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Radiofrequency ablation of benign non-functioning thyroid nodules: 4-year follow-up results for 111 patients

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Abstract
Objectives To evaluate the clinical outcomes and safety of radiofrequency (RF) ablation for benign non-functioning thyroid nodules over a 4-year follow-up.
Methods We evaluated 126 benign non-functioning thyroid nodules of 111 patients treated with RF ablation and followed-up more than 3 years. RF ablation was performed using the Cool-Tip RF system and an internally cooled electrode. Nodule volume and cosmetic and symptom scores were evaluated before treatment and during follow-up. Complications and factors related to efficacy were evaluated.
Results The mean follow-up duration was 49.4±13.6 months. Thyroid nodule volume decreased significantly, from 9.8±8.5 ml before ablation to 0.9±3.3 ml ($P<0.001$) at final evaluation: a mean volume reduction of 93.4±11.7 %. The mean cosmetic ($P<0.001$) and symptom scores ($P<0.001$) improved significantly. Factors related to efficacy were initial solidity and volume. The overall recurrence rate was 5.6 % (7/126). The overall complication rate was 3.6 % (4/111).
Conclusions RF ablation was effective in shrinking benign thyroid nodules and in controlling nodule-related problems over a 4-year follow-up. There were no life-threatening complications or sequelae. Therefore, RF ablation can be used as a non-surgical treatment for patients with benign non-functioning thyroid nodules.
Key Points
- *Radiofrequency (RF) ablation provides a non-surgical option for benign non-functioning thyroid nodules*
- *RF ablation reduced non-functioning thyroid nodular volume by 93.5 % after 49 months*
- *Initial solidity and volume influenced the efficacy of RF ablation*
- *Larger thyroid nodules required more treatment sessions to achieve appropriate volume reduction*
- *Complete treatment of the periphery of the nodule is important in preventing marginal regrowth*

Keywords Radiofrequency ablation · Thyroid nodules · Ultrasound · Laser ablation · Ethanol ablation

Abbreviations

US	Ultrasonography
EA	Ethanol ablation
LA	Laser ablation
RF	Radiofrequency
FNAB	Fine-needle aspiration biopsy

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Introduction

Although ultrasonography (US)-guided ethanol ablation (EA) has been used as a non-surgical treatment of cystic thyroid nodules [1–4], it has shown limited results in solid thyroid nodules [3, 5, 6]. Laser ablation (LA) has been proposed as an alternative treatment of solid thyroid nodules [7, 8], and clinical outcomes for more than 3 years of follow-up have been reported [9, 10]. These mid- to long-term studies have demonstrated volume reductions of 47.8 % at 3 years' and 51 % at 67 months' follow-up, indicating that LA results in satisfactory mid- to long-term clinical response and safety in most patients.

More recently, radiofrequency (RF) ablation has been used in patients with benign thyroid nodules causing symptoms and/or cosmetic problems [6, 11–17]. Although these clinical trials have shown that RF ablation is effective in reducing nodule volume, range 33–58 % at 1-month and 51–85 % at 6-month follow-up, as well as reducing nodule-related symptomatic and/or cosmetic problems, the mean follow-up periods in these trials were relatively short (less than 1 year). In 2009, Spiezia et al. [16] reported clinical outcomes of 94 patients treated with RF ablation and followed-up for 2 years. They showed mean volume reductions at 1 and 2 years of 78.6 % and 79.4 %, respectively, suggesting that RF ablation-induced volume reductions and improvements in nodule-related symptoms were well maintained for at least 2 years. In addition, other studies of RF ablation have shown its efficacy after mean follow-up periods of 21.2 and 18.8 months [6, 18]. Although these studies showed that RF ablation of benign thyroid nodules was effective and safe for up to 2 years, no study has assessed the efficacy and complications of RF ablation for longer periods of time.

Therefore, we evaluated the clinical outcomes and safety of RF ablation for patients with benign non-functioning thyroid nodules over a 4-year follow-up.

