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Role of Sonoelastography in Evaluating Thyroid Nodules - A Comparative Study with Thyroid Imaging Reporting and Data Systems (Tirads) And Fine Needle Aspiration Cytology (Fnac)

Ilango Perarivalan[1], Sony Kushbu[2], Charumathi Vikram[3], V G Kaliaperumal[4], M G Sai Shankar[5], Jenikar Paulraj[6], Balaganesan, Harshavardhan[7], Gomes Fraser[8], Raveendran Remya[9]
[1,2,3,4,5,6,7,8,9]Department of Radiodiagnosis, Sri Balaji Vidyapeeth (Deemed to Be University), Pondicherry-607402.
Corresponding Author: Dr V G, Kaliaperumal, Department of Radiodiagnosis, Sri Balaji Vidyapeeth (Deemed ro Be University), Pondicherry-607402.

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KEYWORDS
Shear wave elastography (SWE) and elastography shear (ES), thyroid nodules, FNAC, ultrasound.

ABSTRACT:
Background: Although a minority of the thyroid nodules is malignant, usually invasive diagnostic procedures are warranted. This prospective study aims to assess the diagnostic performance of the US criteria in addition to the TI-RADS score and the SWE for the differentiation between the benign and malignant thyroid nodules as a potential surrogate for invasive procedures.
Aim of the study: To evaluate the solid thyroid nodule's shear wave elastography value against ultrasound-guided FNAC/HPE.
Methodology: Cross-Sectional Study Patients done in the department of Radiology, Patients with solid thyroid nodules who are referred to the department of radiodiagnosis were selected for the study for 18 months with patients' consent.
Results: The study explores the efficacy of various ultrasound techniques, including shear wave elastography (SWE) and elastography shear (ES), in diagnosing thyroid nodules, emphasizing their ability to distinguish between benign and malignant nodules. Despite discrepancies in findings across studies, these techniques, particularly when used in combination with traditional ultrasound criteria, demonstrate promising sensitivity and specificity for detecting high-suspicion thyroid nodules, highlighting their potential as valuable diagnostic tools in clinical practice This study examined strain wave elastography's role in 125 thyroid nodule assessments and its correlation with FNAC findings. This research suggests high ES levels (ES > 3.5) increase cancer risk. We achieved AUC 0.828, sensitivity 92.4, specificity 60.7, accuracy 79.0, PPV 76.3, and NPV 85.5%.
Conclusion: In this study, found a positive relationship between the strain wave elastography and FNAC findings so that we can decrease the unnecessary biopsies and surgeries in the future.

INTRODUCTION

A large portion of the population, close to 40-50% of all ages and gender are affected by thyroid nodules. Characteristic ultrasonographic features of thyroid cancer include hypoechoic appearance, micro-lobulated or spiculated borders, micro- or macrocalcifications, and a shape that is taller than broad.[1,2] The Thyroid Imaging Reporting and Data System (TI-RADS) helps doctors determine whether further testing, follow-up ultrasonography (US), or neither is needed.[3]

On practical examination, the thyroid feels hard and stiff in people with tiny, deep nodules and multinodular goiter.[4] Using non-invasive, objective shear wave elastography to evaluate thyroid lesion stiffness and distinguish between benign and malignant lesions is becoming more common, thereby increasing diagnostic performance. Strain wave elastography identifies and illustrates local deformation under light pressure by comparing it to tissue strain measurements.[4,5]

Since ultrasound is non-invasive, affordable, widely available, and reproducible, it can help identify the cancer risk of thyroid nodules early, thereby reducing unnecessary fine-needle aspiration cytology (FNACs). Conventional US (B-mode) imaging stratifies patients based on hypoechogenicity, microcalcifications, anteroposterior diameter larger than the transverse diameter, and irregular or lobulated margins. Using these features, many risk stratification algorithms classify nodules into different risk categories. The decision to perform FNAC depends on the assessed cancer risk. Despite its sensitivity ranging from 54% to 90%, FNAC remains the gold standard for categorizing thyroid nodules because it can identify the lesion type with specificity ranging from 60% to 98%.

