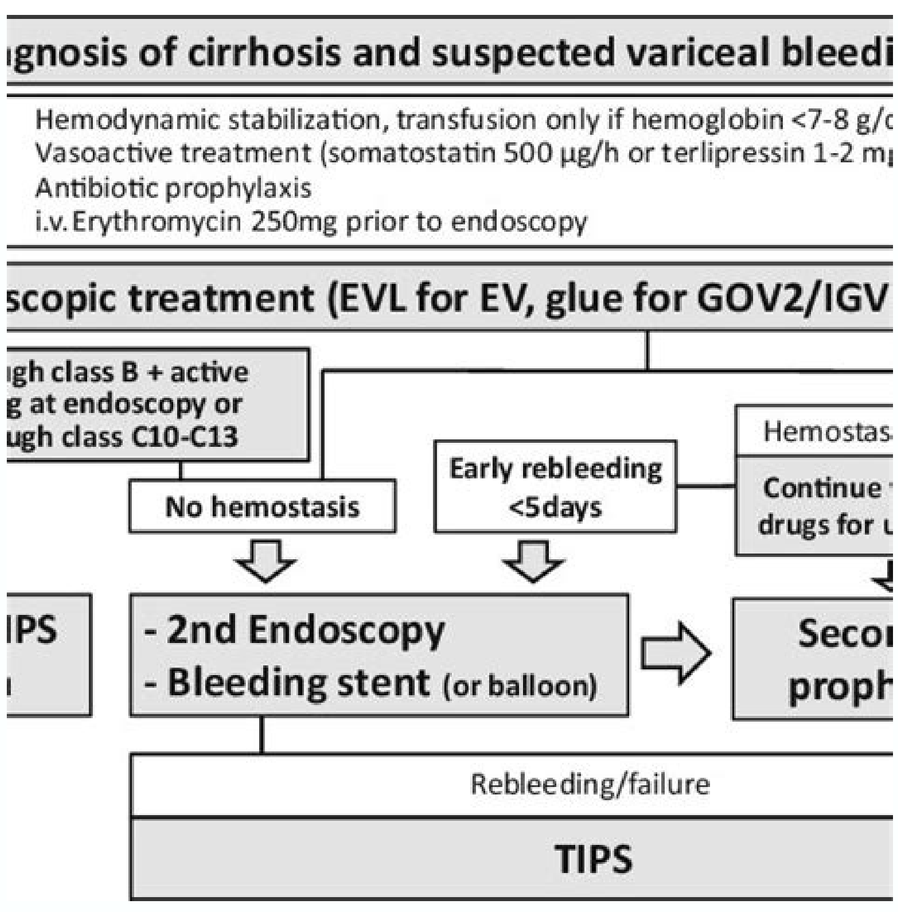
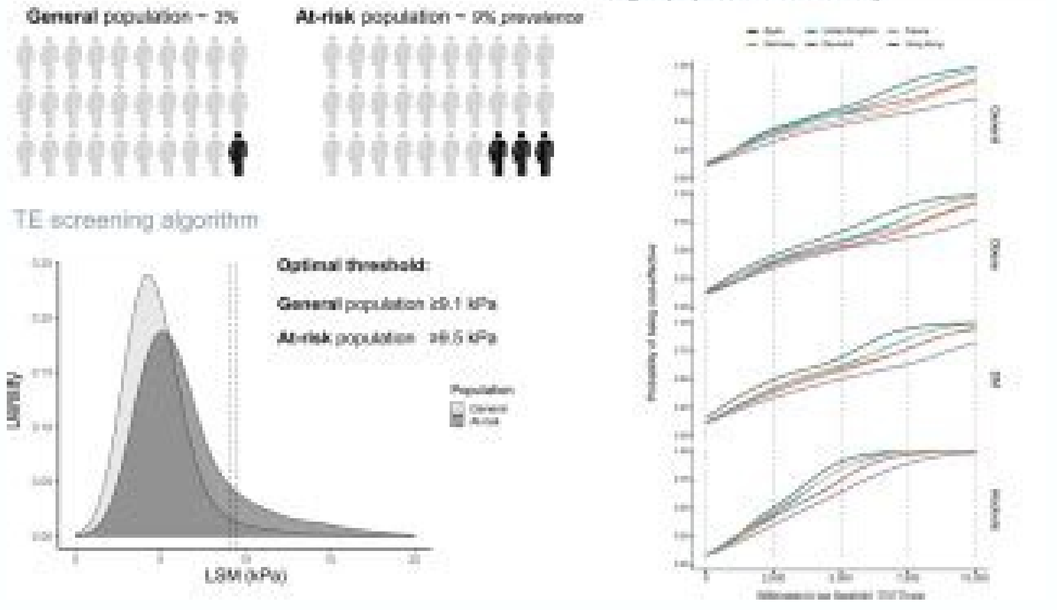
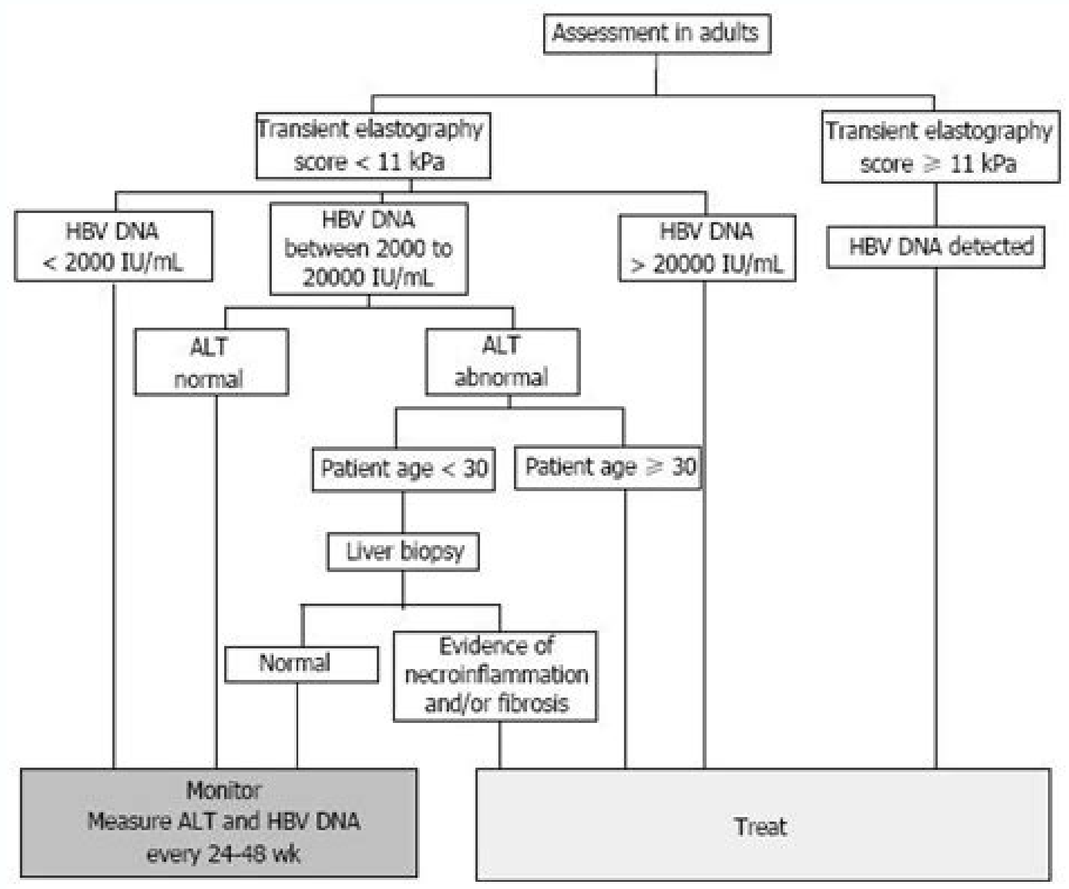
Transient elastography guidelines

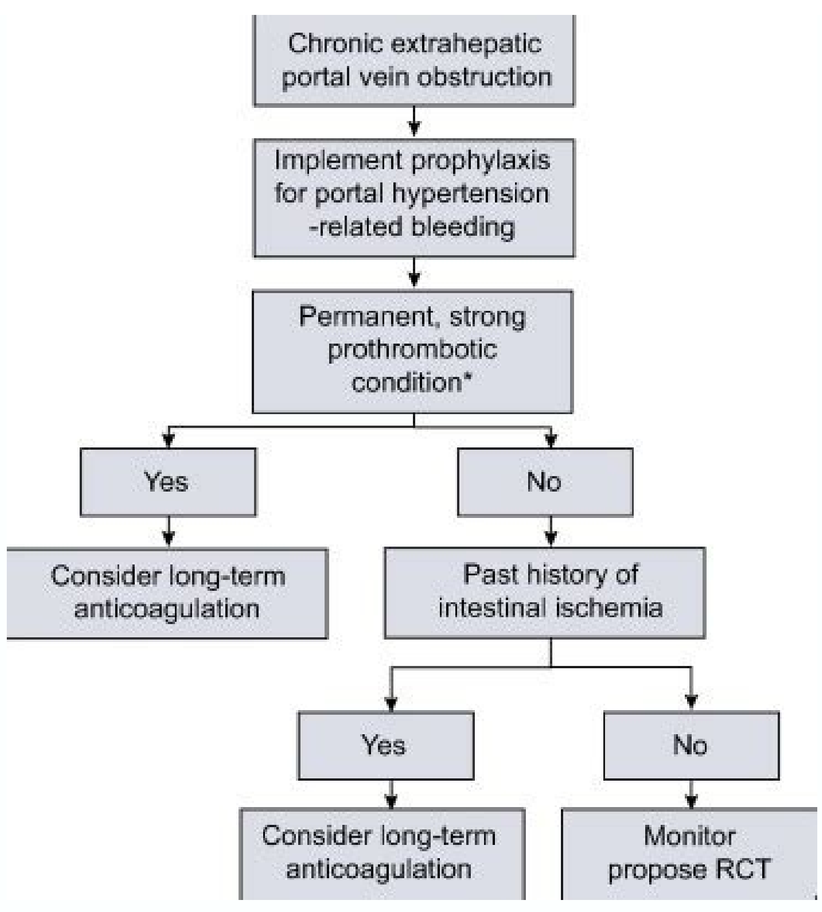

gnosis of cirrhosis and suspected variceal bleedi
Hemodynamic stabilization, transfusion only if hemoglobin <7-8 g/
Vasoactive treatment (somatostatin 500 µg/h or terlipressin 1-2 m
Antibiotic prophylaxis
i.v. Erythromycin 250mg prior to endoscopy
scopic treatment (EVL for EV, glue for GOV2/IGV
gh class B + active
g at endoscopy or
ugh class C10-C13
No hemostasis
Early rebleeding
<5days
Hemostas
Continue
drugs for
IPS
- 2nd Endoscopy
- Bleeding stent (or balloon)
Secor
proph
Rebleeding/failure
TIPS


Target population
General population ~ 3%
At-risk population ~ 9% prevalence
TE screening algorithm
Optimal threshold:
General population ≥9.1 kPa
At-risk population ≥9.5 kPa
Density
LSM (kPa)
Population
General
At-risk
Cost-effectiveness acceptability curves by target population & country
Probability of being cost-effective
Canada
China
UK
Australia


Assessment in adults
Transient elastography score < 11 kPa
Transient elastography score ⩾ 11 kPa
HBV DNA < 2000 IU/mL
HBV DNA between 2000 to 20000 IU/mL
HBV DNA > 20000 IU/mL
HBV DNA detected
ALT normal
ALT abnormal
Patient age < 30
Patient age ⩾ 30
Liver biopsy
Normal
Evidence of necroinflammation and/or fibrosis
Monitor
Measure ALT and HBV DNA every 24-48 wk
Treat


B
C


E



How does transient elastography work. Elastography guidelines. Liver elastography guidelines. Transient elastography score. Transient elastography cost.

