Radiofrequency ablation and alcoholisation: two safe and effective alternative treatments to surgery in clinically relevant benign thyroid nodules

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Aims and objectives

Benign thyroid nodules are very common, but their treatment is mainly justified if they become symptomatic or cause cosmetic alterations. Until a few years ago, surgery was the only treatment available, but radiofrequency ablation (RFA) and ethanol ablation (EA) guided by ultrasonography appeared as safe and effective alternatives (1, 2). These techniques increased the number of indications, including significant growth during follow-up and patients that refuse surgical treatment or with surgical risk (2), but also it can be used in patients with difficult management of post-surgical hypothyroidism, because of decompensation of cardiac failure or malabsorption of levothyroxine.

RFA is contraindicated so far in malignant nodules although several articles favor its usefulness or in benign nodules with endothoracic growth (2).

RFA achieves volume reduction rates of approximately 50% at 6 months and 80% at 12 months, although a non-negligible variability is observed between studies (51-92% at 12 months) (2). Operator experience is one of the main causal factors for this variability.

RFA uses high-frequency alternating current produced by a radiofrequency generator oscillating in a closed loop circuit. This current heats the tissue around the needle to over 60ºC, which causes coagulative necrosis and irreversible damage into the surrounding tissue. During the procedure the needle is internally cooled.

EA results are similar to RFA's in predominantly cystic nodules (solid part <10-20%) (3). The procedure consists in the slow injection of absolute ethanol (99%) after aspiration of intracystic fluid. The introduction of RFA entailed the re-emergence of EA since their combination allows the treatment of mixed solid-cystic nodules.

Objectives:

- To describe the technique of RFA under ultrasonographic guidance, highlighting clues for better results.
- To describe nodule and patient characteristics suitable to RFA and predictors of success.
- To analyze results and complications of RFA in a tertiary-level healthcare hospital.
- To enumerate other applications of this technique.
Methods and materials

We conducted a retrospective study from 2013 to 2018 which included 99 patients with clinically relevant benign thyroid nodules who met the eligibility criteria and provided written informed consent. None of our patients were treated with RFA because of difficult management of post-surgical hypothyroidism.

Thyroid nodules were clinically assessed with a symptomatic score using a 10-cm visual analog scale (0-10) and a cosmetic grading score (1, no palpable mass; 2, no cosmetic problem but a palpable mass; 3, a cosmetic problem on swallowing only; and 4, an easily detected cosmetic problem).

We performed indirect laryngoscopy for evaluating cord functionality and laboratory tests for evaluating thyroid hormones and antibodies and coagulation status. All nodules proved to be benign in two separate fine needle aspiration biopsy (FNAB).

Characteristics of the nodules were evaluated before treatment: size, margins, and proportion of the solid and cystic portions, echogenicity, vascularity and presence of calcifications. Contrast enhanced ultrasonography (CEUS) was also performed immediately before and after the RFA.

RFA was suggested as the first-line treatment for solid nodules (solids >80%), a combination of EA and RFA for mixed nodules (solid between 20-80%) and EA alone for cystic nodules (solid <20%).

RFA was performed using a cool-tip RF system with a straight-type internally cooled electrode with a 1-cm active-tip and a RF generator (Starmed®). 1-2% mepivacaine was used for anesthesia along the trajectory described by the needle.

Clinical and imaging follow-up was performed at 1, 3, 6 and 12 months after treatment. Therapeutic success was defined as a > 50% volume reduction 6 months from treatment.

Statistical evaluation was performed using the Kruskal-Wallis test or Fisher’s exact test for continuous quantitative and qualitative variables. Multiple linear regression analysis was calculated to identify factors that were independently predictive of efficacy. SPSS software version 21 (SPSS, Inc., Chicago, IL) was used. A two-tailed p-value <0.05 was considered statistically significant.
Results

Anatomy

The thyroid region includes several anatomic structures such as carotid artery, internal jugular vein, esophagus and trachea (Fig. 1 on page 8), which are important to recognize in order to avoid complications. For instance, the recurrent laryngeal nerve evaluated directly (Fig. 2 on page 8) or by its function in the vocal cord movement (Fig. 3 on page 9), the middle cervical ganglion (Fig. 4 on page 10), the anterior thyroid veins (Fig. 5 on page 11). These last ones have to be circumvented during the transisthmic approach.

In the vast majority of cases, transisthmic approach and visualization of the full length of the needle during RFA can decrease the rate of complications related to these anatomic structures.

Technical approach

RFA is performed under local anesthesia without sedation in patients with normal coagulation tests (Quick >60% and platelets recount >60.000).

