J Surg Med. 2020;4(11):1068-1072.
DOI: 10.28982/josam.821632

Research article
Araştırma makalesi

Journal of Surgery and Medicine
e-ISSN=2602-2079

Effectiveness and reliability of percutaneous microwave ablation therapy in early stage renal cell cancer: Intermediate term results

Erken evre renal hücreli kanserde perkütan mikrodalga ablasyon tedavisinin etkinliği ve güvenirliği: Ara dönem sonuçları

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Ethics Committee Approval: This study was approved by the Ethics Committee of Sakarya University Faculty of Medicine (Number: 71522473/050.01.04/547). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.
Etik Kurul Onayı: Bu çalışma Sakarya Üniversitesi Tıp Fakültesi Etik Kurulu tarafından onaylandı (Sayı: 71522473/050.01.04/547). İnsan katılımcıların katıldığı çalışmalardaki tüm prosedürler, 1964 Helsinki Deklarasyonu ve daha sonra yapılan değişiklikler uyarınca gerçekleştirilmiştir.

Conflict of Interest: No conflict of interest was declared by the authors.
Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Financial Disclosure: The authors declared that this study has received no financial support.
Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

Published: 11/29/2020
Yayın Tarihi: 29.11.2020

Abstract

Aim: Percutaneous tumor ablation is the most important alternative to surgery in early stage renal cell cancers (RCC). Although many studies are conducted with radiofrequency ablation and cryoablation therapy in RCC, the data regarding microwave ablation (MWA) is more limited. In this study, we aimed to evaluate the efficacy of percutaneous MWA in the treatment of RCC, its safety in terms of residual renal function and other complications, and its clinical results.

Methods: In T1b patients, the suitability for MWA was evaluated with a urologist based on characteristics such as size, and location of the mass (intestinal proximity, proximity to the main renal vascular structures and renal pelvis). Fourteen T1a, five T1b and one T2 RCC patients treated with MWA were included in this retrospective study. MWA was preferred when partial nephrectomy was highly risky or contraindicated due to medical comorbidities or the patients refused to undergo surgical treatment. The patients were ablated with uncooled MWA device with 30W energy under sedation or general anesthesia under ultrasound guidance for an average of 13 minutes. Multiple antennas were used for masses larger than 4 cm. Hydrodissection with saline was performed in cases where there was a non-target organ adjacent to the lesion. Lesion size, location of the lesion, ablation time, complications, Charlson comorbidity index, Hb, and creatinine values were recorded. Patients were followed by CT.

Results: The mean age of the patients was 68.9 years, and the median lesion size was 2.8 cm. While the tumor was exophytic in 12 patients, it was intraparenchymal or endophytic in 8 patients. The average Charlson comorbidity index score of the patients was 6.9. Technical success was achieved in all patients. Average ablation time was 13 minutes. Minor complications occurred in 3 patients. The median follow-up period of the patients was 13.5 months. In Kaplan Meier analysis, progression-free survival was 12 months. During follow up, distant organ metastasis was not observed in any of the patients, recurrence was observed in 2, and no patients died.

Conclusion: MWA can be applied in early stage RCCs with very high technical success. The results of our study show that MWA is effective and highly reliable in RCCs. It can be safely applied, especially in patients who are not suitable for surgery and in residual RCCs.

Keywords: Microwave ablation, RCC, RCC ablation, RCC MWA, Interventional radiology

Öz

Amaç: Bu çalışmada perkütan mikrodalga ablasyonun (MWA) renal hücreli kanser (RCC) tedavisinde etkinliğini, rezidüel renal fonksiyon açısından ve diğer yan etkiler açısından güvenirliğini ve klinik sonuçlarını değerlendirmeyi amaçladık.

Yöntemler: Bu retrospektif çalışmaya MWA ile tedavi edilen 14 T1a, 5 T1b ve 1 T2 RCC hastası dahil edildi. Hastalara soğutmasız sistem MWA cihazı ile 30W enerji ile sedasyon veya genel anestezi altında, ultrason eşliğinde ortalama 13 dakika boyunca ablasyon uygulanmıştır. 4 cm üzerindeki kitlelerde birden çok anten kullanıldı. Lezyon komşuluğunda hedef dışı organ bulunduğu durumlarda salin ile hidrodiseksiyon yapıldı. Lezyon boyutu, lezyonun yerleşimi, ablasyon süresi, komplikasyonlar, Charlson komorbidite indeksi, Hb ve kreatinin değerleri kaydedildi. Hastalar işlem sonrası 1. Gün, 1. Ay, 3.-6.-12.18. ve 24. aylarda CT ile takip edilmiştir.

