Diagnostic Accuracy of Strain Ultrasound Elastography in Thyroid Lesions Compared to Fine-Needle Aspiration Cytology

Aniqua Saleem 1, Umme Kalsoom 1, Sundas Yasin 2, Misbah Durrani 3, Saha Akram 4, Riffat Mushtaq 5

1. Radiology Department, Holy Family Hospital, Rawalpindi Medical University, Rawalpindi, PAK
2. Radiology Department, Benazir Bhutto Hospital, Rawalpindi Medical University, Rawalpindi, PAK
3. Radiology Department, Rawalpindi Institute of Cardiology, Rawalpindi, PAK
4. Radiology Department, Avicenna Medical College, Lahore, PAK
5. Radiology Department, District Head Quarter Hospital, Mirpur Azad Kashmir, PAK

Corresponding author: Aniqua Saleem, aneeqa_068@hotmail.com

Abstract

Introduction
Strain ultrasound-guided elastography (USE) could be used to differentiate malignant from benign thyroid lesions if its sensitivity and specificity are significantly high. Data on whether to rely on USE in differentiating thyroid nodules are unavailable, and fine-needle aspiration cytology (FNAC) remains the gold standard. However, FNAC carries a significant financial burden on hospitals and psychological stress on patients. Therefore, we conducted this study to determine the diagnostic accuracy of strain USE in thyroid lesions.

Methodology
We conducted a descriptive cross-sectional study at the Radiology Department, Benazir Bhutto Hospital, Rawalpindi, from December 6, 2020, to June 5, 2021. The study included adult patients aged between 20 to 70 years who were referred with thyroid nodules or lesions found clinically or on routine neck ultrasound. The study excluded patients who had previous history of surgery or previously diagnosed with malignant thyroid lesions and recurrent thyroid nodules. Strain USE was performed on thyroid nodules, and the degree of strain was color-coded on a scale from red (soft, greatest elasticity) to green (intermediate, average strain) to blue (hard, no elasticity/strain). Lesions were given an elasticity score on a five-point scale. The lesion was given a score of one if the entire lesion was uniformly shaded in green. A lesion with mosaic pattern of green and blue was scored as two. A score of three denoted a lesion with green periphery and blue center on strain elastography. A score of four indicated uniform blue in the entire lesion, with green in the lesion’s periphery. The highest score of five was given if the lesion and its surroundings demonstrated blue color. Ultrasound-guided FNAC of the thyroid nodules was performed following USE. Data was analyzed using IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. Mean ± standard deviation for calculating quantitative variables. Frequencies and percentages were calculated for qualitative variables. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of strain USE were calculated taking FNAC as gold standard. We also conducted a receiver operating characteristic curve analysis to quantify the diagnostic accuracy of strain USE in thyroid lesions.

Results
The study included 207 adult patients (117 women, 56.52%; 90 men, 43.48%). The study population’s mean age was 50.0 ± 11.8 years (range, 20 to 70 years). Most patients (56.52%) were aged 46 to 70 years. FNAC confirmed malignant thyroid nodules in 100 cases (true positive), and nine cases (false positive) had no malignant lesions on FNAC. In USE-negative patients, 91 were true negative, while seven were false negative. Strain USE’s overall sensitivity was 95.46%, specificity was 91.0%, PPV was 91.74%, NPV was 92.86%, and diagnostic accuracy was 92.27% compared to the gold standard FNAC.

Conclusions
Strain USE in thyroid lesions is a noninvasive modality of choice with high diagnostic accuracy and has dramatically improved our ability to diagnose malignant thyroid nodules preoperatively. Strain USE also helps the surgeons in proper decision-making. Strain USE should be used routinely in all patients with thyroid lesions to help diagnose malignant thyroid nodules preoperatively and inform proper surgical and treatment plans.

Categories: Family/General Practice, Pathology, Radiology
Keywords: negative predictive value, positive predictive value, fine needle aspiration, thyroid nodules, sensitivity, ultrasound elastography
Introduction

