Original Article

A comparison of renal vascular control techniques during laparoscopic nephrectomy

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Abstract

Background: We compared outcomes of *en bloc* stapler ligation of the renal hilum with separate Hem-o-lok polymer clip ligation of the renal vessels during laparoscopic nephrectomy (LN).

Materials and Methods: Clinical data of patients who underwent LN for renal surgery from January 2009 to December 2015 were collected. Operation time, estimated blood loss, device malfunction rate, open conversion rate, complications and arteriovenous fistula (AVF) formation were evaluated.

Results: *En bloc* stapler ligation and separate clip ligation were performed in 64 and 66 patients, respectively. The mean operative time was 106.8 ± 20.8 min (range: 70–165) in the *en bloc* stapler ligation group compared with 112.5 ± 24.1 min (range: 70–180) in the separate clip ligation group ($P = 0.147$). The mean estimated blood loss was 141.4 ± 124.1 ml (range: 25–600) in the *en bloc* stapler ligation group compared with 147.6 ± 112.4 ml (range: 25–450) in the separate clip ligation group ($P = 0.767$). The open conversion was required in 7/64 (10.9%) and 2/66 (3.0%) patients in the *en bloc* stapler ligation and separate clip ligation groups, respectively ($P = 0.093$). Stapler device malfunction occurred in 6 patients (9.3%). There were no statistically significant differences in overall complications ($P = 0.726$), minor (Grade 1–2) complications ($P = 0.698$) and major (Grade 3–5) complications ($P = 0.716$). No patient was diagnosed with AVF formation during overall median 33-month (interquartile range: 30, range: 24–96) follow-up.

Conclusions: *En bloc* stapler ligation of the renal hilum during nephrectomy is an effective and safe technique. Although there is no reported AVF formation with *en bloc* stapler ligation of the renal hilum, longer follow-up is necessary.

Keywords: *En bloc*, Hem-o-lok clip, laparoscopic nephrectomy, malfunction, stapler

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Submitted: 15-Dec-2019, **Revised:** 07-Feb-2020, **Accepted:** 10-Feb-2020, **Published:** 16-Mar-2020

INTRODUCTION

Laparoscopic nephrectomy (LN) is the most widely recognised urologic laparoscopic procedure.[1,2] Reduced morbidity, lower post-operative analgesic requirement, early recovery and faster return to daily activities are the major benefits of the laparoscopic approach. Further, LN is the first treatment option for all indications of kidney removal.[3] The standard technique for LN is similar to open surgery. Therefore, the control of the renal hilum is the most important step in LN. Dissection of the renal hilum during the LN requires the laparoscopic experience and skills that may not be developed in the learning curve or novice laparoscopic surgeon.[4] In these

Access this article online	
Quick Response Code:	Website: www.journalofmas.com
	DOI: 10.4103/jmas.JMAS_287_19

How to cite this article: Koc G, Ekin GR, Ergani B, Ilbey YO. A comparison of renal vascular control techniques during laparoscopic nephrectomy. J Min Access Surg 2021;17:192-6.

situations, separation of the renal hilum can lead to massive haemorrhage due to vessel injury.

Many techniques have been depicted for ligation of the renal vessels. Currently, there are two different approaches used by most urologists to close the renal vessels.[3,5-7] In the first approach, the renal artery and vein are separated from each other and ligated with Hem-o-lok polymer clips or endovascular staples.[5-7] In the other approach, the renal artery and vein are ligated *en bloc* with endovascular staples.[5,8] *En bloc* ligation of the renal vessels entails important risks, such as development of arteriovenous fistula (AVF) because of the nearness of the renal artery and vein remnants, substantial blood loss and open conversion due to mechanical device malfunction.[7,9-11] On the other hand, separate ligation of the renal vessels is a time-consuming process and carries the risk of renal vessel injury, causing significant blood loss and open conversion.[12,13] Furthermore, AVF formation can occur in the separate ligation of the renal vessels, as well as from other pathological processes, such as inadequate ligation of the renal artery and vein, difference sutures, foreign body reaction, post-operative infection and recurrent renal tumour.[7,14]

In this study, we compared outcomes of *en bloc* stapler ligation of the renal hilum with separate Hem-o-lok polymer clip ligation of the renal artery and vein during LN.

MATERIALS AND METHODS

The present study protocol was reviewed and approved by the Institutional Review Board of our hospital. Informed consent was obtained by all participants when they were enrolled. After Institutional Review Board approval, clinical data of patients who underwent LN for renal mass between January 2009 and December 2015 were collected. Patients with <2-year follow-up and patients who had missing data were excluded from the study. Benign and malignant reasons, all LN were included in the study.