Materials and methods

This study was approved by the institutional review board of the Daerim St. Mary's hospital, and written informed consent was obtained from all patients prior to US-guided fine-needle aspiration biopsy (FNAB) and RF ablation.

Patients

From June 2002 to December 2007, 538 thyroid nodules of 505 patients were treated with US-guided RF ablation at the Thyroid Center of the Daerim St. Mary's hospital. Among them, patients were enrolled as they fulfilled the following criteria: reported cosmetic and/or symptomatic problems; largest diameter of nodule exceeding 2 cm; cytologically confirmed benign nodule on two separate US-guided FNAB; US imaging finding without suspicious malignant features [19, 20]; serum thyroid hormone and thyrotropin levels within normal ranges; refusal of or ineligible for surgery. Finally, we enrolled 126 nodules of 111 patients (10 men, 101 women; mean ± SD age, 37.9±10.6 years; range, 19–69 years) who were followed up for more than 3 years. Of the 111 patients, 91 participated in previous published studies.

Pre-ablation assessment

All patients were evaluated by US examination, FNAB, and laboratory and clinical examinations. US, US-guided FNAB and RF ablation were performed using a 10-MHz linear probe and a real-time US system (Prosound SSD-5000, Aloka; Aplio SSA-770A, Toshiba Medical System). Three orthogonal diameters of each nodule (its largest diameter and two other perpendicular diameters) and the proportion of solid component were measured before RF ablation. The volume of each nodule was calculated as $V = \pi abc/6$ (where V is volume, a is the largest diameter, and b and c the two other perpendicular diameters). Nodule vascularity was classified using a four-point scale, with 1, 2, 3 and 4 representing respectively: no Doppler signals, signals in < 25 % of the nodule, in 25–50 % of the nodule and in > 50 % of the nodule. Laboratory examinations included measurements of serum thyrotropin (normal range, 0.4–4.0 mIU/l), total triiodothyronine (normal range, 61–173 ng/dl), free thyroxine (normal range, 0.8–1.9 ng/dl), and calcitonin (normal range, 0–10 pg/ml) concentrations, as well as platelet count and blood coagulation tests, including prothrombin time and activated partial thromboplastin time.

At enrolment, patients were asked to rate pressure symptoms on a 10-cm visual analogue scale (0–10 cm), and cosmetic grading score was assessed by the physician, as described [17, 21].

Procedure

RF ablation was performed on an outpatient basis We used an RF generator (Cool-Tip RF system, Covidien; SSP-2000, Taewoong Medical) and a 17- or 18-gauge internally cooled electrode with 1-, 1.5- and 2-cm active tips (Cool-Tip, Covidien; Well-point RF electrode, Taewoong Medical). The patients were treated with 2 % lidocaine for local anaesthesia at the puncture site. Under US guidance, we performed RF ablation using trans-isthmic approach and moving shot technique, as previously described [14, 17, 22]. During the procedure, we payed special attention to the preservation of surrounding important organ to prevent significant complication such as nerve injury [23].

Ablation was begun with 30–80 W of RF power. If a transient hyperechoic zone did not form at the electrode tip within 5–10 s, RF power was increased in 10 W increments to a maximum of 120 W, depending on the size of the active tip and the internal characteristics of each nodule. If the patient did not tolerate pain during the ablation, the power was reduced or turned off for several seconds. The ablation procedure was terminated when all conceptual units had become transient hyperechoic zones. Complications during and after the procedure were evaluated according to clinical signs and symptoms.

Follow-up

Patients were followed-up by US and clinical evaluation at 1, 3, 6, and 12 months, and every 6–12 months thereafter. Thyroid nodule volume, largest diameter, vascularity, cosmetic and symptom scores were evaluated during the follow-up period in the same manner as before ablation. The percentage reduction in volume was calculated as: volume reduction ratio (VRR) = ([initial volume − final volume] × 100)/initial volume. Therapeutic success was defined as a >50 % volume reduction at last follow-up. Additional treatment was allowed if follow-up US showed a remaining viable portion of the nodule, and/or if a patient complained of incompletely resolved clinical problems [14–16, 24].

