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Is percutaneous microwave ablation of liver tumor safe for patients with renal dysfunction☆

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ABSTRACT

Purpose: To determine the safety of percutaneous microwave ablation of primary and metastatic liver tumor for patients with renal dysfunction.
Materials and methods: Fifty primary and metastatic liver tumors in 23 patients with renal dysfunction were retrospectively reviewed at our institution. Renal function was determined by measuring serum creatinine and serum urea before MWA as baseline, within 1 week and at last follow-up. The mean creatinine was 1.69 ± 0.32 mg/dL, 1.71 ± 0.33 mg/dL, and 1.71 ± 0.26 mg/dL respectively, there was not a statistically significant difference between baseline and at last follow-up ($P = 0.26$). The mean serum urea was 52.52 ± 6.48 mg/dL, 56.55 ± 14.72 mg/dL, and 57.90 ± 16.39 mg/dL respectively, there was not a statistically significant difference between baseline and within 1 week ($P = 0.119$), between within baseline and at last follow-up ($P = 0.090$). At the last follow-up examination, all patients had adequately functioning kidneys and did not require any form of renal replacement therapy. This is a small retrospectively study including highly selected patients treated. Therefore, further study should to determine the safety of percutaneous MWA for patients with renal dysfunction in the future.
Conclusions: Percutaneous microwave ablation of primary and metastatic liver tumor is no adverse influence on renal function for patients with renal dysfunction in this preliminary series, which can be a minimally invasive alternative therapy.

1. Background

Advances in imaging have led to an increase in the use of minimally invasive technologies such as radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, high-intensity focused ultrasound (HIFU) as treatment of liver tumors [1–4]. Although surgical excision remains the reference standard for liver tumors, severe cirrhosis, multiple lesions often precludes liver resection or liver transplant in patients with liver tumors, it is only suitable for 30% patients with liver tumors [5,6]. Moreover, tumor recurrence is common after "curative" resection [7,8] and few patients are candidates for further hepatectomy. Therefore, minimally invasive yet effective therapeutic options are essential to improving the prognosis in HCC patients [9].

Microwave ablation (MWA) is an effective local thermal ablation technique for treating HCC which exhibit many advantages over other alternatives to resection [10–18]. MWA is an appealing alternative for patients for whom surgery poses a risk, and as an effective conservative approach to HCC in cirrhosis in China because of the minimal damage to liver function, relative lack of complications, and low mortality, as well as the promising clinical results [14–16]. But when those patients suffering renal dysfunction at the same time, are they still be candidates for MWA? Some studies identified hepatic resection in patients with impaired renal function has a significant risk factor of postoperative mortality [19,20]. Poor tolerance of the patients with renal dysfunction may be a significant risk factor for MWA, treatment decisions in patients with renal dysfunction must balance the potential beneficial effect of MWA on control of the tumor versus the morbidity, mortality, and quality of life risks. Thus, the purpose of our study was to evaluate the clinical and renal functional outcomes of patients with renal dysfunction who underwent MWA at our institution and determine the safety of MWA for patients with liver cancer with renal dysfunction. To the best of our knowledge, this is the first report of MWA of primary and metastatic liver tumors with renal dysfunction.

2. Materials and methods

The entire study protocol was approved by our Institutional Review Board. Because the patients' data were evaluated retro-

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spectively and anonymously, no written informed consent was necessary.

2.1. Patients

We retrospectively reviewed the database of all patients who had undergone percutaneous MWA at our institution for treatment of primary and metastatic liver tumors from July 1996 to October 2007, and identified 23 patients with renal dysfunction. The mean patient age was 60.2 ± 8.9 years (range 41–77), There were 22 men (mean age, 59.6 years ± 8.6 (standard deviation); age range, 41–77 years) and 1 women (74 years old). There were 17 (73.9%) patients with liver cirrhosis caused by chronic infection with the hepatitis B virus, 4 (17.4%) patients with a history of gastric or colorectal adenocarcinoma, and 2 (8.7%) patients without a history of liver cirrhosis and gastric or colorectal adenocarcinoma. The preablation Child–Pugh classification was assessed by the two pathologists in consensus: 3 of 24 patients (13%) had class A disease, 17 (74%) had class B disease, and 3 (13%) had class C disease. The diagnosis of renal dysfunction was made according to the criteria proposed by Bellomo et al. [23], which defined an increase in serium creatinine concentration of 1.44 mg/dL, and an increase in serum urea concentration of 48 mg/dL. Patients underwent ultrasonography and/or contrast-enhanced ultrasonography and magnetic resonance imaging with confirmation of primary and metastatic liver tumors. The mean diameter of largest tumor was 3.2 ± 0.9 cm (range 1.2–5.6). The mean tumor number was 2.2 ± 1.1 (range 1–5) per patient. Histologic diagnosis was confirmed using a sonographically guided biopsy gun with an 18-gauge cutting-edge needle. All patients had pathologic diagnosis before MWA. The biopsy findings were 19 of hepatocellular carcinomas (HCC), 4 of hepatic metastases (colorectal adenocarcinoma in 2 patients, gastric adenocarcinoma in 1 patient, breast carcinoma in 1 patient). Beside the renal dysfunction, patients who received percutaneous MWA were those at high risk of surgery-related complications because of advanced age, severe liver cirrhosis, multiple lesions located in different hepatic segments, or lesions located near a large hepatic vein or the junction of a large portal vein, or tumor recurrence after "curative" resection and not suitable for further hepatectomy, or refusal of surgery. Patients were informed of the developmental nature of MWA and the risks, and the imperative need for radiographic follow-up. Conventional surgical resection was always described as the reference standard treatment and patient informed consent were obtained.

