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Efficacy of Radiofrequency Ablation of Benign thyroid Nodules

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Abstract

Background: Thyroid nodule(s) is the second most common endocrine disorder after diabetes. They are more common in females (4:1-F:M) and have an increasing prevalence with increasing age and reduced iodine intake. **This study aimed to** evaluate the efficacy and safety of ultrasound-guided radiofrequency ablation (RFA) for treatment of benign thyroid nodules as well as preservation of the normal thyroid function. **Methods:** This prospective study included 30 patients with pathologically proved benign thyroid nodules. Patients included in the study were (5 males and 25 females) ranging in age between 21 and 60 years with a mean age of 32.5 years. **Results**: There was significant volume reduction of the ablated thyroid nodules by 68.6% at 3-month follow up (P value = 0.0001). Also, the compressive symptoms score and cosmetic scale improved significantly after RFA (P value = 0.0001). **Conclusion:** RFA was effective in reducing the size of the benign thyroid nodules and in controlling nodule-related compressive symptoms as well as cosmetic problems. RF ablation can be used as an alternative non-surgical minimally invasive treatment for patients with benign thyroid nodules.

Keywords: Radiofrequency Ablation; Benign thyroid Nodules; Ultrasound-Guided; Thyroid Function.

Introduction

Thyroid nodule (s) is the second most common endocrine disorder after diabetes. They are more common in females (4:1-F:M) and have an increasing prevalence with increasing age and reduced iodine intake [(1)].

Thyroid nodules are common incidental finding on imaging, present in ~10% of CT and MRI neck examinations, (range 20-76%) of neck ultrasound and (range 50-65%) of autopsies. They can also be found on clinical examination as palpable lesions in the neck, although this clinical finding does not represent a thyroid nodule if there is no imaging correlate [(2)]. Although most thyroid nodules are benign asymptomatic, stable, slowly- growing over time and

require no treatment. However, some benign nodules may require treatment for associated compression, dysfunction symptoms and/or cosmetic problems [3].

Surgery and radioiodine therapy have been used for patients with symptomatic thyroid nodules, although both surgery and radioiodine therapy can cause complications such as voice change, iatrogenic hypothyroidism, risk of general anesthesia and scarring of the neck [4].

In the last decade, ultrasound-guided minimally invasive techniques have been introduced into clinical practice as an alternative treatment for benign thyroid nodules as well as selected cases of differentiated thyroid cancer (DTC) such as neck recurrences. These techniques go far beyond ethanol ablation, which was the first technique to be introduced in the 90s; they include laser, radiofrequency and microwave ablation as well as high intensity focused ultrasound ablation (HIFU) [5].

A recent European survey on the use of ultrasound-guided minimally invasive techniques for thyroid nodules showed that today radiofrequency ablation (RFA) is the most frequently chosen, and so far, it has been the most thoroughly assessed one [6].

The purpose of this study was to evaluate the efficacy and safety of ultrasound-guided radiofrequency ablation (RFA) for treatment of benign thyroid nodules as well as preservation of the normal thyroid function.

Patients and methods

This prospective study included 30 patients with pathologically proved benign thyroid nodules, was conducted at Radiology Departments of Benha and Zagazig Universities, Egypt from August 2022 till March 2023.

Approval of the study protocol by the institutional review board (IRB). Written informed consent was obtained from each patient before the procedure.

Ethical approval: All enrolled participants gave their agreement in a written consent as well as Benha Faculty of Medicine's Research Ethics Committee authorized the project {M.D.3.5.2022}.

Inclusion criteria were patients with symptomatic “compression or functional symptoms” or cosmetic problems due to a thyroid nodule, No malignant ultrasound findings (i.e., not more than TIRADS-3), Cytological confirmation of a benign thyroid nodule on fine needle aspiration (FNA) or true cut biopsy according to the size of the nodule and native patients with no history of thyroid surgery or intervention.

Exclusion criteria were primary thyroid cancer, history of neck radiation therapy, current pregnancy, contralateral laryngeal nerve palsy and almost completely cystic nodules (< 10% solid components).

Patient preparation:

Before the procedure all patients were clinically evaluated for compression symptoms or cosmetic problems. At the time of enrollment, the patients were asked to rate their nodule-related symptoms on a 10-point visual analogue scale (range 0-10) and a cosmetic grading score was assessed; 1- No palpable mass, 2- No cosmetic problem but a palpable mass.

3- Cosmetic problem on swallowing only and 4- An easily detected cosmetic problem (7).

