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Clinical Efficacy of Fine-Needle Aspiration Biopsy of Thyroid Nodules in Males

Adam J. Schiro, B.S., Scott N. Pinchot, M.D., Herbert Chen, M.D., F.A.C.S., and Rebecca S. Sippel, M.D.¹

Department of Surgery, University of Wisconsin, Madison, Wisconsin

Abstract

Background—It has recently been suggested that the use of fine-needle aspiration (FNA) biopsy of thyroid nodules in male patients is associated with an unacceptably high false-negative rate in the detection of thyroid malignancy. We hypothesize that FNA biopsy is an accurate preoperative tool for detecting thyroid cancer in men, and that false negative rates are significantly lower than recently reported.

Materials and Methods—A retrospective database analysis was performed on all male patients who underwent thyroid surgery from May 1994 through January 2007 at a single institution. The results of preoperative FNA biopsies were compared with final surgical pathologic results. FNA biopsy results were reported as benign, malignant, inconclusive (i.e., follicular neoplasm), or nondiagnostic; final surgical pathology was reported as benign or malignant.

Results—Of 1205 patients who underwent thyroidectomy, 273 (23%) were male. Preoperative FNA biopsy results were obtained in 60% of these male patients and were read as benign in 45/165 (27%) patients, malignant in 47/165 (28%) patients, inconclusive in 66/165 (40%) patients, and nondiagnostic in 7/165 (4%) patients. In male patients with cytology reported as benign, 3/45 (6.7%) FNAs were determined to be malignant on final pathology.

Conclusions—Our study determined that FNA biopsy of thyroid nodules in male patients has an acceptably low false-negative rate of 6.7% and is, therefore, an accurate and useful diagnostic tool. We recommend preoperative FNA biopsy for all male patients presenting with thyroid nodules as a standard of practice.

Keywords

thyroid nodule; thyroid cancer; males; fine-needle aspiration biopsy

INTRODUCTION

In the United States, thyroid nodules are present in approximately 4% to 7% of the general population as detected by palpation, and in up to 50% of the population based on autopsy findings [1, 2]. With ultrasonography now well established and commonly used to identify nodules, the prevalence has been found to be as high as 67% [3]. Regardless of how the nodule is identified, approximately 5% of all thyroid nodules are malignant [4]. Because of the high prevalence of nodules and their accompanying risk of malignancy, a reliable and accurate screening tool is required for the management of nodular disease. The current

standard by which thyroid nodules are initially evaluated is fine-needle aspiration (FNA) biopsy, a technique shown to be cost effective, safe, and useful for thyroid cancer screening [5]. FNA biopsy of thyroid tissue has been repeatedly validated and characterized as having a high specificity (range: 86%–100%) and sensitivity (range: 93%–100%), as well as a low false negative rate (range: 3%–6%) in diagnosing malignancy [6–11]. A malignant FNA diagnosis optimizes surgical management by indicating a definitive operation for a diagnosis of thyroid carcinoma [12]. FNA biopsy can help to avoid unnecessary surgery for benign nodules as well as thyroid lymphoma where resection may not be necessary.

Epidemiologic investigation has found that gender differences exist with respect to thyroid disease. It has been established that although prevalence of thyroid nodules is lower in the male population (1.6% for men *versus* 6.4% for women [13]), the risk of malignancy in males with nodules is significantly higher [14]. Likewise, there exists a tendency for males with thyroid cancer to have more advanced disease at initial presentation, thus leading to higher mortality rates [15]. Recently Berri and Lloyd suggested that FNA biopsy of thyroid nodules is associated with a high rate of false-negative diagnoses in male patients [16]. They concluded that FNA biopsy is unnecessary and that all males with thyroid nodules should therefore proceed directly to surgical management. Our institution has previously investigated the use of FNA biopsy for thyroid nodules in all patients and recommends routine preoperative utilization of this technique [12]. Due to demographic differences between men and women with regard to thyroid cancer, as well as the recently reported high false-negative rate associated with FNA biopsy in the male patient group, the accuracy of this technique in males with thyroid nodules was investigated. The current study is a retrospective database analysis aiming to determine the efficacy of FNA biopsy of thyroid nodules in male patients at our institution, and to examine its effects on surgical management of thyroid nodular disease.

