KIDNEYS, URETERS, BLADDER, RETROPERITONEUM

The effect of tumor size and location on efficacy and safety of US- and CT- guided percutaneous microwave ablation in renal cell carcinomas

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Abstract

Purpose To evaluate the effect of size and central location of the tumor on safety and efficacy of percutaneous CEUS- and CT-guided MWA in biopsy-proven renal cell carcinomas (RCCs).

Materials and methods In this IRB-approved retrospective study, 69 biopsy-proven renal tumors in 56 patients, who underwent MWA in our institution from January 2013 to March 2017, were evaluated. Data collection included demographics, tumor characteristics, procedural protocols, and follow-up visits within 6 months post procedure. Primary outcomes were assessed by technical success (TS), local tumor progression (LTP), and complications. The Kaplan–Meier analysis was used for survival rate.

Results Overall technical success was achieved for all 69 lesions (92.8% primary TS, 100% overall). Median nephrometry score was 8 (4–11) and median tumor size was 2.5 cm (0.8–7). Five lesions which required second ablation had significantly higher median tumor size 4 cm ($P = 0.039$) with the same nephrometry score. Renal function remained stable with no significant change in eGFR before or after ablation. The LTP rate was 5.8%. The most recurrent tumors were clear cell (50%) followed by papillary tumors (25%). The complication rate was 5.8% with minor complications (hematoma and pain) and no major issues. There was no significant association between nephrometry score and technical success, recurrence, or complication rates. Overall and tumor-specific survival rates were 96.7% and 100% at 11.9 months.

Conclusions Image-guided MWA appears to be a safe and effective treatment regardless of nephrometry score and tumor location with high technical success, low recurrence, and complication rates.

Keywords Percutanous microwave ablation · Renal cell carcinoma · Ultrasound · CT guided · Path proven

Introduction

Renal cell carcinoma (RCC) comprises 3% of malignancies and 80–90% of all renal lesions in adults [1]. The majority of lesions are T1a at presentation. For the past 25 years, partial nephrectomy (open, laparoscopic, or robotic) has supplanted radical nephrectomy as the standard of care for treatment to minimize loss of renal function [2–4]. Since 1996, image-guided thermal ablative techniques are increasingly being used as an alternative to surgery for definitive treatment of RCC [1–5]. These minimally invasive, outpatient percutaneous techniques have reported efficacy rates comparable to partial or radical nephrectomy with decreased morbidity, length of hospital stay, and preserved renal function [6]. The two most widely applied thermal ablation methods for the treatment of RCC are radiofrequency ablation (RFA)

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and microwave ablation (MWA). MWA is a magnetic wave-based technique resulting in coagulative necrosis with higher intratumoral temperatures, larger ablation zones, and shorter ablation time with less perfusion-mediated heat sink effect than RFA [7–12]. During the past decade, higher power microwave systems have been developed that perform better than initial systems. However, thermal treatment for endophytic tumors still has a higher risk of injury to the collecting system and incomplete tumor necrosis [4, 10, 13]. There are a limited amount of comparative studies of outcomes of MWA in endophytic RCC or larger size tumors [2, 8].

The purpose of this study was to evaluate the effect of tumor size and central location in short-term safety and efficacy of percutaneous CEUS- and CT-guided MWA in biopsy-proven RCC tumors.

Materials and methods

Patient selection

In compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA) and after Institutional Review Board (IRB) approval, a study cohort of 56 consecutive patients with suspicious renal masses, who underwent percutaneous MWA, were included. All patients were referred by one of our several urologists who deemed them unfit for surgery. Each patient underwent a full history and physical examination before the procedure and was followed regularly after the ablation until the end of the study period. Patients initially underwent a renal imaging protocol: multiphasic contrast-enhanced MRI or MDCT for renal mass characterization to distinguish benign tumors such as oncocytoma, poor fat angiomyolipoma (AML), and Bosniak I or II cysts from renal cell cancer according to the published criteria [14–16]. Before the procedure some laboratory evaluations such as renal function [serum blood urea nitrogen (BUN) and creatinine], hematological parameters (serum hemoglobin, hematocrit, white blood cell count, platelet count), coagulation parameters [prothrombin time (PT)] and international normalized ratio (INR) were also assessed. The renal MWA database was compiled based on the patients' electronic medical records with following data elements: patient demographics, tumor histology, ablation time and power, imaging and clinical follow-up visit assessments, and serum laboratory values for the 6 months following the procedure.

