Siemens Healthineers

Presenters:

Adam Borden
Katherine Soreng
Melanie Pollan

Code: 0014M

Code Descriptor: Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years

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Fibrosis is key for disease progression in most forms of chronic liver disease (CLD)

"In particular**, significant fibrosis at the time of diagnosis is the most important histological feature associated with mortality in NASH, regardless of the presence or severity of other histologic features."**

"In addition, with the advent of potential emergence of potent anti-fibrotic agents for the treatment of NASH, **the accurate assessment of liver fibrosis becomes even more pertinent, not only for identifying suitable patients for treatment**, but also in the evaluation of treatment efficacy."

CMS Annual Lab Meeting, June 22, 2020
Siemens Healthineers, Presenters (Borden, Adam; Soreng, Katherine; Pollan, Melanie)

Cheah, MCC et al. Journal of Clinical and Translational Hepatology 2017 vol. 5 | 261–271

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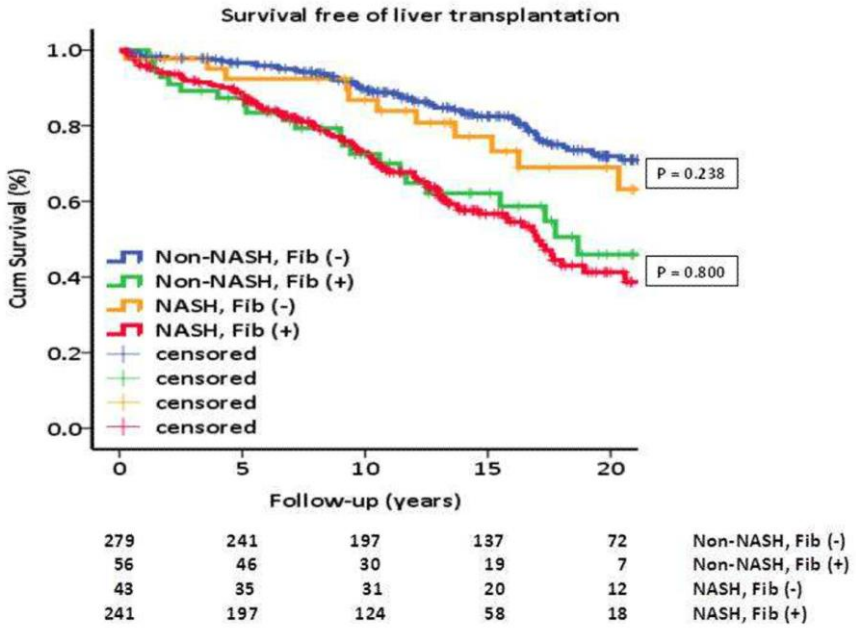
Liver fibrosis, not NASH diagnosis, is associated with liver disease progression and outcomes



(The chart to the left shows survival free of liver transplantation over 20 years grouped by NASH and non-NASH and separated by presence or absence of fibrosis. Survival free of liver transplantation was similar in those without fibrosis and similar among those with fibrosis regardless of having or not the diagnosis of NASH)

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Angulo P et al. Gastroenterology 2015; vol. 2 | 389-397

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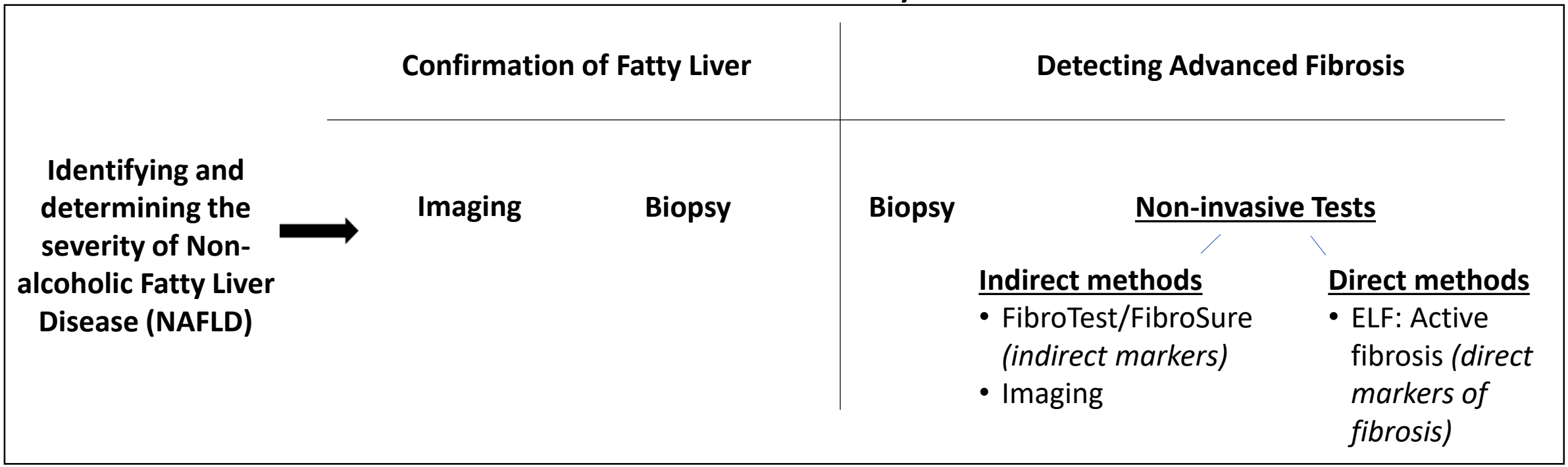

