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Fate of nondiagnostic thyroid fine needle aspirations

Tanner Storozuk MD | Anna Biernacka MD, PhD | Ricardo Lastra MD | Jeffrey Mueller MD | Andrea Olivas MD | Ward Reeves MD | Lindsay Yassan MD | Tatjana Antic MD

Department of Pathology, University of Chicago, Chicago, Illinois, USA

Correspondence
Tanner Storozuk, Department of Pathology, University of Chicago, 5841 S. Maryland Avenue, MC3083, Chicago 60637, IL, USA.
Email: tanner.storozuk@uchicagomedicine.org

Abstract

Background: Thyroid nodules may be detected during the workup of thyroid hormone abnormalities and as incidental findings during unrelated imaging studies. The diagnosis of a thyroid nodule is mainly established by performing fine needle aspiration (FNA) under ultrasound guidance. Thyroid nodules are classified as nondiagnostic, defined in the Bethesda System for Reporting Thyroid Cytopathology as samples with excess blood, cyst fluid only, and lack of thyroid follicular cells. The current study evaluates a series of nondiagnostic FNAs to assess whether repeat sampling improves yield and what patient management, and outcomes are after a nondiagnostic FNA.

Methods: Thyroid FNAs from 2016 to 2023 were retrieved from our institution archives. All cases were performed under ultrasound guidance and with rapid on-site evaluation. Cases were assigned the Bethesda System Category. Nondiagnostic FNAs were further reviewed for repeat FNA procedures, potential molecular testing, or diagnostic resections.

Results: In total 3104 thyroid FNAs were reviewed, with 153 (4.9%) being nondiagnostic. Of the 154 FNAs, there were 129 patients with an average age of 60 and a male-to-female ratio of 1:3.2. Of the 130 patients, there were 50 patients who underwent 55 repeat FNAs. Thirty-seven (67%) of the repeats were benign, 13 (24%) were nondiagnostic again, and 5 (9%) were atypia of undetermined significance (AUS). Molecular testing was performed on repeat FNAs diagnosed AUS. Four cases showed no mutations and had a high likelihood of being benign. One case did have an NRAS Q61R mutation, and resection revealed a noninvasive follicular thyroid neoplasm with papillary-like nuclear features.

Seventeen (13% of all cases) with nondiagnostic FNA were resected. Twelve (71%) thyroidectomies showed benign adenomatous nodules. The remainder showed incidental papillary thyroid microcarcinoma (0.1 cm), an infarcted follicular adenoma, a noninvasive follicular thyroid neoplasm with papillary-like nuclear features, and metastatic renal cell carcinoma (2×).

Conclusion: Thyroid nodules with nondiagnostic cytology are reassuring of being highly likely a benign nodule. Only 5 of the 55 (9%) repeat FNAs yielded abnormalities, with only one of those being truly a follicular neoplasm (confirmed by molecular testing and resection). No primary thyroid malignancies have been identified in follow-up (repeat FNA or surgery). Clinical and ultrasound follow-up may be more appropriate management for nondiagnostic thyroid FNAs.

KEYWORDS
Bethesda, non-diagnostic, thyroid, unsatisfactory

1 | INTRODUCTION

The thyroid is an endocrine organ in the neck that has a prominent role in the body's metabolism. Often, the workup of thyroid abnormalities will include a hormone panel and ultrasound to evaluate for the thyroid parenchyma and look for the presence of nodules. Additionally, thyroid nodules are routinely detected incidentally during unrelated imaging studies.

Thyroid nodules are classified by cytologic analysis via fine needle aspiration (FNA), most often under ultrasound guidance. Classification of thyroid nodules was established in The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), which is now used to classify these nodules based on risk of malignancy and future management. A 6-category system was implemented to standardize the diagnostic terminology, specimen adequacy, cytomorphologic features, and risk of malignancy.[1] With the establishment of TBSRTC, cytopathologists can communicate their interpretations to clinicians, as well as patients, in a meaningful and clinically useful manner.[1] Category I represents nondiagnostic/unsatisfactory, where the specimen is essentially acellular (only blood) or shows only cyst fluid. The third edition of TBRSTC has removed the terminology unsatisfactory; therefore, only nondiagnostic will be used.[3] In current practice, thyroid nodules are rendered nondiagnostic rarely. Attempts to mitigate this occurring include performing the FNA under ultrasound guidance and with on-site adequacy performed by a cytopathologist.

