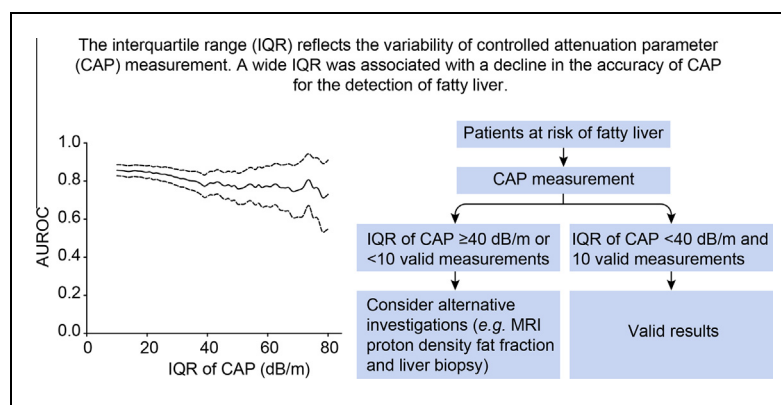


# Validity criteria for the diagnosis of fatty liver by M probe-based controlled attenuation parameter

## Graphical abstract



## Highlights

- Controlled attenuation parameter (CAP) can detect fatty liver with moderate accuracy.
- The interquartile range (IQR) of CAP reflects its measurement variability.
- The accuracy of CAP declines when its IQR exceeds 40 dB/m.
- The accuracy of CAP is not affected by high transaminase or bilirubin levels.

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## Lay summary

Controlled attenuation parameter (CAP) is measured by transient elastography (TE) for the detection of fatty liver. In this large study, using liver biopsy as a reference, we show that the variability of CAP measurements based on its interquartile range can reflect the accuracy of fatty liver diagnosis. In contrast, other clinical factors such as adiposity and liver enzyme levels do not affect the performance of CAP.

## Validity criteria for the diagnosis of fatty liver by M probe-based controlled attenuation parameter

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**Background & Aims:** Controlled attenuation parameter (CAP) can be performed together with liver stiffness measurement (LSM) by transient elastography (TE) and is often used to diagnose fatty liver. We aimed to define the validity criteria of CAP.

**Methods:** CAP was measured by the M probe prior to liver biopsy in 754 consecutive patients with different liver diseases at three centers in Europe and Hong Kong (derivation cohort, n = 340; validation cohort, n = 414; 101 chronic hepatitis B, 154 chronic hepatitis C, 349 non-alcoholic fatty liver disease, 37 autoimmune hepatitis, 49 cholestatic liver disease, 64 others; 277 F3-4; age  $52 \pm 14$ ; body mass index  $27.2 \pm 5.3$  kg/m<sup>2</sup>). The primary outcome was the diagnosis of fatty liver, defined as steatosis involving  $\geq 5\%$  of hepatocytes.

**Results:** The area under the receiver-operating characteristics curve (AUROC) for CAP diagnosis of fatty liver was 0.85 (95% CI 0.82–0.88). The interquartile range (IQR) of CAP had a negative correlation with CAP ( $r = -0.32$ ,  $p < 0.001$ ), suggesting the IQR-to-median ratio of CAP would be an inappropriate validity parameter. In the derivation cohort, the IQR of CAP was associated with the accuracy of CAP (AUROC 0.86, 0.89 and 0.76 in patients with IQR of CAP  $< 20$  [15% of patients], 20–39 [51%], and  $\geq 40$  dB/m [33%], respectively). Likewise, the AUROC of CAP in the validation cohort was 0.90 and 0.77 in patients with IQR

of CAP  $< 40$  and  $\geq 40$  dB/m, respectively ( $p = 0.004$ ). The accuracy of CAP in detecting grade 2 and 3 steatosis was lower among patients with body mass index  $\geq 30$  kg/m<sup>2</sup> and F3-4 fibrosis.

**Conclusions:** The validity of CAP for the diagnosis of fatty liver is lower if the IQR of CAP is  $\geq 40$  dB/m.

**Lay summary:** Controlled attenuation parameter (CAP) is measured by transient elastography (TE) for the detection of fatty liver. In this large study, using liver biopsy as a reference, we show that the variability of CAP measurements based on its interquartile range can reflect the accuracy of fatty liver diagnosis. In contrast, other clinical factors such as adiposity and liver enzyme levels do not affect the performance of CAP.

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### Introduction

Non-alcoholic fatty liver disease (NAFLD) is currently the most common chronic liver disease worldwide and has become an important cause of end-stage liver disease and hepatocellular carcinoma.<sup>1–4</sup> The presence of fatty liver and metabolic syndrome in patients with chronic viral hepatitis is also associated with increased risk of cirrhosis and hepatocellular carcinoma.<sup>5–8</sup> Abdominal ultrasonography is commonly used to diagnose fatty liver, but it cannot reliably diagnose mild steatosis, and its performance is suboptimal in obese patients. Recently, the controlled attenuation parameter (CAP) was developed as a new test for fatty liver. It is based on the physical phenomenon that the amplitude of ultrasound waves is attenuated more rapidly when they traverse across a steatotic liver. In previous studies, CAP had moderate to good accuracy for fatty liver detection, when compared to histology or magnetic resonance spectroscopy.<sup>9–13</sup> CAP is measured simultaneously with liver stiffness (LSM) using

Keywords: FibroScan; Liver stiffness measurement; Non-alcoholic fatty liver disease; Hepatic steatosis; Liver biopsy; Diagnostic accuracy.

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