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RESEARCH

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Long-term follow-up of CT-guided percutaneous radiofrequency ablation of T1 renal cell carcinoma

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Abstract

Background Radiofrequency ablation (RFA) has an established role in effective treatment of renal cell carcinomas (RCCs), as most of RCCs are diagnosed incidentally in early stages. Long-term follow-up is however important to consolidate the technique. Most of the literature contains series of short-term follow-ups of periods shorter than 2 years. This study in hand demonstrates the results of longer-term follow-up than the previously published series.

Results Data analysis of 31 patient records involved in this study demonstrated the high clinical efficacy of RFA for long term, 12-year follow-up, by following the absence of tumor recurrences, as shown on regular interval contrast enhanced computed tomography (CT) and or magnetic resonance imaging (MRI).

Conclusions RFA continues to prove its competent role in treating RCCs on longer-term follow-ups; the smaller the size of a tumor and the more peripheral the tumor is, the more effective the therapy. Even in larger early stages tumors, repeating the ablative sessions results in complete ablation without the need for more invasive surgical interventions.

Keywords Radiofrequency ablation (RFA), Renal cell carcinoma (RCC), Long term follow-up, 12-year follow-up, Computed tomography (CT)-guided radiofrequency ablation (RFA)

Background

Malignancies of the kidneys have been reported to be the 14th among the most common cancers around the world constituting about 2.2%. The most common type of these malignancies is renal cell carcinoma (RCC). Men in their 6th and 7th decades are more frequently affected. Notably the incidence is currently increasing over the past years in younger individuals [1, 2].

Incidental detection of renal cell carcinomas has increased over the past decades owing to the advent of cross-sectional imaging, that now most of renal cell carcinomas are discovered incidentally in an early stage with small localized lesions. These early-stage tumors are preferably treated with nephron sparing surgery or radiofrequency ablation (RFA) in order to minimize later deterioration of renal functions. Special need for these nephron sparing approaches are pivotal in cases with multiple renal masses such as in syndromic renal malignancies or with a solitary functioning kidney [3].

RFA has already proven its initial clinical efficacy in treating those early-stage tumors in several studies published in the literature. Several other studies followed the patients for periods of time, with mean duration of follow-up shorter than 2 years [3]. Longer-term follow-up

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of large cohorts of patients are few in the literature and do not exceed five-year follow-up in the longest of them. We present this study to evaluate the outcome of Computed Tomography (CT)-guided RFA of T1 RCC on long-term follow-up.

Methods

We retrospectively conducted this study for the 31 consecutive patients treated in the radiology department in a single tertiary care urology center in the period from July 2007 to September 2019, by investigating the immediate as well as the remote clinical and radiological response following CT-guided RFA as the treatment of RCC. We meticulously searched the department's picture archiving and communication system (PACS) and the Hospital's information system (HIS). The clinical, radiological and laboratory data from the systems were collected, documented and analyzed.

The clinical decision of management of those patients was elected over other management options by a multidisciplinary team meeting and was taken with putting in consideration the stage of the tumor, the clinical status of the patient, any associated major comorbidities and also willingness of the patients and their preference, these considerations are all recommended by the International Guidelines [4].

We have included in this study, RCC of stages T1a or T1b without nodal or distant metastasis, treated with RFA with radiological as well as documented clinical follow-ups for at least 1 year. Patients were excluded if demographic data, laboratory tests or images (whether CT or magnetic resonance imaging-MRI) were missing.

Ethical considerations

An informed consent was obtained from all patients after full explanation of benefits and risks. No further apparent risks or hazards to the patients were included in this study more than the possible complications of the interventional procedures and those were treated immediately in the hospital. An those were cleared to the participants and the ethical committee on time. Privacy and confidentiality of all patients' data were guaranteed and there was a code number for every patient's file that includes all investigations stored at PACS.

Preprocedural assessment

All patients were subjected to full clinical assessment obtaining full medical history and general examination and exclusion of allergy to contrast media. Laboratory investigations including complete blood count, coagulation profile and renal function tests including serum creatinine (S.Cr), from this S.Cr values eGFR was also calculated using the CKD-EPI equation. Patients then were to perform contrast enhanced studies according to their eGFR as follows; if eGFR was > 45 mg/dL/1.73m^2 (S.Cr in these patients was generally around or less than 1.6 mg/dL), contrast-induced nephropathy was considered as very low (> 60) and low risk (> 45) and no additional measures were to be necessary and patients underwent contrast-enhanced CT. If eGFR was between 45 and 30 mg/dL/1.73m^2, (S.Cr was slightly higher than 1.6 mg/dL in these patients), contrast induced nephropathy was considered as moderate risk and patients were adequately intravenously hydrated before and after the CT procedure or they underwent contrast-enhanced MRI. If eGFR was < 30 ml/min/1.73m^2, due to much higher S.Cr, patients were considered as high risk and no contrast was to be given in our study. Radiological investigations including CT and/or MRI were done for better and accurate assessment of the renal masses (size, location, nature, relation to surrounding structures, renal vascularity), assessing the other kidney and other abdominal organs and after treatment decision for guidance of the RFA.