The current study evaluates a series of nondiagnostic FNAs to assess whether repeat sampling improves yield and what patient management, and outcomes are after a nondiagnostic thyroid FNA. Awareness of these findings will allow clinicians and radiologists to suggest more appropriate management after nondiagnostic cytology.

2 | METHODS

The Institutional Review Board of the University of Chicago approved this study (IRB22-1207, 2022). The pathology archives at the University of Chicago Medical Center were searched for patients who underwent thyroid FNAs from 2016 to 2022. Clinicopathologic data was collected from patients' electronic medical records, including demographics, FNA results, and follow-up information (subsequent repeat FNA, molecular studies, and surgical resections). All cases were performed under ultrasound guidance and had immediate assessment conducted by a board-certified cytopathologist. Four to six FNA passes were performed on each nodule before the cytologic findings were deemed nondiagnostic. Additionally, a liquid-based preparation (CytoLyt) is a part of each case and made into a ThinPrep. Cell blocks were not made for thyroid FNA specimens. Cases were signed out according to the 2017 Bethesda System for Reporting Thyroid Cytopathology. Nondiagnostic FNAs were further reviewed for repeat FNAs, molecular testing, or diagnostic resections. Molecular testing was performed by Interpace with ThyGeNEXT and ThyraMIR testing platforms.

3 | RESULTS

3.1 | Clinical and ultrasound information

In total 3104 thyroid FNAs were reviewed, with 153 (4.9%) being nondiagnostic. Of the 153 FNAs, there were 129 patients with an average age of 60 and a male-to-female ratio of 1:3.2. The average number of passes per nodule was 4.06 with a range of 0–10 passes. The nodule size was available for 146 FNAs with an average size of 2.4 cm and range of 0.3–7.1 cm. The ultrasound appearance was available for 102 nodules: 33 (22%) solid, 34 (22%) solid/cystic, 10 (7%) cystic, 18 (12%) heterogenous, and 7 (5%) spongiform. The echogenicity was available for 80 nodules: 44 (29%) hypoechoic, 3 (2%) hypo-isoechoic, 19 (12%) isoechoic, 3 (2%) iso-hyperechoic, 8 (5%) hyperechoic and 3 (2%) showed variable echogenicity. Calcification was seen in 16 (10%) of nodules with 10 (7%) representing macrocalcifications and 6 (4%) being microcalcifications. Echogenic foci were noted in 3 (2%) of cases. Internal vascularity was noted in 17 (11%) of nodules. Only one nodule was biopsied for PET avidity. These results are summarized in Table 1.

3.2 | Follow-up data

Of the 129 patients, 18 (14%) patients had no follow-up, 54 (42%) patients only had ultrasound follow-up, 7 (5%) were followed up with surgery, and 50 (39%) patients underwent 55 repeat FNAs. Thirty-seven (67%) of the repeats were benign follicular nodules, 13 (24%)

TABLE 1 Patient Demographics and Ultrasound characteristics.

Total # FNAs	3104
Total # nondiagnostic FNAs	153
Total # patients with nondiagnostic FNAs	129
Male	30 (23%)
Female	99 (77%)
Mean age, years (range)	60 (20–93)
Ultrasonographic and on-site data	
Number of passes (mean, range)	4.06 (1–10)
Nodule size (cm) (mean, range)	2.4 (0.3–7.1)
Appearance	
Solid	33 (22%)
Solid/cystic	34 (22%)
Cystic	10 (7%)
Heterogenous	18 (12%)
Spongiform	7 (5%)
Not available	51 (33%)
Echogenicity	
Hypoechoic	44 (29%)
Hypo-isoechoic	3 (2%)
Isoechoic	19 (12%)
Iso-hyperechoic	3 (2%)
Hyperechoic	8 (5%)
Variable	3 (2%)
Not available	73 (48%)
Calcification	16 (10%)
Micro	6 (4%)
Macro	10 (7%)
Echogenic foci	3 (2%)
Internal vascularity	17 (11%)

Abbreviation: FNA, fine needle aspiration.