Thyroid nodules are very common, and their incidence is gradually increasing [1,2]. Most are benign; however, malignancy occurs in 5% to 15% of cases [1]. Thyroid nodules are usually discovered when patients present for physical examination after feeling an enlarged nodule in their neck or experiencing visible neck swelling. The clinician refers the patient for an ultrasound to look for thyroid lesions and characterize them according to the sonological criteria known as Thyroid Imaging Reporting and Data System (TIRADS). A benign nodular goiter is the most common pathology of the thyroid gland, and assessing and diagnosing malignancy in these goiters remains a challenge for radiologists. Elastography and two-dimensional sonography may help categorize individual thyroid nodules [3]. A thyroid hormonal profile, including thyroid-stimulating hormone, T3, and T4 levels, is also performed to categorize the nodules as functional or nonfunctional, which helps characterize nodules as benign or malignant. Similarly, serum calcitonin levels should also be measured to exclude medullary thyroid cancer [4]. The 2015 American Thyroid Association (ATA) guidelines state that the malignant risk of high-suspicion thyroid nodules is >70% to 90% [5]. However, the ATA characteristics of high-suspicion thyroid nodules overlap with degrees 4a to 5 of Kwak’s TIRADS, and the frequency of malignancy ranges from 3.3% to 87.5%. Therefore, using strain elastography to differentiate malignant from benign thyroid nodules of high suspicion could be fruitful [6]. A recent study by Okasha et al. recommended including strain elastography in TIRADS classification for discriminating benign from malignant nodules [7]. Furthermore, according to the sonographic picture, thyroid nodules that show low, intermediate, or high suspicion of malignancy and all nodules with suspicious clinical findings should undergo fine-needle aspiration cytology (FNAC) [4].

FNAC is considered the most valuable preoperative method for differentiating malignant from benign thyroid lesions. Previous studies also suggest that ultrasound is a practical, cheap, and widely used technique in differentiating benign from malignant, but ultrasound does not have high sensitivity, specificity, and accuracy in diagnosing malignant nodules. Also, FNAC could be nondiagnostic, requiring additional sessions [2,8].

Ultrasound-guided elastography (USE) is a noninvasive test used to assess a tissue’s biomedical properties (e.g., elasticity) [1,8]. It is helpful in various diagnostic applications, including thyroid nodules. Different types of USE are available. Strain USE, also known as real-time elastography, is the most widely available type [1]. Its basic principle is that, upon compression, softer parts of tissue deform easier than harder ones. This degree of tissue distortion under external force can be recorded, and thus tissue stiffness/hardness can be measured [1,2]. Strain USE is a qualitative means of measuring tissue stiffness; however, semiquantitative analysis of tissue stiffness can be measured using strain ratio, where stiffness/strain of a target lesion is compared with a reference normal thyroid tissue using real-time elastography [1,9]. Benign tissue is softer, elastic, and more easily deformable than malignant tissue. USE helps in measuring tissue elasticity and therefore helps differentiate benign (soft) from malignant nodules (hard) [10]. FNAC is an excellent method for differentiating benign from malignant nodules, but it is minimally invasive, time-consuming, and expensive, with a risk of serious complications [2,10].

In contrast, USE is noninvasive, cheap, easy to use, less time-consuming than FNAC, and has no adverse effects [8]. We conducted this study to use strain USE as a diagnostic test in differentiating malignant from benign thyroid lesions, provided its sensitivity and specificity are significantly high. The diagnostic accuracy of USE for detecting thyroid lesions is controversial, and no recent study in our region has assessed the use of USE in differentiating thyroid nodules. This study assesses the diagnostic accuracy of USE in local settings, which could limit the use of FNAC, exerting a financial burden on hospitals and psychological stress on patients.

Materials And Methods

Department of Diagnostic Radiology, Benazir Bhutto Hospital, Rawalpindi, was utilized to conduct this descriptive and cross-sectional research from December 6th, 2020, to June 5th, 2021. The sample size of 207 cases has been calculated with a 95% confidence level, 10% desired precision, and taking the expected prevalence of malignant thyroid nodules, i.e., 15% with sensitivity of 92% and specificity of 15% of strain ultrasound elastography in diagnosing malignant thyroid nodules [1].

Non-probability as well as consecutive sampling was done for patients (20–70 years age) referred with thyroid nodule/lesion, found clinically or on routine ultrasound neck examination. The exclusion criteria for this research included those patients who had a previous history of surgery or were previously diagnosed with malignant thyroid lesions, patients with recurrent thyroid nodules, and those patients who were not available for follow-up.

Hospital ethical committee approval, as well as informed consent from the patient, was obtained. Strain ultrasound elastography was performed by a postgraduate resident under the supervision of a consultant radiologist. ESAOTE (Genoa, Italy) ultrasound machine, with elastography procedure capability, attached to a 5–15 MHz high-frequency linear transducer was used. Elastography was performed by at least two radiologists with little or no interobserver difference. USE was performed by gentle pressing up and down motion of the probe on the patient’s neck till optimal pressure is achieved, as shown by the pressure bar.
lateral to the elastogram. The degree of strain within the region of interest was given colors by using the scale from red (soft, greatest elasticity) to green (intermediate, average strain) to blue (hard, no elasticity/strain) [8]. The lesion was scored by Ueno and Itoh’s study [11,12]. Ultrasound-guided FNAC of thyroid nodule was performed on the same day. A consultant pathologist, who was kept blind to elastography results, evaluated cytopathology results.

