobin değerleri karşılaştırıldı. Operasyon ve sıcak iskemik süreleri sırasıyla Grup 1'de 118 ve 23 dk iken Grup 2'de 101 ve 13 dk olarak kaydedildi. Gruplar arasında dren ve hastanede kalış süreleri açısından anlamlı

Abstract

Objective: To compare outcomes of single-layer renorrhaphy suturing and hemostatic agent application with double-layer renorrhaphy among complex renal tumors.

Material and Methods: 51 patients who underwent robotic partial nephrectomy due to complex renal tumors (PADUA score \geq 10) between August 2017 and February 2021 were retrospectively enrolled. A double-layer renorrhaphy was applied in 36 patients (Group 1), and a single-layer renorrhaphy plus hemostatic agent FloSeal® (Baxter Medical, Fremont, CA) was applied in 15 patients (Group 2). Pre- and post-operative serum creatinine, glomerular filtration rate, hemoglobin levels, surgical and warm ischemia time, drainage, hospital stay duration, as well as complications were all evaluated.

Results: Group 1 and Group 2 mean PADUA scores were 11 and 10.47, respectively. The mean preoperative, postoperative 1st day and 6th month serum creatinine were 1.02, 1.15 and 1.09 mg/dL in the Group 1 and were 0.93, 1.02 and 0.90 mg/dL in the Group 2, respectively. The mean preoperative, postoperative 1st day and 6th month glomerular filtration rates were 91.47, 77.31 and 81.90 mL/min/1.73m² in the Group 1 and were 92.07, 84.93 ve 90.73 mL/min/1.73m² in the Group 2, respectively. Operation and warm ischemia time were 118min and 23min in the Group 1, and 101min and 13 min in the Group 2, respectively. There was no significant difference between groups in terms of drain removal time and hospital stay. Periop-

The study was approved by Ethics Committee of Şişli Memorial Hospital (Approval No: 2021/09, Date: 26.02.2021). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

fark izlenmedi. Perioperatif sadece Clavian I ve II komplikasyonlar izlendi. Takipte herhangi nüks izlenmedi.

Sonuç: Robotik parsiyel nefrektomi uygulanan PADUA skoru 10-11 arasındaki kompleks tümörlerde hemostatik ajan eşliğinde tek kat renorrafî güvenle uygulanabilir.

Anahtar Kelimeler: robotik parsiyel nefrektomi, nefron koruyucu cerrahi, renorrafî, kompleks renal tümör

erative only Clavian I and II complications were observed with no recurrence during the follow-up.

Conclusion: A single-layer of renorrhaphy plus hemostatic agent application can be safely applied in complex renal tumors with a PADUA score between 10-11 undergoing robotic partial nephrectomy.

Keywords: robotic partial nephrectomy, nephron sparing surgery, renorrhaphy, complex renal tumor

INTRODUCTION

Nephron sparing surgery (NSS) commonly known as partial nephrectomy (PN), is currently the standard surgical intervention for small renal tumors (cT1, <7cm) (1). Increasing surgical skills with the aid of accurate case selection, NSS may be performed even for selected cT2 (>7cm) renal cortical tumors (2). One of the most important goals is to preserve maximum renal function during the postoperative term. On average there is a 20% renal function loss in kidneys after NSS due to ischemia and nephron loss during reconstruction (3). Thus creating challenging conditions for urologists. Some common surgical skills preferably used to diminish kidney damage are; supplying hypothermia, limited warm ischemia including zero or segmental ischemia, early unclamping (3).

During the last decade, robotic NSS has become the preferred technique among experienced laparoscopists due to lower ischemia times and shorter learning curve (4). Suturing of the tumor floor and renal parenchyma are essentials for hemostasis. In order to decrease the ischemia time and diminish nephron damage, single-layer renorrhaphy seems to be the most common method (5). During renorrhaphy (parenchymal) suturing in order to accelerate operation time while decreasing the ischemia time, certain hemostatic agents seem to be effective to prevent complications and nephron loss (6).

The aim of this study is to compare single-layer renorrhaphy plus hemostatic agent with double-layer renorrhaphy among complex renal tumors (PADUA score \geq 10) in terms of both safety and effectiveness.

