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EARLY EXPERIENCE OF GENE SEQUENCING CLASSIFIER COMPARED TO GENE EXPRESSION CLASSIFIER

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Objective: The Afirma Genomic Sequencing Classifier (GSC) was designed to improve specificity for identification of benign thyroid nodules among cytologically indeterminate thyroid nodules (ITN) as compared to its predecessor the Gene Expression Classifier (GEC). Here we report the early performance of GSC at our institution.

Methods: This is a retrospective study, approved by the institutional review board, of patients with ITN (Bethesda III/IV) at The Ohio State University Medical Center from 7/2017-12/2017. Two needle insertions were obtained for GSC and analyzed at Veracyte, Inc. (San Francisco, CA). Surgery was performed per the treating physician. Statistical analysis was performed with Fisher's exact test for categorical variables. Two-sided P values of <0.05 were considered statistically significant.

Results: 48 cytologically ITN were included: 39 patients (81.3%) with Bethesda III and 9 (18.7%) with Bethesda IV. 47 samples were considered adequate for GSC testing. GSC was benign in 34 patients (72.3%), suspicious in 13 patients (27.7%). GSC benign call rate was significantly higher than the previously observed GEC at our institution (data not shown) (72.3% versus 48.4%, p-value<0.002). 9/13 GSC suspicious cases underwent surgery: 2 classic papillary thyroid carcinomas, 2 follicular thyroid carcinomas, 1 noninvasive follicular thyroid neoplasm with papillary-like nuclear features (NIFTP) and 4 benign nodules. Assuming all unoperated GSC benign patients are truly benign, cancer prevalence (including NIFTP tumor) was 20%. The PPV of GSC was 55.6% for the 69% of Afirma suspicious patients operated to date.

Discussion: Implementation of Afirma has resulted in avoidance of surgery in GEC benign cases. However, low specificity and PPV limited its use as a rule-in test. Our preliminary data of GSC show a statistically significant higher benign call rate compared to our previous data on GEC, which would likely avoid surgery in more patients. The PPV improved to 56% with a cancer prevalence of 20% compared to the originally reported PPV of 37- 38% with GEC where cancer prevalence was 24-25%, consistent with improved test specificity. Future Long-term follow up is needed to confirm benign nature of unoperated benign GSC.

Conclusion: Early results of GSC show statistically significant increase in benign call rate and modest improvement in PPV compared to GEC.