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# The Use of Three Different Hemostatic Agents during Laparoscopic Partial Nephrectomy: A Comparison of Surgical and Early Renal Functional Outcomes

Serdar Aykan[1] iD, Mustafa Zafer Temiz[2] iD, Ismail Ulus[1] iD, Mehmet Yilmaz[1] iD, Serkan Gonultas[1] iD, Serhat Suzan[1] iD, Atilla Semercioz[1] iD, Ahmet Yaser Muslumanoglu[1] iD

## ABSTRACT

**Objective:** This study aimed to compare the effects of three different hemostatic agents on surgical and early renal functional outcomes after laparoscopic partial nephrectomy (LPN).

**Materials and Methods:** A total of 126 cases of LPN performed between November 2008 and September 2016 were enrolled in this study. Spongostan™ Absorbable Hemostatic Gelatin Sponge (Ethicon, Somerville, NJ, USA) or Surgicel® Original Absorbable Hemostat (Ethicon, Somerville, NJ, USA), or a total of 5 mL of Floseal® Hemostatic Matrix (Baxter Healthcare, Deerfield, IL) was used for additional hemostasis. According to the hemostatic agent used, patients were divided into three groups; and patient characteristics, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor characteristics, perioperative parameters, serum creatinine levels, and complications were compared among these three groups.

**Results:** Age, BMI, ASA score, tumor characteristics, operative time, warm ischemia time, complication rates, and length of hospital stay were similar among the groups, whereas estimated blood loss was significantly lower in the Floseal Group (p=0.01). Postoperative serum creatinine levels and differences between preoperative and postoperative serum creatinine levels were also similar among the groups.

**Conclusion:** The type of hemostatic agent used in LPN may affect the estimated blood loss. However, it has no substantial effect on other surgical parameters and early renal functional outcomes.

**Keywords:** Hemostasis, equipment, nephrectomy, laparoscopy

*ORCID IDs of the authors:*
S.A. 0000-0001-8963-6811
M.Z.T. 0000-0002-5736-5495
I.U. 0000-0002-2005-9734
M.Y. 0000-0002-5780-534X
S.G. 0000-0001-6556-7751
S.S. 0000-0002-3344-464X
A.S. 0000-0001-8688-4772
A.Y.M. 0000-0002-8691-0886

[1]Department of Urology, Bagcilar Training and Research Hospital, Istanbul, Turkey
[2]Clinic of Urology, Catalca Ilyas Cokay State Hospital, Istanbul, Turkey

## Introduction

Because of the advancement and extensive application of imaging techniques, kidney cancer has become an early-diagnosed clinical entity in the recent years. The disease is commonly diagnosed incidentally before the occurrence of advanced disease symptoms [1]. As a result, because of its similar oncologic outcomes and better preservation of renal function, partial nephrectomy (PN) has replaced radical nephrectomy as the standard of care for localized kidney cancer [2-4]. Although open PN is considered as the gold standard surgical treatment for T1 renal tumors, laparoscopic technique has been the most preferred approach because of advancement of laparoscopic surgery in recent years. Advanced surgical equipments and new suturing techniques with new suture materials and additional hemostatic agents have eased laparoscopic PN (LPN) [5]. However, the procedure has technical difficulties such as successful tumor excision, renal parenchymal wound closure, and reconstruction of the collecting system with allowable warm ischemia time [6, 7]. These technically demanding aspects may cause some complications such as hemorrhage, urine leakage, and renal functional deterioration [7, 8].

Accurate closing of the parenchymal defect after excision of the renal mass called as renorrhaphy is a crucial and compelling step in the LPN procedure. Excessive depth of the suture line may cause renal damage, whereas superficial suturing may lead to hemorrhage. The well-preserved parenchyma is one of the main predictors of the ultimate renal function after the procedure. Therefore, urologists should pay attention to the residual healthy kidney tissue and avoid its devascularization during renorrhaphy [9]. Timeliness is another important point for ultimate renal function during renorrhaphy; and the primary aim must be to reduce the warm ischemia time with minimal duration of clamping of the renal hilum [10].