Bulgular: Hastaların yaş ortalaması 68,9 (9,8) idi. Ortanca lezyon boyutu 2,8 cm (range, 1,9-7,1 cm) idi. 12 hastada (%60) tümör egzofitik iken 8 hastada (%40) intraparankimal veya endofitikti. Hastaların ortalama Charlson comorbidity index skoru 6,9 (1,8) idi. Tüm hastalarda teknik başarı sağlandı. Ortalama ablation süresi 13 dakikaydı (9-15 mins). 3 hastada (%15) minör komplikasyon gelişti. Hastaların ortanca takip süresi 13,5 ay idi (range 6-24 ay). Kaplan Meier analizinde progresyonsuz sağ kalım 12 ay olarak bulundu. Hiçbir hastada takip sırasında uzak organ metastazı izlenmedi. 2 hastada takip sırasında nüks gözlendi. Kanser-spesifik survival oranı %100 idi.

Sonuç: MWA erken evre RCC'lerde oldukça yüksek teknik başarı ile uygulanabilir. Çalışmamızın sonuçları RCC'lerde MW ablasyonun etkili ve oldukça güvenilir olduğunu göstermektedir. Özellikle cerrahiye uygun olmayan hastalarda ve rezidü RCC'lerde güvenle uygulanabilir.

Anahtar kelimeler: Mikrodalga ablasyon, RCC, RCC ablasyonu, RCC MWA, Girişimsel radyoloji

How to cite/Atıf için: Ateş ÖF. Effectiveness and reliability of percutaneous microwave ablation therapy in early stage renal cell cancer: Intermediate term results. J Surg Med. 2020;4(11):1068-1072.

Introduction

Renal cell carcinoma (RCC) accounts for 2.2-3% of all cancers worldwide [1]. The incidence of RCC, especially the number of small masses, has increased in recent years [2]. According to The European Association of Urology RCC guidelines, the gold standard treatment method for T1a RCC is partial nephrectomy (PN) [3].

Percutaneous tumor ablation is the most important alternative to surgery in early stage RCCs in patients with comorbid diseases or otherwise unsuitable for surgery [4, 5]. Although resection and surgical margin control are higher in PN, it has been shown that ablation methods affect the renal functions less and provide similar survival rates in early stage RCC [6].

The most common thermal ablation methods are radiofrequency ablation (RFA) and cryoablation. Microwave ablation (MWA) applications have also increased in recent years [7, 8]. There are studies showing that there is no significant difference between cryoablation, RFA and MWA methods in terms of therapeutic function, effects on renal function and complications in RCC [9]. Although many studies are conducted with RFA and cryoablation therapy in RCC in the literature, there is more limited data regarding MWA.

In this study, we aimed to evaluate the efficacy of percutaneous MWA in the treatment of RCC, its safety in terms of residual renal function and other complications, and its clinical results.

Materials and methods

This retrospective cohort study was approved by the Ethics Committee of Sakarya University Faculty of Medicine (Number: 71522473/050.01.04/547). Informed consent was obtained before the percutaneous ablation treatment, after the purpose of the procedure and possible complications were discussed with the patient.

Patient selection

Twenty-one consecutive patients who underwent percutaneous microwave ablation for RCC treatment between January 2019 and July 2020, and a total of 25 procedures were included in our study. One patient was excluded from the study because the pathological result was oncocytoma. Twenty patients were T1N0M0 (14 T1a, 6 T1b), and suitable for PN or ablation. One patient had T2N0M0 RCC, and ablation decision was made due to tumor size, comorbidities, and the atrophic kidney of the patient. The patients were referred by urologists experienced in urological oncology in both open and laparoscopic surgery, and MWA was preferred because of age, comorbidities, single kidney, dysfunction in the other kidney (atrophy etc.), shorter hospital stay and the patient's refusal to undergo surgical treatment. In T1b patients, the suitability for MWA was evaluated together with the urologist due to characteristics such as size, location of the mass (intestinal proximity, proximity to the main renal vascular structures and renal pelvis) or when PN is highly risky or contraindicated due to medical comorbidities. Patients with contraindications in terms of thermal ablation (uncorrectable coagulopathy, refusal to accept the procedure), renal vein embolism and those with distant organ or lymph node metastases were excluded from the treatment.

