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Recommendation for Thyroid Ultrasound Screening in Asymptomatic Women Aged 30 and Older

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Abstract

Background: There has been a steady rise in the incidence of thyroid cancer globally. Thyroid cancer is more common in females, has a peak incidence between 30 and 50 years of age, and is the fifth most common cancer in women in the US. Despite the increasing incidence of thyroid cancer, there are no national recommendations for routine thyroid cancer screening in asymptomatic individuals.

Methods: This study was undertaken to estimate the prevalence of undiagnosed thyroid nodules in asymptomatic women aged 30 and older, characterize newly-identified thyroid nodules on the basis of suspicion for malignancy requiring further diagnostic evaluation, and estimate the rate of malignancy in an asymptomatic population of women.

Results: From August 2022 to June 2024, 548 women age ≥30 years without pre-existing thyroid conditions underwent a screening ultrasound. Over half (n=296) were found to have a thyroid nodule ≥1cm; 85 nodules were suspicious for malignancy on ultrasound and each subject with a suspicious nodule on ultrasound underwent fine needle aspiration biopsy. 13 (2.4% of the 548 screened individuals) were found either pre-operatively or post-operatively to have a thyroid malignancy. Intra-operatively, ten individuals (80%) with a malignant nodule had no evidence of lymph node metastasis and 3 (20%) were found to have microscopic lymph node metastasis. Eight individuals (62%) required no post-surgical hormone replacement; the remaining five individuals (38%) required initiation of post-surgical thyroid replacement.

Conclusions: A community-based thyroid screening program identified a high rate of malignancies among asymptomatic individuals when compared to other indications in which screening is conventional in the general and asymptomatic population and suggests a potential role for non-invasive ultrasound to detect thyroid nodules, including thyroid malignancies, in asymptomatic women; such detection may offer an opportunity for early-stage diagnosis of malignancy when surgical treatment may be less complex and additional treatment may not be required. Implementation of a thyroid screening program may lead to less extensive surgeries, reduced requirement for thyroid hormone replacement or post-operative radioactive iodine, and better outcomes for women with thyroid malignancy.

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Introduction

Thyroid cancer is a malignancy arising from the thyroid parenchymal cells with highly variable clinical behavior, ranging from indolent, slowly progressing tumors to highly aggressive and deadly tumors. Thyroid cancer represents 1-4% of all malignancies, with Differentiated Thyroid Cancer (DTC), including Papillary Thyroid Cancer (PTC), accounting for 90-95% of thyroid cancers. Thyroid cancer is more common in females, with a preponderance of 3:1, [1] and is the fifth most common cancer in women in the United States [2]. Interestingly, autopsy reports indicate that thyroid cancer affects both men and women equally, so the preponderance may be due to differences in access to medical care and suggests that the incidence in males may indeed increase with more equal access to healthcare [3].

In the US, there are approximately 44,000 new cases of thyroid cancer diagnosed each year1 and there has been a steady rise in the incidence of thyroid cancer globally, particularly PTC, in both men and women and among all races but particularly in females. PTC is now the most common endocrine cancer, responsible for 96% of all new cases and 66.8% of deaths due to endocrine cancers [4]. In women, the peak incidence is between 30 and 50 years of age. Surgical resection remains the main treatment modality for PTC, with the extent of surgery, which may include lobectomy, complete thyroidectomy and neck dissection, dependent on disease burden. It is recommended that resection be performed by experienced thyroid surgeons to minimize recurrent laryngeal nerve injury and hypoparathyroidism. In addition to the hoarseness of voice that occurs with recurrent laryngeal nerve injury, some patients may experience respiratory failure with bilateral injuries.

Following total thyroidectomy, radioactive iodine may be indicated for ablation of normal residual thyroid tissue, as treatment if significant lymph node involvement is found on final pathology, or for known distant metastasis [5]. Thyroid hormone suppression therapy to suppress TSH and prevent any stimulation of thyroid cancer growth is recommended for most patients [6,7]. Systemic radiation and chemotherapy are rarely used in treatment of PTC, being reserved primarily for patients with more aggressive thyroid cancers. There are a number of chemotherapeutic and targeted agents used in this patient population and because of the significant adverse effects of these agents, physicians often attempt to tailor treatment based on the occurrence of specific gene mutations or signaling irregularities that are present in an individual patient's tumor if possible.

