Correlation between thyroid fine needle aspiration cytology and post-operative histology: A 10-year experience

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Abstract

Introduction Fine needle aspiration cytology (FNAC) forms part of the routine workup for suspicious thyroid nodule. Whilst cytological analysis is less precise than histological assessment, it is quick and easy to perform and may avoid the need for invasive and potentially risky surgery. Methods This retrospective study spanning a 10-year period compared pre-operative FNAC with post-operative histology results to establish the accuracy of diagnosis and malignancy rates within our population. These results were then compared to the published figures in the literature. Results The histological reports of 659 consecutive cases of thyroid surgery between 2006 and 2015 were retrieved from our hospital's database. Among the 471 patients (71.5%) who underwent preoperative FNAC, the postoperative histology was reported as benign in 352 (74.7%) and malignant in 119 cases (25.3%). PTC was the commonest histological diagnosis. Thy1 grade was reported in 165 (30%) cases, with 19.4% had a final histological diagnosis of malignancy. 85.3% of patients in the Thy2 group had a benign final histological diagnosis, while 14.7% had malignancy (false negative results). Malignancy was found in 89% of Thy4 and 100% of Thy5 group patients. Conclusions Rates of malignancy varied considerably from those in the published literature. Each centre should be able to quote a local malignancy rate during patient counselling. It is also prudent for all units performing thyroid diagnostics to investigate the factors that might lead to inaccuracies in reporting.

Main text:

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Conclusions

Rates of malignancy varied considerably from those in the published literature. Each centre should be able to quote a local malignancy rate during patient counselling. It is also prudent for all units performing thyroid diagnostics to investigate the factors that might lead to inaccuracies in reporting.

Keywords: Fine needle biopsy; thyroid cytology; thyroid cancer; diagnostic accuracy

Key Points:

- The diagnostic performance of the tiered FNAC reporting system can be variable between different institutions

- Our results demonstrate higher rates of malignancy compared to other published series.

-Thy1 and Thy2 results (especially from cystic lesions) should be interpreted with caution and repeat testing performed if any other suspicious criteria.

- Individual centres should discuss FNAC cytology in a multidisciplinary team setting, and should quote local malignancy rates during patient counselling.

- It is prudent for all units performing thyroid diagnostics to control the factors that might lead to reporting variability.

Manuscript:

Introduction

Thyroid nodules represent a common problem for surgeons as well as a diagnostic challenge for pathologists. These can be detected in more than 60% of the general population, with incidence of malignancy found to be around 5%, and 3254 new cases diagnosed in the United Kingdom (UK) in 2017.[1-4] The challenge facing clinicians dealing with thyroid nodules is to achieve an accurate preoperative diagnosis of malignancy, and therefore fine needle aspiration cytology (FNAC) can play an important role in the diagnostic workup. It is a relatively safe, cost effective and simple procedure. Although it is less precise than standard histological assessment, it may help avoid invasive and potentially unnecessary surgery.[1]

In current UK practice, FNAC specimens are reported according to the Royal College of Pathologists (RCPath) Thy grading system, first published in 2009 and revised in 2016 (**Table 1)** . In its latest version, the RCPath Thy system had six diagnostic categories (DCs), as it divided the neoplasm possible category (Thy3) into Thy3a (neoplasm possible-atypia/nondiagnostic) and Thy3f (neoplasm possible, suggestive of follicular

neoplasm).[1] Thyroid cysts were also subcategorised within Thy1 and Thy2 grades as Thy1c and Thy2c respectively. The RCPath system is well aligned and largely comparable with the six-tiered Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), and other internationally recognised reporting terminologies for thyroid FNAC (**Table 1**).[5]

Regardless of the terminology used, approximately 20-25% of all thyroid cytology is classified as indeterminate (Thy3a and Thy3f), in which it is not possible to differentiate between benign, malignant, or suspicious

nodules.[5,6,7] For some of these indeterminate lesions the current UK management guidelines recommend diagnostic removal of the affected lobe, guided by the decision of multidisciplinary team (MDT), with potential progression to completion thyroidectomy following review of the post-operative histology.[8] This will inevitably lead to some benign lesions labelled as Thy3 or Thy4 being overtreated with hemithyroidectomy unnecessarily, with all the associated risks. Conversely, a high false negative rate with Thy2 cytology could lead to missed cancers and potential progression of disease. Therefore, optimising the diagnostic performance of the grading systems used in individual centres is of the utmost importance.[7,8]

The aim of this retrospective study was threefold. 1) to correlate pre-operative FNAC results with subsequent histology findings as the gold standard. 2) to audit the utilisation and the diagnostic performance of each category of the RCPath Thy system, including the sensitivity, specificity, accuracy and positive predictive values for malignancy within the patient population in our locality. 3) to compare our diagnostic performance results to previously published literature.

