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Exclusion of Malignancy in Thyroid Nodules with Indeterminate Fine-Needle Aspiration Cytology After Negative 18F-Fluorodeoxyglucose Positron Emission Tomography: Interim Analysis

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Introduction/Background

Fine needle aspiration (FNA) biopsy remains the standard method for diagnosis of a palpable thyroid nodule, or a nodule with suspicious features by imaging criteria. Nodules with indeterminate FNA results remain a diagnostic dilemma, because approximately 20–30% of these will ultimately be found to be malignant by pathologic examination after excision. However, nearly all patients with FNA biopsy demonstrating an indeterminate cytology undergo thyroid lobectomy, at a minimum, to establish the diagnosis. The definition of an indeterminate lesion by FNA cytology includes follicular lesions, Hurthle cell or oncocytic cell lesions, atypical cytology, abnormal cytology, or suspicious cytology. For nearly 80% of patients with benign disease, this surgery would be unnecessary if the diagnosis were established preoperatively. While rare, complications from thyroid surgery can be serious or even life-threatening; these include recurrent laryngeal nerve injury, postoperative bleeding, hypoparathyroidism, or infection. Thus, development of new diagnostic modalities for indeterminate thyroid nodules is an area of ongoing research worldwide.

Several previous studies examined the utility of positron-emission tomography (PET) with 18F-fluorodeoxyglucose (FDG) for detecting malignancy in indeterminate thyroid nodules. Reported sensitivity of FDG-PET to detect malignancy was 100% in four of five of these

studies, with the remaining study reporting sensitivity of 57%.[1–5] Reported specificity ranged from 39% to 66%. One additional study evaluated the association between standardized uptake value (SUV) uptake over time and malignancy in follicular thyroid nodules, by performing serial PET scans over a two hour period and measuring the area under the SUV curve.[6] This study demonstrated no statistically significant difference between the mean area under the curve (AUC) for malignant versus benign cases, though there were significant differences in the dynamics of the change in SUV over time between these groups. Because of the considerable overlap in SUV AUC values between benign and malignant lesions in that study, the authors were unable to identify a cutoff value that would appropriately guide patient management. These studies enrolled modest numbers of participants, with sample sizes ranging from 15 to 44. To date, it is unclear whether FDG-PET has diagnostic utility for indeterminate thyroid nodules. There may be specific patient or nodule characteristics that affect the accuracy of FDG-PET for distinguishing benign from malignant indeterminate nodules. These have been difficult to determine due to the variability in patient characteristics and diagnostic criteria, coupled with the small sample sizes seen in the previous studies.

Presented here are data on the first 51 patients from the largest trial to date examining the utility of FDG-PET to distinguish malignancy in thyroid nodules found to be indeterminate on FNA cytology.

Materials and Methods

This study was conducted with the approval of the Washington University Human Research Protection Office and the Radioactive Drug Research Committee, the Saint Louis University Institutional Review Board, and the St. Louis VAMC Human Studies Subcommittee. This material is based upon work supported in part by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, through a Veterans Administration Merit Review Grant (Grant # 0603-09, PI: Jeffrey F. Moley). Additional funding was provided by a Barnes-Jewish Hospital Foundation Grant.

Patients

Patients were recruited prospectively from endocrine surgery or otolaryngology practices at Washington University, Saint Louis University, or the Saint Louis VA Medical Center, John Cochran Division (St. Louis VAMC). Eligible patients were at least 18 years of age and had a solitary or dominant thyroid nodule, palpable or ≥1 cm by ultrasound, and were scheduled for surgical excision. The minimum size criterion was established to address the limitations of spatial resolution of PET imaging and to avoid partial volume effect. Patients must have undergone FNA biopsy of the nodule of interest with any of the following results: follicular lesion, Hurthle cell or oncocytic cell lesion, atypical cytology, abnormal cytology, or suspicious cytology. Patients with a history of prior radiation treatment or surgical procedures in the neck were excluded, due to concerns of anatomical distortion on PET scans performed without computed tomography (CT). Patients with clinical or laboratory evidence of hyper- or hypothyroidism were excluded, unless they were corrected to a clinically euthyroid state with a stable dose of appropriate medication prior to surgical evaluation.

Eighty-six patients were screened and found to be eligible by these criteria. Fifty-one (41%) of these patients consented to participate and completed the study. One additional patient was consented but refused PET scan due to claustrophobia.

