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ORIGINAL SCIENTIFIC REPORT

Radiofrequency Ablation for Benign Thyroid Nodules: 1-Year Follow-Up in 184 Patients

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Abstract

Background Benign thyroid nodules are common, and must be treated when symptomatic. Non-surgical minimally invasive modalities, including radiofrequency ablation (RFA), have been widely used with good results. The factors related to the efficacy of RFA are still debated. This study was to evaluate the safety, efficacy and related factors of RFA in the treatment of benign thyroid nodules.

Methods A retrospective single-center study was conducted on 251 benign thyroid nodules in 184 patients treated with RFA. The procedure was performed under ultrasound (US) guidance using the trans-isthmic approach and the moving-shot technique. Clinical and US examinations were performed at 1, 3, 6, 12 months, and then at 6 month intervals. Study outcomes were volume reduction ratio (VRR) and complications.

Results There were 153 women and 31 men included in the study. The mean age was 43.9 years. The median initial largest diameter and volume of nodules were 30 mm and 6.18 ml. The median length of follow-up was 12 months. Two minor complications were found. The mean VRR was 66.8; 74.3; and 81% after 3, 6, and 12 months, respectively. Initial solidity was a factor related to the efficacy: cystic nodules had higher VRR compared to solid ones.

Conclusions RFA is safe, effective and can be used as a routine treatment for benign thyroid nodules. More prospective multicenter studies with long-term follow-up are required to improve the safety and efficacy of RFA.

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Introduction

Thyroid nodules are common findings all over the world, present in 20–76% of the general population [1]. Although 85–93% of thyroid nodules are benign [2], they may pose jugular oppression, cosmetic problems, and have potential possibility of malignant transformation [3]. Therefore, it is necessary to treat benign thyroid nodules when they are symptomatic or causing cosmetic problems [4, 5]. Traditional treatments of choice for benign thyroid nodules are surgery and levothyroxine therapy. Although curative, surgery has several drawbacks, including general anesthesia, iatrogenic hypothyroidism, and scar formation. In addition, levothyroxine therapy causes signs of hyperthyroidism and its efficacy is still debated [6]. Thus, in recent years, non-surgical minimally invasive modalities, including ethanol ablation, microwave ablation, laser ablation, and radiofrequency ablation (RFA), have been widely used with good results [7].

For thyroid nodules, RFA is usually performed by the moving-shot technique with the guidance of ultrasonography (US), inducing tissue necrosis using thermal energy. Although RFA has been considered a safe and effective method for the treatment of benign thyroid nodules, it may lead to laryngeal nerve palsy, autoimmune thyroid disease, skin burns, hematoma, and adhesion formation when patients require surgery [8–10]. However, compared to surgery, RFA has fewer complications, shorter hospital length of stay, and preservation of thyroid function [11]. Several studies have reported some factors related to the efficacy of RFA in the treatment of thyroid nodules, including initial volume, US structure and vascularity of the nodules [12–18]. However, the available studies had limited data and their conclusions are still debated. In Vietnam, RFA has been used to treat benign thyroid nodules since 2016 in our institution. The results have been promising, without any major complication, but the efficacy in volume reduction of the nodules has not been reported. Therefore, this single-center study was conducted to evaluate the safety and efficacy of RFA in reducing the volume of benign thyroid nodules and to explore factors related to volume reduction of the nodules.

Materials and methods

Study design and patients' selection

This retrospective single-center study was conducted in the Thoracic and Vascular Department at University Medical Center at Ho Chi Minh City, a tertiary referral center in Ho Chi Minh City, Vietnam. The study was approved by the local institutional ethics committee. A total of 251 benign thyroid nodules in 184 patients treated with US-guided RFA between November 2016 and October 2018 at our institution were eligible to be included in this study. The inclusion criteria were as follows: (1) evidence of benign thyroid nodule(s) on US findings and two separate US-guided fine-needle aspirations (US-FNAs) cytology; (2) anxiety about malignant transformation or presence of subjective symptoms, including pain, compressive symptoms, neck discomfort, or foreign body sensation; and (3) refusal to undergo surgery. The exclusion criteria included: (1) a nodule less than 15 mm in its largest dimension; (2) follicular neoplasm or malignancy findings on US-FNA cytology; (3) a nodule with benign result in US-FNA cytology which was suspicious of malignancy in US findings, including microcalcifications, marked hypoechoic, or ill-defined margins; (4) current hyperthyroidism; (5) previous radiation to the head and neck; and (6) comorbidity of severe diseases with a life expectancy of less than 1 year. Written informed consent was obtained from all patients before the procedure.

