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Main Article

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Can we better advise our patients with nodular thyroid disease?

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Abstract

Background. The 2014 British Thyroid Association guidelines acknowledged the value of risk-stratifying thyroid nodules by utilising an ultrasound reporting system ('U' classification). This study assessed whether using pre-existing parameters in combination can better stratify patients' malignancy and completion thyroidectomy risks.
Method. A multicentre, retrospective, observational review identified 936 NHS Greater Glasgow and Clyde patients from pathology records who underwent hemithyroidectomy between 1 January 2014 and 31 December 2019.
Results. A total of 308 patients had thyroid malignancy, 180 (58.4 per cent) progressed to completion thyroidectomy. A nodule classified as 'U3' (indeterminate) was associated with a 35.4 per cent chance of malignancy and a 21.6 per cent risk of requiring completion surgery. Amalgamation of 'U' score with Thy score enhanced risk prediction. The malignancy rate in U3, Thy-3f nodules was 38 per cent, and 21 per cent required completion surgery. The malignancy and completion thyroidectomy rates were comparatively lower for U3, Thy-3a nodules (22 per cent and 14.3 per cent, respectively).
Conclusion. Combining ultrasound 'U' score and Thy score improves pre-operative thyroid nodule risk stratification, leading to better informed patients regarding the risks of malignancy and completion surgery. A move towards an integrated assessment approach should be considered.

Introduction

Thyroid nodules are common. The lifetime risk for developing a thyroid nodule stands between 5 and 10 per cent, with a higher prevalence in iodine-deficient areas and in older adults.[1] Estimates suggest that approximately 15 per cent of the UK population possess clinically palpable thyroid nodules or goitres. However, in ultrasound studies, the prevalence rises to 70 per cent, increasing with age.[2,3] Of these nodules, only 5–15 per cent are malignant; however, the difficulty lies in discerning which nodules may be cancerous and treating these most appropriately.[4–6]

The management of suspicious thyroid nodules is complex. The primary concern is thyroid malignancy; however, determining the oncological significance is problematic. Whilst the global incidence of thyroid cancer has seen a 3- to 15-fold increase in the last three decades, critics hypothesise that the rise is consequential to increased access to imaging.[7–10] Stable annual mortality rates of 0.5 per 100 000 people appear to support this hypothesis, evidencing the mismatch between increasing incidence and outcomes, whilst suggesting the oncological impact to be minimal.[11,12]

Regardless of the cause, well-differentiated papillary carcinoma accounts for 80–90 per cent of thyroid cancer; it is associated with low malignant potential and a favourable prognosis, with exceptional five-year survival rates.[13–15] Decisions of whether to operate are traditionally based upon fine-needle aspiration cytology (FNAC) findings. However, the 2014 publication of the British Thyroid Association guidelines acknowledged the value of risk-stratifying thyroid nodules via an ultrasound reporting system ('U' classification).[3] These recommendations were reiterated in the UK National Multidisciplinary Guidelines published in 2016 by *The Journal of Laryngology & Otology*.[16]

Furthermore, the British Thyroid Association guidelines recommend that hemithyroidectomy can effectively treat lower-risk malignancies, as defined by size and histology, hence moving towards a more conservative approach. Previously, a more aggressive approach of total thyroidectomy, post-operative radioactive iodine and hormone suppression was advocated in the majority of cases. The guidelines recommend that the pre-operative decision for hemithyroidectomy over total thyroidectomy is based on the risk stratification from pre-operative factors (Thy score, nodule size and 'U' score, presence of adenopathy, pre-existing thyroid disease, family history of thyroid disease, and previous exposure to ionising radiation). However, there exists concern from clinicians of a potential mismatch between sonographic and cytological systems. Moreover, the ambiguity of indeterminate U-classification scores ('U3') and FNAC (Thy-3) is common.[17,18] Hence, definitive diagnosis is frequently only confirmed after hemithyroidectomy.

