Original Article

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Comparative Study to Evaluate the Effect of Using an Electro-Thermal Bipolar Sealing Device and Conventional Ligation on the Incidence of Post-Renal Transplant Lymphoceles in Recipients

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ABSTRACT

Background: Lymphocele development is a well-established complication following kidney transplant. Some devices, such as electrothermal bipolar sealing devices, have been found to reduce lymphatic drain following kidney transplantation.

The aim of the study: The purpose of the study is to compare the usage of conventional lymphatic ligation with the electrothermal bipolar sealing device and its influence on the formation of lymphoceles after kidney transplantation surgery.

Patients and methods: A cohort retrospective and prospective study was conducted from May 2015 to November 2020 at the Basrah renal transplantation center in Al-Sader Teaching Hospital, Basrah. One hundred and thirty anonymized patients with end-stage renal diseases were involved in the present study. They were categorized into two groups: group 1 (conventional ligation group) with 70 patients and group 2 (electrothermal bipolar sealing device group) with 60 patients. The groups were compared and matched for possible risk factors. Patients were followed up for six weeks with full laboratory investigation (complet blood count, renal function tests, and liver function tests) and medical and surgical assessments. Statistical package of social sciences version 25 was used for the statistical analysis of the data. Confidence intervals of 95% were applied as the dependent interval in statistics, and p-values < 0.05 were considered significant.

Results: The mean age of the patients was parallel for both conventional ligation and electrothermal bipolar sealing device groups (34.69 ± 10.28 vs. 33.68 ± 10.35). The operative time (155.57 ± 17.9 vs. 140.33 ± 17.07), lymphocele development (12 (17.1%) vs. 4 (6.7%)), lymphatic drainage volume (974.57 ± 178.39 vs. 493.83 ± 163.65), and the days of drainage (8.28 ± 3.3 vs. 4.6 ± 1.4) showed statistically significant differences between the conventional ligation technique and the electrothermal bipolar sealing device technique ($p < 0.05$).

Conclusion: The cautery of bipolar vessels is advantageous when compared to conventional ligation in kidney transplant lymphatic dissection, reducing the risk of lymphocele occurrence, in addition to its feasibility, safety, and easy performance.

Keywords: electrothermal bipolar sealing device, LigaSure™ kidney transplant, lymphocele.

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INTRODUCTION

Background

Despite the rapid progression in peritoneal and hemodialysis, renal transplantation is still the most effective therapy for end-stage renal disease (ESRD). Joseph Murray performed the first renal transplant in 1954.[1] It reduced the mortality rates by 60% compared to dialysis and doubled the predicted survival time.[2]

A renal transplantation procedure can be considered the best management choice for patients with end stage renal disease (ESRD). However, unfortunately, the postoperative complications may have a negative influence on the outcome of the surgery.[3–7] The common complications are urinomas, hematomas, and lymphoceles.[6]

Lymphocele is defined as a lymphatic fluid collection in the epithelial lining-free retroperitoneal space in kidney transplant patients.[8] Lymphoceles, localized mostly around the graft, differ from the lining in which a tough fibrous capsule covers the lymph content (pseudocysts).[9,10] Their occurrence ranges from 0.6% to 33.9% after ultrasound as the follow-up method,[8–10] with an average occurrence between two weeks and up to six months and a peak incidence at six weeks.[9, 11]

The lymphatic system is essential to maintain the body fluid in normal homeostasis; it removes excess fluids from the interstitium in case of normal or abnormal conditions.[12,13] It also plays a fundamental role in immunity by transferring the immune cells to the site of infection. On the other hand, lymphocytes and antigen presenting cells return through the lymph vessels to the bloodstream.[14]

The etiological factors of lymphocele occurrence are either surgical or medical. The surgical factors should be conducted properly. They include (a) recipient lymphatic dissection surrounding the iliac vessels and (b) donor renal lymphatic dissections. Lymphatic tissue will develop an optimal source of lymphatic collection if not sutured or clipped well during these procedures and, therefore, lead to the development of lymphoceles. Medical factors, including obesity (Body mass index (BMI) > 24 kg/m2),[15–17] age,[18] acute tubular necrosis,[19] duration of dialysis,[20] diabetes, immunosuppressive drugs such as rabbit anti-thymocyte globulin, high dose of mycophenolate mofetil (MMF) (>2 g/day), steroids, and use of diuretics, can increase the incidence of lymphocele development by increasing the lymphatic flow,[21] blood coagulation abnormalities such as decreased concentration of thrombin/anti-thrombin complexes, and prothrombin fragments F1 + 2, and low molecular wight heparin (LMWH) prophylaxis.[22,23] All of these are related to higher risks of lymphocele development.[18,19,24–27]

Lymphatic complications are mostly asymptomatic in kidney transplanted patients. Therefore, ultrasound, CT, and lymphangiography are commonly used to detect lymphoceles[28,29], edematous inguinal regions, graft function deterioration, abdominal pain, vesical tenesmus, urgency, and portal vein or vena cava compression syndrome with or without febrile.

