Reducing Pseudoaneurysm and Urine Leak After Robotic Partial Nephrectomy: Results Using the Early Unclamping Technique

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OBJECTIVE To present our experience using the early unclamping technique for robotic partial nephrectomy with particular attention to delayed complications, namely pseudoaneurysm and urine leak. We hypothesized that early hilar unclamping allows for improved control of end arteries and renorrhaphy after tumor resection, reducing overall delayed complications after partial nephrectomy with no increased risk of blood transfusion.

METHODS This single institution retrospective review of a prospectively maintained database includes patients undergoing robotic partial nephrectomy with early unclamping technique for presumed renal malignancy between 2009 and 2018. Patient demographics and perioperative parameters are described, particularly rates of pseudoaneurysm and urine leak. Results are compared to previously published partial nephrectomy studies using various clamping and renorrhaphy techniques.

RESULTS Four hundred and sixty three patients were included in the study. Mean operative time and warm ischemia time were 186 and 14.7 minutes, respectively. Mean estimated blood loss was 242 cc. Thirty-day postoperative complication rate was 14.7%, with 88% of these Clavien I-II. Urine leak occurred in 1 patient (0.2%) undergoing a simultaneous partial nephrectomy and pyelothitotomy for partial staghorn stone. Postoperative transfusion rate was 1.33% and our pseudoaneurysm rate was 0%.

CONCLUSION The early unclamping technique for robotic partial nephrectomy is reliable and safe, with low pseudoaneurysm and urine leak rates which compare favorably to other published techniques. UROLOGY 132: 130–135, 2019. © 2019 Elsevier Inc.

Nephron sparing surgery is a common treatment for small renal masses. However, postoperative complications have been shown to be higher in partial nephrectomy than in radical nephrectomy.[1] Complications unique to partial nephrectomy include kidney parenchymal bleeding requiring transfusion, renal pseudoaneurysm, and urine leak. Pseudoaneurysm can present in a delayed fashion and may require blood transfusions and additional procedures including angiography and embolization. Urine leak may require ureteral stenting and/or percutaneous drainage.

Various renorrhaphy techniques with or without hemostatic agents have been used to minimize these complications, including standard resection with bolsters and renorrhaphy while "on-clamp," early unclamping (EU) of the renal hilum after 1 layer of sutures, "off-clamp" resection and renorrhaphy, and the "zero ischemia" technique which involves selective control of tertiary renal vessels.[2,3] Some surgeons have eliminated the use of bolsters and hemostatic agents in an effort to improve delayed postoperative bleeding, while others have transitioned from a standard to EU or off-clamp technique to improve ischemia time.[4] Criticisms of off-clamp and selective clamping technique include poor visualization in off-clamp partial nephrectomy and long case time/high degree of difficulty for selective clamping of tertiary renal vessels[5] without any proven long-term renal functional benefit.[6]

The EU technique removes the vascular clamps just after placement of 1 running suture at the base of the resection defect and allows for visualization of any additional arterial or large venous sinuses that might require control prior to complete closure of the renal cortical edges (renorrhaphy). This technique may offer a combination of short warm ischemia time (WIT), excellent visualization during resection, and reproducibility by most

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robotic surgeons. We hypothesize that EU allows for improved control of end arteries and renorrhaphy after tumor resection, reducing overall delayed complications with no increased risk of blood transfusion. Although the EU technique may be widely used by experienced robotic surgeons, it has not been well described in larger series. In this study, we describe, what is to our knowledge, the largest published experience with the EU technique and compare our rates of pseudoaneurysm and urine leak with other published series.

METHODS

This retrospective review of a prospectively maintained database includes patients undergoing EU robotic partial nephrectomy for renal masses from August 2009 to October 2018. Surgery was performed by 2 fellowship-trained urologists at a single academic institution, where all cases involved residents and/or fellows. We excluded surgeries that were performed off clamp, or converted to robotic radical nephrectomy, open partial nephrectomy, or open radical nephrectomy.