Data were analyzed in IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. The age of patients was taken as a quantitative variable and was measured as mean ± SD. Gender of the patient, duration of symptoms, family history, radiation exposure history, occupational history, elastography report, and FNAC reports were taken as qualitative variables and was measured as frequencies and percentages. 2 x 2 table was used to present data for calculation of sensitivity, specificity, PPV, NPV, and accuracy. Data was stratified for age, gender, duration of symptoms, family history, and radiation exposure history. Post-stratification 2 x 2 table was generated to calculate sensitivity, specificity, PPV, NPV, and accuracy. Receiver operating characteristic (ROC) curve analysis was used to quantify the diagnostic accuracy of strain ultrasound elastography in thyroid lesions.

### Results

The study included 207 adult patients aged 20 to 70 (mean age, 50.0 ± 11.8 years). Most patients were aged 46 to 70 (n=117; 56.52%). One hundred seventeen participants were women (56.52%), and 90 were men (43.48%; female-to-male ratio: 1.3:1). The mean duration of the disease was 9.16 ± 3.87 months. Less than one-third (30.92%) of patients had a positive family history, while 20.29% had X-ray radiation exposure.

All the patients were subjected to strain USE. USE supported the diagnosis of malignant thyroid nodules in 109 patients. FNAC confirmed malignant thyroid nodules in 100 cases (i.e., true positive), whereas nine had no malignant lesion on FNAC (i.e., false positive). In USE-negative patients, 91 were true negative, while seven were false negative (p<.0001; Table 1).

| Parameter   | Percent |
|-------------|---------|
| Sensitivity | 93.46%  |
| Specificity | 91.0%   |
| PPV         | 91.74%  |
| NPV         | 92.86%  |
| Diagnostic Accuracy | 92.27% |

**TABLE 1: Diagnostic accuracy of strain USE in thyroid lesions keeping FNAC as the gold standard**

USE: Ultrasound elastography; FNAC: Fine-needle aspiration cytology; PPV: Positive predictive value; NPV: Negative predictive value.

For strain USE in thyroid lesions, the overall sensitivity was 95.46%, specificity was 91.0%, PPV was 91.74%, NPV was 92.86%, and diagnostic accuracy was 92.27% against FNAC as the gold standard. The ROC curve is shown in Figure 1.
FIGURE 1: ROC curve

Table 2 and Table 3 present the stratification of diagnostic accuracy concerning age groups, and Table 4 and Table 5 present the stratification according to sex. Similarly, the stratification of diagnostic accuracy concerning disease duration is presented in Table 6 and Table 7, and positive family history is presented in Table 8 and Table 9. Finally, positive radiation exposure is given in Table 10 and Table 11.
| Age Group (Years) | Parameter     | Percent | P-Value |
|-------------------|---------------|---------|---------|
| 20 to 45 (n=90)   | Sensitivity   | 95.74%  |         |
|                   | Specificity   | 93.02%  |         |
|                   | PPV           | 93.75%  | 0.001   |
|                   | NPV           | 95.24%  |         |
|                   | Diagnostic Accuracy | 94.44% |         |
| 46 to 70 (n=117)  | Sensitivity   | 91.67%  |         |
|                   | Specificity   | 89.47%  |         |
|                   | PPV           | 90.16%  | 0.001   |
|                   | NPV           | 91.07%  |         |
|                   | Diagnostic Accuracy | 91.60% |         |

**TABLE 2: Stratification of USE diagnostic accuracy according to age**

USE: Ultrasound elastography; PPV: Positive predictive value; NPV: Negative predictive value.

| Age Group (years) | USE                        | Positive on FNAC | Negative on FNAC | P-Value |
|-------------------|----------------------------|------------------|-------------------|---------|
| 20 to 45 (n=90)   | USE Positive Result        | 45 (TP)          | 03 (FP)           | 0.001   |
|                   | USE Negative result        | 02 (FN)          | 40 (TN)           |         |
| 46 to 70 (n=117)  | USE Positive Result        | 55 (TP)          | 06 (FP)           | 0.001   |
|                   | USE Negative result        | 05 (FN)          | 51 (TN)           |         |

