Comparison of Bipolar vascular sealing and conventional back-table dissection in terms of post-renal transplant drainage and back-table preparation times

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Abstract. – OBJECTIVE: The usage of vessel sealing devices has been gaining popularity in all surgical specialties. Post-renal transplant drain placement is a common practice among transplant surgeons. However, prolonged drainage accompanied by surgical wound complications and perirenal fluid collections is a frequent complication experienced by the recipients. This study aimed to compare Bipolar vascular sealing with conventional back-table dissection in terms of post-renal transplant drainage duration, amount, surgical wound complication, and back-table preparation time.

PATIENTS AND METHODS: A double-blind clinical study randomizes recipients into 2 groups, using Bipolar vascular sealing (Group 1) and conventional ligation (Group 2) back-table dissection. Variables such as recipient age, gender, body mass index (BMI), cause of end-stage renal disease, amount and duration of surgical drainage, back-table time, and cold ischemia time (CIT) were collected prospectively.

RESULTS: Ninety-eight consecutive living donor (M/F: 69/29) renal transplant recipients were enrolled in this prospective randomized clinical trial. There were 49 patients in each group. The mean BMI was 26.76±4.57. There was no difference among the groups regarding recipient age, BMI, total drainage, and surgical drainage duration. The surgical site infection rate was not different between the two groups. Group 1 had significantly shorter back-table time, with mean back-table time being 15.26±2.51 minutes in Group 1 and 28.83±6.27 minutes in Group 2 ($p<0.001$). The CIT was also significantly different between the 2 groups ($p<0.001$). In Group 1, the recorded CIT was 43.3±11.4, and in Group 2, 57.1±13.3 minutes.

CONCLUSIONS: The use of Bipolar vascular sealing to seal lymphatic vessels at the back-table is feasible, safe, and easy to perform. It also expedites the dissection and shortens the time required for back-table graft preparation.

Introduction

The lymphatic system is pivotal in intercellular and interstitial body fluid homeostasis. The kidney has both capsular and hilar lymphatic systems. Among these, the hilar lymphatic drainage system is predominant[1]. During the living donor nephrectomy procedure, these lymphatic drainage vessels are usually dissected and sealed with electrocautery or ligation. Subsequently, at the back-table, the peri-renal fatty tissue and any remnant of the Gerota's fascia are removed, and the renal vessels are isolated to provide better exposure during the anastomosis at the recipient side[2,3]. During this dissection, the previously sealed lymphatic vessels, capsular and hilar, are usually exposed. If left unnoticed and unsealed, these may cause prolonged drainage from the surgical wound, peri-renal collections, and lymphoceles.

On the other hand, back-table dissection has to be precise, diligent, and quick. As the back-table time is included in calculating the cold ischemic time (CIT), prolongation of this time contributes to delayed graft function[4]. Thus, dissecting and ligating every lymphatic vessel with a silk tie is not practical as in the conventional method. Using the Bipolar vascular sealing device may help fasten the back-table step by sealing these vessels efficiently within a shorter time[5]. Electrothermal Bipolar Vessel Sealing devices such as Bipolar vascular sealing use the body's collagen and elastin

to create a permanent fusion zone. This technology can seal vessels up to 7 mm, lymphatics, and tissue bundles and has an average faster seal cycle of 2 to 4 seconds in most surgical situations[6]. This study aimed to compare the use of Bipolar vascular sealing with conventional back-table dissection.

Patients and Methods

Consecutive recipients receiving a living donor kidney transplant at Istinye University Organ Transplantation Center were enrolled in a prospective randomized clinical study. Istinye University Hospital Ethical Review Committee approved the clinical study (2/2021.K-66). This trial was registered to the ClinicalTrials.gov with the registration number NCT00552604. Informed consent was obtained from all individual participants included in this study. The recipients were randomized into two groups by a simple randomization (i.e., flipping coin) method. In Group 1, Bipolar vascular sealing was used, and in Group 2, conventional silk tie ligature was used during the back-table dissections (Figure 1). Data parameters including recipient age, gender, body mass index (BMI), cause of end-stage renal disease, dialysis modality, postoperative pain, surgical drainage duration, back-table time, CIT, and surgical site infections were collected on a database by a research nurse. The exclusion criteria were pediatric recipients and recipients who had received a kidney transplant previously.