Untreated thyroid cancer can be locally invasive into the airway, esophagus and other nearby neurovascular structures and metastatic disease most commonly involves the lung, bone, and other soft tissue structures. Despite the increasing incidence of thyroid cancer, the significant incidence in asymptomatic patients, and the side effects and long-term sequelae of surgery, post-surgical treatment and systemic chemotherapy and radiotherapy, there are no national recommendations for routine thyroid cancer screening in asymptomatic individuals. Current medical guidelines emphasize screenings for other malignancies, such as breast, cervical, dermatological and colorectal cancers, leaving a gap in early thyroid carcinoma detection when early detection can significantly impact the complexity of surgical resection and its sequelae and the need for post-surgical treatment, including hormone replacement.

Given the increasing incidence of thyroid cancer and the current gap in early detection, we analyzed data from a community-based thyroid ultrasound screening program to investigate the use of non-invasive, facile thyroid ultrasound as a screening modality to detect thyroid abnormalities in asymptomatic women aged 30 and older, to estimate the rate at which identified abnormalities met criteria for further evaluation and the rate at which thyroid cancer was detected in this asymptomatic female population.

Methods & material

From August 2022 to June 2024, 638 individuals provided written informed consent for a screening thyroid ultrasound at community-wide voluntary thyroid cancer screening events across multiple sites in the Tampa, FL area. Mobile ultrasound machines were used to perform routine screening ultrasounds of the thyroid gland; one thyroid surgeon (RR) read and interpreted all of the ultrasounds throughout the screening program in an effort to eliminate variability.

Primary goals of this data analysis were to estimate the prevalence of undiagnosed thyroid nodules in asymptomatic women aged 30 and older; characterize identified thyroid nodules on the basis of border irregularity, vascularity and presence of microcalcifications; determine the prevalence of nodules assessed as suspicious for malignancy and requiring further diagnostic evaluation; and estimate the rate at which a cancerous nodule was observed in this asymptomatic population of women.

Thyroid nodules identified by screening ultrasound were evaluated on the basis of border irregularity, increased vascularity and presence of microcalcification. A nodule was considered suspicious for malignancy if it exhibited any of these features. Anyone with a suspicious nodule was offered a Fine-Needle Aspiration (FNA) biopsy per standard of care. If FNA biopsy results demonstrated the presence of malignancy or were classified as Bethesda Category 3 or higher [8], lobectomy with ipsilateral central neck dissection was recommended; further surgical interventions were guided by intra-operative pathology findings per standard of care.

Statistical Considerations This report summarizes observations from a community-based thyroid ultrasound screening program. The screening program was not prospectively developed as a research study and thus was not intentionally and prospectively designed with a statistical endpoint for demonstration of malignancy. No statistical analyses were performed.

Study Oversight The community-based screening program study was conducted under standard medical evaluation and care guidelines at the Hospital for Endocrine Surgery. The research and data analysis components of the study were carried out in accordance with the Declaration of Helsinki and the principles of Good Clinical Practice. The study was reviewed and approved by a centralized IRB and the study was conducted under established research guidelines at the Hospital for Endocrine Surgery. All participants provided written informed consent for ultrasound screening and subsequent data analysis.

Results

Derivation of Population for Analysis A total of 638 individuals (male and female) without a known thyroid nodule provided written informed consent for and underwent a screening thyroid ultrasound; all were provided or offered appropriate standard of care medical follow-up based on specific and individual findings from the ultrasound screening.

To evaluate the rate of thyroid abnormalities and thyroid malignancy in asymptomatic women aged 30 and older, a specific subset of subjects was derived from the total screened population. Specifically, males, women with a known thyroid condition including thyroiditis-related abnormalities, and women under the age of 30 were excluded from this data analysis. This resulted in an initial analysis population of 548 asymptomatic women aged 30 and older without known pre-existing thyroid nodules or disorders (Table 1). This is the population upon which data in this report, including prevalence and characterization of previously undiagnosed thyroid nodules and thyroid malignancies, is based.

Results of thyroid malignancy screening are presented in (Table 2). Among the 548 women age ≥30 years without pre-existing thyroid condition who underwent screening ultrasound, 296 were found to have a thyroid nodule ≥1cm in longest dimension; 8 individuals were found to have a thyroid nodule <1cm and were provided appropriate medical follow-up but were excluded from this analysis.

