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Diagnostic Accuracy of Sonography in Differentiation Benign and Malignant Thyroid Nodules in Sana'a city, Yemen, 2022

(A Research Submitted To The Faculty Of Medicine & Health Sciences As Agraduation Requirement For Obtaining A Bachelor's Degree In Medicine - MBBS)

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DEDICATION

This project is dedicated to our parents who have never failed to give us financial and moral support, for meeting all our needs throughout our educational journeys and for teaching us that even the largest task can be accomplished if it is done one step at a time.

To our family members who believed in us more than we believed in ourselves. To our friends who have been of much support and encouragement until this work was successfully done.

To our first love Yemen.

To Allah before and after everything.

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LIST OF ABBREVIATIONS

AACE	American Association of Clinical Endocrinologists
ANOVA	Analysis of Variance (a statistical test)
BI-RADS	Breast imaging reporting and data system
CEUS	Contrast enhanced ultrasound
CPS	Contrast pulsed sequences
CT	Computerized Tomography
DM	Diabetes Mellitus
FNAB	Fine-needle aspiration biopsy
FN	False negative
FNC	Fine-needle cytology
FP	False positive
FTA	Follicular thyroid adenoma
FTC	Follicular thyroid carcinoma
NPV	Negative predicative values
PPV	Positive predicative values
PTC	Papillary thyroid carcinoma
SPSS	Statistical Package for the Social Sciences (a software)
T3	Triiodothyronine
T4	Thyroxin or Thoracic 4 Area
TI-RADS	Thyroid imaging reporting and data system

TP	True positive
TN	True negative
USG	Ultrasonography
USS	Ultrasound scan
WHO	World Health Organization
YER	Yemeni Rial

Abstract

Background:

The thyroid nodule is an abnormal tissue growth in the thyroid gland that results in the production of a solid or cystic mass and highly prevalent medical issue among the general public. Sonography and histopathology are universally acknowledged as the modalities of choice for comparing between benign and malignant nodules. Despite the sensitivity and specificity levels of ultrasonography in differentiating benign and malignant thyroid nodules were determined in several countries, but the diagnosis accuracy of this method is still not assessed up to our best knowledge in Yemen. Therefore, this study aimed to assess the accuracy of ultrasonography to differentiate between benign and malignant thyroid nodules.

Methods:

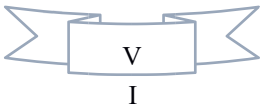
A retrospective study was conducted during October to December 2022, using secondary data of patients with thyroid nodules in 2022, were obtained from the departments of Radiology and Histopathology in two tertiary centers of Sana'a city (National Center for Public Health Laboratories & Al-Mammon center). The study sample consisted of any patients of both gender at any age with thyroid nodule (diagnosed on clinical examination by primary physician), who are referred to radiology department, for thyroid ultrasound and histopathology of thyroid nodules in 2022, has been included in the study.

Results:

A total of (112) thyroid specimens were included in this study. The Sonography could predict the malignancy with a (10%) of specimens and could predict the Benign with a (62%) of specimens, byhistopathology, only (26%) specimens was malignant, and (74%) was benign thyroid disease.The Sensitivity, Specificity, and Accuracy of ultrasonography to differentiate between benign and malignant thyroid nodules with a (38%), (83%), and (71%) respectively, the positive predictive value was (44%), while the negative predictive value (79%).

Conclusion:

Ultrasonography without histopathology can reliably distinguish benign vs malignant nodules with a (71%) of patients.



CHAPTER1

Introduction and Literature review

Introduction

The thyroid nodule is an abnormal tissue growth in the thyroid gland that results in the production of a solid or cystic mass (Tamhane & Gharib, 2016). Thyroid nodules are a highly prevalent medical issue among the general public, more common in women, the elderly, individuals who have been exposed to ionizing radiation, and people who live in iodine-deficient areas (Kant, Davis, & Verma, 2020).

Globally, thyroid nodularity affects about half of the population over the age of 40, and its prevalence ranges from 19% to 67%, it also increases with age (Dauksiene et al., 2017). The incidence of cancer differs from country to another; thyroid cancer accounts for approximately 5–15% of patients with thyroid nodules (L.-Y. Gao et al., 2017), with the highest incidence rate recorded in Korea (62.5/100,000).The Other countries with high incidence rates include the USA 13.2%, Canada 12.7%, Turkey 10.9% and Italy 10.8% (Ferlay et al., 2015; Oh et al., 2018).

In the Middle East, the other studies showed thyroid cancer with a 10.5% of patients with thyroid nodules in Jordan (Abdullah, Hajeer, Abudalu, & Sughayer, 2018) and rates of 10.4% in Saudi Arabia (AlDawish et al., 2017). In the United Arab Emirates, the prevalence was 9% among those of Emiratiorigin (Alseddeeqi et al., 2018) and 5% among those with thyroid nodules in Pakistan (Khan, Malik, Khan, & Shahzad, 2017).

In Yemen, the thyroid cancer prevalence among the patients was 13.8% during a 3 -year period from October 2016–2019, it is higher than that in the other middle eastern countries (Al-Sharafi, AlSanabani, Alboany, & Shamsher, 2020).

Sonography and fine-needle aspiration cytology (FNAC) are universally acknowledged as the modalities of choice for comparing benign and malignant nodules. FNAC is the most reliable approach for determining the presence or absence of thyroid nodules. On the other hand, FNAC is painful, requires money, and poses a danger of infection and bruising (Ardakani, Gharbali, & Mohammadi, 2015). Approximately 10–20% of fine-needle aspiration biopsies are non-diagnostic, indicating that the thyroid nodule has a high risk of cancer and that the aspiration should be repeated. As a result, ultrasonography is commonly mentioned as the preferred imaging modality for early diagnosis. Because it is a helpful, non-ionizing, cost- effective, generally available, and

easily repeatable imaging modality for the diagnosis of clinically suspected thyroid cancer, it is widely used (Wolinski, Stangierski, & Ruchala, 2017).

The Evaluation of the patient with thyroid nodule requires detailed history and imaging. The High resolutionultrasonography (USG) is the initial line investigations in clinically discovered thyroid nodules. Thyroid Imaging Recording And Data System (TI-RADS) is a risk stratification system for classifying thyroid nodules similar to BIRADS grading for breast lesions. In addition, thyroid nodules have been classified into 5 TI-RADS categories based on 5 descriptors (composition, echogenicity, shape, margin, echogenic foci/calcification). Each descriptor gives a point, adding one of all descriptors and a numerical value is calculated which gives the TI-RADS score. Sonographic findings suggestive of malignancy are solid nodules, hypoechogenicity, irregular margins, micro calcifications, and a shape taller than wide on a transverse view (L. Gao et al., 2019).

