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Original Research Article

Concordance Between Cytological Bethesda And Ultrasound Based Ti-Rads Reporting Systems In Thyroid Nodules

Dr. Manmohan[1*], Dr. Monika B. Gathwal[2], Dr. Chiranjeev Gathwal[3], Dr. Deepti Agarwal[4], Dr. Naveen Sharma[5], Dr. Swaran Kaur[6]

[1*]Junior Resident, Department of Pathology, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat
[2]Associate Professor, Department of Pathology, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat
[3]Associate Professor and Head, Department of Radiology, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat
[4]Professor, Department of Pathology, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat
[5]Associate Professor, Department of ENT, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat
[6]Professor and Head, Department of Pathology, B.P.S. Government Medical College For Women, Khanpur Kalan, Sonepat

***Corresponding Author:**Dr. Manmohan

*Junior Resident, Department of Pathology, BPS GMC for Women, Khanpur Kalan, Sonepat.
E-mail: manmohanyadav418@gmail.com

Permanent Residential Address: Village Palri, Panihara, Palri (38), Mahendragarh, Haryana-123029.

ABSTRACT

Background : Thyroid nodules are common entities, frequently discovered in clinical practice, either during physical examination, but also incidentally, during various imaging procedures. They are clinically important primarily due to their malignant potential. The literature indicates that the incidence of nodules is around four times higher in women than men.

Material and Methods : A total of 90 patients with thyroid nodules which were referred to Department of Pathology and Radio-diagnosis and underwent USG guided FNAC and TIRADS scoring were included. USG guided FNAC were examined and categorized according to Bethesda system. The Bethesda categories were correlated with TIRADS scoring in all 90 cases and with histopathological findings in 22 cases.

Results: A total of 90 patients were included out of which 83 were females. These thyroid nodules are predominantly found in females with right lobe preponderance in approximately 50% cases and in third–fifth decade of life. A total of 14 were categorized under TIRADS 1, 25 were categorized under TIRADS 2, 6 were categorized under TIRADS 3, 29 were categorized under TIRADS 4 and 16 were categorized under TIRADS 5. Out of the 90 nodules, 46 were categorized under Bethesda II, 6 were categorized under Bethesda III, 21 were categorized under Bethesda IV, 7 were categorized under Bethesda V and 10 were categorized under Bethesda VI. Proportion of risk of malignancy as TIRADS 2, TIRADS 3, TIRADS 4, and TIRADS 5 were 4.0%, 83.3%, 82.8% and 87.5%, respectively. In the present study, 86.36% sensitivity, 84.78% specificity, 84.44% PPV, and 86.67% NPV derived. Significant association was noticed between TIRADS and Bethesda system of classification ($P < 0.001$). On Histopathological diagnosis of 22 thyroid cases, sixteen out of 22 nodules (72.7%) were proven to be malignant by postoperative histopathological examination. On histopathological and Bethesda comparison, 93.75% sensitivity, 16.67% specificity, 75.00% PPV, and 50.00% NPV were observed (P <0.001). Concordence between Bethesda classification and TIRADS scoring system of USG guided FNAC of the lesions showed very good association in both benign (84.7%) and malignant (86.3%) lesion ($p < 0.001$).

ISSN 2515-8260 Volume 10, Issue 04, 2023

Conclusion: The thyroid ultrasound report using the TIRADS criteria has a good concordance with the Bethesda cytology findings using USG guided FNAC. Correct interpretation by the two diagnostic modalities helps the clinician to stratify the thyroid nodules and reduce the risk of unnecessary invasive procedures in patients with low TIRADS score (TIRADS I AND 2) and nodules with high TIRADS score (TIRADS 4 and 5) should undergo USG guided FNAC and if Bethesda categories were suspicious of carcinoma or carcinoma should undergo surgery.

