THE ROUTINE COLLECTION OF "JUST IN CASE" THYROID ASPIRATES FOR MOLECULAR TESTING AT THE TIME OF INITIAL FINE NEEDLE ASPIRATION. IMPACT ON WORKFLOW

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Molecular testing in Thyroid FNA

- Commonly utilized at our institution for indeterminate thyroid aspirates, typically Bethesda III (Atypia of Undetermined Significance)
- Prevents unnecessary surgeries, since the majority of Bethesda III samples have a high likelihood of benignity on molecular testing
- Samples for molecular testing are typically acquired on a subsequent visit, after initial biopsies have been reported by pathologists
- Repeat biopsies create anxiety and frustration for patients
- Collecting “just in case” samples for molecular testing at the time of initial biopsy may provide a solution

Afirma®
Genomic Sequencing Classifier

- Uses next-generation RNA sequencing and whole transcriptome analysis combined with machine learning algorithms
- Provides a benign or suspicious result for indeterminate thyroid nodules
- The primary goal of the test is to allow patients to avoid unnecessary surgery by ruling out thyroid cancer.

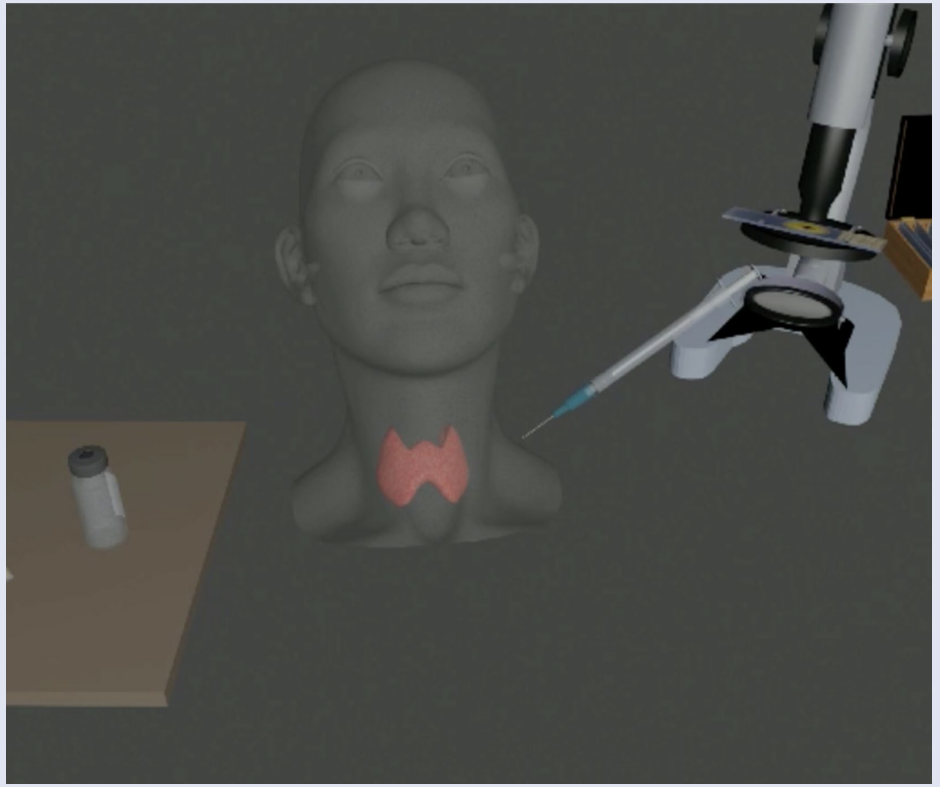
- Meta-analysis of 13 independent studies
  - 97% sensitivity
  - 99% NPV
  - 65% PPV
  - 67% Benign call rate

- Typical reports
  - "The result of this x cm Bethesda III nodule is Afirma GSC Benign, which suggests a low risk of cancer at approximately 4%...".
  - "The result of this x cm Bethesda III nodule is Afirma GSC Suspicious, which suggests a risk of cancer at approximately 50%...".

