



Clinical practice guidelines on ultrasound-guided fine needle aspiration biopsy of thyroid nodules: a critical appraisal using AGREE II

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Abstract

Purpose To appraise the quality of current guidelines on fine needle aspiration biopsy (FNAB) of thyroid nodules for adults using the AGREE II quality assessment tool.

Methods We conducted an online search for guidelines on FNAB of thyroid nodules published between 2013 and October 2018. They were evaluated by four independent reviewers previously trained to apply the AGREE II instrument, which is organized into items and domains. A fifth independent reviewer calculated scores for each domain and guideline as well as inter-appraiser agreement.

Results Six sets of guidelines were included, respectively, provided by the American Thyroid Association (ATA), the American Association of Clinical Endocrinologists/American College of Endocrinology/Associazione Medici Endocrinologi (AAACE/ACE/AME), the Korean Society of Thyroid Radiology (KSThR), the European Thyroid Association (ETA), the American College of Radiology (ACR) and the Korean Society of Radiology and National Evidence-Based Healthcare Collaborating Agency (KSR/NECA). Five out of the six guidelines (ATA, AAACE/ACE/AME, ETA, ACR and KSR/NECA) reached a high level of overall quality, having at least five domain scores >60%. An average level of overall quality was achieved in one case (KSThR recommendations). Inter-appraiser agreement ranged from moderate to excellent.

Conclusions Overall, the quality of guidelines on FNAB of thyroid nodules is satisfactory when evaluated using the AGREE II instrument.

Keywords Thyroid · Fine needle aspiration · Guideline · AGREE · Evidence-based medicine

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Introduction

Thyroid nodules are observed in up to 68% of general population with higher frequencies in the elderly and in women. They are mostly asymptomatic and occur in euthyroid individuals [1]. The main challenge of thyroid

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nodule management is to rule out thyroid cancer with ultrasound (US)-guided fine needle aspiration biopsy (FNAB) serving as a diagnostic cornerstone [2–5]. The cytological evaluation of the specimens obtained with FNAB is accurate for identifying nodules that need to be removed, such as malignancies and indeterminate follicular lesions [6]. The number of unnecessary surgical procedures may also be reduced by the use of FNAB in favour of both conservative and minimally invasive treatment of benign thyroid nodules [7–12].

Thyroid malignancies are detected in 3–10% of patients with nodular disease [13]. As a result, the critical role of the radiologist is to decide whether to perform FNAB balancing the risk of a potentially delayed diagnosis and that of an unnecessary procedure [14]. In this light, medical societies and specialized working groups have developed several recommendations and guidelines for the management of thyroid nodules. They mainly focus on individual risk factors, sonographic features, and nodule size [15–21]. Although based on the highest level of evidence and expert opinions, these guidelines may, however, vary extensively in methodologies and strategies of development and, as a consequence, in quality [22–24]. Different quality appraisal tools address the issue of variability in guideline quality. Among them, the Appraisal of Guidelines for Research & Evaluation version II (AGREE II) is described as a reliable, widespread used and validated instrument [25].

The evaluation of guidelines in various fields of diagnostic and interventional radiology is a topic of current interest to many researchers and has captured the attention of the European Network for the Assessment of Imaging in Medicine European Institute for Biomedical Imaging Research (EuroAIM), which aims to increase the evidence for the rational use of imaging technology [24]. Thus, the purpose of this study is to appraise the quality of current guidelines on FNAB of thyroid nodules for adults using the AGREE II quality assessment tool.

Materials and methods

A systematic literature search was carried out in PubMed using the following keywords: “recommendations”, “guidelines” or “official positions” combined with “fine needle aspiration” or “biopsy”, even combined with “thyroid”, “nodule” and their expansions. Additionally, the references of identified publications were checked for further papers to include. Inclusion criteria were: (i) guidelines published between 2013 and October 2018; (ii) guidelines issued by international medical societies; (iii) guidelines aimed at providing evidence and expert-opinions regarding the management of thyroid nodules with a focus on indications for FNAB; (iv) guidelines focused on adult

population (age > 18 years); (v) full-manuscript available in English. Papers unintended as guidelines for the management of thyroid nodules, although the role of FNAB and US in assessing thyroid nodules was marginally discussed, were excluded from the study.

