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Long-Term Follow-Up Results of Ultrasound-Guided Radiofrequency Ablation for Low-Risk Papillary Thyroid Microcarcinoma: More Than 5-Year Follow-Up for 84 Tumors

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Background: Despite reports describing favorable short-term results for thermal ablation of thyroid cancer, there remains a need to evaluate long-term results because of its indolent characteristics. The purpose of this study was to evaluate the long-term efficacy and safety of ultrasound (US)-guided radiofrequency ablation (RFA) for low-risk papillary thyroid microcarcinoma (PTMC) over a follow-up period of more than five years.
Methods: From a cohort of patients under surveillance after US-guided RFA for primary low-risk PTMC, those with a record of follow-up data of more than five years were selected for this study. Before RFA, all patients underwent US and computed tomography to evaluate the PTMC and the presence of neck metastasis. RFA was performed using thyroid-dedicated electrodes. Follow-up US was performed 6 and 12 months after initial RFA, and then every 12 months. The status of ablated tumors was evaluated according to volume reduction, local tumor progression, newly developed cancers, lymph node (LN) or distant metastasis, and delayed surgery during follow-up. Complications during the procedure and follow-up period were evaluated.
Results: A total of 84 nodules from 74 patients were included in this study. All patients tolerated RFA, and the mean follow-up duration was 72 months. After RFA, complete disappearance rates of 98.8% and 100% were achieved at 24 and 60-month follow-up, respectively. Additional ablations were performed in 13 of 84 tumors. The mean number of RFA sessions was 1.2. There were four newly developed cancers in three patients, and these were also treated with RFA and completely disappeared. During the follow-up period, there was no local tumor progression, no LN or distant metastasis, and no patients underwent delayed surgery. The major complication rate was 1.4% (1/74), and there was no delayed complication or procedure-related death.
Conclusions: RFA is effective for treating low-risk PTMC patients, without occurrence of local tumor progression, LN or distant metastasis, delayed complications, procedure-related death, or delayed surgery over more than five years of follow-up.

Keywords: radiofrequency ablation, papillary thyroid microcarcinoma, ultrasound, long-term, efficacy, safety

Introduction

Active surveillance (AS) has been adopted as a new option for low-risk papillary thyroid microcarcinoma (PTMC), even though surgery remains the standard treatment it may be associated with complications (1). Although AS has shown promising results, the proportion of delayed surgeries is substantial (3.4–32%) (2–5). Furthermore, a recent systematic review and meta-analysis reported that patient anxiety was the reason for a large proportion (32–69%) of patients having delayed surgeries, not disease progression (6).

Recently, ultrasound (US)-guided thermal ablation has shown excellent results as an alternative treatment option for low-risk PTMC. In two recent systematic reviews and meta-analyses, thermal ablation revealed a mean volume reduction of 98.1% and a lymph node (LN) metastasis rate of only

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0.4%, without local tumor recurrence or distant metastasis (7,8). According to a recent meta-analysis, the results of thermal ablation seem to be similar or slightly superior to those of AS, with AS showing a 6.7% mean size enlargement at 5 years, and a rate of 1.6% for LN metastasis over 5 years (6). Moreover, the differences in the number of patients undergoing delayed surgery are prominent, with a systematic review reporting a delayed surgery rate of only 1.1% in patients undergoing thermal ablation, including three patients with unknown etiology other than LN metastasis (7). However, direct comparisons are limited because of a lack of paired comparisons, and the follow-up periods are relatively short for thermal ablation than for AS (6,7).

Therefore, there is a need to report the long-term follow-up results of thermal ablation to permit accumulation of sufficient data to allow comparisons between the different management options for low-risk PTMC. The purpose of this study was to evaluate the efficacy and safety of radiofrequency ablation (RFA) for low-risk PTMC in a cohort with ongoing postprocedural surveillance and follow-up data of more than five years.

Materials and Methods

This retrospective study was approved by our institutional review boards, and written informed consent was obtained from all patients before RFA.

