


Correlation of ACR TI-RADS and Patient Outcomes in a Real-World Cohort Presenting for Thyroid Ultrasonography

Tom Wilkinson,¹  Tom Cawood,¹ Anthony Lim,² David Roche,³ Jasmine Jiang,¹ Ben Thomson,⁴ Michelle Marais,² and Penny Hunt^{1,5}

¹Department of Endocrinology, Te Whatu Ora/Health New Zealand Waitaha/Canterbury, Christchurch 8011, New Zealand

²Department of Radiology, Te Whatu Ora/Health New Zealand Waitaha/Canterbury, Christchurch 8011, New Zealand

³Canterbury Southern Community Laboratories, Christchurch 8051, New Zealand

⁴Department of Otolaryngology, Te Whatu Ora/Health New Zealand Waitaha/Canterbury, Christchurch 8011, New Zealand

⁵University of Otago (Christchurch), Christchurch 8011, New Zealand

Correspondence: Tom Wilkinson, MBChB, Department of Endocrinology, Christchurch Hospital, 2 Riccarton Ave, Christchurch 8011, New Zealand.

Email: thomas.wilkinson@cdhb.health.nz.

Abstract

Context: The American College of Radiology Thyroid Image Reporting and Data System (ACR TI-RADS) was developed to predict malignancy risk in thyroid nodules using ultrasound features. TI-RADS was derived from a database of patients already selected for fine-needle aspiration (FNA), raising uncertainty about applicability to unselected patients.

Objective: We aimed to assess the effect of ACR TI-RADS reporting in unselected patients presenting for thyroid ultrasound in a real-world setting.

Methods: Records for all patients presenting for thyroid ultrasonography in Canterbury, New Zealand, were reviewed across two 18-month periods, prior to and after implementation of TI-RADS reporting. Patient outcomes were compared between the 2 periods. Malignancy rates were calculated for nodules 10 mm or larger with a definitive FNA or histology result.

Results: A total of 1210 nodules were identified in 582 patients prior to implementation of TI-RADS; 1253 nodules were identified in 625 patients after implementation of TI-RADS. TI-RADS category was associated with malignancy rate (0% in TR1 and TR2, 3% in TR3, 5% in TR4, 12% in TR5; $P = .02$); however, 63% of nodules were graded TR3 or TR4, for which malignancy rate did not meaningfully differ from baseline risk. After implementation of TI-RADS there was a small reduction in the proportion of patients proceeding to FNA (49% vs 60%; $P < .01$) or surgery (14% vs 18%; $P < .05$), with no difference in cancer diagnoses (3% vs 4%, not significant).

Conclusion: TI-RADS category is associated with malignancy rate and may alter clinical decision-making in a minority of patients; however, it is nondiscriminatory in the majority of nodules. In this study of unselected patients, nodules classified as TR5 and thus considered “highly suspicious” for cancer had only a modest risk of malignancy.

Key Words: thyroid ultrasound, thyroid nodule, thyroid cancer, TI-RADS

Abbreviations: ACR, American College of Radiology; FNA, fine-needle aspiration; TI-RADS, Thyroid Image Reporting and Data System.

Asymptomatic thyroid nodules are estimated to be present in 23% to 68% of the general population and are therefore a frequent incidental finding on imaging [1–4]. Once detected, the possibility that a nodule is malignant becomes relevant, although overall the majority of nodules are benign. Therefore, discerning the small number that represent significant cancer is challenging.

In the past, the need for further investigation of nodules with fine-needle aspiration (FNA) would be based primarily on clinical suspicion. However, FNA can be inconclusive and lead to surgery for ultimately benign disease. A meta-analysis of 25 445 FNA results found that 8283 (33%) were nondiagnostic or indeterminate (Bethesda I, III, or IV), and where such nodules proceeded to surgery the final histological diagnosis was benign in 78% [5]. Furthermore, small differentiated thyroid cancers are common and often of no prognostic significance: Autopsy studies report an incidental finding of

thyroid cancer in 11% of patients [6]. Indiscriminate investigation of thyroid nodules risks overdiagnosing low-grade cancer that may never have been of clinical consequence.