Materials and Methods

Study subjects and data Acquisition

We conducted a retrospective single-centre observational study in a UK district general hospital. As we used deidentified routinely collected data, this was not classified as research using the NHS health research authority online decision tool (accessible from www.hra-decisiontools.org.uk/research), and therefore IRB approval was not required, **supplementary material, Figure** . We included all patients who had thyroid resection (total or hemithyroidectomy) performed over a ten-year period, between January 2006 and December 2015. Eligible thyroid histology data was extracted from our digital pathology database and was correlated with FNAC where available. Data collected included age, gender, indication for surgery, details of FNAC, and the final histological diagnosis. If a patient had abnormal aspirate results taken from more than one nodule, the most abnormal result was used for analysis. If final histology reported incidental malignant lesions that were not sampled during the FNAC, these reports were excluded from the analysis.

Fine needle aspiration sample processing

In our institution, FNAC samples are routinely aspirated using ultrasound guidance (UGFNAC), with a minority obtained by palpation-guidance (PGFNAC), generally from the early years of the study. Each specimen contains at least an air-dried slide and an alcohol fixed slide. Samples were prepared by the conventional methods using Papanicolaou Romanowsky-type stains. The department uses a 'Quick Dip' Rapid Romanowsky staining kit for air-dried slides. Samples are distributed for reporting among eight general histopathologists in the department.

Data Management

All FNAC data was sorted in to six cytopathological groups according to the RCPath Thy grading system. For those cytology results from the earlier years of the study, reports were 'translated' into Thy categories and slides were reviewed if needed. Incidence rates of malignancy for each Thy grading and other diagnostic performance indicators were calculated and compared with figures from previously published literature and guidelines.

Statistical analysis

The performance of thyroid cytology was assessed for its sensitivity, specificity, diagnostic accuracy, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), and negative likelihood ratio (NLR). These parameters were calculated according to the statistical equations described in the **supplementary material, Table A** . For the purpose of yielding accurate results, patients with Thy1 results have been excluded when measuring the diagnostic performance of other categories, and were reported separately.

Results

In the ten-year period of our study, a total of 659 patients underwent thyroid resection. The mean age at operation was 49.6 ± 10.3 years, and 76.5% of patients were females. A total of 520 thyroid specimens were reported as benign (78.9%), and 139 (21.1%) as malignant (**Table 2)** . Papillary thyroid cancer (PTC) was the commonest malignancy, reported in 106 patients (76.3%), of which one third (29.2%) were < 1 cm, and were classified as PTC microcarcinomas (PTMC) (**Table 2**). Follicular thyroid cancer (FTC) was diagnosed in 22 patients (15.8%), while medullary (MTC), anaplastic thyroid cancer, and thyroid lymphoma (TL) were collectively diagnosed in under 8% of the patients (**Table 2**). More than 80% of the patients with benign histological diagnoses had benign nodular goitre (N=418), while follicular and Hürthle cell adenomas, Hashimoto's thyroiditis and Graves' disease were histologically diagnosed in 68, 26 and 5 patients respectively (**Table 3**).

Correlation between Thy grading system and histology diagnosis

Among the 471 patients (71.5%) who underwent preoperative FNAC, the postoperative histology was reported as benign in 352 (74.7%) and malignant in 119 cases (25.3%), **Table 2** . Thy1 grade was reported in 165 cases, with 32 (19.4%) had final histological diagnosis of malignancy. Around 10% (N=16) of Thy1 lesions were cystic (Thy1c) with malignancy encountered in around 23% of these lesions. The majority of patients in Thy2 group had a benign final histological diagnosis. However, 28 patients (14.7%) with Thy2 cytology had malignant nodules on post-operative histology (false negative). The false negative rate increased to 50% for the Thy2c sub-category (**Table 2**). Thy3a and Thy3f FNAC categories were reported in 48 and 41 patients respectively, with histology confirming malignancy in 14 (29.2%) and 21 (51.2%) patients respectively (**Table 2**). Thy4 and Thy5 categories where only recorded in 18 (3.82%) and 7 (1.5%) patients respectively, with malignancy diagnosis confirmed in 16 (89%) of Thy4 and 7 (100%) of Thy5 patients. PTC was the commonest histological diagnosis in all six DCs. Interestingly, the only two patients with MTC and 2 out of 5 with TL had non-diagnostic (Thy1) FNAC, and were operated on mainly based on clinical and radiological suspicion.

Diagnostic performance of RCPath Thy grading system (Table 4 and supplementary Table B)

We measured the diagnostic performance of our FNAC categories and compared the results with the most up-to-date figures published in the latest RCPath guidelines in 2016[1], and the latest meta-analyses published by Poller *et al.* [5,6] for the RCPath Thy system (13 articles, 3911 nodules), and Bongiovanni *et al.* [9] for TBSRTC (8 articles, 6362 nodules),**Table 4** .