Study population

Our group previously published a study (mean follow-up, 39 months) on the US-guided RFA of 152 primary low-risk PTMCs (size, 0.3–1 cm) in 133 patients performed between September 2008 and January 2017 (9). From the cohort still undergoing postprocedural surveillance, those patients with follow-up data covering more than five years were identified. The inclusion criteria were as follows: confirmation of the absence of aggressive pathology on pre-RFA fine needle aspiration (FNA) cytology (10,11); no evidence of gross extrathyroidal extension on US and computed tomography (CT) (5,12); and contraindications for surgery (including old age >80 years; comorbidity such as cardiovascular disease, history of stroke, central nervous system vascular malformation, other malignancy, and immunocompromised state) or refused surgery. The exclusion criteria were as follows: thyroid cancer with gross extrathyroidal extension, LN metastasis (either radiological or cytological evidence), distant metastasis, and pregnancy (9). This retrospective study included 84 PTMCs in 74 patients.

Pre-RFA assessment

All patients underwent pre-RFA assessment US examinations using either iU22US (Philips Healthcare, Bothell, WA, USA) or EUB-7500 (Hitachi Medical Systems, Tokyo, Japan) systems equipped with a linear high-frequency probe (5–14 MHz). The orthogonal three-dimensional maximal diameters and tumor volume of each nodule were evaluated on the US examination. The volume of each tumor was calculated as $V = \pi abc/6$ (where V is the volume, a is the largest diameter, and b and c are the two other perpendicular maximal diameters) (13). After evaluation of the PTMC itself, a screening neck US was performed to detect the presence of LN metastasis. For cytopathological confirmation, US-guided FNA was performed after the US examination (11).

Contrast-enhanced neck CT was acquired from all patients to exclude LN or distant metastasis. Routine laboratory examinations, including thyroid function test, serum thyroglobulin, thyroglobulin antibody, platelet count, and blood coagulation tests, were also performed.

All patients' radiological evaluations, such as US and CT images, and the results of their laboratory tests were reviewed by a radiologist (S.M.B.) with 19 years of experience in thyroid imaging.

RFA procedure

All RFA procedures were performed by one expert radiologist (S.M.B.; 13 years of experience with thyroid RFA) on an outpatient basis. An 18-gauge thyroid-dedicated internally cooled electrode and 0.5, 0.7, and 1 cm active tips were used, depending on the size of the targeted tumor (14). Detailed information on the equipment was provided in a prior report (9). A supine position with neck extension was the routine posture for the patients. To prevent bleeding, the detailed vascular anatomy along the approach route was evaluated by Doppler US. The relationships between the tumor and critical functional structures such as nerves, esophagus, and trachea were carefully evaluated to prevent injury.

One percent lidocaine was used for local anesthesia at the puncture site and perithyroidal area. A trans-isthmic approach was used for the RFA (15,16). The initial RF power ranged from 15 to 40 W, according to the size of the electrode tip. If a transient hyperechoic zone did not form at the electrode tip within 5–10 s, the RF power was increased in 5–10 W increments, up to 25–50 W. The electrode tip was fixed in the center of the tumor when the tumor was small, whereas larger tumors were treated unit by unit, using a moving-shot technique (13,17–19). According to the situation, during or after procedure, a 25-gauge needle was used to inject a cold lidocaine solution between the tumor and critical functional structures to prevent thermal injury and obtain a safety margin, the so-called hydrodissection technique (9,20). To prevent marginal recurrence, a sufficient quantity (at least 2 mm) of adjacent normal thyroid tissue was also ablated. If the tumor was located in a subcapsular area, we added hydrodissection to the affected site to ensure safety. The presence of any complications occurring during and immediately after ablation was carefully evaluated, and all patients were observed for four to five hours in the hospital after ablation.

Postablation assessment

Patients were followed using US and clinical evaluations at 1, 6, and 12 months, and then every 12 months afterward. The follow-up US examinations included measurement of the tumor volume and its orthogonal three-dimensional maximal diameters to evaluate local tumor progression (recurrence and growth of the ablated tumor), and evaluation of newly developed cancers (detection of new cancer other than the ablated tumor, with cytological confirmation), LN or distant metastasis, and delayed surgery (any cause of thyroid surgery during the follow-up period). The volume reduction rate was calculated as follows: volume reduction ratio (VRR) = ([initial volume – final volume] × 100)/initial volume (13). CT was performed in all patients at two and four years after ablation to

check for LN metastasis. If an abnormal radiological finding was apparent on the US and CT, a US-guided biopsy was performed on the lesion. A thyroid function test was performed immediately after the ablation, and then at 2, 6, and 12 months afterward.

Additional RFA was performed in those cases where the first RFA did not completely cover the tumor margins, and where new cancer had appeared on follow-up. The treatment efficacy was evaluated according to serial change in the mean VRR and complete disappearance (18). Complications during the procedure or follow-up were assessed using the reporting standards of the Society of Interventional Radiology (21). Both early (within 30 days after RFA) and delayed (>30 days after RFA) complications were evaluated (22).

