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Percutaneous US-guided RF thermal ablation for malignant renal tumors: preliminary results in 13 patients

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Abstract Minimally invasive treatment for small renal cell carcinoma (RCC) can be necessary in selected patients and, anyway, is desirable. In situ ablation techniques, including RFA, have been developed. The aim of this study is to evaluate the feasibility, safety and short-term local effectiveness of percutaneous US-guided RFA in a small series, as well as mid-term patient outcome. Thirteen patients with a total of 18 tumors (17 small lesions, 35 mm in size or less, and a larger one, 75 mm in size) underwent 19 RFA sessions. Seven patients had a solitary kidney, and three suffered from VHL disease, too. We treated four lesions in a patient with a bilateral tumor. In another patient, three lesions were ablated. Seventeen tumors were RCC; one was a metastasis from lung cancer. Eight lesions were parenchymal, six exophytic, two parenchymal/exophytic, one parenchymal/central and one central. A monopolar RF system with multitined expandable electrode needles was used. The 35-mm lesion underwent two sessions; the 75-mm lesion was treated with transcatheter arterial embolization before RFA. Tumors with complete loss of contrast enhancement at short-term CT (or MR) were considered successfully treated. Percutaneous US-guided RFA was always feasible without major complications. The success rate after a single treatment in tumors less than 35 mm in size was 88.2% (15/17) and rose to 94.1% (16/17) after the second treatment of the largest lesion. After a mean 14-month follow-up, no successfully treated lesions recurred locally. Only the patient with metastasis from lung cancer died from disease progression in a further location, while all other patients are alive, with renal function still sufficient to avoid dialysis. US guidance allows an easy and safe percutaneous approach for RFA of small non-parahilar RCC. The treatment is locally effective and can be proposed as a minimally invasive therapy for patients with contraindications to surgery or to those expressing an informed consent. Based on the results of this study and of the literature, mid-term results on the clinical usefulness are very encouraging.

Keywords Kidney neoplasms · Therapy · Kidney · Interventional procedures · Radiofrequency ablation · Ultrasound · Guidance

Introduction

Extensive application of modern imaging modalities such as US and CT has led to a greater incidental detection of renal masses. Such incidental tumors are likely to be small and in an early stage [1]. They are mostly found in elderly patients with significant co-morbidity [2] and in patients with previous or synchronous homolateral/contralateral renal cell carcinoma (RCC) or with hereditary carcinomas, like in von Hippel-Lindau (VHL) syndrome [3, 4]. These tumors represent a lowly aggressive disease in patients unfit to undergo major surgery; therefore, they should undergo nephron-conserving and minimally invasive treatment [5].

Surgical treatment options for RCC are radical nephrectomy and partial resection or nephron-sparing surgery (open or laparoscopic). All are similarly effective, but carry their own morbidity, with a complication rate up to 30% in several series [6]. Some patients have contraindications to general anesthesia. Moreover, patients with congenital or acquired solitary kidney cannot undergo radical nephrectomy without subsequent dialysis or transplantation.

Recently, several minimally invasive techniques for local destruction of parenchymal tumors without surgical removal (so-called in situ ablation) were developed, including RFA [7, 8], which was shown to be useful in causing necrosis of small RCC both in experimental studies [9] and in several clinical series. Potential advantages of RFA versus surgery are that it can be performed percutaneously, under US or CT guidance, without general anesthesia and without damage to adjacent tissues, preserving the surrounding renal parenchyma and reducing the complication rate.

Our aim is to present our preliminary experience with a small consecutive series of patients who underwent percutaneous US-guided RFA for renal tumors, because it was clinically indicated as the treatment of choice instead of surgical resection. We evaluated the feasibility, safety and short-term local efficacy of RFA and mid-term patient outcome.

Materials and methods

Patients

Between December 2000 and July 2003, we treated 13 patients at our institution, 8 males and 5 females, aged between 39 and 83 years old (median, 65 years old). Seven of 13 (54%) patients had a solitary kidney (5 right, 2 left; 1 congenital, 6 after contralateral nephrectomy); three also had VHL. These patients had a total of 18 neoplastic lesions (10 in the right kidney, 8 on the left): 11 patients had one lesion each, two females underwent two separate sessions for several lesions (patient no. 4, first for one, then for three lesions, and patient no. 5, for two earlier tumors and one subsequent lesion).