Literature Review

Clinical Assessment

Should we aske the patients about his/her age and gender in the history taking?

history of thyroidal disease for the patient and his/her family, any palpable mass or pain in the neck, presence of dysphonia, dysphagia or dyspnea, symptoms of hyper or hypothyroidism and usage of thyroid supplementation, Risk factors for malignancy in patients with thyroid nodules, History of head and neck RT, Familial cancer (medullary cancer, MEN2, papillary cancer), People younger than 14 or older than 70, Male gender, Increase in nodule size, Hard or fixed nodule, Cervical lymph nodes, Persistent dysphonia-dysphagia-dyspnea (Mitchell, Gandhi, Scott-Coombes, & Perros, 2016).

Laboratory Examination

Blood samples were obtained by venipuncture after an 8-hfastin the morning. The following factors were measured and available for analysis: triiodothyronine (T3), free triiodothyronine (FT3), thyroxine (T4), free thyroxine (FT4), thyroid-stimulating hormone (TSH), fasting blood glucose (FBG), hemoglobin A1c (HbA1c), uric acid (UA), triglycerides (TG), total cholesterol (TC), high-density lipoprotein (HDL), and low-density lipoprotein(LDL). Participants were

classified into high, normal, and low groups based on the normal ranges of these indicators (Li et al., 2021).

Diagnosis

Ultrasonography

Ultrasonography has been used as primary imaging modality in the evaluation of thyroid nodules since its first use and its use has increased steadily (Baser et al., 2017) to detection and assessment of nodules he characterization of the nodules should be noted with careful and emphatic attention to detailing the dominant nodule properties. The features to be assessed in the presence of a nodule: Echogenicity (iso-hypo-hyper), halo (thin ,thick [>2 mm], absent, disrupted), calcification (macro-amorphous, micro, eggshell-disrupted or undisrupted) capsular proximity, shape-contour (oval-circular, taller of wider), content (solid or cystic), margins (regular, irregular, microlobulated, spiculated), vascularization (absent, peripheral, central, mixed) (Sturgeon, Yang, & Elaraj, 2016).

Thyroid Nodule FNA Biopsy and Cytological Evaluation

Fine-needle aspiration cytology is the next step in the triage of a thyroid nodule. It should be reserved for lesions found to be sufficiently suspicious on the basis of US and clinical findings. The results play a key role in optimizing subsequent management. The Bethesda System for Reporting Thyroid Cytopathology (BSRTC) was discussed in 2007 by a panel of experts at the U.S. National Institutes of Health in Bethesda, MD. The first edition of the system was published in 2010, and an updated version followed in 2018 (Cibas & Ali, 2017).

The robust diagnostic framework provided by the BSRTC offers valuable guidance in developing management strategies for patients with thyroid nodules (Baloch & LiVolsi, 2020). Nonetheless, several potential diagnostic pitfalls exist that can lead to false-positive, falsenegative, nondiagnostic, or indeterminate results (Rossi, Adeniran, & Faquin, 2019). Cytology itself has limitations: it cannot, for example, distinguish between follicular-patterned hyperplastic/adenomatoid nodules, follicular adenomas, follicular carcinoma, and some cases of follicular variants of papillary thyroid carcinoma. Thyroid cytology can be considered only a screening test for these follicular-patterned lesions, the results of which will almost invariably reported as “indeterminate,” that is, assigned to Bethesda class III (“atypia of undetermined

significance" or "follicular lesions of undetermined significance") or IV ("follicular neoplasm or suspicious for a follicular [or Hürthle cell] neoplasm"). For most papillary thyroid cancers, as well as medullary, poorly differentiated, and undifferentiated carcinomas, the cytology report will usually be unambiguously diagnostic (Bethesda class VI, malignant), whereas some degree of uncertainty persists for nodules assigned to Bethesda class V (suspicious for malignancy) nodules, which is associated with a very broad range of malignancy risks (Baloch & LiVolsi, 2020).

MRI and PET/CT

Sectional examinations should generally be preferred in cases where sonographic orientation is impossible such as giant nodular enlargement in the thyroid gland, extension into the mediastinum or local soft tissue invasion. Regardless of an extra criterion, the malignancy potential of a node in the centimetric level seen on tomography was described as 11%. CT can also demonstrate calcifications, irregular contour, invasion and associated lymphadenopathies better than US PET/CT is not preferred in the management of thyroid neoplasms, although it can be used as the primary evaluation in cases where the tumor is too undifferentiated to uptake radioiodine. PET/CT is usually involved in thyroid imaging when it demonstrates diffuse or focal uptake in thyroid in examinations done for another cause. While the diffuse involvement of parenchymal is (correlating with TSH and T3-T4 values) interpreted in favor of dysfunction, malignancy risk is up to 40% in focal uptake. The risk of malignancy increases especially in case of a SUV max value greater than 5.5. Combining the grey-scale, Doppler window and recently elastographic properties in sonography, these nodules are managed successfully with follow-up, biopsy or surgery (Eren et al., 2016).

Radioisotope Imaging

Thyroid scintigraphy with either iodine-(123) or technetium-99m-pertechnetate remains the standard method to assess whether a nodule is autonomously functioning, and therefore whether nodules require further diagnostic evaluation. The use of technetium(99m)MIBI scintigraphy is supported by robust clinical data as a second line procedure for the prediction of malignancy in cold nodules with indeterminate fine-needle cytologies, and the inclusion of this imaging method in future versions of clinical guidelines may require consideration. Fluorine-18-FDG-PET/CT

studies present controversial results in differentiating benign from malignant lesions in cytologically indeterminate thyroid nodules, and deserves further investigation (Rager et al., 2019).

Molecular Testing

Identifying patients with asymptomatic benign thyroid nodules or small and low-risk thyroid cancer, in whom thyroid surgery is likely not beneficial, is critical (Ospina, Iñiguez-Ariza, & Castro, 2020). Indeterminate cytology is usually evident in approximately 15–30% of thyroid nodules (Paschke et al., 2017). Further evaluation with molecular testing can help refine thyroid cancer risk in these nodules and provide additional guidance in personalizing management in some instances (Ospina et al., 2020; Sauter et al., 2019).

Management

Benign Nodules

Benign thyroid nodules requiring treatment are rare. The most common are hyper functioning nodules and whose growth is associated with compression of vital structures like the trachea or esophagus, general neck discomfort, and/or cosmetic problems—all of which can negatively impact quality of life. Surgery is an option in these cases, but there are also several nonsurgical, minimally invasive alternatives. These include US-guided ablation procedures involving percutaneous ethanol injection (the traditional method and currently the least expensive) or the application of heat in the form of laser, Radiofrequency, High-intensity Focused US, or Microwave Energy. Radiofrequency and laser ablations can significantly reduce nodule volumes, these techniques differ in terms of their indications, adverse effects, and associated costs. Hyperfunctioning nodules can also be treated with radioiodine (Trimboli et al., 2020).