Radiofrequency ablation procedure

All the procedures were performed by the same operator (TTV), who is a thoracic surgeon experienced in thyroid US, US-FNA, and RFA. Patients underwent the RFA procedure in a supine position with mild neck extension. Local anesthesia was performed at the puncture site before inserting the electrode tip to the nodule, using 10 ml of 2% lidocaine hydrochloride. For the ablation, we used 18-gauge internally cooled monopolar electrodes, with 7-mm active tips, which were connected to a radiofrequency generator delivering up to 200 W (CoATherm AK-F200, APRO KOREA Inc.). The whole procedure was performed under US guidance. Firstly, the electrode was inserted into the thyroid nodule using the trans-isthmic approach and then the ablation was performed using the moving-shot technique, as proposed and described by Baek et al. [19–21]. During the procedure, we payed special attention to preventing injury to the adjacent important structures. If a nodule had unfavorable anatomy, i.e. the distance between nodule edge and one of the important structures (the laryngeal nerve, the carotid artery and vein, the esophagus, and the trachea) was less than 3 mm, it was ablated as much as possible, but with incomplete ablation to minimize the injury to these structures. Otherwise, complete ablation was performed until the whole nodule became a transient hyperechoic zone. Aspiration for cystic fluid in the case of cystic and mixed nodules was performed as much as possible. After the procedure, patients were under observation for several hours and were discharged if having no severe pain or complications. Oral

analgesics (acetaminophen) were prescribed for the next 3 days.

Assessment and follow-up of the patients

The clinical, laboratory, and US examinations were evaluated at baseline (before the RFA procedure). Clinical and US examinations were performed at 1, 3, 6, 12 months, and then at 6 month intervals. Before ablation, thyroid nodules were classified into three types of solidity. Nodules were defined as solid when the solid component was greater than 75%, cystic when the solid component was less than 25%, and others were defined as mixed nodules. Safety outcomes, including complications and side effects, were evaluated and classified as reported by the international working group on image-guided tumor ablation [22]. In summary, a major complication leads to substantial morbidity and disability which increases the level of care, or results in hospital admission, or substantially lengthens the hospital stay, e.g. a case with bleeding in which a blood transfusion or an interventional procedure is required; or a case with permanent voice dysfunction. All other complications were considered as minor complications. The efficacy outcome was volume reduction ratio (VRR), which was assessed by US imaging. The VRR was calculated by the percentage of reduction of the nodule's volume during the follow-up period, compared to the initial volume: $\text{VRR}\ (\%) = \frac{\text{initial volume} - \text{final volume}}{\text{initial volume}} \times 100\%$. Several patients had an additional ablation due to the following reasons: (1) the VRR was less than 50% at 3 months or later after the first ablation; or (2) evidence of a viable portion of the thyroid nodule on the follow-up US, including the presence of intra-nodular vascularity or the same echogenicity with the nodule before any ablation.

Statistical analysis

Statistical analysis was performed using statistical software R version 3.4.4 (The R Foundation for Statistical Computing 2018). The safety outcome was summarized using number of events and percentage. For the efficacy outcome, which is a numeric outcome, we aimed to address the mean and 95% confidence interval (CI) of the VRR during the follow-up period. Although the scheduled examinations were at 1, 3, 6, 12 months and every 6 months after that, the included patients did not exactly follow this schedule due to individual reasons, as a limitation of a retrospective study. Thus, to assess the progress of VRR during the follow-up period, instead of trying to categorize the time of follow-up into the pre-defined periods as scheduled visits, we treated it as a continuous variable and performed a linear regression model on the outcome with a non-linear effect of the time of follow-up using natural cubic splines. In order to explore factors related to the progress of the VRR, we used a multivariable linear mixed effects model including gender, age, initial volume of the nodule, echogenicity, solidity, number of RFA sessions, and accounting for correlated data from participants with more than one treated thyroid nodules, and repeated measures of the VRR for one nodule during the follow-up period. Results of this model were reported as mean differences (MDs) and their 95% CIs of the VRR between categories for categorical variables (such as gender, echogenicity, solidity, single or multiple RFA sessions) and for each one-unit increase of numeric variables (such as age, initial volume of the nodules). Statistical significance was defined when p value was less than 0.05.

