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The Bethesda System for Reporting Thyroid Cytopathology: A Single Center Experience over Five Years

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Abstract

Background—The Bethesda System for Reporting Thyroid Cytopathology (BSRTC) was developed to refine fine needle aspiration (FNA) cytology definitions and improve clinical management. This study evaluates the impact of the BSRTC five years after its adoption at a single institution.

Methods—A total of 1625 patients undergoing thyroidectomy in the pre-(group-1: 7/07–1/09) and post-BSRTC (group-2: 2/09–9/13) periods were reviewed. Cytologic diagnoses in group-1 included nondiagnostic, benign, follicular neoplasm, suspicious for malignancy and malignant. Atypia/follicular lesion of undetermined significance (AUS/FLUS) was included in group-2. The proportions of each FNA category and malignancy rate per cytologic diagnosis were compared.

Results—Fifty-four percent (187/347) of group-1 patients had a preoperative FNAs vs. 61% (777/1278) in group-2 ($p=0.02$). Group-1 FNA results included 3% nondiagnostic, 48% benign, 17% follicular, 13% suspicious for cancer and 19% cancer. Group-2 results included 3% nondiagnostic, 36% benign, 9% follicular, 8% suspicious for malignancy, 18% malignant and 26% AUS/FLUS. In group-2, the proportions of benign, follicular and suspicious for malignancy FNAs decreased significantly ($p<0.05$). In group-2, there were more indeterminate FNA diagnoses overall (30% vs. 43%, $p<0.001$). The rate of cancer in suspicious for cancer FNA lesions increased from 44% to 65% ($p=0.07$). The AUS/FLUS malignancy rate was 15%.

Conclusions—Since the adoption of the BSRTC at our institution, the proportion of indeterminate FNAs has increased, however the diagnostic accuracy of the suspicious for cancer category improved. We recommend periodic review of the utilization and malignancy rates per cytologic category at each institution to help tailor clinical management.

Introduction

Fine needle aspiration (FNA) biopsy and cytologic interpretation plays an essential role in the diagnosis and evaluation of thyroid nodules.¹ FNA results can be used to stratify the malignant risk of thyroid nodules and therefore triage patients to appropriate therapy; surgery, repeat biopsy or observation.

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Despite FNAs widespread use and clinical utility, cytologically indeterminate thyroid nodules continue to present a diagnostic dilemma for clinicians. This results in a large number (10–30%) of patients undergoing thyroidectomy to obtain a definitive histologic diagnosis.^{2, 3} In 2009, The Bethesda System for Reporting Thyroid Cytopathology (BSRTC) was released to help refine cytologic definitions and improve communication and clinical management. It recommends that each FNA report begin with one of six general diagnostic categories: non-diagnostic, benign, atypia of undetermined significance/follicular lesion of undetermined significance (AUS/FLUS), follicular neoplasm or suspicious for follicular neoplasm, suspicious for malignancy or malignant. Before the BSRTC was reported, categories for thyroid cytology typically included non-diagnostic, benign, follicular or Hürthle neoplasms (FN/HN), suspicious for malignancy and malignant. This terminology and interpretation varied significantly from one laboratory or cytopathologist to the next.^{1, 4–7} The category of follicular neoplasms posed the greatest dilemma, as follicular carcinomas look similar on an individual cellular level to benign follicular neoplasm, thus limiting the ability of cytology to accurately diagnose these lesions without tissue architecture demonstrating vascular or capsular invasion.^{1, 8} The new cytologic category of AUS/FLUS was meant to encompass a subset of lesions not otherwise easily classified as benign, suspicious or malignant.¹ The additional benefit of creating the AUS/FLUS category was that follicular neoplasm was then reserved for specimens in which a follicular carcinoma was suspected and should be subsequently triaged to operative intervention.¹

Our institution adopted the BSRTC in February 2009 and after two years of its use our group published an initial experience with the new classification system as it relates to utilization and malignancy rates for each cytology category.⁹ This study evaluates the impact of the BSRTC five years after its adoption at a single institution. As a secondary measure this study serves as an internal review of the malignancy rates of each BSRTC category.

Methods

After obtaining institutional review board approval, we performed a retrospective review of 1625 patients who underwent thyroidectomy from July 2007 through September 2013. Among the 1625 patients, 964 had a preoperative FNA and these patients are the main focus of this study. Our early institutional experience using the Bethesda System for Reporting Thyroid Cytopathology (BSRTC) included some of these patients.⁹ Vanderbilt's Division of Anatomic Pathology, which includes cytopathology, adopted the BSRTC and implemented its terminology in their reports starting February 2009. From the patients with FNAs, we created two groups: Group 1, pre-BSRTC (July 2007 through January 2009; n=187) and Group 2, post-BSRTC (February 2009 through September 2013; n=777).

