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ORIGINAL ARTICLE

Reproducibility and Diagnostic Value of Elastography in Evaluation of Breast Masses

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ABSTRACT

Keywords: ; Shear wave elastography, Reproducibility, Diagnostic performance, Solid breast masses, Breast ultrasound

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Background; SWE is highly reproducible for assessing elastographic features of breast masses within and across observers. SWE interpretation is at least as consistent as that of BI-RADS ultrasound B-mode features.**Aim and objectives;** was to assess the role of elastography in diagnosis and differentiation of breast masses.**Subjects and methods;** this was a Cross sectional study, was carried on all patients admitted to Radiology department, ultrasound unit at Aswan university hospitals, from March 2019 till September 2020.**Result;** In Malignant group there were 2(2.9%) aged between 20-29, 52(76.5%) aged between 30-39, 14(20.6%) aged above 40, the mean age 36.04(± 3.43 SD) with range (28-42), 2(2.9%) were single, 66(97.1%) married, 49(72.1%) with housewife, 19(27.9%) employee.cIn benign group there were 22(68.8%) aged between 20-29, 10(31.3%) aged between 30-39, the mean age 27.94(± 3.91 SD) with range (22-35), 4(12.5%) were single, 28(87.5%) married, 20(62.5%) with housewife, 12(37.5%) employee.There was significant difference between 2 groups as regard Elastography score (strain ratio).**Conclusion**; The qualitative and quantitative SWE provided good diagnostic performance in differentiating malignant and benign masses. The maximum elasticity of the quantitative SWE parameters had the best diagnostic performance.

INTRODUCTION

Breast cancer accounts for 25% of all female cancers diagnosed worldwide. However, there is a large global disparity between continents and countries in its incidence as well as mortality **(1)**.

Breast cancer is the most common cancer worldwide for females, and the second most common cancer overall, with more than 1,676,000 new cases diagnosed in 2012 worldwide. This accounts for 25% of all female cancers and 12% total of all cancers. According to the World Health Organization (WHO), out of 8.2 million cancer deaths in 2012, 521,000 of these were due to breast cancer. This compares to 1.59 million deaths from lung cancer and 695,000 deaths from colorectal cancer.

Although breast cancer is thought to be a disease of the developed world, almost 50% of breast cancer cases and 58% of deaths occur in less-developed countries **(2)**.

Mammographic screening is a valuable tool for early detection of breast cancer **(3)**. However, the increased density of breast tissue significantly reduces the diagnostic accuracy. Among other imaging methods, gray-scale ultrasonography is a valuable adjunct technique. It shows highly sensitive in distinguishing benign breast lesions from malignant ones.**(4)**

US elastography combines US technology with the basic physical principles of elastography. US elastography is noninvasive and assesses tissue deformability by providing information on the elasticity. It is based on the premise that there are significant differences in the mechanical properties of tissues that can be detected by applying an external mechanical force **(5).**

Elastography has proven to be highly specific in the evaluation of lesions situated in various organs: breast, prostate, thyroid, lymph nodes and testes. However, this technique is still new, and considering that there are several technological solutions, its role in clinical practice is still to be defined **(5, 6)**

SUBJECTS AND METHODS

This study was a Cross sectional study. This study was carried at Radiology department, ultrasound unit at Aswan university hospitals from March 2019 till September 2020

Thirty female patients, who were referred to Diagnostic Radiology and Medical Imaging Department, for evaluation of clinically suspected cervical masses

Inclusion criteria: Female patient with breast mass, at any age, referred to radiology department.

Exclusion criteria: Patients who already underwent biopsy from the breast lesion.

Sample size: was calculated to include all patients admitted to Radiology department, ultrasound unit at Aswan university hospitals in 6 months and to be 100.

Sampling technique: This study was performed on systematic random sampling technique.