Each nodule is evaluated for its composition either solid "defined as more than 75 % solid component", cystic defined as more than 75 % cystic component" or complex "defined as 25 % - 75 % solid component" as well as three orthogonal diameters (the largest diameter and two perpendicular diameters) for each nodule and its volume was calculated according to "ellipsoid formula": $V = \pi abc/6$ where (V) is the volume, (a) is the largest diameter and (b) and (c) are the two perpendicular diameters. Laboratory examination included thyroid profile (serum free T3, free T4 thyroid hormone level and TSH) as well as coagulation profile (PT and INR).

Procedure:

RFA is typically performed as a single-day admission, outpatient procedure. The ablation procedure is performed by an interventional radiologist with expertise in thermal ablation. The patient is positioned supine with their neck extended, rolls and wedges may be used to optimize patient comfort. Sedation may range from local anesthesia only to moderate sedation based on patient factors (anticipated pain tolerance, ability to remain still, anesthetic risks and expected procedure duration), but most of the thyroid ablations are now performed under sedation. After sterilization of the neck at the site of electrode insertion, we inject lidocaine 2% in the subcutaneous tissues with copious amounts at the thyroid capsule and sometimes along the tracheal surface to limit the patient pain (8).

Ground adhesive pads are adhered to both thighs and connected to the RF generator while the generator is connected to RF electrode. Hydro-dissection is done using 5 % dextrose as it is easily re-absorbed by the tissues. It is performed either under the skin to prevent the skin burn or to distance other critical structures adjacent to the ablation zone (9). An electrode with an active tip 5, 7, and 10 mm according to the size of the nodule is usually used.

After US confirmation of the target lesion, the RFA electrode is inserted in an oblique plane through tans-isthmic approach to enter the thyroid gland and the target nodule along its largest dimension.

This trans-isthmic approach has several advantages; allowing the real-time confirmation of electrode placement, increases the distance between the active tip and the skin surface, helping to reduce skin burns, reduce the exposure of the danger triangle to heat as well as minimize the movement of the electrode during swallowing and talking. Also, it prevents the hot liquids from extending back along the electrode and into the perithyroidal tissue (10).

Techniques of thyroid RFA:

Multiple-shot technique: This technique involves dividing the thyroid nodule into multiple small ablation units which are then ablated to create a larger ablation area that fits the contour of the ablated nodule. The power of the electrode is switched off during repositioning of the electrode (11).

Moving-shot technique: It is similar to the multiple shot technique but the power delivery to the electrode remains on during repositioning of the electrode. The

electrode is inserted at the deepest and most remote portion of the target nodule and then moved backward as the needle is gradually withdrawn. This technique is for more advanced users and it is the fastest, most efficient method as it ensures adequate coverage of the nodule and prevents overtreatment of the periphery of the nodule.

The size of the ablation zone depends on ablation power, time and electrode size. Generally it can ablate 1 mm distal to the electrode tip and 7 mm in width surrounding this active tip (12).

Patient and pain monitoring:

To reduce the pain during RFA, it is important to inject sufficient lidocaine (5-10 ml) into the skin puncture site and thyroid capsule as the sensory nerves are usually present at the thyroid capsule but not inside the thyroid gland. It is important to keep talking to the patient during the procedure to monitor any voice change and asking the patient for any pain. So general anesthesia or heavy sedation may delay detection of complication and can cause serious complications during ablation. However, if the pain is not tolerated by the patient, the ablation should be stopped, reduce the RF power or use mild sedative (13).

Postprocedural Care:

After the procedure, patients who received moderate sedation are observed for 30 minutes and those who received general anesthesia are observed for 2 hours. The monitoring includes pain scoring, blood pressure, heart rate and oxygen saturation. Adequate pain relief is maintained with ice packs and oral analgesic medication such as acetaminophen if needed. Most patients are dismissed without any prescription of pain medication. The patients should be followed up clinically and sono-graphically for the residual volume of the ablated thyroid nodule, the compressive symptoms, cosmetic problems and for thyroid function test (14).

Outcome:

The primary outcome was the volume reduction after three months post RF ablation, the volume reduction ratio (VRR) was calculated as follows: VRR = (initial volume - final volume) x 100/ initial volume. In addition, outcomes such as changes in the largest diameter, compressive symptoms score and the cosmetic scale before and after RF ablation were compared.

