Combination therapy of three-dimensional (3D) visualisation operative treatment planning system and US-guided percutaneous microwave ablation in larger renal cell carcinomas (D ≥ 4 cm): preliminary results

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ABSTRACT

Purpose: To analyse the clinical outcomes of combination therapy of three-dimensional (3D) visualisation operative treatment planning system and US-guided percutaneous microwave ablation (PMWA) in larger renal cell carcinomas (RCCs) (D ≥ 4 cm).

Materials and methods: The results from 20 patients with 20 larger RCCs treated with a 3D visualisation operative treatment planning system and US-guided PMWA were reviewed retrospectively. The patients were followed up by contrast-enhanced images at 1, 3, and 6 months and every 6 months thereafter. The outcomes of overall survival and local tumour progression rate were statistically analysed.

Results: The median follow-up period was 26 months. The mean time of ablation for one tumour was 1.1 ± 0.3 sessions. The average number of ablation points of one tumour was 4.5 ± 0.9. The mean output power of ablation was 50.50 ± 2.2 W. The mean time of ablation for one tumour was 1374.4 ± 391.1 s. Artificial ascites was used in 12 (60%) tumours adjacent to the intestinal tract, and thermal monitoring system was used in all tumours (100%). Technical effectiveness and metastasis-free status were achieved in all tumours. The 1- and 2-year local tumour progression rates were both 5%. The cancer-specific survival rate and 2-year overall survival rates were both 100%. No severe major complications occurred. There was no significant difference in creatinine or urea nitrogen before or 3 days after ablation.

Conclusions: Combination therapy of 3D visualisation operative treatment planning system and US-guided PMWA appeared to be a safe and effective technique for the management of larger RCCs, which could improve clinical efficacy.

Introduction

The incidence of renal cell carcinoma (RCC) has been increasing over the past few decades. It accounts for 3% of all malignancies and is responsible for 1.5% of all cancer deaths worldwide [1–3]. Although improvements in abdominal imaging have increased the ability to detect and diagnose RCC, some patients have detected and are diagnosed with larger tumours accidentally [4]. Traditionally, the reference standard for treatment of RCC has been surgical resection treatment, such as radical nephrectomy and partial nephrectomy [5–7], while some patients cannot tolerate surgery and anaesthesia, or they refuse to undergo surgery due to older age and multiple organ dysfunction. Thermal ablation techniques, including cryoablation, radiofrequency ablation (RFA), and microwave ablation (MWA), have been widely implemented clinically [8–10]. In our preliminary and intermediate-term studies, we have reported that US-guided percutaneous microwave ablation (US-guided PMWA) is a safe and effective technique for the management of small RCC (maximum diameter (D) < 4 cm) with little loss of renal function and could provide comparable results to open surgical nephrectomy (ORN) in oncologic outcomes [9,11–13]. For larger and boundary-irregular RCC tumours (D ≥ 4 cm), it is difficult to treat them depending only on 2-dimensional imaging. The relationships of tumours with surrounding organs (intestinal tract and renal pelvis) are close, but they are difficult to view in stereo on US imaging. To achieve complete ablation, the number and pathways of the arranging needle antennas must be planned precisely; the thermal-field distributions must be calculated accurately. Traditionally, 2-dimensional imaging can provide valuable information about the anatomical structure, but it lacks the spatial positioning information of volumetric data that clinicians must know for minimally invasive treatment. The results of human error, such as weakness in spatial sense and imperfect hand-eye coordination, often lead to imprecise needle positioning [14]. 3D visualisation preoperative planning can display the location and
relationships of the tumour with surrounding tissues, predict the time-temperature profile during ablation, improve surgical skills and the safety of surgery, reduce surgical complications and promote better long-time prognoses [15–17]. In our preliminary study, 3D-visualisation operative treatment planning system was used in PMWA for liver cancer, and it promoted precise therapy, decreased the rate of complications, ensured tumour-free safety margins and improved long-term survival outcomes [18,19]. Therefore, this novel technique might provide more information and valuable assistance in PMWA treatment for larger RCCs. To protect the intestinal tract from thermal damage, artificial ascites was employed in this study because it is a safe and effective assistive method for the treatment of tumours adjacent to the intestinal tract and can achieve good local control of such tumours [20,21]. During the ablation procedure, monitoring of the temperature of the tumour periphery and intestinal tract periphery was extremely important.

