2023-2025

ANAMTA SHAFIQ

SU91-MSAHW-F23-073

FAHS

Correlation of Ultrasonographic Grades of Fatty Liver With Elastography in Adult Patients

SUPERIOR UNIVERSITY

Thesis Submitted to

The Superior University Lahore

In Partial Fulfillment of the

Requirement for the Degree of

Master of Science in Allied Health Sciences

By

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Roll No. SU91-MSAHW-F23-073

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Signature: _____

Supervisor Name: Dr. Farah Javed
Designation: Assistant Professor

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This is to certify that the research work presented in this thesis, titled **"Correlation of Ultrasonographic Grades of Fatty Liver With Elastography In Adult Patients "** was conducted by **"Anamta Shafiq"** under the supervision of **"Dr. Farah Javed"**

No part of this thesis has been submitted anywhere else for any other degree. This thesis is submitted to the Faculty of Allied Health Sciences, The Superior University, Lahore in partial fulfillment of the requirements for the degree of Master of Science in the field of "**Allied Health Sciences"** in Faculty of Allied Health Sciences at The Superior University, Lahore.

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DEDICATION

I dedicate this research thesis to my respected Supervisor, **Dr. Farah Javed** whose invaluable guidance, academic insight, and continuous support provided the foundation for this work. Her thoughtful feedback, patience, and encouragement throughout every stage of this research journey have deeply inspired me and helped me grow both academically and personally. I would also like to dedicate this work to my co-supervisor for her generous support, critical input, and constructive suggestions that added clarity and depth to this recent researches. Furthermore, I extend my heartfelt dedication to my family, whose unconditional love, prayers, and moral support have always been my strength and motivation. Their constant belief in my abilities enabled me to pursue and complete this research with determination and resilience.

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TABLE OF CONTENTS

Page

DEDICATION v
ACKNOWLEDGEMENT vi
TABLE OF CONTENTS vii
LIST OF TABLES viii
LIST OF FIGURES ix
LIST OF ABBREVATION x
ABSTRACT xi
CHAPTER 1 01
INTRODUCTION 01
OBJECTIVES 05
CHAPTER 2 06
LITERATURE REVIEW 06
CHAPTER 3 11
METHODOLOGY 11
1. Research design 17
2. Clinical settings 17
3. Sample size 17
4. Sampling technique 17
5. Duration of study 18
6. Selection criteria 18
   6.1 Inclusion criteria 18
   6.2 Exclusion criteria 18
7. Ethical consideration 19
8. Data collection procedure 19
9. Data analysis 20
10. Ethical Consideration 20

CHAPTER 4 21
RESULTS 21
CHAPTER 5 40
DISCUSSION 40
CHAPTER 6 47
CONCLUSION 47
REFERENCES 48
APPENDICES xii
Appendix- 1 xiii
Appendix- 2 xiv
Appendix- 3 xv

LIST OF TABLES

Table No. **Description** **Page**

Table 4.1 Gender 28
Table 4.2 Diabetes 28
Table 4.3 Hypertension 29
Table 4.4 Liver Echogenicity 29
Table 4.5 Correlations 30
Table 4.6 Fatty Liver Grades 31

LIST OF FIGURES

Figure No. **Description** **Page**

Figure 2.1 Details..... 23
Figure 3.1 Details..... 24
Figure 4.1 Details..... 25
Figure 5.5 Details..... 26

LIST OF ABBREVIATIONS

(Abbreviations not explained in the text)

ACC	Acyl CoA-Carboxylase
AFIP	Armed Forces Institute of Pathology
AGEs	Advanced Glycation End Products
BMI	Body Mass Index
DNL	de novo hepatic lipogenesis
ETC	Electron Transport Chain
FDA	Food and Drug Administration

ABSTRACT

NAFLD can develop into hepatocellular cancer and cirrhosis, which can have major clinical repercussions. The histological stage of NAFLD determines the prognosis. NASH is associated with a worse prognosis because it progresses into end-stage liver disease too quickly, while simple steatosis usually shows a benign, moderate course. As a result, identifying steatohepatitis and fibrosis as soon as feasible is essential to treating patients with NAFLD. Both males and females experience NAFLD at similar rates**.** To evaluate the correlation of ultrasonographic grades of fatty liver with elastography in adult patients. After preforming the scan, all the required variables like age, gender, clinical findings history and the radiological features of patients' scan were noted in the questionnaire. All the data was recorded after taking consent from the patient.**:** In this study, 90 patients that fulfilled the inclusion criteria were included. Patients exhibiting the typical clinical presentations for NAFLD were included. All the patients were the scanned subsequently using the ultrasound and elastography machines. In our study, We included a total of 90 patients. Out of these 90 patients, 42 were females and 48 were males. A total of 42 patients had diabetes while the remaining 48 patients did not had diabetes. In our study, 46 patients had hypertension while 44 patients did not had any pretaining history of hypertension. Upon the ultrasonographic examination of liver, we found that 27(30%) patients had diffuse liver echogenecity, while 63(70%) patients had hyperechoic echogenicity. There was a significant correlation between liver grading and KPa values($p < 0.001$).Out of 90 patients included in our study, 34 patients were found to have a fatty liver of grade 1 while 56 patients had grade 2 fatty liver.

There is a significant correlation between ultrasonographic grades of ultrasound and elastography of adult patients.

Keywords: Elastography, Ultrasonography, Fatty Liver, Fatty Liver Grading, Kpa

Chapter 1

INTRODUCTION

Worldwide, the prevalence of NAFLD is rising; in Western communities, it ranges from 15–30%, whereas in Indian populations, it is 9–32%. NASH is the result of a range of illnesses that begin with simple steatosis and progress to lobular inflammation with variable degrees of fibrosis. NAFLD can develop into hepatocellular cancer and cirrhosis, which can have major clinical repercussions. The histological stage of NAFLD determines the prognosis (*Clinical Trials for NAFLD & NASH - NIDDK*). NASH is associated with a worse prognosis because it progresses into end-stage liver disease too quickly, while simple steatosis usually shows a benign, moderate course. As a result identifying steatohepatitis and fibrosis as soon as feasible are essential to treating patients with NAFLD. Both males and females experience NAFLD at similar rates [1]. The fourth or fifth decade of life is usually when the majority of cases are diagnosed. Even said, there have also been reports of the entire spectrum in children. NAFLD patients may also have hypertension and are frequently fat. The right upper quadrant pain or dullness and exhaustion are the most frequently reported symptoms, while a considerable proportion of patients may not exhibit any symptoms at all. One of the most common physical examination results is mild to severe hepatomegaly[2]. Biochemically, individuals with NAFLD may exhibit hyperlipidemia, hyperglycemia, hyperinsulinemia, and diminished insulin sensitivity[3].

In adults in the US, NAFLD is the most common cause of elevated liver enzymes. It is also the main cause of cryptogenic cirrhosis, or cirrhosis with no apparent cause, such as hepatitis, alcoholism, autoimmune diseases, and other conditions [4]. In the US, estimates of the prevalence of NAFLD range from 16 to 23 percent. Nonetheless, using nuclear magnetic spectroscopy, 31% of subjects in a recent population-based investigation with 2,287 participants were found to have steatosis. Notably, these numbers included alcohol users, yet there was no difference in the prevalence of steatosis between alcohol users and non-users. Higher body weight raises the risk of NAFLD, with two-thirds of people with a body mass index (BMI) of at least 30 kg/m2 exhibiting steatosis symptoms. In addition, more than 90% of those whose BMI is more

than 39 kg/m2 have steatosis. Up to 8.6 million fat people in the US are thought to be at risk of developing steatohepatitis. Abnormalities in the laboratory are frequently the first sign of non-alcoholic fatty liver disease[5]. increased alanine transaminase (ALT) and aspartate transaminase (AST) levels, usually between one and four times the upper limits of normal, are the most common aberrant laboratory findings. However, it's important to note that some people with the disease could have normal transaminase values. In cases of alcoholic liver disease, the AST/ALT ratio often rises to 2, but it normally stays below 1. However, depending on how severe the liver damage is, this ratio can rise. Both alkaline phosphatase and γ-glutamyl transferase (GGT) levels have the potential to increase to twice the upper limit of normal [6].

NAFLD develops at equal rates among males and females. The majority of cases are typically detected during the fourth or fifth decade of life, although the full spectrum has also been described in children. Patients with NAFLD are often obese and may have hypertension. The prevalent symptoms often include fatigue and dull or painful sensations in the right upper quadrant, although a considerable number of patients remain asymptomatic. Mild to moderate hepatomegaly frequently emerges as one of the primary physical examination findings [7].

Most people with NAFLD don't show any signs or have vague symptoms before being diagnosed. Feeling tired and having discomfort in the upper right side of the belly are common early signs. Some may also feel bloated, have irregular bowel movements, or have trouble sleeping. NAFLD is often discovered by chance when doctors find abnormal liver tests or changes on imaging tests done for other reasons, or when they notice symptoms of metabolic syndrome. Doctors usually suspect NAFLD early on in people with metabolic syndrome or slight increases in liver tests, even though these tests might not be high in many patients, no matter how severe the liver damage is. Those whose liver disease gets worse because of NAFLD might develop symptoms like yellowing of the skin, fluid buildup in the belly, bleeding from swollen veins in the esophagus or stomach, or problems with brain function due to liver problems. NAFLD is linked with metabolic syndrome, often found in people with obesity and type 2 diabetes. It's also seen in those with high cholesterol, sleep apnea, ovarian cysts, hormone problems, low vitamin D levels, thyroid issues, and high uric acid levels.

Doctors should consider these factors when testing for NAFLD [8].

In the majority of NAFLD cases, liver function tests (LFTs) usually show normal or near-normal results. Some patients may have slightly raised liver enzyme levels, like ALT being higher than AST, and/or GGT. Even if these levels are higher, ALT tends to decrease (while AST may go up) as fibrosis progresses towards cirrhosis. However, relying solely on ALT levels to diagnose NASH from histological findings isn't very reliable. When patients show abnormal LFTs, it's crucial to investigate other potential causes such as alcohol abuse, Hemochromatosis, celiac disease, autoimmune liver illnesses, drug-induced liver injury, and Wilson's disease (particularly in those under 45 years old). Some individuals with NAFLD may have low levels of autoantibodies, like ANA below 1:100 and/or ASMA below 1:40, but their IgG levels are typically normal. Elevated ferritin levels in some patients may suggest underlying inflammation or insulin resistance [9].

Serum transaminases, such as ALT and AST, are frequently employed as biomarkers to show generalized hepatic cell injury. Moderately increased levels of ALT have been seen in hospitalized NASH patients; these levels usually do not reach four times the normal amount. Furthermore, increased AST values that are twice the usual range are frequently thought to be a sign of advanced liver fibrosis [10].

About 10% of NASH patients, however, may have normal AST values. Male gender, younger age, larger waist circumference, alcohol consumption, and greater serum ALT levels are associated with higher ALT levels. Higher triglycerides, fasting blood sugar, and BMI are associated with elevated ALT levels, indicating a strong correlation with symptoms of metabolic syndrome. Additionally, physicians utilize the AST/ALT ratio often to forecast liver fibrosis and distinguish between NAFLD and alcoholic hepatitis. When the AST/ALT ratio is greater than 2, it usually indicates alcoholic hepatitis; however, when the ALT level is greater than the AST level, it may indicate NASH when cirrhosis is not present [11].

When NAFLD is suspected, transabdominal ultrasonography is advised as the main imaging modality. The liver parenchyma's higher echogenicity as compared to the right kidney cortex which is indicative of intracellular fat vacuole formation by the ultrasound

beam, is a crucial marker of steatosis. Usually, steatosis is ranked as follows: Grade 0: The right liver lobe's echogenicity about the right kidney's cortex is normal. Grade 1: The diaphragm and intrahepatic artery boundaries can be seen normally, but there is a modest, widespread rise in liver parenchyma fine echoes. Grade 2: A moderately diffuse increase in fine echoes accompanied by a little impairment in the visibility of the diaphragm and intrahepatic arteries. Grade 3: A noticeable increase in fine echoes accompanied by inadequate or absent intrahepatic visibility. B-mode ultrasonography has a sensitivity of 53–76% and a specificity of 76–93% for detecting hepatic steatosis. In cases when sonographic criteria reveal higher-grade steatosis, such as reduced diaphragm visualization, the probability of hepatic steatosis is almost 100% [12].

A quantitative ultrasonic classification approach was proposed by Saadeh et al. to classify steatosis: A little, widespread rise in hepatic echogenicity accompanied by normal appearance of the diaphragm and hepatic arteries characterizes Grade 1 (mild) conditions.

Hepatic echogenicity is moderately widespread, and the diaphragm and hepatic arteries appear blurry in Grade 2 (moderate) cases. Hepatic arteries, the diaphragm, and the posterior liver are not apparent, indicating a grade 3 (significant) rise in hepatic echogenicity.

For non-invasive evaluation of liver fibrosis in a variety of chronic liver illnesses, including NAFLD, transient elastography is the preferred method[13].

The precision of transient elastography (TE) in NAFLD has been evaluated in several investigations. A cut-off value of 8 kPa for fibrosis stage F3 had a negative predictive value of 95.6% in one study with 67 NAFLD patients; for stage F4, a cut-off value of 17 kPa elevated the negative predictive value to 100%. According to their updated guideline on the clinical efficacy of liver elastography, the European Society of Ultrasonography in Medicine and Biology (EFSUMB) suggests using TE in patients with NAFLD in light of these findings. In a clinic or by the patient's bed, transient elastography is a quick, painless, and straightforward procedure. For those with long-term liver conditions such as NAFLD, chronic hepatitis C, and chronic hepatitis B, it provides a quick and non-invasive method of evaluating hepatic fibrosis. Promising

results were obtained from a study comparing liver tissue stiffness determined by transient elastography with liver biopsy. For the fibrosis phases F1, F2, F3, and F4, the corresponding AUROC values were 0.82, 0.85, 0.94, and 0.96. Transient elastography's cut-off values for fibrosis stages F2-4 ranged from 6.2 to 11 kPa, with a sensitivity of 62–90% and a specificity of 74–100%. Cut-off values for fibrosis stages F3–4 varied from 8 to 12 kPa, with a sensitivity of 84%–100% and a specificity of 83%–97%. Last but not least, cut-off values for stage F4 fibrosis varied from 9.5 to 20 kPa, with a sensitivity of 90–100% and a specificity of 75.9–98.4% [14].

Even though is becoming more typical, there’s still a big gap in research. We need thorough studies that combine different ways of diagnosing NAFLD. Doing this could make diagnoses more accurate and help us better monitor the condition. Two promising methods for this are ultrasonography and elastography. These could significantly improve our understanding and the way we diagnose and treat this common liver issue. NAFLD is a big health concern globally, often linked to obesity, insulin resistance, and high cholesterol. It is important to figure out how the severity of fatty liver seen in ultrasounds relates to elastography results. This knowledge is crucial for finding NAFLD early, assessing risks, and managing it effectively[15].

AIM AND OBJECTIVES

To evaluate the correlation of ultrasonographic grades of fatty liver with elastography in adult patients.

