Image-Guided Thyroid Ablation: Proposal for Standardization of Terminology and Reporting Criteria

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Background: Image-guided tumor ablation is commonly performed in clinical practice. Trying to standardize terminology and data collection to enable a more reliable comparison among the different studies, in 2003, a document entitled “Image-Guided Tumor Ablation: Proposal for Standardization of Terms and Reporting Criteria” was published by the International Working Group on Image-Guided Tumor Ablation. Since then, ablations have evolved significantly, with the development of new technology and techniques and applications. This has included benign thyroid nodules, and their ablation has become increasingly accessible, not only among radiologists but also among other specialists involved in thyroid care, including endocrinologists and surgeons. This has resulted in further inhomogeneity in how data are presented and reported among different studies, resulting in a need for standardization to homogenize language and data reporting on the topic.

Summary: In February 2018 in Milano, Italy, a meeting involving specialists concerned with minimally invasive treatments of thyroid lesions was organized, and the Italian Working Group on Minimally Invasive Treatments of the Thyroid was founded with the aim of establishing a collaborative network among all clinicians working in this field. The first work of this group is to present a proposal for standardization of terminology and reporting criteria on image-guided ablations to treat benign thyroid nodules.

Conclusion: This proposal was drafted with the goal of providing guidance for standardized reporting of results in studies regarding image-guided thyroid ablations. We encourage adoption of this terminology worldwide, anticipating that this will facilitate improved communication and understanding within the field and stimulate further discussion on the topic over the next years.

Keywords: thyroid nodules, radiology, radiology—treatment

Introduction

IN 2003, A DOCUMENT ENTITLED “Image-Guided Tumor Ablation: Proposal for Standardization of Terms and Reporting Criteria” was published by the International Working Group on Image-Guided Tumor Ablation (1). As these procedures were mostly in their infancy and most studies were reporting data in an inconsistent and nonhomogeneous fashion, the purpose of that document was to standardize terminology and data collection to enable a more reliable comparison among the different studies arising on that mat-

ter. Since then, ablation procedures have evolved significantly, with the development of new technology and techniques and application in an increasing number of fields in medicine (2–9). Thus, the original document has been modified over the years (10) and was last updated in 2014 (11). However, all of these documents focus mainly on procedures aimed to treat malignant diseases, the main ablation indications discussed being liver disease (both primary and metastatic) and, to a lesser extent kidney, lung, and bone lesions.

In the recent past, the application of image-guided ablations has expanded to include benign conditions, such as benign

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thyroid nodules (12–17). Ablation of thyroid lesions has become highly popular, not only among radiologists but also among other specialists involved in thyroid care, including endocrinologists and surgeons. Thus, several evidence-based guidelines on the topic have been produced in recent years (18–21). Nevertheless, similar to what happened in the hepatology and urology communities, this has resulted in further inhomogeneity in how data are presented and reported among different studies, resulting in a need for standardization to homogenize language and data reporting on the topic (22).

For this purpose, in February 2018 in Milano, Italy, a meeting involving specialists concerned with minimally invasive treatments of thyroid lesions was organized (23). Minimally invasive treatments include but are not limited to thermal and chemical ablations, nuclear medicine treatments, or minimally invasive surgery. On that occasion, the Italian Working Group on Minimally Invasive Treatments of the Thyroid was founded, with the aim of establishing a collaborative network among clinicians working in this field (23). This group has extensive clinical and scientific experience in image-guided ablation for treating benign thyroid nodules (17,18,24–30). Additionally, in order to maximize consistency with prior reporting documents, several authors of the original “Image-Guided Tumor Ablation: Proposal for Standardization of Terms and Reporting Criteria” paper (1,11) were included in the committee writing the current recommendations.

Here, this group presents a proposal for standardization of terminology and reporting criteria on image-guided ablations to treat benign thyroid nodules based on the previously published proposals on terminology and reporting for tumor ablation (11). The present document only discusses specific issues related to benign thyroid nodule ablation, while general concepts regarding ablation of cancerous lesions remain those reported in the 2014 update (11).

