Award ID:
RP170427

Project Title:
Ambient Mass Spectrometry for Preoperative Molecular Diagnosis of Thyroid Fine Needle Aspirate Biopsies

Award Mechanism:
Bridging the Gap: Early Translational Research Awards

Principal Investigator:
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Entity:
The University of Texas at Austin

Lay Summary:

The incidence of thyroid cancer is one of the most rapidly rising in America. New cancers are being detected in both large and small thyroid nodules. Thyroid nodules are extremely common in the general population and more than 50% of patients will have thyroid nodules detected by ultrasound. Because each thyroid nodule has a potential for malignancy, it is essential to have an efficient way of diagnosing the nodule. Fine Needle Aspiration (FNA) biopsy is the standard test used to diagnose malignancy in thyroid nodules. During FNA, a doctor uses an ultrasound machine to guide a small needle (the size of a hair) into a nodule and sample the cells within the thyroid nodule. These cells are then gently spread onto a glass slide and a specially trained thyroid pathologist looks at the slide underneath a microscope and categorizes whether or not the nodule is malignant. The categories can be: benign, insufficient (not enough cells obtained to make a diagnosis), malignant, or indeterminate. Indeterminate means that the cells do not look normal but the pathologist cannot say for sure whether or not a cancer exists. Unfortunately, up to 30% of cases of FNA biopsy can be indeterminate causing significant stress and concern for the patient and patient's family.

Indeterminate thyroid nodules must undergo additional genetic analysis or diagnostic surgery. Genetic analysis involves an extra test with extra cost ($300-$3000, depending on insurance) and takes an additional 1 to 2 weeks for results to be returned during which time there is extreme stress for the family and patient. The results of the genetic test may still say that the lesion is “suspicious”, prompting the patient to go to surgery. Unfortunately, final surgical results will generally be benign. If genetic testing is not available to the patient, then the patient must undergo diagnostic surgery. Surgery involves removing the side of the thyroid in which the nodule exists. With surgery comes risk of injury to the nerve that controls the voice as well risk of needing to take thyroid hormone replacement for the rest of the patient's life. While the risk of nerve injury is low (less than 3%) the need for thyroid hormone replacement is common (20% - 40%). Each of these results in significant decrease in quality of life for the patient.

We propose to use a technology called mass spectrometry to develop a new and better test for analyzing thyroid nodules. Mass spectrometry uses a machine to determine the chemical composition of cells and tissues. Using this technique, we will analyze the same cells that are obtained from FNA biopsy and identify the types and patterns of molecules

that make up the cells. Benign and malignant cells have unique molecular composition which will allow us to characterize whether the nodule is malignant or benign. We believe that using this technology, we will be able to obtain better results than the current methods used to determine malignancy in the thyroid nodules.

Even though this technology is new, it is less expensive than current methods and has the potential to significantly decrease the cost of care for patients requiring thyroid nodule biopsy. Furthermore, it has the potential to eliminate the need for surgery to obtain a diagnosis of a thyroid nodule. This would eliminate the possibility of surgical complication as well as the need for lifelong thyroid hormone replacement following surgery and by doing so improve the quality of life for these patients. The test is rapid and gives results within a few minutes which is a significant improvement over current practice. Additionally, since it does not require the availability of an expert pathologist to review the cells under a microscope, the test can be offered to many more patients preventing the need for them to travel to specialized centers where only thyroid clinicians work.

This project has the potential to revolutionize the care of thyroid patients and significantly advance the field of utilization of mass spectrometry for the diagnosis of cancer. Because we are developing a new test which will be piloted here in Texas, there is significant opportunity for business development and commercialization around this technology with direct positive impact to the state. This represents a major opportunity for economic growth in addition to increasing access to care and improving the quality of life for patients with thyroid nodules and thyroid cancer.