

Quality Improvement in Thyroid Fine-Needle Aspiration Biopsy accuracy at San Juan City Hospital Endocrinology Clinics

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Objective: This study aimed to determine if there was a reduction in the amount of non-diagnostic cytopathology results of thyroid fine-needle aspiration (FNA) biopsies performed at San Juan City Hospital (SJCH) endocrinology clinics since the inclusion of a cytopathologist at the clinics.

Methods: This research consisted of a retrospective analysis of thyroid nodule FNA biopsy results performed at SJCH endocrinology clinics. The biopsies analyzed were performed during academic years from July 2017-June 2018 and July 2018-June 2019, a period that reflects one academic year prior and a year after the inclusion of a cytopathologist to the clinics. The patients were classified into “pre-group” and “post -group.” Descriptive analysis was conducted, taking into consideration variables including sex, age, period, location, size of the nodule, and cytology results. A Chi-square test and Confidence Interval were used to assess the association and estimates between predictors and outcomes.

Results: From the 145 thyroid nodules biopsied, a total of 121 nodules (83.4%) resulted in diagnostic cytologic results, while 24 nodules (16.6%) were non-diagnostic. From the “pre-group,” 57 nodules (78.1%) had a diagnosis, while the other 16 (21.9%) were reported as non-diagnostic. From the “post group,” 64 nodules (88.9%) had a diagnosis, while the other 8 (11.1%) resulted in non-diagnostic findings (p-value: = 0.08). Even though results were statistically non-significant, a clear trend towards a decrease in non-diagnostic samples was evident.

Conclusion: In our study, there was a decrease in the number of non-diagnostic thyroid nodule FNA results after on-site adequacy determination guided by a cytopathologist.

Key words: Thyroid nodules, Thyroid fine-needle aspiration biopsy, Cytology

Nodularity of thyroid tissue is extremely common with an increasing incidence worldwide, as evidenced by recent epidemiologic data. Although the prevalence of palpable thyroid nodules is approximately 5% in women and 1% in men, high-resolution ultrasound can detect thyroid nodules in 19%–68% of individuals (1, 2). Even though most thyroid nodules are benign, thyroid cancer should be ruled out once a nodule is detected as it occurs in 7%-15% of cases with an increasing incidence during the last decades (2).

The evaluation of thyroid nodules includes ultrasound-guided fine-needle aspiration (FNA) biopsy, which is an accurate, quick, cost-effective, and safe method to differentiate between benign and malignant pathologies. Despite being considered the gold standard in the diagnosis, non-diagnostic FNA results are encountered 3%-22% of the time (3). Data regarding the risk of malignancy for non-diagnostic thyroid nodules is not clearly defined and varies among studies ranging from 2% to 15% (4). This study aimed to determine if there was a reduction in the

amount of non-diagnostic cytopathology results of thyroid FNA biopsies performed since the inclusion of a pathologist to the clinics.

Method

This research consisted of a retrospective analysis of thyroid FNA biopsy results, performed at SJCH endocrinology clinics. We analyzed biopsies executed during academic years from

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The authors have no conflict of interest to disclose.

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July 2017 through June 2018, classified as the pre-group; and July 2018 through June 2019 assigned as the post-group. This period reflected one academic year prior and a year after the inclusion of a cytopathologist to the clinics. Our sample population consisted of patients 21 years and older, referred for evaluation.

At our clinics, the patient was evaluated by a group of two or three endocrinology fellows, sonographer, and attending physicians. The patient was oriented about the procedure and consent was obtained. Thyroid ultrasound was performed by a sonographer or by endocrine certified in neck ultrasound (ECNU) endocrinologist using a Terason ultrasound machine with a linear transducer with a frequency setting between 5-15 MHz. Ultrasound-guided FNA biopsy was performed by a fellow using a 25-gauge needle and capillary action technique. The material obtained was smeared on glass slides and stained with Giemsa stain. Another fellow was in charge of reviewing the sample and determine if there was adequate cytological material while the other fellow was in charge of documentation. The fellows changed tasks between patients with the purpose that each of them was able to perform different roles. From July 2018 through June 2019, a cytopathologist performed the cytological analysis of the samples and determined adequacy.

We reviewed 145 cytology reports of biopsies performed to 115 patients, given that some patients had more than one nodule biopsied. Patients were identified by a unique number. They were classified as male or female, and age was collected. The location of the nodule was identified as in the right or left thyroid lobes, or isthmus. Size of the nodule was classified as ≤1 cm, 1-2 cm, and ≥ 2cm. Pathology results were classified using the Bethesda System for Reporting Thyroid Cytopathology including non-diagnostic, benign, atypia of undetermined significance, follicular, or suspicious for follicular neoplasm, suspicious for malignancy, and malignant. Statistical analysis was performed using MedCalc Software. Descriptive analysis was conducted, taking into consideration variables including sex, age, period of time, location, size of the nodule, and cytology results. A Chi-square test and Confidence Interval were used to assess the association and estimates between predictors and outcomes. Statistical significance was determined as a p-value of less than 0.05. This investigation was approved by the San Juan Hospital Institutional Board Review.