Regrowth and/or recurrence were defined as increases in nodule volume (> 50 %) compared with previous US examination [19, 25]. All recurrent thyroid nodules were evaluated by FNAB. Complications during follow-up were assessed using the reporting standards of the Society of Interventional Radiology [26, 27].

Statistical analysis

All data were analysed using the statistical software package R for Windows (version 2.13.0, http://www.R-project.org). Continuous data are reported as mean ± SD (range). Paired *t*-tests were used to compare changes in largest diameter, volume, vascularity, cosmetic score and symptom score from before RF ablation to last follow-up. Wilcoxon signed rank tests were used to compare changes in largest diameter, volume, and cosmetic and symptom scores before RF ablation and at each follow-up.

Multiple linear regression analysis was used to determine factors independently predictive of efficacy (last VRR). Factors entered into the model included age, gender, number of treatment sessions, mean energy per millilitre of pre-treatment nodule volume, initial nodule volume, initial nodule solidity and initial nodule vascularity.

For subgroup analysis, we divided thyroid nodules into three groups according to their initial volume: ≤ 10 ml, 10–20 ml and >20 ml, and compared last VRR and number of treatment sessions among the three groups using the Kruskal Wallis test. We also divided nodules into two groups based on their initial solidity, ≤ 50 % and > 50 %, and compared VRR at each follow-up period using the Kruskal Wallis test.

Differences were considered statistically significant when the *P* value was less than 0.05.

Table 1 Baseline characteristics of initial thyroid nodules, and patients' initial cosmetic and symptom scores

Characteristics	
Largest diameter (cm)	3.3±1.0 (2–6)
Volume (ml)	9.8±8.5 (2–43)
Volume ≤10 ml	81
Volume > 10 ml to≤20 ml	28
Volume >20 ml	17
Proportion of solid component (%)	65.1±32.9 (5–100)
Solidity ≤50 %	45
Solidity >50 %	81
Vascularity	1.7±0.7 (1–4)
Cosmetic score	3.2±0.8 (1–4)
Symptom score	4.3±1.6 (0–10)

Values are presented as mean ± SD (range) or number of nodules

Results

The baseline characteristics of the thyroid nodules, and the initial cosmetic and symptom scores of the patients are summarised in Table 1. All patients were followed-up for more than 3 years, with the mean ± SD follow-up duration after RF ablation being 49.4±13.6 months (range, 36–81 months).

Changes in thyroid nodule volume and cosmetic and symptom scores at each follow-up evaluation are shown in Fig. 1. We found that largest diameter (1.1±0.8 cm), volume (0.9±3.3 ml), vascularity (1.1±0.4), cosmetic score (1.3±0.6) and symptom score (0.8±0.9) were significantly lower at last follow-up than before treatment ($P<0.001$ for all comparison). The mean ± SD VRRs at 6 months, 1 year, 2 years, 3 years and last follow-up were 70.3±17.2 % (range, 30–98 %), 89.9±10.2 % (range, 51–100 %), 90.1±10.1 % (range, 51–100 %), 90.7±15.8 % (range, 17–100 %) and 93.5±11.7 % (range, 17–100 %), respectively (Table 2). At last follow-up, the

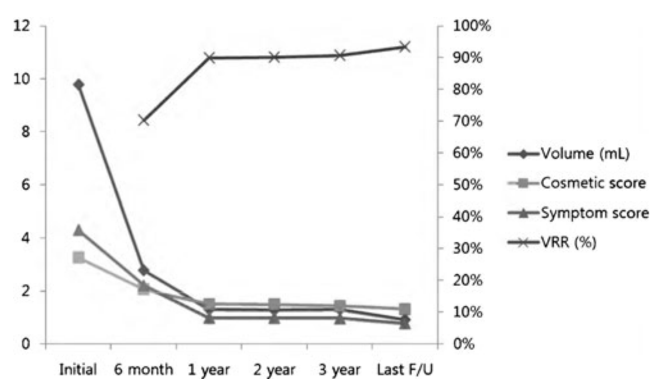

Fig. 1 Changes of thyroid nodule volume, cosmetic score, symptom score and volume reduction ratio (*VRR*) before RF ablation and at each follow-up

