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Genomic 'Markers' May Head Off Thousands of Thyroid Surgeries

Doctors at the University of Colorado School of Medicine were concerned recently when they found a nodule in the thyroid of a 64-year-old Colorado man. They extracted cells from the nodule, hoping to determine whether the man had cancer. But the biopsy results were inconclusive.

Even a few months ago, such uncertainty would have likely led to surgery to remove all or part of the thyroid. At least this patient would have faced a tense waiting period to see if, over time, he developed clear signs of cancer.

This time, however, the CU doctors simply sent the cell sample to a laboratory. There, a test analyzed the cells' molecular patterns, producing a result that was a relief for the patient: there was a high level of certainty he didn't have cancer.

The CU doctors are helping lead the way nationally in the use of this genomic approach to evaluating suspicious thyroid nodules. The test that benefitted the 64-year-old patient could eliminate the need for tens of thousands of unnecessary thyroid surgeries every year. The patient is willing to talk with reporters.

"This should allow many patients to avoid the cost, discomfort and risk of surgery," says Bryan Haugen, MD, who heads the Division of Endocrinology, Metabolism and Diabetes at the CU medical school.

Usually, when cells are extracted from suspicious nodules in the thyroid, they're found to be benign. No cancer. But here's the problem -- in 15-30 percent of those samples, it's hard to tell. The next step in most cases has been for a surgeon to remove part, or all, of the thyroid. That tissue is examined further. More than 70 percent of the time, there's no cancer, yet the patient had to undergo surgery to get that good news -- and is often subjected to lifelong thyroid hormone therapy as a result.

Haugen and the national team sought to determine if the new test could help avoid those surgeries and still identify when there's no cancer. The answer, it now turns out, is yes. The secret lies in the genes.

"When we see test results showing the right patterns we can say with a great deal of certainty that, despite initial concerns, the patient does not have cancer," Haugen says.

The test was developed by Veracyte, a California-based molecular diagnostics company. The company is marketing its thyroid test -- branded Afirma -- on a limited basis and plans additional commercialization in early 2011.

Veracyte's researchers developed the test by identifying genomic patterns that would reliably tell when a patient has no cancer present. Haugen's team at CU, along with researchers at Brigham and Women's Hospital, a part of Harvard Medical School, is now co-leading a national trial to validate Veracyte's test. The trial involves more than 40 sites that are comparing the genomic test's results to analyses by two pathology experts of tissue obtained by traditional surgery. In September Haugen presented early information to an international thyroid conference in Paris. The findings confirmed the test's premise -- that when certain patterns appear among 142 thyroid genes (out of tens of thousands), the odds are very high -- more than 95 percent -- that there's no cancer.

That's a probability but not a certainty. Those odds are similar, however, to when an expert pathologist looks at the cells and determines there is no cancer -- but this time without surgery.

The American Cancer Society estimates that 44,670 new thyroid cancer cases (33,930 in women and 10,740 in men) will be diagnosed nationwide this year. Nearly two-thirds of the cases occur in people between the ages of 20 and 55. The chance of being diagnosed with thyroid cancer has doubled since 1990, in part because of better detection.