Original Article

Compliance with thyroid nodule ultrasound reporting guidelines in an Australian Area Health Service

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Background: Thyroid nodules are a common clinical finding often detected in asymptomatic patients. The dilemma regarding the need for biopsy can be directed by ultrasound and guidelines have been developed to aid in the decision including the British Thyroid Association (BTA) Guidelines, the American Thyroid Association (ATA) Guidelines and the American College of Radiology "Thyroid Reporting and Data System" (TI-RADS). We sought to assess compliance with these guidelines in a modern Australian context.

Methods: A retrospective case series was conducted in the Hunter New England area health service. Patients undergoing a neck ultrasound over a 7-year period were eligible for review. Primary outcome was the proportion of reports mentioning the ultrasound criteria described in the various guidelines. Secondary outcomes were results of any subsequent histopathology or surgery.

Results: A total of 11,000 neck ultrasounds were reported in our time period, and of these 300 were selected for analysis. 71 of these reports commented on a nodule. Size was mentioned in 97.2%. Reporting on individual features was poor with none mentioned in more than 51% of reports. "Spongiform appearance", "Eggshell calcification", "Extrathyroid extension", "Extrusive Component", and reference to any nodule classification as proposed by a variety of International Guidelines, were not mentioned in a single report

Conclusions: Uptake of the various guidelines available has been poor in our thyroid ultrasound reports. Increased utilisation of these International guidelines would aid in clinical decision making for primary practitioners and specialists, in turn reducing risk to patients and costs to the health system.

Keywords: Ultrasound; guidelines; thyroid nodule; imaging; thyroid gland; Australia

Received: 11 May 2019; Accepted: 13 December 2019; Published: 05 August 2020.

doi: 10.21037/ajo.2019.12.03

View this article at: http://dx.doi.org/10.21037/ajo.2019.12.03

Introduction

Thyroid nodules are a common entity in clinical practice with 40–50% of asymptomatic patients demonstrating nodules on routine sonography (1). A strong body of evidence now advocates use of ultrasound (USS) +/- fine needle aspiration biopsy (FNAB) for investigation (2). The decision to perform a FNAB is guided by the presence of sonographic features; including but not limited to size, nature of margin, shape, presence of microcalcification and echogenicity (2-5). These features have been utilised in the creation of several guidelines including the American Thyroid Association (ATA), British Thyroid Association and the American College of Radiology "Thyroid Imaging Reporting and Data System" (TI-RADS). These guidelines provide an important tool for the Radiologist, General Practitioner, Endocrinologist or Surgeon faced with the discovery and management of a patient with a thyroid nodule. Anecdotally we noted that the presence of high-risk

Table 1 Primary outcomes for our study as developed from the ATA, BTA and TI-RADS guidelines

Sonographic features of nodule mentioned on review of sonography reports (Developed from ATA, BTA and TI-RADS Guidelines)
Nodule size
Presence or absence of microcalcification
Echogenicity
Irregular margins
Shape taller than wider
Intranodular vascularity or peripheral vascularity
Presence of macrocalcification
Spongiform appearance
Solid, cystic or mixed
Extrathyroidal extension
Extrusive component
Cervical lymph node status
Egg shell type calcification around periphery of nodule +/– extension of hypoechoic mass beyond it
Mention of thyroid nodule ultrasound classification system
Overall "suspicion"

sonographic features that determine the need for biopsy are not routinely conveyed by reporting radiologists.

We sought to determine the utilisation of international guidelines in radiology reports with respect to thyroid nodules within our Area Health Service. The application of guidelines when reporting high risk features of thyroid nodules on ultrasound has not previously been studied. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/ajo.2019.12.03).

Methods

Study design

Ethics approval was granted by the Hunter New England Human Research Ethics Committee (Approval Number AU201703-03). A retrospective chart review of patients undergoing thyroid or neck ultrasounds was performed, based on a random selection using a random number generator on all thyroid and neck ultrasounds undertaken between January 2010 and July 2017. Ultrasound reports were selected from studies undertaken across a broad array of radiology departments in the Hunter New England Radiology network. A cohort of 300 patients was initially randomly selected for review with scope to expand if statistical significance was not obtained in the data. Detailed chart review was undertaken with consultation from other authors when required.

Ultrasound reports which did not describe the presence of thyroid nodules were excluded. If a nodule was present, the ultrasound report was audited for mention of the diagnostic nodule criteria in *Table 1*. These 15 criteria were developed from the British Thyroid association guidelines for the Management of Thyroid Cancer (BTA), the American Association of Clinical Endocrinologists and Associazione Medici Endocrinologi Guidelines for the management of patients with thyroid nodules (AACE/AME), the American Thyroid Association Management Guidelines for Patients with Thyroid Nodules (ATA) and the American College of Radiology (TI-RADS) Guidelines (2,3,5,6). For each criterion, it was noted whether the criterion was mentioned, as well as the actual detail (for example for "size", we recorded "mentioned or not mentioned" and the actual dimensions of the nodule). In addition, further clinical information (e.g., whether an FNAB was undertaken, relevant cytology results as per Bethesda classification, surgical intervention, formal histopathology of the specimen) was obtained.