Review of General Definitions

In the literature, different terms have been used to define ablation therapies in the thyroid. For consistency with the 2014 guidelines (11), similarly the term “image-guided ablation” is proposed to identify this kind of procedure. The definition of “minimally invasive” or “percutaneous” should be avoided, as these can identify also other types of treatments (e.g., surgical treatments) and might be misleading.

Use of the term “procedure” is recommended when referring to a single intervention. Although uncommon, the term “course of treatment” should be used to define a series of ablations performed at different time points but as a part of a predetermined treatment plan. The number of planned sessions should always be reported. Devices for image-guided thermal ablation should be generally defined as “applicators.” Where internal cooling is used, the term “internally cooled applicator” should be used.

Specific Items Pertinent to Image-Guided Ablation of Benign Thyroid Nodules

Indications

In all studies, indication(s) for treatment should be reported (e.g., compression symptoms, cosmetic reasons, abnormal thyroid function, other) (21).

Nodule description

Currently, no classification of thyroid nodules according to solid component percentage has been adopted and recognized as standard, and nodule classification might vary among different studies. To provide better uniformity in future studies, it is suggested that a detailed description of the internal structure of each treated nodule should be stated. The following classification is proposed: solid ($\leq 10\%$ of fluid component), predominantly solid (11–50% of fluid component), predominantly cystic (51–90% of fluid component), or cystic ($>90\%$ of fluid component). If the cystic portion is aspirated prior the procedure, it should be stated as such. As “spongiform” appearance of nodules has been reported to be correlated with benign nodules, it is proposed that “spongiform nodules” be reported differently from other nodules. Spongiform nodules are defined as those nodules containing multiple small cysts <5 mm interspersed within solid tissue for nearly all the volume (21,31,32).

Nodule size

Nodule volume should be reported in mL using the ellipsoid volume formula:

$$\text{length} \times \text{width} \times \text{depth} \times 0.524$$

with measures expressed in centimeters, and nodules should also be classified according to their size. In the literature, several different cutoffs have been proposed (13,15,21). To increase uniformity, identifying nodules as small (≤ 10 mL), medium (11–30 mL), or large (>30 mL) as appropriate is proposed.

Blood tests

Blood tests including at least thyrotropin (TSH) and free thyroxine (fT4) should be performed prior to the procedure. Free triiodothyronine (fT3) should also be performed in case of TSH and fT4 abnormalities. If fT4 and fT3 are not available in a specific setting, total T4 and total T3 can be performed (21).

Finality of treatment

In defining “technical success” for each procedure, it is suggested that authors should define *a priori* the goal of their treatment, for example to achieve a nodular volume ablation of 50% at a specific time point etcetera, 50% volumetric reduction at one year is proposed as a reasonable threshold for defining technical success. For autonomously functioning thyroid nodules, the technical purpose of treatment should be achieving the largest amount possible of nodule ablation to destroy the largest amount of autonomously functioning thyroid tissue, with a proposed threshold of at least 80% nodule volume destruction to define technical success. In association with such a threshold, it should be pointed out that the ultimate goal of treatment is to achieve satisfactory normalization of thyroid function.

Type of ablation

Image-guided thyroid ablation procedures can be performed using either thermal energy or chemical agents such as ethanol instillation.

Energy-based ablation. Different types of energy can be used to perform thyroid image-guided thermal ablation (17). The most commonly used are radiofrequency ablation, which it is recommended abbreviating as RFA, and laser ablation. Fewer studies have reported the use of microwave ablation (which it is recommended abbreviating as MWA) or high-intensity focused US (US; which it is recommended abbreviating as HIFU). The use of definitions other than those provided above is discouraged, as they might be misleading. When referring to all these ablation methods, energy should be reported as “applied.” All other definitions (e.g., “irradiation” or “deliverance” and their derivatives) should be avoided, as they can be misleading.

