Diagnostic utility of strain and shear wave ultrasound elastography in differentiation of benign and malignant solid breast lesions

Ahmed Tohamy Ahmed

Abstract

Background: The purpose of our study was to assess diagnostic performance and comparison of strain and shear wave ultrasound elastography for differentiation of benign and malignant breast lesions compared to histopathological diagnosis as a reference standard. Our single center study involved 100 female patients with 132 solid breast masses. All patients underwent supervision of medical history, clinical examination, conventional B-mode ultrasound which was evaluated according to the BI-RADS (Breast Imaging Reporting and Data System), and strain and shear wave ultrasound elastography. Strain ratio for strain elastography, mean elasticity value, and stiff ratio for shear wave elastography were calculated. All breast lesions were biopsied. Comparison of the elastography results with the histopathological diagnoses was done.

Results: There was no statistically significant difference as regard the AUCs for calculated values of strain and shear wave ultrasound elastography (strain ratio, 0.916; mean elasticity, 0.884; and stiff ratio, 0.872; \( P > 0.05 \)). The AUCs for the combined use of B-mode US and elastography techniques were improved as the following: B-mode + strain, 0.920; B-mode + shear wave 0.952 with a significant \( P \) value < 0.001. Higher diagnostic accuracy was noted with the combination of strain and shear wave elastography than each single elastographic modality (\( P = 0.02 \)).

Conclusions: Ultrasound elastography of breast masses is a non-invasive procedure with high sensitivity. Strain and shear wave elastography had almost similar diagnostic performance and displayed higher diagnostic performance if combined with B-mode ultrasound which helps in decreasing the number of unneeded breast biopsies.

Keywords: Ultrasound elastography, Strain ratio, Shear wave elastography, Stiff ratio, Breast mass

Background

Over the past two decades, many non-invasive imaging techniques are emerged and developed to examine the soft tissue elasticity (stiffness). Elastography techniques examined the effect of an external mechanical stimulus or compression on the soft tissue. The resultant deformation can be used to obtain qualitative and quantitative measurements for tissue elasticity [1].

Strain elastography assesses the relative strain between a lesion and also the encompassing tissue. Tsukuba score is a physical property score which is used for differentiating benign lesions from malignant ones [2, 3]. The pseudo-quantitative strategies like the strain ratio (the ratio of the lesion stiffness to fat), and the quantitative relation or ratio of the length of the lesion on elastography to its length on B-mode imaging have been employed in routine clinical settings owing to practicability and feasibility through real-time US, albeit true quantitative stiffness imaging has been also obtainable [4, 5].
Shear wave elastography is an imaging technique that measures and quantifies the tissue stiffness, and this is obtainable by measuring the speed and assessment of propagation pattern of shear waves in target tissue [6]. On basis of shear wave speed through the tissue, stiffness can be quantified and assessed; that lower speed indicates soft tissue and higher speed means hard or stiff tissue. Shear wave elastography quantifies tissue stiffness on an absolute scale [7, 8].

Breast cancer is the commonest neoplasm among females which represents 31% of feminine tumors, and the second-leading reason behind death among females. Breast lesions were initially classified into malignant and benign categories [9, 10]. Shear wave elastography imaging permits quantification of the breast lesion stiffness in comparison to adjacent tissue [2, 11, 12].

Magnetic resonance elastography has the advantage of its ability to assess the speed, propagation of stimuli and measure tissue deformation in any direction with equal sensitivity. Magnetic resonance imaging is expensive, not appropriate to be used in all clinical settings, and needs long acquisition time compared to real-time US [8].

Ultrasound elastography, non-invasive imaging modality used for measurements of tissue stiffness (elasticity). It is the foremost widely used imaging modality, because of low cost, feasibility, accessibility, and easy fast technique. Shear wave elastography measurements can be acquired by ultrasound in few seconds, compared to longer periods with MR [15].

So, this study aimed at assessment of the diagnostic performance of combination and comparison of strain and shear wave US elastography in differentiation of benign and malignant breast solid masses in comparison to histopathological diagnosis as a reference gold standard.

Methods
This is a comparative, cross-sectional, prospective single-center study approved by the local institutional ethics committee; written informed consent was obtained from the patients.

Study population
Our study involved 100 female patients with a mean age of 42.4 years and age range 20–72 years, sampled in a simple random manner over a period of one year from December 2018 to December 2019.

