Preliminary results of a prospective study on the efficacy and safety of single-session radiofrequency ablation in treating benign thyroid nodules

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Abstract

Objective: This study aimed to assess the safety and effectiveness of radiofrequency ablation (RFA) for benign thyroid nodules and identify independent factors affecting nodule volume reduction rates at one and six months post-treatment. **Materials and Methods**: Conducted at a single medical center, this prospective study included 80 benign thyroid nodules in 68 patients undergoing RFA. The procedures employed two key techniques: the trans-isthmic and moving-shot approaches. Clinical and ultrasound evaluations were performed at one and six months after treatment. The primary outcomes measured were the volume reduction ratio (VRR) at these intervals, while secondary outcomes included therapeutic success rates and complication rates. Multiple linear regression analysis was applied to pinpoint independent factors influencing VRR. **Results**: The study followed 68 patients with 80 nodules over one and six months. The average VRR was 41.00% at one month and 69.65% at six months, with an 82.9% therapeutic success rate at the six-month mark. Symptom and cosmetic scores showed significant improvement after one month, while thyroid function remained stable. Three cases of minor complications (temporary voice changes) were noted. Regression analysis indicated that both the internal component and initial volume of nodules were significantly associated with VRR at the one-month follow-up, while no significant associations were found between VRR at 6 months and any clinical or ultrasound features. **Conclusion**: RFA was shown to be a safe and effective treatment for benign thyroid nodules, offering an alternative therapeutic option with promising outcomes.

Keywords: *Radiofrequency ablation, thyroid nodules, efficacy and safety.*

1. INTRODUCTION

Thyroid nodules are the second most prevalent endocrine disorder after diabetes, with their occurrence widely varying based on the diagnostic technique employed. High-frequency ultrasound detects these nodules in 20 - 76% of adults [1, 2]. When a nodule is confirmed as benign, treatment generally aims to alleviate any related compressive or cosmetic symptoms [3, 4]. In Vietnam and worldwide, the main treatments for thyroid nodules include surgery and T4 suppressive therapy. Nonetheless, both approaches have drawbacks. Surgery poses risks such as complications from general anesthesia, potential iatrogenic hypothyroidism, and neck scarring [5]. Meanwhile, T4 suppressive therapy remains controversial and may result in adverse effects like iatrogenic hyperthyroidism, reduced bone density, atrial fibrillation, and an increased risk of cardiovascular events [6], [7].

Radiofrequency ablation (RFA) has become a minimally invasive technique alternative to surgery for treating benign thyroid nodules. It shows promising outcomes, including fewer complications, suitability for outpatient settings, and the preservation of thyroid function [8-10]. RFA works by using RF energy to heat and destroy thyroid tissue, resulting in nodule reduction and alleviation of related symptoms or cosmetic issues [11]. Two primary techniques, the moving-shot and trans-isthmic approaches, are typically employed for RFA under ultrasound guidance [12]. Numerous studies globally, including in Vietnam, have explored factors affecting RFA effectiveness for benign thyroid nodules, such as initial nodule volume, ultrasound characteristics, vascularity grade, and initial ablation ratio (IAR) [13-18]. However, some conclusions remain contentious. This prospective study at a single medical center aims to assess the safety

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and effectiveness of RFA in treating benign thyroid nodules and to identify independent factors related to nodule volume reduction rates after 1 month and 6 months post-ablation.

2. MATERIALS AND METHODS

Study design and patients' selection

This prospective single-center study was approved by The Institutional Ethics Committee of Hue University of Medicine and Pharmacy (number: H2023/050). All patients provided written informed consent for the procedures.

Inclusion criteria following: (1) Benign thyroid nodule(s) confirmed by ultrasound (US) and at one or two separate US-guided fine-needle aspirations (US-FNAs) or US-guided core needle biopsies (US-CNBs), following the guidelines of the Asian Conference on Tumor Ablation Task Force [19]; (2) Reports of pressure symptoms (pain, compressive symptoms, neck discomfort), cosmetic concerns, or anxiety related to the tumor. Refusal to undergo surgery.

Exclusion criteria following: (1) Largest nodule dimension less than 20 mm. (2) Nodule(s) exhibiting established or suspected malignant features on US (ACR-TIRADS 4 to 5) or cytology (Bethesda Class III to VI). (6) Current thyrotoxicosis. (7) Patients with a short life expectancy due to severe comorbidities. (8) Pregnancy. (9) Patients lost to follow-up.