Patient demographics, whether FNA was performed, results of FNA biopsy as well as final histologic diagnoses were collected. Two certified cytopathologists read all the internal thyroid cytology specimens. The majority of outside cytology (>95%) was reviewed internally. Patients with >1 nodule biopsied or undergoing more than one FNA biopsy at a separate time were classified by the FNA result with the highest estimated risk of malignancy. This occurred in 21 (11%) patients in the pre-BSRTC era and 98 (12.6%)

patients in the post-BSRTC era. The cytology categories for Group 1 included non-diagnostic, benign, FN/HN, suspicious for malignancy and malignant. Specimens with the word “atypia,” “cannot rule out follicular neoplasm,” or “follicular/cellular lesion” present on the FNA cytology report before adoption of the BSRTC were included in the follicular/Hürthle cell classification. The cytology categories for Group 2, detailed fully in the BSRTC, included non-diagnostic, benign, AUS/FLUS, FN/HN, suspicious for malignancy and malignant.

Indeterminate FNA diagnoses were grouped and analyzed. Indeterminate FNA diagnoses in Group 1 included FN/HN and suspicious for malignancy. In Group 2, the categories FN/HN, AUS/FLUS and suspicious for malignancy were considered indeterminate FNA diagnoses.

The proportion of surgical patients with a preoperative FNA was recorded as well as the percentage utilization of each cytologic category in those patients. The rates of malignancy of each cytology category were also recorded. A detailed review of the cytology and pathology reports was also conducted in an attempt to exclude incidental cancers not contained within the index nodule.

Statistical analysis was performed using STATA version 13.0. Univariate analysis was conducted to compare selected variables using Student’s t test, Chi-square tests, probability testing and Wilcoxon rank sum. The proportions of each FNA category, malignancy rate per cytologic diagnosis, overall malignancy rate and rate of indeterminate FNAs were compared. Statistical significance was defined as a p-value of <0.05. Missing data was excluded from the analysis.

Results

A total of 1625 patients underwent thyroidectomy during the study period, 347 (21%) patients in the pre- and 1278 (79%) in the post-BSRTC era. Patient demographics, operative indication and utilization rates of FNA are detailed in Table I. There was no significant difference between periods regarding age of patients. There were more women in the pre-BSRTC era when compared to the post-BSRTC era (84% vs. 79%, $p=0.025$). The most common indication for thyroidectomy was benign disease. Overall the number of patients going to the operating room for the clinical indication of an indeterminate FNA increased from 17% to 26%. Fifty-four percent (187/347) of patients in the pre- and 61% (777/1625) in the post-BSRTC era ($p=0.011$) had preoperative FNAs.

The utilization rates of each cytology category in patients undergoing thyroidectomy who had a FNA are detailed in Table II. Group 1 FNA results included: 3% nondiagnostic, 48% benign, 17% FN/HN, 13% suspicious for malignancy and 19% malignant for an overall “indeterminate” rate of 30%. Group 2 results included: 3% nondiagnostic, 36% benign, 26% AUS/FLUS, 9% FN/HN, 8% suspicious for malignancy and 18% malignant for an overall “indeterminate” rate of 43%. There was a significant decrease in the proportion of benign ($p=0.003$), FN/HN ($p=0.002$) and suspicious for malignancy ($p=0.014$) cytology reports in Group 2 when compared to Group 1. The number of indeterminate lesions excised was

significantly lower in Group 1 compared to Group 2, 30% and 43%, respectively ($p=0.001$). The proportion of FNAs read as malignant remained essentially the same (19% vs. 18%).

The malignancy rates per cytologic category pre- and post-BSRTC in patients undergoing thyroidectomy are detailed in Table III. The rate of cancer in suspicious for malignancy FNA lesions increased from 44% to 65%; however, this difference failed to reach statistical significance ($p=0.07$). The AUS/FLUS malignancy rate in patients undergoing thyroidectomy was 15%. The overall malignancy rate excluding incidental cancers among patients with an FNA undergoing thyroidectomy was 30% in Group 1 and 30% in Group 2 ($p=0.9387$). The overall rate of malignancy among patients with indeterminate lesions in Group 1 and 2 was 33% vs. 26%, respectively ($p=0.271$).