Keywords: Cytological, Bethesda, Ultrasound, Ti-Rads Thyroid Nodules

INTRODUCTION

The thyroid gland is located in the anteroinferior part of the neck in a space outlined by muscles, trachea, esophagus, carotid arteries and jugular veins. Thyroid gland is made up of two lobes located along either side of trachea and connected across the midline by the isthmus.[1]

A spectrum of diagnostic studies is available to aid in the evaluation of a thyroid nodule. A normal or high TSH level should raise concerns for possible malignant potential of a nodule, whereas a low TSH is an indicator of benignity in most cases. Hyperfunctioning thyroid nodules are almost always benign and generally do not require further cytological investigation but a nonfunctioning or "cold" nodule in a patient with low TSH may indicate malignant potential and further evaluated with Ultrasonography (USG) and FNAC (Fine Needle Aspiration cytology). Ultrasound is the initial imaging tool for the assessment of thyroid lesions, due to its easy availability and no radiation risk. USG based TIRADS uses particular lesions for reporting a focal thyroid nodule, based on which risk of malignancy is calculated and finally a TIRADS category is assigned. The USG based TIRADS system is helpful for effective communication between the practitioner.[2]

According to American thyroid association thyroid nodules are defined as discrete lesions within the thyroid gland, radiologically distinct from surrounding thyroid parenchyma.[3] Their prevalence rates are largely dependent on the identification method. By just palpation, the prevalence rate ranges from 4 to 7% whereas by using the imaging modalities such as the high-resolution ultra-sonogram, it ranges from 20 to 76% in the adult population. The nodules discovered with radiographic studies are called "thyroid incidentalomas.[4]

High-resolution ultrasound of the thyroid is recommended as the first-line modality in the evaluation of thyroid nodules and therefore, a reliable, non-invasive ultrasound-based stratification method to identify which nodules require FNA based on a reasonable likelihood of biologically significant malignancy is highly desirable.[5]

Thyroid imaging reporting and data system (TI-RADS) can be used to stratify the risk of malignancy of thyroid nodule according to its USG characteristics. The Thyroid Imaging Reporting and Data System (TI-RADS), first proposed by Horvath et al.[6] It was established to standardize the scoring system of thyroid USG and provide recommendations for using FNAC and to improve appropriate patient management. The TI-RADS categories as suggested by American College of Radiology (ACR) in 2017 and known as ACR TI-RADS are: I) Benign; II) Not Suspicious; III) Mildly Suspicious; IV) Moderately Suspicious; V) Highly Suspicious.[7]

It is reported that using US-guided percutaneous core needle biopsy (CNB) is useful, especially in cases where diagnostic surgery is planned as the cases have been reported as 'Inadequate for diagnosis' or 'Atypia with unclear undetermined significance/ Follicular lesion with unclear undetermined significance (AUS/FLUS) after repetitive FNA results.[8] Using FNA and CNB together has been reported to provide higher diagnostic sensitivity than either method alone in certain studies.[9]

ISSN 2515-8260 Volume 10, Issue 04, 2023

The six diagnostic categories suggested by TBSRTC in 2017 are: I) Non-diagnostic or unsatisfactory; II) Benign; III) Atypia of Undetermined Significance (AUS) or Follicular Lesion of Undetermined Significance (FLUS); IV) Follicular Neoplasm (FN) or Suspicious for Follicular Neoplasm; V) Suspicious for Malignancy; VI) Malignant.[10] Thus the present was conducted to observe the concordance between the TI-RADS and TBSRTC on thyroid nodules of patients.

MATERIAL AND METHODS

The present cross-sectional study was conducted in the Department of Pathology, Bhagat Phool Singh Government Medical College for Women, Khanpur Kalan, Sonepat. A total of 90 patients of Thyroid nodule on ultrasound whose USG guided FNAC and TI-RADS grading were done were included in the study over a period of one year. Those patients who had received any chemotherapy or radiotherapy to head and neck area were excluded.

Data from the patient having thyroid nodule on ultrasound and who had been followed by USG guided FNAC was collected after obtaining informed written consent. Patient confidentiality was ensured by deidentifying data and patient was given a unique code in numbers. Other relevant history, clinical and biochemical findings were collected from requisition form.