Inclusion criteria involved patients with solid breast mass lesions diagnosed by conventional breast ultrasound. Exclusion criteria involved (a) patients with purely cystic lesions on conventional breast ultrasound, (b) breast implants, (c) cutaneous lesions, (d) superficial lesions (< 5 mm deep to the skin surface), (e) patients refused to participate in the study.

All patients were subjected to revision of their medical history, clinical breast examination, conventional B-mode breast ultrasonography scan with categorization of masses according to BI-RADS categories, and combined strain and shear wave ultrasound elastography. Histopathological assessments for all masses were done. Comparison of conventional US and US elastography results with histopathological results was done, as the following:

History and clinical breast examination
The following points were assessed: (a) age, (b) clinical presentation and complaint (breast lump, nipple discharge, pain, breast enlargement), (c) past and family history of breast cancer. Clinical examination of both breasts was done by referring clinician and examining radiologist.

Breast ultrasound imaging
All patients were subjected to conventional B-mode ultrasonography, strain, and shear wave elastography by using Logic P9 (GE Healthcare Medical System, USA) with high frequency linear transducer L3-12 (12 MHz).

Patient position
After clinical examination of both breasts, locate any detected obvious abnormality. The patient was asked to lie supine and turn slightly to the contra-lateral side with the ipsilateral arm raised over her head. Images of strain and shear wave elastography were acquired in the same plane and patient position. Firstly, strain elastographic images were obtained then shear wave images.

Conventional B-mode ultrasonography technique
Conventional B-mode US imaging of both breasts was performed with radial scanning of the whole breast tissue and axillary tail. Longitudinal and transverse images of detected breast lesions were obtained.

Assessment of detected breast lesions for location, size, shape, borders, margin, orientation, echogenicity, posterior acoustic shadowing, presence of calcifications foci, and surrounding tissue. Lesions were classified according to BI-RADS for conventional breast sonography as the following: category 1 referred to negative results, category 2 lesions referred to benign lesions, category 3 as probably benign, category 4 (a, b and c) as suspicious...
lesions for being malignant, category 5 as most probably of malignancy, category 6 lesions were pathologically proven to be malignant.

**Strain elastography technique**

Repeated vertical light compression and decompression of the target lesion was performed [3]. Once the pressure and speed of the used manual compression to express the subcutaneous fat as a mixture of red and green for the reference region were adjusted, representative strain elastographic images were obtained (as a split image with conventional US in B-mode) (Fig. 1). A ROI rectangular box was applied on the detected target lesion and involved fat tissue surrounding it. The ROI size was adjusted according to the lesion size. Six additional ROIs were placed at the target lesion at different planes. Another ROIs of the same constant size were placed in normal breast fat tissues. Depth placement of the ROIs had been adjusted to be as similar as possible to prevent and avoid decay of the applied stress [16]. After that, the mean strain ratio (which is fat strain/target lesion strain) within ROIs was calculated automatically.

The elasticity score (color coded qualitative method) and lesion classification were done on basis of a scoring system by Tsukuba [10] projected by Itoh et al. as the following: score 1 indicates strain seen throughout the hypoechoic lesion (the whole lesion is similarly shaded in green); score 2 indicates that strain is not seen in part of the lesion (the lesion appeared as mixture of green and blue); score 3 indicates strain is seen only peripherally (green peripheral areas); score 4 indicates no strain seen throughout the lesion (lesion is shown in blue); score 5 indicates no strain within the whole lesion or the encompassing surrounding area (both the whole lesion and its surrounding area are shown in blue color). A stiffer tissue indicated by higher elasticity score.

**Shear wave elastography technique**

Elastographic images of the shear wave were obtained without any transducer pressure [8, 16]. A ROI rectangular box was adjusted on the observed target lesion including sufficient amount of surrounding healthy breast tissue. After a few seconds of no motion to permit stabilization of the shear wave image, freeze shear wave elastography once an ideal image has been obtained. Quantitative elasticity values were ranged from 0 to 180 kPa and displayed as a color scale ranged from dark blue (lowest stiffness) to red (highest stiffness) (Figs. 2 and 3). The investigator placed automated fixed sized ROIs over the hard or stiff portion of the lesion involving the nearby stiff tissue halo, six additional ROIs were placed at the target lesion at different planes. Another ROIs of similar size were placed in subcutaneous fat. Measurement of mean elasticity value and stiff ratio were automatically calculated.