The selected guidelines were examined by four independent reviewers with 2 to 8 years of experience in diagnostic and interventional thyroid imaging and scientific research using the AGREE II instrument [25]. The AGREE II instrument comprises 23 items organized into 6 quality domains as follows: domain 1, “Scope and Purpose” (items 1–3); domain 2, “Stakeholder Involvement” (items 4–6); domain 3, “Rigour of Development” (items 7–14); domain 4, “Clarity of presentation” (items 15–17); domain 5, “Applicability” (items 18–21); domain 6, “Editorial Independence” (items 22–23). Table 1 details a description of the AGREE II items for each quality domain. Additionally, an “Overall Assessment” is included and concerns with “the rating of the overall quality of the guideline”. Prior to the appraisal, all reviewers were trained to effectively apply the AGREE II instrument by means of the user manual and training tools, including an overview tutorial and practice exercises, which were available online on the AGREE II official website [<http://www.agreetrust.org/agree-ii/> accessed on February 20, 2019]. According to the AGREE II instructions [26], each item was rated on a 7-point scale ranging from 1 (strongly disagree, i.e. no relevant information provided or very poorly reported concept) to 7 (strongly agree, i.e. exceptional quality of reporting).

Data collection, extraction and analysis were performed by a fifth independent reviewer with 5 years of experience in diagnostic and interventional thyroid imaging and scientific research using the SPSS software (version 24, IBM, Armonk, NY). For each guideline, the final domain scores were independently obtained by summing up all the individual item scores and by scaling the total as a percentage of the maximum possible score for that domain, as follows [26]: final domain score = (obtained score – minimum possible score)/(maximum possible score – minimum possible score). As for previous studies [27, 28], the final domain scores were classified as good (≥80%), acceptable (60–79%), low (40–59%) or very low (<40%). The total score of each guideline and domain was also calculated and expressed as mean ± standard deviation (SD). The guideline overall quality was assessed establishing a threshold of 60% for the final score of each domain, thus including acceptable to good final domain scores similarly to previous appraisers [29–32]. Specifically, the number of domains scored >60% was considered as the criterion for defining the guideline quality: ≥5 stated high quality, 3 or 4 average quality, ≤2 low quality. Inter-reviewer agreement was calculated using the intraclass correlation coefficient (ICC), interpreted as follows: <0.20, poor; 0.21–0.40, fair; 0.41–0.60, moderate;

Table 1 Scheme of AGREE II structure and detailed list of items within each domain according to Brouwers et al. [25]

| | |
|-----------------------------------|---|
| Domain 1: Scope and Purpose | |
| Item 1 | The overall objective(s) of the guideline is (are) specifically described |
| Item 2 | The health question(s) covered by the guideline is (are) specifically described |
| Item 3 | The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described |
| Domain 2: Stakeholder Involvement | |
| Item 4 | The guideline development group includes individuals from all the relevant professional groups |
| Item 5 | The views and preferences of the target population (patients, public, etc.) have been sought |
| Item 6 | The target users of the guideline are clearly defined |
| Domain 3: Rigour of Development | |
| Item 7 | Systematic methods were used to search for evidence |
| Item 8 | The criteria for selecting the evidence are clearly described |
| Item 9 | The strengths and limitations of the body of evidence are clearly described |
| Item 10 | The methods for formulating the recommendations are clearly described |
| Item 11 | The health benefits, side effects and risks have been considered in formulating the recommendations |
| Item 12 | There is an explicit link between the recommendations and the supporting evidence |
| Item 13 | The guideline has been externally reviewed by experts prior to its publication |
| Item 14 | A procedure for updating the guideline is provided |
| Domain 4: Clarity of Presentation | |
| Item 15 | The recommendations are specific and unambiguous |
| Item 16 | The different options for management of the condition or health issue are clearly presented |
| Item 17 | Key recommendations are easily identifiable |
| Domain 5: Applicability | |
| Item 18 | The guideline describes facilitators and barriers to its application |
| Item 19 | The guideline provides advice and/or tools on how the recommendations can be put into practice |
| Item 20 | The potential resource implications of applying the recommendations have been considered |
| Item 21 | The guideline presents monitoring and/or auditing criteria |
| Domain 6: Editorial Independence | |
| Item 22 | The views of the funding body have not influenced the content of the guideline |
| Item 23 | Competing interests of guideline development group members have been recorded and addressed |

AGREE II Appraisal of Guidelines for Research & Evaluation version II

0.61–0.80, good; 0.81–1.00, excellent. The confidence interval (CI) was set at 95%.

