Ultrasound Guided Percutaneous Microwave Ablation of Benign Thyroid Nodules — Experimental and Clinical Studies

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Abbreviations

MWA = microwave ablation
Purpose: To obtain the treatment parameters of internally cooled microwave antenna and to evaluate the feasibility of ultrasound-guided percutaneous microwave ablation for benign thyroid nodules.

Materials and Methods: Microwave ablations were performed by using microwave antenna (16 G) in ex vivo porcine liver. The lesion diameters achieved in different groups (20, 25, 30 W for 3, 5, 7, 10, 12 minutes) were compared. The clinical study was ethics committee approved. Written informed consent was obtained from all patients. Microwave ablation was performed in 11 patients (male to female ratio =1:10; mean age, 50±7 years) with 11 benign thyroid nodules. Ultrasound scan, laboratory data and clinical symptoms were evaluated before and 1 day, 1, 3, 6, 9 and 12 months after the procedure.

Results: In ex vivo study, the ablation lesion at 30W12min tended to have appropriate scope and spherical shape. In clinical study, the follow-up periods ranged from 1 to 9 months. At the last follow-up, the largest diameter decreased from 2.9±1.0 (range, 1.6-4.1) cm to 1.9±0.7 (range, 0.4-3.0) cm (p<0.01), and the volume decreased from...
5.30±4.88 (range, 0.89-14.81) mL to 2.40±2.06 (range, 0.02-6.35) mL (p<0.01). The volume reduction ratio was 45.99±29.90 % (range, 10.56%-98.15%). The cosmetic grading score was reduced from 3.20±0.79 to 2.30±0.95 (P<0.05). One patient experienced temporary nerve palsy and was recovered within 2 months after treatment.

**Conclusion:** The internally cooled microwave antenna can yield ideal ablation lesions and ultrasound guided percutaneous microwave ablation is a feasible technique for benign thyroid nodules.

**Introduction**

Thyroid nodules are found in 3% to 7% of general population by means of palpation, and in 20% to 76% by means of ultrasound scan, with a prevalence similar to that reported from autopsy data (1). Most thyroid nodules are benign but some require treatment for the cosmetic reason, subjective symptoms or anxiety about a malignant change (2). In cases of thyroid cytologically benign lesions, it is difficult to decide the best management for patients. Both surgical and conservative approaches have drawbacks. Surgery has problems including long hospitalization, general anesthesia, scar formation, iatrogenic hypothyroidism and difficulty in re-operation. The conservative approach is not helpful for uncomfortable feeling of a lump in throat or cosmetic concerns. Therefore, non-surgical minimally invasive modalities, such as ethanol injection, laser ablation and radiofrequency ablation (RFA), have been attempted, yielding good results (2-5).
Microwave ablation (MWA) is a minimally invasive technique that has been used to treat benign and malignant tumors of liver, kidney, adrenal gland, spleen and lung by inducing tissue necrosis through heat (6-10); however, its use in thyroid nodules has not been reported. Compared with RFA, MWA may offer larger ablation zone, less treatment time and more complete tumor kill. MWA is also less affected by the perfusion mediated heat sink effect, which may be helpful for treating tumors with a rich blood supply (11). The aim of our study is to obtain the treatment parameters of internally cooled microwave antenna such as ablation shape, scope and temperature rise curve, and to evaluate the feasibility of ultrasound-guided percutaneous microwave ablation for benign thyroid nodules.

**Materials and Methods**

**Microwave Ablation Equipment**

A MWA instrument (KY-2000, Kangyou Medical, China) was used to administer microwave energy. The generator is capable of producing 1 to 100 W of power at 2450 MHz. The internally cooled needle antenna (16 G) in this study is designed specially to treat superficial neck organ diseases. It has a diameter of 1.6 mm, and a 10 cm shaft coated with polytetrafluoroethylene to prevent tissue adhesion. A narrow radiating segment of 3 mm is embedded on the shaft, 3 mm away from the tip for 2450 MHz applicator (Fig. 1).

Iron-constantan thermocouple was used to measure the temperature in ex vivo study. A thin insulation-Epoxy Resin was used to insulate the metallic shaft of the thermocouple needle to avoid any interference from the metal in the electric field. A
data acquisition (34970A, HP, USA) with 16-bit analog output function was used.