2.2. Microwave ablation procedure

All treatments were performed at our institution. Tumors were treated by means of microwave ablation with two microwave applicator: UMI-I system (PLA General Hospital and Institute 207 of the Aerospace Industry Company, Beijing, China) from July 1996 to September 2004 with a frequency of 2450 MHz delivering a maximum power of 80 W through 16-gauge guide needle antennas, KY-2000 system (Kangyou Industry Company, Nanjing, China) from October 2004 to October 2007 with a frequency of 2450 MHz delivering a maximum power of 100 W through 15-gauge needle antennas. After induction of general anesthesia, patients were placed in a modified flank position, tumor localization was performed, and a biopsy was taken. A single antenna or multiple antennas were positioned in the tumor using US guidance depending on the tumor size [16]. The mean time of microwave ablation was 423.6 ± 166.3 s (range 180–1050 s) per patient, the mean number of microwave ablation was 2.4 ± 1.6 (range 1–9) per patient, the mean number of microwave antennas used was 2.1(range 1–5) per patient. A detailed protocol was worked out for each patient on an individual basis before treatment and included the placement of the antennas, power output setting, emission time, and appropriate approach [16]. A thermal monitoring system was used during treatment in our previous report [24]. Our general strategy was to perform multiple overlapping ablations to treat the tumor fully in a single session and defined successful ablation as a lack of enhancement or resolution of the liver tumor.After the procedure, all patients recovered in the postanesthesia care unit, and pain was controlled with oral medications, then all patients were observed for 3 nights in the hospital. All patients were adequately hydrated prior to or after treatment.

2.2.1. Follow-up

Patients underwent a uniform follow-up regimen, consisting of routine contrast-enhanced MR imaging and Color-flow Doppler US or contrast-enhanced ultrasound imaging and laboratory studies for serum creatinine and serum urea at 1 week, 1 months, 3 months, 6 months, and semiannually thereafter. Any enhancement in the zone of ablation after contrast administration was considered evidence of incomplete treatment. When incomplete necrosis or local tumor progression was confirmed with use of imaging modalities or post treatment biopsy, the antennas is reinserted and additional ablation performed for all patients as long as the patient still met the requirements for percutaneous MWA.

2.3. Statistical analysis

All continuous variables are expressed as mean ± SD. The SPSS statistical package version 10 (SPSS Inc., Chicago, IL) was used to analyze the results. The paired *t*-test were used to assess the differences between the continuous variables, respectively, with $P < 0.05$ considered significant.

3. Results

From May 1994 to October 2007, we ablated 50 tumors in 23 patients with a mean follow-up of 24 months (range 1–88 months). Table 1 lists the patient, procedure, and follow-up data. Table 2 lists the serum creatinine and serum urea before MWA as baseline, within 1 week and the last follow-up. The mean creatinine was 1.69 ± 0.32 mg/dL, 1.71 ± 0.33 mg/dL, and 1.71 ± 0.26 mg/dL respectively, there was a statistically significant difference between baseline and within 1 week ($P = 0.037$, paired *t* test), there was not a statistically significant difference between the last follow-up and baseline ($P = 0.260$, paired *t* test). The mean serum urea was 52.52 ± 6.48 mg/dL, 56.55 ± 14.72 mg/dL, and 57.90 ± 16.39 mg/dL respectively, there was not a statistically significant difference between within 1 week and baseline ($P = 0.119$, paired *t* test), there was no significant difference between the last follow-up and baseline ($P = 0.090$, paired *t* test).