The RF generator used in our hospital is the Starmed® (Fig. 6 on page 12) with internally cooled electrode needles of different lengths of active-tip (5, 7 and 10 mm) each of which needs different power and time of RF and creates ablation circumferences of different diameters. In our hospital, we use needles of 10mm active-tip.

The length of the active-tip influences the distance you can placed the needle from the capsule: 1-2 mm from the tip (Fig. 7 on page 13) and non less than 5 mm from the lateral margin of the needle (Fig. 8 on page 14). The volume of coagulative necrosis that can achieve without causing pain by approaching the needle tip close to the capsule. The distance of the ablation circumference from the capsule influences in the residual cortical volume of the lesion during follow-up (Fig. 9 on page 15).

Transisthmic approach

It has several advantages since it allows the electrode to pass through sufficient amount of thyroid parenchyma. It prevents the needle or the electrode from moving when the
patient swallows or talks and it also allows us to avoid the expected location of the recurrent laryngeal nerve or the esophagus.

The needle is placed perpendicular to the long axis of the nodule in its middle portion. The entrance point should be through the superior, middle or inferior portion of the isthmus depending on the location of the nodule (Fig. 10 on page 16).

Initially, we can start abrating the proximal part of the nodule near the isthmus to avoid bleeding.

**Moving-shot**

The nodule is divided in 3 to 5 segments along the cranio-caudal axis, each of one is subdivided in 2 or 3 transversal portions at the poles or the middle part of the nodule, respectively (Fig. 11 on page 17). The needle should be repositioned as many times as necessary to treat all these portions (Fig. 12 on page 18).

For a 10 mm needle, the ablation begins with RF power ranging from 35-40W. If a transient hyperechoic vapour zone did not form at the electrode tip within 5-10 seconds, the RF power was increased in 5-10 W increments, up to 55-60 W. When the hyperechoic zone appeared, the electrode tip was moved backwards to the next unit.

The moving shot technique creates a cylinder of RFA (Fig. 13 on page 19) but it has two practical problems (Fig. 14 on page 20): It leaves triangular zones at the periphery without ablation and implies an excess of ablation at the vertex.

To solve this problem, a conus shape cylinder of ablation should be accomplished (Fig. 15 on page 21, Fig. 16 on page 22). However, in practice, the backwards movement is based on step-by-step intervals that create a beaded conus-shape cylinder (Fig. 17 on page 23, Fig. 18 on page 24).

After the RFA is completed, CEUS should be performed to ensure that relevant peripheral parts of the nodule persist without treatment (Fig. 19 on page 25).

**Patients and nodules characteristics**

From 2013 to 2018, 99 patients with benign thyroid nodules were treated with RFA and/or EA in tertiary-level healthcare hospitals (Hospital Vall d'Hebron and Teknon clinical hospital, Barcelona, Spain). 80.8% of them were women, with a mean age ± SD: 49.8
± 10.7 years-old, ranging from 21 to 74.2 years-old. Characteristics of the patients and nodules are summarized in Table 1 on page 39.

67.4% of nodules were mostly solid (>80%) and only RFA was performed. 17.6% of nodules were mixed (20-80% of solid portion) and EA performed prior RFA. EA alone was performed in 15% of the nodules, where the solid portion was less than 20%.

All patients tolerated RFA or EA without major complications. The little pain during the procedure helps us to avoid putting close-up the heating ball from the capsule or decrease momentarily the power. Only 9 patients needed analgesia after the treatment and only 2 had a minor complication, self-limited hematomas, that were observed ultrasonographically immediately after the procedure. We offered the patients the possibility of taking sublingual diazepam (5-10 mg) before the treatment and 15 patients chose to do so. A psychiatric patient was treated with conscious sedation.

**Volume reduction** (Fig. 20 on page 26, Fig. 21 on page 27)

Mean volume reduction was 45.1% at 3 months, 61.4% at 6 months and 68% at 12 months. Therapeutic success (volume reduction >50%) was achieved in 80.1% of patients after 6 months and 90.5% after 12 months (Table 2 on page 40). Only 4 patients needed an additional RFA session (5.8%).

Follow-up after RFA was performed in 72.1% of patients after 3 months, 50% after 6 months and 32% after 12 months.

Symptomatic score decreased to 3.5 ± 2.0 (pre-treatment 7.5 ± 2.3) and the cosmetic grade score decreased to 1.5 ± 0.6 (pre-treatment 3.4 ± 1.3).

Multiple linear regression analysis was performed including age, sex, solid portion of the nodule, echogenicity, vascularity and calcifications.

As expected, the percentage of volume reduction after 6 months was significantly higher in those nodules predominantly cystic (solid part <20%), independently to other variables, as opposed to the predominantly solid nodules (solid portion >80%).