RFA. RFA applicators should be referred to as “electrodes.” Monopolar electrodes are generally used for this procedure. Thus, this does not need to be specified. However, in cases where bipolar electrodes or other modifications are used, this should be noted as such. A description of the applicator should include length, active component, and size preferably expressed by their gauge. Due to the different types of applicators among vendors (e.g., straight tip, umbrella-shape, Christmas tree-shape, other), the exact design of the applicator should be specified (25).

Laser ablation. Type of laser and precise light wavelength should be specified. Laser ablation applicators should be referred to as “fibers.” A description of the applicators should include the number of simultaneous fiber insertions, the type of fibers (e.g., flexible or glass-dome), tip design, and fiber length and diameter.

MWA. MWA applicators should be referred to as “antennas.” A description of the antennas should include length, active component, and diameter expressed by gauge size.

HIFU. The type of guidance for HIFU (e.g., US or magnetic resonance) and the features of HIFU generator transducer (e.g., frequency, diameter, single or multiple elements) should be specified.

Chemical ablation. This refers to the use of a chemical agent for the treatment of cystic or predominantly cystic nodules. These procedures should be identified by the name of the chemical agent used followed by the word “ablation,” such as ethanol ablation, which is the most common procedure. All other definitions should be avoided. When reporting these procedures, it is recommended reporting the concentration and amount of the used agent (e.g., 95% ethanol) and the type and size of needle. The method of delivery should also be stated (e.g., “aspiration of fluid component immediately followed by chemical injection” or “aspiration followed by saline washing and subsequent chemical injection”) and also whether ethanol is either re-aspirated after injection or left inside the cavity. It should also be stated whether the treatment is completed immediately as one procedure or whether it is split into different phases (e.g., aspiration and ablation performed in two different sessions). If divided into more than one session *a priori*, then completion of all steps of the procedure will constitute technical success. If different from cyst/nodule shrinkage, any other intended effect should be reported (1,11,33,34).

Procedure Details

If used, the type, amount, and technique of local anesthesia and/or conscious sedation should be clearly documented. Intra-procedural use of other drugs (e.g., intravenous steroids, nonsteroidal anti-inflammatory drugs [NSAIDs], or painkillers) should be disclosed with justification of their adjuvant use.

Likewise, the use of ancillary procedures, such as hydrodissection, should be declared and thoroughly explained.

The technical approach to the nodule should be specified. When the approach to the nodule involves a path through the thyroid isthmus to keep some normal thyroid tissue in between the nodule and the thyroid capsule puncture site, the term “trans-isthmus” approach is suggested (35). When the approach to the nodule allows direct puncture to achieve a shorter path or insertion along the major axis, the term “direct nodule puncture” is suggested (36). In case multiple ablations are planned, with multiple expected movements of the applicator into the thyroid nodule to be treated, the term “moving-shot” technique should be used (35,36). In case planning involves insertion of the applicator(s) in the deepest part of the nodule, with an eventual subsequent ablation of the more superficial part of the nodule by a simple retraction of the applicator(s), the term “pull-back” technique should be used (34). When a single insertion and ablation is prevised, the term “fixed-applicator” technique is suggested (35).

In cases of energy-based ablations, energy application parameters should be provided (i.e., power, duration of application, energy applied per volume, and/or total amount of applied energy).

Results

Technical success

This term indicates whether the nodule was treated according to the planned protocol. This parameter is important to differentiate nodules that were treated according to a predefined protocol from those where protocol could not be completed due to a specific reason (which should be stated).

Technique efficacy

Distinction between technical success and technique efficacy is essential. Technique efficacy indicates the ability of the treatment to achieve a predetermined clinical result and should be assessed using specific clinical or instrumental parameters.

In the setting of ablation of benign nodules, technique efficacy should be defined as a volumetric reduction $\geq 50\%$ of the initial nodule volume, that is:

$$\frac{\text{final nodule volume}}{\text{initial nodule volume}} \times 100$$

Technique efficacy should be always related to specific follow-up time points, generally a minimum follow-up of one year is considered optimal. Ideally, long-term follow-up should be reported, with a proposed time interval of one year after the first year.

