SAT-659

Afirma Genomic Sequencing Classifier Experience among the First 5,478 Consecutive Samples from Cytologically Indeterminate Thyroid Nodules

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BACKGROUND

The Afirma Genomic Sequencing Classifier (GSC) was designed to improve test specificity for identification of benign thyroid nodules among cytologically indeterminate lesions while maintaining high sensitivity for malignant nodules compared to its predecessor, the Gene Expression Classifier (GEC), with the goal of sparing more patients diagnostic surgery. The blinded GSC clinical validation performance was previously reported. Here we report the initial GSC experience since its July 26, 2017 introduction in a consecutive series of samples received by the Veracyte CLIA laboratory compared to the GEC experience.

METHODS

Veracyte analyzed the results of all Afirma GEC and GSC testing in Bethesda III and IV samples from January 1, 2011, and July 26, 2017, respectively, through March 5, 2018.

RESULTS

The Afirma GEC was performed on 97,519 Bethesda III and IV thyroid nodule samples. Considering adequate samples (90,140, 92%), Afirma GEC was benign in 39,701 (44%) (Figure 1A). Extrapolating from 27 published studies of 2,263 GEC-tested patients in which only 11.8% of the GEC benign patients underwent surgery, we infer that 35,016 patients may have been spared diagnostic surgery because of their GEC benign result, representing 39% of patients with adequate GEC samples (Figure 2A). Since its introduction, the Afirma GSC was performed on 5,478 Bethesda III and IV thyroid nodule samples. Considering adequate samples (5,090, 93%), Afirma GSC was benign in 3,281 (64%), and suspicious in 1,809 (36%) (Figure 1B). Thus, the GSC benign call rate was significantly higher than for the GEC ($p < 2.2 \times 10^{-16}$). Applying the reported operative rates for GEC benign patients to GSC benign patients, 57% of patients with adequate GSC samples may avoid surgery ($p < 2.2 \times 10^{-16}$ compared to GEC) (Figure 2B).

CONCLUSION

While both the Afirma GEC and GSC have reliable benign results (i.e., high negative predictive values), the GSC provides significantly more benign results. This is likely to permit more clinical observation and less diagnostic surgery, reducing surgical complications, enhancing patients' qualities of life, and decreasing healthcare expenditures.

FIGURE 1.

Afirma GSC has a Significantly Higher Benign Call Rate

Figure 1A. Afirma GEC Call Rates

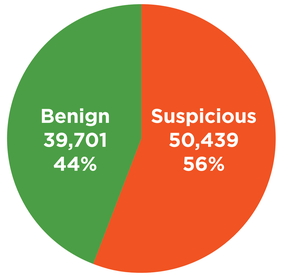
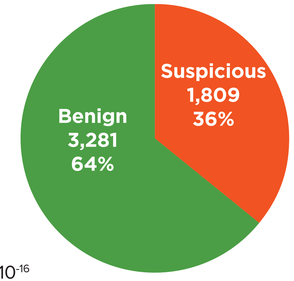


Figure 1B. Afirma GSC Call Rates



$p < 2.2 \times 10^{-16}$

TABLE 1.

Demographics Table*

Variable	Afirma GEC	Afirma GSC
Patients		
Age (yrs)** — mean (range)	56 (21–100)	56 (21–95)
Gender		
Male	21%	21%
Female	79%	79%
Thyroid Nodules		
Cytology		
Bethesda III	81%	80%
Bethesda IV	19%	20%
Nodule size — mean (range)	2.3 cm (0.6 cm–11.0 cm)	2.4 cm (0.6 cm–9.0 cm)

*Missing data was excluded.
** Data for patients ≥21.

FIGURE 2.

Estimated Unnecessary Surgeries Avoided

Figure 2A. Afirma GEC (n=90,140)

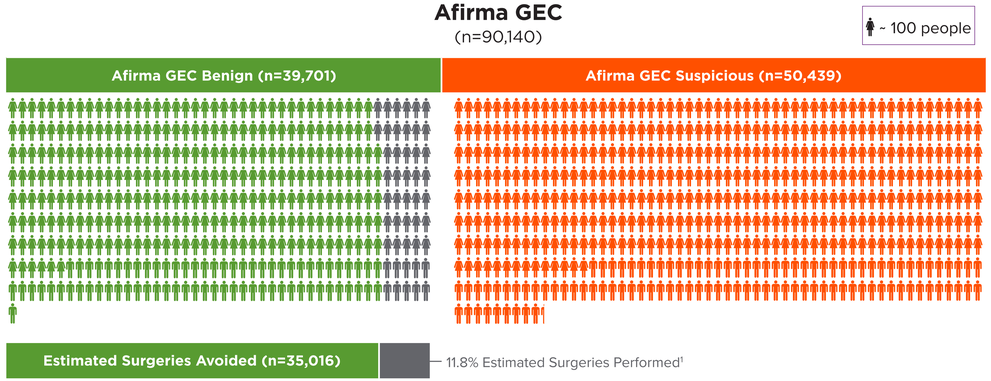
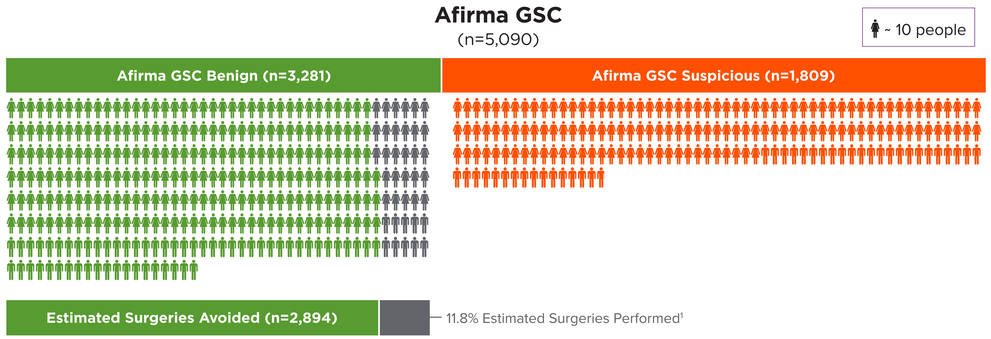


Figure 2B. Afirma GSC (n=5,090)



References

1. Data on file from meta-analysis of 27 clinical experience studies.