High-intensity focused US is a newer needle-free technique that is producing promising results (Lang, Woo, & Chiu, 2017), but it requires further clinical validation. More evidence and experience are also needed before microwave ablation is used on a large-scale basis. The use of these techniques for the treatment for symptomatic benign nodules has been addressed by several groups of experts (Dobnig et al., 2020; Papini et al., 2019). In general, consensus statements by these groups list US-guided aspiration as the first-line treatment for cystic or predominantly cystic nodules. Ethanol injection can be used for recurrences, and thermal ablation techniques

are reserved for cases in which symptoms persist after ethanol. Thermal ablation can be used for nodules that are predominantly solid and/or growing, but only after the benign nature of the lesion has been confirmed with 2 serial FNABs and serum calcitonin assessment. For nodules with lower risk features on US or autonomously functioning lesions, a single aspirate with benign cytology is sufficient (J.-h. Kim et al., 2018). The clinical and US-based follow-up of benign nodules that undergo treatment require expert clinical and US evaluation, because the morphologic features may change over time. If regrowth occurs, a new cytological assessment is indicated.

When surgery is indicated, decisions on the extent of resection will depend on multiple factors, including symptoms, the presence of contralateral nodules, thyroid functional status, comorbidities, family history, surgical risk, and patient preferences (Patel et al., 2020). Common reasons for surgery are large goiters, local compressive symptoms or progressive nodule or thyroid enlargement, or large toxic multinodular goiters. In most patients with multiple nodules, both lobes of the gland are involved and total thyroidectomy is necessary. Consensus is lacking in the procedure of choice for patients with an asymmetric nodular goiter. In some cases, lobectomy can be considered as a safer alternative to total thyroidectomy. However, it requires long-term follow-up, is associated with nodule recurrence risk (Zatelli et al., 2018), and may subsequently require a second operation (Barczyński & Stopa-Barczyńska, 2019)**.**

Indeterminate and Suspicious Nodules

For cytologically indeterminate nodules that cannot be molecularly classified as benign, lobectomy with isthmusectomy is generally the procedure of choice. However, thyroidectomy may be indicated in patients with larger indeterminate nodules (≥3-4 cm), nodules displaying progressive growth and/or worrisome features on ultrasound, or a family history of thyroid cancer or radiation exposure, Lobectomy and isthmusectomy (or rarely an isthmusectomy alone) is usually the least extensive procedure that can be considered when malignancy is suspected (Patel et al., 2020).

Furthermore, 50% to 80% of the patients ,who undergo lobectomy, do not require thyroid hormone replacement therapy (the likelihood varies according to the preoperative TSH level and the presence of thyroid autoimmunity) (Barczyński & Stopa-Barczyńska, 2019; Zatelli et al.,

2018). Minimally invasive US-guided ablation techniques are also being prolapsed by some groups for nonsurgical treatment of small suspicious nodules (Zhang et al., 2020).

Previous Studies

There are several studies have been performed using high frequency ultrasonography to determine suspicious features of malignant TN like taller than wider in shape, microcalcifications, solid texture, central vascularity, hypoechogenicity, and irregular margin (Koike et al., 2001).

A study was performed in Japan concluded that they can predict malignancy of nonfollicular neoplasms of the thyroid by using multiple logistic regression analysis based on only 5 features: margin, shape, echo structure, echogenicity, and calcification. (Koike et al., 2001).

On the other hand, A study was conducted in Korea proved that the diagnostic accuracy of USG criteria is dependent on tumor size which is statistically significant (P<.05), findings of malignancy were a taller-than-wide shape (sensitivity, 40.0%; specificity, 91.4%), a spiculated margin (sensitivity, 48.3%; specificity, 91.8%), marked hypoechogenicity (sensitivity, 41.4%; specificity, 92.2%), micro calcification (sensitivity, 44.2%; specificity, 90.8%), and macro calcification (sensitivity, 9.7%; specificity, 96.1%). The USG findings for benign nodules were isoechogenicity (sensitivity, 56.6%; specificity, 88.1%; P<.001) and a spongiform appearance (sensitivity, 10.4%; specificity, 99.7%; P< 001). The presence of at least one malignant USG finding had a sensitivity of 83.3%, a specificity of 74.0%, and a diagnostic accuracy of 78.0%. For thyroid nodules with a diameter of 1 cm or less, the sensitivity of micro calcifications was lower than that in larger nodules (36.6%vs 51.4%, P<.05) (Moon et al., 2008).

In addition, another study was conducted in Karachi Pakistan, it concluded that the USG have a high diagnostic accuracy in detecting malignancy in thyroid nodules on basis of features like echogenicity, margins, micro calcifications and shape. Radiologists , must be familiar with these signs on ultrasound that aid to distinguish benign from malignant thyroid nodules and thus avoiding unnecessary FNAC (Alam et al., 2014).

Furthermore, In Alexandria, Egypt, another study proved that the Ultrasonography is a very essential sensitive tool in detection of thyroid nodule type, especially if it is done by wellexperienced radiologist. The sensitivity of ultrasound in detecting different types of thyroid

nodules was 100%, with specificity 94.12% and accuracy 96% (Youssef, Abd-Elmonem, Ghazy, El Shafei, & Zahran, 2020).

Another study resulted that the overall accuracy for classification into discrete histopathological categories by expert ultrasound was 71.3% and Cohen's Kappa was 0.62. The sensitivity and specificity for detecting malignancy were 97.3% and 78.1%. The diagnostic accuracy for malignancy was 85.1%. ACR-TI-RADS scores for the same nodules had a sensitivity of 97.3%, specificity of 26.6%, and accuracy of 52.5% (Håskjold, Foshaug, Iversen, Kjøren, & Brun, 2021).

Study in India found that the USG and FNAC are equally sensitive in diagnosing malignant thyroid nodule but FNA is more specific (90%). It's a minimally invasive method which can be used to distinguish malignant from benign lesions with a high degree of accuracy (85%). In patient having high risk feature on USG, a benign cytology needs to be repeat FNAC and they should undergo surgical biopsy for confirmation (De et al., 2020).

Dedicated expert high-resolution ultrasound without FNC can reliably distinguish benign vs malignant nodules, but also differentiate between several histopathological entities in thyroid nodules. There is potential for a reduction in the number of invasive FNC biopsies. Despite the sensitivity and specificity levels of ultrasonography in differentiating benign and malignant thyroid nodules were determined in several countries, but the diagnosis accuracy of this method is still not assessed up to our best knowledge in Yemen. Therefore, this study will be carried out with the aim of getting results that will help better understanding of the diagnosis of thyroid malignancy as well as assist clinical decision-making.

Study Objectives

General objectives

The main goal of this study is to assess the accuracy of ultrasonography to differentiate between benign and malignant thyroid nodules.