Therefore, we performed this study to review retrospectively the clinical outcomes of larger RCCs treated with combination therapy of 3D visualisation operative treatment planning system and US-guided PMWA.

Materials and methods

Patients and tumours

From April 2012 to March 2016, a total of 20 patients with 20 larger RCCs were admitted, and they underwent combination treatment of 3D visualisation operative treatment planning system and US-guided PMWA in our department. The clinical features of the patients and tumour variables are listed in Table 1. All patients were closely followed up until March 2016. This retrospective study was approved by our institutional review board, and medical and imaging records were reviewed and analysed. Written informed consent for the procedures was obtained from each enrolled patient.

Pre-ablation examination

The inclusion criteria for our study were as follows: (1) non-resectable tumours or patient refusal to undergo surgery; (2) single RCC lesion ≥4 cm; (3) absence of renal vein thrombosis or distant metastases; (4) prothrombin time <25 s; (5) prothrombin activity >40%; (6) platelet count >60 cells × 10⁹/L; and (7) diagnosed as RCC by histopathology or clinical imaging and medical history. The exclusion criteria were as follows: (1) patients with severe cardiopulmonary diseases who could not tolerate intravenous anaesthesia; (2) serious and acute renal function failure; (3) severe liver function failure with an index of transaminase twice more than normal levels; and (4) active severe infection with the number of white blood cells more than normal levels or the percentage of neutrophils more than 80%.

3D visualisation operative treatment planning and microwave ablation protocol

Contrast-enhanced CT scanning was performed in the arterial, venous and later phases within 7 days before ablation.

In Table 1, the clinical features of patients and tumour variable are listed. The data are means ± standard deviations; data in parentheses are ranges. The imaging data were imported into the EFILM software and were analysed by the 3D visualisation platform. Patient-specific anatomical information about tumours and surrounding vital structures was stereoscopically displayed. The tumour volume, stereo relationship between the tumour and surrounding organs, antenna parameters (number, insertion pathway and angle), thermal field distribution and pre-assessment ablation effects were demonstrated precisely in the preoperative 3D visualisation treatment planning.

The preoperative planning of MWA abided by the following principles: (1) covering the entire tumour; (2) minimising antenna insertion number and ablation points; and (3) avoiding via critical structures along the insertion pathway and damage to any vital structures.

US-guided core needle biopsy (18 G, Bard, Japan) was performed immediately before the ablation during the same procedure. If the lesion was biopsied and verified as benign, it was excluded from this analysis in the follow-up period. All of the ablations were performed using a microwave unit (KY-2000; Kangyou, Medical, Nanjing, China) producing microwave energy (maximum power 100 W) through a 15 G cooled shaft needle antenna with an emitting frequency of 2450 MHz. Inside the antenna shaft were dual channels through which distilled water at room temperature was pumped by a peristaltic pump. The patients underwent MWA

| Table 1. Clinical features of patients and tumour variable. |
|------------------------------------------------------------|
| **Patient analysis**                                        |
| No. of patients: 20                                         |
| No. of men: 16 (80%)                                        |
| No. of female: 4 (20%)                                      |
| No. of one mass ablated: 18 (90%)                           |
| No. of two mass ablated: 2 (10%)                            |
| Mean age (y): 60.4 ± 13.5 (31–84)                           |
| Male: 58.9 ± 13.6 (31–84)                                   |
| Female: 61.5 ± 13.9 (43–76)                                 |
| **Tumour analysis**                                         |
| No. of tumour: 20                                           |
| Mean tumour diameter (cm): 5.3 ± 1.2 (4.0–8.4)              |
| Right kidney: 9 (45%)                                       |
| Left kidney: 11 (55%)                                       |
| Upper: 6 (30%)                                              |
| Middle: 7 (35%)                                             |
| Bottom: 7 (35%)                                             |
| Exophytic growth pattern: 9 (45%)                           |
| Parenchymal growth pattern: 7 (35%)                         |
| Endophytic growth pattern: 4 (20%)                          |
| No. of tumours adjacent to the bowel: 12 (60%)              |
| No. of tumours adjacent to the pelvis: 4 (20%)              |
| **Pathologic diagnosis**                                    |
| Clear cell carcinoma: 16 (80%)                              |
| Papillary carcinoma: 3 (15%)                                |
| Chromophobe carcinoma: 1 (5%)                               |
| **Ablation parameters**                                     |
| Ablation time (s): 1374.4 ± 391.1 (960–2340)                |
| Ablation power (W): 50.50 ± 2.2 (50–60)                     |
| Median follow-up (mo): 17 (3–31)                            |