Protocol of renal MSCT

All examinations were performed using a multidetector CT machine with 64 parallel detector rows (Brilliance CT, Philips Medical Systems, Best, The Netherlands). We obtained an un-enhanced CT scan, early arterial phase (10–20 Sec.), late arterial phase (Cortico-medullary phase) (30–40 Sec), nephrographic phase (80–180 Sec.) and excretory phase (3 Minutes). Contrast agent used was water soluble non-ionic iso osmolar iodinated compound; iodixanol (Visipaque) (320 mg iodine/ml) administered intravenously at a dose of 1.5 ml/kg body weight, and a rate of 5 cc/sec via an 18-gauge cannula.

Protocol of renal MRI

All MRI examinations were performed using a 1.5 T MRI scanner (SIGNA Horizon, General Electric Medical Systems, Milwaukee, WI, USA). Pre- and post-contrast MRI sequences including pre- and post-contrast T1 with fat saturation, T2, DWI and MRA were done to assess the renal masses before and after RFA. Contrast agent used was macrocyclic ionic gadolinium-based compound; Gadoteric acid–Gadoterate meglumine (Dotarem, Guerbet GmbH) at a dose of 0.2 mL/kg (0.1 mmoles/ kg) at a rate of 10 mL per 15 s intravenously via an 18-gauge cannula.

RFA procedure

Preparation of patients was done by stopping and oral anti-coagulants before the procedure. Patients were intravenously (IV)-hydrated, and given prophylactic antibiotics and instructed to abstain food intake 6 h prior to

procedure. For anaesthesia and medications, a peripheral IV access was obtained, monitoring for vital signs was done. After spinal anaesthesia, the patient was placed prone. Local anesthesia was given to the site of skin using 10 mL of 2% xylocaine.

Radiofrequency ablation system

Two different devices were used for RFA:

RITA device (RITA Medical Systems, Mountain View, CA, USA), a 150-watts generator using multi-tined expandable needle electrode (Starburst TM, 2–3 cm; or Starburst TM XL, 3–5 cm).

Radionics device (Radionics, Burlington, MA, USA), a 200-watts generator with internally cooled electrodes and impedance-controlled pulsed current, treatment was performed with either a cluster (2.5- or 3-cm active tip) or a single (17 gauge, 2- or 3-cm active tip) needle electrode.

Type of electrode was decided by the operator to fit size of the tumor.

Number of ablations per session was from 1 to 4 ablations.

Technique of RFA

The procedure was done in CT unit after skin disinfection local anesthesia. Under CT guidance, the needle was inserted into the mass and RF energy was delivered. The technique was monitored with temperature-based/cool tip system by allowing the probes to heat to a specific temperature for about 12–15 min. Cooling by saline irrigation within the tip of the probe to eliminate the charred tissue from the probe to ensure perfect ablation zone. Some specific maneuvers were done in selected patients: A ureteric catheter was placed to reduce risk of thermal injury to the ureter and allow healing of ureter in case of injury, hydro-dissection by injecting D5W was used for displacement of adjacent bowel loops away from the tumor, additional procedures such as selective embolization of the tumor may be performed before the radiofrequency ablation in patients with hypervascular or central tumors near large vessels to reduce heat dissipation.

The aim was to ablate the main renal mass and 1 cm safety margin at least of normal renal parenchyma.

During withdrawal of the probe, its track was ablated to avoid tumor seeding.

CT images were then acquired to evaluate the procedure, detect any residual tumor, and repeat session if needed.

Post procedure patient care

Patients were recovered in post anesthesia care unit with monitoring of vital signs and observing for 24 h and prophylactic IV antibiotics (Augmentin or Fortum, and Flagyl) were started, and continued for 3 days.

Post procedure follow ups

Contrast-enhanced CT or MRI follow-up was done for all patients After 1 month to detect any residual enhancing tumor tissues, and if there is any, another RFA session was done. Follow-up were continued at 2, 3 or 6 months in the first year, then yearly onwards, contrast-enhanced CT and or MRI was done to detect any recurrent or new renal tumors and to evaluate size of the ablated lesion and images were interpreted by radiologists as follows:

Complete necrosis was presumed if lack of contrast enhancement in the treated region on all follow-up studies.

Residual disease if persistent enhancement in an area or areas of the tumor after ablation, as determined at the 1-month follow-up study.

Recurrent disease: new tumor enhancement, after at least 1 imaging study had demonstrated complete eradication of enhancement.

At contrast-enhanced CT, the enhancement of renal lesions considered pseudo enhancement if 10–15 HU increased from precontrast study. If density increased more than 15 HU, it was considered as a viable tumor tissue. At MRI the tumor enhancement was determined through the qualitative evaluation of the pre- and post-contrast images.