**Histopathological diagnosis**

Histopathological diagnosis of all examined breast lesions were performed by two expert pathologists. Samples were taken either with fine needle aspiration cytology (FNAC), core biopsy, surgical excision, or radical surgery. Comparison between histopathological data as reference gold standard for diagnosis and ultrasound elastography values (strain ratio, mean elasticity value and stiff ratio) were done.

**Statistical analysis**

Statistical analysis and tests were specified according to the variable type. A commercially available IBM Statistical Package for Social Sciences software (SPSS), 21st edition, IBM, USA, was used.

Results of conventional B-mode US, strain ratio, stiff (elasticity) ratio, and mean elasticity value were compared with the results of histopathological diagnosis. The sensitivity, specificity, and total accuracy were determined.

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**Fig. 1** A 53-year-old patient with Rt. breast mass proved to be invasive ductal carcinoma “grade II” on histopathological examination. Left, B-mode ultrasound showed ill-defined hypoechoic mass with irregular margins and few speculations was seen at 11 o’clock location, which is considered to be BI-RADS 5 category. Right, strain elastography, the entire hypoechoic lesion was shaded in blue color with elasticity score (4), strain ratio = 5.72
Continuous data were displayed as mean ± standard deviation, while the categorical data were expressed as percentage. To compare between the qualitative data, chi-squared test and spearman correlation test were performed.

Cut-off values for strain ratio, mean elasticity value, and stiff (elasticity) ratio were determined with area under curve (AUC), specificity, and sensitivity. Multivariate ROC curves were performed to assess combination of B-mode conventional US and ultrasound elastography.

Results

Our study involved 100 female patients with a mean age of 42.4 years and age range of (20–72 years). The mean age was higher for patients with malignant lesions (45.7 ± 10.518) than for patients with benign lesions (30.6 ± 10.729) with a statistically significant difference as regarding the age between the two groups (P < 0.05).

We examined 132 breast lesions in 100 female patients. Of the 132 lesions, 68 were malignant, and 64 were benign; based on histopathological diagnosis. The malignant lesions involved invasive ductal carcinoma (n = 42), ductal carcinoma in situ (n = 16), and invasive lobular carcinoma (n = 10). Benign lesions involved fibroadenomas (n = 44), non-specific granulomatous mastitis (n = 4), adenosis (n = 11), and fibrosis (n = 5).

The mass lesions diameter on B-mode conventional US displayed a range of 0.5–5.6 cm and mean size of (1.8 ± 1.1 cm). The calculated sensitivity and specificity of conventional US in diagnosis of solid breast lesion were 85% and 94%, respectively, as compared to histopathological diagnosis.

As regards ultrasound elastography, the mean elasticity value and stiff ratio for shear wave elastography and strain ratio for strain elastography were determined for all examined solid breast lesions as presented in (Table 1).
The malignant lesions showed a significantly higher elasticity value than that of benign lesions. AUCs for mean elasticity values and stiff ratio calculated by shear wave elastography were not significantly different from the strain ratio obtained by strain elastography.

However, the AUCs for stiff ratio calculated by shear wave elastography were lower than the mean elasticity values (stiff ratio, 0.872 and mean elasticity value, 0.884), but it evoked no statistically significant difference ($P > 0.5$).

At a strain ratio of 2.57 and a mean elasticity value of 66.4 kPa as cut-offs for strain and shear wave elastography, the strain ratio displayed a higher sensitivity than that for mean elasticity, but the specificity for mean elasticity was higher than the strain ratio. There was no statistically significant difference determined in our study as regard both sensitivity and specificity of calculated strain and shear wave elastography ($P > 0.05$).

Of the examined 132 breast lesions (68 malignant and 64 benign lesions), there were 9 benign breast lesions showed false-positive results and 7 malignant lesions displayed false-negative results on conventional US. While on strain elastography; eight benign lesions displayed false positive results and three malignant breast lesions had a false negative result. Finally, on shear wave elastography examination, there were two benign lesions showed a false-positive results and five malignant ones displayed false-negative results.

