SCANDINAVIAN JOURNAL OF UROLOGY
2021, VOL. 55, NO. 3, 203–208
https://doi.org/10.1080/21681805.2021.1900386

ARTICLE

Safety and oncological outcome following radiofrequency ablation of small renal masses in a single center

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ABSTRACT

Objective: To evaluate the safety and efficacy of percutaneous CT-guided radiofrequency ablation (RFA) for small renal masses (SRMs) at a large single-institution center during a period of 12 years.

Materials and methods: A total of 118 patients underwent RFA for SRM between July 2006 and July 2018 at our institution. We included demographic information, comorbidity, procedural details, and oncological outcome in the analysis. Survival analysis was performed using competing risk.

Results: 87 males and 31 females with median age 66 years underwent RFA. Median tumor size was 23 mm. Tumor biopsy was performed in 94% of cases, of which 56% were confirmed renal cell carcinoma (RCCs). Twenty-eight patients had benign tumors or underwent treatment for recurrence of prior RCC. Median follow-up of 5 years. Median Charlson Comorbidity Index was 5. Major complications occurred in 1.7%. No change in kidney function was observed. The initial treatment response was 98%. Among patients treated for newly diagnosed radiological suspected RCC without Von Hippel-Lindau or benign biopsy (90 pts), the cumulative incidence of radiological recurrence after 5 and 10 years was 6.6% (95% CI: 0.8–12%) and 16% (95% CI: 4.2–28%), respectively. Three patients died of RCC during follow-up. The cumulative incidence of kidney cancer death was 4.5% (95% CI: 4.3–13%) after 10 years. The incidence of other-cause mortality was 50% (95% CI: 34–67%).

Conclusion: CT-guided RFA is a safe and effective treatment option for patients unsuitable for surgery. RFA is a good alternative to partial or radical nephrectomy for SRMs, although randomized trials comparing surgery to minimally invasive thermal ablation techniques are missing.

ARTICLE HISTORY
Received 17 December 2020
Revised 1 March 2021
Accepted 3 March 2021

KEYWORDS
Renal cell carcinoma; radiofrequency ablation; localized kidney cancer; long-term oncological outcomes; small renal mass

Introduction

Renal cell carcinoma (RCC) represents 5% of all oncological diagnosis in men and 3% in women [1]. The incidence of renal tumors and renal cancer has increased due to the increment in number of abdominal imaging performed for unspecific abdominal symptoms [2]. The incidence of stage 1 tumors has increased most dramatically, now accounting for 40–50% of newly diagnosed RCC [3]. Until now, increased detection has not led to a reduction in kidney cancer-specific mortality in these small tumors [4].

Small renal masses (SRMs) are defined as incidentally image detected, contrast-enhancing solid or cystic lesions up to 4 cm in diameter and classified as clinical T1a kidney tumors if malignant. SRMs can be non-malignant or represent other non-RCC tumors such as sarcomas, lymphomas or metastasis from other organs. Guidelines recommend renal tumor biopsy of SRM before treatment, as 20% of all surgically removed SRMs are benign. Only 20% of malignant tumors are high-grade or invasive, leaving most SRMs with limited metastatic potential [5].

There are several treatment options for localized masses suspicious for RCC, including active surveillance (AS), surgery and thermal ablation (TA). In the elderly population, including those with comorbidity, AS should be considered as studies have shown that patients over 70 years with SRMs have low disease-specific mortality and high treatment-free survival [6]. Surgery remains the primary curative treatment option with nephron-sparing surgery as gold standard [7]. TA is a treatment option for patients who are not fit for surgery and where complete ablation is possible [5].

TA includes several different techniques such as radiofrequency ablation (RFA), microwave ablation (MWA) and cryoablation (CA). RFA for treatment of kidney tumors was first described in Zlotta et al. [8]. The RFA technique consists of a radiofrequency energy delivered through needles inserted into the SRM, resulting in localized tissue necrosis.

Guidelines recommend TA for SRMs in elderly comorbid patients unfit for surgery, patients with a genetic disease with high risk of developing multiple tumors and patients with bilateral tumors or a solidary kidney with a high risk of complete loss of kidney function after partial nephrectomy

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(PN) [9]. There is currently no evidence to support one TA technique over the other.

Here, we analyze a cohort of patients who underwent RFA at our institution in a 12-year period. The aim was to describe tumor and treatment characteristics, complications, kidney function, recurrence rate, retreatment rate and overall survival.