Patient baseline information, perioperative characteristics, intraoperative and postoperative factors including blood loss, transfusion rate, complications, and need for further intervention were obtained. Means and standard deviations were calculated, and ranges were reported when appropriate.

EU Surgical Technique

After mobilization of the kidney and renal hilum, the renal artery is clamped using laparoscopic bulldog clamps. Venous occlusion is performed at the discretion of the surgeon. Pneumoperitoneal pressure is increased to 20 mm Hg during sharp tumor resection. Bipolar cautery is used for coagulation of obvious segmental arteries encountered during resection. After the tumor is excised, a single running 2-0 or 3-0 polyglyconate v-lock V20 suture (Covidien Inc) is used to oversew the base of the resection defect, occluding any obvious end arteries or large venous sinuses, as well as closing any visualized collecting system violations. Care is taken during this suture to only include renal sinus tissue/collecting system and medullary tissue and avoid deep throws that could occlude major segmental vessels. Bulldog clamps are immediately removed prior to any additional suturing. Any pulsatile arterial bleeding or brisk venous bleeding is controlled with figure-of-eight sutures using a 3-0 v-loc V20 suture. The cortical edges are then reapproximated using a standard sliding clip renorrhaphy technique: 0-Vicryl suture on a CT-1 needle (Ethicon Inc), with a Hem-o-lok clip (Teleflex Medical) and LapraTy in an interrupted fashion.[7] Bolsters or hemostatic agents were never applied; however, for larger renal bed defects, a pedicalized flap of perirenal fat may be used as an "autologous bolster" and secured with the sliding clip renorrhaphy vicryl sutures. An experienced bedside assistant (senior urology resident or fellow) was present for the majority, but not all, of these cases.

RESULTS

A total of 490 patients underwent robot-assisted partial nephrectomy at our institution between August 2009 and October 2018 and have follow-up of at least 30 days. Of these, 7 patients (1.4%) were converted to radical nephrectomy for oncologic reasons and were excluded from this analysis. Two patients were converted from a robotic partial nephrectomy to an open radical nephrectomy. In the first patient, the mass initially appeared cystic on imaging, but intraoperative findings revealed a large solid mass that was adherent to the pancreas. In the second patient, there was a propagating tear in the renal vein which necessitated open surgery and a radical nephrectomy. Two patients were converted to open partial nephrectomy. The first patient had significant intra-abdominal adhesions. The second conversion was an 8 cm tumor within a horseshoe kidney. Additionally, 16 patients underwent off-clamp partial nephrectomy and were excluded. These tumors in general were exophytic and smaller or on a solitary kidneys. Therefore, a total of 463 patients underwent EU and were included in the study cohort.

The mean age of patients was 56.8 years, 62.6% were men, and 43.8% were considered obese with BMI >30. Mean tumor size was 3.1 cm (Table 1). The majority of tumors (63.3%) were considered intermediate difficulty with a RENAL nephrometry score of 7-9.[8]

Mean operative time and WIT were 186 and less than 15 minutes, respectively (Table 1). WIT exceeding 25 minutes occurred in 18 (3.9%) cases. Mean estimated blood loss was 242 cc. The patient with the highest blood loss of 1600 cc had several arterial bleeders after EU that were difficult to suture ligate and required reclamping to improve visualization. This patient did not require intraoperative or postoperative blood transfusion. Four patients (0.9%) required intraoperative transfusion. One patient suffered a laceration of the renal vein, and the other a laceration of a lower pole renal artery. The third case was unremarkable, but a transfusion was given for hypotension during the surgery. The last patient requiring transfusion was noted to have brisk arterial bleeding at various portions of the resection site.