We obtained the following primary and secondary outcome measures as defined by the international reporting standards and guidelines [5, 6].

Primary statistical measures

Overall survival rate (OS), which is duration of patients' survival starting from first session of RFA whatever the cause of death was.

Disease-free survival (DFS), calculated by the time during which the patient did not exhibit and radiological findings of RCC since the date of the technically successful RFA.

Progression-free survival (PFS), which is calculated by the duration during which the patient has a viable RCC since the RFA was done, but without progression of the disease (progression is defined as primary lesion increase in size and/or new lesion and/or metastasis).

Cancer-specific survival (CSS) rate; which is calculated by the percentage of patients who did not die of RCC within the whole study time.

Secondary outcome statistical measures

Local recurrence, was judged by the appearance of any enhancing tumor tissue inside or around the ablated area after previous images have proved negative scan.

Primary technical success, was judged by absence of any enhancing tumor tissue inside or around the ablated area in the imaging following the procedure.

Technical success, was judged by the absence of any enhancing tumor tissue following second ablative sessions or more.

Complications and events related to the procedure or during the hospital stay of the procedure was documented and staged according to Clavien–Dindo system [6].

Statistics and data analysis

Counts and percentages were used to report discrete variables. Median and interquartile range (IQR) in parentheses or mean ± standard error (SE) were used to report data derived from normal distributions according to the Kolmogorov–Smirnov goodness-of-fit test. Kaplan–Meier method was used to estimate primary endpoints (OS, DFS, PFS and CSS) and the rates were reported only for SE < 10% to derive valid statistics of the outcomes. Statistical analysis was performed using the SPSS/PASW software (version 22.0, 2013; IBM). The threshold of statistical significance we used was $p < 0.05$.

Results

This study, done in a tertiary urology center, included 31 consecutive patients (25 male, 80.6%; mean age, 55 ± 10.3 years; age range, 39–72 years) where 44 lesions were included. Most of the lesions treated were electively selected to be in early stage; T1a. The mean tumor diameter was 2.98 ± 0.83 cm (range, 1.5–5 cm) (Table 1). Primary technical success was 95.5% (42/44 lesions) (Figs. 1, 2).

Technical success obtained was 100% (44/44 lesions) including two patients who have shown residual tumor tissue during initial follow-up imaging after the first ablation, for which they have undergone a further ablative session for each: one of these two patients had residual tumor due to the high vascularity of the RCC, that high vascularity prompted to perform a super-selective embolization of the feeding artery followed by a second RFA session that was successful technically and clinically evidenced by follow-up imaging (Fig. 3).

The mean of the follow-up duration was 126.8 ± 7.3 months (range, 15–193 months) one example is demonstrated in (Fig. 4). One patient demonstrated metachronous RCC masses during follow-up for which he