Chapter 2

LITERATURE REVIEW

Gupta et al. 2019 investigated to address whether non-invasive measures (FibroScanTM; NAFLD score, FIB4 and APRI) were better than liver biopsy in evaluating the level of liver fibrosis among patients with NAFLD. The patients enrolled in the study were all aged 18 years or older and underwent liver biopsy at two tertiary centers in Brazil. Transient hepatic elastography (THE) was performed using FibroScanTM; APRI, FIB4, and NAFLD scores were also used. The diagnostic value of several non-invasive methods was assessed by positive predictive values(PPV), negative predictive values(NPV), sensitivity, specificity and the liver biopsy as a reference for advanced fibrosis. A total of 104 patients were included in this study. For advanced fibrosis, the available three different cutoffs (7.9, 8.7 and 9.6 kPa) with maximal NPV values (98%, 96.4% and 95.1%, respectively) and sensitivity value (95%,90% and 85%, respectively). It also had the maximum AUROC (area under ROC curve) area under the curve of 0.87 (95% confidence interval

According to Constantinescu et al. (2020), Prior to liver biopsy, NAFLD patients underwent measurements of liver stiffness using point shear wave elastography (pSWE) and transient elastography (TE). Patients with a history of concurrent active hepatitis B infection, autoimmune hepatitis, chronic hepatitis C, or suspected drug or alcohol abuse were not included in the calculations of sensitivity and specificity. This allowed for the creation of 2x2 contingency tables using reported case numbers. Eleven TE trials with 1753 patients and nine pSWE studies with a total of 982 participants were included in the analysis. The summary area under the receiver operating characteristic curve (AUC) for pSWE was 0.86 (95% CI 0.83 to 0.89), 0.94 (95% CI 0.91 to 0.95), and 0.95 (95% CI 0.93 to 0.97), in that order, to identify significant fibrosis, advanced fibrosis, and cirrhosis. The overall AUC for TE under the identical conditions was, in that order, 0.85 (95% CI 0.82 to 0.88), 0.92 (95% CI 0.89 to 0.94), and 0.94 (95% CI 0.93 to 0.97). Additionally, the study found that the percentage of failed measurements with TE was about ten times higher than with pSWE, particularly when a M probe was utilized (Constantinescu et al., 2020).

The aim of the 2022Cetinic et al. was to assess the performance of elastography point quantification (ElastPQ), a novel liver stiffness evaluation technique, in patients with non-alcoholic fatty liver disease (NAFLD) and compare its diagnostic accuracy with other non-invasive indices for liver fibrosis 4 stages. A total of 108 patients with NAFLD and without were recruited in this study. A number of non-invasive LF tests were carried out, such as AST/Platelet-ratio-index (APRI), Fibrosis-4 (FIB-4) index, NAFLD fibrosis score, ratio of AST to ALT and BARD score. The LS assessments were carried out via the ElastPQ technique. The LSM, the liver size LS, APRI, FIB 4 index, NAFLD fibrosis score, AST/ALT ratio and BARD score were significantly higher in patients with NAFLD. LS was the only predictor found to be independently associated with NAFLD. For every 0.5 kPa increase in LS, the risk of NAFLD increased by 2.12 times0.51204ff; absurd". By using ROC method, the diagnostic accuracy of LS for nonalcoholic fatty liver disease (NAFLD) was high and that the area under a curve is 0.967. With a cut-off value of 5 kPa in LS measurement, the risk of NAFLD can be detected with specificities and sensitivities of 94.4 % and 88.9 %. When LS measured by ElastPQ was tested versus different non-invasive laboratory diagnostic approaches, it better identified NAFLD. Furthermore, there was a strong linear association between LS and the (Cetinic et al., 2022).

(Pi et al., 2021) recruited a total of 260 patients, who visited hepatology, gastroenterology, internal medicine and infective departments at Benha University Hospital during the period from March 20, 2018 to September 1, 2019 in prospective case-control study. participants were categorized to two groups: 60 healthy control participants constituted Group II and 200 non-alcoholic fatty liver disease (NAFLD) cases constituted Group I. FIB-4 values of both groups significantly differed statistically (-0.75 ± 0.32 in Group II and 1.39 ± 1.02 in Group I, respectively; $p < 0.001$). Moreover, mean ± SD of NAFLD fibrosis scores were also significantly different between the 2 groups (-1.74 ± 1.17 in Group I and -2.75 ± 0.91 in Group II; $p < 0.001$). Based on RTE diagnosis, fibrosis phases were significantly higher in NAFLD patients compared to the control group ($p = 0.001$). There was 93% agreement between RTE and FIB-4 index ($p<0.001$), and in 86%,

there was agreement between RTE and the NAFLD fibrosis score. When compared to

the FIB-4 index, the diagnostic performance of RTE was evaluated for detecting advanced liver fibrosis (≥ F3). The results showed 90% sensitivity, 93.3% specificity, 60% positive predictive value, 98.8% negative predictive value, and 93% accuracy, with an area under the curve (AUC) of 0.917 (p = 0.001). In a similar vein, RTE demonstrated sensitivity of 52.6%, specificity of 93.8%, PPV of 66.7%, NPV of 98.4%, and accuracy of 86%, with an AUC of 0.732 (p = 0.002), in comparison to the NAFLD fibrosis score (Pi et al., 2021).

Ultrasound elastography as a tool for detecting hepatic fibrosis and steatosis in patients with metabolic syndrome and type 2 diabetes mellitus was assessed in the study by A. Marie et al. in 2014. Elastography results were assessed from January 1 st to December 31 st of 2013. The performance of ultrasound elastography and conventional ultrasonography alanine (ALT) transaminase and aspartate transaminase (AST) was tested in sensitivity and specificity, using fibrosis score as the surrogate gold standard. Of the total pool of patients, 102 met inclusion/exclusion criteria. Elastography showed higher sensitivity than conventional ultrasound in patients with diabetes and metabolic syndrome at high and moderate risk of fibrosis (100% versus 82.5% p = 0.0036, 96% versus 76.4% p = 0.0036). Moreover, elastography was significantly more specific than ultrasound for fatty liver and fibrosis (86.49% vs. 32.43%, p value = 0.0000). Importantly, elastography was the only modality with an indication of a strong association with the study's surrogate gold standard, indicating better accuracy to detect fibrosis and fatty liver more precisely in this patient population. These findings bring up the promise for ultrasound elastography as a non-invasive diagnostic tool of liver health in patients with type 2 diabetes mellitus and metabolic syndrome (Marie et al. 2014).

P. Viven et al. 2023: In a realm with limited evidence, the diagnostic accuracy of vibration-controlled transient elastography (VCTE) in children with nonalcoholic fatty liver disease (NAFLD) was studied prospectively. The primary objectives were to evaluate the technical performance of VCTE in juvenile NAFLD, and to determine its adherence with imaging, and/or biopsy reference standards. Patients with confirmed or suspected NAFLD were recruited and underwent VCTE examinations using a FibroScan Mini 430 apparatus. Each patient received ten valid CAP values and ten valid stiffness by VCTE (in dB/m, kPa). Reference standards included clinically derived

magnetic resonance elastography, magnetic resonance imaging proton density fat fraction (PDFF), liver ultrasound shear wave elastography and biopsy. The series involved 84 consecutive patients, with a male preponderance (55/29) and mean age of 15.0 ± 3.5 years and BMI at 36.6 ± 9.4 kg/m2. Thirty-seven of the 83 subjects completed a VCTE exam and 37 also had an XL probing exam. The study found no correlation between VCTE liver stiffness and MR elastography stiffness or between CAP and PDFF. VCTE median liver stiffness >5.1 kPA had an AUC on receiver operating characteristic curve of 0.52 (95% CI: 0.26, 0.78) with sensitivity of 88.9% and specificity of 16.6%, p > 0.99 when predicting any fibrosis stage ≥1 on biopsy (9/15). This finding suggests that the predictive accuracy of VCTE in children with NAFLD for fibrosis is low (Vajro et al. 2023).

In 2023, a research project of Qiafeng et al. explored the value of shear wave elastography (SWE) and ultrasonic attenuation imaging(ATI) in patients with metabolism-related fatty liver disease (MAFLD). Patients were identified in two groups (n=84 inhibitors; n=126 non-psyllium) retrospectively as follows. Receiver operating characteristic (ROC) curve analysis was performed to assess the diagnostic accuracy of ATI and SWE measurements for MRFLD. According to above criteria, patients in MAFLD group were further classified into three subgroups as mild (n = 39), moderate (n = 28) and severe (n = 17). Spearman correlation was used to examine the inter-relationship between ATI, SWE and severity of MAFLD. The results suggest that a notable difference (P 15%. MRE and MR fat quantification were acquired simultaneously with routine clinical care of the patient; MRI PDFF was considered the standard, >6.4% indicating NAFLD. Statistical analysis were conducted using T-tests and Pearson correlation. Of the 140 patients included, 112 met dependability criteria for SWE measurements. MRE and 2D-SWE exhibited a positive correlation (r = 0.27; P = 0.004) for the whole population. A significant correlation between MRE and SWE was observed in patients with fibrosis (r = 0.30; P = 0.03), without fibrosis (r = 0.27; P = 0.03), and NAFLD patients (r = 0.28, P = 0.02) on the basis of subgroup according to the status of steatosis and fibrosis_. However, none of the elastography techniques correlated (P > 0.52) with liver fat measurement. There was no significant difference in MRE between patients with and without fibrosis among SWE (P = 0.09, P < 0.0001).

MRE and SWE were positively associated in patients with suspected or diagnosed NAFLD (Aylin et al. 2023).

Chaudary and colleagues in 2023 carried out a retro-prospective observational study at the Department of Radiodiagnosis, Dr. BRAM Hospital, and Pt. JNM Medical College, Raipur (C.G). The study included 198 patients who were diagnosed with fatty liver and were 18 years of age or older. Shear wave elastography was used for fatty liver grading and quantification, with a p-value <0.05 designated as the statistical significance level. The study participants' average age was 48.47±15.21 years, with 52.02% of the sample being female. 75.25% of the individuals evaluated with 2D ultrasonography were found to have grade I fatty liver, whereas 24.24% had grade II fatty liver. The results of shear wave elastography revealed that 13.64% of the livers had normal liver stiffness, 57.58% had F1 liver stiffness, and 28.28% had fibrosis (F2 or F3). Furthermore, a significant correlation was observed between elevated blood VLDL levels and increasing hepatic stiffness stages (p=0.04) (Chaudary et al. 2023).

Jufeng et al. carried out a retro prospective study in 2022 with the aim of investigating the relationship between bedtime during the night and nonalcoholic fatty liver disease (NAFLD) as determined by liver ultrasound transient elastography (LUTE). For the study, a cohort of 4572 people was enrolled. The controlled attenuated parameter (CAP) score from LUTE was used to diagnose NAFLD; CAP scores of at least 263 dB/m and at least 285 dB/m were the diagnostic thresholds. CAP (263 dB/m) (odds ratio [OR], 1.04 [95% confidence interval [CI], 0.99, 1.09]) and CAP (285 dB/m) (OR, 1.00 [95% CI, 0.95, 1.05]) showed a positive connection with weekday bedtime. The results of the study also showed a positive correlation between weekend bedtime and both CAP (263 dB/m) (OR, 1.05 [95% CI, 1.00, 1.10]) and CAP (285 dB/m) (OR, 1.05 [95% CI, 1.00, 1.10]). The relationship between weekday bedtime and NAFLD showed a linear trend when the condition was classified as having a CAP score of > 263 dB/m. On the other hand, the correlation showed a non-linear pattern for weekend bedtime. To be more precise, the relationship was statistically significant (OR, 0.96 [95% CI, 0.88, 1.05]) between 22:00 and 1:00, whereas it was negative (OR, 1.26 [95% CI, 1.06, 1.50]) before 22:00. The correlation turned positive again after 1:00 (OR, 1.26 [95% CI, 1.02, 1.57]) (Jufeng et al.2022).

Chapter 3

METHODOLOGY

3.1. Research Design:

This research employed cross-sectional analytical research design to study the correlation between ultrasonographic grades of fatty livrer with the elastography in adult patients.

3.2. Clinical setting:

The study was conducted in radiology department of Sir Ganga Raam Hospital,Lahore and data was collected in form of questionnaire

3.3. Sample Size:

The formula for sample size calculation was:

$$n = \frac{Z^2 \times p \times (1-p)}{d^2}$$

n= 90

3.4. Sampling Technique:

Non-Probability Convenient sampling technique was used.

3.5. Duration of Study:

This descriptive study lasted for 4 months.

3.6. Selection Criteria:

3.6.1. Inclusion Criteria:

- Adults across all age groups
- Patient exhibiting NAFLD Symptoms
- Patients who have undergone Elastography

3.6.2. Exclusion Criteria:

- Patients with history of chronic hepatopathis
- Patients that have undergone anti-viral treatments
- Patients with Liver Transplant

3.7. Equipment:

"TOSHBA Aplio 500 with a linear array transducer with a frequency range of 3 to 5Mhz"

3.8. Ethical Consideration:

The rules and regulations of the ethical committee Superior University, Lahore were maintained during this research work and the rights of the subjects would be upheld. Participants were provided with a written informed consent .The information and data collected are strictly confidential. Participants will be anonymous throughout the study. The participants have been informed that there are no negative aspects or risks associated with their participation in this study. They were also informed that they would be able to withdraw at the study any moment .This research posed no risks to participants. We will take all reasonable steps to ensure your privacy is protected. No identifying information will be published in any report of this study. Your participation in this research study is voluntary. You may choose not to participate and you may with draw your consent to participate any time. You will not be penalized if you choose not to participate or decide to withdraw from this study.

3.9. Data Collection Procedure

After preforming the scan, all the required variables like age, gender, clinical findings history and the radiological features of patients' scan were noted in the questionnaire. All the data was recorded after taking consent from the patient.

Scanning technique: Ultrasound examination was performed with the patient fasting for at least 6–8 hours to reduce bowel gas and ensure optimal visualization of the liver. The patient is positioned in the supine and left lateral decubitus positions for comprehensive liver assessment using a low-frequency (3–5 MHz) convex transducer. Grading of fatty liver is done on grayscale ultrasound based on liver echogenicity relative to the renal cortex, visualization of intrahepatic vessels, and posterior beam attenuation. For elastography, shear wave or transient elastography is performed in the same session using the right lobe of the liver through an intercostal approach while the patient holds a quiet breath. Multiple (typically 10) valid measurements are obtained, and the median value is recorded to assess liver stiffness, ensuring interquartile range (IQR) is within acceptable limits to maintain accuracy and correlation with ultrasonographic grading.

3.10. Data Analysis Procedure

Data was evaluated and analyzed using the Statistical Package for the Social Sciences (SPSS) version 25. All variables were analyzed in which all continuous variables were presented as mean standard deviations. Descriptive analysis was performed to investigate the distribution of data. Mean and standard deviation (SD) were calculated for continuous variables. Additionally, the chi-square test was used to analyze categorical variables

Chapter 4

RESULTS

In this study, 90 patients that fulfilled the inclusion criteria were included. Patients exhibiting the typical clinical presentations for NAFLD were included. All the patients were the scanned subsequently using the ultrasound and elastography machines. In our study, We included a total of 90 patients. Out of these 90 patients, 4**2** were females and 4**8** were males. A total of 42 patients had diabetes while the remaining 48 patients did not had diabetes. In our study, 46 patients had hypertension while 44 patients did not had any pretaining history of **hypertension. U**pon the ultrasonographic examination of liver, we found that 27(30%) patients had diffuse liver echogenecity, while 63(70%) patients had hyperechoic echogenicity. There was a significant correlation between liver grading and KPa values($p < 0.001$).

Out of 90 patients included in our study, 34 patients were found to have a fatty liver of grade 1 while 56 patients had grade 2 fatty liver.

GENDER:

In our study, we included a total of 90 patients. Out of these 90 patients, 42(46.7%) were females and 48(53.3%) were males.

Table: 4.1

Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	42	46.7	46.7	46.7
	Male	48	53.3	53.3	100.0
	Total	90	100.0	100.0	

DIABETES

Out of 90 patients included in our study, a total of 42(46.7%) patients had diabetes while the remaining 48(53.3%) patients did not have diabetes.

Table 4.2

Diabetes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	48	53.3	53.3	53.3
	Yes	42	46.7	46.7	100.0
	Total	90	100.0	100.0	

HYPERTENSION:

In our study, 38 patients had hypertension while 52 patients did not had any pretaining history of hypertension.

Table:4.3

Hypertension

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	44	48.9	48.9	48.9
	Yes	46	51.1	51.1	100.0
	Total	90	100.0	100.0	

LIVER ECHOGENECITY:

In our study, upon the ultrasonographic examination of ultrasound, we found that 27(30%) patients had diffuse liuver echogenecity, while 63(70%) patients had hyperechoic echogenicity.

Table:4.4

Liver Echogenicity

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Diffuse	27	30.0	30.0	30.0
	Hyperechoic	63	70.0	70.0	100.0
	Total	90	100.0	100.0	

CORRELATION BETWEEN GRADING AND KPA VALUES:

There was a significant correlation between grading and KPa values.