Table 2 Comparison of VRRs in all nodules and in nodules assorted by solidity at pairs of follow-up times

	6 months	1 year	2 years	3 years	Last
Total	70.3±17.2	89.9±10.2	90.1±10.1	90.7±15.8	93.5±11.7
P value	< 0.001	> 0.999	< 0.001	< 0.001	
Solidity ≤50 %	80.9±14.6	93.6±8.8	93.1±8.9	92.0±20.3	96.0±8.8
Solidity >50 %	67.6±16.8	87.8±10.4	88.4±10.4	90.0±13.0	92.0±12.9
P value	< 0.001	0.003	0.021	0.002	0.002

Values are presented as mean ± SD (%)

therapeutic success rate was 98.4 % (124/126) and the complete disappearance rate was 18.3 % (28/126).

The mean number of treatment sessions was 2.2±1.4. Fifty-three nodules were treated in a single session, whereas 73 required two or more sessions, including 30 requiring two sessions, 24 requiring three sessions, 9 requiring four sessions, 4 requiring five sessions, 4 requiring six sessions, and 2 requiring seven sessions. Mean total energy delivered per nodule was 21,085.2±16,417.0 J (range, 2,940–101,400 J), and mean energy delivered per millilitre of pre-treatment nodule volume was 2,935.7±1,994.7 J (range, 271–9,943 J).

Multiple linear regression analysis showed that initial nodule volume ($P<0.001$) and solidity ($P=0.010$) were independent factors predicting final VRR (Table 3). Subgroup analysis showed that last VRR did not differ significantly among the three groups of nodules assorted by volume ($P=0.074$), although the number of treatment sessions was significantly increased as the initial nodule volume increase (Table 4). When we compared VRR of nodules assorted by initial solidity, we found that the VRRs at each follow-up were greater for nodules of ≤ 50 % solidity than those of >50 % solidity (Table 2).

The overall recurrence rate was 5.6 % (7/126). All recurrent nodules showed regrowth of the undertreated peripheral portion of the nodule. All patients showed benign results on repeat FNAB. Four of these recurrent nodules decreased in size after additional RF ablation, two were treated with additional RF ablation without further follow-up, and one did not receive further treatment due to patient refusal and was lost to follow-up. At last follow-up, no nodule was larger than its initial size.

The overall complication rate was 3.6 % (4/111). Major complications were observed in two patients (one with voice change and one with brachial plexus injury), and minor complications were observed in two patients (one with a haematoma and one with vomiting). In addition, two patients experienced local pain. All of these patients recovered without sequelae. No patient experienced a life-threatening or delayed complication during follow-up.

Table 3 Multiple linear regression analysis of factors independently predictive of the efficacy of RF ablation of benign thyroid nodules

Variable	Coefficient (β)	Standard error[a]	*P* value
Age	0.005	0.099	0.959
Gender	−3.093	3.492	0.378
Number of treatment sessions	1.640	0.864	0.060
Delivered energy[b]	0.140	0.879	0.810
Initial volume	−0.587	0.141	< 0.001
Initial solidity	−0.084	0.032	0.010
Initial vascularity	2.174	1.427	0.130

[a] Standard error of the estimated coefficient

[b] Mean energy delivered per millilitre of pre-treatment nodule volume

Discussion

The present evaluation of 111 patients in 4-year follow-up demonstrated that RF ablation resulted in significant reductions in the volumes of benign thyroid nodules, as well as improving cosmetic and/or symptomatic problems. We found that the efficacy of RF ablation was influenced by the initial volume and solidity of the nodules. Subgroup analysis showed that larger nodules required more treatment sessions than smaller nodules to achieve similar reductions in volume. Although RF ablation was effective for thyroid nodules regardless of their proportion of solid component, volume reduction was greater in cystic nodules. The recurrence rate was low and there were no life-threatening or delayed complications.