Primary efficacy rate is defined as the percentage of nodules successfully treated following the initial procedure or at

TABLE 1. PROPOSED MODIFIED CLASSIFICATION SYSTEM FOR ADVERSE EVENTS BY OUTCOME IN THYROID NODULE ABLATION

Type	Grade	Description	Occurrence
Side effects	A0	Undesired events that are somewhat expected during or after a procedure	Expected
Minor complication	A	No therapy, no consequence	Unexpected
	B	Nominal therapy, no consequence; includes overnight admission for observation only	
Major complication	C	Require therapy, minor hospitalization (<48 hours)	
	D	Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)	
	E	Permanent adverse sequelae	
	F	Death	

This table is a modification of table 2 reported in the SIR Classification System for Complications by Outcome (28) in combination with what reported in the Image-Guided Tumor Ablation: Standardization of Terminology and Reporting Criteria—A 10-Year Update report concerning side effects (11).

the end of the planned course of treatment. Secondary or assisted efficacy rate includes nodules that have undergone successful retreatment after continued nodule regrowth. Nodule regrowth should be defined as nodule volume increase of $\geq 50\%$ compared to the minimum recorded volume measured at a given follow-up time point (12,37,38). Although some authors have proposed considering the regrowth of nodule periphery as a marker of recurrence, this parameter may not be easy to assess and standardize with conventional US techniques (37,39,40).

TABLE 2. COMMON TOPICS AND REPORTING CRITERIA FOR IMAGE-GUIDED ABLATIONS OF BENIGN THYROID NODULES

Topic		Reporting criteria
1	Indications	Compression symptoms palliation/aesthetic concerns/normalization of thyroid function
2	Patient information	Demographics Relevant comorbidities Inclusion/exclusion criteria Additional previous/ongoing treatments for the same condition
3	Nodule features	Blood tests (fT3, fT4, TSH) Solid, predominantly solid, predominantly cystic, cystic, spongiform Volume in milliliters Small (≤ 10 mL), medium (11–30 mL), and large (>30 mL)
4	Type of ablation	
	Energy-based ablation	Device name/model/manufacture
	Radiofrequency	Monopolar, bipolar, multipolar Length, active exposure, size (in gauge) Electrode design (straight tip, others)
	Laser	Type of laser Light wavelength Fiber design and size (in gauge)
	Microwave	Length, active component, size (in gauge)
	HIFU	Type of guidance, features of HIFU generator transducer
	Chemical ablation	Concentration/amount of chemical agent Type/size of needle (Gauge) Method of delivery Single/multiple phases
5	Procedure details	
	Anesthesia	Local anesthesia and/or conscious sedation
	Adjuvant drugs	If any, provide full details
	Ancillary procedures	Hydrodissection, other
	Technique	Direct puncture/transisthmia Moving shot/pull-back/fixed applicator
6	Energy parameters	Power, duration of application, and total amount of applied energy
7	Results	Technique efficacy Primary efficacy rate Secondary or assisted efficacy rate Nodule regrowth
	Clinical success	Complete/partial/absent
	Adverse events	Major complications/minor complications/side effects (see Table 1)
8	Follow-up	Immediate (0–24 hours)/peri-procedural (1–30 days)/delayed (>30 days) Early (1–3 months)/intermediate (6 months)/1 year/annual follow-up

fT3, free triiodothyronine; fT4, free thyroxine; TSH, thyrotropin; HIFU, high-intensity focused ultrasound.

