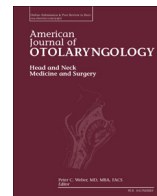




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The contemporary utility of intraoperative frozen sections in thyroid surgery[☆]

Samuel J. Trosman^a, Rohith Bhargavan^b, Brandon L. Prendes^a, Brian B. Burkey^a, Joseph Scharpf^{a,*}

^a Head and Neck Institute, Cleveland Clinic Foundation, United States

^b Case Western Reserve University School of Medicine, Cleveland, OH, United States

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ABSTRACT

Purpose: To determine the accuracy of intraoperative frozen section analysis on thyroidectomy specimens stratified by the Bethesda classification scheme and its utility for intraoperative decision-making.

Study design: Retrospective chart review.

Methods: A retrospective review was performed on all patients who underwent thyroidectomy or thyroid lobectomy with intraoperative frozen sections at a tertiary care academic center from 2009 to 2015.

Results: There were 74 total patients who underwent partial or total thyroidectomy with intraoperative frozen section analysis of a thyroid nodule whom had previously undergone a thyroid fine needle aspiration of the nodule. The sensitivity, specificity, positive predictive value, and negative predictive value for a thyroid frozen section with respect to its prediction for malignancy was 81%, 95%, 98%, and 66%, respectively, with a diagnostic accuracy of 85%. For 37 patients with an indeterminate cytologic diagnosis on fine needle aspiration (Bethesda categories III–V), the sensitivity, specificity, positive predictive value, and negative predictive value for a thyroid frozen section was 81%, 91%, 95%, and 67%, respectively, with a diagnostic accuracy of 84%. False positives and false negatives resulted in 1 completion thyroidectomy for benign pathology and 3 reoperations for malignancy not discovered on frozen section.

Conclusion: While intraoperative frozen sections on thyroid specimens may be helpful if positive, the false negative rate remains high. There appears to be limited value in routine frozen sections to guide clinical management and decision-making in the era of the Bethesda system.

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1. Introduction

The increasing incidence and detection of thyroid nodules over the past decade [1] has led to an increase in fine needle aspiration biopsies. While there was initially much variability with regards to the classification and subsequent management of these results, this has improved greatly with the standardization brought on by the Bethesda classification system, introduced in 2007 and used widely since 2009 [2]. Within the classification scheme, studies have shown a high level of accuracy for the Bethesda II (benign) and Bethesda VI (malignant) categories [3]; however, the indeterminate Bethesda categories III (atypia of undetermined significance or follicular lesion of undetermined significance), IV (follicular neoplasm or suspicious for follicular neoplasm), and V

(suspicious for malignancy) have highly variable reported rates of malignancy and greater discordance amongst cytopathologists, resulting in a lack of a clear management strategy for the clinician.

One proposed solution for the ambiguity regarding the indeterminate Bethesda categories is the use of intraoperative frozen section analysis on thyroidectomy specimens to determine the need for completion thyroidectomy. While frozen sections are used frequently and with great accuracy for head and neck aerodigestive tract malignancies, prior studies on thyroid specimens have shown mixed results [4–7], leading some to assert that cytologically indeterminate nodules cannot be accurately diagnosed intraoperatively [8]. Most of the aforementioned reviews, however, were performed prior to the adoption of the Bethesda system; therefore, there is a paucity of data regarding the accuracy and utility of frozen section analysis on nodules classified within this system. This lack of data is reflected in the 2015 American Thyroid Association (ATA) management guidelines, which neither argues for nor against the use of intraoperative frozen sections [9].

The purpose of our study was to determine the accuracy of intraoperative frozen section analysis on thyroidectomy specimens stratified by the Bethesda classification scheme and its utility for intraoperative decision-making, with a focus on indeterminate (Bethesda categories III–V) nodules.

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* Corresponding author at: Head and Neck Institute, Cleveland Clinic Foundation, 9500 Euclid Ave., Cleveland, OH 44195, United States

E-mail addresses: trosmas@ccf.org (S.J. Trosman), Rxb430@case.edu (R. Bhargavan), prendeb@ccf.org (B.L. Prendes), Burkeyb1@ccf.org (B.B. Burkey), Scharpfj@ccf.org (J. Scharpf).

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2. Materials and methods

The study was approved by the Cleveland Clinic institutional review board. A retrospective chart review was performed on all patients who underwent thyroid lobectomy or total thyroidectomy with intraoperative frozen section analysis at a tertiary care academic center from 2009 to 2015, after the adoption of the Bethesda classification system. Frozen sections were performed at the clinician's discretion in order to determine the need for completion thyroidectomy, for immediate feedback regarding the disease process, and/or for determining the need for central neck lymph node sampling. All patients included had a prior fine needle aspiration biopsy (FNAB) of a thyroid nodule performed with available cytopathologic results interpreted within the Bethesda classification, as well as subsequent intraoperative frozen section analysis of the same nodule. Patients with FNABs and/or frozen section analyses performed on adjacent lymph node specimens only were excluded, as were patients for whom final pathologic results were unavailable for comparison.

Data regarding patient demographics, nodule size and ultrasound characteristics, and perioperative complications and subsequent management were collected from the electronic medical records. Worrisome ultrasound characteristics are based on the 2015 ATA guidelines regarding sonographic risk patterns [9].

Performance statistics for sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were performed. Statistical analysis was performed using JMP (JMP®, Version <10>. SAS Institute Inc., Cary, NC, 1989–2007) software.