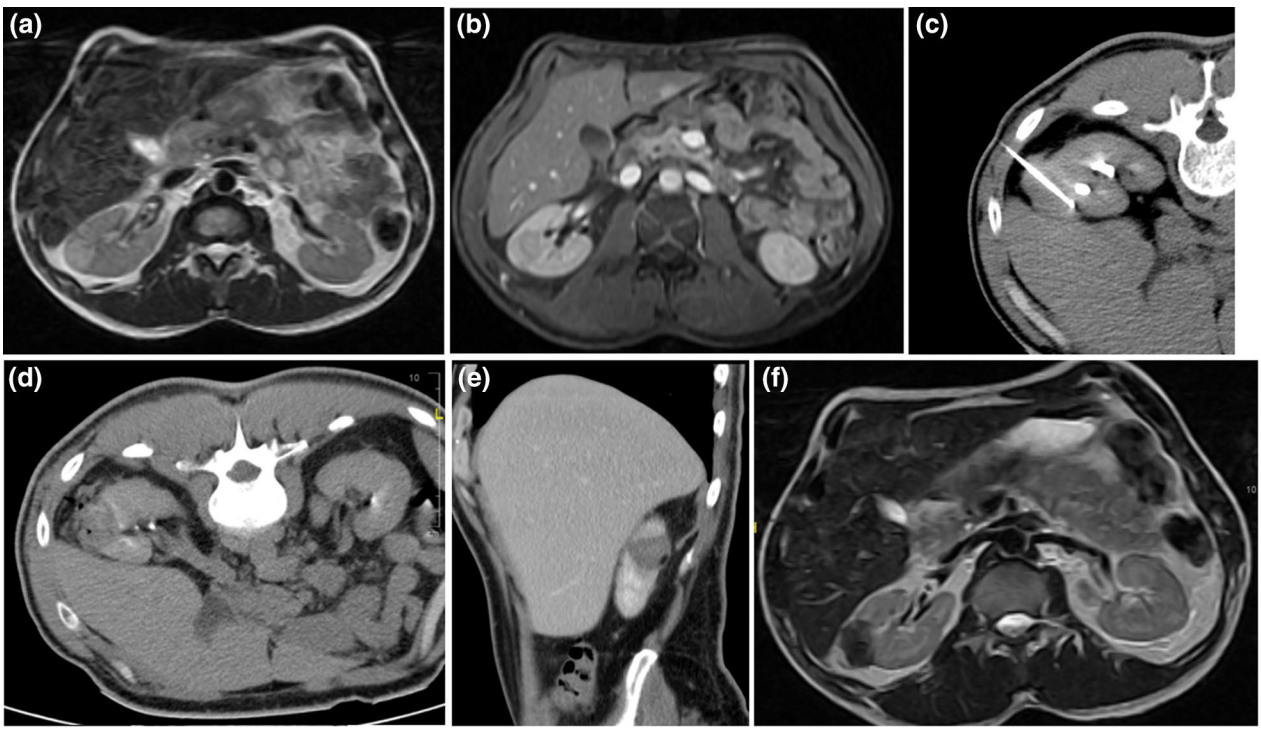

Fig. 1 **a** In this, 44-year-old male patient, T2 weighted MRI shows an incidentally discovered hyperintense soft tissue mass measuring about 2.3 cm in diameter in middle zone of right kidney; stage T1a. **b** The mass enhances mildly following IV contrast administration. **c** Image during CT RFA of the RCC. **d** Image immediately following CT-guided RFA of the RCC shows heterogeneous densities of blood and air attenuations. **e** Image 1-month following the procedure; the mass does not show any enhancement after IV contrast administration denoting complete necrosis of the tumor tissue. **f** Image 1-month following the procedure, the mass appears totally hypointense secondary to complete necrosis of the tumor tissue

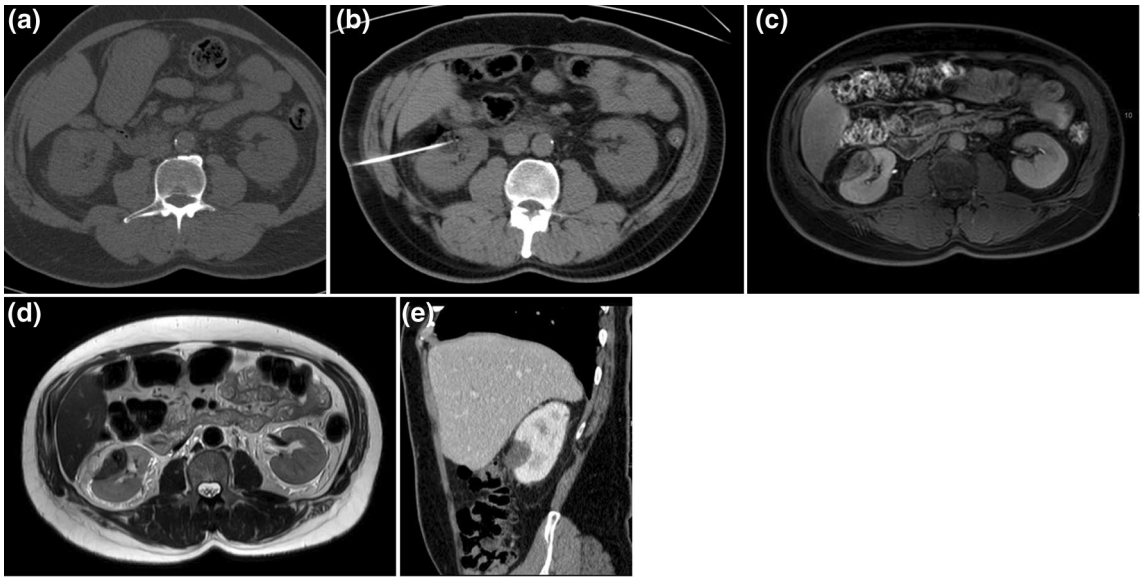

Fig. 2 **a** 55-year-old man, non-contrast CT done to exclude renal stones, shows contour bulge of the right kidney due to a lower polar mass 3 cm in diameter; stage T1a. **b** Same patient, image obtained during CT-guided RFA procedure, note the clue of successful ablation during procedure is the presence of air densities inside the mass, and outside in the perirenal fat. **c** Same patient, after 1 month, T1 weight MRI with fat sat image shows no discernible enhancement following IV contrast administration. **d** Same MRI study, the T2 image shows hypointensity replacing the mass secondary to fibrosis and hyperintensity in the anterior perirenal space due to fat necrosis. **e** Same patient after 1 year, showing non-enhancing fibrous tissue, with small peripheral fat component

Table 1 Patients' demographics and the cohort tumor characteristics

Age (years), Mean ± SD (min–max)	55.03 ± 10.32 (39–77)
Male gender, *n* (percent)	25 (80.6%)
Mass size in cm	2.98 ± 0.83 (1.5–5)
Exophytic location of the mass, *n* (percent)	24 (54.6%)
Central location, *n* (percent)	2 (4.5%)
RENAL score	6.2(± 2.2)

underwent four consecutive RFA procedures when the cancers were at T1a stage. Eventually, 46 procedures were performed including 2 for suboptimal ablations. One patient demonstrated residual enhancing tumor tissue on follow-up imaging which did not show any progression in size or enhancement. Overall, only 5 patients actually died during the 12-year follow-up duration (5/31, 16.1%).