There were three malignant lesions (two lesions were pathologically proven to be invasive lobular carcinoma and one lesion diagnosed as ductal carcinoma in situ) revealed false negative results on both conventional US and US elastography modalities, that the calculated lesion’s strain ratio and mean elasticity value were low compared to the determined cutoff values (1.9, 1.6, and 1.8; and 15.7, 14.9, and 15.3 kPa, respectively). Two cases of benign fibroadenoma displayed false positive results on both conventional ultrasound and US elastography (strain and shear wave) with higher strain ratio and mean elasticity value compared to the determined cutoff (5.2, 4.6, 90.7, and 87.9 kPa, respectively).

There were seven breast lesions displayed discrepant results. Only on strain elastography, three cases with invasive ductal carcinomas evoked correct results. While only the shear wave showed correct results in four cases with fibroadenoma (Table 2).

Following the downgrade of BI-RADS category 4a lesions based on elastographic cut-offs for strain and shear wave, the AUCs for B-mode conventional US and elastography combination have been improved (B-mode + strain, 0.920; B-mode + shear wave; 0.952; and B-mode, 0.716; $P < .001$). Combined both elastographic modalities, strain and shear wave displayed significantly higher diagnostic precision and accuracy than each single elastographic modality ($P = 0.02$) (Table 3).

**Discussion**

Ultrasound elastography is a non-invasive imaging tool which identifies malignant tumors on basis of tissue elasticity (stiffness) compared to normal tissue, that tissue of breast cancer is more stiffer than healthy normal breast tissue [17].

According to our study results, the calculated sensitivity and specificity for conventional US were 85% and 94%, respectively. Our results showed higher sensitivity and comparable specificity to results mentioned by Schaefer et al. [18] and Itoh et al. [10] (sensitivity 57.8, 71%; specificity 96.1, 96.6%, respectively). These difference are mainly attributed to the fact that they chose a higher cut-off of BI-RADS category (BI-RADS 1, 2, 3, and 4 considered as benign lesion, while BI-RADS category 5 considered as malignant lesion).

In our study, similar diagnostic performance of strain and shear wave elastography was shown for differentiation of benign and malignant lesions. By this result, we agreed with some previous studies carried by Mirinae Seo et al., chang et al., and Youk et al. [16, 19, 20]

Our results as regards strain and shear wave elastography values displayed a statistically significant difference in differentiation between benign and malignant lesions ($P < 0.001$). Our results are comparable to results mentioned by Mirinae Seo et al. [16], Kumm and Szabunio

**Table 1** Quantitative analysis of mean elasticity value, stiff ratio, and strain ratio of solid breast masses ($n = 132$) for differentiation of benign from malignant lesions

| Variable       | Mean elasticity value (at cut-off = 66.4 kPa) | Stiff ratio (at cut-off = 5.8) | Strain ratio (at cut-off = 2.57) |
|----------------|---------------------------------------------|-------------------------------|---------------------------------|
| Benign         | 38.13 ± 25.56                               | 3.45 ± 2.13                   | 1.46 ± 0.97                    |
| Malignant      | 101.54 ± 34.58                              | 16.97 ± 10.84                 | 5.36 ± 2.03                    |
| $P$ value      | < 0.001                                     | < 0.001                       | < 0.001                        |
| Sensitivity (%) | 92.6 (63/68)                                | 91 (61/68)                    | 96 (65/68)                     |
| Specificity (%)| 97 (62/64)                                  | 81 (52/64)                    | 87.5 (56/64)                   |
| AUC (area under curve) | 0.884                                     | 0.872                         | 0.916                          |
| $P$ value*     | 0.487                                       | 0.246                         |

*Comparison of AUC of mean elasticity value and stiff ratio with the strain ratio
[21], and Thomas et al. [22], where benign lesions displayed a mean strain ratio of 2.06 ± 0.97, 2.7, and 1.6 ± 1, respectively, while the malignant lesions revealed a mean strain ratio of 5.26 ± 2.73, 10.5, and 5.1 ± 4.2, respectively.

Our study results showed that the AUC for the strain ratio was 0.916, as compared to AUC values from other systems (0.929 and 0.926) [16, 23]. The previous studies found that the best cutoff values for differentiation of benign and malignant lesions were 2.63 and 4.01, compared to a lower cut-off value determined in our study (2.57).

Our study results evoked that the AUC for the mean elasticity value and stiff (elasticity) ratio were 0.884 and 0.872, compared to AUC value of 0.898 and 0.868 as reported by Mirinae Seo et al. [16], 0.907 and 0.917 from Youk et al. [20].