Inevitably, a cohort of patients who undergo hemithyroidectomy subsequently require a second surgery of completion thyroidectomy, potentially increasing the patient's risk of complications. Conversely, unnecessary total thyroidectomies commit patients to lifelong thyroid hormone replacement therapy and the consequences thereof. However, it does negate any uncertainty over the presence of contralateral lobe malignancy and, thus, makes thyroglobulin interpretation more straightforward. In addition, hemithyroidectomy is associated with a decreased complication rate and earlier hospital discharge, leading those favouring hemithyroidectomy to advocate its role in minimising peri-operative morbidity.[19]

The primary aim of this project was to determine if, using pre-existing parameters, we can better identify patients at risk of thyroid nodule malignancy, by considering factors other than FNAC results in isolation. The secondary aim was to better predict which patients with malignancy are more likely to require completion surgery.

Materials and methods

All patients who underwent thyroid surgery at NHS Greater Glasgow and Clyde between 1 January 2014 and 31 December 2019 were identified from the pathology records.

Only patients who underwent hemithyroidectomy as primary surgery were included. Patients in whom analysis reported a primary extra-thyroidal pathology were excluded.

Patient parameters were accessed via the TrakCare® healthcare information system and recorded on a secure Microsoft Access database. These parameters included: sex; age; nodule size on ultrasound scanning; the ultrasound scoring system if the details were available (ultrasound 'U' score, or American College of Radiology Thyroid Imaging Reporting and Data System ('TIRADS')); the Thy score (if FNAC was performed); the date of, and indication for, hemithyroidectomy; the pathology found; and, if malignant, the tumour (T) stage. In addition, in patients identified as having undergone completion thyroidectomy, the date of, and indication for, the completion surgery was recorded, and the final T stage was noted. If only a Thyroid Imaging Reporting and Data System score was recorded, this was converted to the corresponding 'U' score.

Consequently, the division of the dataset created two groups: those who underwent hemithyroidectomy only and those who progressed to completion surgery. Further analysis divided these groups into cancer-positive and cancer-negative sub-classes.

Statistical analysis

Statistical analysis was performed using IBM SPSS® statistical software. Categorical variables were conveyed as percentages. Descriptive statistics were obtained, and linear tests for trend, chi-square tests for association, or two-sample t-tests were carried out to compare groups and obtain p-values, with a p-value of less than 0.05 considered statistically significant. Data were excluded from analyses if the variable was unavailable.

The analysis focused on two groups: patients in whom the thyroid nodule was suspicious, as defined by a 'U' or Thy score of 3 or greater, and those in whom the nodule appeared benign.

Ethics

Ethical approval and individual patient consent were not required as the study design was observational and retrospective (i.e. there was no change to patient management).

Results

A total of 1761 patients underwent thyroid surgery between 1 January 2014 and 31 December 2019. Of these, 936 (53.2 per cent) underwent hemithyroidectomy and were eligible for inclusion in the study, with 755 patients (80.7 per cent) receiving only a hemithyroidectomy and 81 (19.3 per cent) progressing to completion thyroidectomy.

Of the overall group, 79.3 per cent were female (mean age of 49.45 ± 15.95 years, *vs* 52.57 ± 16.02 years for males). Similar sex divisions were observed in the hemithyroidectomy and completion thyroidectomy groups: 79.5 per cent and 78.5 per cent of females constituted each group, respectively. Statistical analysis revealed no significant difference between the percentages of females and males who progressed to completion surgery, 19.1 per cent compared to 20.1 per cent respectively ($\chi^2 = 0.092$; $p = 0.762$). Univariate analysis revealed males to be 1.063 times more likely to require completion surgery than females, indicating no significant difference between sexes ($p = 0.792$; confidence interval = 0.716, 1.580). In addition, there was no statistical significance in the malignancy rates between females and males, 32.2 per cent versus 35.6 per cent respectively ($\chi^2 = 0.785$, $p = 0.376$).

