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Medical Policy Manual

Topic: Microwave Tumor Ablation

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1]

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue by using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors considered to be inoperable or not amenable to resection or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. MWA may be performed as an open procedure, laparoscopically, percutaneously or thoracoscopically under image guidance (e.g., ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) with sedation, or local or general anesthesia. This technique may also be referred to as microwave coagulation therapy.

Background

Microwave Ablation (MWA)

MWA is a technique in which the use of microwave energy induces an ultra-high speed, 915 MHz or 2.450 MHz (2.45 GHz), alternating electric field which causes water molecule rotation and the creation of heat. This results in thermal coagulation and localized tissue necrosis. In MWA, a single microwave antenna or multiple antennas connected to a generator are inserted directly into the tumor or tissue to be ablated; energy from the antennas generates friction and heat. The local heat coagulates the tissue adjacent to the probe, resulting in a small, approximately 2-3 cm elliptical area (5 x 3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, 2-3 antennas may be used simultaneously to increase the targeted area of MWA and shorten operative time. Multiple antennas may also be used

simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within 1 minute after a pulse of energy, and multiple pulses may be delivered within a treatment session depending on the size of the tumor. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it occurs at the edges. Treatment may be repeated as needed. MWA may be used to: 1) control local tumor growth and prevent recurrence; 2) palliate symptoms; and 3) extend survival duration.

Complications from MWA are usually considered mild and may include pain and fever. Other potential complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during MWA of the kidney or liver), structural damage along the probe track (e.g., pneumothorax as a consequence of procedures on the lung), liver enzyme elevation, liver abscess, ascites, pleural effusion, diaphragm injury or secondary tumors if cells seed during probe removal. MWA should be avoided in pregnant patients since potential risks to the patient and/or fetus have not been established and in patients with implanted electronic devices such as implantable pacemakers that may be adversely affected by microwave power output.

MWA is an ablative technique similar to radiofrequency or cryosurgical ablation; however, MWA may have some advantages. In MWA, the heating process is active, which produces higher temperatures than the passive heating of radiofrequency ablation and should allow for more complete thermal ablation in a shorter period of time. The higher temperatures reached with MWA (over 100° C) can overcome the "heat sink" effect in which tissue cooling occurs from nearby blood flow in large vessels potentially resulting in incomplete tumor ablation. MWA does not rely on the conduction of electricity for heating, and therefore, does not have electrical current flow through patients and does not require grounding pads be used during the procedure to prevent skin burns. Unlike radiofrequency ablation, MWA does not produce electric noise, which allows ultrasound guidance to occur during the procedure without interference. Finally, MWA can be completed in less time than radiofrequency ablation since multiple antennas can be used simultaneously.

MWA was first used percutaneously in 1986 as an adjunct to liver biopsy. Since that time, MWA has been used for ablation of tumors and tissue for the treatment of many conditions including: hepatocellular carcinoma, colorectal cancer metastatic to the liver, renal cell carcinoma, renal hamartoma, adrenal malignant carcinoma, non-small cell lung cancer, intrahepatic primary cholangiocarcinoma, secondary splenomegaly and hypersplenism, abdominal tumors and other tumors not amenable to resection. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of MWA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Hepatic Tumors

Hepatic tumors can arise either as primary liver cancer (hepatocellular carcinoma, HCC) or by metastasis to the liver from other primary cancer sites. Local therapy for hepatic metastasis may be indicated when there is no extrahepatic disease, which rarely occurs for patients with primary cancers other than colorectal carcinoma or certain neuroendocrine malignancies. At present, surgical resection with adequate margins or liver transplantation constitutes the only treatments available with demonstrated curative potential. Partial liver resection, hepatectomy, is considered the gold standard. However, the majority of hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, or underlying liver reserve.

Among other locoregional therapies, MWA has been investigated as a treatment for unresectable hepatic tumors, both as primary treatment, palliative treatment, and as a bridge to liver transplant. In the case of liver transplants, it is hoped that MWA will reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient's candidacy for liver transplant during the wait time for a donor organ.

Renal Cell Carcinoma

Radical nephrectomy remains the principal treatment of renal cell carcinoma; however, partial nephrectomy or nephron-sparing surgery has been shown to be as effective as radical nephrectomy, with comparable long-term recurrence-free survival rates, in a select group of patients. Prognosis drops precipitously if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic renal cell carcinoma. Alternative therapies such as MWA are of interest in patients with small renal tumors when preservation of renal function is necessary (e.g., in patients with marginal renal function, a solitary kidney, bilateral tumors) and in patients with comorbidities that would render them unfit for surgery. Another consideration would be in patients at high risk of developing additional renal cancers (as in von Hippel-Lindau disease).