In recent years there has been interest in the role of sensitive ultrasound to help identify those nodules more likely to represent significant cancer and thus guide the use of FNA, and ultimately better use health resources. The American College of Radiology Thyroid Image Reporting and Data System (ACR TI-RADS) assigns a score to thyroid nodules on the basis of 5 ultrasound features (composition, echogenicity, shape, margin, and echogenic foci) and uses this score to assign each nodule to 1 of 5 categories: benign (TR1), not suspicious (TR2), mildly suspicious (TR3), moderately suspicious (TR4), or highly suspicious (TR5). FNA criteria are defined, recommending FNA in TR5 nodules 10 mm or larger, TR4 nodules 15 mm or larger, and TR3 nodules 25 mm or larger. FNA is not recommended for TR1 or TR2 nodules [7].

The incorporation of nodule size into ACR TI-RADS FNA criteria is on the basis of a higher risk of metastasis in larger malignant nodules, favoring more expedient investigation [7, 8]. Nodule size is not predictive of the likelihood of malignancy [9, 10].

TI-RADS category has been shown to correlate with the risk of malignancy in multiple large cohorts [9-18]; however, these cohorts derive from patients already selected for FNA or thyroidectomy and therefore are likely to have a higher malignancy rate (overall and for each TR category) than found in the general population of patients with thyroid nodules. The question thus arises as to whether TI-RADS recommendations are valid in unselected patients presenting for thyroid ultrasound in a real-world setting [19]. We aimed to assess the effect of ACR TI-RADS reporting in such a cohort.

Materials and Methods

Routine reporting of TI-RADS was introduced in Canterbury, New Zealand, in January 2019. Radiologist reports from all thyroid ultrasound scans completed in the region between January 1, 2020 and June 30, 2021, were reviewed, including public and private health care providers. Of note, the radiologists reporting ultrasound scans in the public and private sector comprised the same group. This time frame allowed 12 months for implementation of TI-RADS and time for resulting FNA procedures and thyroid surgery to occur. Maximum dimension and TI-RADS category were recorded for all reported nodules measuring at least 10 mm. Ultrasound images were not rereviewed for this study, as the intent was to assess the effect of TI-RADS reporting as it occurred in a real-world setting.

Patient health records were searched for any available FNA or histology results. These results were included if they directly related to the nodule scored by TI-RADS. Although ACR TI-RADS FNA criteria were reported, the decision to proceed to FNA was at the discretion of individual clinicians. Due to the large data set, histology and cytology specimens were not reexamined for this study.

Malignancy rates were calculated using the subset of nodules that could be classified as either malignant or benign, using available histology and/or FNA results.

Nodules were classified as malignant on the basis of the histology report from thyroid surgery, and not solely on the basis of FNA.

Nodules were classified as benign if histology from thyroid surgery was reported as benign (including noninvasive follicular thyroid neoplasm with papillary-like nuclear features; NIFTP), or if there was a benign FNA result (Bethesda II) in the absence of histology.

Nodules were also classified as benign if there was no FNA or histology result available after the index ultrasound but a benign FNA was obtained in the 5 years prior to that ultrasound. This approach was taken on the basis of a large cohort reporting a very low 5-year malignancy rate of 0.3% following a benign FNA result [20].

Of note, it was possible for a nodule to be classified as malignant or benign in the absence of an FNA result if an ultrasound identified multiple nodules 10 mm or larger and the patient proceeded to surgery; the histology report was used to classify all nodules that had been identified on ultrasound as either malignant or benign. However, if histology identified malignancy that was located separately to any ultrasound-detected nodule 10 mm or larger, that cancer was considered

incidental and excluded from the calculation of malignancy rate.

Nodules were separately noted for which no histology result was available, and FNA was either not performed or had a result considered nondiagnostic (Bethesda I) or indeterminate (Bethesda III or IV). These nodules were excluded from the calculation of malignancy rate.

Malignancy rates were compared for nodules in each TI-RADS category and for nodules that did, and did not, meet ACR TI-RADS criteria for FNA. Statistical significance was assessed by chi-square tests of association, with P less than .05 considered significant.