35% of the samples in our series were categorised as Thy1, which is higher than previously published figures (18-27%).[1,6]There were also some minor differences in the utilisation of Thy1 and Thy2 categories between the RCPath system and TBSRTC (Grade I, II), where the later system identifying fewer grade I and more grade II samples (**Table 4**).

While the risk of malignancy (ROM or PPV) in our Thy5 category (100%) was comparable to published literature for the RCPath system (98-100%)[1,5] and TBSRTC (99%)[9], our malignancy rates were higher for all other categories (**Table 4**). ROM was higher for Thy2 grade in our study (15%) compared to RCPath system rates (1.4-5%), and TBSRTC (4%). ROM was also surprisingly much higher for our Thy 4 patients (90%) compared to the RCPath figures (up to 68%)[1], the meta-analysis of results using the Thy system by Poller *et al.* [5](79%), or the TBSRTC system meta-analysis by Bongiovanni *et al.* [9] (75.2%). Combining Thy4 and Thy5 groups together (suspicious or malignant FNAC) demonstrated a high specificity, PLR and PPV for malignancy (99.1%, 30.1, and 92.3% respectively), with low sensitivity (27.6%), and moderate NPV (77.4%) and accuracy (78.7%) (**Table 4 and supplementary Table B).** Combining Thy3-5 groups together (any abnormal FNAC) improved the sensitivity and the NPV (67.8% and 85.3% respectively) at

the expense of reducing the specificity, PPV and the overall accuracy (74.3%, 51.3%, 72.5% respectively).

Discussion

FNAC plays an important role in the initial evaluation and decision planning for patients with thyroid nodules. However, FNAC has drawbacks especially with its relatively high rate of inadequate or unsatisfactory samples, necessitating repeat testing, and its inability to distinguish between benign and malignant lesions in some situations.[8,10-12] Moreover, false positive diagnosis of malignancy can sometimes occur, which can lead to unnecessary thyroid surgery with a 2-10% risk for long-term postoperative morbidity.[13,14] As the decision to pursue surgery as opposed to conservative management is greatly influenced by the FNAC results, there is a need for a consistent reporting process and rigorous evaluation of the diagnostic utility of thyroid FNAC.[1,13,15,16]

The RCPath Thy grading system was designed to refine and improve the reporting process, and to provide clarity for patient management.[1] It can provide consistent, reproducible and auditable thyroid cytopathological reports, improve the communication process between clinicians and patients, and give figures for the predicted risk of malignancy with each cytological diagnosis.[8,9]

This study builds on the growing body of literature to validate the diagnostic utility of the RCPath Thy system in guiding the day-to-day clinical management.[1,5,6] While the validity of using six-tiered systems (like the RCPath system or TBSRTC) is justifiable by the strong reported cyto-histological correlation, there was a notable variability in the implied risk of malignancy for different DCs and subsequently the percentage of patients undergoing surgery.[1,5,6,9] As standards for FNAC reporting outcomes are not universally set, quality assurance at individual institutions by undertaking regular audit is paramount to maintaining accuracy.[1,6,17]

Our results demonstrate higher rates of malignancy and utilisation of the Thy1 non-diagnostic category in our cohort. This can be partially explained by sampling error from using the less-precise PGFNAC technique in cases from the early years of the study, and possibly poor operator techniques. [19] In addition, unsatisfactory sample preparation and preservation, especially from cystic lesions, are well recognised factors leading to higher rates of non-diagnostic aspirates.[5,8] The Thy2 category also had a higher rate of malignancy in our cohort. Interestingly, 40% of the false negative Thy2 cases had PTMC (<1cm), which can further explain the sampling challenges of smaller lesions, especially with PGFNAC technique. In the meta-analysis performed by Wang *et al.* [20], the authors noted a significant difference between the FN rates for benign FNAC between academic (2%) and community hospitals (10%). The authors attributed this difference to higher sampling error with PGFNA and differences in cytological interpretation.[20] Moreover, selection bias for treatment may also skew the ROM figures, as patients with Thy1 or Thy2 results will only undergo surgery if they show suspicious clinical or radiological features.[5,7]

Cystic changes and degenerative processes in thyroid nodules can often cause florid atypia, with a considerable potential for FN results and malignancy in around 14-17% of Thy1c and 4-33% of Thy2c nodules.[13,21-24] Interestingly, our results when compared to the published figures, showed a higher ROM in Thy1c (19%) and Thy2c (50%), which can only be partially explained by treatment selection bias. However, we agree with the BTA guidelines that FNAC should be repeated for all Thy1 and Thy2 cases with suspicious clinical or sonographic features.[8] **Table 5** summarises the recommended clinical actions for each RCPath FNAC category.

