

RESEARCH ARTICLE

Ultrasound-guided percutaneous microwave ablation of solitary T1N0M0 papillary thyroid microcarcinoma: Initial experience

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Abstract

Purpose: The aim of this study was to evaluate the feasibility, safety and efficacy of ultrasound-guided percutaneous microwave (MW) ablation for solitary T1N0M0 papillary thyroid microcarcinoma. **Materials and methods:** A total of 21 patients (six men and 15 women; age range, 29–81 years; mean, 52.1 ± 13.6 years) with 21 nodules of pathologically proven solitary papillary carcinoma 3.7 to 10.0 mm in diameter without clinically apparent lymph node, or distant metastasis at diagnosis (T1N0M0) were treated with MW ablation in our department. Microwaves were emitted at 40 W for 400 s and prolonged as necessary to attain confluent ablation zones. All patients were treated with levothyroxine after MW ablation to maintain thyroid stimulating hormone (TSH) levels below 0.1 mU/L. Follow-up consisted of ultrasound in 21 patients, biopsy in five patients, and surgical treatment in three patients. **Results:** Four patients complained of hoarseness immediately after the MW ablation procedure, and all of them recovered within 3 months spontaneously. All tumours were completely ablated at a single session and no serious or permanent complications occurred. No recurrence at the treatment site and no distant metastases were detected, with a mean follow-up of 11 months. Histological examination showed no evidence of a tumour in the treated lesions in eight patients. Follow-up ultrasound examinations showed disappearance of previously detected colour Doppler flow, as well as mass shrinkage, or both. **Conclusion:** During the short-term follow-up period, ultrasound-guided percutaneous MW ablation appears to be a safe and effective technique for solitary T1N0M0 papillary thyroid microcarcinoma.

Keywords

Microwave, thermal ablation, thyroid cancer, thyroid carcinoma, thyroid ultrasound

History

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Introduction

Thyroid cancer is the most common endocrine malignancy, accounting for an estimated 60,220 new cases in the USA in 2013 alone [1]. Papillary thyroid carcinoma (PTC) is the most common subtype of the thyroid cancer, and it has a clinically silent course and a relatively low mortality rate [1,2], although it frequently spreads locally and recurs by metastasising to local cervical lymph nodes. The overall recurrence and mortality rates for well-differentiated thyroid cancers (papillary and follicular thyroid carcinomas) are 20.5% and 8.4%, respectively, at a mean follow-up of 11.3 years [3]. The 2009 American Thyroid Association guidelines suggest that thyroid lobectomy alone may be sufficient treatment for small (<1 cm), low-risk, unifocal, intrathyroidal papillary carcinomas in the absence of prior head and neck irradiation or radiologically or clinically involved cervical lymph node metastasis [4]. However, management occasionally becomes a dilemma because of either high surgical risk in an elderly patient or a patient with microcarcinoma who refuses surgery.

If a minimally invasive technique could eradicate these small nodules, then it may become a potential therapeutic approach in these patients.

Ultrasound-guided microwave (MW) ablation is a relatively novel procedure that is being widely used as an alternative to surgery for both primary and metastatic liver carcinoma [5], lung, renal and adrenal malignancies [6–8]. In relation to the thyroid gland, MW has shown promise as an effective treatment for benign thyroid nodules [9]. In malignancy, ablative techniques including ethanol, radiofrequency (RF), and laser ablation have been proposed for treating recurrent nodal metastases of PTC [10–11]. With regard to the papillary thyroid microcarcinoma (PTMC), Valcavi et al. [12] reported that laser ablation was technically feasible for complete PTMC destruction. However, to our knowledge application of MW energy to PTMC has not yet been reported.

In this study we present our initial experience in using ultrasound-guided MW ablation to treat patients with PTMCs considered low-risk on imaging studies, including ultrasonography; that is, measuring 10 mm or less without massive extra-thyroid extension, lymph node metastasis, or distant metastasis at diagnosis, corresponding to T1N0M0 in the UICC/AJCC TNM classification [13] to evaluate the efficacy and safety of MW ablation on PTMC as a primary treatment.

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Materials and methods

Patients

This study was a prospective study design and was approved by our hospital ethics committee. A written informed consent document was obtained from each patient before the procedure.

The inclusion criteria of this study were as follows: (1) a single lesion 10 mm or smaller, (2) no contact and disruption of thyroid capsule, (3) no tumour invasion to the extra-thyroid organs (tracheal or esophageal), (4) an appropriate puncture route noted on ultrasound, (5) ineligibility or refusal to undergo surgery for high thyroid surgical risk or other reasons. The exclusion criteria were: (1) clinically apparent multicentricity, (2) tumours larger than 10 mm, (3) contact and disruption of thyroid capsule, (4) biopsy showing pathologically proven anaplastic carcinoma or other coexisting thyroid malignancies such as medullary carcinoma, (5) ultrasound examination and a chest and upper abdomen computed tomography (CT) scan revealing cervical or distant metastasis.