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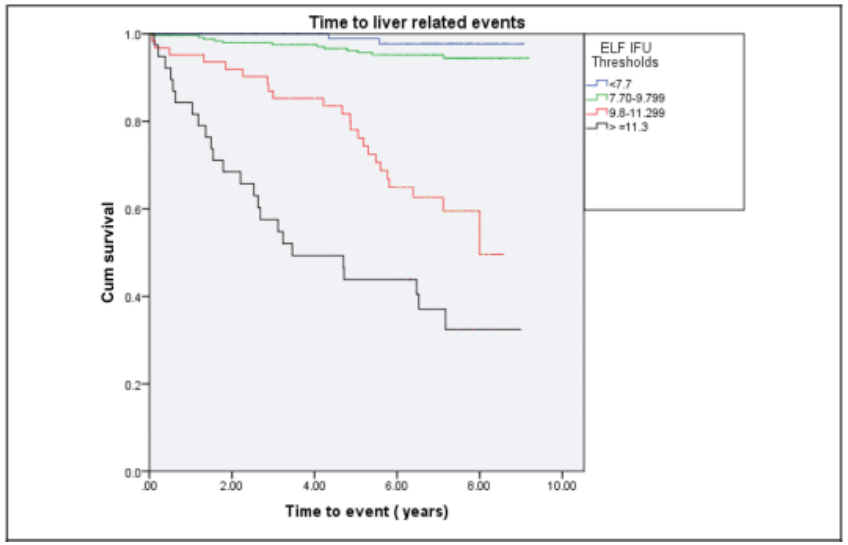
ELF Score Indicates Fibrosis Severity

None to Mild <7.7	Moderate ≥7.7–<9.8
Severe ≥9.8	Cirrhosis ≥11.3†

Fibrosis assessment using ELF predicts likelihood of liver-related events and mortality (mixed CLD including NAFLD)



(The chart to the left displays Kaplan–Meier survival curves for survival free of liver-related events including complications of portal hypertension, liver cancer, liver transplantation, and death for patients with ELF scores in the ranges <7.70, 7.7–9.79, 9.80-11.29, and ≥11.30.)

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Day J et al. J Appl Lab Med 2019; vol. 3 | 815-826

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Comparison of codes for score-based liver fibrosis tests 0003M: NASH FibroSure® 0014M: ELF™	0003M: NASH FibroSure®	0014M: ELF™
	• Relies on ten (10) **routine *(and typically low-cost)*** biochemical assays that act as **indirect** markers of fibrosis • Indirect markers can reflect, but not directly detect fibrosis by assessing for markers of inflammation and liver dysfunction	• Relies on three (3) **specialized** immunoassays that act as **direct** markers of fibrosis • As fibrosis is dynamic (progression/repair), the ELF test detects overall fibrosis using two (2) markers directly involved in scarring (Hyaluronic acid and PIIINP) and one that inhibits the ability to repair (TIMP-1)

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https://www.labcorp.com/tests/550140/nash-fibrosure

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Costs & Charges → The ELF Test is currently performed out of one site at the Siemens Healthcare Laboratory* in California → **List Price: $250**

Received Breakthrough Status from the FDA and is currently being reviewed by the Agency

**Siemens Healthcare Laboratory (SHL) ELF Test Testing Service is developed, and performance characteristics are determined by Siemens Healthcare Laboratory, LLC. The ELF Test has not been cleared or approved by the US Food and Drug Administration. SHL is regulated under CLIA as qualified to perform high-complexity testing. The ELF Testing Service performed by SHL is used for clinical purposes and should not be regarded as investigational use only or research use only.*

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Public Comment	**Rationale**
Crosswalk to a multiplier of 0.35 of 0003M; CY2020 NLA = $503.40 x 0.35 = $176.19	0014M is similar in clinical use to 0003M. Three (3) analytes in code 0014M versus ten (10) analytes in code 0003M, but 0014M is a specialized immunoassay that has more costs and resources, so recommend a multiplier of 0.35 of 0003M.