MATERIALS AND METHODS

Data Acquisition and Patient Selection

A retrospective analysis was conducted using the University of Wisconsin thyroid surgery database, which includes all consecutive patients receiving surgical intervention for thyroid disease at the University of Wisconsin Hospital from May 1994 to January 2007. Indications for surgery included compressive symptoms associated with thyroid enlargement or preoperative cytopathology positive for thyroid carcinoma, follicular neoplasm, or nondiagnostic FNA biopsy. This constituted a total of 1205 patients, of whom 273 (23%) were males. Of these male patients, preoperative FNA biopsy results were able to be obtained in 165 patients. In addition to preoperative cytopathology and surgical histopathology, data were collected on various demographic parameters, including patient age and nodule size. FNA diagnoses were recorded prospectively in the thyroid surgery database and were compared with the “gold standard” surgical pathologic results, which were evaluated by board-certified pathologists in the Department of Pathology at the University of Wisconsin.

FNA Biopsy Technique

In the earlier chronological half of the study period (1994–2000), FNA biopsies were performed selectively and generally with the assistance of palpation, and ultrasound guidance was reserved for patients with nonpalpable nodules, highly cystic nodules, or nodules where previous FNA biopsy was unsuccessful. In the second chronological half of the study period (2000–2007), ultrasound-guided FNA biopsy was the standard of care for all patients with a palpable thyroid nodule or image detected nodule greater than 1 cm, especially if suspicious features were present. FNA biopsies at our institution were generally

performed by clinicians and, more recently in the study period, included a cytopathologist present for immediate on-site analysis.

Cytopathologic and Surgical Pathologic Definitions

Upon evaluation by board-certified cytopathologists, FNA biopsy results were classified according to four groups: benign, malignant, inconclusive, or nondiagnostic. The benign category included samples indicating: benign, cyst, goiter, or no evidence of malignancy. Malignant samples were those with a definitive diagnosis of malignancy. Inconclusive samples were described as follicular neoplasm, suspicious for papillary thyroid carcinoma, indeterminate, or Hürthle cell neoplasm. Nondiagnostic samples were those unable to be evaluated by the cytopathologist due to a lack of cellular material in the aspirate. Surgical pathology was categorized as either benign or malignant. Benign diagnoses included: cyst, goiter, thyroiditis, follicular cell adenoma, or Hürthle cell adenoma. Malignant diagnoses included: papillary thyroid carcinoma, follicular thyroid carcinoma, medullary thyroid carcinoma, Hürthle cell carcinoma, or anaplastic thyroid carcinoma.

Statistical Analysis

Continuous variables were analyzed utilizing the Student's *t*-test to compare two means, whereas categorical data were compared with Fisher's and χ^2 analysis where appropriate. *P* values of less than 0.05 were considered statistically significant.

RESULTS

Of the 273 male patients in our cohort, 103 (38%) had malignant final pathology and 170 (62%) demonstrated benign pathology. Comparing the patients with benign and malignant disease, there was no difference in the mean age of the patients (51 *versus* 52 years, *P*=0.62), however, the mean nodule size in the benign group was significantly larger than in the malignant group (3.4 *versus* 2.3 cm, *P*=0.0001) (Table 1). In the malignant group, 23% of nodules were greater than 4.0 cm in diameter, while 29% of nodules were greater than 4.0 cm in the benign group. In the benign group, 10 patients had Hashimoto's thyroiditis and 32 were found to have multinodular goiter, whereas in the malignant group only one patient had thyroiditis and one had multinodular disease (Table 2).