To reduce hemorrhage for a long time, various hemostatic agents and tissue sealants have been used during LPN as an adjuvant to suturing. However, there is a lack of comparison of different hemostatic agents in the urology literature. Further, most of the previous relevant studies primarily evaluated the hemorrhagic complications; and renal functional outcomes of the use of hemostatic agents were commonly ignored. In this study, we hypothesized that the use of hemostatic agents may provide better renal functional recovery by preventing the deep suturation and longer warm ischemia time. Thus, we aimed to compare the effects of three different hemostatic agents on surgical outcomes, particularly early renal functional outcomes.

## Materials and Methods
A total of 126 cases of LPN for renal tumors performed with the use of three different types of hemostatic agents between November 2008 and December 2016 were enrolled in this retrospective study. Approval was taken from the institutional independent ethics committee (2018.01.2.03.006). The study was conducted with the principles of the Declaration of Helsinki. All data including patient characteristics, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor characteristics, perioperative parameters and details, preoperative and postoperative serum creatinine levels, and perioperative and postoperative complications were obtained from the computer-based patient record system and our institutional nephrectomy case assessment forms. The surgical complications were determined using the Clavien-Dindo classification system [11]. All renal tumors were visualized and characterized by axial, sagittal, and coronal computed tomography imaging; and preoperative tumor characteristics were determined using the preoperative aspects and dimensions used for anatomic classification (PADUA) renal tumor scoring system. The American Joint Committee on Cancer tumor-node-metastasis (TNM) staging system and Fuhrman grading system were used for pathologic staging and grading.

Transperitoneal laparoscopic approach in the flank position was used for PN. After providing of pneumoperitoneum with the Veress needle technique, the primary 10-mm camera port was inserted three fingers below the costal margin at the lateral border of the rectus. The other two 10-mm ports were inserted at the lateral border of the rectus at umbilicus level and at the lateral border of the rectus near the costal margin. Additional 5-mm port for lateral retraction of the kidney was placed

at the anterior axillary line when necessary. After incision of the Toldt line, the colon was reflected medially, and further peri-tumoral dissection between renal capsule and Gerota's fascia was performed. The Gerota fascia and fatty tissue of tumoral mass were preserved for healthy pathologic examination. Renal pedicle was exposed, and renal artery was identified for clamping with bulldog clamps (Aesculap-Braun, Tuttlingen, Germany). Resection line was determined using a J hook with electro cautery at least 1-cm border with the tumor; and tumor resection was completed with cold scissors immediately after arterial clamping. In case of the collecting system involvement of the resection, collecting system was closed with running 4-0 polyglactin suture, and then hemostasis was provided with monopolar cautery. Additional hemostasis was provided with the application of Spongostan™ Absorbable Hemostatic Gelatin Sponge (Ethicon, Somerville, NJ, USA) or Surgicel® Original Absorbable Hemostat (Ethicon, Somerville, NJ, USA) or a total of 5 mL of Floseal® Hemostatic Matrix (Baxter Healthcare, Deerfield, IL). Application of Floseal was performed through laparoscopic port site directly into the parenchymal defect. Spongostan and Surgicel were lied down to the parenchymal defect. Renorrhaphy was then conducted with sliding-clip renorrhaphy technique as described before with vertical mattress sutures incorporating Spongostan or Surgicel pledges [12]. The tumor specimen was extracted with Endobag™ 5''×8'' Specimen Retrieval System (Covidien AG, Dublin, IE) at the lateral port side with a small incision, and drainage catheter was placed through the inferior port.

### Statistical Analysis
The statistical analyses were performed using the Number Cruncher Statistical System

2007 statistical software (Utah, USA). The Kolmogorov-Smirnov test was used to test normality. Descriptive statistical methods as mean and standard deviation were used to report the continuous variables, whereas frequency along with percentages was used for qualitative variables. The one-way analysis of variance (ANOVA) test was used to compare the continuous variables between the groups. Post-hoc analysis was performed with the Scheffe test. Comparisons of qualitative data were performed using chi-square and Fischer's exact tests. Statistical significance was established at $p<0.05$.