Among the 296 individuals with thyroid nodule ≥1cm, 85 nodules exhibited border irregularity, hypervascularity or microcalcifications and were assessed as suspicious for malignancy. Consistent with standard of care, each individual (n=85, 100%) with a nodule with characteristics of malignancy was offered and underwent FNA biopsy. Any individual with a Bethesda 3 or higher score on FNA was scheduled for lobectomy and ipsilateral lymph node dissection with intra-operative frozen section analysis of the lymph nodes. The surgical plan allowed for conversion to a total thyroidectomy if diffuse lymph node involvement was found during the intra-operative frozen section analysis.

Among the 85 women with an asymptomatic nodule assessed via screening ultrasound as suspicious for malignancy, 13 (2.4% of the overall analysis population; 15% of the population with nodule ≥1cm suspicious for malignancy) were found to have a pathologically-confirmed thyroid malignancy (Table 2).

Among the 13 individuals with a thyroid cancer diagnosis, 5 had a biopsy that demonstrated malignancy prior to surgery (Bethesda category 6) and the remaining 8 individuals were diagnosed during surgery with intra-operative pathology or after surgery with final pathology (Table 3). All of the malignancies were identified through pathology as papillary thyroid carcinoma.

Surgical and Post-Surgical Patient Outcomes Each of the 13 individuals with a newly-diagnosed malignancy had a lobectomy with ipsilateral lymph node dissection and intra-operative frozen section analysis with allowance for conversion to total thyroidectomy if needed based on intra-operative findings. Intra-operative frozen section analysis of the dissected ipsilateral lymph nodes revealed that 10 individuals (80%) with a malignant thyroid nodule had no evidence of malignancy in the lymph nodes and 3 (20%) were found to have microscopic lymph node metastasis (< 3 lymph nodes involved and measuring < 3mm). No patient was found to have diffuse lymph node metastasis; thus, no patient required complete thyroidectomy and no patient required post-operative radioactive iodine treatment. Eight individuals (62%) required no post-surgical hormone replacement; the remaining five individuals (38%) required post-surgical initiation of thyroid replacement medication and most likely will require this on an ongoing basis.

Table 1: Derivation of Individuals Eligible for Analysis.

Total Number of Individuals who Underwent Ultrasound Screening	**638**
Male	18 (2.83%)
Female	620 (97.2%)
Excluded from Analysis	**90 (14%)**
Male	18 (2.8%)
Female with known pre-existing thyroid condition	51 (8.0%)
Female < 30 years of age	21 (3.3%)
Initial Analysis Population[1]	**548 (86%)**
Female age ≥30 years of age without known pre-existing thyroid condition	548 (6%)

[1]The initial analysis population was composed of females, age ≥30 and without known pre-existing thyroid condition or thyroid nodule who underwent thyroid ultrasound screening.

Table 2: Results of Thyroid Malignancy Screening.

Number of individuals in initial analysis population eligible for malignancy screening[1]	548
Number with thyroid nodule ≥1cm in longest dimension	296 (54%)
Number with nodule ≥1cm suspicious for malignancy[2]	85 (16%)
Number with nodule ≥1cm suspicious for malignancy who underwent FNA biopsy	85 (16%)
Number with thyroid cancer diagnosis	13 (2.4%)[3]

[1]An eligible individual was female, age ≥30 and without known pre-existing thyroid condition or thyroid nodule as described in (Table 1).
[2]A nodule with border irregularity, hypervascularity or microcalcification was considered suspicious for malignancy
[3]All malignant nodules were papillary thyroid carcinoma.

Table 3: Malignancy Diagnoses.

Total number of malignancies diagnosed	**13**
Identified prior to surgery	5 (38%)
Identified intraoperatively or after surgery	8 (61%)
Bethesda Category	
Bethesda Category 3	1
Bethesda Category 4	3
Bethesda Category 5	4
Bethesda Category 6	5

Discussion

Papillary thyroid cancer is the fifth most common malignancy in women, with peak incidence between the ages of 30 and 50. A study of thyroid cancer incidence across 25 countries with a population of more than 2 million individuals and covered by a cancer registry indicate that not only is papillary thyroid cancer the main histological subtype of thyroid cancer in all the studied countries, it is also increasing in prevalence systematically albeit with variability across countries [9,10]. Unfortunately, papillary thyroid cancer is the subtype most likely to be found in a subclinical asymptomatic form and only detected by intentional population screening. Despite the rising incidence and the known incidence in symptomatic individuals and in contrast to other malignancies that also present in the absence of symptoms, there are no recognized guidelines for routine thyroid cancer screening.