No severe complications were observed. Twenty patients (86.9%) experienced local pain. Minor to medium pleural effusion developed in two patients whose tumors were located near the liver dome. Skin burns never occurred in all patients. At the last follow-up examination, all patients had adequately functioning kidneys and did not require any form of renal replacement therapy. None of them had any long-term sequelae of the incident during the follow-up period.

4. Discussion

With the rapidly development of the localized thermal ablative therapies for malignant liver tumors, several studies have been developed regarding the safety and efficacy of these treatment modalities for unresectable malignant liver tumors [25–28]. Microwave ablation has been used in China as an effective conservative approach to HCC in cirrhosis because of the minimal damage

Table 1
Patient, tumor, and procedure characteristics and radiographic and clinical follow-up data.

Variable	Result
Age (year)	
Mean	60.2 ± 8.9
Range	41–77
Sex	
Men	22
Woman	1
Child–pugh classification	
Class A	3
Class B	17
Class C	3
Liver cirrhosis	
Present	17
Absent	6
Diameter of largest tumor (cm)	
Mean	3.2 ± 0.9
Range	1.2–5.6
<2.5	4
2.5–4	16
>4.0	3
Tumor number	
Mean	2.2 ± 1.1
Range	1–5
Pathologic diagnosis (cases)	23
Hepatocellular carcinoma	19
Metastatic tumors	4
Percutaneous MWA procedure time (s)	
Median	423.6 ± 166.3
Range	180–1050
Percutaneous MWA procedure number per patient	
Median	2.4 ± 1.6
Range	1–9
Microwave antennas number per patient	
Median	2.1
Range	1–5
Follow-up (mo)	
Median	24
Range	1–88

to liver function, relative lack of complications, and low mortality, as well as the promising clinical results [14–16]. Previous several studies had been developed mainly focused on assessments of feasibility, safety, and therapeutic effectiveness [10,14–16]. At present, patients who are at high risk of surgery-related complications appear to have the most to gain from MWA. However, renal dysfunction inherently imply reduced renal reserve and increase the risk associated with MWA for patients with liver tumor and fewer data exist regarding the safety, efficacy, and indications for treating tumors with renal dysfunction with MWA. Liang et al. had reported two patients with chronic renal disease who were treated with MWA for liver metastases is safety and well tolerated [24]. To the best of our knowledge, no detailed data are available for the effect on renal function of the patients who undergo MWA with renal dysfunction.

Poon et al. caution against hepatic resection in patients with impaired renal function, because elevated serum creatinine level was a significant risk factor of mortality [19]. Melendez et al. also identified elevated serum creatinine level as a risk factor of post-operative mortality on extended hepatic resection [20]. The most common causes on renal function changes about hepatectomy are renal hypoperfusion from prolonged hypotension, hypovolemia, or renal toxic drugs. With the rapidly development of localized ablative therapies, these treatments are now considered as safe and effective techniques for local treatment for patients with tumor and multiple medical problems that preclude standard operative management. Shingleton and Sewell had reported their experience in 14 patients undergoing percutaneous cryoablation therapy for tumors in a solitary kidney and proved cryoablation was safe and well tolerated with no effect on renal function [29]. Johnson et al. demonstrated that temperature-based RFA does not appear to worsen hypertension or to have a negative effect on renal function [30]. Likewise, Arzola et al. found no significant change in renal function using resistance-based RFA, even in patients with renal dysfunction [31]. Although those studied confirmed the safety of localized ablative therapies and found no lasting toxicity with respect to various renal function parameters. There are some case reports about renal failure relate to those local ablative therapies. Kohli et al. had reported acute renal failure as a complication of cryoablation [21]. The lethal complication may relate to the release of toxic substances from the cryolesion, which caused a systemic inflammatory reaction after the thawing process of the cryoablation [32]. Keltner et al. had reported a case of prolonged radiofrequency liver ablation for large metastatic carcinoid tumor complicated by hemolysis, rhabdomyolysis, and transient acute renal failure [22]. Those cases remind us to pay attention to the safety of the local ablative therapies.