The primary outcome was the proportion of reports commenting on high risk sonographic features including mention of thyroid nodule classification system (ATA, BTA, Ti-RADS).

Secondary outcomes were whether nodules had further intervention in the form of FNAB or surgery.

Statistical analysis

Data was entered to *Microsoft Excel*™ (2016) and confidence intervals were generated to 95% confidence with data assumed to be normally distributed.

Results

A total of 11,000 neck or thyroid ultrasounds (as defined in the Area Health database search keywords) were performed within our Area Health Service during the study period. Of these, 300 were selected at random for review. Of the 300 selected, 71 contained nodules and were included for analysis.

Table 2 Results from our study with 95% confidence intervals

Criteria	Proportion	95% CI
Nodule size	97.20%	93.6–100%
Microcalcification	14.1%	6.0–22%
Echogenicity	49.2%	37.7–60.9%
Irregular margins	2.80%	0–6.6%
Shape taller than wide	0%	0%
Intranodular/peripheral vascularity	22.5%	12.8–32.2%
Macrocalcification	12.6%	4.9–20.4%
Spongiform appearance	1.4%	0–4.1%
Solid *vs*. cystic *vs.* mixed	50.7%	39.1–62.3%
Extrathyroidal Extension	0.00%	N/A
Extrusive component	0.00%	N/A
Cervical lymph node status	43.70%	32.1–55.2%
Egg shell type calcification	0.00%	N/A
Thyroid Nodule Classification System	1.4%	0–4.1%
Overall "suspicion"	21.1%	11.6–30.6%

Primary outcomes are available in *Table 2*. Of the 71 cases analysed the inclusion of the size of the nodule was well reported (97.2%). However, all other criteria were mentioned in less than 51% of cases. Additionally, the criterion of "Spongiform appearance", "Eggshell calcification", "Extrathyroid extension", "Extrusive Component", and "Thyroid Nodule Classification" were not mentioned in a single report. One report did make mention of "guidelines" though failed to identify which guideline and recommended biopsy based on size alone. Radiologists overall impression was indicated in 21% of cases (low n=7, intermediate n=7, high n=1). Given the profound lack of guideline utilisation we felt that this result was beyond the realm of statistical aberration and as such further reports were not analysed for inclusion.

Interestingly in three reports it was suggested that the patients have nuclear medicine studies to determine if the nodules were cold. One patient had an FNA for a cold nodule.

Of the 71 patients, 15 had a FNAB, of which 3 were Bethesda 1, 9 were Bethesda 2, 2 were Bethesda 3 and 1 was Bethesda 6. The one patient with Bethesda 6 disease went on to have surgery and papillary thyroid carcinoma was proven. Both patients who were Bethesda 3 went on to have surgery which revealed papillary thyroid carcinoma on formal pathology. Of the patients who were Bethesda 2, three had FNA recommended based on the size of the nodule alone and from the other 6 the indication for FNA was unclear.

A total of 9 patients underwent surgery of which 4 had benign disease and 5 had malignant disease.

Discussion

Thyroid nodules are an increasingly encountered finding, proving a management dilemma in clinical practice for General Practitioners, Endocrinologists and Surgeons. The gold standard for investigation is ultrasound plus FNAB, though ultrasound alone has been shown to be safe in the absence of specific features. The cost of full workup with FNAB is upwards of $225 Australian Dollars and involves psychological stress and risk of physical harm for the patient (7-10). To reduce these downsides, authors have examined the ultrasound features of nodules which are predictive of malignancy and warrant a FNAB. Features of microcalcification, marked hypoechogenicity, "*lobulated margin*" and a "*well defined spiculated margin*" are statistically more likely to be found in malignant nodules. Some nodules demonstrate an "*eggshell*" calcification at their periphery, which can potentially lower the sensitivity of ultrasound in evaluating other features of malignancy., A hypoechoic halo or disruption of this rim is a marker of malignancy (11). A thyroid nodule shape of "*Taller rather than wider*", "*blurred margins*" and intra-nodular vascular flow have also been positively correlated with malignancy (12,13). Features of rim calcification, dense or large calcification and a well-defined smooth margin are features statistically more likely to be seen in benign nodules regardless of their size (13-15). Unfortunately, many of the FNAB's undertaken in our study were done on patients where the ultrasound report had not described any of these suspicious features.

Up to 16% of patients undergoing CT or MRI of the neck and 51% of patients undergoing a routine carotid ultrasound demonstrate incidental thyroid nodules (1,7). Most of these lesions will be benign (91–99.5%). A growing body of evidence has shown scintigraphy to be inferior with regard to sensitivity and specificity when compared with ultrasound +/– FNAB (2). In our study one patient had been referred for biopsy based on Nuclear Imaging (scintigraphy). Additionally, three reports advocated the use of Nuclear Imaging in further evaluation of the nodule.

