The Safety and Efficacy of Adjuvant Hemostatic Agents During Laparoscopic Nephron-Sparing Surgery: Comparison of Tachosil and Floseal Versus No Hemostatic Agents

Senol Tonyali*, Artan Koni, Sertac Yazici, Cenk Y. Bilen

Purpose: To compare the effectiveness of TachoSil and Floseal during laparoscopic nephron-sparing surgery (LNSS), and to evaluate postoperative complications, especially hemorrhage and urinary leakage.

Materials and Methods: The medical records of all patients that underwent LNSS for a small renal mass (SRM) performed by the same experienced surgeon were retrospectively analyzed. The patients were divided into the following 3 groups, based on hemostatic agent: group 1: no adjuvant hemostatic agent (no AHA); group 2: TachoSil; group 3: Floseal.

Results: The study included 79 patients; no AHA group: n = 18; TachoSil group: n = 25; Floseal group: n = 36. The 3 groups were similar in terms of diameter [29.6 ± 11.5 mm, 26.4 ± 13.4 mm and 30.4 ± 9.6 mm, respectively (P = .218)] and PADUA scores [6.9 ± 0.9, 6.7 ± 1 and 6.9 ± 0.9, respectively (P =.540)]. Mean duration of surgery was significantly shorter in the Floseal group (120.9 ± 23.1 minutes) than in the no AHA group (156.6 ± 34.4 minutes). Mean ischemia time was longest in the no AHA group (24.3 ± 4 minutes) and shortest in the Floseal group (21.3 ± 4.3 minutes).
Intra-abdominal (IA) catheter drainage on postoperative day 1 was significantly higher in the no AHA group than in the TachoSil and Floseal groups [156.9 ±78.3 mL vs. 72.6 ± 64.5 and 60.8 ± 30.2 mL, respectively (P < .05)]. Mean duration of hospitalization was 3.2 ± 0.5 days in the no AHA group that was significantly longer than in the Floseal group (2.8 ± 0.7 days) (P = .043). There were not any differences in intraoperative complications, the transfusion rate, surgical margin positivity, or postoperative complications between the 3 groups (P = .596, P = .403, P = 1.0, P = .876, respectively). However, pseudoaneurism as a late term complication occurred in 27.7% patients in the no AHA group.

Conclusion: TachoSil and Floseal are safe and effective adjuvant treatments for patients undergoing LNSS. They might be useful especially in preventing pseudo aneurisms, shortening intraoperative ischemia time and hospital stay and decreasing postoperative drainage. Shortened operation and warm ischemia time may also be attributed to long learning curve of LNSS.

Keywords: Floseal; tachoSil; nephron-sparing surgery; laparoscopy; nephrectomy; hemostatic agent.

INTRODUCTION

Laparoscopic nephron-sparing surgery (LNSS) has been used since 1990's and yields similar oncologic results as the open approach[1,2]. LNSS is a challenging technique with a shallow learning curve that requires constant technical support. LNSS is associated with potential complications such as urinary leakage and bleeding that requires transfusion[3]. Adjuvant hemostatic agents (AHAs) and tissue sealants have been used since late 1970's and are known to be safe[4,5]. Numerous studies have shown that use of AHAs during LNSS reduces the complication rate[6-10].
Despite the increasing use of minimally invasive surgery, intra- and postoperative kidney hemorrhage following tumor resection remains a challenge. The current standard hemostatic method is suturing, although AHAs are also widely used. AHAs consist of topical hemostats, sealants, and adhesives. Gelatin, collagen, and cellulose can also be use to achieve hemostasis [11]. Among AHAs, Floseal and TachoSil are both well known. Tachosil acts via creation of a fibrin clot at the surgical site upon contact with blood or other fluids and have shown to decrease intraoperative time to hemostasis[11,12]. Floseal plays a role in fibrin formation, promotes coagulation thus minimizes blood loss[13].
Although many AHAs are currently in use, head-to-head comparative data are lacking; therefore, it is difficult for surgeons to choose one agent over another. The present study aimed to retrospectively evaluate the impact of using TachoSil and Floseal on surgical outcomes of LNSS such as operation time, intraoperative ischemia time, hospital stay and postoperative complications, especially hemorrhage and urinary leakage.

