Introduction

Image-guided ablation techniques have emerged as minimally invasive alternatives to surgery for selected thyroid nodules. Over the past decade, international societies have published guidelines supporting ablation for benign nodules and limited malignant indications. However, differences in disease presentation, resource availability, imaging quality, cytopathology standards, medico-legal environments, and follow-up infrastructure limit the direct applicability of these guidelines in India.

Recognizing the growing use of thyroid ablation across India and the absence of national guidance, the Indian Association of Endocrine Surgeons (IAES) initiated a structured consensus process. The objective was to develop Indian-specific, evidence-informed, and feasibility-based recommendations using an adolopment framework (adopt, adapt, and de-novo recommendations).

Methods

Guideline Development Framework: The Indian Association of Endocrine Surgeons (IAES) developed these guidelines using an adolopment framework, integrating elements of adoption, adaptation, and de novo recommendation development. This approach was chosen to ensure that high-quality international evidence could be contextualized for Indian clinical practice while allowing formulation of original recommendations where evidence was limited or contextual factors were critical.

International guidelines, including those from major endocrine and surgical societies, were reviewed as source documents. Recommendations were then classified as:

Adopted (used without modification),

Adapted (modified to reflect Indian healthcare realities), or

De novo (newly developed where no suitable guidance existed).

Expert Panel Composition: A multidisciplinary expert panel was convened, comprising clinicians with recognized expertise in thyroid surgery, endocrine oncology, interventional ablation techniques, thyroid imaging, and perioperative care. Panelists were selected based on clinical experience, academic involvement, and familiarity with thyroid ablation in real-world practice. Participation was voluntary, anonymized, and uncompensated. The panel represented a range of institutional settings, reflecting variability in resources and practice environments across India.

Statement Development

Draft statements were generated through:

Review of international guidelines and key published evidence,

Identification of recommendations requiring contextual modification for Indian practice,

Development of de novo statements addressing training, credentialing, safety monitoring, and implementation gaps.

Each statement was clearly labeled internally as adopted, adapted, or de novo, although this categorization was not disclosed to panelists during scoring to minimize bias.

Modified Delphi Consensus Process

A two-round modified Delphi process was used to achieve expert consensus. This method was selected to systematically aggregate expert judgment in areas where evidence was evolving, heterogeneous, or context-dependent.

Panelists independently rated each statement using a 9-point Likert scale, where:

1–3 indicated disagreement or inappropriateness,

4–6 indicated uncertainty or equipoise,

7–9 indicated agreement or appropriateness.

Free-text comments were solicited to capture rationale, concerns, and suggested modifications.

Definition of Consensus

Consensus was defined a priori as agreement by ≥75% of respondents assigning a score of 7–9 to a statement. This threshold aligns with established Delphi methodology and has been used in prior surgical and endocrine consensus initiatives.

Delphi Rounds

Round-1: All draft statements were circulated electronically and scored independently. Quantitative scores and qualitative comments were collated and reviewed by the guideline working group.

Round-2: Statements that failed to reach the predefined consensus threshold in Round-1 were revised using panel feedback. Revisions included clarification of scope, conditional language, or restriction to research settings where appropriate. Only revised statements were redistributed for reassessment in Round-2.

Data Analysis and Finalization of Recommendations

Descriptive statistics were used to summarize responses, including median scores and proportion of panelists scoring 7–9. Statements achieving consensus were accepted as recommendations. Statements failing to achieve consensus after two Delphi rounds were designated as conditional recommendations or research-only statements, consistent with the principles of the adolopment framework.

Each final recommendation was assigned a strength of recommendation and quality of evidence rating based on the balance of benefits and risks, level of agreement, and confidence in the supporting evidence.

Ethical Considerations: As this study involved anonymized expert opinion without patient data, formal institutional ethics approval was not required.

Overview of the Delphi Consensus Process

Eighteen expert panelists completed both rounds of the modified Delphi process, resulting in a 100% response rate and retention. In Round-1, a total of 26 statements were evaluated across domains including indications, pre-procedure assessment, technique and safety, follow-up, complication reporting, training, and implementation.

Using a predefined consensus threshold of ≥75% agreement (scores 7–9 on a 9-point Likert scale), 21 of 26 statements (80.8%) achieved consensus in Round-1. Five statements (19.2%) did not meet the consensus threshold and were revised and re-evaluated in Round-2.

In Round-2, all 18 panelists again completed the survey. Consensus was achieved for 4 of the 5 revised statements (80%), while 1 statement continued to fall below the predefined threshold and was therefore retained as a conditional recommendation. Final recommendations were classified as adopted, adapted, or de novo in accordance with the adolopment framework.

Final Consensus Recommendations

1. Indications for Thyroid Ablation

1.1 Predominantly Cystic Benign Thyroid Nodules (Adapted Recommendation)

Recommendation
Ethanol ablation may be offered as a preferred minimally invasive treatment option for symptomatic, predominantly cystic benign thyroid nodules when performed in centres with adequate ultrasound capability and interventional expertise. Surgery remains an acceptable alternative.