Results

The characteristics of the study cohort, tumors, and RFA parameters are described in Table 1. Eighty-four PTMCs in 74 patients were evaluated in this study. The mean follow-up duration after RFA was 72 ± 18 months (range, 60–124 months). The median largest tumor diameter was 0.4 cm (range, 0.3–0.99 cm), and the median volume was 0.02 mL (range, 0.001–0.234 mL). Among the 84 tumors, 52 had a largest diameter between 0.3 and 0.5 cm, while the other 32 tumors were ≥0.5 cm. The mean number of RFA treatment sessions per tumor was 1.2 ± 0.4.

Table 1. Study Cohort Characteristics

Characteristics	*Data*
Patients ($n=74$)	
Female:male, no. (%)	66 (89.2):8 (10.8)
Mean age ± SD, years	46 ± 12
Mean follow-up ± SD, months	72 ± 18
PTMCs ($n=84$)	
<0.5 cm: ≥0.5 cm, no. (%)	52 (61.9):32 (38.1)
Location, no. (%)	
Right	33 (39.3)
Left	44 (52.4)
Isthmus	7 (8.3)
Median largest diameter, cm (range)	0.4 (0.3–0.99)
Median volume, mL	0.02 (0.001–0.234)
Radiofrequency ablation	
RF sessions, one:two, no. (%)	71 (84.5):13 (15.5)
Total number of RF sessions	97
Mean RF sessions ± SD	1.2 ± 0.4
Median RF power, W	20 (Range, 20–40)
Median ablation time, seconds	151 (Range, 30–326)
Median total energy, J	3150 (Range, 600–7880)
Median delivered energy (J)/mL	185,237 (Range, 13,088–4,716,379)
Active tip size, no. (%)	
5 mm	92 (94.8)
7 mm	4 (4.1)
10 mm	1 (1)

PTMC, papillary thyroid microcarcinoma; RFA, radiofrequency ablation; SD, standard deviation.

All ablated tumors completely disappeared during the 60-month follow-up. The complete disappearance rates were 34.5%, 74.1%, 98.8%, 98.8%, 98.8%, and 100% at 6, 12, 24, 36, 48, and 60 months, respectively (Supplementary Table S1). A representative case and the mean VRR for the study cohort are presented in Figures 1 and 2, respectively. The tumor volumes increased immediately after RFA and then decreased gradually. At 24 months, the mean VRR was near to 100%, and this VRR was maintained until the 60-month follow-up. There was no local tumor progression and no LN or distant metastasis, and no patients underwent delayed surgery. However, there were four new cancers in three patients in the remaining thyroid gland, with these being separate from the initially ablated tumor. These new cancers were also successfully ablated by RFA. There were four complications, which consisted of three minor complications (4.1%, 3 of 74 patients: two hematomas with immediate recovery and one first-degree burn) and one major complication (1.4%, 1 of 74 patients: a voice change that had recovered at the 2-month follow-up). However, there was no RFA-related life-threatening immediate complication, and no delayed complications during the mean follow-up period of 72 months.

Discussion

This study presents long-term follow-up results over >5 years for RFA treatment of 84 PTMCs. The RFA resulted in the complete disappearance of all ablated tumors, with no local tumor progression, no LN or distant metastasis, and no need for delayed surgery because of patient anxiety during the long-term follow-up period. Although there were four new cancers (separated from the initially ablated tumor) in three patients in the remaining thyroid gland, these were also successfully ablated by RFA. The major complication rate was 1.4% (1/74), and there were no life-threatening or delayed complications. Therefore, RFA was an effective and safe treatment for PTMC.