Figure 1 summarises the identification, inclusion and exclusion, and division of patients within the study.

Hemithyroidectomy indications

Diagnostic hemithyroidectomy performed for a suspicious nodule was the most common reason for surgery, in 709 cases (75.7 per cent). Of these, 164 (23.1 per cent) required completion thyroidectomy. Table 1 outlines the pre-operative indications for hemithyroidectomy for all 936 cases.

Ultrasound grading system

Across all hemithyroidectomies undertaken, scans from 636 patients (67.9 per cent) were accompanied by a sonographic score (ultrasound 'U' score or the American College of Radiology Thyroid Imaging and Reporting Data System). Of these, 626 scans reported a 'U' score. Conversely, only 46 scans reported a Thyroid Imaging and Reporting Data System score, and 36 of these were co-reported with a 'U' score.

Pre-operative nodule size

The mean index nodule size data are summarised in Table 2. No difference was noted between the benign and malignant groups, nor between the hemithyroidectomy group and those who progressed to completion thyroidectomy.

Ultrasound score in isolation

Only three patients' ultrasound scans were given a classification of 'U1' (benign with a normal thyroid gland), with one of these patients (33.3 per cent) requiring completion surgery.

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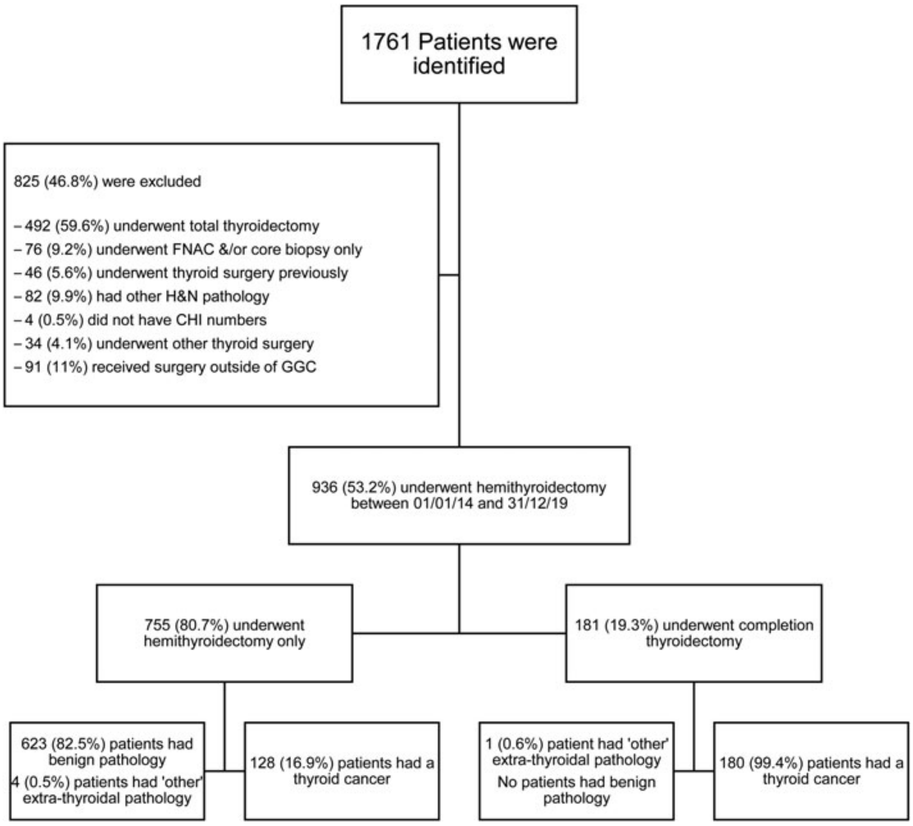

Figure 1. Identification, selection and division of patients in the study. FNAC = fine-needle aspiration cytology; H&N = head and neck; CHI = Community Health Index; GGC = NHS Greater Glasgow and Clyde