Methods:

- History: complete history taking : In history taking, age, , residency, occupation, Parity, gravidity, previous abortion, previous pregnancy outcomes, presence of comorbidities, such as hypertension were evaluate
- Clinical examination: General examination, Local examination

Procedure:

- Request examination from surgery department or outpatient clinic was obtained.
- Informed consent mentioning all the examine details and the undergoing research.
- Conventional ultrasound examination o Three-step ultrasound elastography procedure to assess the tissue stiffness: Manual compression

- Press “Elasto” button at the console to activate. • Select Strain on Touch panel. • Adjust the position of the ROI to place the suspicious area at the center. • Adjust the size to include surrounding tissue (ROI's size = x3 dimension of the lesion per axis).
- Manual compression depends on the type of probe. • Linear probes: Perform slight compressions keeping transducer perpendicular to the skin.
- Duration: 5 sec or 10 compressions. • Convex probes: Turn the patient on his left side more than 90 deg. pressing with the probe above the lesion, allowing the heart and lungs to create the compressions.
- Endocavitary probes: Perform soft, angular movement in plane of the probe. Duration: 5 sec or 10 compressions.
- • Using the trackball or “frame by frame” knob, select a frame on a plateau of the quality graph (Image 1, A) or when consistent frames with green bars are visualized. (Image 1, B).

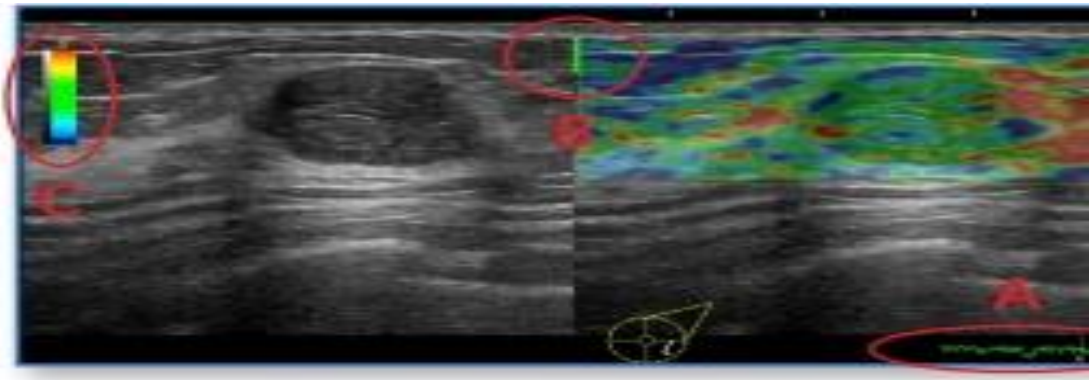

Image 1: Elastography image with quality graph (A), quality bar (B) and elasto color bar (C).

Strain Elastography Measure: A/B Ratio† • Press “measure”. • Select “A/B Ratio” measurement and type “Area”. • Draw the first measurement at the elastography image (right) and the second at the reference B-mode image (left). E-Index† • Press “measure”. • Select “Elasto” measurement. • Draw the circle at the lesion of interest either on the elastogram or the B-Mode image. This measurement gives an absolute value between 0 (softest) and 6 (hardest). E-Ratio† • Press “measure”. • Select “E-Ratio” measurement and type “Circle” or “Area”. • Draw the first measurement at the reference tissue and the second at the lesion of interest. This measurement results in the calculation of the ratio of the E-Indexes of the two areas (reference and lesion).

Administrative design:

1-Approvales: -An informed verbal consent from all participants was taken and confidentiality of information was assured. -An official written administrative permission letter was obtained from dean of faculty of medicine, Aswan University hospital manager, head of Diagnostic Radiology and Medical Imaging Department.

2- Ethical committee: Permission from the faculty of medicine ethical committee was also obtained and approval from institutional review board was taken.