Anticipated target enrollment is 125 patients at study completion. With a 30% malignancy rate, this will provide power to estimate a sensitivity of 0.90 with 95% confidence interval (0.75, 0.97), and specificity of 0.90, 95% CI (0.81, 0.95).

FDG-PET or FDG-PET/CT

PET imaging scanners used for Washington University were a Siemens Biograph 40 PET/CT scanner (n=1) and a Siemens ECAT HR+ PET scanner (n=49). The scanner used for St. Louis University participants was a Gemini PET/CT scanner (Philips Medical Systems) (n=1). The St. Louis VAMC participants underwent PET imaging at Washington University. All patients fasted for at least 4 hours prior to PET study. To exclude fasting hyperglycemia, a blood sample for determination of blood glucose level (by glucometer) was obtained prior to FDG injection to ensure a level <200. Ten mCi FDG was injected intravenously. Patients were instructed to minimize talking after administration of FDG until completion of the examination to minimize uptake in the laryngeal muscles. With the patient in a supine position, imaging from the base of the brain to the superior chest was initiated 50–60 minutes following FDG injection. For ECAT HR+, a series of 2–5 minute transmission scans, centered at the level of the thyroid gland, with the use of 68Ge/68Ga rod source was performed at each level. Following completion of transmission scan, a series of 10–15 minutes emission scans was performed over the same anatomic extent. PET images were reconstructed with the use of an ordered-subset expectation maximization iterative algorithm and a 7-mm Gaussian filter. Attenuation correction was performed with the segmentation method developed by Xu et al. [7] For Biograph 40, the CT imaging parameters were the factory recommended preset low-dose whole-body PET/CT imaging protocol (50 mAs, 120KV, 0.5 sec/rotation, 0.8 pitch) with appropriate adjustments based on patient size and weight. PET images centered at the level of the thyroid gland were obtained, with imaging times of 1–5 minutes per bed position, depending on patient weight. PET images were corrected for scatter, random coincidences, and attenuation, and reconstructed using standard alogorithms by the scanner manufacture. For Gemini PET/CT scanner, imaging protocol similar to Biograph 40 was used.

All PET images were evaluated qualitatively by an experienced nuclear medicine radiologist in a routine clinical fashion, including correlation with other imaging studies if available. The reader was blinded to the final pathologic diagnosis at the time of the reading, but was aware that the PET examination was being performed to evaluate a patient with a thyroid nodule having a follicular or indeterminate FNA. The reader characterized the nodule uptake in qualitative terms on an ordinal scale: no uptake, mild, moderate, and marked uptake. Diffuse or focal uptake was also noted. For this analysis, an FDG-PET or FDG-PET/CT study was considered negative if no focal uptake was seen in the nodule of interest.

FDG uptake in the nodules was evaluated semiquantitatively by calculating maximum standardized uptake values (SUV), a quantitative measure of uptake. Calculations also were corrected for lean body mass. The SUV is a decay-corrected measurement of activity per unit volume of tissue (nCi/mL) adjusted for administered activity per unit of body weight (nCi/kg).

Diagnostic Standard

Pathologic diagnosis was performed as standard of care for all patients at each institution. Pathologists performing the diagnosis were blinded to the patient's FDG-PET results. Final histopathologic diagnosis served as the standard to which FDG-PET results were compared. Incidental thyroid papillary microcarcinoma in a location other than the indeterminate nodule of interest was not considered to be a positive finding for comparison with FDG-PET results.

Results

Individual patient characteristics, imaging and pathologic data, and PET results are listed in Table 1. The mean age (± standard deviation (SD)) of participants was 49.5 ± 10.6 years (range 22–77 years). Most patients were female (80.4%). Of the fifty-one lesions, ten were malignant (19.6%) by pathologic analysis. Three patients (5.9%) were found to have thyroid papillary microcarcinoma at sites separate from the lesion of interest by pathologic analysis. One additional patient had two >1 cm foci of papillary thyroid carcinoma contralateral to the lesion of interest. For benign lesions with focal uptake, the mean (± SD) SUV_{max} was 1.91 ± 2.64 (range 1.87 to 11.1). For malignant lesions with focal uptake, the mean (±SD) SUV_{max} was 12.7 ± 5.71 (range 2 to 51.9). On univariate analysis, there were no statistically significant differences in age, gender, malignancy status, gross pathology size or imaging size between the 51 study participants and the 35 who were eligible but refused participation.

