EnM
ENDOCRINOLOGY AND METABOLISM

Review Article

Endocrinol Metab 2025;40:307-341
https://doi.org/10.3803/EnM.2025.2461
pISSN 2093-596X · eISSN 2093-5978

2025 Korean Thyroid Association Clinical Management Guideline on Active Surveillance for Low-Risk Papillary Thyroid Carcinoma

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The increasing detection of papillary thyroid microcarcinoma (PTMC) has raised concerns regarding overtreatment. For low-risk PTMC, either immediate surgery or active surveillance (AS) can be considered. To facilitate the implementation of AS, the Korean Thyroid Association convened a multidisciplinary panel and developed the first Korean guideline. AS is recommended for adults with pathologically confirmed Bethesda V–VI PTMC who have no clinical evidence of lymph node or distant metastasis, gross extrathyroidal extension, invasion of the trachea or recurrent laryngeal nerve, or aggressive histology. A baseline assessment requires

Received: 17 May 2025, **Revised:** 25 May 2025, **Accepted:** 29 May 2025

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This guideline has been originally written in Korean and published in the *International Journal of Thyroidology* 2025;18(1):30-64.

high-resolution neck ultrasound performed by experienced operators to exclude extrathyroidal extension, tracheal or recurrent laryngeal nerve invasion, and lymph node metastasis; contrast-enhanced neck computed tomography is optional. Patient characteristics, including age, comorbidities, and the capacity for long-term follow-up, should be thoroughly assessed. Shared decision-making should carefully weigh the benefits and risks of surgery versus AS, considering expected oncologic outcomes, potential complications, quality of life, anxiety, medical costs, and patient preference. Follow-up involves neck ultrasound and thyroid function tests every 6 months for 2 years and annually thereafter. Disease progression, defined as significant tumor growth or newly detected nodal or distant metastasis, warrants surgery. Despite remaining uncertainties, this guideline provides a structured framework to ensure oncologic safety and supports patient-centered AS.

Keywords: Active surveillance; Guideline; Korean; Papillary thyroid microcarcinoma; Thyroid neoplasms

INTRODUCTION

The incidence of thyroid cancer has increased sharply worldwide since the early 2000s [1]. As of 2022, the global incidence rate was 9.1 per 100,000 people, making it the seventh most common cancer globally [2]. Korea has a substantially higher incidence rate, which reached 48.4 per 100,000 people in 2022, making it the most common cancer type in the country [3].

The rapid increase in thyroid cancer incidence in Korea has been attributed to the widespread utilization of high-resolution ultrasound (US) and the general adoption of health screening programs. Incidence rates rose markedly from 24.1 per 100,000 in 2005 to 74.8 per 100,000 in 2012 [3,4]. Although this trend has since declined, approximately 35% of diagnosed thyroid cancers remain papillary thyroid microcarcinomas (PTMCs), measuring 1 cm or less [5]. This situation has sparked ongoing societal concerns about the over-diagnosis and overtreatment of thyroid cancer [6,7].

The primary treatment goals for differentiated thyroid cancer include improving patient survival and reducing the risk of disease persistence or recurrence [8], while simultaneously minimizing treatment-related complications and avoiding unnecessary interventions. PTMC generally exhibits an excellent long-term prognosis, with disease-specific mortality below 0.1% and recurrence rates around 3% [9]. Although clinically apparent lymph node (LN) metastasis accompanies 9%–42% of cases at diagnosis [10-13], many patients present no evidence of distant metastasis or extrathyroidal extension (ETE). In such cases, the prognosis is especially favorable. Therefore, upon detecting PTMC, it is optimal to assess for metastasis or ETE, and if these factors are absent, active surveillance (AS), rather than immediate surgery, may represent a suitable approach [14].

AS involves monitoring patients with low-risk PTMC through regular US examinations without immediate surgery, reserving surgical intervention for cases where disease progression is observed during follow-up. This strategy was first implemented in Japan in 1993, with the initial results published in 2003 [14]. In 2011, the Japanese clinical guidelines formally adopted AS [15]. Based on subsequent international studies, numerous clinical guidelines now recommend AS as a viable management option for low-risk PTMC [16]. Prospective cohort studies evaluating AS in Korea began in 2016, with several prospective and retrospective studies published since then [17-20].

The Korean Thyroid Association (KTA) first addressed the feasibility and limitations of AS in its 2016 guideline [21]. In response to accumulating clinical evidence [22], the 2023 guidelines for thyroid nodules and the 2024 guidelines for differentiated thyroid cancers included AS among the management strategies for low-risk PTMC [8,23]. However, to effectively implement AS in clinical practice, it is essential to appropriately identify candidates for AS, employ suitable methods and intervals for patient monitoring, and determine optimal timing for surgical intervention. Addressing these needs, the current guideline provides evidence-based recommendations derived either from a systematic literature review or expert consensus. Key points for each section are outlined within a framework containing specific recommendations and corresponding evidence levels. This guideline has been published in the official journal of the KTA, the *International Journal of Thyroidology* [24], and is also available on the KTA website (www.thyroid.kr).

DEVELOPMENT PROCESS OF THE KTA CLINICAL PRACTICE GUIDELINE FOR ACTIVE SURVEILLANCE

Composition of the guideline development committee and purpose of the guideline

The KTA clinical practice guideline for AS of low-risk PTMC was developed by the KTA Committee for the Development of Clinical Guidelines for Thyroid Nodules and Cancer, composed of representatives recommended by six relevant academic societies: the Korean Endocrine Society, Korean Association of Endocrine Surgeons, Korean Society for Head and Neck Surgery, Korean Society of Nuclear Medicine, Korean Society of Thyroid Radiology (KSThR), and Korean Society of Pathologists. An advisory committee was also established, including members recommended by these societies, as well as board members from the 2023 to 2025 KTA, representing internal medicine, pathology, radiology, surgery, otolaryngology, and nuclear medicine.

This guideline targets adult patients (aged 19 years or older) diagnosed with PTMC, defined as thyroid nodules ≤1 cm diagnosed as suspicious for malignancy or malignant (Bethesda category V or VI) through cytopathologic testing. Although recent studies in some countries are investigating the extension of AS to low-risk papillary thyroid carcinomas (PTCs) up to 1.5 or 2 cm [25-29], current evidence remains insufficient for general clinical adoption. Thus, this guideline limits its scope to PTMCs ≤1 cm in size.

The guideline aims to support physicians treating thyroid cancer in healthcare settings when selecting and monitoring treatment strategies—particularly when choosing between surgery and AS—for adult patients diagnosed with PTMC. This document cannot serve as an absolute standard of care; rather, it provides recommendations based on the current evidence, especially in areas of ongoing clinical debate.

Process of developing recommendations

In January 2024, the KTA conducted an online survey among its members regarding treatment strategies for low-risk thyroid cancer and opinions on imaging criteria for AS [30]. According to the survey, 36% of respondents expressed the greatest concern about legal problems or patient complaints related to disease progression. Patient anxiety and worry ranked next (26%), followed by concerns about an increased treatment burden due to disease progression (24%) [30]. Additionally, 88% of respondents emphasized the need for psychological support for anxious patients and insurance coverage for long-term US follow-ups, and 85% highlighted the shortage of adequate patient education materials.

Based on these findings, this guideline addresses the diagnosis and treatment of low-risk PTMC, criteria for candidate selection for AS, follow-up strategies, and evaluation methods. Five critical clinical questions requiring systematic literature review were identified. These questions were formulated referencing the Agency for Healthcare Research and Quality Effective Health Care Program framework [31] and then refined by the guideline development committee members.

Search terms were developed through discussions among committee members and methodology experts. Literature searches were conducted using Medline, Embase, and Cochrane databases and were supplemented by manual searches. Inclusion and exclusion criteria were applied based on the PICO (population, intervention, comparator, outcome) format for each question. Evidence synthesis included both quantitative meta-analysis and qualitative review.

For other content, this guideline refers to the 2024 KTA guideline for differentiated thyroid cancers [8] and the 2024 KSThR consensus statement [32], as well as recommendations and systematic reviews from countries such as Japan and South American nations [33,34].

The initial draft was prepared by committee members specializing in internal medicine, pathology, radiology, and preventive medicine, and subsequently reviewed by members specializing in surgery and otolaryngology. An open discussion involving KTA members took place during the Spring Scientific Meeting in March 2025. Following this discussion, the draft was revised based on feedback from advisory committee members representing the six relevant academic societies and recommendations derived from key questions finalized through a Delphi questionnaire process. Final approval was granted after incorpo-

Table 1. Levels of Recommendation in the Korean Thyroid Association Clinical Management Guidelines

Grade	Level	Definition
1	Strongly recommend for/against	Sufficient and objective evidence exists that performing (or avoiding) the recommended action leads to significant health benefits or harms.
2	Conditionally recommend for/against	Evidence suggests important health benefits or harms, but the evidence is uncertain or indirect, making a uniform recommendation difficult.
3	Expert consensus recommendation	In the absence of strong clinical evidence, the recommendation is based on expert consensus and patient-specific considerations.
4	Inconclusive	Insufficient or conflicting evidence exists regarding significant health benefits or harms; no definitive recommendation for or against the action can be made.

rating additional feedback gathered from KTA members via the website and securing endorsements from relevant societies.

Levels of recommendation and summary

Key points in each section are presented as specific recommendations, each accompanied by the appropriate recommendation level. The classification system for recommendation levels is detailed in Table 1. Recommendations for the clinical management of AS for low-risk PTMC are summarized in Table 2.

1. DIAGNOSIS AND MANAGEMENT OF PTMC

1.1. Diagnosis of PTMC

Pathologic diagnosis of thyroid nodules should adhere to the 2021 KSThR and 2024 KTA guidelines [35,36]. When thyroid nodules are classified as 'high-suspicion' (K-TIRADS 5) according to the Korean Thyroid Imaging Reporting and Data System (K-TIRADS) on US, a pathologic examination—such as fine-needle aspiration (FNA) or core-needle biopsy (CNB)—should be performed if the nodule exceeds 1 cm [35,36]. However, a pathologic examination is required regardless of nodule size if any of the following conditions exist: (1) suspected neck LN metastasis; (2) obvious invasion of adjacent structures such as the trachea, larynx, pharynx, recurrent laryngeal nerve (RLN), or perithyroidal vessels; (3) suspected distant metastasis; or (4) suspicion of medullary thyroid carcinoma. Additionally, a pathological examination is recommended for small (>0.5 to ≤1 cm), high-suspicion (K-TIRADS 5) nodules that appear attached to the trachea or posteromedial capsule along the course of the RLN, as these may represent cancers with poor prognostic risk factors requiring surgery.

If a small (>0.5 to ≤1 cm), high-suspicion nodule without poor prognostic risk factors is identified on US, monitoring with neck US rather than immediate pathologic examination is appropriate. In such cases, nodules are managed similarly to AS for low-risk PTMC, and pathologic examination is pursued only if disease progression occurs. Particularly, nodules resembling focal thyroiditis may be monitored with neck US without immediate biopsy, as they frequently regress or disappear on subsequent imaging. However, if pathologic diagnosis is necessary for treatment planning, a FNA may be considered even for a small (>0.5 to ≤1 cm), high-suspicion nodule without poor prognostic risk factors.

International guidelines advocate AS without pathologic examination for high-suspicion thyroid nodules smaller than 1 cm [37,38]. The 2015 American Thyroid Association (ATA) guideline recommends FNA only for high-suspicion nodules ≥1 cm [39] whereas the 2023 European Thyroid Association (ETA) guideline advises FNA for high-suspicion nodules measuring 0.5 to 1 cm only when there is suspicion of LN metastasis, risk of ETE, or location in a concerning area (e.g., proximity to the trachea or RLN) [37]. Reflecting these data and the excellent prognosis of low-risk PTMC, the 2024 KSThR consensus statement suggests that for high-suspicion nodules without suspicious imaging features of gross ETE, LN metastasis, or distant metastasis, AS without biopsy can be considered after incorporating patient preferences [32]. However, in children, a pathologic examination remains necessary even for small (>0.5 to ≤ 1 cm), high-suspicion nodules without poor prognostic risk factors, while considering clinical factors [36].

1.2. Management strategy for PTMC

1.2.A. When PTMC is diagnosed, imaging and pathologic findings should be thoroughly reviewed to determine whether the tumor is classified as low-risk. **[Recommendation level 1]**

1.2.B. Adult patients (aged ≥19 years) diagnosed with low-risk PTMC may be considered for AS. **[Recommendation level 2]**
[Clinical consideration] For patients under the age of 19 with PTMC, surgery is recommended regardless of whether the tumor is classified as low-risk.

1.2.C. For PTMCs not meeting the low-risk criteria, surgery is recommended. **[Recommendation level 1]**

1.2.D. The extent of surgery for PTMC should follow the KTA guidelines on the management of differentiated thyroid cancers. **[Recommendation level 1]**

Because low-risk PTMC has a favorable natural history [22], both surgery and AS are acceptable treatment options. Therefore, thorough evaluation for poor prognostic risk characteristics is essential for pathologically confirmed PTMC.