Statistical analysis of the data: Data were fed to the computer and analyzed using IBM SPSS software package version 20.0**. (**Armonk, NY: IBM Corp**)** Qualitative data were described using number and percent. Significance of the obtained results was judged at the 5% level.

RESULTS

This table shows that in group A there were 2(2.9%) aged between 20-29, 52(76.5%) aged between 30-39, 14(20.6%) aged above 40, the mean age 36.04(± 3.43 SD) with range (28-42), 2(2.9%) were single, 66(97.1%) married, 49(72.1%) with housewife, 19(27.9%) employee, 56(82.4%) urban,12(17.6%) rural. In group B there were 22(68.8%) aged between 20-29, 10(31.3%) aged between 30-39, the mean age 27.94(± 3.91 SD) with range (22-35), 4(12.5%) were single, 28(87.5%) married, 20(62.5%) with housewife, 12(37.5%) employee, 26(81.3%) urban,6(18.8%) rural. There was significant difference between 2 groups as regard Age. **As table (1)**

This table shows that in group A there were 24(35.5%) with positive Family history, 5(7.4%) with 1 parity, 14 (20.6%) with 2 parities, 17(25%) with 3 parities, 22(32.4%) with more than 4 parities, the mean parities 3.1(± 1.18 SD) with range (1-5). In group B there were 12(37.5%) with positive Family history, 2(6.3%) with 1 parity, 10(31.3%) with 2 parities, 4(12.5%) with 3 parities, 8(25%) with more than 4 parities, the mean parities 2.83(± 1.17 SD) with range (1-5). There was no significant difference between 2 groups**. As table (2)**

This table shows that in group A there were 41(60.3%) right side, 25(36.8%) left side, 2(2.9%) both, 41(60.3%) with upper quadrant, 27(39.7%) elsewhere, 30(44.1%) smooth surface, 38(55.9%) speculated, 40(58.8%) abnormal surrounding, 12(17.6%) LN positive, 20(29.4) with calcification, the mean size 5.91(± 0.82 SD) with range (5-8). In group B there were 24(75%) right side, 4(12.5%) left side, 4(12.5%) both, 18(56.3%) with upper quadrant, 14(43.8%) elsewhere, 12(37.5%) smooth surface, 20(62.5%) speculated, 18(56.3%) abnormal surrounding, 6(18.8%) LN positive, 12(37.5) with calcification, the mean size 6.44(± 1.52 SD) with range (3-8). There was significant difference between 2 groups as regard side and as regard size. **As table (3)**

This table shows that in group A the mean Elastography score (strain ratio) 4.54(± 0.4 SD) with range (1.5-5.1). In group B the mean Elastography score (strain ratio) 2.82(± 0.74 SD) with range (1.5-3.7). There is significant difference between 2 groups as regard Elastography score (strain ratio). **As table (4)**

Table (1): Comparison between malignant and benign patients according to demographic data

	Total (n = 100)		Pathology					
			Group A (n = 68)		Group B (n = 32)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Age (years)								
20 – 29	24	24.0	2	2.9	22	68.8	χ^2= 53.031*	<0.001*
30 – 39`	62	62.0	52	76.5	10	31.3		
40+	14	14.0	14	20.6	0	0.0		
Min. – Max.	22.0 – 42.0		28.0 – 42.0		22.0 – 35.0		t= 10.543*	<0.001*
Mean ± SD.	33.45 ± 5.21		36.04 ± 3.43		27.94 ± 3.91			
Median (IQR)	34.0(30.0 –36.0)		35.0(34.0 –38.5)		28.0(25.0 – 31.0)			
Marital Status								
Single	6	6.0	2	2.9	4	12.5	χ^2= 3.525	^{FE}p= 0.081
Married	94	94.0	66	97.1	28	87.5		
Occupation								
Housewife	69	69.0	49	72.1	20	62.5	χ^2= 0.930	0.335
Employee	31	31.0	19	27.9	12	37.5		
Residence								
Urban	82	82.0	56	82.4	26	81.3	χ^2= 0.018	0.893
Rural	18	18.0	12	17.6	6	18.8		