Microwave ablation procedure

While the patient was in the lateral decubitus position with the relevant kidney on the upper side, the area to be punctured was determined with ultrasound and properly disinfected with 10% povidone iodine. After a sterile pouch was put on the 2-5 Mhz ultrasound probe (Affiniti, Philips Healthcare, Bothell, Washington), local anesthesia was administered with 1% lidocaine, and an approximately 5 mm smooth incision was made on the skin with a No.11 scalpel. Core biopsy was performed with an 18G, fully automatic needle under ultrasound guidance, and the MWA antenna was placed in the appropriate position within the lesion. The procedure was performed with the patient under conscious sedation (by increasing the dose of sedation when the patient felt pain), and general anesthesia was administered in 3 patients, considering the patient's compliance and preference.

For MWA, a 2.45 Mhz 17G uncooled system that allows treatment with multiple antennas at the same time (TATO, Biomedical, Italy) was used. If the lesion size exceeded 4 cm (T1b), two antennas were used at the same time. Approximately 2 cm distance was left between these two antennas depending on the size of the lesion. A 7.1 cm sized RCC was treated by placing 3 antennas at the same time so that the distance between the antennas was approximately 2.5 cm.

Ultrasound-guided hydrodissection was performed with a 21G needle when there was an intestinal loop, colon, or liver neighboring the lesion at 1 cm or closer to the targeted ablation area. Saline was used for hydrodissection, and saline injection (50-250 cc) was given until there was a minimum of 1 cm between the non-target organ and the tumor.

To reach the targeted ablation zone, 30W energy was applied for an average of 13 minutes (9-15 minutes depending on the target ablation zone size). During ablation, the extension of the ablation area with ultrasound was continuously followed by the gas echogenicity generated during ablation. Ablation continued until we were sure that the ablation zone covered the tumor with a minimum margin of 5 mm. After the ablation was completed, the antenna was removed by ablating the antenna tract.

Follow-up

After the patients were controlled by ultrasonography immediately after the procedure, they were followed up clinically. Hb, Htc, urea and creatinine values were evaluated before the procedure, at the 6^{th} hour and 24 hours after the procedure. Multiphasic contrast-enhanced (precontrast, arterial venous and late phase) CT (64-row multidetector CT scanner, LightSpeed VCT; GE Healthcare, Milwaukee, WI, USA) was obtained 24 hours after the procedure to control effective ablation. Patients were followed up with control CT imaging at the 1^{st}, 3^{rd}, 6^{th}, 12^{th}, 18^{th} and 24^{th} months. Complementary ablation procedure was applied to the patient after one week in case of insufficient ablation. If there was an area of enhancement in the mass in the CT performed at the 24^{th} hour after the procedure, it was considered an insufficient ablation. Although there was no enhancement area in the first CT after the procedure, if there was nodular or heterogeneous enhancement in the mass in the subsequent follow-up CT, it was considered recurrence.

Patients' age, gender, tumor size, tumor location (exophytic, partially exophytic, intraparenchymal), pre- and post-procedure Hb, Htc, creatinine values, number of repetitive procedures and complications were evaluated. The tumor was considered exophytic if there was significant bulging in the kidney contours, intraparenchymal in the case of no bulging in the kidney contour but extension towards the sinus and endophytic if it was adjacent to the collecting system (Figures 1-2). Ablation time, number of antennas used, hospital stay were recorded. Charlson comorbidity index was calculated [10]. Complications that did not require treatment or hospitalization were defined as minor complications. Complications that required additional treatment or prolonged hospital stay were major complications.