If the tumor is not classified as low-risk, surgery is recommended; if it is low-risk, either AS or surgery can be considered. If surgery is recommended or chosen, the extent of surgery for PTMC should adhere to the KTA guidelines on the management of differentiated thyroid cancers [8]. The 2024 KTA guideline recommends thyroid lobectomy for low-risk PTMC patients without prior head-and-neck radiation and without familial thyroid carcinoma, unless clear indications exist to remove the contralateral lobe [8]. Long-term survival is comparable between thyroid lobectomy and total thyroidectomy in this patient group [40]. Although total thyroidectomy may reduce contralateral-lobe recurrence risk, lobectomy alone still results in a low recurrence rate, and recurrences can be effectively managed if they

Table 2. Summary of the KTA Clinical Management Guideline on Active Surveillance for Low-Risk PTMC

1. Diagnosis and management of PTMC

1.1. Diagnosis of PTMC

1.2. Management strategy for PTMC

1.2.A. When PTMC is diagnosed, imaging and pathologic findings should be thoroughly reviewed to determine whether the tumor is classified as low-risk. [Recommendation level 1]

1.2.B. Adult patients (aged ≥19 years) diagnosed with low-risk PTMC may be considered for AS. [Recommendation level 2]

[Clinical consideration] For patients under the age of 19 with PTMC, surgery is recommended regardless of whether the tumor is classified as low-risk.

1.2.C. For PTMCs that do not meet the criteria for low-risk, surgery is recommended. [Recommendation level 1]

1.2.D. The extent of surgery for PTMC should follow the KTA guidelines on the management of differentiated thyroid cancers. [Recommendation level 1]

2. Selection of candidates for AS

2.1. Definition of low-risk PTMC eligible for AS

2.1.A. Low-risk PTMCs eligible for AS are defined as follows. [Recommendation level 1]:

Thyroid nodules ≤ 1 cm diagnosed as Bethesda category V ('suspicious for malignancy') or VI ('malignant') on FNA or CNB, provided all the following criteria:

(1) No clinical evidence of LN metastasis or distant metastasis

(2) No evident imaging features of gross ETE into strap muscles, trachea, or RLN

(3) No suspicious imaging features suggestive of tracheal or RLN invasion

(4) Absence of aggressive histologic subtypes of papillary thyroid carcinoma (e.g., tall cell, columnar cell, hobnail, solid, or diffuse sclerosing subtypes)

2.2. Diagnostic evaluation for tumor risk assessment

2.2.A. Appropriate imaging of the thyroid and neck LNs should be performed to confirm eligibility for AS. [Recommendation level 1]

2.2.B. High-quality US examinations of the thyroid and neck should be conducted by physicians experienced in thyroid and neck US imaging. [Recommendation level 1]

2.2.C. In addition to US, contrast-enhanced neck CT may be considered for evaluating neck LNs. [Recommendation level 2]

2.2.D. If LN metastasis is suspected, US-guided FNA with washout thyroglobulin measurement should be performed. [Recommendation level 1]

2.2.E. Routine chest CT for evaluating lung metastasis in PTMC patients is not recommended. [Recommendation level 3]

2.2.F. If aggressive subtypes are suspected based on pathology, they should be explicitly reported in the pathology report. [Recommendation level 3]

2.2.G. Surgery is recommended if high-risk genetic mutations or multiple genetic mutations are identified. [Recommendation level 3]

[Clinical consideration] Although preoperative genetic panel testing may provide prognostic information, its routine use in PTMC is not currently supported by sufficient evidence. However, if mutation results are available, they should be considered in decision-making.

2.3. Imaging-based criteria for tumor risk assessment

2.3.A. Subcapsular and paratracheal tumors should be carefully evaluated for the risk of gross ETE. [Recommendation level 1]

2.3.B. The following imaging features are associated with a high-risk of gross ETE and should prompt consideration of immediate surgery:

- Anterior subcapsular tumors with strap muscle replacement
- Paratracheal tumors abutting ≥90° of the trachea
- Posteromedial subcapsular tumors lacking intervening normal thyroid parenchyma
- Posterolateral subcapsular tumors with obvious protrusion beyond the thyroid capsule

[Recommendation level 2]

2.3.C. Gray-scale and color Doppler US should be used to thoroughly assess neck LNs in both central and lateral compartments for evidence of metastasis. [Recommendation level 2]

2.3.D. If LN metastasis is confirmed, surgery is recommended. [Recommendation level 1]

Table 3. Image-based risk stratification and pathologic diagnosis criteria for LN evaluation in patients with thyroid cancer

Fig. 1. US-based appropriateness criteria for AS in PTMC

(Continued to the next page)

Table 2. Continued

2.4. Characteristics of patients suitable for AS

2.4.A. When considering AS, a comprehensive evaluation of the patient's characteristics—including tumor features, general health status, age, and ability to undergo regular follow-up—is necessary. [Recommendation level 1]

2.4.B. AS may be preferentially considered for older patients or those with smaller tumors. [Recommendation level 2]

2.4.C. Patient preferences regarding disease prognosis (progression or recurrence), potential complications, QoL and anxiety, and the medical and/or societal costs of AS versus immediate surgery should be considered. [Recommendation level 2]

2.5. Evaluation of suitability for AS

2.5.A. Suitability for AS must be evaluated carefully by an expert capable of accurately identifying high-risk US features. Assessment of suitability for AS should be performed by experienced physicians capable of accurately identifying high-risk US features. [Recommendation level 3]

2.5.B. The appropriateness of AS should be determined through a comprehensive assessment of both tumor-specific factors (e.g., size, location, histopathology, or presence of LN metastasis) and patient-related factors (e.g., age, preference, comorbidities, or feasibility of follow-up). Based on this assessment, tumors can be classified as ideal, appropriate, or inappropriate candidates for AS. [Recommendation level 3]

[Clinical consideration] AS should be implemented for tumors classified as ideal or appropriate. If disease progression (e.g., tumor growth or newly developed LN metastasis) leads to reclassification into the inappropriate category, surgical intervention is then recommended.

Table 4. Appropriateness criteria for AS in patients with PTMC

3. Considerations in determining the management strategy for low-risk PTMC

3.A. Clinicians should provide adult patients with low-risk PTMC sufficient information about the benefits and risks of both surgery and AS. [Recommendation level 3]

3.B. Clinicians should determine the management strategy for low-risk PTMC through a shared decision-making process with the patient. [Recommendation level 3]

3.1 Pros and cons of surgery and AS, and selection of a management strategy

3.2. Natural course of low-risk PTMC

3.3. Prognosis and complications of immediate vs. delayed surgery

3.3.A. In patients with low-risk PTMC, delayed surgery following AS may be associated with a higher risk of temporary surgical complications compared to immediate surgery; however, delayed surgery does not increase the risk of permanent complications or disease recurrence. Thus, AS can be considered an appropriate management strategy. [Recommendation level 2]

3.4. Costs of immediate surgery vs. AS

3.4.A. In patients with low-risk PTMC, both short-term and long-term costs vary depending on the treatment strategy. Therefore, social healthcare costs should be comprehensively considered when determining the treatment strategy. [Recommendation level 3]

[Clinical considerations] Social healthcare costs include direct and indirect components, each influenced by individual factors such as employment status, proximity to medical facilities, and productivity loss. Therefore, a thorough and individualized evaluation is necessary when selecting a treatment strategy.

3.5. QoL of immediate surgery vs. AS

3.5.A. Although studies directly comparing QoL between treatment modalities in patients with low-risk PTMC are limited, PROs should be considered during treatment decision-making, as they may help reduce patient anxiety. [Recommendation level 3]

[Clinical considerations] PROs refer to self-reported assessments of health status that reflect the patient's subjective experience. In patients with low-risk thyroid cancer, these include evaluations of quality of life, anxiety, and depression.

4. Follow-up during AS

Fig. 2. Algorithm for follow-up during AS

4.A. During AS, periodic and comprehensive evaluation of tumor status, including neck LNs, using neck US is required. [Recommendation level 1]

4.B. During AS, periodic thyroid function tests should be performed to monitor hormonal status. [Recommendation level 3]

[Clinical considerations] The need to modify the management strategies should be evaluated in the context of the patient's comorbidities, preferences, and other individual clinical characteristics.

4.1. Thyroid US

4.1.A. To evaluate disease progression, US should be performed every 6 months for the first 1–2 years following diagnosis. If no progression is observed, annual US is recommended thereafter. [Recommendation level 1]

(Continued to the next page)

Table 2. Continued

[Clinical considerations] Tumor progression should be assessed using consistent methodology throughout follow-up. The follow-up interval may be adjusted according to tumor growth patterns observed on serial US.
4.1.B. Tumor size, ETE, and LN metastasis should be assessed using US during AS. [Recommendation level 1]
4.1.C. Tumor size should be measured in three dimensions during each US examination. [Recommendation level 1]
4.1.D. If LN metastasis is suspected, FNA should be performed under US guidance, along with measurement of thyroglobulin in the FNA washout fluid. [Recommendation level 1]
4.2. Assessment of thyroid function
4.3. Assessment of patient characteristics
5. Evaluation of disease status during AS
5.1. Criteria for disease progression
5.1.A. Disease progression during AS is defined by the presence of at least one of the following criteria:
(1) Tumor enlargement: An increase in maximal tumor diameter of ≥ 3 mm or an increase of ≥ 2 mm in at least two dimensions. [Recommendation level 3]
(2) Newly detected clinical evidence of ETE, LN metastasis, or distant metastasis. [Recommendation level 1]
5.2. Indications for Surgery During AS
5.2.A. Surgery is recommended during AS if any of the following are met:
(1) The tumor's maximal diameter reaches ≥ 13 mm, or at least two dimensions measure ≥ 12 mm. [Recommendation level 3]
(2) A new US finding is identified that corresponds to image features considered inappropriate for AS, as outlined in Fig. 1. [Recommendation level 1]
(3) New LN or distant metastasis is confirmed or suspected. [Recommendation level 1]
(4) The patient elects to undergo surgery. [Recommendation level 1]
5.2.B. The extent of surgery should be determined according to the KTA guidelines on the management of differentiated thyroid cancers. [Recommendation level 1]
6. Issues to be addressed in the future
6.1. Evidence on long-term outcomes
6.2. Predictive factors for disease progression
6.3. Treatments to prevent disease progression
6.4. US-guided minimally invasive therapy
6.5. Need for research on AS without pathologic diagnosis

KTA, Korean Thyroid Association; PTMC, papillary thyroid microcarcinoma; AS, active surveillance; FNA, fine-needle aspiration; CNB, core-needle biopsy; LN, lymph node; ETE, extrathyroidal extension; RLN, recurrent laryngeal nerve; US, ultrasound; CT, computed tomography; QoL, quality of life; PRO, patient-reported outcome.

occur. Moreover, total thyroidectomy carries a higher complication risk than lobectomy. Thus, a more conservative initial surgical approach is preferable, even at the expense of slightly higher recurrence rates.

AS for low-risk PTMC should be restricted to adults (≥19 years), given insufficient safety data for children and adolescents. While direct evidence is lacking in patients under 19 years of age, several studies have suggested increased disease progression risk in younger individuals. This is supported by a Japanese cohort study, which reported 10-year progression rates of 13%–36% in patients in their 20s–30s, 5%–14% in those in their 40s–50s, and only 3%–6% among individuals in their 60s–70s [41]. Similarly, a Korean study reported disease progression in 17.9% of patients under 30 years of age, compared to 6.7% in those aged 30 and older during a median follow-up of 41 months [19].

In summary, clinicians must carefully evaluate whether a tumor truly qualifies as low-risk before deciding on treatment strategies for adult PTMC patients. If it does, treatment selection should involve shared decision-making, carefully balancing immediate surgery against AS, while incorporating patient values and preferences.

2. SELECTION OF CANDIDATES FOR ACTIVE SURVEILLANCE

When considering AS for a patient with PTMC, it is crucial to confirm thoroughly that the tumor meets low-risk criteria by reviewing imaging findings, including neck US, as well as pathologic findings.

2.1. Definition of low-risk PTMC eligible for AS

2.1.A. Low-risk PTMCs eligible for AS are defined as follows. **[Recommendation level 1]**

Thyroid nodules ≤1 cm diagnosed as Bethesda category V ('suspicious for malignancy') or VI ('malignant') on FNA or CNB, provided all the following criteria:

(1) No clinical evidence of LN metastasis or distant metastasis
(2) No evident imaging features of gross ETE into strap muscles, trachea, or RLN
(3) No suspicious imaging features suggestive of tracheal or RLN invasion
(4) Absence of aggressive histologic subtypes of papillary thyroid carcinoma (e.g., tall cell, columnar cell, hobnail, solid, or diffuse sclerosing subtypes)

PTMCs typically exhibit slow growth and excellent prognosis, with disease-specific mortality below 0.1% and recurrence rates around 3% [9]. In contrast, tumors with aggressive histologic subtypes (e.g., tall cell, columnar cell, hobnail, solid, or diffuse sclerosing subtypes) typically grow more rapidly, making surgery preferable. When invasion of the trachea or RLN is suspected, complete resection becomes challenging and is associated with a higher recurrence rate. While PTMCs without clinical LN metastasis recur in approximately 2% of cases, recurrence rates increase to about 22% when clinical LN metastasis is suspected [42].