Thyroid USG technique:

The patient was placed in the supine position and hyper-extended neck and then Real-time B - mode USG and Doppler assessment of the thyroid nodules was done by a radiologist with a good practice in thyroid USG. The USG scans were completed on HD11XE PHILIPS 730 PRO machine with a high frequency linear array transducer (7.5–12 MHz). Images were inspected on the real-time two-dimensional grayscale and Doppler imaging. The neck was scanned in transverse, sagittal, and oblique sections to ideally see both thyroid lobes, isthmus. Also, the regions of the jugular veins and carotid arteries, as well as the supra-clavicular fossa, were visualized for any lymph node enlargement. The sonographic features in all saved images were examined; such as the internal composition, echogenicity, margins, presence of calcifications, and the shape of the nodule. For a patient with more than one thyroid nodule was classified as multinodular goiter (MNG) and the nodule with the most suspicious sonographic features was recorded as the nodule of interest. The internal structure of the nodule demarcated as cystic, solid, or mixed. The USG parameters define the suspicion of malignancy as follows: irregular border, micro-calcifications, hypo-echogenicity, and central flow by Doppler study.

USG-guided FNAC Technique:

All procedures was performed by the pathologist and the radiologist, after obtaining a written informed consent, the patient was placed in the supine position with the hyper-extended neck. The skin and the 7.5–12 MHz linear transducer were cleansed with Betadine solution. A sterile gel was used. The Initial USG study was done to recognize the nodule of interest that indicated for FNAC according to the guidelines. Then, under complete aseptic precautions, USG guided FNAC was done by 23-25 G needle. Then needle with syringe was to be held in the right hand and the transducer in the left hand. The needle was connected to a 10ml syringe, then it was entered through the skin at an oblique angle under USG guidance, then it will be moved through the centre of the nodule gently and rapidly with a mild suction. When aspirated fluid contained much blood, a non-aspiration technique was applied, and the needle was moved in back and forth directions. Smears were air dried and then stained with Leishman stain, May Grunwald Giemsa stain and alcohol fixed smears (in coplin jar) with Papanicolaou (PAP) stain.[11,12]

The thyroid nodule was reported on USG according to TI-RADS categories as suggested by American College of Radiology (ACR) and known as ACR TI-RADS as follows:

ISSN 2515-8260 Volume 10, Issue 04, 2023

TI-RADS categories as suggested by American College of Radiology (ACR TI-RADS)[13,14]

Categories	Points	Description	Risk of malignancy
TI-RADS 1	0/1	Benign	< 2%
TI-RADS 2	2	Not suspicious	< 2%
TI-RADS 3	3	Mildly suspicious	5%
TI-RADS 4	4-6	Moderately suspicious	5-20%
TI-RADS 5	>7	Highly suspicious	>20%

All cytology slides of USG guided FNAC was examined in detail initially by postgraduate student and later was reviewed by supervisor and co-supervisor pathologists. Cytology was reported according to the Bethesda System 2017. Diagnostic categories of Bethesda are as follows:

Diagnostic categories of Bethesda reporting system of thyroid Cytopathology[15]

Diagnostic category	Description	Risk of malignancy	
		NIFTP≠CA	NIFTP=CA
Bethesda I	Non-diagnostic or unsatisfactory sample	5-10%	5-10%
Bethesda II	Benign	0-3%	0-3%
Bethesda III	Atypia /Follicular lesion of undetermined significance (AUS/FLUS)	6-18%	10-30%
Bethesda IV	Follicular tumor or suspicious for follicular tumor	10-40%	25-40%
Bethesda V	Suspicious for malignancy	45-60%	50-75%
Bethesda VI	Malignant	94-96%	97-99%

NIFTP: Noninvasive follicular thyroid neoplasm with papillary like nuclear features, CA: Carcinoma

Then the grading of both systems was correlated to find the concordance between Bethesda system and TI-RADS system in focal thyroid nodule.

Statistical Analysis

Statistical analysis was done by using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA). Descriptive statistics included percentages, means and standard deviations. The chi square test was used for quantitative data comparison of all clinical indicators. Sensitivity, specificity, PPV, NPV and accuracy were also calculated. Level of significance was set at $P \leq 0.05$.

RESULTS

Maximum number of cases was in the age group 31-40 years (34.4%) followed by 41-50 years (18.9%) with mean age of 42.83±15.18 years. Thyroid lesions were more common in females as compared to females i.e. 83(92.2%) in females and 7(7.8%) in males with slight preponderance of benign lesions and all male patients showed malignant lesions. Age and gender wise distribution of thyroid lesions showed females with less than or equal to 30 years of age shows more malignant lesions and females with age more than 30 years shows more benign lesions. All males of both age groups show malignant lesions. Thyroid lesions were more common in right lobe in 50% cases followed by left lobe involvement in 31.1% cases.