Regulatory Status

There are several devices cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for MWA. Covidien's (a subsidiary of Tyco Healthcare) Evident Microwave Ablation System has 510(k) clearance for soft tissue ablation, including partial or complete ablation of non-resectable liver tumors. The following devices have 510(k) clearance for MWA of (unspecified) soft tissue:

- BSD Medical Corporation's MicroThermX Microwave Ablation System (MTX-180);
- Valleylab's (a subsidiary of Covidien) VivaWave Microwave Ablation System;
- Vivant's (acquired by Valleylab in 2005) Tri-Loop Microwave Ablation Probe;
- MicroSurgeon Microwave Soft Tissue Ablation Device;
- Microsulis Medical's Acculis Accu2i; and
- NeuWave Medical's Certus 140

These devices are considered substantially equivalent to previously FDA-approved radiofrequency and MWA devices.

MEDICAL POLICY CRITERIA

Microwave ablation is considered investigational as a treatment of primary and metastatic tumors, including but not limited to tumors of the breast, liver, lung, and kidney.

SCIENTIFIC EVIDENCE

The principal health outcomes associated with treatment of malignancies are typically measured in units of survival past treatment: disease-free survival (DFS), a period of time following treatment where the disease is undetectable; progression-free survival (PFS), the duration of time after treatment before the

advancement or progression of disease; and overall survival (OS), the period of time the patient remains alive following treatment.

In order to understand the impact of microwave ablation (MWA) on these outcomes, well-designed randomized controlled trials (RCTs) are needed that compare this therapy with standard medical and/or surgical treatment of primary and metastatic tumors.

Literature Appraisal

Breast

Systematic Review

A 2010 review of ablation techniques by Z. Zhao et al., for breast cancer found only 0-8% of breast tumors were completely ablated with microwave ablation (MWA).[2] The authors noted that studies identified for the review were mostly feasibility and pilot studies conducted in research settings.

Nonrandomized Trials

In 2012, W. Zhou and colleagues reported on 41 patients treated with MWA directly followed by mastectomy for single breast tumors with a mean volume of 5.26 cm + 3.8 (range, 0.09 to 14.14 cm).[3] Complete tumor ablation was found by microscopic evaluation in 37 of the 41 tumors ablated (90%; 95% confidence interval [CI]: 76.9-97.3%). Reversible thermal injuries to the skin and pectoralis major muscle occurred in 3 patients. Results from this study should be met with caution due to its small sample size and lack of comparison group.

Conclusion

Current evidence regarding the use of MWA as a treatment for breast tumors is limited to a single RCT and systematic review of nonrandomized studies. It is unclear whether MWA is comparable to other ablative techniques or surgical resection. Large RCTs comparing MWA to both invasive and noninvasive techniques are needed in order to assess the efficacy of this treatment in patients with nonmetastatic breast tumors.

Hepatocellular Carcinoma

Systematic Reviews and Meta-Analysis

- In 2009, Ong and colleagues conducted a systematic review of studies on MWA for primary and secondary liver tumors.[4] Based on the results from 25 clinical studies, the authors concluded that MWA was an effective and safe technique for liver tumor ablation with low complication rates and survival rates comparable to hepatic resection. However, rates of local recurrence after MWA were noted to be higher than hepatic resection. In most studies of MWA, hepatocellular carcinoma recurrence rates were approximately 10% but were also noted to be as high as 50%, which the authors indicated could be addressed with further ablation. Survival rates in the studies on MWA for hepatocellular carcinoma were as high as 92% at 3 years and 72% at 5 years, which was noted to be comparable to radiofrequency ablation (RFA) and percutaneous ethanol injections. Pain and fever were the most frequently reported complications, but complications increased when there were more tumors, larger tumors, and more microwave antennas used. The authors concluded that MWA may

be a promising option for the treatment of HCC tumors but should be reserved for patients not amenable to hepatic resection. The authors also noted further randomized clinical trials are warranted to compare MWA to other ablation procedures.

- In 2011, Bertot and colleagues conducted a systematic review evaluating mortality and complication rates of ablation techniques for primary and secondary liver tumors.[5] This review included 2 studies using MWA totaling 1,185 patients.[6,7] The pooled mortality rate for MWA was 0.23% (95% confidence interval [CI]: 0.0–0.58%). Major complication rates were 4.6% for MWA (calculated by using a random effects model since there was significant heterogeneity). The authors concluded that percutaneous ablation techniques, including MWA, are safe and have acceptable complication rates for the treatment of liver tumors.