TABLE 2 Follow-Up Data.

Number of patients with no follow-up	18 (14%)
Number of patients with ultrasound follow-up	54 (42%)
Number of patients with follow-up (surgery w/o repeat FNA)	7 (5%)
Number of patients with follow-up (repeat FNAs)	50 (39%)
Number of repeat FNAs	55
Category 1. Nondiagnostic	13 (24%)
Category 2. Benign	37 (67%)
Category 3. Atypia of undetermined significance (AUS)	5 (9%)
Molecular results	5
Negative (likely benign)	4 (80%)
Positive mutation	1 (20%)
Surgical Resections	17 (13%)
Adenomatous nodules	12 (71%)
Follicular neoplasm	2 (12%)
Incidental papillary thyroid microcarcinoma	1 (6%)
Metastatic renal cell carcinoma	2 (12%)

Abbreviation: FNA, fine needle aspiration.

were nondiagnostic again, and 5 (9%) were AUS. Molecular testing was available only for cases diagnosed as AUS. Four cases showed no mutations and had a high likelihood of being benign. One case did have an NRAS Q61R mutation, and resection revealed a noninvasive follicular thyroid neoplasm with papillary-like nuclear features.

Seventeen patients with nondiagnostic FNA(s) were resected (13% of all cases). Twelve (71%) resections showed benign micro/macro adenomatous nodules. The remainder showed incidental papillary thyroid microcarcinoma (0.1 cm), an infarcted follicular adenoma, a noninvasive follicular thyroid neoplasm with papillary-like nuclear features, and metastatic renal cell carcinoma (2×). These results are summarized in Table 2.

4 | DISCUSSION

Of the approximately 3100 FNAs performed over the last 8+ years, repeat FNA on nondiagnostic nodules rarely identified actionable findings. The overwhelming majority of thyroid nodules are benign; hence, any difficulty sampling them should be relatively reassuring. Adequacy, as stated in the first edition of TBSRTC, is defined as at least 6 groups of benign follicular cells, each with at least 10 cells (60 cells in total).[1] There have been attempts at reducing the required number of follicular cells to decrease the non-diagnostic rate and prevent repeat FNA.[4] The goal is to minimize the nondiagnostic rate without impacting the false-negative rate. However, there has yet to be a consensus on the lower number of follicular cells.[4,5] The number of nodules deemed nondiagnostic is reduced by using ultrasound guidance and having on-site adequacy by a cytopathologist. All nodules in this cohort were performed under ultrasound guidance with on-site adequacy by a cytopathologist.

Since the inception of TBSRTC in 2010, some questions regarding the associated risks of malignancy and appropriate management have become apparent.[1] In the original 2010 TBSRTC, the stated risk of malignancy for nondiagnostic nodules was 1%–4%,[6–8] and repeat ultrasound-guided FNA was ultimately diagnostic in 50%–88% of cases.[7,9–13] Excision of persistently nondiagnostic nodules revealed that ~10% were malignant.[9] The second iteration of TBSRTC was released in 2017 with additional data available for these nondiagnostic cases. The malignancy rate was reported as 9%–32% among surgically resected nodules with nondiagnostic cytology. These resected nodules, however, were removed based on either repeat nondiagnostic cytology or other clinical/radiographic features that warranted

resection. This resulted in the over-representation of malignancy when considering all nondiagnostic nodules.[2] The adjusted rate of malignancy was reported in this 2017 edition as 5%–10%.[14] Toward the end of last year, the third edition of TBSRTC was released. No significant changes were made to the adequacy criteria; however, the now-reported risk of malignancy in nodules with nondiagnostic cytology is 13% (with a range of 5%–20%).[3] The American Thyroid Association (ATA) now also states that there is no longer a need to wait several months to repeat FNA of nondiagnostic nodules.[14]

The ATA additionally makes several recommendations regarding nodules with nondiagnostic cytology. Like TBSRTC, repeat FNA with ultrasound guidance is recommended; however, they also recognize that repeatedly nondiagnostic nodules with worrisome sonographic features require close follow-up or surgical excision. Sonographic features are useful in identifying, which nodules with repeat nondiagnostic cytology results are more likely to be malignant.[14] In one series of 104 nodules with two nondiagnostic cytology results, thyroid cancer was found in 25% of cases with worrisome sonographic features, including microcalcifications, irregular margins, a taller-than-wide shape, or hypoechogenicity. Cancer was only found in 4% of cases lacking these features.[15] Additionally, studies have suggested there may be utility of thyroid core-needle biopsy[16] or molecular testing[17–19] in the management of patients with nodules with nondiagnostic cytology.