Procedure

The tumor microwave ablation was performed by an abdominal imaging fellow and one of our board-certified abdominal radiologists who have 10–18 years of experience in renal interventional procedures.

After induction of general anesthesia in the multidetector CT (MDCT) ablation suite, the patient was optimally positioned (usually sleeping oblique for anterior and lateral lesions or prone for posterior lesions) and initially an unenhanced US was performed to localize the target lesion and determine its relationship to the renal cortex and sinus. Then, a contrast-enhanced US (CEUS (iU22, Philips Healthcare, Bothell, WA) was performed after intravenous injection of microbubbles [0.3 cc (Definity; Lantheus Medical Imaging, North Billerica, MA)] to confirm the size, number, enhancement pattern, vascular supply, and location of each lesion. An unenhanced MDCT (Definition; Siemens Medical Solutions, Erlangen, Germany) was done to determine the relationship of each lesion to the collecting system, ureteropelvic junction, adjacent bowel, abdominal wall, and psoas muscle.

A percutaneous coaxial core biopsy was performed either prior to ablation or at the time of ablation in patients without prior biopsy confirmation. After sterilizing the entry region with 2% chlorhexidine and sterile drape using real-time US guidance and repeated CEUS, a 19-G cannula needle was guided to the margin of the target lesion. Then, using a coaxial technique a 20-G biopsy gun was used to retrieve 4–6 core biopsy samples for surgical pathology analysis to confirm lesion subtype determined by preprocedural imaging. Then, the ablation procedure started by one or two commercially available 15-cm, 17-G needle antennas (NeuWave PR 15; NeuWave Medical, Madison, Wis) mated to a 2.45-GHz microwave generator capable of 65 W per antenna (Certus; NeuWave Medical, Madison, Wis). The needle antenna was inserted into each lesion under real-time CEUS and with intermittent MDCT guidance. For exophytic lesions 2 cm or less, a single antenna was guided to the center of the lesion, bisecting it. For endophytic or larger than 2-cm lesions, two antennas were placed in the outer third of the lesion to trisect it. The tip of the antenna was generally placed at the margin of the lesion and went 5 mm deep relative to the entry point.

For endophytic lesions adjacent to the renal pelvis, the antenna was inserted perpendicular to the renal sinus, if it is possible, approximately 3–5 mm from the inner edge of the tumor. But, for lesions abutting or within 1 cm of the renal pelvis, ureteropelvic junction, or ureter, pyeloperfusion with chilled 0.9% saline at 5 cc/s was performed. For these tumors, prior to MWA, a urologist helped us to insert an open ended 5-Fr stent cystoscopically and in a retrograde fashion. In general, a 5-Fr sheath was inserted in the perirenal fat adjacent to the lesion for retroperitoneal hydrodissection with chilled 0.9% saline (500–1000 cc) at 5 cc/s. This was done to minimize thermal injury to retroperitoneal nerves, bowels (colon, duodenum, or jejunum), abdominal wall muscles, and skin. After placement of

antennas, imaging ensured satisfactory positioning. Then, MWA initially started at 65 W with target temperatures reaching 120–140 °C. Generally exophytic lesions under 2 cm required ablation times of 3–5 min, while endophytic lesions larger than 2 cm required ablation times of 6–8 min. If endophytic lesions were larger than 4 cm, 15–20 min of ablation times was typically required. In addition to temperature, an intraprocedural unenhanced imaging helped us to observe the gas distribution throughout the lesion. For example, the "echogenic cloud" on US and/or dispersed gas on unenhanced MDCT with corresponding increased density and decreased size due to coagulative necrosis.