Material and methods

The study was approved by The Danish Data Protection Agency (File #: RH-2018-75) and the Danish Patient Safety Authority (File #: 3-3013-2779/1). We included all patients who underwent percutaneous CT-guided RFA at our institution between July 2006 and July 2018. Demographic information, comorbidity according to Charlson Comorbidity index (CCI), kidney function, survival data, and complication were recorded. In case of other cancer, two points were added to the total score in CCI. Kidney cancer was not included in the total score. Pre-procedural and post-procedural imaging (CT or MRI) were reviewed. Nephrometry score was not used in our institution.

RFA indication and technique

According to our protocol, patients with kidney tumors under 40 mm, who met the following requirements were candidates for RFA: high risk for surgical complications, bilateral tumors, genetic disease such as Von Hippel-Lindau (VHL) and/or patients with a history of prior RCC who had previously undergone PN or contralateral radical nephrectomy (RN). Not all patients underwent pre-procedural tumor biopsy, which was at the discretion of the treating physician in the given case. We used a cool-tip RF ablation system. The system consists of a single needle electrode or a unit of three electrodes in a triangular cluster. From 2017, RFA was only performed with single needle electrode. The practice was changed after a patient experienced a major complication (necrosis in the psoas).

In each tumor, one to three ablations were performed, depending on tumor size. Hydrodissection was used in 40 cases to separate the tumor from the surrounding organs. Two patients underwent prophylactic placement of a double-J stent prior to the procedure due to a central tumor location. Immediate assessment of the treatment and the intraprocedural monitoring and modifications were performed by CT. All patients were under general anesthesia. After treatment, patients were monitored with vital signs and were discharged when appropriate.

Patient follow-up

Patients were examined with CT or MRI quarterly during the first year, followed by annual imaging for a minimum of 5 years. Patients with known genetic disease underwent lifelong follow-up, typically with MRI. Patients with inadequate tumor histology were perceived as malignant and monitored accordingly. eGFR was measured simultaneously with follow-up imaging. Residual tumor (in-complete ablation) was defined as residual enhancement in the tumor location detected on the first post-procedural imaging. Tumor recurrence was defined as tumor enhancement which was not present on the first post-procedural image. If a radiological diagnosis of recurrence could not be defined, a biopsy of the new lesion was initiated. The follow-up concluded at the last recorded follow-up date or at the time of the patient's death.

Data collection and statistical methods

The primary endpoints were the incidence of recurrence and incidence of mortality. Secondary endpoints included complications, post-procedural kidney function, and re-treatment rate. We also recorded number of ablations per tumor, total time for each ablation, recurrence rate and number of in-complete ablations. The follow-up time was estimated using the reverse Kaplan–Meier method. Three patients died of RCC during follow-up. Risk of recurrence and mortality was estimated using a Fine and Gray competing risk models with death before recurrence and other-cause mortality as competing events, respectively. Patients with histologically verified benign tumors were excluded from the calculation. Patients with VHL and previous history of RCC were excluded when calculating the cumulative risk of recurrence and cumulative risk of death before recurrence. Procedure-related complications were graded according to the Clavien-Dindo classification [10]. The difference between eGFR before and after RFA was assessed by a box plot of the median. Postprocedural eGFR was estimated three months after primary RFA. There were missing data regarding eGFR for 19 patients. Statistical analysis was performed in IBM SPSS Statistics 25 and R software.

Results

A total of 124 patients were identified. Six patients were excluded due to lack of information on treatment and follow-up data leaving 118 patients (87 males, 31 females) for evaluation. Median follow-up of 5 years. Patient characteristics are demonstrated in Table 1. The median age at the time of RFA was 66 years (range: 33–86) and the median CCI was 5. At primary RFA, a total of 113 patients had one tumor ablated, four patients had two, and one patient had three tumors. The median treatment time per tumor was 12 min (interquartil range 12–12 min). The median size was 23 mm (range: 9–36). Complete response was achieved at the first treatment for 111 out of 118 patients (94%) and after second RFA 116 patients (98%) had complete response (Table 2). For patients with incomplete RFA, the median tumor size was larger [median 30 mm (range 27–34)]. Six out of the seven tumors were exophytic and located in the upper pole. Two patients had no effect of RFA and underwent nephrectomy and CA as alternative. The average length of stay was 1 day (range: 0–45). The majority (72/118) of the patients were discharged within 24 h.

Table 1. Demographic characteristics.