χ^2: **Chi square test** FE**: Fisher Exact** **t: Student t-test**

*: Statistically significant at $p \leq 0.05$

Group A : malignant

Group B : benign

Table (2): Comparison between malignant and benign patients according to history taking

History taking	Total (n = 100)		Pathology					
			Group A (n = 68)		Group B (n = 32)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Family history								
Negative	64	64.0	44	64.7	20	62.5	χ^2= 0.046	0.830
Positive	36	36.0	24	35.3	12	37.5		
Parity								
No	18	18.0	10	14.7	8	25.0	χ^2= 4.361	0.359
1	7	7.0	5	7.4	2	6.3		

2	24	24.0	14	20.6	10	31.3		
3	21	21.0	17	25.0	4	12.5		
4+	30	30.0	22	32.4	8	25.0		
Min. – Max.	1.0 – 5.0		1.0 – 5.0		1.0 – 5.0		U= 601.0	0.318
Mean ± SD.	3.02 ± 1.18		3.10 ± 1.18		2.83 ± 1.17			
Median (IQR)	3.0 (2.0 –4.0)		3.0 (2.0 –4.0)		2.50 (2.0 –4.0)			

χ^2: **Chi square test** **U: Mann Whitney test**
Group A : malignant
Group B : benign

Table (3): Comparison between malignant and benign patients according to distribution and ultrasonic characteristics of the breast masses

	Total (n = 100)		Pathology					
			Group A (n = 68)		Group B (n = 32)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Side								
Right	65	65.0	41	60.3	24	75.0	χ^2= 8.482*	^{MC}p= 0.010*
Left	29	29.0	25	36.8	4	12.5		
Both	6	6.0	2	2.9	4	12.5		
Site								
Upper quadrant	59	59.0	41	60.3	18	56.3	χ^2= 0.147	0.701
Elsewhere	41	41.0	27	39.7	14	43.8		
Surface								
Smooth	42	42.0	30	44.1	12	37.5	χ^2= 0.391	0.532
Speculated	58	58.0	38	55.9	20	62.5		
Surrounding								
Abnormal	58	58.0	40	58.8	18	56.3	χ^2= 0.059	0.808
Normal	42	42.0	28	41.2	14	43.8		
LN								
Negative	82	82.0	56	82.4	26	81.3	χ^2= 0.018	0.893
Positive	18	18.0	12	17.6	6	18.8		
Calcification								
No	68	68.0	48	70.6	20	62.5	χ^2= 0.654	0.419
Yes	32	32.0	20	29.4	12	37.5		
Size (mm)								
Min. – Max.	3.0 –8.0		5.0 –8.0		3.0 –8.0		U= 822.0*	0.039*
Mean ± SD.	6.08 ±1.12		5.91 ±0.82		6.44 ±1.52			
Median (IQR)	6.0 (5.0 –7.0)		6.0 (5.0 –6.0)		6.50 (5.0 –8.0)			

χ^2: **Chi square test** MC: **Monte Carlo** **U: Mann Whitney test**
*: Statistically significant at $p \le 0.05$
Group A : malignant
Group B : benign

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Table (4): Comparison between malignant and benign patients according to Elastography score (strain ratio)

Elastography score (strain ratio)	Total (n = 100)	Pathology		U	p
		Group A (n = 68)	Group B (n = 32)		
Min. – Max.	1.50 –5.10	3.80 –5.10	1.50 –3.70	0.000*	<0.001*
Mean ± SD.	3.99 ±0.96	4.54 ±0.40	2.82 ±0.74		
Median (IQR)	4.30 (3.6 –4.8)	4.70 (4.3 –4.9)	2.85 (2.2 –3.6)		

U: Mann Whitney test
*: Statistically significant at $p \le 0.05$
Group A: malignant
Group B: benign