Between June 2023 and September 2024, 68 patients with 80 thyroid nodules who underwent RFA treatment were enrolled in this study.

Measurement and assessment

Pre-treatment assessment and radiofrequency ablation procedure

Before the RFA, patients completed a full evaluation including: a conventional clinical exam, ultrasound (US) imaging, one or two US-guided fine-needle aspirations (US-FNAs) or core needle biopsies (US-CNBs), and necessary laboratory tests. Patients rated their compression symptoms on a 10-cm visual analog scale (VAS) ranging from 0 to 10 upon registration. An endocrinologist assessed cosmetic impact using a grading scale: grade 1 (no palpable mass), grade 2 (palpable mass without a cosmetic issue), grade 3 (cosmetic issue upon swallowing), or grade 4 (visible cosmetic concern) [4, 19, 20].

Experienced radiologists with over five years in this field performed real-time ultrasound examinations, utilizing an 8 - 12 MHz linear probe (Acuson NX2 or NX3, Siemens Medical Solution, California, USA) to evaluate the nodules' position (right, left, isthmus lobe), size, volume, solid/cystic composition, echogenicity, vascularity, and volume ($V = \pi abc/6$, where a, b, c are the 3 diameters). US-guided FNA or CNB tests were conducted by a licensed endocrinologist with similar experience, and thyroid-stimulating hormone (TSH) and free thyroxine (FT4) levels were measured. Before proceeding, each patient received information about the benefits and risks of RFA.

All procedures were performed by the same endocrinologist in the outpatient department at the Center of Endocrinology and Diabetes, Danang Family Hospital, Vietnam. During RFA, patients were positioned supine with slight neck extension (**figure 1**). After sterilizing the skin, 2% lidocaine was administered locally at the needle entry site. A monopolar electrode (18-gauge, 5 mm or 7 mm active tip) connected to a radiofrequency generator (CoATherm AK- F200, APRO KOREA Inc., Gyeonggi-do, Korea) (**figure 2**) was inserted into the nodule via the trans-isthmic approach under ultrasound guidance.

Figure 1. Radiofrequency ablation (RFA) procedure.

Nodules were ablated with the moving-shot technique, and in certain cases, hydro-dissection with a slow 5% dextrose injection was applied to safeguard critical structures such as nerves and arteries. Complete ablation was confirmed by observing a transient hyperechoic zone [12, 19, 20]. For cystic or predominantly cystic nodules, aspiration was performed prior to ablation. Patients were monitored in the hospital for 60 minutes after the procedure and were discharged if no complications occurred.

Figure 2. Radiofrequency generator and monopolar electrode

Follow-up of the patients

Follow-up evaluations took place at 1 and 6 months after treatment. These follow-up assessments included ultrasound (US) examinations, thyroid function tests (TSH, FT4), and evaluations of symptom and cosmetic scores. The volume reduction rate (VRR) of the treated nodule was determined using the formula:

$$\text{VRR (\%)} = \frac{(\text{Baseline volume} - \text{posttreatment volume})}{\text{Baseline volume}} \text{ X } 100\%$$

A VRR over 50% at the 6-month follow-up ultrasound was defined as a therapeutic success [16]. Additionally, any specific complaints or concerns raised by patients during the follow-up period were documented.

Efficacy Outcome

The primary outcomes were evaluated based on the reduction in nodule volume (VRR) at 1 and 6 months following ablation. Achieving a VRR greater than 50% of the initial nodule volume, as measured during each follow-up ultrasound, was defined as therapeutic success [16]. Secondary outcomes focused on improvements in symptom severity, cosmetic appearance, and maintenance of stable thyroid function test results.

Safety Outcome

Safety outcomes, such as complications and side effects, were monitored following the guidelines set by the international working group on image-guided tumor ablation [21]. Major complications were classified as those causing significant morbidity or disability, requiring advanced care, hospital admission, blood transfusion due to hemorrhage, or leading to permanent voice changes. Minor complications included pain, temporary voice changes, nausea, and skin burns.

Demographic Characteristics and Other Factors

Demographic data collected in this study included age (as a continuous variable) and sex (as a categorical variable: male or female). Treatment variables included ablation time (in minutes), RF energy (kwat), maximum and minimum RF power (in watts), and the volume of lidocaine used (in ml) using cold dextroxe 5% (as a categorical variable: yes or no), volume of fluid aspiration (ml).