**Experimental Study**

Microwave ablations were performed in ex vivo porcine liver at room-temperature (15-20 °C) for a range of treatment durations and power settings. Five time increments (3, 5, 7, 10, 12 minutes) and three power increments (20, 25, 30W) were used, constituting 15 time-power combinations. For each combination of parameters, trails were performed in four times, for a total of 60 ablations. Microwave antenna was submerged 6 cm into the liver to ensure that the entire ablation zone would be within the liver parenchyma. For each ablation, iron-constantan thermocouple was used to be inserted in the liver 5 mm, 10 mm and 15 mm from the electrode radiating segment to measure the temperature.

**Clinical Study**

**Patients**

The study was prospective. The study was approved by our hospital ethics committee, and written informed consent was obtained from each patient. From November 2010 to August 2011, 11 patients (male to female ratio =1:10; mean age, 50±7 years; age range, 39–59 years) with 11 benign thyroid nodules (9 patients with nodular goiter and 2 with Hashimoto's thyroiditis) underwent ultrasound-guided percutaneous MWA with internally cooled antenna.

The inclusion criteria of this study were as follows: (a) ultrasound criteria for benign nodule; (b) the presence of subjective symptoms (neck discomfort or pain, foreign body sensation, compressive symptom); (c) cosmetic problems; (d) ineligibility or
refusal to undergo surgery; (c) anxiety about malignancy change.

The exclusion criteria were: (a) biopsy pathological proven malignancy; (b) ultrasound criteria for malignancy (anteroposterior/transverse diameter ratio (A/T) > 1, microcalcifications, marked hypoechoic, ill-defined margins), although biopsy pathological result was benign.

**Pre-ablation assessment**

The diameters, composition, vascularity and enhancement modality of nodules on ultrasound examination, laboratory data and clinical symptoms were examined in all patients. All ultrasound examinations were performed on a real time ultrasound system (Sequoia 512, Acuson, Mountain View, CA). Three orthogonal diameters of thyroid nodules (the largest diameter and the two other perpendicular ones) were measured. The volume of the nodules was calculated by the following equation: \( V = \frac{\pi abc}{6} \) (V: volume, a: the largest diameter, b and c: the other two perpendicular diameters). The composition of the nodules was assessed by ultrasound examiner subjectively, and was classified as mainly solid (having a solid portion > 80%), mainly cystic (having a cystic portion > 80%), or mixed type. Nodule vascularity was classified with a five-point scale: 0 (no color signal in nodule), 1 (a few spotty color signals in nodule), 2 (color signals in < 25% of the nodule), 3 (color signals in 25-50% of the nodule), and 4 (color signals in > 50% of the nodule) (5).

Laboratory tests including thyroid function (thyroid stimulating hormone [TSH], triiodothyronine [T3], free thyroxine [fT4]), complete blood count and blood coagulation test (prothrombin time, activated partial thromboplastin time) were
assessed. Fiber laryngoscopy was performed on all patients before MWA and on patients who complained of hoarseness or other symptoms related to nerve injury after MWA.

Clinical symptoms were evaluated using the symptom grading scores (visual analogue scale, 0–10 cm) and the cosmetic grading score (grade 1: no palpable mass, grade 2: invisible but palpable mass, grade 3: visible mass only by experienced clinician’s eyes, grade 4: easily visible mass) (5).

**Procedure**

All treatments were performed at our institution on an inpatient basis. The patient was placed in the supine position with hyperextended neck, and a venous catheter was inserted in a forearm vein. A multiparametric monitor was connected to the patient showing continuous blood pressure, pO2 and electrocardiogram. Local anesthesia with 1% lidocaine was performed subcutaneously on the puncture site. A small incision less than 2 mm in length was made after local anesthesia. Ultrasound guided biopsy was performed on all patients by the automatic biopsy instrument and disposable core tissue biopsy needle (Bard, Tempe, AZ, USA). Then the internally cooled microwave antenna (16 G) was placed into the thyroid nodule along its longest axis under ultrasound guidance by two of the experienced radiologists (P.L., XL.Y, ZG.C, and ZY.H). After the antenna was placed at designated site, unconscious intravenous anesthesia (propofol, 6-12 mg/kg/h; ketamine, 1-2 mg/kg) was administered via the forearm vein by an anesthesiologist. A power output of 20-30 W was used during MWA. The extent of ablation area was presumed by the echogenic change around the
antenna. If the heat generated hyperechoic water vapor did not completely encompass the entire nodule at one site, the tip of antenna was moved backward. In cases of mainly cystic nodules, percutaneous puncture needle (18 G, Hakko Co, Chikuma-Shi, Japan) was inserted to the cystic portion and contained fluid was aspirated, then microwave ablation was performed on the solid portion. At the end of procedure, all patients remained under observation for 30 minutes with compression on the neck to prevent bleeding or hematoma formation.