As a result, attaining hemostasis is important in all surgical procedures, but it is challenging in minimal access surgery.

Therefore, cautious ligation of lymphatics of the iliac vessels is recommended.[30] Several techniques such as clips, staples, sutures, ultrasonic and monopolar or bipolar coagulation have been used to achieve the desired goal.[31] However, there is no single surgical technique that has been proven better to others in the prevention of the occurrence

of lymphocele. Some studies prove the efficacy of different surgical techniques, while some find no statistically significant variation.[32–34]

In 1940, new technology was introduced under the name of electrothermal bipolar vessel sealing device. At that time, the main obstacle in its use was the inability to dissect vessels larger than 3 mm. In 1984, a Swedish neurosurgeon modified it to reduce the inadvertent burning and charring often produced by these systems, but it was still ineffective in sealing vessels larger than 3 mm. Till 1988, when researchers from Covidien devised the first reliable system,[35] the application of the electrothermal bipolar sealing device developed by Valley lab was considered to be better than other vessel sealing methods, despite continuous studies to elaborate the efficacy of the electrothermal bipolar sealing device in comparison with other techniques in lymphatic vessels management. While the conventional method relies mainly on the manual ligation of the lymphatic vessels by special sutures or clips, the electrothermal bipolar sealing device applies a combination of pressure and energy (high current and low voltage) to create a consistent seal with each application.[36] It acts to obliterate the lumen by denaturing the connective tissue components (elastin, collagen, and others) to make proteins fuse the wall by forming a seal.[37] It can seal vessels up to 7 mm in diameter, and these seals can withstand a minimum of three times the normal systolic pressure.[31] This study was conducted to compare the usage of conventional lymphatic ligation with the electrothermal bipolar sealing device and its influence on the incidence of lymphocele development post-renal transplant surgery.

PATIENTS AND METHODS

Study design and patients

A cohort retrospective and prospective study was conducted at Basrah renal transplantation center, Al-Sader teaching hospital, Basrah. A total of 130 end-stage renal diseases patients were enrolled in the study. They were categorized into two groups: Group 1 had 70 patients who had undergone renal transplant using the conventional ligation technique using clips and sutures, while group II had 60 patients who had undergone renal transplant using the electrothermal bipolar sealing device technique. All patients were anonymized before starting their assessments. The cases of 110 patients (70 from group I and 40 from group II) were reviewed and followed up on retrospectively by reviewing their files from May 2015 to February 2020, while the cases of the remaining patients (20 from group II) were followed up on prospectively from February to November 2020.

Inclusion criteria: Any patient who had undergone renal transplantation surgery.

Exclusion criteria: Any patient with uncontrolled diabetes, on high doses of immunosuppressive drugs such as rabbit anti-thymocyte globulin and mycophenolate mofetil (MMF) (> 2 g/day), on diuretics treatments and anti-coagulants, and with BMI > 24, age > 60 years.

Mechanism of dissection: The conventional method was based on the ligation of the blood vessels from proximal and distal sides using non-absorbable sutures (silk) or clips, followed by dissection in between. On the other hand, the electrothermal bipolar sealing device used was curved, had a small jaw, an open sealer, and a divider, and featured an 18.8 cm shaft for use in open procedures, a 16.5 mm seal length, and a 14.5 mm cut length. The electrothermal bipolar sealing device based on an automated compression of the lymphatic vessels with subsequent denaturation of the collagen and the

connective tissue followed by dissection.

Figure 1. Covidien LigaSure System.

Patient follow-up: All the enrolled patients were followed up for 7–20 days after the surgery (early postoperative period), in which lymphatic drainage was measured by the closed system surgical drain. Biochemical analysis was performed on the collected fluid to detect creatinine ratio to ensure that it was lymph rather than urine; the second follow-up stage, consisting of ultra-sonographic evaluation, was done weekly throughout the six weeks after discharge. During these follow-up periods, full laboratory investigation (CBC, RFT, and LFT) and full medical and surgical assessments were performed for the patients. Both groups were compared and matched for possible risk factors such as BMI and age.