No	118
Missing data	6
Median age (years)	66 (33–86)
Sex	
Male	87 (74%)
Female	31 (26%)
Charlson comorbidity index (%) (117/118)	
1	5 (4%)
2	17 (15%)
3	19 (16%)
4	33 (28%)
5	15 (13%)
6	12 (10%)
7	4 (3%)
8	9 (8%)
9	2 (2%)
12	1 (1%)
No. of tumors	124
One tumor	113 (96%)
Two tumors	4 (3%)
Three tumors	1 (1%)
Median tumor size (mm) (121/124)	23 (9–36)
Tumor stage	
T1a	124 (100%)
Tumor laterality (118/124)	
Right	57 (48%)
Left	60 (51%)
Bilaterale	1 (1%)
Tumor location (119/124)	
Upper pole	39 (33%)
Midpole	34 (28%)
Lower pole	46 (39%)
Tumor subtype (113/118)	
Malignant	
Papillary	15(13%)
Clear cell	50 (44%)
Metastasis	1 (1%)
Cytologi	1 (1%)
Benign	
Adenoma	3 (3%)
Oncocytoma	6 (5%)
Angiomylipoma	2 (2%)
Cytologi	1 (1%)
None representative	34 (30%)
Median follow-up (months)	60 (3–156)

Table 2. Procedure details.

No. electrodes placements (105/139)	
1	75 (71%)
2	28 (27%)
3	1(1%)
4	1 (1%)
Median treatment time (min)	12 (IQR 0)
Adjunctive maneuvers	
Hydrodissection	40 (29%)
Ureteric stents	2 (1.4%)
Complications (113/118)	
Clavien dindo grade 0	71 (63%)
Clavien dindo grade 1	35 (31%)
Clavien dindo grade 2	5 (4%)
Clavien dindo grade 3–4	2 (2%)
In-complete ablation	7 (6%)
Recurrence	6 (5%)
Time to recurrence (years)	4.9 (1.5–8.4)
Median GFR	
Pre-procedure (100/118)	70 (30–99)
Post-procedure (96/118)	65.5 (27–90)

Table 3. Complications after RFA.

No. of patients	Complication	Treatment
7	Unknown	
71	None	None
18	Pain	Analgesic
3	Wound swelling	None
1	Urinary retention	Catheter
1	Small skin burn	None
1	Dyspnea	Oxygen
2	Nausea	Antiemetic
1	Transient disturbance in the left arm	None
3	Small diaphragm lesion	Observation
1	Haematuria	Catheter
1	Dysuria	None
1	Obstipation	Oral fluids
2	Urosepsis	Iv. antibiotics
3	Pneumonia	Iv. antibiotics
1	Psoas necrosis	Surgery
1	Large skin burn	Surgery

About 95% (112) underwent a tumor biopsy of which 80% (94) were perioperative. In patients with malignant histopathology, a total of 44% (50) were clear cell RCC, papillary RCC in 13% (15), and one case with metastasis from colon cancer. One patient was identified with malignant cells in a cytology specimen from a cystic tumor. There were 12 benign histological examinations (3 adenomas, 6 oncocytomas, 2 angiomyolipomas, 1 benign cytology), resulting in 34 inadequate histological examinations.

Major complications were seen in two patients (1.7%). One patient was admitted with abdominal pain 1 week after RFA. An abdominal CT showed necrosis in the psoas muscle and quadratus lumborum muscle. After 2 weeks, a scan showed uroplania and a ureteral stent was placed. Within the following month, the patient developed a large abscess, necessitating the patient undergoing nephrectomy and splenectomy. The other patient developed a large burn and infection in the skin and was treated with antibiotics for 1 week and later required surgery. Of minor complications, 5 (4.2%) had grade 2 and 35 (29.7%) patients grade 1 (Table 3). Comparison of the pre-procedural eGFR and the 3-month post-procedural eGFR is shown in Figure 1 and shows no difference. During follow-up, recurrence was observed on imaging in six patients of which four underwent rebiopsy confirming recurrence of RCC. The median tumor size for the patients experienced recurrence was 33 mm (range 25–35 mm) at the time of RFA. Three patients underwent retreatment with RFA, two patients were recommended observation, and one patient underwent a salvage nephrectomy (Table 4).Thirty-three patients died during follow-up. Of the three deaths from RCC, one patient had metastatic disease at the time of RFA, whereas two progressed to metastatic RCC after 5 and 9 years, respectively. Other causes of death were non-RCC neoplasm (11), cardiac arrest (2), respiratory insufficiency (2), complication to surgery (1), and 14 were unknown causes of death. Twelve patients had a previously history of RCC and out of these six had metastatic disease at the time of RFA. In three cases, the RFA was for local recurrence after PN and in nine cases treatment of metastasis in the opposite kidney after nephrectomy. In patients who underwent treatment for a new diagnosis of suspected RCC who did not have VHL or benign biopsy (90 patients), the cumulative incidence of radiological recurrence after 5 and 10 years was 6.6% (95% CI: 0.8–12%) and 16% (95% CI: 4.2–28%), respectively (Figure 2). The cumulative incidence of kidney cancer death was 4.5% (95% CI:

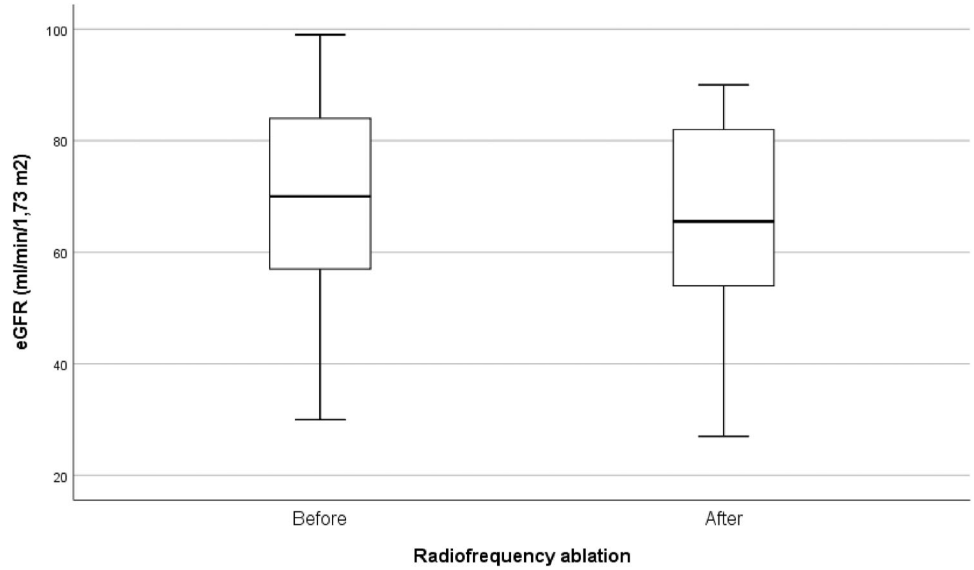

Figure 1. Box plot of changes in median preprocedural and postprocedural eGFR.

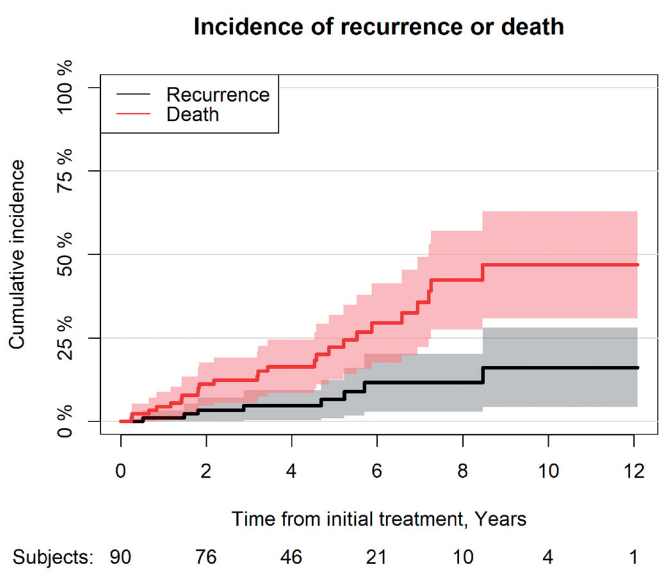

Figure 2. The cumulative incidence of recurrence or death.