Vibration-controlled transient elastography (VCTE) can accurately diagnose cirrhosis in most patients with chronic liver disease, particularly those with chronic hepatitis B or C, states a new guideline from the AGA Institute, published in the May issue of Gastroenterology (doi: 10.1053/j.gastro.2017.03.017).However, magnetic resonance elastography (MRE) is somewhat more accurate for detecting cirrhosis in nonalcoholic fatty liver disease, wrote Joseph K. Lim, MD, AGAF, of Yale University in New Haven, Conn., with his associates from the Clinical Guidelines Committee of the AGA. VCTE is convenient but performs unevenly in some liver conditions and is especially unreliable in patients with acute hepatitis, alcohol abuse, food intake within 2-3 hours, congestive heart failure, or extrahepatic cholestasis, the guideline notes. Yet, VCTE remains the most common imaging tool for diagnosing fibrosis in the United States, and the guideline addresses "focused, clinically relevant questions" to guide its use.When possible, clinicians should use VCTE instead of noninvasive serum tests for cirrhosis in patients with chronic hepatitis C, the guideline asserts. In pooled analyses of 62 studies, VCTE detected about 89% of cirrhosis cases (95% confidence interval, 84%-92%), Fibrosis-4 test (FIB-4) detected 87% (95% CI, 74%-94%), and aspartate aminotransferase to platelet ratio index (APRI) detected 77% (95% CI, 73%-81%). The specificity of VCTE (91%) also equaled or exceeded that of FIB-4 (91%) or APRI (78%), the guideline noted.For chronic hepatitis C, MRE had "poorer specificity with higher false-positive rates, suggesting poorer diagnostic performance," compared with VCTE. Lower cost and lower point-of-care availability make VCTE "an attractive solution compared to MRE," the guideline adds. It conditionally recommends VCTE cutoffs of 12.5 kPa for cirrhosis and 9.5 kPa for advanced (F3-F4) liver fibrosis after patients have a sustained virologic response to therapy. The 9.5-kPa cutoff would misclassify only 1% of low-risk patients and 7% of high-risk patients, but noncirrhotic patients (less than 9.5 kPa) may reasonably choose to continue specialty care if they prioritize avoiding "the small risk" of hepatocellular carcinoma over the "inconvenience and risks of continued laboratory and fibrosis testing."For chronic hepatitis B, the guideline conditionally recommends VCTE with an 11.0-kPa cutoff over APRI or FIB-4. In a pooled analysis of 28 studies, VCTE detected cirrhosis with a sensitivity of 86% and a specificity of 85%, compared with 66% and 74%, respectively, for APRI, and 87% and 65%, respectively, for FIB-4. However, the overall diagnostic performance of VCTE resembled that of the serum tests, and clinicians should interpret VCTE in the context of other clinical cirrhosis data, the guideline states.Among 17 studies of VCTE cutoffs in hepatitis B, an 11.0-kPa threshold diagnosed cirrhosis with a sensitivity of 81% and a specificity of 83%. This cutoff would miss cirrhosis in less than 1% of low-risk patients and about 5% of high-risk patients and would yield false positives in 10%-15% of patients. Thus, its cutoff minimizes false negatives, reflecting "a judgment that the harm of missing cirrhosis is greater than the harm of over diagnosis," the authors write.For chronic alcoholic liver disease, the AGA conditionally recommends VCTE with a cirrhosis cutoff of 12.5 kPa. In pooled analyses, this value had a sensitivity of 95% and a specificity of 71%. For suspected compensated cirrhosis, the guideline conditionally suggests a 19.5-kPa cutoff when assessing the need for esophagogastroduodenoscopy (EGD) to identify high-risk esophageal varices. Patients who fall below this cutoff can reasonably pursue screening endoscopy if they are concerned about the small risk of acute variceal hemorrhage, the guideline adds.The guideline also conditionally recommends a 17-kPa cutoff to detect clinically significant portal hypertension