Statistical analysis

Statistical calculations were carried out using version 25 of the Statistical Package for the Social Sciences (SPSS Inc.), in which categorical data were expressed as numbers and percentages. The differences between the groups were analyzed using a chi-square test (X2). Continuous data were expressed as medians or mean ± SD, and the variations between the study groups were analyzed by the Mann–Whitney U test for abnormally distributed data and by an independent t-test for normally distributed data. The Shapiro–Wilk test was used to test the normality of the data, and outliers were detected using a boxplot. Confidence intervals of 95% were applied as the dependent interval in statistics, and p-values < 0.05 were accepted as statistically significant.

RESULTS

A total of 130 renal-transplanted patients were involved in this study. The electrothermal bipolar sealing device technique (in 60 patients) and the conventional ligation method (in 70 patients) were used in the operative procedure for lymphatic vessel sealing. Among the conventional ligation group, the majority of the enrolled patients were men (87.1%) in comparison to women (12.9%), which is equivalent to the share of men (81.7%) and women (18.3%) in the electrothermal bipolar sealing device-using group.

The mean age of the patients was parallel for both groups (34.69 ± 10.28 and 33.68 ± 10.35).

The comparison between the study groups showed that the operative time of the

conventional ligation group was 155.57 ± 17.9 minutes compared to 140.33 ± 17.07 minutes of the electrothermal bipolar sealing device group ($p < 0.05$). In the case of lymphocele development, the study reported that lymphocele formation was less for group 2 compared to group 1 (12 (17.1%) VS 4 (6.7%)) ($p = 0.02$). Additionally, the volume of lymphatic drainage in the conventional group was 974.57 ± 178.39 compared to the electrothermal bipolar sealing device group (493.83 ± 163.65) ($p < 0.05$). Moreover, with regard to the days of drainage, there were statistically significant differences between the conventional ligation technique and the electrothermal bipolar sealing device technique (8.28 ± 3.3 and 4.6 ± 1.4), respectively (Tables 1 and 2).

On the other hand, there were no significant results for the hospitalization period, BMI, intra-operative complication, surgery site infection, and recurrent lymphocele (Tables 1 and 2).

Table 1: Demographical Distribution Data of the Involved Patients.

Variables		Conventional Ligation Technique No. (%)	LigaSure™ Technique No. (%)	P-Value
Age (mean ± SD)		34.69 ±10.28	33.68 ±10.35	0.582
Gender	Male	61 (87.1%)	49 (81.7%)	0.468
	Female	9 (12.9%)	11 (18.3%)	
BMI (mean ± SD)		20.62±4.2	19.62±3.2	0.24

Table 2: Surgical Operation Related Data Distribution of the Involved Patients.

Variables		Conventional Ligation Technique No. (%)	LigaSure™ Technique No. (%)	P-Value
Hospitalization period (days) (mean ± SD)		8.09 ± 0.65	8.03 ± 0.73	0.67
Operative time (minutes) (mean ± SD)		155.57 ± 17.9	140.33 ± 17.07	< 0.05
Intra-operative complications	No	66 (94.3%)	58 (96.7%)	0.686
	Yes	4 (5.7%)	2 (3.3%)	
Surgery site infection	No	68 (97.1%)	59 (98.3%)	0.09
	Yes	2 (2.9%)	1 (1.7%)	
Recurrent lymphocele		3 (4.28%)	0 (0%)	0.02
Lymphocele development	No	58 (82.9%)	56 (93.3%)	0. 02
	Yes	12 (17.1%)	4 (6.7%)	
Volume of lymphocele (ml) (mean ± SD).		974.57 ± 178.39	493.83 ± 163.65	< 0.05
Duration of drainage (days) (mean ± SD)		8.38 ± 3.3	4.6 ± 1.4	0.03

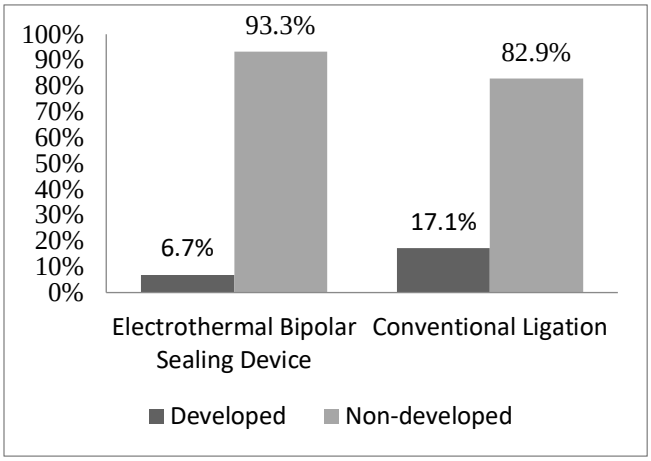

Figure 2. Incidence of Lymphocele Occurrence Among the Compared Groups.