If the unenhanced imaging measures suggested a successful ablation, after 5–10 min when the gas cloud dissipates completely the CEUS was performed to confirm there is no residual enhancement. This was followed by renal protocol MDCT before and after injection of contrast (40–45 mg iodixanol [Visipaque 320] at 3–4 cc/s). MDCT imaging was performed in 4 phases: premonitoring, corticomedullary, nephrographic, and excretory at approximately 50, 90, and 240 s after contrast injection. If one or more intratumoral regions of enhancement were detected on US or CT, the

antenna was reinserted to the target regions and ablation was performed, repeatedly.

After satisfactory ablation, the patient was extubated and monitored for 3–6 h until fully conscious with stable vital signs, normal bowel and bladder function and ambulation. Prior to discharge, patients without contraindications to contrast MRI underwent a multiphasic MRI study with 0.1 mmol/kg of Gadolinium (Magnevist, Bayer, Berlin, Germany) injected at 2 cc/s on either a 3.0 Tesla or 1.5 T (Trio or Avanto, Siemens Medical Solutions, Erlangen, Germany). This was done as a baseline for future assessment of treatment efficacy. For patients with renal function insufficiency (GFR < 30 cc/min) or on dialysis, unenhanced MR imaging was performed. After the last successful ablation, each patient had a follow-up at the interventional oncology clinic with multiparametric MRI or MDCT at month 1 and every 3 months during the first 2 years and every 6 months thereafter (Figs. 1, 2, 3).

Data collection and statistical analysis

Patients' demographics, imaging and ablation information were obtained from medical records, retrospectively. All
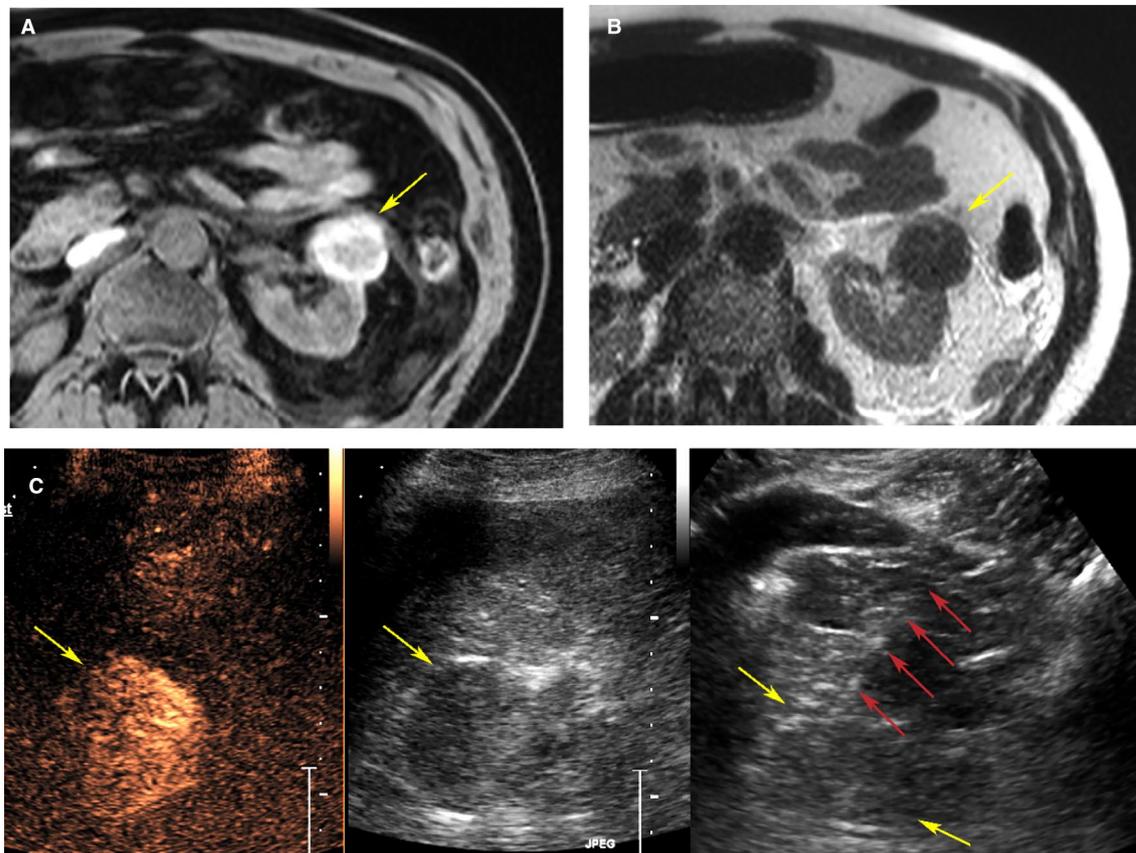

