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Title : The Clinical Significance and Burden of Thyroid Nodules Discovered Incidentally

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Statements and Declarations

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Abstract

Background: The majority of thyroid nodules are benign, however current guidelines suggest that thyroid incidentalomas should be appropriately evaluated to rule out malignancy.

Aims: This study aims to determine the incidence of thyroid incidentalomas and the likelihood that they harbour sinister pathology in the largest Irish cohort studied to-date.

Methods: A retrospective observational chart review was conducted using data from July 2018 - December 2018 using the Radiology Database in use at Cork University Hospital. The text of 1,000 imaging reports (500 carotid doppler and 500 computed tomography thorax) was manually screened for phrases such as “thyroid mass” or “thyroid nodule”.

Results: On 1,000 scans, 14 (1.4%) thyroid incidentalomas were discovered. The occurrence of incidentalomas by imaging was 2/500 (0.4%) for ultrasound and 12/500 (2.4%) for Computed Tomography. Three of these nodules (21.4%) were further evaluated with a subsequent ultrasound and due to a size of more than 1 cm underwent fine needle aspiration. Using the Thy classification, all three were given a Thy 2 (non-neoplastic) grading.

Conclusion: This study found that there was no clinical benefit to reporting the presence of thyroid incidentalomas incidentally noted on radiology investigations. Although the overall percentage of thyroid incidentalomas is low, this number may be enough to cause unnecessary strain on the healthcare system, and burden patients with invasive investigations in addition to causing unnecessary anxiety.

Keywords: thyroid nodules, thyroid cancer, incidentalomas,

Introduction

Thyroid incidentalomas (TI) are radiologically described thyroid masses discovered by medical imaging performed for non-thyroid indications. These nodules are generally asymptomatic and small in size (usually < 10 mm in diameter), therefore have previously avoided clinical attention (1). Thyroid nodules are a common occurrence with age. Studies suggest that by the age of 50, approximately 50% of the population have at least one nodule (2, 3). However, screening for thyroid nodules is not common practice, therefore nodules are usually discovered clinically or incidentally on radiology imaging.

While the majority of these nodules are indolent, the primary goal after discovery of a new nodule is to exclude a thyroid malignancy. Thyroid carcinoma represents a small percentage of all thyroid nodules (4-7%) leading to a clinical dilemma when making decisions about the management of an incidentaloma (4–6). Identifying clinically significant cancers among the numerous patients with incidentalomas has proven to be challenging. Currently, practice guidelines of the American Thyroid Association advise a diagnostic ultrasound of the neck and cervical lymph nodes should be performed in all patients with a suspected thyroid nodule (7). However, little research has reported the proportion of TIs that actually reveal a sinister pathology. In recent years, there has been a noticeable increase in the incidence of thyroid cancer without significant changes to mortality (8). Data from 185 countries extracted from the publicly accessible GLOBOCAN database reported incidence rates of thyroid cancer of 10·1 per 100 000 women and 3·1 per 100 000 men, with age-standardised mortality rates remaining low at 0·5 per 100 000 women and 0·3 per 100 000 men in 2020 (9). The rise in incidence is likely due to the advancements in technology, and the increased reliance on imaging (10, 11). For these reasons, it

is important to determine whether the discovery of these incidentalomas actually proves to be beneficial to the patients' health or if it subjects patients to an unnecessary burden of further investigations, resulting in increased anxiety over their health, and increased costs.

This study aims to establish the clinical significance and burden of thyroid nodules discovered incidentally on imaging by determining their incidence on carotid doppler and computed tomography (CT) thorax. The follow-up and outcome of each nodule was traced to help determine the likelihood that these nodules are of a sinister nature.

Materials and Methods

Study Population

This study was designed as a retrospective observational chart review and was conducted at Cork University Hospital (CUH), a tertiary care centre in Cork, Ireland. The study protocol was reviewed and approved by the Clinical Research Ethics Committee (CREC) at CUH. The hospital's radiology database (PACS) was used to retrieve CT thorax and carotid doppler imaging that was conducted between July 2018 to December 2018. Those under the age of 18 at the time of imaging were excluded from the study. CT thorax and carotid doppler were chosen based on their likelihood of including the thyroid. The imaging must have been conducted on the main CUH campus; satellite campuses and imported reports from other institutions were excluded.