From October 2010 to February 2013, a total of 101 nodules in 79 patients were proven malignant tumours by ultrasound-guided biopsy and pathological examination. Of these, 21 patients with 21 nodules of pathologically proven solitary papillary carcinoma measuring 3.7–10.0 mm (mean 7.3 ± 3.0 mm) in diameter received percutaneous MW ablation as the treatment at our department. A total of 41 patients

with 53 nodules were referred to traditional open surgery during the study period. The rest of the patients were treated with other methods or followed-up periodically (see flow chart, Figure 1). A total of 21 patients elected for MW ablation instead of thyroidectomy because of high risk of thyroid surgery or fearing of post-operative pain or for cosmetic reasons. The clinical information regarding the demographic characteristics of tumour size and location is summarised in Table I. There were six men and 15 women aged 29 to 81 years old (mean age 52.1 ± 13.6). All patients who underwent MW ablation treatment had a positive ultrasound-guided biopsy of PTMC prior to the procedure. Serum thyroid-stimulating hormone, thyroglobulin, antithyroglobulin antibodies, and thyroid hormones were within normal limits. No patients were taking antiplatelet or anticoagulant medications for at least 1 week before the procedure.

Equipment

MW ablation instrument

The MW ablation system (KY2000, Kangyou Medical Instruments, Nanjing, China) consists of a MW ablation generator, a flexible low-loss coaxial cable and a thyroid-dedicated cooled shaft antenna (Figure 2). The generator is capable of producing 1–100 W of power at 2450 MHz either pulsed or continuous. The MW shaft antenna was developed and modified for the thyroid gland with a 16-gauge needle

Figure 1. Flow chart for management of thyroid nodules.

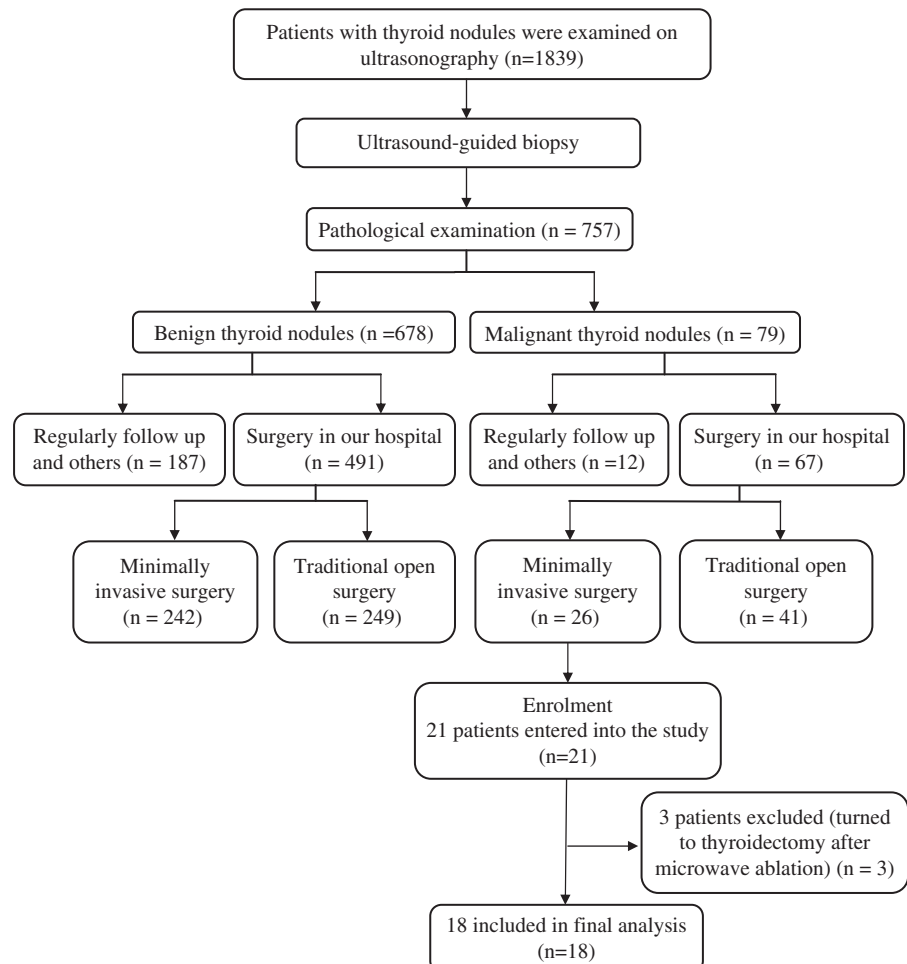


Table I. Demographic and clinical characteristics of papillary thyroid microcarcinoma by MW ablation.