None of the characteristics of the solid or predominantly solid nodules proved to be statistically significant in the prediction of better outcome during follow-up.
Future analysis of elastography of the nodules before the RFA may be helpful in detecting those nodules with better outcome.

Elastography performed in several patients after RFA shows that there was an important component of low elasticity early in the follow-up that evolve in higher elasticity overtime.

5 patients (10%) with hyperfunctionant nodules showed therapeutic success similar to the rest of patients in our cohort. Thyroid antibodies measured during follow-up changes after RFA.

The results of RFA and EA are exemplified with several cases of our cohort (Fig. 22 on page 28, Fig. 23 on page 29, Fig. 24 on page 30, Fig. 25 on page 31, Fig. 26 on page 32, Fig. 27 on page 33, Fig. 28 on page 34, Fig. 29 on page 35, Fig. 30 on page 36)

Other applications (Fig. 31 on page 37)

Other lesions located in the neck can benefit from the same skills achieved for the EA technique, such as EA of laterocervical lymphadenopathies or instillation of bleomycin in vascular malformations and lymphangiomas.
Fig. 1: Anatomy of thyroid region, with vital structures adjacent to the thyroid gland. RFA circumference (transparent red circle). RLN: Recurrent laryngeal nerve

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Fig. 2: Recurrent laryngeal nerve, visible in this case because of the atrophy of the gland (triangle in a and arrow in b). In most cases, it is necessary to assume its expected location between the trachea and the thyroid gland.

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**Fig. 3:** Vocal cord functionality evaluated by ultrasonography

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**Fig. 4:** Middle cervical ganglion, close to internal carotid artery (arrows)

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**Fig. 5:** Thyroid veins, only visible without compression (b), close to the anterior margin of the thyroid gland. They have to circumvent during the transisthmic approach (discontinuous arrows in d)

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**Fig. 6:** Cool-tip RF system with a straight-type internally cooled electrode with a 1-cm active-tip and a RF generator Starmed®

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Fig. 7: Position of the tip of the needle at the right distance from the capsule (1-2mm)

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Fig. 8: Position of the active portion of the needle at the right distance from the capsule, >5mm (linear arrow) according to the active-tip length (square arrow).

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Fig. 9: For an oval nodule of 30 mm of diameter and 14.14 cc of volume, lack of ablation of the peripheral 1 mm (a), 2 mm (b) and 3 mm (c) implies a residual volume during follow up of 17 mm and 2.65 cc (18.7%) (a), 21 mm and 4 cc (28.8%) (b) and 24 mm and 6.9 cc (47.8%) (c).

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Fig. 10: In the transisthmic approach, the needle is placed parallel to the nodule, so the entrance point should be through the superior, middle or inferior portion of the isthmus.

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**Fig. 11:** The nodule is divided in 3 to 5 craniocaudal axes, each of one is subdivided in 2 or 3 transversal portions at the poles or the middle part of the nodule, respectively.

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**Fig. 12:** The needle should be repositioned as many times as necessary to treat all these portions, according to the crano-caudal axis (a) and the transversal axis in the superior and inferior poles (b and d) and the middle portion (c)

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Fig. 13: Moving shot technique creates a cylinder of RFA.

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**Fig. 14:** Moving shot technique creates a cylinder of RFA but it has two practical problems: It leaves triangular zones at the periphery without ablation and conditioned an excess of ablation at the vertex (blue circle)

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Fig. 15: A conus shape cylinder of ablation should be accomplished

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**Fig. 16:** Area of ablation with a cylinder shape of the conus.

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Fig. 17: Moving shot technique with step-by-step backwards movement creates a beaded conus-shape cylinder.

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**Fig. 18:** Patient of our cohort to exemplified the step-by-step backwards movement, where it can be differentiated the circumferences of ablation from the periphery to the vertex of the segment nodule.

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Fig. 19: CEUS performed at the end of RFA to ensure the completed treatment of the nodule. Notice triangular portion of periphery without treatment.

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Fig. 20: Volume reduction of thyroid nodules treated with RFA.

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**Fig. 21:** Percentage of volume reduction of thyroid nodules treated with RFA.

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**Fig. 22:** 36 years-old woman with solid thyroid nodule with heterogeneous echostructure and hyperechoic foci inside the lesion, peripheral and central vascularity and homogeneous contrast-enhancement. After RFA, the nodule appears hypoechoic with hyperechoic foci representing necrosis, lack of central vascularity or contrast-enhancement at CEUS.

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Fig. 23: Follow-up of the nodule of figure 9. At 3 years after RFA, residual lesion with low fibrosis is observed.