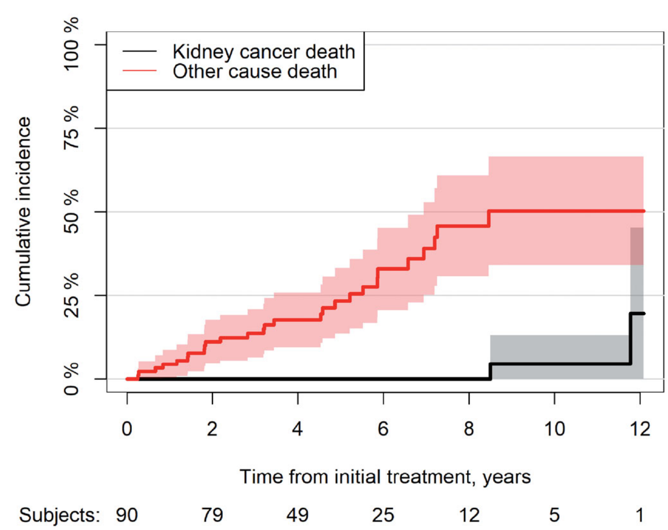

Figure 3. The cumulative incidence of kidney cancer mortality and incidence of other-cause mortality.

4.3–13%) after 10 years and the incidence of other-cause mortality was 50% (95% CI: 34–67%) in that patient group (Figure 3).

Discussion

The optimal management of localized renal cancer remains at debate. Although nephron-sparing surgery has gained increasing popularity for T1–T2 tumors, there is limited evidence to support the use of PN over RN [7]. It is well known that SRMs may not have an aggressive tumor growth and therefore observation/surveillance could be considered over any surgical intervention in this patient group. To date, no randomized trial has compared surgical interventions or surgery to observation in pT1a RCC [11]. A recent review suggests that SRMs may be safely managed with repeated imaging and delayed intervention without compromising oncological safety [4]. PN and RN carry an implicit risk of perioperative morbidity and mortality, especially in elderly patients and/or patients with comorbidity [12]. This has led to a growing interest for minimally invasive surgical procedures. In the absence of comparative surgical trials, there is a continuous need for reporting experience and complications associated with RFA to better understand the clinical benefit.

We reviewed 118 patients who underwent RFA for SRMs in a 12-year period at our institution which is a large series in the current literature. Patient characteristics in terms of age and tumor size seems comparable to previous publications [13–16]. Our patients were comorbid with a median CCI of 5 which is typically associated with risk of other-cause mortality in kidney cancer patients [17]. Unfortunately, other RFA publications have not systematically reported comorbidity using CCI or other standard references which makes comparison difficult.

Overall, we found a low risk of complications with only two patients (1.7%) experiencing major complications and the majority of grade 1 complications consisting of mild

Table 4. Details for patients with recurrence.

Age	CCI	Histopathology	Tumor size	Months to recurrence	Treatment of recurrence	Location of recurrence	Cause of death
75	3	Inadequate	30	34.5	Partial nephrectomy	Local recurrence	A live
74	4	Inadequate	32	56.3	RFA	Local recurrence	A live
59	3	RCCcc	35	17.8	RFA	Local recurrence	Metastatic oesophageal cancer
86	4	RCCcc	25	21.7	RFA	Local recurrence	Unknown
74	3	Inadequate	35	101.7	Palliative treatment	Large new in the opposite kidney	Metastatic kidneycancer
62	3	RCCcc	30	64.4	Nephrectomy	Local recurrence	Metastatic kidneycancer

pain. Previous RFA cohorts have reported major complications such as ureteric stricture, renal abscess, hemothorax, bowel perforation and urine leak requiring surgical intervention in 3.9–6.6% of these cases [13,15,16]. Wah et al. [15], who used ultrasonography-guided RFA in the first 31 treatments, included Clavien Dindo grade 2 as major complication, thus reporting a major complication rate of 6.6%. We used CT-guided RFA which may explain differences in the overall major complication rate. On the other hand, two publications reported a higher rate of both major and minor complications even with the use of CT-guided RFA and identical classification system [13,16]. It remains questionable if RFA is associated with less complications compared to other minimally invasive procedures. A systematic review showed a lower overall perioperative complication rate for TA (CA or RFA) compared to RN and PN [18]. The review demonstrated a higher blood transfusion rate for PN than for TA (4.6 vs. 0.4%) and shorter length of stay (3.9 vs 1.8 days). There was an identical rate of overall minor and major complications for patients undergoing RN, PN and TA, respectively. However, the type of complication varied in between the different surgical approaches. RN had the highest rate of respiratory complications and resulted in the highest risk for loss of kidney function. The risk for stage 3 chronic kidney disease was 3.5-fold higher for RN compared to TA but similar between PN and TA. Patients undergoing PN had higher rates of acute kidney failure, cardiovascular, hematological, and respiratory complications but lower rates of infectious disease and wound complications compared to TA [18]. These findings are supported by a systematic review by Katsanos et al. [19] who compared TA (RFA or microwave) to PN/RN and found a significantly lower overall complication rate (7.4 vs 11%) for TA compared to RN/PN but no significant difference in major complication rate (2.3 vs. 5%).