Nasr CE, Andrioli M, Endo M, et al. Real-World Performance of the Afirma Genomic Sequencing Classifier (GSC)-A Meta-analysis. *J Clin Endocrinol Metab*. 2023;108(6):1526-1532. doi:10.1210/clinem/dgac688

Methods

- Initiate the collection of “just in case” samples for molecular testing (Afirma ®) for all thyroid biopsies
- Coordinate with pathologists who will store samples and send for molecular testing if required
- Two additional 25-27 gauge FNA samples will be acquired and stored for molecular testing
- Impact on workflow will be reviewed after a 7 month period



Results

-69 total patients

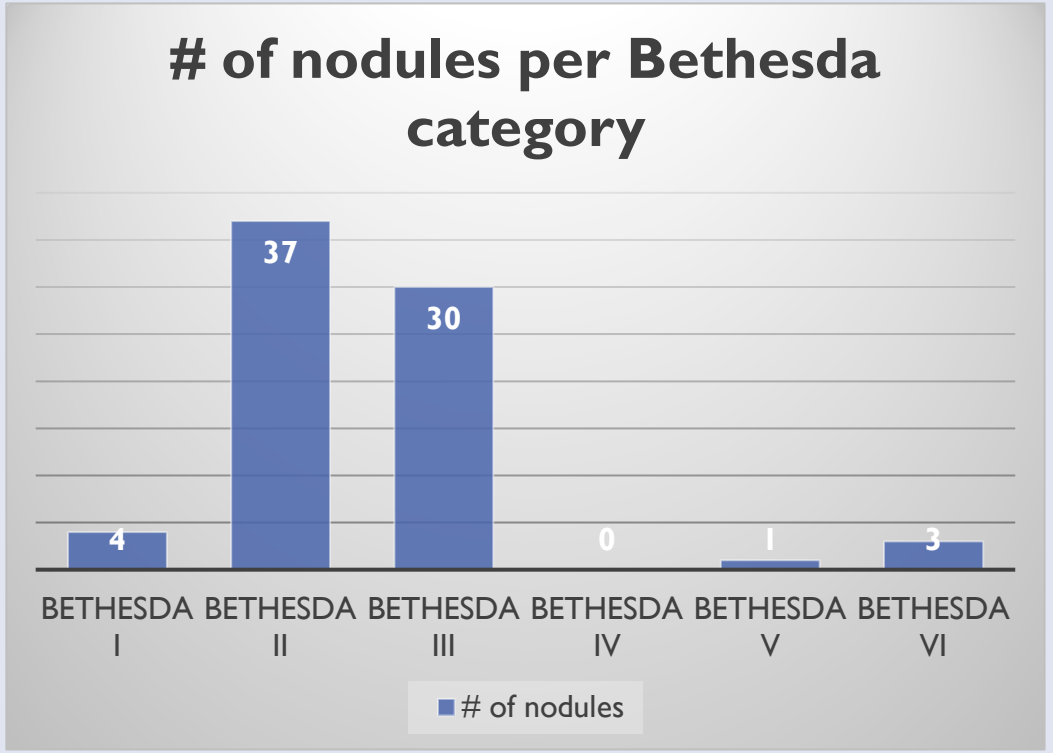
-Ages ranged from 24 to 88 years

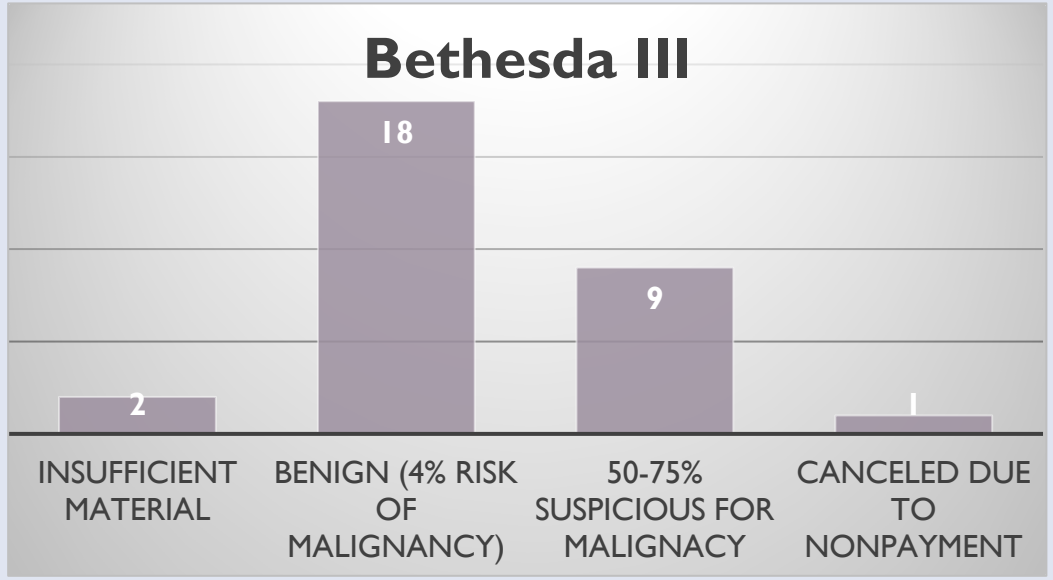
-16 male and 63 female

-Of the 69 patients, 6 had two nodules sampled, yielding a total of 75 nodules

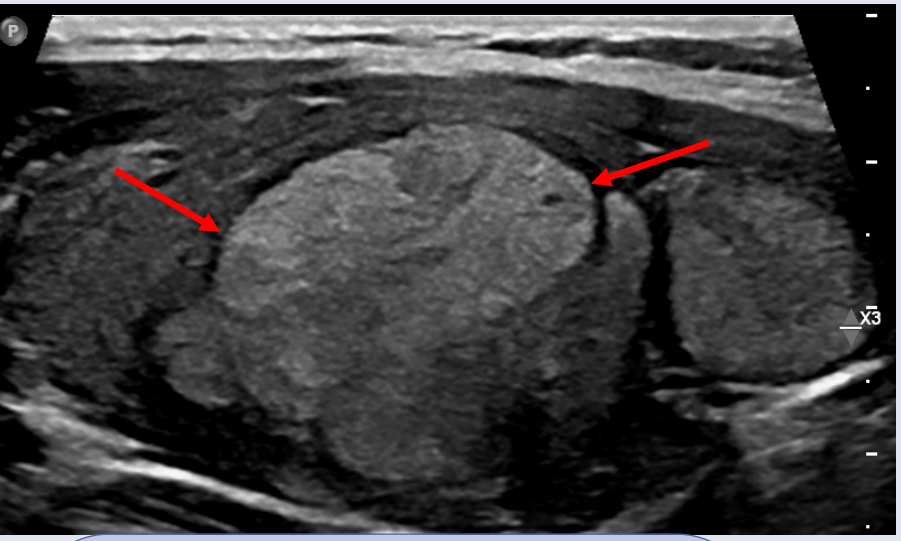
-Two additional passes + time taken to complete the Afirma request form/paperwork added an estimated ten minutes to overall procedure length