Patient No.	Sex	Age (years)	Lobar location	Size (mm)	MW ablation time (s)	Follow-up (months)
1	M	48	Left	10.0 × 3.6 × 6.7	600	13
2	M	51	Right	6.0 × 5.2 × 4.6	450	22
3	F	50	Right	7.6 × 4.0 × 6.4	500	12
4	F	44	Right	9.3 × 5.3 × 6.2	500	14
5	M	56	Left	4.2 × 3.9 × 3.8	500	16
6*	F	29	Left	5.3 × 4.9 × 5.0	500	0
7	F	45	Right	8.9 × 3.3 × 6.2	550	17
8	F	47	Left	6.4 × 5.0 × 5.8	500	12
9	F	49	Right	6.7 × 3.5 × 5.1	550	6
10	F	42	Right	10.0 × 4.7 × 3.4	600	3
11	F	48	Left	7.8 × 6.5 × 3.6	400	6
12*	F	45	Left	8.5 × 7.4 × 6.2	400	0
13	F	39	Left	4.6 × 3.5 × 3.7	400	3
14	F	73	Left	7.2 × 5.7 × 6.6	550	6
15	F	51	Left	9.7 × 4.6 × 5.9	500	14
16	F	81	Left	8.5 × 7.2 × 5.7	450	18
17	M	69	Left	3.7 × 3.2 × 2.7	400	9
18	M	74	Right	6.6 × 4.3 × 5.4	400	9
19*	F	38	Right	7.6 × 3.8 × 4.4	600	0
20	F	71	Left	5.9 × 3.5 × 5.6	500	3
21	M	45	Left	9.7 × 4.5 × 6.4	650	9

*Patients worried that the tumours might not be treated thoroughly, and underwent subtotal thyroidectomy and central node dissection within two months after the MW ablation.

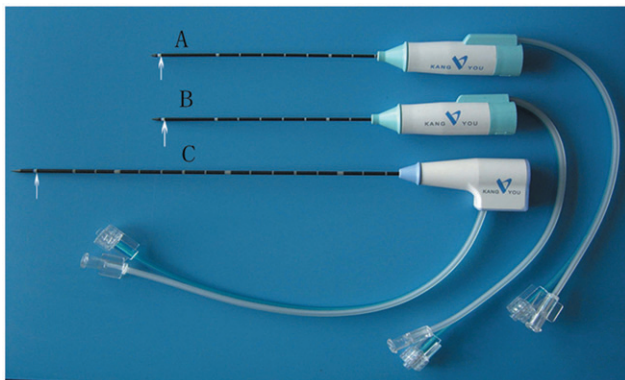


Figure 2. Photographs of MW antennae. (A) The 16-gauge antenna in this study is 10 cm over the entire length, and 3 mm between the narrow radiating segment and the tip of antenna. It is specially designed to treat superficial neck organ nodules less than 10 mm in diameter. (B) Usually, for tumours larger than 20 mm in diameter the antenna with 5 mm between the narrow radiating segment and the tip of the antenna was used. (C) The 14-gauge antenna, 20 cm over the entire length, 11 mm between the narrow radiating segment and the tip of antenna (arrow), is used for abdominal tumours.

(3 or 5 mm in length and 1.9 mm in diameter), coated with polytetrafluoroethylene to prevent tissue adhesion, and was designed for easy control and minimal normal tissue injury. To prevent the shaft overheating, distilled water was circulated through dual channels inside the antenna continuously cooling the shaft.

Ultrasound system

Sonograms for thyroid nodules were performed with GE LogiqE9 (GE Healthcare, Wauwatosa, WI) and Toshiba 790A (Toshiba, Italy) to guide the MW ablation procedure and

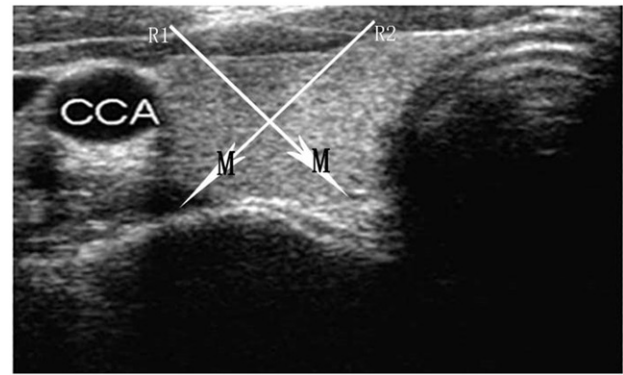


Figure 3. On transverse scan, we can divide the thyroid gland into four quadrants. For a nodule located in the lower inner quadrant, the MW ablation was conducted through lateral cervical approach (R1), but for a nodule located in the lower outer quadrant, a median line approach MW ablation therapy was used (R2). If the nodule was located in one of the other two quadrants, either approach was acceptable. The core principle of the puncture route we adopted was not only that the MW antenna could be percutaneously inserted into the tumour and positioned in its designated place, but that injury of the major structures (carotid artery, trachea, oesophagus) could also be avoided. CCA, common carotid artery; M, tumour.

evaluate the tumours before ablation and at each follow-up, in terms of 2D, colour Doppler ultrasound and contrast enhanced ultrasound.

MW ablation procedures

Before treatment, all patients with pathologically proven papillary cancers were assessed with ultrasound examination and ultrasonic contrast, and an appropriate puncture route was chosen on ultrasound (Figure 3). The size, volume, vascularity and characteristics of each tumour were carefully evaluated immediately before MW ablation and during each follow-up.

