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# Research Article

# ACCURACY DETECTION SIGNIFICANT FIBROSIS OF LIVER OF SHEAR WAVE ELASTOGRAPHY IN 3 TYPES: 2D SWELOGIQ 9ETM, ELASTQ AND ELASTPQ

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**ABSTRACT**

The proper evaluation staging of liver fibrosis is important for treatment such as begin antiviral treatment for patient significant fibrosis of liver (F >2) stop progression to cirrhosis and reverse to normal liver. Liver biopsy is gold standard but invasive method. There are many non-invasive methods as shear wave elastography. Transient elastography (Fibroscan) is the first and acceptance from many guidelines. There are new shear wave elastography technique pSWE and 2D-SWE that can be used in the same session of gray scale images. **Objective:** to evaluated the accuracy of 3 types of shear wave elastography (2D SWE LOGIQ 9ETM, ElastQ, ElastPQ for detection significant fibrosis (F > 2) using transient Elastography (TE) as the reference method. **Method:** 198 subjected with underlying liver disease, the LSMs by 3 SWE were evaluated in the same session for discriminated significant fibrosis and not significant fibrosis compare to the LSM by TE (fibroscan) for evaluation accuracy, sensitivity, specificity. **Results:** The LSM for the 3 SWE techniques can discriminate significant fibrosis (F> 2) from the non-significant fibrosis group even all give difference LSM value. All 3 types had good diagnostic performance AUROC curve (0.773-0.856) and high sensitivity (63.3-75.6%) and specificity (82.4-84.3%) accuracy (73.7-80.3%). The best cut-off LSM value for 2D SWE LOGIQ 9ETM, ElastQ, ElastPQ were 7 kPa, 5.7 kPa, 5.7 kPa respectively. **Conclusion:** SWE are good diagnostic performance and diagnostic test. The best cut-off LSM value for 2D SWE LOGIQ 9ETM, ElastQ, ElastPQ were 7 kPa,5.7 kPa, 5.7 kPa respectively.

***Keywords:*** liver stiffness measurement (LSM), significant fibrosis, accuracy,shear wave elastography (SWE), fibroscan.

## INTRODUCTION

Chronic liver disease (CLD) and cirrhosis is a worldwide health problem with estimated mortality of 1.32 million[1], causing a high rate of disability and increase health care burden and utilization[2]. By definition, chronic liver disease (CLD) is the set of diseases with decrease hepatic function as a result of chronic inflammation or chronic liver injury. The advanced stage of CLD often leads to the development of cirrhosis, which defined as the irreversible distortion architecture by fibrosis, scar and abnormal nodule[3]. The proper evaluation of staging liver fibrosis is very important for treatment, prognosis assessment and long-term follow up[4].

For many years, liver biopsy has been the gold standard for evaluating the degree of fibrosis. The procedure is invasive, costly, and has limitation in the diagnostic utility and accuracy due to inadequate sampling. As a result, noninvasive modalities for liver assessment are now being increasingly used. Non-invasive assessment of liver fibrosis can be performed by biological test[5]or by elastography measurement. Recently, the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)[6,7]and the Canadian Association for the Study of the Liver (CASL) have recommended elastography as a method for assessment of liver fibrosis. Elastographic methods can be divided into two main types: displacement techniques and shear wave speed techniques. The former includes Transient Elastography (TE); Fibroscan(EchoSens, Paris, France) while the latter include point shear wave elastography pSWE); the ElastPQ technique; Acoustic Radiation Force Impulse elastography (ARFI); and shear wave elastography imaging which included 2D-SWE and 3D-SWE[8-10].