TIRADS 3 nodules are controversial to treat because histological tests reveal malignancy in only 5-30% of cases. There is a growing demand for better diagnostic methods to reduce unnecessary treatments for benign

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conditions and improve cancer risk assessment of ambiguous nodules. Elastography, a novel diagnostic imaging method, evaluates thyroid nodule stiffness to detect malignancy. The World Federation of Ultrasound in Medicine and Biology (WFUMB) and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) have established international standards for strain-ratio elastography. The pros and cons of the USE technique are outlined in these recommendations. [6]

Sonoelastography is recommended for B-mode ultrasounds due to its strong negative predictive value (3% false negatives). The researchers set out to find out how FNAC results compare to strain wave elastography while evaluating thyroid nodules

The novelty of the study- Sonoelastography is a widely available, less expensive, real-time imaging method for measuring nodule elasticity, which can be used in addition to grayscale imaging to distinguish benign from malignant nodules. Few studies have been done on this topic in our state.

PATIENTS AND METHODS

Study Design- Cross-Sectional Study

Area: Department of Radiodiagnosis, Shri Sathya Sai Medical College & Research Hospital.
Population: Patients with solid thyroid nodules.
Duration: 18 months.
Sample Size: 125, calculated based on 83.3% prevalence.

Inclusion Criteria:

- Solid and solid-cystic thyroid nodules detected by ultrasound.

Exclusion Criteria:

- Diffuse thyroid disease, purely calcified/cystic nodules, unwilling patients, ectopic thyroid.

Methodology:

- Imaging: Grayscale ultrasound, elastography, and US-guided FNAC.
- Procedure: Use Mindray DC 60, assess nodules with B-mode and color Doppler. Elastography performed with SWE, measured in kPa, and elastic ratio (ER) calculated.
- FNAC: Performed with a 20–22G needle; samples fixed in 95% ethanol.

Statistical Analysis:

- Data Presentation: Median, range, mean, standard deviation, numbers, and percentages.
- Tests: Student's t-test, Mann–Whitney U test, Chi-square test, Fisher exact test.
- ROC Analysis: SWE and TI-RADS for predicting malignancy; $p < 0.05$ is significant.
- Software: SPSS version 23.

Ethical Considerations:

Approval: Institutional ethical committee.
Consent: Informed consent in local language.
Confidentiality: Maintained throughout the study

RESULTS

The study evaluated the role of strain wave elastography in assessing thyroid nodules and correlating findings with FNAC in 125 cases. Patients' ages ranged from 20 to over 60 years, with 55.2% aged 20-40, 30.4% aged 41-60, and 14.4% over 60 years. The study included 57 males and 68 females. TIRADS classification showed 36.8% of nodules as TIRADS 1, 30.4% as TIRADS 2, 14.4% as TIRADS 3, 12% as TIRADS 4, and 6.4% as TIRADS 5. Diagnostic accuracy, measured by ROC area, was 0.8992 for SE (standard), 0.6828 for SWE (KPa), and 0.7689 for K-TIRADS. Combined methods' ROC areas were SE + K-TIRADS (0.8466), SE + SWE (KPa) (0.7374), and SE + SWE (KPa) + K-TIRADS (0.7290). Correlation analysis between elastography, TIRADS, and FNAC yielded significant results, with elastography t = 3.292, TIRADS t = 4.364, and FNAC t = 6.139. Logistic regression analysis indicated that features such as microcalcification, taller-than-wide shape, irregular margins, extra-thyroid extension, elasticity score, and SR value significantly predicted malignant thyroid nodules

Table 1: Showing Category of Thyroid Nodule among the studied population

Category Of Thyroid Nodule	Frequency	Percent
TIRADS 1	46	36.8
TIRADS 2	38	30.4
TIRADS 3	18	14.4
TIRADS 4	15	12
TIRADS 5	8	6.4
Total	125	100.0

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Table 2: Single and multivariate analysis, stratified by size, related to the diagnostic accuracy of the different methods (K-TIRADS, SE, SWE expressed in KPa)