Table 4.5

Correlations

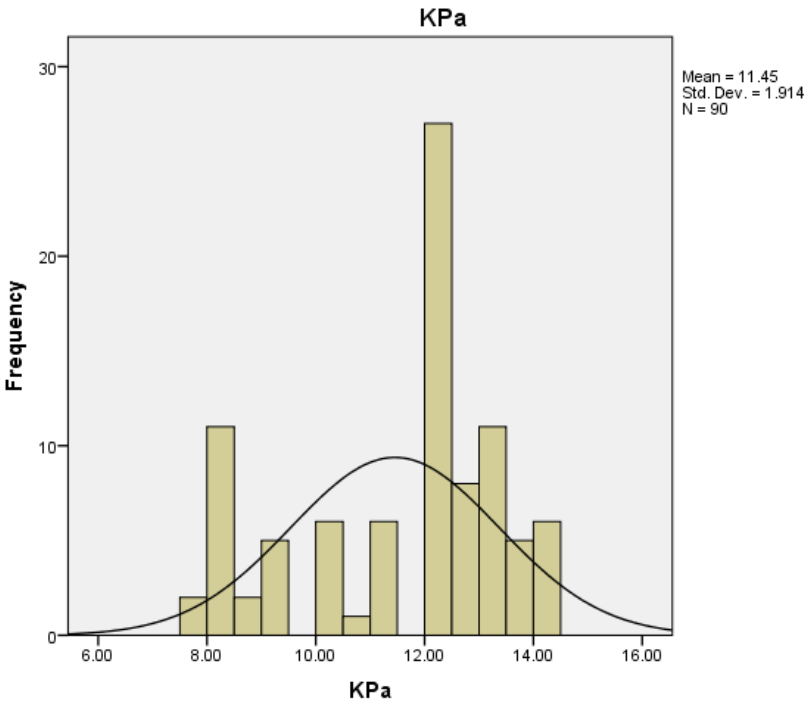
			Grading	Kpa values
Spearman's rho	Grading	Correlation Coefficient	1.000	.723**
		Sig. (2-tailed)	.	.000
		N	90	90
	Kpa values	Correlation Coefficient	.723**	1.000
		Sig. (2-tailed)	.000	.
		N	90	90

KPa * Fatty Liver Grade Crosstabulation

Count

		FattyLiverGrade		Total
		Grade 1	Grade 2	
KPa	7.60	0	1	1
	7.80	1	0	1
	8.00	6	5	11
	8.80	0	1	1
	8.90	1	0	1
	9.20	0	2	2
	9.40	0	3	3
	10.00	0	2	2
	10.20	0	1	1
	10.30	0	1	1
	10.34	1	0	1
	10.40	0	1	1
	10.80	0	1	1
	11.00	1	2	3

	11.20	0	1	1
	11.40	2	0	2
	12.00	19	5	24
	12.10	0	1	1
	12.30	0	1	1
	12.40	0	1	1
	12.50	0	1	1
	12.60	0	1	1
	12.80	0	4	4
	12.90	0	2	2
	13.00	0	4	4
	13.20	0	5	5
	13.30	0	2	2
	13.50	0	1	1
	13.60	1	1	2
	13.80	1	0	1
	13.90	0	1	1
	14.00	1	4	5
	14.20	0	1	1
Total		34	56	90



FATTY LIVER GRADES:

Out of 90 patients included in our study, 34 patients were found to have a fatty liver of grade 1 while 56 patients had grade 2 fatty liver.

Table 4.6

Fatty Liver Grade

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Grade 1	34	37.8	37.8	37.8
	Grade 2	56	62.2	62.2	100.0
	Total	90	100.0	100.0	

Chapter 5

DISCUSSION

In this study, 90 patients that fulfilled the inclusion criteria were included. Patients exhibiting the typical clinical presentations for NAFLD were included. All the patients were the scanned subsequently using the ultrasound and elastography machines. In our study, we included a total of 90 patients. Out of these 90 patients, 42 were females and 48 were males.

A total of 42 patients had diabetes while the remaining 48 patients did not have diabetes.

In our study, 46 patients had hypertension while 44 patients did not had any pretaining history of hypertension.

Similarly (Pi et al., 2021) carried out 260 patients who visited the departments of hepatology, gastroenterology, infectious diseases, and internal medicine at Benha University Hospital between March 20, 2018, and September 1, 2019, participated in prospective case-control research. participants were split into two groups: sixty healthy control participants made up Group II, while 200 cases of non-alcoholic fatty liver disease (NAFLD) made up Group I. The two groups' FIB-4 values increased statistically significantly (1.39 ± 1.02 in Group I and -0.75 ± 0.32 in Group II, respectively, with $p < 0.001$). The mean ± SD of NAFLD fibrosis scores also increased statistically significantly between the two groups (-1.74 ± 1.17 in Group I and -2.75 ± 0.91 in Group II, respectively, with $p < 0.001$).While in our study, upon the ultrasonographic examination of liver, we found that 27(30%) patients had diffuse liver echogenecity, while 63(70%) patients had hyperechoic echogenicity. There was a significant correlation between liver grading and KPa values ($p < 0.001$).

Out of 90 patients included in our study, 34 patients were found to have a fatty liver of grade 1 while 56 patients had grade 2 fatty liver. In a similar sort of study conducted by A. Chaudhry et al 2023, 75.25% patients had grade 1 fatty liver, while 24.75% had grade 2 fatty liver. Furthermore a significant correlation between Kpa values and gradings was seen as well.

The diagnostic accuracy of conventional ultrasound and shear wave elastography (SWE) has been compared in prior literature, with elastography consistently demonstrating superior diagnostic performance. Studies have reported AUROC values ranging from 0.81 to

0.92 for SWE in differentiating fibrosis stages F2 to F4, confirming its value in quantifying early hepatic stiffness this study conducted by H., Moriyasu. Comparative studies evaluating strain elastography and SWE further supported this superiority, with SWE yielding higher diagnostic precision across fibrosis stages . Other investigations assessing real-time tissue

elastography also found strong correlations between stiffness measurements and histological stages, underscoring its clinical utility in disease staging. These findings align closely with the outcomes of the present research, reinforcing the role of elastography as an adjunctive tool for stratifying NAFLD severity in clinical practice. The strengths of the current study lie in its analytical design, direct comparison of ultrasonographic and elastographic parameters, and the use of a standardized protocol for imaging evaluation. These element allowed for robust internal consistency and reliability in data interpretation. However, the study was not without limitations. The sample size was relatively small, and the singlecenter design limited generalizability. The exclusion of pediatric and advanced cirrhotic populations constrained the evaluation of disease extremes. Additionally, the study did not include histopathological confirmation, which would have provided a definitive reference standard for validating imaging findings. Despite these constraints, the study contributes valuable evidence supporting the diagnostic complementarity of ultrasonography and elastography in assessing hepatic steatosis and fibrosis. Future studies should include larger,multicenter cohorts and incorporate histological validation to further substantiate these correlations. Longitudinal designs examining disease progression over time and the influence of therapeutic interventions would offer deeper clinical insights. Integrating quantitative ultrasound parameters with elastographic indices could refine diagnostic accuracy and enable non-invasive staging algorithms suitable for routine clinical application. Overall, the current findings emphasize that the combined use of ultrasonography and elastography holds substantial promise for early detection, risk stratification, and management of NAFLD in diverse patient populations.

Limitation :

- Limited Data Availability
- Strict Data Acquiry Rules
- Not a lot of Prior Studies

Recommendations:

- More researches Should be conducted

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APPENDICES

ENGLISH CONSENT FORM

The study you are about to participate is a randomized control trial survey titled as;

"Correlation of Ultrasonographic grades of fatty liver with elastography in adult patients"

The study has no potential harm to participants. All data collected from you will be coded in order to protect your identity, and should not be disclosed to anyone. Following the study there will be no way to connect your name with your data. Your answers to the questions will not affect the quality of education given to you. Any additional information about the study results will be provided to you at its conclusion, upon your request.

You are free to withdraw from the study at any time. You agree to participate, indicating that you have read and understood the nature of the study, and that all your inquiries concerning the activities have been answered to your satisfaction.

NAME _____ **SIGNATURE_____**

DATE_____

URDU CONSENT FORM

میں_____ تصدیق کرتا/ کرتی ہوں کہ **محترمہ (YOUR NAME IN URDU)**نے اپنی اس تحقیق

“YOU TITLE ”

.زیرنگرانی **(YOUR SUPERVISOR NAME)**کے متعلق بتا دیا ہے۔ مجھے اس تحقیق کی نوعیت، مقاصد، احداف، توقعات، فوائد اور خطرات کے متعلق ، ۔ساری معلومات فراہم کر دی گئی ہیں

اس تحقیق کے دوران ساری معلومات صیغۃ راز میں رہیں گی اور مریض کا نام اور دیگر معلومات صرف تحقیق کے لیے استعمال ہوں گی۔مجھے یہ بھی بتا دیا گیا ہے کہ میں اس تحقیق سے متعلقہ ہر قسم کے سوال پوچھنے کا مجاز ہوں اور یہ تحقیق صرف ایک شخص ک مفاد میں نہیں ہے بلکہ بحسثیت مجموعی انسانیت کا مفاد اس سے وابسطہ ہے۔ تمام تفصیلات جاننے کے بعد یس تحقیق میں شامل ہونے یا نہ ہونے پر کسی کا قائل نہیں ہوں۔ اس تحقیق سے کسی بھی وقت علیحدہ ہونے پر مجھ پر کوئی پابندی نہیں ہو گی۔ میں بذاتِ خود بقائمی حوش و حواس

۔اور رضا مندی سے اس تحقیقاتی عمل میں شامل ہوتی/ ہوتا ہوں

---------- دستخط محقق

---------- دستخط شرکت کار

---------- تاریخ

DEMOGRAPHICS FORM & QUESTIONNAIRES

Patient ID : _____

Age	
Gender	
History of Liver Disease(Yes/No)	If yes, then Specif y _____
Diabetes Melitus(Yes/No)	If yes, Specify duration _____
History of Hypertension(Yes/No)	

Ultrasound Features:

Fatty Liver Grade	Specify grade _____
Hepatomegaly	Specify Size _____
Nodularity(Yes/No)	
Ascites(Yes/No)	
Liver Echogenecity(Diffuse/Hyperechoic)	

Elastography:

Liver stiffnes Measurement	Specify Kpa Value _____
Interquartile Range of Measurements	
Reliability of Measurement(Valid/Invalid)	

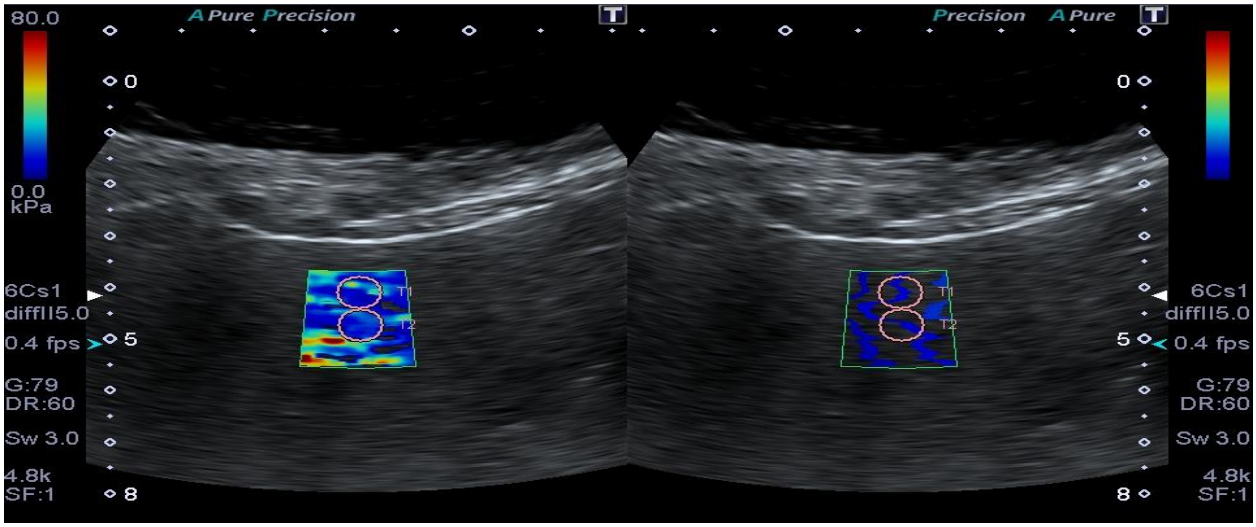
Ten Patient Data Sheet

Sr. No	Age	Gender	Diabetes		Hypertension		Fatty Liver Grade			Kpa
			Yes	No	Yes	No	0	1	2	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Sr. No	Gender	Diabetes	Hypertension	Fatty Liver Grade	Kpa
1	Male	No	Yes	Grade 2	7.6
2	Female	Yes	No	Grade 1	7.8
3	Female	Yes	Yes	Grade 1	8
4	Male	Yes	Yes	Grade 2	8.8
5	Female	Yes	Yes	Grade 1	8.9
6	Male	Yes	Yes	Grade 2	9.2
7	Female	Yes	Yes	Grade 2	9.4
8	Male	No	Yes	Grade 2	10
9	Female	No	No	Grade 2	10.2
10	Female	No	No	Grade 2	10.3
11	Male	Yes	Yes	Grade 1	10.34
12	Female	Yes	Yes	Grade 2	10.4
13	Male	Yes	No	Grade 2	10.8
14	Male	No	Yes	Grade 1	11
15	Female	Yes	Yes	Grade 2	11.2
16	Female	Yes	Yes	Grade 1	11.4
17	Male	No	No	Grade 2	12
18	Female	Yes	Yes	Grade 2	12.1
19	Male	Yes	Yes	Grade 2	12.3
20	Female	No	No	Grade 2	12.4
21	Female	No	No	Grade 2	12.5
22	Female	Yes	Yes	Grade 2	12.6
23	Male	Yes	No	Grade 2	12.8
24	Male	Yes	No	Grade 2	12.9
25	Male	Yes	Yes	Grade 2	13
26	Female	No	Yes	Grade 2	13.2
27	Female	No	No	Grade 2	13.3
28	Male	Yes	Yes	Grade 2	13.5
29	Male	No	No	Grade 1	13.6
30	Male	Yes	No	Grade 1	13.8
31	Female	No	Yes	Grade 2	13.9
32	Male	Yes	No	Grade 1	14
33	Female	Yes	No	Grade 2	14.2
34	Male	No	Yes	Grade 2	8
35	Female	Yes	No	Grade 2	8
36	Female	Yes	Yes	Grade 1	8
37	Male	Yes	Yes	Grade 1	8
38	Female	Yes	Yes	Grade 1	8
39	Female	Yes	Yes	Grade 1	8
40	Female	Yes	No	Grade 1	8
41	Male	Yes	Yes	Grade 2	8
42	Male	Yes	Yes	Grade 2	8
43	Male	No	No	Grade 2	8
44	Female	Yes	No	Grade 2	9.2
45	Female	Yes	No	Grade 2	9.4
46	Male	Yes	No	Grade 2	9.4
47	Female	No	No	Grade 2	10
48	Male	Yes	No	Grade 2	11
49	Female	No	No	Grade 2	11
50	Female	No	No	Grade 1	11.4
51	Male	No	No	Grade 1	12
52	Male	No	No	Grade 1	12
53	Male	Yes	No	Grade 1	12
54	Male	Yes	No	Grade 1	12
55	Male	Yes	No	Grade 1	12
56	Female	Yes	No	Grade 1	12
57	Male	No	No	Grade 1	12
58	Male	Yes	No	Grade 1	12
59	Female	No	No	Grade 1	12
60	Female	Yes	No	Grade 1	12
61	Female	Yes	No	Grade 1	12
62	Male	Yes	No	Grade 1	12
63	Male	No	No	Grade 1	12
64	Male	Yes	No	Grade 1	12
65	Female	No	No	Grade 2	12
66	Female	No	No	Grade 1	12
67	Female	No	No	Grade 1	12
68	Male	No	Yes	Grade 1	12
69	Male	No	Yes	Grade 1	12
70	Male	No	Yes	Grade 1	12
71	Male	No	Yes	Grade 2	12
72	Male	No	Yes	Grade 2	12
73	Male	No	Yes	Grade 2	12
74	Female	No	Yes	Grade 2	12.8
75	Male	No	Yes	Grade 2	12.8
76	Female	No	Yes	Grade 2	12.8
77	Female	No	Yes	Grade 2	12.9
78	Male	No	Yes	Grade 2	13
79	Male	No	Yes	Grade 2	13
80	Female	No	Yes	Grade 2	13
81	Male	No	Yes	Grade 2	13.2
82	Male	No	Yes	Grade 2	13.2
83	Female	No	Yes	Grade 2	13.2
84	Female	No	Yes	Grade 2	13.2
85	Male	No	Yes	Grade 2	13.3
86	Male	No	Yes	Grade 2	13.6
87	Male	No	Yes	Grade 2	14
88	Female	No	No	Grade 2	14
89	Male	No	No	Grade 2	14
90	Female	No	No	Grade 2	14

