

ThyroSeq test helps patients avoid unnecessary diagnostic thyroid surgery, study shows

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A genetic test developed by researchers at UPMC and the University of Pittsburgh School of Medicine can help avoid costly diagnostic surgery that involves removing one or both lobes of the thyroid gland, by reliably distinguishing between benign and cancerous thyroid nodules using a very small sample of cells, according to the results of an international clinical trial published today in the journal *JAMA Oncology*.

The performance of the test, called the ThyroSeq Genomic Classifier, was assessed in a prospective double-blinded study conducted across 10 medical centers. The study involved 257 thyroid nodules with an ambiguous biopsy result evaluated by ThyroSeq and diagnostic surgery. The results showed that the test was highly sensitive, correctly identifying cancerous nodules as positive 94 percent of the time. The test also demonstrated a high specificity, correctly identifying benign nodules as negative 82 percent of the time. The researchers compared the performance of ThyroSeq with other molecular tests and showed that it can prevent the highest number of unnecessary diagnostic surgeries.

"Our study showed ThyroSeq can help avoid surgery in the vast majority of [patients](#) with [benign nodules](#) where the initial biopsy returns an ambiguous result," said Yuri Nikiforov, M.D., Ph.D., professor of pathology at Pitt's School of Medicine and director of the UPMC Molecular & Genomic Pathology Division, and the senior study author. "With such a high proportion of preventable surgeries, this test should

practically resolve the decades-long struggle and inefficiency of medical care for patients with indeterminate cytology [thyroid nodules](#). In an era of overdiagnosis and overtreatment, ThyroSeq can improve quality of life for patients by sparing them a lifetime of synthetic thyroid medications and specialist visits, while significantly reducing health care costs."

ThyroSeq was recently approved for Medicare coverage, making it accessible to more than 50 million Medicare patients nationwide.

The thyroid is a butterfly-shaped gland in the neck that is important to hormone regulation and development. Thyroid nodules are common, and approximately 600,000 patients with nodules undergo a fine needle aspiration (FNA) biopsy every year, where cells are extracted from the nodule and examined to determine whether it is benign or cancerous. While the biopsy test is mostly accurate, it returns an indeterminate finding in approximately one-in-four to -five cases, which forces patients to undergo either a repeat FNA, or diagnostic surgery where at least half of the patients' thyroid is removed for further assessment.

ThyroSeq is a next-generation sequencing-based test that uniquely evaluates cells collected by FNA from a thyroid nodule for alterations in 112 genes linked to thyroid cancer. It is designed to diagnose all types of thyroid cancer, including Hurthle cell cancer, as well as medullary carcinoma and parathyroid lesions.

"Beyond simply differentiating benign and malignant nodules, the study shows that ThyroSeq also provides a detailed genetic profile of the positive nodules," said David Steward, M.D., a professor of otolaryngology at the University of Cincinnati (UC) College of Medicine and director of head and neck surgery at UC Health, and the first author of the study. "Since thyroid cancer is known to progress differently based on the mutation involved, ThyroSeq potentially allows physicians

to employ a precision medicine approach, modifying treatment for each patient based on the mutations present."

The impact on [health care costs](#) of adopting ThyroSeq could be significant, noted Nikiforov, pointing to an independent analysis by Mayo Clinic researchers recently published in the journal *Endocrine Practice* that found ThyroSeq testing saved thousands of dollars compared to when patients underwent diagnostic [thyroid surgery](#).

A full list of study authors and their affiliations, along with relevant conflict-of-interest disclosures, is available with the online version of the study.

More information: *JAMA Oncology* (2018). [DOI: 10.1001/jamaoncol.2018.4616](#)

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