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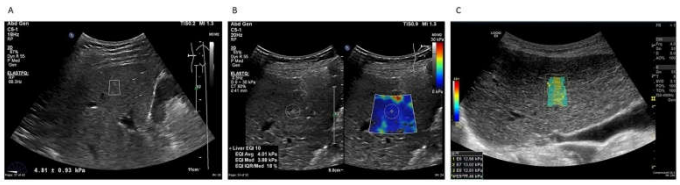
Transient elastography (Fibroscan, Echosens) is an ultrasound base method using a vibrator mounted to an ultrasound transducer which creates low frequency wave. The shear wave speeds is calculated into tissue elasticity using Young's modulus and displayed as kilopascals (kPa)[5]. It has been widely used since 2003[11], and now accepted as a reference for liver stiffness evaluation. However, TE has limitation to measure liver stiffness in patients with as cites and has carry up to 20% failure rate, especially in patients with a high body mass index. Additional gray scale images of the liver, the newer ultrasound machine can be used to evaluate liver stiffness in the same session. Newer ultrasound-based elastography techniques, included point shear wave elastography pSWE) and 2-dimensional shear wave elastography (2D-SWE) were performed by placing the region of interest (ROI) using the same probe as that used in the conventional diagnostic ultrasound system[12-14]. Acoustic Radiation Force Impulse (ARFI) quantification, which measured the speed of the shear wave in a small region has been developed in 2008[15], and classified by the European federation of societies for ultrasound in medicine and biology (EFSUMB) [7] as point shear wave elastography (pSWE). Virtual touch quantification (VTQ; Siemens Healthcare, Erlangen, Germany) of acoustic radiation force impulse was the first P-SWE system to be developed and has been validated by many large-scale studies[16,17]. This technology provided quantitative elastography which is embedded in a conventional ultrasound machine. In 2012, a real time SWE technique for liver stiffness quantification has been implemented in Supersonic Imagine by Aixplorer[18-19], which provide bidimensional elastography information called real time 2D-SWE[19]. SWE has various benefits above TE in the evaluation of liver fibrosis in patient with as cites. Both pSWE and 2D-SWE have shown comparable or better diagnosis performance and a lower rate of technical failure than TE when evaluating fibrosis[20-21].A relative new pSWE technique, ElastPQ showed good

diagnostic performance in prediction significant fibrosis (F ≥2) and cirrhosis with high success rate and reliable measurements[14,22]. The recent advent of 2D-SWE (LOGIQ™ E9 and ElastQ) has allowed for visaulization of multiple shear waves and has enable both qualitative and quantitative evaluation of LSM by providing real-time colored elastographic maps of tissue stiffness. The latest 2D-SWE system, ElastQ imaging, provided the latest elastographic map available and a unique confidence map the help physician selected and adequate measuring area Many studies have reported usefulness, accuracy of both TE and SWE for the evaluation liver stiffness[23] but few studies have directly compared TE and SWE results obtained using various ultrasound device in the same patients. The purpose of this study to determine the accuracy of shear wave elastography 3 techniques: 2D-SWE (ElastQ) imaging and point shear wave elastography (ElastPQ) on the same machine and 2D-SWE LOGIQ™ E9) for detection significant fibrosis of liver (F≥2) and assessment the reliability measurement of each technique.

## MATERIAL AND METHOD

This was a single-center cross-sectional study conducted in a tertiary center. The 217subjects from the hepatobiliary and Gastroenterology units between September 2017 and August 2018 who received transient elastography (fibroscan) and ultrasound of the upper abdomen in the Radiology department less than one-month interval were included. All transabdominal ultrasonographic procedures were performed by single experienced radiologist while the transient elastography was performed by experienced nurse certificated in performing Transient elastography. Nine patients were excluded due to hearing problem, and difficult to control respiration causing technical difficulty in performing the elastography procedure. After ultrasound examination of the upper abdomen, elastography was performed using the EPIQ7 ultrasound system (Philips Healthcare, Bothell, WA, USA) with convex broad base probe (ElastPQ technique)(Figure 1a). After finished evaluation with pSWE(ElastPQ) technique then the patient rest on the table then evaluation with 2D-SWE(ElastQ) technique (Figure 1b) with same probe and near the same position till have finished. Then patients were moved to another machine GE LOGIQ™ 9E (Figure 1c). After 10minute rest, the evaluation by 2D shear wave elastography using GE LOGIQ™ 9E (GE Healthcare, Wauwatosa, WI, USA)(Figure 1c) was carried out in the same session.



(a) (b) (c)

**Figure 1.** Shear wave elastography. The figure illustrated point swear wave elastography (a)2D-SWE by ElastQ, (b) 2D-SWE by LOGIQ™ E9, (c) performed on the patient. The box (center) represented the shear wave measurement area

We calculated the sample size based on the previous study of Castera L et al, with the success rate of about 60 percent. The calculate sample size with minimal requirement was 135 subjects.The study was approved by the local ethics Committee and was performed in accordance with the Helsinki Declaration of 1975. Mean value and standard deviation were calculated for numeric variables with normal distribution. Qualitative variable was presented as numbers and percentage. Parametric (t-test) were used for assessment of differences between numeric variables. Chi-square ($X^2$) test was used for comparing proportional expresses as percentages ("n" designates the total number of patients included particular subgroup). Area under receiver operating characteristics (AUROC) was built for shear wave 3 elastographic techniques to discriminate between significant fibrosis (F ≥2) and non-significant fibrosis (F0 and F1). The highest Youden index (sensitivity+specificity-1) was used as the optimum cut off for significant fibrosis (F ≥2). The 95%confidence intervals were calculated for predictive value. Diagnostic accuracy included sensitivity, specificity, PPV, NPV and accuracy using the cutoff by manufacturer's recommendation and predictive cut-off from this study was also calculated. The p value for all tests was considered significant as the level of 5% ($p<0.05$)