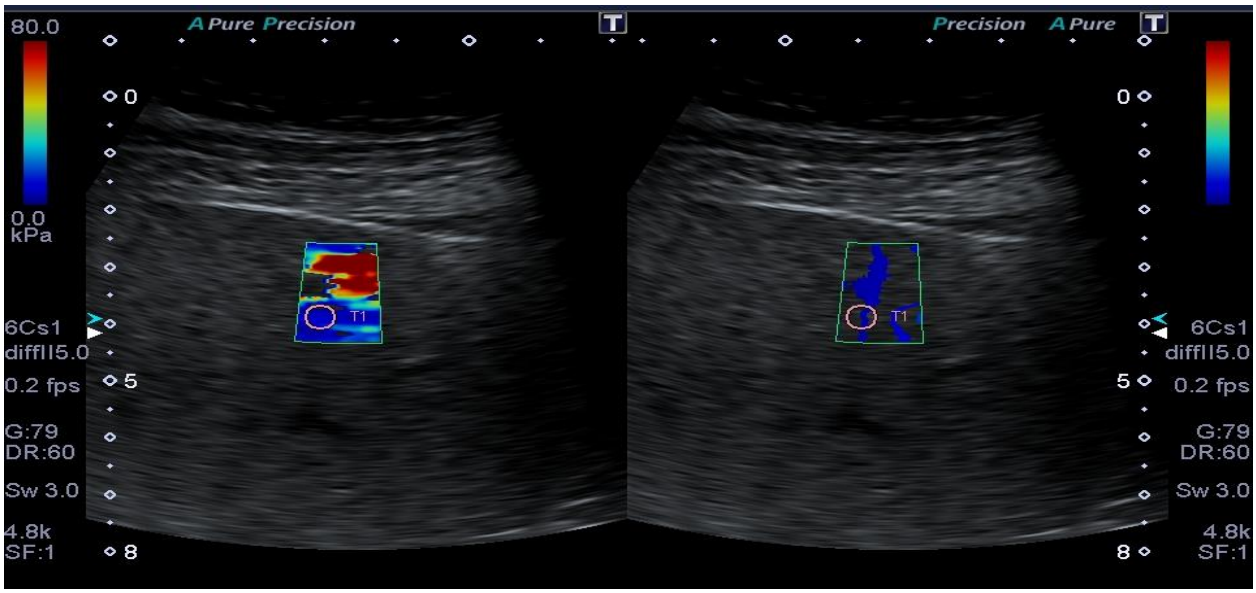
ANNEXURE

Case:1



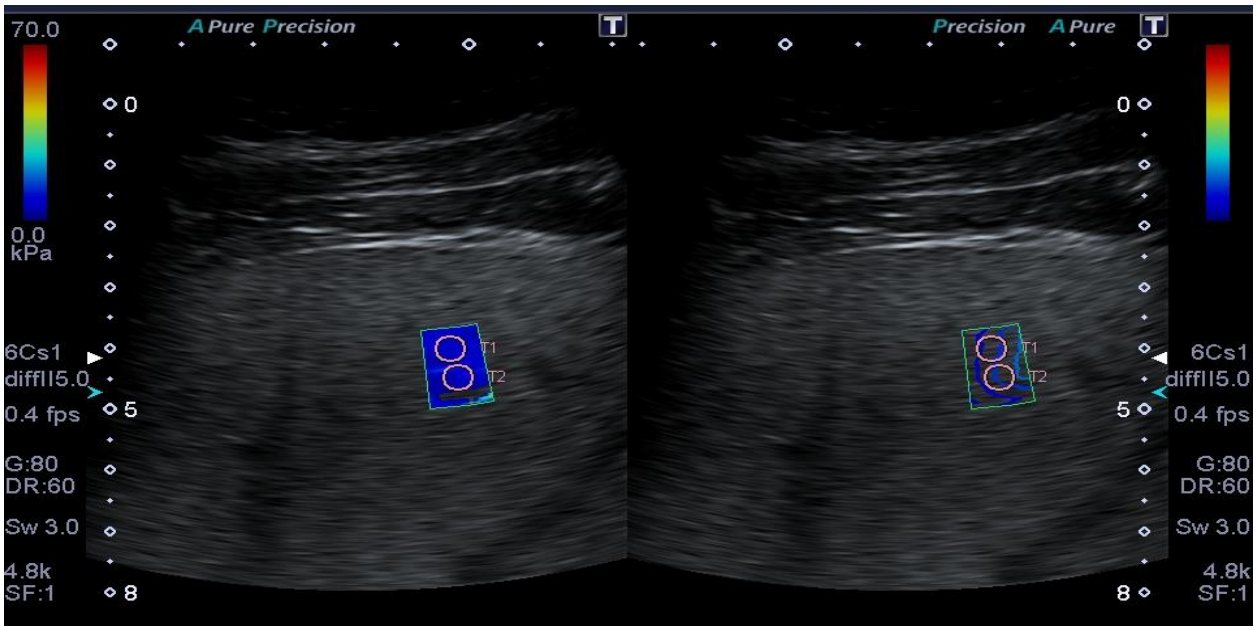
A 52-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 14 Kpa.

Case:2



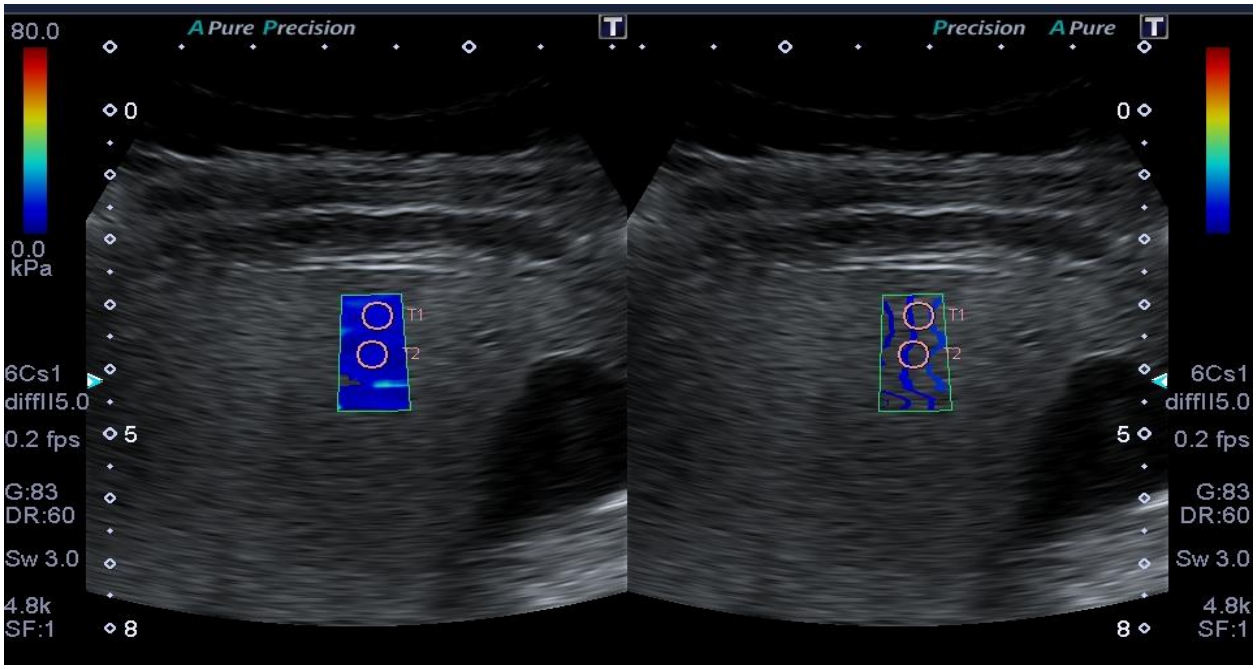
A 37-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 8 Kpa.

Case:3



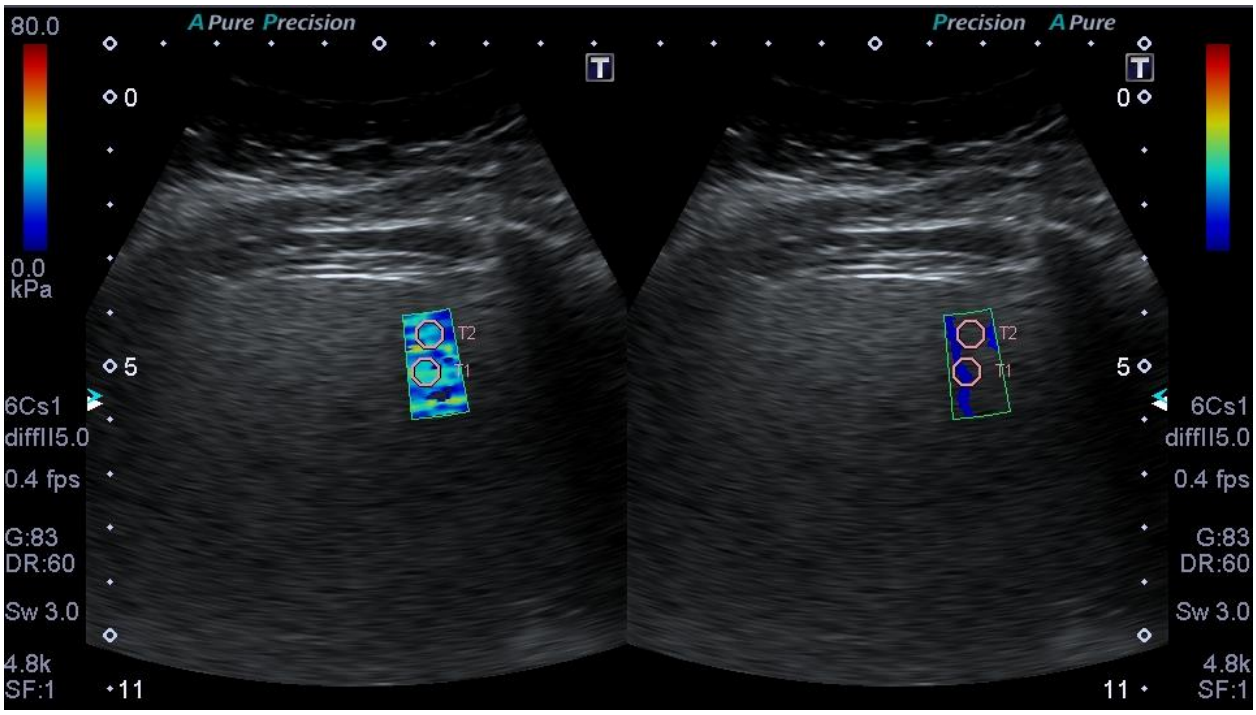
A 58-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 7 Kpa.

Case:4



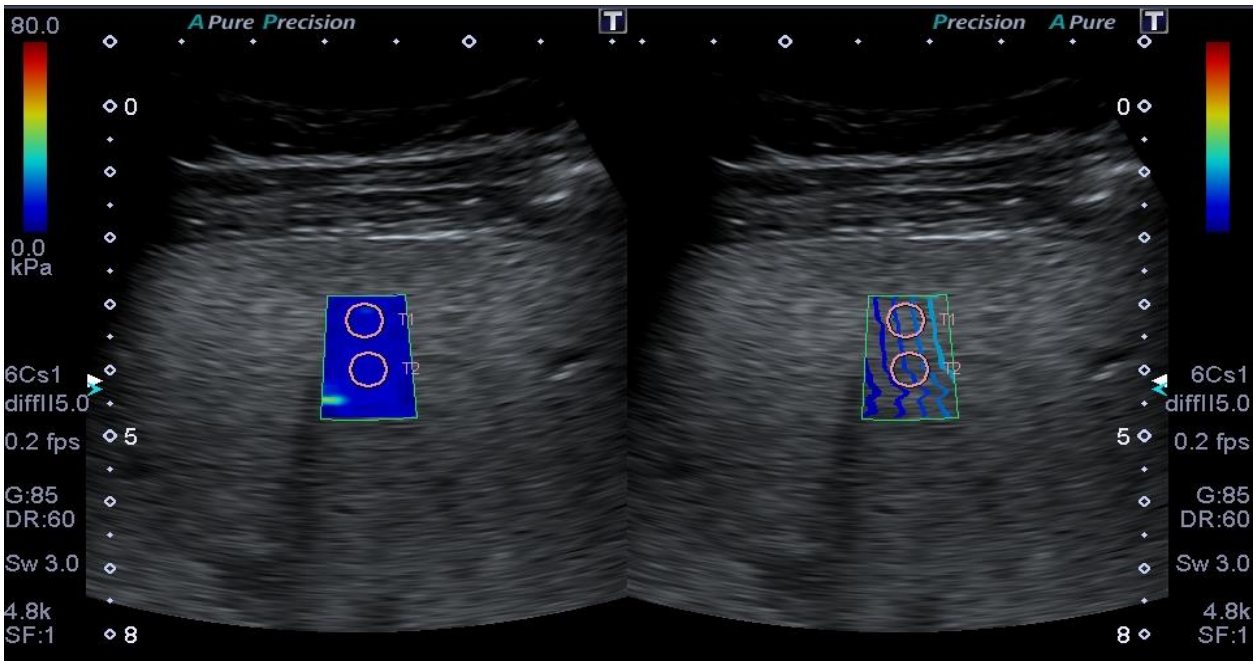
A 36-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 10 Kpa.

Case:5



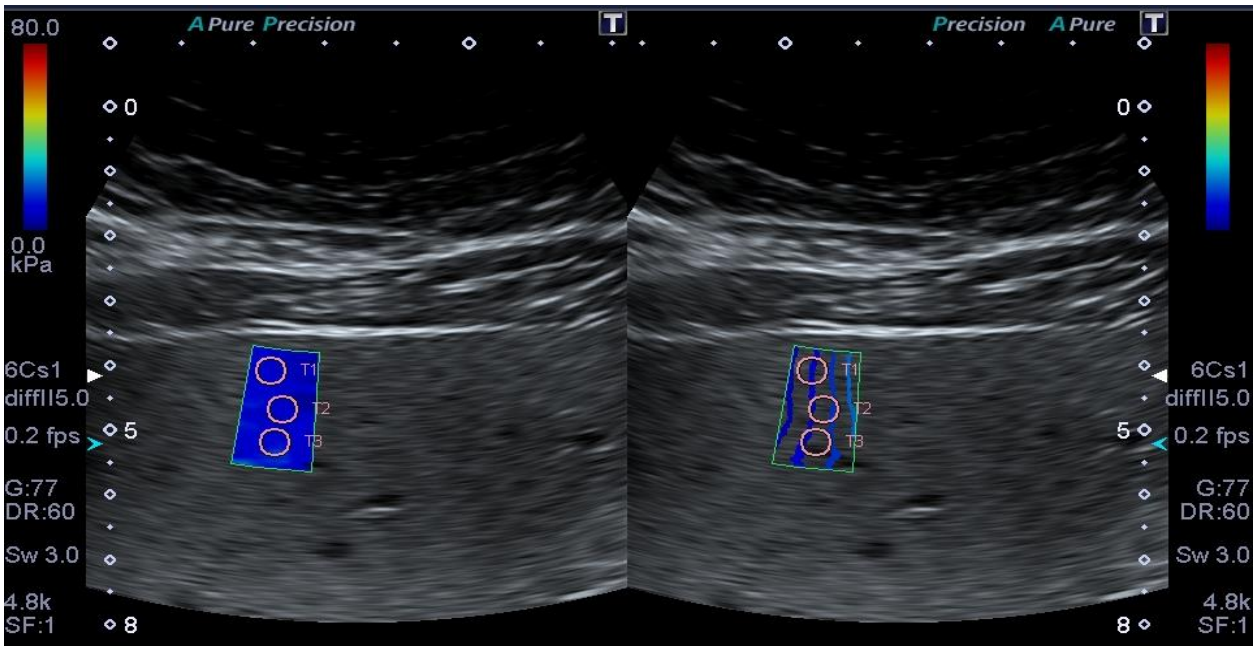
A 61-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 14 Kpa.