All surgical procedures were done by an experienced surgeon through a transperitoneal approach using 3 or 4 ports and 30° optics. First, the colon was mobilised and separated from the Gerota's fascia. The ureter was determined and separated, and then, the renal hilum was identified by blunt and sharp dissections. *En bloc* stapler ligation of the renal hilum was implemented by identifying the renal hilum without separating the surrounding tissues. The renal hilum was stapled using an endovascular gastrointestinal anastomosis stapler (45-mm staple line, 2.5-mm staple length) in the *en bloc* stapler ligation group.

In the separate Hem-o-lok polymer clip ligation group, the renal hilum was dissected. The renal artery and vein were dissected and separately ligated with polymer ligation clips (10-mm Weck Hem-o-lok clips [Weck, Research Triangle Park, NC, i.e., Hem-o-lok clips]). The method is chosen by a surgeon's preference. In both the groups, after the renal vessels were ligated, dissection of the kidney was continued superiorly and posteriorly to the upper pole. Finally, the ureter was ligated, and then, the specimen was removed from the abdomen through a separate incision.

Collected data were divided into pre-operative, intraoperative and post-operative. Pre-operative data included patient's age, sex, operation side and American Society of Anesthesiologists (ASA) score. Intraoperative data included operation time, type of renal vessel ligation, estimated blood loss, rate of haemorrhage due to dissection of the renal vessels, intraoperative blood transfusion, device malfunction rate, open conversion rate and intraoperative complications. Post-operative data included complications, length of follow-up, outpatient follow-up which include medical history, vital signs and physical examination, complete blood count, renal function and blood chemistry tests, abdominal computed tomography (CT) and evaluation of AVF formation. AVF formation was evaluated with measurement of blood pressure and heart rate, diastolic hypertension, abdominal auscultation, diagnosis of congestive heart failure (CHF) after LN, features of CHF and suspicious findings on the follow-up abdominal CT scan. Complications were reported according to the Clavien classification system.[15]

The main outcome was the comparison of overall complication rate between the groups, especially AVF formation. The secondary outcomes were the rate of stapler device malfunction, haemorrhage and open conversion due to dissection of the renal vessels, operation time and estimated blood loss.

Statistical analyses were performed with SPSS version 22.0 for Windows (IBM, NY, USA). Numerical variables were summarised with mean ± standard deviation and categorical variables with frequency and percentage. The significance of differences among the groups was assessed by Student's t-test, and analysis of categorical variables was examined by Chi-square test. $P < 0.05$ was considered statistical significance.

RESULTS

Between January 2009 and December 2015, 156 patients were treated by LN at our institution. Twenty-one patients

with follow-up shorter than 2 years, and five patients who had missing data, were excluded from the study. The final study population consisted of 130 patients. Patient characteristics and outcomes are presented in Table 1.

En bloc stapler ligation and separate clip ligation were performed in 64 and 66 patients, respectively. There were no statistically significant differences in pre-operative characteristics (age, gender, ASA score and operative site) between the two groups. Operative characteristics were better in the *en bloc* stapler ligation group, but they were statistically insignificant. The mean operative time was 106.8 ± 20.8 min (range: 70–165) in the *en bloc* stapler ligation group compared with 112.5 ± 24.1 min (range: 70–180) in the separate clip ligation group ($P = 0.147$). The mean estimated blood loss was 141.4 ± 124.1 ml (range: 25–600) in the *en bloc* stapler ligation group compared with 147.6 ± 112.4 ml (range 25–450) in the separate clip ligation group ($P = 0.767$). Seven patients (10.9%) in the *en bloc* stapling group required a blood transfusion compared with 6 patients (9.1%) in the separate clip group ($P = 0.726$).

The open conversion was required in 7/64 (10.9%) and 2/66 (3.0%) patients in the *en bloc* stapler ligation and separate clip ligation groups, respectively ($P = 0.093$). Of 7 patients in the *en bloc* stapler ligation group, three cases presented due to an inadequate vascular control with an endovascular stapler (stapler malfunction), two due to an endovascular stapler not releasing, one due to bleeding from an aberrant artery and one due to failure to kidney dissection due to massive perirenal inflammation. In the separate clip ligation group, 2 patients required the open conversion due to bleeding from the renal vein during the renal hilum dissection. In the *en bloc* stapler ligation group, stapler device malfunction occurred in 6 patients (9.3%). Five of 6 patients (83.3%) required the open conversion. In the separate clip ligation group, bleeding from the renal vessels during the renal hilum dissection occurred in 4 patients (6.0%). Two of 4 patients (50.0%) required the open conversion. There was no surgical margin positivity at the ligated renal hilum in both the groups.

