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Microwave ablation of focal hepatic malignancies regardless of size: A 9-year retrospective study of 64 patients

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ABSTRACT

Purpose: To retrospectively evaluate the safety and efficacy of microwave ablation (MWA) as treatment for single, focal hepatic malignancies.

Materials and Methods: Institutional review board approval was obtained for this HIPAA-compliant study. From December 2003 to May 2012, 64 patients were treated with MWA for a single hepatic lesion, in 64 sessions. Hepatocellular carcinoma (HCC) was treated in 25 patients (geometric mean tumor size, 3.33-cm; 95% CI, 2.65–4.18-cm; range, 1.0–12.0-cm), metastatic colorectal cancer (CRC) was treated in 27 patients (geometric mean tumor size, 2.7-cm; 95% CI, 2.20–3.40-cm; range, 0.8–6.0-cm), and other histological-types were treated in 12 patients (geometric mean tumor size, 3.79-cm; 95% CI, 2.72–5.26-cm; range, 1.7–8.0-cm). Kaplan–Meier (K–M) method was used to analyze time event data. Chi-square and correlation evaluated the relationship between tumor size and treatment parameters.

Results: Technical success rate was 95.3% (61/64). Treatment parameters were tailored to tumor size; as size increased more antennae were used ($p < 0.001$), treatment with multiple activations increased ($p < 0.028$), and treatment time increased ($p < 0.001$). There was no statistically significant relationship between time to recurrence and tumor size, number of activations, number of antennae, and treatment time.

At one-year, K–M analysis predicted a likelihood of local recurrence of 39.8% in HCC patients, 45.7% in CRC metastases patients, and 70.8% in patients with other metastases. Median cancer specific survivals for patients were 38.3 months for HCC patients, 36.3 months for CRC metastases, and 13.9 months for other histological-types.

Complications occurred in 23.4% (15/64) of sessions.

Conclusion: In our sample, tumor size did not appear to impact complete ablation rates or local recurrence rates for focal hepatic malignancies treated with MWA.

1. Introduction

Over the past several decades the percentage of Americans developing liver cancer has been steadily rising. This increase is thought to be attributable to a rise in risk factors such as cirrhosis secondary to alcohol use and chronic hepatitis B and C infection. In 2013 there will be an estimated 30,640 new cases of primary liver cancer and intrahepatic bile duct cancer in the US. This number is superseded by the spread of malignancies to the liver, with the majority of hepatic lesions representing metastases [1].

Traditionally treatment options have included surgery, chemotherapy, and radiation therapy. While surgical resection remains the reference standard for the treatment of early stage hepatocellular carcinoma (HCC) or isolated metastatic disease, many patients are not surgical candidates due to medical comorbidities,

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poor hepatic reserve or advanced staging at the time of diagnosis [1,2]. Given the unresectability of many lesions, less invasive options such as thermal ablation have emerged as safe and valuable treatment alternatives. Radiofrequency ablation (RFA) is presently considered first-line treatment for small, unresectable (<3 cm) HCC lesions, with considerable research supporting its efficacy [3,4]. However, growing experience over the last several years has shown that microwave ablation (MWA) may be a valuable alternative to RFA [5–7].

MWA uses electromagnetic waves in the microwave energy spectrum to produce tissue-heating effects, leading to cellular death through coagulation necrosis. It is regarded as a potentially superior treatment option to RFA due to much broader energy deposition, the capacity to produce a larger zone of active heating, higher intratumoral temperatures, larger tumor ablation volumes, faster ablation times, and a decreased heat sink effect compared to RFA [8,9].

Several large multi-center studies have been published evaluating the safety and associated complications of MWA in liver [5–7]. The strength of these studies has been the inclusion of patients with a wide spectrum of tumor sizes in both cirrhotic and normal livers. However, as adoption of microwave therapy increases we're better able to assess treatment effectiveness in targeted patient populations. The purpose of our study was to evaluate the safety and efficacy of MWA in treating solitary primary and metastatic liver tumors. We believe that this study provides a more specific interpretation of recurrence, as all patients had treatable, unifocal disease.

2. Materials and methods

2.1. Patient selection and study design

Institutional review board approval was obtained for this Health Insurance Portability and Accountability Act-compliant study. Informed consent was waived by the institutional review board because of the retrospective nature of the study. The authors who did not receive grants and/or personal fees from Neuwave Medical, BSD Medical, and Covidien had control of the inclusion of any data and information that might present a conflict of interest for the author who is a consultant for these industries.