## RESULTS

Among 198 patients who received both fibroscan and shear wave elastography, the 93(47%) were female and 105(53%) were male with mean age of 49.87±12.02 years. With the Mean body weight of 65.18±13.94 kg and mean height of 162.74±7.9 cm, the calculated Body mass index was considered normal in 59.6%, overweight (BMI 25 to 30 kg/m$^2$) in 27.3% and obese (BMI >30 kg/m$^2$) in 13.1%,based on the Asian BMI criteria. The causes of chronic liver disease were hepatitis B (44.9%), hepatitis C (29.3%), alcoholic hepatitis (2.3%), fatty liver (fatty liver, NASH and NAFLD) (9.6%). There are 90 patients were evaluated with fibroscan and had found liver stiffness more than 7kPa, so classified at significant fibrosis (F ≥2) and 108 patient had liver stiffness less than7 kPa. (F0-1). The mean age of fibroscan (F ≥ 2) was 52.97±11.2% and F0-F1 was about 47.98±12.13. In group of significant fibrosis (F ≥ 2) had 56 male (62.2%) 34 female (37.8%). The weight and height of significant fibrosis (F ≥2) and F0-1 were no significant difference: 68.76 +18.36 kG and 65.02+17.65 kG, 162.56 +12.5 cm and 160.08 cm. respectively. The BMI of significant fibrosis group and no significant fibrosis group were no difference. Underlying disease of liver were significant difference between significant and no significant fibrosis group. Patient's characteristics were presented on Table 1.

**Table 1** Baseline Characteristic of patients (n=198)

| Characteristics | Total (n =198) | Fibroscan | | p-value |
|---|---|---|---|---|
| | | Positive (n = 90) | Negative (n = 108) | |
| Age (years) | 49.87±12.02 | 52.97±11.20 | 47.28±12.13 | 0.001* |
| Gender | | | | 0.018** |
| Male | 105 (53) | 56 (62.2) | 49 (45.4) | |
| Female | 93 (47) | 34 (37.8) | 59 (54.6) | |
| Weigh (kg) | 65.18±13.93 | 68.76±18.36 | 65.02±17.65 | 0.146 |
| Height (cm) | 162.74±7.90 | 162.56±12.50 | 160.08±16.91 | 0.251 |
| BMI (kg/m$^2$) | | | | 0.112 |
| Normal (<25) | 118 (59.6) | 47 (52.2) | 72 (66.7) | |
| Overweight (25-30) | 54 (27.3) | 29 (32.2) | 23 (21.3) | |
| Obese (>30) | 26 (13.1) | 14 (15.6) | 13 (12.0) | |
| Underlying | | | | <0.001** |
| Hepatitis B | 89 (44.9) | 18 (20.0) | 71 (65.7) | |
| Hepatitis C | 58 (29.3) | 42 (46.7) | 16 (14.8) | |
| Fatty liver | 19 (9.6) | 10 (11.1) | 9 (8.3) | |
| Alcoholic | 10 (5) | 8 (8.9) | 2 (1.8) | |
| HIV and HIV co-infection | 10 (5) | 4 (4.4) | 6 (5.55) | |
| other | 12 (6.2) | 8 (6.7) | 4 (0.9) | |

Values are represented as n (%), mean ± SD.,

* = Significant at p<0.05; using Chi-square test

** = Significant at p<0.05 using Independent t-test

**Diagnostic performance of elastography and Fibroscan®**

Among 198 patients who had been examined with Fibroscan® and shear wave elastograhy, the median liver stiffness evaluated by Fibroscan, 2D-SWE by LOGIQ™ E9, 2D-SWE ElastQ, pSWE(ElastPQ) were 6.55± 9.93, 6.44±4.65, 4.97±3.71 and 5.32± 23.2, respectively. The reliability of Fibroscan® and each type of shear wave elastography 2D-SWE LOGIQ™ E9, 2D-SWE (ElastQ), pSWE(ElastPQ) were 97.5, 98.5, 83.3 and 69.2 percent, respectively. When compare among two type of shear wave elastography, 2D-shear wave elastography has reliability better than point shear wave elastography. The value liver stiffness measurement and reliable measurement were presented in Table 2.