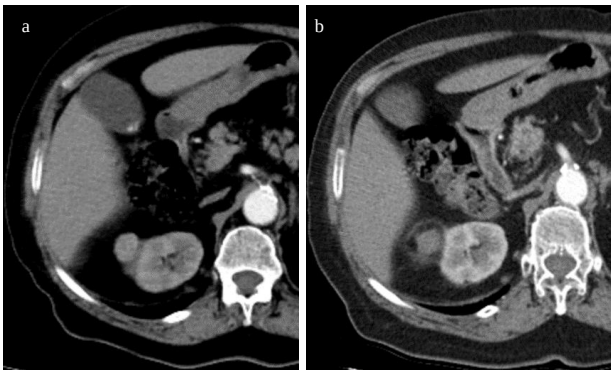

Figure 1: a. Preoperative CT image shows exophytic contrast enhanced mass on right kidney b. Postoperative 18. months CT image shows no contrast enhancement on the mass

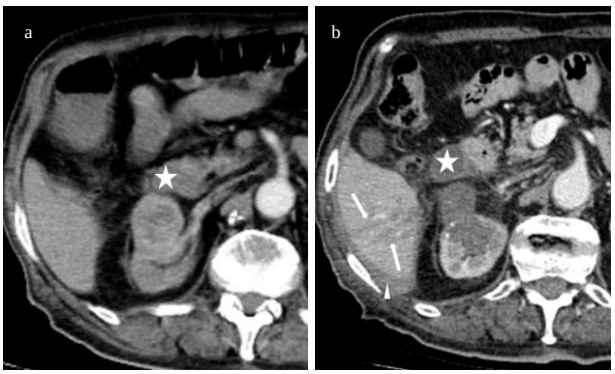

Figure 2: a. Preoperative contrast-enhanced axial CT image shows exophytic contrast enhanced mass on right kidney. The intestinal loop is located almost adjacent to the mass (star). b. Postoperative 24 hour contrast-enhanced CT shows no enhancement in the mass. Fluid density in the perihepatic area due to hydrodissection (arrowhead). Intestinal wall damage is not observed. Hypodense lines are observed in the liver due to transhepatic placement of the antennas and tract ablation at the end of the procedure (arrows).

Statistical analysis

MedCalc (ver. 12, Ostend, Belgium) was used for statistical analysis. Descriptive statistics were presented as median (minimum-maximum) and mean (standard deviation). Categorical variables were expressed as frequencies and percentages. Correlation analysis was performed with the Pearson correlation coefficient. Progression-free survival was evaluated by the Kaplan-Meier method. Progression-free survival was defined as the time between ablation and the last CT.

Results

Fifteen (75%) of 20 patients were male and 5 (25%) were female. The mean age of the patients was 68.9 (9.8) years. Median lesion size was 2.8 cm (1.9-7.1 cm). Pathological diagnosis was clear cell carcinoma in 10 patients (50%), chromophobe cell carcinoma in 3 patients (15%) and papillary cell carcinoma in 5 patients (25%). While the tumor was exophytic in 12 patients (60%), it was intraparenchymal or endophytic in 8 patients (40%). The average Charlson comorbidity index score of the patients was 6.9 (1.8). Patient and pathology characteristics are summarized in Table 1.

Table 1: Patient, tumor and procedure characteristics

Characteristics	Value
Median Age (years)	68.9 (49-81)
Gender, n (%)	
Male	15 (75)
Female	5 (25)
Median Charlson Comorbidity Index	6.9 (4-10)
RCC Stage, n (%)	
T1a	14 (70)
T1b	5 (25)
T2a	1 (5)
Tumor Localization, n (%)	
Exophytic	12 (60)
Partially Exophytic	7 (35)
Intraparenchymal	1 (5)
Histologic subtype, n (%)	
Clear Cell	10 (50)
Papillary	5 (25)
Chromophobe	3 (15)
Carcinoma NOS	2 (10)
Median ablation time (min)	13 (9-15)
Median Duration of Hospitalization (days)	1
Multiple Ablation Sessions (%)	4 (20)

In 10 patients, surgical treatment was not appropriate due to severe comorbidities, while ablation treatment was not considered appropriate in 4 patients due to borderline kidney functions, in 2 patients due to having a single kidney or because the other kidney was atrophic, and in 4 patients because the patient refused surgical treatment.

Average ablation time was 13 minutes (9-15 mins). All patients were discharged the day after the procedure and followed up on an outpatient basis. Two sessions were applied to 4 patients (20%), and one session was applied to 16 patients (80%). Hydrodissection was performed with an average of 120 cc saline (50-250 cc) in 10 of 24 procedures.

