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Outcomes of partial nephrectomy in patients who meet percutaneous ablation criteria

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The James Buchanan Brady Urological Institute and Department of Urology The Johns Hopkins School of Medicine Marburg 134 1800 Orleans Street Baltimore, MD 21212 phone: 410 955 5000 harriskt16@ihmi.edu **Introduction** Treatment options for small renal masses include partial nephrectomy (PN), ablation and active surveillance. We sought to compare patients who met the criteria for percutaneous ablation but underwent robotic PN to the rest of our robotic PN cohort. This was done in order to detect any safety concerns and to define any risk factors that might contraindicate the use of robotic PN, an oncologically superior procedure, in patients who qualify for ablation.

Material and methods Our departmental renal mass registry was queried for patients who underwent robotic PN but also met criteria for percutaneous ablation. These were compared to the rest of the robotic PN cohort. Demographics, perioperative characteristics and recurrence data were compared.

Results Overall, 321 robotic PNs were identified. Of these, 26 (8.1%) met ablation criteria. Among patient characteristics, age and BMI were similar in both groups. Among operative characteristics, estimated blood loss (EBL) and operative time were similar. Warm ischemia time was significantly less for patients who met ablation criteria (14 *vs.* 17 minutes, p = 0.002). Mean tumor size was smaller for patients who met ablation criteria (2.3 *vs.* 2.7 cm, p = 0.012). Among postoperative characteristics, complications were similar overall and when present, stratified by Clavien grade.

Conclusions Robotic PN is a safe, effective treatment option for small renal masses, even in patients who meet ablation criteria. There were no recurrences in our cohort and the majority of complications were Clavien grade 1.

Key Words: partial nephrectomy opercutaneous ablation operation and small renal mass operation renal cell carcinoma

INTRODUCTION

Over the past few decades, there has been a marked increase in the incidence of small renal masses [1]. Increased utilization of cross-sectional imaging has changed the treatment paradigm for many renal masses. Now that computed tomography (CT) and magnetic resonance imaging (MRI) are detecting more small and asymptomatic renal masses, the management of renal masses is shifting toward less invasive and nephron sparing techniques. The treatment options for small renal masses include partial nephrectomy (PN), ablation and active surveillance. For most small masses under 7 cm, laparoscopic or robot–assisted partial nephrectomy (RAPN) has emerged as the standard of care [2]. Previous studies have demonstrated similar oncologic outcomes for PN and radical nephrectomy for T1 lesions [3]. In addition, laparoscopic and robotic PN have shown comparable morbidities and oncologic outcomes with faster convalescence than open procedures [4, 5]. Another minimally invasive approach to small renal masses is percutaneous cryo– or radio–frequency ablation. The ideal candidate for percutaneous ablation is a patient with a single mass or small (\leq 3 cm) masses that are completely exophytic and on the posterior aspect of the kidney [6]. Although ablation has been shown to confer equivalent perioperative

and renal functional outcomes to PN [7, 8], the risk of recurrence is significantly higher with this treatment approach [8, 9]. For example, a recent metaanalysis found that PN is associated with a 7.8% lower risk of recurrence at 20 months compared to ablation [10]. Nevertheless, many patients presenting with small renal tumors are elderly and/or have significant medical comorbidities [11] and thus are offered ablation as a temporizing approach. Unfortunately, however, the prediction of life expectancy remains an imperfect science and it is often difficult to know for which patient this less invasive approach is truly appropriate. If an oncologically superior procedure such as PN is found to be safe, then this would be the more appropriate treatment modality. We sought to compare patients who met the criteria for percutaneous ablation but underwent robotic PN to the rest of our robotic PN cohort. This was done in order to detect any safety concerns and to define any risk factors that might contraindicate the use of robotic PN in patients who qualify for ablation.

MATERIAL AND METHODS

Study design and statistical analysis

Our institutional review board-approved renal mass registry was queried for patients with available pre-operative imaging who underwent RAPN from 2007–2013. A total of 321 patients were identified. Preoperative CT or MRI were reviewed for all available cases. Each mass was scored using the R.E.N.A.L. nephrometry scoring system [12]. Using the (R) (E), and (A) descriptors in the R.E.N.A.L. scoring system, we were able to identify patients who met the criteria for percutaneous ablation. Ideal percutaneous ablation criteria was defined as a single, <3 cm, completely exophytic, posterior tumor. A total of 26 (8.1%) cases were identified.