The third edition TBSRTC states the risk of malignancy for nondiagnostic nodules of 13% (range 5%–20%) with repeat FNA recommended, and that benign nodules have a risk of malignancy of 4% (range 2%–7%) with clinical and ultrasound follow-up. Of our 153 nondiagnostic FNAs, 55 (~36%) had repeat FNAs. Of them, 50 (91%) cases resulted as either nondiagnostic again or benign. There were 5 nodules reported as atypical of undetermined significance. Molecular testing was performed on these nodules and showed that 4 had likely benign molecular testing results. Only 1 of 55 (2%) repeat FNAs resulted in a true abnormality (AUS) with an NRAS Q61R mutation and subsequent surgical resection that showed a noninvasive follicular thyroid neoplasm with papillary-like nuclear features.

Follow-up surgical resection data again showed most of these nondiagnostic nodules are benign (12/17% or 71%). The abnormalities seen on surgical resection were obscured by the excess blood (in cases of metastatic renal cell carcinoma) or not actually sampled in the case of an incidental papillary thyroid microcarcinoma. TBSRTC acknowledges that the risk of malignancy of 13% (range 5%–20%) is among surgically resected nodules with nondiagnostic cytology. This overrepresents the incidence of malignancy as the majority of nodules with nondiagnostic cytology are not resected.[3] Ycaza et al. reported that 15/495 (3%) of cases with nondiagnostic cytology were found to be malignant and confirmed by histology. Thirteen of the malignancies were papillary thyroid carcinoma, while the other two cases were follicular thyroid carcinoma and medullary thyroid carcinoma.[20] Primary thyroid malignancy can be initially nondiagnostic on FNA. Therefore, nodules deemed nondiagnostic do carry a small risk of malignancy; however, in our data, no primary thyroid malignancies have been identified in the follow-up of 153 nondiagnostic nodules. Therefore, the likelihood of having a primary thyroid malignancy with nondiagnostic cytology is extremely low, and in our cohort was 0%. The overall risk of malignancy (including the two cases of metastatic renal cell carcinoma) is also very low at 1.3% (2 cases/153 nodules with nondiagnostic cytology).

The first iteration of TBSRTC, stated thyroid nodules with nondiagnostic cytology and cyst fluid only carried a higher risk of malignancy (4%) compared with nodules that were just nondiagnostic (1%–4%).[1] None of the sixteen nodules with nondiagnostic cytology and cyst fluid only were found to be malignant on follow-up (Table 3). The sonographic features of the nodule are likely to determine the follow-up in these cystic nodules. Nodules that are entirely cystic with nondiagnostic cytology may be treated as benign nodules.[3] Although, this only accounts for two nodules in the data (entirely cystic on imaging and cyst fluid only on cytology).

We recommend that nondiagnostic nodules without worrisome clinical or sonographic features should be managed similarly to category II benign nodules. Since these nodules only rarely represent neoplasms warranting surgical resection, clinical and sonographic follow-up would be more appropriate. Nodules with nondiagnostic cytology and worrisome clinical or sonographic features should have their management escalated to either repeat FNA, core biopsy (CB), or diagnostic lobectomy. The Korean Society of Thyroid Radiology

TABLE 3 Nodules with cyst fluid only on initial fine needle aspiration (FNA).