Ultrasound based categorization of 90 thyroid cases based on ACR-TIRADS system showed that most of the cases belonged to TIRADS 4 (32.2%) followed by category 2 (27.8%). For statistical purpose in this study we grouped TR1, TR2 and TR3 cases as benign and TR4 and TR5 cases as malignant lesions.

Diagnostic categorization of 90 thyroid FNAC based on Bethesda classification show most of the cases belonged to Bethesda II (51.1%) followed by Bethesda IV (23.3%). We exclude all the unsatisfactory cases categorized in Bethesda I. For statistical purpose in this study we grouped Bethesda II cases as benign and Bethesda III to Bethesda VI cases as malignant lesions.

Table 1: Cytological diagnosis of 90 thyroid cases

	Bethesda		Frequency	Percent
Benign	Bethesda II	Colloid nodule	27	30
		Colloid nodule with cystic changes	8	8.8
		Colloid nodule with hyperplasic changes	11	12.2
Malignant	Bethesda III	Atypia of undetermined significance	6	6.7
	Bethesda IV	Follicular neoplasm	16	17.7
		Hurthle cell neoplasm	5	5.6
	Bethesda V	Suspicious of Papillary carcinoma	7	7.7
	Bethesda VI	Papillary carcinoma	8	8.8
		Medullary carcinoma	2	2.2
		Total	90	100.0

Table 1 shows that maximum number of thyroid FNAC were diagnosed as colloid nodule 27 cases (30%) and the most common malignancy diagnosed was papillary carcinoma of thyroid in 8 cases (8.8%) cases.

Table 2: Distribution of 90 cases of thyroid lesions using TIRADS and Bethesda subcategorization

			Bethesda					Total
			Bethesda II	Bethesda III	Bethesda IV	Bethesda V	Bethesda VI	
TIRADS	TR1	N	14	-	-	-	-	14
		%	100.0%	-	-	-	-	100.0%
	TR2	N	24	1	-	-	-	25
		%	96.0%	4.0%	-	-	-	100.0%
	TR3	N	1	3	2	-	-	6
		%	16.7%	50.0%	33.3%	-	-	100.0%
	TR4	N	5	2	18	4	-	29
		%	17.2%	6.8%	62.0%	13.7%	-	100.0%
	TR5	N	2	-	1	3	10	16
		%	12.5%	-	6.2%	18.7%	62.5%	100.0%
Total		N	46	6	21	7	10	90
		%	51.1%	6.7%	23.3%	7.8%	11.1%	100.0%

Table 2 shows that TIRADS and Bethesda correlation of 90 cases of thyroid lesions shows the frequency of benign lesions was 46/90 (51.1%) in Bethesda II (benign lesions) and 39/90 (43.3%) in TIRADS (TR1,TR2,TR3 –benign lesions) while frequency of malignant lesions was 44/90 (48.8%) Bethesda III, IV, V, VI (malignant lesions) and 38/90 (42.2%) in TIRADS (TR4,TR5-malignant lesions).

Table 3: TIRADS and correlation with risk of malignancy

TIRADS	Bethesda category					
	Benign	Malignant	Total	OR	95% CI	P value
TR1	14(100%)	-	14	-	-	-
TR2	24(96%)	1(4%)	25	References	-	-
TR3	1(16.7%)	5(83.3%)	6	0.47	0.11-1.09	0.001(S)

TR4	5(17.2%)	24(82.8%)	29	2.31	1.23-4.85	0.001 (S)
TR5	2(12.5%)	14(87.5%)	16	1.90	0.59-2.76	0.001 (S)
Total	46	44	90			

Table 3 shows that TIRADS and correlation with risk of malignancy in100% cases of TR1 and 96% cases of TR2 show benign lesions (Bethesda II) with risk of malignancy is 0% and 4% in TR1 and TR2 lesions respectively while more than 80% in TR3,TR4 and TR5.

Overall agreement between USG and FNAC by TIRADS and Bethesda was 84.7 % in benign lesions and 86.3% in malignant lesions which was very good agreement between Bethesda and TIRADS with significant p value (<0.001) .