Statistical analysis

Statistical analyses were conducted using SPSS version 20.0 for Windows. Safety outcomes were presented as the number of events along with their respective percentages. To evaluate RFA efficacy, the mean and standard deviation (SD) of the volume reduction ratio (VRR) at 1 and 6 months post-ablation were calculated. Changes in nodule volume, largest diameter, FT4, and TSH from baseline to 1 and 6 months post-treatment were assessed using either the ANOVA test or Kruskal-Wallis test, as appropriate. To compare volume reduction rate and therapeutic success rates between the 1-month and 6-month follow-ups, the Friedman test or Wilcoxon signed-rank test was applied when data did not meet the assumptions for normal distribution, serving as an alternative to paired t-tests. Multiple linear regression analysis was used to identify independent predictors of efficacy, specifically VRR at 1 and 6 months. Statistical significance was defined as a p-value of less than 0.05.

3. RESULTS

From June 2023 and September 2024, 68 patients with 80 nodules who had undergone treatment using the RFA were enrolled in this study.

Baseline characteristics of the patients and nodules

Table 1 presents the baseline characteristics of the patients and thyroid nodules. The majority of patients were female (83.8%), with a mean age of 44.82 ± 15.3 years (ranging from 17 to 77). The mean scores for symptoms and cosmetic appearance were 4.91 and 3.10, respectively. At the initial assessment, the average largest diameter of the thyroid nodules was 32.21 ± 10.00 mm (range 20.7 - 70), with an average volume of 10.05 ± 10.31 ml (range 1.26 - 58.82). Of the 80 nodules treated, 62 were solid (77.5%), 14 were mixed solid (17.5%), and 4 were cystic (5.0%). Thyroid function tests showed mean TSH and FT4 levels of 1.32 mUI/ml and 1.26 ng/dL, respectively.

Table 1. Baseline characteristics of the patients and nodules

Characteristics	Summary statistics
Number of patients	68
Number of nodules	80
Age (years) [(mean ± SD) (range)]	44.6 ± 15.3 (17 - 77)
Female [n (%)]	57 (83.8)
Nodule position [n (%)]	
Left	39 (48.8)
Isthmus	1 (1.3)
Right	40 (50.0)
Mean nodule volume (ml) [(mean ± SD) (range)]	10.05 ± 10.31 (1.26 - 58.82)
Mean largest nodule diameter (mm) [(mean ± SD) (range)]	32.21 ± 10.00 (20.7 - 70)
Internal nodule component [n (%)]	
Solid	62 (77.5)
Mix solid	14 (17.5)
Cyst	4 (5.0)
Vascularity grade [(mean ± SD) (range)]	1 ± 0.99 (0 - 4)
FT4 (ng/dL) [(mean ± SD) (range)]	1.26 ± 0.28 (0.66 - 2.35)
TSH (mIU/ml) [(mean ± SD) (range)]	1.32 ± 0.72 (0.24 - 3.47)
Thyroglobulin [(mean ± SD) (range)]	144.24 ± 162.54 (3.98 - 500)
Cosmetic score [(mean ± SD) (range)]	3.10 ± 1.05 (1 - 4)
Symptom score [(mean ± SD) (range)]	4.91 ± 3.83 (0 - 10)

Characteristics of nodule treatment and safety outcome

Table 2 provides a summary of treatment characteristics and safety outcomes. The average volume of 2% lidocaine used was 8.68 ml, ranging from 4 to 20 ml. RF power ranged from a minimum of 23.09 watts to a maximum of 49.93 watts. The average energy and ablation duration were 26.60 KJ and 16.81 minutes, respectively. Minor complications occurred in only 3 cases (4.41%), presenting as transient voice changes that fully resolved within one month following an injection of cold 5% dextrose (0°C to 4°C). No major complications were reported.

Table 2. Characteristics of nodule treatment and safety outcome.

Characteristics	Summary statistics
Lidocaine 2% (ml) [(mean ± SD) (range)]	8.68 ± 3.08 (4 - 20)
Min RF power (Walt) [(mean ± SD) (range)]	23.09 ± 5.11 (15 - 40)
Max RF power (Walt) [(mean ± SD) (range)]	49.93 ± 15.96 (25 - 85)
Energy (KJ) [(mean ± SD) (range)]	26.60 ± 23.03 (3.81 - 125.93)

Ablation time (minute) [(mean ± SD) (range)]	16.81 ± 10.4 (4 - 58)
Complication [n (%)]	
Minor complication	3 (4.41)
Major complication	0