MATERIALS AND METHODS

Study population and design

The medical records of all patients that underwent LNSS for a small renal mass (SRM) performed by the

Hacettepe University School of Medicine, Department of Urology, Ankara, Turkey.
*Correspondence: Hacettepe University, School of Medicine, Department of Urology, Sihhiye 06100 Ankara, Turkey.
Tel: +90 312 305 1885. E-mail: senoltonyali@hotmail.com.
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Table 1. Patient Demographics and Tumor Characteristics

Variables	No AHA	TachoSil	Floseal	*P*
Sex				0.64
Male, n	12 (66.7%)	17 (68%)	28 (77.8%)	
Female, n	6 (33.3%)	8 (32%)	8 (22.2%)	
Age (years)	55.7 ± 8.6	57.2 ± 9.6	51.2 ± 11.7	0.043
Mean BMI (kg/m^2)	24.8 ± 3.2	29.5 ± 5	25.3 ± 3.3	0.000
Mean ASA	1.6 ± 0.7	1.4 ± 0.5	1.2 ± 0.4	0.042
Tumor Side				0.56
Right	10 (55.6%)	16 (64%)	18 (50%)	
Left	8 (44.4%)	9 (36%)	18 (50%)	
Mean Tumor Diameter Based on CT (mm)	29.6 ±11.5	26.4 ± 13.4	30.4 ± 9.6	0.218
Mean Padua Score	6.9 ± 0.9	6.7 ± 1	6.9 ± 0.9	0.540
Vessel Alteration				0.717
1 Artery, 1 Vein	13 (72.2%)	20 (80%)	30 (83.3%)	
Other	5 (27.8%)	5 (20%)	6 (16.7%)	
Clinical Stage				0.48
T1a	12 (66.7%)	21 (84%)	28 (77.8%)	
T1b	6 (33.3%)	4 (16%)	8 (22.2%)	
Mean Presurgical Creatinine Level (mg/dL)	1.13 ± 0.4	0.85 ±0.1	0.86 ± 0.1	0.017

same experienced laparoscopic surgeon between July 2007 and June 2015 were retrospectively reviewed. Demographic data, body mass index (BMI), American Society of Anesthesiologists (ASA) score, anatomic characteristics of renal masses [Preoperative Aspects and Dimensions Used for an Anatomical Score (PADUA)] and pre- per-, and postoperative data were retrospectively reviewed. All patients underwent LNSS with elective, relative or imperative indications were included the study. Patients whom all data was not available were excluded. Preoperative imaging suggested renal malignancy in all patients.

The standard diagnostic method for renal cell carcinoma (RCC) computerized tomography (CT) was performed in every patient. Although most of the patients had stage T1b or lower renal masses, LNSS was performed whenever surgical resection was possible. AHA was not used for initial surgeries because of the lack of AHA. Available AHA in the operation room was used in consequent patients without a tendency. The patients were divided into the following 3 groups, based on hemostatic agent: group 1: no adjuvant hemostatic agent (no AHA); group 2: TachoSil; group 3: Floseal.

Follow-up abdominal ultrasonography was performed at postoperative 3rd, 6th, 12th months. Abdominal CT was performed annually. Serum Cr levels was measured at postoperative 1st, 3rd, 6th, 12th months then annually.

Surgical technique

Each patient was positioned for surgery according to renal mass characteristics the modified flank position for transperitoneal LNSS and the flank position for retroperitoneal LNSS. The same experienced surgeon performed each surgery using the same surgical principles. In all groups the renal pedicle was controlled using a Satinsky clamp in cases of central and endophytic masses, and selective clamping of the renal artery with a Bulldog clamp was used in cases of peripheric and exophytic masses. Following tumor resection using cold scissors, the tumor bed was sutured using 2.0 Vicryl for hemostasis of vessels and closure of the collecting system. Thereafter, parenchymal hemostasis was achieved by approximating both edges using continuous 1.0 Vicryl sutures around a Surgicel (Ethicon Inc., Somerville, NJ) bolster placed in the tumor bed. TachoSil or Floseal was layered before placement of a Surgicel bolster. After the hilar was unclamped, a 20 F sump drainage catheter was inserted and the procedure was terminated via closing the layers anatomically.

Statistical analysis

Mean ± Standard deviation (SD), minimum- maximum values and percentages were used to describe the quantitative variables. Comparison of quantitative measurements among the groups was assessed with the non-parametric independent samples Kruskal- Wallis test. Dual comparisons between the groups were investigated with Chi-square test. Statistical analysis was performed via IBM SPSS statistics version 21 and P-value of less than .05 was considered significant.