In previous studies, several thermal ablation methods showed favorable local control efficacy for treating low-risk PTMCs, with VRR of 80–100% and no local tumor recurrences or distant metastases (9,15,23–31). These studies reported only two cases of LN metastasis (1/64 in Zhang *et al.*, 1/37 in Ji *et al.*, both studies using laser ablation) and one newly developed cancer (1/185 in Teng *et al.*, a study using microwave ablation) during follow-up after ablation (27,29,30). However, longer-term results are required for several reasons. First, most of the published studies had relatively short-term follow-up or small study cohorts. The longest follow-up RFA treatment results reported are those by Kim *et al.*, who reported four-year follow-up results, but only for four patients (25). Second, PTMC is typically indolent, making it difficult to ascertain durable efficacy on short-term follow-up (1). Third, long-term follow-up provides added information on LN metastasis, as PTMC is known to frequently result in LN metastases in the central compartment, which cannot easily be detected preoperatively (32,33). Finally, the current thyroid guidelines do not recommend RFA for the first-line treatment of PTMC, but as a second-line option. The European Thyroid Association Guidelines suggest that in patients with refractory primary cancer requiring treatment, RFA should only be performed at

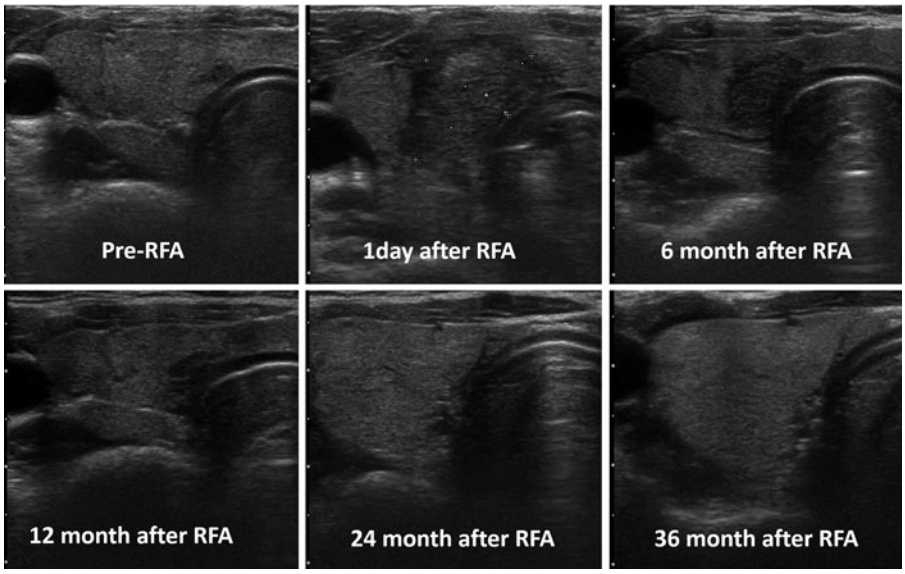

FIG. 1. Pre-RFA and post-RFA follow-up example of PTMC. The proven hypoechoic PTMC located on right side of the isthmus with spiculated margin in a 29 years old female (pre-RFA). Serial follow-up after ablation demonstrated the large ablation zone, including the primary cancer gradually decreased, and eventually disappeared. PTMC, papillary thyroid microcarcinoma; RFA, radiofrequency ablation.

the site of the disease or a metastasis that is growing (34). The 2017 Korean Radiofrequency Ablation Guideline recommends RFA for patients with primary thyroid cancer who refuse surgery or who cannot undergo an operation, and that thermal ablations can be considered as an alternative (20). Nevertheless, they commonly agree on the effectiveness and safety for local control of tumors. Therefore, confidence in the long-term results for the treatment of PTMC by thermal ablation may be needed. This study reports the longest follow-up results for thermal ablation for treating low-risk PTMC, demonstrating favorable efficacy for patients with a mean follow-up duration of 72 months, and all with >5 years of follow-up. It is, however, important to note that some guidelines do not recommend that such small tumors need to be biopsied.

Recently, AS has been suggested as a first-line management option for low-risk PTMC (2,35,36). A systematic review and meta-analysis showed favorable results for AS, with only a small proportion of tumors showing size enlargement (5.3%) and LN metastasis (1.6%) during 5-year follow-up (6). However, the study also mentioned the limitations of AS. First, a large proportion (range, 8.7–32%) of patients underwent delayed surgery during follow-up. Moreover, many of the patients suffered from anxiety, as more than half of their symptoms were not related to tumor enlargement or LN metastasis. In a systematic review that presented results for 503 low-risk PTMCs in 470 patients treated by thermal ablation, there was no local tumor recurrence or distant metastasis (7), although two patients (0.4%) suffered LN metastasis, and one patient (0.2%) developed a new PTMC,