Case:6



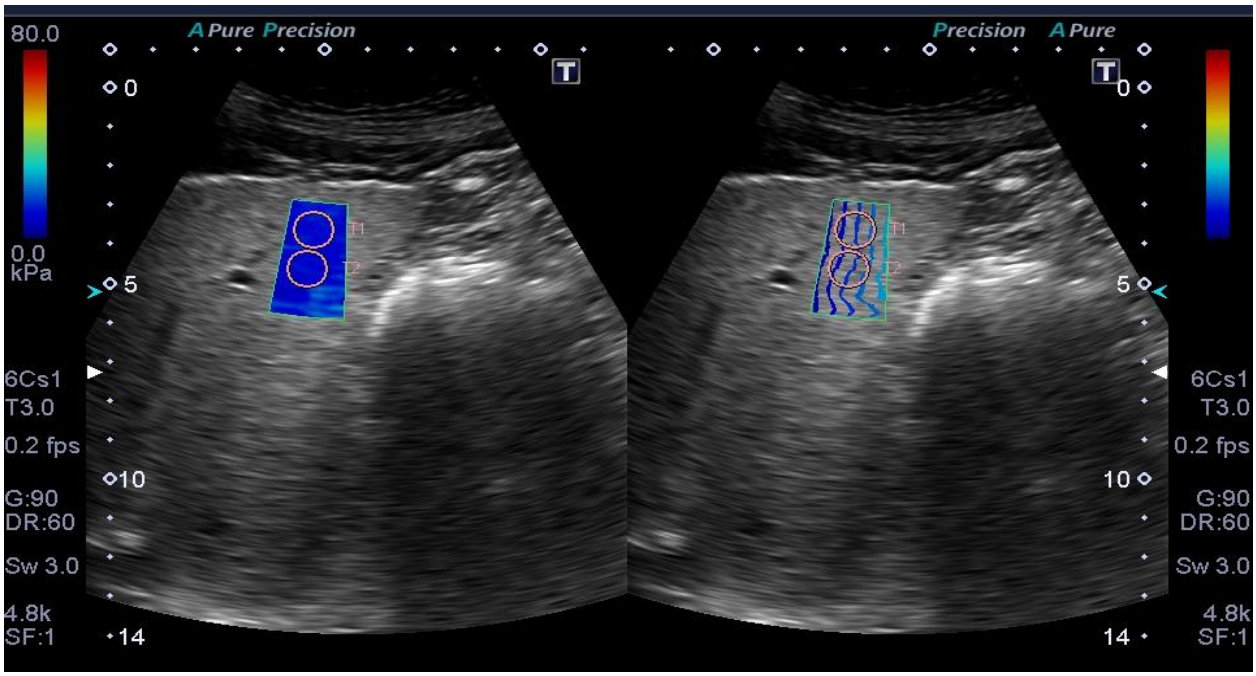
A 58-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 7 Kpa.

Case:7



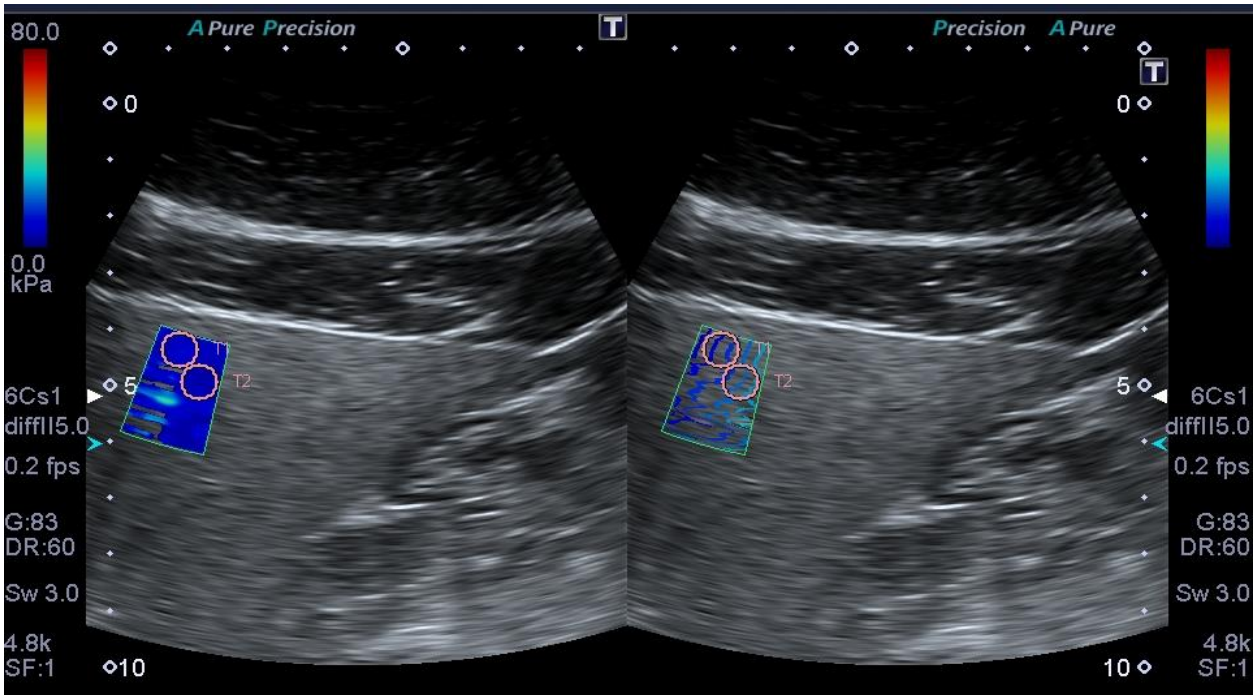
A 31-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 9 Kpa.

Case:8



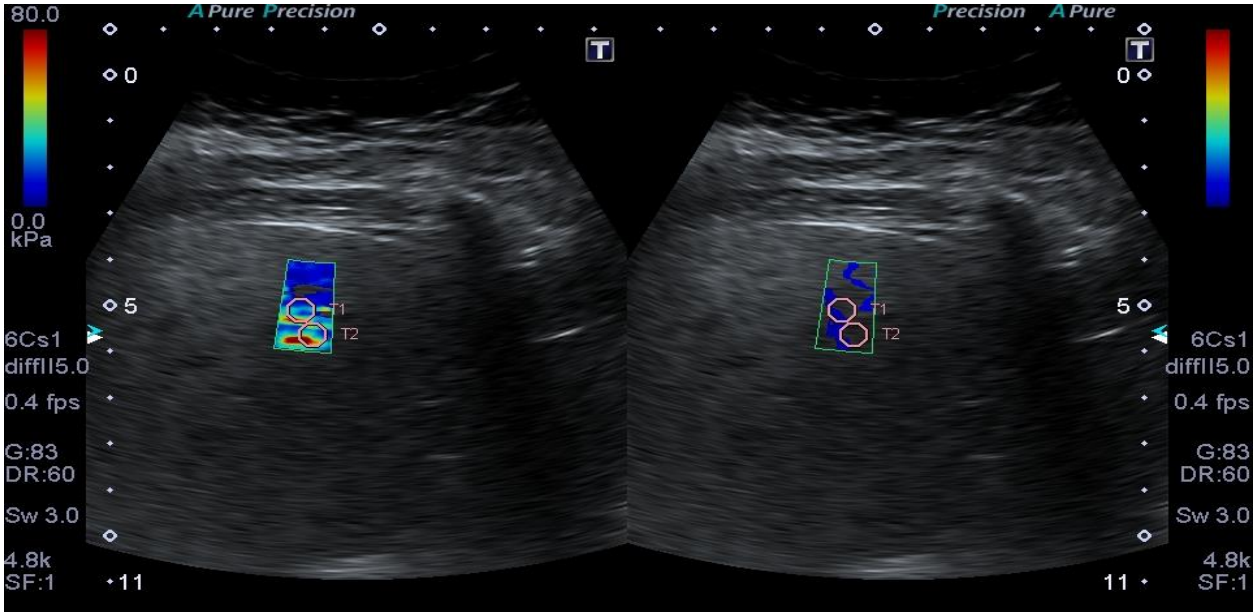
A 61-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 11 Kpa.

Case:9



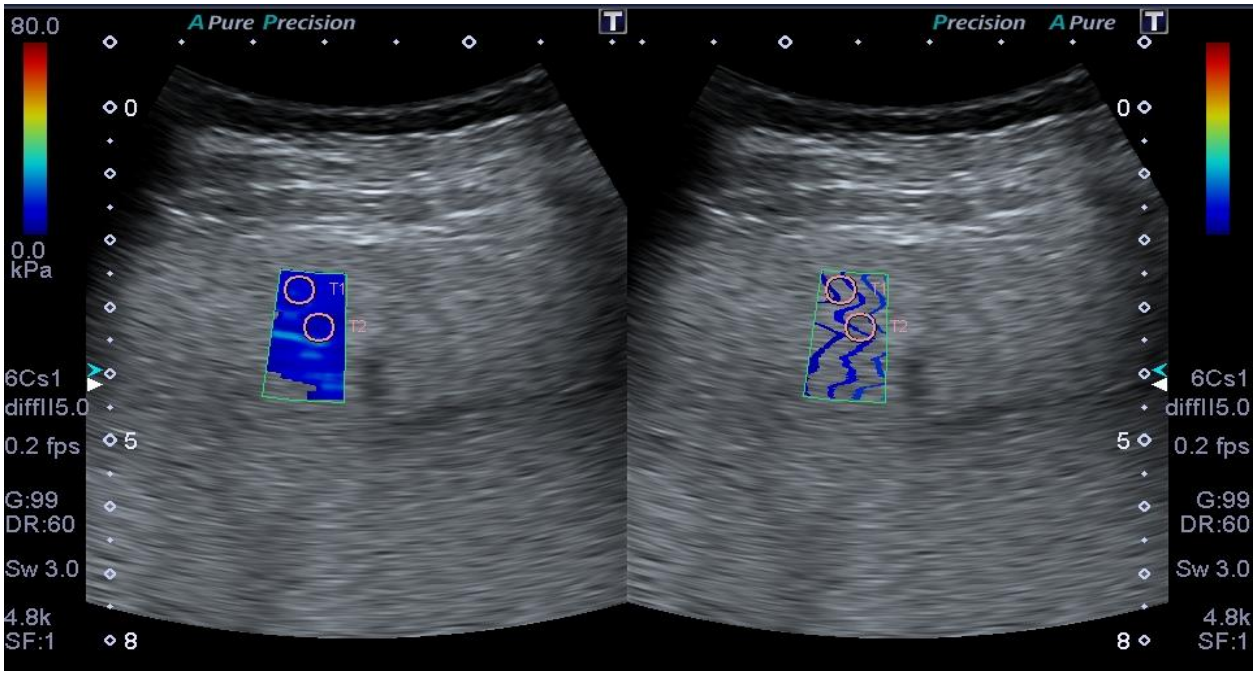
A 39-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 8 Kpa.

Case:10



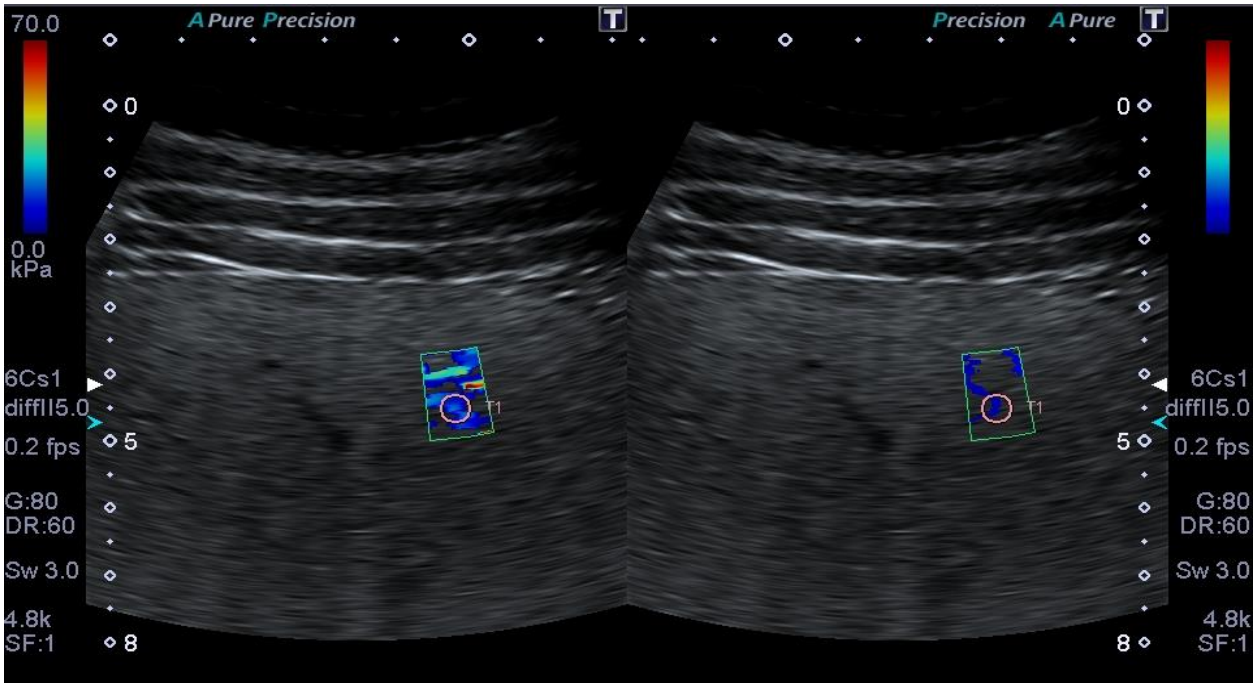
A 35-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 14 Kpa.

Case:11



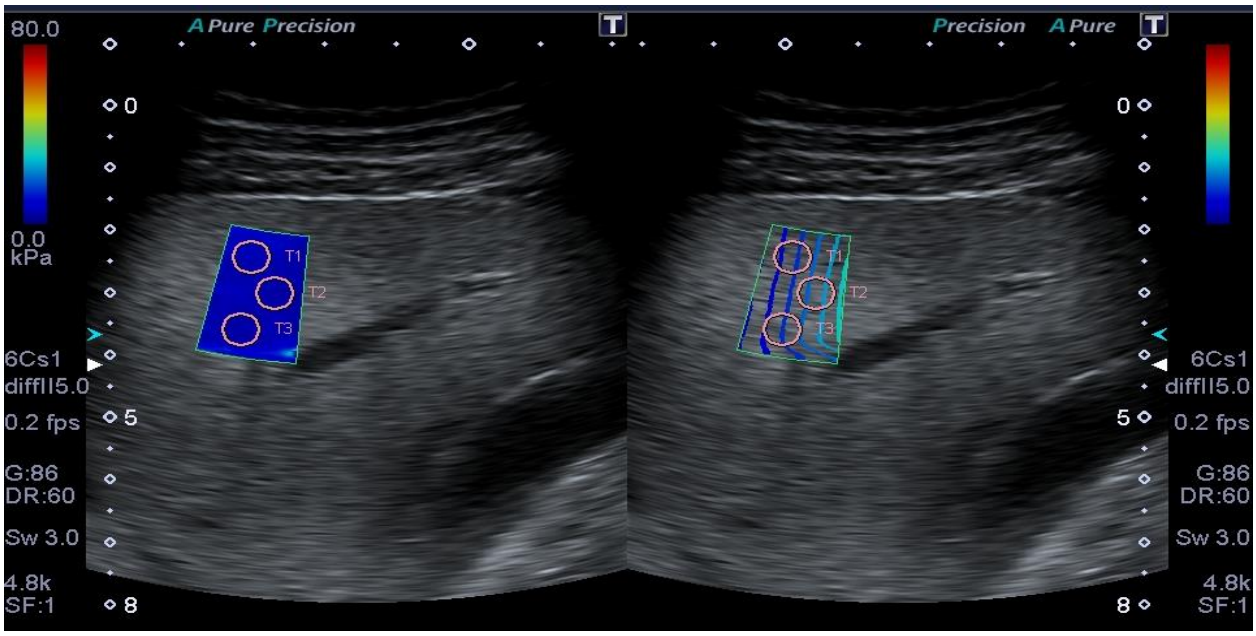
A 33-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 9 Kpa.