Fig. 1 Percutaneous MWA of a 62-year-old man with 4-cm clear cell RCC partially exophytic (yellow arrow) on axial T1, T2 Weighted MRI before the ablation (**a**, **b**). Contrast-enhanced US helps to confirm precise placement of applicator (red arrow (**c**))

Fig. 2 A 62-year-old man with 4-cm clear cell RCC. Two microwave probes (red arrow) placed into the tumor (yellow arrow) with MDCT (corticomedullary, nephrographic, and excretory phases) (**a**, **b**, **c**). After the procedure, MR confirmation on coronal view shows the successful ablation with no residual tissue (**d**)
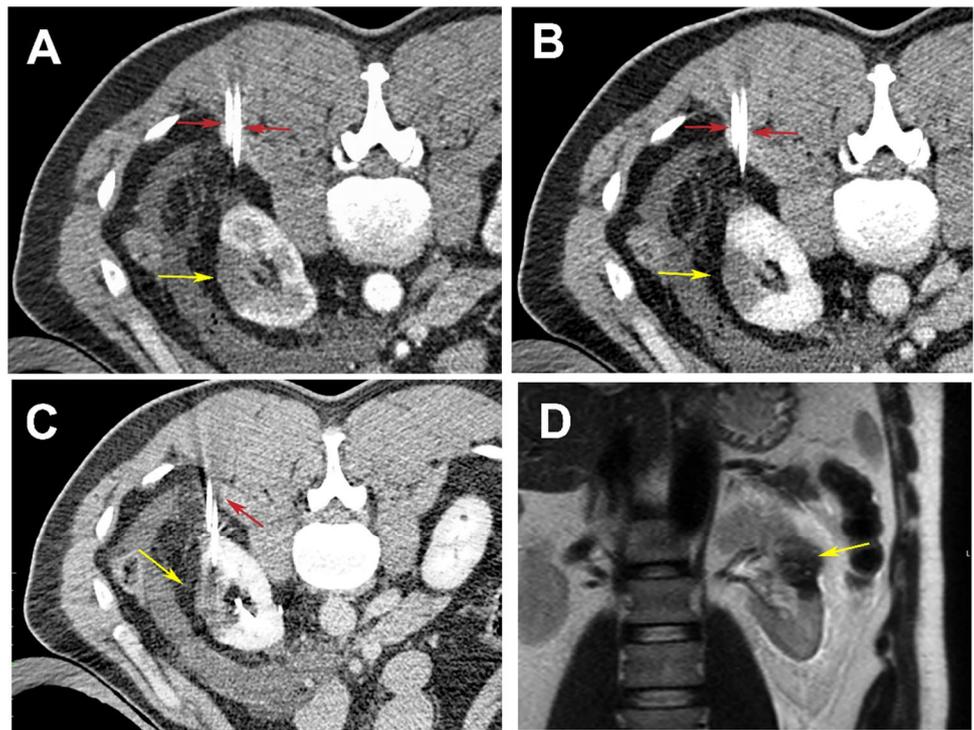
Fig. 3 A 72-year-old man with 2.5-cm papillary RCC. The contrast CT before the procedure shows the tumor characteristics (yellow arrow) (**a**). The biopsy was performed under the guidance of US (red arrow, needle) (**b**). Then two microwave probes (yellow arrows) placed into the tumor under the guidance of MDCT (corticomedullary phase) and the tumor was ablated completely (**c**). After the procedure, MRI confirmation on coronal view shows the successful ablation with no residual tissue (**d**)
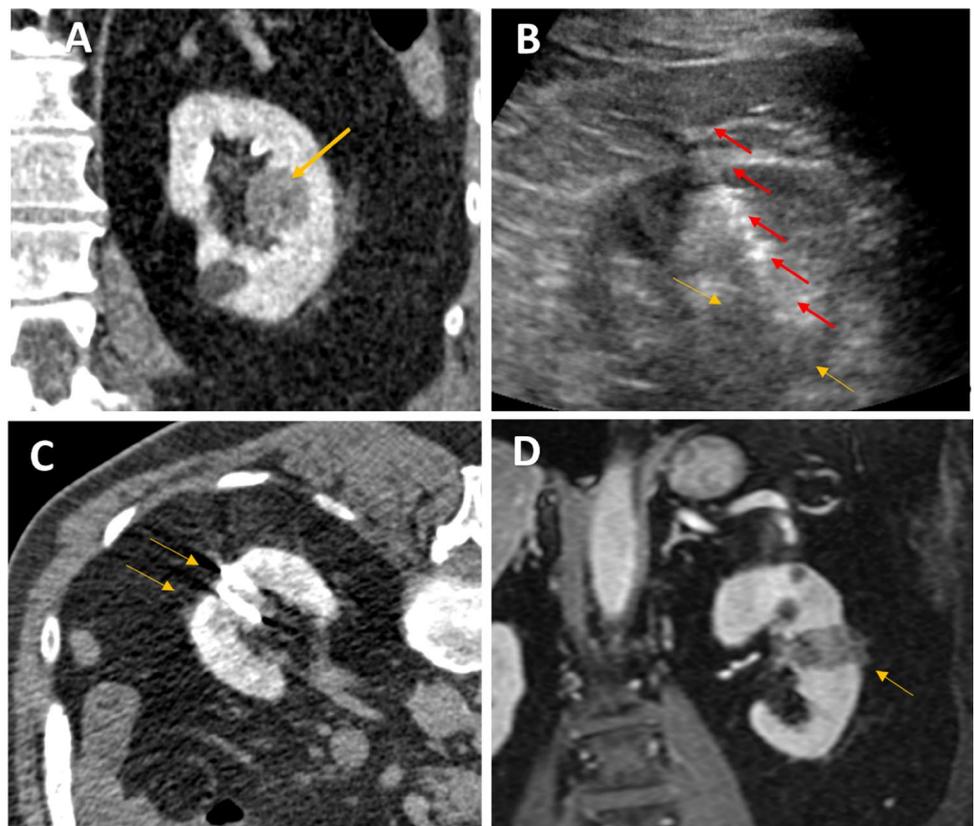
determinants of success were based on International Working Group on Tumor Ablation IWG Criteria [15]. Overall technical success (TS) was defined as no residual tissue in the original lesion on post-contrast MRI or MDCT within

1 month of initial ablation. Primary technical success (PTS) was defined as a complete ablation after one session, while secondary technical success (STS) was defined as complete ablation after two or more sessions within 6 months. Local Tumor Progression (LTP) was defined as persistence of appearance of tumor focus at the edge of the ablation zone. This one was determined after at least one contrast-enhanced imaging which documented adequate ablation by the absence of viable tissue in the target and surrounding ablation margin. Overall survival (OS) was defined as all alive patients after the procedure related to the target follow-up time and the tumor-specific survival rate was defined as all alive RCC-free patients during that time. The pre- and post-procedure eGFR were obtained within 6 months before and after the ablation, respectively. R.E.N.A.L. nephrometry score was calculated for each lesion [17, 18]. Complications were classified according to the Clavien–Dindo system [15, 17, 19–23].