All tumors were RCC but one, a metastasis from lung cancer. The diameter range was 15–75 mm; except for the biggest lesion, submitted to "combined" therapy (transcatheter arterial embolization followed by RFA), the range was 15–35 mm, and the median diameter was 25 mm. Eight lesions were parenchymal, six exophytic, two parenchymal/exophytic, one parenchymal/central and one central. The 35-mm lesion underwent two sessions, so that the total number of treatments was 19.

The first patient treated, a 62-year-old male affected by VHL, underwent RFA after right nephrectomy and multiple left nephron-sparing surgical resections. The second, a 60-year-old male with congenital right solitary kidney, had two other neoplasms and a biopsy-proven primary parahilar tumor in the mid-kidney (28 mm in size). The patient with lung cancer developed one metastasis in the left mid-kidney. After 6 months, we agreed to treat the renal lesion because of its slow increase and the absence of other metastases. Patient no. 4, a 68-year-old female affected by multiple synchronous bilateral RCC, refused radical bilateral nephrectomy and accepted only left nephrectomy and RFA of the main lesion in the right mid-kidney (Fig. 1). Seventeen months later, she underwent a new RFA session because of the increase of three other lesions. Also patient no. 5, a young female affected by VHL, underwent two sessions, first to treat two lesions (Fig. 2) and then one more lesion.

Regarding our selection criteria, our five patients without solitary kidney are also to be analyzed: the first two, who were elderly, had contraindications to general anesthesia; the last three with small exophytic lesions were recruited not because of surgical contraindications, but because they chose this type of treatment, considering the good technical conditions for RFA and, of course, after signing an informed consent. An informed consent was also obtained from all other patients.

Patients with VHL did not undergo biopsy because solid renal tumors on CT in these cases are invariably clear-cell neoplasms [10]. In all other cases, clinical history and CT features before and after contrast administration were conclusive as well, except in pa-

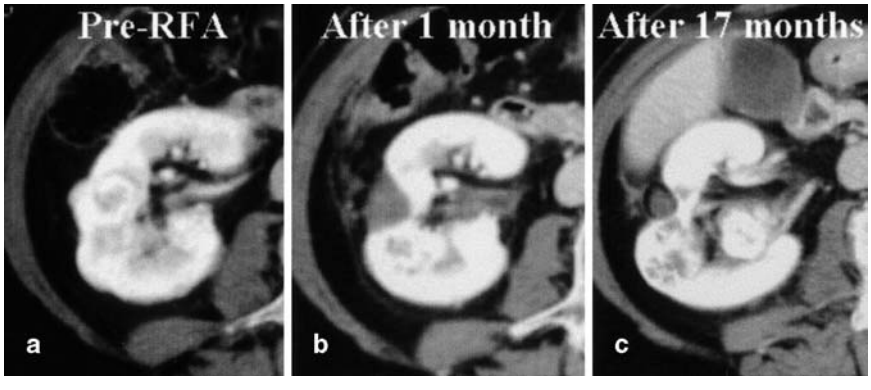

Fig. 1 **a** Patient no. 4, with bilateral multiple RCC: left nephrectomy and chemotherapy, plus RFA of the main mid-right renal lesion. **b**,**c** "Collapse" of the lesion at mid-term follow-up CT