Results

Clinical characteristics of included patients

Clinical profiles of included patients are shown in Table 1. There were 184 patients (153 women and 31 men) included in the study, with a mean age of 43.9 years. The median time of thyroid nodule diagnosis before ablation was 3 years, and the maximum was 30 years. All patients had subjective symptoms of a thyroid nodule but refused to undergo surgery. Nine cases had a history of surgery for thyroid nodule. There were 48 patients (26.1%) with two or more treated nodules. The median length of follow-up was

Table 1 Clinical characteristics of included patients

Characteristics	Summary statistics (N = 184)
Age (years) [mean ± SD (range)]	43.9 ± 12.8 (12–76)
Female [n (%)]	153 (83.2)
Time from diagnosis to first RFA (years) [median (range)]	3 (0–30)
Number of treated thyroid nodules [n (%)]	
1 nodule	136 (73.9)
2 nodules	30 (16.3)
3 nodules	14 (7.6)
4 nodules	3 (1.6)
5 nodules	1 (0.5)
History of thyroid surgery [n (%)]	9 (4.9)
Complication [n (%)]	
Minor complication	2 (1.1)
Major complication	0 (0.0)
Length of follow-up (months) [median (range)]	12 (1–25)

RFA radiofrequency ablation, *SD* standard deviation

12 months. At the final follow-up, 182 patients (98.9%) had resolution of their initial symptoms.

Ultrasound characteristics of thyroid nodules before ablation

A total of 251 benign thyroid nodules were treated with an average largest diameter of 30 mm, and an average volume of 6.18 ml. We found that 139 nodules (55.4%) were spongiform or partially cystic. The majority of the nodules (142 nodules, 56.6%) were classified as solid type. There were 61 nodules (24.3%) received incomplete ablation at the first ablation because of unfavorable anatomy, and so required multiple RFA sessions. The others (190 nodules, 75.7%) were treated in a single session (Table 2).

Safety outcome (complications and side effects)

There were two cases (1.1%) with minor complications after RFA procedures. Both of them had voice change due to temporary recurrent laryngeal nerve palsy but had fully recovered after 1 month and 3 months respectively. No major complication was found (Table 1).

Table 2 Ultrasound characteristics of the treated thyroid nodules before ablation

Characteristics	Summary statistics (N = 251)
Largest diameter (mm) [median (range)]	30 (15–70)
Volume (ml) [median (range)]	6.18 (0.60–96.27)
Echogenicity [*n* (%)]	
Spongiform or partially cystic	139 (55.4)
Hyperechoic	79 (31.5)
Isoechoic	33 (13.1)
Solidity [*n* (%)]	
Solid	142 (56.6)
Mixed solid and cyst	75 (29.9)
Cyst	34 (13.5)
Number of RFA sessions [*n* (%)]	
1 session	190 (75.7)
2 sessions	41 (16.3)
3 sessions	10 (4.0)
4 sessions	6 (2.4)
5 sessions	3 (1.2)
6 sessions	1 (0.4)

RFA radiofrequency ablation

Efficacy outcome (volume reduction ratio) and related factors

Figure 1 and Table 3 showed the follow-up VRR of treated nodules estimated from linear regression model with the non-linear effect of the time of follow-up. The VRR enormously increased within the first 2 months after ablation to approximately 60%, then gradually augmented to 81% at 12 months. Our multivariable linear mixed effects model showed that initial solidity and number of RFA sessions were significantly related to the efficacy outcome (Table 4). After correcting for age, gender, initial volume, echogenicity of the nodule, number of RFA sessions, and time of follow-up, compared to a solid nodule, mixed and cystic types had significantly higher VRR of 6.52% (95% CI 0.90; 12.13) and 17.44% (95% CI 10.23; 24.64), respectively. Nodules with single RFA session had higher VRR of 7.30% (95% CI 2.64; 11.96) compared to those with multiple sessions. All other clinical and US characteristics, including age, gender, initial volume and echogenicity of the nodule, did not show significant relations to the VRR.

Discussion

This retrospective study showed a safe and effective profile of RFA in the treatment of benign thyroid nodules. Only two cases with temporary laryngeal nerve palsy occurred within 2 years on 184 patients with benign thyroid nodules treated by RFA. No major complication was found. Regarding efficacy, RFA reduced nodule volume by 46, 67, 74, and 81% after 1, 3, 6, and 12 months, respectively. In addition, we found that initial solidity in US examination significantly related to the VRR, of which mixed and cystic nodules had higher VRR compared to solid ones during the follow-up period.