-There were no additional post-procedural complications

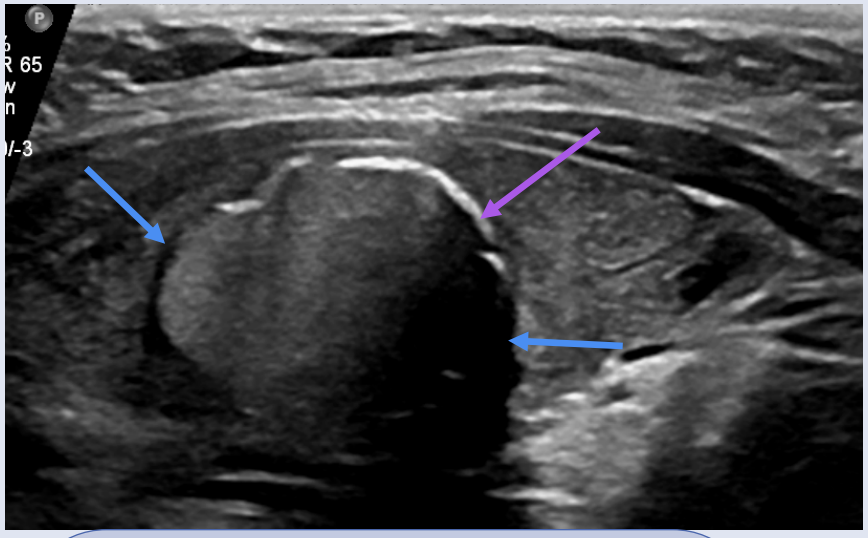




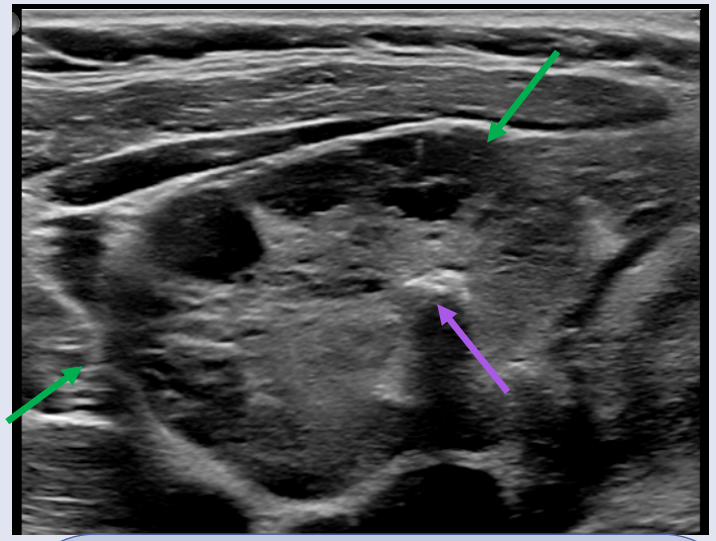
Atypia of Undetermined Significance Sonographic Examples



Sagittal sonographic view of a 3cm nodule in the right lobe of the thyroid (red arrows). This was scored as a TI-RADS 3 nodule (solid and hyperechoic) and met FNA criteria by virtue of size.

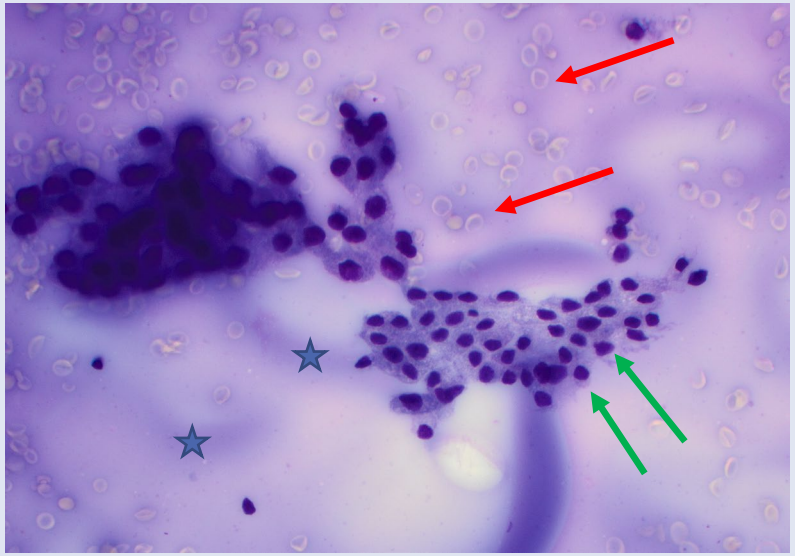


Sagittal sonographic view of a 2.2cm nodule in the right lobe of the thyroid (blue arrows). This was scored as a TI-RADS 4 nodule i.e. solid, isoechoic with peripheral calcification (purple arrow) and met FNA criteria by virtue of size.