MATERIAL AND METHODS

Following the hospital's ethical committee approval (approval number 26022021/09), a total

of 51 patients with complex renal cortical tumors that underwent robotic NSS between August 2017 and February 2021 were retrospectively collected. Complex renal cortical tumors were defined according to the PADUA classification (10-14) preoperatively by advanced radiologic imaging (7). All patients had preoperative standardized computerized tomography (CT) or magnetic resonance imaging (MRI) scans with adequate and correct enhancement protocols. All renorrhaphy sutures were performed with 3-0 V-lock™ (V-20 Taper 6" 15cm ½ 26mm, Covidien Inc., Mansfield, MA, USA). Sliding clip renorrhaphy technique with hem-o-lock clips was performed in all procedures (8). Considering the renal parenchymal hemostasis and reconstruction patients were classified in two groups. The group 1 (n=36) consisted of double-layer 3-0 V-lock™ renorrhaphy sutures and the group 2 (n=15) was consisted of single-layer 3-0 V-lock™ renorrhaphy sutures plus hemostatic agent FloSeal® (Baxter Medical, Fremont, CA) application. Total surgery and warm ischemia time (WIT), pre- and post-operative hemoglobin levels (g/dL), pre- and post-operative creatinine levels (mg/dL), pre- and post-operative glomerular filtration rate (GFR) (mL/min/1.73m²), total drainage (mL), hospitalization and drain removal times (day) were all recorded. The GFR values were calculated with MDRD formulazation.

Inclusion-exclusion Criterias

Patients with <10 cm renal cortical tumors (PADUA score \geq 10) who underwent robot assisted laparoscopic NSS were included. Among them, patients with previously impaired renal functions and with a history of coagulopathy disorder were all excluded.

Surgical Technique

All the robotic NSS procedures were performed by

a robotic surgery trained surgeon with more than 500 case experience. According to tumor location opponent side lateral flex decubitus nephrectomy position was given to each patient. Patients prepped and draped in a regular fashion. The Da Vinci Xi robotic system (Intuitive Surgical, CA, USA) was docked with active 3 robotic arms. Three 8 mm robotic trocars were placed as in triangular manner. A 12 mm assistance trocar placed on midline superior to umbilicus. Taking in consideration the upper pole right kidney tumors in certain cases, an extra 5 mm assistance trocar was placed in the midline inferior to the xiphoid. On the left robotic arm bipolar fenestrated grasper, on the right robotic arm monopolar scissor and needle-holder were placed. The ascendant/descendant colonic segments were all medialized and access to retroperitoneal area was sustained. The kidney and tumor areas were all prepared for NSS. Bulldog clamp was used in each case during the warm ischemia. 3-0 V-lock™(V-20 Taper 6" 15cm ½ 26mm, Covidien Inc., Mansfield, MA, USA) sutures and sliding Hem-o-lock clips were used during the renorrhaphy steps. FloSeal® (Baxter Medical, Fremont, CA) was used as hemostatic agent. The tumor with its own Gerota's fat tissue were all placed inside an Endo bag. A Jackson-Pratt drain was placed at the end of each intervention.

Statistical Analysis

The data analyzed by GraphPad Prism version 9 (GraphPad Software, California, USA). The Shapiro-Wilk test was used for the normality and the distribution of variables. One-way ANOVA test used to

compare GFR values across times in both group 1 and group 2 separately. Multiple comparisons adjusted by the Tukey test. Adjusted p values are given in the Table 2. Friedman test and Dunn's multiple comparison test were used for the comparison of creatinine values across timelines in both group 1 and group 2 separately. Numerical variables were compared using independent samples t-test or a Mann-Whitney U test. A $p < 0.05$ value was considered statistically significant.

RESULTS

The mean age of patients was 50 years, and the female/male ratio was 18/33 in the study cohort. Group 1 and Group 2 mean PADUA scores were 11 and 10.47, respectively. The mean pre-, post-operative 1st day and 6th month serum creatinine values were 1.02, 1.15 and 1.09 mg/dL in the Group 1 and were 0.93, 1.09 and 0.92 mg/dL in the Group 2, respectively (Table 2). In Group 1, there were significant differences in between pre- and post-operative serum creatinine levels ($p < 0.05$) whereas there was no significant difference in between the post-operative 1st day and 6th month serum creatinine levels ($p = 0.1377$). In Group 2, there was a significant difference in between pre- and post-operative serum creatinine levels ($p < 0.05$) and a significance was relevant between the post-operative 1st day and 6th month serum creatinine level ($p = 0.0002$) (Table 2). The mean pre-, post-operative 1st day and 6th month glomerular filtration rates were 91.47, 77.31 and 81.90 mL/min/1.73m² in Group 1 and were 92.07, 84.93 ve 90.73 mL/min/1.73m² in Group 2, respectively.