Kaplan–Meier analysis determined overall and tumor-specific survival rates. Quantitative variables were presented as median (IQR) and were compared with Wilcoxon signed rank test. The Fisher Exact test was performed for comparison of categorical variables. The association between multiple parameters such as technical success, tumor size/location, nephrometry score, progression rate, overall survival rate, and complications were determined. All statistical analyses were performed using SPSS software 24.0 and P value ≤ 0.05 was considered significant.

Results

This study cohort was comprised of 105 consecutive patients with 128 lesions who underwent renal MWA from January 2013 to March 2017. Patients with lesions (soft tissue, residual tissue, benign lesions) rather than biopsy-proven solid renal tumors or patients with less than 1-month postablation follow-up were excluded from the study. The remaining 56 patients with 69 solid renal tumors were included for final evaluation. The demographic characteristics of patients and procedure outcomes are summarized in Table 1. There were 44 (63.8%) men and 25 (36.2%) women with a median age of 66 years (27–93). The predominant subtype of the lesions were clear cell (CC) 75.4% (52/69) followed by papillary 17.4% (12/69). The median lesion diameter was 2.5 cm (0.8–7). The majority of patients (67%) had a follow-up within 6–12 months while 17% (1–2 years), 10.2% (2–3 years), and 5.8% (3–5 years). The median overall nephrometry score was 8 (range: 4–11). According to the nephrometry score, there were 39% (27/69) low complexity, 37.7% (26/69) moderate complexity, and 23.3% (16/69) high complexity tumors. Primary technical success was 92.8% (64/69). Five lesions which required second session

Table 1 Patient demographics, tumor characteristics, and procedure outcomes

	Value
Patients (*n*)	56
Male (%)	44/56 (63.8%)
Female (%)	25/56 (36.2%)
Age in years, median (range)	66 (27–93)
Number of lesions	69
Lesion size, median (range cm)	2.5 (0.8–7)
Nephrometry score, median (range)	8 (4–11)
ASA Score (mean ± SD)	2.7 ± 0.5
Positive past medical history of RRC (%)	36/56 (52.1%)
Primary technical success (%)	64/69 (92.8%)
Secondary treatment (%)	5/69 (7.2%)
Secondary technical success (%)	5/5 (100%)
Number of ablation zones, median (range)	1.6 (1–6)
Local tumor progression (%)	4/69 (4.8%)
Month of local tumor progression, median (range)	4 (4-27)
eGFR preablation (ml/min/1.73 m²), median	63
eGFR postablation (ml/min/1.73 m²), median	61
Complication (%)	3/69 (5.8%)
Short time survival rate (%)	54 (96.7%)
Tumor-specific survival rate (%)	56 (100%)

ASA American Society of Anesthesiologists

MWA had a significantly larger median diameter (4 cm) than overall median diameter (2.5 cm) ($P = 0.039$), but they had the same median nephrometry score of 8. The secondary and overall technical success rates were both 100%. Table 2 shows different characteristics of the tumors and their pathological grades.

The local tumor progression rate was 5.8% (4/69) with a mean follow-up time of 6.4 months and the histology of these lesions were CC (3/4; 75%) and papillary (1/4; 25%). There were no significant associations between local tumor progression and PTS, STS, or nephrometry score. We did not find any significant change in eGFR before and after MWA (63 vs. 61 ml/min/1.73 m²). The overall complication rate was 5.8% (4/69) which was entirely comprised of grade I and II events such as a self-limited retroperitoneal hematoma and post-procedural pain requiring narcotics (Table 3). The overall and tumor-specific survival rates were 96.7% (54/56) and 100% (56/56), respectively. Two patients died 11 and 42 months after MWA due to progressive metastatic melanoma and sepsis-related pneumonia, respectively.