Through a facile community-based screening program, we found that over half of 548 women age 30 and older with no known thyroid abnormalities and no symptoms of malignancy or abnormality who underwent a screening thyroid ultrasound harbored a previously unknown thyroid nodule. Importantly, ultrasound screening was able to non-invasively and easily identify nodules with established characteristics of malignancy (border irregularities, hypervascularization and/or microcalcifications), which was subsequently borne out by biopsy or subsequent surgical pathology.

Analysis of data from the screening program demonstrate a high rate of malignancies when compared to other indications in which screening is now conventional and established in the general and asymptomatic population, including breast cancer, gynecologic malignancies and prostate cancer. Only about 0.5% of women who get regular mammograms will be diagnosed with breast cancer [11,12]. Fewer than 1% of women undergoing routine pap smears will be found to have cervical cancer at the time of testing [13,14].

This analysis suggests that routine high-resolution non-invasive screening ultrasound is a facile and feasible method not only for identification of thyroid abnormalities in asymptomatic women aged 30 and older, but also for characterization of nodules suspicious for malignancy and requiring further diagnostic evaluation per standard of care. At present and in contrast to some other malignancies, there is no tumor marker or blood analyte that can be used to diagnose papillary thyroid cancer or indicate an abnormality that might require additional follow-up. In addition, most patients with an abnormality are asymptomatic; thus, a screening ultrasound may be the only way to detect papillary thyroid malignancy early in its development.

The data presented herein suggest that ultrasound-based screening may offer an opportunity for early-stage diagnosis of malignancy when surgical treatment may be less complex and adjuvant or additional treatment may not be required. Among the subjects found to have a thyroid malignancy, no subject had either diffuse lymph node involvement or lateral neck or distant metastasis at the time of surgery; thus surgical intervention was able to be limited to lobectomy and no subject required complete thyroidectomy and no subject required post-operative radioactive iodine treatment. This is particularly important as acute side effects of RAI include nausea, neck pain, lacrimal and salivary dysfunction, and altered taste and smell, while long-term side effects include secondary primary malignancy, sialoadenitis, nasolacrimal duct obstruction, and infertility [5].

The observation that all subjects with a diagnosed malignancy were able to undergo lobectomy for treatment of their disease and no patient required total thyroidectomy contrasts favorably with the typical 60-90% of patients who require total thyroidectomy [15].

The observation that among the asymptomatic individuals who were found to have papillary thyroid malignancy of ≥1cm in this screening study, only 3 (20%) had microscopic lymph node micrometastasis and none had diffuse lymph node involvement is significant when compared to a report of data from the National Cancer Database (1998 to 2012) which showed that almost 50% of subjects with localized ≥1cm papillary thyroid cancer were found to have node-positive disease [10].

Requirement for thyroid hormone replacement following lobectomy varies considerably (15-50%), with a recent long-term study with a follow-up of 7.2 years showing a 46.8% rate of thyroid hormone replacement therapy after lobectomy [16]. The finding that only 35% of participants in this screening study who were found to have a malignancy and required post-lobectomy treatment suggests that earlier intervention may result in an enhanced degree of thyroid preservation and reduce the requirement for post-surgical treatment.

In sum, this screening program suggests that facile thyroid ultrasound is capable of identifying malignancy in asymptomatic women at a disease stage sufficiently early that complete thyroidectomy and further post-operative treatment, including radioactive iodine, is avoided. A larger follow-on study will be required to confirm that earlier detection prior to symptom emergence results in a lower rate of lymph node metastasis, reduces the requirement for complete thyroidectomy and post-surgical treatment, and allows preservation of thyroid function without need for supplemental thyroid medication. Recognizing the potential financial impact of a broad screening program, a cost analysis for implementing and carrying out a thyroid ultrasound screening program in an asymptomatic population will be an important consideration that requires evaluation.

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Author Contribution Statement for each Author

Rashmi Roy: Conceptualization (lead); Methodology (lead); Data analysis (lead); Writing – original draft (lead); Writing - review and editing (lead).

Darya Bushuev: Methodology (supporting); Data analysis (supporting); Writing - review and editing (supporting)

Gary L. Clayman: Conceptualization (supporting); Methodology (supporting); Data analysis (supporting); Writing – review and editing (supporting).

Author Disclosure Statement for each Author

Rashmi Roy has no financial disclosures or conflicts to declare.

Darya Bushuev has no financial disclosures or conflicts to declare.

Gary L. Clayman has no financial disclosures or conflicts to declare.

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