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Microwave Ablation Versus Partial Nephrectomy for Small Renal Tumors: Intermediate-Term Results

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Background and Objectives: Prospective randomized comparison of intermediate-term outcomes of patients with small renal tumors who were treated with partial nephrectomy (PN) or microwave ablation.

Methods: Of 102 selected patients with solitary small renal tumors who had prospectively completed at least 2 years of follow-up since December 2004, randomizedly, 54 had either open (19) or laparoscopic (35) PN and 48 had laparoscopic (28) or open (20) microwave ablation. Patient and tumor characteristics, surgical data, complications, histologic and oncologic data, and functional data of the two approaches were compared.

Results: Patients in microwave ablation group and PN group matched for age, sex, American Society of Anesthesiologists score, body mass index, and tumor size and were respectively followed for median 32 and 36 months. Surgical and hospitalization times were comparable in both groups. Estimated blood loss, complication rates, and decline of postoperative renal function were significantly less in the microwave ablation group ($P = 0.0002$, $P = 0.0187$, and $P = 0.0092$, respectively). The decrease in estimated glomerular filtration rate at the last available follow-up was similar in both groups ($P = 1.0000$). There were no disease-specific deaths. Kaplan–Meier estimates of overall local recurrence-free survival at 3 years were 91.3% for microwave ablation and 96.0% for PN ($P = 0.5414$); the respective numbers for renal cell carcinomas were 90.4 and 96.6% ($P = 0.4650$).

Conclusions: Microwave ablation can be also safely and efficiently done for patients with small renal tumors. This intermediate analysis showed that microwave ablation provides favorable results compared to PN. However, longer term data are still needed.
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KEY WORDS: **kidney neoplasms; microwaves; catheter ablation; nephrectomy; treatment outcome**

INTRODUCTION

Small renal tumors are being increasingly detected at an early stage because of the widespread use of various noninvasive imaging modalities. Partial nephrectomy (PN) or nephron-sparing surgery has gained popularity for the management of renal lesions 4 cm or less in diameter, because local tumor resection without removing the entire kidney has proved effective [1]. However, open partial nephrectomy (OPN) and laparoscopic partial nephrectomy (LPN) are technically challenging and they may have serious complications, such as excessive blood loss and urinary fistula. Alternatively, ablative techniques offer other nephron-sparing minimally invasive approaches with significantly lower complication rate and greater likelihood of technical mastery [2].

So far probe ablation with radiofrequency ablation (RFA) and cryoablation is increasingly being utilized as primary surgical therapy for small renal tumors (SRTs) [3]. Microwave ablation (MWA) has been widely used in China for hepatocellular carcinoma. Comparing with RFA, potential benefits of MWA are larger ablation zone and more complete tumor kill. MWA is also less affected by the perfusion mediated heat sink effect, which may be helpful for treating tumors with a rich blood supply. In addition, multiple antennae can be used simultaneously to ablate larger tumors [4,5]. To our knowledge studies regarding the clinical use of MWA in kidney tumors are sparse. However, limited results suggest that MWA is also feasible for small localized renal cell carcinoma (RCC) [6–8].

On this basis, we started a single-center prospective study, intending to summarize our experience with SRTs treated with either PN or in situ MWA.

METHODS

Patient Selection

Between December 2004 and June 2008, according to the sample size formula suggested by Schulz et al. [9], 102 patients with a solitary, unilateral, solid renal mass 4 cm or smaller in maximum diameter were prospectively randomized to undergo OPN (19), LPN (35), open MWA (20), or laparoscopic MWA (28). Patients were prospectively randomized by a computer-generated program. All patients had no absolute contraindications to nephrectomy. None of them had bilateral synchronous or metachronous tumors, metastatic disease at presentation, or hereditary renal cancer syndromes. There was no previous treatment for the patients in our series. Before treatment, all patients were informed the risks and benefits of MWA versus PN and the possibility of local failure that could require retreatment or radical nephrectomy. All data were prospectively maintained in a computerized database with Institutional Review Board approval.