Table 2 Tumor characteristics

	Value
Lesion type	
Clear cell	52/69 (75.4%)
Papillary	12/69 (17.4%)
Metastatic	1/69 (1.4%)
Epithelia neoplasm	2/69 (2.9%)
Unclassified	2/69 (2.9%)
Tumor size (*P* value)	
≤4 cm	61/69 (88.4%)
>4 cm	8/69 (11.6%)
RENAL Score	
Median RENAL score	8 (4–11)
R.E.N.A.L. complexity	
Low (4–6)	27/69 (39.1%)
Medium (7–9)	26/69 (37.7%)
High (10–12)	16/69 (23.2%)
Polarity	
Upper pole	16/69 (23.2%)
Interpolar	25/69 (36.2%)
Lower pole	28/69 (40.6%)
Exophytic/endophytic	
Exophytic	37/69 (53.6%)
Endophytic	32/69 (46.4%)
Ant/post	
Anterior	24/69 (34.8%)
Posterior	8/69 (11.6%)
Lateral	37/69 (53.6%)
Fuhrman grade	
I/IV	1/69 (1.4%)
II/IV	52/69 (75.5%)
III/IV	9/69 (13%)
Non specified	7/69 (10.1%)

Table 3 Tumor characteristics and association with procedure outcomes

	Technical failure	Complication	Local tumor progression
Tumor size			
≤4 cm	3/5 (60%)	4/4(100%)	3/4 (75%)
>4 cm	2/5 (40%)	0	1/4 (25%)
P value	**0.039***	–	0.286
R.E.N.A.L. complexity			
Low (4–6)	1/5 (20%)	2/4 (50%)	3/4 (75%)
Medium (7–9)	2/5 (40%)	–	–
High (10–12)	2/5 (40%)	2/4 (50%)	1/4 (25%)
P value	0.557	0.218	0.441
Exophytic/endophytic			
Exophytic	3/5 (60%)	2/4 (50%)	2/4 (50%)
Endophytic	2/5 (40%)	2/4 (50%)	2/4 (50%)
P value	0.767	0.881	0.400

*P ≤ 0.05 is significant

Discussion

In recent years, prior studies have demonstrated good efficacy in short- and intermediate-term oncological outcomes of different ablation techniques. However, their comparison outcomes are still controversial [13, 18, 24]. Cryoablation is an ideal technique for peripheral and posterior kidney tumors which arise from the inferior pole and it is far from the bowels. This technique is also safe enough for central tumors with minimum injury to the collecting system. However, cryoablation is time consuming and has a higher risk of bleeding [11, 25]. RF ablation is known to have limited efficacy for tumors larger than 3 cm, endophytic tumors or tumors near the collecting system [11]. MWA is a faster and more homogeneous modality for stage T1a RCC treatment and unlike the RF ablation and cryoablation, the technical success of this modality was not influenced by

tumor complexity [13, 24]. However, tumor location has an important role in thermal treatment especially in endophytic tumors which are located close to the renal sinus. There is a higher risk of incomplete necrosis and injury to the collecting system [7].

In our study with 69 biopsy-proven tumors, we achieved primary and overall technical success of 92.8% and 100%, respectively. Of 69 lesions, 5 lesions required second ablation. Those that required second ablation did not show that the incomplete necrosis would be related to the tumor location (2 of 5 were endophytic) and after the second ablation the complete necrosis was achieved without increasing the rates of complication or tumor recurrence. But we found that the technical failure occurred significantly more in large tumors (4 cm) vs the overall sample size (2.5 cm) ($P = 0.039$), regardless of their location. Our study showed that lesion size can be the potential predictor for technical success of a procedure, but it does not statistically affect other outcomes such as complications, progression, or survival rates.