**TABLE 3: Stratification of USE diagnostic accuracy by age compared to FNAC results**

USE: Ultrasound elastography; FNAC: Fine-needle aspiration cytology; TP: True positive; FP: False positive; TN: True negative; FN: False negative.
| Sex        | Parameter    | Percent  | P-value |
|------------|--------------|----------|---------|
| **Males (n=90)** |              |          |         |
|            | Sensitivity  | 89.80%   |         |
|            | Specificity  | 92.68%   |         |
|            | PPV          | 93.62%   | 0.001   |
|            | NPV          | 88.37%   |         |
|            | Diagnostic Accuracy | 91.11% |         |
| **Females (n=117)** |            |          |         |
|            | Sensitivity  | 96.55%   |         |
|            | Specificity  | 89.83%   |         |
|            | PPV          | 90.32%   | 0.001   |
|            | NPV          | 96.36%   |         |
|            | Diagnostic Accuracy | 93.16% |         |

**TABLE 4: Stratification of USE diagnostic accuracy according to sex**

USE: Ultrasound elastography; PPV: Positive predictive value; NPV: Negative predictive value.

| Sex        | USE                        | Positive on FNAC | Negative on FNAC | P-Value |
|------------|----------------------------|------------------|------------------|---------|
| **Males (n=90)** | USE Positive Result        | 44 (TP)          | 03 (FP)          | 0.001   |
|            | USE Negative result        | 05 (FN)          | 38 (TN)          |         |
| **Females (n=117)** | USE Positive Result        | 56 (TP)          | 06 (FP)          | 0.001   |
|            | USE Negative result        | 02 (FN)          | 53 (TN)          |         |

**TABLE 5: Stratification of USE diagnostic accuracy by sex compared to FNAC results**

USE: Ultrasound elastography; FNAC: Fine-needle aspiration cytology; TP: True positive; FP: False positive; TN: True negative; FN: False negative.
### TABLE 6: Stratification of USE diagnostic accuracy according to disease duration

USE: Ultrasound elastography; PPV: Positive predictive value; NPV: Negative predictive value.

| Disease Duration | Parameter       | Percent | P-value |
|------------------|-----------------|---------|---------|
| ≤ 9 months (n=138) | Sensitivity     | 91.67%  |         |
|                   | Specificity     | 90.91%  | 0.001   |
|                   | PPV             | 91.67%  |         |
|                   | NPV             | 90.91%  |         |
|                   | Diagnostic Accuracy | 91.30% |         |
| > 9 months (n=117) | Sensitivity     | 91.14%  |         |
|                   | Specificity     | 91.18%  |         |
|                   | PPV             | 91.89%  | 0.001   |
|                   | NPV             | 96.88%  |         |
|                   | Diagnostic Accuracy | 94.20% |         |

### TABLE 7: Stratification of USE diagnostic accuracy by disease duration compared to FNAC results

USE: Ultrasound elastography; FNAC: Fine-needle aspiration cytology; TP: True positive; FP: False positive; TN: True negative; FN: False negative.

| Disease Duration | USE                | Positive on FNAC | Negative on FNAC | P-Value |
|------------------|--------------------|------------------|------------------|---------|
| ≤ 9 months (n=138) | USE Positive Result | 66 (TP)          | 06 (FP)          | 0.001   |
|                   | USE Negative result | 06 (FN)          | 60 (TN)          |         |
| Females (n=117)  | USE Positive Result | 34 (TP)          | 03 (FP)          | 0.001   |
|                   | USE Negative result | 01 (FN)          | 31 (TN)          |         |

### TABLE 8: Stratification of USE diagnostic accuracy according to family history

USE: Ultrasound elastography; PPV: Positive predictive value; NPV: Negative predictive value.

| Family History | Parameter       | Percent | P-value |
|----------------|-----------------|---------|---------|
| Positive (n=64) | Sensitivity     | 97.22%  |         |
|                 | Specificity     | 89.29%  |         |
|                 | PPV             | 92.11%  | 0.001   |
|                 | NPV             | 96.15%  |         |
|                 | Diagnostic Accuracy | 93.75% |         |
### Table 9: Stratification of USE diagnostic accuracy by family history compared to FNAC results

| Family History | USE | Positive on FNAC | Negative on FNAC | P-Value |
|----------------|-----|------------------|------------------|---------|
| Positive (n=64)| USE Positive Result | 35 (TP) | 03 (FP) | 0.001 |
|                | USE Negative result | 01 (FN) | 25 (TN) |         |

**USE:** Ultrasound elastography; **FNAC:** Fine-needle aspiration cytology; **TP:** True positive; **FP:** False positive; **TN:** True negative; **FN:** False negative.