Mirinae Seo et al. [16] reported that 67.8 kPa and 6.43 were the best cutoff values for mean elasticity value and stiff ratio, respectively, at which benign and malignant lesions could be differentiated, which were comparable to our results (66.4 kPa and 5.8, respectively).

Also in a study done by Thomas et al. [22] which assessed 227 lesions and showed that the strain elastography had a sensitivity and specificity of 90% and 89%. Also displayed a comparable cutoff value of 2.45 (AUC, 0.949) which enabled significant differentiation between benign and malignant breast lesions ($P < 0.001$).

Another study was done by Zhi et al. [24] upon 559 solid lesions and revealed a statistically significant difference ($P < 0.001$) between the calculated strain ratios of benign and malignant lesions (mean, 1.83 and 8.38) respectively. It was found that the sensitivity of strain ratio was 92.4%, while its specificity reached 91.1% at a cut-off value of 3.05 (AUC, 0.944).

This cut-off value’s difference was likely because of the difference in ROIs number which were applied to the target lesion and subcutaneous fat, also the depth on which ROI was applied in subcutaneous fat, to measure mean values of elastography. In our study, 6 ROIs were placed for the target lesion and subcutaneous fat as similar as possible to prevent decay of the applied stress. Also, the mean lesion size differences could have affected the results.

According to other studies by Cho N et al. [25], Lee JH et al. [26], and Thomas et al. [22] performed by another ultrasound systems; the group with larger mean lesion size displayed a higher cut-off point as the following (cut-off values of 2.00, 2.24, and 2.45 for groups with corresponding mean lesion size of 0.7, 0.9, and 1.6 cm), respectively.

Our results agreed with results recorded by Leong et al. [27] which compared the diagnostic performance of conventional US and strain elastography in a study included 110 breast mass lesions. The sensitivity and specificity of conventional US were 88.5% and 42.9%, respectively, while the sensitivity and specificity of strain elastography were 100% and 73.8%, respectively. The investigators reported that ultrasound elastography was more specific and accurate than conventional ultrasound in assessment of breast lesions. Combination of conventional US and elastography revealed improved specificity and accuracy which can significantly decrease the number of false positives.

We agreed with results of a study done by Richard G [28], as the strain ratio displayed a higher sensitivity than that for mean elasticity, but the specificity for mean elasticity was higher than the strain ratio.

Unlike our study results, Chang et al. [19] found that the sensitivity of shear wave was higher than that of strain elastography, while strain elastography displayed higher specificity than that of shear wave. Barr and Zhang [29] found better diagnostic performance of strain elastography compared to shear wave.

### Table 2 Discrepant results of breast mass lesions at strain and shear wave elastography

| Number | Correct diagnosis by; | Strain ratio | Mean elasticity value (kPa) | BIRADS category | Size on ultrasound (cm) | Pathological diagnosis |
|--------|------------------------|--------------|-----------------------------|-----------------|------------------------|------------------------|
| 1      | Strain                 | 2.81         | 51.32                       | 4b              | 0.7                    | *IDC grade I           |
| 2      | Strain                 | 5.46         | 46.57                       | 4b              | 1.2                    | *IDC grade II          |
| 3      | Strain                 | 4.32         | 48.83                       | 4c              | 1.8                    | *IDC grade II          |
| 4      | Shear wave             | 2.79         | 13.59                       | 3               | 2.5                    | Fibroadenoma           |
| 5      | Shear wave             | 2.95         | 22.27                       | 4a              | 4                      | Fibroadenoma           |
| 6      | Shear wave             | 3.69         | 39.64                       | 4a              | 2.3                    | Fibroadenoma           |
| 7      | Shear wave             | 3.24         | 36.83                       | 4a              | 3.5                    | Fibroadenoma           |

*IDC invasive ductal carcinoma

### Table 3 Diagnostic performance of combination of B-mode ultrasonography, strain, and shear wave elastography following selective downgrading of BI-RADS 4a masses using determined cut-offs for elastographic values calculated from ROC curves

| Modality                  | Sensitivity | Specificity | AUC  | $P$ value |
|---------------------------|-------------|-------------|------|----------|
| B-mode                    | 0.716       |             |      |          |
| +Strain elastography      | 99          | 82          | 0.920| < 0.001  |
| +Shear wave elastography  | 100         | 89          | 0.952| < 0.001  |
We agreed with the results of a broad multicenter research performed by Berg WA et al. [30] and Tomoyuki Fujioka et al. [31], who reported that the addition of shear wave elastography to conventional US examination of breast masses increased accuracy and improved the diagnostic performance of the BI-RADS score.