Case:12



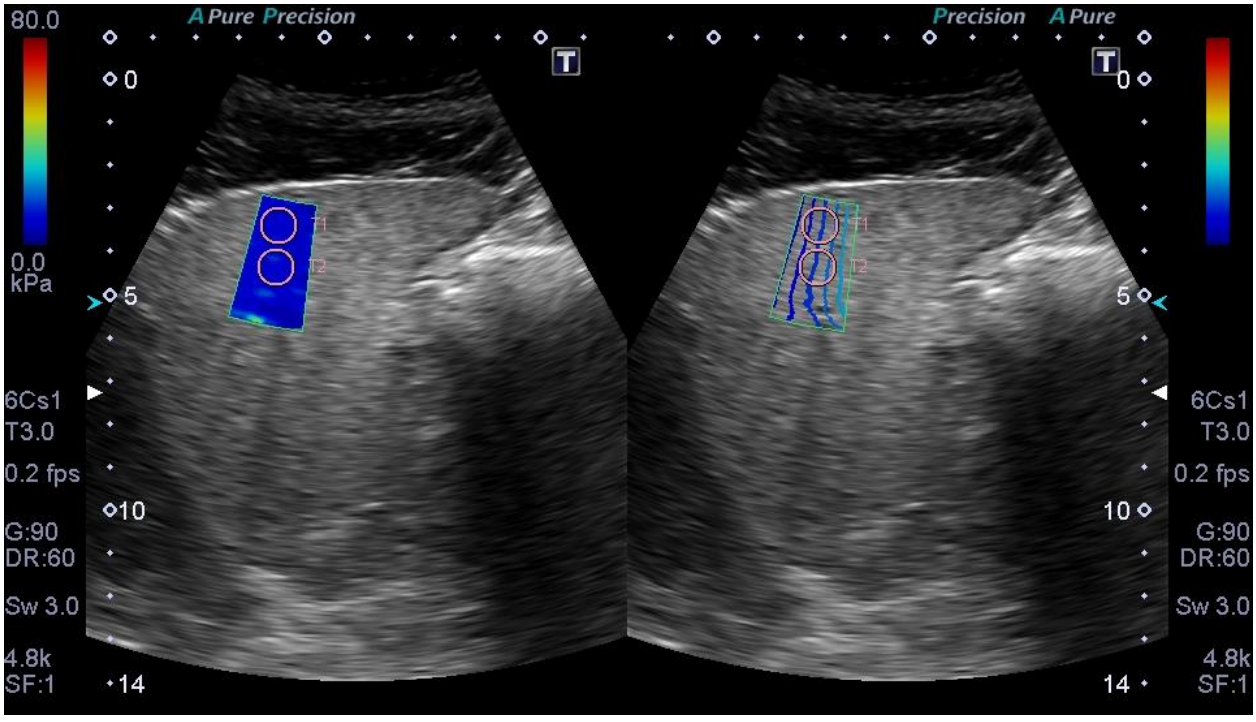
A 56-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 11 Kpa.

Case:13



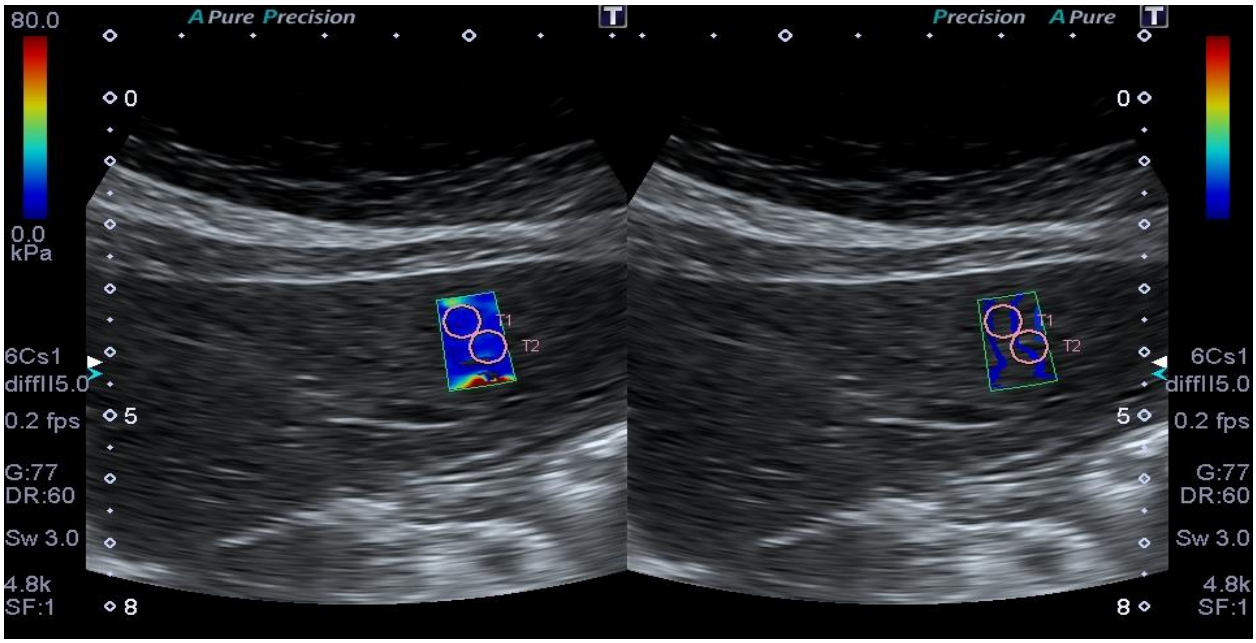
A 45-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 8 Kpa.

Case:14



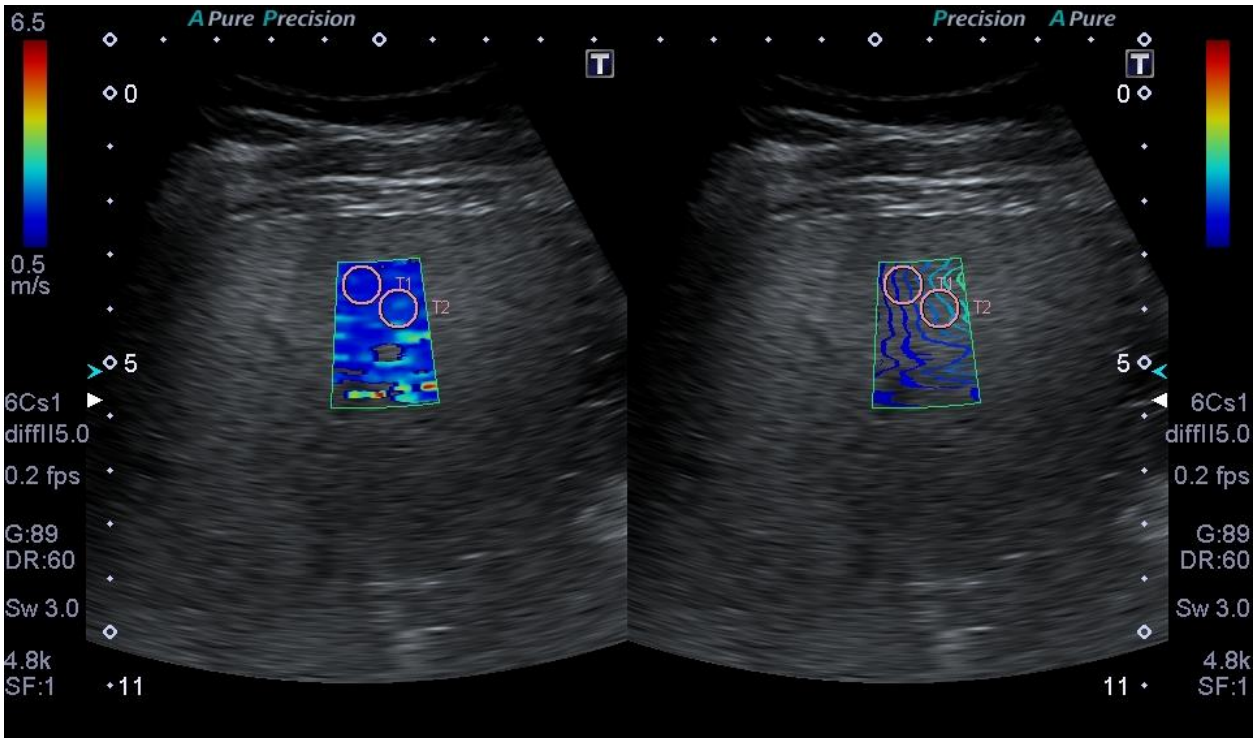
A 39-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 9 Kpa.

Case:15



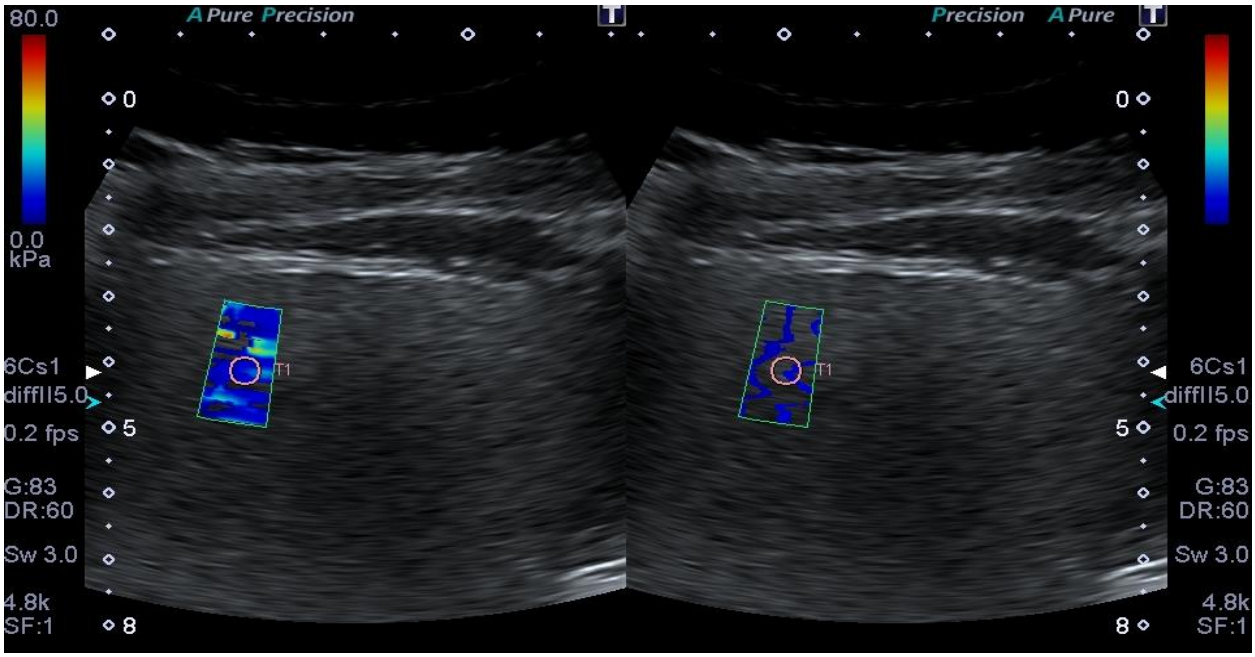
A 61-year- grade 2 fatty liver and elastography values of stiffness showed values to be around 11 Kpa.

Case:16



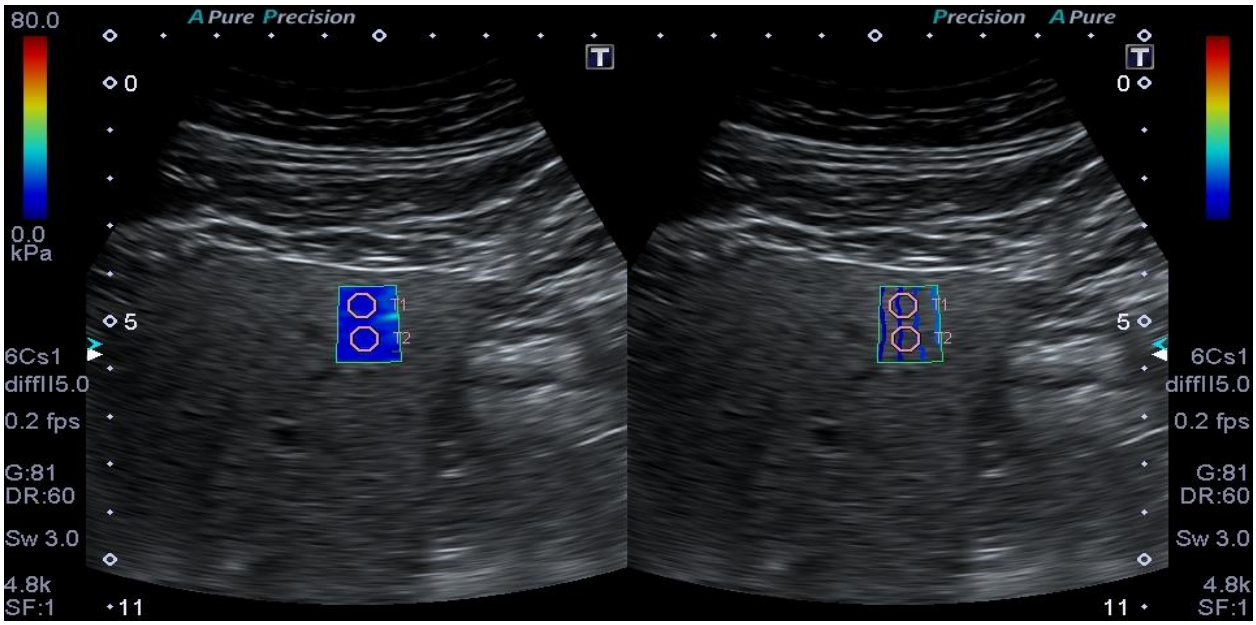
A 34-year-old showed grade 2 fatty liver and elastography values of stiffness showed values to be around 13 Kpa.

Case:17



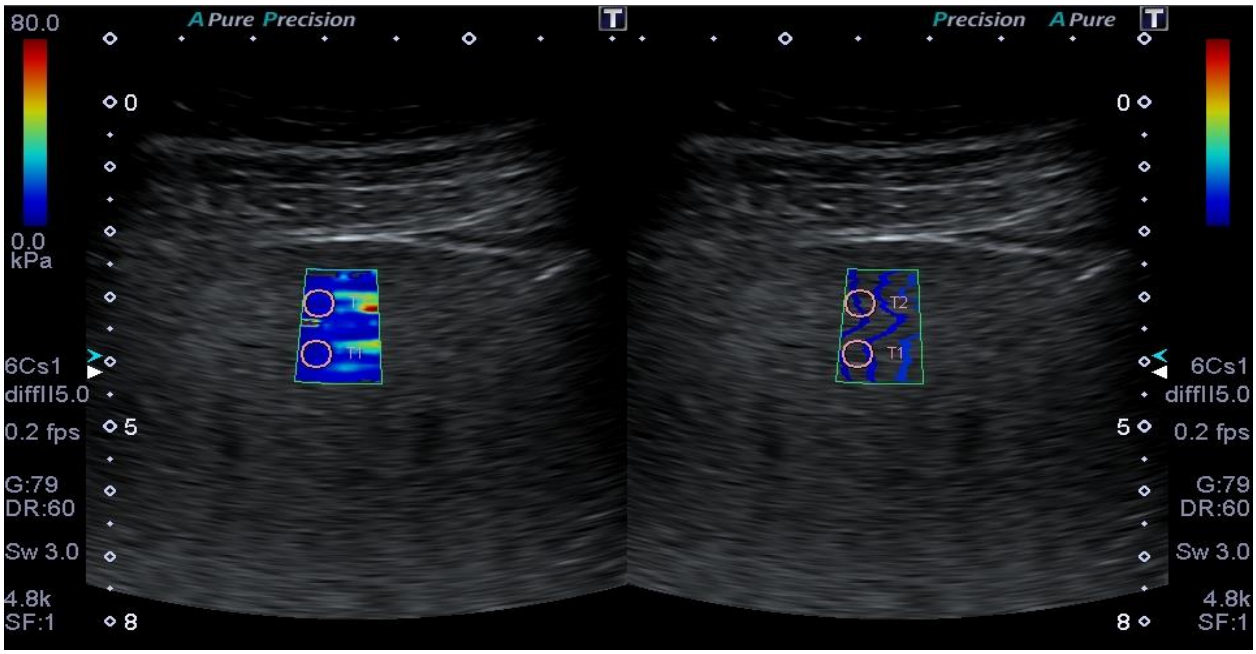
A 36-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 10 Kpa.