## Results
A total of 126 patients with the mean age of 57.96±12.8 years were included in the study. Patient demographics and characteristics are shown in Table 1. Majority of the patients were male (n: 83, 66.6%), with right-sided (n: 67, 53.1%) and lower pole (n: 47, 37.3%) lesions. The mean tumor size was 40±24.8 mm, and the mean warm ischemia time was 23±11 min. The mean PADUA score was 8.9±2.1 (Table 1). Conventional renal arterial clamping was performed in 101 patients (80.1%), whereas non-ischemic procedure was used in 25 cases with peripheral smaller tumor. Closure of the collecting system was required in 6 (4.7%) patients. The mean operative time and warm ischemia time were 173±82 and 23±11 min, respectively. Estimated blood loss (EBL) was 169 mL (10-400). Intraoperative and postoperative blood transfusions were given in four and seven patients, respectively (Table 2).

Overall 21 (16.6%) patients had complications of which 4 (3.1%) were intraoperative. All intraoperative complications were blood loss that necessitated transfusion (Clavien

**Table 1.** Patient and tumor characteristics

|  |  | PN with Spongostan | PN with Surgicel | PN with Floseal | p |
|---|---|---|---|---|---|
| Number of cases | | 22 (17.4%) | 53 (42.2%) | 51 (40.4%) | |
| Age (year) | | 56.05±11.81 | 56.57±12.31 | 54.86±13.35 | 0.78* |
| Gender (n) (%) | Male | 17 (20.2%) | 38 (45.3%) | 29 (34.5%) | 0.14# |
| | Female | 5 (11.9%) | 15 (35.7%) | 22 (52.4%) | |
| BMI (kg/m²) | | 24.5±4.83 | 24.5±4.83 | 26.11±3.93 | 26.56±5.05 |
| Tumor size (mm) | | 36.41±22.34 | 36.78±18.63 | 39.76±11.06 | 0.70* |
| ASA score (n) (%) | 1 | 16 (19.5%) | 32 (29%) | 34 (41.5%) | 0.73# |
| | 2 | 4 (12.5%) | 16 (50%) | 12 (22.5%) | |
| | 3 | 2 (16.6%) | 5 (41.65%) | 5 (41.65%) | |
| PADUA score | | 8.77±1.85 | 9.00±1.71 | 9.04±1.75 | 0.83* |

*One-way ANOVA test, #Fisher's exact test, BMI: Body mass index: ASA: American Society of Anesthesiologists: PADUA: Preoperative aspects and dimensions used for anatomic classification

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**Table 2.** Perioperative parameters

|  | Spongostan group | Surgicel group | Floseal group | p |
|---|---|---|---|---|
| Operative time (min) | 175.68±63.77 | 164.53±49.16 | 158.95±51.19 | 0.50* |
| WIT (min) | 15.55±10.52 | 16.19±11.51 | 14.24±6.99 | 0.66* |
| EBL (mL) | 193.18±76.05 | 172.26±75.41 | 135.79±80.52 | 0.01* |
| Preoperative SCr level (mg/dL) | 0.9±0.16 | 0.89±0.21 | 0.87±0.26 | 0.87* |
| Postoperative SCr level (mg/dL) | 1.18±0.2 | 1.14±0.22 | 1.07±0.23 | 0.16* |
| Change in SCr level (mg/dL) | 0.28±0.25 | 0.26±0.22 | 0.20±0.21 | 0.40* |
| LOS (day) | 4.55±0.8 | 4.43±0.53 | 4.45±054 | 0.74* |
| Blood transfusion (n) (%) | 4 (36.3%) | 4 (36.3%) | 3 (27.4%) | 0.55# |
| Complications (n) (%) | 3 (33.3%) | 4 (44.4%) | 2 (22.3%) | 0.45# |

*One-way ANOVA test, #Chi-square test, WIT: Warm ischemia time: EBL: Estimated blood loss: SCr: Serum creatinine: LOS: Length of hospital stay.

