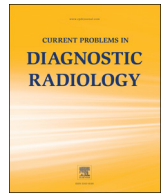




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Improving Access to Image-guided Procedures at an Integrated Rural Critical Access Hospital: Ultrasound-guided Thyroid Biopsy Program



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Purpose: Critical access hospitals face difficulty providing all services locally and may need to refer patients off-site for additional care. Providing on-site minimally invasive biopsies, may obviate visits to tertiary or quaternary care centers. This study aims to assess feasibility and outcomes of an ultrasound-guided thyroid biopsy program in a critical access hospital.

Methods: In this HIPAA compliant, IRB approved study, the Interventional Radiology (IR) database of a 19-bed, island, rural, critical access hospital without onsite pathology services affiliated with our quaternary care institution was retrospectively reviewed to identify all thyroid biopsies that were performed on site since inception of the service in April 2014 through August 2016. A specialized biopsy and specimen collection protocol was created as each specimen was transferred to and analyzed by the pathology department at our affiliated quaternary care institution.

Results: Two IR physicians carried out thyroid biopsies on 34 nodules in 29 patients during the study period. The mean age of patients was 56.5 ± 14.0 , with a range of 35–85 and 86% female, 14% male. 94.1% of nodules had adequate material for interpretation on the first biopsy and 97.1% upon repeat biopsy. Ultimately, 5 patients (with 6 nodules) underwent surgical resection at the integrated quaternary care center. Surgical resection identified one atypical follicular adenoma, one follicular variant of papillary thyroid carcinoma, two papillary carcinomas, and two Hürthle cell tumors.

Conclusion: IR thyroid biopsy services may be successfully provided in the rural setting without onsite pathology analysis and adequacy checks, enhancing patient access and streamlining care while also expanding the reach of tertiary care centers.

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Introduction

Although 25% of patients live in rural communities, only 10% of physicians practice in such settings.¹ Combined with geographic and socioeconomic barriers, access and timely delivery of health care are obstacles for a subset of Americans in rural areas.² These hospitals typically cannot offer all services and thus, transferring care to larger tertiary or quaternary centers is often necessary when more specialized medical expertise is needed.

One such specialty is interventional radiology (IR), which provides expertise in image-guided, minimally invasive procedures. These procedures continue to have a strong impact in modern medicine, and it is predicted that they are going to continue to grow because of recognized advantages in safety and cost effectiveness when compared with more traditional surgical options.^{3–6} Enabling access to basic IR services to rural and critical access hospitals (CAH) may be feasible and potentially advantageous for health care organizations, referring providers, and patients.⁶

For example, in 2016, thyroid cancer had an estimated incidence of 64,300 cases per 100,000 persons associated with approximately 1980 deaths.⁷ The prevalence of incidental thyroid nodules in adults detected by ultrasound (US) is approximately 20%–67%, by contrast enhanced computed tomography (CT) approximately 25%, by noncontrast CT and magnetic resonance imaging (MRI) of the neck nearly 16%–18%, and seen in 1%–2% of PET/CT.^{8–13} Typically, diagnosis of thyroid cancer is through US-guided, fine-needle aspiration (FNA) and thus it is an essential diagnostic tool for exclusion of underlying thyroid malignancy. However, as CAHs may not always have physicians who can perform these procedures, patients may have to travel to outside institutions (which could be far given how remote CAHs can be) to have biopsies. In addition, if repeat biopsies or additional treatments are indicated after these biopsies, repeat visits may be needed. This is inconvenient to patients, may delay care, and could cause difficulty in coordinating appropriate medical services. Ideally, a patient would have the diagnostic study and biopsy at the initial site of presentation, and only if additional treatment is required would they seek specialty medical services at a tertiary care center.

Thus, our study aims to describe the implementation and assess the feasibility of implementing an US-guided thyroid biopsy program in an isolated, island CAH, which is limited by the

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absence of on-site pathology service. In addition, we assessed the outcomes of patients who were transferred from the CAH for further evaluation postbiopsy.

Methods

Study Site

This study was performed at a 19-bed, CAH in affiliation with our 999-bed quaternary care academic and level 1 trauma center. The CAH is able to provide basic and advanced imaging services including radiography (X-ray), US, CT, and MRI. No on-site pathology interpretation services or cytotechnologist assessment are available. All imaging services are available 24/7, with the exception of MRI. This hospital is located on an island and the only transportation between the CAH and our main academic medical center is either by air or water. There is a seasonal community on the island, and thus the population ranges from 10,000–65,000 people. For purposes of payment, the hospital changed its Medicare reimbursement status to prospective payment system in 2008.

A team of radiologists travels to the hospital twice a week to perform fluoroscopic and interventional procedures. Diagnostic radiology services are sent through teleradiology to the main hospital for interpretation, thereby providing subspecialist coverage on all imaging done at the CAH.