in patients with suspected chronic liver disease who are undergoing elective nonhepatic surgeries. This cutoff will miss about 0.1% of very low-risk patients, 0.8% of low-risk patients, and 7% of high-risk patients. Because the failure to detect portal hypertension contributes to operative morbidity and mortality, higher-risk patients might "reasonably" pursue screening endoscopy even if their kPa is below the cutoff, the guideline states.The guideline made no recommendation about VCTE versus APRI or FIB-4 in adults with nonalcoholic fatty liver disease (NAFLD), citing "unacceptable bias" in 12 studies that excluded obese patients, used per-protocol rather than intention-to-diagnose analyses, and ignored "unsuccessful or inadequate" liver stiffness measurements, which are relatively common in NAFLD, the guideline notes. It conditionally recommends MRE over VCTE in high-risk adults with NAFLD, including those who are older, diabetic, or obese (especially with central adiposity) or who have alanine levels more than twice the upper limit of normal. However, it cites insufficient evidence to extend this recommendation to low-risk patients who only have imaging evidence of fatty liver.Overall, the guideline focuses on "routine clinical management issues, and [does] not address comparisons with proprietary serum fibrosis assays, other emerging imaging-based fibrosis assessment techniques, or combinations of more than one noninvasive fibrosis test," the authors note. They also limited VCTE cutoffs to single thresholds that prioritized sensitivity over specificity. "Additional studies are needed to further define the role of VCTE, MRE, and emerging diagnostic studies in the assessment of liver fibrosis, for which a significant unmet medical need remains, particularly in conditions such as NAFLD/[nonalcoholic steatohepatitis]," they add. "In particular, defining the implications for serial liver stiffness measurements over time on management decisions is of great interest."Dr. Muir has served as a consultant for AbbVie, Bristol-Myers Squibb, Gilead, and Merck. Dr. Lim has served as a consultant for Bristol Myers-Squibb, Gilead, Merck, and Boehringer Ingelheim. Dr. Flamm has served as a consultant or received research support from Gilead, Bristol-Myers Squibb, AbbVie, Salix Pharmaceuticals, and Intercept Pharmaceuticals. Dr. Dieterich has presented lectures for Gilead and Merck products. The rest of the authors disclosed no conflicts related to the content of this guideline. $${\text{APRI }} = \left({{\text{ AST }}\left({{\text{ IU}}/{\text{L}}} \right)/{\text{upper level of normal value}}\left({{\text{IU}}/{\text{L}}} \right) \, /{\text{ PLT }}\left({{1}0^{{9}} /{\text{L}}} \right) \, } \right) \times {100;{\text{ FIB}} - {\text{4 Index }} = \, \left({{\text{age}}\left({{\text{year}}} \right) \times {\text{AST }}\left({{\text{ IU}}/{\text{L}}} \right) \, } \right)/({\text{ PLT }}\left({ 1}0^{{9}} /{\text{L }} \right) \times {\text{ALT}}^{{1}/{2}} \left({{\text{IU}}/{\text{L }}} \right);{\text{AST}} - {\text{to}} - {\text{ALT ratio}}({\text{AAR}}) = {\text{ AST }}\left({{\text{ IU}}/{\text{L }}} \right)/{\text{ALT }}\left({{\text{ IU}}/{\text{L }}} \right)$$ SPSS 20.0 software and MedCalc software were used for statistical analysis. Median and inter-quartile range (IQR) were calculated for continued non-normal distribution measurement data as APRI, FIB-4 index, AAR, and LSM values. Categorical variables were expressed as the number and percentage of patients. Liver fibrosis stages F0 to F4 were identified by the gold standard for liver fibrosis according to LB.We classified patients into two groups in two ways: no hepatic fibrosis group (F0) and fibrosis group (F ≥ 1), no significant hepatic fibrosis group (F 0.05 indicates good calibration [9]. Selecting the point corresponding to the maximum Yorden index was considered as the cut-off point. Then, using MedCalc software analyzed ROC curve to obtain the positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (+ LR) and negative likelihood ratio (− LR). The ROC contrast test was used to compare ROC curves. Excel software was used to calculate the Z value based on the comparison of AUC between different groups through the calculation formula (Z = (S1 − S2)/(SE1 ^ 2 + SE22) ^ 0.5), where S1 and S2 indicate the area under ROC curve while SE1 and SE2 signify the corresponding standard error. Then the value of P was calculated by the formula P value = 1 – NORMSDIST (Z value).ResultsAmong 148 CHB children who experienced LB, the youngest one was 0.83 years old and the oldest one was 14.58 years old as well as a median of 3.96 years old. In detail, 6 (4.00%) were under 1 year old, 42 (28.40%) were 1–3 years old, 47 (31.80%) were 3–5 years old, 40 (27.00%) were 5–10 years old, and 13 (8.80%) were above 10 years old.There were 28 (18.92%) cases with F0, 94 (63.51%) cases with F1, 19 (12.84%) cases with F2, 5 (3.38%) cases with F3 and 2 (1.35%) cases with F4 (Table1).Table 1 Patient variablesAmong the 43 patients who underwent both TE and LB, the youngest was 1.08 years old, the oldest was 14.58 years old. 9 (21.00%) were 1–3 years old, 14 (32.50%) were 3–5 years old, 16 (37.20%) were 5–10 years old, and 4 (9.30%) were above 10 years old. There were 9 (20.93%) cases with F0, 23 (53.49%) cases with F1, 8 (18.60%) cases with F2, 2 (4.65%) cases with F3 and 1 (2.33%) case with F4 (Table1).In terms of the disease course, the longest case reached 13 years while the shortest last for 1 week with a median value of 1.08 years. There were 107 males and 41 females, accounting for 72.30% and 27.70%, respectively. The HBeAg positive cases were 136, making up for 91.89%. Mothers of 130 (87.84%) patients had a history of hepatitis B virus infection.The detailed information was shown in Table 1.Based on LSM value, AUC for the diagnosis of liver fibrosis in CHB patients was 0.740 (95% CI: 0.543–0.938), and the cut-off value, sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (+ LR) and negative likelihood ratio (− LR) for fibrosis were 5.9 kPa, 94.12%, 55.56%, 88.90%, 71.40%, 2.12 and 0.11 respectively. AUC for the diagnosis of liver fibrosis in CHB patients based on APRI value was 0.701 (95% CI: 0.603–0.800), the cut-off value, Se, and Sp for fibrosis were 0.50, 60.00%, and 78.57%, respectively. Based on the FIB-4 index, AUC for the diagnosis of liver fibrosis was 0.651 (95% CI: 0.546–0.755), the cut-off value, Se, and Sp for fibrosis were 0.10, 65.00%, and 64.29%, respectively. As for AAR value, AUC for the diagnosis of liver fibrosis was 0.440 (95% CI: 0.328–0.552), the cut-off value, Se, and Sp for fibrosis were 0.90, 35.83%, and 85.71%, respectively. AUC for the diagnosis of liver fibrosis in CHB patients based on a combination of LSM, APRI and FIB-4 was 0.771 (95% CI: 0.580–0.942), which meant that the combination had a good discrimination of liver fibrosis, and a result of the Hosmer-Lemeshow goodness-of-fit test for logistic regression confirmed that the combination was well calibrated ($\chi 2 = 0.170$, $P = 0.264$). The AUC value (0.740) of liver fibrosis diagnosed by LSM value was higher than that of APRI value (0.701), the differences of which showed no statistical significance (Z was equal to 0.346 while P was equal to 0.364). The AUC value (0.740) of liver fibrosis diagnosed by LSM value was higher than that of FIB-4 value (0.651), the differences of which showed no statistical significance (Z was equal to 0.780 while P was equal to 0.218). The AUC value (0.771) of liver fibrosis diagnosed by combining LSM and APRI as well as FIB-4 index was higher than that of LSM value (0.740), which showed no significant difference (Z was equal to 0.225 while P was equal to 0.411). The values of Se, Sp, PPV, NPV, + LR and − LR in the diagnosis of liver fibrosis with biochemistry indicators were listed, all of which were shown in the following Table2, Figs. 2, and 3.Table 2 The area under ROC curve and its relevant parameters of liver fibrosis diagnosed by four non-invasive diagnostic indicators single or in combinationFig. 