The treatment outcome and its related factors

Table 3 summarizes the treatment outcomes. The average largest nodule diameter significantly decreased from 32.21 ± 10.00 mm initially to 26.85 ± 9.18 mm at 1 month post-ablation and further to 19.37 ± 7.10 mm at 6 months post-ablation ($p < 0.0001$). Mean nodule volumes were 10.05 ± 10.31 ml initially, reducing to 5.64 ± 5.61 ml at 1 month and 2.42 ± 3.20 ml at 6 months post-treatment ($p < 0.0001$). This corresponded to a volume reduction ratio (VRR) of approximately 41.00% at 1 month and 69.65% at 6 months. Therapeutic success rates were 33.8% at 1 month and 82.9% at 6 months. Symptom scores and cosmetic scores significantly improved by the 1-month follow-up, decreasing from 4.91 to 2.00 (symptom score) and from 3.10 to 1.45 (cosmetic score), both with $p < 0.05$. Thyroid function tests remained stable throughout.

Table 3. Outcomes for 80 benign thyroid nodules after RF ablation

Variables	Before	1 Month	6 Months	p
Largest diameter (mm)	32.21 ± 10.00	26.85 ± 9.18	19.37 ± 7.10	< 0.05
Volume (ml) (mean ± SD)	10.05 ± 10.31	5.64 ± 5.61	2.42 ± 3.20	< 0.05
Volume reduction rate (%)		41.00 ± 23.86	69.65 ± 21.09	< 0.05
Symptom score	4.91 ± 3.83	2.00 ± 2.56		< 0.05
Cosmetic score	3.10 ± 1.05	1.45 ± 0.78		< 0.05
Therapeutic success [n(%)]		26/77 (33.8)	29/35 (82.9)	< 0.05
TSH (mIU/ml) (mean ± SD)	1.32 ± 0.72	1.39 ± 1.01	1.33 ± 0.75	> 0.05
FT4 (ng/dL) (mean ± SD)	1.26 ± 0.28	1.25 ± 0.19	1.23 ± 0.16	> 0.05

Table 4 details the multiple linear regression analysis results, indicating that initial nodule volume (β = 0.92; 95% CI [0.13-1.71]) and internal component of the nodule (β = 10.64; 95% CI [1.26 - 22.5]) were independent predictors of the VRR at 1 month post-ablation ($p < 0.05$). No significant associations were found between VRR at 6 months and clinical or ultrasound characteristics such as age, sex, initial volume, TSH, FT4, cosmetic and symptom scores, ablation time, lidocaine volume, RF power, internal component, or largest nodule diameter.

Table 4. Factors independently predictive of volume reduction at 1 month post-ablation via multiple linear regression analysis

Variable	B	95% CI of B		p
		Lower	Upper	
(Constant)	45.14	-10.42	100.69	0.11
Age	-0.56	-0.47	0.35	0.78
Sex	-5.34	-23.56	12.88	0.23
Internal component of the nodule	10.64	1.26	22.55	0.04
TSH	-5.32	-14.1	3.45	0.229
FT4	-4.85	-25.56	15.86	0.64
Cosmetic	-2.25	-10.77	6.28	0.59
Symptom	0.10	-2.59	2.81	0.94
Ablation time	0.469	-1.33	2.26	0.60
Volume lidocaine 2%	0.97	-1.106	3.05	0.35

min RF power	0.16	-1.18	1.5	0.86
max RF power	-0.213	-1.12	0.7	0.6
Initial volume	0.92	0.13	1.7	0.023

Representative typical cases

A 60-year-old woman presented with a tumor on the left side of her neck (**figure 3A**, red arrow), experiencing difficulty swallowing and expressing cosmetic concerns. Thyroid ultrasound revealed a solid nodule on the left side with an approximate volume of 7.7 ml (**figure 4A**). Her cosmetic score was 4, symptom score was 7, and vascularity grade was 3 (**figure 4B**). Pre-ablation ultrasound images, thyroid function tests, and two US-FNA procedures confirmed the nodule was benign.