**Post-ablation evaluation**

Ultrasound examination, laboratory data and clinical symptoms were evaluated at 1 day, 1, 3, 6, 9 and 12 months after the procedure. The ultrasound examination was acquired to assess the changes of MW-induced lesions, including the size, vascularity, echogenicity and the enhancement modality. The volume reduction was calculated by the following equation: volume reduction ratio (%) = [(initial volume – final volume) ×100]/initial volume. The laboratory data such as T3, fT4, TSH and the symptom grading score and cosmetic grading score were also evaluated and recorded at each follow up. Side effects and complications of MWA were evaluated at the end of ablation as well as at 24 hours and 1 month after the procedure.

**Statistical Analysis**

Data analysis was performed with statistical software (SPSS for Windows version 13.0). Values for quantitative variables were expressed as mean ± standard deviation and range. Differences in the long-axis diameter (Dl), short-axis diameter (Ds) and Ds/Dl ratio between groups of ex vivo were evaluated by Kruskal – Wallis H test.
Variables at enrollment and the follow-up visit were compared by Wilcoxon’s signed
rank test. Differences were considered significant when the P value was less than
0.05.

Results

Experimental Study

All ablation lesions were ellipsoidal. Four well-defined zones of the ablated lesion
were noted around the antenna: charring zone, coagulation zone, congestion zone and
normal liver parenchyma. The D1 and Ds enlarged with the increase of microwave
energy (Table.1 and 2). The difference in Ds/D1 ratio was not significant in groups
either when the time was increased with the same power or the power was increased
with the same time (P>0.05). The ablation lesion at 30W12min tended to have
appropriate scope and spherical shape, which provided a reference for clinical
application. The D1, Ds and ratio of Ds/D1 of the ablation lesion at 30W12min was
2.5±0.2 cm, 1.7±0.3 cm and 0.7±0.1, respectively. The mean temperature at 5mm site
from the electrode was driven rapidly high to 60°C which ensured tumor necrosis,
while the maximum temperatures at 10mm and 15mm were low which could
guarantee the safety of surrounding tissue (Fig. 2).

Clinical Study

Treatment Characteristics

Ten lesions were completely ablated in a single session and one lesion at two sessions.
A single antenna was used in 9 patients and two antennae were used in 2 patients. The
main power was 26±4 (range, 20-30) W and total treatment time was 9.5±4.7 (range,
4-16.5) min. For the No.4 patient with mainly cystic thyroid nodule, the obsolete bloody fluid (30 mL) was aspirated, and then microwave ablation (20W3min, changed to 30W3min) was performed on the solid portion.

**Ultrasound, Laboratory and clinical results**

Follow-up periods ranged from 1 to 9 months. The nodules were located in the left lobe in 4 cases, the right lobe in 6 cases, and the isthmus in 1 case. The composition of the nodules was mainly solid (n = 5), mixed (n = 5), and mainly cystic (n = 1). After ablation, color Doppler ultrasound showed significant reduction of vascular signals (before vs. after ablation, 2.60±0.84 vs. 0.40±0.52, p< 0.01). Non-enhancement was showed on contrast enhanced ultrasound after treatment as a consequence of coagulative necrosis induced by MWA.

Because No. 4 patient was mainly cystic and was drained before MWA, the changes observed in this lesion were reported and evaluated separately (Table 3 and 4). For other patients, the largest diameter of the nodules decreased from 2.9±1.0 (range, 1.6-4.1) cm before ablation to 1.9±0.7 (range, 0.4-3.0) cm at the last follow-up (p<0.01). The volume decreased from 5.30±4.88 (range, 0.89-14.81) mL before ablation to 2.40±2.06 (range, 0.02-6.35) mL at the last follow-up (p<0.01). The volume reduction was 45.99±29.90 % (range, 10.56% to 98.15%) at the last follow-up (Table 4).