Thirty day postoperative complication rate was 14.7%; 88% of these were minor complications (Clavien grade I-II) (Table 2). Postoperative transfusion rate was 1.3% and no pseudoaneurysms

Table 1. Patient characteristics and intraoperative parameters

	Early unclamping *n* = 463
Sex - Male (*n*, %) - Female (*n*, %)	Male: 290 (62.6%) Female: 173 (37.4%)
Mean age (y)	56.8 (SD: 12.0, range: 19-88)
BMI - <25 - 25-30 ->30	Mean: 29.7 (SD: 6.2) - <25: 101 (21.8%) - 25-30: 159 (34.3%) - >30: 203 (43.8%)
Mean tumor size (cm)	3.1 (SD: 1.4, range: 0.6-9.9)
RENAL score - 4-6 - 7-9 - 10-12	Mean 7.2 (SD: 1.7, range 4-11) 4-6: 142 (30.7%) 7-9: 293 (63.3%) 10-12: 28 (6.0%)
CCI - 0-2 - 3-4 - 5+	Mean: 2.7 (SD: 2.0, range 0-10) 0-2: 236 (51.1%) 3-4: 158 (34.0%) 5+: 69 (14.9%)
Mean operative time (min)	186.0 (SD: 49.7, range: 72-455)
Mean WIT (min)	14.7 (SD: 5.3, range: 5-45)
Mean EBL (cc)	242 (SD: 230, range: 10-1600)
Intraoperative complications (n, %)	8 (1.7%)
Intraoperative transfusion (n, %)	4 (0.9%)

Table 2. Postoperative outcomes

	Early Unclamping
Mean LOS (d)	2.4 (range: 1-13)
Readmission rate (*n*, %)	7 (1.5%)
Overall post-op complications (*n*, %)	68 (14.7%)
Clavien grading (*n*, %)	Minor: 60 (88.2%)
- Minor (1-2)	Major: 8 (11.8%)
- Major (3-5)	
Post-op transfusion (*n*, %)	6 (1.3%)
- Mean units transfused	2.0 (range 1-3)
Urine leak (*n*, %)	1 (0.2%)
Pseudoaneurysm (*n*, %)	0 (0)
Positive margin status (*n*, %)	15 (3.2%)

occurred. One patient developed symptomatic postoperative blood loss anemia from a trocar injury to an epigastric vessel, and required embolization. Another patient required transfusion and embolization for a retroperitoneal hematoma. Urine leak occurred in 1 patient (0.2%) who had a history of stage IV non-Hodgkins lymphoma on chronic Rituximab immunotherapy and underwent simultaneous robotic partial nephrectomy with pyelolithotomy for a partial staghorn calculus. She required stenting and percutaneous drainage of a urinoma. All other grade III complications were unrelated to pseudoaneurysm and urine leak.

Readmission within 30 days occurred in 7 patients (1.2%). One patient presented to the ER for flank pain. She was hemodynamically stable and underwent negative diagnostic angiography. She was found to be anemic and thus received a transfusion. Other readmissions were not due to pseudoaneurysm or urine leak.

Our positive margin rate of 3.2% was comparable to the series of SU studies listed in Table 3 (range 0.8%-10%), with the exception of the Kaouk et al. Positive margins could be secondary to technical error by surgeon in dissecting near tumor, poor visualization during tumor excision from brisk bleeding, inadequate bedside assistance and exposure, more aggressive pathology or endophytic or complex tumors in our series that are enucleated at their base.

Table 3 compares perioperative factors in our series of EU during robotic partial nephrectomy with previously published data of standard unclamping and off clamp renorrhaphy in either open or laparoscopic approaches.

DISCUSSION

Urine leak and pseudoaneurysm are known complications after partial nephrectomy that may require secondary procedures. Pseudoaneurysm rates range from 0.8% to 5.6%[9-15] while urine leak rates range from 0.6% to 3.6%.[12,13,16,17] Symptomatic pseudoaneurysm can be life threatening, often requiring angiography and selective embolization.[18] Urine leak can require ureteral stent placement and/or percutaneous drainage.[16] Despite variations in renorrhaphy techniques and use of hemostatic agents, these complications still persist. EU was initially described laparoscopically as a technique primarily used to minimize WIT.[19] Subsequent studies evaluating the safety of laparoscopic and robotic EU demonstrated benefits of decreased WIT without significant increased bleeding or complications,[17,20-23] and perhaps a lower incidence of pseudoaneurysm.[22]