Complications according to the Clavien classification system are presented in Table 2. There were no statistically significant differences in overall complications ($P = 0.726$), minor (Grade 1–2) complications ($P = 0.698$) and major (Grade 3–5) complications ($P = 0.716$) between the two groups.

The overall median follow-up was 33 (interquartile range [IQR] 30, range 24–96) months. The *en bloc* stapling and separate clip groups were followed for a median duration of 30 (IQR 24, range 24–96) and 36 (IQR 33, range 24–96) months, respectively. At follow-up, no patient developed AVF formation upon medical history, physical examination and abdominal CT.

Table 1: Comparison of patient characteristics and outcomes among the *en bloc* stapling and separate clip groups

	En bloc stapling	Separate clip	*P*
Number patients (*n*)	64	66	
Mean±SD age (range) (year)	56.89±12.11	55.59±11.34	0.529
Number of gender (%)			
Male	30 (46.9)	24 (36.4)	0.224
Female	34 (53.1)	42 (63.6)	
Median ASA score (IQR)	2 (1)	2 (2)	0.380
Number of operation site (%)			
Right	33 (51.6)	28 (42.4)	0.297
Left	31 (48.4)	38 (57.6)	
Mean±SD operative blood loss (range) (ml)	141.4±124.1 (25-600)	147.6±112.4 (25-450)	0.767
Mean±SD operative time (range) (min)	106.8±20.8 (70-165)	112.5±24.1 (70-180)	0.147
Number of blood transfusion (%)	7 (10.9)	6 (9.1)	0.726
Number of conversion to open surgery (%)	7 (10.9)	2 (3.0)	0.093
Number of overall complications (%)	12 (18.7)	14 (21.2)	0.726
Median length of follow-up (IQR) (months)	30 (24)	36 (33)	0.526
Number of AVF formation (%)	0	0	

SD: Standard deviation, ASA: American Society of Anesthesiologists, IQR: Interquartile range, AVF: Arteriovenous fistula

Table 2: Complications according to the Clavien classification system among the *en bloc* stapling and separate clip groups

	En bloc stapling	Separate clip	*P*
Number of patients (*n*)	12	14	0.726
Number of complications (*n*)	15	15	0.871
Number of minor complications (Grade 1-2)	11	12	0.698
Number of major complications (Grade 3-5)	4	3	0.716
Number of Grade 1 complications (*n*)	4	3	
Number of Grade 2 complications (*n*)	7	9	
Number of Grade 3 complications (*n*)	3	2	
Number of Grade 4 complications (*n*)	1	1	
Number of Grade 5 complications (*n*)	-	-	

DISCUSSION

We evaluated outcomes of *en bloc* stapler ligation of the renal hilum with separate Hem-o-lok polymer clip ligation of the renal artery and vein during LN in this study. We found that *en bloc* stapler ligation of the renal hilum during LN had reduced operative time, decreased estimated blood loss and increased rate of open conversion compared with separate Hem-o-lok polymer clip ligation

of the renal vessels. However, these findings were statistically insignificant. We demonstrated that stapler device malfunction occurred in 9.3% of the patients. Of these, 83.3% were required the open conversion. Further, bleeding from the renal vessels during the renal hilum dissection occurred in 6.0% of the patients in the separate clip ligation group. Of these, 50.0% were required the open conversion. However, no statistically significant difference was found in terms of complication in both the groups. At overall median 33-month follow-up, no patient developed AVF formation in either group.

Laparoscopic surgery is increasingly performed by urologists. LN is the most common urologic laparoscopic procedure.[1,2] Dissection and ligation of the renal hilum is the most important step. Although many techniques have been described for ligation of the renal vessels, most widely accepted ligation techniques are endovascular stapler devices and Hem-o-lok polymer ligation clips.[3,5-7] Each one of these has its own advantages and disadvantages.