Initial mean T3, fT4 and TSH were 1.68±0.23 nmol/L, 15.38±2.65 pmol/L, and 2.71±1.96 mU/L, respectively. A significant change of mean fT4 and TSH was observed at 1 day after ablation (fT4: 18.08±2.64 pmol/L, P<0.05; TSH: 1.42±1.78
mU/L, P<0.01). Serum T3 did not change (T3: 2.02±0.60 nmol/L, P>0.05). The symptom grading score was reduced from 1.20±1.87 to 0.40±0.70 (P > 0.05), and cosmetic grading score was reduced from 3.20±0.79 to 2.30±0.95 (P < 0.05).

**Side Effects and Complications**

After MWA, eight patients complained of a sensation of heat in the neck and/or slight pain at the ablated site. All patients could tolerate the symptoms needing no analgesics. During or immediately after ablation, mild bleeding (thyroid capsule hemorrhage <1 mm on ultrasound) developed in 4 patients. Slight fever (37-37.5°C) was found in 3 patients lasting 1 day. One patient complained of coughing and choking when drinking (so she could not drink water) and a little voice changes 6 hours after ablation. Laryngoscopic evaluation demonstrated ipsilateral vocal cord palsy. She could drink water and her voice recovered within 2 months after corticosteroids, physical therapy, water training and vocal exercises. There were no complications such as esophageal perforation, tracheal injury, infection or skin burn.

**Discussion**

Since the first trial of ethanol injection to an autonomous thyroid nodule in 1990 (12), many investigators have used this agent as an alternative therapeutic procedure in various benign thyroid diseases (3, 13-15). The results have confirmed that percutaneous ethanol injection is effective for nodule volume reduction, but ethanol injection has side effects related to the leakage of ethanol outside the capsule of nodule and the need for multiple ethanol injection. The side effects of ethanol injection include extraglandular fibrosis, vocal chord paresis, hematoma, abscess,
dysphagia and mild to severe pain (3, 15). Thermal ablation such as laser and radiofrequency ablation is a recently developed procedure (2, 4, 5, 16, 17), and the advantage includes well-defined area of complete tissue ablation with a regular, homogeneous and reproducible pattern (17). However, laser ablation requires up to three sessions or the insertion of multiple fibers for treating large nodules, which increases the risk of local adverse events (18).

Microwave ablation has been used to treat hepatocellular carcinoma in our department with a 5-year survival rate comparable to that of hepatectomy for small hepatocellular carcinoma (6). We mostly used microwave antenna 11 mm from the narrow radiating segment to the tip with 2450-MHz applicator to treat abdominal tumors (19, 20). However, thyroid nodules are different from abdominal tumors on account of superficial location, thin thyroid gland, usually small tumors and surrounding vital structures. The internally cooled needle antenna in this study is modified specially to treat superficial neck organ diseases, which has finer diameter, shorter shaft, and closer distance from the narrow radiating segment to the tip.

Laser and radiofrequency ablation, techniques using thermal injury to destroy tissue, obtain variable nodule volume reduction (2, 4, 5, 17, 18, 21, 22). The mean volume reduction ratio in laser ablation was 44.0%-74.3% (4, 17, 23, 24), while in RFA it ranged from 50.9% to 91.3% (21, 25-28). In our study, the mean nodule volume reduction ratio was 45.99% and the cosmetic grading score was reduced significantly at the last follow up. The mixed or mainly cystic nodules showed a better treatment response than the mainly solid tumors. This might be due to the homogeneous
conduction of heat, the absence of a heat sink effect and removal of the cystic component (2). In this study, serum TSH levels significantly decreased (p<0.01), fT4 levels significantly increased (p<0.05), and Serum T3 did not change (p>0.05) at 1 day after MWA. It was likely that ablation-induced fT4 release from intraglandular stores and serum TSH level decreased due to feedback regulation (4).