Parameters		TP	TN	FP	FN	Se(95%CI)	Sp(95%CI)	PPV(95%CI)	NPV(95%CI)	AUC(95%CI)
K-TIRADS	**All**	20	56	12	8	71.4% (51.3%-86.8%)	82.4% (71.2%-90.5%)	62.5% (43.7%-78.9%)	87.5% (76.8%-94.4%)	0.769(0.672%-0.866%)
	≤1cm	6	6	6	1	85.7% (42.1%-99.6%)	50% (21.1%-78.9%)	50% (21.1%-78.9%)	85.7% (42.1%-99.6%)	0.679(0.475%-0.882%)
	>1cm	14	50	6	7	66.7% (43%-85.4%)	89.3% (78.1%-96%)	70% (45.7%-88.1%)	87.7% (76.3%-94.9%)	0.78 (0.669%-0.891%)
	All	16	54	14	12	57.1% (37.2%-75.5%)	79.4% (67.9%-88.3%)	53.3% (34.3%-71.7%)	81.8% (70.4% -90.2%)	0.683 (0.578% -0.783%)
	≤ 1 cm	5	12	0	2	71.4% (29%-96.3%)	100% (73.5%-100%)	100% (47.8%-100%)	85.7% (57.2%-98.2%)	0.857 (0.676%-1%)
	>1 cm	11	42	14	10	52.4% (29.8%-74.3%)	75% (61.6%-856%)	44% (24.4%-65.1%)	80.8% (67.5%-90.4%)	0.637 (0.513%-0.76%)
	All	26	52	16	2	92.9% (76.5%-99.1%)	76.5% (64.6%-85.9%)	61.9% (45.6%-76.4%)	96.3% (87.3%-99.5%)	0.847 (0.776%-0.917%)
	≤1 cm	7	4	8	0	100% (59%-100%)	33.3% (9.92%-65.1%)	46.7% (21.3%-73.4%)	100% (39.8%-100%)	0.667 (0.527%-0.806%)
	>1cm	19	48	8	2	90.5%(69.6%-98.8%)	85.7% (73.8%-93.6%)	70.4% (49.8%-86.2%)	96% (86.3%-99.5%)	0.881 (0.802%-0.96%)

Table 3: Correlation between Elastography, TIRADS and FNAC

	t	**Mean**	**Sd Deviation**	**Sig. (2-tailed)**	**Mean Difference**	**95% Confidence Interval of the Difference**	
						Lower	Upper
Elastography	3.292	0.5082	1.20586	0.002	0.50820	0.1994	0.8170
TIRADS	4.364	0.8525	1.52574	0.000	0.85246	0.4617	1.2432
FNAC	6.139	1.3934	1.77274	0.000	1.39344	0.9394	1.8475

- As shown in table 3, t value of elastography, was 3.292 with mean of 0.5082, Standard deviation of 1.20586, and mean difference was found to be 0.50820. On calculating 95% confidence interval using one sample t test we found upper limit of 0.8170 and lower limit of 0.1994.
- On calculating TIRADS t value was 4.364, with mean of 0.8525, Standard deviation of 1.52574, and mean difference was found to be 0.85246. On calculating 95% confidence interval using one sample t test we found upper limit of 1.2432 and lower limit of 0.4617
- Similarly, for FNAC- t value was 6.139, with mean of 1.3934, Standard deviation of 1.77274, and mean difference was found to be 1.39344. On calculating 95% confidence interval using one sample t test we found upper limit of 1.8475 and lower limit of 0.9

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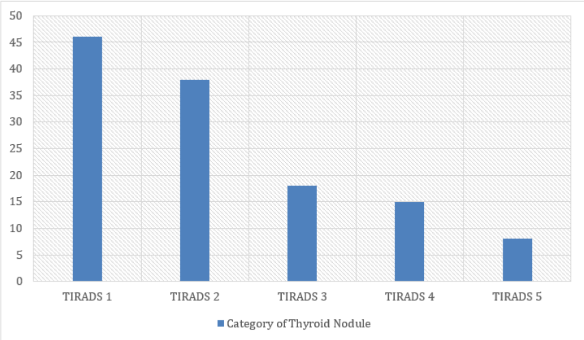

Figure 1: Bar diagram Showing Category of Thyroid Nodule among the studied population

On investigating category of thyroid nodule among the studied population, around 36.8% were from TIRADS 1 category, 30.4% from TIRADS 2 category, and 14.4% from TIRADS 3 category. Also, 12% subjects belonged to category TIRADS 4, and 6.4% from TIRADS 5 as shown in figure 1

