

Poster 450

Thyroid Nodules & Goiter Saturday Poster Clinical

PERFORMANCE OF AFIRMA GENOMIC SEQUENCING CLASSIFIER: THE INITIAL CLEVELAND CLINIC EXPERIENCE

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The objective of our study was to report our initial experience with the novel Afirma Genomic Sequencing Classifier (GSC) in the evaluation of cytologically indeterminate thyroid nodules, and to compare its performance against the previously utilized Afirma Gene Expression Classifier (GEC). Retrospective chart review of all patients with cytologically indeterminate thyroid nodules (Bethesda III/IV) who underwent testing with either Afirma GEC or GSC from December 2011 through December 2017 at the Cleveland Clinic (Cleveland, OH). Differences between the two tests were assessed using a 2-sample test for equality of proportions. Histopathological data were collected on patients who underwent thyroid surgery after GEC or GSC testing to calculate measures of test performance. Afirma GEC was performed on 191 cytologically indeterminate thyroid nodule samples (December 2011 - July 2017). Considering adequate samples (182, 95.3%), GEC was benign in 76 (41.8%) cases, and suspicious in 106 (58.2%) cases. Afirma GSC was performed on 48 cytologically indeterminate thyroid nodule samples (July 2017 - December 2017). Considering adequate samples (46, 95.8%), GSC was benign in 31 (67.4%) cases, and suspicious in 15 (32.6%) cases. The benign call rate for GSC was 25.6% higher than for GEC ($p = 0.003$). The overall thyroid surgery rate for nodules tested with GEC was 47.3% versus 32.6% for nodules tested with GSC ($p = 0.105$). The calculated sensitivity of GEC was 97.1%, with a specificity of 63%, a positive predictive value (PPV) of 43.6%, and a negative predictive value (NPV) of 98.7%*. The calculated sensitivity of GSC was 92.3%, with a specificity of 93.8%, a PPV of 85.7%, and a NPV of 96.8%*. [*calculations assumed that unoperated GEC/GSC benign nodules were true negatives]. The benign call rate among cytologically indeterminate thyroid nodules was significantly higher with Afirma GSC. GSC maintained a high sensitivity and NPV (consistent with previously reported validation results), while providing a significantly higher specificity and PPV. In the long run, GSC testing may help prevent more unnecessary diagnostic thyroid surgeries, along with reducing potential associated costs and life-long consequences.