To assess the effect of TI-RADS reporting on patient outcomes, data were collected from a “pre-TI-RADS” cohort, encompassing all thyroid ultrasound scans performed between January 1, 2017 and June 30, 2018. This time frame was chosen to match the “post-TI-RADS” cohort, with equivalent start and end dates to allow for any seasonal effects. The number of nodules 10 mm or larger was quantified. The 2 cohorts were compared with regard to the proportion of patients who proceeded to FNA, the proportion of patients who proceeded to surgery, and the proportion of patients who were diagnosed with thyroid cancer on histology. As the intent was to assess the effect of TI-RADS reporting on the decision to proceed to FNA, patients were excluded from this analysis if they had undergone thyroid FNA with a diagnostic result in the preceding 5 years. Patients with thyroid ultrasound scans during both time periods were included only in the pre-TI-RADS cohort.

This work was considered an audit, therefore ethical approval was not required.

Results

Between January 1, 2017 and June 30, 2018, 582 patients (455 female, 127 male; mean age 58 years; range, 14-87 years) underwent thyroid ultrasonography with a result identifying at least 1 nodule 10 mm or larger. TI-RADS classification was reported in 25 patients (4%). A total of 1210 nodules 10 mm or larger were identified. Twenty-three nodules were identified as malignant, further classified on final histology as papillary carcinoma (19 nodules), follicular carcinoma (1 nodule), Hürthle cell carcinoma (1 nodule), anaplastic carcinoma (1 nodule), and poorly differentiated carcinoma (1 nodule). Twenty-one of these nodules had undergone FNA prior to surgery, reported as Bethesda II (1 nodule), Bethesda III (1 nodule), Bethesda IV (3 nodules), Bethesda V (5 nodules), and Bethesda VI (11 nodules). A total of 468 nodules were identified as benign, resulting in a calculated malignancy rate of 5% (Table 1).

Between January 1, 2017 and June 30, 2018, 625 patients (496 female, 129 male; mean age 57 years; range, 14-91 years) underwent thyroid ultrasonography with a result identifying at least 1 nodule 10 mm or larger. TI-RADS classification was reported in 603 patients (96%). In total, 1253 nodules 10 mm or larger were identified and assigned a TI-RADS classification. As outlined in Table 2, 139 nodules (11%) were classified as TI-RADS 1, 225 (18%) as TI-RADS 2, 386 (31%) as TI-RADS 3, 397 (32%) as TI-RADS 4, and 106 (8%) as TI-RADS 5. Twenty nodules were identified as malignant, further classified on final histology as papillary carcinoma (16 nodules), follicular carcinoma (3 nodules), and Hürthle cell carcinoma (1 nodule). All 20 of these nodules

Table 1. Malignancy rate in nodules in pre-Thyroid Image Reporting and Data System cohort

Malignant ^a	Benign				Malignancy rate	Unknown			Total nodules
	Benign FNA, no histology	Benign histology, had prior FNA	Benign histology, no prior FNA	Total benign nodules		Nondiagnostic FNA, no histology	Indeterminate FNA, no histology	No FNA or histology	
23	275	98	95	468	5% (23/491)	55	8	655	1210

Overall number of nodules classified as benign or malignant, and total nodules, indicated in bold text.

Abbreviation: FNA, fine-needle aspiration.

^aAll malignancies were confirmed on histology.

had undergone FNA prior to surgery, reported as Bethesda IV (6 nodules), Bethesda V (3 nodules), or Bethesda VI (11 nodules). The malignancy rate was 0% in nodules classified as TI-RADS 1 or 2, 3% in TI-RADS 3, 5% in TI-RADS 4, 12% in TI-RADS 5, and 5% overall ($P = .02$ for association with TI-RADS category). A total of 501 nodules fulfilled ACR TI-RADS criteria for FNA, with a malignancy rate of 7%. There were 752 nodules that did not fulfill ACR TI-RADS criteria for FNA, with a malignancy rate of 2% ($P = .03$ for difference).

Across both cohorts, every nodule with an FNA result of Bethesda V or VI proceeded to surgery and was found to be malignant on histology.