Data Collection

This Health Insurance Portability and Accountability Act (HIPAA)-compliant study was approved by the institutional review board, including waiver of patient consent. Using our radiology reporting system, we queried patients who had thyroid biopsies from April 2014 to August 2016. We retrospectively reviewed radiology and medical records to characterize provider team, process, technical success rate, findings, and follow-up of these patients.

Specimen Collection and Transportation

Two fellowship-trained IR physicians from our institution performed all the US-guided thyroid biopsies. The transfer pathology protocols were tailored to allow for shelf-stable specimens compliant with air transportation regulations. These adjustments to the pathology protocol were developed in close partnership with the pathology department at our main institution.

The process of specimen collection and transportation was as follows. The overlying skin on every patient was prepped and draped in the usual, sterile fashion and local 1% xylocaine anesthesia was administered. Under US guidance, multiple (typically 6) fine-needle aspirates were obtained using a 25-gauge needle. Unlike standard protocols used at our main medical center, slides were spray fixed with a cytology spray fixative (Becton Dickinson Clay Adams Brand Spray-Cyte). It is noteworthy that the typical protocol used at the quaternary referral center used 100% alcohol for fixation and storage and this was not allowed due to air transportation regulations. A total of 12 slides per patient were prepared using this adjusted protocol. Additionally, a needle wash was performed with 10 mL of Cytosolv Red (Thermo Scientific: Cytosolv Red), which allowed for room temperature specimen stability. Specimens were flown to our institution within 24–72 hours depending on the day the biopsy was performed. As a general example, specimens collected on Monday were transferred on Tuesday and specimens collected on Friday were transferred on Monday. Once the quaternary hospital pathology department

received the specimens, they were analyzed per routine protocols. Molecular testing (Affirma) is not routinely used in our institution unless specially requested (typically during repeat biopsies).

Results

Patient Characteristics

A total of 29 patients underwent an US-guided thyroid biopsy from April 2014 to August 2016. Five patients had 2 nodules biopsied each. Thus, 34 nodules were biopsied and each had separate pathologic analysis. The average size of the thyroid nodule biopsied was 2.6 ± 1.3 cm.

The mean age for our study population was 56.5 ± 14.0 . The age range was 35–85 years, with 86% female and 14% male patients. A total of 14 patients (14/29; 48.2%) had thyroid nodules found incidentally on imaging (CT, MRI, or US). CT was the most common imaging modality in which incidental thyroid abnormalities were detected (11/14; 78.6%), followed by MRI (2/14; 14.3%) and US (1/14; 7.1%). One IR physician biopsied 12 (12/34; 35.2%) nodules and the other IR physician biopsied 22 (22/34; 64.7%) nodules.

Technical Success of Thyroid Biopsies

Thirty-two nodules had diagnostic results on first attempt (32/34; 94.1%). Two nodules were nondiagnostic (2/34; 5.9%) on initial attempt. Four nodules (4/34; 11.8%) underwent repeat biopsy, despite 2 of these nodules having a diagnostic result on the first biopsy. All biopsies were repeated at the integrated quaternary hospital. One nodule underwent repeat FNA and core biopsy by IR, but remained nondiagnostic on repeat biopsy. Three nodules (including 1 that was nondiagnostic) underwent repeat biopsy by the Endocrinology service and were diagnostic. Thus, on second biopsy, the diagnostic yield rose to 97.1% (33/34).

Fine-Needle Aspiration Pathology Outcomes

Based on the first biopsy results, 27/34 (79.4%) of nodules were interpreted as benign. One nodule, initially determined to be a follicular lesion of undetermined significance, was found to be benign on repeat FNA biopsy with molecular genetics testing. Thus, 28 of 34 (82.4%) of nodules were ultimately determined to be benign. In all, 1 nodule (1/34; 2.9%) was papillary thyroid cancer, 2 nodules (2/34; 5.9%) were Hürthle cell cancer, 1 nodule (1/34; 2.9%) was follicular neoplasm, and 1 nodule (1/34; 2.9%) was follicular lesions of uncertain significance.

Surgical Results

Five patients (representing 6 nodules) underwent surgery. Surgical resection identified 1 atypical follicular adenoma, 1 follicular variant of papillary thyroid carcinoma, 2 papillary carcinomas, and 2 Hürthle cell tumors. The [Figure](#) demonstrates a case example of a biopsy that results in a surgical diagnosis of papillary thyroid carcinoma.

Discussion

Critical access and rural hospitals have limitations in access to health care that often require patients to travel to larger tertiary or quaternary facilities for more specialized care. Our study demonstrates the feasibility and impact of implementation of US-guided thyroid biopsies at an island hospital without pathology services

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