Table 1. Comparison of the study groups

	Group 1 (n=36)	Group 2 (n=15)	p value
Age	51.44 ± 14.958	46.73 ± 14.074	0.302
Tumor size (cm)	5.53 ± 1.7269	4.93 ± 1.6586	0.258
PADUA score	11 ± 0.793	10.47 ± 0.516	0.021
Operation time (min)	118.19 ± 28.212	101.33 ± 14.573	0.034
WIT (min)	23.39 ± 7.299	13.07 ± 7.601	0.00
Bleeding (mL)	172.78 ± 68.603	114 ± 31.122	0.003
Duration of drain (days)	2.11 ± 0.465	2.13 ± 0.516	0.881
Duration of hospital stay (days)	2.97 ± 0.506	2.73 ± 0.594	0.151

Data given as Mean ± SD. **Group 1:** Double-layer renorrhaphy suture, **Group 2:** Single-layer renorrhaphy suture, + hemostatic agent, **N:** number of patients, **WIT:** Warm ischemia time, **min:** minutes, **mL:** Milliliter, **cm:** centimeter.

Table 2. The comparison of preoperative, post-operative early and at 6th months serum creatinine and GFR

Study Groups		Serum Creatinine	p value	GFR	p value
1 (N=36)	Preoperative ^a	1.022 ± 0.637	0.0003 ^{a,b}	91.47 ± 33.88	< 0.0001 ^{a,b}
	Postoperative ^b	1.158 ± 0.619	0.1377 ^{b,c}	77.31 ± 25.94	0.279 ^{b,c}
	Postoperative 6 th month ^c	1.096 ± 0.628	0.04 ^{a,c}	81.90 ± 27.58	0.011 ^{a,c}
2 (N=15)	Preoperative ^x	0.938 ± 0.306	0.003 ^{x,y}	92.07±28.11	0.117 ^{x,y}
	Postoperative ^y	1.093 ± 0.326	0.0004 ^{y,z}	84.93±28.59	0.024 ^{y,z}
	Postoperative 6 th month ^z	0.922 ± 0.288	>0.999 ^{z,x}	90.73±26.28	0.814 ^{z,x}

Data presented as mean ± standard deviation (Mean ± SD). **Group 1:** Double-layer renorrhaphy suture, **Group 2:** Single-layer renorrhaphy suture + hemostatic agent, N: Number of patients, GFR: Glomerular filtration rate.

One-way ANOVA test used to compare GFR values across times in both group 1 and group 2. Multiple comparisons adjusted by the Tukey test. Adjusted p values are given in the Table. Friedman test and Dunn's multiple comparison test were used for the comparison of creatinine values across timelines. Adjusted p values are given in the Table.

Table 3. The distribution of pathology results among groups

	Group 1 (N=36)	Group 2 (N=15)
Malignant (N=42)		
Clear cell RCC	24	9
Papillary RCC		
Type 1	1	3
Type 2	3	-
Chromophobe RCC	1	1
Benign (N=9)		
Oncocytoma	4	-
Renal adenoma	-	1
Angiomyolipoma	2	-
Simple cortical cyst	1	1
Pathology stage (N=42)		
pT1a	12	4
pT1b	13	8
pT2a	3	1
pT2b	-	-
pT3a	1	-

Group 1: Double-layer renorrhaphy suture, **Group 2:** Single-layer renorrhaphy suture + hemostatic agent, N: Number of patients, RCC: Renal cell carcinoma.

Table 4: The distribution of complications according to Clavian-Dindo classification

	Group 1 (N=36)	Group 2 (N=15)
Grade I		
Antipyretics	2/36 (5.5%)	1/15 (6.6%)
Grade II		
Blood transfusion	1/36 (2.7%)	0/15 (0%)

Group 1: Double-layer renorrhaphy suture,

Group 2: Single-layer renorrhaphy suture +hemostatic agent, N: Number of patients.

There were significant differences in between pre- and post-operative 1st day and 6th months GFR in Group 1 ($p < 0.0001$). In Group 2, post-operative 1st day and 6th months GFR also showed significant difference ($p = 0.0246$) (Table 2). During pre-, post-operative 1st day and 6th month controls there were no significant difference among serum creatinine levels and GFR in between groups ($p > 0.05$). The mean pre- and post-operative hemoglobin values were 13.4 and 12.4 g/dL in Group 1 while they were 14.3 and 13.6 g/dL in Group 2, respectively ($p > 0.05$). There was a significant difference in between the operation and WIT in between the groups ($p < 0.05$) (Table 1). No significant difference was observed between groups in terms of drain removal and hospital stay. Perioperative only Clavian I and II complications as fever and blood transfusion were observed and listed on Table 4. The distribution of pathology results was listed on Table 3. No recurrence of any tumor was observed during the follow-up among both groups.

