American Association of Clinical Endocrinologists (AACE),
Associazione Medici Endocrinologi (AME),
and European Thyroid Association (ETA)

Medical Guidelines for Clinical Practice
for the Diagnosis and Management of Thyroid Nodules

Hossein Gharib, Enrico Papini, Ralf Paschke, Daniel S. Duick, Roberto Valcavi,
Laszlo Hegedus, Paolo Vitti, and the AACE/AME/ETA Task Force on Thyroid Nodules
Introduction

Thyroid nodules are a frequent clinical finding for which the exclusion of thyroid cancer or thyroid autonomy is necessary. The management of thyroid nodules has significantly changed due to the widespread availability of novel diagnostic and therapeutic resources. Imaging techniques and laboratory tests are continuously improving the assessment of the risk of malignancy and of the function status of thyroid nodular disease.

This document is unique because it represents collaboration and consensus between associations on both sides of the Atlantic. It was prepared as a collaborative effort of the American Association of Clinical Endocrinologists (AACE), the Italian Association of Clinical Endocrinologists (AME), and the European Thyroid Association (ETA).

These guidelines cover diagnostic and therapeutic aspects of thyroid nodular diseases. They do not cover thyroid cancer management. The evidence level of each reference was rated on a scale of 1 to 4 and the strength of the recommendations was graded on the basis of grade designations A (action based on strong evidence) through D (action not based on any evidence or not recommended). The best evidence level (BEL), corresponding to the best conclusive evidence found, accompanies the recommendation grade. All recommendations resulted from a consensus among the AACE, AME, and ETA primary writers and were influenced by input from the Task Force members and reviewers.

R. Paschke, E. Papini, H. Gharib, L. Hegedüs

1. The Scope of the Problem

Thyroid nodules are common, with an estimated prevalence ranging from 3% to 7% on the basis of palpation. The prevalence of incidental thyroid nodules detected by US is estimated to be 20% to 76% in the general population. Moreover, 20% to 48% of patients with one palpable thyroid nodule are found to have additional nodules when investigated by US.

2. Clinical Evaluation and Diagnosis

<table>
<thead>
<tr>
<th>History</th>
<th>Record the following information</th>
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<tbody>
<tr>
<td></td>
<td>Age, Sex</td>
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<tr>
<td></td>
<td>Family history of MTC, MEN 2, or papillary thyroid cancer</td>
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<td></td>
<td>History of head or neck irradiation</td>
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<td>Rate of growth of the neck mass</td>
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<td></td>
<td>Persistent dysphonia, dysphagia, or dyspnea</td>
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<td>Symptoms of hyperthyroidism or hypothyroidism</td>
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<td></td>
<td>Use of iodine-containing drugs or supplements</td>
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<td></td>
<td>Most nodules are asymptomatic, and absence of symptoms does not rule out malignancy</td>
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</tbody>
</table>

| Physical Examination | A careful physical examination of the thyroid gland and cervical lymph nodes is mandatory |
|                     | Record |
|                     | Location, consistency or fixation, and size of the nodule(s) |
|                     | Neck tenderness or pain |
|                     | Cervical adenopathy |
|                     | The risk of cancer is similar in patients with a solitary nodule or with MNG |

*B; 2

C; 3

A; 3

C; 3

B; 2

*Explanation see Appendix I
### 3. Ultrasonography (US) and Other Diagnostic Imaging Studies

#### 3.1. Ultrasonography

**When to Perform Thyroid US**
- US evaluation is not recommended as a screening test in the general population nor in patients with a normal thyroid on palpation and a low clinical risk of thyroid cancer.
- US evaluation is recommended for:
  - Patients at risk for thyroid malignancy
  - Patients with palpable thyroid nodules or MNGs
  - Patients with lymphadenopathy suggestive of a malignant lesion

**How to Describe US Findings**
- Report should focus on risk stratification for malignancy
- Describe position, shape, size, margins, content, echogenic pattern, and vascular features of the nodule(s)
- For multiple nodules, detail the nodule(s) bearing the US characteristics associated with malignancy (hypoechoic pattern and/or irregular margins, a more-tall-than-wide shape, microcalcifications, or chaotic intranodular vascular spots) rather than describing the largest ("dominant") nodule.