We used data derived from Kaplan–Meyer analysis to illustrate that OS was 100%, 92.7%, 69.9%, 50.5% and 46.6% at 1, 5, 8, 10 and 12 years (Fig. 5a). DFS (RCC free survival) was 100%, 96.4%. 72.7%, 52.5% and 48.5% at 1, 5, 8, 10 and 12 years (Fig. 5b). PFS was 100%, 96% and 86.4% at 1, 6 and 12 years (Fig. 5c). Two patients developed metastasis from RCC and eventually died (6.4%); this has resulted in a very high CSS reaching about 93.6% at 12-year follow-up (Fig. 5d). The remaining three deaths were documented due to other causes possibly related to old age with increasing comorbidities such as cardiovascular events (1 case), metastatic metachronous hepatocellular carcinoma (1 patient) and metastatic metachronous gastric adenocarcinoma (1 patient).

The overall adverse event rate was 8.6% (4/46 procedures). Among those, 6.5% (3/46 procedures) have been defined as Clavien–Dindo grade I; of those three patients, two patients who developed post-ablation syndrome having fever, myalgia and nausea successfully treated with antipyretics, antiemetics and analgesics and one patient developed ascites from liver cirrhosis that resolved spontaneously in three days, the fourth case was classified as

(See figure on next page.)

Fig. 3 **a** Pre- and post-contrast series before (upper set) and after (lower set) first session RFA reveals persistent enhancement after the RFA denoting residual viable tumor tissue due to hypervascularity. **b** same patient, Angiography series (upper set) reveals mild tumor blush before embolization for which super-selective embolization of a middle arterial feeder … Lower set images show procedure during second RFA session after embolization. **c** Same patient, pre- and post-contrast series at one-month (upper set) set and at 6-month (lower set) follow-up show absence of any enhancement at different phases of contrast-enhanced studies, note also marked size reduction at the 6-month CT study