DISCUSSION

During the last decades the interest and preference of robot assisted laparoscopic NSS has been increased among urologists in the scope of minimal invasive surgery to lower complications rates, better surgical outcomes and shorter hospital stay (9). Besides the successful resection of tumor during NSS renal reconstructions to preserve renal function and to decrease complication rates are other key factors. Several renorrhaphy techniques such as early unclamping, segmental clamping, tumor enucleation, usage of hemostatic agents are some of the techniques utilized during renal reconstruction via NSS.

Sliding-clip renorrhaphy has become as universal standardized technique among urologists (10). Williams et al. demonstrated that omitting collecting system repair during robotic NSS a single-layer sliding-clip renorrhaphy decreases WIT without altering complications (11).

Shatagopam et al. compared single and double-layer renorrhaphy techniques in their literature review (12). The resected renal parenchymal volume and WIT are important parameters for renal function; however,

recently renal reconstruction is also gaining importance for preserving renal functions (13). Bahler et al. showed that volume loss can be decreased by modifying the renorrhaphy technique (14). According to their study the single and double-layer renorrhaphy groups were consisted of 15 and 30 patients respectively. There were significant renal volume loss and GFR decrease between the groups whereas no differences in blood loss or complications. The median nephrometry scores were 6 while only in one patient with complex tumor (nephrometry score 10-12) single-layer renorrhaphy was performed (14). In another study Porpiglia et al. included a total of 50 patients with PADUA scores > 8 (15). According to their results there were no significant differences considering serum creatinine and GFR in between the single and double-layer groups. However post-operative 3rd month renal scan demonstrated significant difference in between groups (15).

Antonelli et al. showed that adding hemostatic agents as FloSeal or TachoSil to renorrhaphy during NSS among clinical stage cT1a - cT1b tumors does not provide better surgical outcomes (16). However, Wille et al. evaluated a total of 102 patients underwent laparoscopic NSS (tumor sizes 0.5-8.5 cm) followed to collecting system repair the hemostasis was sustained only with FloSeal (17). Li et al. also demonstrated that laparoscopic NSS can be completed by usage of hemostatic agents as FloSeal or Tisseel on 31 patients with mean tumor size 2.9 cm (1.8-6.3 cm) and mean RENAL nephrometry score 6.3 (4-7) without intracorporeal suturing (6).

According to our results Group 2 where we used FloSeal, showed significantly lower PADUA scores, less WIT, operation time and bleeding. Post-operative transfusion was performed in only 1 of the patients who underwent double-layer renorrhaphy. There was a significant difference in terms of amount of drainage ($p = 0.003$). We can say that patients who underwent a single-layer of renorrhaphy are the cases that do not have any expectation of bleeding. Also, in Group 2 preservation of renal function on long term seems to be better than in Group 1 (Figure 1). The post-operative 1st day and 6th months GFR in Group 2 showed significant difference. However, in Group 1

the post-operative 1st day and 6th months results did not differ (Table 2). During tumor resection, clipping of the vessels feeding the tumor, removal of the tumor with enucleation, and an effective single-layer suturing can better options to preserve kidney functions in the long term.

To the best of our knowledge this is the first study only evaluating the single-layer renorrhaphy among complex renal tumors with PADUA score ≥ 10 . Comparison of pre- and post-operative scintigraphy evaluation is missing which may be a main limitation. Further studies including long term scintigraphy evaluations are needed.

CONCLUSION

In terms of lowering WIT and preserving long term kidney function, selected complex renal cortical tumors with PADUA score between 10-11 seem to be safely and successfully operated with single-layer renorrhaphy plus a usage of hemostatic agents by experienced robotic surgeons.

Conflict of Interest

The authors declare to have no conflicts of interest.

Financial Disclosure

The authors declared that this study has received no financial support.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Ethical Approval

The study was approved by Şişli Memorial Hospital Ethics Committee (Approval Number: 26.02.2021/09) and written informed consent was received from all participants. The study protocol conformed to the ethical guidelines of the Helsinki Declaration.

Author Contributions

Conception and design; Binbay M, Data acquisition; Aydoğan TB, Data analysis and interpretation; Aydoğan TB, Binbay M, Drafting the manuscript; Aydoğan TB, Critical revision of the manuscript for

scientific and factual content; Binbay M, Statistical analysis; Aydoğan TB, Supervision; Binbay M.

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