DISCUSSION

The electrothermal bipolar sealing device is a new technology introduced by Covidien to overcome the various challenges present in surgeries. The electrothermal bipolar sealing device has the highest burst pressure and fastest sealing time. It was also the highest-rated technique overall, compared to other techniques, such as sutures and clips,[38] in terms of the significant reduction in procedure time,[39] blood loss,[40] perioperative blood transfusion,[41] and length of hospital stay after urologic surgery.[39] However, its action and role in reducing lymphocele development after renal transplantation is still a challenge.

There are some well-known complications after kidney transplantation, and one of the most common complications is lymphocele. Recently, it has been detected more often due to ultrasound admission as a part of the follow-up protocol in kidney transplantation. Such complications can emerge due to several reasons, including the kind of surgical technique used, and to this date, there are no surgical techniques that can prevent the development of lymphocele.[42]

Most studies using electrothermal bipolar sealing device technology in renal transplant surgery have been conducted using various kinds of laparoscopic techniques, some of which have been experimental. The technology was found to be superior to others in terms of sealing time, burst pressure, thermal spread, intraoperative blood loss, operative time, conversion rate, and postoperative course, mostly in the case of donor nephrectomy.[37, 38,43] It was superior in open surgeries as well.[41,44] Although only a few studies explore its role and performance in renal transplantation surgery in lymphatic dissection, many studies investigate the utility of the electrothermal bipolar sealing devices in post-surgical lymphatic complication reduction, especially in breast surgeries.[44]

The main aim of the current study is to determine which techniques excel at reducing the incidence of lymphoceles following renal transplantation. A study by Seki et al. demonstrated results similar to this study—a bipolar vessel sealing system (BVSS; small jaw) was more effective compared to the conventional methods in axillary dissection.[45]

Operative time was significantly less in the electrothermal bipolar sealing device-using group. This result is dissimilar to that of the

study by Tsuda et al., where the operative time in the tie ligation group and the Electro thermal bipolar vessels sealing system device (EBVSD) group was 311 ± 92 and 340 ± 95 minutes, respectively.[46]

There was also a non-significant difference regarding the surgery site infection with a value of 2.9% in the conventional ligation group combared to 1.7% in the Ligasure group. Similarly, Simforoosh et al. reported that non-significant differences regarding the site of infection were found between the groups in their study, with one patient in the silk ligature group having a site infection. The bipolar cautery group did not register any infection.[47]

The present study also indicated a significant reduction in the rate of lymphoceles development among electrothermal bipolar sealing device group compared to the conventional group (p = 0.02). Likewise, Lucan et al. observed a significant decrease in the lymphocele development in 4.16% of the electrothermal bipolar sealing device group and the development of this complication in 20.83% of the conventional ligation group (p = 0.04).[42] Simforoosh also did not find any case of lymphocele formation when bipolar electrocoagulation was used instead of clips for sealing the lymphatic vessels during laparoscopic retroperitoneal lymph node dissection (LRPLND) [(48)].A study by Farouk et al. did not find any case of lymphoceles in the electrocoagulation group compared to 2.2% in the suture ligation group.[49] Atray et al. also reported lymphoceles in 26% of renal transplant recipients.[50] Tsuda reported a significant reduction in the incidence of lymphoceles among the EBVSD group in comparison to the tie ligation group (33 (18%) and 75 (56%), respectively).[46]

The current study also pointed to a significant difference between the conventional ligation technique and the electrothermal bipolar sealing device technique in the lymphatic drainage volume. This finding is similar to that of Lucan et al. who reported a significant decrease in the lymphatic drainage volume when an electrothermal bipolar sealing device was used, compared to conventional techniques: 131.46 ± 54.2 ml vs. 99.8 ± 39.87 ml, p = 0.02.[42]

Simforoosh et al. also reported that none of their transperitoneal LPRLND patients experienced prolonged lymphatic drainage or lymphocele formation during the follow-up period.[48]

CONCLUSION

The cautery of bipolar vessels was found to be extremely beneficial when compared to conventional ligation in lymphatic dissections; it led to a reduction in the risk of developing lymphoceles, in addition to being superior in terms of feasibility, safety, and easy performance.

RECOMMENDATIONS

1. Conduct a study with a larger sample.
2. Evaluate how the electrothermal bipolar sealing device can be used to decrease the risk of post-renal transplantation lymphocele development.
3. Compare the electrothermal bipolar sealing device with a harmonic device.

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