Randomized Controlled Trials (RCTs)

- In 2002, Shibata and colleagues reported on 72 consecutive patients with 94 small hepatocellular carcinoma (HCC) nodules randomized to receive either percutaneous MWA or RFA performed by a single surgeon.[8] No significant differences were identified between the 2 treatment group characteristics, e.g., sex, age, nodule size, Child-Pugh cirrhosis class and number of nodules. In the radiofrequency ablation group, complete therapeutic effect was seen in 46 (96%) of 48 nodules (mean size 2.3 cm, range 1.0-3.7) versus 41 (89%) of 46 nodules (mean size 2.2 cm, range 0.9-3.4) treated with percutaneous MWA (p=0.26). Treatment outcomes were not significantly different between the percutaneous MWA and radiofrequency ablation groups in the rates of untreated disease (follow-up range of 6-27 months [8 of 46 nodules vs. 4 of 48 nodules, respectively]), and major complication rates (4 vs. 1, respectively). Major complications included one case of segmental hepatic infarction in the radiofrequency ablation group. In the MWA group, major complications included one case of each of the following: liver abscess, cholangitis with intrahepatic bile duct dilatation, subcutaneous abscess with skin burn and subcapsular hematoma. Life-threatening complications were not experienced. The number of treatment sessions required per nodule in the radiofrequency ablation group was significantly lower than in the percutaneous MWA group (1.1 vs. 2.4; p<0.001). However, treatment time per session was significantly shorter in the MWA group (33 minutes ± 11) than the radiofrequency ablation group (53 minutes ± 16).

- In 2006, Taniai and colleagues reported on 30 patients with multiple HCC tumors who underwent reduction hepatectomy with postoperative transcatheter arterial embolization.[9] Prior to surgery, patients were randomly assigned to receive no intraoperative adjuvant therapy (n=15) or intraoperative adjuvant therapy with either MWA (n=10) or radiofrequency ablation (n=5) of satellite lesions. No significant differences in characteristics were identified between the two treatment groups of no intraoperative adjuvant therapy vs. intraoperative adjuvant therapy, e.g., sex, age, nodule size (maximum tumor size 42.7 mm ± 23.5 vs. 37.8 mm ± 16, respectively), Child-Pugh cirrhosis class and number of nodules. Cumulative survival rates at 3 and 5 years were not significantly different in the group that did not receive intraoperative adjuvant therapy (35.0% and 0%, respectively) versus the intraoperative adjuvant therapy group (35.7% and 7.7%, respectively). A-fetoprotein, number of tumors, maximum tumor size and clinical stage, but not intraoperative adjuvant therapy, were identified as independent prognostic survival factors.

Nonrandomized Trials

In addition to the studies noted above, a number of nonrandomized studies have been published on the use of MWA in patients with hepatocellular carcinoma. However, the results of these studies should be interpreted with caution due to the following limitations:

- Results from small sample sizes (n<100), limit the ability to rule out the role of chance as an explanation of study findings.[10-12]
- Results from studies with short-term follow-up (>1 year) are not adequate to determine the durability of the treatment effect.[10,13,14]
- A lack of comparison group, without which it is not possible to account for the many types of bias that can affect study outcomes.[6,7,13-18]

Given the limitations noted above, nonrandomized studies do not provide reliable data to demonstrate the efficacy of MWA treatment in patients with HCC.

Conclusion

Although many publications of MWA for hepatocellular carcinoma were identified, the evidence primarily consists of small case series and retrospective reviews. Only two small (n<100) RCTs were identified[8,9] and no RCT was found which compared the use of MWA for hepatocellular carcinoma to the gold standard of surgical resection.

Overall nonrandomized studies suggest the technique of MWA provided good tumor ablation (87-100% ablation of targeted tumors) with low procedural complication rates. However, these studies are limited primarily by a lack of comparison group allowing for potential bias in reported conclusions. Additional, large RCTs with long-term follow-up are needed in order to evaluate the efficacy of MWA treatment in patients with HCC tumors.