Irrespective of the promising results and improved confidence in the outcome if both types of ultrasound elastography revealed concordant results; there were seven lesions with discrepant results are noted in our study. Only on strain elastography, three cases with invasive ductal carcinomas showed correct results. While only the shear wave showed correct results in four cases with fibroadenoma.

Nearly similar results were reported by Mirinae et al. [16], Barr et al. [12], and Bait et al. [32], and this was clarified that poor generation of shear waves in invasive cancers could lead to false-negative results, also small-sized malignant masses are more liable to give false-negative results on ultrasound elastography [28, 33–35].

Also, with strain elastography, interobserver and intraobserver biasing is deemed unavoidable and possible. All the causes that would influence the lesion stiffness or elasticity such as calcifications and hemorrhage can contribute to inaccurate misleading outcomes, false-positive results and might impact the ultrasound elastography diagnosis [36].

A small field of view applied during examination of breast lesion on strain elastography could lead to false positive results, so a larger filled of view involving different tissue types with variable stiffness is mandatory to acquire accurate images and measurements without misleading results. The use of conventional US should be considered even with concordant results obtained from strain and shear wave elastography in cases of stiff benign tumors such as; fibroadenomas, sclerosing adenosis, and papillomas, due to sliding of the US transducer around the lesion during acquisition of elastographic data which may contribute to false-negative or false-positive outcomes. Although shear wave elastography is assumed to be more objective, realistic, and reproducible compared to strain elastography, that no manual compression was used, but pre-compression may induce higher shear wave speed regardless of the tissue stiffness, and this can contribute to misleading false positive results in benign masses [28, 37].

AUCs for B-mode conventional US and elastography combination have been improved (B-mode + strain, 0.920; B-mode + shear wave; 0.952; and B-mode, 0.716; \( P < .001 \)). Combined both elastographic modalities, strain and shear wave displayed statistically significantly higher diagnostic precision and accuracy than each single elastographic modality \( (P = 0.02) \). These results are agreed with results reported Mirinae Seo et al. [16] which displayed improved AUCs for combined B-mode + strain, 0.940; B-mode + shear wave; 0.964; and B-mode, 0.724; \( P < .001 \) and statically significant higher diagnostic accuracy than each single elastographic modality \( (P = 0.031) \).

We recommend combining B-mode conventional ultrasound, strain, and shear wave elastography (when possible) may solve the problem, that combination of them has been found to increase the diagnostic performance.

Our study had some limitations. Firstly, larger sample size was better to provide strengthy conclusions. Secondly, different ultrasound systems and elastographic protocols were available, so more additional prospective studies with larger number of lesions are mandatory for further determination and standardization of elastographic protocols and cutoff values by different US systems. Thirdly, ultrasound is operator dependent, needs experienced radiologists as well as good equipment to avoid misinterpretation of the lesions and to reduce the number of false-positive and false-negative outcomes. Studies with larger sample size are required to provide more realistic representative and to increase external validity.

**Conclusions**

Strain and shear wave US elastography had almost similar diagnostic performance and accuracy in differentiation of benign and malignant breast lesions. The diagnostic performance of US elastography was significantly improved when combined with B-mode conventional US, and this could help in decreasing the number of unneeded breast biopsies.

**Abbreviations**

BIRADS: Breast Imaging Reporting and Data System; FNAC: Fine Needle Aspiration Cytology

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**Authors’ contributions**

AT participated in the formulation of the study, preparation of methodology, data collection, analysis of the data, and writing of the paper. The author has read and approved the manuscript.

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**Availability of data and materials**

The dataset used and/or analyzed during the current study are available from the corresponding author on reasonable request

**Ethics approval and consent to participate**

Approved by the local institutional ethics committee (Committee of Scientific Research Ethics (CSRE), Suez Canal University, Egypt); written informed consent was obtained from all patients.

The reference number is not applicable and/or not available

**Consent for publication**

Consent for publication was obtained from the patients.
Competition interests
The author of this manuscript declares no relationships with any companies, whose products or services may be related to the subject matter of the article.

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