#### 3.2. Indications for FNA Biopsy

**How to Select Nodule(s) for Fine-Needle Aspiration Biopsy**
- Fine-Needle Aspiration (FNA) biopsy is recommended for nodule(s):
  - Of diameter >10 mm, and solid, hypoechoic on US
  - Of any size with US findings suggestive of extracapsular growth or metastatic cervical lymph nodes
  - Of any size with: patient history of neck irradiation in childhood or adolescence; PTC, MTC, or MEN2 in first-degree relatives; previous thyroid surgery for cancer; increased calcitonin levels in the absence of interfering factors
  - Of diameter <10 mm along with US findings associated with malignancy; the coexistence of 2 or more suspicious US criteria greatly increases the risk of thyroid cancer
- Nodules that are hot on scintigraphy should be excluded from FNA biopsy.

**FNA Biopsy of Multinodular Glands**
- It is rarely necessary to biopsy more than 2 nodules when they are selected on the basis of previously described criteria.
- If a radioisotope scan is available, do not biopsy hot areas.
- In the presence of suspicious cervical lymphadenopathy, FNA biopsy of both the lymph node and suspicious nodule(s) is essential.

**FNA Biopsy of Complex (Solid-Cystic) Thyroid Nodule(s)**
- Always sample the solid component of the lesion by US-guided FNA (UGFNA) biopsy.
- Submit both the FNA biopsy specimen and the drained fluid for cytologic examination.

**FNA Biopsy of Thyroid Incidentalomas**
- Thyroid incidentalomas should be managed according to previously described criteria for nodule diagnosis.
- Incidentalomas detected by CT or MRI should undergo US evaluation before consideration for UGFNA biopsy.
- Incidentalomas detected by positron emission tomography with 18F-fluorodeoxyglucose should undergo US evaluation plus UGFNA biopsy because of the high risk of malignancy.

#### 3.3. Other Diagnostic Imaging Techniques

- MRI and CT are not indicated for routine thyroid nodule evaluation.
- MRI and CT are of value for assessment of size, airway compression, or substernal extension of a nodular goiter.

#### 3.4. Novel US Techniques

- Elastography and US contrast media currently are not used routinely in the evaluation of thyroid nodules.
### 4. Thyroid FNA Biopsy

**Thyroid FNA Biopsy**
- Clinical management of thyroid nodules should be guided by the combination of US evaluation and FNA biopsy
- Cytologic diagnosis is more reliable and the nondiagnostic rate is lower when FNA biopsy is performed with US guidance

**Cytologic Reporting**
- Thyroid smears or liquid-based cytology should be reviewed by a cytopathologist with a special interest in thyroid disease
- The request form accompanying the cytologic specimen should include all the relevant clinical and US information
- The cytologic report should be descriptive, and, whenever possible, a diagnosis should be made

**Cytologic Diagnosis**
FNA biopsy results may be diagnostic (satisfactory) or nondiagnostic (unsatisfactory). Even if the evaluation of adequacy is difficult to standardize, the specimen is labeled “diagnostic” if it contains a minimum of 6 groupings of well-preserved thyroid epithelial cells, consisting of at least 10 cells per group.