3. Results

There were 74 total patients, median age 44 years old (range 14–81), who underwent thyroid lobectomy or total thyroidectomy with intraoperative frozen section analysis whom also had a preoperative FNAB performed on a thyroid nodule that was classified by the Bethesda system. Demographics and clinical characteristics of all patients are shown in Table 1. Thirty-seven of the 74 patients (50%) had a cytologically indeterminate FNAB; characteristics of these patients are shown separately in Table 2. The total malignancy rate for all patients was 73%. The malignancy rate for the cytologically indeterminate group was 70%. Malignancy rates for the individual Bethesda categories on preoperative FNAB are shown in Table 3.

Of the 74 total patients who underwent frozen section analysis, 45 (61%) were determined to be positive for malignancy intraoperatively. Only 1 of these 45 patients (2%) had a false positive; there was no evidence of malignancy on final pathology. In contrast, of the 29 patients

Table 1 Patient and nodule characteristics for all 74 patients.

| | | |
|-------------------------|---------------------|----------|
| Age (years) | <25 | 6 (8%) |
| | 25–45 | 32 (43%) |
| | >45 | 36 (49%) |
| Gender | Male | 23 (31%) |
| | Female | 51 (69%) |
| Nodule size on U/S (cm) | <1 | 2 (3%) |
| | 1–4 | 48 (65%) |
| | >4 | 15 (20%) |
| | Unknown | 9 (12%) |
| Suspicious U/S? | Yes | 32 (43%) |
| | No | 36 (49%) |
| | Unknown | 6 (8%) |
| History of XRT? | Yes | 2 (3%) |
| | No | 72 (97%) |
| Bethesda category | Non-diagnostic | 4 (5%) |
| | Benign | 11 (15%) |
| | AUS | 13 (18%) |
| | Follicular neoplasm | 11 (15%) |
| | Suspicious | 13 (18%) |
| | Malignant | 22 (30%) |

U/S, Ultrasound; XRT, radiation therapy; AUS, atypia of undetermined significance.

Table 2

Patient and nodule characteristics for 37 patients with indeterminate fine needle aspiration biopsies.

| | | |
|-------------------------|---------------------|----------|
| Age (years) | <25 | 4 (11%) |
| | 25–45 | 17 (46%) |
| | >45 | 16 (43%) |
| Gender | Male | 10 (27%) |
| | Female | 27 (73%) |
| Nodule size on U/S (cm) | <1 | 1 (3%) |
| | 1–4 | 29 (78%) |
| | >4 | 7 (19%) |
| | Unknown | 0 (0%) |
| Suspicious U/S? | Yes | 20 (54%) |
| | No | 14 (38%) |
| | Unknown | 3 (8%) |
| History of XRT? | Yes | 1 (3%) |
| | No | 36 (97%) |
| Bethesda category | AUS | 13 (35%) |
| | Follicular neoplasm | 11 (30%) |
| | Suspicious | 13 (35%) |

U/S, Ultrasound; XRT, radiation therapy; AUS, atypia of undetermined significance.

who had no evidence of malignancy on initial frozen section, 10 patients (34%) had evidence of carcinoma on final histological analysis. The sensitivity, specificity, positive predictive value, and negative predictive value for a thyroid frozen section for all patients with respect to its prediction for malignancy was 81%, 95%, 98%, and 66%, respectively, with a diagnostic accuracy of 85%.

There were 37 patients with cytologically indeterminate FNABs who subsequently underwent thyroid lobectomy or total thyroidectomy with intraoperative frozen section. Twenty-two of the 37 specimens (59%) were read as positive for malignancy intraoperatively. One of the 22 patients (5%) had a false positive, while 5 of the 15 patients with no evidence of carcinoma on frozen section ultimately were diagnosed with thyroid cancer on final pathology (33%). The sensitivity, specificity, positive predictive value, and negative predictive value for a thyroid frozen section on a previously cytologically indeterminate nodule with respect to its prediction for malignancy was 81%, 91%, 95%, and 67%, respectively, with a diagnostic accuracy of 84%.

Thirty-one total patients underwent completion thyroidectomy after the results of the intraoperative frozen section analysis were obtained on an initial thyroid lobectomy specimen. While 9 of the 31 completion thyroid specimens (29%) showed evidence of carcinoma in the contralateral lobe, 8 of the 9 were microcarcinomas ≤5 mm in size; the only contralateral malignant nodule >1 cm in size was in a patient with a 7.7 cm thyroid carcinoma with extensive extrathyroidal invasion. The false positive and false negatives resulted in 1 completion thyroidectomy for benign pathology and 3 reoperations for malignancy not discovered on frozen section, respectively.

4. Discussion

The widespread use of a 6-tiered Bethesda classification system, along with the corresponding ATA guidelines, has greatly streamlined the cytopathologic diagnosis and subsequent management of thyroid masses and nodules. However, the cytologically indeterminate

Table 3 Final malignancy rate for each FNAB classified by the Bethesda system.

| Bethesda category | Total patients | Malignant on frozen section | Malignant on final pathology | Malignancy rate |
|---------------------|----------------|-----------------------------|------------------------------|-----------------|
| Non-diagnostic | 4 | 2 | 3 | 75% |
| Benign | 11 | 2 | 3 | 27% |
| AUS | 13 | 4 | 7 | 54% |
| Follicular neoplasm | 11 | 6 | 7 | 64% |
| Suspicious | 13 | 12 | 12 | 92% |
| Malignant | 22 | 19 | 22 | 100% |

AUS, atypia of undetermined significance.

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