Incidentaloma Identification

Working backwards from December 2018, the first 500 studies from both imaging modalities that fit the criteria of the study were included. This year provided relatively current data and also allowed time for further work-up of the incidentaloma to be performed in order to determine their outcome. It was critical to have a complete data set in order for this study to meet its aims and objectives.

The body and summary of each imaging report was manually screened for mentions of phrases such as “thyroid mass” or “thyroid nodule”. Imaging studies were excluded if:

1. The query section on the radiology request mentioned “thyroid”
2. The patient has a history of thyroid disease or has had a previously identified thyroid incidentaloma

Excluding these radiology studies, ensures that the results reported in the study are not skewed.

The imaging reports identified to have a suspected TI were reviewed by a Consultant Radiologist to confirm their presence.

Chart and Radiology Review

In those with confirmed TIs, the electronic records and medical charts were reviewed to gather data about the follow-up and the outcome of these nodules. In addition, each patient’s comorbidities at the time that the imaging study was conducted, were used to identify whether further follow-up of the incidentaloma was warranted. Patients with significant comorbidities like metastatic cancer were deemed as not appropriate for follow-up. The decision was made based on the relevance of an incidentaloma in the context of the patient’s overall health.

Statistical Analysis

In order to determine statistical significance, the incidence of TIs discovered on CT thorax and carotid doppler were compared using a Pearson Chi-Square test ($p=0.05$). The analysis was done using SPSS version 25. The number of thyroid nodules reported was too small to allow for further statistical testing hence the rest of the data was presented in a descriptive manner.

Results

Study Population

A 1,000 imaging studies, 500 in each group, conducted between July 2018 and December 2018 were reviewed. The population of this study was derived from adults who underwent CT thorax or carotid dopplers at CUH. Due to the differences in volume of the two imaging modalities, only a month and half was required for 500 CT thorax images whereas 6 months of imaging was required for 500 carotid dopplers.

The average age of those studied is 65.2 years old. The study had a distribution of 581 males and 419 females. The characteristics highlighted in Table 1 suggests that the study population is well randomized hence generalizable to the larger Irish population.

Incidence of Thyroid Incidentaloma

The overall incidence of TIs was found to be 1.4% (14/1000). Further broken down, the occurrence of incidentalomas on carotid doppler was 0.4% (2/500) and 2.4% (12/500) on CT Thorax. Using Pearson Chi-Square analysis, the number of TIs discovered on CT is significantly

higher than those found on carotid doppler ($p=0.05$). The average age of an individual found to have a TI was 68 years old. An equal distribution amongst men and women was seen, with 7 incidentalomas in each group. Table 2 shows the age distribution of the discovered TIs with the majority of the incidentalomas recorded in 71-80 age group.

Reporting of Thyroid Incidentaloma: body versus summary of radiology report

All 14 incidentalomas were discovered through manually screening for suggestions of thyroid nodules on the radiology report. The presence of both TIs discovered by carotid doppler were noted in the summary section, whereas only 3 of the 12 discovered by CT thorax were mentioned in the summary section; the remainder were only mentioned by the reporting radiologist in the body of the report. The summary of the imaging reports highlights the radiologist's main findings, whereas the body provides details on every area analyzed.

Follow-up of Thyroid Incidentaloma

Of the TIs discovered, 3/14 (21.4%) were investigated using a subsequent thyroid ultrasound. Figure 1 tracks all 14 discovered incidentalomas, identifying which ones were followed-up and which ones were not. In the carotid doppler group, 1/2 (50%) were further investigated. Based on the patient's medical history and size of the TIs, the other TI also warranted a follow-up.