Cytologic diagnoses should be organized into 5 classes:
- **Class 1. Nondiagnostic (inadequate or insufficient):** samples with processing errors or an insufficient number of follicular cells
- **Class 2. Benign (or negative for malignancy):** includes colloid or hyperplastic nodules, Hashimoto or granulomatous thyroiditis, and cysts
- **Class 3. Follicular lesions:** all follicular-patterned lesions, including follicular neoplasms, Hürthle cell lesions, and the follicular variant of PTC. In centers with specific experience in thyroid cytology, follicular cytology may be further subdivided into “follicular lesion/atypia of undetermined significance” and “follicular neoplasm.” This distinction separates 2 cytologic groups at different risk for thyroid malignancy but with the same operative indications
- **Class 4. Suspicious:** samples that suggest a malignant lesion but do not completely fulfill the criteria for a definite diagnosis
- **Class 5. Malignant (or positive):** samples characterized by malignant cytologic features that are reliably identified by the cytopathologist and are diagnostic of primary or metastatic tumors

**Pitfalls in FNA Biopsy**
- False-negative results are usually due to inadequate sampling or inappropriate target selection
- False-positive results are usually due to specimens with suspicious findings
- Gray zones in cytologic reports are follicular lesions and cytologic findings suggestive of but not diagnostic for PTC
- In follicular lesions, consider performing thyroid scintigraphy to exclude a hot nodule at very low risk for malignancy

**Ways to Minimize False-Negative Results**
- Use UGFNA biopsy
- Aspirate multiple nodule sites
- For multiple nodules, prioritize the nodule to biopsy according to US findings
- For cystic lesions, sample solid areas with UGFNA biopsy and submit cyst fluid for examination
- Review slides with an experienced cytopathologist
- Follow up cytologically benign nodules
- Consider performing a repeated UGFNA biopsy for follow-up of benign nodules

**Core-Needle Biopsy**
- Core-needle biopsy performed under US guidance may offer additional information in selected cases with thyroid or neck masses and inadequate FNA biopsy cytologic results

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<thead>
<tr>
<th>Grade; BEL</th>
<th>A, 3</th>
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<tbody>
<tr>
<td>B, 3</td>
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<td>C, 3</td>
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## 5. Laboratory Evaluation

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<thead>
<tr>
<th>Laboratory Evaluation in Patients With Thyroid Nodules</th>
<th>Grade; BEL</th>
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<tbody>
<tr>
<td>Always measure serum thyrotropin (TSH)</td>
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<tr>
<td>If TSH level is decreased, measure free thyroxine and total or free triiodothyronine; if TSH level is increased, measure free thyroxine and thyroid peroxidase antibodies</td>
<td>B; 3</td>
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<tr>
<td>Testing for antithyroglobulin antibodies should be restricted to patients with US and clinical findings suggestive of chronic lymphocytic thyroiditis when serum levels of thyroid peroxidase are normal</td>
<td>C; 3</td>
</tr>
<tr>
<td>Assessment of serum thyroglobulin is not recommended in the diagnosis of thyroid nodules. In patients undergoing surgery for malignancy, serum thyroglobulin measurement is useful to detect potential false-negative results</td>
<td>C; 3</td>
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<tr>
<td>TSH-receptor antibody measurement should be performed in patients with TSH levels below the reference range</td>
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<thead>
<tr>
<th>Calcitonin</th>
<th>Grade; BEL</th>
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<tbody>
<tr>
<td>Measurement of basal serum calcitonin level may be a useful test in the initial evaluation of thyroid nodules</td>
<td>B; 3</td>
</tr>
<tr>
<td>Measurement of nonstimulated serum calcitonin level may be considered before thyroid surgery for nodular goiter</td>
<td>B; 3</td>
</tr>
<tr>
<td>Measurement is mandatory in patients with a family history or clinical suspicion of medullary thyroid carcinoma or multiple endocrine neoplasia type 2</td>
<td>A; 2</td>
</tr>
<tr>
<td>If calcitonin level is increased, the test should be repeated and, if confirmed in the absence of modifiers, a pentagastrin or calcium stimulation test will increase the diagnostic accuracy</td>
<td>B; 3</td>
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<thead>
<tr>
<th>Other Tests</th>
<th>Grade; BEL</th>
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<tbody>
<tr>
<td>Measure serum calcium, parathyroid hormone, or both if a nodular lesion is suspicious for intrathyroidal parathyroid adenoma on US examination</td>
<td>D</td>
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## 6. Radionuclide Scanning