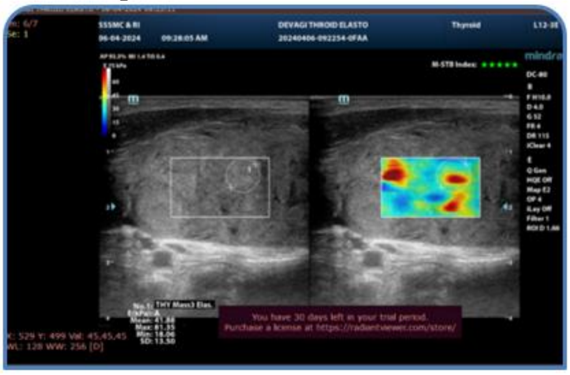

Figure 2: Showing sonoelastography image of malignant thyroid nodule

a) Axial ultrasound B-mode image shows heterogeneous right solid thyroid nodules that are hypo to isoechoic with punctuate and macro calcification (TI-RADS 4) b)Axial SWE of the nodule(E mean=41.42kPa and ECI =4.15).

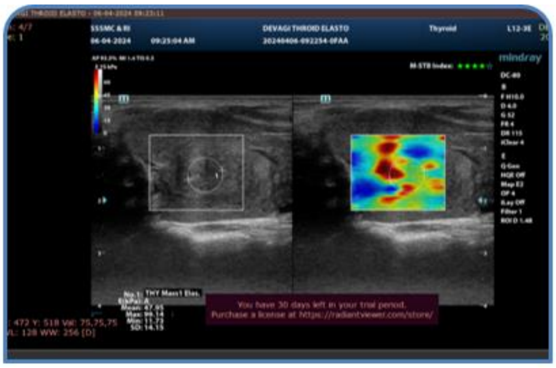

Figure 3: Showing sonoelastography image of malignant thyroid nodule

a) Axial ultrasound B-mode image shows heterogeneous right solid thyroid nodules that are that are isoechoic with calcification b)Axial SWE of the nodule(E mean=47.95kPa and ECI =4.45).

Figure 4: sonoelastography image of benign thyroid nodule

a) Axial ultrasound B-mode image shows left thyroid isoechoic (solid) nodule with no evidence of calcification (TI-RADS 2).
b) Axial SWE of the nodule (E mean=25.55kPa and ECI =2.15).

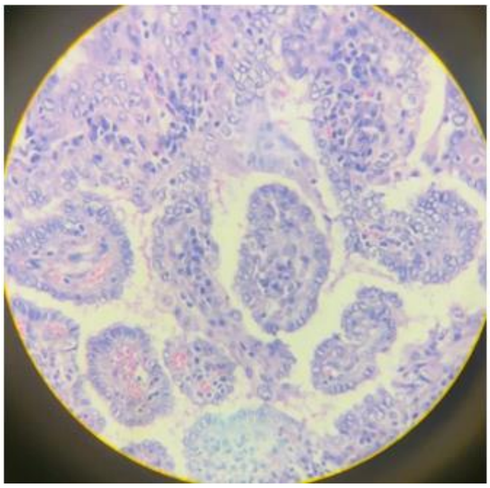

Figure 5: Histopathological examination (HPE) image of Papillary Thyroid Carcinoma

- Malignant neoplasm characterized by papillary architecture composed of round to ovoid tumor cells showing nuclear clearing, and some with nuclear grooves. Foci of psammatous calcification also seen

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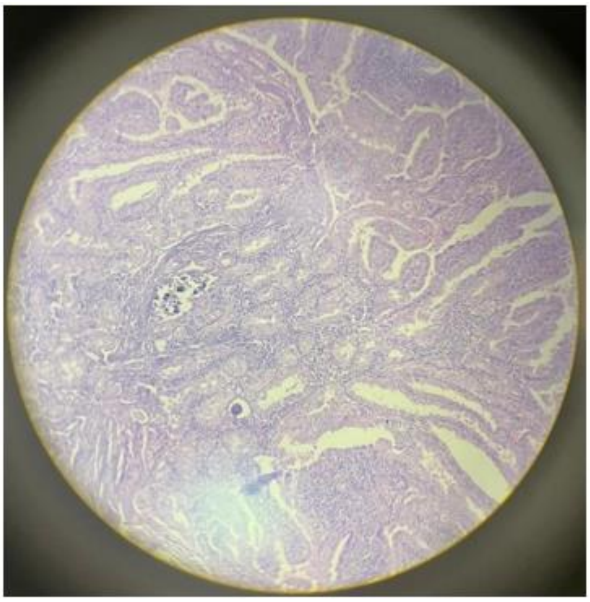