RESULTS

In total, 79 patients underwent LNSS for SRM: no AHA group: n = 18; TachoSil group: n = 25; Floseal group: n = 36. Patient demographics are shown in **Table 1**. There were not any significant differences in gender distribution, tumor side and diameter, PADUA score, vessel alteration, or clinical stage between the 3 groups ($P > .05$), but age, BMI and ASA score differed significantly ($P < .05$). Mean tumor diameter based on CT was 29.6 ±11.5 mm, 26.4 ±13.4 mm, and 30.4 ± 9.6 mm in the no AHA, TachoSil, and Floseal groups, respectively. Although the preoperative creatinine level was significantly higher in the no AHA group ($P = .017$) (**Table 1**), the postoperative creatinine level was similar in all groups ($P = .184$) after a mean follow-up of 13 months. Mean duration of surgery was significantly shorter in the Floseal group than in the no AHA group (120.9 ± 23.1 versus 156.6 ± 34.4 minutes) ($P = .004$), whereas mean duration of surgery was similar in the Floseal and TachoSil groups (**Table 2**).

Intraoperative estimated blood loss (EBL) was lower in the no AHA group (72.7 ± 24.4 mL) than in the TachoSil (118 ±112.3 mL) and Floseal (130 ± 203 mL) groups which was not statistically significant ($P = 0.995$). Mean ischemia time was longest in the no AHA group (24.3 ± 4 minutes) and shortest in the Floseal group (21.3 ± 4.3 minutes). There weren't any differences in intraoperative complications (adjacent organ and vessel injury, pneumothorax, etc.), the transfusion rate, surgical margin positivity, or postoperative complications between the 3 groups ($P = .596$, $P = .403$, $P = 1.0$, $P = .876$, respectively). In all, 3 patients in the Floseal

Table 2. Operation Characteristics and Postoperative Course

	No AHA(n = 18)	TachoSil (n = 25)	Floseal (n = 36)	*P*
Approach				0.030
Transperitoneal, n	12 (66.6%)	19 (76%)	34 (94%)	
Retroperitoneal, n	6 (33.3%)	6 (24%)	2 (6%)	
Mean Duration of Surgery (min)	156.6 ±34.4	137.4 ± 42.4	120.9 ± 23.1 *	0.004
Mean EBL (mL)	72.7 ±24.4	118 ±112.3	130 ± 203	0.995
Mean Ischemia Time (min)	24.3 ±4	23.1 ± 6.3	21.3 ± 4.3	0.101
Intraoperative Complications				0.596
No, n	17 (94.4%)	25	34 (94.4%)	
Yes, n	1	0	2	
Surgical margin				1.00
Positive, n	1 (5.6%)	1 (4%)	1 (2.8%)	
Negative, n	17 (94.4%)	24 (96%)	35 (97.2%)	
Postsurgical Complications				0.876
≤ Clavien 2, n	3 (16.6%)	5 (20%)	5 (13.8%)	
> Clavien 2, n	1 (5.5 %)	0	1 (2.7%)	
Transfusion Required				0.403
Yes, n	0	1 (4%)	3 (8.3%)	
No, n	18 (100%)	24 (96%)	33 (91.6%)	
Mean 1st d IA Catheter Drainage (mL)	156.9 ±78.3	72.6 ± 64.5*	60.8 ± 30.2*	0.000
Mean Duration of Hospitalization (d)	3.2 ±0.5	2.9 ± 0.7	2.8 ± 0.7*	0.043
Mean Postsurgical Creatinine Level (mg/dL)	1.28 ±0.8	0.96 ± 0.2	1.17 ±1.1	0.184

Abbreviations: d, day; IA, intraabdominal; AHA, adjuvant hemostatic agent; EBL, estimated blood loss

group had hematuria on first or second postoperative day, which lowered the hemoglobin level and was treated conservatively with blood transfusion. Additionally, 1 patient in the TachoSil group required blood transfusion due to a rectus hematoma on the trocar tract. Intra-abdominal (IA) catheter drainage on postoperative day 1 was significantly higher in the no AHA group than in the TachoSil and Floseal groups [156.9 ±78.3 mL vs. 72.6 ±64.5 and 60.8 ±30.2 mL, respectively (*P* < .05)]. Mean duration of hospitalization was 3.2 ± 0.5 days in the no AHA group, versus 2.9 ± 0.7 days in the TachoSil group and 2.8 ± 0.7 days in the Floseal group; the difference between the Floseal and no AHA groups was significant (*P* = .043)(**Table 2**).

