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Title: The use of three different hemostatic agents during laparoscopic partial nephrectomy: A comparison of surgical and early renal functional outcomes

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Abstract:

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

Methods: A total of 126 LPN cases performed between November 2008 and September 2016 were enrolled to the 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) were used for additional hemostasis. Patients were divided three groups according to hemostatic agent used and, patient characteristics, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor characteristics, perioperative parameters, serum creatinine levels and complications were compared between the groups.

Results: Age, BMI, ASA score, tumor characteristics, operative time, warm ischemia time, complication rates and length of hospital stay were similar between 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 between the groups.

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

Keywords: Hemostasis, Equipment, Nephrectomy, Laparoscopy

Introduction:

During the recent years, kidney cancer has become an early diagnosed clinical entity due to the advancement and extensive application of imaging techniques. Currently, the disease is commonly diagnosed incidentally before the occurrence of advanced disease symptoms [1]. As a result, partial nephrectomy (PN) has replaced radical nephrectomy (RN) as the standard of care for localized kidney cancer with similar oncologic outcomes and better preservation of renal function [2-4]. Although open PN considered as the gold standard surgical treatment for T1 renal tumors, laparoscopic technique has been the most preferred approach due to 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 including 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 bothersome complications including hemorrhage, urine leakage and renal functional deterioration [7,8].

Accurate closing of the parenchymal defect after excision of the renal mass called as renorraphy is a crucial and compelling step in 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 to devascularization of it during the renorraphy [9]. Timeliness is another important point for ultimate renal function during renorraphy and reducing the warm ischemia time with minimal duration of clamping of the renal hilum must be primary aim [10].

Various hemostatic agents and tissue sealants have been used during LPN as an adjuvant to suturing in efforts to reduce hemorrhage for a long time. 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 are commonly ignored. In the current 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.

Methods:

Between November 2008 and December 2016, a total of 126 LPN cases for renal tumors performed with the use of three different type of hemostatic agents were enrolled to this retrospective study. Approval of the institutional independent ethics committee was given (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

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creatinine levels, periopeartive and postoperative complications were obtained from computer-based patient record system and our institutional nephrectomy case assessment forms. The surgical complications were determined using Clavien-Dindo classification system [11]. All renal tumors visualized and characterized by axial, saggital 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 the providing of pneumoperitoneum with the Veress needle technique, the primary 10 mm camera port was inserted 3 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 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 one centimeter 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 is 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 Surgicell 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 Surgicell pledges [12]. The tumor specimen was extracted with Endobag™ 5" x 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.

The statistical analyses were done using NCSS (Number Cruncher Statistical System) 2007 statistical software (Utah, USA). Kolmogorov–Smirnov test was used for test of normality. Descriptive statistical methods as mean and standard deviation were used in reporting of the continuous variables, whereas frequency along with percentages were used for qualitative variables. One way ANOVA test was used to comparison of the continuous variables between the groups. Post- hoc analysis was performed with 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 a mean age of 57.96±12.8 years were included 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. Mean tumor size and warm ischemia time were 40 ±24.8 mm and 23±11 min, respectively. Mean PADUA score was 8.9±2.1 (Table-1). Conventional renal arterial clamping was performed in 101 patients (80.1%), whereas nonischemic procedure was used in 25 cases with peripheral smaller tumor. In 6 (4.7%) patients, closure of the collecting system was required. 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 4 and 7 patients, respectively (Table-2).

Overall 21 patients (16.6%) have complications of which 4 (3.1%) were intraoperative. All intraoperative complications were blood loss that necessitate transfusion (Clavien grade II). Among the postoperative complications, 4 (3.1%) were urinary leakage (Clavien I), 7 (5.5%) were transfusion required hemorrhage (Clavien grade II), and 6 patients (4.7%) had clavien grade III complications composed of prolonged urinary leakage (more than 7 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 between the groups (Table-1), whereas EBL was significantly lower in the Floseal Group (Table2 and 3). Postoperative serum creatinine levels and differences between preoperative and postoperative serum creatinine levels were also similar between 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 a main surgical step during LPN. The main handicap of these clamping procedures is various forms of renal ischemia that may result in impaired renal functional recovey 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 parencyhimal bleeding may obstruct the renoraphy. It also usually extends the warm ischemia time during the surgery. In our opinion, initial bleeding control before renoraphy with hemostatic agents may help to overcome to this issue. Our hypothesis was that more clear visibility without bleeding could ease renoraphy with less warm ischemia time.

A wide variety of hemostatic agents has been developed to reduce the hemorrhage following the excision of the kidney tumor during PN [14]. These agents are commonly separated into four categories as mechanical agents, active agents, flowable agents and fibrin sealants. The first group, mechanical agents, consisting of porcine gelatin, cellulose, bovine collagen, and polysaccharide spheres 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 which have flowable structure directly into the bleeding site through a syringe. The gelatin granules get swollen with the absorbsion of the blood and act as tampon. Fibrin sealants include the mixture of fibrinogen and thrombin and represent the imitation of a fibrin clot as is in the last phase of coagulation cascade [15, 16].

The most widely intended 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 we described above, the most important theoretical benefit of the use of them 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 the use of them. In a multi-institutional study with a large study cohort, Breda et al [7] reported a survey from the United States 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 and more studies are needed to assess the potential role of them. 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 that 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 found no any differences 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 hemostatic agents use was not associated with postoperative transfusion or hemoglobin decline. However, several studies especially consisting of laparoscopic case series have reported favourable 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 comparing the 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 includes the mixture of open, laparoscopic and robot assisted PN procedures. We think that this technical complexity may hinder the healthy comparison of renal functional outcomes. Another study which reported that hemostatic agents did not affect the rate of hemorrhagic complications during PN by Abu-Ghana et al. [28] similarly 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 the current study, our primary aim was the comparison 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 impact 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 postoperative changes in serum cratinine levels were not exihibited a significant difference between the groups, as well. As a result, we can say hemostatic agent type does not influence early

renal functional outcomes when considered the similar warm ischemia time and serum creatinin levels.

Our study has some limitations. The most important one of them is retrospective nature of the study. However, prospective randomized trial might have provided more precious results. In the present study, we used the hemostatic agents randomly according to our state of stocks. However, the lack of the well designated randomization is another limitation. The third one, we included some non-ischemic PN procedures to 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 which 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 estimated blood loss. However, it has no any substantial effects on other surgical parameters and early renal functional outcomes.

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Conflict of interest:

None.

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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/m^2)		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 classsification**

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*

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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 ıschemia time, EBL: Estimated blood loss, SCr: Serum creatinine, LOS: Lengt 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.

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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)
		Cromofob	6 (%4,76)

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	Oncocytoma	12 (%9,52)
	Angiomyoliphoma	14 (%11,11)
Furhman grade	1	36 (%28,57)
	2	80 (%63,49)
	3	10 (%7,93)
Positive surgial margine		4 (%3,17)

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

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