All patients were pre-medicated with 100 mg of bucinazine hydrochloride injection and 1U intramuscular haemocoagulase injected to relieve the discomfort and reduce bleeding during the procedure. Under ultrasound control all the MW ablations were carried out by the same experienced radiologist (Wang Shurong) according to a previously reported procedure [10]. The patient was placed in the supine position with hyperextended neck, and a multiparametric monitor was connected to the patient monitoring continuous electrocardiogram, breath rate, PO₂ and blood pressure.

After localisation of the best puncture site, local anesthesia with 2% lidocaine was administered. Then we carefully injected a mixture of 0.9% lidocaine and physiological saline solution into the surrounding thyroid capsule to achieve a ‘liquid isolating region’ (Figure 4B) to protect the major structures (carotid artery, trachea, oesophagus, and the nerve) from thermal injury. After that, a MW antenna was percutaneously inserted into the nodule and positioned in its designated place under ultrasound guidance (Figure 4C). The therapy was not stopped until the hyperecho covered the whole tumour. Based on our previous experience for MW ablation of benign thyroid nodules, for thyroid carcinomas a power output of 40 W for 400 s was routinely used. If the heat-generated hyperechoic water vapor did not completely

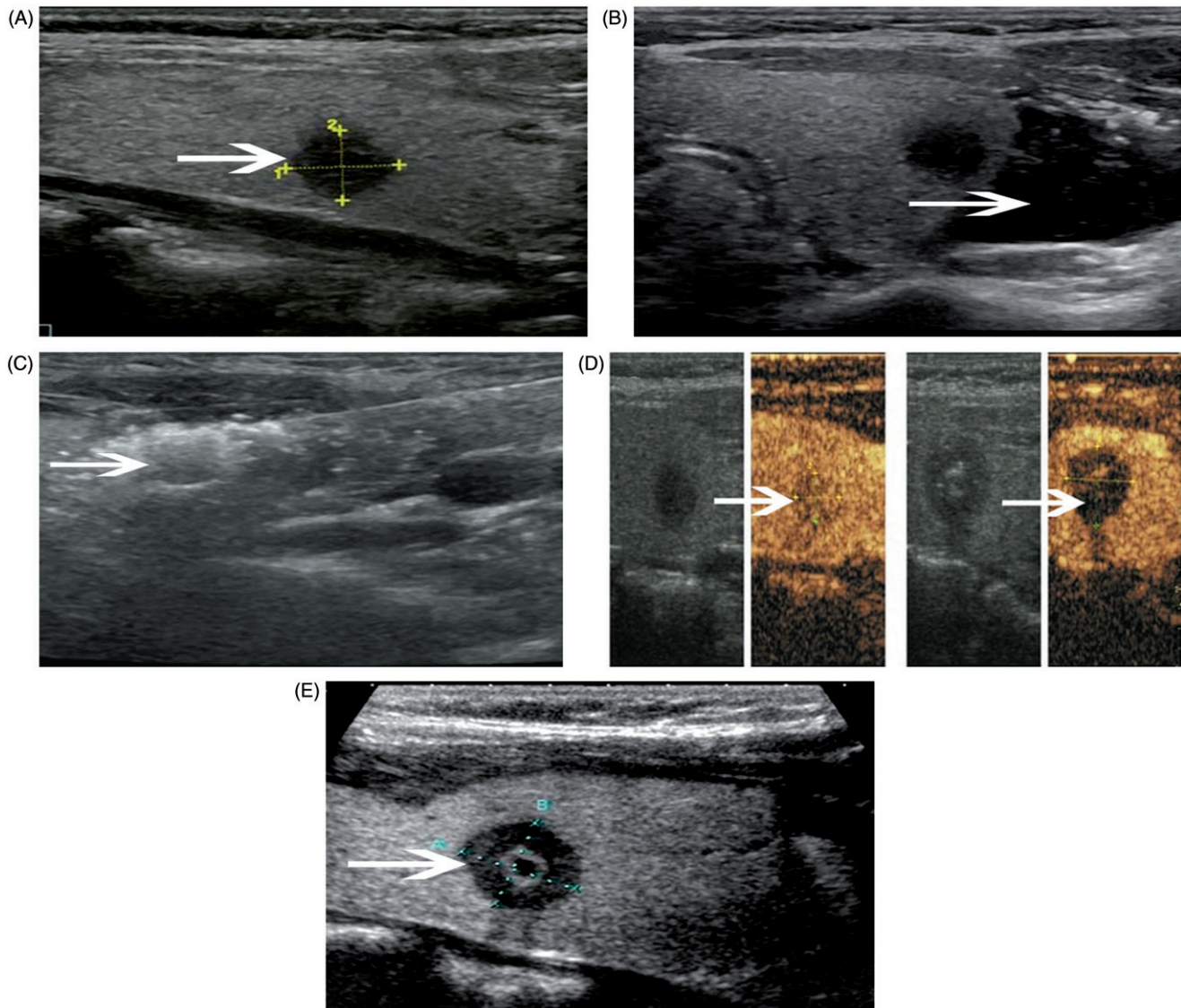


Figure 4. A 48-year-old woman (Patient 11) had a papillary carcinoma in the left lobe of her thyroid gland. The key procedure of the MW treatment is shown here, and the changes in the volume of the tumour before MW ablation and at 1-month follow-up are also presented. (A) Before the ablation, ultrasound examination with ultrasound-guided biopsy confirmed the tumour as papillary thyroid carcinoma 96 mm³ in volume, with inhomogeneous internal echoes and microcalcification. (B) Under local anaesthesia a mixture of 0.9% lidocaine and physiological saline was infused into the surrounding thyroid capsule to achieve a 'liquid