Results of FDG-PET compared with final histopathologic diagnosis for all patients are shown in Table 2. For all lesions, sensitivity, specificity, positive-predictive value (PPV), and negative-predictive value (NPV) were 80%, 61%, 33%, and 93%, respectively. The 95% confidence interval for this 80% sensitivity was 44 to 97% and for this 61% specificity was 49 to 80%.

Eight lesions were found to be < 1 cm in greatest dimension by gross pathology, despite measurements ≥1 cm on preoperative imaging. One lesion did not have a gross pathology correlate to the imaging finding, so no pathology size was reported. Per our inclusion criteria, these lesions would be below the expected resolution of PET scan to detect. Results for all lesions ≥1 cm are shown in Table 3. For these 42 lesions, sensitivity, specificity, PPV, and NPV were 100%, 59%, 36%, and 100%, respectively. For sensitivity and specificity in the ≥1 cm lesions, the 95% confidence intervals were (69%, 100%) and (41%, 75%), respectively.

Discussion

These data suggest that FDG-PET is an accurate diagnostic modality to identify malignancy in indeterminate thyroid nodules at least 1 cm in diameter, with 100% sensitivity and negative predictive value in our series. These values were somewhat lower when all lesion sizes were included. Two false negatives occurred in lesions smaller than 1 cm, because their size was overestimated on ultrasound. Preoperative ultrasound overestimated lesion size in benign and malignant lesions in our data set, leading to the inclusion of eight nodules below the diameter threshold required for accurate detection by PET imaging. This discordance has been previously reported in a large series from the University of Pennsylvania, where 33% of solid thyroid nodules measuring 1.1 to 2.0 cm on ultrasound were later found to be ≤1 cm on gross pathology.[8] Gross pathologic size is obviously not known prior to surgical excision, and therefore cannot be used as a selection criterion. However, there may be imaging characteristics that could refine the selection of appropriate patients who might benefit from FDG-PET.

Although our sample size is still somewhat limited, in a post-hoc analysis, if we excluded predominantly cystic lesions and used an ultrasound size cutoff of 1.5 cm or larger, we would have eliminated the lesions measured as subcentimeter in diameter by gross pathology. These ultrasound criteria, however, were not assessed on a prospective basis in our study population. Accrual of a larger patient pool to our target of 125 patients will provide better statistical power to reassess this observation on final study analysis.

Incidental papillary thyroid carcinomas present a dilemma. This analysis was restricted to evaluating the ability of PET scan to detect cancer in the nodule of interest. However, four of our patients had papillary thyroid carcinoma (PTC) found at locations separate from the nodule of interest on pathologic analysis. Each of these patients was found to have benign disease in the nodule that underwent FNA. Three of these incidental lesions would be considered papillary microcarcinomas (< 1 cm diameter), but one patient had two PTCs 1.7 cm and 1.2 cm in diameter, contralateral to the nodule of interest. Those two lesions had not been biopsied prior to thyroidectomy, despite their visualization on preoperative ultrasound and the identification of calcifications within one of the nodules. Clearly, that patient benefited from thyroidectomy for her benign nodule, or her multifocal PTC would have remained undiagnosed and untreated. However, for the purposes of this analysis her test was interpreted as a false positive, since in her case marked focal PET uptake was seen in her benign nodule, not within her incidental PTCs.

In one recent study, incidental papillary microcarcinomas (<1 cm) undetected by imaging, or without suspicious ultrasound features of hypoechogenicity and microcalcifications, have significantly fewer poor prognostic features on pathology (multifocality, extracapsular extension, lymph node metastasis) than nodules with those ultrasound features.[9] The ultrasound and histopathologic characteristics of the three papillary microcarcinomas found so far in our study were consistent with those findings. It is unclear what consequences would result for our three patients if these previously undetected papillary microcarcinomas had not been discovered, in the absence of another surgical indication. The incidental manner of diagnosis may confer some prognostic information. One recent study by Pisanu et al. found that nonincidental diagnosis was an independent poor prognostic factor for nodal metastasis, along with capsular invasion, for papillary microcarcinomas.[10] In that study, patients with an incidental diagnosis of papillary microcarcinoma, after thyroidectomy for another indication, had lower prevalence of central or lateral lymph node involvement (1.4%) than those with microcarcinomas detected prior to surgery (21.0%). Ito et al.[11] reported that over 70% of patients with known papillary microcarcinomas who chose observation with serial ultrasound over immediate surgery had no increase in size in follow-up, even in those followed for five years. However, papillary microcarcinomas can exhibit aggressive behavior with recurrence rates up to 20% after thyroid lobectomy, as well as metastases to cervical lymph nodes or distant sites, becoming a significant cause of morbidity and in some cases, mortality.[12–17]