Reflecting these observations, a Japanese prospective study excluded PTMCs with suspected LN metastasis, invasion of the trachea or RLN, or aggressive histologic subtypes from AS due to poorer prognoses [14]. Similarly, the 2015 ATA guideline restricts AS to PTMCs without clinically evident metastasis or local invasion, and without cytologic evidence of aggressive histologic subtypes [39].

The 2024 KTA guideline maintains these core requirements. In alignment with the 2024 KSThR consensus statement, it further clarifies 'evident' invasion (including strap muscles) versus 'suspicious' invasion (excluding strap muscles) and explicitly includes the solid and diffuse sclerosing subtypes among aggressive histologic subtypes. Therefore, eligibility criteria for AS are: (1) no clinical evidence of LN or distant metastasis, (2) no evident imaging features of gross ETE into strap muscles, trachea, or RLN, (3) no suspicious imaging features suggestive of tracheal or RLN invasion, and (4) absence of aggressive histologic subtypes of PTCs.

2.2. Diagnostic evaluation for tumor risk assessment

To establish that a PTMC is truly low-risk, imaging studies should evaluate LN metastasis, distant metastasis, and gross ETE, while pathological examination must clearly identify and exclude aggressive histologic subtypes whenever feasible.

2.2.A. Appropriate imaging of the thyroid and neck LNs should be performed to confirm eligibility for AS. **[Recommendation level 1]**

2.2.B. High-quality US examinations of the thyroid and neck should be conducted by physicians experienced in thyroid and neck US imaging. **[Recommendation level 1]**

2.2.C. In addition to US, contrast-enhanced neck CT may be considered for evaluating neck LNs. **[Recommendation level 2]**

2.2.D. If LN metastasis is suspected, US-guided FNA with washout thyroglobulin measurement should be performed. **[Recommendation level 1]**

2.2.E. Routine chest CT for evaluating lung metastasis in PTMC patients is not recommended. **[Recommendation level 3]**

2.2.F. If aggressive subtypes are suspected based on pathology, they should be explicitly reported in the pathology report. **[Recommendation level 3]**

2.2.G. Surgery is recommended if high-risk genetic mutations or multiple genetic mutations are identified. **[Recommendation level 3]**
[Clinical consideration] Although preoperative genetic panel testing may provide prognostic information, its routine use in PTMC is not currently supported by sufficient evidence. However, if mutation results are available, they should be considered in decision-making.

(1) Thyroid US

US is the primary imaging method for assessing malignancy risk in thyroid nodules [43-45], and is essential both for identifying AS candidates and ongoing monitoring. US provides precise measurements of nodule size, detection of ETE (e.g., invasion of strap muscles, trachea, or RLN), and evaluation for LN metastasis [44]. High-resolution US with high-frequency probes (10 to 15 MHz) is crucial [46]. Because accuracy in detecting metastatic LNs greatly depends on the examiner's expertise, evaluations should be performed by physicians with expertise in thyroid and neck US imaging. The assessment should include central (level 6) and lateral neck compartments (levels 1–5).

(2) Contrast-enhanced neck computed tomography

Key question 1: Is contrast-enhanced neck CT useful for risk assessment in PTMC patients being considered for AS?

While most LN metastases occur in the central neck compartment, US has limited sensitivity in this area [47-50]. Therefore, contrast-enhanced computed tomography (CT) can serve as a complementary modality [35,44,45]. A systematic review by the committee identified four studies comparing US alone to US plus CT in PTMCs. Adding CT improved sensitivity from 48% to 64%, although specificity slightly decreased from 83% to 75%.

CT outperforms US in identifying metastatic LNs, especially in mediastinal and retropharyngeal spaces [47-50]. CT can also clarify LNs judged benign or indeterminate on US [51,52], substantially influencing clinical management decisions [53]. Although PTMC-specific data are limited, a recent Korean study demonstrated that CT provided an additional advantage for detecting LN metastases in PTMC patients [54]. Therefore, in PTMC patients considered for AS, adding contrast-enhanced neck CT to US may be beneficial for detecting neck LN metastases.

(3) US-guided biopsy of LNs

If suspicious LNs are identified on US or CT, US-guided biopsy must be performed. The KSThR recommends FNA for suspicious nodes with a short-axis diameter ≥3 to 5 mm, or indeterminate nodes ≥5 mm [35,55]. Although US-guided FNA is typically reliable, sampling small or cystic LNs can produce nondiagnostic or false-negative results [56-58]. To enhance diagnostic sensitivity and accuracy, measurement of thyroglobulin in the FNA washout fluid is recommended [35,39]. An LN is considered metastatic when the washout thyroglobulin concentration exceeds the corresponding serum thyroglobulin level [59-61]. Furthermore, a washout thyroglobulin value >2 to 10 ng/mL is highly suggestive of metastasis, demonstrating a sensitivity of 88.5%–95.0% and specificity of 93.1%–96.3% [58, 62-64]. If biopsy results are negative but imaging remains suspicious, repeat FNA with washout thyroglobulin measurement is warranted, as a single negative result may give false reassurance [58].

(4) Chest CT

The lungs are the second most common site of metastasis in differentiated thyroid cancer following the LNs. However, distant metastasis in PTMC is exceedingly rare, occurring in less than 0.1% of cases in a Korean cohort [65]. A Japanese study of 1,000 PTMC patients observed no cases of lung metastasis [66], and another long-term Japanese study spanning 30 years identified only two cases of lung metastases, both diagnosed more than 12 years after initial diagnosis [67]. Given this rarity, especially in the absence of LN metastasis or ETE, routine chest CT is neither warranted nor efficient for low-risk PTMC patients.

(5) Histologic subtypes

Identifying aggressive histologic subtypes of PTC is essential for accurate risk stratification and appropriate management planning. However, classifying histologic subtypes based on FNA can be challenging, as PTC commonly exhibits mixed cellular and architectural patterns, and aspirates may not fully represent the entire lesion. Moreover, the positive predictive value for specific cytologic features is constrained by the retrospective nature of most studies and the low prevalence of individual aggressive subtypes [68,69]. Nevertheless, aggressive subtypes may be suggested when biopsy specimens exhibit distinct cellular and architectural features that are different from those of classic PTC [68,70-72].

CNB provides the advantage of larger tissue samples with preserved architecture, thereby enhancing the ability to suggest histologic subtype. However, CNB often yields only a presumptive diagnosis; for instance, definitive identification of the tall cell subtype requires that tall cells comprise at least 30% of the tumor. As such, accurate classification of PTC subtypes should be based on a comprehensive integration of pathological, clinical, and imaging findings.

Ki-67 immunostaining have been correlated with clinical outcomes: a Ki-67 index ≥5% in surgical specimens has been associated with higher recurrence rates and poorer prognosis in PTCs [73]. Although the routine clinical application of Ki-67 requires further validation, a high Ki-67 index (≥5%) identified on biopsy should raise suspicion for an aggressive PTC subtype.

(6) Molecular markers

Molecular testing is primarily used to improve diagnostic accuracy when cytopathology reveals atypia of undetermined significance (AUS) or follicular neoplasm. In addition to its role in the diagnosis of an AUS or follicular neoplasm, molecular testing may also be informative when PTC is suspected or confirmed, particularly in evaluation tumor aggressiveness.

BRAF^{V600E} mutations are commonly found in PTC, whereas *RAS* mutations are observed in both malignant and benign thyroid tumors. However, neither *BRAF*^{V600E} nor *RAS* mutations alone reliably predict clinical outcomes [74,75].

Mutations in the telomerase reverse transcriptase (*TERT*) promoter, tumor protein P53 (*TP53*), or phosphatidylinositol 3-kinase catalytic subunit alpha (*PIK3CA*) typically occur during later tumor evolution stages and are linked to distant metastasis, radioactive iodine (RAI) refractoriness, or recurrence. These mutations are therefore considered high-risk mutations [76,77]. *TERT* promoter mutations are frequently observed in older patients, and their co-occurrence with *BRAF*^{V600E} or *RAS* mutation is recognized as a strong adverse prognostic marker, compared to the presence of each mutation alone [78]. Nonetheless, Korean retrospective data show that *TERT* promoter mutations are present in only 1.3% of tumors ≤1 cm, compared to 5.6% in those >1 cm [79-83]. Given that preoperative molecular testing is not routinely performed and the evidence supporting its prognostic utility for PTMC remains limited, such testing is generally not recommended. However, if molecular testing is conducted and reveals high-risk alterations such as the presence of two or more mutations, the tumor should not be classified as low-risk, and surgery is recommended.

2.3. Imaging-based criteria for tumor risk assessment

(1) Evaluation of gross ETE of the tumor

2.3.A. Subcapsular and paratracheal tumors should be carefully evaluated for the risk of gross ETE. **[Recommendation level 1]**

2.3.B. The following imaging features are associated with a high-risk of gross ETE and should prompt consideration of immediate surgery:

- Anterior subcapsular tumors with strap muscle replacement
- Paratracheal tumors abutting ≥90° of the trachea
- Posteromedial subcapsular tumors lacking intervening normal thyroid parenchyma
- Posterolateral subcapsular tumors with obvious protrusion beyond the thyroid capsule. **[Recommendation level 2]**

ETE refers to the direct extension of primary thyroid cancer into surrounding perithyroidal tissues. ETE can range from minor ETE, identified only on histopathologic examination, to gross ETE, which is often identifiable through preoperative imaging or intraoperative findings. ETE was recognized as a significant prognostic factor in the 6th edition of the American Joint Committee on Cancer (AJCC) Staging. However, in the current 8th edition, minimal ETE has been excluded from staging due to its minimal prognostic impact and the subjectivity and variability of pathological assessment. In contrast, gross ETE involving the strap muscles constitutes T3b disease, and ETE involving critical structures defines T4 disease [84]. Therefore, if clinical or imaging findings suggest gross ETE, immediate surgical intervention is warranted. Even microcarcinomas with a high likelihood of invading critical structures should not be considered low-risk, and surgery should be recommended in such cases [32]. If gross ETE is newly detected during AS, it represents disease progression and indicates the need for conversion to surgical treatment. Accordingly, accurate US evaluation for gross ETE is essential not only at the time of initial diagnosis but also throughout follow-up in patients undergoing AS.

In 2024, the KSThR published a recommendation on imaging evaluation during AS for PTMC [32]. This committee endorses the US criteria for ETE proposed in this guideline. To assess ETE, tumors are classified as subcapsular tumors (anterior and posterior subcapsular) or paratracheal tumors (Fig. 1) [32]. Subcapsular tumors refer to tumors abutting the thyroid capsule (margin). The anterior thyroid capsule contacts the strap muscles, while the posterior capsule refers to the opposite area not contacting the strap muscles. Tumors contacting the anterior capsule are classified as anterior subcapsular tumors, whereas those contacting the posterior capsule are posterior subcapsular tumors. Posterior subcapsular tumors are further subdivided into posteromedial or posterolateral subcapsular tumors depending on their location in the medial or lateral half of the posterior capsule, respectively. Tumors directly contacting the trachea are classified as paratracheal tumors.

Immediate surgery should be considered when US findings suggest clinical gross ETE in subcapsular or paratracheal tumors. Tumors that should not be managed by AS are defined by tumor location and capsular contact patterns: anterior subcapsular tumors with strap muscle replacement, paratracheal tumors abutting ≥90° of the trachea, posteromedial subcapsular tumors lacking intervening normal thyroid parenchyma, or posterolateral subcapsular tumors showing outward protrusion beyond the thyroid capsule.

These distinctions reflect the poor prognosis associated with gross ETE involving perithyroidal structures. In particular, invasion of the trachea or RLN not only worsens prognosis but is also associated with increased morbidity, often requiring extensive surgery and substantially affecting quality of life (QoL). Therefore, immediate surgery is recommended not only when ETE into the trachea or RLN is definitive but also when it is suspected [39].