According to our study, the difference in size did not influence median nephrometry score or nephrometry complexity. This confirms that the 5 different parameters which contribute to nephrometry score have their own specific roles, but are not necessarily correlated to final outcomes.

The relationship between nephrometry score and RF ablation efficacy in RCCs was first reported by McClure et al. study [26] which was confirmed by Camacho et al. [18.]. Furthermore, the association between nephrometry score and MWA ablation efficacy was reported in studies by Ierardi and Klapperich et al. [7, 24]. Our study confirms the findings of Klapperich et al. [24] which showed that

the MWA is an effective and safe treatment for T1a RCCs regardless of tumor complexity without increasing complication rates. In contrast, Ierardi et al. [7] and Camacho et al. [18.] confirmed nephrometry scores ≥ 8 predict increased MWA recurrence and complication rates.

Our post-operative complication rate was 5.8% (4/69); all were self-limited Clavien–Dindo I–II, which is as good as those reported in other studies. This low complication rate can be achieved by using the appropriate needle size (17 G), inserting multiple antennas simultaneously to obtain optimal thermal ablation within a shorter time and good needle positioning The MWA system (Certus; NeuWave Medical, Madison, Wis) that we used was equipped with a gas-cooled 2.45-GHz powered system, which helps us to have better control of temperature during ablation. This effective new system was also used in Klapperich et al. [24], which treated 96 patients with 100 stage T1a (median 2.6 cm) RCCs with a median follow-up time of 17 months. They also used multiple needles (median 2) and reported 100% overall technical success for both low and intermediate/high nephrometry scores. They reported an 11% early complication rate consisting of Clavien–Dindo grade I–IV.

An initial study published in 2012 by Yu et al. [4] evaluated a cohort of 46 patients with 49 biopsy-proven RCCs who had a follow-up within 20 months. Their MWA system was an initial version which allows using up to two antennas simultaneously but the investigators used it with a single MW needle. They reported an average of 8-min ablation time with 79.6% primary technical effectiveness, with 8 lesions requiring two sessions and 2 lesions requiring three sessions. But, they had only one complication, which was perinephric hematoma requiring intravenous hemostatic therapy. Klapperich et al. [24] reported 6 complications which were procedure related; asymptomatic urinomas which were initially the MW needle tip punctured deep lesions into the collecting system. Later, they modified the technique by placing the needle parallel to the collecting system and reported no urinomas. Our experience generally confirms the results reported by Klapperich et al. [24] with 100% overall technical efficacy and only a 5.8% complication rate. No urinomas were detected in our cohort. The ablated lesions requiring a second ablation session in our study were larger lesions which did not influence the nephrometry scores, like Klapperich et al. while their focus was on T1a lesions [24]. Our tumor progression rate was 5.8% within of median follow-up time of 6.4 months which is in accordance with low progression rate 1% in Klapperich et al. study [24]. However, Yu et al. reported greater local tumor progression 37.5% (3/8) for T1b lesions [4].

According to our study, MWA did not have significant adverse effect on renal function, which decreased by 3% in our study, compared to 14% in the study by Klapperich et al.

[24]. In both cohorts, no clinically significant renal function sequelae were observed.

In regard to hospitalization, all our cases were performed on an outpatient basis and unlike other studies required no hospital admission [4, 7, 24].

Our study has some limitations; the limitation of a single arm and being a single institutional retrospective study. All these findings would be better evaluated in a larger trial comparing specific ablation devices using each technique within a longer follow-up period.

In conclusion, our study cohort showed that CEUS- and CT-guided MWA is a safe and effective treatment for RCCs regardless of tumor location and nephrometry score with a high rate of technical success, low complication and local tumor progression rates within a short-term follow-up period.

Compliance with ethical standards

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