Statistical analysis:

All data were collected, tabulated and statistically analyzed using (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.2015). Quantitative data were expressed as the mean ± SD & median (range), and qualitative data were expressed as numbers and percentage. Wilcoxon Signed Ranks test was used to compare paired non-normally distributed variables. McNemar test was used to compare paired categorical variable Pearson' correlation coefficient was calculated to assess relationship between various study variables, (+) sign indicate direct correlation & (-) sign indicate inverse correlation, also values near to 1 indicate strong correlation & values near 0 indicate weak correlation. All tests were two sided. P-value < 0.05 was considered statistically significant and p-value ≥ 0.05 was

considered statistically non-significant (NS).

Results

The mean age of studied patients was 32.5 ± 9.34 years with a range between 21 and 60 years. Among the included cases there were 5 males (16.7%) and 25 females (83.3%). The mean initial volume of the thyroid nodules was 11.02 ± 14.4 ml with a range between 0.4- and 77.33-ml. **Table 1**

There was significant volume reduction of the ablated thyroid nodules by 68.6% at 3-month follow up (P value = 0.0001). As the mean initial volume of thyroid nodules was 11.02 ± 14.4 ml with a range between 0.4 and 77.33 ml, reduced post ablation to 3.84 ± 4.44 ml with a range between 0.04- and 19.66-ml. Also, there was significant improvement in the compressive symptoms score after RFA (P value = 0.0001). As the mean initial compressive symptoms score was 5.33 ± 1.83 with a range between 4 and 10 that was reduced in post ablation follow up to 2.47 ± 1.57 with range between 0 and 5. **Table 2**

There was significant improvement in cosmetic scale post RFA, (P value = 0.0001). As the mean initial cosmetic scale was 2.87 ± 0.68 with range between 2 and 4 that was reduced in post ablation follow up to 1.87 ± 0.78 with range between 1 and 4. **Table 3**

The initial thyroid function in the studied patients was euthyroid in 28 patients (93.3%) and hyperthyroid in 2 patients (6.7%), that was converted to euthyroid state in all post ablation patients. **Table 4**

A 37-year-old female patient with RT lower neck bulge, complaining of dysphagia and dyspnea (her cosmetic scale was 4 and compressive symptoms score was 7) with normal thyroid function. US showed well defined predominantly solid isoechoic nodule "TIRADS-3" seen at the RT thyroid lobe with an initial volume about 14.18 ml. FNA revealed follicular lesion "Bethesda II". The patient refused surgery. **Figure 1**

Table 1: Age distribution characteristics and Characters of thyroid nodules of the studied group

Demographic data		**Number of cases (N = 30)**
Age (Years)		
Mean ± SD		32.5 ± 9.34
Gender		
Male		5 (16.7%)
Female		25 (83.3%)
Characters of thyroid nodules		
Mean initial volume of the nodule (ml)		11.02 ± 14.4
US findings (TIRADS)	TIRADS-2	8 (26.7%)
	TIRADS-3	22 (73.3%)
Consistency		
Solid		21 (70%)
Cystic		2 (6.7%)
Complex		7 (23.3%)
Function of thyroid nodules		
Nonfunctioning thyroid nodules		28 (93.3%)
Autonomous functioning thyroid nodules (AFTN)		2 (6.7%)

Table 2: Volume of the thyroid nodules pre and post RFA, and Compressive symptoms score pre and post RF procedure

Volume of thyroid nodule	Pre ablation	Post ablation	VRR	^{W}p
Mean ± SD	11.02 ± 14.4	3.84 ± 4.44	68.6%	0.0001*
Median (Range)	7.2 (0.4 - 77.33)	2.07 (0.04 - 19.66)		
Compressive Symptoms score				0.0001*
Mean ± SD	5.33 ± 1.83	2.47 ± 1.57		
Median (Range)	4 (4 - 10)	3 (0- 5)		

*: statistically significant as P value <0.05

Table 3: Cosmetic scale pre and post RF procedure

Cosmetic Scale	Pre ablation	Post ablation	p
Mean ± SD	2.87 ± 0.68	1.87 ± 0.78	0.0001*
Median (Range)	3 (2 - 4)	2 (1 - 4)	

*: statistically significant as P value <0.05

Table 4: Thyroid function pre and post RF procedure.