Late-term complications (after 3 months) following hospital discharges were observed in 5 patients (27.7%) in the no AHA group and in 1 patient (2.77%) in the Floseal group. In the AHA– group 5 patients developed pseudoaneurism: 2 were treated successfully with angio embolization, 1 patient was followed-up conservatively, and 1 patient underwent angio embolization 2 times during the first year following LNSS (radionuclide examination showed a non-functioning kidney after the second embolization). The fifth patient in the no AHA group was misdiagnosed as RCC recurrence during routine follow-up and underwent radical nephrectomy at another hospital; histopathological examination showed not only a stage T0 tumor, but also pseudo aneurism. In the Floseal group 1 patient developed a pseudo aneurism that was treated successfully with angio embolization. None of these late complications were observed in the TachoSil group.

DISCUSSION

Open nephron-sparing surgery yields oncologic outcomes comparable with open radical nephrectomy and long-term preservation of renal function in patients with small renal tumors. Along with technological advancements, refinement of surgical tools, and surgical experience, LNSS has become a feasible alternative to open partial nephrectomy[1,2]. LNSS is a challenging surgical technique with a shallow learning curve and is associated with potentially troublesome complications. Achieving hemostasis and repair of the collecting system are the most challenging aspects of the procedure, whereas intraoperative and postoperative bleeding and urine leakage are well-known complications that occur in 1.2%-9.5 % and 1.2%-4.5 % of patients, respectively [3,14].

The use of AHAs during LNSS has become more wide spread since 2000's, as it is associated with reductions in postoperative bleeding and urinary leakage. Several studies have reported these AHA benefits and that the use of AHAs was superior to the standard procedure, in terms of the rates of hemorrhage and urine leakage[3,14]. Several AHAs are currently available, but there are no comparative data concerning their effectiveness. TachoSil (Takeda Nycomed, Linz, Austria) is a ready-to-use fibrin sealant patch consisting of equine collagen coated with human fibrinogen and thrombin. It helps to achieve hemostasis in 3-5 min via creation of a fibrin clot at the surgical site upon contact with blood or other fluids, and it can also be use for tissue sealing[11,15].

Many studies report that TachoSil is a safe and effective hemostatic agent[12,16,17]. In an open randomized, prospective study conducted with 185 patients TachoSil was observed to be superior to standard suturing during nephron-sparing surgery and time to hemostasis was significantly shorter in the TachoSil group than in the standard suturing group (5.3 min vs. 9.5 min, respectively)[12]. Similarly, Fanari et al.[17] reported that mean time to hemostasis using TachoSil was 5.5 min (range: 3-16 min). TachoSil can be used safely regardless of patient age. In a preliminary study Mele et al.[16] observed that TachoSil was safe and effective for achieving hemostasis, as well as sealing the collecting system in children undergoing nephron-sparing surgery. Some researchers reported that combined manual suturing and AHA use might be the best method for achieving hemostasis during laparoscopic partial nephrectomy. Falsaperia et al.[18] reported that TachoSil is safe and effective, and easy to apply, even when surgery is performed without hilar clamping.

Use of TachoSil might reduce the cost of surgery. A re-

cently published review by Colombo et al.[19] examined the economic effect of TachoSil. They screened studies that included patients that underwent hepatic, cardiac, and renal surgery with the use of TachoSil. They observed that time to hemostasis, duration of hospitalization (2.01 days vs. 3.58 days), and the postoperative complication rate were lower in the TachoSil group than in the standard technique group. In accordance with Colombo et al., mean durations of hospitalization were 4 and 5.5 days in earlier studies[17,18]. In the present study mean duration of surgery, postoperative catheter drainage time, and duration of hospitalization were lower (but not significantly) in the TachoSil group than in the no AHA group. Moreover, serious postoperative bleeding and late complications were not observed in the TachoSil group.

Floseal (Baxter Corp., Deerfield, IL) consists of a cross-linked bovine gelatin matrix and human-derived thrombin. Its use in ear, nose, and throat, cardiac, and vascular surgery is well known. It also can be used for urological surgery, including both open and laparoscopic procedures such as radical-partial nephrectomy and prostatectomy[20]. Floseal use during LNSS can have a positive effect on the surgical procedure and outcome, including warm ischemia time, estimated blood loss, duration of surgery, duration of hospitalization, and hemorrhagic complications. Gill et al.[6] retrospectively compared Floseal and their standard technique without AHA, and there was not any significant difference in duration of surgery, warm ischemia time, estimated blood loss, or duration of hospitalization between the 2 techniques. Nonetheless, Floseal was associated with fewer procedural and hemorrhagic complications. Wille et al.[21] reported that Floseal is a safe and reproducible tool that reduces warm ischemia time and precludes damage induced by sutures. They used Floseal to achieve hemostasis, and used suturing only to repair the collecting system or to occlude the great vessels damaged during deep excision via scissors or a harmonic scalpel (Ethicon Endo-Surgery, Livingston, West Lothian, UK). Mean clamping time was 25.8 minutes, mean duration of surgery was 201 minutes (range: 110-355 minutes), and mean estimated blood loss was 181 mL.