In comparison, 2/12 (16.7%) were followed-up in the CT thorax group. This left ten TIs which did not undergo subsequent investigations. While, four of these did not warrant further follow-up, the other five did. Whether the last TI required further investigation remains unknown because the medical chart of this individual was missing for the duration of the study.

The three TIs that underwent a thyroid ultrasound were found to be ≥ 1.0 cm in size (Table 3). These three TIs were then subjected to a fine needle aspiration (FNA) investigation in accordance with the British Thyroid Association Guidelines for the Management of Thyroid Cancer (12)..

Cytology

The Thy grading of these three nodules was recorded from electronic records. All three (100%) of the followed-up incidentalomas were graded as Thy2 (non-neoplastic). According to the 2015 American Thyroid Association guidelines for managing thyroid nodules, the grading of these TIs suggests that they do not require further investigations (7).

Discussion

Our study was designed in response to current disagreements in the literature on the incidence of TIs. Using carotid doppler and CT thorax imaging conducted in 2018, we report the TI incidence to be 1.4% in the Irish population. This incidence rate is on the lower end of the spectrum reported to date. Some studies report incidence rates as low as 0.1%, while others report rates as high as 69% (2, 13). This variability can be explained by analyzing the different types of population studied.

Bahl *et al.*, reported a TI incidence of 69% by comparing the number of people undergoing surgery due to an incidental finding, to all those who underwent thyroid surgery (13). Studies conducting retrospective analysis of surgical patients tend to report higher incidence rates (14–16).

In comparison, Davies *et al.*, report an incidence rate of 0.1% after reviewing 109, 220 imaging studies for mentions of a TI in the radiology report (2). These imaging studies represent all the images taken in the hospital between June 2011 and July 2012 (2). Studies of a similar nature reported incidence rates on the lower end of the 0.1% - 69% range (2, 17, 18). The variation in results between these studies may be explained by the difference in the reporting culture seen between institutions.

While our reported incidence is lower than we expected, the data supports the results of studies with a similar methodology (2, 17, 18). In particular to our study, the lower incidence rates may be due to a recent shift in the reporting culture at CUH influenced by Guidelines from the American College of Radiologists (19). Over the last few years, members of the radiology department have informally advocated for reducing the reporting of certain incidental findings. In theory, tracking the trend of TIs discovered each year over a number of years would help in identifying whether the change in culture has had an impact on the reporting of these incidental findings.

Traditionally, it is thought that older women have the highest incidence of thyroid nodules (3). Unlike previous research, our study showed an equal distribution between the two genders. This may be explained by the fact that the number of imaging cases studied marginally favours men, hence representing a slightly larger proportion of this study's population. As expected, the majority of the TIs were seen in the older population. The 71-80 age group (Table 2) recorded the most TIs, representing 42.9% of the total TIs discovered from only 26.9% of the imaging studies conducted. In other words, this age group represents about half the TIs identified but only about a quarter of the imaging studied. In theory, the 80+ group should represent the majority of the discovered TIs. However, this group underwent the least imaging investigations

(Table 1) and, while this population is more likely to have nodules, the reduced use of imaging may lead to them remaining undetected.

When analyzing the data according to the imaging modality used to discover the TI, an incidence of 0.4% and 2.4% in the carotid doppler and CT thorax group is seen respectively. The discovery of more TIs by CT thorax imaging than by carotid doppler is comparable to the latest study published by Drake *et al.*, which reports an incidence of 0.8% using carotid doppler and 5.4% using CT thorax (18).

The difference in incidence rates is likely due to technical differences between the two modalities. CT thorax has a wider imaging field and tends to be less specific and less targeted when compared to carotid doppler. As a result, the thyroid is more likely to be captured in a CT thorax image than a carotid doppler. Secondly, when analyzing the carotid doppler, the radiologist is dependent on the images the ultrasonographer has captured. If the sonographer fails to notice and capture an incidentaloma at the time of imaging, the radiologist will never have the chance to report this nodule. In contrast, the entire imaging series for a CT thorax is available for analysis. As a result, there is a higher chance that a TI will be discovered on CT thorax than on carotid doppler.