isolating region' (arrow) protecting the vital structures of the neck (carotid artery, oesophagus, nerve) from thermal injury. (C) Under the guidance of ultrasound, a thyroid-dedicated cooled shaft antenna was positioned in the tumour. A sonogram obtained during treatment shows the typical hyperechoic region (arrow) surrounding the antenna. (D) For the PTMC, we achieved slightly more necrosis than the preoperation nodule, evaluated with the contrast-enhanced ultrasound just at the end of each procedure. (E) At follow-up ultrasonography examination 1 month after treatment, the nodule exhibited change to a hypoechoic nature, with a pin site hyperechoic inside (arrow) and a little larger in size (121 mm³ in volume).

encompass the entire tumour, prolonged MW emission was applied at an increment of 50 s to obtain confluent ablation zones. Usually for tumours 10 mm or smaller in diameter, mono-section ablation was enough. When withdrawing the antenna, the needle track was coagulated to prevent tumour cell seeding.

For the PTMC, we achieved a little larger necrosis than the nodule preoperation (a ≥ 5 -mm ablative margin around the entire tumour [14] than the nodule preoperation), and evaluated with the contrast-enhanced ultrasound just at the end of each procedure. (Figure 4D) During the whole procedure, we intermittently asked the patients how they felt in order to assess the status of phonation.

Post-procedural observation and follow-up

After MW ablation, patients were closely monitored for 30 min with compression of the neck lasting 20–30 min. The possible complications such as skin burns, voice change, oesophageal perforation and tracheal injury were evaluated carefully. All the patients were advised to have treatment with levothyroxine after MW ablation to maintain TSH levels below 0.1 mU/L.

Clinical follow-up consisted of a physical examination, imaging tests such as ultrasonography, chest X-ray or CT scan, and serum thyroglobulin measurement were evaluated 1, 3, 6, 9 and 12 months after treatment and every 6–12