Cyst fluid only cytology	16 (10%)
Appearance	
Solid	0
Solid/cystic	7
Cystic	2
Heterogenous	0
Spongiform	3
Not available	4
Echogenicity	
Hypoechoic	1
Hypo-isoechoic	1
Iscoechoic	1
Not available	13
Calcification (macro)	1
Follow-up	
None	4
Ultrasound	6
FNA—benign	4
Surgical	2
Macroadenomatous nodule	1
Infarcted follicular adenoma	1

released recommendations regarding thyroid CB in 2016. Core needle biopsy has been recommended in a few clinical situations including for nodules with nondiagnostic cytology to lower the nondiagnostic rate. In one study, nondiagnostic readings on CB were significantly lower than repeat FNA (1.5% vs. 28.1%).[21] Other studies have suggested that a combination of repeat FNA and core biopsy (CFNACB) improves diagnostic yield when compared with FNA or CB. In nodules with prior nondiagnostic FNA, CB was diagnostic in 74%, FNA was diagnostic in 52%, and CFNACB was diagnostic in 87%.[22] The Korean Society of Thyroid Radiology recommended core needle biopsy as an alternative for thyroid nodules with nondiagnostic cytology in previous FNA; however, considerations including standardized safe and effective CB technique has yet to be established.[23] Additionally, 20–30 min of manual compression was recommended to prevent bleeding, which is a significant limitation compared with FNA where significant bleeding is not expected. Our institution does not perform thyroid core needle biopsies, and repeat FNA is typically performed. Rarely lobectomies without repeat FNA occurred in patients with large nodules that had clinical symptoms, and where surgery was planned regardless of FNA results.

A few limitations of our study should be noted. Namely, some of the thyroid nodules with nondiagnostic cytology were performed as recently as 2022, and not enough time has passed to see all potential follow-up or repeat testing of the nodules. Additionally, there was no standardized approach to the number of FNAs per nodule before the nodule was called nondiagnostic. In some cases, as many as 10 FNAs were performed before the procedure ended, and thyroid follicular cell quantity was still insufficient. Future studies would be necessary to examine how many passes are considered appropriate sampling. Factors such as the number of needle sticks acceptable for the patient and resources, the availability of radiology and cytopathology staff, and procedure time should be considered. Anecdotally, there seems to be little utility in more than six needle passes as the nodules start bleeding, and it is more likely to yield blood-obscured smears. The proceduralists technique and experience with FNA also undoubtedly plays a significant role. Liquid-based preparations such as ThinPrep may be helpful in resolving bloody aspirates. The follow-up of the thyroid nondiagnostic nodules faces some patient and clinical issues. Some patient's included in this study were referred only to have FNA performed and did not follow-up with internal endocrinology or head and neck clinicians. Conversations between the patients, radiologists, and clinicians may influence whether these nodules are subject to repeat aspiration and this is difficult to account for. Finally, the ultrasonographic features of the nodules have been included; however, there is no ATA or TIRADS score stated in the reports, and therefore this cannot be included in the data.

In conclusion, thyroid nodules with nondiagnostic cytology is reassuring of being highly likely a benign nodule. The majority of cases ultimately resulted in benign follicular nodules or nondiagnostic a second time on repeat aspiration. Only 5 of the 55 (9%) repeat FNAs yielded abnormalities, with only one of those being a noninvasive follicular thyroid neoplasm with papillary-like nuclear features (2%). Of our cohort, no primary thyroid malignancies were identified in follow-up (repeat FNA or surgery). We recommended that:

1. Thyroid nodules with nondiagnostic cytology and no worrisome features should be managed similarly to benign thyroid nodules with clinical/ultrasound follow-up.
2. Thyroid nodules with nondiagnostic cytology and worrisome features could attempt resampling with repeat FNA or escalate to a CB or a diagnostic thyroid lobectomy.

AUTHOR CONTRIBUTIONS

Tanner Storozuk (conceptualization, data curation, formal analysis, investigation, writing—original draft, review and editing), Anna Biernacka (investigation, writing—reviewing and editing), Ricardo Lastra (investigation, writing—reviewing and editing), Jeffrey Mueller (investigation, writing—reviewing and editing), Andrea Olivas (investigation, writing—reviewing and editing), Ward Reeves (investigation, writing—reviewing and editing), Lindsay Yassan (investigation, writing—reviewing and editing), and Tatjana Antic (conceptualization, data curation, formal analysis, investigation, supervision, writing—original draft, review and editing).

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Tanner Storozuk https://orcid.org/0000-0002-6687-9236

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