Table 1. Indications for hemithyroidectomy by group

Indication for hemithyroidectomy	All cases (*n*)	Hemithyroidectomy-only cases (*n*)	Completion thyroidectomy cases (*n*)	Numbers of cases requiring completion surgery
Compressive symptoms	165	154	11	6.67
Cosmetic	9	7	2	2.22
Cyst	37	36	1	2.70
Patient wishes	1	0	1	100
Suspicious lesion	709	545	164	23.13
Toxicity	15	13	2	13.33
Total	936	755	181	19.34

Table 2. Mean index nodule size by group

Comparison	Group	Nodule size (mean ± SD; mm)	*P*-value
1	Malignant	29.87 ± 16.54	0.933
	Benign	34.32 ± 16.70	
2	Malignant (no completion surgery)	28.50 ± 17.32	0.535
	Malignant (completion surgery required)	30.87 ± 15.93	
3	Completion surgery required	30.84 ± 15.88	0.534
	Hemithyroidectomy	33.29 ± 16.96	
4	Completion surgery required	30.84 ± 15.88	0.96
	Hemithyroidectomy (U score / Thy score ≥3)	31.35 ± 16.35	

SD = standard deviation

Given such small numbers, the classification of U1 was excluded from statistical analysis. However, linear-by-linear association revealed a statistically significant increase in the likelihood of malignancy and the requirement of completion surgery with an increasing 'U' score (χ^2 trend = 23.125, $p < 0.001$). Figure 2 summarises the percentages of patients per 'U' score according to benign or malignant disease and the requirement for completion thyroidectomy.

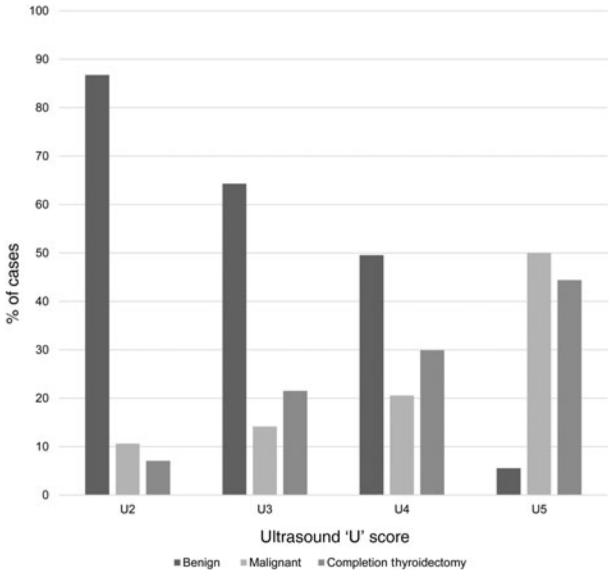

Figure 2. Percentages of cases per ultrasound 'U' score according to findings of benign or malignant disease, and completion thyroidectomy.

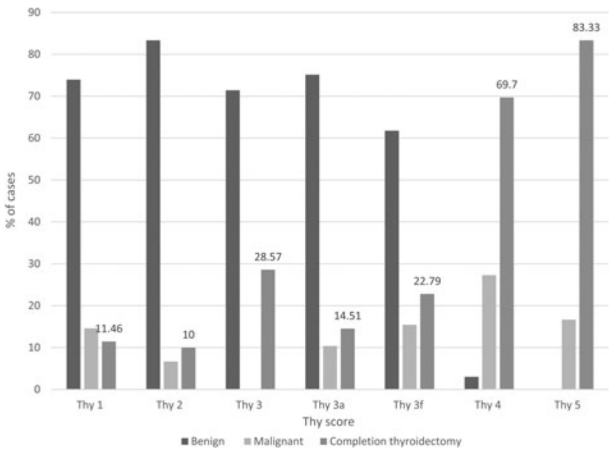

Figure 3. Percentages of cases per Thy score according to findings of benign or malignant disease, and completion thyroidectomy.