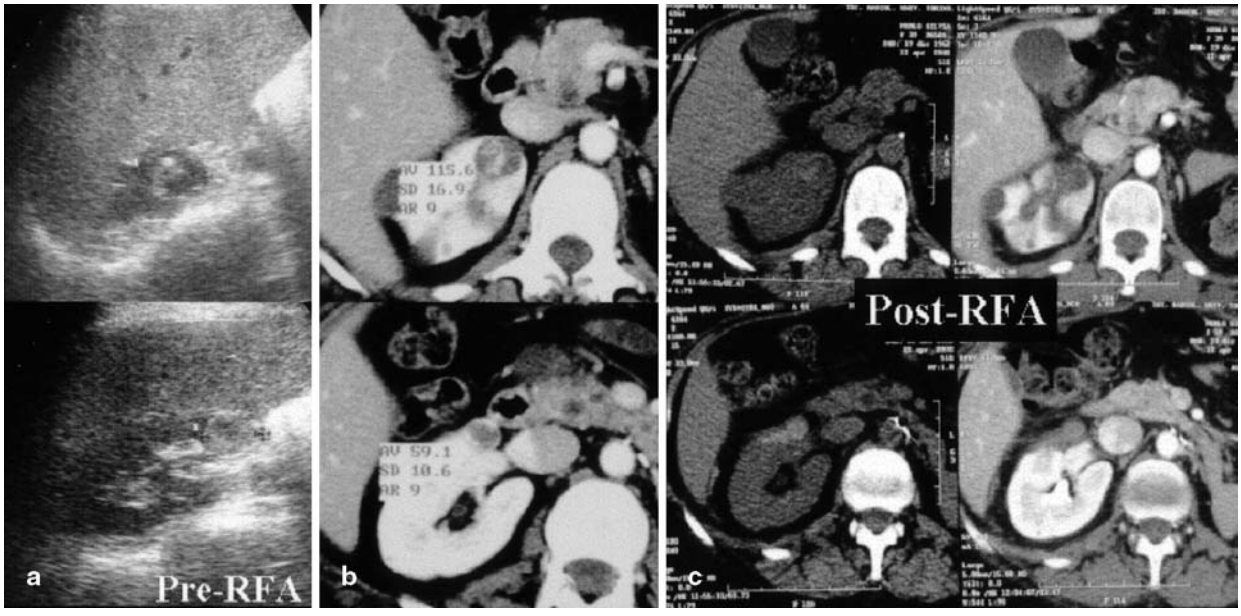

Fig. 2 Patient no. 5, VHL and solitary right kidney. Synchronous treatment of two small tumors in the upper and mid portion, via a retroperitoneal approach (partially transparenchimal). **a**,**b** US and CT before the treatment. **c** Contrast-enhanced CT study after RFA depicted that both lesions were completely devascularized