**Table 2** Liver stiffness measurement (kPa), reliable measurement rate of Fibroscan, LOGIQ, ElastQ and ElastPQ (n=198)

| Parameters | TE Fibroscan | 2D-SWE LOGIQ™ E9 | 2D-SWE (ElastQ) | P-SWE (ElastPQ) |
|---|---|---|---|---|
| Mean | 10.51 | 7.93 | 6.46 | 10.54 |
| Median | 6.55 | 6.44 | 4.97 | 5.32 |
| Standard deviation (SD) | 9.93 | 4.65 | 3.71 | 23.2 |
| Reliability n (%) | 193 (97.5) | 195 (98.5) | 165 (83.3%) | 137 (69.2) |

The liver stiffness of all three types of shear wave elastography were significant difference between significant fibrosis (F ≥2) group and non-significant fibrosis group (F0-F1). The liver stiffness of three types were quite difference, In significant fibrosis group ElastPQ technique had lowest than 2D-SWE by LOGIQ and ElastQ: 8.30, 10.79 ,17.07 kPa respectively. No significant correlation the liver measurement values from 3 type shear wave elastography were observed. The liver stiffness measurement in significant fibrosis and non-significant fibrosis group measured by 3 types shear wave elastography were present in Table 3.

**Table 3** Comparison liver stiffness measurement between significant fibrosis (F≥2) and no significant fibrosis (F0-F1) with difference type of shear wave elastography (n=198)

| Shear wave elastography | Fibro scan | | p-value |
|---|---|---|---|
| | Positive (n = 90) | Negative (n = 108) | |
| 2D-SWE LOGIQ™ E9 | 10.79±5.27 | 5.54±2.01 | <0.001 |
| 2D-SWE(ElastQ) | 17.07±33.25 | 5.09±2.25 | 0.001 |
| pSWE(ElastPQ) | 8.30±4.50 | 4.92±1.81 | <0.001 |

Values are represented as mean ± SD., * = Significant at p<0.05using Independent t-test for study significant fibrosis

**Diagnosis performance of 3 technique of shear wave elastography**

The AUROC of three shear wave elastography for diagnosis significant fibrosis (F ≥ 2) were good diagnosis performance with AUROC values ranging from 0.773-0.856. 2D-SWE LOGIQ™ E9 value and 2D-SWE ElastQ showed AUROCs: 0.86 (95% CI:0.80-0.91) and 0.80 (95% CI: 0.74-0.87) respectively which better than pSWE, ElastPQ with AUROC 0.77 (95 CI: 0.70-0.84).

**Table: 4** AUC of 3 type shear wave elastography for diagnosis significant fibrosis (F>2) using fibroscan=7 kPa for reference standard

| Test Result Variable(s) | Area | Asymptotic Sig.[b] | Asymptotic 95% Confidence Interval | |
|---|---|---|---|---|
| | | | Lower Bound | Upper Bound |
| 2D-SWE LOGIQTM E9 | .856 | <0.001 | .802 | .911 |
| 2D-SWE (ElastQ) | .803 | < 0.001 | .739 | .867 |
| P-SWE (ElastPQ) | .773 | < 0.001 | .705 | .841 |