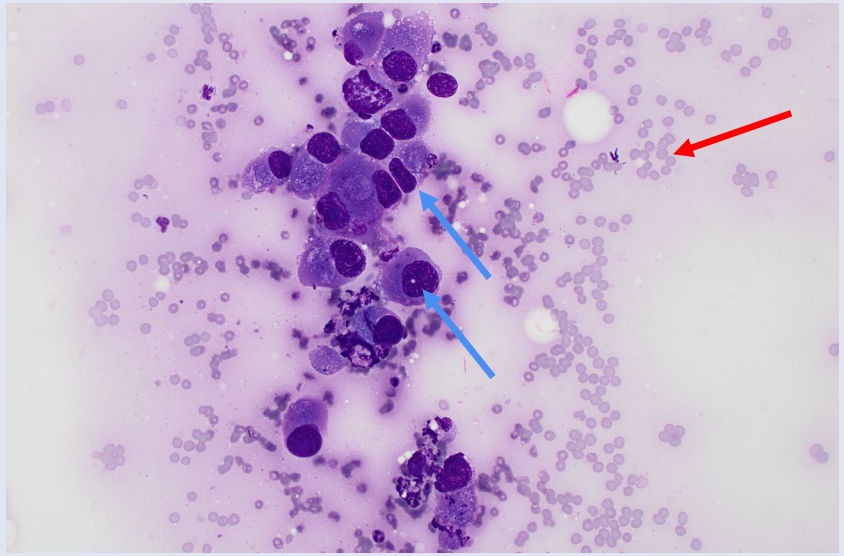


Transverse sonographic view of a 4.6cm nodule in the right lobe of the thyroid (green arrows). This was scored as a TI-RADS 3 nodule i.e. mixed cystic/solid, isoechoic and containing macrocalcification (purple arrow).

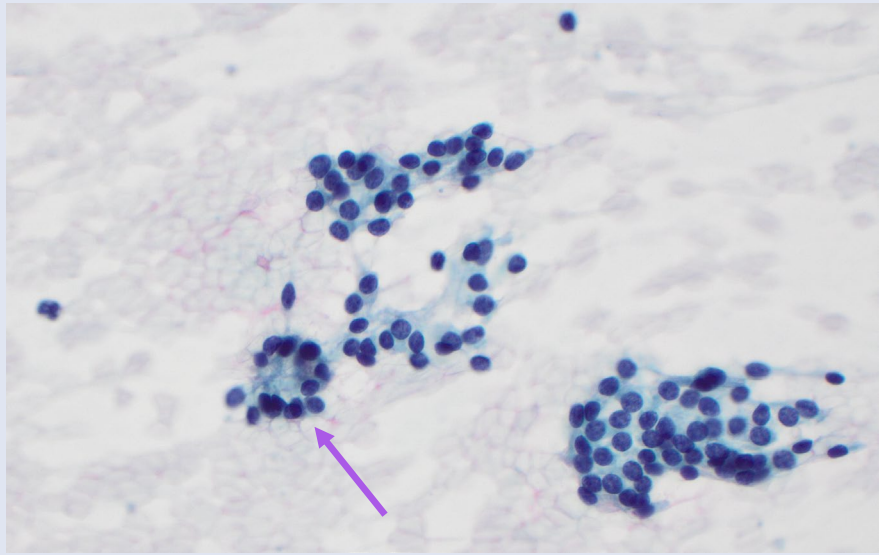
Bethesda Categories. Examples



Benign thyroid aspirate. (Bethesda category II). Generally abundant colloid, seen as purple material in the background (stars) and scant bland follicular cells are present (green arrows). In-plane nuclei do not touch (uncrowded) and are about the size of an RBC (red arrows).



Malignant thyroid aspirate. (Bethesda category VI). Generally enlarged cells with prominent nucleoli and abundant finely vacuolated cytoplasm. Nuclei are pleomorphic i.e. different shapes (blue arrows). Note the cells are much larger than an RBC (red arrow).



Atypia of Undetermined Significance (AUS). (Bethesda category III). Moderately cellular with no colloid in the background. Although the nuclei in this case do not demonstrate cytologic atypia, atypical architectural features including microfollicles (less than 15cells) are present (purple arrow).

Conclusion

"Just in case" samples had a favorable impact

While procedure length was increased by ten minutes, repeat biopsies were avoided for 30 of 75 (40%) nodules

No patient complications despite additional passes for molecular testing

The "just in case" workflow will be standardized to provide sustained enhanced efficiency