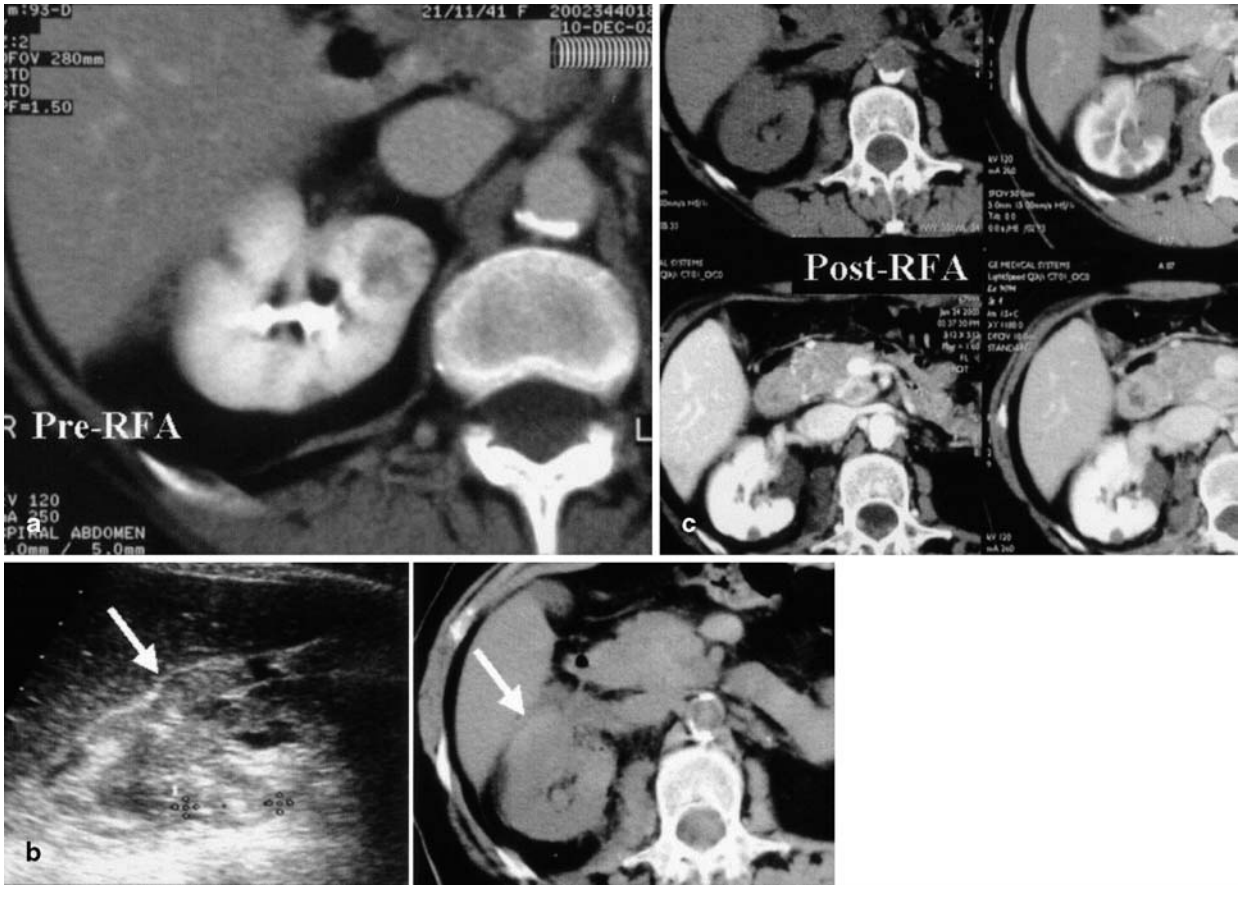

Fig. 3 Patient no. 7, **a** VHL and right solitary kidney, with a small RCC between the upper pole and the mid-renal medial side. **b** Transperitoneal/transhepatic US-guided RFA, without complications, but a thin hemorrhagic fluid collection is visualized in the Morison's pouch both at US during the treatment and at unenhanced CT at the end of the maneuver (*arrows*). **c** At short-term multi-phase CT, no residual hematoma or enhancing tumoral tissue was seen