The final histology of lesions with a preoperative FNA report of AUS/FLUS is detailed in Table IV. The most common histology in patients with an AUS/FLUS diagnosis and subsequent malignancy was papillary thyroid cancer (13/31 nodules, 42%). When the final histology for AUS/FLUS was benign, 63/171 (36%) of nodules were called follicular or Hürthle cell adenomas. The final histology distribution pre- and post-BSRTC among patients with FN/HN (Table IV), demonstrated no change in the proportion of benign or malignant follicular lesions (50% in both time periods) and a non-significant decrease in the proportion of papillary and follicular variant papillary cancers (25% to 14%, $p=0.148$).

Seventy-six percent of patients undergoing surgery for AUS/FLUS did so without repeat FNA. The rate of malignancy for AUS/FLUS with a repeat FNA was 9%, whereas for those without a repeat FNA it was 18% ($p=0.239$).

Discussion

Since the adoption of BSRTC at this institution, there has been an increase in the proportion of patients who receive a preoperative FNA. This finding was previously described by Sosa et al who reviewed public and private insurance claims databases to determine the rate of FNAs from 2006 to 2011 and found that thyroid FNA utilization increased at an annual rate of 16%.¹⁰ This observation is in part due to increased use of highly sensitive imaging modalities allowing for identification of smaller lesions as well as improved awareness of the utility of FNA in the evaluation of thyroid nodules.

The present study also found an apparent increase in the proportion of patients undergoing surgery for indeterminate FNA results. This observation may be attributable to several factors. This is a surgical series and as such the patients with benign lesions by FNA who did not undergo thyroidectomy are excluded from the calculated rate of cytology category utilization. In addition, the exclusion of said patients results in a shift away from benign to other categories including indeterminate. Thus, the increased proportion of patients undergoing surgery for indeterminate lesions may simply be a result of an increased number of patients with benign FNA results avoiding thyroidectomy.

Another explanation for the increased proportion of patients undergoing thyroidectomy with indeterminate FNA results is the addition of the cytology category AUS/FLUS. In this series there was a decrease in the number of benign, FN/HN and suspicious for malignancy lesions

in the post-BSRTC era. This suggests a possible shift from these categories to AUS/FLUS. This observation may reflect increased comfort reporting findings of AUS/FLUS for lesions that previously would have been described as suspicious for neoplasm or malignancy. The explanation for the decrease in the benign cytology category remains unclear, but could represent over-reading by our cytopathologists.

The overall percentage of utilization of AUS/FLUS among patients undergoing thyroidectomy was 26%, which is higher than recommended by BSRTC (<7%). The finding of greater than expected utilization of AUS/FLUS has been described by several other authors and ranges from 2.3%–29%.^{5, 9, 11–13} The etiology of this discrepancy between predicted and actual values remains unclear but a possible explanation maybe that this is a surgical series and as such fails to capture patients with an AUS/FLUS FNA who did not go to surgery. In addition, although not documented in our database, rates of lymphocytic thyroiditis, previous biopsy attempts, history of radioactive iodine use and other unknown factors may have influenced/confound the observed AUS/FLUS rate.

There were no significant differences in the rate of malignancy within cytologic categories in the pre- and post-BSRTC era. However the rate of cancer in suspicious for malignancy FNA lesions increased from 44% to 65%. This trend suggests that the addition of AUS/FLUS has resulted in improved categorization of lesions with presence of nuclear grooves, prominent nucleoli, elongated nuclei and cytoplasm, and/or intranuclear cytoplasmic inclusions in a predominantly benign-appearing sample to AUS/FLUS rather than suspicious for malignancy.¹ Another proposed benefit of creating the AUS/FLUS category was that follicular neoplasm would be reserved for specimens in which a follicular carcinoma is suspected.¹ However, in this study, the final histology distribution in patients with FN/HN lesions demonstrated a decrease in the proportion of papillary and follicular variant papillary cancers (25% to 14%, $p=0.148$) and no change in the number of follicular lesions (benign or malignant) between time periods (Table IV). Additionally, the overall cancer rate among FN/HN specimens did not change between time periods (25% vs. 26%).