A recent systematic review reported that Floseal use during various surgical procedures reduces the time to obtain hemostasis, duration of hospitalization, and intraoperative and postoperative bleeding[13]. Another study compared the safety and efficacy of Floseal and a surgeon-prepared gelatin hemostatic agent. Median duration of surgery was similar in both groups (150 min), whereas median warm ischemia time was shorter in the Floseal group (16 min vs. 20 min). The postoperative transfusion rate was 0% in the Floseal group, versus 4.8% in surgeon-prepared gelatin hemostatic agent group (P = .33). Both AHAs exhibited similar safety and efficacy profiles, whereas the surgeon-prepared material reduced the cost of treatment per case by $200-$450[22].

Antonelli et al.[23] compared the efficacy of Floseal, TachoSil, and no hemostatic agent during both open and laparoscopic partial nephrectomies. In all, 48 procedures were minimally invasive (TachoSil: n = 18; Floseal; n = 14; no hemostatic agent: n = 16) and 150 were open procedures. The researchers reported that the hemostatic agents did not provide any clinical benefit in terms of medical and surgical complications, transfusion, and reinterventions. Moreover, estimated blood loss was highest in the Floseal group. The researchers concluded that it was not possible to confirm the efficacy of AHAs, as compared to standard suturing. The study by Antonelli et al. seems similar to our study at first sight however there were main differences between the methodology and outcomes of the two studies. First of all both open and minimal invasive operations were included that prospective, multi-institutional study. To use or not to use HA, the type of used HA and surgical approach was decided on centers' and surgeons' preference on that study which might cause a selection bias and affect surgical outcomes. We reported the results of the consecutive LNNS's of a single surgeon in a retrospective fashion and found HA to be useful in LNSS. Similarly, to that study intraoperative EBL was highest in Floseal group in our study.

The present study's findings in the Floseal group are consistent with most of the aforementioned studies. Mean duration of surgery, duration of hospitalization, and postoperative drainage were significantly lower in the present study's Floseal group than in the no AHA group. Mean ischemia time was also lower, but not significantly, in the Floseal group. On the other hand, postoperative bleeding that reduced the hemoglobin level was observed in 3 patients in Floseal group. In addition, 27.7% patients in the no AHA group had a pseudo aneurism as a late complication, which shows the importance of AHAs during LNSS. Use of AHAs in the present study provided many advantages during LNSS, such as shorter duration of surgery, duration of hospitalization, and warm ischemia time (not significant), and a decrease in postoperative drainage. In terms of duration of surgery and hospitalization, and warm ischemia time, Floseal was superior to TachoSil, whereas postoperative drainage was similar in the Floseal and TachoSil groups. Although all procedures were performed by the same experienced laparoscopic surgeon, shortened operation and warm ischemia time may also be attributed to long learning curve such that our first cases were mainly in no AHA group.

The present study has some limitations, including its retrospective design and relatively small patient population. The patients were divided into 3 groups, sequentially. The first cases were performed without AHA because of the lack of AHA in the operation room. After than the supply of AHA available AHA in the operation room was used in consequent patients without a tendency. Although many features of the tumors and patients were similar, including clinical stage, size, and PADUA score, others differed. Additional randomized prospective studies with larger numbers of patients matched according to demographics and tumor characteristics are required to confirm the present findings.

CONCLUSIONS

In conclusion, both TachoSil and Floseal can be considered safe and effective, and easy to use adjuvant treatments during LNSS. They might be useful especially in preventing pseudo aneurisms, decreasing postoperative drainage and shortening intraoperative ischemia time and hospital stay. Shortened operation and warm ischemia time may also be attributed to long learning curve of LNSS such that our first cases were mainly in no AHA group.

CONFLICT OF INTEREST

The authors declare there are no conflicts of interest financial or otherwise related to the material presented herein.

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