Of the 165 patients receiving preoperative FNA biopsy, 72 were malignant based on the final surgical pathology. The distribution of specific diagnoses is as follows: 52 of 72 (72%) were papillary carcinoma, 9 of 72 (12%) were follicular carcinoma, 3 of 72 (4%) were Hürthle cell carcinoma, 6 of 72 (8%) were medullary carcinoma, 1 of 72 (1%) was anaplastic, and 1 of 72 (1%) was B-cell lymphoma (Table 3).

Of the 165 patients with FNA biopsies, 27% (45/165) were read as benign, 28% (47/165) were read as malignant, 40% (66/165) were read as inconclusive, and 4% (7/165) were read as nondiagnostic (Table 3). Among those 45 patients with benign FNAs, three turned out to be malignant on final surgical pathology, representing a false-negative rate of 6.7%. All three patients had papillary thyroid carcinomas ranging from 3.5 to 4.5 cm. The first of the false-negative cases received a benign FNA but proceeded to surgery due to the large nodule size and presence of compressive symptoms. The surgical pathology revealed papillary carcinoma in a setting of Hashimoto's thyroiditis. The second of the false-negative cases also received a benign FNA biopsy and proceeded to surgery due to the presence of worsening dysphagia and tracheal deviation. The third of the false-negative cases received a benign FNA biopsy, but over the subsequent 2 y, the nodule enlarged markedly. The patient returned for thyroidectomy and was found to have papillary thyroid carcinoma by surgical pathology. Interestingly, all three false-negative cases were performed under ultrasound-

guidance. There were no suspicious findings on ultrasound to suggest malignancy and none of these patients had any family history of thyroid cancer or history of neck radiation. One additional patient with a benign FNA was found to have a micropapillary carcinoma measuring 5 mm, which was not categorized as malignant as it was an incidental finding and not located in the index nodule.

Among patients with nondiagnostic, inconclusive, and malignant preoperative FNA biopsies, the risks of malignancy found on final surgical pathology were 14%, 35%, and 96%, respectively. The 96% risk of malignancy for malignant FNA result reflects the inclusion of two false-positive cases in our data set. One of the cases was identified by FNA biopsy as papillary thyroid carcinoma, but surgical pathology determined it to be a follicular adenoma in a setting of Hashimoto's thyroiditis. The other false-positive case was described as highly suspicious for papillary thyroid carcinoma based on FNA biopsy, but on re-review was called consistent with papillary thyroid cancer. Surgical pathology determined this case to be a follicular adenoma as well. Of the 12 patients with inconclusive biopsies that were found to have papillary thyroid cancer on final pathology, three patients had a follicular variant of papillary thyroid cancer.

DISCUSSION

FNA biopsy provides a useful and effective method for screening thyroid nodules in males. By detecting malignancy in thyroid nodules, this technique optimizes the surgical management of patients. It has been concluded that FNA biopsy of thyroid nodules has reduced the number of patients that proceed to surgery by half, while simultaneously doubling the detection rate of malignancy in patients who undergo thyroid surgery [17]. The addition of ultrasonography, as well as the increasingly common practice of including on-site cytopathology analysis, has served to improve the sensitivity and specificity of FNA even further [18]. Ultrasound facilitates the identification and localization of nodules. Having an available cytopathologist eliminates the need for additional patient visits by recommending additional needle passes in the event that initial aspirate samples were unsatisfactory for evaluation.

The controversy of using FNA for thyroid nodules in male patients has arisen from the inherent epidemiologic differences between males and females. The prevalence of thyroid nodules is much lower in men than in women, but nodules found in male patients have a much higher rate of malignancy. This higher risk of malignancy predicts that negative FNA results will have a greater percentage of false-negatives compared with the female cohort. Even with this expectation, our 6.7% false-negative rate is sufficiently low to ensure confident clinical utilization of FNA in male thyroid patients. Even with the higher prevalence of malignancy in males with thyroid nodules (38% at our institution), we are able to achieve a level of accuracy that demonstrates that this technique is clinically valuable.

