

# Preliminary experience with the AFIRMA Gene-Classifer Method in the Evaluation of Thyroid Nodules with Indeterminate Cytology

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## Background

- Indeterminate (Bethesda 3 and 4) cytopathology results are reported in 15-30% of fine needle aspirations of thyroid nodules. (Table 1.)
- Until recently, this inevitably led to surgery. However at surgery 70-80% of these cases turn out to be benign.
- ATA guidelines suggest the use of molecular markers for patients with indeterminate cytology, as a benign molecular pattern can justify observation rather than lobectomy.
- Among the available molecular approaches the AFIRMA<sup>®</sup>, gene classifier technique is reported to have a 94-96% negative predictive value.

## Study Aim and Design

- To report on our initial experience with the AFIRMA-augmented FNA in nodules with indeterminate cytology.
- In recent months, we started to evaluate thyroid nodules with Bethesda score 3 or 4 by adding the AFIRMA technique on US-guided freshly obtained cytological samples
- Nineteen patients – 11 women and 8 men, mean age 51 y (range – 27-72) have so far undergone the procedure.

## Results

- Nineteen nodules, 13 Bethesda 3 (68%) and 6 Bethesda 4 (32%) were sampled.
- AFIRMA results are still pending for 2 samples.
- The AFIRMA technique yielded benign results in 9/17 nodules (52%), 8 were Bethesda 3, and only 1 Bethesda 4. Suspicious AFIRMA results were obtained in the 8 remaining nodules. 3 out of the 8 (37%) were Bethesda score 3, and 5/8 (63%) Bethesda 4.
- Two patients with Bethesda 3 and suspicious AFIRMA results underwent surgery.
- Pathology was benign in 1 and consistent with papillary thyroid cancer in the other.
- Two patients with Bethesda 4 and suspicious AFIRMA recently underwent surgery, pathology results are still pending. (Table 2.)

## Conclusions

- In our limited experience, The AFIRMA-augmented aspiration of thyroid nodules may indeed cut down on unnecessary surgery.
- This appears to be particularly the case with Bethesda 3 nodules.
- We are hoping to expand our experience with this technique, whose main obstacle remains its current cost.

Patient	Age (y)	Gender	Size (cm)	Bethesda	Afirma	Surgery
1	39	F	1.72	3	B	
2	55	M	1.3	3	S	PTC
3	40	M	2.2	4	S	
4	67	F	2.5	3	S	FA
5	55	F	1.6	3	B	
6	72	M	1.64	4	S	
7	41	M	2.2	3	B	
8	50	M	4	4	S	YES
9	41	M	3.4	3	B	
10	64	F	1.3	4	B	
11	38	F	1.4	4	S	
12	27	F	2.8	3	B	YES
13	57	F	1.43	3	B	
14	42	F	2.36	4	S	
15	45	M	7.6	3	S	
16	72	F	1,4.5	3	B	
17	74	F	3.6	3	B	
18	40	F	2.6	3	-	
19	51	M	1.3	3	-	

Bethesda	Risk of Malignancy (%)	Management
1 - Nondiagnostic or Unsatisfactory	1-4	Repeat FNA with US
2 - Benign	0-3	Clinical Follow up
3 - Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance	5-15	Repeat FNA
4 - Follicular Neoplasm or Suspicious Follicular Neoplasm	15-30	Lobectomy
5 - Suspicious for malignancy	60-75	Thyroidectomy
6 - Malignant	97-99	Thyroidectomy