Specific objectives

- Describing the thyroid nodules characteristics according to age, sex, resident.
- Determing the sensitivity and specificity of sonography in diagnosis of thyroid nodules.
- Calculating the PPV and NPV for the probability of a patient having or not thyroid malignancy.

CHAPTER2

Materials and Methods

Study Design

A retrospective study was conducted during October to December 2022 by using secondary data of patients with thyroid nodules in the year of 2022 .Which were obtained from the departments of Radiology and Histopathology in two tertiary centers of Sana'a city (National Center for Public Health Laboratories & Al-Mammon center).

Study Population

In this study, all patients who referred to radiology department for thyroid ultrasound and histopathology of thyroid nodules in 2022 were considered as the study population.

Inclusion Criteria:

Patients of both genders at any age with thyroid nodule (who were diagnosed on clinical examination by primary physician) were referred to radiology department for thyroid ultrasound and histopathology in 2022 have been included in this study.

Exclusion Criteria:

Patients with indeterminate, non-diagnostic, suspicious finding in USG, Histopathology, receiving radioactive iodine and reports dated other than 2022 or any history of thyroid surgery have been excluded from this study.

Sampling and Sample Size

Exhaustive sampling methods have been used in this study where all patients with thyroid nodules at the two centers of Sana'a city met the inclusion criteria during the period of 2022 has been included in this study.

Data Collection and Management:

The sources of data for this study are health facility registers, patient fills. Then training manual and trainer guide have been developed for data collectors. Training has been given to data collectors and their supervisors on the data collection tools, ethical issues, assurance of data quality and how to deal with challenges that may appear during data collection process and team work. After the training the collectors will test the tools of data collection (from registers). The supervisors will oversee the data collection process in both the pretesting and actual data collection time. They also give on- the-spot corrections and feedback for the data collectors to ensure the quality of the data.

They also collect the filled checklists on daily basis and check for its completeness, consistency, and quality.

USG Image Analysis:

If one or more of the following sonographic traits are observed on a thyroid nodule, it will be termed positive on USG or malignant-micro calcification (less than 2mm) hyperechoic Foci. Micro-lobulation is defined as the presence of several small lobules on a nodule's surface or uneven edges. Hypo-echogenicity is defined as a reduction in echogenicity as compared to the surrounding neck muscle. Shape is defined as a nodule that is taller than it is wide (E.-K. Kim et al., 2002). A thyroid nodule is considered True positive (TP), i.e. malignancy detected, when specimens showed atypical cytological cells (nuclei crowded, overlapping, enlarged and pleomorphic) a thyroid nodule is considered True negative (TN), i.e. malignancy not established, when specimens did not show cytological atypical cells (nuclei crowded, overlapping, enlarged and pleomorphic) (Yunus & Ahmed, 2010). When ultrasonography findings are suggestive of malignancy, a thyroid nodule is considered false positive (FP). However, when there are no cytological abnormal cells in the specimen, a thyroid nodule is showed as benign on ultrasound

it is dubbed false negative (FN). When a nodule is identified as malignant on ultrasonography, positive predictive values (PPV) are calculated to evaluate the likelihood of a patient to have thyroid cancer. Similarly, negative predictive values (NPV) are determined to determine the percentage of patients who do not have malignancy among all those who have a benign on ultrasonography report. The proportion of correctly identified subjects (patients with thyroid malignancy, TP+TN, and patients with benign thyroid nodules, TP+TN) among all subjects (TP+TN+FP+FN) will be computed. All USG were carried out by radiologist specialists.
The TIRADS score was used to create the ultrasound report. Benign (No FNA), Not Suspicious (No FNA), Mildly Suspicious (FNA if 2.5 cm and followup if 1.5 cm), Moderately Suspicious (FNA if 1.5 cm and followup if 1 cm), and Extremely Suspicious (FNA if 1 cm and follow-up if 0.5 cm).

For that TI-RADS < 3 was considered as benign and TI-RADS >4 as malignant according to the following categories which were established:

• TI-RADS 1: normal thyroid gland.

• TI-RADS 2: benign conditions (0% malignancy).

• TI-RADS 3: probably benign nodules (<5% malignancy).

• TI-RADS 4: suspicious nodules (5–80% malignancy rate).

• TI-RADS 5: probably malignant nodules (malignancy 80%).

Data Analysis:

The data has been entered and analyzed by SPSS. Categorical variables such as sex and thyroid nodule malignancy, descriptive analysis calculate the frequencies and the percentages. The following parameters have been calculated: sensitivity, specificity, positive predictive value (PPV), and negativepredictive value (NPV). In addition, each feature's diagnostic accuracy has been provided. With histopathology as a reference, the diagnostic accuracy of ultrasound in detecting malignancy of thyroid nodules also has been calculated. Probability ratios also has been calculated and provided.

Ethical Consideration

✓ Ethical clearance to conduct the study will be obtained from the institutional ethics review committee of the Faculty of Medicine, University of 21September. Then, the consent will be obtained from the health facilities where data will be collected. There will be no interventionor manipulation of variables, results of reports or files and patient decisions. ✓ As researchers, honesty will be kept because collecting objective data in a socially responsible way is basic to scientific research.

CHAPTER3

Results

Results

One hundred and twelve patients with thyroid swelling have been included in the analysis of the present study. Table 3.1 shows the distribution of patients according to demographic characteristics (sex, age groups and residence) in this study population. In the current study, 82% of patients (n = 92) were female, and 18% were male (n = 20). The mean age of the patients was 38 years. However, more patients were in age groups of less than 35 years and 35-45 years (37%) and 26% were in the age group of over 45 years. 63% of cases were from Sana'a Governorate, followed by Ibb Governorate (11%).

Table 3.1: Distribution of studied cases according to demographic characteristics, Sana'a city- Yemen, 2022 (n=112).

Variables	No.	%
Gender		
Male	20	18
Female	92	82
Age		
Less than 35 years	42	37
35-45	41	37
Over 45 years	29	26
Residency		
Sana'a	70	63
Ibb	12	11
Taiz	7	6
Al-Mahwit	7	6
Dhamar	7	6
Hajjah	5	4
Hodeidah	2	2
Saada	1	1
Hadramout	1	1

Table 3.2 shows that there is no statistically significant relationship between ultrasonography and histopathologic as diagnostic methods, as the value of the X2 Chi-square test was (4.151) and the P-value was (0.386), which is greater than (0.05), edict (32) specimens. By histopathology, only (29) specimens were malignant, and (83) were benign thyroid disease. (Figure 1).

Table 3.2: The Relation between histopathology and TI-RADS Grade, Sana'a city- Yemen, 2022 (n=112).