The study population consisted of patients with a single liver neoplasm treated with microwave ablation (MWA) at a single institution over a 9-year period, with intent for complete eradication of the treated tumor. From December 11, 2003, to May 7, 2012, 64 patients (40 men, 24 women) underwent MWA of 64 hepatic malignancies in 64 MWA sessions performed intra-operatively ($n = 13$) or percutaneously ($n = 51$) under ultrasound (US) or computed tomographic (CT)-guidance. Patients either refused surgical resection or were deemed non-surgical candidates, as a result of advanced staging, poor hepatic reserve, anatomic restrictions, and/or other medical comorbidities. Certain patients in the study were concomitantly treated with resection and ablation; in these cases, MWA was required for one of the tumors due to anatomical location. MWA was the chosen modality over RFA or cryoablation based on lesion size (greater than 3 cm) and/or close proximity to vascular structures. Exclusion criteria for MWA included radiographic evidence of nodal disease, adenopathy, extrahepatic disease at the time of ablation, and/or an international normalized ratio greater than 1.8 on the day of ablation. A prior history of hepatic resection, extrahepatic resection, or treatment with adjuvant chemotherapy or radiation was not grounds for exclusion, if the site of disease was technically amenable to complete treatment. All patients who met these criteria and were treated with MWA during the study timeframe were included in our analysis.

2.2. Preablation assessment

The decision to perform liver MWA was made by the treating radiologist or surgeon in conjunction with the patient and referring physician. Prior to ablation, patients were seen at the Diagnostic Imaging Department's Tumor Ablation Clinic by 1 of 6 board-certified radiologists trained in image-guided tumor ablation and interventional procedures, with between 1 and 15 years of experience, or in pre-operative consultation with one of three hepatobiliary or oncologic surgeons with between 2–12 years of intra-operative ablation experience. At this time a focused history was taken, a physical examination was performed, and all relevant imaging studies were reviewed. The indications, risks, benefits, and alternatives were discussed in full with patients. Complete blood cell counts, platelet counts, and INR values were routinely obtained.

2.3. Microwave ablation technique

Radiologists performed all percutaneous MWA sessions. The majority of percutaneous treatments, 82.4% (42/51), were performed under CT fluoroscopic guidance with 5-mm collimation and 10–50 mA (CTi; GE Medical Systems, Milwaukee, WI). The remaining 17.6%, (9/51), of percutaneous treatments were performed under real-time US-guidance (Logic 9, GE Medical Systems). US-guidance was infrequently used in percutaneous sessions due to limitations in adequately visualizing the target tumor as a result of patient body habitus and/or specific tumor location within the liver. All 13 intra-operative ablation sessions were performed under US-guidance by hepatobiliary surgeons. Visualization of the target tumor in these cases was facilitated by surgical exposure of the liver and application of the US probe directly on the liver capsule. Percutaneous MWA was generally performed under conscious sedation with IV midazolam (Versed; Abbott Laboratories; North Chicago, IL) and fentanyl (Sublimaze; Abbott Laboratories; North Chicago, IL). Intra-operative procedures were performed under general anesthesia.

Five different MW systems were utilized for the study. The systems used either a 915 MHz generator (Evident, Covidien, Mansfield, MA; MicrothermX, BSD Medical, Salt Lake City, UT; Avecure, Medwaves, San Diego, CA) or a 2450 MHz generator (Certus 140, Neuwave, Madison, WI; Amica, Hospital Service, Rome, Italy). The MW antennae used were straight applicators with active tips ranging in lengths from 0.6 to 4.0 cm. The outer shaft of each antenna was continuously perfused, according to vendor specifications, with either room temperature normal saline or carbon dioxide gas, to prevent tissue charring at the antenna tip and to protect proximal tissue from conductive heating by the antenna shaft. Percutaneous entry site and antenna trajectory, antennae type (active tip and shaft length), and number were determined on the basis of tumor location and size.

If the patient was stable post percutaneous ablation, with no complications, they were discharged home within 4–5 h. Any moderate or large pneumothorax (>1 cm separation between the visceral and parietal pleura) found intra-procedurally or on 2-hour post-procedure chest radiograph was initially treated by aspiration (Yueh catheter; Cook, Bloomington, IN), followed by placement of a chest tube if not resolved. At the discretion of the treating physicians, patients were admitted overnight for observation, chest tube management, or pain control.

2.4. Treatment evaluation

Follow-up CT was performed at 1-, 3-, and 6-month intervals following the initial ablation session. A multi-detector row helical CT scanner (LightSpeed Quad or LightSpeed VCT; GE Medical Systems) was used, and three phase images of the abdomen were