Thy score in isolation

Linear-by-linear association revealed a statistically significant increase in the rates of malignancy and requirement for completion surgery with an increasing Thy score (χ^2 trend = 32.263, $p < 0.001$).

Results show that 782 (83.5 per cent) of patients underwent FNAC. The pathology data and need for completion thyroidectomy for the 782 patients who underwent FNAC are categorised in Figure 3.

Eleven patients (7.1 per cent) who did not undergo FNAC progressed to completion thyroidectomy, eight were a result of multidisciplinary team recommendations, two were at the bequest of the patients and one was because of a second lesion on imaging.

Pathology

The pathology findings of diagnostic hemithyroidectomies with a malignant diagnosis are summarised in Table 3.

Cancer incidence and completion rates over time

The 2014 British Thyroid Association guidelines do not consider thyroid lymphomas or metastasis to the thyroid; hence, the 'other' (extra-thyroidal pathology) category was excluded from the analysis. Figure 4 depicts the percentages of primary thyroid cancer cases requiring completion thyroidectomy from 2014 to 2019. Diagnostic hemithyroidectomy identified 308 patients with primary thyroid cancer, with 180 (58.4 per cent) progressing to completion thyroidectomy. Linear-by-linear association did not identify a trend for a decrease in completion surgery rates from 2014 to 2019 (χ^2 trend = 1.150, $p = 0.284$) (Figure 4).

Nodules classified as U3–5, with cytological scoring

In our cohort, a pre-operative classification of a 'U3' (indeterminate) nodule was associated with a 35.4 per cent risk of malignancy and a 21.6 per cent risk of requiring completion surgery, with these likelihood rates rising to 50 per cent and 29.6 per cent for a nodule classified as 'U4' (suspicious)

Table 3. Histological classification of primary thyroid cancers

Pathology	All cases (*n*)	Hemithyroidectomy-only cases (*n*)	Completion thyroidectomy cases (*n*)	Numbers of cases requiring completion surgery	Numbers of cancers found in patients
Anaplastic thyroid cancer	1	1	0	0	0.32
Follicular thyroid cancer	81	22	59	72.84	26.30
Incidental medullary microcarcinoma	1	1	0	0	0.32
Incidental papillary microcarcinoma	66	53	13	19.69	21.43
Medullary thyroid cancer	3	0	3	100	0.91
Papillary thyroid cancer	153	49	104	67.97	49.68
Poorly differentiated thyroid cancer	1	0	1	100	0.32
SCC of thyroid	2	2	0	0	0.65
Total	308	128	180	58.44	100

SCC = squamous cell carcinoma

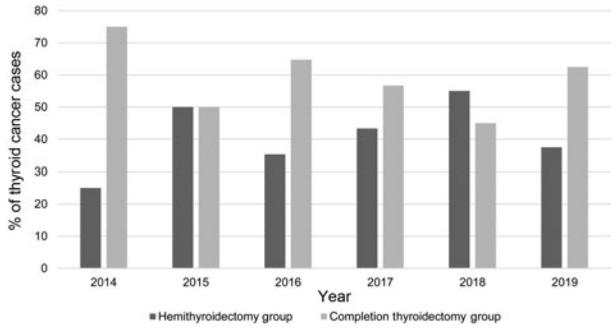

Figure 4. Percentages of thyroid cancers progressing to completion surgery, by year.

respectively. A nodule classified as 'U5' (malignant) carried a 94.4 per cent risk of malignancy and a 66.1 per cent risk of completion thyroidectomy. Table 4 depicts the implication of risk modification on the 'U' score when subcategorised by Thy score.

Tumour stage

Between 2014 and 2019, no primary thyroid cancers were found to be T_4 stage. Figure 5 depicts the difference in the final T stage between the two groups. The results show a propensity for the completion thyroidectomy group to have a higher final T stage ($\chi^2 = 44.867$, $p < 0.001$).