*Data in parentheses are percentages.  
*Data are means ± standard deviations; data in parentheses are ranges.  
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under intravenous anaesthesia (combination of propofol [Diprivan; Zeneca Pharmaceuticals, Wilmington, DE] and ketamine [Shuanghe Pharmaceuticals, Beijing, China]), with a US-guided percutaneous and monitored approach using an Acuson Sequoia 512 scanner (Signature 10.2; Siemens Medical Solutions, Mountain View, CA) with 3.5–5.0 MHz curved-array multi-frequency transducers. For the larger tumours, two antennas were inserted 2–3 times with an inter-antenna distance of no more than 1.8 cm and according to the 3D visualisation preoperative treatment planning. Power output of 50–60 W was routinely used during MWA. If the heat-generated hyperechoic water vapour did not completely encompass the entire tumour, prolonged microwave emission was applied until the desired temperature was attained. Three days after the ablation, contrast-enhanced imaging was performed. If the result was positive, another ablation was required.

**Artificial ascites and thermal monitoring during the procedure**

Following the administration of local anaesthesia with 1% lidocaine, a 16 G intravenous (IV) catheter (BD Angiocath; Sandy, UT) was inserted into the peritoneal cavity between the tumour and gastrointestinal tract under ultrasound guidance. CEUS was performed to reveal the catheter position if conventional ultrasound failed to visualise the catheter clearly. Then, a sufficient amount of 0.9% saline solution was injected until a separation of at least 0.5 cm between the tumour and gastrointestinal tract was achieved. We then considered the induction of artificial ascites successful and performed the MWA procedure. The volume of 0.9% saline solution used was from 1000 to 2000 ml. The drip infusion was continued while performing PMWA. No special management was performed for artificial ascites after the operation due to the strong absorption ability of the greater omentum within the abdominal cavity. The 0.9% saline solution (1000–2000 ml) could be absorbed completely within 24 h after surgery.

A thermal monitoring system was equipped with the microwave machine that could measure temperature during ablation in real time. For tumours located in the parenchyma, if the measured temperature at a site 5–10 mm away from the tumour margin reached 60°C or 54°C for at least 3 minutes, complete tumour necrosis was considered achieved. For tumours located close to the intestinal tract or renal pelvis, the real-time temperature was monitored. The microwave emission was cut off when the temperature reached 54°C. The emission was reactivated after the temperature decreased to 45°C. Discontinuous ablation was performed to achieve complete necrosis.

**Follow-up and image analysis**

The parameters of creatinine and urea nitrogen before ablation and 3 days after ablation were compared (Table 2). After one to two sessions of US-guided PMWA, contrast-enhanced imaging (CEUS + CECT) was performed, and the post-operative 3D visualisation operative treatment planning system was used to evaluate treatment effectiveness, which was then repeated at 1, 3, and 6 months and every 6 months subsequently. If CEUS and CECT were both negative, the patient continued into the follow-up stage. However, if the results were not consistent or were both positive, US-guided core needle biopsy was performed for the enhanced area, and the patient underwent another ablation session for the possible residual area.

**Statistical analysis**

Statistical analysis was performed with the SPSS statistical software package, version 17.0 for Windows (SPSS, Chicago, IL). The baseline characteristic of the patients and tumours are expressed as the mean±SD or the median. *p < .05* was considered to indicate a difference with statistical significance.