Our overall rate of malignancy for AUS/FLUS lesions in this series was 15%. This is in agreement with the recommended rate of 5–15% described in BSRTC.¹ In our initial report the rate of malignancy in AUS/FLUS was 20% (first two years of experience). As this was higher than recommended, the investigators discussed the findings with their institutional colleagues to increase awareness and promote quality improvement. Additionally, the rate of malignancy in our initial report and that which continues to be observed in other surgical series (Table V) prompted the same investigators to examine the overall malignancy rate of all AUS/FLUS lesions in addition to the utility of repeat FNA, not just those who underwent thyroidectomy. This study included 322 patients with the diagnosis of AUS/FLUS from 2009–2012 and found the overall utilization and malignancy rate to be 10% and 9.2%, respectively. Additionally there was no difference in the overall malignancy rate between patients who did or did not undergo repeat FNA (9.9% vs. 8.8%, $p=0.749$) which is in agreement with our current study.² Further analysis showed that the malignancy rate for AUS/FLUS was 13.5% in patients who underwent thyroidectomy or who avoided surgery after repeat biopsy ultimately demonstrated benign disease, and 16.5% when only including surgical patients ($p=NS$). Thus, analyzing a surgical series alone, such as the current series,

overestimates the risk of malignancy in AUS/FLUS lesions. It does suggest that patients who self-select to surgery or have additional indications for thyroidectomy are more likely to have underlying malignancy (in the index nodule) than those who do not although the reason is unclear for this association.

The rate of repeat FNA biopsy for AUS/FLUS lesions in the current surgical series was 24% and 33% in our previously reported overall series.² The recommendation in the BSRTC states that repeat biopsy should be performed for AUS/FLUS category lesions with the caveat that actual management may depend on other factors (e.g., clinical symptoms or sonographic features) not just the FNA interpretation.¹ Information regarding clinical symptoms and sonographic findings was not collected and therefore we are unable to demonstrate the impact of these factors on our overall rate of repeat FNA biopsy for AUS/FLUS lesions. However, it is routine at our institution to recommend repeat FNA biopsy for AUS/FLUS lesions in patients without clinical history, symptoms or sonographic findings that would otherwise convince us to recommend thyroidectomy. Thus, the low rate of repeat biopsy may indicate that a large proportion of patients with AUS/FLUS lesions either elected to proceed to surgery without repeat biopsy and/or had additional indications for thyroidectomy.

Since the introduction of BSRTC at our institution there has been an apparent change in the rate of malignancy of AUS/FLUS from 20% in the first two years to 15% over 5 years. The importance of institutional review of cytology to histology correlations to both refine cytopathologic categories but also to accurately reflect the malignancy rates of the different BSRTC categories at each institution can not be overemphasized. The need for individual institutional review and clinical management based on institutional cancer rates is further highlighted by a recent multi-institutional prospective study by Cibas et al that analyzed the inter- and intra-observer variability for thyroid nodule cytopathology. This study found the intra-observer variability to be 25.3% and the inter-observer variability when comparing central cytopathologists to local pathologists was 36% when using the 6 cytology categories as defined by BSRTC.¹⁴

This study has several limitations. First, any retrospective study is limited by the quality and inconsistency of data in the medical record. Second, as with any evaluation of cytology, there is inter- and intra-observer variability in the report of findings.¹⁴ Third, this study only evaluates patients who eventually underwent operative resection, inherently introducing bias into the analysis. Patients who underwent operative resection likely had other factors such as family history, ultrasound features, etc. that influenced the preoperative probability of malignancy. These confounding factors were not considered in the analysis. However, despite these limitations, the analysis does help to inform thyroid surgeons in their evaluation of the select patient population that has been referred for surgical evaluation. Fourth, as has been previously described, it can at times be difficult to accurately correlate the FNA biopsy sample to a specific nodule on final histology.^{6, 7, 15} Efforts were made, while reviewing the records, to determine whether the final histologic diagnosis represented the index nodule. Despite this, we cannot say with certainty that all incidental carcinomas were in fact, excluded.

In conclusion, five years after the implementation of BSRTC there remains a large percentage of patients undergoing thyroidectomy for indeterminate cytology with the majority being AUS/FLUS. Additionally AUS/FLUS continues to be utilized more frequently than recommended (26% vs. 7%). However, with continued experience our multi-disciplinary thyroid group has achieved a malignancy rate of AUS/FLUS of 15%, which is within the range recommended by BSRTC. It remains unclear if this is in fact an over utilization of AUS/FLUS or an accurate representation based on the non-specific criteria. We recommend rigorous cytopathology to histopathology correlation to accurately reflect the malignancy rates of the different BSRTC categories at each institution. Additionally we recommend communication on an institutional level regarding the rates of malignancy for each cytologic category, as clinical management should be tailored to institutional findings.