Discussion

This study demonstrated that, between 2014 and 2019, around 1 in 5 of the 936 patients who underwent hemithyroidectomy required completion thyroidectomy. The sex of patients had no bearing on this; however, as with previous studies, approximately four-fifths of those with thyroid disease, including malignancy requiring hemithyroidectomy or completion surgery, were female. Diagnostic hemithyroidectomy was the most common indication for primary surgery. This procedure was performed on approximately 75 per cent of patients, because of a suspicious thyroid nodule, with around 40 per cent of these patients subsequently found to have primary thyroid cancer. In our cohort of patients with primary thyroid cancer, the final T stage of the completion thyroidectomy group was significantly higher than that of the hemithyroidectomy group, although this would not have been known pre-operatively.

In contrast to other malignancies, differentiated thyroid cancer has a comparatively indolent disease course and is associated with excellent disease-specific survival rates, with studies showing the disease-specific survival rate to be as high as 98 per cent.[20,21] However, as our study excluded those who underwent primary total thyroidectomy ($n = 492$), the rate of differentiated thyroid cancer papillary thyroid carcinoma subtype was lower than that reported in the established literature. In our cohort, 234 patients (76 per cent) had differentiated thyroid cancer; papillary thyroid cancer comprised 153 (65.4 per cent) of differentiated thyroid cancer cases and 81 (34.6 per cent) of cases were follicular thyroid cancer. However, independent evaluation of all thyroid cancers revealed 26.3 per cent of patients to have follicular thyroid cancer; this rate is in line with other UK studies, but is higher than reported in seminal international series. Moreover, over one-fifth of study patients were found to have incidental papillary thyroid microcarcinoma, as defined based on nodules with a

Table 4. Patients with U3–5 nodules found to be malignant who underwent completion thyroidectomy, per Thy score

Ultrasound 'U' score	Thy score	Cases (n)	Numbers of malignant cases	Numbers of completion surgery cases
U3 (indeterminate) ($n = 384$)	Thy-1	23	30.43	21.74
	Thy-2	9	11.11	11.11
	Thy-3			
	Thy-3a	91	21.98	14.29
	Thy-3f	234	38.03	21.37
	Thy-4	15	93.33	66.67
	Thy-5	3	100	100
U4 (suspicious) ($n = 108$)	Thy-1	10	30	10
	Thy-2	1	0	0
	Thy-3	2	50	50
	Thy-3a	23	30.43	13.04
	Thy-3f	57	50.88	29.82
	Thy-4	9	100	55.56
	Thy-5	5	100	100
U5 (malignant) ($n = 18$)	Thy-1	1	100	0
	Thy-2	1	100	0
	Thy-3			
	Thy-3a	1	100	0
	Thy-3f	6	83.33	16.67
	Thy-4	5	100	80
	Thy-5	3	100	66.67