	Histopathology			
TI-RADS Grade	**Benign (n = 83)**	**Malignant (n = 29)**	$\chi 2$	P-value

	No.	%	No.	%		
TI-RADS 1 n=(33)	**26**	**31.3%**	**7**	**24.1%**	**7.304a**	**0.12**
TI-RADS 2 n=(32)	**27**	**32.5%**	**5**	**17.2%**		
TI-RADS 3 n=(22)	**16**	**19.3%**	**6**	**20.7%**		
TI-RADS 4 n=(18)	**11**	**13.3%**	**7**	**24.1%**		
TI-RADS 5 n=(7)	**3**	**3.6%**	**4**	**13.8%**		

X2 Chi-square test, p value for comparing between the studied groups

[a] Statistically not significant at p ≤ 0.05

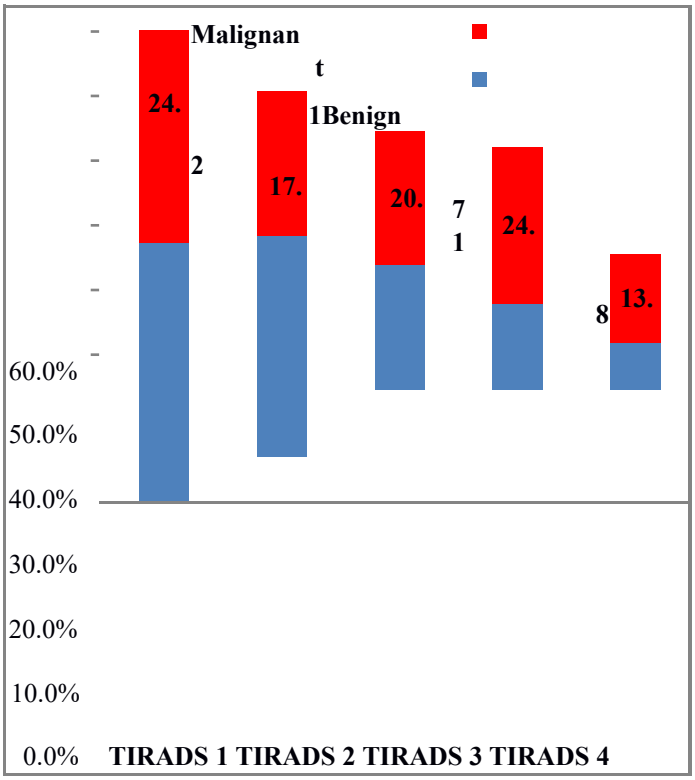


Figure 3.1: Distribution of TI-RADS ultrasound classification.

Table 3.3. indicates that the sensitivity of ultrasound in detecting thyroid nodules was (38%), with specificity (83%) and Accuracy (71%). The positive predictive value was (44%), and the negative predictive value was (79%).

The results of ultrasound decision in relation to the histopathology results were statistically significant at (p ≤ 0.05), wherethevalueof theChi-squaretest was(5.499) and theP-value was (0.02), Also the value of the ROC curve (0.61) (Figure 3.2).

Table 3.3: Sensitivity and Specificity for Ultrasound Decision in relation to the Histopathological results, Sana'a city- Yemen, 2022.

Ultrasound decision	Histopathology				Sensitivity	Specificity	PPV	NPV	Accuracy	ROC curve	P value	χ^2
	Benign (n = 83)		Malignant (n = 29)									
	No.	%	No.	%								
Non-suspicious	69	83.1%	18	62.1%	38%	83%	44%	79%	71%	0.61	0.02	5.499
Suspicious	14	16.9%	11	37.9%								

PPV positive predictive value, NPV negative predictive value, X2 chi-square test, p value for comparing between the statistically significant at p ≤ 0.05studiedgroups.

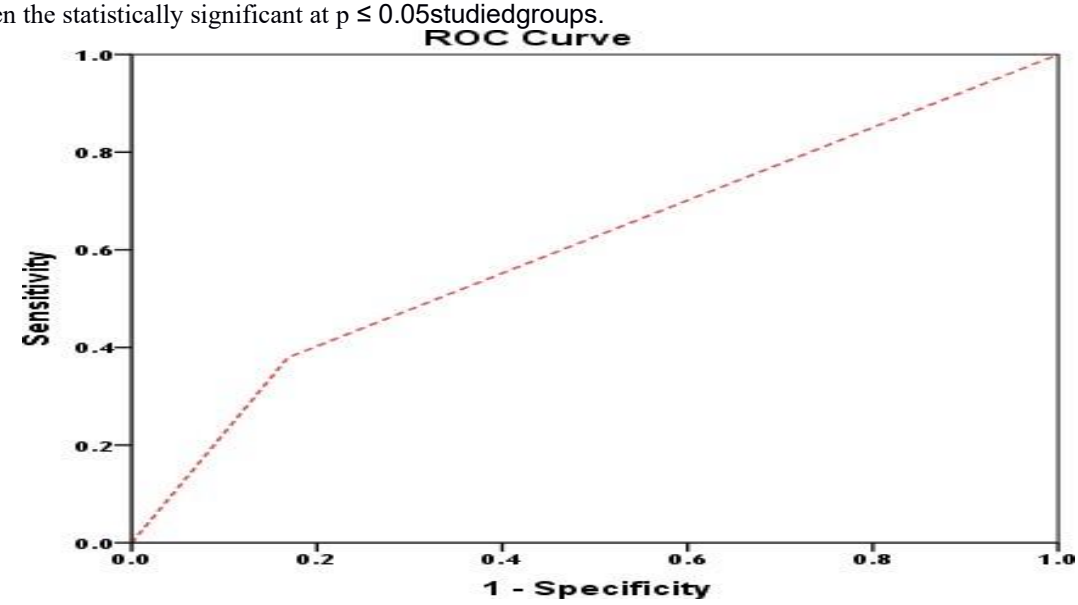


Figure 3.2: Distribution of ROC curve Sensitivity and specificity.

The results indicate that the level of agreement of ultrasound in detecting of thyroid nodules compared to histopathology was Fair, where Similar Ultrasound decision results compared to histopathology in (71%) of studied cases, while results of ultrasound accuracy differ from histopathology in (29%) of studied cases. Also the value of the KAPPA coefficient (0.221), Pvalue (0.02), were statistically significant at (p ≤ 0.05).This confirms that the level of agreement was Fair (Table 3. 4).

Table 3.4: Distribution of the Studied Cases According to Measure of The Final Agreement Results, Sana'a city- Yemen, 2022. (n = 112).

Measure of Agreement	No.	%	KAPPA coefficient	P-value	Level of Agreement
Similar Ultrasound decision results compared to histopathology	**80**	**71%**	**0.221**	**0.02**	**Fair**
Results of ultrasound accuracy differ from histopathology	**32**	**29%**			

KAPPA Agreement test, p value for comparing between the studied groups [a]

Statistically significant at $p \leq 0.05$

CHAPTER4

Discussion

Discussion

In evaluating thyroid nodules, the accuracy of USG was analyzed in diagnosis of thyroid nodules in predicting benign and malignancy depending on TI-RADS LEVEL results from level 1-5 and these results were compared with histopathology results. So all USG were performed by Radiologists who were trained in the field. Ultrasound report was prepared according to the TIRADS Score. TI-RADS 1: Benign, TI-RADS 2: Not Suspicious, TI-RADS 3: Mildly Suspicious TI-RADS 4: Moderately Suspicious, and TI-RADS 5: Highly Suspicious.