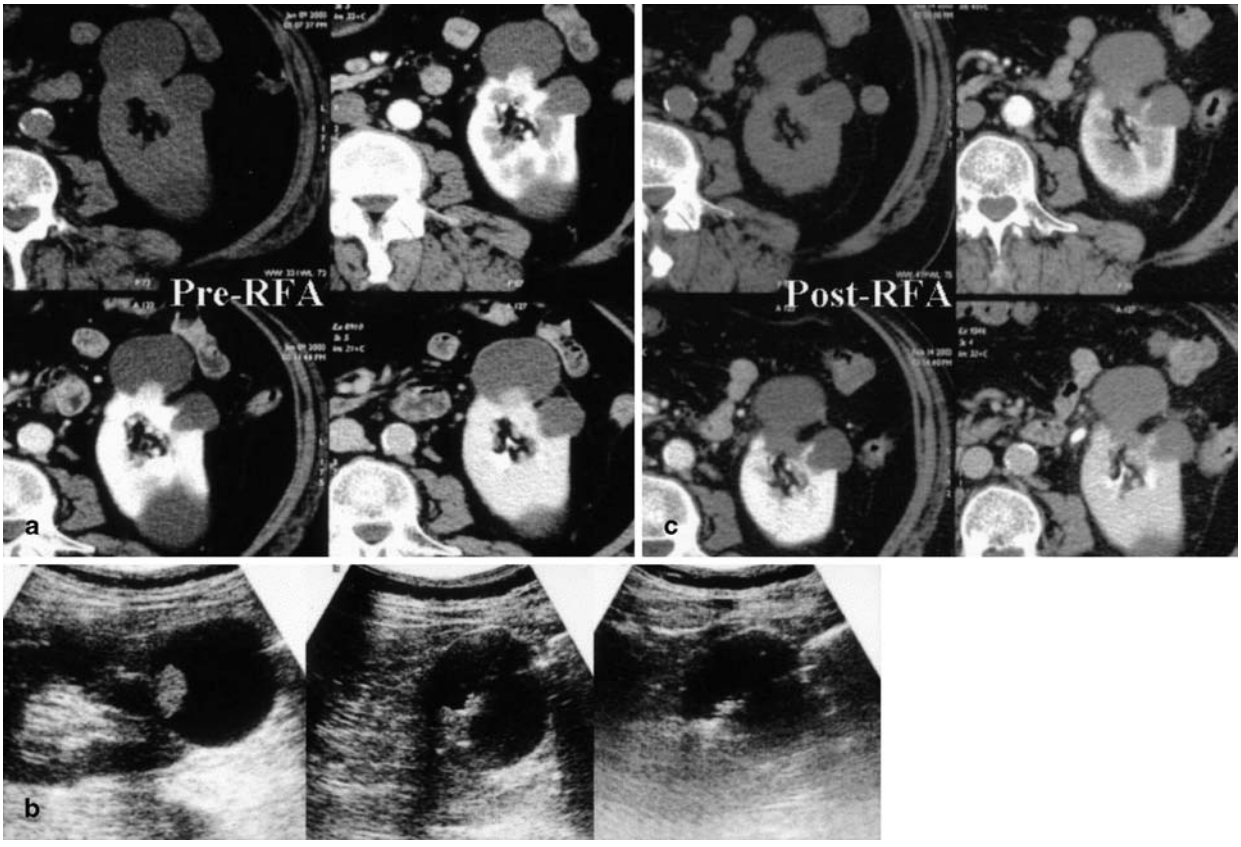

Fig. 4 Patient no. 8, elderly, with prostate cancer and left solitary kidney, developing a very small RCC exophytic towards the lumen of a subcapsular cyst. **a** Multi-phase CT before **b** US-guided transperitoneal transcystic RFA, and **c** after the treatment

tient no. 2, who also had a colonic tumor, and in the last three patients without solitary kidney, who also underwent needle biopsy.

RF ablation procedure

Preoperative serum creatinine was evaluated. All patients received intravenous hydration the night before treatment as well as antibiotic prophylaxis with intravenous cephtizoxime (1 g twice daily). Prophylaxis was also continued on an outpatient basis with oral ciprofloxacin for 5 days. All patients were treated in the oblique or lateral position after monitoring of vital signs.

All RF ablations were performed by a single interventional radiologist with extensive percutaneous RFA experience (V.A.). Conscious sedation was performed by an anesthesiologist; he administered midazolam, fentanyl, droperidol and ondansetron. Local anesthesia was added, with 1% lidocaine injected both superficially and at mid-depth. In some cases, deep sedation and ventilation with an oxygen mask was required.

A monopolar RF device, consisting of an "active" needle with nine retractable electrodes and two neutral electrodes applied to the anterior face of the patients' thighs (RITA Medical Systems, Inc. Mountain View, CA), was used. The maximum spread reached by the expandable electrodes was 5 cm. The electrode needles (Starburst XL) were powered by a 150-W RF generator (RITA Model 1500). Treatment was performed with ultrasound guidance only (Technos, ESAOTE, Genoa, Italy). Needle insertion was guided up to the periphery of the lesions, and US was also used for real time monitoring of each step of the procedure. When possible, we chose a retroperitoneal approach. In two patients with a lesion on the deep side of the right upper pole, we opted for a transperitoneal transhepatic path, which was easier to perform without crossing renal parenchyma and easier to follow with US thanks to the "hepatic window" (Fig. 3). In two other anterior lesions located on the internal margin of a lower pole cyst in the left kidney, a transperitoneal transcystic path was chosen (Fig. 4). At the periphery of the tumors, the needle tips were expanded to an initial 2-cm width and the generator was activated, increasing the delivered power up to the target temperature (100°C). This was verified by measurements taken by five thermistors located on the central electrode and on four of the eight lateral tips (average). The delivered power was then automatically regulated by the device in order to keep both temperature and impedance constant. After an initial 5-min application, the electrodes were gradually expanded to approximately 1 cm beyond the lesion diameter to obtain a safety rim: at each 1-cm step, a 5-min RF application was performed; when the sufficient opening was reached, the application lasted over 10 min. Therefore, in our series, session time ranged between 15 and 25 min.