Although these earlier reports showed feasibility, few studies have thoroughly investigated EU using the robot-assisted approach.[11,21,22,24] To our knowledge, we report the largest evaluation of robotic EU with special attention to complications, specifically delayed bleeding episodes, pseudoaneurysm, and urine leak. The complication rate, specifically our low rate of delayed bleeding, pseudoaneurysm and urine leaks in this EU series compares favorably to other partial nephrectomy series using standard techniques. For example, the largest study to focus specifically on complications after standard robotic partial nephrectomy was a multicenter study by Tanagho et al. They evaluated 886 patients from 5 academic centers after robotic partial nephrectomy, most of whom had standard clamping technique demonstrating a 4.6% perioperative transfusion rate and approximately 1% pseudoaneurysm and 1% urine leak rates.[25] A subsequent analysis by the same authors of 1800 patients found urine leak to be 0.78%.[16] Additionally, Garisto et al's recent series of 203 complex robotic partial nephrectomies demonstrated a delayed bleeding risk of 3.4%, pseudoaneurysm risk requiring embolism in 1%, and a urine leak risk of 1.5%.[11] We did experience 1 urine leak in a complex patient undergoing simultaneous stone removal while on chronic immunotherapy. We suspect our low delayed complication rate is a result of improved visualization and control of active bleeding following unclamping of the renal hilum (but prior to complete closure of the renal parenchyma). Psuedoaneurysms are thought to arise from an arterial sidewall injury that is initially controlled. These usually resolve, however, in some cases, bleeding occurs with increasing hypertension, or after a clot degrades or mobilizes. Bleeding then enters the surrounding tissue, specifically connecting with the collecting system in the case of pseudoaneurysm.[9] Additional suturing during renorrhaphy and oversewing of arterial bleeders could potentiate additional vessel injury. We attribute our low pseudoaneurysm rate to shallow and accurate placement of figure-of-eight sutures to control arterial bleeders if present as well as closure of dead space within the renorrhaphy bed, occasionally utilizing an autologous fat bolster for larger defects. Additionally, we strictly avoided the use of exogenous bolsters and all hemostatic agents which might "cover up" active bleeding or control bleeding through compression rather than suturing under direct vision. Although we did not specifically evaluate the utility of these agents in this study, our series does reinforce the notion that bolsters and hemostatic agents are unnecessary in routine cases.[4] Lastly, we routinely examine the renal bed under low pressure to identify significant bleeding that would have otherwise been masked by higher pneumoperitoneum. In regards to urine leak, other groups have evaluated and found some risk factors including tumor size, WIT, and hilar tumor location.[9] However as the rate of urine leakage after robotic partial nephrectomy (RPN) should be extremely low, these factors may have limited clinical utility.

Table 3. Comparison of current study of robotic partial nephrectomy with early unclamping (EU) compared to RPN with standard unclamping in those series reporting complications

	N	Clamp	WIT (min)	EBL (cc)	Perioperative Transfusion rate (%)	Pseudoaneurysm rate (%)	Urine Leak (%)	Overall Complication Rate (%)
Current study	463	EU	14.7	242	0.8	0	0.2	14.7
Garisto et al, 2018[12]	203	SU	28	200	3.0	1.0	1.5	28.1
*(only RENAL score >9)[12]								
Potretzke et al, 2016[17]	1791	SU	23.8	263	n/a	n/a	0.78	n/a
Tanagho et al, 2012[26]	886	SU, off clamp	20.3	191	4.6	1.1	1.1	15.5
Ficarra et al, 2012[13]	347	SU	18	100	3.7	1.4	0.6	15.3
Kaouk et al, 2011[15]	252	SU and EU	18.9	290	33.6	0.8	1.5	22.6
Scoll et al, 2010[14]	100	SU	25.5	127	3.0	1.0	1.0	12.0

One presumed drawback of EU is blood loss occurring after unclamping but prior to complete renorrhaphy. However, this was not observed in our experience; indeed, only 4 patients required intraoperative blood transfusions (0.9%). Moreover, the postoperative transfusion rate was reasonable at 1.3%. Only 2 cases of postoperative anemia required embolization, notably, of an actively bleeding epigastric artery and another for lumbar arteries that resulted in a retroperitoneal hematoma. Another patient underwent diagnostic angiography for symptomatic anemia which was negative for pseudoaneurysm. The remaining 3 patients were transfused for symptomatic blood loss anemia, but did not require procedures. Of note, 3 patients who required transfusions remained on perioperative aspirin 81 mg and Coumadin was later restarted in 2 of these patients.