A. Anterior subcapsular tumors

For anterior subcapsular tumors, the risk of gross ETE into the strap muscles should be carefully evaluated. US features predictive of anterior ETE include capsular abutment, disruption, protrusion, and replacement of the strap muscles, the last of which is the most strongly predictive finding [35,84]. The Japanese Association of Endocrine Surgeons (JAES) guideline proposed

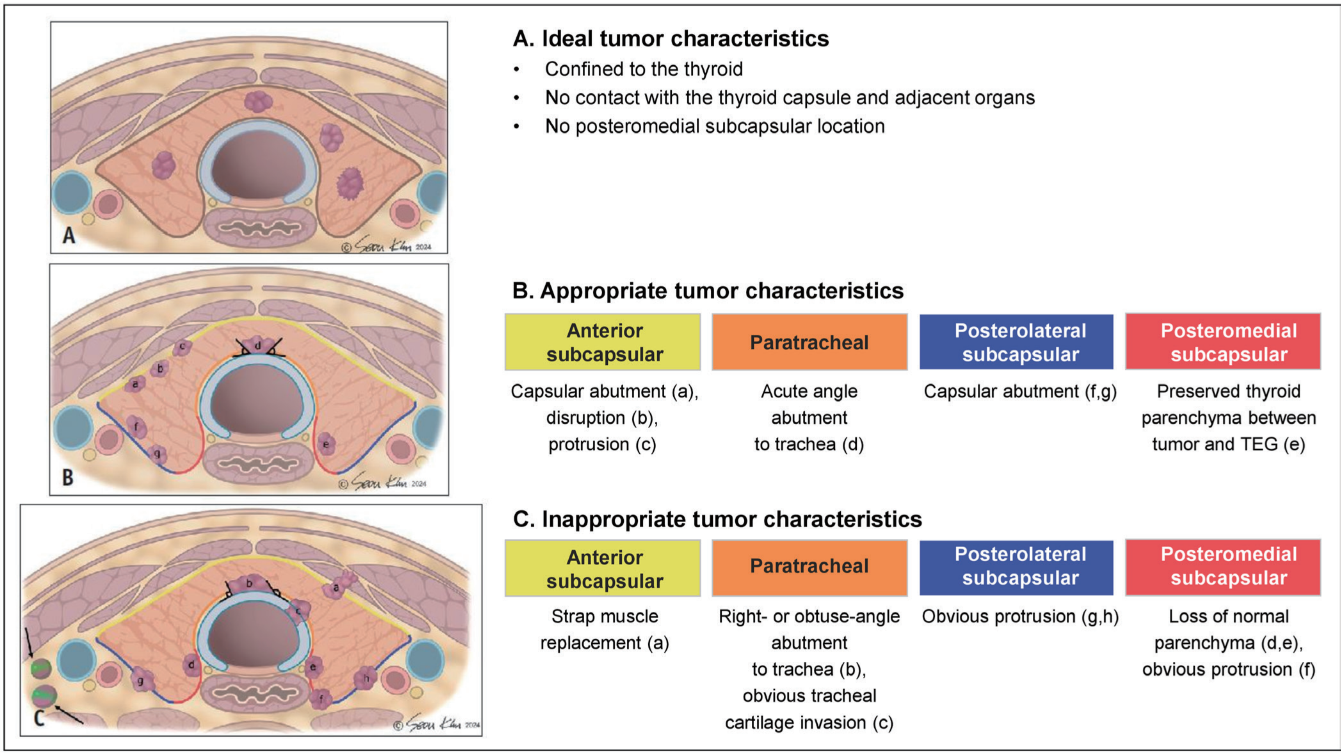

Fig. 1. Ultrasound-based appropriateness criteria for active surveillance in papillary thyroid microcarcinoma. Subcapsular tumors are defined as lesions that abut either the anterior or posterior thyroid capsule. A tumor in contact with the anterior capsule (yellow line) is categorized as an anterior subcapsular tumor, whereas tumors that touch the posteromedial capsule (red line) or the posterolateral capsule (blue line) are classified as posteromedial and posterolateral subcapsular tumors, respectively. Modified from Lee et al. [32]. TEG, tracheoesophageal groove.

that anterior subcapsular tumors invading the strap muscles may not necessarily require immediate surgery, considering that extended resection of neck muscles has little influence on patient QoL and prognosis [33]. However, more recent studies have reported higher recurrence rates in T3b tumors, although the prognostic impact may be attenuated in smaller tumors [85]. Accordingly, the current guideline defines anterior subcapsular PTMCs as inappropriate for AS when gross ETE into strap muscle is strongly suspected on US, specifically when strap muscle replacement is observed, given its potential association with a higher risk of recurrence [35,84].

B. Posterolateral subcapsular tumors

Posterolateral subcapsular tumors suspected of capsular invasion can present on US either as simple capsular contact or as protrusion into the perithyroidal soft tissue, the latter being more suggestive of gross ETE. Although the current AJCC staging system does not classify capsular protrusion as gross ETE, recent evidence has documented an association between capsular protrusion and an increased risk of lymphovascular invasion and lateral LN metastasis [86]. Therefore, the committee concluded that tumors with capsular protrusion are inappropriate for AS, whereas those showing only simple capsular contact remain suitable candidates [32].

C. Paratracheal tumors

In paratracheal tumors, the relationship between the tumor and the trachea is a critical determinant for AS eligibility. The risk of tracheal invasion is assessed based on the angle formed between the PTMC and tracheal cartilage, with an obtuse angle regarded as the most sensitive and accurate indicator of tracheal invasion [84,87]. However, because differentiating between right-angle and obtuse-angle abutment can be challenging and prone to interobserver variability, the committee recommends that paratracheal tumors abutting the trachea at either a right or obtuse angle should be considered inappropriate for AS [32].

D. Posteromedial subcapsular tumors

In posteromedial subcapsular tumors, clinicians should assess the risk of RLN invasion by determining whether normal thyroid parenchyma remains between the tumor and the tracheoesophageal groove (TEG). Absence of intervening thyroid parenchyma indicates a high likelihood of RLN involvement [33,84,87]. Therefore, this guideline considers any posteromedial subcapsular tumor lacking intervening normal thyroid parenchyma between the tumor and the TEG inappropriate for AS.

(2) Evaluation of neck LN

2.3.C. Gray-scale and color Doppler US should be used to thoroughly assess neck LNs in both central and lateral compartments for evidence of metastasis. **[Recommendation level 2]**

2.3.D. If LN metastasis is confirmed, surgery is recommended. **[Recommendation level 1]**

US is the primary imaging modality used to determine N staging. Gray-scale US is used to assess LN size, shape, and internal structure, while color Doppler US assesses vascular distribution within LNs [35,44]. US findings for LNs in thyroid cancer patients can be classified according to their malignancy risk, with assessment criteria varying by national clinical guidelines [88].

The KSThR statement classifies LNs as suspicious, indeterminate, or probably benign based on their malignancy risk [35]. Four suspicious US features—cortical hyperechogenicity, cystic changes, echogenic foci, and abnormal vascularity—demonstrate high specificity and strongly predict metastasis (malignancy risk, 73% to 88%). Probably benign LNs are characterized by either an echogenic hilum or hilar vascularity (malignancy risk <3%). Round shape or loss of hilar echogenicity alone has low specificity for distinguishing benign from suspicious LNs (malignancy risk, 20% to 29%) [89]; therefore, when loss of hilum occurs without any of the four suspicious US features, the LN is classified as indeterminate (Table 3) [44].

Similarly, CT findings of LNs can be categorized into three groups based on malignancy risk: suspicious LNs (cancer risk 73% to 88%), indeterminate LNs (cancer risk 20%), and probably benign LNs (cancer risk <3%) (Table 3) [35].

The frequency of neck LN metastasis in PTC ranges from 20% to 50%, and PTMC specifically presents clinically suspicious LN metastasis preoperatively in approximately 9% to 42% of cases [10-13]. Even without clinically detectable LN metastasis prior to surgery, prophylactic central neck dissection reveals LN metastasis in roughly 33% of patients [90]. LN metastasis is associated with a high-risk of locoregional recurrence following surgery [42]. Consequently, confirmed clinical LN metastasis necessitates immediate surgery [8]. Due to the crucial role LN metastasis in surgical decision-making, comprehensive evaluation of both central and lateral neck LNs should be meticulously conducted prior to selecting AS.

(3) Assessment of suitability for AS based on imaging findings

After imaging evaluations for ETE and LN metastasis are complete, a comprehensive assessment should be conducted to determine whether the diagnosed PTMC is suitable for AS. Using a structured checklist during this evaluation is recommended. Although definitively assessing ETE with US is often challenging, the 2024 KSThR statement has proposed US-based eligibility criteria for AS of PTMC [32]. These criteria build upon accumulated clinical evidence and the framework previously sug-

Table 3. Image-Based Risk Stratification and Pathologic Diagnosis Criteria for Lymph Node Evaluation in Patients with Thyroid Cancer

Category	US	CT	Pathologic diagnosis criteria[d]
Suspicious[a]	Any of four suspicious features	Any of three suspicious features	>3–5 mm
	Cystic change	Cystic change	
	Echogenic foci (calcifications)	Calcification	
	Cortical hyperechogenicity (focal/diffuse)	Strong (focal/diffuse) or heterogeneous enhancement	
	Abnormal vascularity (peripheral /diffuse)		
Indeterminate[b]	Loss of echogenic hilum and hilar vascularity	Loss of hilar fat and vessel enhancement	>5 mm
Probably benign[c]	Echogenic hilum Hilar vascularity	Presence of hilar fat or vessel enhancement and no suspicious CT features	Not indicated

US, ultrasound; CT, computed tomography.
[a]Lymph nodes (LNs) with suspicious imaging features are included in this category, regardless of the presence of imaging features of probably benign or indeterminate LNs; [b]LNs not included in the suspicious or probably benign categories; [c]LNs with any imaging feature of echogenic hilum or hilar vascularity are considered probably benign, if there are no suspicious imaging features; [d]Short diameter on US or CT images.

gested by Brito et al. [91] (Fig. 1).

Tumors are classified by imaging characteristics into ideal, appropriate, or inappropriate tumors [32]. Tumors categorized as 'ideal' or 'appropriate' are suitable candidates for AS, whereas tumors classified as 'inappropriate' do not meet low-risk PTMC criteria, thus necessitating surgical intervention.

An ideal candidate is a tumor completely confined within the thyroid gland, not abutting the thyroid capsule or adjacent critical structures, and without suspicious findings for LN or distant metastasis.

An appropriate candidate includes tumors in contact with the anterior or posterolateral thyroid capsule or adjacent critical structures, but without evidence of gross ETE. Representative examples include anterior subcapsular tumors adjacent to the capsule with capsular abutment, disruption, or protrusion; paratracheal tumors forming an acute angle (<90º) with the trachea; posterolateral subcapsular tumors with capsular abutment; and posteromedial subcapsular tumors with intervening normal thyroid parenchyma separating them from the TEG. Tumors with ill-defined margins are also categorized as appropriate for AS, although their indistinct features may complicate lesion evaluation during follow-up.

In contrast, tumors showing definite gross ETE or features suggestive of invasion into critical structures—such as the strap muscles, trachea, or RLN—are considered inappropriate for AS and require immediate surgical intervention. These include anterior subcapsular tumors invading the strap muscles; paratracheal tumors forming a right or obtuse angle (≥90º) with the trachea; posteromedial subcapsular tumors lacking intervening normal thyroid parenchyma between the tumor and TEG or exhibiting pronounced protrusion; and posterolateral subcapsular tumors with obvious protrusion.

(4) Tumor characteristics that may influence imaging assessment

Thyroid cancers smaller than 2 cm typically appear as hypoechoic nodules compared to surrounding thyroid parenchyma, often with relatively well-defined margins. However, in patients with diffuse thyroid diseases such as Hashimoto's thyroiditis or Graves' disease, echogenicity may be diffusely reduced throughout the thyroid gland or parts thereof [92]. This decreased echogenicity can obscure nodule margins, complicating accurate size measurement. Additionally, variability related to the examiner, examination timing, or the type of US equipment used should be considered.

When macrocalcifications are present within a nodule, strong posterior acoustic shadowing may limit accurate assessment of the nodule's posterior margin and size measurement. This issue is particularly relevant for AS, as acoustic shadowing can hinder consistent caliper placement for accurate monitoring of nodule size. Therefore, careful interpretation is essential in such cases. However, the presence of diffuse thyroid disease or calcification-associated shadowing does not constitute an absolute contraindication for AS [33].

2.4. Characteristics of patients suitable for AS

2.4.A. When considering AS, a comprehensive evaluation of the patient's characteristics—including tumor features, general health status, age, and ability to undergo regular follow-up—is necessary. **[Recommendation level 1]**

2.4.B. AS may be preferentially considered for older patients or those with smaller tumors. **[Recommendation level 2]**

2.4.C. Patient preferences regarding disease prognosis (progression or recurrence), potential complications, QoL and anxiety, and the medical and/or societal costs of AS versus immediate surgery should be considered. **[Recommendation level 2]**

Once the tumor is classified as low-risk PTMC, patient eligibility for AS should be assessed. According to the 2024 KTA guidelines, AS may be prioritized under the following circumstances:

- a. Patients with high surgical risk due to comorbidities.
- b. Patients with a limited life expectancy (e.g., severe cardiovascular disease, other malignancies, or advanced age).
- c. Patients with coexisting medical or surgical conditions that need to be resolved prior to thyroid surgery.