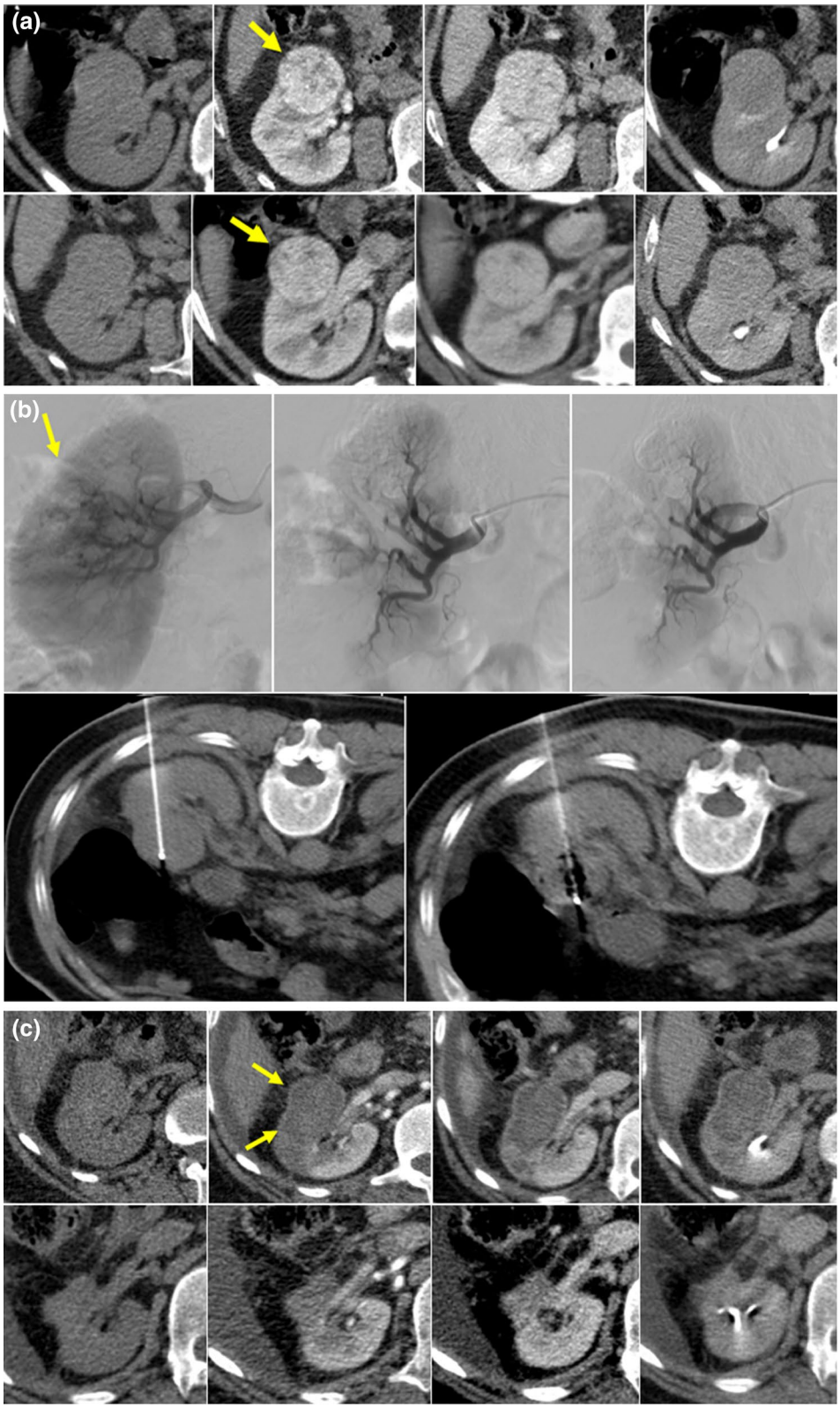

Fig. 3 (See legend on previous page.)

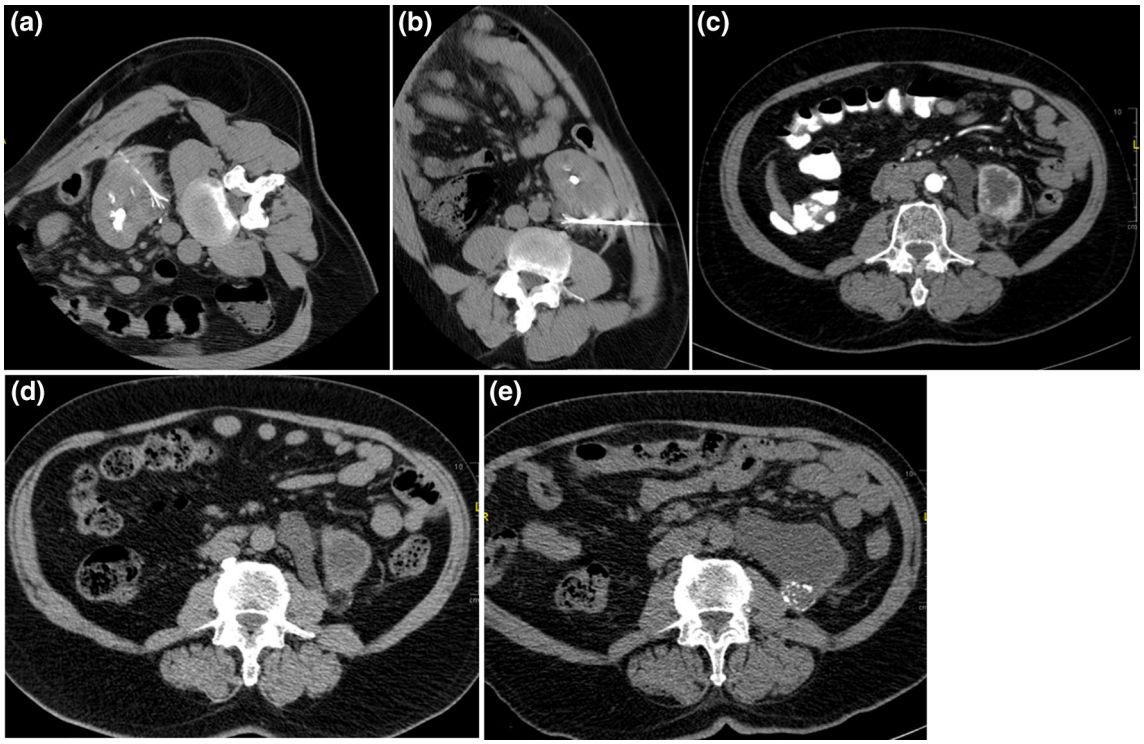

Fig. 4 **a** 77-year-old man, presented in 2007 with a 3 cm diameter lower polar enhancing soft tissue mass as shown in this delayed phase of a contrast-enhanced CT study, for which RFA was done. **b** Same patient during the session, air bubbles are seen around the probe, reflecting successful delivery of the waves and tissue necrosis. **c** Same patient. Contrast-enhanced CT; coticomedullary phase at 1-month follow-up reveals the density of the mass is heterogeneous with areas of fat and non-enhancing tissue strands. **d** Follow-up was continued yearly onwards, this is a contrast-enhanced CT image from the 4-year follow-up reveals the decreasing size of the lesion, also noted are fine dystrophic calcifications around the fibrous capsule. The kidney shows hydronephrotic changes, with thin parenchyma and dilated kinked ureter down to the level of the mass, thought to be secondary to entangling of the ureter within the focal fibrotic process of the lesion, for which the patient refused further management. **e** Same patient, contrast-enhanced CT study at nephrographic phase at 13-year follow-up reveals the increase in dystrophic calcifications inside the lesion with absence of measurable enhancement