Radiofrequency ablation has been used in the treatment of benign thyroid nodules in many countries. Many studies have evaluated its efficacy but the results have been heterogenous. The VRR varied from 50 to 85.5% after 3 months; 44.6 to 84.1% after 6 months; and 58 to 89.6% after 12 months [11–18, 23–36]. This may be due to different instruments, techniques, and types of thyroid nodules among the studies. Our results showed an average VRR during the follow-up period, compared to the literature. A few longer follow-up studies showed a gradual progression of VRR after 12 months, which was approximately 84–88% at 2 years, 89–90% at 3 years, 90–92% at 4 years, and 92–95% at 5 years [15, 17]. The expeditious increase of VRR within the first 3 months after RFA helps to solve the main problems of thyroid nodules, including jugular oppression, cosmetic problems and subjective symptoms,

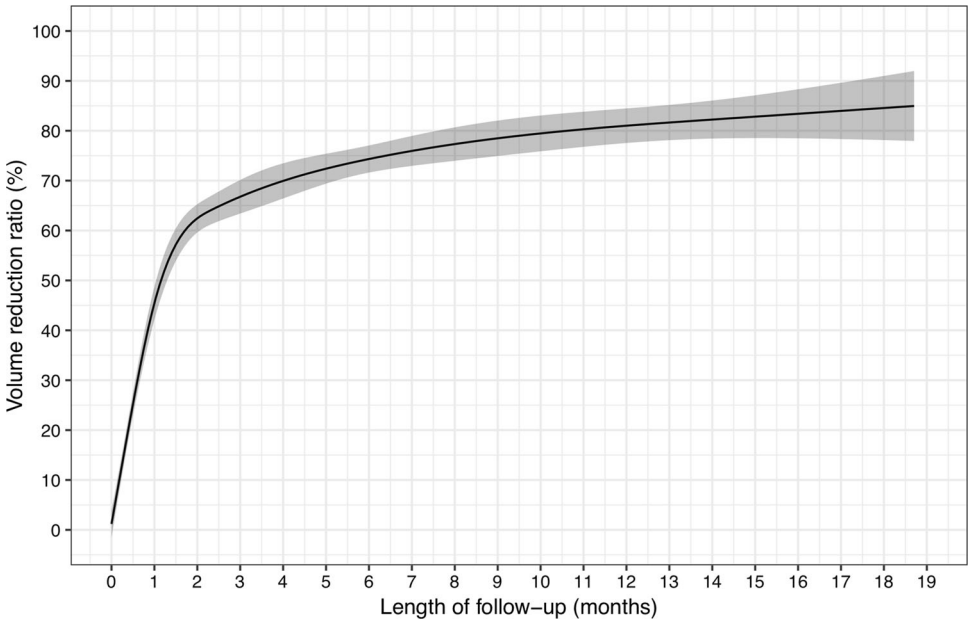

Fig. 1 Volume reduction ratio during follow-up period

Table 3 Volume reduction ratio estimation at 1, 3, 6, and 12 months

Follow-up	1 month	3 months	6 months	12 months
VRR (%) (95% CI)	45.5 (41.2; 49.7)	66.8 (62.4; 71.1)	74.3 (70.5; 78.2)	81.0 (76.5; 85.5)

CI: confidence interval, *VRR* volume reduction ratio

and the gradual progress of VRR after 3 months confirms the long-term efficacy of RFA in the treatment of thyroid nodules.

Although RFA could not remove thyroid nodules completely and immediately, as with surgery, its complication rate was found to be lower than that of surgery [11]. Literature demonstrated the safety profile of RFA in the treatment of thyroid nodules. A meta-analysis showed a trivial prevalence of complications of RFA in patients with benign thyroid nodules, which was 2.11% for overall complications, and 1.27% for major complications [37]. We found no major complication and 1.2% of minor complications in our current study. The low prevalence of complications in this study might be due to strictly applying the trans-isthmic approach and the moving-shot technique with a careful avoidance of the injury to the surrounding structures, including the laryngeal nerve, the carotid artery and vein, the esophagus, and the trachea, during RFA procedure. The trans-isthmic approach helps to pass the electrode through enough thyroid parenchyma, which prevents the leakage of hot fluid and a change in the position of the electrode tip when patients swallow or cough. Moreover, we did not try to perform complete ablation in case of unfavorable anatomy of the nodule, i.e. the distance between nodule edge and one of the important structures was less than 3 mm, to minimize the injury to these structures. A report of Xiaoyin et al. [38] assessed the risk for RFA based on specific location of the nodules, in which they classified the risk of complication into four grades (low risk, median risk, high risk, and very high risk), depending on the distance between nodule edge and adjacent important structures (the carotid sheath, the trachea, the esophagus, and the recurrent laryngeal nerve). They concluded that RFA safety was enhanced by using a hydrodissection technique according to risk assessment based on zoning and risk grading of thyroid nodules. With the advantages of a minimally invasive technique and a comparable efficacy to surgery, RFA gains the satisfaction of patients. In addition, RFA reduced the rate of hypothyroidism and hypoparathyroidism compared to surgery [11].