To identify patient characteristics suitable for AS, the committee formulated a key question and conducted a systematic review evaluating whether age, sex, and tumor size could predict disease progression. Additionally, a literature review addressing other patient- and healthcare-system-related characteristics was conducted. Although criteria for disease progression during AS varied slightly across studies, disease progression was generally defined as an increase of ≥3 mm in tumor diameter or new evidence of neck LN metastasis, distant metastasis, or ETE.

Key question 2. Do specific clinical factors (age, sex, and tumor size) predict disease progression in patients with low-risk thyroid cancer undergoing AS?

(1) Age

In six cohort studies, older patients demonstrated significantly lower hazard ratios (HR) for disease progression (HR, 0.35; $P<0.001$) [19,25,93-96]. Similarly, four retrospective cross-sectional studies reported lower odds ratios (ORs) for disease progression in older patients (OR, 0.34; $P<0.001$) [29,97-99]. Three Korean cohort studies specifically reported HRs ranging from 0.26 to 0.46 [19,93,95]. Progression rates varied depending on the age cutoff used. In one United State study using 50 years as the cutoff, tumor growth ≥3 mm over 5 years occurred in 27.3% of patients <50 years compared to only 4.6% of those ≥50 years [25]. In a large Japanese study, among patients under 40 years, rates of tumor growth ≥3 mm were 7.1% at 5 years, 12.2% at 10 years, and 16.2% at 15 years [96]. For those aged 40 to 59 years, these rates were 2.7%, 4.7%, and 5.2%, respectively, and for patients ≥60 years, they remained low at 2.7%, 4.4%, and 4.4%, respectively. These findings suggest that patients older than 40 to 60 years have a 5-year disease progression rate of less than 10%, making AS relatively safe for this group. However, further studies are needed to determine the optimal age cutoff. Accordingly, this guideline defines patients aged ≥60 years as ideal candidates for AS, and those aged 19 to 59 years as appropriate candidates.

(2) Sex

Although male sex is generally associated with a worse prognosis in thyroid cancer, the results from a meta-analysis of five cohort studies [19,25,94,96,100] and four retrospective studies [29,97-99] were inconsistent; no statistically significant difference in the risk of disease progression between sexes was observed [29,97-99]. One Korean cohort study found no significant difference [100], whereas a multicenter Korean study indicated a significantly higher HR for disease progression among males [19]. Overall, current evidence remains insufficient to consider sex a contraindication for AS. Accordingly, this guideline does not differentiate AS eligibility based on sex.

(3) Tumor size

Initial tumor size is one of the most critical factors when considering AS for low-risk PTMC. A meta-analysis of four cohort studies [19,25,94,96] and three retrospective studies [29,98,99] showed that tumors <0.9 to 1.0 cm were associated with a 44% to 48% lower risk of growth by ≥0.3 cm compared to larger tumors. When data from four cohort studies were pooled, smaller baseline tumor size was significantly associated with reduced disease progression risk (HR, 0.54; $P=0.001$). Similarly, a meta-analysis of three retrospective cross-sectional studies demonstrated significantly lower progression risk (OR, 0.48; 95% confidence interval [CI], 0.26 to 0.89).

In a Korean cohort study, tumors <0.5 cm had a 9.5% risk of growing ≥0.3 cm or developing LN metastasis over 10 years, compared to 13.7% for tumors ≥0.5 cm—a 30% lower risk [94]. In a multicenter Korean study, tumors <0.6 cm had a 52% lower risk compared to tumors ≥0.6 cm [19]. These findings support recommendations against biopsy for nodules <0.6 cm without high-risk features, indicating AS as a safer option for tumors ≤0.5 cm. Accordingly, this guideline does not differentiate AS eligibility by tumor size within >0.5 to ≤1.0 cm range, which corresponds to nodules can be considered for FNA.

(4) Multifocality

Guidelines vary regarding whether multifocal disease should exclude patients from AS [33,101]. Two large Japanese cohort studies noted a tendency toward increased tumor growth or new LN metastasis development in multifocal disease; however, these findings were not statistically significant [94,96]. Accordingly, this guideline does not consider multifocality as a criterion for determining AS eligibility.

(5) Coexisting autoimmune thyroiditis

Evidence regarding the impact of coexisting autoimmune thyroiditis on PTMC progression is inconsistent. A United States study observed a higher prevalence of autoimmune thyroiditis among patients with disease progression [25]. A Japanese study showed a higher 10-year disease progression rate in patients with autoimmune thyroiditis (17.7%) compared to those without (10.3%), though this difference was not statistically significant [94]. Another large Japanese cohort study found no significant association between chronic thyroiditis and progression risk [96]. Similarly, Korean studies reported comparable rates of autoimmune thyroiditis between progression and non-progression groups [95]. Therefore, several guidelines suggest that autoimmune thyroiditis should not be a contraindication for AS [33,102], and the present recommendation adopts the same position.

(6) Family history of thyroid cancer

Guidelines differ regarding family history as a contraindication for AS. The European Society for Medical Oncology (ESMO) guideline recommends AS only for patients without a family history of thyroid cancer [101], whereas the Japanese JAES consensus allows AS regardless of family history [33]. A Japanese study indicated that family history was not a significant risk factor for disease progression during AS, although additional data are required to confirm this finding [98]. Epidemiological studies suggest familial differentiated thyroid cancer is associated with increased multifocality, LN metastasis, and recurrence rates, yet there are no significant differences in disease-specific or overall survival compared to sporadic cases [103-105]. Therefore, family history is not considered a contraindication for AS in this guideline.

(7) Pregnancy

Pregnancy may promote the growth of thyroid nodules and cancers [106]. Nevertheless, a large Japanese study found that 92% of pregnant women undergoing AS exhibited no tumor growth during pregnancy [107]. Thus, pregnancy is not considered a contraindication to AS, nor should pregnancy itself be restricted during AS.

However, it should be noted that, for newly diagnosed PTMC during early pregnancy, US monitoring is recommended prior to 24–26 weeks gestation. If progression occurs before this time point, surgery should be considered. However, if no progression is observed by 24 to 26 weeks or the thyroid cancer diagnosis occurs after 20 weeks of gestation, surgery can safely be deferred until after delivery, consistent with existing guidelines for differentiated thyroid cancers [108].

(8) Comorbidities

Assessment of the patient's overall health status is crucial when considering AS for PTMC. The ATA guideline recommends AS for patients with severe cardiopulmonary disease, other malignancies, or limited life expectancy [39]. Patients requiring treatment for medical or surgical conditions before thyroid surgery are also considered suitable for AS [39]. This guideline supports these recommendations as well. The 2019 ESMO guideline recommends AS specifically for patients without a history of childhood radiation exposure [101], although the supporting evidence is limited.

In summary, older patients or those with smaller tumors are

Table 4. Appropriateness Criteria for Active Surveillance in Patients with Papillary Thyroid Microcarcinoma

	Ideal[a]	Appropriate	Inappropriate[b]
Tumor margin	Smooth or irregular margin	Ill-defined margin	
Tumor location			
Anterior subcapsular	No contact with the thyroid capsule and adjacent organs	Capsular abutment, capsular disruption or protrusion	Replacement of strap muscle
Paratracheal	As above	Acute angle abutment to the trachea	Right- or obtuse-angle abutment to trachea
Posterolateral subcapsular	As above	Capsular abutment	Obvious protrusion
Posteromedial subcapsular	Not indicated	Preserved thyroid parenchyma between tumor and TEG	Loss of normal parenchyma between TEG and tumor, or obvious protrusion
LN metastasis	No suspicious feature	No suspicious feature	Presence of biopsy proven or clinical LN metastasis
Subtype of PTC			Tall cell, columnar cell, hobnail, solid, or diffuse sclerosing variants
Molecular marker[c]			Presence of high-risk genetic alternation such as two or more mutation
Age	≥60 years[d]	19–59 years	<19 years
Comorbidities	Patients with high surgical risk due to comorbidities Patients with a limited life expectancy	Patients with medical or surgical issues that need to be addressed before thyroid surgery	
Patient preference	AS is desired	AS desired	Surgery is desired
Feasibility of regular follow-up	When regular surveillance is feasible and the patient's willingness and adherence have been confirmed	When regular surveillance is feasible and the patient's willingness and adherence have been confirmed	When regular follow-up is impracticable or the patient lacks sufficient commitment to it

TEG, tracheoesophageal groove; LN, lymph node; PTC, papillary thyroid carcinoma; AS, active surveillance.
[a]Considered ideal when all of the following conditions are met; [b]Considered unsuitable if any of the following conditions applies; [c]Although a comprehensive genetic panel is not generally recommended, when such testing has been performed; [d]Although patients aged 40–59 years appear to have a disease progression rate comparable to those aged ≥60 years, patients ≥60 years are regarded as the ideal candidates because the 40–59 year group would require a substantially longer follow-up period.

better suited for AS. However, if regular follow-up cannot be ensured, surgical treatment should be prioritized to prevent delays in appropriate care (Table 4). Younger patients have a relatively higher risk of disease progression, and prolonged surveillance may elevate risks, costs, and negatively affect QoL in this group. Therefore, these factors should be comprehensively considered when making treatment decisions.

2.5. Evaluation of suitability for AS

2.5.A. Suitability for AS must be evaluated carefully by an expert capable of accurately identifying high-risk US features. Assessment of suitability for AS should be performed by experienced physicians capable of accurately identifying high-risk US features. **[Recommendation level 3]**

2.5.B. The appropriateness of AS should be determined through a comprehensive assessment of both tumor-specific factors (e.g., size, location, histopathology, or presence of LN metastasis) and patient-related factors (e.g., age, preference, comorbidities, or feasibility of follow-up). Based on this assessment, tumors can be classified as ideal, appropriate, or inappropriate candidates for AS. **[Recommendation level 3]**

[Clinical consideration] AS should be implemented for tumors classified as ideal or appropriate. If disease progression (e.g., tumor growth or newly developed LN metastasis) leads to reclassification into the inappropriate category, surgical intervention is then recommended.

Determining AS suitability requires a comprehensive, multidimensional assessment of both tumor and patient characteristics. Specifically, tumor factors—such as size, location, molecular or pathological features, and presence of LN metastasis—should be evaluated alongside patient-related factors, including age, patient preferences, comorbidities, and the feasibility of long-term follow-up (Table 4). Based on this assessment, patients can be classified as ideal, appropriate, or inappropriate candidates for AS.

AS is suitable for tumors classified as ideal or appropriate; 'ideal' denotes very low-risk of disease progression, while 'appropriate' reflects a slightly elevated, yet still low-risk. If a tumor progresses and subsequently meets the criteria for the inappropriate category during follow-up, surgical intervention should be recommended. It is important to note that tumors initially classified as appropriate based on US features are more likely to transition to an inappropriate status compared to those initially classified as ideal. Relevant US features determining suitability are detailed in Fig. 1.

If histopathology indicates a high-risk subtype, or molecular testing identifies high-risk mutations or multiple coexisting mutations, surgery should be prioritized due to their association with poor prognosis. Patient-related factors, such as age, comorbidities, and life expectancy, must also be considered. AS is not recommended for patients under 19 years, for whom surgery is preferred. Conversely, adults aged 19 years or older may be considered for AS. Based on available data regarding disease progression and life expectancy, patients aged 60 years or older are generally regarded as ideal candidates. AS is also appropriate for patients at high surgical risk, those with limited life expectancy, or unresolved medical conditions. Patient preference is another critical determinant. Patients who prefer AS can be suitable candidates, whereas those favoring surgery should proceed surgically.

In summary, for patients classified as ideal or appropriate candidates for AS, physicians should provide comprehensive explanations as outlined in the following section, 'Considerations in determining the management strategy for low-risk PTMC.' Final treatment decisions should be made through a shared decision-making process between physician and patient, recognizing that the management strategy can evolve over time based on patient preferences.

The safe implementation of AS also depends heavily on physician expertise. Evaluations must be conducted by clinicians with sufficient experience to accurately assess ETE and LN metastasis. High-resolution US and expert interpretation is crucial. In addition, a well-established healthcare system supporting consistent, structured follow-up is essential for effectively applying AS.

3. CONSIDERATIONS IN DETERMINING THE MANAGEMENT STRATEGY FOR LOW-RISK PTMC

3.A. Clinicians should provide adult patients with low-risk PTMC sufficient information about the benefits and risks of both surgery and AS. **[Recommendation level 3]**

3.B. Clinicians should determine the management strategy for low-risk PTMC through a shared decision-making process with the patient. **[Recommendation level 3]**

For patients with low-risk PTMC, both surgery and AS are viable management options. Therefore, physicians must provide patients comprehensive information about each strategy's benefits and risks, supporting them in making informed, autonomous decisions. This guideline summarizes up-to-date information crucial for patient decision-making, including the natural history of low-risk PTMC. To assist this process, three key questions were identified and systematically reviewed: (1) outcomes of delayed surgery versus immediate surgery, (2) medical cost differences between surgery and AS, and (3) QoL differences between surgery and AS.