Clavien–Dindo grade IIIb as he developed a perinephric hematoma with associated air densities inside the pelvicalyceal system of the kidney for which a ureteric catheter was inserted under general anaesthesia without further sequelae. No other major complications, deaths or injuries have been documented during the time frame from the start of the procedure until discharge from the hospital. No cases were reported to have commenced dialysis following the procedure until end of follow-up period of the study.

Discussion

In this study we retrospectively investigated 31 patients who had undergone CT-guided RFA of their early-stage RCCs. Through a long-term unprecedented follow-up period of up to 12 years (10.5 years as the mean follow-up duration). The study solidifies the confidence and effectiveness of RFA in such cases, as the OS of the 12-year follow-up was 46.6%, and the cancer specific survival was 93.6%. To the best of our knowledge this study presents the longest duration of follow-up in the literature. Data previously published were for smaller follow-up periods, though our study have demonstrated better results [7–10].

Not surprisingly the estimated survival rate dropped steeply from 92.7% at 5 years to 50.5% at 10 years then to 46.6% at 12 years owing to the advancing age of the patients (at the time of RFA, the mean age of the patients was 55 years), and comorbidities or metachronous developed other cancers. However, the cancer-related survival rate (CSS) was still very high even at extended follow-up periods of time and was 93.6%.

Prior studies have repeatedly proven the effect of other comorbidities on the overall survival that we thought it would be unnecessary to repeat the multivariable analysis of these comorbidities on the overall survival. Effect of the size of RCC and low RENAL score was also repeatedly proven as the single most important predictor of long-term non-recurrence [11]. In this study, early-stage RCCs were only selected of stage T1a with sizes less than 4 cm to emphasize not only the short-term effectiveness