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Partial Nephrectomy Technique

OPN used lumbar incision above the 12th rib under general anesthesia. Mannitol was applied intravenously for diuresis before the temporary occlusion of renal arteries with bulldog clamps. Crushed ice was placed around the kidney to allow tumor excision under cold ischaemia. The tumor was excised sharply. The removed specimen consisted of the tumor circumscribed by a rim of normal-appearing parenchyma. Negative surgical margins were confirmed during surgery by frozen section analysis. Tumor staging was performed according to the 2002 TNM system. The pelvicalyceal openings and vessels were oversutured and the cut surface overlaid with hemostatic gauze, and the edges of the parenchyma were reapproximated using 2-0 Vicryl-sutures. Retroperitoneal LPN was previously described in detail [10]. Tumors were excised with at least 5 mm normal renal parenchymal margin, no matter malignant or benign.

Microwave Ablation System

Microwave energy was applied using a KY2000 microwave ablation system (Kangyou Medical Instruments, Nanjing, China), which consists of a cooled shaft antenna connected by a flexible coaxial cable to a microwave generator. The generator is capable of producing 1–100 W of power at 2,450 MHz. The 15-gauge cooled shaft antenna is coated with polytetrafluoroethylene to prevent adhesion. Inside the antenna shaft there are dual channels through which distilled water is circulated by a peristaltic pump, continuously cooling the shaft to prevent overheating and uncontrolled tissue damage. A 10 MHz Acuson Sequoia™ 512 ultrasound probe was used to guide percutaneous MWA [8].

Ablative Procedure

The operative route and anesthesia modality of open or laparoscopic MWA were identical to the PN technique. Notably, a 5–6 cm minimal incision was applied at the flank-site closest to the tumor in the open MWA group. Biopsy specimens were obtained after sufficient exposure of the renal tumor, using core biopsy or a toothed biopsy forceps. The antenna was inserted into the tumor under direct visual guidance, placed at designated site and adjusted to the best puncture depth. The first microwave coagulation point was usually 0.5 cm or less away from the tumor margin most close to the pelvis, a 20-gauge thermocouple was then parallelly inserted in the renal parenchyma about 0.5–1 cm away from the tumor for real-time temperature monitoring. A power output of 50 W for 8 min per puncture was routinely used. The diameter of spherical coagulation zone was around 2.5 cm. MWA therapy was carried out successively with 1–5 points for each tumor, ensuring an ablation zone diameter 1 cm beyond the computerized tomography (CT)-measured maximum tumor diameter, and preceded from deep to superficial, and internal to external. If the measured temperature did not attain 60°C or remain above 54°C for at least 3 min, prolonged microwave emission was applied until the desired temperature was achieved. When withdrawing the antenna, the needle track was carbonized to prevent tumor cell seeding.

Follow-up Protocol

After treatment, all patients were closely monitored for possible complications. Postoperative complications were graded according to the modified Clavien classification system [11,12]. Urinalysis and serum creatinine were tested within 24 hr, and contrast-enhanced computerized tomography (CE-CT) was performed to assess treatment efficacy. If residual tumor was found, a further process was planned or patients entered the follow-up protocol, which included laboratory and radiological examinations (liver and kidney function tests, chest radiography, ultrasound, and CE-CT) at 1, 3, and 6 months, 1 year, and every 6 months thereafter. Incomplete ablation was defined as residual enhancement in the treated lesion on the 1-month CE-CT. Local recurrence was defined as any new enhancement after a non-enhancing 1-month scan or lesion growth. Patients were deemed to have no evidence of disease (NED) if there were no clinical or radiologic evidence of distant metastasis or local disease [13]. Patients with incompletely ablated or recurrent tumors were given the option of re-ablation or surgery. Patients with re-ablated tumors were followed up at the intervals defined above.

Statistical Analysis

We applied Student's *t*-test and Chi-square test or Fisher's exact test to compare differences in values for the groups using GraphPad Prism 5 (La Jolla, CA). Cumulative survival and recurrent rates were calculated by the Kaplan–Meier method, and the difference between survival curves was evaluated using the log rank test. All tests were two-sided with significance considered at 0.05.