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Table I

Patient demographics, operative indication and utilization of FNA

	Total n=1625	Pre-BSRTC n= 347	Post-BSRTC n= 1278	p-value
Age*	50 (39–60)	49 (38–60)	50 (39–60)	0.2482
Gender				0.025
Male	322 (20)	54 (16)	268 (21)	
Female	1303 (80)	293 (84)	1010 (79)	
Operative Indications				<0.001
Nodules/growth	597 (37)	167 (48)	430 (34)	
Cancer or history of cancer	190 (12)	36 (10)	154 (12)	
Graves disease	223 (14)	43 (12)	180 (14)	
Toxic MNG/hyperthyroid	176(11)	35 (10)	141 (12)	
Indeterminate FNA	350 (24)	55 (16)	295 (23)	
Indeterminate FNA plus	44 (3)	2 (1)	42 (3)	
Nodule growth	28	0	28	
Clinical suspicion of cancer	4	0	4	
Graves' disease	3	0	3	
Toxic MNG/hyperthyroid	7	0	7	
MEN2a	2	2	0	
Insufficient FNA	11 (1)	0 (0)	11 (1)	
Other	34 (2)	9 (3)	30 (2)	
FNA performed	964 (59)	187 (54)	777 (61)	0.011

* Age is presented as median with interquartile range other values are presented as n (%)

FNA, fine needle aspiration; BSRTC, Bethesda System for Reporting Thyroid Cytopathology; MNG, multinodular goiter, MEN2a, Multiple Endocrine Neoplasia type 2a

Table II

Utilization rates of each cytology category in the pre and post BSRTC era

	Pre-BSRTC n= 187	Post-BSRTC n= 777	p-value
Non-diagnostic	3% (6)	3% (24)	0.932
Benign	48% (89)	36% (280)	0.003
AUS/FLUS	NA	26% (203)	-----
FN/HN	17% (32)	9% (74)	0.002
Suspicious for malignancy	13% (25)	8% (60)	0.014
Malignant	19% (35)	18% (136)	0.696

Values reported as % (n)

BSRTC, Bethesda System for Reporting Thyroid Cytopathology; AUS/FLUS, atypia of undetermined significance/follicular lesion of undetermined significance; FN/HN, follicular neoplasm/Hürthle cell neoplasm

Table III

Malignancy rates per cytologic category in the pre and post BSRTC era

	Pre-BSRTC n= 187	Post-BSRTC n= 777	p-value
Nondiagnostic	0% (0)	4% (1)	0.611
Benign	3.3% (3)	4.3% (12)	0.703
AUS/FLUS	-----	15% (31)	-----
FN/HN	25% (8)	26% (19)	0.941
Suspicious for malignancy	44% (11)	65% (39)	0.073
Malignant	100% (35)	97% (132)	0.304
Total	30% (57)	30% (234)	0.938

Values reported as % (n)

BSRTC, Bethesda System for Reporting Thyroid Cytopathology; AUS/FLUS, atypia of undetermined significance/follicular lesion of undetermined significance; FN/HN, follicular neoplasm/Hürthle Cell neoplasm

Table IV

Final histology in patients undergoing thyroidectomy with AUS/FLUS and FN/HN preoperative cytology

Final histology	AUS/FLUS	FN/HN Pre-BSRTC	FN/HN Post-BSRTC
PTC	6% (13)	12.5% (4)	8% (6)
Follicular Variant PTC	5% (11)	12.5% (4)	5% (4)
Follicular Carcinoma	3% (6)	3% (1)	5% (4)
Hurthle Cell Carcinoma	0% (0)	6% (2)	8% (6)
Follicular Adenoma	28% (57)	19% (6)	25% (18)
Hürthle Cell Adenoma	2% (5)	22% (7)	12% (9)
Benign *	54% (109)	25% (8)	34% (25)
Other **	1% (2)	0% (0)	3% (2)
Total	100% (203)	100% (32)	100% (74)

Values reported as %, n

* Benign lesions not including follicular adenoma or Hürthle cell adenoma

** Other: 1 lost specimen; 1 poorly differentiated trabecular carcinoma

FN/HN, Follicular neoplasm/Hürthle cell neoplasm; AUS/FLUS, atypia of undetermined significance/follicular lesion of undetermined significance; BSRTC, Bethesda system of reporting cytopathology; PTC, papillary thyroid carcinoma

Table V

Reported Malignancy Rates of AUS/FLUS lesions in selected surgical series 2013–2014

Authors	Year	N	Malignant
Current study	2014	203	15%
Cuhaci et al. ¹⁶	2014	268	22.8%
Jeong et al. ¹⁷	2013	162	55.2%
Yoo et al. ¹⁸	2013	249	40.2%
Walts et al. ¹⁹	2013	127	33.8%
Mehta et al. ^{20*}	2013	230	5.2%

* FNA + molecular testing