Strength of Recommendation: Strong
Quality of Evidence: Moderate

In Round-1, ethanol ablation for predominantly cystic benign nodules achieved a median score of 8, with 66.7% (12/18) of panelists scoring the statement 7–9, failing to reach consensus. Following revision emphasizing centre expertise and retention of surgery as an alternative, Round-2 responses demonstrated improved agreement, with a median score of 7.5 and 77.8% (14/18) of panelists scoring 7–9, thereby achieving consensus.

This recommendation was classified as adapted, reflecting contextual modification of international guidance to emphasize operator expertise and institutional readiness.

1.2 Solid or Mixed Benign Thyroid Nodules (Bethesda II) (Adapted, Conditional Recommendation)

Recommendation
For symptomatic benign solid or mixed thyroid nodules (Bethesda II), RFA/MWA may be offered as a minimally invasive **alternative to surgery** in appropriately selected patients, where imaging/cytology quality and operator expertise are adequate.

Strength of Recommendation: Conditional
Quality of Evidence: Low–Moderate

Justification
Consensus was not achieved after two Delphi rounds (**66.7%, 12/18** in Round-2). Concerns included durability, cost, and diagnostic variability.

In Round-1, ablation for symptomatic solid or mixed benign nodules demonstrated a median score of 7.5, with 72.2% (13/18) agreement, narrowly missing the consensus threshold. After revision, Round-2 agreement declined slightly, with 66.7% (12/18) of panelists scoring 7–9, despite a median score of 8.

Given the persistent lack of consensus after two Delphi rounds, this recommendation was retained as conditional. Panelist comments highlighted concerns regarding durability of response, cost-effectiveness, diagnostic variability, and patient expectations, supporting individualized rather than routine use.

2. Ablation in Differentiated Thyroid Carcinoma

2.1 Papillary Thyroid Microcarcinoma (≤1 cm) (Adapted, Research-Only Recommendation)

Recommendation
Thermal ablation for papillary thyroid microcarcinoma (≤1 cm) should currently be restricted to ethically approved clinical trials or prospective registries in high-volume centres with multidisciplinary thyroid cancer expertise..

Strength of Recommendation: Research-only
Quality of Evidence: Very Low

In Round-1, ablation for papillary thyroid microcarcinoma failed to reach consensus, with a median score of 6 and 38.9% (7/18) agreement. After revision restricting ablation to ethically approved clinical trials or registries, Round-2 responses demonstrated a marked increase in agreement, with a median score of 8 and 77.8% (14/18) of panelists scoring 7–9.

This recommendation was classified as adapted and explicitly designated as research-only, reflecting strong panel consensus against routine clinical use in current Indian practice.

2.2 Low-Risk Papillary Thyroid Carcinoma (≤2 cm) (Adapted Recommendation)

Recommendation
For low-risk PTC (≤2 cm) patients who refuse surgery after adequate counseling, thermal ablation may be considered only in select centres with multidisciplinary thyroid oncology

capability, ideally under IRB/ethics oversight. Ablation should **not** be routinely offered as first-line therapy.

Strength of Recommendation: Weak
Quality of Evidence: Very Low

In Round-1, ablation for low-risk PTC ≤2 cm achieved 55.6% (10/18) agreement, with a median score of 7, failing to reach consensus. After revision clarifying that ablation should not be offered as first-line therapy and should be limited to highly selected patients refusing surgery, Round-2 agreement increased to 77.8% (14/18), with a median score of 8, meeting the consensus threshold.

This recommendation was therefore accepted as an adapted recommendation, emphasizing surgical standard-of-care and exceptional use of ablation.

3. Recurrent Nodal Papillary Thyroid Carcinoma (Adopted Recommendation)

Recommendation
Image-guided ablation may be offered for biopsy-proven, accessible recurrent nodal disease in poor surgical candidates or those refusing re-operation.

Strength of Recommendation: Strong
Quality of Evidence: Moderate

Ablation for biopsy-proven, accessible recurrent nodal disease in poor surgical candidates achieved consensus in Round-1, with a median score of 8 and 100% (18/18) agreement. No revision was required in Round-2.

This recommendation was classified as adopted, aligning directly with existing international guidance.

4. Pre-Procedure Assessment and Patient Selection

4.1 Radiology Quality and TI-RADS Scoring

Because many Indian centres lack standardized thyroid ultrasound expertise, we propose that thermal/chemical ablation should be performed only after the nodule has been evaluated by a radiologist or ultrasonologist trained in TI-RADS classification and thyroid imaging, to minimize the risk of missing malignancy.