Of the 582 patients in the pre-TI-RADS cohort, 49 had a previous diagnostic thyroid FNA result. Of the remaining 533 patients, 322 (60%) proceeded to FNA after ultrasound, 98 (18%) proceeded to thyroid surgery, and 26 (5%) were diagnosed with a thyroid cancer on histology. Of the 26 patients diagnosed with thyroid cancer, the diagnosis was adjudicated as incidental in 7 patients. Therefore the overall rate of nonincidental cancer diagnoses was 19 of 533 (4%).

Of the 625 patients in the post-TI-RADS cohort, 26 had previously undergone ultrasonography in the pre-TI-RADS cohort and 41 had a previous diagnostic thyroid FNA result. Of the remaining 558 patients, 274 (49%) proceeded to FNA after ultrasound, 78 (14%) proceeded to thyroid surgery, and 19 (3%) were diagnosed with a thyroid cancer on histology. The thyroid cancer diagnosis was adjudicated as incidental in 2 patients, resulting in an overall rate of nonincidental cancer diagnoses of 17 of 558 (3%). If FNA had been performed in strict accordance with ACR TI-RADS criteria in the post-TI-RADS cohort, 324 of the 558 patients (58%) would have proceeded to FNA.

Outcomes for the 2 cohorts are compared in Table 3. Patients in the post-TI-RADS cohort were 19% less likely to proceed to FNA ($P < .01$) and 24% less likely to proceed to surgery ($P = .048$). The rate of nonincidental cancer diagnoses was small and did not significantly differ between the cohorts. There would have been no significant difference in FNA procedures between the pre-TI-RADS and post-TI-RADS cohorts if all nodules that met ACR FNA criteria proceeded to FNA ($P = .43$).

Discussion

TI-RADS category was associated with the rate of malignancy in patients presenting for thyroid ultrasonography in Canterbury, New Zealand, between January 1, 2020 and June 30, 2021; however, this rate remained relatively low across all

categories. In nodules reported as “highly suspicious for malignancy” (TR5), the observed malignancy rate was 12%.

Other studies [9-18] have reported consistently low malignancy rates in TR1 and TR2 nodules (0%-4.4%). Absolute malignancy rates reported by these studies at higher TI-RADS categories have been variable; however, this is likely attributable to differences in cohort-wide malignancy rates. In general, the malignancy rate in TR3 nodules has been reported as higher than TR2 but lower than the cohort-wide malignancy rate; in TR4 nodules as similar to the cohort-wide malignancy rate; and in TR5 nodules as higher than the cohort-wide malignancy rate. In the setting of a cohort-wide malignancy rate of 5%, data from this study are therefore consistent with previous studies and add to the literature by providing reassurance that the rate of malignancy may be relatively low across all TI-RADS categories when applied to an unselected population at low risk for thyroid cancer. Observation, rather than FNA, may be appropriate in selected patients regardless of TI-RADS category.

The introduction of routine reporting of TI-RADS in Canterbury appeared to alter clinical outcomes, with 19% fewer patients proceeding to FNA and 24% fewer patients proceeding to surgery following the introduction of TI-RADS. However, this reflects decisions made by individual clinicians and patients rather than strict adherence to ACR TI-RADS recommendations. If all nodules meeting ACR TI-RADS FNA criteria had undergone FNA, then the rate of FNA procedures would not have changed after the introduction of TI-RADS (60% vs 58%). Interestingly, recent real-world data from other New Zealand centers have demonstrated an increase in the rate of FNA procedures following implementation of routine reporting of TI-RADS [21, 22], although one study noted radiologist recommendations for FNA deviated from TI-RADS criteria. In contrast, studies that retrospectively applied TI-RADS criteria to nodules that had already undergone FNA predicted that implementation of TI-RADS would reduce FNA procedures by 49% to 66% [23-26], although by nature of their design these studies were unable to account for the possibility of TI-RADS prompting clinicians to refer nodules for FNA that would have otherwise been observed.