Our robotic transperitoneal partial nephrectomy technique has previously been described [13]. Briefly, the renal hilum is dissected, perinephric fat surrounding the tumor is cleared, and the tumor is identified with the aid of intraoperative ultrasonography. The hilum is clamped, the tumor is excised with a 0.5 cm margin, and a two step-renorraphy is completed.

The demographic, perioperative, and recurrence outcomes of the patients who qualified for percutaneous ablation but who underwent RAPN were compared to all other RAPN patients using appropriate comparative tests (Mann–Whitney U test, Fisher's exact test). Complications were classified prospectively by Clavien grade [14]. Statistical analysis was performing using STATA Version 13 software (College Station, TX). Two sided p values <0.05 were considered significant.

RESULTS

Overall, 321 robotic partial nephrectomies were identified. Of these, 26 (8.1%) met percutaneous ablation criteria while 295 did not. Patient and tumor characteristics are detailed in Table 1. Of note, age and body mass index (BMI) were similar in both groups; however, females were more likely to meet ablation criteria (p = 0.009). There was no difference in ASA score between the groups. The tumor diameters were significantly smaller in the group that met ablation criteria (2.3 vs. 2.7 cm, p = 0.012); this was expected due to the inclusion criteria for percutaneous ablation. Similarly, the nephrometry score was significantly less for tumors that met ablation criteria (5 vs. 8, $p \le 0.0001$).

Peri-operative outcomes are detailed in Table 2. Of note, estimated blood loss (EBL) and operative time were similar (100 vs. 100 mL, p = 0.33; 154.5 vs. 159 minutes, p = 0.52). Warm ischemia time (WIT) was significantly less for the group that met ablation criteria (14 vs. 17 minutes, p = 0.002). The renal cell carcinoma (RCC) positive margin rates were both low and comparable between groups (5.6% vs. 2.2% p = 0.41). There were no recurrences in either cohort at a median follow-up time of 12.5 months. Among post-operative characteristics, complications were

Table 1. Patient and tumor characteristics of patients who do and do not meet percutaneous ablation criteria

	Total cohort (n = 321)	Meet ablation criteria (n = 26)	Do not meet criteria (n = 295)	P value
Age	59.6 (51.3–67.0)	60.8 (54.0–67.0)	59.5 (50.9 – 67.0)	0.72
BMI	29.1 (25.3 – 33.0)	29.9 (25.8–32.4)	29.0 (25.0–33.2)	0.83
ASA score	2 (2–3)	3 (2–3)	2 (2–3)	0.41
Tumor diameter (cm)	2.6 (1.9–3.7)	2.3 (1.0–2.7)	2.7 (1.9–3.8)	0.012
Nephrometry score	6 (5–8)	5 (4–6)	7 (5–8)	<0.0001
CCI	0 (0–1)	0 (0–1)	0 (0–1)	0.084

	Total cohort (n=321)	Meet ablation criteria (n=26)	Do not meet ablation criteria (n=295)	P value
EBL (mL)	100 (50–200)	100 (50–150)	100 (50–150)	0.33
Operative time (minutes)	166 (143–206)	154.5 (141.5–177.5)	159 (138.5–187)	0.52
WIT (minutes)	17 (14–21)	14 (10–18)	17 (14–20)	0.002
RCC positive margin (%)	6 (2.4%)	1 (5.6%)	5 (2.2%)	0.41
Conversions (%)	6 (1.9%)	0 (0)	6 (2.0%)	0.76
Recurrence (%)	0 (0)	0 (0)	0 (0)	1.0
Complications (%)	45 (14.0%)	5 (19.2%)	40 (13.6%)	0.59
Clavien I–II	36 (11.2%)	4 (15.4%)	32 (10.8%)	
Clavien III–IV	9 (2.8%)	1 (3.8%)	8 (3.4%)	

Table 2. Perioperative outcomes of patients who do and do not meet percutaneous ablation criteria

Values are expressed as medians (interquartile range) unless otherwise specified EBL – Estimated Blood Loss; WIT – Warm Ischemia Time; RCC – renal cell carcinoma

similar overall (19.2% vs. 13.6%, p = 0.59) and when present, stratified by Clavien grade.

DISCUSSION

Currently, extirpative surgery is the gold standard treatment for small renal masses. The American Urological Association (AUA) published guidelines for the management of stage T1 renal masses, stating that surgical removal yields better oncologic outcomes than ablative therapies [10]. In a metaanalysis of 114 articles on surgical treatment, ablative therapy, and active surveillance, local recurrence-free survival was 90.6% at a mean follow-up of 19.5 months for ablation and 98.4% at a mean follow-up of 20.8 months for PN. Therefore, the AUA concluded that extirpative surgery provides the best oncologic outcomes for patients with small renal masses. Among surgical options, partial nephrectomy is preferred for small renal masses due to comparable oncologic outcomes to radical nephrectomy, but is with superior renal function and reduced cardiovascular complications postoperatively [15, 16].