DISCUSSION

Ultrasound elastography is a newer modality which assesses the tissue differences regarding stiffness or elasticity of lesions that were, historically assessed by palpation. Elastography was first introduced in 1990 and entered clinical practice in 1997 (**7).**

Elastography is a non-invasive imaging technique in which local tissue strains are measured directly or indirectly by application of external stress. The tissue displacement is measured and a calculation of tissue stiffness is made based on tissue displacement. Shear-wave elastography (SWE) reduces operator dependency which was encountered previously in free hand elastography **(8).**

As regard sociodemographic data , in group A there were 2(2.9%) aged between 20-29, 52(76.5%) aged between 30-39, 14(20.6%) aged above 40, the mean age 36.04(± 3.43 SD) with range (28-42), 2(2.9%) were single, 66(97.1%) married, 49(72.1%) with housewife, 19(27.9%) employee, 56(82.4%) urban,12(17.6%) rural. In group B there were 22(68.8%) aged between 20-29, 10(31.3%) aged between 30-39, the mean age 27.94(± 3.91 SD) with range (22-35), 4(12.5%) were single, 28(87.5%) married, 20(62.5%) with housewife, 12(37.5%) employee, 26(81.3%) urban,6(18.8%) rural. There is significant difference between 2 groups as regard Age.

However, **Farooq et al., (9)** reported that their study sample comprised of 155 women with a mean age of 45.41 ± 14.24 years (range 20-70 years).

In the study of **Cosgrove et al., (10)**, a total of 758 women, each contributing a single mass, were available for analysis. Their mean age was 50.0 years (median 48.9, SD 13.9, range 21.2–89.5).

The present study showed that in group A there were 24(35.5%) with positive Family history, 5(7.4%) with 1 parity, 14(20.6%) with 2 parities, 17(25%) with 3 parities, 22(32.4%) with more than 4 parities, the mean parities 3.1(± 1.18 SD) with range (1-5). In group B there were 12(37.5%) with positive Family history, 2(6.3%)

with 1 parity, 10(31.3%) with 2 parities, 4(12.5%) with 3 parities, 8(25%) with more than 4 parities, the mean parities 2.83(± 1.17 SD) with range (1-5). There is no significant difference between 2 groups.

In Meta-analysis conducted by **Nindrea et al., (11)** showed that of the known modifiable risk factors for breast cancer, parity (nulipara) had the highest odd ratio (OR = 1.85 [95% CI 1.47-2.32]) followed by body mass index (overweight) (OR = 1.61 [95% CI 1.43-1.80]) and use of oral contraceptives (OR = 1.27 [95% CI 1.07-1.51]). Of non-modifiable risk factors, family history of breast cancer had the highest odd ratio (OR = 2.53 [95% CI 1.25-5.09]), followed by age (≥ 40 years) (OR = 1.53 [95% CI 1.34-1.76]) and menopausal status (OR = 1.44 [95% CI 1.26-1.65]).

In the study of **Youk et al., (12)**, the patient age, associated symptoms of the palpable mass, and breast density on mammography were significantly different between benign and malignant lesions.

The current study showed that in group A there were 41(60.3%) right side, 25(36.8%) left side, 2(2.9%) both, 41(60.3%) with upper quadrant, 27(39.7%) elsewhere, 30(44.1%) smooth surface, 38(55.9%) speculated, 40(58.8%) abnormal surrounding, 12(17.6%) LN positive, 20(29.4) with calcification, the mean size 5.91(± 0.82 SD) with range (5-8). In group B there were 24(75%) right side, 4(12.5%) left side, 4(12.5%) both, 18(56.3%) with upper quadrant, 14(43.8%) elsewhere, 12(37.5%) smooth surface, 20(62.5%) speculated, 18(56.3%) abnormal surrounding, 6(18.8%) LN positive, 12(37.5) with calcification, the mean size 6.44(± 1.52 SD) with range (3-8). There is significant difference between 2 groups as regard side and as regard size.