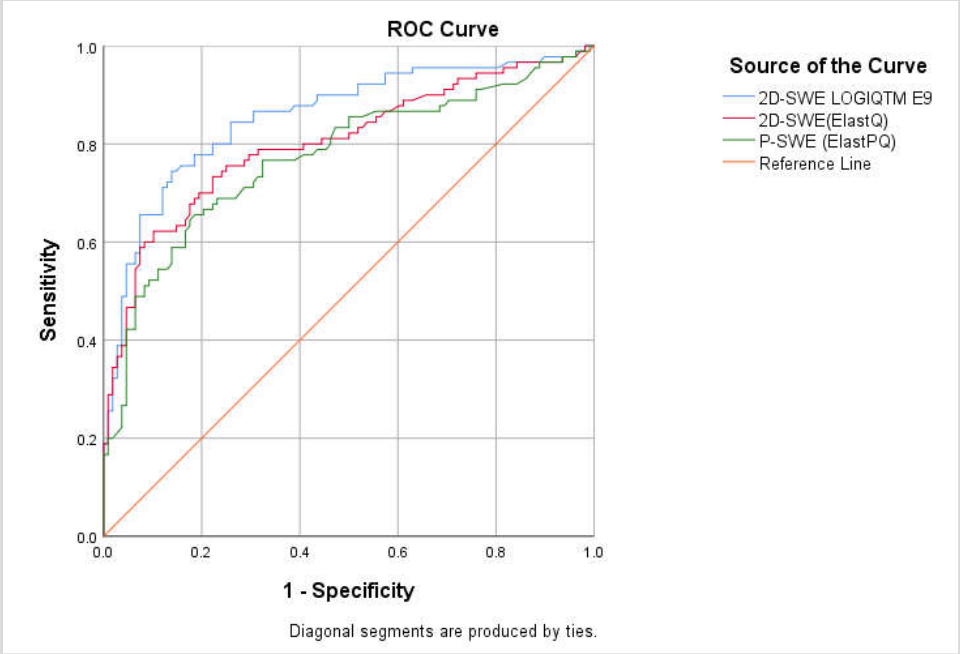



**Figure2** Receiver operation characteristic curve (AUROC) of for detection significant fibrosis (F ≥ 2) of 3 shear wave elastography : 2D-SWE LOGIQ™ E9, 2D-SWE(ElastQ), P-SWE (ElastPQ) using transient elastography (TE) for reference standard

For staging liver fibrosis by Fibroscan as reference method used liver stiffness value for diagnosis significant fibrosis≥ 7 kPa. Difference methods had difference liver stiffness value for diagnosis significant fibrosis. According to manufacturer recommendation, the value for determined significant fibrosis of LOGIQ™ E9, ElastQ and ElastPQ were more than 8.29kPa, 5.7 kPa and 5.7 kPa respectively. The used this value the sensitivity of ElasQ was better than ElastPQ and LOGIQ™ E9 (74.4%, 64.4% and 62.2% respectively). LOGIQ™ E9 is high specificity 92.6% higher than ElastQ(76.9%) and ElastPQ(82.4%). The accuracy of 3 type were high (74.2-78.8%). From this study the cut point of LOGIQ™ E9 was 7kPa which better sensitivity 75.6%, specificity 84.3% and accuracy 80.3%. The cut-off for significant fibrosis (F ≥ 2) of ElastQ and ElastPQ were 5.7kPa, the same as manufactory suggestion.

**Table 5** Sensitivity, Specificity, PPV, NPV and Accuracy of shear wave elastogrphy: LOGIQ, ElastQ and ElastPQ for diagnostic significant fibrosis using Fibrosan as reference (cutoff 7pKa for F≥2)

| Shear wave elastography | Cut-point | | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|---|---|---|---|---|---|---|
| (manufacture recommendation) | A | 8.29 | 62.2% | 92.6% | 87.5% | 74.6% | 78.8% |
| | B | 5.7 | 74.4% | 76.9% | 72.8% | 78.3% | 75.8% |
| | C | 5.7 | 64.4% | 82.4% | 75.3% | 73.6% | 74.2% |
| (the optimum cutoff from this study) | A | 7 | 75.6% | 84.3% | 80.0% | 80.5% | 80.3% |
| | B | 5.7 | 73.3% | 77.8% | 73.3% | 77.8% | 75.8% |
| | C | 5.7 | 63.3% | 82.4% | 75.0% | 73.0% | 73.7% |

A = 2D-SWE LOGIQTM E9, B = 2D-SWE(ElastQ), C = pSWE(ElastPQ) PPV = Positive predictive values, NPV = Negative predictive values