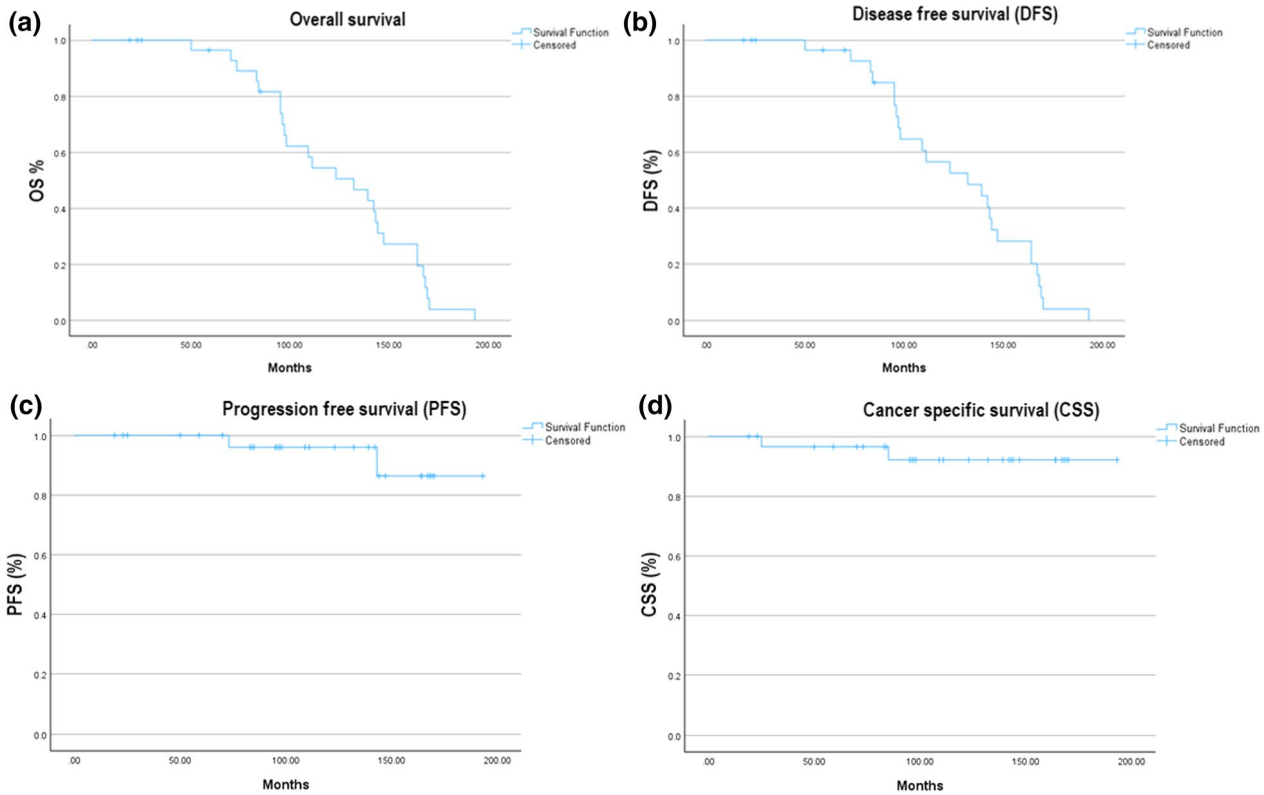

Fig. 5 Kaplan–Meier plots of patients', **a** overall survival, **b** disease-free survival, **c** progression-free survival, and **d** cancer-specific survival

of RFA in these small-sized tumors, but also the long term.

The CSS in our 12-year follow-up was such high in this long-term follow-up of such elderly population group. Similar high CSS rates were also reported in other studies, such as an 8-year follow-up study in which the cancer specific survival was 95.8% [11], in others CSS ranged from 85.7% at 2-year follow-up and 100% at 3-year follow-up for mixed T1a/b lesions [8, 9, 12].

Selection of small tumor sizes in our study had led to a high primary technical success rate of 95.5% which was again comparable to others reported in the literature. The recommended cutoff value for percutaneous treatment is 3 cm as stated by the latest consensus of European Association of Urology. Two lesions required second session ablation, both were larger sized lesions (5 and 4.5 cm) both were moderate complexity lesions according to RENAL score. Other lesions with sizes larger than 3 cm were successfully ablated in the first session.

The overall technical success rate (regardless of single or multiple ablations) in our study was 100%, again comparable to previous studies. Patients who are unfit for surgery or who require minimally invasive interventions for treatment of such small RCCs are the optimal candidates for percutaneous ablations [13]. Having said that, different studies have emerged subsequently documenting high effective rates for radiofrequency ablation and cryoablation of 90% and 89%, respectively [14].

The procedure is proven to be safe as the adverse effects rate was about 8.6%, including four patients, three of them were classified as Clavien–Dindo grade I and one classified as grade IIIb. No major complications were noted related to the ablation procedure.

It is however important to mention that other ablative modalities such as cryoablation and microwave ablation are also competent treatments giving comparable results with high technical and high long-term clinical success rates with associated low complication rate. In order to pinpoint one of these percutaneous ablative techniques as the superior one, larger, multicentric randomized trial studies with large number of patients around 1000 or more are mandated [15, 16].

Being a single center, single arm type of study, has rendered the results of this study limited for weighting against other types of percutaneous/minimally invasive management procedures or for its reproducibility. The relatively small sample number also limits the validity of the acquired statistical analysis. We did not include T1b stage of RCC in the study; so comparison between a and b subtypes of T1 stage is not applicable in this study.

Conclusions

In conclusion, this study further emphasizes the effective role of percutaneous radiofrequency ablation despite longer-term follow-up up to 12 years with low complication rate and low propensity for recurrence provided that small tumor is selected for such type of minimally invasive treatment procedure. Larger sample comparative studies are awaited to sort different percutaneous minimally invasive procedures according to their effectiveness and safety.

Abbreviations

RCC	Renal cell carcinoma
CT	Computed tomography
RFA	Radiofrequency ablation
PACS	Picture archiving and communication system
HIS	Hospital information system
MRI	Magnetic resonance imaging
S.Cr	Serum creatinine
IV	Intravenous
cm	Centimeter
HU	Hounsfield unit
OS	Overall survival rate
DFS	Disease-free survival
PFS	Progression-free survival
CSS	Cancer-specific survival
IQR	Interquartile range

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Author contributions

TE and MF contributed to the study's conception and design. TE performed the intervention procedures. MF collected, analyzed, and interpreted the data; revised the clinical data; performed statistical analyses and under supervision of TE contributed to the drafting of the manuscript. MG, MS, MT contributed to the study's conception and design; contributed to writing and revising the manuscript. All authors mentioned read and approved the final manuscript.

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Availability of data and materials

The sets of data used and/or analyzed during the study are available upon sensible request.

Declarations

Ethics approval and consent to participate

No individual data were included in the study. This study was approved by the Research Ethics Committee of the Faculty of Medicine at Mansoura University in December 2018. Reference number of approvals: MD.18.12.112. All patients participating in this study were informed of what it entails and gave verbal informed consent to take part in this research. If the patient was unconscious at the time of the study, written informed consent for their participation was provided by their legal guardian.

Consent for publication

Revision of the patients' records included in this study revealed that all patients gave written informed consent to use and publish the data obtained within this study. If the patient was unavailable when consent for publication was requested, written informed consent for the publication was provided by their legal guardian.

Competing interests

The authors of this study declare that they have no competing interests.

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