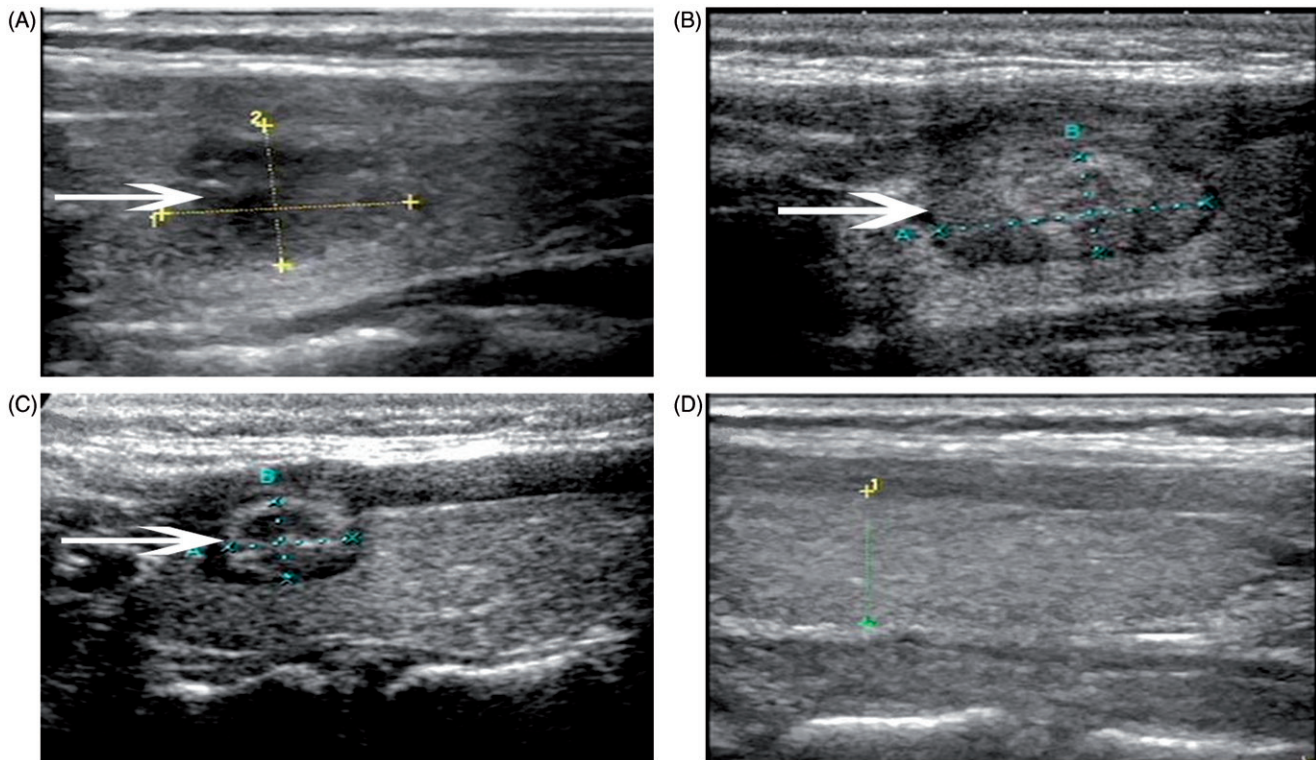


Figure 5. A 50-year-old woman (Patient 3) had a papillary carcinoma in the right lobe of her thyroid gland. The changes in the volume of the nodules before MW ablation and at each follow-up period were presented in the following pictures. (A) Ultrasound examination revealed the solid nodule to be 102 mm^3 in volume before MW ablation. (B) Three months after the ablation, the volume of the nodule decreased to 966 mm^3 . (C) Six months after the ablation, the volume of the nodule decreased to 541 mm^3 . (D) At another follow-up of this patient approximately 12 months later, we could not find any evidence of tumour and there was no scar at the previous tumour site.

months thereafter. At ultrasound examination we were required to evaluate changes in tumour size, intratumoural vascularity, and development of recurrent and metastatic tumours (Figures 5 and 6). Three diameters of the tumour were measured, and the tumour volume was calculated with the equation $V = \pi abc/6$, and the volume reduction = initial volume – final volume $\times 100/\text{initial volume}$.

Lymph nodes suspected of metastasis were evaluated using criteria similar to those proposed by Antonelli et al. [15]: (1) diameter of 10 mm or more, (2) clear hypoechoic pattern or non-homogeneous pattern, with alternating hypoechoic and hyperechoic areas, (3) irregular cystic appearance, (4) rounded or bulging shape with increased anteroposterior diameter, and (5) presence of internal calcification. When lymph nodes were suspected of metastasis, we performed ultrasound-guided biopsy for the nodes to determine whether the nodes were metastatic or reactive.

Analysis and statistics

Statistical analysis was performed using SPSS, version 17.0. Post-MW ablation nodule volume recorded was compared with pretreatment volume by means of the paired-samples *t* test. Data were reported as mean \pm standard deviation (SD), and the significance was set at 0.05.

Results

All tumours were clear PTMC on pathological examination, and the treatment outcome after MW ablation is summarised in Table II. A total of 21 adult patients (age range, 29–81

years; mean, 52.1 ± 13.6 years, 15 women and six men) were treated with MW ablation. Three patients had thyroidectomy shortly after MW ablation and complete necrosis of the tumour was confirmed. The mean volume reduction rates of the other tumours were -0.28 ± 1.42 , 0.48 ± 2.86 , 0.91 ± 0.13 , and 0.90 ± 0.14 at the 1-month, 3-month, 6-month and last follow-up visit respectively (all $p < 0.05$, Figure 7). Four tumours had completely disappeared (Figure 5D), five tumours remained as small scar-like lesions.

Ultrasound-guided biopsy was performed 6 months after MW ablation in five of these patients and demonstrated necrosis with inflammatory cells in all the patients with no viable neoplastic cells (Figure 6).

Immediately after MW ablation, ultrasound imaging revealed that hypoechoic tumours had changed to hyperechoic on grey-scale imaging, but it was lower than that observed before ablation on the follow-up ultrasound examination ((Figure 4E). At follow-up, well-treated tumours exhibited change to a hypoechoic nature, a marked decrease in size, and loss of internal vascularity at power Doppler ultrasound examination (Figures 5B and 5C).

Treatment was well tolerated. Although most patients reported a burning sensation, pain, or both, no one asked to stop, and the symptoms were relieved without treatment within 12 h. Four patients complained of hoarseness immediately after the MW ablation procedure. The most likely explanation was nerve injury because of direct thermal injury or nerve compression caused by perinodular oedema. All of them recovered within 3 months spontaneously. Choking and coughing at the end of treatment appeared in two individuals,