Our results were supported by study of **Suvannarerg et al., (13)** as they reported that the mean size of benign lesions was 1.25±0.78 and that of malignant lesions was 2.19±2.15 cm. There was statistically significant difference between both groups as regard size of tumor.

In the study of **Rehman et al., (8)**, the size of the lesion ranged from 2.0 to 6.0 cm, a mean = 3.97 ±1.26 cm.

Also, **Cosgrove et al., (10)** demonstrated that mass size on B-mode with the house system (mean 12.9 mm, SD 7.5, range 1.5–53) was slightly larger than on the RUBI system (mean 12.4 mm, SD 7.2, range 2.6–50.2 [mean difference 0.6 mm, CI 0.3 to 0.8, $P < 0.001$]). Of the 758 masses, 102 were classified as BI-RADS 2 by site investigators (all presumed benign), 285 as BI-RADS 3 (6 [2.1%] malignant), 180 as BI-RADS 4a (13 [7.2%] malignant), 79 as BI-RADS 4b (27 [34%] malignant), 38 as BI-RADS 4c (27 [71%] malignant), and 74 as BI-RADS 5 (71 [96%] malignant).

In the study in our hands, in group A the mean Elastography score (strain ratio) 4.54(± 0.4 SD) with range (1.5-5.1). In group B the mean Elastography score (strain ratio) 2.82(± 0.74 SD) with range (1.5-3.7). There is significant difference between 2 groups as regard Elastography score (strain ratio).

Our results were supported by study of **Au et al., (14)** as they reported that there was a statistically significant difference in mean elasticity, maximum elasticity, and elasticity ratio between benign and malignant masses. Malignant masses showed statistically significantly higher values for all three parameters. The mean values for mean elasticity, maximum elasticity, and elasticity ratio were 24.8 ± 22.1 kPa (range, 3.1– 136.4 kPa), 30.3 ± 26.1 kPa (range, 6.9–161.9 kPa), and 1.90 ± 1.7 (range, 0.4–11), respectively, for the benign masses; and 130.7 ± 84.1 kPa (range, 16–300 kPa), 154.9 ± 93.7 kPa (range, 18.9–300 kPa), and 11.52 ± 11.9 (range, 1.1–62.6), respectively, for the malignant masses ($p < 0.001$).

Similarly, **Farooq et al., (9)** found that the overall average mean elastography value was 108.45 kPa ± 52.75. The mean elastography (E Mean) value for benign breast lesions was 48.96 kPa ± 42.32 and 132.78 kPa ± 42.32 for malignant lesions. The difference in mean elastography values of benign and malignant breast lesions was statistically significant (48.96 kPa ± 42.32 vs 32.78 kPa ± 42.32, $P <0.001$).

Furthermore, **Suvannarerg et al., (13),** demonstrated that the quantitative SWE parameters of the malignant masses were higher than those of the benign masses ($P<0.001$); the mean elasticity, maximum elasticity, and elasticity ratio of the benign masses were 19.73 kPa, 23.98 kPa, and 2.78, respectively; and the mean elasticity, maximum elasticity, and elasticity ratio of the malignant masses were 88.13 kPa, 98.48 kPa, and 10.64, respectively.

In the study of **Park et al., 2015**, stiffness values of malignant lesions (n = 85, 60.41 [47.81] kPa) were significantly higher than those of benign lesions (n = 51, 22.05 [17.24] kPa, $P < 0.0001$). In the study of **Athanasiou et al. (15)** who reported a mean elasticity value of 45.3 kPa for benign lesions and 146.6 kPa for malignant lesions.

CONCLUSION

The qualitative and quantitative SWE provided good diagnostic performance in differentiating malignant and benign masses. The maximum elasticity of the quantitative SWE parameters had the best diagnostic performance.

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