TABLE 3. PROPOSED CASE REPORT FORM FOR STUDIES ON IMAGE-GUIDED
ABLATION OF BENIGN THYROID NODULES

Patient's name	Sex	Date of birth
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Pretreatment evaluation

Date of pretreatment evaluation		Internal references	
Nodule location		Nodule volume	
Type of nodule	Solid	Predominantly solid	Predominantly cystic
			Cystic
TSH	fT3	fT4	
Visual analogue scale compression value (0–10)		Cosmetic score (1–4)	

Treatment

Applied energy	Time
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Technical success

Major complications
Minor complications
Side effects
Complication management and recovery time

Follow-up

Time point	Nodule volume	Volume reduction ratio	VAS compression score (0–10)	Cosmetic score (1–4)

For autonomously functioning nodules, a volumetric reduction of at least 80% of the initial nodule volume is proposed as the preferred target for technique efficacy. In association with volumetric reduction, the ultimate goal of treatment is to achieve satisfactory normalization of thyroid function (24,41–43).

In general, US is the method of choice for evaluation of nodule volume, while contrast-enhanced US may provide a more precise evaluation of the ablated area immediately after the procedure.

Clinical success

As thyroid ablation is aimed in these cases to treat a benign condition (mainly resulting in compression symptoms or cosmetic concerns), the concept of clinical success is introduced, which should be defined as the ability of treatment to resolve the condition itself. It is recommended classifying clinical success as complete (i.e., complete resolution of presenting symptoms), partial (i.e., symptom improvement but still present), or absent (i.e., no symptom improvement). In addition, a validated visual analogue scale (grade 0–10) may be used to have a semi-quantitative assessment of treatment (21). Cosmetic assessment should be ideally performed on the basis of a four-point scale: 1=no palpable mass; 2=palpable mass without cosmetic problems; 3=cosmetic problems on swallowing only; and 4=visible mass (21). For autonomously functioning thyroid nodules, clinical success is defined as the normalization of serum thyroid hormones and TSH, and the suspension of oral therapy.

Adverse events related to the procedure

To assess adverse events related to the procedure, a combination of the SIR standardized grading system (44) and Image-Guided Tumor Ablation: Standardization of Terminology and Reporting Criteria—A 10-Year Update (11) is proposed.

Adverse events should be reported on a per session and per patient basis, and their severity should be reported. They should be classified as major complications, minor complications, and side effects. A major complication is regarded as an unexpected event that leads to substantial morbidity and disability, which also increases the level of care. All other unexpected adverse events should be regarded as minor. It is noted that complications may be classified as either major or minor according to their severity. Side effects are those adverse events that are potentially anticipated during or after a procedure and do not result in long-term clinical sequelae. Peri- or post-procedural discomfort and/or pain that is or is not treated with local ice and/or oral NSAIDs and/or painkillers and that does not increase the expected level of care should be considered as a side effect and not as a minor complication. A proposed grading scale for adverse events associated with thyroid thermal ablations is reported in Table 1.

Events should be also differentiated as immediate (0–24 hours), peri-procedural (1–30 days), and delayed (>30 days) (1,11).

Follow-Up

As the effect of treatment on benign thyroid nodules can only be appreciated over time, results should be reported at standard time points to make results comparable among

studies. It is recommended reporting treatment results at early (between one and three months), intermediate (six months), and one year follow-up. Then, it is suggested reporting annual follow-up data for long-term studies. At each follow-up, the same variables of baseline should be reported.

Regarding blood tests, at a minimum, the TSH test should be performed at every reported follow-up.

Table 2 reports common topics and reporting criteria for image-guided ablations of benign thyroid nodules. Table 3 includes a proposal for a Case Report Form (CRF) for studies on image-guided ablation of benign thyroid nodules.

Result Stratification

As treatment results might be affected by the amount of solid tissue in the nodule, results should also be stratified according to nodule internal structure (i.e., solid, predominantly solid, mixed solid and cystic, predominantly cystic, cystic, spongiform).

Conclusion

This proposal was drafted with the goal of providing guidance for standardized reporting of results in studies regarding image-guided thyroid ablation procedures. This has been done in the past for ablation of malignant lesions, but these recommendations specifically focus on the ablation of benign thyroid lesions. Adoption of this terminology is encouraged worldwide, anticipating that this will facilitate communication and understanding within the field and stimulate further discussion on the topic over the coming years.

Author Disclosure Statement

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