## DISCUSSION

Chronic liver disease is a world-wide problem which major consequence is increasing deposition of fibrous tissue leading to the development of cirrhosis which give risk portal hypertension, hepatic insufficiency and hepatocellular carcinoma. The stage of liver fibrosis is important to determine the prognosis, for surveillance and treatment and even to determine the potential of reversibility[24]. Although liver biopsy is historically the gold standard for staging fibrosis, it is limited by several disadvantage including sampling errors, inter-observer variability and potential complications such as pain, bleeding and even death. The use of noninvasive test is favored due to the need for longitudinal monitoring and safety screening for large population. The Advanced progression in the non-invasive ultrasound tool, many clinical guidelines recommend the use of noninvasive tests for detection and staging liver fibrosis[3,6]. TE or Fibroscan is considered one of the most used alternatives for liver biopsy and already put in the patient management. However, some limitation was observed the use of TE (Fibroscan) regarding obesity and as cites and the machine is quite expensive. ARFI and 2D-SWE are integrated in the ultrasound machines. They can be used for elastographic evaluation many organ (liver, thyroid, breast, kidney) and for other purposes such as B-mode ultrasound examination, Doppler examination. To choose between various elastography methods, there are several factors should be taken into considerations: the feasibility, the reproducibility and the accuracy for prediction various stage of liver fibrosis. Because TE is a recognized method for the in-invasive evaluation of liver fibrosis included in various guideline. In our study decided to use TE as reference method instead of liver biopsy. Because of fewer patients accept invasive method for liver injury assessment. In our study, using TE (fibroscan) as reference method, liver stiffness measurement $\geq$ 7 kPa indicated significant fibrosis (F$\geq$2). The liver stiffness value of significant fibrosis ground (F$\geq$2) and no significant fibrosis (F0, F1) are significant difference in all three SWEs. These techniques are accurate for diagnosis significant fibrosis show high sensitivities and specificities even our study show lower sensitivities and specificities than previous study which higher than 90%[19]. With manufacturer's recommendation cutoff LSM value for diagnosis significant fibrosis (F$\geq$2) of 2D-SWE LOGIQ = 8.29 kPa[25], 2D-SWE (ElastQ) = 5.7 kPa and pSWE(ElastPQ) = 5.7 kPa. All three techniques give high specificity (82.4-92.9%) and sensitivity 63.3-74.4%, AUC 0.773-0.856 when compare to previous study have lower sensitivity, high specificity and the same AUROCs. The published meta-analysis of 2D-SWE in patients with mid chronic liver disease reveals summary sensitivities, specificity and AUROCs of 84-85%, 79-83% and 0.81-0.88 respectively[47-50]. In our study, we found that the cutoff LSM value for the assessment significant fibrosis (F$\geq$2) of 2D-SWE LOGIQ was similar to that of transient elastography (7 kPa)[24]. The sensitivity, specificity and accuracy are 75.6%, 84.3% and 80.3% that increase sensitivity and accuracy, slight decrease specificity. The suggestion for the patients with LSM value in equivocal significant fibrosis (LSM 7-8.29 kPa) group should be further investigation such as Fibroscan or biopsy. So the patients in this group will get proper diagnosis and treatment. Early diagnosis significant fibrosis and get medication or intervention will increase number patients reverse from significant fibrosis, severe fibrosis to no significant fibrosis group (F0-F1) that will decrease the number patient progression to liver cirrhosis or hepatocellular carcinoma. As compare to the previous study the cutoff LSM is higher than previous study of 6.7 kPa for diagnosis significant fibrosis (F$\geq$2) but lower than manufacturer's recommendation 8.29 kPa[25]. The difference could be difference on subjects' group, underlying disease, antiviral treatment. The cutoff for assessment significant fibrosis of 2D SWE (ElastQ) and pSWE are similar to the manufacturer recommendation that are 5.7 kPa and 5.7 kPa. In all three SWE techniques 2D-SWE LOGIQ has highest specificity (92.6%) and ElastQ has high sensitivity (73.3%). We found the rate of reliable LSM of TE and 2D SWE (2D-SWE LOGIQ) were similar (97.5% vs 98.5%) which better than 2D-SWE ElastQ(83.3%). The pSWE had lowest reliable rate (69.25%). 2D-SWE techniques had high reliable rate than point shear wave Elastogrpahy. With high reliable measurement rate the operation time for shear wave elastographic examination will decrease. Regarding the use of quality parameters (10 valid measurement and IQR/median <30%), the feasibility of 2D SWE (2D-SWE LOGIQ) was very good. According to the published data, three or five LS measurements by 2D-SWE. SSI the feasibility can be obtained in 90-98.9% of cases[25]. The limitation of our study is the absence of liver biopsy as the ''gold standard but our reference method was TE (Fibroscan) which validated method and recommendation from many international guidelines. The cutoff for another fibrosis grades (F3, F4) and subgroup of specific disease such as hepatitis B, hepatitis C or NAFLD are not included in this study. In conclusion, we found that shear wave elastography, all 3 techniques had good diagnostic performance and diagnostic test for assessment significant fibrosis of liver and also high reliable measurement rate. The best cutoff LSM value for diagnosis significant fibrosis for 2D-SWE LOGIQ, ElastQ and ElastPQ were 7 kPa, 5.7 kPa and 5.7 kPa respectively.

**conflict of interest**
none

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