Therapeutic response evaluation

Patients with treatments that were technically more difficult underwent unenhanced CT at the end of the procedure in order to exclude an immediate bleeding that might not have been visible at US. However, bed rest and clinical observation for at least 4 h were arranged. In addition, blood cell count after 2–3 h, presence of macroscopic hematuria and serum creatinine level were evaluated and compared with pre-procedural values. Besides, a short-term CT study was scheduled after approximately 1 month, ac-

Table 1 Characteristics of patients and lesions

Patient no.	Age (years)/ sex	Disease	Lesion site	Lesion size (mm)	Lesion type/location	No. of treatments/approach	Ablation	F-U (months)
1	62/M	VHL/solitary kidney	L-upper	21	RCC/parenchymal-exophytic	1/retroperitoneal	Complete	34
2	60/M	CLL/colonCa/solitary K	R-mid	28	RCC/central	1/retroperitoneal	Incomplete	22
3	69/M	LungCa	L-upper/mid	25	MTS/parenchymal	1/retroperitoneal	Complete	6[a]
4	68/F	Bilateral RCC/solitary K	R-mid	27	RCC/parenchymal	1/retroperitoneal	Complete	26
4	–		R-upper	25	RCC/parenchymal	1/retroperitoneal	Complete	
			R-mid	30	RCC/parenchymal	1/retroperitoneal	Complete	
			R-lower	25	RCC/parenchymal	1/retroperitoneal	Complete	
5	39/F	VHL/solitary kidney	R-upper	25	RCC/parenchymal	1/retroperitoneal	Complete	18
5	–		R-mid	20	RCC/exophytic	1/retroperitoneal	Complete	
			R-upper	16	RCC/parenchymal-exophytic	1/transperitoneal-transhepatic	Complete	
6	64/M	Bilateral RCC/solitary K	R-upper/mid	15	RCC/exophytic	1/retroperitoneal	Complete	10
7	61/F	VHL/solitary K	R-upper/mid	20	RCC/parenchymal	1/transperitoneal-transhepatic	Complete	9
8	75/M	ProstateCa/solitary K	L-lower/mid	19	RCC/exophytic (endocystic)	1/transperitoneal-transcystic	Complete	8
9	77/F	Old age/hypertyroidism	L-upper/mid	35	RCC/parenchymal-central	2/retroperitoneal	Complete	7
10	83/M	Old age/obesity/COPD	L-lower	75	RCC/exophytic (deep to a cyst)	1[b]/transperitoneal-transcystic (post-TAE)	Incomplete	7
11	65/M	–	L-mid	23	RCC/exophytic	1/retroperitoneal	Complete	5
12	53/F	–	L-lower	16	RCC/exophytic	1/retroperitoneal	Complete	3
13	69/M	–	L-mid	30	RCC/parenchymal	1/retroperitoneal	Complete	3

[a] Deceased.
[b] Not completed.

cording to the clinical outcome of each patient. CT study was performed with a multi-phase protocol (contrast flow rate 3 ml/s; unenhanced, arterial and venous phases; slice thickness 2.5 mm) and, recently, by a multidetector scanner (General Electric, LightSpeed QX/I, Milwaukee, WI). The absence of contrast enhancement on CT (evaluated by comparing HU measurements before and after contrast administration) was considered as complete ablation of the tumor (technical success). At that time, serum biochemistry and urine analysis were also obtained. Patients were then clinically and radiologically followed up with US every 3 months and (if US did not depict any lesion growth or other abdominal changes earlier) with CT or MRI every 6 months. Serum creatinine and electrolytes were evaluated at every follow-up visit. Clinical success was defined as the absence of local recurrence during follow-up (3–34 months, mean 14 months, median 9 months), provided that a sufficient renal function was maintained (Table 1).

Results

RFA was feasible in all patients, except for the one with the largest lesion, which was already embolized. In this patient, the procedure could not be carried on for more than 10 min because of inadequate compliance of the patient without deep sedation, which we were unable to use because of his severely impaired respiratory function.