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<thead>
<tr>
<th>When to Perform Thyroid Scintigraphy</th>
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<tbody>
<tr>
<td>Perform scintigraphy for a thyroid nodule or MNG if the TSH level is below the lower limit of the reference range or if ectopic thyroid tissue or a retrosternal goiter is suspected</td>
<td>B; 3</td>
</tr>
<tr>
<td>In iodine-deficient regions, consider performing scintigraphy to exclude autonomy for a thyroid nodule or MNG even if TSH is normal</td>
<td>C; 3</td>
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<table>
<thead>
<tr>
<th>How to Perform Thyroid Scintigraphy</th>
<th>Grade; BEL</th>
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<tbody>
<tr>
<td>Either $^{123}$I or $^{99m}$TcO$_4^-$ (sodium pertechnetate) can be used for thyroid scintigraphy</td>
<td>B; 3</td>
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<tr>
<td>$^{131}$I thyroid uptake is not recommended for routine diagnostic use unless low-uptake thyrotoxicosis is suspected</td>
<td>A; 3</td>
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</table>
### 7. Management and Therapy

#### 7.1. Nodules Benign by FNA Biopsy

**Follow-up**
- Cytologically benign nodules should be followed up
- Perform repeated clinical and US examination and TSH measurement in 6 to 18 months
- Perform repeated UGFNA biopsy in cases of appearance of clinically or US suspicious features
- Perform repeated UGFNA biopsy in cases of a greater than 50% increase in nodule volume
- Consider routine repeated UGFNA biopsy in 6 to 18 months, even in patients with initially benign cytologic results

**Levothyroxine Therapy for Benign Nodules**
- Routine levothyroxine therapy is not recommended
- Levothyroxine therapy or iodine supplementation may be considered in young patients with small nodular goiter and no evidence of functional autonomy
- Levothyroxine suppressive therapy is not recommended for preventing recurrence after lobectomy if TSH remains normal

**Surgical Indications for Benign Nodules**
- Presence of local pressure symptoms clearly associated with the nodule(s), previous external irradiation, progressive nodule growth, suspicious US features, or cosmetic issues
- The preferred extent of resection for benign unilobular goiter is lobectomy plus isthmectomy and for MNG is (near) total thyroidectomy

**US-Guided Percutaneous Ethanol Injection**
- Percutaneous ethanol injection is effective in the treatment of benign thyroid cysts and complex nodules with a large fluid component
- Percutaneous ethanol injection should not be performed in solitary solid nodules, whether hyperfunctioning or not, or in MNGs

**Image-Guided Thermal Ablation**
- Laser ablation may be considered for the treatment of thyroid nodules causing pressure symptoms or cosmetic issues in patients who decline surgery or are at surgical risk. Its use should be restricted to specialized centers
- RFA is not recommended in the routine management of thyroid nodules

#### 7.2. Radioiodine Therapy for Benign Nodular Goiter

**Considerations**
- Indications are hyperfunctioning and/or symptomatic goiter, previous thyroid surgery, or surgical risk
- Before treatment, UGFNA biopsy should be performed per the recommendations given for nontoxic MNG
- Avoid use of iodine contrast agents or iodinated drugs before administration of radioiodine; withdraw antithyroid drugs at least 1 week before treatment and consider resumption 1 week after radioiodine therapy

**Contraindications**
- Radioiodine is contraindicated in pregnant or breastfeeding women
- Always perform a pregnancy test before administration of radioiodine in women of childbearing age

**Follow-up after Radioiodine Therapy**
- Regular thyroid function monitoring is mandatory
- Consider repeating treatment in cases of persistent or recurrent hyperthyroidism or inadequate size reduction

#### 7.3. Follicular Lesions

**Management**
- Repeated FNA biopsy of follicular lesions is not recommended because it does not provide additional information
- Core-needle biopsy is not recommended in the management of follicular lesions because it does not add additional information to FNA biopsy
- Molecular and histochemical markers are currently not recommended for routine use; their use may be considered in selected cases