**Table 3.** Post-hoc analysis for determination of the source of difference in EBL

|  | Hemostatic agent | Hemostatic agent | Difference between means | p |
|---|---|---|---|---|
| EBL (mL) | Spongostan | Surgicel | 10.92 | 0.11* |
|  |  | Floseal | 57.39 | 0.01* |
|  | Surgicel | Spongostan | -10.92 | 0.11* |
|  |  | Floseal | 36.47 | 0.03* |
|  | Floseal | Surgicel | -36.47 | 0.03* |
|  |  | Spongostan | -57.39 | 0.01* |

EBL: Estimated blood loss; *Scheffe post-hoc test.

**Table 4.** Pathologic features of the cases

|  |  |  | (n) (%) |
|---|---|---|---|
| TNM stage | T1a |  | 76 (60.31%) |
|  | T1b |  | 37 (29.36%) |
|  | T2a |  | 13 (10.31%) |
| Pathology | RCC | Clear cell | 83 (65.87%) |
|  |  | Papillary | 11 (8.73%) |
|  |  | Chromophobe | 6 (4.76%) |
|  | Oncocytoma |  | 12 (9.52%) |
|  | Angiomyolipoma |  | 14 (11.11%) |
| Fuhrman grade | 1 |  | 36 (28.57%) |
|  | 2 |  | 80 (63.49%) |
|  | 3 |  | 10 (7.93%) |
| Positive surgical margin |  |  | 4 (3.17%) |

TNM: tumor-node-metastasis classification: RCC: Renal cell carcinoma

grade II). Among the postoperative complications, 4 (3.1%) were urinary leakage (Clavien I), 7 (5.5%) were hemorrhage that required transfusion (Clavien grade II), and six patients (4.7%) had Clavien grade III complications consisting of prolonged urinary leakage (more than seven days) that resolved with DJ stent placement.

Age, BMI, ASA score, PADUA score, operative time, warm ischemia time, complication rates, and length of hospital stay were similar among the groups (Table 1), whereas EBL was significantly lower in the Floseal Group (Tables 2 and 3). Postoperative serum creatinine levels and differences between preoperative and postoperative serum creatinine levels were also

similar among the groups. Tumor characteristics including final pathologic stage and grade are listed in Table 4.

## Discussion

Clamping of the renal hilum, main renal artery, or selective segmental renal artery for bleeding control is the main surgical step during LPN. The main drawback of these clamping procedures is various forms of renal ischemia that may result in impaired renal functional recovery after the surgery. Therefore, one of the most important aim of the urologists is to reduce warm ischemia time [10, 13]. After the excision of tumor, excessive parenchymal bleeding may obstruct the renorrhaphy. It also usually extends the warm ischemia time during the surgery. In our opinion, initial bleeding control before renorrhaphy with hemostatic agents may help to overcome this issue. Our hypothesis was that more clear visibility without bleeding could ease renorrhaphy with less warm ischemia time.

A wide variety of hemostatic agents have been developed to reduce the hemorrhage following the excision of the kidney tumor during PN [14]. These agents are commonly divided into four categories: mechanical agents, active agents, flowable agents, and fibrin sealants. The first group, mechanical agents, consists of porcine gelatin, cellulose, bovine collagen, and polysaccharide spheres. They become a matrix at the bleeding location with activating the extrinsic coagulation cascade. Active agents containing thrombin have direct effect on intrinsic coagulation cascade with the conversion of fibrinogen to fibrin. Gelatin or gelatin and thrombin mixtures compose the flowable hemostats that have flowable structure directly into the bleeding site through a syringe. The gelatin granules get swollen with the absorption of the blood, and act as tampon. Fibrin sealants include the mixture of fibrinogen and thrombin, and they represent the imitation of a fibrin clot as is in the last phase of coagulation cascade [15, 16].