US allowed us to localize all lesions and to guide their puncture. However, simultaneous review of CT images (in order to exploit anatomic references, cysts, etc.) was useful to better delineate smaller or isoechoic tumors. Therefore, in our experience, US guidance was suitable to reach each lesion and to follow the treatment in real-time (despite the characteristic intense echoes spreading from the tissue during RFA). Moreover, RFA proved to be a safe treatment, as demonstrated by the absence of major complications. Two patients had persistent pain for a few hours after the procedure, whereas only in one patient, for whom we used a transperitoneal transhepatic path, a minimal hemorrhage in Morison's pouch was detected by US during the treatment and was confirmed by an unenhanced CT at the end of the procedure. No additional symptoms or significant serum value alterations were detected, and the hematoma was completely resolved at the 10-day CT (Fig. 3). No late complications were detected during the follow-up.

Short-term contrast-enhanced CT examinations were performed between 3 and 62 days after the first RFA (median 26 days) and were compared with pre-procedural CT studies. Complete devascularization (loss of all contrast enhancement) was shown in 15/18 lesions (83.3%). Due to the intent of obtaining a safety rim, in completely ablated tumors the hypodense area at the site of the treated lesion was often slightly larger than the previous tumor area. Except for the largest tumor (treated with an incomplete combined therapy due to RFA interruption), the complete necroses after one session were 15/17 (88.2%). The two tumors with partial residual con-

trast enhancement were the biggest (35 mm) and the nearest to the hilum (central). The former underwent one more session and was completely hypodense at the following CT, while the latter has not been retreated yet (after 22 months) because of its slow growth and serious neoplastic co-morbidity (patient no. 2, with chronic lymphatic leukemia and previous metastatic colon cancer). In summary, the success rate for lesions ≤35 mm in diameter after one or two session was 94.1% (16/17) (Table 1).

According to the above-mentioned protocol, radiological follow-up was always performed with US and CT, except in patient no. 1. In this patient, after the 6-month CT study, the administration of iodinated contrast agent was precluded due to severe chronic renal failure, and MR imaging replaced CT in the radiological follow-up. The devascularized area (hypodense on CT) was stable or decreasing in size in all patients (Fig. 1). We had no mid-term local recurrences. Only the small parahilar hypervascular residual lesion in patient no. 2 showed a minimal growth of its viable portion almost 2 years after the treatment. In patient no. 4, who had four treated lesions, venous thrombosis was detected at the last check because of progression of a further neoplastic lesion. This patient has now accepted radical intervention and will undergo nephrectomy more than 2 years after her first RFA. Only patient no. 3, with metastasis from lung cancer, died from brain metastases 6 months after the treatment. All other patients are alive with normal or reduced renal function, but still sufficient to avoid dialysis.

Discussion

RCC have a potential for local progression, metastatic disease and fatal outcome even when 3 cm in diameter or less. Therefore, treatment is always necessary [11]. However, up to that diameter, hereditary renal tumors do not develop metastases and can undergo renal parenchymal-sparing surgery [3]. Our study is not designed to compare RFA results with those of conservative surgery; however, in terms of safety, short-term local efficacy and mid-term patient outcome, RFA results seem to be better compared to those from surgical series [6]. Its clinical use in association with laparoscopic surgery has already been reported [12, 13], and the substitution of laparoscopic partial nephrectomy by minimally invasive techniques has been suggested [14]. Our RFA series cannot be correctly compared with other non-surgical treatments (cryotherapy above all), but according to data from the literature, it does not seem to be less useful [1]. In any case, long-term (>5 years) results are not yet available either for cryotherapy or RF ablation, and we should consider them as experimental techniques [15].

Thanks to the many experimental studies on RFA of liver neoplasms that are already available, the applications of RFA for RCC developed almost simultaneously in experimental and clinical fields; for example, in 1997, Zlotta presented the first cases of RFA in ex vivo and in vivo human kidney (only before surgical resection) [16], and in 1999, he published an experimental study on an animal model (rabbit) [17]. Similarly, the first case of RCC completely treated by RFA via percutaneous placement of an electrode needle under US guidance was published in 1999 by McGovern [18], and experimental studies on rabbit and porcine models have been reported up to 2003 [9, 19–23]. Our first patient was treated in 2000.