Minor complications occurred in 3 patients (15%). A moderate increase in liver function tests was observed in the patient who was treated transhepatically and with 2 antennas. Since it was asymptomatic, the patient was followed up on an outpatient basis. In the 1st week, values returned to normal. Minimal hemorrhage was observed in the post-procedure ultrasound image in 1 patient. The hemorrhage did not increase, Hb values of the patient were stable and the patient, who did not require transfusion during follow-up, was discharged the day after the procedure. Urinoma was detected in 1 patient at the 1st month follow-up after the procedure. The urinoma of the patient, who was asymptomatic, regressed at the 3rd month follow-up and no additional treatment was needed. No significant decrease in Hb or increase in creatinine values were observed in any of the patients.

Patients were followed for at least 6 months and the median follow-up period of the patients was 13.5 months (range 6-24 months). In Kaplan Meier analysis, progression-free survival was 12 months. Distant organ metastasis was not observed in any of the patients during follow-up. Recurrence was observed in 2 patients during follow-up. Recurrence in one patient occurred at the 6th month after the first procedure and the other, at the 12th month. Since the patients were not suitable for surgery due to their comorbidities, MW ablation was performed again in these patients and recurrence was treated. There were no recurrences at the 9th and 12th months following the second procedures in the patients who developed recurrences at the 6th

and 12th months following the first procedures (Figure 3). No patients died during follow-up. Median progression-free survival was 12 months in Kaplan-Meier analysis (Figure 4).

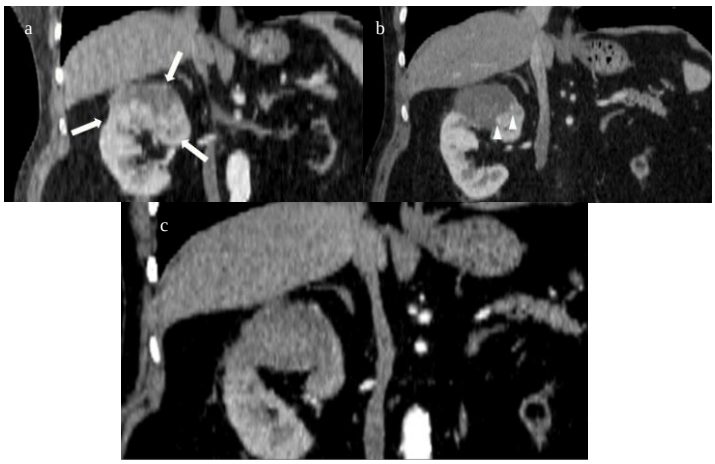

Figure 3: a. Preoperative coronal CT image shows endophytic contrast enhanced mass (Arrows), RCC b.Postoperative 12. Month postcontrast coronal CT image shows nodular enhancement compatible with relapse (arrowheads). c. No enhancement is observed in the CT taken after the treatment of the recurrent lesion

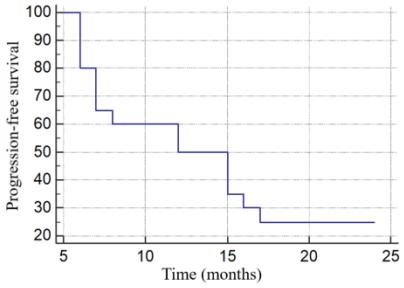

Figure 4: Kaplan-Meier analysis

Discussion

The most important result of our study is that technically successful MW ablation was achieved in all patients. Although 5 of our patients were T1b and 1 was T2a, and multiple sessions were performed in 4 patients (3 T1b, 1 T2a), the ablation procedure was successfully completed in all patients. In 2 patients, the reason for the recurrent procedure was recurrence (no increase in size, but enhancement in follow-up CT), and none of the patients progressed in the tumor stage. There was no cancer-related mortality or morbidity. Although the Charlson Comorbidity Index of the patients who were treated was quite high, no major complications were observed in any patient. Although 3 of the patients had minor complications, all of the patients could be discharged after 1 day of observation.