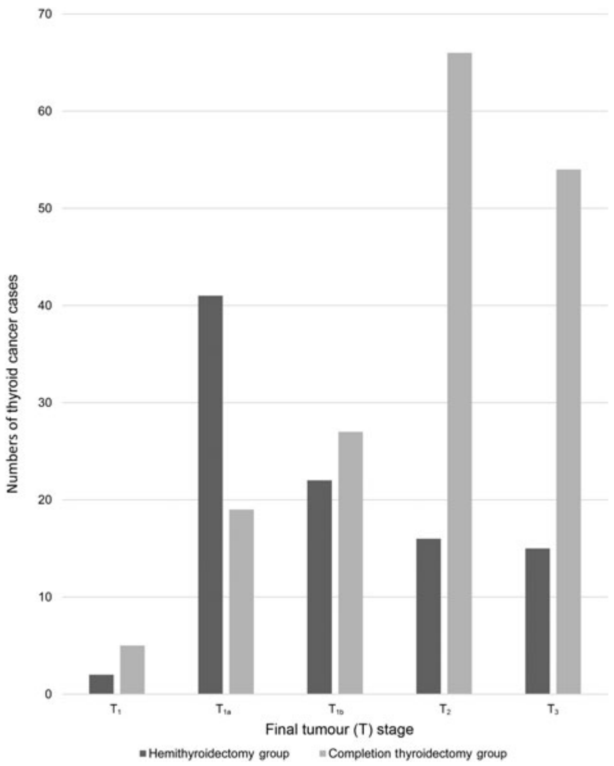

Figure 5. Numbers of final tumour (T) stages of patients with thyroid cancer who underwent hemithyroidectomy or completion thyroidectomy.

diameter of 10 mm or smaller. When differentiated thyroid cancer was extended to include papillary thyroid microcarcinoma, the incidence of differentiated thyroid cancer rose to 97.4 per cent and papillary thyroid cancer comprised 73 per cent of differentiated thyroid cancer cases.

Given the aforenoted incidence of papillary thyroid microcarcinoma and one further diagnosis of incidental medullary carcinoma, incidental cancer accounted for 21.8 per cent of cancer diagnoses. Our findings are consistent with previous literature suggesting thyroid nodule size to be a poor predictor of underlying malignancy, with no difference in the mean index nodule size, even when only those with suspicious nodules (an ultrasound ('U') score or Thy score of ≥3) were compared with the completion surgery group, in which all nodes were malignant.[3]

In addition to advocating an increased role of hemithyroidectomy, the British Thyroid Association guidelines recommend using ultrasound grading systems ('U' scores) when reporting thyroid ultrasound scans.[3] Our results show a significant increase, from 2014 to 2019, in the reporting of thyroid ultrasound scans with a classification system, though not to 100 per cent. However, we acknowledge that the latest practice takes time to become the standard.

Whilst the risks of thyroid malignancy and completion surgery are associated with higher ultrasound ('U') and Thy scores, in our cohort, two-thirds of 'U' and Thy scores were indeterminate (classified as 'U3', or as Thy-3, Thy-3a or Thy-3f). Of the ultrasound scans graded as benign (classified as 'U2'), 17.6 per cent turned out to be cancerous nodules, indicating a problem with false negative results. We cannot definitively conclude that the graded nodule was found to be malignant on histopathological analysis, as opposed to the actual malignancy being an occult and incidental finding. The thyroid nodule T stage data indicated that patients who progressed to completion thyroidectomy had a higher final T stage. Moreover, a number of pre-operative fine-needle aspiration samples were insufficient ($n = 97$, 12.4 per cent were graded Thy-1), and, of those in the benign (Thy-2) category, 16.7 per cent were malignant. Whilst 16.5 per cent of patients did not undergo FNAC, this rate may have been reasonable if these nodules were very small. Hence, whilst indicative, these scores are only one of several factors that need to be considered when determining whether completion surgery is likely to be required.

The increased detection of incidental thyroid cancer is heavily dependent upon high-frequency ultrasound and FNAC. These investigations may contribute to the rising incidence of thyroid malignancy.[22] This compounds the view that the assessment of thyroid nodules remains complex.