In our study thyroid nodules were commonly seen in females compared to males, suggestive of female predominance and was almost 82.1% of total study population while males were 18%. In the current study the number of cases were reported were aged less than 35 years the group was (42 case,38%), followed by ages between 35-45 years (41 cases, 37%) and over 45 years the group was (29 case, 26%).

From (112) thyroid specimens, the Sonography could predict the malignancy in (11) specimens and could predict the benign in (69) specimens, by histopathology, only (29) specimens were malignant, and (83) were benign thyroid diseases. The Sensitivity of ultrasound in detecting of thyroid nodules was (38%), with Specificity (83%) and Accuracy (71%), The positive predictive value was (44%), and the negative predictive value was (79%).

The Similar Ultrasound decision results compared to Histopathology in (71%) of studied cases, while Results of Ultrasound accuracy differ from Histopathology in (29%) of studied cases.

In one study conducted in India (De et al., 2020), revealed that TIRAD was sensitive in 80 % of cases and accurate in 61 % of case which contradicts with our study in which sensitivity was 38% and accuracy was 71% . In this study, TIRAD was slightly less specific in detecting malignant thyroid nodule in 47% of case in comparison with our study with specificity of 83%. Also in this study the PP and NP value was 51%, and 77% respectively, while in our study was 44% and 79%

respectively.

Other study was done in Norway (Alam et al., 2014), the result was as (ACR-TI-RADS) the scores of USG for the nodules had a sensitivity of 97.3%, specificity of 26.6%, and accuracy of 52.5%) in comparison with our study which revealed 38% sensitivity, 83% specificity and 71% accuracy. With slight agreement in accuracy and variation in sensitivity and specificity.

Also there is study for 50 cases in Egypt (Youssef et al., 2020) revealed that USG sensitivity, specificity and accuracy was 100%, 94%, 96% respectively.

There is difference in the results between previous study and our study especially in the sensitivity which was 80-100% in previous studies while was 38% in our study and there is agreement in the specificity of previous studies 27-94% in comparison with 83% in our study. Also between the accuracy 52-96% in previous studies with 71% in our study. The different which happen may be due to lack of information obtained from the USG reports, where some doctors wrote reports inadequately which made it difficult to USG to interpret the result of TIRADS level. In all of previous studies, there is agreement with our study in the age of the cases which was predominantlybetween 20-40 years with female predominance which represented 7086 % of cases. Our data shows that thyroid ultrasound alone without histopathology can have a high diagnostic value when performed by an expert. The results show the potential of thyroid ultrasound to help avoid invasive FNC and reduce the number of diagnostic thyroidectomies. So, the Sonography is a very essential tool in detection of thyroid nodule type, especially if it is done by well-experienced radiologist.

CHAPTER5

Conclusion and Recommendations

Conclusion

Ultrasonography has a good diagnostic accuracy in detecting malignancy in thyroid nodules. It is a very essential sensitive tool in detection of thyroid nodule type, especially if it is done by well-experienced radiologist.

Recommendations

- USG has a paramount importance in the successful management of thyroid nodules.
- Radiologists' must be familiar with signs on ultrasound that aid to distinguish benign from malignant thyroid nodules and thus avoiding unnecessary FNAC.
- It is recommended that every facility which uses Ultrasound for imaging of the thyroid must apply the TI-RAD Standards Criteria as guidelines in the final reports ofthe radiology.
- It should be considered that the Ministry of Public Health and Population is responsible to ensure that a standardized guideline must be applied as it is the reference of most different medical disciplines
- The TI-RADS classification allows for a better selection of nodules submitted to Histopathology, thus avoiding unnecessary procedures.

Limitations

- In most cases, their files were not complete, and this is one of the biggest obstacles that we faced, as it resulted-in lack of information obtained from ultrasonography reports, waste of time and effort.
- Non-compliance with internationally recognized standards, so the reports were not described according to the standard criteria as TI-RADS level and they were writing some reports without benefiting from it.
- The reports of the samples were not sufficient and contain a significant lack of information, details, criteria, and diagnosis of the thyroid nodules due to randomness and lack of adherence to a unified global scale.

CHAPTER6

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Appendixes

Appendix (1): Data Collection form

Diagnostic Accuracy of Sonography in Differentiating Benign and Malignant Thyroid Nodules in Sana'a city, Yemen, 2022 **Personal Data: -**

Name

Age …….

Sex ○ **Male** ○ **Female**

Marital state ○ **Single** ○ **Married** ○ **Widowed** ○ **Divorce**

Place & ○ **Urban** ○ **Rural**

Address ○ **Occupation……..**

Habit ○ **Chewing qat** ○ **Smoking** ○ **Other……**

Hospital ○ **Althawra** ○ **Algomhori** ○ **Alkwite** **Other……**

Ultrasonography finding: -

Number of nodule ○ **Absent**

○

Nodule types ○ **Smooth**

Echogenicity status

○ **Anechoic** ○ **Hypoechogenicity** ○

Nodule edge status ○ **Regular**

○

Nodule Size ○ **Normal**

○

Nodule shape

○ **Normal** ○ **Round** ○ **Oval**

Single ○ Multi

Solid Partiallycystic ○ Cystic ○ Mixed

Hyperechogenicity ○ Isoechogenicity ○ Hypoisoechogenicity

Irregular ○ Microlobulated ○ Infiltrative

Calcification ○ Absent ○

Smallerthan1cm ○ Larger than1cm

○○

Widerthantaller Taller thanwider ○ Smaller than wider

Microcalcification ○ Macrocalcification

2
6

Cervical lymph node ○ Normal Invasion ○ Absent ○ Enlarged

Vascularity ○ Absent ○

Central vascularity ○ Peripheral vascularity ○ Mixed

Present

TI-RADS LEVEL :-

……

…….....

.....

Histopathology Finding :

○ Insufficient	○ cellularityObscuring	○ bloodAbundant colloid
○ Sparely cellularMild	○ nuclear	○ changesHypercellular
○ CrowdinScant	○ colloidPapillary clusters	○
○ Follicular	○ clustersDefinitive nuclear	○ changesPsammoma body
○ Nuclear atypiaCell	○ hyperplasiaCystic	○ degeneration
○ Cellular	○ hemorrhageCellular	○ fibrosisCellular necrosis
○ Capsular	○ invasionVascular	○ invasionNuclear clearing
○ Nuclear	○ grooveScattered	○ groupsHyperchromatic cells
○ Polymorphic	○ CellsOthers:……..	