At this time, we have insufficient data to comment on the accuracy of FDG-PET in the setting of incidental PTCs or papillary microcarcinomas separate from the nodule of interest. In this series, some patients underwent hemithyroidectomy, while others underwent near-total thyroidectomy, based on their clinical findings and the preferences of the surgeon and patient. Therefore, we cannot know the total number of additional nodules, benign or malignant, that may have been present in all patients. Incidental papillary microcarcinomas are likely to represent a different population than nodules with indeterminate FNA cytology, since they have either been undetected or deemed sufficiently low risk to forego biopsy prior to surgery for another indication. Our study was not designed to examine the role of FDG-PET for this lesion population.

One consistent observation among most studies evaluating the utility of FDG-PET for identifying malignancy in this patient population is poor specificity in the setting of high sensitivity. Our study thus far corroborates this finding with PET identifying malignancy in lesions ≥1 cm in diameter with a sensitivity of 100% but a specificity of only 59%. Additionally, current data indicates that an FDG-PET study demonstrating focal uptake in the nodule of interest provides little or no diagnostic benefit for identifying malignancy. This study also demonstrates a high negative predictive value for FDG-PET to exclude

malignancy in these indeterminate thyroid nodules. This high NPV in combination with a high sensitivity makes exclusion of malignancy a more meaningful parameter. Despite poor specificity, the ability of a negative FDG-PET exam to exclude malignancy would be helpful in surgical decision-making as over 80% of patients with this cytology are currently having thyroid surgery for benign disease. While data from this interim analysis are encouraging for the utility of FDG-PET in this clinical setting, completion of accrual for this study to a total of 125 patients will add statistical power to the data analysis to generate more meaningful recommendations for future clinical applications.

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Table 1

Characteristics of study participants, lesions, and PET imaging.

Patient	Age	Gender	Biopsy Result	Final Diagnosis	Malignancy status	Imaging Gr. Dim. (mm)	Solid on Imaging	Path Gr. Dim. (mm)	PET Subjective Intensity	PET Pattern	SUV max
1	59	M	Follicular	FVPTC	M	11	Y	7	No uptake	No lesion	
2	56	F	Hurthle cell	Nod hyp, Hurthle change	B	18	N	5	No uptake	No lesion	
3	44	F	Follicular	FA	B	15	Y	12	Moderate	Diffuse	3.9
4	59	M	Follicular	FA	B	29	Y	17	Marked	Focal	6.2
5	38	F	Follicular	Nod hyp	B	17	Y	13	No uptake	No lesion	
6	40	F	Atypical	Nod hyp, Hurthle change	B	16	Y	14	Marked	Focal	5.9
7	47	F	Atypical	Nod hyp	B	32	Y	35	Mild	Diffuse	1.1
8	59	F	Follicular	Nod hyp	B	24	Y	17	No uptake	No lesion	
9	45	F	Follicular	FVPTC	M	28	Y	12	Mild	Focal	2
10	22	F	Hurthle cell	Nod hyp	B	14	N	15	Mild	Focal	1.87
11	48	F	Follicular	FA	B	25	Y	24	No uptake	No lesion	
12	46	F	Atypical	FVPTC	M	13	Y	9	No uptake	No lesion	
13	48	F	Follicular	Nod hyp	B	18	Y	19	No uptake	No lesion	
14	41	F	Hurthle cell	PTC	M	35	Y	19	Moderate	Focal	4.25
15	30	F	Follicular	FVPTC	M	43	Y	20	Moderate	Focal	2.9
16	44	F	Follicular	FA	B	22	Y	17	No uptake	No lesion	
17	54	F	Suspicious	Nod hyp	B	16	N	12	No uptake	No lesion	
18	49	F	Follicular, adenomatous	Nod hyp	B	30	Y	15	Mild	Focal	2.9
19	44	F	Sparse follicular cells	Nod hyp	B	34	Y	25	No uptake	No lesion	
20	60	F	Follicular	Nod hyp	B	13	Y	11	Moderate	Focal	2.72
21	49	F	Abnormal	Nod hyp	B	33	N	14	Mild	Focal	2.1
22	65	M	Atypical	Nod hyp, Hurthle change *inc 0.4 cm PTC	B	20	Y	15	Moderate	Focal	2.6