Results

In our study, we examined a total of 145 thyroid nodules cytopathology reports from 115 patients. Table 1 presents information regarding demographics, nodule location, and sizes between both studied groups. Overall, there was a significant

Table 1. General characteristics of both groups

	Pre-group	Post-group	
<i>Demographics</i>			
<i>Sex</i>			
M	5 (9.1%)	6 (10.0%)	X ² = 0.02,
F	50 (90.9%)	54 (90.0%)	DF: 1, p= 0.869
Mean Age	53.4 years	50.2 years	95% CI (-7.9 to 1.4) p= 0.165
<i>Nodule Location</i>			
Right	35 (47.9%)	31 (44.3%)	X ² =1.49
Left	27 (37.0%)	32 (45.7%)	DF: 2
Isthmus	11 (15.1%)	7 (10.0%)	p= 0.474
<i>Size of Nodule</i>			
≤1cm	11 (15.1%)	15 (20.8%)	X ² for trend = 0.01
1-2cm	42 (57.5%)	32 (44.4%)	DF: 1
≥2cm	20 (27.4%)	25 (34.7%)	p=0.891

Note: Two nodules are missing location

difference regarding variable of sex, with females representing 90.4% of all subjects, and males representing 9.6%. However, once groups were subdivided into pre-group and post-group, the sex variable was found to be equally distributed, meaning no significant difference among groups. Additionally, both subgroups were determined to be equally distributed based on age, size, and locations of the nodules. The locations of two nodules are missing.

From the thyroid nodules biopsied, 73 (50.3%) were from the pre-group and 72 (49.7%) from the post group. Table 2 presents the distribution of the results. A total of 121 nodules (83.4%)

Table 2. Thyroid Nodule FNA Biopsy results distribution

Group	Benign	Non-Diagnostic	SF	AUS	Suspicious for Malignancy	Malignant
Pre-group	48 (46.6%)	16 (66.67%)	2 (50.0%)	5 (41.67%)	0 (0.0%)	2 (100%)
Post-group	55 (53.40%)	8 (33.3%)	2 (50.0%)	7 (58.3%)	0 (0.0%)	0 (0.0%)

SF= follicular or suspicious for follicular neoplasm, AUS=Atypia of undetermined significance

Table 3. General characteristics based on diagnostic and non-diagnostic results

	Diagnostic	Non-Diagnostic	
<i>Demographics</i>			
<i>Sex</i>			
M	13 (92.9%)	1 (7.1%)	95% CI
F	108 (82.4%)	23 (17.6%)	(0.059 to 2.78)
<i>Nodule Location</i>			
Right	52 (78.8%)	14 (21.2%)	X ² =2.39
Left	52 (88.1%)	7 (11.9%)	DF:2
Isthmus	16 (88.9%)	2 (11.1%)	p=0.302
<i>Size of Nodule</i>			
≤1cm	21 (80.8%)	5 (19.2%)	X ² for trend=0.48
1-2cm	61 (82.4%)	13 (17.6%)	DF:1
≥2cm	39 (86.7%)	6 (13.3%)	p=0.485

Note: Two nodules are missing location

resulted in diagnostic cytology, while 24 nodules (16.6%) were non-diagnostic. From the pre-group, 57 nodules (78.1%) had a diagnosis, while the other 16 (21.9%) were reported as non-diagnostic. From the samples obtained from the post group, 64 nodules (88.9%) had a diagnosis, while the other 8 (11.1%) resulted in non-diagnostic findings (p-value: = 0.08). Even though results were statistically non-significant, a clear trend towards a decrease in non-diagnostic samples was evident.

We compared thyroid nodules with reported diagnostic cytology against the non-diagnostic based on sex, location, and size of the nodules. Table 3 presents these findings. Even though not statistically significant, there was a higher number of non-diagnostic results in the female population. Regarding the location of the nodule, more non-diagnostic results were found on the right thyroid lobe. With respect to nodule size, a small tendency was noted of a higher prevalence of non-diagnostic results in smaller-sized nodules.

Discussion

The incidence of thyroid nodules and thyroid cancer has significantly increased in the past decades. Studies have demonstrated that Ultrasound-guided FNA biopsy is the most accurate approach for the diagnosis of thyroid malignancy (1). Nevertheless, as reported in the literature, the rate of non-diagnostic FNA results varies from 2% to as high as 29%, but it should be no more than 10% (1, 5).