The current malignancy rates for the various cytology subgroups have been reported as follows: Thy-1 = 4.5–12 per cent; Thy-2 = 5 per cent; Thy-3 = 9.5–43 per cent; Thy-3a = 25 per cent; Thy-3f = 31 per cent; Thy-4 = 68–79 per cent; and Thy-5 = 98–99 per cent.[3,23] Moreover, within the Thy-3 category, where the risk of malignancy is reported to markedly vary, the risk was greatest with concurrent suspicious ultrasound features.[24] A retrospective observational study published in 2020 reported that 129 patients underwent thyroid surgery, with 35 (27.1 per cent) reported cases of thyroid malignancy. The percentages of patients with cancer classified as 'U1' (benign with a normal thyroid gland), 'U2' (benign thyroid nodule), 'U3' (indeterminate), 'U4' (suspicious thyroid nodule) and 'U5' (malignant nodule) were 0 per cent, 13.6 per cent, 30.4 per cent, 40 per cent and 100 per cent, respectively.[25,26] In a study by Weller *et al.* comprising 73 patients with 17 histologically confirmed malignant nodules, the negative predictive value and sensitivity of the 'U' score was 100 per cent, and the specificity and positive predictive value was 34 per cent and 32 per cent respectively.[20,27] Our study reported a 'U4', Thy-4 nodule as having a 100 per cent risk of malignancy, compared to isolated U4 and Thy-4 scores which yielded rates of 40 per cent and 79 per cent respectively. Thus, we recommend that contemporary management incorporate both the 'U' and Thy classification systems in the decision-making process.

This study suggests that the risk of malignancy in a thyroid nodule should be determined on a multi-assessment basis, in line with other complex evaluations such as breast lump assessment. Thus, the risk of thyroid nodule malignancy should consider both the ultrasonographical classification and the cytology findings, rather than relying on cytology alone. This also enables patients in higher-risk groups to be better informed, and avoids overly aggressive treatment of low-risk malignancies. The management of thyroid malignancy has seen a significant move away from a standardised approach to a newer risk-stratified treatment algorithm, in which the degree of surgery, use of radioactive iodine therapy, extent of thyroid-stimulating hormone suppression and intensity of follow up are tailored to each patient based upon the perceived risk of malignancy.[28] Stratification of the likelihood of malignancy and consequently of completion surgery allows a cost-effective and risk-adapted approach to the selection of patients for either surgery or long-term follow up.

In order to assess whether the British Thyroid Association guidelines and introduction of the 'U' score have influenced the surgical management of suspicious lesions, future research should also include populations that underwent total thyroidectomy as a primary procedure ($n = 492$), to determine whether the incidence of total thyroidectomies has fallen

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since 2014. Although the literature suggests that completion thyroidectomy is a safe surgical intervention, Shaha *et al.* found a more significant risk associated with completion thyroidectomy compared to active observation.[29–31]

There are several limitations to our study. Firstly, grading of ultrasound scans using the 'U' score was operator-dependent and, where scans were reported with two scores, the higher was taken. Secondly, as the eighth edition of the *TNM Classification of Malignant Tumours* was published in 2016, differences between the two tumour–node–metastasis classifications may have resulted in potential variations, depending on the year of reporting in this study.[32] This investigation is also limited in terms of the longitudinal follow up of patients with thyroid malignancy. Whilst the literature recognises that most recurrences are identified within the first three years of follow up, insufficient time will have passed, particularly for patients seen from 2016 onwards, for potential malignancies that required hemithyroidectomy to develop into recurrences needing completion surgery; however, long-term follow up was not the aim of the project.[20,33]

- Thyroid nodules are primarily assessed by ultrasound to determine the need for biopsy
- Since 2014, the 'U' classification of thyroid ultrasounds has been recommended to guide decisions to perform biopsy
- Current practice uses biopsy Thy scores in isolation to define the malignancy risk and direct patient management
- By combining ultrasound and biopsy scores, a greater degree of risk stratification can be achieved
- In conjunction with clinical assessment, this supports a move to a tripartite system of thyroid assessment as per the triple assessment system for breast lumps

Strengths of this study include the identification of patients via pathology records rather than records from a single hospital, leading to a relatively large sample size and the recruitment of all eligible patients from the region. Furthermore, the inclusion of patients over a five-year period allowed for potential trends across the years of guideline management uptake to be identified.

Conclusion

Combining ultrasound 'U' score and FNAC results improves the predictability of risks of malignancy and need for completion thyroidectomy in patients presenting with thyroid nodules. Thus, we would advocate that contemporary management incorporate both the 'U' and Thy classification systems in the decision-making process.

Competing interests. None declared

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