RESULTS

Patient Characteristics

The baseline characteristics of the 102 eligible patients are shown in Table I. Although the groups were matched for age, sex, American Society of Anesthesiologists (ASA) score, body mass index, and tumor size, the preoperative serum creatinine and estimated blood loss (EBL) were significantly lower for the ablation approach ($P = 0.0031$ and $P = 0.0002$, respectively, Tables II and IV). In the groups, 11 patients (10.8%) had impaired renal function requiring no dialysis. Table III shows the pathological diagnoses. All malignant tumors were pT1 stage RCCs in both groups. Clear cell RCC and angiomyolipoma were predominant (55.9 and 20.6%, respectively). The confirmed RCC rate was similar in both techniques, at 62.5% ($n = 30$) for MWA and 66.6% ($n = 36$) for PN. There was one nondiagnostic case in each group. Furthermore, no biopsies were taken in four cases.

Therapeutic Effect and Local Recurrence

Table V lists oncologic outcomes. Initial MWA was successful in 46 (95.8%) of 48 tumors. Two incomplete ablations were detected on 1-month CT scan in the MWA group. Both patients underwent percutaneous re-ablation, principally determined by the peripheral position of tumor and patient's choice, and had NED at last follow-up (41 and 50 months, respectively). In the follow-up period, two patients (4.2%) developed local recurrences within the ablated tumor margin and one patient (2.1%) with successfully ablated RCC died of cerebral hemorrhage 26 months after MWA. Of the recurrences, one had initially undergone laparoscopic RFA, but it recurred again 16 months after open MWA of a recurrent 1.5-cm clear cell carcinoma. Whether this recurrence was attributable to tumor spillage from the original RFA or the subsequent MWA was uncertain. This patient underwent OPN and final pathology showed a pT1a Fuhrman grade 2 clear cell RCC, and NED was found at 2 years of follow-up. Another patient was diagnosed with angiomyolipoma and lost to follow-up after a negative 4-week CT. Suddenly a 0.8 cm lesion growth was seen on the 16-month CT graph. She accepted the active surveillance under surgeon's suggestion.

In the PN group of 54 patients, 52 (96.3%) showed complete therapeutic effect and two (3.7%) had recurrent tumors. One patient developed a 1.0 cm mixed mass 5 months after OPN of

TABLE I. Demographic Data

	MWA	PN	*P* Value
No. patients	48	54	Not applicable
Mean ± SD age (range)	45.5 ± 14.4 (23–75)	46.4 ± 13.2 (21–79)	0.7426
No. male (%)	19 (39.6)	28 (51.9)	0.2378
Mean ± SD ASA score (range)	2.4 ± 0.7 (1–4)	2.5 ± 0.6 (1–4)	0.4731
Mean ± SD kg/m^2 body mass index (range)	23.5 ± 2.0 (20.3–25.4)	23.1 ± 2.8 (18.6–30.1)	0.4137
Mean ± SD cm tumor size (range)	3.1 ± 0.8 (1.2–3.9)	2.8 ± 1.3 (0.6–4.0)	0.1699
No. tumor side (%):			0.0093
Left	14 (29.2)	30 (55.6)	
Right	34 (70.8)	24 (44.4)	
No. tumor location (%):			0.2377
Upper	12 (25.0)	22 (40.7)	
Middle	16 (33.3)	15 (27.8)	
Lower	20 (41.7)	17 (31.5)	
No. tumor depth (%):			0.3159
Central	17 (35.4)	25 (46.3)	
Peripheral	31 (64.6)	29 (53.7)	
No. tumor aspect (%):			0.0001
Anterior	3 (6.2)	23 (42.6)	
Posterior	26 (54.2)	20 (37.0)	
Lateral	19 (39.6)	11 (20.4)	

ASA, American Society of Anesthesiologists.

angiomyolipoma, which remained no change during the observation period and had not been intervened further. The second patient developed a 3.2 cm enhancing nodule adjacent to the surgical margin on CT scan 20 months after LPN. Subsequent radical nephrectomy revealed a pT3a Fuhrman grade 3 clear cell RCC. All 102 patients had no evidence of metastatic disease progression.

Survival

At 3 years, Kaplan–Meier estimates for recurrence-free survival rate from all patients were 91.3% (95% confidence interval [CI]: 74.7–97.2) and 96.0% (95% CI: 83.8–99.1) after MWA and PN, respectively ($P = 0.5414$, Fig. 1a). For patients with pathologically confirmed RCCs, the 3-year recurrence-free survival rate in the MWA group was 90.4% (95% CI: 65.3–97.6), obviously lower than 96.6% (95% CI: 78.0–99.6) in the PN group, though not significant ($P = 0.4650$, Fig. 1b). There were no disease-specific deaths in either group, i.e., a 100% disease-specific survival.