3.1. Pros and cons of surgery and AS, and selection of a management strategy

(1) Advantages and disadvantages of surgery

Choosing surgery enables the complete removal of thyroid cancer, potentially achieving a cure and reducing patient anxiety or fear related to disease progression. However, surgery necessitates hospitalization, general anesthesia, and the surgical procedure itself, generating substantial upfront medical costs. Additionally, postoperative complications may occur, with their frequency and severity varying according to the extent of surgery.

Postoperative hypothyroidism may necessitate long-term thyroid hormone replacement. Although hypothyroidism rates of approximately 30% have been reported following lobectomy, this figure includes surgeries for benign disease or surgeries less extensive than lobectomy [109]. In contrast, studies restricted to thyroid cancer patients report postoperative hypothyroidism rates around 60% following lobectomy [110-113]. Furthermore, thyroid hormone therapy is required in more than 73% of patients to maintain target thyroid-stimulating hormone (TSH) levels (≤2 mIU/L) [114].

Surgical complications such as RLN palsy and hypoparathyroidism may also occur. After total thyroidectomy for PTMC, permanent RLN palsy occurs in approximately 0.9% of cases, and permanent hypoparathyroidism in approximately 1.8% [115]. Conversely, after lobectomy, RLN palsy incidence is about 0.2%, and hypoparathyroidism is rarely observed [115].

(2) Advantages and disadvantages of AS

Choosing AS offers the advantage of avoiding surgery, thus preventing risks associated with general anesthesia, postoperative complications, and the need for thyroid hormone replacement. However, during AS, tumor growth occurs in 2.2% to 10.8% of patients, and new LN metastasis is observed in 0% to 4.5% of cases over a follow-up period of up to 10 years [22]. If disease progression occurs, surgery becomes necessary; compared to immediate surgery, delayed surgery might require a more extensive procedure, carry a higher risk of postoperative complications, and increase the likelihood of requiring RAI therapy [22].

AS necessitates regular follow-up examinations, including neck US, however a definitive endpoint for the duration of monitoring has not been established. Therefore, lifelong surveillance may be required, potentially leading to higher cumulative medical costs than those of immediate surgery [116].

Data regarding the long-term prognosis of AS remain limited. In PTMC patients, surgery generally results in cure, with a recurrence rate of approximately 3% [9]. In a long-term Japanese study of low-risk PTMC [67], the 10-year recurrence rate after immediate surgery was 0.4% for LN metastasis and 1.0% for newly developed PTMC. In the AS group, the corresponding rates were 1.0% and 0.4%, respectively. Among patients who underwent conversion (delayed) surgery, recurrence during follow-up was observed in 0.7% of cases. Importantly, no significant differences were found between the immediate and delayed surgery groups in terms of the number of surgeries, the rate of distant metastasis. To date, no thyroid cancer-related deaths have been reported in either group.

On the other hand, 2% to 24% of patients undergoing AS eventually chose to undergo conversion surgery despite the absence of disease progression [116].

(3) Selection of a management strategy

Because both surgery and AS have distinct advantages and disadvantages, physicians must provide patients sufficient information to determine the appropriate management strategy for low-risk PTMC. Clinicians should assist patients in recognizing their personal values and preferences, facilitating choices that reduce anxiety and improve QoL. Patients' values and preferences significantly influence treatment choice. If decisions inadequately reflect these factors, patients may experience dissatisfaction or regret—for instance, opting for delayed surgery despite no disease progression during AS, or regretting surgery due to postoperative complications or lifelong thyroid hormone replacement. The collaborative approach by which physicians and patients make decisions together is termed 'shared decision-making' and is particularly suitable when multiple medical options present comparable benefits and risks [117].

Currently, data regarding the values and preferences of patients with low-risk PTMC remain limited. Previous studies primarily assessed QoL or anxiety at single time points, and most were cross-sectional, with scarce longitudinal data. Therefore, further research is necessary to comprehensively understand the values and preferences of this patient population.

Although physicians generally recognize the importance of shared decision-making, its adequate implementation in clinical practice is often hindered by constraints such as limited time and staffing. Consequently, tools facilitating shared decision-making in real-world settings are under investigation [118]. Decision aids have reportedly assisted patients in selecting a management strategy for PTMC [119]. The KTA plans to release patient decision aids for low-risk PTMC on its website in 2026 to support shared decision-making.

3.2. Natural course of low-risk PTMC

A meta-analysis of nine studies implementing AS for low-risk PTCs measuring ≤2 cm reported that, over a follow-up period ranging from 1.5 to 7.6 years, tumor growth of ≥3 mm in maximal diameter occurred in 2.2% to 10.8% of cases, tumor volume increases ≥50% were noted in 16.0% to 28.8%, and new LN metastases appeared in 0% to 4.5% during follow-up periods of up to 10 years [22].

Another meta-analysis of 17 studies published up to 2023 indicated that disease progression occurred in 14.5% of cases, tumor size increased ≥3 mm in 6.78%, tumor volume increased ≥50% in 20.19%, and new LN metastases developed in 1.53% [120]. Specifically, among studies analyzing only tumors ≤1 cm, disease progression occurred in 8.86%, tumor size increased ≥3 mm in 4.51%, new LN metastases developed in 1.55%, and tumor volume increased ≥50% in 17.48%. In contrast, studies including tumors >1 cm reported higher rates: disease progression occurred in 19.85%, tumor size increased ≥3 mm in 8.76%, new LN metastases developed in 1.46%, and tumor volume increased ≥50% in 21.64%. Notably, disease progression and tumor size increases ≥3 mm were significantly higher in tumors >1 cm compared to those ≤1 cm [120].

In a cohort of 291 patients with low-risk PTCs ≤1.5 cm observed for a median of 25 months, a ≥3 mm tumor size increase occurred in 3.8%, with a projected 5-year progression rate of 12.1% [25]. Another study following 402 patients over 5 years reported that 17.2% exhibited rapid growth (tumor volume doubling time <5 years), 10.9% had slow growth (doubling time >5 years), 67.7% showed no change, and 4.2% demonstrated volume reduction [121]. Importantly, disease progression was consistently observed from diagnosis throughout the entire observation period.

3.3. Prognosis and complications of immediate vs. delayed surgery

The committee formulated four key questions to compare health outcomes between immediate surgery and AS. To investigate differences in surgical complications, pathological findings, recurrence rates, QoL, and medical costs, particular emphasis was placed on comparing delayed surgery following AS to immediate surgery. Immediate surgery is defined as surgery performed shortly after diagnosis, whereas delayed surgery applies to cases initially choosing AS but later converting to surgery due to tumor progression or patient preference. In reviewed literature, delayed surgery was typically defined as surgery performed 6 to 18 months after initial diagnosis.

Key question 3. Is there a difference in outcomes (surgical complications, pathological findings, and recurrence rates) between patients with low-risk thyroid cancer who undergo immediate surgery and those who undergo delayed surgery following AS?

> **3.3.A.** In patients with low-risk PTMC, delayed surgery following AS may be associated with a higher risk of temporary surgical complications compared to immediate surgery; however, delayed surgery does not increase the risk of permanent complications or disease recurrence. Thus, AS can be considered an appropriate management strategy. **[Recommendation level 2]**

Nine observational studies [26,122-129] evaluated the reasons for delayed surgery, including patient choice without tumor progression (11.0%–70.5%), tumor size increase (16.7%–50.0%), and new LN metastasis (0.0%–13.3%). A pooled analysis of six studies [122-127] showed no difference in recurrence risk between delayed and immediate surgery (OR, 0.749; 95% CI, 0.424 to 1.321). In a Japanese retrospective study [130], among 72 patients who underwent delayed surgery due to disease progression, recurrence occurred in only one patient (1.4%) during a mean follow-up of 8.4 years. No recurrence was observed in 170 patients undergoing delayed surgery without progression. Among 1,625 patients who underwent immediate surgery, recurrence occurred in nine patients (0.6%) over a mean follow-up of 7.9 years, indicating a very low recurrence rate in both groups.

A meta-analysis of six studies [26,123,126-129] showed that delayed surgery was associated with higher risks of temporary hypoparathyroidism (OR, 1.705; 95% CI, 1.188 to 2.448) and temporary vocal cord paralysis (OR, 1.519; 95% CI, 1.038 to 2.222). However, no significant differences were observed for permanent hypoparathyroidism (OR, 1.304; 95% CI, 0.583 to 2.915) or permanent vocal cord paralysis (OR, 0.842; 95% CI, 0.198 to 3.799). In a Korean multicenter prospective study [129], no statistically significant differences in overall complication rates were observed. Nonetheless, rates of central/lateral neck dissection following disease progression were significantly higher in the delayed surgery group compared to immediate surgery group (95% vs. 89%, $P=0.02$). Although RAI therapy appeared to be more commonly performed in the delayed surgery group, this difference was not statistically significant (18.9% vs.

14.6%, $P=0.235$).

In summary, compared to immediate surgery, delayed surgery during AS does not increase recurrence risk or the likelihood of permanent surgical complications. Consequently, AS does not appear to adversely impact long-term prognosis in patients with low-risk thyroid cancer. Nonetheless, patients should be informed about the potential for more extensive surgery or the need for additional RAI therapy when considering management strategies.

3.4. Costs of immediate surgery vs. AS

Initial surgical costs are substantial when immediate surgery is performed. In contrast, AS incurs periodic US examination costs, as well as potential surgical costs if a transition to surgery becomes necessary during follow-up. Healthcare costs vary widely according to national health insurance systems, medical service fees, individual insurance coverage, and patterns of conventional or complementary and alternative medicine usage. Consequently, evaluating and directly comparing healthcare costs between immediate surgery and AS is complex and challenging. Moreover, decision-making for a management strategy should consider not only direct medical costs but also indirect social healthcare costs. These include factors influenced by employment status, distance to medical facilities, productivity loss, and variability in health insurance coverage.

Although currently available data remain limited, the committee conducted a systematic literature review to address the following key question.

Key question 4. Is there a difference in social healthcare costs according to the treatment strategy (immediate surgery vs. AS) in patients with low-risk thyroid cancer?

3.4.A. In patients with low-risk PTMC, both short-term and long-term costs vary depending on the treatment strategy. Therefore, social healthcare costs should be comprehensively considered when determining the treatment strategy. **[Recommendation level 3]** **[Clinical considerations]** Social healthcare costs include direct and indirect components, each influenced by individual factors such as employment status, proximity to medical facilities, and productivity loss. Therefore, a comprehensive and individualized evaluation is necessary when selecting a treatment strategy.

The medical costs associated with thyroid cancer management vary significantly depending on factors such as patient age, type of surgery, and healthcare system structures. Reported costs range widely, from approximately $1,400 to as high as $17,000, underscoring substantial international variability. When comparing the costs of immediate surgery and AS for thyroid cancer, consideration must be given not only to initial costs but also to long-term follow-up expenses and broader social healthcare costs. Nevertheless, most studies evaluating treatment costs for low-risk thyroid cancer primarily focus on direct medical expenses related to surgery, treatment, and interventions [131-136]. Additionally, many cost analyses are reported within the context of national or regional insurance coverage structures [116,132, 133,135-137].

Economic evaluations generally suggest that initial surgery involves costs at least 2.6 times—and in some cases up to 16 times—higher than those associated with AS. However, the cumulative cost of AS begins to surpass that of surgery after approximately 15 years of follow-up. This finding suggests that AS may be economically advantageous for patients with a life expectancy shorter than 15 years. Nonetheless, additional studies are needed to evaluate variables such as intervals between follow-up US examinations and indirect costs, including productivity loss and use of complementary and alternative medicine, all of which could influence total costs.

Cost-effectiveness analyses have generally found surgery to be more cost-effective than AS [131-133,136,138]. However, many studies reported only small differences in quality-adjusted life years (QALYs) between the two strategies and did not use representative QALY values in their assessments. Further research is necessary to confirm appropriate QALY values for low-risk thyroid cancer patients across diverse populations and to explore cost-effectiveness accordingly.

Two Korean studies assessing only direct medical costs found that surgery incurred higher expenses than AS over long-term follow-up periods (10 to 50 years) [114,131]. However, when both direct and indirect medical costs were considered, the cumulative costs of AS eventually exceeded those of surgery after approximately 16 years. Thus, when deciding upon a treatment plan, societal healthcare costs—including employment status, distance to healthcare facilities, productivity loss, and insurance coverage—should be carefully factored into the decision-making process.

3.5. QoL of immediate surgery vs. AS

A substantial number of patients diagnosed with thyroid cancer experience fear, anxiety, and depression, frequently related to uncertainty about prognosis, treatment-related risks, and complications. Postoperative complications, such as voice changes, paresthesia in the hands and feet due to hypocalcemia, cosmetic concerns regarding surgical scars, and swallowing difficulties, may negatively affect QoL even after curative surgery. Conversely, patients opting for AS rather than surgery might experience ongoing anxiety related to potential cancer progression. Understanding the impact of different treatment options on QoL can thus aid in treatment decision-making. Accordingly, the committee performed a systematic literature review to address the following key question.