4.2 Cytopathology Reliability

Given variability in cytopathology standards across India, ablation should be undertaken only after confirmation of ***Bethesda II benign cytology by experienced thyroid cytopathologist****, after two concordant benign FNAs/Core biopsies*

4.3 Pre-procedure Patient Counseling and Shared Decision-Making

Before ablation, the treating clinician must have a detailed discussion with the patient explaining: (a) that the procedure is not a "tumor removal" but a "tumor shrinkage" therapy; (b) that success is defined as > 50 % reduction in volume with symptomatic relief;

(c) that there is a small possibility of regrowth or need for re-treatment; and (d) that surgery remains a definitive alternative. A standardized counseling checklist should be used and documented.

4.5 Patient Selection and Expectation Alignment

In the Indian context, ablation should be reserved for well-informed, motivated patients who accept its conservative nature and understand that nodular regrowth may occur. Patients who demand "complete removal" or are anxious about residual tissue should be guided towards surgery instead.

All statements related to pre-procedure evaluation achieved consensus in Round-1, with median scores ranging from 8 to 9 and agreement rates of 100% (18/18). These included mandatory TI-RADS-based ultrasound assessment, confirmation of benign disease with two concordant cytology results prior to ablation, and standardized patient counseling and shared decision-making.

5. Procedural Technique and Safety

5.1 The procedure should be performed under real-time ultrasound guidance using the trans-isthmic moving-shot technique where feasible.
5.2 Hydro-dissection should be used to protect critical structures when nodules are adjacent to the recurrent laryngeal nerve or trachea.
5.3 Local anaesthesia ± superficial cervical plexus block is appropriate for most benign nodule ablations; general anaesthesia is reserved for complex cases.
5.4 Power and duration settings should be adjusted to achieve complete coverage without capsular overheating (technique optimization left to device-specific protocols).
5.5 Routine antibiotic prophylaxis is not required for clean percutaneous procedures.

Statements addressing ultrasound guidance, trans-isthmic technique, hydro-dissection near critical structures, and anesthesia approach achieved 80–100% agreement in Round-1, with median scores of 8–9, and were retained without modification.

6. Real-Time Voice Monitoring (De novo Recommendation)

Recommendation
Real-time voice monitoring using a simple "talk test" is strongly recommended whenever feasible during thyroid ablation, with availability of nerve rescue protocols.

Strength of Recommendation: Strong
Quality of Evidence: Low (expert consensus)

In Round-1, mandatory real-time voice monitoring failed to achieve consensus, with 72.2% (13/18) agreement and a median score of 8. After revision acknowledging feasibility constraints, Round-2 agreement increased to 88.9% (16/18), with a median score of 8, achieving consensus.

This recommendation was classified as de novo, reflecting the absence of explicit guidance in existing international documents.

7. Follow-Up and Outcome Assessment

7.1 Baseline and follow-up ultrasounds should be done at 1, 3/6, and 12 months to calculate Volume Reduction Ratio (VRR).

7.2 VRR ≥ 50 % at 12 months plus symptom/cosmetic improvement defines treatment success.
7.3 Retreatment should be considered if VRR < 30 % or if symptoms persist beyond 6–12 months.
7.4 Routine thyroid function tests at 3 and 12 months are recommended.

Strength of Recommendation: Strong
Quality of Evidence: Moderate

All follow-up-related statements achieved consensus in Round-1, with 100% agreement and median scores of 8, including standardized ultrasound follow-up, use of volume reduction ratio (VRR) to define treatment success, retreatment criteria, and thyroid function testing.

8. Complication Reporting

8.1 All centres should document and report complications according to the Clavien–Dindo classification.
8.2 Major complication rate should remain < 1 %, with voice change > 3 months < 0.5%.
8.3 Every procedure should include real-time voice monitoring (“talk test”) and availability of laryngeal nerve rescue protocol.

Standardized reporting using the Clavien–Dindo classification and a target major complication rate of <1% achieved 100% agreement (18/18) in Round-1, with median scores of 9, and were adopted without modification.

9. Training, Credentialing, and Maintenance of Competence (De novo Recommendations)

Recommendation
Independent thyroid ablation should be performed only by operators who have completed:
• ≥50 supervised neck ultrasounds
• ≥20 supervised US-guided FNAs
• ≥10 supervised ablations
• ≥10 ablations/year to maintain proficiency

Strength of Recommendation: Strong
Quality of Evidence: Moderate

Training and credentialing thresholds demonstrated among the highest agreement levels across both rounds. In Round-2, agreement rates were 94.4% (17/18) for minimum supervised diagnostic ultrasounds, 94.4% (17/18) for minimum supervised ablations prior to independent practice, and 88.9% (16/18) for minimum annual procedural volume, with median scores of 8 across all items.

These recommendations were classified as de novo, addressing critical gaps in existing guidance.

10. **Indian Context and Implementation**

10.1 Ablation should preferably be offered as a day-care procedure to reduce cost and hospital burden.
10.2 Standardized informed consent should include possible need for retreatment and rare complications.
10.3 Regular audit of VRR, complication rates, and follow-up completion should be mandatory for centre accreditation.

These recommendations were classified as de novo, addressing critical gaps in existing guidance.