**Treatment**
- Surgical excision is recommended for most follicular thyroid lesions
- Intraoperative frozen section is not recommended as a routine procedure
- Consider clinical follow-up in the minority of cases with favorable clinical, US, cytologic, and immunocytochemical features
### 7.4. Management of FNA Biopsy–Suspicious Nodules

- Surgery is recommended
- Intraoperative frozen section is useful

### 7.5. Nodules Malignant by FNA Biopsy

<table>
<thead>
<tr>
<th>Management</th>
<th>Management of FNA Biopsy–Malignant Nodules During Pregnancy</th>
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</thead>
<tbody>
<tr>
<td>Grade; BEL</td>
<td>For a thyroid nodule with FNA biopsy results positive for differentiated thyroid carcinoma, surgical treatment is recommended</td>
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<tr>
<td></td>
<td>For anaplastic carcinoma, metastatic lesions, and lymphoma, further diagnostic work-up is recommended before surgery</td>
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<td>Review US and cytologic results with the patient; discuss treatment options and obtain consultation with a surgeon experienced in endocrine surgery before surgery</td>
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<td>US examination of the neck, UGFNA biopsy of any concomitant suspicious nodule or lymph node, and vocal cord assessment should be performed</td>
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<td></td>
<td>In case of suspicious US features, the metastatic nature of a lymph node may be confirmed with measurement of thyroglobulin or calcitonin in the washout of the needle used for UGFNA biopsy</td>
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<td>MRI and/or CT is useful in selected cases</td>
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### 8. Pregnancy and Childhood

<table>
<thead>
<tr>
<th>Management of Thyroid Nodules During Pregnancy</th>
<th>Management of Thyroid Nodules in Children</th>
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<tbody>
<tr>
<td>Grade; BEL</td>
<td>Thyroid nodules in pregnant women should be managed in the same way as in nonpregnant women; in the presence of suspicious clinical or US findings, diagnosis necessitates FNA biopsy</td>
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<td></td>
<td>Avoid use of radioactive agents for both diagnostic and therapeutic purposes</td>
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<td>During pregnancy, suppressive levothyroxine therapy for thyroid nodules is not recommended</td>
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<td></td>
<td>For a growing thyroid nodule during pregnancy, follow-up should include US and FNA biopsy</td>
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<tr>
<td></td>
<td>If FNA biopsy shows a follicular lesion, surgery may be deferred until after delivery</td>
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<tr>
<td>Management of FNA Biopsy–Malignant Nodules During Pregnancy</td>
<td>Management of Thyroid Nodules in Children</td>
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<tr>
<td>Grade; BEL</td>
<td>When a diagnosis of thyroid malignancy is made during the first or second trimester, thyroidectomy may be done during the second trimester, if recommended. Women with no evidence of aggressive thyroid cancer may be reassured that surgical treatment performed soon after delivery is unlikely to adversely affect prognosis</td>
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<tr>
<td></td>
<td>When a diagnosis of thyroid malignancy is made during the third trimester, surgical treatment can be deferred until the immediate postpartum period</td>
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<td>Evaluation of nodular disease in children is similar to that in adults</td>
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<td>Because of a higher prevalence of malignancy in children, surgery is often necessary for cold as well as hot nodules</td>
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Appendix I

Levels of Evidence and Grading of Recommendations

The American Association of Clinical Endocrinologists (AACE) protocol for standardized production of clinical practice guidelines was followed to rate the evidence level (EL) of each reference on a scale of 1 to 4 and to link the guidelines to the strength of recommendations on the basis of grade designations A (action based on strong evidence) through D (action not based on any evidence or not recommended). The BEL, corresponding to the best conclusive evidence found, accompanies the recommendation grade. All recommendations resulted from a consensus among the AACE, Italian Association of Clinical Endocrinologists, and European Thyroid Association primary writers and were influenced by input from the Task Force members and reviewers. Some recommendations were upgraded or downgraded on the basis of expert opinion. In these cases, subjective factors such as clinical experience, cost, risk, and regional availability of specific technologies and expertise took priority over the reported BEL.