Hepatic Metastasis

The literature search identified several small studies on MWA for hepatic metastases and 4 systematic reviews.[4,5,19]

Systematic Reviews and Meta-Analysis

- In 2013, Vogl and colleagues reviewed evidence regarding RFA, laser-induced thermotherapy (LITT) and MWA treatment of breast cancer liver metastasis.[20] Local tumor response, progression and survival rates were evaluated. Authors reported positive response rates of 63 % to 97 % in RF-ablated lesions, 98.2 % in LITT-treated lesions and 34.5-62.5 % in MWA lesions. Median survival was 10.9-60 months with RFA, 51-54 months with LITT and 41.8 months with MWA. Five-year survival rates were 27-30 %, 35 % and 29 %, respectively. Local tumour progression ranged from 13.5 % to 58 % using RFA, 2.9 % with LITT and 9.6 % with MWA. The authors called for additional, large RCTs to further explore the benefits of ablation therapies.

- In the Ong review described above[4], local recurrence rates for liver metastases after treatment with MWA averaged approximately 15% but varied between 0 and 50% in the 7 studies reviewed that addressed liver metastases. As noted above, Ong and colleagues concluded MWA may be a promising treatment option for the treatment of liver tumors but should be reserved for patients not amenable to hepatic resection.

- In 2011, Pathak and colleagues also conducted a systematic review of ablation techniques for colorectal liver metastases, which included 13 studies on MWA, totaling 406 patients with a minimum of 1-year follow-up.[19] Mean survival rates were 73%, 30% and 16% and ranged from 40–91.4%, 0–57% and 14–32% at 1-, 3- and 5-years' follow-up, all respectively. Minor and major complication rates were considered acceptable and ranged from 6.7–90.5% and 0–19%, respectively. Local recurrence rates ranged from 2-14%. The authors acknowledged limitations in the available studies but concluded survival rates for MWA are more favorable than for palliative chemotherapy alone.

Randomized Controlled Trials (RCTs)

Only one RCT comparing the use of MWA for hepatic metastases to the gold standard of surgical resection was identified. In 2000, Shibata et al. reported on a trial of 30 patients with hepatic metastases from colorectal cancer randomly assigned without stratification to treatment with either MWA after laparotomy (n=14) or hepatectomy (n=16).[21] The study began with 40 patients, but 10 patients were excluded because the researchers discovered intraoperatively that these patients did not meet study criteria due to having extensive metastasis or equal to or greater than 10 tumors. The treatment groups of MWA vs. hepatectomy were not significantly different in age (mean age 61 in both groups) number of tumors (mean 4.1 vs. 3.0, respectively) or tumor size (mean 27 mm vs. 34 mm, respectively). The authors reported no significant differences in survival rates following MWA or hepatectomy (27 months vs. 25 months, respectively) and mean disease-free survival (11.3 vs. 13.3 months, respectively). However, intraoperative blood loss was significantly lower and no blood transfusions were required in the MWA group whereas 6 patients in the hepatectomy group required blood transfusions. Complications in the microwave group consisted of one hepatic abscess and one bile duct fistula. In the hepatectomy group, complications were one intestinal obstruction, one bile duct fistula and one wound infection.

Nonrandomized Trials

Several nonrandomized trials regarding MWA treatment in patients with liver metastases were identified; however, these studies were limited by a lack of comparison group,[22-24] short-term follow-up[22,23] and small sample size.[22,24] These limitations preclude reaching a conclusion regarding MWA treatment in this patient population.

Conclusion

Similar to the evidence found regarding MWA and HCC tumors, there is a lack of RCTs comparing MWA to other ablative techniques or to surgical resection. Conclusions from nonrandomized studies and from systematic reviews based on nonrandomized trials must be met with caution, as possible confounding factors and bias may have impact upon any study results.

Lung

Randomized Controlled Trials (RCTs)

No published RCTs were identified which evaluating the efficacy of MWA compared to surgical resection or other nonablative techniques in patients with lung cancer.

Nonrandomized Trials

Evidence regarding MWA for lung tumors is limited to four nonrandomized retrospective studies.[25-28] These studies are all limited by lack of comparison group and small sample size. One study was also limited by short-term follow-up.[28]

Conclusion

Evidence regarding the use of MWA as a treatment for lung tumors consists of 4 nonrandomized trials which are limited by small sample size (n<100) and lack of comparison. Large, long-term RCTs are needed in ordered to effectively assess the use of MWA compared to other techniques in this patient population.