In our study, most patients (90.4%) were female, a finding that resembles the reported in literature where women are more commonly affected (6). We found that benign cytology accounted for most of the thyroid nodule FNA results, followed by non-diagnostic results. The incidence of non-diagnostic results in two academic years was as high as 16.8%. This result is like that described by Alvarado-Santiago et al., where 16.3% of the FNABs conducted at endocrinology clinics of the University Hospital of Puerto Rico were non-diagnostics results (7). Furthermore, as expressed by Gharib et al. in a study that evaluated approximately 11,000 FNAB results, the non-diagnostic results rate was as high as 21% (8).

In this research, even though not statistically significant, it was determined that the rate of non-diagnostic results decreased by half after the inclusion of the cytopathologist. We understand that the sample size was not sufficiently ample to be statistically significant. Further analysis showed that in our study, the prevalence of non-diagnostic results was higher in the female population, which was expected given that thyroid nodules, in general, are more common in females. Regarding location, it was noticed that there was a higher prevalence of non-diagnostic results localized at the right thyroid lobe. This finding is similar to a study conducted by Alexander et al where it was reported that the non-diagnostic rate was higher on the right thyroid lobe specifically the right mid or upper portions (9). A possible explanation for this finding is the position of the physician performing the biopsy. The physician is positioned

on the left side of the patient and when the nodule is biopsied in the perpendicular approach the nodules localized at the right thyroid lobe are more distant from the physician for and getting to the precise point of entry can be more challenging. Concerning the size of the nodule, a trend was observed that with an increase in nodule size, there was a decrease in the non-diagnostic rate. Comparable outcomes were reported by Leenhardt et al with an increase in adequate cytological material results with an increase in nodule size (10).

Upon review of literature, studies have shown that the on-site determination of tissue adequacy by cytopathologists is associated with decrease in non-diagnostic results (11-13) and a decrease in false-negative results (11) as we established in our investigation. This finding coincides with that reported by Redman et al where they had the lowest inadequacy rate when university endocrinologist and pathologist worked together (11). There are countless benefits of having a cytopathologist on-site, including but not limited to ensure appropriate sample collection at the same procedure with educational benefits by providing immediate feedback for specimen collectors, adequacy of histology specimen preparation, and fewer passes with therefore less complications. It gives the cytopathologist the benefit of a better correlation of the clinical situation, imaging findings, and microscopic findings, improve specimen handling by repeating aspiration or taking additional specimens for ancillary tests if needed during the same visit, and cost savings to the health system may also be achieved by reducing repeat procedures or appointments (14,15).

As the incidence of thyroid nodules and thyroid cancer is on an increasing trend is important to reach a diagnosis in a precise way by reducing the number of non-diagnostic results. In our study, we were able to present a decrease in the number of non-diagnostic thyroid nodule FNA results after on-site adequacy determination guided by a cytopathologist.

Resumen

Objetivo: Determinar si hubo una reducción en la cantidad de resultados no diagnósticos en las biopsias de aspiración de aguja fina de nódulos tiroideo realizadas en las clínicas de endocrinología del Hospital Municipal de San Juan desde la inclusión de un citopatólogo. **Métodos:** Análisis retrospectivo de los resultados de las biopsias realizadas durante los años académicos de julio 2017-junio 2018 y julio 2018-junio 2019. Este período refleja un año antes y después de la inclusión de un citopatólogo. Los pacientes fueron clasificados en “pre-grupo” y “post-grupo”. El análisis descriptivo se llevó a cabo teniendo en cuenta variables como sexo, edad, período, localización, el tamaño del nódulo y los resultados de citología. Se utilizó una prueba de Chi-cuadrado y un intervalo de confianza para evaluar la asociación y las estimaciones entre los predictores y los resultados. **Resultados:** De los 145 nódulos tiroideos biopsiados, un total de 121 nódulos (83,4%) obtuvieron un resultado citológico, mientras que 24 nódulos (16,6%) fueron

no diagnósticos. Del “pre-grupo”, 16 nódulos (21,9%) fueron no diagnósticos mientras del “post-grupo”, 8 nódulos (11,1%) fueron no diagnósticos (valor p : 0,08). Aunque los resultados no fueron estadísticamente significativos, hubo una clara tendencia hacia una disminución en muestras no diagnósticas desde la incorporación de un citopatólogo. Conclusión: En nuestro estudio, hubo una disminución en el número de resultados no diagnósticos en las biopsias de aspiración de aguja fina de nódulos tiroideo realizadas en las clínicas de endocrinología desde que se incorporó la determinación de la adecuación in situ guiada por un citopatólogo.

Acknowledgement

We would also like to show our gratitude to R. Ivan Iriarte MD, MS who performed statistical data analysis of our research project.

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