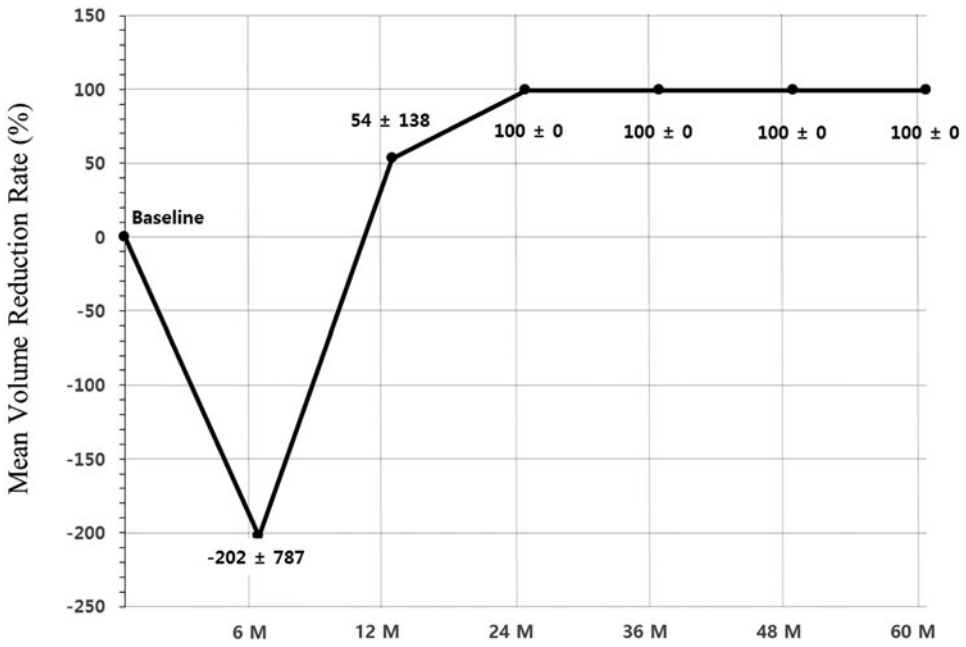

FIG. 2. Serial mean volume reduction rates during long-term follow-up. The values of mean volume reduction rates ± standard deviation.

which was successfully treated by additional ablation. In addition, only five patients (1.1%) underwent delayed surgery after ablation, two patients with LN metastasis and three additional patients for unknown reasons. Similarly, in this study covering 84 tumors, we found no local tumor progression, no LN or distant metastasis, and no delayed surgery due to anxiety over a long-term follow-up period of more than five years. Although a direct comparison study is not available and the original published studies included only PTMCs, we believe that thermal ablation may alleviate or eliminate patient anxiety by treating the primary tumor.

In contrast to our results, there are a few reports describing unsatisfactory results for ablation of low-risk PTMC. For example, Ma *et al.* reported the results of 12 papillary thyroid carcinoma patients who were treated by thermal ablation (37). The cytological results after surgery demonstrated residual cancers and LN metastasis. However, their inclusion criteria were nonlow-risk PTMC (>1 cm, demonstrated capsule invasion and LN metastasis), and we suggest that only low-risk PTMC should be considered for treatment by thermal ablation.

Although there are a few discrepancies in the definition of low-risk PTMC among the guidelines, low-risk PTMC is currently considered suitable for AS (38–42). A systematic review suggested the importance of strict inclusion criteria for thermal ablation for PTMC, criteria that can be adopted from AS (7). In addition, to verify the diagnosis of low-risk PTMC and rule out LN metastasis before ablation, detailed pretreatment imaging work-up is required, including contrast-enhanced CT (43). Therefore, RFA for primary cancer should be performed only in low-risk PTMC with accurate staging of patients. If other studies show similar efficacy of RFA treatment for low-risk PTMC, RFA can be considered as an alternative to AS.

This study has several limitations. First, it is subject to a selection bias due to the retrospective study design. A further long-term multicenter prospective study is needed to confirm the results, even though our study reports the longest follow-up results to our knowledge. Second, in enrolling patients with long-term follow-up data of more than five years, we inevitably included tumors treated in the early experience period of the RFA performer, which could have affected the complication rate. However, there was no life-threatening immediate complication and no delayed complications during the mean follow-up period of 72 months. Third, we included tumors diagnosed by FNA cytology before RFA that might have been false positive. Finally, we assessed the presence of extrathyroidal extension by imaging, not by histopathology.

In conclusion, RFA is effective and safe for long-term local tumor control for low-risk PTMC. RFA could be considered a treatment option for low-risk PTMC.

Author Disclosure Statement

No competing financial interests exist.

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Supplementary Material

Supplementary Table S1

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