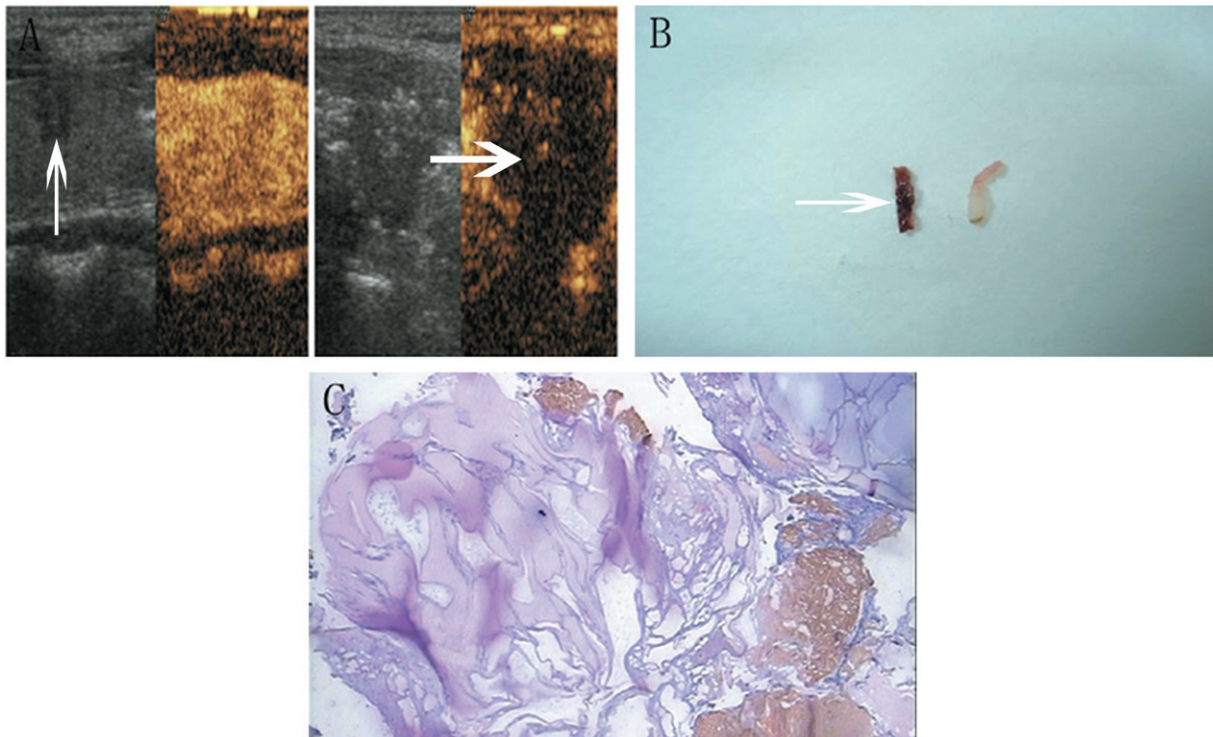


Figure 6. The papillary carcinoma in the left lobe of the thyroid gland of a 45-year-old man (Patient 21) in contrast-enhanced ultrasound and ultrasound-guided biopsy 6 months after MW ablation. (A) During the follow-up period, enhanced contrast ultrasound was performed on the patient. Pre-ablation of the nodule was enhanced inhomogeneously on enhanced contrast ultrasound, whereas non-enhancement (arrow) showed 6 months after the treatment. (B) Ultrasound-guided biopsy was performed 6 months after the MW ablation, and it showed some carbonisation (arrows) visible to the naked eye. The microscopic appearance of the thyroid nodule sample (C) showed necrosis with inflammatory cells in the patient. No cells were noted to be suspicious for malignancy on pathological analysis of the specimen (haematoxylin and eosin staining, original magnification: $\times 200$).

Table II. Outcome of MW ablation.

Measurement	Before	After (last month)	<i>p</i>
Mean largest diameter (mm)	7.3 ± 3.0	0.3 ± 1.9	0.002
Mean volume (mm^3)	89.5 ± 20.1	8.7 ± 9.3	0.002
Mean volume reduction rate		90%	

Values are mean \pm SD.

but disappeared in 24 h and 7 days respectively without any treatment. No tranquilliser medicines were given before or after ablation. No cases of local infection, skin burning or damage to the vital structures of the neck were observed. During a mean follow-up of 11 months (range 3–22) one patient died of acute bleeding from a peptic ulcer 10 months after MW ablation (Table I, patient 17). The remaining patients had no suspicious recurrence by either clinical and ultrasound examination or distant metastases by chest and upper abdomen CT scans.

Discussion

The widespread use of neck imaging procedures and ultrasound-guided biopsy has resulted in an increasing number of papillary thyroid carcinomas (PTC). Currently the standard treatment for solitary T1N0M0 PTMC is thyroid lobectomy alone [4]. However, for some elderly patients who are at increased surgical risk because of relevant co-morbidities [16], or some patients with microcarcinoma who, for post-operative pain or cosmetic reasons, do not want to receive

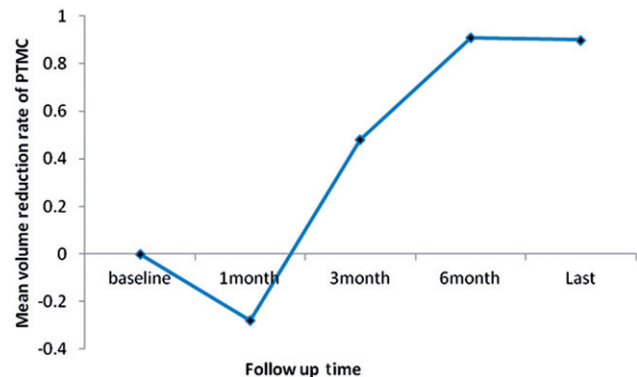


Figure 7. The graph reveals the mean volume reduction ratio at each follow-up visit after MW ablation. Because we achieved larger necrosis than the preoperation nodule, the mean volume of the tumours in the 3-month and the 6-month follow-up reduced more quickly than that in the 1-month follow-up.

thyroidectomy, PTMC is followed up without treatment [17]. Although disease progression is infrequent, a few cases of local spread or nodal metastases are reported in the long term [18]. Moreover, most patients are understandably concerned about their cancer and ask for repeated, regular follow-up if PTMC is left untreated.