However, percutaneous ablation still remains an option, particularly among patients who are not surgical candidates. Allen et al. described criteria for optimizing patient selection for percutaneous ablation [6]. They suggested that patients who are not surgical candidates and have an exophytic, posterior tumor that is less than 3 cm are ideal for percutaneous ablation.

Our results suggest that when using a patient selection algorithm based on tumor characteristics, there is no difference in terms of perioperative outcomes between patients undergoing PN or ablation. By definition, the patients who met percutaneous ablation had smaller tumors and lower nephrometry scores, but overall both cohorts had similar ASA scores

and Charlson co-morbidity indices (CCI). ASA scores are used by anesthesiologists as a measure of preoperative risk and CCI scores are used to define preoperative co-morbidities. Therefore, our cohort of patients who met ablation criteria but underwent robotic PN represents a population of patients who are fit for surgery but have T1 tumors. Perioperatively, WIT is shorter for patients who met the criteria. indicating that their surgical procedure may yield better renal functional outcomes than the comparative cohort postoperatively. There was no difference in complications between groups - notably, nearly all of the complications in the group that met percutaneous ablation criteria were Clavien grade I. In addition, the group that met ablation criteria contained only one positive margin for RCC and one for other tumor subtypes, no conversions to a laparoscopic or open procedure, and no recurrences.

Considering our observations, we conclude that for patients who qualify for percutaneous ablation, the decision to undergo ablation or robotic PN depends on patient preference regarding oncologic control. Considering the superior oncologic outcomes of PN versus percutaneous ablation, the fact that most patients require some anesthesia for percutaneous ablation and that PN is well-tolerated with low complication rates, PN may be preferable.

Another option for patients with small renal masses who may not be surgical candidates or who could delay treatment is active surveillance. In recent years, a few centers of excellence have shown an interest in identifying these patients and reducing the medical and surgical burden when possible [17, 18]. A number of well-conducted studies demonstrate that, for a specific population who cannot undergo extirpative surgery, active surveillance may be very effective at controlling disease progression and avoiding unnecessary intervention [18, 19, 20]. In terms of oncologic outcomes, the cancer-specific survival rates appear to be comparable to those of ablation. In fact, they may even be superior because of consistent monitoring for disease progression and conversion to an intervention when tumor growth is noted. Therefore, in selected patients who are at high surgical risk, delaying or avoiding treatment is a useful alternative to ablative strategies. Specifically, for patients who meet ablative criteria, active surveillance is a comparable treatment approach and may be considered rather than subjecting patients to an oncologically inferior procedure. However, ablation may be an excellent salvage treatment for patients who fail active surveillance and cannot or desire not to undergo PN. The decision to undergo treatment versus active surveillance should be decided upon on an individualized basis, taking into account each patient's goals of care.

There are a few limitations to this study, including the retrospective nature of our analysis and the absence of some information not captured in our registry. Among this information is long-term follow-up data. Because our mean follow-up is only 12.5 months, we based all oncologic outcomes on previous reports, not our own cohort. In addition, there is some selection bias in our patient cohort – most patients were healthy outpatients with little to no comorbidities. Although this demonstrates that for healthy patients, PN is the preferred treatment strategy, regardless of other procedural options, our conclusions may not be entirely generalizable to all patients. Finally, our conclusions are based on data collected at a single academic institution. Although multiple surgeons perform robotic PN, one surgeon performed 87% of the procedures, which suggests our results may not be entirely generalizable. Ideally, this study would be expanded to a randomized control trial, ultimately investigating the outcomes of patients randomized to robotic PN versus ablation.

CONCLUSIONS

In conclusion, robotic PN is a safe, effective treatment option for small renal masses. There were no recurrences in our cohort and the majority of complications were Clavien 1. There were no safety concerns or differences in outcomes that might contraindicate the use of robotic PN in patients who qualify for ablation. Furthermore, larger scale studies have demonstrated that PN has superior oncologic control compared to ablation. Therefore, in most patients, robotic PN may be the preferred treatment option for renal masses meeting ablation criteria, as it is oncologically superior and a relatively safe procedure. However, due to the inherent risks associated with surgery, ablation should remain a reasonable treatment option for interested patients. For non-surgical candidates, active surveillance may be comparable to ablation and goals of treatment should be addressed on an individualized basis.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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