Complications and Renal Function

Two significant intraoperative complications occurred. One patient had 1600 ml EBL because of omitted blockage of the renal artery branches due to the unskillful LPN techniques during 2005. Another patient with a peripelvic angiomyolipoma developed pyonephrosis and nearby tissue serious adhesion. In the process of OPN, we injured the inferior vena cava and resulted in about 3,000 ml of massive hemorrhage.

There were 26 postoperative complications in 24 patients (23.5%) including six in the MWA (12.5%) and 18 in the PN (33.3%) group ($P = 0.0187$). They experienced complications ranging from grade I to III when using a standardized Clavien complication reporting system (Table II). In the MWA group, one patient with a right-sided tumor developed urine leak and abscess-formation, leading to repeated wound infections, kidney atrophy, and ultimately nephrectomy. Asymptomatic gross hematuria occurred in the second patient but returned to normal by 7 days after treatment. The other four patients complained of temporary flank-site pain and numbness. However, in the PN group significantly incremental morbidity included twenty complications, which consisted of perinephric hematoma (occurred in four cases), urinary tract infection (three), hemorrhage (three), hydrocalyx (three), flank paresthesia (three), lumbar plexus pain (two), and wound disunion or delayed union (two). None of grade IV or V complications was documented in both groups.

On preoperative evaluation, 4.2% of patients in the MWA group and 9.3% in the PN group had chronic kidney disease stage 3, not worsen enough to necessitate dialysis. Serum creatinine did not increase after MWA but it significantly increased after PN in the short term ($P = 0.0004$). As determined by estimated glomerular filtration rate (eGFR), the decline of postoperative renal function was more

TABLE II. Perioperative Data

	MWA	PN	*P* Value
No. approach (%):			0.5446
Open	20 (41.7)	19 (35.2)	
Retroperitoneal	28 (58.3)	35 (64.8)	
Median mins operative time (range)	148 (117–273)	154 (60–277)	0.0955
Median mins ablation/ischemia time (range)	18 (7.5–41.0)	24 (20.6–34.2)	Not applicable
Mean ± SD ml estimated blood loss (range)	138.3 ± 69.4 (0–200)	465.9 ± 577.1 (50–3000)	0.0002
Median days hospital stay (range)	15 (13–26)	19 (10–47)	0.7566
No. patients with complications (%):	6 (12.5)	18 (33.3)	0.0187
No. complications:	6	20	0.7522
Grade I	4	10	
Grade II	1	4	
Grade III	1	6	

TABLE III. Histopathological Data

	No.MWA	No. PN
No. patients	48	54
RCC histology (%):	30 (62.5)	36 (66.6)
Clear cell	27	30
Papillary	3	4
Cystic renal cell	0	2
Benign conditions/biopsy (%):	14 (29.2)	16 (29.6)
Angiomyolipoma	9	12
Oncocytoma	3	1
Fibrolipoma	1	2
Benign mesenchymoma	0	1
Benign tissue	1	0
Not diagnostic (%)	1 (2.1)	1 (1.9)
No biopsy available (%)	3 (6.2)	1 (1.9)

significant after PN (19.4%) than MWA (5.5%, $P = 0.0092$). After a median of 36 months, however, the decline in eGFR was identical in both groups ($P = 1.0000$, Table IV).

DISCUSSION

In the present series, we compared oncologic, surgical, and functional outcomes after PN and MWA at a median follow-up of 36 months. Our data suggest that MWA yield equivalent oncologic efficacy compared with PN in the treatment of SRTs. RCC and all cause 3-year recurrence-free survival were 96.6 and 96.0% for PN, and 90.4 and 91.3% for MWA, respectively, which did not attain statistical significance. Similarly, Stern et al. reported that the 3-year recurrence-free probability for RCCs and clinical T1a renal tumors were comparable, 95.2 and 95.8% for PN, and 91.4 and 93.4% for RFA, respectively. They conclude that ablation has, and will continue to have, technical and oncological success when used for SRTs [14]. However, recent study also suggested that LPN oncological outcomes with significantly higher 2-year disease-free survival (100%) were more superior than cryoablation (61.0%) and RFA (33.2%) for renal tumors in solitary kidneys [15]. They doubt about the oncological adequacy of ablative techniques and believe that a definitive evaluation of the ability of ablation to destroy SRTs is clearly needed [16]. Deficiencies and differences in our follow-up length might facilitate this controversy. Also, our oncologic data have to be interpreted carefully since the percutaneous MWA was performed scarcely, unlike most other series [8,13–15]. Nevertheless, postoperative radiological assessment showed the ablative zone obviously beyond the tumor margin.