On statistical analysis we found TIRADS test show sensitivity, specificity, PPV, NPV and diagnostic accuracy of 86.36%, 84.78%, 84.44%, 86.67% and 85.56% respectively with significant P value of <0.001(S).

Histopathological diagnosis of 22 thyroid cases shows maximum cases were categorized as Papillary carcinoma 9 cases (40.9%) followed by follicular adenoma 5 cases (22.7%).

Table 4: Histopathological spectrum of thyroid lesions and its correlation with Bethesda categories

	Bethesda				Total
	Bethesda II	Bethesda IV	Bethesda V	Bethesda VI	
Adenomatoid nodule	1	-	-	-	1
Follicular adenoma	-	5	-	-	5
Follicular carcinoma	-	2	-	-	2
Hurthle cell carcinoma	-	2	-	-	2
Medullary carcinoma	-		-	1	1
Minimally invasive follicular carcinoma	-	1			1
Papillary carcinoma	1		2	6	9
Papillary carcinoma with warthin feature	-	-	-	1	1
Total	2	10	2	8	22

P value=0.01 (S)

Table 4 shows histopathological spectrum of thyroid lesions and its correlation with bethesda categories of 22 thyroid cases shows maximum cases are categorized in Bethesda IV 10 cases (45.4%) followed by Bethesda VI 8 cases (36.3%).

On statistical analysis, Bethesda reporting system of thyroid Cytopathology show sensitivity, specificity, PPV, NPV and diagnostic accuracy of 93.75%, 16.67%, 75.00%, 50.00% and 72.73% respectively with significant P value of <0.001(S).

Table 5: Histopathological spectrum of thyroid lesions and its correlation with TIRADS categories

	TIRADS		Total
	TR4	TR5	
Adenomatoid nodule	-	1	1
Follicular adenoma	5	-	5
Follicular carcinoma	2	-	2
Hurthle cell carcinoma	2	-	2
Medullary carcinoma	-	1	1
Minimally invasive follicular carcinoma	1	-	1
Papillary carcinoma	-	9	9
Papillary carcinoma with warthin feature	-	1	1
Total	10	12	22

P value=0.01 (S)

Table 5 shows histopathological spectrum of thyroid lesions and its correlation with TIRADS categories of 22 thyroid cases shows maximum cases are categorized in TR5 (12 cases) out of

which 10 cases were reported as Papillary carcinoma on histopathology. Correlation of TIRADS categories with histopathological diagnosis of 22 thyroid cases show that all cases categorized in TR4 showed follicular lesions and 11 out of 12 cases of TR5 category showed malignant lesions on histopathology.

DISCUSION

The mean age of the patient was 42.83±15.18 years. The range varies from 16-80 years of age. The age distribution pattern was similar to other studies. The observation regarding the age distribution in the present study matches with Grandhi et al[16] and Abdelkader et al[17] in which they reported 43.8 years with a range of 21-82 years and 43.7±11.5 years with a range of 22-60 years, respectively. Thyroid swellings were more common in females accounting for 83 cases as compared to seven males with Female:Male ratio of 11.85:1. The observation regarding the gender distribution in the present study matches with the study by Regmi et al[18] in which they reported 12.5:1 female:male ratio.

Comparison of TIRADS score distribution in various studies

STUDY	TR1	TR2	TR3	TR4	TR5	TOTAL
Grandhi et al[16]	1	7	28	10	1	47
Regmi et al[18]	0	46	2	1	5	54
Uricoechea et al[19]	0	45	41	62	32	180
Siddheshwar et al[2]	0	29	7	8	6	50
Present study	14	25	6	29	16	90

In the present study maximum number of the nodules were categorized under category 4 of TIRADS followed by category 2 of TIRADS. The study showed similar result with Uricoechea et al[19] in which maximum cases were categorized in same category as like in the present study and rest of the studies show more cases in TR 2 category.

Comparison of Bethesda score distribution in various studies

STUDY	Bethesda I	Bethesda II	Bethesda III	Bethesda IV	Bethesda V	Bethesda VI	TOTAL
Grandhi et al[16]	0	38	0	2	2	5	47
Regmi et al[18]	6	37	1	3	3	4	54
Uricoechea et al[19]	0	65	39	41	35	0	180
Siddheshwar et al[2]	0	36	2	6	4	2	50
Present study	0	46	6	21	7	10	90

In the present study maximum number of the nodules were categorized under category II of Bethesda followed by category IV of Bethesda. The study showed similar results with Uricoechea et al[19] and Siddheshwar et al[2] in which maximum cases were categorized in same category as like in the present study.