Patient	Age	Gender	Biopsy Result	Final Diagnosis	Malignancy status	Imaging Gr. Dim. (mm)	Solid on Imaging	Path Gr. Dim. (mm)	PET Subjective Intensity	PET Pattern	SUV max
23	69	M	Follicular	FA, *inc <0.3 cm PTC	B	35	Y	37	No lesion seen	No lesion	
24	51	F	Follicular	Nod hyp	B	15	Y	8	Mild	Focal	1.89
25	59	F	Follicular	Nod hyp	B	26	Y	18	No uptake	No lesion	
26	55	F	Follicular	FA, lymph thyroiditis	B	34	Y	25	No uptake	No lesion	
27	32	F	Follicular	FA	B	43	Y	30	No uptake	No lesion	
28	38	F	Follicular	Nod hyp	B	35	N	25	Moderate	Focal	4.1
29	38	F	Follicular	Nod hyp, chronic thyroiditis	B	25	Y	15	Mild	Focal	2.3
30	60	F	Follicular	FA, lymph thyroiditis	B	27	Y	15	Marked	Focal	11.1
31	51	F	Atypical	Nod hyp	B	6	Y	5	No uptake	No lesion	
32	54	F	Follicular	FVPTC	M	56	Y	50	Moderate	Focal	4.6
33	31	F	Atypical	Nod hyp	B	20	Y	11	Moderate	Focal	2.99
34	56	F	Follicular	Nod hyp *inc 0.8 cm PTC	B	24	Y	25	No uptake	No lesion	
35	54	F	Follicular	FA	B	30	Y	19	Moderate	Focal	3.45
36	45	F	Follicular	Nod hyp	B	45	Y	NR	Moderate	Focal	2.99
37	77	F	Hurthle cell	Hurthle adenoma *inc 1.7 cm & 1.2 cm PTC	B	46	Y	38	Marked	Focal	10.2
38	48	F	Follicular	FC	M	22	Y	25	Marked	Focal	51.9
39	55	M	Follicular	Nod hyp	B	51	N	20	Mild	Diffuse	2
40	57	F	Follicular	FA,	B	11	Y	8	No uptake	No lesion	
41	64	M	Follicular	Nod hyp	B	80	N	15	Mild	Diffuse	2.78
42	56	F	Atypical	Nod hyp	B	31	Y	15	No uptake	No lesion	
43	49	M	Atypical	Nod hyp, cyst cavity	B	49	N	5	No uptake	No lesion	
44	48	F	Hurthle cell	Hurthle cell ca	M	36	Y	40	Marked	Focal	21.5
45	59	F	Follicular	FA	B	12	Y	8	No uptake	No lesion	
46	50	M	Follicular	Nod hyp	B	47	Y	40	Mild	Diffuse	3.2
47	46	M	Follicular	Nod hyp	B	22	Y	15	No uptake	No lesion	

Patient	Age	Gender	Biopsy Result	Final Diagnosis	Malignancy status	Imaging Gr. Dim. (mm)	Solid on Imaging	Path Gr. Dim. (mm)	PET Subjective Intensity	PET Pattern	SUV max
48	41	F	Follicular	Nod hyp	B	16	Y	10	Mild	Focal	2.16
49	51	M	Atypical	Mixed medullary ca and FC	M	48	Y	25	Moderate	Focal	3.28
50	56	F	Follicular	Nod hyp	B	16	Y	10	No uptake	No lesion	
51	30	F	Follicular	PTC	M	26	Y	30	Marked	Focal	36.6

Abbreviations: Gr. Dim = Greatest Dimension, SUV_{max} = Maximum standardized uptake value, FVPTC = follicular variant of papillary thyroid carcinoma, Nod hyp = nodular hyperplasia, FA = follicular adenoma, PTC = papillary thyroid carcinoma, FC = follicular carcinoma, ca = carcinoma, NR = not reported, inc = incidental. For a lesion to be characterized as solid on imaging, the ultrasound report must have characterized the lesion as “solid” or “predominantly solid”.

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Table 2

PET results compared with malignancy status – all lesions.

PET Result	Malignant		Total
	+	−	
+	8	16	24
−	2	25	27
	10	41	51

For these lesions, sensitivity = 80%, specificity = 61%, positive predictive value = 33%, negative predictive value = 93%.

Table 3

Lesions less than 1 cm in greatest dimension by pathologic analysis.

PET Result	Malignant		Total
	+	−	
+	8	14	22
−	0	20	20
	8	34	42

For these lesions, sensitivity = 100%, specificity = 59%, positive predictive value = 36%, negative predictive value = 100%.