Previous studies have shown that RF ablation is effective and safe for up to 2 years [16]. Our study showed that its efficacy not only remained significant at 3 years but was well maintained throughout the follow-up. When we compare our results to mid- to long-term LA studies [9, 10], our

Table 4 Number of sessions and last VRR according to initial nodule volume

Initial nodule volume	0–10 ml (*n*=81)	10–20 ml (*n*=28)	> 20 ml (*n*=17)
Number of session	1.7±0.9	2.8±1.7	3.8±1.5
P value	0.001	0.023	
Last VRR (%)	94.5±9.6	93.6±9.7	88.2±20.4
P value	0.928	0.297	

Values are presented as mean ± SD (%)

study is superior to those of LA, as shown by mean VRR at last follow-up (93.4 % versus 47.8–51.0 %). When we compared serial changes in volume of our result to those of LA, our data showed a gradual reduction of nodule volume during follow-up, whereas LA treated nodules tended to increase in volume at last follow-up [9, 10], with the latter possibly due to the regrowth of undertreated peripheral portions of nodules [10, 11, 22]. However absolute comparison of RF ablation and LA is not reliable because the characters of thyroid nodules and number of treatment sessions are different.

All recurrent nodules in our study showed regrowth at their peripheral portions, which had been undertreated during previous RF ablation. Although well-treated nodules showed a > 90 % decrease in volume over 1–2 years, incompletely treated nodules may start to enlarge 1–2 years after ablation. We found that the overall regrowth rate was 5.6 % (7/126), with regrowth defined as a > 50 % increase in nodule volume compared with the previous follow-up volume. For LA, Valcavi et al. [9] reported 9 % of regrowth by the definition of an increase of nodule volume over initial volume; however, none of our nodules grew to a size larger than its initial volume. Repeat FNAB showed that all regrown nodules were benign, indicating that recurrence was not associated with malignancy.

As we described, complete ablation of the periphery of the nodule is important to prevent marginal regrowth. To prevent marginal regrowth, the moving shot technique has been suggested as a suitable method [11, 22, 28]. This technique has been shown to completely ablate the entire nodule [22, 28]. Several previous studies [13, 15, 29] reported that one treatment session was sufficient for treatment of thyroid nodules, because the primary purpose of thyroid nodule ablation was the resolution of cosmetic problems and nodule-related symptoms rather than complete ablation. However, marginal regrowth of an incompletely treated nodule may be a major cause of recurrent symptoms during follow-up. Large nodules require multiple treatment sessions, because a single session cannot result in complete ablation.

In agreement with previous findings [9, 10, 14, 17], we found that the factors affecting final reduction in volume of thyroid nodules were initial solidity and initial nodule volume. Larger nodules required more treatment sessions than smaller nodules to achieve similar reductions in volume.

Regarding safety, previous studies showed low complication and low sequelae rates after RF ablation [14, 15]. Our study also showed a similar low complication rate and no sequelae. In addition, there were no life-threatening or delayed complications. Thus, RF ablation of thyroid nodules is a safe procedure even after longer follow-up.

Our study had several limitations, including the absence of histological confirmation, similar to other studies of non-surgical methods, including EA, LA and RF ablation. To overcome this limitation, we carefully enrolled patients with cytologically confirmed benign nodules on two separate US-guided FNAB and US imaging findings without suspicious malignant features. Another limitation was the retrospective design of this study and its performance at a single centre. Future prospective multicentre and/or multinational studies are necessary to confirm our results.

In conclusion, RF ablation is effective in shrinking benign thyroid nodules as well as in controlling nodule-related problems during a 4-year follow-up without life-threatening complications or sequelae. These findings indicate that RF ablation is an effective and safe non-surgical treatment for benign non-functioning thyroid nodules.

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