Comparison of diagnostic value of TIRADS and Bethesda in various studies

STUDY	SENSITIVITY	SPECIFICITY	PPV	NPV	ACCURACY
Abdelkader et al[17]	76.9	91.3	71.4	76.4	-
Periakaruppan et al[3]	61.5	81.3	40	91	77.9
Chaturvedi et al[5]	88	49	49	88	94
Horvath et al[6]	92.3	94.15	54.54	99.38	-
Present study	86.36	84.78	84.44	86.67	85.56

In the present study Sensitivity of TI-RADS was 86.36% which was similar to Chaturvedi et al[5] and Horvath et al[6] and Specificity of 84.78% was obtained which was similar to Periakaruppan et al[3]. There was a wide range of sensitivity and specificity reported in various studies. It varies from 61.5% - 92.3% for sensitivity and 49% - 94.15% for specificity. In the present study Positive predective value of 84.44%, Negative predictive value of 86.67% which was close to the results obtained by Abdelkader et al[17]. There was a wide range of PPV and NPV reported in various studies. It varies from 40% - 71.4% for PPV, 76.4%-99.38% for NPV. In the present study, diagnostic accuracy of 85.56% was obtained, which was close to the results obtained by Periakaruppan et al [3].

Comparison of diagnostic value of Bethesda with histopathological diagnosis in various studies

STUDY	SENSITIVITY	SPECIFICITY	PPV	NPV	ACCURACY
Abdelkader et al[17]	81.8	98	90	96	-
Goswami et al [20]	85.71	96	85.71	96	93.33
Muratli et al[21]	87.1	64.6	76.1	79.5	77.3
Sheikh et al[22]	83.2	63.3	74.3	76.4	74.4
Present study	93.75	16.67	75.00	50.00	72.73

In the present study Sensitivity of 93.75% was obtained which show similarity with Goswami et al[20] and Muratli et al[21]. Specificity of 16.67% was obtained. There was a wide range of sensitivity and specificity reported in various studies. It varies from 63.3% - 98% for specificity. Present study show less specificity because of less number of cases and differences in categorisation of follicular neoplasm & suspicious of follicular neoplasm cases in malignant category in Bethesda reporting while on histopathological reporting these cases were reported as benign lesions of thyroid like follicular adenoma, hurthle cell adenoma etc. In the present study Positive predective value of 75% was obtained which show similarity with Muratli et al[21] and Sheikh et al[22]. Negative predictive value of 50% was obtained which was less as compare to other studies. It varies from 76.4% - 96% in various studies. In the present study, diagnostic accuracy of 72.73% was obtained which was similar with Muratli et al [21] and Sheikh et al[22].

CONCLUSION

The thyroid ultrasound report using the TIRADS criteria has a good concordance with the Bethesda cytology findings using USG guided FNAC. If the nodules are properly classified on ultrasound, the probability of a particular nodule being malignant can be inferred from the ultrasound‐based TIRADS system with a certain level of confidence and appropriate measures for management of the nodule can be initiated, thus avoiding unnecessary FNA procedures. To conclude, the correct interpretation by the two diagnostic modalities helps the clinician to stratify the thyroid nodules and reduce the risk of unnecessary invasive procedures in patients with low TIRADS score (TIRADS I AND 2) and nodules with high TIRADS score (TIRADS 4 and 5) should undergo USG guided FNAC and if Bethesda categories were suspicious of carcinoma or carcinoma should undergo surgery. TI-RADS and TBSRTC classification systems could be considered as feasible and effective diagnostic modalities for provide a uniform terminology for reporting thyroid nodules and helps the clinician to reduce the risk of unnecessary invasive procedures in patients with a low probability of presenting thyroid cancer, while facilitating the identification of patients at higher risk of cancer. There is a need to develop study and monitoring protocols for cases classified as “discordant”, particularly when extreme categories are identified. predicting malignant lesions in patients having thyroid nodules.

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