**Results**

All of the patient and tumour characteristics and ablation data are listed in Table 1. The pathologic diagnoses of the tumours were clear cell carcinoma (16, 80%), papillary carcinoma (3, 15%) and chromophobe carcinoma (1, 5%). All of the patients underwent pre- and post-operative 3D visualisation treatment planning and US-guided PMWA successfully (Figure 1). Among the 20 tumours, 18 (90%) tumours achieved complete ablation in one session, and 2 (10%) tumours required two sessions. One tumour had a maximum diameter 7.1 cm and was adjacent to renal pelvis, and the other had a maximum diameter of 8.4 cm and was exophytic toward the intestinal tract. The mean times of ablation for one tumour was 1.1 ± 0.3 sessions. The average ablation point of one tumour was 4.5 ± 0.9 (range 4–6). The mean ablation power was 50.50 ± 2.2 W (range 50–60 W). The mean time of ablation for one tumour was 1374.4 ± 391.1 s (range 960–2340 s). Technical effectiveness (complete ablation on follow-up enhanced imaging 3 days after MWA) was achieved in 20 (100%) tumours (Figure 2). Artificial ascites was used in 12 (60%) tumours adjacent to the intestinal tract, and a thermal monitoring system was used in all tumours (100%). All of the patients showed good tolerability to US-guided PMWA treatment, and there were no serious complications, such as intestinal thermal injury, urinary fistula, renal abscess, renal function failure, intratumoral bleeding or tumour seeding. Minor side effects were reported, including 11 fevers (55%) which ranged from 37 to 38.7°C, 1 cases of gross haematuria (5%), 3 cases of microscopic haematuria (15%), 5 cases of creatinine increases (20%) and 16 cases of pain that was endurable. All of the side effects disappeared with conservative treatment in 24–72 h. The parameters of

| Parameters | Pre-operative | Post-operative | *p* |
|------------|---------------|----------------|-----|
| Creatinine ([μmol/L]) | 110.2 ± 81.9 | 120.4 ± 103.3 | .73 |
| Urea nitrogen ([mmol/L]) | 7.0 ± 5.3 | 7.2 ± 4.9 | .87 |

*p < .05* was regarded as statistically significant.
Figure 1. Pre-treatment images from a 67-year-old man with $7.0 \times 5.0 \times 4.0$ cm RCC (pathological diagnosis was renal clear cell carcinoma) treated with combination therapy. (A, B) Conventional ultrasound showed a hypo-echoic lesion in the upper pole of the right kidney with the entire range of $7.0 \times 5.0 \times 4.0$ cm (yellow arrows). (C, D) Contrast-enhanced CT demonstrated a low density irregular lump in the right kidney with heterogeneity enhancement in the artery phase and hypo-enhancement in the venous phase (yellow arrows). (E, F) Contrast-enhanced US showed the RCC lesion in the upper pole with hyper-enhancement in the cortical phase and local non-enhancement, necrosis, slow contrast agent wash-out and hypo-enhancement in the corticomedullary and late phases (yellow arrows). (G) The pre-treatment 3D visualisation operative treatment planning system stereo display of the relationship between the tumour and surrounding organs (yellow arrow: tumour; blue arrow: kidney; red arrow: liver; green arrow: gall bladder). (H) The tumour volume was calculated, the parameters of the antenna (number, insertion pathway and angle) were planned and the thermal field distribution was predicted precisely. The simulative thermal field (green) overlapped the entire tumour (yellow). (I, J) The ablation procedure according to the pre-operative 3D visualisation operative treatment planning system. First, two antennas were placed in right upper and left upper parts of the lesion, respectively; second, two antennas were placed in right upper and left lower parts of the lesion, respectively (yellow arrows).
creatinine and urea nitrogen before ablation were 110.2 ± 81.9 µmol/L and 7.0 ± 5.3 mmol/L, respectively, which, compared to those 3 days after ablation of 120.4 ± 103.3 µmol/L and 7.2 ± 4.9 mmol/L, showed no significant difference (p = .73 and p = .87, p > .05).

The median follow-up period was 26 months (range 12–43 months), and all of the patients were followed up. With the post-operative 3D visualisation treatment planning system, all the tumours were completely ablated, and the ablation zone shrank gradually (Figure 2). Local tumour progression occurred in 1 case (5%) at 3 months after MWA, and the patient underwent another inpatient ablation and achieved complete ablation. By the end point of the follow-up period, all of the patients were still alive. The 1- and 2-year local tumour progression rates were both 5%. The cancer-specific survival rate and 2-year overall survival rate were both 100%.