Thyroid function	Pre ablation N (%)	Post ablation N (%)	^{M}p
Euthyroid	28 (93.3%)	30 (100%)	0.5
Hyperthyroid	2 (6.7%)	0%	

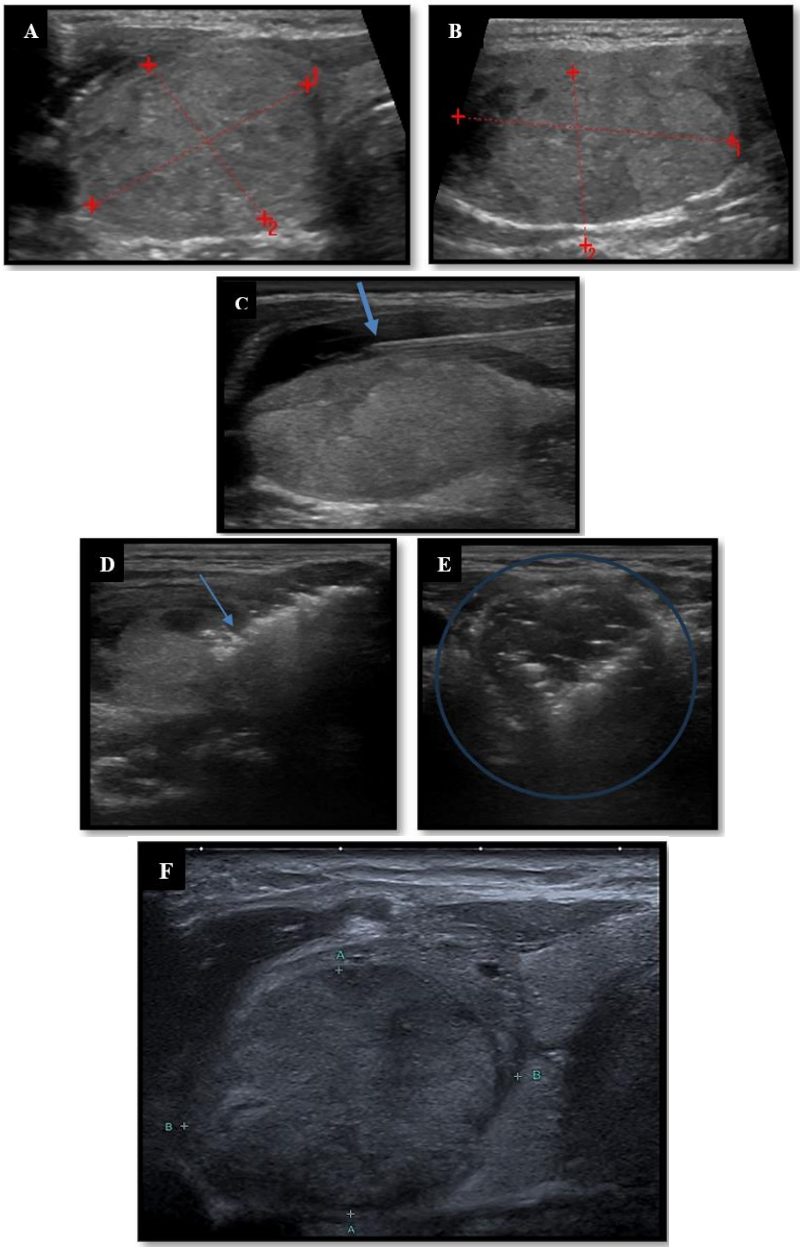

Figure 1: A & B: RT thyroid nodule "TIRADS-3" with an initial volume about 14.18 ml, (C) Before beginning of the RF procedure, hydro-dissection was done using 5 % dextrose injected through syringe, (D) Gas bubbles surrounding the RF electrode "arrow", (E) Gas bubbles and necrotic hyperechoic vaporization within the ablated region "circle" during RF procedure and (F) Ablated RT thyroid nodule with a final volume about 7.78 ml.

Discussion

This prospective study was conducted at Radiology Departments in Benha and Zagazig Universities, Egypt to assess efficacy of radiofrequency ablation of benign thyroid nodules & performed on 30 patients with pathologically proved benign thyroid nodules, their mean age was 32.5 years and range between 21 and 60 years.

Along this result, who reported that their study was conducted on 37 participants with mean age about 45 years and range between 22 and 60 years which is close to our age group [(15).]

In the current study most of the included participants were females representing

83.3 % of the study population while the remaining patients were males representing 16.7 % of the study population. This is almost agreed with as in the study previously done where it was reported that the thyroid nodules were common in female gender representing 77.1% of their included cases [16]. The same findings were also confirmed by another study, the females formed 88.2 % of their studied group [17].