The findings reported by Berri and Lloyd [16] describe FNA biopsy of thyroid nodules in males as inaccurate enough to warrant discontinuing clinical use. Of their benign FNA category, 38% of cases were found to be malignant by surgical pathology. This was defined as the false-negative rate. This is far higher than our analogously calculated false-negative rate of 6.7%. Our three cases with benign FNA biopsies that were determined to be malignant on surgical pathology included one patient who had a benign FNA 2 y prior to thyroid resection, during which time the nodule enlarged. FNA biopsy was not repeated prior to resection, so it is unknown whether doing so would have detected the malignancy. Excluding this case lowers our false-negative rate to 4.4%. The reason for the discrepancy between our data and that of Berri and Lloyd likely has to do with regional and institutional variations in FNA interpretation. Even amongst different cytopathologists, there may be

different thresholds to call an FNA malignant. At our institution, cytopathologists are fairly aggressive in calling an FNA malignant or suspicious, so it is uncommon that a benign biopsy will turn out to be malignant on final pathology. However, at other institutions, if cytopathologists are less likely to call a lesion suspicious, the surgeons may need to have a much lower threshold to operate on a benign biopsy, especially when it is large or there are worrisome clinical or ultrasound findings.

At our institution, recent efforts have been made to use ultrasound-guided FNA as a routine preoperative procedure for all thyroid surgery patients; however, in the first half of our study period, FNA was mostly used in patients with small or incidentally discovered nodules that otherwise may not have required surgical excision. For this study, our cohort consisted of male patients on the basis of having received previous thyroid resection surgery (either lobectomy with or without isthmusectomy, or total thyroidectomy) at the University of Wisconsin Hospital and also having received preoperative FNA biopsies. There is likely a significant population of patients who received FNA biopsy of the thyroid and never proceeded to surgery at our institution, which are not captured in our database, introducing some selection bias into our study. Patients who underwent surgery despite a benign biopsy may have had other features that caused them to be referred for surgery, making it more likely that they would end up having a malignancy on final pathology. This would suggest that the true negative rate for FNA is likely even higher than stated in our study, thus making the associated false negative rate proportionately lower.

One potential limitation of this study is the issue of incidental malignancy. FNA biopsy is useful as a tool for screening known nodules or nodules detected by ultrasound during the procedure, but it is entirely possible that malignancy exists in alternative locations. Insufficient data were available to always correlate our FNA results exactly with pathology findings regarding the specific location of the nodule referred to in the report. In other words, it cannot be certain that an FNA biopsy result and a surgical pathology report for the same patient are referring to the same nodule, especially in cases of multinodular disease. For the false-negative cases, however, FNA and surgical pathology reports did appear to reference the same lesion as there was only one nodule present in each of the cases. The risk of this occurring is especially high for cases of multinodular goiter and micropapillary carcinoma (papillary thyroid carcinoma less than 1 cm in size). These occult foci of malignancy are exceedingly common in the general population, but few result in overt tumors [19]. One of the benign FNAs in our study was determined to be a micropapillary carcinoma per surgical pathology report, and this was not considered a false negative result. Nodules are generally not biopsied unless they are at least 1 cm, which decreases the likelihood that micropapillary carcinomas would be detected by FNA.

Cytopathologic discrimination between benign and malignant follicular neoplasms requires evidence of capsular or vascular invasion and is considered impractical by FNA biopsy. Due to this uncertainty, patients with FNA results indicating the presence of a follicular neoplasm are offered surgical excision. While the risk of malignancy in these nodules is typically around 20%, the risk can be as high as 80%, particularly in males with large follicular neoplasms [20]. In our cohort, the risk of malignancy for an inconclusive FNA was 35%. Additionally, for inconclusive FNA biopsies of nodules larger than 4 cm diameter, the risk of malignancy was also 35%.