**Discussion**

With the aging of the population and improvement of thin-section abdominal imaging, the incidence of larger RCC detection has been increasing in recent decades, although advancements in surgery have been attained and many minimally invasive treatments have been widely used, achieving gratifying clinical efficacy is difficult. It has been reported that the size and location of RCC tumours were important factors that affected curative effects and even influenced the prognosis [13,22]. For larger RCC tumours, the relationship of the tumour with the surrounding vital structures is more complex. In imaging-guided percutaneous ablation, the radiologist must reconstruct the anatomical relationship in his or her own perception, which is dependent on his or her spatial awareness and experience. Sometimes, the radiologist’s “subjective operation planning in the brain” is not consistent...
with the actual situation, and this inconsistency can lead to treatment failure or major complications [23]. How to calculate the tumour volume precisely and programme the operation planning scientifically and objectively is of optimal importance in imaging-guided percutaneous ablation. 3D visualisation treatment planning can be used in the quantitative calculation of tumour volume and the distance between the tumour and surrounding vital structures, as well as accurate simulation of 3D thermal fields and planning of the puncture pathway. 3D visualisation preoperative planning has been applied in liver thermal ablation [18,24,25]. On the basis of the characteristics and clinical application requirements of US-guided PMWA for larger RCC, we combined 3D visualisation treatment planning, US-guided PMWA, artificial ascites and a thermal monitoring system for larger RCC. In this study, all of the tumours underwent pre- and post-operative 3D visualisation treatment planning. In US-guided PMWA, the surrounding intestinal tract can be closely adjacent to the tumour, especially with larger and exophytic RCCs. Artificial ascites is a safe and effective assistive method for the treatment of tumours adjacent to the intestinal tract, and it was used in 60% of larger RCCs. A temperature monitoring system can demonstrate in real time the temperature at the tumour periphery and intestinal tract periphery, and it was used in all tumours. There was no intestinal thermal injury, urinary fistula, renal abscess, renal function failure, intratumoral bleeding or tumour seeding that occurred. The results were superior to those of previous studies in smaller RCC (D ≤ 4 cm) [12]. In this study, an integrated and precision treatment system for pre- and post-operative 3D visualisation operation planning, intraoperative artificial ascites adjuvant treatment and real-time temperature measuring system expanded the indications of US-guided PMWA and reduced the incidence of complications in larger RCC.

In the follow-up period, one patient was detected to have undergone tumour progression at 3 months after MWA. The 1- and 2-year local tumour progression rates were both 5%. The tumour had a maximum diameter of 8.4 cm and was adjacent to both the intestinal tract and the renal pelvis. The relationship of the tumour with the surrounding vital structures was complex, and the distance between the tumour and renal pelvis was only 2 mm. The progression tumour occurred very close to the renal pelvis, so the size and location of the tumour remain important factors in imaging-guided ablation [23].

For larger sized RCCs (D ≥ 4 cm), radical nephrectomy and partial nephrectomy are the main treatments [6,7,26], and it was reported that the estimated overall survival rates at 1, 3, 5, 7, and 10 years following radical nephrectomy and partial nephrectomy for larger RCC were 96%, 89%, 79%, 70%, and 57%, respectively [6]. This combination therapy of 3D visualisation operative treatment planning and US-guided PMWA in larger RCC is an innovative technique, which is not widely used clinically. From the preliminary results, the cancer-specific survival rate and 1- and 2-year overall survival rates were all 100%, comparable to those with radical and partial nephrectomy, although the long-term outcomes should be verified.

There were some limitations in this study. First, the operation of ultrasound-guided PMWA, intraoperative artificial ascites and a real-time temperature measuring system caused some difficulties in practice. The operators require solid knowledge of the anatomy and extensive experience in clinical practice. Second, a more intelligent 3D visualisation operation planning platform is needed for further research, which could expand the spatial imagination ability of younger surgeons. Third, a comparison between this combination therapy with partial nephrectomy and/or radical nephrectomy should be performed, and enlarging the sample and conducting multi-centre studies would be more convincing.

Conclusions
Combination therapy of 3D visualisation operative treatment planning system and Ultrasound-guided PMWA appears to be a safe and effective technique for the management of RCC with larger tumours (D ≥ 4 cm). Further, the 3D visualisation operative treatment planning system could provide more valuable information to assist ablation. Intraoperative artificial ascites and the real-time temperature measuring system improved the safety of the ablation. Combination treatment expanded the indications of US-guided PMWA and improved clinical efficacy.

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Disclosure statement
All of the authors have read the final manuscript and declare no conflicts of interest.

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