Regarding the initial base line data & characteristics of the thyroid nodules; in the current study the mean initial volume (pre-ablation) of thyroid nodules was 11.02 ± 14.4 ml with a range between 0.4 and 77.33 ml.

This is close to what reported in the researchers study that mean initial volume of the pre ablation nodules was 15.6 ml with a range between 2.5 and 74 ml [15]. Also, reported that the mean initial volume of the pre ablation nodules was 13.07 ± 8.45 ml and range between 2.2 and 35.5 ml [18].

In our study eight thyroid nodules (26.7%) were TIRADS-2 and 22 thyroid nodules (73.3%) were TIRADS-3. In contrast to they reported that all their candidates (100%) with benign thyroid nodules were of TIRADS-3 in spite of few of these nodules were complex representing 40.9% of the nodules & 27.3 % were cystic but this score may be due to calcifications either macro or peripheral rim calcifications [19].

The current study revealed that 21 nodules (70%) had solid consistency “more than 75 % solid component”, 2 nodules (6.7%) were cystic “more than 75 % cystic component” while 7 nodules (23.3%) had complex consistency “25% - 75 % solid component”.

In agreement with this, it was reported that thirty-nine nodules were predominantly solid and 8 nodules were mixed solid-cystic complex nodules [20]. In contrast with their study they reported that most of the ablated nodules were of complex consistency representing 40.9%, while solid nodules represent 31.8% and cystic nodules represent 27.3% [19].

The base line thyroid profile, in the current study revealed that 28 patients (93.3%) were euthyroid presented with nonfunctioning thyroid nodules and only 2 patients (6.7%) were hyperthyroid presented with autonomous functioning thyroid nodules (AFTN). In agreement with their study that included 40 participants; 38 patients (95%) were euthyroid while 2 patients (5%) were hyperthyroid presented with AFTN [21]. In contrast with their reported that most of their participants (24 patient) had initial pre ablation hyperthyroid state due to AFTNs representing 51.07 % of the study group while 23 patients (48.93%) were euthyroid denoting nonfunctioning thyroid nodules [20].

The size of the detected nodules in our study had mean volume of 11.02 ± 14.4 ml before RF procedure which declined down to 3.84 ± 4.44 ml at three-month follow up post RFA denoting significant volume reduction by about 68.6% (P value = 0.0001). This is compatible with their study the mean volume of thyroid nodules was 6.11 ± 5.46 ml before the procedure and decreased to 2.07 ± 1.93 ml post ablation with mean volume reduction ratio

about 64.72% after three month follow up post RFA [22].

In 2023, it was reported that there was significant difference in compressive symptoms score upon comparing the mean initial compressive symptoms score (7.5 ± 1.8) with that of 3 months post ablation follow up (2.7 ± 1.3) as the P value was < 0.001 [23]. The same findings also were confirmed in our study that revealed significant improvement in the compressive symptoms score (P value = 0.0001). As the mean initial compressive symptoms score was 5.33 ± 1.83 that is reduced in post ablation follow up to 2.47 ± 1.57

Regarding the cosmetic scale, in our study the mean initial cosmetic scale was 2.87 ± 0.68 with range between 2 and 4, that is reduced in post ablation follow up to 1.87 ± 0.78 with range between 1 and 4, So there is significant improvement in cosmetic scale post ablation, (P value = 0.0001). This is compatible with what reported in their study as the mean pre ablation cosmetic scale was 4.9 ± 2.4 with significant decrease to 1.4 ± 1.9 in post ablation at 3 months follow up (P value < 0.001) [24].

In our study the initial thyroid function of the participants was euthyroid in 28 patients (93.3%) and hyperthyroid function in 2 patients (6.7%), that is converted to euthyroid state in all post ablation patients, as a result RFA did not affect the thyroid functions. It was also reported that 92.86% of their participants were initially euthyroid and 7.14% had hyperthyroid state that was normalized 4 months after ablation [25].

Conclusion

US-guided RF ablation is an alternative non-surgical minimally invasive safe modality in the treatment of the benign thyroid nodules. It is an effective method in reducing the size of the benign thyroid nodules and in controlling nodule-related compressive symptoms and cosmetic problems.

Abbreviations

RFA: Radiofrequency ablation; US: Ultrasound; FNA: Fine needle aspiration; AFTN: Autonomously functioning thyroid nodule; TSH: Thyroid stimulating hormone; T3: Triiodothyronine; T4: Thyroxine; VRR: Volume reduction ratio.

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