Key question 5. In patients with low-risk thyroid cancer, does the QoL differ according to the treatment strategy (AS vs. immediate surgery)?

> **3.5.A.** Although studies directly comparing QoL between treatment modalities in patients with low-risk PTMC remain limited, patient-reported outcomes (PROs) should be incorporated into treatment decision-making, as they may help reduce patient anxiety. **[Recommendation level 3]**
> **[Clinical considerations]** PROs refer to self-reported assessments reflecting patients' subjective experiences of health status. In patients with low-risk thyroid cancer, these encompass evaluations of QoL, anxiety, and depression.

A meta-analysis of 10 studies [127,139-148] reported that symptoms such as voice changes and reduced concentration were more frequently observed in patients who underwent surgery. Conversely, patients in the AS group had higher physical and mental health scores and lower levels of anxiety and depression. However, at the time of diagnosis, patients choosing AS generally exhibited lower diagnosis-related anxiety and higher baseline mental health scores [140,141]. This suggests that preexisting differences may partially account for the more favorable psychological outcomes observed in AS patients. Among patients who subsequently underwent surgery due to disease progression during AS, no significant deterioration in QoL was observed at the time of surgery. Interestingly, their QoL was better than that of patients who opted for surgery due to anxiety or other non-progression-related reasons during AS [143]. These findings imply that patient characteristics related to QoL may significantly influence treatment choice.

In a Korean study, patients choosing AS showed higher QoL and lower anxiety at diagnosis compared to patients choosing surgery [143,148]. However, among the AS group, those who later opted for surgery without evidence of progression had lower QoL than those undergoing surgery due to progression [143,148]. Similarly, a United States study indicated that patients choosing surgery exhibited higher anxiety than those selecting AS, and this anxiety did not significantly diminish even after surgery [26]. A Canadian study found patients fearing lifelong thyroid hormone therapy were more likely to choose AS, whereas those more concerned about cancer progression typically selected surgery [27]. In contrast, a Japanese study reported higher anxiety among patients selecting AS compared to those choosing surgery [146].

These findings highlight that evaluating patients' QoL and anxiety at diagnosis, alongside their perceptions and concerns regarding surgery or AS, may facilitate better-informed treatment decisions, ultimately preserving patient QoL. However, such comprehensive assessments necessitate additional time and trained personnel, posing challenges in clinical practice. If future healthcare policies support routine QoL assessments, comprehensive evaluation and management of PROs in clinical settings would become more feasible. This could improve patient satisfaction with treatment decisions and ultimately enhance long-term QoL for individuals with low-risk thyroid cancer.

4. FOLLOW-UP DURING ACTIVE SURVIELLANCE

The primary goal of AS for low-risk PTMC is to identify patients whose disease remains stable, thereby avoiding unnecessary surgery. Equally crucial, however, is ensuring timely surgical intervention if disease progression occurs during follow-up, minimizing potential harm from delayed treatment. Thus, during AS, appropriate periodic assessments are essential to accurately detect disease progression and carefully evaluate other factors that might necessitate changes in management (Fig. 2).

> **4.A.** During AS, periodic and comprehensive evaluation of tumor status, including neck LNs, using neck US is required. **[Recommendation level 1]**
> **4.B.** During AS, periodic thyroid function tests should be performed to monitor hormonal status. **[Recommendation level 3]**
> **[Clinical considerations]** The need to modify the management strategies should be evaluated in the context of the patient's comorbidities, preferences, and other individual clinical characteristics.

4.1. Thyroid US

> **4.1.A.** To evaluate disease progression, US should be performed every 6 months for the first 1–2 years following diagnosis. If no progression is observed, annual US is recommended thereafter. **[Recommendation level 1]**
> **[Clinical considerations]** Tumor progression should be assessed using consistent methodology throughout follow-up. The follow-up interval may be adjusted according to tumor growth patterns observed on serial US.

4.1.B. Tumor size, ETE, and LN metastasis should be assessed using US during AS. **[Recommendation level 1]**
4.1.C. Tumor size should be measured in three dimensions during each US examination. **[Recommendation level 1]**
4.1.D. If LN metastasis is suspected, FNA should be performed under US guidance, along with measurement of thyroglobulin in the FNA washout fluid. **[Recommendation level 1]**

(1) Timing of US follow-up

As with the initial evaluation to determine whether a PTMC is low-risk, US is the most important imaging modality for monitoring and assessing disease progression during AS. In serial US examinations, the size of thyroid cancer should be measured and the development of new ETE or LN metastasis should be monitored. However, evidence regarding the optimal frequency of US during AS remains limited. The initial prospective study from Japan employed US once or twice annually [14]. Subsequent prospective studies adopted follow-up schedules involving US every 6 months for the initial 2 years, transitioning to annual examinations thereafter [17,25,149]. Based on these findings, clinical guidelines from various countries have recommended similar follow-up intervals [33,102,150,151].

Similarly, there is also limited evidence regarding when US surveillance during AS can safely be discontinued. Current Japanese and French guidelines advocate lifelong US surveillance [33,152].

Accordingly, this guideline recommends US every 6 months during the first 1–2 years following initiation of AS, then annually if no tumor progression is observed. These follow-up examinations should monitor changes in tumor size and the development of new gross ETE or LN metastasis [32,33]. However, the follow-up interval may be adjusted based on recent US findings. Shorter intervals may be warranted if tumor enlargement or other suspicious (though not definitive) features (e.g., gross ETE or LN metastasis) are identified. Conversely, if the tumor size has decreased or remained stable over an extended period, particularly in the case of very small tumors, extending the follow-up interval may be considered.

(2) US technique for assessing disease progression

Definitions of disease progression during AS vary across studies and guidelines; however, tumor growth commonly serves as a surrogate indicator. Consequently, accurate, consistent, and reproducible measurement of tumor size during follow-up US examinations is essential [153].

Despite its clinical utility, US measurements of thyroid nod-

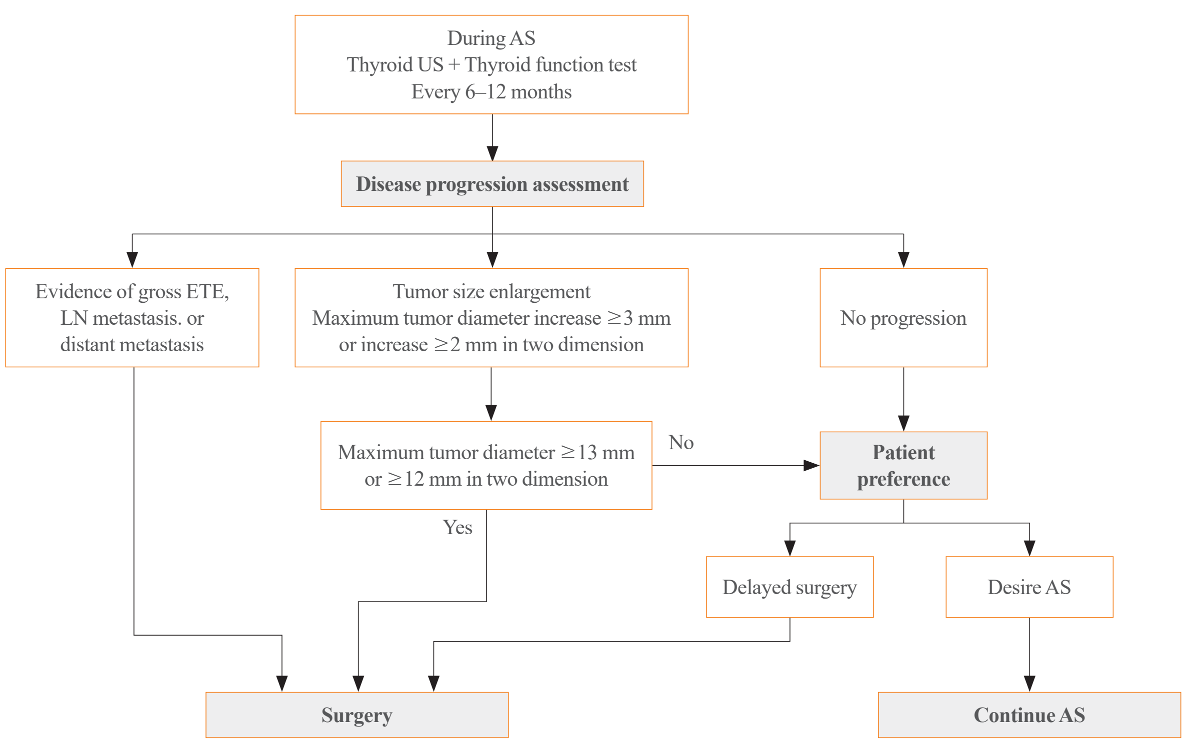

Fig. 2. Algorithm for follow-up during active surveillance (AS). US, ultrasound; ETE, extrathyroidal extension; LN, lymph node.

ule size are subject to considerable inter- and intra-observer variability [154,155]. To ensure consistent and reproducible results, employing a three-dimensional measurement method recommended by the American College of Radiology (ACR) Thyroid Imaging, Reporting and Data System (TI-RADS) is advised [153,156]. Nodule size should be assessed in both transverse and longitudinal planes. In the transverse plane, the largest observed transverse diameter should be measured, while the anteroposterior diameter should be measured perpendicular to the transverse diameter within the same image. In the longitudinal plane, measurements should follow the thyroid's long axis but need not strictly align with the anatomical sagittal plane. To measure the largest tumor dimension in either plane, the transducer may be angled obliquely (within 45°) to accommodate obliquely oriented nodules, thereby facilitating reproducible measurements. If a hypoechoic halo is present, it should be included in the measurement.

For consistent comparisons across serial US examinations, using the same imaging plane as previous measurements is recommended. However, the imaging plane for measurement may be adjusted if tumor growth or shape changes occur.

(3) Imaging criteria for assessing disease progression

During AS, disease progression is defined as an increase in tumor size or the appearance of new ETE, LN metastasis, or distant metastasis. As previously stated, a size increase is defined as growth of ≥3 mm in at least one dimension or ≥2 mm in two dimensions. While some guidelines and studies recommend surgery when this threshold is met once, Japanese and French guidelines [67,152] and Canadian prospective studies [149,153] advocate surgery only if growth is confirmed on two consecutive US exams. This more conservative approach accounts for possible inter- and intra-observer variability in US measurements [154,155] and the possibility that some tumors may exhibit transient growth followed by stabilization or regression [157].

If LN metastasis is suspected during follow-up, FNA should be considered based on LN size [35]. However, since FNA alone can yield nondiagnostic or false-negative results [56-58], combining FNA with thyroglobulin measurement in the aspirate is recommended to enhance diagnostic sensitivity [35,39].

4.2. Assessment of thyroid function

Studies have inconsistently reported associations between thyroid function and disease progression risk during AS. In one Japanese cohort study, no significant association with disease progression was observed when patients were grouped based on a TSH cutoff of 2.5 mIU/L [94]. However, another large Japanese cohort study found that corrected TSH values >2 mIU/L were significantly associated with increased disease progression risk (HR, 2.954; 95% CI, 1.282 to 6.802) [96]. Similarly, two Korean cohort studies reported that higher TSH levels correlated with greater progression risk [19,93]; notably, one study indicated a significant association between progression and a TSH level >7 mIU/L [20,100].

Therefore, for low-risk PTMC patients undergoing AS, thyroid hormone therapy is indicated when overt hypothyroidism occurs. Therapy may also be necessary in cases of subclinical hypothyroidism.

Nonetheless, current evidence is insufficient to confirm whether TSH suppression effectively reduces disease progression risk. A large Japanese cohort study [96] and a Korean study [95] both found no significant association between TSH suppression and disease progression, and further research is warranted.

Despite this uncertainty, given previous findings suggesting potential benefits from maintaining TSH levels below 2 to 7 mIU/L, regular assessment of thyroid function is recommended for patients undergoing AS.

4.3. Assessment of patient characteristics

Ongoing evaluation of patient characteristics is also necessary during AS. In particular, changes in patient preferences regarding management strategy should be regularly reassessed, as some patients opt for surgery despite stable disease.

Other important factors warranting regular evaluation include comorbidities, overall health status, and pregnancy status for women of childbearing age. Although concerns exist regarding thyroid nodule or cancer enlargement during pregnancy, long-term follow-up studies have reported no significant changes in tumor size [106,158]. Additionally, several studies found no significant disease progression in women diagnosed with thyroid cancer during pregnancy [159,160]. In a Japanese study of 50 patients becoming pregnant during AS, four patients (8%) experienced a ≥3 mm tumor growth, but none developed LN metastasis [107]. Among these four patients, two underwent surgery after delivery without recurrence, while two continued AS without further tumor growth. These findings suggest that AS with regular neck US is feasible during pregnancy. If disease progression is confirmed by US, surgery may be considered during the second trimester or after delivery [36].