The side effect and complication rate in this preliminary study was higher than what was published with the other ablation techniques (2, 4, 16, 17, 22), and it partly related to the use of a thick device for MWA. The 16 G antenna used in the study was more invasive than the 17 G needle used for RFA (22) and 21 G needle for laser ablation (29). Nerve injury was the most serious complication in our study. Iatrogenic nerve injury cannot be avoided completely even in surgical field where the nerve trunk can be identified with naked eye. The average incidence of temporary recurrent laryngeal nerve palsy after thyroidectomy is 9.8% and the incidence of permanent palsy is 2.3% (30). Transient recurrent laryngeal nerve palsy rate in video-assisted thyroid lobectomy was 2.6% (31). Previous studies using radiofrequency or laser ablation described the incidence of transient or permanent nerve injury to be 0%-8.3% (2, 4, 17, 18, 21, 22, 24, 25). The most likely explanation for nerve injury in thermal ablation was thermal injury directly or nerve compression caused by perinodular edema. To decrease the incidence of nerve injury, the following aspects can be considered: firstly, if there are nodules on both lobes of thyroid gland, perform MWA on nodule on one side at a session to avoid nerve injury of both sides which cannot be compensated; secondly, complete ablation of the whole nodule is not always
necessary if thyroid benign nodules are too close to the nerve; thirdly, temperature
monitoring or infusion of saline into the surrounding thyroid capsule was necessary to
protect nerve from thermal injury.

In conclusion, our experimental and clinical results suggest that the modified
superficial tissue microwave antenna can yield ablation lesions with ideal shape and
appropriate scope, and ultrasound guided percutaneous microwave ablation is a
feasible technique for cytologically benign thyroid nodules. However, this procedure
should be performed by trained doctors experienced in neck anatomy, ultrasound
scanning and microwave ablation. The limitations of this study are the small case
number and short follow-up period, so further study with large sample and long-term
follow up will be necessary.

Declaration of interest

There is no conflict of interest that could be perceived as prejudicing the impartiality
of the research reported.

Funding

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References

Association of Clinical Endocrinologists, Associazione Medici Endocrinologi, and European
Thyroid Association medical guidelines for clinical practice for the diagnosis and management


Fig. 1. Photographs of microwave antennae.

*Top*: the antenna in this study, 16-gauge, a 10 cm shaft, 3 mm between the narrow radiating segment and the tip of antenna (arrow). It is designed specially to treat superficial neck organ diseases. *Bottom*: 15-gauge, an 18 cm shaft, 11 mm between the narrow radiating segment and the tip of antenna (arrow). It is used for abdominal tumors.

Fig. 2. Gross specimen and temperature rise curve of MWA in ex vivo porcine liver on 25W10min.

The long-axis diameter of the ablation lesion was 2.2 cm and the short-axis diameter was 1.2 cm. The mean temperature at 5mm site from the electrode was driven rapidly high to 60°C which ensured tumor necrosis, While the maximum temperatures at 10mm and 15mm were low which could guarantee the safety of surrounding tissue.

Fig. 3. Transverse US scans of the neck of a 53-year-old treated female patient showed a mixed nodule in the thyroid isthmus before (a, 0.92 mL), 3 months (c, 0.14 mL), and 9 months (d, 0.02 mL) after MWA. b. During the procedure, multiple echogenic microbubbles (arrow) around the antenna tip were noted. e. Before MWA, an almond-sized nodule could be seen outside the skin of neck (arrow) and tenderness could be felt. f. Three months after MWA, thyroid nodule completely disappeared and no scars were left on the neck.
Figure 1.

10x3mm (600 x 600 DPI)
7x2mm (600 x 600 DPI)
Figure 3.

23x25mm (600 x 600 DPI)
Table 1

Coagulation lesion diameter of ex vivo with the same power 30W

<table>
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<th>Ds (cm)</th>
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Notes: Data are mean values± standard deviation. Dl: long-axis diameter, Ds: short-axis diameter.
Table 2

Coagulation lesion diameter of ex vivo with the same time 5 minutes

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Notes: Data are mean values ± standard deviation. Dl: long-axis diameter, Ds: short-axis diameter
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*: For the No.4 patient with mainly cystic thyroid nodule, the obsolete bloody fluid (30 mL) was aspirated, and then microwave ablation (20W3min, changed to 30W3min) was performed on the solid portion.
Normal range: T3 1.01-2.95 nmol/L, fT4 10.42-24.32 pmol/L, TSH 0.35-5.5 mU/L. +: higher than normal range. -: lower than normal range.