Strength-of-Evidence Scales Reported in the Medical Literature

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Level of Evidence</strong></td>
<td><strong>Level of Evidence</strong></td>
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</table>
| 1 | Well-controlled, generalizable, randomized trials  
Adequately powered, well-controlled multicenter trials  
Large meta-analyses with quality ratings  
All-or-none evidence |
| 2 | Randomized controlled trials; limited body of data  
Well-conducted prospective cohort studies  
Well-conducted meta-analyses of cohort studies |
| 3 | Methodologically flawed randomized clinical trials  
Observational studies  
Case series or case reports  
Conflicting evidence with weight of evidence supporting the recommendation |
| 4 | Expert consensus  
Expert opinion based on experience  
"Theory-driven conclusions"  
"Unproven claims" |

Evidence Grade Description for Recommendation Grades

<table>
<thead>
<tr>
<th>Level of Recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>A</strong></td>
<td>&gt;1 Conclusive level 1 publications demonstrating benefit &gt;&gt; risk</td>
</tr>
</tbody>
</table>
| **B** | No conclusive level 1 publication  
≥1 Conclusive level 2  
Publication demonstrating benefit >> risk |
| **C** | No Conclusive level 1 or 2 publication  
≥1 Conclusive level 3 publication demonstrating benefit >> risk  
or  
No conclusive risk at all and no benefit at all |
| **D** | No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk  
Conclusive level 1, 2, or 3 publication demonstrating risk >> benefit |

More detailed information:

http://www.hotthyroidology.com/  
http://www.eurothyroid.com/  
http://www.aace.com/  
http://www.associazionemediciendocrinologi.it/

Abbreviations:

AACE = American Association of Clinical Endocrinologists; AFTN = autonomously functioning thyroid nodule; AME = Associazione Medici Endocrinologi; BEL = best evidence level; CNB = core-needle biopsy; CT = computed tomography; EL = evidence level; ETA = European Thyroid Association; FNA = fine-needle aspiration; LNB = large-needle biopsy; MEN 2 = multiple endocrine neoplasia type 2; MeSH = Medical Subject Headings; MNG = multinodular goiter; MRI = magnetic resonance imaging; MTC = medullary thyroid carcinoma; PEI = percutaneous ethanol injection; PLA = percutaneous laser ablation; PTC = papillary thyroid carcinoma; rTSH = recombinant human TSH; TPOAb = anti-thyroid peroxidase antibody; TRAb = anti-TSH-receptor antibody; TSH = thyrotropin (thyroid-stimulating hormone); UGFNA = US-guided FNA; US = ultrasonography, ultrasonographic.
Appendix II

Flowchart Indicating a Scheme for the Diagnosis and Management of Palpable Thyroid Nodules

History (2)
Physical Examination (2)

Thyroid US with focus on risk stratification for malignancy (3.1)

Nodule diameter < 1 cm without suspicious history or suspicious US findings

Follow-up (4 and 7)

Nodule diameter > 1 cm or < 1 cm with suspicious history or suspicious US findings

TSH + Free thyroxine Calcitonin? (5)

Normal TSH

Suspicion for malignancy by clinical or US criteria (3.1; and 2)

Low TSH or MNG in iodine deficient region

Normofunctioning or cold on thyroid scintigraphy (6)

No

Yes

FNA biopsy (4)

Follicular lesion Suspicious Positive for malignant cells

Surgery (7.3–5)

Recommendations shown in parentheses, correspond to the relevant sections in this brochure.

FNA, fine-needle aspiration; MNG, multinodular goiter; TSH, thyrotropin; US, ultrasonography

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Acknowledgment

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This brochure has been made possible by Merck Serono