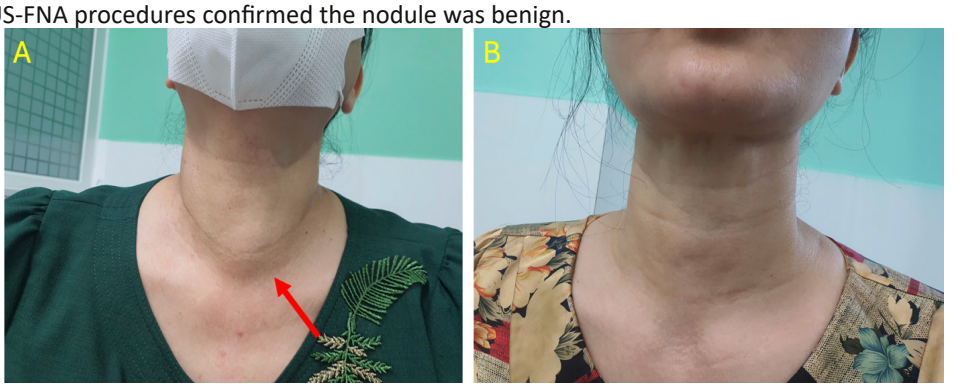

Figure 3. A 60-year-old woman with a left thyroid nodule at baseline and 6 months after ablation

We treated her using radiofrequency ablation (RFA) with 18-gauge, internally cooled electrodes with a 7 mm active tip. The procedure utilized a trans-isthmic approach and moving-shot technique. At one - and six-month follow-ups, the volume reduction rates (VRR) were 40.26% and 75.32%, respectively, with noted improvements in both cosmetic and symptom scores (**figure 3B**). Vascularity grade after 6 months is 0 (**figure 4C and 4D**).

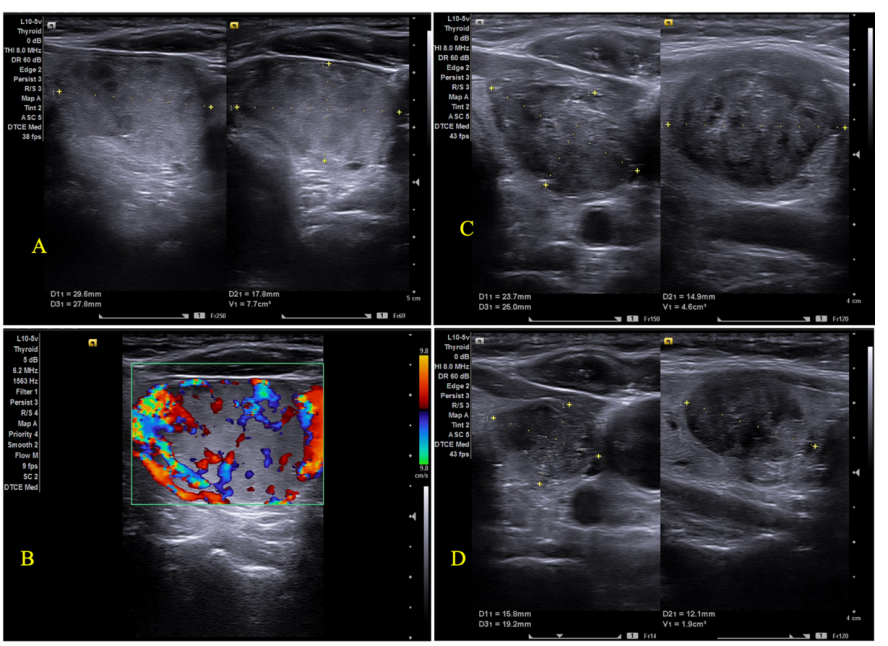

Figure 4. A 60-year-old woman presented with left neck bulging who underwent radiofrequency ablation for benign thyroid nodule treatment. (A) initial volume of large thyroid nodule:, V = 7.7 ml. (B) vascularity grade 3 in US. (C) and (D) After 1 month and 6 months ablation, VRR were 40.26% and 75.32%

4. DISCUSSION

In a one-year study of 68 patients, transient voice changes occurred in only three cases (4.41%), with no major complications reported. Thyroid function remained stable at both 1-month and 6-month follow-ups. In terms of efficacy, RFA reduced nodule volume by 41.00% at 1 month and 69.65% at 6 months post-ablation, corresponding to therapeutic success rates of approximately 33.8% and 82.9%, respectively. Additionally, patients showed significant improvements in symptom and cosmetic scores after 1 month. Our findings indicated that initial nodule volume and internal components were significantly associated with VRR at the 1-month follow-up, though no factors were significantly related to VRR at the 6-month post-ablation.

