

Can ultrasound be used to predict malignancy in patients with a thyroid nodule and an indeterminate fine-needle aspiration biopsy?

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Purpose. The purpose of this study was to evaluate whether ultrasonography is helpful in predicting malignancy in patients with a thyroid nodule and atypia/follicular lesion of undetermined significance (AFLUS).

Methods. All patients with a preoperative ultrasound who underwent thyroidectomy for a nodule with AFLUS comprised the study population. A blinded review of gray-scale and color-Doppler sonographic images of the thyroid nodule was performed by an expert sonographer; results were compared with the original interpretation and were correlated with histopathology. All images were reviewed for hypoechogenicity, irregular margins, shape that was taller than wide, micro and macrocalcifications, absent halo, and intranodular hypervascularity.

Results. From 2010 to 2012, 61 patients underwent thyroidectomy for AFLUS with an ultrasound examination for review; 6 (10%) with cancer. Nodule shape that was taller than wide, was associated with cancer ($P < .05$). The original sonographer commented on an average of two of seven features important in assessment of a thyroid nodule.

Conclusion. With the exception of nodule height greater than width, sonographic criteria were not helpful in deciding which patients with AFLUS should undergo thyroidectomy. Thyroidectomy is recommended in lieu of repeat biopsy for a nodule that is taller than wide. Standardized sonographic reporting should be implemented. (*Surgery* 2014;156:967-71.)

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IN 2008, THE NATIONAL CANCER INSTITUTE initiated the Bethesda System for Reporting Thyroid Cytopathology, a six-tiered classification system, to help standardize the management of nodular thyroid disease and enable effective communication among health care providers.¹ Atypia/follicular lesion of undetermined significance (AFLUS) was a new category introduced for cytologic features that were neither definitively benign nor definitively neoplastic and for which a repeat fine-needle aspiration biopsy (FNAB) was recommended. The AFLUS category was projected to account for

<7% of thyroid aspirates and was estimated to have a 5–15% risk of malignancy.^{1,2}

AFLUS is a heterogeneous category with at least eight different clinical scenarios and a wide range of cytologic features. The reported rates of malignancy vary from 6 to 48%.²⁻⁴ It remains unclear which patients are at increased risk for cancer and warrant more aggressive treatment. The detection of oncogenic mutations to help establish a diagnosis of cancer and the use of gene expression classifiers to help predict benign disease are being used in patients with an indeterminate FNAB; their role is evolving and they have yet to be uniformly adopted into routine clinical practice. There is a 5% false-negative rate for the gene expression classifier for nodules with AFLUS, and 6% of malignant nodules are mutation negative, limiting their clinical usefulness.^{5,6}

It has been reported that certain sonographic features of a thyroid nodule are associated with an increased likelihood of malignancy, including

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hypoechoogenicity, microcalcifications, macrocalcifications, irregular borders, a shape that is taller than wide, absence of a halo, and increased intranodular vascularity^{7,8}; however, on an individual basis, these features are less specific than FNAB.⁹ The purpose of this study is to evaluate whether specific sonographic features are helpful in predicting malignancy and refining the management of patients with a thyroid nodule and an FNAB categorized as AFLUS.

METHODS

All patients with a preoperative ultrasound examination of the neck who underwent thyroidectomy for a nodule with AFLUS comprised the study population. Demographic and clinical information was obtained from a retrospective review of patients' medical records and a prospectively maintained thyroid database. Clinical and demographic information included patients' age, sex, serum thyroid-stimulating hormone (TSH) levels, antithyroglobulin and antimicrosomal antibody levels, family history of thyroid disease or thyroid cancer, compressive symptoms, and previous history of radiation exposure to the head or neck.

A blinded retrospective review of grayscale and color-Doppler sonographic images of the thyroid nodule was performed by an expert sonographer; results were compared with the original interpretation and were correlated with histopathology. The original ultrasound reports were reviewed, and it was determined how often the presence or absence of specific sonographic features important in the assessment of malignancy were documented, including echogenicity, smooth or irregular nodule borders, nodule shape that is taller than wide, punctate microcalcifications, macrocalcifications, increased intranodular vascularity, and associated lymphadenopathy.

Diagnostic thyroid ultrasound was performed with a Philips HDI 5000 ultrasound machine using a linear 12.5 MHz transducer. A sector transducer was used for large nodules. The nodules were imaged and measured in sagittal and transverse planes, and color Doppler ultrasound was used to assess the vascularity of the nodule. Images were reviewed on a General Electric Centricity Picture Archiving and Communication System.

The index nodule was defined as the dominant nodule with an FNAB classified as AFLUS. The index nodule was classified as predominantly solid, predominantly cystic, or mixed solid-cystic. Nodule shape was described as being taller than wide, when the anteroposterior axis was larger in dimension than the transverse dimension. Echogenicity

was assessed relative to the surrounding tissue and categorized as predominantly hypoechoic, hyperechoic, isoechoic, or heterogeneous echogenicity. Calcifications were classified as either microcalcifications or macrocalcifications. The margin or border of the nodule was classified as either irregular or smooth.

Data were analyzed to determine whether specific sonographic features were predictive of malignancy. The initial ultrasound reports were reviewed to see how many of the distinct sonographic features and characteristics were commented on in the original report. Descriptive statistics were used to examine the demographic data. A chi-square or Fisher exact test with a Yates correction was used for analysis of categorical data. This study was approved and reviewed by the institutional review board at MetroHealth Medical Center.

RESULTS

From 2010, when the Bethesda System for Reporting Thyroid Cytopathology was instituted at our institution to 2012, a total of 61 patients had a preoperative sonographic examination of the neck and underwent thyroidectomy for a thyroid nodule and a FNAB classified as AFLUS; 50 (82%) were women and 11 (18%) were men. Indications for surgery were: persistent AFLUS, compressive symptoms, previous neck irradiation, family history of thyroid cancer, sonographic features suspicious for malignancy, and patient preference. Clinical and demographic data are presented in [Table I](#). The average age was 52 years. The mean size of the index nodule was 3.1 ± 2.0 cm. Fifty (82%) patients had more than one nodule, 32 (54%) presented with compressive symptoms, 39 (64%) had a family history of thyroid disease, 7 (11%) had a family history of thyroid cancer, and 4 (7%) had prior history of radiation exposure to the head and neck. Serum TSH, antimicrosomal, and antithyroglobulin antibodies were examined. The mean TSH level was 3.08 ± 7.5 uIU/mL. Only 10 (16%) patients had an abnormal antimicrosomal antibody and only 3 (5%) patients had an abnormal anti-thyroglobulin antibody. A total of 33 (54%) patients underwent a total thyroidectomy, and 28 (46%) a thyroid lobectomy and isthmusectomy.

There was agreement between the expert blinded review and the original interpretation with respect to the findings that were documented in the original report; however, radiologists who dictated the original ultrasound report, on average, only commented on two of the seven features examined ([Table I](#)). The features that

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