Various renorrhaphy techniques have been described to reduce ischemia time and improve renal preservation. Zero ischemia partial nephrectomy is performed without hilar clamping and with occasional ligation of vessels with clips or sutures simultaneously during tumor dissection with or without controlled hypotension.[2,26,27] Pseudoaneurysms have not been reported in these studies likely due to real time control of bleeding vessels. Overall, transfusion rates were low and both short- and long-term renal function was preserved.[2,26,27] For unknown reasons urine leak seemed high early in the learning curve perhaps due to decreased visualization during renorrhaphy. Continued limitations of this technique include increased technical difficulty, higher blood loss during surgery, and poor visualization.[27] Moreover, this technique is often performed under controlled hypotension, which may not be suitable for patients with pre-existing cardiovascular comorbidities.

Super selective arterial clamping is also considered zero-ischemia as this approach eliminates global ischemia and controls vessels that directly supply the tumor.[28] Preoperative CT angiogram provides a roadmap for renal arterial dissection and when necessary, injection of intravenous indocyanine green fluorescence dye followed by super selective arterial clamping confirms devascularization of the tumor and immediate surrounding parenchyma.[28] This approach has been shown to preserve renal function at 6 months postoperatively, however data on pseudoaneurysm and urine leak have not been studied.[28] Although this superselective technique is elegant, it is technically very challenging and time consuming, even in experienced hands.[5] Desai et al compared superselective clamping to standard clamping of the renal artery and although change in estimated GFR slightly favored the superselective group, 3 of 58 patients undergoing superselective clamping had a urine leak.[5] Importantly, up to 20% of superselective cases required conversion to main arterial clamping.[28,29] In addition, the superselective clamping approach is not suitable for more lateral masses or those with a broad based or large contact surface area because various blood sources supply the tumor.[28]

Compared to other techniques, EU appears to have fewer limitations and has an acceptably low complication

profile, even when performed by less experienced surgeons.[21] The EU technique has been routinely performed by 2 surgeons at our institution over the past 12 years for essentially every robotic partial nephrectomy except those very exophytic tumors which have been resected "off clamp." We have shown that EU can be performed on virtually any tumor location and nephrometry score and allows for excellent visualization during resection and reconstruction, yet allows for a short WIT and an extremely low rate of delayed complications even early in a surgeon's learning curve. It does not require supplemental 3-D reconstructed vascular imaging with contrast or additional technology (ie, intravenous indocyanine green dye and required imaging) or hemostatic agents.

Limitations of this study include a single institution experience and the lack of randomization compared to standard hilar unclamping. Although our pseudoaneurysm rate and urine leak rates are very low, underreporting is a possibility if patients present to outside institutions with postoperative complications. Both of the surgeons in this study were experienced fellowship-trained robotic surgeons in an academic setting and results might not be applicable in all settings, however these results do represent all of the robotic partial nephrectomy cases performed at this hospital regardless of position in the learning curve. Future multi-institutional randomized studies could consider comparing standard and early hilar unclamping.

CONCLUSION

In our series of 463 patients undergoing EU robotic partial nephrectomy, we found a low rate of postoperative pseudoaneurysm and urine leak. Our complication rate compares favorably to prior published studies, demonstrating that EU is safe and technically feasible even for larger renal masses with complex nephrometry scores.