Any benefit of TI-RADS reporting needs to be weighed against potential cost: Implementation of TI-RADS at a new clinical site requires resources for education and training of radiologists and sonographers, as well as reporting becoming more time consuming [27]. In this context it is important to note that 63% of nodules in our cohort were classified TR3 or TR4 and that the malignancy rate was not meaningfully different from the cohort-wide rate in these nodules. Therefore,

Table 2. Malignancy rate in nodules in post-Thyroid Image Reporting and Data System cohort

TI-RADS category	Malignant ^a		Benign		Malignancy rate		Unknown		Total nodules
	Benign FNA, no histology	Benign histology, had prior FNA	Benign histology, no prior FNA	Total benign nodules	Nondiagnostic FNA, no histology	Indeterminate FNA, no histology	No FNA or histology		
1	0	4	2	13	0% (0/13)	2	0	124	139
2	0	17	7	47	0% (0/47)	8	0	170	225
3	3	41	17	93	3% (3/96)	10	2	278	386
4	8	117	27	166	5% (8/174)	14	16	193	397
5	9	53	12	65	12% (9/74)	8	4	20	106
ACR FNA criteria met	18	175	49	255	<i>P</i> = .02 7% (18/273)	22	21	185	501
ACR FNA criteria not met	2	58	16	129	2% (2/131)	21	1	599	752
All nodules	20	233	65	384	<i>P</i> = .03 5% (20/404)	43	22	784	1253

Overall number of nodules classified as benign or malignant, and total nodules, indicated in bold text.

Abbreviations: ACR, American College of Radiology; FNA, fine-needle aspiration; TI-RADS, Thyroid Image Reporting and Data System.

^aAll malignancies were confirmed on histology.

Table 3. Comparison of outcomes between pre–Thyroid Image Reporting and Data System (TI-RADS) and post–TI-RADS cohorts

Cohort	Total No. of patients	Proceeded to FNA after USS	ACR FNA criteria met	Proceeded to thyroid surgery	Thyroid cancer diagnosed in nodule identified on USS
Pre–TI-RADS	533	322 (60%)	N/A	98 (18%)	19 (4%)
Post–TI-RADS	558	274 (49%)	324 (58%)	78 (14%)	17 (3%)
Rate ratio for post–TI-RADS cohort, <i>P</i>		0.81; <i>P</i> < .01	0.96; <i>P</i> = .43 ^a	0.76; <i>P</i> = .048	0.85; <i>P</i> = .64

Abbreviations: ACR, American College of Radiology; FNA, fine-needle aspiration; N/A, not available; USS, ultrasonography scan.

^aCompared to FNA rate in pre–TI-RADS cohort.

TI-RADS was nondiscriminatory in the majority of nodules, lending weight to previous cost-benefit analyses questioning the value of routine reporting of TI-RADS [19].

A limitation of our study is the absence of definitive outcome data for a majority of nodules surveyed. This is a necessary trade-off in a study where the cohort is defined as patients presenting for ultrasound: It would be unethical to submit all patients presenting for ultrasound to FNA purely for research purposes. This limitation was mitigated by taking a permissive approach to the identification of applicable histology and FNA results, including histology results for all nodules present in each surgical specimen (not just those sampled by FNA) and FNA results predating the ultrasound.

It is also important to note that we did not independently validate TI-RADS reporting in this cohort and therefore cannot exclude the possibility of inaccurate scoring by reporting radiologists. It is possible that systematic reevaluation of all nodules in this cohort by a radiologist with expertise in thyroid ultrasonography would result in TI-RADS appearing more discriminatory; however, the intent of this audit was to assess real-world performance, which would not be fairly assessed if TI-RADS scoring had been retrospectively adjusted.

Conclusion

TI-RADS category is associated with malignancy rate in patients presenting for thyroid ultrasound; however, it is nondiscriminatory for the majority of nodules and may alter clinical decision-making in only a minority of patients. Terminology attached to the current reporting of TI-RADS may be misleading. The results of this study show that in unselected patients without risk factors, nodules labeled “highly suspicious for malignancy” (TR5) have only a modest rate of malignancy. The benefit of routine implementation of TI-RADS reporting at a population level are modest and may be insufficient to justify the associated time and cost.

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Disclosures

The authors have nothing to disclose.

Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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