Owing to the preliminary introduction of MWA in the treatment of SRTs, our objective is more inclined to emphasize its therapeutic efficacy and safety while not minimally invasive features. There are three reasons to explain why we seldom use percutaneous MWA. First, the percutaneous ablations only used core biopsy for detecting tumor malignancy, which had a higher false negative rate [17], despite the fact that it should not be frequently used

TABLE IV. Renal Function Data

	MWA	PN	*P* Value
Mean ± SD μmol/l serum creatinine (range):			
Preoperative	55. 6 ± 12.7 (39.6–86.8)	69.6 ± 29.6 (31.1–178.1)	0.0031
Postoperative	51.0 ± 25.1 (20.8–115.4)	114.1 ± 83.8 (29.5–403.0)	<0.0001
Follow-up	58.9 ± 9.7 (49.6–74.7)	90.1 ± 29.2 (48.6–136.0)	<0.0001
Mean ± SD ml/min/1.73 m^2 eGFR (range):			
Preoperative	130.5 ± 31.7 (73.0–205.0)	113.0 ± 36.4 (35.0–219.0)	0.0115
Postoperative	123.0 ± 47.9 (60.0–322.5)	88.1 ± 49.7 (14.0–264.0)	0.0005
Follow-up	120.6 ± 28.4 (77.0–185.1)	107.5 ± 53.4 (50.0–298.0)	0.1320
No. baseline chronic kidney disease[a] (%):	2 (4.2)	5 (9.3)	0.4425
% decline in eGFR from pre- to postoperative	5.5	19.4	0.0092
% decline in eGFR from preoperative to follow-up	6.7	7.9	1.0000

eGFR, estimated glomerular filtration rate.
eGFR is calculated by the formula: $186 \times (\text{Creatinine}/88.4)^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if black})$.
[a]eGFR less than 60 ml per min per 1.73 m^2.

TABLE V. Oncological Outcomes

	MWA	PN	*P* Value
Median months follow-up (range)	32 (24–54)	36 (25–66)	0.7571
No. failures (%):			
Incomplete MWA	2 (4.2)	Not applicable	Not applicable
Recurrence	2 (4.2)	2 (3.7)	0.9043
No. death (%):	1 (2.1)	0	0.4706
% recurrence-free survival for all tumors (95% CI):			0.5414
1-Year	100	98.6 (90.6–99.8)	
2-Year	95.1 (81.8–98.7)	96.0 (83.8–99.1)	
3-Year	91.3 (74.7–97.2)	96.0 (83.8–99.1)	
% recurrence-free survival for RCCs (95% CI):			0.4650
1-Year	100	100	
2-Year	96.4 (77.2–99.5)	96.6 (78.0–99.6)	
3-Year	90.4 (65.3–97.6)	96.6 (78.0–99.6)	

CI, confidence interval.