The renal hilum contains the renal vessels and fibrolymphatic tissue. A careful and meticulous dissection of the renal hilum during LN required. Complete dissection of the renal vessels is beneficial to avoid inadequate locking mechanism closure and risk of clip slippage.[3] Therefore, separate Hem-o-lok polymer clip ligation of the renal vessels is a time-consuming process and carries the risk of renal vessel injury, causing significant blood loss and open conversion.[12,13] Although a few studies were found that the estimated blood loss and open conversion is higher in the separate clip ligation when compared to *en bloc* stapler, it is controversial.[3,16] In a recent meta-analysis, there were no significant differences in the estimated blood loss between the *en bloc* stapler ligation and separate clip ligation groups.[7] In our study, separate clip ligation has been no statistically significant difference in terms of estimated blood loss and open conversion.

Endovascular stapler device is one of the safest ligation techniques of renal vessels. *En bloc* stapler ligation of the renal hilum requires much less dissection of the renal hilum than separate ligation of renal vessels.[12] Therefore, the risk of renal vessel injury is reduced in *en bloc* stapling. *En bloc* stapler ligation is suitable for almost all patients, especially fibrotic renal hilum, many vascular branches or early vascular divisions.[12] In a meta-analysis, *en bloc* stapler ligation showed significantly decreased operative time (from 122 to 78 min) compared to traditional separate ligation.[7] However, there were no significant differences in the estimated blood loss and complication rate.[7] In our study, we found no significant difference in the operative time, estimated blood loss and complication rate between the *en bloc* stapler ligation and separate clip ligation groups. As all surgical procedures were done by an experienced surgeon in our study, we may have been found no significant differences in the operative time, estimated blood loss and complication rate between the groups. Despite these advantages, malfunction of stapler device can occur. As a result, it causes complications such as bleeding and open conversion in particular.[9-11] In literature, the overall open conversion rate in the *en bloc* stapler ligation procedures is 0%–4.6%.[3,5,7,12,16,17] We found that the open conversion rate in the *en bloc* stapler ligation group is 10.9% ($n = 7$). Of these 7 patients, five presented due to stapler device malfunction. The malfunction rate of vascular stapler device is up to 1.7%.[9,11] If improper stapling techniques were excluded, the rate of device malfunction reduced <0.5%.[11] However, endovascular stapler device malfunction is not negligible. In our study, we found that stapler device malfunction occurred in 9.3% of the patients ($n = 6$), and of these, 83.3% ($n = 5$) required the open conversion. In our study, we used stapler devices from many different brands. Therefore, the rate of stapler device malfunction in our study may have been higher than the other studies. Despite our high device malfunction rate, there is no demonstrated association between *en bloc* stapler ligation and increased risk for stapler malfunction.[12] Indeed, most of the reported cases of stapler malfunction occurred during separate stapling of the renal vein and not during *en bloc* stapler ligation.[9,11,12]

AVF formation after nephrectomy is a rare and serious complication. It is characterised by side pain, pulsating mass, abdominal bruit, increased diastolic blood pressure and heart rate, cardiomegaly and CHF.[5,7,16] Historically, *en bloc* ligation of the renal hilum has been associated with AVF formation.[7,12] Almost half of the AVF formation is associated with infection in historical studies.[7,18] Other risk factors of AVF formation are *en bloc* ligation of the renal hilum, foreign body reaction, braided sutures for renal hilum ligation, inadequate ligation of the renal artery and vein, transfixation sutures and recurrent renal tumour.[7,12,14] After surgical and technological improvements, AVF formation was evaluated by contemporary studies.[3-8,12-14] To our knowledge, there is no study showing the association between *en bloc* ligation of the renal hilum and AVF formation. However, average time from nephrectomy to AVF formation may be another risk factor. All contemporary studies are shorter follow-up compared to historical studies in which follow-up was between 4 and 20 years.[7,12] Compared to other contemporary studies, our study in which follow-up period is up to 96 months is one of the longest follow-up studies. Nevertheless, no

patient was diagnosed with AVF formation in this study, as in other contemporary studies.

The current study has several limitations. First, it was a retrospective study with an inherent potential for bias. The second limitation is the relatively small sample size and short follow-up period to determine whether there is any difference in fistula formation. Finally, stapler devices from many different brands were used and all procedures were performed by an experienced single surgeon. Therefore, a multicentre randomised study is required. Both of them may have affected the perioperative outcomes.

CONCLUSIONS

En bloc stapler ligation of the renal hilum during LN is effective and safe. Its outcomes are comparable with separate polymer Hem-o-lok clip ligation of the renal vessels in terms of operative and post-operative features. Although there is no reported AVF formation with *en bloc* stapler ligation of the renal hilum, longer follow-up is necessary to ensure that AVF formation does not occur in the late post-operative period.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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