2The diagnostic values of LSM and combination of LSM, FIB-4 and APRI for liver fibrosis. AUCs of LSM for the diagnosis of liver fibrosis was 0.740 (95% CI: 0.543–0.938); Of FIB-4 combined LSM was 0.758 (95% CI: 0.555–0.961); Of APRI combined LSM was 0.761 (95% CI: 0.580–0.942); Of combination of LSM, APRI and FIB-4 was 0.771 (95% CI: 0.580–0.942)Fig. 3The diagnostic values of APRI, FIB-4 and AAR for liver fibrosis. AUCs of APRI for the diagnosis of liver fibrosis was 0.701 (95% CI: 0.603–0.800); Of FIB-4 was 0.651 (95% CI: 0.546–0.755); Of AAR was 0.440 (95% CI: 0.328–0.552); Of the combination of APRI and FIB-4 was 0.703 (95% CI: 0.605–0.801)AUC for the diagnosis of significant liver fibrosis in CHB patients based on LSM value was 0.849 (95% CI: 0.713–0.986), and the cut-off value, Se, Sp, PPV, NPV, + LR and − LR for significant liver fibrosis were 8.4 kPa, 81.82%, 78.12%, 56.20%, 92.60%, 3.74 and 0.23 respectively. AUC for the diagnosis of significant liver fibrosis in CHB patients based on APRI value was 0.701 (95% CI: 0.591–0.810), the cut-off value, Se, and Sp for fibrosis were 0.76, 61.54%, and 72.95%, respectively. Based on the FIB-4 index, AUC for the diagnosis of significant liver fibrosis was 0.509 (95% CI: 0.388–0.630), and the cut-off value, Se, and Sp for fibrosis were 0.08, 84.62%, and 27.87%, respectively. As for AAR value, AUC for the diagnosis of significant liver fibrosis was 0.458 (95% CI: 0.329–0.586), the cut-off value, Se, and Sp for fibrosis were 1.13, 69.23%, and 48.36%, respectively. AUC for the diagnosis of significant liver fibrosis in CHB patients based on a combination of LSM, APRI and FIB-4 was 0.869 (95% CI: 0.741–0.998), which means that the combination had a good discrimination of significant liver fibrosis, and a result of the Hosmer-Lemeshow goodness-of-fit test for logistic regression confirmed that the combination was well calibrated ($\chi 2 = 4.619$, $P = 0.797$). The AUC value (0.849) of significant liver fibrosis based on LSM value was higher than that of APRI value (0.701), the differences of which reached statistical significance (Z were equal to 1.650 while P were equal to 0.049). The AUC value (0.849) of significant liver fibrosis based on LSM value was higher than that of FIB-4 (0.509),the differences of which reached statistical significance (Z were equal to 3.636 respectively while P were equal to 0.000). The AUC value (0.869) of significant liver fibrosis by the combination of LSM value and APRI value as well as FIB-4 index was higher than that of LSM value (0.849). There were no significant statistical differences in this case when Z was equal to 0.208 and P was equal to 0.418. The values of Se, Sp, PPV, NPV, + LR, and − LR in the diagnosis of significant liver fibrosis with biochemistry indicators were listed. They were clearly shown in the following Table 3, Figs. 4, and 5.Table 3 The area under ROC curve and its relevant parameters of significant liver fibrosis diagnosed by four non-invasive diagnostic indicators single or in combinationFig. 4The diagnostic values of LSM and a combination of LSM, FIB-4 and APRI for significant liver fibrosis. AUCs of LSM for the diagnosis of significant liver fibrosis was 0.849 (95% CI: 0.713– 0.986); Of FIB-4 combined LSM was 0.855 (95% CI: 0.723–0.986); Of APRI combined LSM was 0.866 (95% CI: 0.740–0.993); Of combination of LSM, APRI and FIB-4 was 0.869 (95% CI: 0.741–0.998)Fig. 5The diagnostic values of APRI, FIB-4 and AAR for significant liver fibrosis. AUCs of APRI for the diagnosis of significant liver fibrosis was 0.701 (95% CI: 0.591–0.810); Of FIB-4 was 0.509 (95% CI: 0.388–0.630); Of AAR was 0.458 (95% CI: 0.329–0.586); Of the combination of APRI and FIB-4 was 0.684 (95% CI: 0.565–0.802)Page 2The diagram of patient recruitment

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