Results

Six sets of guidelines on FNAB of thyroid nodules for adults were included, respectively, provided by the American Thyroid Association (ATA) [18], the American Association of Clinical Endocrinologists/American College of Endocrinology/Associazione Medici Endocrinologi (AACE/ACE/AME) [16], the Korean Society of Thyroid Radiology (KSThR, published in 2016) [20], the European Thyroid Association (ETA) [19], the American College of Radiology (ACR) [21] and the Korean Society of Radiology and National Evidence-Based Healthcare Collaborating Agency (KSR/NECA, published in 2018) [17]. The main

characteristics of the selected guidelines are detailed in Table 2. Guidelines for the management of thyroid cancer in which the role of thyroid FNAB was marginally discussed, namely those provided by the British Thyroid Association [33], were excluded from the study because they were not intended as guidelines for management of thyroid nodules, as clearly stated in the aim of these guidelines. We also excluded a previous consensus statement by the KSThR, published in 2015 and focussed on technical aspects of thyroid FNAB and related complications rather than indications for performing FNAB [34].

Table 3 reports the final domain scores for each guideline as well as the total scores for each guideline and domain, also including the overall assessment of guideline quality. The final domain scores ranged between 40.28% (domain 2 of the KSThR recommendations) and 94.44% (domain 4 of both the ATA and AACE/ACE/AME guidelines). When comparing

Table 2 Main characteristics of the current guidelines on fine needle aspiration biopsy of thyroid nodules included in the analysis

| Guideline title | Area of origin | Year of publication | Organization(s) |
|---|----------------------|---------------------|--|
| 2015 ATA Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer [18] | North America | 2016 | American Thyroid Association (ATA) |
| AACE/ACE/AME Medical Guidelines for Clinical Practice for the Diagnosis and Management of Thyroid Nodules – 2016 Update [16] | Europe North America | 2016 | American Association of Clinical Endocrinologists (AACE)–American College of Endocrinology (ACE)–Associazione Medici Endocrinologi (AME) |
| Ultrasonography Diagnosis and Imaging-Based Management of Thyroid Nodules: Revised KSThR Consensus Statement and Recommendations [20] | Korea | 2016 | Korean Society of Thyroid Radiology (KSThR) |
| ETA Guidelines for Ultrasound Malignancy Risk Stratification of Thyroid Nodules in Adults: The EU-TIRADS [19] | Europe | 2017 | European Thyroid Association (ETA) |
| ACR Thyroid Imaging, Reporting and Data System (TI-RADS): White Paper of the ACR TI-RADS Committee [21] | North America | 2017 | American College of Radiology (ACR) |
| Primary Imaging Test and Appropriate Biopsy Methods for Thyroid Nodules: Guidelines by KSR and NECA [17] | Korea | 2018 | Korean Society of Radiology (KSR)–National Evidence-Based Healthcare Collaborating Agency (NECA) |

the total domain scores, “Scope and Purpose” (domain 1) and “Clarity of Presentation” (domain 4) obtained the highest results with a total score of 84.49 ± 5.08 (%), mean \pm SD) and 88.43 ± 6.73 (%), mean \pm SD), respectively. The domain with the lowest result was “Stakeholder Involvement” (domain 2) with a total score of 67.59 ± 16.40 (%), mean \pm SD). The guidelines provided by the ATA, AACE/ACE/AME, ETA, ACR and KSR/NECA achieved a high level of overall quality with a total score of 86.66 ± 7.54 (%), mean \pm SD), 80.21 ± 8.0 (%), mean \pm SD), 79.69 ± 6.84 (%), mean \pm SD), 72.16 ± 10.04 (%), mean \pm SD) and 73.50 ± 18.32 (%), mean \pm SD), respectively. The KSThR recommendations reached an average level of overall quality with a total score of 66.26 ± 16.96 (%), mean \pm SD). Reviewers’ detailed scores of the AGREE II individual items for each guideline are provided as supplementary material (Supplementary Tables 1–6).