Figure 6: Histopathological examination (HPE) image of Papillary thyroid Carcinoma
Micrograph of papillary thyroid carcinoma, tall cell variant - high magnification. Abundant eosinophilic cytoplasm.

DISCUSSION

- The invention of high-frequency ultrasonic equipment increased thyroid nodule detection. Choosing the proper therapy requires distinguishing benign from malignant thyroid nodules, Thyroid nodules may be identified via elastography because it reflects the rigidity of malignant lesions. Many studies have demonstrated that elastography can identify benign from malignant nodules. However, some studies demonstrate the opposite. This large-scale study used the 2015 ATA guidelines to see whether real-time strain elastography could distinguish benign from malignant thyroid nodules with high-suspicion characteristics.
- This study examined shear wave elastography's role in 125 thyroid nodule assessments and its correlation with FNAC findings. About 55.2% of participants were 20–40 years, 30.4% were 41–60 years, and 14.4% were 60 years and older. There were 57 males and 68 females among the patients. Similar results were seen in 81 people (24 males and 57 females) with a median age of 59.4±15.3 years and a single nodule at their first FNAB, according to Gay S. et al. (2018)[7]. Notably, out of 50 patients, only 6 (10.7%) were male and 89.2% were female, according to Sekhar CG et al. (2015)[8]. Peak frequency was between 30s and 40s. The oldest patient was a 60-year-old woman, while the youngest was 17. Even though female patients outnumbered male patients, this study found four times more male cancer patients than female patients. Malignancy was 33.33 % in men and 8% in women.
- In the present study, 44.28% of subjects reported feeling fatigue while 55.7% showed no such symptom. At the same time, weight loss was reported by 60% of individuals and 70% reported a history of fever along with it. When asked about bone pain, 55.7% of subjects said yes, that they experienced the same, while 44.2% presented no such history. The majority of subjects presented a history of neck pain which is 82.85%. Also, on asked about hoarseness of voice 62.85% said yes and 37.14% said no for such symptoms in the past. The majority, that is 74.2% of subjects presented no difficulty in breathing or swallowing. Additionally, only 49.3% of patients had involvement of the cervical lymph node. Sekhar CG, et al., (2015)[8] found similar results: all patients had swelling in the thyroid area; pain(7.14%), change in voice(5.35%), and difficulty swallowing (5.35%) were the other most prevalent symptoms. The thyroid function test of almost all individuals were within the normal range (98.2%). Cervical lymphadenopathy affected only around 3.5% of the population. All cases of benign and malignant solitary thyroid nodules showed swelling at the front of the neck. Though not exclusive to malignant nodules, a history of rapid enlargement and a change in vocal quality resembling hoarseness or deepening of voice are frequent symptoms. The majority of patients under 30 years old have had no additional symptoms but swelling. The results of both the studies are not in agreement. On examining other features of nodule, around 44.8% nodules were mobile and 55.2% were fixed to underlying structures. Concurrently, 56.8% had a soft consistency and 43.2% were firm, however 5.35%, were hard, according to Sekhar CG, et al., (2015)[8]. All individuals underwent preoperative indirect laryngoscopy; however, only one instance showed recurring right-sided laryngeal nerve palsy, which was subsequently shown to be cancerous.
- It has been shown that when many auxiliary procedures are used together, diagnostic accuracy is higher than when using only one. Our results corroborated those of earlier research that used conventional ultrasonography as the evaluation's foundation because of the time and money saved compared to other methods. But it's becoming more and more clear that we need a scoring system that outperforms individual item evaluations. We now know that hypo-echogenicity, uneven margins, and

microcalcifications are risk factors for cancer, but the exact function of intra-nodular vascularization is still up for discussion, and several techniques have been developed to address this requirement. [7]