Thus, minimally invasive ultrasound-guided ablation therapies come to be an attractive treatment option. Both RF, laser and ethanol ablation have been attempted with recurrent well-differentiated thyroid carcinomas, yielding good results [19–27]. They revealed that RF, laser and

ethanol ablation appeared to have significant clinical application with recurrent well-differentiated papillary carcinoma. At the last follow-up visit, RFA of recurrent thyroid cancers in the neck resulted in a mean volume reduction of 50.9% to 93% [21–22], with 50% of the nodules completely disappearing [22], and the figures were 37.5% to 96%, 31–44.7% after ethanol ablation, respectively [23–25]. By using laser ablation the mean volume reduction was 87% [26], and 80% of the nodes demonstrated complete ablation [27]. Papini et al. [28] directed their first trial of ultrasound-guided laser ablation towards primary thyroid carcinoma. Valcavi et al. also [12] presented their results on PTMC with laser ablation treatment in the literature. They all showed that percutaneous laser ablation was a rapid, safe, and inexpensive procedure for the ablation of a small-sized papillary thyroid tumour with no evidence of extra-glandular spread or nodal metastases.

MW ablation is a relatively novel technique that has been used to treat benign and malignant liver, lung, renal and adrenal tumours, both primary and metastatic [5–9]. Especially for small liver cancers, the long-term efficacy is similar to that of hepatectomy. Compared with RF, MW ablation may offer larger ablation zones, less treatment time and more complete tumour kill, and is less affected by the heat-sink effect that is thought to contribute to local recurrence after RF ablation [29–30]. The considerably advanced MW antenna can yield significantly larger ablation diameters, sufficient to ablate hepatic tumours 4 cm or smaller [31–32]. Therefore, percutaneous MW ablation may be clinically feasible for small localised PTMC.

Based on our previous experience with MW ablation for hepatocellular carcinoma and thyroid benign nodules, to our knowledge we performed the first study of percutaneous MW ablation for a select small group of patients with solitary T1N0M0 PTMCs. Treatment efficiency was encouraging, with complete tumour necrosis achieved at a single session of no more than 650 s in all lesions and no evidence of disease recurrence apparent during a mean follow-up of 11 months (range 3–22). Because of the larger necrosis than the nodule preoperation we achieved, the post-operative mean volume was a little larger than preoperative during initial follow-up. But in the latter follow-up, the volume of the tumours reduced quickly (Figure 5).

In our study we assessed the efficiency of this method with volume reduction rate (0.90 ± 0.14 at last follow-up visit), the complete disappearance success ratio (19%), and the recurrence and metastases rate (0%) as well. In all cases, MW ablation treatment was performed rapidly and without any serious side effects or complications except some temporary or local discomfort such as a burning sensation, hoarseness, choking, coughing and so on.

Our good results may be attributed to the following reasons. (1) We have had extensive experience in the MW ablation of hepatocellular carcinoma and benign thyroid nodules [9]. (2) There were strict inclusion criteria as all solitary lesions were 10 mm or less in diameter without clinically apparent lymph node, or distant metastasis at diagnosis (T1N0M0). (3) We achieved slightly more necrosis than the preoperation nodule. (4) All patients were treated with levothyroxine after MW ablation to maintain TSH levels below 0.1 mU/L. No severe and permanent complications

were observed in this study, perhaps in part due to the mixture solution we injected into the surrounding thyroid capsule, which served as a protective thermal barrier to MW energy. Selecting an appropriate puncture route also helped minimise complications. Because MW ablation yielded effective tumour kill in these patients without causing complications, it may become a safe and effective technique for solitary T1N0M0 PTMCs at favourable locations.

However, this study has some limitations. (1) Inclusion criteria were strict: tumour size was limited to 10 mm or smaller and without lymph node metastasis. (2) Only 21 patients were included in this study. (3) Follow-up is relatively short and the long-term results are not certain. So further multi-centre randomised clinical trials of larger sample size are needed to prove long-term efficacy compared with surgery.

Conclusion

Surgery is the gold standard for treatment of PTMC. However, during the short-term follow-up period, ultrasound-guided percutaneous MW ablation appears to be safe and effective for inducing complete necrosis of solitary T1N0M0 PTMC. Given the frequent multifocality of PTMC and the limitations of ultrasound evaluation in assessing the presence of extra-thyroid extension, greater experience with this technique will be required before its widespread clinical application.

Declaration of interest

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