### Table 10: Stratification of USE diagnostic accuracy according to radiation exposure

| Radiation Exposure | Parameter  | Percent | P-value |
|--------------------|------------|---------|---------|
| Positive (n=42)    | Sensitivity| 95.83%  |         |
|                    | Specificity| 88.89%  | 0.001   |
|                    | PPV        | 92.00%  |         |
|                    | NPV        | 94.12%  |         |
|                    | Diagnostic Accuracy | 92.86% |         |

**USE:** Ultrasound elastography; **PPV:** Positive predictive value; **NPV:** Negative predictive value.

### Table 11: Stratification of USE diagnostic accuracy by radiation exposure compared to FNAC results

| Radiation Exposure | USE | Positive on FNAC | Negative on FNAC | P-Value |
|--------------------|-----|------------------|------------------|---------|
| Positive (n=42)    | USE Positive Result | 23 (TP) | 02 (FP) | 0.001 |
|                    | USE Negative result | 01 (FN) | 16 (TN) |         |

**USE:** Ultrasound elastography; **FNAC:** Fine-needle aspiration cytology; **TP:** True positive; **FP:** False positive; **TN:** True negative; **FN:** False negative.

## Discussion

Thyroid nodules are frequent, and sonography is an economical, widely available modality free from potential radiation hazards; sonography could be used for diagnosing thyroid nodules. Various sonographic features like shape (e.g., elliptical, taller-than-wide, irregular), margins (e.g., lobulated, spiculated, poorly marginated), and presence of calcification (e.g., noncalcified, microcalcification, macrocalcification, crystals) aid in categorizing the thyroid nodule as benign or malignant. Furthermore, a Doppler assessment contributes by indicating the presence of color flow within or at the lesion’s periphery. The elastography component of ultrasound provides information on the stiffness of the lesion; the stiffer the tissue, the more likely it is malignant [12]. We conducted this study to determine the diagnostic accuracy of strain USE in thyroid lesions against the gold standard of FNAC.

In Pakistan, the accuracy of FNAC approaches 95% in the best centers, with sensitivity ranging from 65% to 98% and specificity from 72% to 100% [13]. The overall sensitivity and specificity of strain USE in thyroid lesions against FNAC as the gold standard was 93.46% and 91.0%, respectively. This was higher than the results from Cabanillas et al., who reported strain USE sensitivity and specificity of 77% and 85%, respectively [4].

In 2015, Cantisani et al. conducted a meta-analysis of 10 studies which showed that the mean sensitivity of elastography was 92%, and the mean specificity was 90% in detecting malignancy within a thyroid nodule [1]. They reported that elastography in conjunction with ultrasound enhances accuracy for detecting thyroid malignancy, thus reducing the risk of diagnosing a large number of nodules via invasive FNAC. While FNAC
Conclusions

Strain USE in thyroid lesions is the noninvasive modality of choice with high diagnostic accuracy. We...
suggest that thyroid lesions should be routinely assessed in a similar way to triple assessment in breast lesions, that is clinical assessment, radiological imaging, and pathological assessment. In thyroid imaging, USE should be used in conjunction with gray scale USG. We suggest that nodules with TIRADS score up to 2 and USE score of 1 and 2 should only be followed up clinically and by gray scale USG in combination with USE; however, a thyroid nodule with USE score of 3 and above should proceed for pathological examination. However, we do not recommend following up on a thyroid nodule with USE if there is clinical suspicion of thyroiditis or patients who had a previous history of FNAC or thyroid surgery. Strain USE has dramatically improved our ability to diagnose malignant thyroid nodules preoperatively and helps surgeons make proper decisions. Therefore, strain USE should be conducted routinely in all thyroid lesion patients for accurate diagnosis of malignant thyroid nodules preoperatively and to inform proper surgical and treatment planning.

**Additional Information**

**Disclosures**

*Human subjects:* Consent was obtained or waived by all participants in this study. Research Evaluation Unit, College of Physicians and Surgeons Pakistan issued approval REU No. 34535. The research proposal titled ‘Diagnostic Accuracy of Strain Ultrasound Elastography in Thyroid Lesions Keeping Fine Needle Aspiration Cytology as Gold Standard’ has been reviewed and it conforms to the accepted ethical standards and therefore has been approved. *Animal subjects:* All authors have confirmed that this study did not involve animal subjects or tissue. *Conflicts of interest:* In compliance with the ICMJE uniform disclosure form, all authors declare the following: 

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