Inter-reviewer agreement was moderate for the ATA guidelines (ICC = 0.562; 95% CI: 0.219–0.786), excellent for the AACE/ACE/AME guidelines (ICC = 0.818; 95% CI: 0.656–0.915), excellent for the KSThR recommendations (ICC = 0.874; 95% CI: 0.735–0.944), excellent for the ETA guidelines (ICC = 0.829; 95% CI: 0.680–0.919), good for the ACR guidelines (ICC = 0.741; 95% CI: 0.511–0.879) and excellent for the KSR/NECA guidelines (ICC = 0.941; 95% CI: 0.889–0.972).

Discussion

The main finding of this study is that the AGREE II appraisal of guidelines on FNAB of thyroid nodules revealed satisfactory results, as the overall guideline quality was high in five out of the six guidelines (ATA, AACE/ACE/AME, ETA, ACR and KSR/NECA guidelines) and average in one case (KSThR recommendations). These results acquire relevance in the light of our selection criteria, as the guidelines included in our analysis are updated, widespread used and applicable in all geographic areas. Moderate-to-excellent agreement between the appraisers also supports the validity of our results.

Each AGREE II domain is intended to capture a unique dimension of guideline quality [26]. In our analysis, the final domain scores never decreased <40%. They were classified as acceptable to good in the guidelines provided by the ATA, AACE/ACE/AME, ETA and ACR, resulting substantially uniform when considering the within-guideline scores. Contrastingly, KSThR recommendations and KSR/NECA guidelines revealed some degree of variability across the six domains with final domain scores ranging from low to good. The domains 1 (“Scope and Purpose”) and 4 (“Clarity of Presentation”) reached the highest total domain scores, both >80%. This finding

Table 3 Analysis of the current guidelines on fine needle aspiration biopsy of thyroid nodules according to AGREE II: report of final domain scores for each guideline and total scores of each guideline and domain, along with guideline overall quality

| Domain | ATA guidelines | AACE/ACE/AME guidelines | KSThR guidelines | ETA guidelines | ACR guidelines | KSR/NECA guidelines | Total per domain (mean ± SD) |
|---------------------------------|------------------------|-------------------------|------------------------|------------------------|------------------------|------------------------|------------------------------|
| 1. Scope and Purpose | 88.89% [good] | 80.56% [good] | 76.39% [acceptable] | 88.89% [good] | 84.72% [good] | 87.50% [good] | 84.49 ± 5.08 (%) |
| 2. Stakeholder Involvement | 90.28% [good] | 70.83% [acceptable] | 40.28% [low] | 72.22% [acceptable] | 61.11% [acceptable] | 70.83% [acceptable] | 67.59 ± 16.40 (%) |
| 3. Rigour of Development | 83.85% [good] | 75.00% [acceptable] | 58.33% [low] | 73.96% [acceptable] | 69.79% [acceptable] | 80.21% [good] | 73.52 ± 8.93 (%) |
| 4. Clarity of Presentation | 94.44% [good] | 94.44% [good] | 86.11% [good] | 84.72% [good] | 77.78% [acceptable] | 93.06% [good] | 88.43 ± 6.73 (%) |
| 5. Applicability | 72.92% [acceptable] | 81.25% [good] | 78.13% [acceptable] | 75.00% [acceptable] | 79.17% [acceptable] | 67.71% [acceptable] | 75.69 ± 4.92 (%) |
| 6. Editorial Independence | 89.58% [good] | 79.17% [acceptable] | 58.33% [low] | 83.33% [good] | 60.42% [acceptable] | 41.67% [low] | 68.75 ± 18.26 (%) |
| Total per guideline (mean ± SD) | 86.66 ± 7.54 (%) | 80.21 ± 8.00 (%) | 66.26 ± 16.96 (%) | 79.69 ± 6.84 (%) | 72.16 ± 10.04 (%) | 73.50 ± 18.32 (%) | |
| Overall quality | High | High | Average | High | High | High | |