The main purpose of hemostatic agents is to minimize intraoperative and postoperative bleeding. They may also prevent postoperative urinary leakage with increased healing capacity of collecting system after PN [17]. As described above, their most important theoretical benefit is shorter warm ischemia time by easing intracorporeal suturing. Although a wide variety of previous studies have investigated the use of hemostatic agents in PN, the lack of evidence-based clear results remains; and there are conflict results about their use. In a multi-institutional study with a large cohort, Breda et al. [7] reported a survey from the United States

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and Europe about the use of hemostatic agents during LPN. Postoperative transfusion requiring bleeding and urinary leakage rates with the use of hemostatic agents were 2.7% (in 28 patients) and 1.9% (in 20 patients), respectively. The authors concluded that although most centers use routine hemostatic agents during LPN, their use should be limited to control minor bleeding. More studies are needed to assess their potential role. The other multicenter study conducted by Lange et al. [18] prospectively evaluated the use of several hemostatic agents in 570 PN cases. The authors did not found significant difference in terms of operative time, blood loss, hospital stay, and transfusion rate between cases performed with and without hemostatic agents. Similarly, Siemer et al. [19] aimed to determine the efficacy of hemostatic agent, TachoSil® Fibrin Sealant Patch, for open PN in their prospective randomized control trial; and they found no difference in transfusion rates or hemoglobin concentration of drainage fluid. Most recently, Maurice et al. [20] assessed the impact of hemostatic agents on postoperative bleeding after robotic PN. The authors found that use of hemostatic agents was not associated with postoperative transfusion or hemoglobin decline. However, several studies especially those consisting of laparoscopic case series have reported favorable results on behalf of hemostatic agents [21-26]. A great majority of these studies have primarily assessed the efficacy of hemostatic agents on bleeding complications or urinary leakage. Very few of them have investigated the renal functional outcomes of PN with use of hemostatic agents. One of those published by Antonelli et al. [27] in 2014 and designed as observational multicenter prospective study compared TachoSil® Fibrin Sealant Patch (Baxter, Westlake, CA Village), Floseal® Hemostatic Matrix (Baxter Healthcare, Deerfield, IL), and control groups in 19 Italian centers. The authors concluded that hemostatic agents do not provide better renal functional outcomes for PN, but their study cohort included the mixture of open, laparoscopic, and robot-assisted PN procedures. We think that this technical complexity might have hindered the healthy comparison of renal functional outcomes. Another study by Abu-Ghana et al. reported that hemostatic agents did not affect the rate of hemorrhagic complications during PN [28]. It showed comparable renal failure rates with the use of hemostatic agents. That study also included open and laparoscopic cases, and the authors did not provide a clear statement about the renal failure criteria. Moreover, these previous studies did not compare different hemostatic agents in terms of renal recovery. In this study, our primary aim was the com-

parison of different hemostatic agents in terms of early renal functional outcomes of LPN.

Our findings revealed that the use of different hemostatic agents has similar efficacy; and the type of hemostatic agent had no substantial effect on surgical outcomes except that the use of Floseal provided significantly less EBL (135.79 mL vs. 172.26 mL vs. 193.18 mL). Postoperative serum creatinine levels and changes in these levels did not exhibit a significant difference between the groups, as well. As a result, we can say that when the similar warm ischemia time and serum creatinine levels are considered, the type of hemostatic agent used does not influence early renal functional outcomes.

Our study has some limitations. The most important one is its retrospective nature. Prospective randomized trial might have provided better results. In this study, we used the hemostatic agents randomly according to our state of stocks. The lack of the well-designated randomization is another limitation. The third one is that we included some non-ischemic PN procedures in the study. Postoperative renal functional status might have affected differently in these cases. As a last limitation, we did not evaluate the postoperative blood loss from drainage catheter that may also give some information about the efficacy of hemostatic agents. Besides these limitations, our study has strength with the consideration of tumor complexity with PADUA scoring system; and even if an optimal randomization was not provided, comparable PADUA scores between the groups may be a positive aspect.

In conclusion, the type of hemostatic agent used in LPN may affect the EBL. However, it has no substantial effect on other surgical parameters and early renal functional outcomes.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the Ethics Committee of Bagcilar Training and Research Hospital/2018.01.2.07.010 (19/01/2018).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

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