

Quantitative ultrasound for liver steatosis & fibrosis in a health screening Program

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Key Message (Why is it needed?)

- ① The clinical significance of diagnosing fatty liver disease is increasing along with the rising prevalence of metabolic dysfunction-associated steatotic liver disease (MASLD).
- ② Identify patients in the "at risk metabolic dysfunction-associated steatohepatitis (MASH)" stage through fatty liver screening, allowing for systematic and quantitative management of fatty liver.
- ③ Unlike Fibroscan, a single ultrasound device can perform basic abdominal ultrasound exams as well as additional tests such as quantitative ultrasound for liver steatosis (QUS (TAI™, TSI™)) and liver fibrosis (S-Shearwave Imaging™) which is shear wave elastography. It is possible to measure on the appropriate region.
- ④ Based on the experience at Samsung medical center, Samsung's QUS (TAI™, TSI™) and S-Shearwave Imaging™ are useful and effective screening tool that can accurately quantify the degree of intrahepatic fat deposition and even detect fibrosis. [4]
- ⑤ Differentiate screening program for MASLD with non-invasive, accurate fatty liver quantification ultrasound and transverse elastography ultrasound will be possible.

Why is MASLD/MASH important?

Metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as non-alcoholic fatty liver disease (NAFLD), is characterized by the accumulation of excess triglycerides in the liver along with at least one cardiometabolic risk factor. [1]

The term MASLD comprises different conditions, including isolated liver steatosis such as metabolic dysfunction associated steatotic liver (MASL), metabolic dysfunction associated steatohepatitis (MASH), fibrosis, and cirrhosis. [1]

Over time, MASLD can cause inflammation of the liver tissue (metabolic-associated steatohepatitis), liver fibrosis, and ultimately cirrhosis. Early detection and management of MASLD can help prevent progression to more severe liver fibrosis and improve overall liver health. [1]

Who should be screened for MASLD/MASH and How?

Who should be screened?

Healthcare providers may consider strategies to identify MASLD with liver fibrosis in individuals with cardiometabolic risk factors, liver enzyme abnormalities, and/or radiological signs of hepatic steatosis. [1]

In particular, healthcare providers should look for MASLD with liver fibrosis in individuals with (A) type 2 diabetes, (B) abdominal obesity with one or more additional metabolic risk factors, or (C) abnormalities on liver function tests. [1]

Early diagnosis and proper management of fibrosis can potentially prevent progression to cirrhosis and its complications, supporting the rationale for screening these high-risk populations. [1]

How can screening be done?

Since this is a gradually progressing disease, the primary focus should be on identifying individuals who are at the highest risk of developing MASLD-related complications in the near future. Thus, screening efforts should primarily target those with MASH and at least stage F2 fibrosis, or those with fibrosis alone (stage F2 or higher, or F3 or higher). [3]

Comorbid conditions associated with MASLD

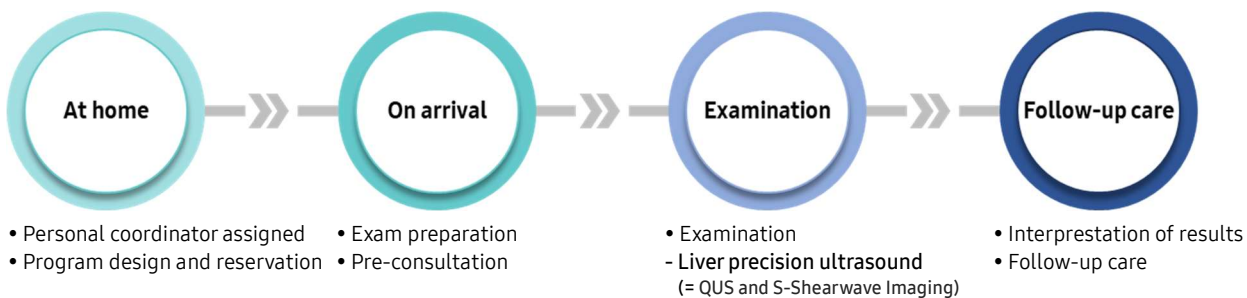
Laboratory tests and physical examinations are recommended at the initial diagnosis of MASLD and during regular follow-up to determine if there are any associated comorbidities.

The related metabolic dysfunction factors are as follows: [1]

- Obesity
- Type 2 diabetes or insulin resistance
- Dyslipidemia
- Kidney disease
- Cardiovascular disease
- Atherosclerosis
- Obstructive sleep apnea
- Polycystic ovary syndrome

Samsung Medical Center Health screening Programs

Procedure

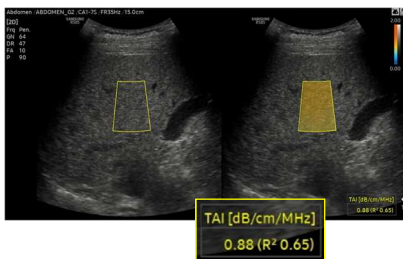


Liver precision ultrasound in a health screening Programs

Liver steatosis quantification

TAI™

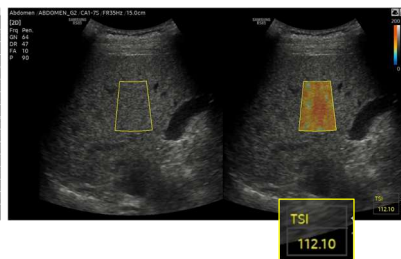
Provides quantitative tissue attenuation measurement to assess Steatosis, the fatty changes in liver



Liver steatosis quantification

TSI™

Provides quantitative tissue scatter distribution Measurement to assess Steatosis