The donor nephrectomies were performed using a pure laparoscopic technique. A standard right/left lower Gibson incision was made in every recipient, and the renal bed was prepared extra-peritoneally. The external iliac vein and external iliac artery were used for graft vessel anastomosis. Lymphatic vessels were tied by 3/0 and 2/0 silk sutures in the conventional group, whereas Bipolar vascular sealing was used in the other.

Study investigators were blinded to patient randomizations. All vascular anastomoses and bladder-ureter anastomoses were performed by the primary surgeon (E.E). One closed-suction Hemovac drain was placed at the lower pole of the graft in all recipients, and it was removed when discharge was less than 50 ml over 24 hours. The Gregoir-Lich anti-reflux anastomosis technique performed all ureteroneocystostomies with Polydioxanone (PDS) sutures. A double J stent was inserted in all cases. A Foley catheter was also placed in the bladder and removed on the fourth postoperative day as recommended in the literature[7]. All patients were evaluated for pain on the postoperative 1st day. The pain was assessed with a visual analog scale, scoring from 0 to 10, with 0 being no pain and 10 being the worst pain ever experienced.

Triple immunosuppression with tacrolimus, mycophenolate mofetil, and steroid was initiated on post-renal transplant day 1 to all recipients. In addition, high-risk recipients received thymoglobulin as induction, while low-risk recipients received Basiliximab on days 0 and 4 post-transplant. All recipients were anticoagulated by daily subcutaneous enoxaparin 0,6 cc injections starting on the day of surgery until the day of discharge. Patients were followed in terms of pain, drainage length, and wound complications for 6 months. Surgical wounds were assessed daily during the post-transplant 1st week, then weekly afterward.

Statistical Analysis

Data were analyzed with SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean values and
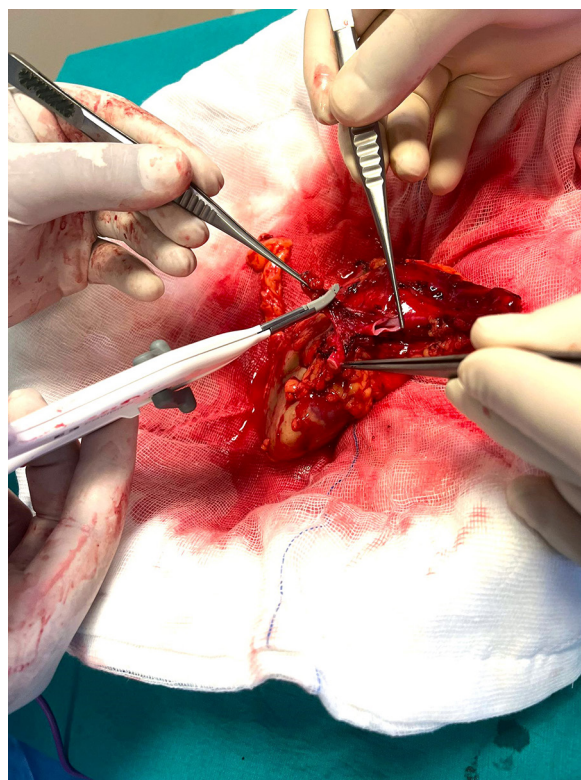
Figure 1. Use of Bipolar vascular sealing during ligation of a small venous branch at the back-table.

standard deviation, and categorical variables were reported as percentages. Cold ischemia time and post-transplant surgical drainage duration were the primary and secondary end-points. Analysis of variance was used to compare the surgical drainage duration and the total amount of drainage between the Bipolar vascular sealing and conventional dissection groups. The Pearson correlation test was applied to assess the correlation between the variables. The *p*-value was significant when it was lower than 0.05.