One of the main aims of the RCPath Thy nomenclature, is to reduce the cytological reporting variability for the indeterminate thyroid nodules. These are often challenging for clinicians and pathologists because of their heterogenous morphology, and the difficulty to establish cytologically any invasive characteristics without thorough histopathological examination.[6] Our malignancy rates for Thy3a and Thy3f categories are notably higher as shown in**Table 4.** It is well recognised that Thy3a category can often be conceived by cytopathologists as a 'haven of safety', avoiding false negatives when assigned instead of Thy2, and potentially unnecessary surgery when assigned instead of Thy3f, and avoiding false positives when assigned instead of Thy4.[7]

In our cohort, Thy4 patients also had a higher malignancy rate (90%) compared to the published figures. The BTA recommendation of diagnostic hemithyroidectomy for Thy4 lesions is based on the RCPath guidelines which quotes a 30-35% possibility of benign disease in this cohort and hence avoiding the potential long-term morbidity of total thyroidectomy[8]. However, In centres with a malignancy rate of >90% for Thy4 cytology, an argument could be made for offering total thyroidectomy in patients with larger nodules(>4cm) to avoid a second procedure of completion hemithyroidectomy.[8] Malignancy is almost always histologically confirmed in Thy5 patients, justifying our standard practice of therapeutic hemi- or total thyroidectomy ± central compartment neck dissection guided by the MDT decision.[1,8]

In our cohort, Thy4 patients also had higher malignancy rates compared to the published figures. In keeping with the BTA recommendations (**Table 5)** , our results confirm that total thyroidectomy should not be offered to Thy4 lesions as this would put at least one in ten patients at risk of unnecessary surgery with its potential long-term morbidity.[8] However, malignancy is almost always histologically confirmed in Thy5 patients, justifying our standard practice of therapeutic hemi- or total thyroidectomy ± central compartment neck dissection guided by the MDT decision.[1,8]

The limitations of our study include a possibly heterogenous population, inclusion of samples taken using PGFNAC techniques, and our study period crosses multiple revisions of the Thy system nomenclature. Since this was a retrospective study, it is sometimes difficult to ascertain that a histologically diagnosed malignant nodule is the same one aspirated for FNAC preoperatively. Moreover, we only included histologically-correlated FNAC samples, which likely skewed our malignancy rates in the lower risk categories when cancer is not frequently encountered. While using a tiered classification nomenclature like the Thy or TBSRTC systems may improve comparability of results between various institutions, these comparisons must be taken with caution as the results are often influenced by multiple factors. These factors include differences in thyroid cancer prevalence, variations in nodule selection for aspiration, the skill of the aspirators, the aspiration techniques, the experience of the cytopathologists, and the percentage of cases progressing to have surgery.[6,7]Moreover, the methods of calculating the ROMs and PPVs rates are widely variable in the literature, making it incredibly difficult to compare different studies.[6,7,16]

The other issue limiting the generalisability of the FNAC outcomes is the inherent inter- and intraobserver variability of thyroid cytology reporting.[6,13,15,25] In a large multi-centre prospective study by Cibas *et al.* [16] that assessed the reporting variability of the TBSRTC system, concordance level between the local cytopathologists and a central review panel was only 64%, with 74.7% intraobserver concordance. The false positive rate of category VI (Thy5) was 6%, and these patients could potentially have undergone unnecessary surgery if they were not downgraded by the central review panel.[15] Studies on the RCPath Thy system show very similar pattern with highest concordance for Thy1 and Thy5, moderate concordance for Thy2 and Thy3f, and lowest concordance for Thy3a and Thy4 categories.[25]

Conclusion

The use of tiered classification nomenclature, such as the RCPath Thy system, have paved the way to standardized thyroid FNAC reporting. However, diagnostic performance can be variable between different institutions. Our results demonstrate generally higher rates of malignancy compared to other published series. Each individual centre should be able to discuss suspicious cytology results in a multidisciplinary team setting, and to be able to quote local malignancy rates during patient counselling. It is prudent for all units performing thyroid diagnostics to control the factors that might lead to reporting variability, and to undertake regular audit of their performance. Adjunct immunohistochemical and molecular testing is promising, and may in future provide a route to improve thyroid cytology outcomes and so help in standardising the reporting outcomes.

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Tables:

Table 1. Comparison between the Royal College of Pathologists and the Bethesda systems for thyroid fine-needle aspiration cytology reporting

Table 2. Cyto-histological correlation for malignant and benign cases

Table 3. Benign diagnoses at the final histology reports

Table 4. The utilisation of different FNAC cytology categories and the implied risk of malignancy in our cohort and the published literature[1,5,6,9].

Table 5. Recommended clinical actions for each RCPath FNAC category

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