Benign thyroid nodules are relatively common, with traditional treatments including surgery and T4 suppressive therapy. However, these approaches have limitations, such as risks from general anesthesia, iatrogenic hypothyroidism, neck scarring, atrial fibrillation, and an increased risk of cardiovascular morbidity and mortality [6], [7]. Radiofrequency ablation (RFA) has been widely adopted globally as a minimally invasive treatment for benign thyroid nodules and has shown to be safe and effective, though results across studies have varied. Reported VRR values range from 32.7% to 58.2% at 1 month [22-24] and from 50% to 85.5% after 3 months, depending on the specific ablation system, technique, and nodule characteristics [25-27]. Our study's VRR outcomes at 1 month and 6 months align with these findings. Studies with extended follow-up show a progressive increase in VRR - approximately 44.6% to 84.1% at 6 months, 58% to 89.6% at 12 months, and 84% to 88% at 2 years [25], [28-33]. The significant nodule volume reduction within the first 6 months post-ablation contributes to the relief of symptoms and cosmetic concerns.

The safety profile of thyroid RFA has been well-documented in the literature. Complication rates in RFA treatment of benign thyroid nodules show an overall complication rate of 2.11% and a major complication rate of 1.27% [34-36]. In our study, no major complications occurred, and only 2.56% of cases experienced minor complications (transient voice change). This favorable outcome is likely due to the strict application of two key techniques: the moving-shot technique and the trans-isthmic approach - which help prevent hot fluid escape and minimize the electrode's movement when patients speak, swallow, or cough, thereby reducing damage to surrounding tissues [12, 19]. Additionally, in cases requiring complete ablation near sensitive structures like nerves and arteries, the hydro-dissection technique was applied by slowly injecting 5% dextrose. For transient voice changes post-RFA, we also used cold 5% dextrose (0°C to 4°C) via hydro-dissection for management [37]. Our study also found that thyroid function tests remained stable, consistent with findings from other studies that report a lower incidence of hypothyroidism and hypoparathyroidism with RFA compared to surgery.

Various studies have identified different factors associated with the efficacy of RFA in treating benign thyroid nodules. Some suggest that initial nodule volume is a strong predictor of RFA success [13, 14, 15, 31], while others point to nodule solidity as a key factor influencing treatment outcomes [14, 15, 17]. Jung et al. identified both solidity and delivered energy as independent predictors of final volume reduction [16]. Our findings align with these, confirming that the nodule's internal composition, especially cystic or predominantly cystic nodules, is an independent factor influencing VRR. Higher VRRs were observed in these cases, likely due to the pre-RFA aspiration of cystic fluid, which quickly reduced nodule size. Additionally, ablating the vascular solid components reduced recurrence in cystic nodules. However, our data did not reveal any correlation between these factors (baseline patient and nodule characteristics, treatment details) and VRR at the 6-month follow-up. Sim et al. recently highlighted the Initial Ablation Ratio (IAR) as highly correlated with VRR, suggesting that an IAR over 70% and a VRR over 50% are indicators of therapeutic success post-RFA [18].

This study has some limitations, including irregular follow-up intervals, a single-center setting, a modest sample size, and a relatively short follow-up period of 1 and 6 months. Additionally, variables such as nodule vascularity and Initial Ablation Ratio (IAR) were not included, which limits the findings. These constraints suggest the need for larger, multicenter prospective studies with extended follow-up to validate these results.

In conclusion, RFA was shown to be a safe and effective treatment for benign thyroid nodules, achieving VRRs of 41.00% and 69.65% at 1 and 6 months post-ablation, respectively. Minor complications, specifically transient voice change, occurred in three cases, and thyroid function remained stable throughout. Our findings identified

initial nodule volume and internal component as key factors influencing VRR at the 1-month follow-up, while no significant associations were found between VRR at 6 months and any clinical or ultrasound features. RFA thus offers a promising alternative treatment with encouraging results and minimal complications.

List of Abbreviations:

ACR-TIRADS: American College Of Radiology - Thyroid Imaging Reporting and Data Systems

CI: Confidence interval

CNB: Core needle biopsy

FNA: Fine Needle Aspiration

FT4: Free Thyroxine

IAR: Initial ablation ratio

RF: Radiofrequency

RFA: Radiofrequency ablation

SD: Standard deviation

TSH: Thyrotropin

VRR: Volume Reduction Rate

US: ultrasound

Declarations

Ethics approval and consent to participate: Written informed consent form was given to patients

Consent for publication: Not applicable

Availability of data and materials: Availability of data and materials supporting our findings will be shared upon request.

Competing interests: Conflict of interest relevant to this article was not reported.

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