Factors related to the efficacy of RFA for thyroid nodules are still debated. Several studies found that initial volume and solidity of the nodule related to the rate of VRR: smaller and cystic nodules increased VRR during the follow-up period [12–17]. Other studies showed an

Table 4 Related factors to the progress of volume reduction ratio

Characteristics	MD	95% CI	*p* value
Gender			
Female	Ref	–	–
Male	− 0.07	− 5.79; 5.65	0.980
Age (per 1-year increase)	0.09	− 0.07; 0.24	0.273
Initial volume (per 1-ml increase)	0.12	− 0.05; 0.29	0.167
Echogenicity			
Spongiform or partially cystic	Ref	–	–
Hyperechoic	3.85	− 1.69; 9.39	0.175
Isoechoic	1.48	− 5.60; 8.56	0.683
Solidity			
Solid	Ref	–	–
Mixed solid and cyst	6.52	0.90; 12.13	0.024
Cyst	17.44	10.23; 24.64	<0.001
Number of RFA sessions			
Single session	Ref	–	–
Multiple sessions	− 7.30	− 11.96; − 2.64	0.002

The MDs of the VRR (%) and their 95% CIs between the categories (for categorical variables) and for each one-unit increase (for numeric variables) were estimated from a multivariable linear mixed effects model including gender, age, initial volume of the nodule, echogenicity, solidity, number of RFA sessions, and accounting for correlated data from participants with more than one treated thyroid nodules, and repeated measures of the VRR for one nodule during the follow-up period

CI confidence interval, *MD* mean difference, *Ref* reference, *RFA* radiofrequency ablation, *VRR* volume reduction ratio

association between vascularity and applied energy with VRR [13]. In agreement with previous findings, our study confirmed initial solidity as a factor affecting the VRR. Cystic or mixed nodules had higher VRRs compared to solid nodules. This may be due to the aspiration of cystic fluid of the nodules performed during the RFA procedure, which assists in reducing the nodule's volume quickly. The ablation destroys the nodule tissues which secrete the fluid and therefore prevent recurrence of a cystic nodule. In addition, we found that nodules with single RFA session had higher VRRs compared to those with multiple sessions. This is easy to explain because in our study, nodules with single RFA sessions were those that underwent complete ablation, and those with multiple sessions were those with incomplete ablation at the first RFA due to unfavorable anatomy. However, our results showed no association between initial volume of the thyroid nodule and the VRR. This might be because multiple sessions of ablation were used in our study, which helped us to ablate the viable portion of thyroid nodules detected during the follow-up period.

Our study has several limitations. Firstly, the retrospective design of this study did not allow us to follow-up the patients with the scheduled visits. To overcome this limitation, we used an appropriate method of analysis to estimate the VRR during the follow-up period. Secondly, there was an absence of histological confirmation of thyroid nodules, similar to other studies without surgery. However, we carefully enrolled patients with benign nodule(s) confirmed by two separate US-FNAs cytology and without suspicion of malignancy in US findings. Another limitation is that it was a single-center study with a relatively small sample size. This limitation motivates us to perform larger prospective multicenter studies to confirm our results.

In conclusion, RFA is safe and effective in the treatment of benign thyroid nodules. The VRR reached 66.8; 74.3; and 81% after 3, 6, and 12 months. Only two cases with minor complications occurred after RFA procedure. We also found the relation between initial solidity and the efficacy outcome, of which cystic nodules had significantly higher VRR compared to solid ones. Thus, RFA can be used as a routine treatment for patients with benign thyroid nodule(s). In the future, more prospective multicenter studies with long-term follow-up are required to improve the safety and efficacy of RFA.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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