Note:……

Data Collector:

……

إستمارة **جمع** البيانات

الدقة التشخيصية **للتصوير** بالموجات فوق الصوتية **في** التفريق **بين** عقيدات الغدة الدرقية الحميدة والخبيثة**مدينة في**صنعاء، اليمن**2022**،

البيانات الشخصية:-

الاسم :-.....العمر :-.....

الجنس:- ◯ ذكر ◯أنثى .

الحالة الاجتماعية:- ◯عازب /ه. ◯ متزوج /ه. ◯ أرمل /ه. ◯ **/ مطلق** ه.

◯ مكان الإقامة :- ريف . **حضر** ◯ . المهنة . :-.....

العادات:- ◯ **/ مدخن**ه . ◯**مضغ** القات. آخر .....

المستشفى:-**مركز** ◯ ◯المختبر المركزي آخر ..... المأمون. .

ظهور الموجات فوق الصوتية:-

عدد العقيدات:- ◯ ◯متعدد . **يوجد لا** ◯ واحد. .

تركيبالعقيدات:-

صلبة ◯او.**تقريبا بالكامل صلبة** ◯ **كيسي** ◯او **بالكامل كيسي** ◯ . **مختلط**أسفنجية.

. **تقريبا حالة**الصدى:-

عديم ◯الصدى ◯. **نقص** ◯زيادة الصدى. ◯ **ناقص**الصدى جداً. الصدئ .

الحواف:-**غير**واضح. ◯ ◯

◯

ى

م

تد

خ

◯

. ناعم◯ . منتظم غير . مفصص

حجم العقيدات:- ◯اعرض من ◯اطول. عرضة من الاطوال.

ش ك ◯ ◯ ◯بيضاوي.
طبيعي. دائري .

ا ل ع ق ى دا ت ت - : (◯

ال ت ك ل س - :)

. لايوجد ◯. ◯التكلس ◯التكلس الكبير. التكلس المحيطي(الحافة.) ◯في نقطة الجزئي .

بؤرة الصدى .

◯ ◯ طبيع ي. . متوسعة ◯

العقدة الليمفاوية لعنقية:-

2^{1}_{28}

الأوعية الدموية :-

◯أوعية دموية طرفية . ◯أوعية دموية مركزية . ◯ أوعية دموية مختلطة . ◯لا يوجد.

درجة ال (TI-RADS).....

ظهور التحليل النسيجي :-

○ خلوية غير كافية . ○ التعتيم على الدم . ○ غروانية وفيرة . ○ نادر الخلوي .

○ تغيرات نووية معتدلة . ○ زيادة الخلايا . ○ الحشد في غروانية ضئلية .

○ العناقيد الحليمية . ○ مجموعات مسامي . ○ تغيرات نووية حاسمة .

○ جسم ساموما . ○ النمطية نووية . ○ تضخم الخلايا . ○ التنكس الكيسي .

○ نزيف خلوي . ○ تليف خلوي . ○ نخر خلوي . ○ غزو المحفظة .

○ غزو الأوعية الدموية . ○ المقاصة النووية . ○ الأخدود النووي .

○ مجموعات متفرقة . ○ خلايا مفرطة اللون . ○ خلايا متعددة الإشكال . ○ آخرى .

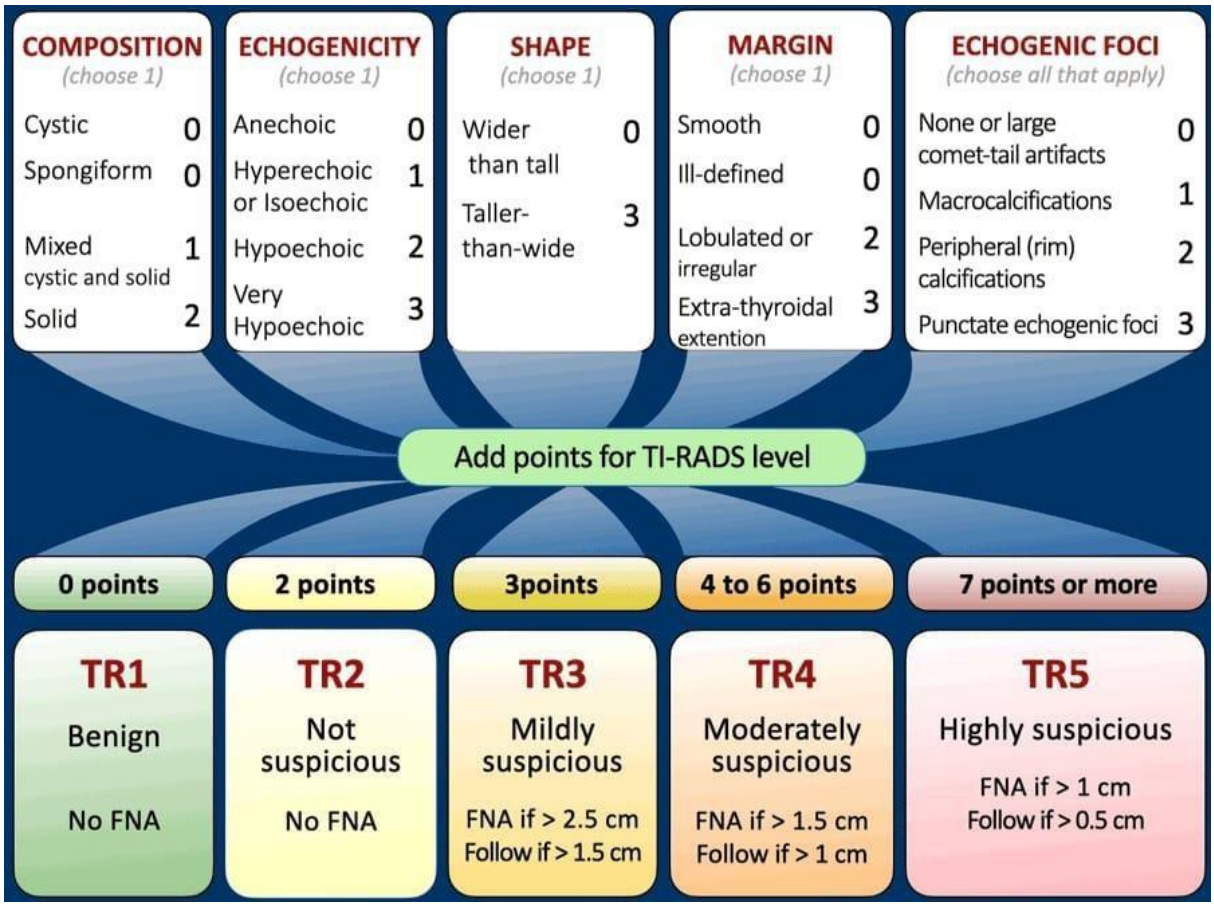
.....

التشخيص

جامع البيانات

.....