Nodule size has not been shown to correlate with likelihood of malignancy, however larger tumours are associated with a worse prognosis (12,14). In our study nodule size was the most consistently reported feature, and very frequently no other high-risk features were mentioned. In addition, ultrasound reports regularly declared a thyroid gland as a "multinodular goitre" based on nodule size, despite the risk of malignancy in multinodular goitre (16).

The process of recognising patterns of the above features rather than individual features has also been studied, which may further decrease the need for proceeding to FNAB (17,18).

To synthesise information from clinical trials several guidelines have been developed regarding the evaluation of thyroid nodules with ultrasound.

The AACE/AME guidelines define microcalcifications, irregular/micro-lobulated margins, intra-nodular vascularity, marked hypoechogenicity and shape taller than wider as suspicious features and a biopsy is recommended if two or more are present in both impalpable and palpable nodules (3). In addition, these guidelines talk about extrathyroidal extension and suspicious cervical lymphadenopathy as always warranting FNAB (3).

The BTA guidelines recommend use of a scoring system (U1-U5) to determine the need for biopsy. The score for a nodule is based on multiple features including echogenicity, cystic/spongiform change, eggshell calcification and its integrity, peripheral and central vascularity, margin, presence of microcalcification and shape taller than wide (2). Additionally, extrathyroidal extension and suspicious lymphadenopathy are cited as absolute indications for biopsy (2). In fact, the guidelines specifically states with regard to radiology reporting that "*The clinician should be competent in identifying the characteristic signs that can allow differentiation of thyroid nodules*" (2).

Similarly, the ATA guidelines break nodules into 5 categories from benign to high suspicion based on features of echogenicity, margins, microcalcification, taller than wide shape, rim calcification with extrusive component, extrathyroidal extension and spongiform character correlated with the overall size of the nodule in determining the need for biopsy (5).

Commonly used in Australia, the TI-RADS guidelines also depend on reporting which outlines nodule composition, echogenicity, shape, margin and echogenic foci and uses these descriptors to generate a score which stratifies patients into a degree of risk thereby determining the need for biopsy (6).

Without access to information regarding the presence or absence of these specific features, the decision regarding whether to biopsy or not to biopsy a thyroid nodule becomes very difficult for clinicians, potentially leading to over-investigation with ramifications for costs, risk and anxiety. To our knowledge, no studies have examined compliance with description of thyroid nodule guidelines in Australia or radiologists' compliance with reporting ultrasounds as specified in clinical guidelines. Other studies have demonstrated that the use of these guidelines by clinicians varies throughout the world but is generally lower than expected (19,20). The application of these guidelines has been shown to reduce the costs for the health system with regard to reductions in over-investigation and treatment (19,21). Of interest, our population demonstrated a biopsy rate of 21%, which compares to only 4.2% of patients deemed to require biopsy in a large series representing significant potential for improvement (22).

Our study is limited by its small size, retrospective nature and heterogeneous group of patients and clinicians. However, we feel that this has allowed us to provide an approximation of the poor utilisation of well documented guidelines in a modern setting in a "real world" demonstration during routine diagnostic imaging, rather than a regimented research situation. In order to increase the "real world" nature of our study, we used the broad search term "ultrasound neck" but excluded reports which did not identify a nodule. As such, despite using a wide search term, it was felt that if a thyroid nodule was identified the report should ideally have gone on to elaborate on the nodule in order to help referring clinician with decision making about whether to proceed to biopsy. Due to the heterogeneity of our sample, we feel our results would be applicable to a wide range of clinical settings. These findings highlight the need for ongoing education of sonographers, radiologists, general practitioners, endocrinologists and surgeons about the use of validated Imaging guidelines, in the description of Ultrasound defined thyroid nodules. This would help in stratifying high-risk lesions which would warrant diagnostic FNAB and appropriate further management: and this should maximise the positive predictive value of the test, to minimise patient anxiety and health costs of an unnecessary procedure.

Conclusions

Use of thyroid ultrasound nodule reporting guidelines in our Area Health Service is poor and these results may be

applicable to other settings. Increased awareness of these guidelines among primary care practitioners, radiologists, endocrinologists and surgeons would reduce costs for the health system in addition to minimising patient anxiety and physical harm.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/ajo.2019.12.03

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Ethics approval was granted by the Hunter New England Human Research Ethics Committee (Approval Number AU201703-03) and individual consent for this retrospective analysis was waived.

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doi: 10.21037/ajo.2019.12.03
Cite this article as: Roberts ST, Darlow J, Williamsz G, Cope D. Compliance with thyroid nodule ultrasound reporting guidelines in an Australian Area Health Service. Aust J Otolaryngol 2020;3:29.