- Having said that, there are research that show the exact reverse. In particular, for nodules measuring 1 cm or larger (95.0%) and for distinguishing benign from malignant high-suspicion thyroid nodules (87.8%), the combination of USE and ES demonstrated remarkable sensitivity (92.4%), accuracy (79.0%), and NPV (85.5%). Both the ES and the SR were shown to be independent cancer predictors in the logistic regression study. Thyroid nodules are often treated using ultrasound because of its portability, affordability, and ease of usage. In contrast to benign nodules, malignant ones were taller than broad, had uneven borders, microcalcifications, and hypoechogenicity. Microcalcifications, Extra thyroid extension, and higher margins than irregular or broad ones were predictive of cancer, according to logistic regression studies. But previous research has shown that there are different sensitivities and specificities. This instance could not be diagnosed using traditional US criteria either. Sensitivity was elevated due to irregular margins and Extra thyroid extension, while specificity was low. Particularly insensitive were taller-than-wide rim calcifications that were disordered and had a little amount of extruding hypoechoic soft tissue, even though they were highly specific. There are concerns with the correctness of traditional US standards.
- Elastography shows that poor USE elasticity is linked to cancer due to physiological and pathological reasons. Since elastography was created, sensitivity, specificity, PPV, and NPV have been high. However, conventional US lacks flexibility, the gold standard for detecting and predicting malignant thyroid nodules. This research suggests high ES levels increase cancer risk. We achieved AUC 0.828, sensitivity 92.4, specificity 60.7, accuracy 79.0, PPV 76.3, and NPV 85.5%. ES > 3.5 for Itoh's five score variables. Different viewpoints exist. Elastography was less accurate than grayscale ultrasonography in distinguishing benign from malignant thyroid nodules in a multicenter study by Moon et al. Studies included hyperechogenic, iso-echogenic, hypoechogenic, and hypoechogenic nodules. ATA 2015 guidelines were used to include solid hypoechoic nodules in this study. USE has limited sensitivity but excellent predictive value for malignant thyroid nodules compared to US with three grading systems. A retrospective investigation employing the iU22 elastography system to identify color mapping as blue or not blue indicated that the ES and SR failed to discriminate benign from malignant thyroid nodules. A total of 197 thyroid nodules were evaluated.[9] However, Magri et al. showed that benign thyroid nodules had a greater strain index than malignant ones, improving diagnostic performance.[10] Elastography's diagnostic usefulness depends on equipment reliability and scoring technique. Elasticity is qualitative and sensitive to researcher bias. The objective, semiquantitative SR technique solved this problem.[11] Whether ES or SR is more reliable is questionable. The SR cut-off numbers employed in the different experiments varied widely.[10, 13, 12] When SR > 2.99, this study found no improvement over the ES, which had an AUC of 0.738, sensitivity of 81.1, specificity of 50.1, accuracy of 65.9, and PPV of 67.9%. The SR around thyroid nodules is affected by even a semiquantitative measurement of thyroid echogenicity—the ratio of the lesion's mean strain to the surrounding normal tissue. Because SR takes longer than ES, it may not be able to distinguish benign from malignant thyroid nodules. While shear wave elastography (SWE) may provide more accurate findings, USE has been around longer. Range from [13 to 16] Tian and Hu et al. found that USE performed better than SWE despite equal specificity. Recent research with 243 nodules found USE outperformed TI-RADS and SWE.[17] Studies have demonstrated that USE can differentiate normal from malignant thyroid nodules.
- FNA is recommended by the 2015 ATA for nodules with a diameter of 1 cm or more with a high-suspicious sonographic pattern. The diagnostic effectiveness of elastography in nodules ≥1 cm was 0.875, with good specificity, accuracy, PPV, and NPV compared to nodules <1 cm. All measures above were better than nodules under 1 cm. SR patterns were comparable in nodules 1 cm or bigger, although sensitivity and NPV dropped below 1 cm. Wang found that elastography worked better on nodules above 1 cm. Flexibility may help combat benign and malignant thyroid nodules.[18]FNA is unattractive to poor countries without qualified cytologists since it depends so much on the operator and cytologist. Fine needle aspiration (FNA) is invasive, costly, and laborious.

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