Case:18



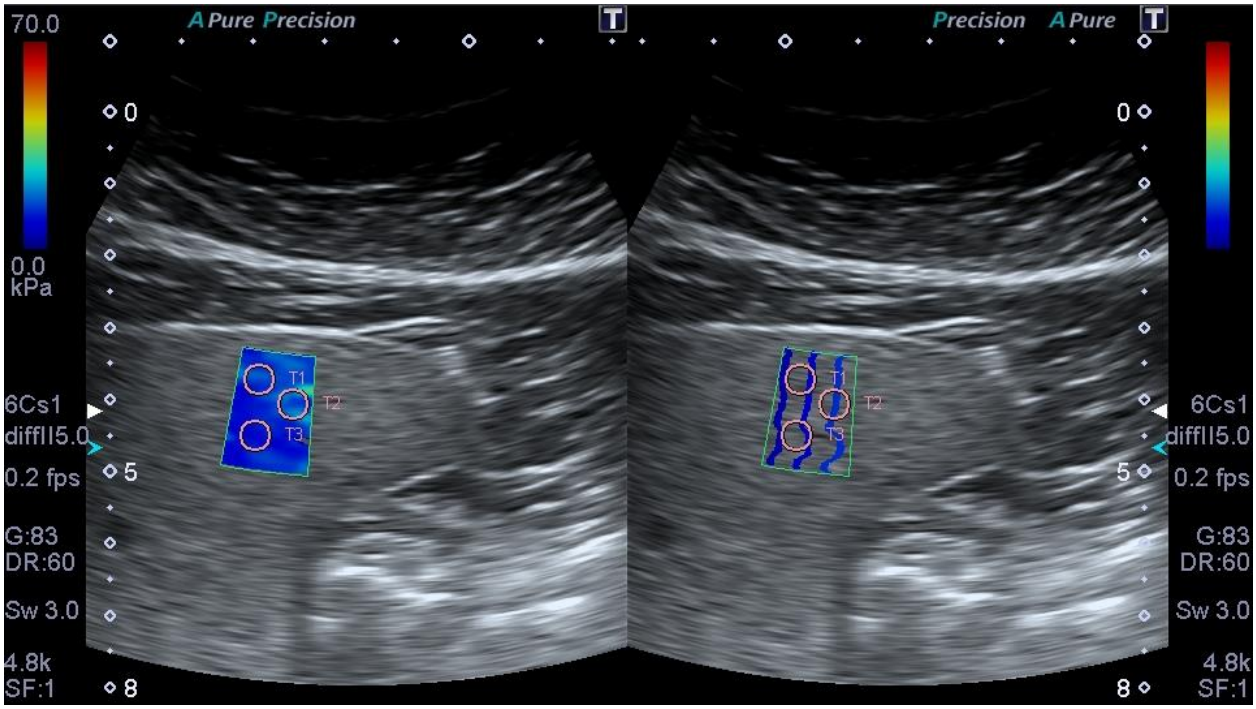
A 46-year-old patient and showed grade 2 fatty liver and elastography values of stiffness showed values to be around 12 Kpa.

Case:19



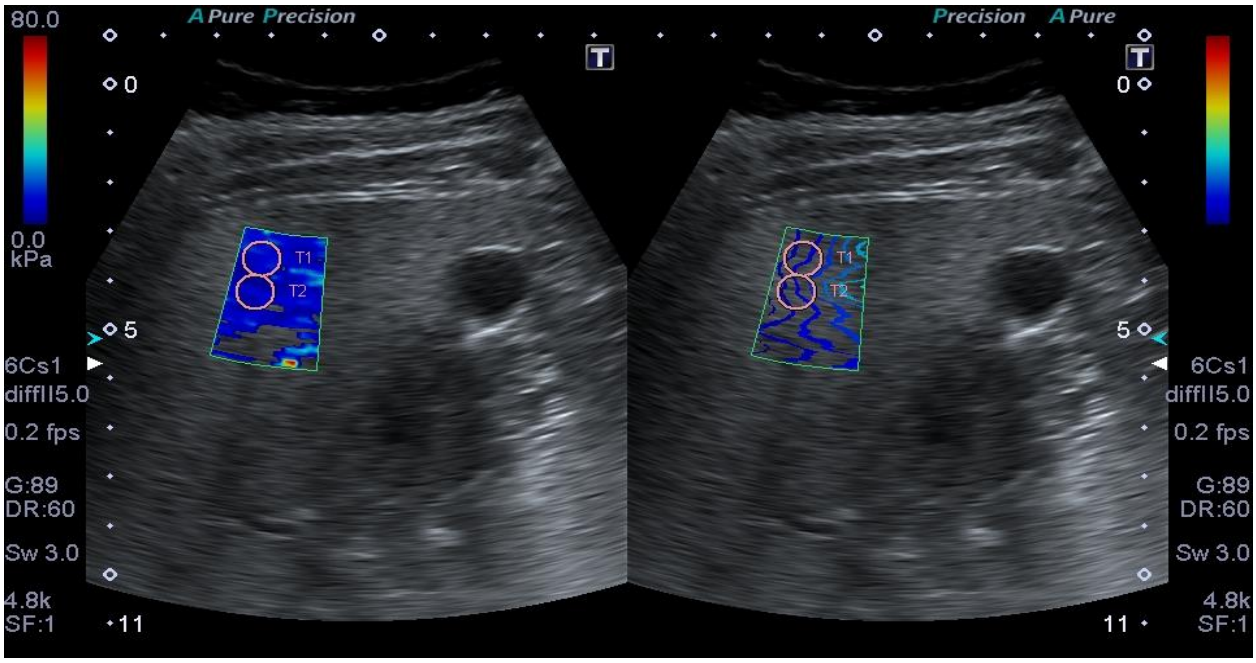
A 51-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 7 Kpa.

Case:20



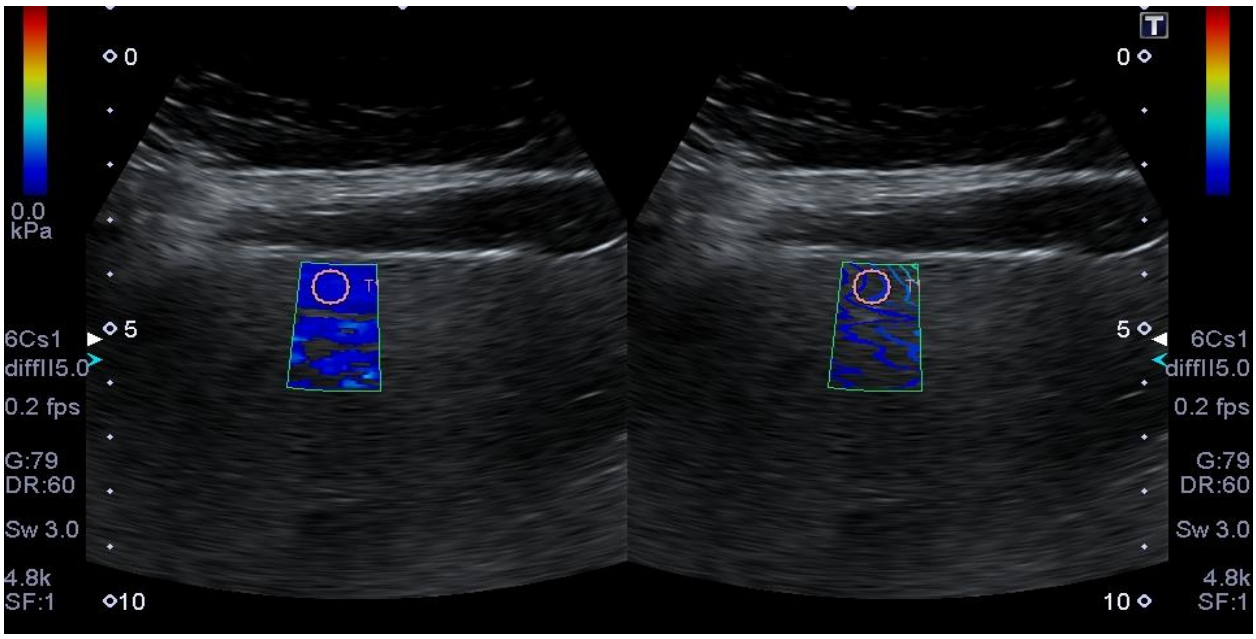
A 47-year-old showed grade 2 fatty liver and elastography values of stiffness showed values to be around 14 Kpa.

Case:21



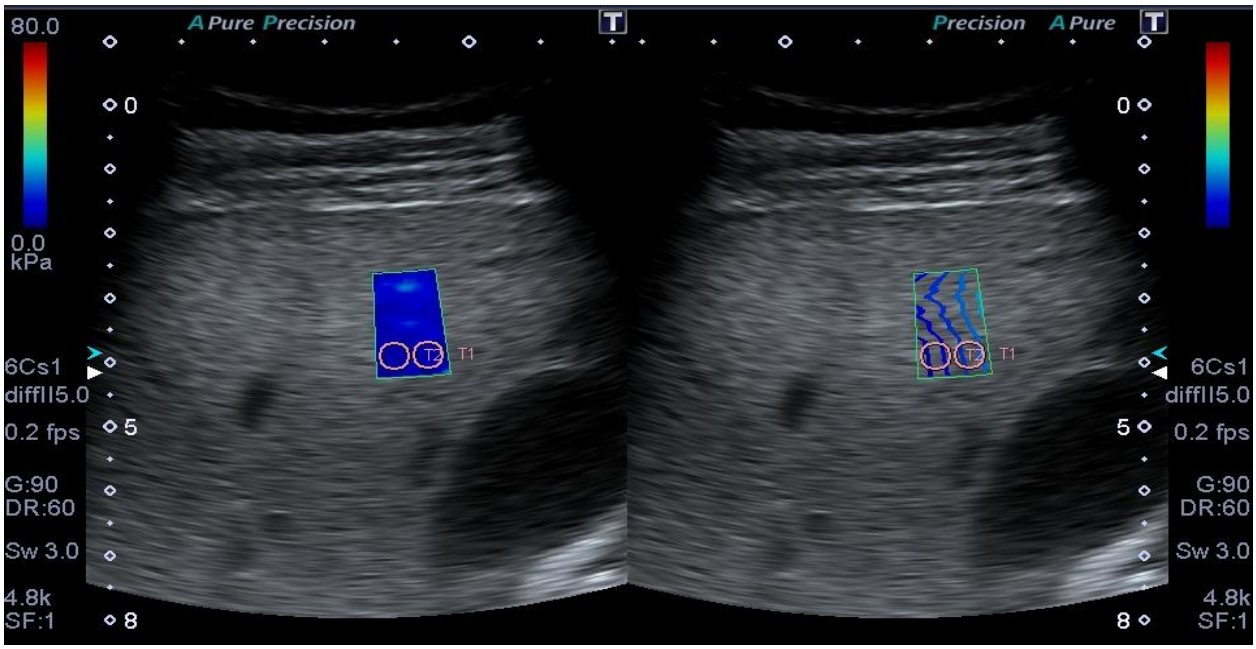
A 40-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 9 Kpa.

Case:22



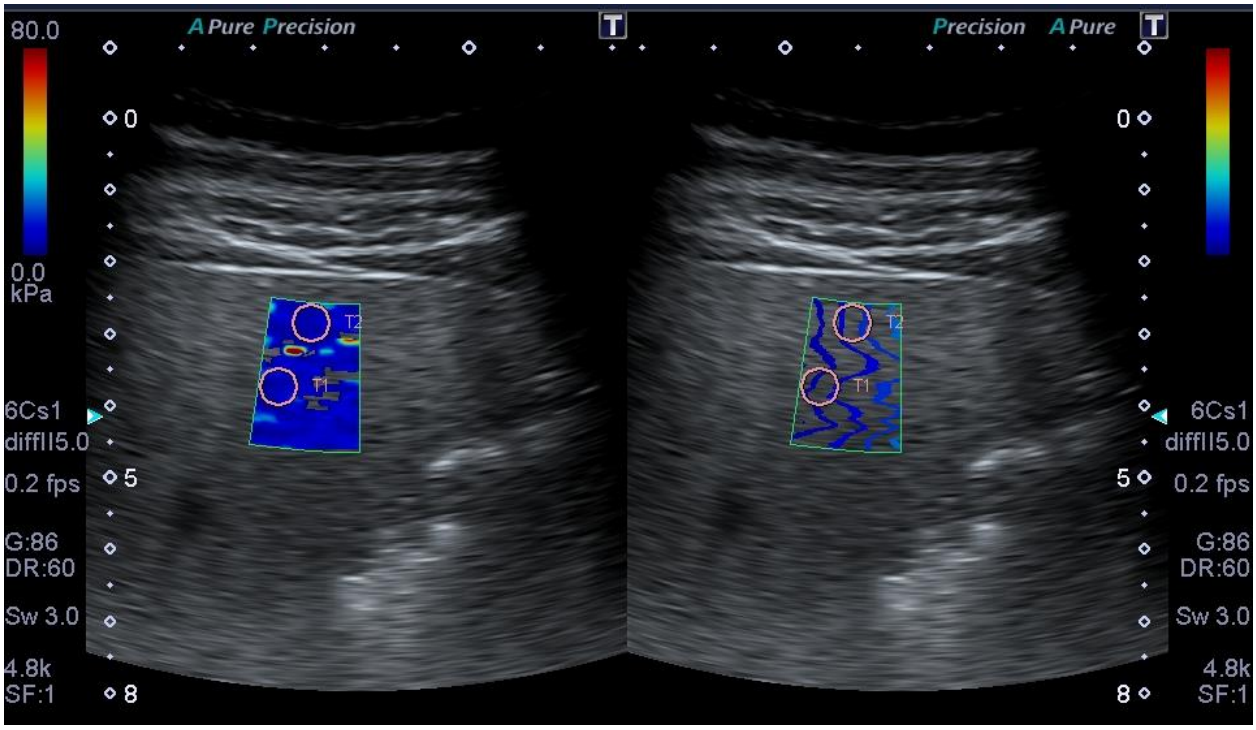
A 53-year-old patient grade 2 fatty liver and elastography values of stiffness showed values to be around 8 Kpa.