Primary Renal Tumors

Randomized Controlled Trials (RCTs)

In 2012, Guan and colleagues reported on a prospective randomized study to compare the use of MWA to partial nephrectomy (the gold standard of nephron-sparing surgical resection) for solitary renal tumors less than 4 cm.[29]. Forty-eight patients received MWA and 54 had partial nephrectomy. Patients in the MWA group had significantly fewer postoperative complications than the partial nephrectomy group (6 [23.5%] vs. 18 [33.3%]; p=0.0187). MWA patients also had significantly less postoperative renal function declines (p=0.0092) and estimated perioperative blood loss (p=0.0002) than partial nephrectomy patients. At last follow-up, estimated glomerular filtration rate declines in both groups were similar (p=1.0000). Disease-specific deaths did not occur and overall local recurrence-free survival by Kaplan-Meier estimates at 3 years were 91.3% for MWA and 96.0% for partial nephrectomy (p= 0.5414). Studies with longer follow-up are needed in order to assess the benefits of MWA compared to nephrectomy.

Nonrandomized Trials

Evidence regarding MWA treatment in patients with primary renal tumors primarily consists of several nonrandomized case studies, all of which are limited by lack of comparison and small sample size.[30-34] In addition, one studies were also limited by short-term follow-up.[31]

Conclusion

Evidence regarding MWA treatment for renal cell tumors is limited to one RCT and several case series. Additional large, long-term RCTs are needed in order to evaluate the efficacy of MWA compared to other ablative therapies and nephrectomy.

Other Tumors or Conditions

No RCTs on the use of MWA for other tumors or conditions were identified. Case studies and retrospective reviews on MWA for adrenal carcinoma,[35] intrahepatic primary cholangiocarcinoma,[36] benign thyroid tumors,[37] and other non-oncologic conditions (i.e., bleeding peptic ulcers, esophageal varices, secondary hypersplenism) were identified; however, all of these studies were limited by a lack of comparison group.

Clinical Practice Guidelines

National Comprehensive Cancer Network (NCCN)

- The NCCN guidelines on hepatobiliary cancers lists MWA (along with radiofrequency ablation, cryoablation, and percutaneous alcohol injection) as a treatment option for hepatocellular carcinoma tumors in patients who are not candidates for potential curative treatments (e.g., resection and transplantation).[38] The guidelines indicate hepatocellular carcinoma tumors should be equal to or less than 3 centimeters and accessible by percutaneous, laparoscopic or open approaches. Hepatocellular carcinoma tumors between 3-5 centimeters may also be treated with ablation when used in combination with arterial embolization. Additionally, the tumor location must be accessible to permit ablation of the tumor and tumor margins without ablating major vessels, bile ducts, the diaphragm or other abdominal organs. However, there are only 2 reviews cited in the guideline on ablative techniques to support these recommendations, and neither review is specific to MWA [category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate].
- In the NCCN guidelines on neuroendocrine tumors, MWA is listed as one treatment option (along with radiofrequency ablation or cryoablation) for liver metastases as hepatic regional therapy in carcinoid tumors and pancreatic endocrine (islet cell) tumors when there is unresectable disease and/or distant metastases.[39] These guidelines note, currently, there are limited prospective data and no randomized clinical trials on ablative therapies (including MWA), and data on these ablative techniques are emerging. Additionally, the 2 articles cited in the guideline on ablative techniques are not specific to MWA [category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate].

American College of Chest Physicians (ACCP)

The ACCP evidence-based guidelines on the treatment of non-small cell lung cancer note that insufficient data are available on ablative therapies including MWA of tumors.[40]

Summary

Based on a review of the published data (which consist largely of small case series and limited randomized trials), there is insufficient evidence to permit conclusion concerning the effectiveness of microwave ablation (MWA) compared to surgical resection or other ablative techniques on health outcomes. Patient selection criteria and rationale for using MWA over other established techniques such as surgical resection or radiofrequency ablation are needed. Additional well-designed, randomized controlled trials are needed which assess the efficacy of MWA for the treatment of tumors for control of local tumor growth, palliation of symptoms, and extended survival durations in tumors that are not amenable to resection or in patients who are not surgical candidates. Therefore, MWA is considered investigational as a treatment of tumors.

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CROSS REFERENCES

Radiofrequency Ablation of Tumors (RFA), Surgery, Policy No. 92

CODES	NUMBER	DESCRIPTION
CPT	19499	Unlisted procedure, breast
	32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral
	32999	Unlisted procedure, lungs and pleura
	38589	Unlisted laparoscopy procedure, lymphatic system
	47382	Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency
	47399	Unlisted procedure, liver
	49999	Unlisted procedure, abdomen, peritoneum and omentum
	50592	Ablation, renal tumor(s), unilateral, percutaneous, radiofrequency
	53899	Unlisted procedure, urinary system
	60699	Unlisted procedure, endocrine system
	76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
HCPCS	None	