Results

Ninety-eight (M/F: 69/29) consecutive living donor renal transplant recipients were enrolled in the clinical trial. The mean age was 42.69±13.92. The mean BMI was 26.76±4.57. Diabetes was the leading cause of end-stage renal disease in the cohort (n=28%). This was followed by hypertension (n=26), glomerulonephritis (n=16), reflux nephropathy (n=9), renal stone disease (n=7), polycystic disease (n=7) and tuberous sclerosis (n=1). The cause of the end-stage renal disease was unknown in 5 recipients. A preemptive transplant was performed on 10 patients. Among the 87 patients on dialysis, 69 were on hemodialysis, while 19 were on peritoneal dialysis (Table I).

Mean postoperative pain was scored as 6.8±1.2. The mean surgical drainage duration was 4.8±2.44 days with a total drainage amount of 582.22±539.44 ml. No lymphoceles were detected in our cohort and no case was diagnosed with lymphorrhea. Surgical site infection was encountered in 4 patients, none of which required additional intervention other than daily dressing changes. The mean back-table time was 22.18±8.5 mins, whereas the mean CIT was 50.3±14.2 mins (Table I).

Each study group included 49 recipients. There was no significant difference between the 2 groups regarding recipient age, BMI, total drainage, and surgical drainage duration (Table II).

The surgical site infection rate was not different between the 2 groups. However, Group 1 had significantly shorter back-table time, with mean back-table time for Group 1 being 15.26±2.51 mins and Group 2 being 28.83±6.27 mins (*p*<0.001). The CIT was also significantly different between the 2 groups (*p*<0.001). In Group 1, the recorded CIT was 43.3±11.4, and in Group 2 was 57.1±13.3 mins.

Discussion

In recent years, post-transplant collections have been observed more commonly with the frequent use of ultrasound in the follow-up of

Table I. Recipient demographics and surgical data.

Patient Data	Mean	Median	Standard Deviation
Age	42.69	43	13.92
BMI	26.76	25.6	4.57
Gender (M/F)	69/28	-	-
End Stage Renal Disease Cause			
· Glomerulonephritis	16		
· Diabetes Mellitus	28		
· Hypertension	26		
· Reflux Nephropathy	9		
· Renal Stone Disease	7		
· Polycystic Kidney Disease	7		
· Tuberous Sclerosis	1		
· Unknown	4		
Dialysis Type			
· Hemodialysis	69		
· Peritoneal Dialysis	19		
· Preemptive	10		
Postoperative Pain	6.8	7	1.2
Surgical Drainage Duration (days)	4.8	4	2.44
Total Drainage (ml)	582.22	395	539.44
Surgical Site Infection	4	-	-
Back-Table Time (mins)	22.18	10.0	8.50
Cold Ischemia Time (mins)	50.3	44.5	14.2

Table II. Comparison of Bipolar vascular sealing (Group 1) and conventional (Group 2) back table dissection techniques.

	Group 1 (n=49)	Group 2 (n=49)	*p*-value
Age	39.3	42.1	0.760
BMI	26.6	25.9	0.852
Total Drainage (ml)	596.4	567.7	0.826
Surgical Drainage Duration (days)	4.76	4.85	0.842
Surgical Site Infection	2	2	1.0
Back Table Time (mins)	15.26±2.51	28.83±6.27	<0.001
Cold Ischemia Time (mins)	43.3±11.4	57.1±13.3	<0.001

transplant recipients[8]. Namely, these collections can be urinomas, seromas, hematomas, abscesses, and lymphoceles[9]. The most common among these is the lymphocele, with post-transplant symptomatic lymphocele formation reported around 5-20% in the literature[10]. The lymphatic system has a pivotal role in the homeostasis of interstitial body fluid, and the kidney has rich capsular and hilar lymphatic systems[1]. On the other hand, the external iliac vessels are the primary drainage site for the lymphatic draining of the leg, pelvic and inguinal areas. Therefore, transplantation of a donor's kidney to the iliac fossa using external iliac vessels is associated with a high risk of postoperative collections[8].

Furthermore, these collections may impair the graft function by causing direct pressure onto the adjacent structures such as the graft ureter, causing hydronephrosis or graft vasculature, thus causing thrombosis[11]. Placing a surgical drain at the end of transplant surgery is a common practice to prevent them. However, drain placement has its setbacks[8,11]. Drains may prolong hospital stay, are associated with surgical wound infections, and thus, increase the overall cost of kidney transplant surgery[12]. Additionally, patients with drains report higher discomfort and pain rates postoperatively[13].