In 2001, Wood described the first case of "combined" treatment of a 7-cm tumor because of persistent hematuria despite transcatheter embolization [24]. Combining hilar occlusion or arterial embolization with RFA can be considered a treatment option for larger tumors, and it has been used experimentally on an animal model [12] and in clinical practice [25, 26], respectively. The aim is to increase the necrosis volume by ischemia, despite the higher risk of damaging the whole kidney in the study on a porcine model treated after hilar occlusion [12]. We used this technique only once and incompletely, so we cannot express our opinion.

In our series, feasibility of percutaneous renal RFA is similar to that reported in the studies of the above-mentioned authors [2, 4, 5, 27] and in a few others [28]. However, we always performed our treatments under US guidance, never using CT guidance. This technique allows real-time control of electrode-needle placement and makes the procedure less time consuming and less expensive. Nevertheless, in a few difficult patients or locations, CT guidance can be necessary in order to better visualize the lesion and precisely position any electrode. Moreover, due to hyperechoic artifacts caused by RF, CT might be better than US in detecting needle displacement during the procedure and correctly replacing it.

Regarding safety, in our small series no renal or collecting-system major complications occurred (neither intranephric or perinephric hematomas, nor macroscopic hematuria), but only a minimal asymptomatic blood collection in Morison's pouch resulting from a complex transperitoneal transhepatic path. It was only detected by imaging, and it resolved spontaneously before the short-term CT control; so, high safety of percutaneous treatment (no procedure-related mortality; acceptable morbidity) [4, 27] was confirmed also for difficult approaches.

Regarding clinical aspects, our experience confirms other authors' results, although the small number of patients and lesions treated precludes a statistical analysis. First of all, the decision to perform a needle biopsy of the lesions only when strictly necessary was taken on the basis of risk/benefit ratio criteria to reduce the risk of complications.

Like Gervais et al., short-term and mid-term follow-up of the treatment were based on loss of contrast en-

hancement at CT scans, except for patients with compromised renal function, in which gadolinium-enhanced magnetic resonance imaging was used [27]: technical success was defined as the absence of contrast-enhancement at the first (about 1-month) follow-up study, and then after at least 6 months. Local efficacy of RFA is the most controversial topic: while some studies on lesions treated with RFA and then resected immediately or within a short period assert that necrosis induced by the treatment is often incomplete [29, 30], others demonstrate that tissue destruction can be complete [31, 32]. These differences can reflect the scarce standardization of the procedure, which is performed with different ablation systems and techniques (single or multiple-electrode arrays, cooled or hooked needles, dry or wet-tip probes; varying power and time settings; temperature- or impedance-based protocols) [15]. Moreover, Gervais demonstrated that the technical success of the therapy depends on the tumor size and location, being maximum for exophytic or parenchymal tumors (that are different from central tumors, i.e., those with extension into renal fat) and for those 3 cm or smaller [27]. Also in our series, the two non-completely ablated tumors after the first session were, respectively, a central lesion and a lesion larger than 3 cm; the latter, parenchymal-central, required two sessions for a complete treatment.

To date, in all published studies the median follow-up period is relatively short (also considering the natural history of RCC). In our series, the only death was not related to RCC. All other patients have a stable local result at imaging with normal or reduced renal function, but still sufficient to avoid dialysis. These clinical results are very encouraging; however, considering the rationale to treat these lesions (potential long-term mortality for metastatic or multifocal progression of the disease) [11], a much longer follow-up time is required before clinical usefulness of the technique can be validated. Comparative studies with nephron-sparing surgery and other minimally invasive techniques should be recommended, too [33].

Conclusions

US-guided RF thermal ablation for RCC is feasible and safe. Our experience and most published reports show that RF thermal ablation can be proposed in clinical practice for small non-parahilar renal tumors in patients with solitary kidney (especially those with hereditary renal tumors), with coexisting morbidity, short life expectancy or other surgical contraindications, e.g., in case of transplanted kidney [34]. Treatment can be effective in these patients in order to avoid or delay nephrectomy or dialysis. A wide standardization and larger follow-up are necessary to permit RFA to develop past its "infancy" [28, 33].

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