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EDITORIAL COMMENT

We commend the authors on the publication of this large series of robotic partial nephrectomy using the early unclamping technique. This retrospective study presents a single center experience of 463 patients over a 9-year period with an impressive cohort and range of tumor complexities. The manuscript pays special attention to operative, perioperative outcomes, and complications, specifically pseudoaneurysm and urine leak which are of particular concern after this procedure. Patients had a minimum follow-up time of 30 days, which should be adequate to detect pseudoaneurysm and urine leak. Though these complications are rare they typically present within this time frame. The authors hypothesize that early unclamping reduces rates of pseudoaneurysm by facilitating identification of arteries that otherwise may have been concealed by completing the renorrhaphy prior to unclamping.

Pseudoaneurysm occurs when an artery wall is injured and the vessel bleeds into a potential space. These lesions are weak, unstable, and have a potential for life-threatening hemorrhage that can be devastating if not recognized and managed urgently. Partial nephrectomy creates the perfect scenario for development of pseudoaneurysm by exposing vessels during tumor resection, likely on occasion creating sidewall branch arterial injuries, then rapidly reapproximating the renal parenchyma with fairly imprecise sutures. Every needle pass thrown to achieve immediate hemostasis is a potential source of arterial injury and delayed hemorrhage. Unanswered questions remain about pseudoaneurysms and their pathophysiology – why are they so rare? Why are they painful at presentation? Why do patients typically develop hematuria as the high pressure blood finds its way into the collecting system – is this a testament to the nature of the repair or directly related to the pathology of the complication?

Though this series detected no symptomatic pseudoaneurysms over their follow-up period, we would caution attributing this to the use of early unclamping technique. After all, once the clamps are released, suturing continues until hemostasis is assured, and one might even expect pseudoaneurysm rates to be higher, given more sutures are thrown in the defect compared to fully clamped renorrhaphy. There are a number of other factors that may have contributed to this favorable finding including the surgeons being fellowship trained, experienced assistants, and avoidance of bolsters, which could otherwise contribute to dead space when the bolster breaks down and a false sense of security. If we are interested in investigating pseudoaneurysm and urine leak rates, studies should ideally be randomized and patients should be screened for the outcome. However, since it would require over 5700 patients to detect a 50% reduction in this rare complication, perhaps our efforts are better spent elsewhere.

This study shows that early unclamping is safe in experienced hands with immediate and delayed complication rates that are comparable to standard methods. We look forward to seeing this group's data on long-term renal functional outcomes, which is the primary goal of reducing ischemic time.

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AUTHOR REPLY

We would like to thank the reviewers for their insightful comments. In our experience, we have reported low rates of pseudoaneurysm (PA) and urine leak after robotic partial nephrectomy utilizing the early unclamping (EU) technique. We agree that good surgical technique, experience of the surgeon and team, and elimination of bolsters are contributing factors that minimize complications. However in our opinion, the EU technique as described is the main difference here, not surgeon experience. The other series of partial nephrectomy discussed in our manuscript come from very accomplished surgeons, yet PA and urine leak still occurred, perhaps due to technique.

We also agree that the pathophysiology of PA is not completely understood. Vessels that bleed may favor the path of least resistance – the renorrhapy bed and any violated collecting system that has been inadequately repaired – causing blood to enter this space, resulting in hematuria. Whatever the cause, PA should be exceedingly rare using a properly performed EU approach, even early in one's experience. In our opinion, as discussed in the manuscript, direct control of arterial bleeding prior to renorrhaphy, and direct repair of the collecting system during suturing of the resection bed are the most important factors preventing PA formation and urine leak.

We also acknowledge that additional suturing during EU could theoretically cause further vessel injury. There is no evidence however that the EU technique uses more suturing than other techniques. In fact, there may be fewer overall sutures used as we do not oversew venous bleeders, only arterial bleeding. Furthermore, using the robotic bipolar device to control individual segmental vessels during resection may be helpful. In our opinion the EU approach is more straightforward than superselective clamping or "off-clamp" partial nephrectomy, allowing both for low complication rates and a short warm ischemia time (WIT). Although renal functional outcomes were not the focus of this particular study, shorter WIT is still an important modifiable risk factor for kidney injury during partial nephrectomy and efforts to safely minimize WIT should continue.

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