Electrothermal sealing devices Bipolar vascular sealing have been shown to reduce lymphatic and other fluid collections in several gynecologic and urologic surgeries[14,15]. Recently, the electrothermal sealing device Bipolar vascular sealing has also proven superior to other vessel sealing techniques for breast cancer surgeries[16]. Its technology creates vessel fusion using a combination of pressure and energy. The denatured collagen, elastin fibers, and the rest of the connective tissue within the vessel allow a protein seal to form, fusing the walls. This seal obliterates the vessel lumen and prevents leakage[14-16]. Bipolar vascular sealing use has shown advantages in sealing time,

burst pressure, thermal spread, intraoperative blood loss, and surgery time compared to other devices. Seki et al[17] showed a significant reduction in the mean duration of drain removal and amount of total surgical drainage with Bipolar vascular sealing use[17]. We were unable to detect such a correlation in our study probably because the duration of drain removal was relatively shorter in our study. This shorter removal time might have led to a type 2 of statistical error where we could not recognize an existent correlation.

Another denominator regarding the amount and duration of surgical drainage is BMI[18]. High BMI has been associated with increased lymphoceles and increased drain output postoperatively. There was no difference in BMI between the study groups in our study. Additionally, our cohort consisted of patients with normal BMIs. However, the effects observed with Bipolar vascular sealing use can be more profound in obese patients. Therefore, further clinical studies using different patient populations should generalize the study outcomes. High BMI is also associated with higher rates of surgical site infections[19]. Like BMI values, Bipolar vascular sealing and conventional dissection groups did not differ significantly in surgical site infection rates.

Although there was no difference in total surgical drainage amount and duration, a significant difference was observed in the back-table preparation time. This difference was projected to the total cold ischemia time, which also proved to be shortened in the Bipolar vascular sealing dissection group. CIT has an essential role in developing delayed graft function (DGF). Delayed graft function is well known to influence the mid-term outcome of kidney transplantation and increases the frequency of acute rejection[20,21]. Thus, any means of shortening the cold ischemic time may potentially decrease the DGF rate. Unfortunately, in our study, the DGF rates were not recorded, and thus a positive association between shortened

CIT and decreased DGF rate with the use of Bipolar vascular sealing could not be established.

Additionally, since our study included only living donor kidney transplants, the benefit of using Bipolar vascular sealing dissection might not have had a pronounced effect on the DGF rates. However, it can be speculated that using the Bipolar vascular sealing back-table dissection technique can positively impact the deceased donor kidney back-table where the kidney arrives with ample surrounding connective tissue. Moreover, CIT gains more significance with the deceased donation as an inherent prolonged CIT is related to this process. Therefore, the impact of the Bipolar vascular sealing back-table dissection technique on the post-renal transplant drainage and CIT should be analyzed for future research.

Conclusions

Our findings suggest that the use of Bipolar vascular sealing to seal lymphatic vessels at the back-table is feasible, safe, and easy to perform. It also expedites the dissection and shortens the time required for back-table preparation of the graft. This finding was also reflected in the CIT of the transplants. Considering the vast literature on the association of CIT and DGF, the use of Bipolar vascular sealing may help prevent the development of DGF in selected patient groups by shortening the CIT in both live donor and deceased donor kidney transplants. Therefore, studies including live and deceased donor transplants with a more extended follow-up period are required to delineate this relationship.

Conflict of Interest
The Authors declare that they have no conflict of interests.

Ethics Approval
Istinye University Hospital Ethical Review Committee approved the clinical trial (2/2021.K-66).

Trial Registration Number
NCT05917054.

Informed Consent
All patients gave consent before participating in this study.

Availability of Data and Materials
All study data and materials can be obtained from the corresponding author.

Authors' Contributions
Eryigit Eren: data curation, supervision, writing original draft. Mehmet Tokac: investigation, supervision, visualization. Umit Ozcelik: data curation, data analysis. Taylan Sahin: methodology, data analysis. Gurkan Tellioglu: conceptualization, methodology, writing. Caghan Peksen: study design, data curation. Ayhan Dinckan: investigation, project administration, revision of the original draft.

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