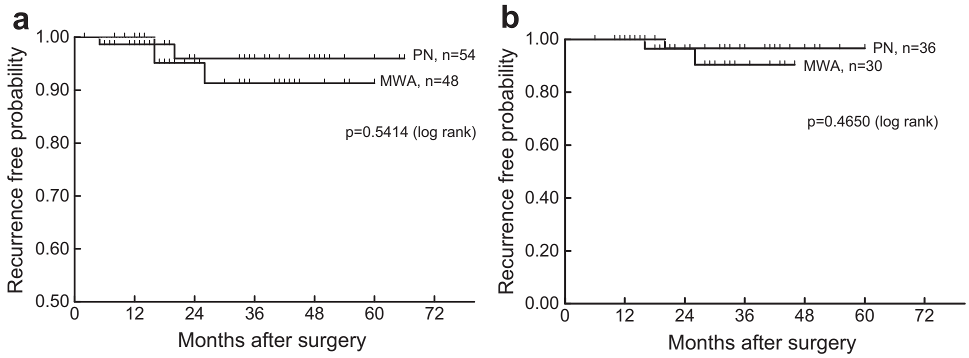

Fig. 1. Kaplan-Meier estimates with log rank test for recurrence-free survival probability after PN and MWA. **a**: recurrence-free survival curves of patients with SRTs, revealing an actual 3-year survival rate of 91.3% for MWA and 96.0% for PN; and (**b**) with diagnosed RCCs, 90.4% for MWA and 96.6% for PN in 3-year survival.

at time of percutaneous RFA and cryoablation. Second, it is difficult to insert the microwave antenna into the non-peripheral tumors. Third, if multipoint ablations were simultaneously manipulated, the percutaneous MWA is not trustworthy as compared with the directly visual operation, in spite of the guidance of ultrasound or CT.

As expected, less EBL following the MWA approach reveal advantages in terms of intraoperative hemostasis. Both groups were comparable with regards to operating time and hospital stay. Pain and parasthesia were common complications in our cohort whereas postoperative hemorrhage and hematoma are arguably the most important urological complications after PN [18]. Overall complication rates for PN in the literature range from 4.1 to 38.6% but for MWA extremely low or even nought [8,19]. However, the morbidity and complication rate was relatively high (12.5%) for MWA in the current series despite significantly lower than that of PN (33.3%), perhaps in part due to the tumor complexity, unskilled technology, and absence of percutaneous MWA. Our experience reinforces the concern about ablative treatments, particularly for lesions adjacent to the renal hilum, is the potential for injury to the collecting system and vital renal vessels [15]. One patient with a right parapelvic tumor suffered from severe urine leak after laparoscopic MWA and ultimately sacrificed the whole atrophic kidney surrounded by liquor puris and fibrosis. Thus, scrupulous case selection might be a crucial aspect for the prevention of MWA complications. Only patients with low-grade exophytic tumors <4 cm should be considered for treatment with MWA. Furthermore, the application of a new technology (e.g., single-port laparoscopy), may diminish the invasiveness of the procedures, reducing the possible risks and maintaining the same efficacy. However, longer follow-up is needed before MWA can be established as a valid alternative option for the treatment of small renal masses [20].

Hakimi et al. [21] recently evaluated the incidence and risk factors of postoperative complication rates in a cohort of patients who underwent PN. They attributed preoperative renal insufficiency to an independent risk factor for increased postoperative complications. Only 9.3% of patients in our PN group had preoperative renal insufficiency with eGFR less than 60 ml per minute per 1.73 m^2 which might predict the follow-up decline in eGFR [22]. Meanwhile, the significantly higher decline rate in renal function was noticed after PN than MWA in the early postoperative phase. Lately in the study by Jeldres et al. [23] the independent predictors of renal failure after PN in patients with RCCs focused on the clamping time and EBL. Especially warm ischemia time could potentially jeopardize both short- and long-term renal function [24]. Nguyen and Gill [25] modified their LPN technique to decrease average warm ischemia time to less than 15 min, which may improve functional outcomes for LPN in solitary kidneys in the future. In addition, laparoscopic capnoretroperitoneum may be another negative impact factor for postoperative eGFR deficit [22]. However, potential mechanisms causing persistent deterioration of eGFR in a long term after MWA are multiple yet not precisely defined.

We acknowledge several limitations of our study. Chiefly this is a single center experience in a highly select patient population with small sample size and short follow-up. Next, the baseline serum creatinine, tumor side, and location were different between groups. Yet complete pathological analysis is not available since the success of MWA mainly relies on radiographic imaging. Another limitation regarding the presented renal function outcomes is the lack of differential data on the operated and the nonoperated kidney. Despite these limitations this study presents the first comparison of outcomes of MWA to PN and adds to the understanding of this new promising nephron-sparing technique.

CONCLUSION

In conclusion, compared with PN, the intermediate surgical, oncologic, and renal function outcomes for SRT patients treated with MWA were favorable, even better at some short term results, in this randomized, prospective study. Nevertheless, longer follow-up are required to further define the role of MWA in the management of SRTs.

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