

Abstract #1200

AFIRMA GSC: EARLY ENDOCRIN URGICAL PRACTICE PERFORMANCE

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Objective: Veracyte Inc. specializes in RNA expression screening tools for determining which cytologic Bethesda 3 and 4 fine-needle aspiration (FNA) biopsied thyroid nodules should be surgically removed (suspicious) and which should be observed (benign). The first generation screening technology, Afirma gene expression classifier (GEC), became clinically available in Jan. 2011 and has been reported to identify 80-90% of oncocyte-dominant Bethesda 3 and 4 aspirates as “suspicious.” The next generation screening tool, Afirma genetic sequence classifier (GSC) became available for clinical use in August 2017, with the intent of improving the specificity of the clinical screening; in addition, Afirma GSC was designed to discriminate oncocyte dominant thyroid cytology more accurately. In this abstract we report our experience with the Afirma GSC to date, and contrast these early data with our 6.5 years of experience with Afirma GEC.

Methods: We analyzed Afirma GEC and Afirma GSC screening results from our endocrine surgery practice for the period from 1/2011-2/14/2018; Afirma GEC technology was used exclusively from 1/1/2011 – 7/31/2017, and Afirma GSC technology was used from 8/1/2017 – 2/14/2018. All biopsy results were read exclusively by Thyroid Cytopathology Partners in Austin, TX. Significant differences were ascertained by confidence interval analysis.

Results: Over the study time interval, Afirma GSC identified significantly less (~21%) Bethesda 3 and 4 nodule patients as suspicious (Afirma GEC Benign 200 (39.3%) vs Suspicious 274 (53.9%); Afirma GSC Benign 48 (60%) vs Suspicious 26 (32.5%)). Oncocytic Bethesda 3 and 4 nodules constituted 21% and 22.5% of our indeterminate cytology thyroid nodules for the GEC and GSC groups respectively; there was a significant decrease of in the percentage (~50%) of oncocytic subjects classified as suspicious in the GSC screened population (Afirma GEC Benign 19 (17.8%) vs Suspicious 83 (77.6%); Afirma GSC Benign 12 (66.7%) vs Suspicious 5 (27.8%)).

Discussion: Our early experience (6.5 months) with Afirma GCS suggests that this new technology assigns fewer patients for surgical intervention than the previous generation of screening technology. A primary contributor to this performance change may be the significant improvement in the accuracy of the Afirma GSC screening for oncocyte- dominant Bethesda 3 and 4 FNA's.

Conclusion: Recent modifications of Afirma technology (GEC to GSC) have improved the specificity of the Afirma test in our community endocrine surgical practice. Surgical outcomes analysis of GSC patients who have undergone thyroidectomy will be required to see if this improved specificity has been attained at the expense of test sensitivity