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**Fig. 24:** 27 years-old woman with solid-cystic nodule with predominantly peripheral vascularity and homogeneous contrast-enhancement. Almost complete ablation was achieved. During follow-up, enlargement of the peripheral viable part of the nodule was observed (asterisk at 6 months) although there was a regression of size and vascularity at 18 months (asterisk in 18 months)

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Fig. 25: 32 years-old woman with solid-cystic nodule with predominantly peripheral vascularity and homogeneous contrast-enhancement. Persistence of peripheral viable nodule was observed at 3 months of follow-up.

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Fig. 26: 38 years-old woman with solid-cystic nodule treated with EA before the RFA.

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Fig. 27: Follow-up of the treated nodule of figure 14. Notice the appearance of dystrophic calcifications inside the residual lesion (arrow)

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Fig. 28: Important decrease of nodule in follow-up was observed, with improvement of cosmetic grade in the previous nodule treated with EA and RFA.

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Fig. 29: 30 years-old woman with solid-cystic nodule with cysts at the periphery, treated with EA. Notice the hyperechoic foci representing ethanol inside the nodule immediately after EA (arrowheads)

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**Fig. 30:** 31 years-old woman with solid-cystic nodule treated with EA. No volume reduction was achieved with this treatment.

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**Fig. 31:** EA of a cystic lymphadenopathy located in region IV of the laterocervical space.

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Fig. 32: Same patient as figure 18 with another cystic lymphadenopathy of 8-9mm close to recurrent nerve. Hydrodissection (red lines) was performed before EA.

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tr>
<td>Sex (% female)</td>
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</tr>
<tr>
<td>Age (mean ± SD, years)</td>
<td>49.8 ± 10.7</td>
</tr>
<tr>
<td>Symptom score(^1)</td>
<td>7.5 ± 2.3</td>
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<tr>
<td>Cosmetic score(^1)</td>
<td>3.4 ± 1.3</td>
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<tr>
<td>Cytology (% Bethesda II)(^2)</td>
<td>100</td>
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<tr>
<td>Hiperfuncionant nodules (%(^2))</td>
<td>8</td>
</tr>
<tr>
<td>Nodule volume (mL)(^2)</td>
<td>8.5</td>
</tr>
<tr>
<td>Solid part(^2)</td>
<td></td>
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<tr>
<td>&gt;50%</td>
<td>67.4</td>
</tr>
<tr>
<td>20-50%</td>
<td>6.5</td>
</tr>
<tr>
<td>&lt;20%</td>
<td>26.1</td>
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<tr>
<td>Margins (% well-defined)(^2)</td>
<td>52.9</td>
</tr>
<tr>
<td>Ecogenicity (% hiperecogenic)(^2)</td>
<td>47</td>
</tr>
<tr>
<td>Vascularity (% peripheral)(^2)</td>
<td>41.2</td>
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<td>Calcifications (%)(^2)</td>
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**Table 1:** Demographic and nodule characteristics of the cohort before treatment. 1 Symptom score and cosmetic score were evaluated in a representative portion of patients (15%) and 2 characteristics of the nodules at diagnosis were evaluated in patients from Vall d'Hebron hospital (29.3%)

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<table>
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<th></th>
<th>Basal</th>
<th>6 months</th>
<th>Significance</th>
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<tr>
<td>Volume (mL) solid nodules</td>
<td>14.2</td>
<td>8.7</td>
<td>p&lt;0.01</td>
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<td>Volume reduction (%)</td>
<td></td>
<td>38.6</td>
<td></td>
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<tr>
<td>Volume (mL) cystic nodules</td>
<td>3.7</td>
<td>1.2</td>
<td>p&lt;0.001</td>
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<tr>
<td>Volume reduction rate (%)</td>
<td></td>
<td>68.8</td>
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<tr>
<td>Symptomatic score</td>
<td>7.5 ± 2.3</td>
<td>3.5 ± 2.0</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Cosmetic score</td>
<td>3.4 ± 1.3</td>
<td>1.5 ± 0.6</td>
<td>p&lt;0.001</td>
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**Table 2:** Outcomes of nodules after RFA and EA ablation

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Conclusion

- RFA and EA are safe and effective alternative treatments to surgery in clinically relevant benign thyroid nodules.
- The greatest volume reduction is observed after 6-months follow-up.
- The only variable in our cohort that predicts a better outcome after 6-months follow-up was the greater percentage of cystic portion.
- Antibodies measured during follow-up didn’t change after RFA.
- In patients with hyperfunctionant nodules, hormonal indicators were stabilized after the treatment.
- There are several important anatomic structures in the thyroid region to consider during RFA and EA.
- Other lesions located in the neck can benefit from the same skills achieved for the RFA and EA (lymphangioma, cystic lymphadenopathies…)
- Future evaluation of the role of elastography in the basal characteristics and follow-up of thyroid nodules treated with RFA is needed.
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References