An important argument for the use of minimally invasive procedures in kidney surgery is the impact on global kidney function. In this cohort, RFA did not impair kidney function. This remains an important advantage for TA, especially for patients with marginal preoperative kidney function in which RN or even PN could result in symptomatic renal impairment. A study from 2018 investigated kidney function following RFA, CA, or MWA for T1 biopsy-verified RCCs and found no change in renal function which supports our findings [20]. Another advantage for ablation techniques is the short treatment time and short hospitalization. The treatment time of 12 min and an average stay of 1 day in our study seems comparable to previous publications [13,15,21,22].

Recent guidelines have advocated for the use of biopsy of SRMs as one in five tumors may not be malignant despite suspicious radiological signs. However, the success of a biopsy depends on several technical aspects. We found a lower percent of malignant histopathology examinations (58%) compared to other studies which may have several explanations [13,15]. Biopsies from cystic renal masses have a lower diagnostic yield and are not recommended alone unless the cystic lesion is at least classified as Bosniak type 4 [23]. Half of the inadequate histological findings in this study occurred in cystic lesions. Also, we performed the majority of biopsies simultaneously to the procedure for practical purposes. According to the EAU guidelines, it is now recommended to perform renal tumor biopsy in patients considered for AS or TA before treatment is initiated [9].

In this study, the cumulative incidence of recurrence after 5 and 10 years was 6.6 and 16%, respectively. Metastatic progression was seen in two patients and the disease-specific mortality was low with only three patients dying from RCC. Other studies have shown a 2.0–7.4% risk of local disease progression after 1.9–4.9 years [13,15,24,25]. Other cohort studies have reported recurrence-free survival rate of 88–93% which corresponds to our findings. The small difference between the studies is likely explained by selection bias [13,15,16,24–26].

A systematic review and meta-analysis from 2015, including 3974 patients who had undergone PN, RFA or CA, found no significant difference in local recurrence (HR, 1.32; 95% CI: 0.79–2.22; $p = 0.228$) or risk for metastatic disease (HR, 1.83; 95% CI: 0.67–5.01; $p = 0.239$) between TA and PN [27]. In terms of overall survival previous publications have reported a 3, 5 and 7 years OS rates of 73.4–82%, 75.6–80% and 50.3%, respectively [13,15,16,25], which seems comparable to our study. It is noticeable that the risk of death before recurrence was significant, which underlines that we treated an elderly and comorbid population of patients in which the risk of progression to advanced kidney cancer was small. A study of CA found a similar OS rate [28].

The most imperative question is whether treatment of SRMs is necessary at all. Trials addressing curative treatment options versus surveillance are missing. A large review with the aim of identifying the utility of AS in SRMs for patients >70 years demonstrated a disease-specific mortality or progression to metastases of <5% (0–5%) during follow-up (range: 9.5–96.6 months). There were no differences in the risk of metastatic progression between active treatment and AS [6]. Another study found that AS is safe for tumors under 2 cm, especially in comorbid or elderly patients, and demonstrated that tumor kinetics is important to determine if a patient is suited for AS [29]. As in other surveillance strategies, it is not well-known what triggers should be used for switching strategy or stopping surveillance but most studies have proposed that tumor growth (generally >0.5 cm/year), development of metastatic disease, absolute size over 3–4 cm and patient acceptability of AS regimen should be involved in the decision-making process [6].

Our study has certain limitations. Our data is retrospective and thus prone to bias. Naturally, our results may not be generalizable to other institutions. Additionally, we did not compare RFA with AS, other thermal modalities, or with surgery. Nevertheless, RFA was an effective and safe procedure for the treatment of pT1a tumors at our institution.

Conclusion

CT-guided RFA ablation is a safe and effective treatment option for patients unsuitable for surgery. This study demonstrated favorable oncological outcomes, no impairment of renal function, and low complication rate in tumors under 3 cm. The complete ablation rate was 98% after retreatment. TA is an alternative treatment option to RN or PN and should be considered as a treatment option in SRMs.

Disclosure statement

The authors have nothing to declare, nor any potential conflict of interest.

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