Appendix (2): TI-RADS level



Appendix (3): RESEARCH PERMISSION LETTERS

Republic of Yemen
Ministry of Higher Education and Scientific Research
21 SEPTEMBER UNIVERSITY OF MEDICAL S & APPLIED SCIENCES
CHANCELLOR OFFICE

الجمهورية اليمنية
وزارة التعليم العالي والبحث العلمي
جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية
رئاسة الجامعة

جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية
الإدارة العامة
السكرتارية
التاريخ
الرقم

الأخ/ مدير عام المختبر المركزي صنعاء المحترم

الموضوع: تسهيل مهمة تدريب

تهديكم رئاسة جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية أطيب تحياتها وتقديرها وإشارة إلى الموضوع أعلاه تكرموا مشكورين التوجيه الى من يلزم بتسهيل مهمة بحث طلاب كلية الطب البشري المذكورين بالجدول أدناه المجموعة الرئيسية (C) (C6b).

م	الاسم	المجموعة
١	علي عبده علي قاسم السعيدي	(C6b)
٢	بشير هادي ناصر الزكري	
٣	عمار حسن بجاش فيوع	
٤	هاني محمد سعيد الضبيبي	
٥	محمد خالد سفيان	
٦	محمد ناصر العمري	
٧	نصر علي الجريدي	
٨	عادل عبد الخالق غيلان	
٩	أميمة طلال سلطان	
١٠	أميمة محمد العماري	
١١	سمية محمد الخياني	
١٢	عبير عبد الخالق غيلان	

،،، تفضلوا بقبول خالص تحياتي وعميق احترامي ،،،

20 JUN 2022 / استاذ دكتور
مجاهد علي معصار
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السكرتارية

لاخوة/ مركز المأمون التشخيصي المحترم

الموضوع: تسهيل مهمة تدريب

ديكم رئاسة جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية أطيب تحياتها وتقدير
شارة إلى الموضوع أعلاه تكرموا مشكورين التوجيه الى من يلزم بتسهيل مهمة بحث طلا
لية الطب البشري المذكورين بالجدول أدناه المجموعة الرئيسية (C) الفرعية (C6b) .

م	الاسم	المجموعة
١	اميمة طلال سلطان	(C6b)
٢	اميمة محمد العماري	
٣	سمية محمد الخياني	
٤	عبير عبد الخالق غيلان	

... تفضلوا بقبول خالص تحياتي وعميق احترامي ...

استاذ دكتور /
مجاهد علي معصار
رئيس الجامعة

Arabic Summary

الملخص العربي

الخلفية عقيدة الغدة الدرقية هي نمو غير طبيعي للانسجة في الغدة الدرقية يؤدي هذا النمو الى انتاج كتلة صلبة او كيسية وهي مسالة طبية منتشرة بشكل كبير بين عامة الناس التصوير فوق الصوتي وعلم الانسجة المرضي معترف به عالميا على انهما الاختيار الافضل لمقارنة العقد او الاورام الحميدة والخبيثة على الرغم من حساسية ودقة مستويات الموجات فوق الصوتية في التفريق بين العقيدات الدرقية الحميدة والخبيثة في العديد من البلدان، ولكن بحسب معلوماتنا فإن دقة التشخيص لهذه الطريقة لم يتم تقييمها حتى الان في اليمن، لذلك هدفت هذه الدراسة الى تقييم دقة التصوير بالموجات فوق الصوتية للتمييز بين عقيدات او اورام الغدة الدرقية الحميدة والخبيثة وذلك عبر مقارنة نتائج الموجات فوق صوتيه مع نتائج فحوصات الانسجة التي تعتبر الافضل في تشخيص نوع عقد او اورام الغدة الدرقية.

الطريقة: دراسة رجعية تمت خلال الفترة من اكتوبر الى ديسمبر 2022 باستخدام البيانات الثانوية لمرضى عقيدات الغدة الدرقية لعام 2022 (المختبرات المركزية الوطنية ومركز المأمون) اخذت من اقسام الاشعة والتشريح المرضي في مركزين من الدرجة الثالثة في مدينة صنعاء تالفت عينة الدراسة من مرضى من كلا الجنسين في اي عمر يعانون من عقيدات الغدة الدرقية (تم تشخيصهم سريريا من قبل الطبيب) وتم احالتها الى قسم الاشعة لاجراء الموجات فوق الصوتية للغدة الدرقية واقسام الانسجة لفحوصات. تم استخدام برنامج الحزمة الاحصائية للعلوم الاجتماعية (SPSS) 2022.

Republic of Yemen
Ministry of Higher Education and Scientific Research
21 SEPTEMBER UNIVERSITY
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الجمهورية اليمنية
وزارة التعليم العالي والبحث العلمي
جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية
كلية الطب البشري
FACULTY OF MEDICINE

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العقيدات الدرقية خلال عام

النتائج: شملت الدراسة على اجمالي(112) عينة من مرضى المصابون بتضخم الغدة الدرقية. التصوير بالموجات فوق الصوتية استطاع اكتشاف الاورام الخبيثة في (10٪) من العينه وايضا الحميدة في(62٪) من العينة، ايضا فحص الانسجة اظهر انه (26٪) من العينة كانت خبيثة، و(74٪) من العينة كانت حميدة. حساسية وخصوصية ودقة التصوير بالموجات فوق الصوتية للتمييز بين عقيدات الغدة الدرقية الخبيثة والحميدة كانت (38٪) و (83٪) و (71٪) على التوالي، كانت القيمة التنبؤية الايجابية (44٪)، بينما كانت القيمة التنبؤية السلبية(79٪).

الاستنتاج: يمكن أن يميز التصوير بالموجات فوق الصوتية بشكل موثوق بين العقيدات الحميدة والخبيثة بنسبة 71٪ من المرضى بدون الحاجة الى فحص الانسجة.

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الدقة التشخيصية للتصوير بالموجات فوق الصوتية في التفريق بين عقيدات الغدة الدرقية الحميدة والخبيثة في مدينة صنعاء، اليمن ، 2022م

(بحث مقدم إلى كلية الطب والعلوم الصحية كمتطلب للحصول على درجة بكالوريوس طب عام وجراحة)

الباحثون: المجموعة (C6b)

1- علي عبده علي قاسم السعيدي
2- بشير هادي ناصر يحيى الزكري
3- أميمه طلال سلطان سعيد
4- سميه محمد حسين الخباني
5- عمار حسن بجاش قبوع
6- محمد خالد عبده سفيان
7- عبير عبدالخالق غيلان
8- أميمه محمد صالح العماري
9- هاني محمد سعيد الضبيبي
10- -محمد ناصر علي العمري
11- نصر علي محمد الجريدي

مشرفو البحث: -

د/ محمود الحداد د/ خالد الجمرة د/ منير الشكري

1444 2022 م

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