Liver fibrosis quantification

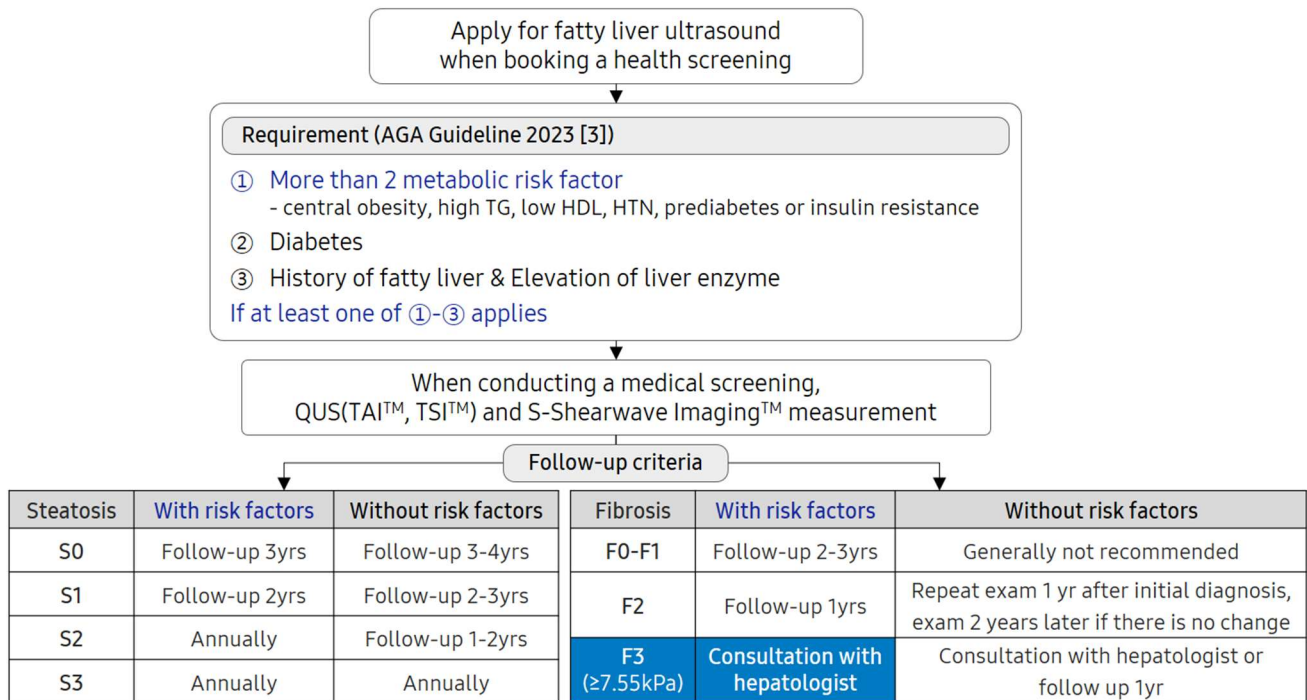
S-Shearwave Imaging™

Exciting shear wave using focused ultrasound beam
Measuring shear wave propagation using ultrafast imaging
Calculating shear wave speed and shear modulus



- Liver precision ultrasound includes TAI™, TSI™ and S-Shearwave Imaging™
- Ultrasound's quantitative fatty liver fraction value is calculated automatically. This intuitively shows the fat fraction of liver in percentages such as MRI-PDFF.
 - After the QUS (TAI™, TSI™) scan, the report displays the fat fraction value (%) of liver similar to MRI-PDFF
- Billable to patient as statutory non-reimbursable expense in Korea

Liver precision ultrasound workflow



The Cut-off tables of QUS (TAI™, TSI™) & S-Shearwave Imaging™

Steatosis grade	TAI™ (dB/cm/MHz)	TSI™	Fibrosis grade	S-Shearwave Imaging™ (kPa)
S1 (MRI-PDFF ≥ 5%)	0.708	98.78	F0-F1	~ 5.82
S2 (MRI-PDFF ≥ 10%)	0.748	99.05	F2	5.83 ~ 7.54
S3 (MRI-PDFF ≥ 20%)	0.835	101.22	F3	7.55 ~ 9.57

The cut-off table values of steatosis grades are derived from clinical research conducted at Samsung Medical Center. Depending on the hospital environment, cut-off values can be calculated and used separately.

The cut-off values of fibrosis grades are referred to previous research result. [5]

What to do with the result of the screening?

For patients with simple fatty liver classified as S3, it is advisable to undergo annual follow-up examinations at a health screening center, regardless of the presence of metabolic dysfunction factors. In this regard, Quantitative fatty liver ultrasound, closely correlates with MRI-PDFF, providing a clear understanding of the fatty liver severity, thus enhancing its clinical relevance.

Patients exhibiting advanced fibrosis (F3) should be referred to outpatient care following liver fibrosis treatment guidelines. Given the inherent measurement errors of the examination method, the referral criterion for the SWE test is set at ≥ 7.55 kPa. While there are no specific follow-up intervals recommended for the SWE test, guidelines suggest that for the FIB-4 test, a blood test, follow-ups should occur every 1-2 years for patients with metabolic risk factors and every 2-3 years for those without. [6]

Based on the experience of operating Samsung Medical Center Health screening program, integrating precision liver ultrasound programs into health screening initiatives could significantly reduce individual medical expenses and stabilize health insurance finances. The considerable socio-economic burden of MASLD represents a global health challenge requiring attention from medical societies and policymakers. Systematic screening and early management of MASLD using advanced techniques like quantitative ultrasound (QUS) and shear wave elastography (S-Shearwave Imaging™) are essential for improving patient outcomes and mitigating the economic impact of the disease. Hence, proactive measures and collaborative efforts are crucial to combat the growing prevalence of MASLD worldwide.

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