One interesting finding from our data was the significant difference in average nodule size between the malignant and benign surgical pathology data subsets. Our benign group had an average nodule size almost 50% larger than the malignant group. A correlation between tumor size and malignancy has been investigated thoroughly for its potential predictive value, but whether this exists continues to be controversial. Several groups have found that

malignancy is not accurately predicted by nodule size [21–23] and a correlation could also not be made between nodule size and FNA result [21]. Others have shown that with nodules greater than 4 cm, higher rates of cancer are found [24, 25]. Our group recently concluded that for nodules larger than 4 cm, the diagnostic utility of FNA biopsy is limited and characterized by inaccuracy [26]. Furthermore nondiagnostic FNA biopsies of these large nodules are associated with a high rate of malignancy and are therefore best managed by surgical resection of the thyroid. More of a consensus exists with Hürthle cell neoplasms, where a direct correlation between nodule size and risk of malignancy has been shown [27–29]. Since we only evaluated patients who underwent surgical excision, there is a bias with respect to different indications for surgery. Most of the small lesions were removed because of malignancy, while benign lesions were removed due to large size and presence of symptoms. This bias makes us unable to conclude anything regarding nodule size.

Overall, FNA biopsy of thyroid nodules in males is a reliable, accurate, and valuable tool for optimizing surgical management. This technique provides useful diagnostic information that may direct a patient to surgery for medullary thyroid carcinoma or papillary thyroid carcinoma, while avoiding an unnecessary operation in patients with benign nodules. The false negative rate for detecting malignancy of 6.7% found at the University of Wisconsin is sufficiently low and supports the continued use of this procedure as a preoperative screening tool for males with thyroid nodules.

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TABLE 1

Characteristics of Male Thyroid Surgery Patients at our Institution

	Surgical pathology finding			Significance
	Malignant	Benign	Total	
<i>n</i>	103 (38%)	170 (62%)	273	
Age				
Mean±SEM (y)	51±1.5	52±1.3	52±1.5	<i>P</i> =0.62
Nodule size				
Mean±SEM (cm)	2.3±0.2	3.4±0.2	3.0±0.2	<i>P</i> =0.0001

TABLE 2

Prevalence of Lymphocytic Thyroiditis and Multinodular Goiter Among Benign and Malignant Surgical Pathology Patient Subgroups

	Surgical pathology finding		Total
	Malignant	Benign	
<i>n</i>	103 (38%)	170 (62%)	273
Lymphocytic thyroiditis			
Present	1	10	11
Absent	102	160	262
Multinodular goiter			
Present	1	32	33
Absent	102	138	240

TABLE 3

Specific Surgical Histopathologic Diagnosis for each of the FNA Categories

Preoperative FNA result					
Surgical pathology diagnosis	Benign (%)	Inconclusive (%)	Malignant (%)	Nondiagnostic (%)	Total
<i>n</i>	45	66	47	7	165
Carcinoma (%)					72
Papillary thyroid carcinoma	3 (6.7)	12 (18.2)	37 (78.7)	0	52
Follicular thyroid carcinoma	0	6 (9.1)	2 (4.3)	1 (14.3)	9
Hürthle cell carcinoma	0	3 (4.5)	0	0	3
Medullary thyroid carcinoma	0	1 (1.5)	5 (10.6)	0	6
Anaplastic	0	0	1 (2.1)	0	1
B-cell lymphoma	0	1 (1.5)	0	0	1
Benign neoplasm (%)					52
Follicular adenoma	13 (28.9)	24 (36.4)	2 (4.3)	5 (71.4)	44
Hürthle cell adenoma	0	7 (10.6)	0	0	7
Other	0	1 (1.5)	0	0	1
Benign pathology (%)					41
Multinodular goiter	18 (40.0)	2 (3.0)	0	0	20
Benign nodule/cyst	11 (24.4)	9 (13.6)	0	1 (14.3)	21