Although at present, enough evidence is not available to suggest that MWA should be considered the treatment of choice for all patients with primary and metastatic liver tumors with renal dysfunction, we believe that selected high surgical risk patients could benefit from this minimally invasive technique. Currently, no widely accepted, standardized follow-up regimen has been determined for liver caner patients with impaired renal function undergoing MWA. In our study, the follow-up protocol was performed mainly according to previously published recommendations [14,16]. Taking into account the renal dysfunction of those patients, the follow-up protocol made some necessary changes. Due to the iodinated contrast material is cleared from kidney, increase the kidney burden and worse renal function or potentially induce renal failure, we did not chose routine contrast-enhanced CT to evaluate therapeutic effectiveness. To protect residual renal function from MWA, all patients were adequately hydrated prior to or after treatment. The mean creatinine was 1.69 ± 0.32 mg/dL, 1.71 ± 0.33 mg/dL, and 1.71 ± 0.26 mg/dL before MWA, within 1 week and at last follow-up, the mean serum urea was 52.52 ± 6.48 mg/dL, 56.55 ± 14.72 mg/dL, and 57.90 ± 16.39 mg/dL respectively. Serum creatinine levels and serum urea levels are related not just to renal function but also to the release of tissue degradation products due to tissue necrosis and apoptosis after MWA. Post microwave ablation creatinine levels and urea levels rised due to tissue necrosis and apoptosis and not just worse renal function. The clinical outcomes of the patients with renal dysfunction treated by MWA have demonstrated that the procedure can be performed successfully, with minimal impact

Table 2
Renal function outcomes in patients with primary and metastatic liver tumors undergoing percutaneous MWA.

	Baseline	Within 1 week	At last follow-up (all patients)
Serum creatinine (mg/dL)			
Mean ± std. deviation	1.69 ± 0.32	1.71 ± 0.33	1.71 ± 0.26
Range	1.24–2.92	1.26–3.02	1.39–2.66
Serum urea (mg/dL)			
Mean	52.52 ± 6.48	56.55 ± 14.72	57.90 ± 16.39
Range	45.15–65.87	45.87–116.11	44.55–118.86

on renal function for most patients. At the last follow-up examination, all patients had adequately functioning kidneys and did not require any form of renal replacement therapy. Percutaneous MWA does not adversely influence the renal function in patients with renal dysfunction. The results of the present study support the contention that percutaneous microwave ablation is safe and offers a minimally invasive alternative therapy for patients with renal dysfunction.

There are several potential reasons for the safety of percutaneous MWA appears to maintain adequate renal function in select patients with renal dysfunction in our study. First, higher temperatures by MWA results in cellular protein denaturation and subsequent apoptosis, and cellular coagulation necrosis. Cellular coagulation necrosis ensured the relative intact cytoplasmic membranes after MWA, which was similar with RFA [33]. Second, the tumor size was relative small, the mean diameter of largest tumor was 3.2 ± 0.9 cm, the tumor number was relative few, the mean liver tumor number was 2.2 ± 1.1 per patient, it is important to decrease the potential risks to the renal function. To some relative large tumor and/or a large number of tumors, we choose perform MWA in several sessions for patients to maximum decrease the potential risk of per MWA for the renal function. Third, the mean time of microwave ablation was 423.6 ± 166.3 s (range 180–1050 s) per patient, relative short time for tumor ablation may important for decrease the potential risks to the renal function. Some patients had a relative long MWA proceduce due to liver tumors near any critical structures such as the bowels, stomach, gallbladder and else. For those patients, we turn down the microwave applicator power and prolong the MWA proceduce time under the monitor of a thermal monitoring system. Last, but not the least, percutaneous MWA requires surgeon familiarity with device manipulation and image interpretation, it is very important for the accurate placement of the single antenna or multiple antennas in the tumor and MWA monitoring by ultrasound.

There were some limitations that may affect clinical value of our study. Firstly, this study was retrospectively evaluating the renal functional outcomes of patients with renal dysfunction who underwent MWA, most patients with normal renal function who underwent MWA were not usually measured serum creatinine and serum urea for follow-up evaluation. Secondly, the study were only measured serum creatinine and serum urea to evaluate the renal functional outcomes of patients, more renal function tests should add to evaluate the renal functional outcomes of the patients. Thirdly, the size and the number of tumor lesions were relatively small and few, respectively, large or multiple tumors should included for comprehensively determine the safety of percutaneous MWA in the future.

5. Conclusions

Percutaneous microwave ablation of primary and metastatic liver tumor is no adverse influence on renal function for patients with renal dysfunction in this preliminary series, which can be a minimally invasive alternative therapy. Although the currently available data show that MWA does not adversely influence the renal function in patients with renal dysfunction, studies with larger data sets and longer follow-up are clearly needed to fully confirm the clinical efficacy of MWA for patients with renal dysfunction.

Author contributions

P. Liang, B.W. Dong and X.L. Yu designed the research, C. Liu, Y. Wang and P. Zhou performed the research, H. Ren carried out the statistical analysis; Y. Wang helped in writing and correcting the article, and P. Liang supervised the organization process.

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