AGREE II Appraisal of Guidelines for Research & Evaluation version II, *ATA* American Thyroid Association, *AACE/ACE/AME* American Association of Clinical Endocrinologists/American College of Endocrinology/Associazione Medici Endocrinologi, *KSThR* Korean Society of Thyroid Radiology, *ETA* European Thyroid Association, *ACR* American College of Radiology, *KSR/NECA* Korean Society of Radiology/National Evidence-Based Healthcare Collaborating Agency

compares well with previous studies evaluating guidelines by means of the AGREE II instrument regardless of the topic [28, 29, 35, 36], thus highlighting that these domains deal with essential elements that are not easily omitted. The domains 2 (“Stakeholder Involvement”) and 6 (“Editorial Independence”) obtained the lowest total domain scores, being both <70%. This can be at least partially attributed to the results achieved by the KSThR recommendations and KSR/NECA guidelines. Specifically, the reviewers identified no explicit information regarding target users and authors’ disclosure of competing interests, i.e. the items 6 and 23, in the KSThR recommendations and KSR/NECA guidelines, respectively. However, the AGREE II scale does not include a “Not Applicable” response and excluding items in the appraisal process is discouraged [26]. AGREE II may serve as a helpful tool to improve the quality of these domains. Specifically, although the KSR/NECA adopted AGREE II to perform a quality appraisal of selected literature [17], this instrument could be used extensively in the guideline development process and each AGREE II item could be addressed.

The AGREE II instrument recommends at least two but preferably four reviewers [26], as in our appraisal. This recommendation relies on the perceived improvement in inter-appraiser level of agreement. In our analysis, agreement between the reviewers was moderate to excellent despite their different years of experience in diagnostic and interventional thyroid imaging and scientific research. This finding agrees with previous studies stating that the level of

appraisers’ experience does not impact the scores in the different AGREE II domains [37].

Some authors have previously compared the accuracies of different guidelines in the prediction of thyroid cancer focussing on sonographic findings that should lead to FNAB of thyroid nodules [38–40]. Differently, we purposely assessed the methodological rigour of guideline development using the AGREE II quality assessment tool without, however, testing the clinical validity of the guidelines included in our analysis. One previous study has evaluated the quality of the recommendations of international clinical practice guidelines for the diagnosis and management of thyroid nodules and cancer using the AGREE II tool [41]. This study included guidelines published before June 2013, and it revealed some variability in methodological quality. Specifically, only three out of the ten guidelines performed satisfactorily, achieving a score >50% in all six AGREE II domains [41]. In our updated analysis, the guidelines on FNAB of thyroid nodules published between 2013 and October 2018 performed satisfactorily, as the overall guideline quality was high in five out of the six guidelines and average in one case. This may reflect increased efforts to improve the quality of guidelines on the diagnosis and management of thyroid nodules.

The present study has several limitations. Some are due to the characteristics of the AGREE II instrument, which does not aim to assess all aspects of a guideline. First, as mentioned above, AGREE II evaluates the rigour of guideline development without, however, focusing on both

the clinical content and the degree of consistency between guideline recommendations and the reported evidence [25]. Second, in the AGREE II instrument there are no threshold domain scores for distinguishing between high-quality and poor-quality guidelines [25]. This leaves the user open to interpret scores, thus we established a threshold of 60% for the final score of each domain as for previous studies [29–32]. Further, according to the AGREE II requirements, a subjective assessment of overall guideline quality should be made independently from domain scores along with a recommendation for use [25]. Differently from this but similarly to previous studies [42], we calculated the overall quality of the selected guidelines only on the basis of the final domain scores.

In conclusion, evidence-based guidelines are of paramount importance to provide valuable recommendations to radiologists in daily practice. Our study proved satisfactory overall quality of the guidelines on thyroid nodule FNAB provided by the ATA, AACE/ACE/AME, KStHR, ETA, ACR and KSR/NECA according to the AGREE II quality assessment tool. The AGREE II instrument can be usefully embedded in the development process of future guidelines. Each AGREE II item and domain should be addressed in order to ensure optimal methodologies and strategies of development and, as a consequence, the highest guideline quality.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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