Presence of an TI was recorded after manually reviewing the body and summary section of each radiology report. Generally, remarks made in the summary are of significant value and highlight the radiologist's main important findings. Both the TIs discovered by carotid doppler and three of the 12 found by CT thorax were noted in the summary section. The remaining nine found by CT thorax were only mentioned in the body of the report. This might explain why the 5 TIs discovered by CT which may have required follow-up, were not further evaluated. This large degree of variability in reporting is likely due to a lack of thyroid reporting guidelines for CT

thorax. The decision to emphasize the presence of an incidentaloma on CT lies with the radiologist. This decision is likely influenced by many factors including the patient's clinical picture, indication for the imaging procedure, age, and the radiologist's previous experience reporting on thyroid nodules. These concerns are not as evident using ultrasound because of existing guidelines. Therefore, it is important to develop proper guidelines for CT imaging, to provide radiologists with a systematic approach to identifying nodules that require follow-up (20, 21). These guidelines would protect patients from undergoing unnecessary investigations.

Of the 14 discovered TIs, only three underwent further follow-up. One was discovered by carotid doppler and the other two by CT thorax (Figure 1). There was no consistency in the management of these TIs. Four of them were justifiably not followed-up due to patients' comorbidities. Follow-up was required for six, but this was not conducted. Lack of standard guidelines to report thyroid nodules noted on CT may impact on the radiologist's decision to express an opinion regarding an incidental finding in the summary of the report.

Based on cytology obtained from FNA, all three investigated TIs were reported to be non-neoplastic. With this knowledge, it is clear that CT thorax tends to overcall nodules that are of little clinical significance. This further suggests that clear guidelines on reporting thyroids are required for CT imaging. Since all the nodules that underwent a complete workup were benign, and the others have not been referred for an endocrinology opinion, as would have occurred if there were adverse outcomes related to same, it may be assumed that these nodules did not cause adverse clinical consequences. As a result, it is less concerning that the six incidentalomas that required follow-up were not properly evaluated. On the contrary, the results of this study suggest that the three patients who were worked-up, were subjected to unnecessary investigations.

While an incidence of 1.4% may seem relatively low, this number extrapolated over a year would amount to ~100 TIs. There were 2 TIs found over a six month period on carotid doppler and 12 TIs found over a month and half. Assuming the incidence remains the same throughout the year, this would mean 96 TIs would have been found by CT and another 4 found by carotid doppler, making a total of 100 TIs found in 2018 using these two modalities. If all these incidentalomas were to be investigated, this could potentially add an additional 100 patients to endocrinology's caseload. Based on the outcome of our study, we would argue that this would place unnecessary strain on the department and add costs to the healthcare system with very little benefits in return. As a whole, the data from this study supports not following TIs unless they become clinically relevant. Therefore, the only management guidelines required would be to leave these incidental findings alone.

This data was obtained using the largest Irish cohort studied thus far. This provides us with important information about the Irish population and represents a population that has not been studied previously. The study reduced selection bias by reviewing imaging in a sequential manner until 1,000 studies per modality were reviewed. By choosing a random cohort of individuals, the study avoids selection bias resulting from selecting participants consulted by specific specialities.

Although the study began with a population size of a 1,000, few TIs were identified, and even fewer were worked-up. This was perhaps the biggest limitation of the study. Even though the data is well supported, the small sample size prevents the use of statistical analysis. The population size was restricted to a 1,000 because each imaging report was manually screened. Increasing the population size required us to have access to more manpower which was not feasible at the time.

Adding to the data from this study, it would be interesting to analyze incidence rates over a number of years. An upward trend would be expected as the medical field has become more reliant on imaging. This trend may be impacted by the changing attitude towards incidental findings. Being the only study of this nature conducted in Ireland, there is room for further research. A similar study using a multicentre approach would shed light on the variability of reporting TIs in different institutions while also further providing data on their incidence rates in the Irish population.

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