Tumor size was over 4 cm in all patients who required repeat ablation. All T1a tumors were successfully treated in a single session, and no residual tumors or recurrence was observed in these patients. One of the patients had a single functioning kidney, and the largest length of the tumor in this patient was 7.1 cm. However, no increase was observed in the creatinine values of the patient after the ablation procedure. The treatment of the patient was carried out in 2 sessions as adequate ablation could not be achieved in the first session. The patient was in the 7th month of follow-up and no recurrence was observed. Although ablation therapy is a treatment option especially in T1a RCCs, as in our patient, ablation treatment can be tried with the decision of the oncologic council in patients who have a single kidney and are not suitable for surgical treatment (partial or total nephrectomy) due to their comorbidities and after discussing the risks with the patient. Especially in large tumors, MW will be more useful as it provides a faster and wider ablation compared to RF ablation [9,11].

Unlike RF ablation, since MW ablation provides heating of water molecules with microwave stimulation, independent of the thermal conductivity of the tissue, carbonization does not occur and it is possible to reach a larger ablation area [12]. In addition, effective ablation is more difficult to achieve with RF, since the "heat sink effect" will be more intense during RF ablation, especially in large tumors, in a highly perfused kidney, which contains many arterial structures [13,14]. Some centers even apply arterial embolization before RF ablation to reduce the heat sink effect and enhance effectiveness [15]. However, in MW ablation, this effect is minimal since heat is transmitted directly to the target tissue rather than through the tissue [16].

While ablation is easier in T1a tumors due to their size, the ablation procedure is more complex in larger tumors. We preferred to use more than one antenna at the same time in these patients. This meant that there were at least two different electromagnetic energy sources at the same time, which meant that more energy could be delivered at once, however, it was possible to reach even more ablation fields due to electromagnetic synergy in the boundary zones [17,18].

It is known that during microwave ablation therapy, a less controlled ablation area is provided compared to RF due to rapid ablation [19]. However, the MW antenna we used provided a more controlled ablation with low energy (30W) in a long time (approximately 13 minutes). This is a very facilitating factor, especially in avoiding off-target ablation of adjacent organs or anatomical structures. In addition, ultrasound-guided hydrodissection was applied between the tumor and the non-target organ in the presence of non-target organs such as the bowel loop, colon loop, vascular structure, and liver in the vicinity of the targeted ablation area to prevent off-target ablation and possible complications. Hydrodissection is a very safe procedure [20,21], and our patients did not develop complications due to hydrodissection or off-target ablation.

Due to the development and increasing use of imaging methods, the frequency of detecting small-sized RCC is increasing [2,22]. In these patients, the first treatment option for guidelines is surgery, especially partial nephrectomy rather than nephrectomy due to better kidney function and lower risk of complications. However, ablation is an alternative treatment option to surgical treatment in elderly patients with comorbidities and are considered unfit in terms of surgery, patients with multiple tumors, with a single kidney, and those at risk of completely losing kidney function to surgery [4]. Even in studies with solitary kidney patients, ablative therapies have been shown to be fairly safe for kidney function [15,23]. It has been demonstrated that ablation therapy has similar efficacy in T1a lesions compared with partial nephrectomy, although less complication rates have been observed [24–26].

Studies have reported effective treatment success ranging from 91% to 97% and tumor progression varying between 0% and 23% for tumors below 4 cm with RF [27-29]. High recurrence or progression has been reported in some studies

with MW [30]. However, as in our study, technical success with MW is similar to RF in many studies [7,9]. In addition, studies with MW show that much larger masses are treated with ablation [31].

Some studies have reported no tumor progression with MW, even if the tumor size is over 4 cm [31]. However, in ablation treatments, it has been shown that as the tumor size increases, the incidence of recurrence increases and disease-free survival decreases [32,33]. In our study, recurrence was observed in 2 patients, and 2 patients with recurrence were RCC stage T1b.

Limitations

Our study has some important limitations. The first is that the study is retrospective and the number of patients is relatively small. Especially the number of T1b and T2 patients is not sufficient for such a study. Studies with more patients and centers are needed to demonstrate the efficiency and reliability of MW in large tumors. In addition, the follow-up period was not long in our study, a longer follow-up period is required to show long-term results.

Conclusion

The results of our study show that MW ablation is effective and highly reliable in early stage RCCs. It can be safely applied, especially in patients who are not suitable for surgery and in residual RCCs. However, multicenter randomized controlled studies with larger populations and longer follow-up periods designed in comparison with other treatment methods are required.

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