Case:23



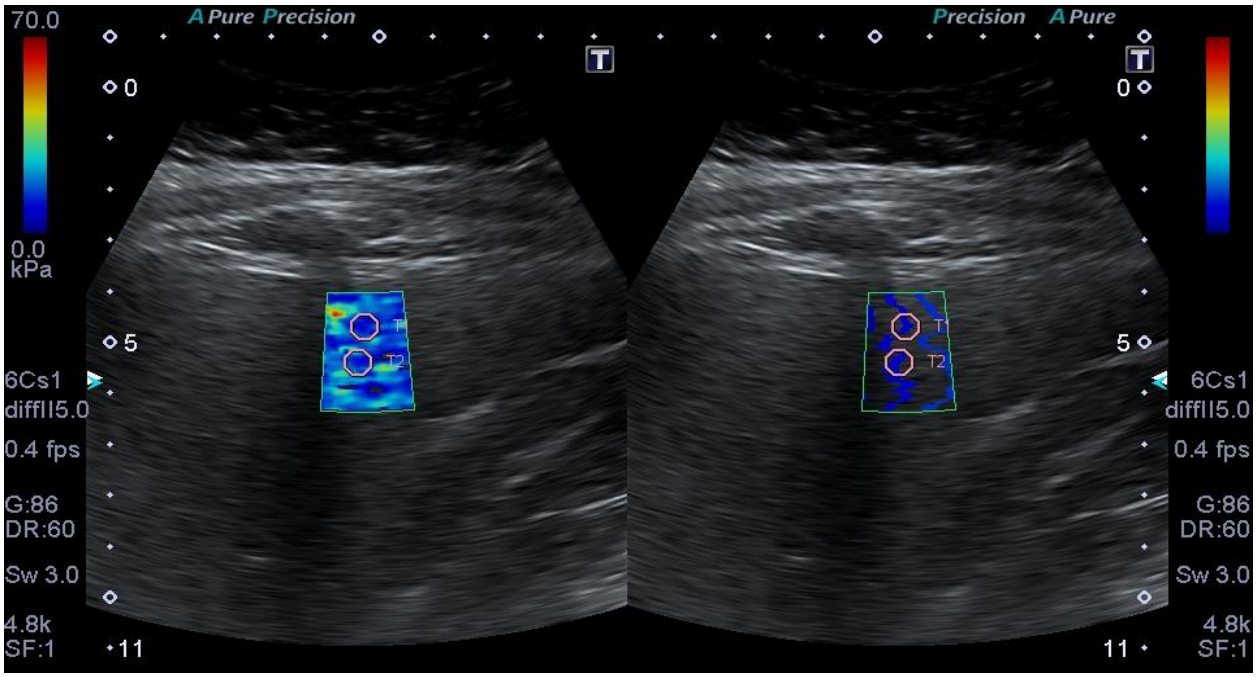
A 40-year-old patient grade 2 fatty liver and elastography values of stiffness showed values to be around 6 Kpa.

Case:24



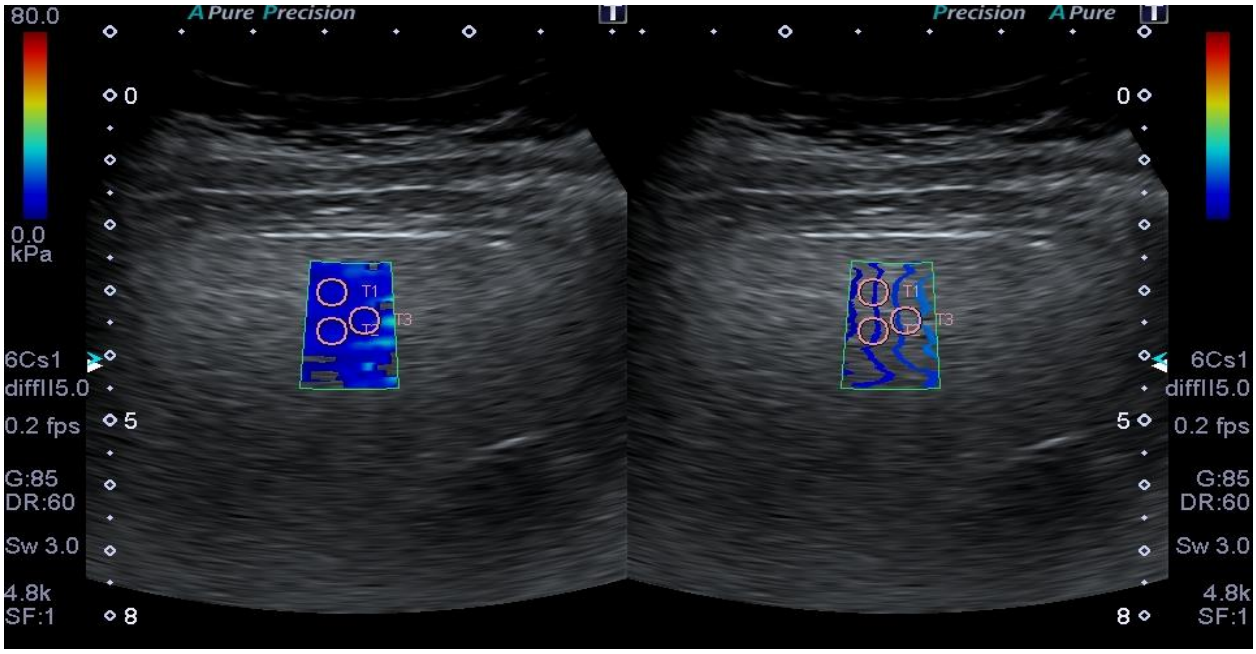
A 30-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 10 Kpa.

Case:25



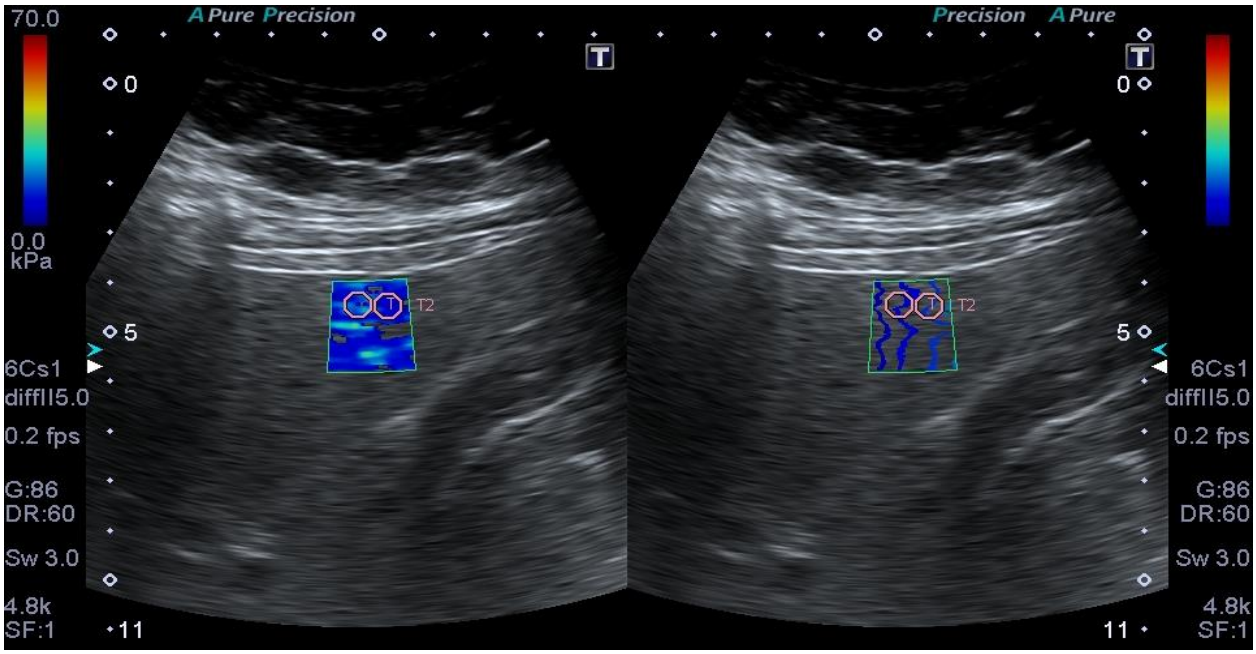
A 55-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 13 Kpa.

Case:26



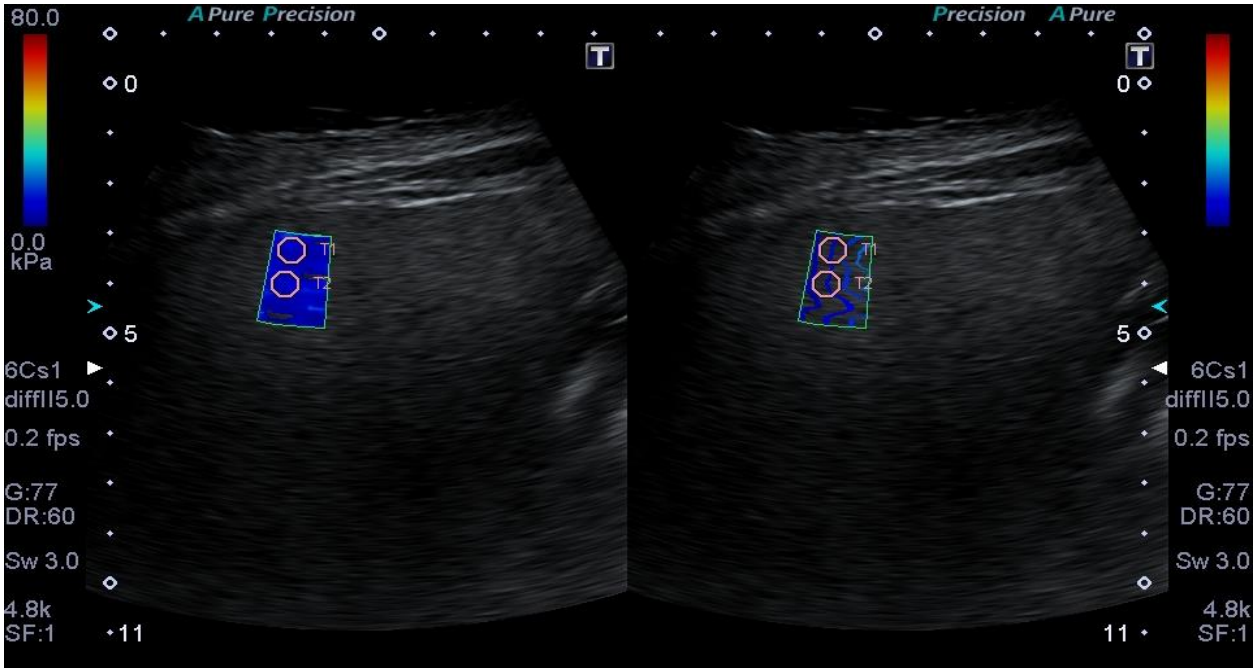
A 45-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 8 Kpa.

Case:27



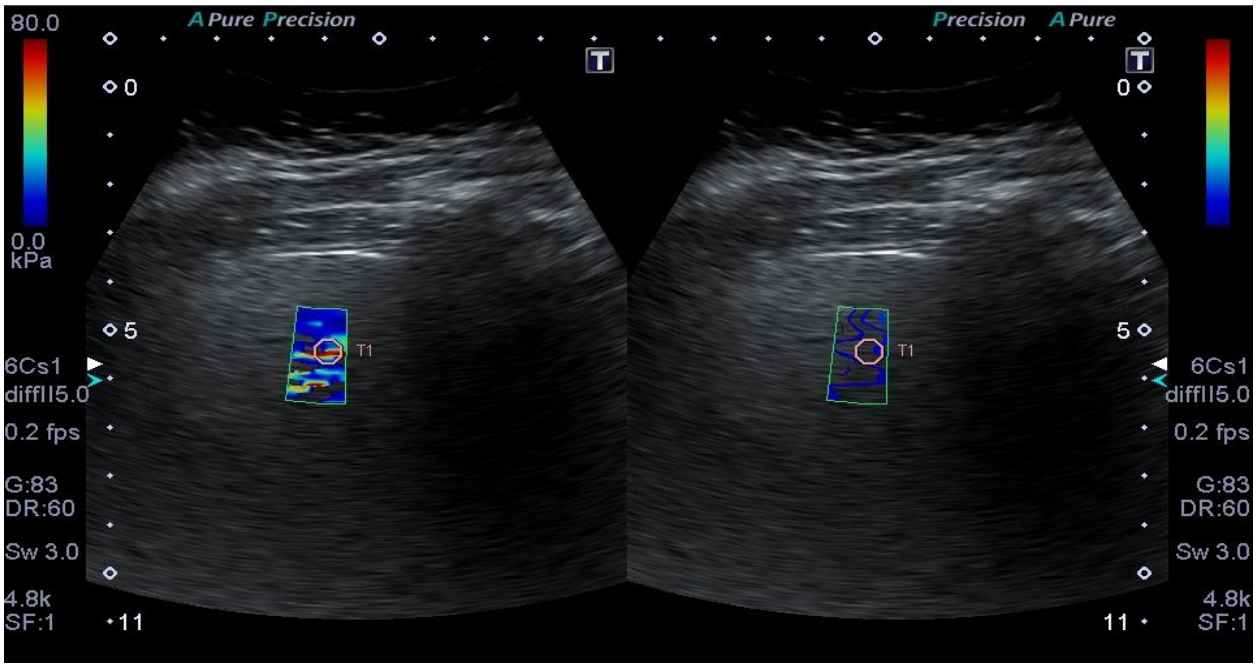
A 47-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 14 Kpa.

Case:28



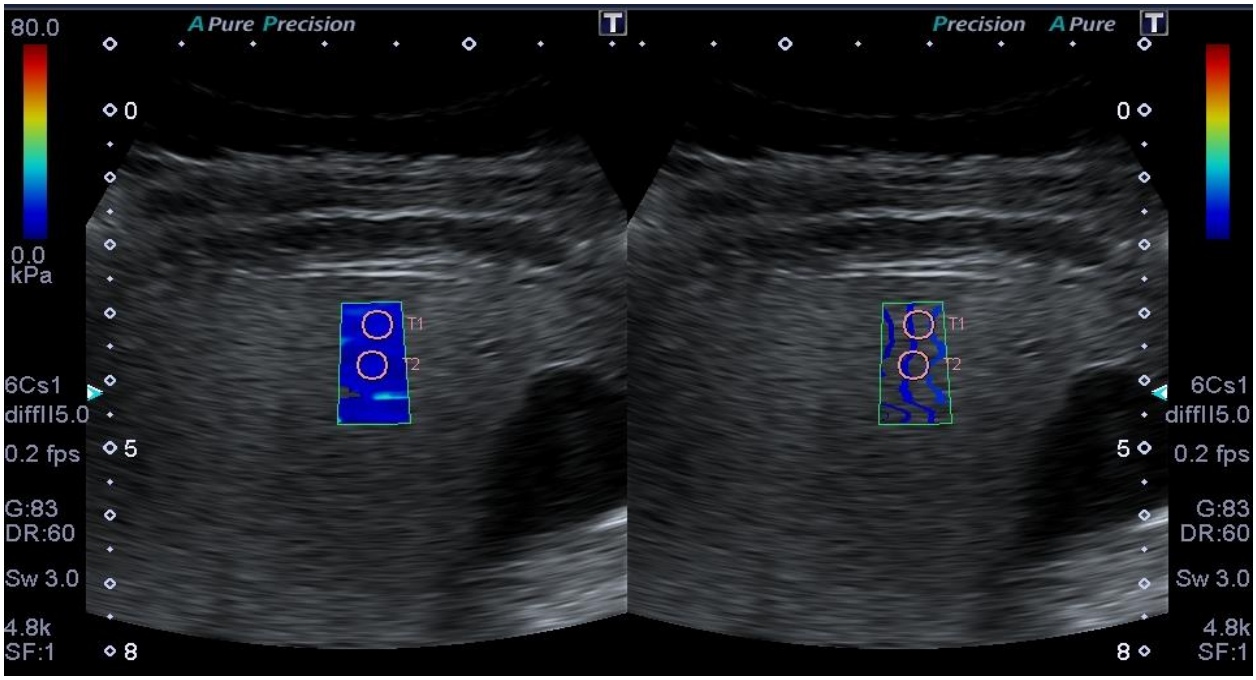
A 52-year-old patient grade 1 fatty liver and elastography values of stiffness showed values to be around 7 Kpa.

Case:29



A 32-year-old patient showed grade 2 fatty liver and elastography values of stiffness showed values to be around 13 Kpa.

Case:30



A 39-year-old patient showed grade 1 fatty liver and elastography values of stiffness showed values to be around 9 Kpa.

PERMISSION LETTER

ETHICS COMMITTEE LETTER

PLAGIARISM SI CERTIFICATE

PLAGIARISM REPORT