5. EVALUATION OF DISEASE STATUS DURING ACTIVE SURVEILLANCE

5.1. Criteria for disease progression

5.1.A. Disease progression during AS is defined by the presence of at least one of the following criteria:

(1) Tumor enlargement: An increase in maximal tumor diameter of ≥ 3 mm or an increase of ≥ 2 mm in at least two dimensions. **[Recommendation level 3]**

(2) Newly detected clinical evidence of ETE, LN metastasis, or distant metastasis. **[Recommendation level 1]**

Disease progression during AS is defined by tumor enlargement, new evidence of ETE, or new LN or distant metastases [161]. New ETE, LN metastasis, or distant metastasis are incompatible with continued AS and are uniformly regarded as disease progression indicators across prospective studies and guidelines.

However, criteria defining tumor enlargement vary among studies and guidelines. The most commonly used criterion, proposed in the initial Japanese study, defines tumor enlargement as a ≥3 mm increase in maximal diameter [33,161,162]. A United States study defined enlargement as a ≥3 mm increase in maximal diameter or a ≥50% increase in tumor volume from baseline [25]. Another United States study considered a ≥5 mm increase in maximal diameter or a ≥100% volume increase as tumor growth [26]. A Korean prospective cohort study defined tumor growth as either a ≥3 mm increase in maximal diameter or a ≥2 mm increase in at least two dimensions [17,19]. To reduce measurement error and enhance reproducibility, a Korean retrospective study defined tumor growth as a ≥24% increase in maximal diameter or a ≥72% increase in tumor volume [163].

This guideline adopts the Korean prospective study criteria, defining tumor enlargement as an increase ≥3 mm in maximal diameter or ≥2 mm in at least two dimensions.

5.2. Indications for surgery during AS

5.2.A. Surgery is recommended during AS when at least one of the following criteria is met:

(1) The tumor's maximal diameter reaches ≥13 mm, or at least two dimensions measure ≥12 mm. **[Recommendation level 3]**

(2) A new US finding is identified that corresponds to image features considered inappropriate for AS, as outlined in Fig. 1. **[Recommendation level 1]**

(3) New LN or distant metastasis is confirmed or suspected. **[Recommendation level 1]**

(4) The patient elects to undergo surgery. **[Recommendation level 1]**

5.2.B. The extent of surgery should be determined according to the KTA guidelines on the management of differentiated thyroid cancers. **[Recommendation level 1]**

If disease progression occurs during AS, surgery is recommended. Specifically, surgery is indicated when tumor enlargement occurs or new evidence of gross ETE, neck LN metastasis, or distant metastasis emerges. In particular, US findings suspicious for gross ETE, LN metastasis, or distant metastasis require immediate surgical intervention. However, tumor size increase alone is not always considered a sufficient indication for surgery. The appropriate tumor growth threshold triggering surgery remains debated. Several guidelines suggest surgery when maximal tumor diameter increases by ≥3 mm [16]. However, considering that low-risk PTMC ≤10 mm can be managed with AS, the Japanese guideline recommends surgery only maximal diameter exceeds 13 mm—a ≥3 mm increase beyond the 10 mm threshold [33]. Consistent with this approach, the present guideline recommends surgery when maximal diameter reaches ≥13 mm or when at least two dimensions measure ≥12 mm, unless new high-risk features appear.

To mitigate the impact of measurement variability, confirming tumor size criteria on two consecutive US examinations within a 6-month interval is recommended. Due to inter- and intra-observer variability in US measurements [154,155] and the possibility of transient tumor growth followed by spontaneous stabilization or regression [157], these criteria should be satisfied on two serial US assessments before surgery. Importantly, even in the absence of disease progression, surgery should be performed if the patient opts for it. The extent of surgery should adhere to the 2024 KTA guidelines on the management of differentiated thyroid cancers [8].

6. ISSUES TO BE ADDRESSED IN THE FUTURE

6.1. Evidence on long-term outcomes

Although prospective investigations of AS are ongoing, epidemiologic data on long-term outcomes across diverse populations remain limited. In particular, there is currently no evidence defining the optimal duration of AS. While one prospective Japanese study has reported follow-up extending to 30 years (median 11.9 years) [67], most studies published to date had mean follow-up periods of less than 5 years [22], restricting accurate assessment of the true long-term natural history and prognosis of low-risk PTMC. To confirm the safety and effectiveness of AS, prospective studies with at least 10-year follow-up durations are needed. Moreover, as patterns of disease progression may differ by ethnicity and geographic region, generating long-term natural history and prognostic data specific to each population—including Koreans—is crucial.

6.2. Predictive factors for disease progression

Identifying reliable predictors of disease progression during AS is essential for informed decision-making in low-risk PTMC management. Accurate prediction allows clinicians to recommend surgery selectively for patients at higher progression risk, while confidently maintaining AS for those at lower progression risk, thereby enhancing patient safety and reassurance.

At present, patient age and tumor size are the clinical variables most consistently associated with disease progression. Although the *BRAF*^{V600E} mutation is frequently detected in PTC, it has not been shown to predict progression during AS [97,129]. In contrast, the co-occurrence of *TERT* promoter mutation with *BRAF*^{V600E} or *RAS* mutations is associated with significantly worse outcomes. Consequently, identifying two or more such mutations (or other high-risk mutations) should prompt consideration of immediate surgery. Further research is necessary to clarify the role of molecular markers in the management strategy of low-risk PTMC.

Other US features, aside from gross ETE or LN metastasis, that might influence follow-up decisions or predict tumor progression remain insufficiently established. Diffuse thyroid disease, characterized by global or focal parenchymal hypoechogenicity, and calcification may interfere with accurate tumor size measurement, potentially resulting in overestimated tumor growth. Such features might also inherently influence tumor growth patterns. A Japanese study reported that tumors with calcifications (macro- or rim-calcification) or low vascularity exhibited lower progression rates [164], a finding reflected in the 2020 JAES guideline [165]. However, the association between calcification and tumor growth remains unclear [20,97]. A Korean prospective cohort found that diffuse thyroid disease and greater intratumoral vascularity were associated with increased tumor growth [20].

Although several factors have been suggested as potential predictors of PTMC progression, their clinical utility remains limited. Therefore, further research is necessary to identify additional clinical, pathological, and molecular markers to enhance predictive accuracy regarding tumor progression during AS.

6.3. Treatments to prevent disease progression

Currently, no treatment strategy has definitively prevented disease progression during AS for low-risk PTMC. Although TSH suppression therapy is commonly administered postoperatively to lower recurrence risk, evidence supporting its efficacy in preventing PTMC progression during AS remains unclear. Several studies have suggested that higher TSH levels correlate with increased disease progression risk, but findings across studies have been inconsistent [20,93,166]. One Japanese study proposed that TSH suppression therapy might reduce progression risk during AS; however, the sample size was inadequate, necessitating further validation before broad clinical implementation [15]. Therefore, large-scale prospective studies are required to confirm the efficacy of TSH suppression during AS, and additional strategies aimed at preventing progression should be actively explored.

6.4. US-guided minimally invasive therapy

Minimally invasive, US-guided thermal ablation therapies—including radiofrequency ablation (RFA), laser ablation, and microwave ablation—are well-established, safe, and effective for benign thyroid nodules and recurrent thyroid cancer [167-170]. Among these methods, RFA is most frequently utilized, and its indications have recently expanded to encompass primary PTMC [171]. Remarkably, excellent long-term oncologic outcomes have been reported, with tumor control sustained over 10 years post-RFA [172].

Since Italian scientific societies first highlighted the potential role of US-guided RFA for PTMC without LN metastasis in 2015 [173], global interest in minimally invasive therapy has significantly increased. In 2018, the KSThR proposed RFA as an alternative for patients with primary thyroid carcinoma who refuse surgery or have unresectable tumors [168]. In 2021, the ETA and the Cardiovascular and Interventional Radiological Society of Europe jointly recommended thermal ablation for patients with low-risk PTMC who are not surgical candidates, have limited life expectancy or significant comorbidities, or refuse both surgery and AS [169]. They also emphasized the importance of fully informing patients about thermal ablation as an additional option alongside surgery and AS, clearly outlining its benefits and limitations [169]. Similarly, a 2021 international multidisciplinary guideline stated that although RFA is not considered a first-line treatment for primary thyroid cancer, it may serve as an alternative strategy for selected low-risk patients unsuitable for surgery [174].

More recently, multiple studies—including a prospective Korean study—have demonstrated RFA's feasibility and safety as a potential first-line therapy for low-risk PTMC [175-182]. Based on accumulated clinical data on thermal ablation in both benign thyroid nodules and low-risk PTMC, international consensus statements have recommended thermal ablation as a potential treatment option for low-risk PTMC [174,183]. However, guidelines have not yet provided specific criteria defining which low-risk PTMC patients are suitable candidates for RFA. Appropriate patient selection should follow comprehensive management principles, rather than focusing solely on the technical feasibility of RFA. Given the high prevalence of low-risk thyroid cancer, integrating thermal ablation into healthcare frameworks requires careful systematization to prevent overuse or misuse [184,185]. Comprehensive discussion and consensus are essential regarding appropriate indications, procedural techniques, and operator qualifications for RFA in low-risk thyroid cancer management.

6.5. Need for research on AS without pathologic diagnosis

As interest in AS for low-risk PTMC grows, there is increasing debate about whether cytopathologic diagnosis is necessary for sonographically suspicious malignant nodules measuring ≤1 cm without evidence of ETE, LN metastasis, or distant metastasis.

Traditionally, AS has been reserved for nodules cytologically diagnosed as either ‘suspicious for malignancy’ (Bethesda V) or ‘malignant’ (Bethesda VI). The JAES guideline recommends performing FNA for highly suspicious nodules larger than 0.5 cm based on US findings [33]. The 2021 KSThR and 2024 KTA guidelines recommend biopsy for high-suspicion (K-TIRADS 5) nodules exceeding 1 cm. However, they permit biopsy for nodules ≤1 cm when gross ETE is suspected, and suggest selective biopsy for highly suspicious nodules >0.5 and ≤1 cm without poor prognostic features if a treatment decision is needed [35]. In Korea, many highly suspicious nodules between 0.5 and 1 cm still undergo biopsy in clinical practice.

In contrast, most international guidelines recommend biopsy only for nodules ≥1 cm, even with highly suspicious US features [37,39], and propose AS without pathologic diagnosis for nodules <1 cm lacking poor prognostic features [37,38]. Recent retrospective studies demonstrated the feasibility and favorable outcomes of AS without biopsy in carefully selected patients with subcentimeter high-suspicion nodules [186,187]. Accordingly, the 2024 KSThR guideline acknowledges that AS without biopsy can be considered for high-suspicion nodules >0.5 and ≤1 cm based on patient preference; this guideline adopts the same stance. Nevertheless, further research is needed to clarify long-term outcomes of AS conducted without pathologic confirmation.

CONCLUSIONS

AS has emerged as an important management strategy for low-risk PTMC. The KTA first acknowledged AS’s potential role in the 2016 guideline on the management of thyroid nodules and cancer [21]. Despite this recognition, a substantial gap remains between physician recognition of AS and its practical implementation [188]. Barriers identified by physicians include patient reluctance, concerns regarding loss to follow-up, patient anxiety about cancer progression, medicolegal risks, and the burden of indefinite surveillance [188,189]. From the patient perspective, challenges include insufficient information, fear of cancer progression, uncertainty or difficulty in decision-making, emotional distress related to living with cancer, and logistical and financial burdens associated with repeated clinic visits [190].

To foster appropriate use of AS, these barriers must be addressed through comprehensive, coordinated, and multifaceted efforts.

As part of these efforts, the KTA has developed this guideline to provide physicians and patients with objective, evidence-based information supporting shared decision-making for low-risk PTMC management. The guideline outlines appropriate tumor and patient characteristics for AS, considerations when choosing between AS and surgery, recommended follow-up protocols, criteria defining disease progression, and surgical conversion indications. It is hoped that this guideline will provide practical support for physicians managing low-risk PTMC patients and contribute to improved patient outcomes and QoL. Moreover, by discouraging misuse or overuse of AS, it may also mitigate broader medical and societal concerns regarding overdiagnosis and overtreatment of thyroid cancer.

CONFLICTS OF INTEREST

Young Joo Park is an editor-in-chief of the journal. But she was not involved in the peer reviewer selection, evaluation, or decision process of this article. No other potential conflicts of interest relevant to this article were reported.

ACKNOWLEDGMENTS

The authors would like to thank Dr. Mi Young Choi who participated in the Korean Cancer Management Guideline Network (KCGN) for technical support and Ms. Jae-Eun Lee of the Korean Thyroid Association for her administrative support. This research was supported by a research grant funded by National

Cancer Center (grant number: 2112570) and a grant from the Korea Health Technology R&D Project through the Patient-Doctor Shared Decision Marking Research Center (grant number: RS-2023-KH142322).

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