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GASTROENTEROLOGY & HEPATOLOGY

BOARD REVIEW 2023

September 7-10, 2023



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~~NONALCOHOLIC FATTY LIVER DISEASE~~

METABOLIC ASSOCIATED STEATOTIC LIVER DISEASE (MASLD)

BIOMARKERS, SCREENING & TREATMENT

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DISCLOSURES

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- TaiwanJ
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Speaker's Bureau/ Education

- MedScape
- Simply Speaking NASH
- Terra Firma, LLC
- Clinical Care Options
- Fishawack, Inc
- Chronic Liver Disease Foundation

No off-label use of pharmaceutical products will be discussed.

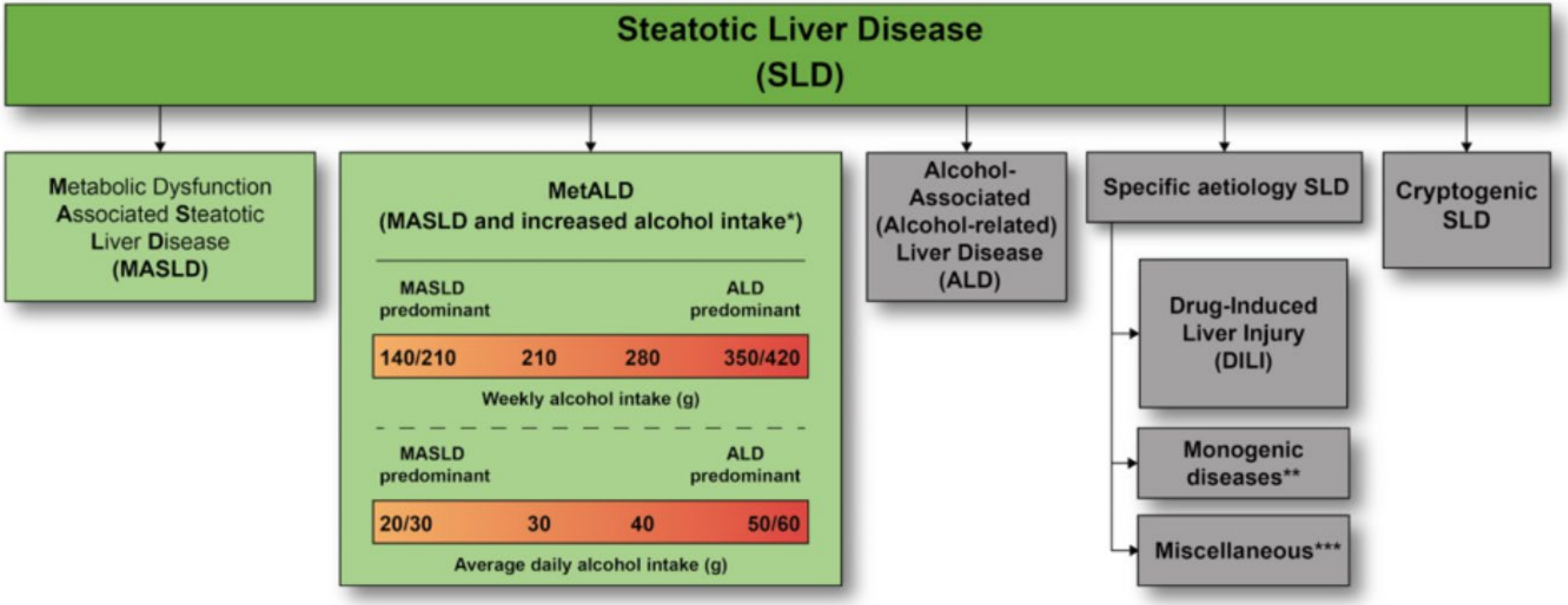
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LEARNING OBJECTIVE

- Define nonalcoholic fatty liver disease (NAFLD) or what is now metabolic dysfunction associated fatty liver disease (MASLD)
- Review disease pathogenesis
- Understand epidemiology of disease and risk factors for fibrosis progression
- Discuss clinical presentation and diagnosis
- Discuss approaches to treatment in absence of FDA approved therapy

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Introducing MASLD and MetALD

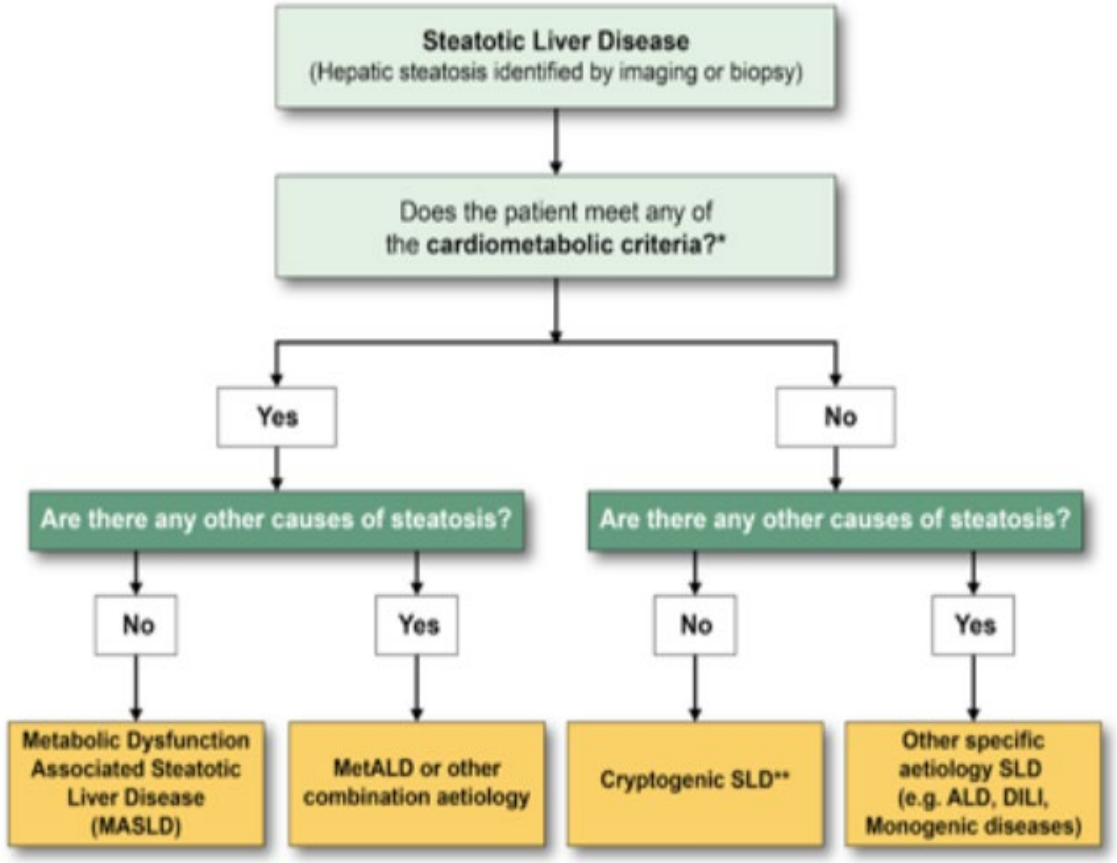


*Weekly intake 140-350g female, 210-420g male (average daily 20-50g female, 30-60g male)
**e.g. Lysosomal Acid Lipase Deficiency (LALD), Wilson disease, hypobetalipoproteinemia, inborn errors of metabolism
***e.g. Hepatitis C virus (HCV), malnutrition, celiac disease

Rinella M, et al. Hepatology. 2023

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MASLD DIAGNOSTIC CRITERIA



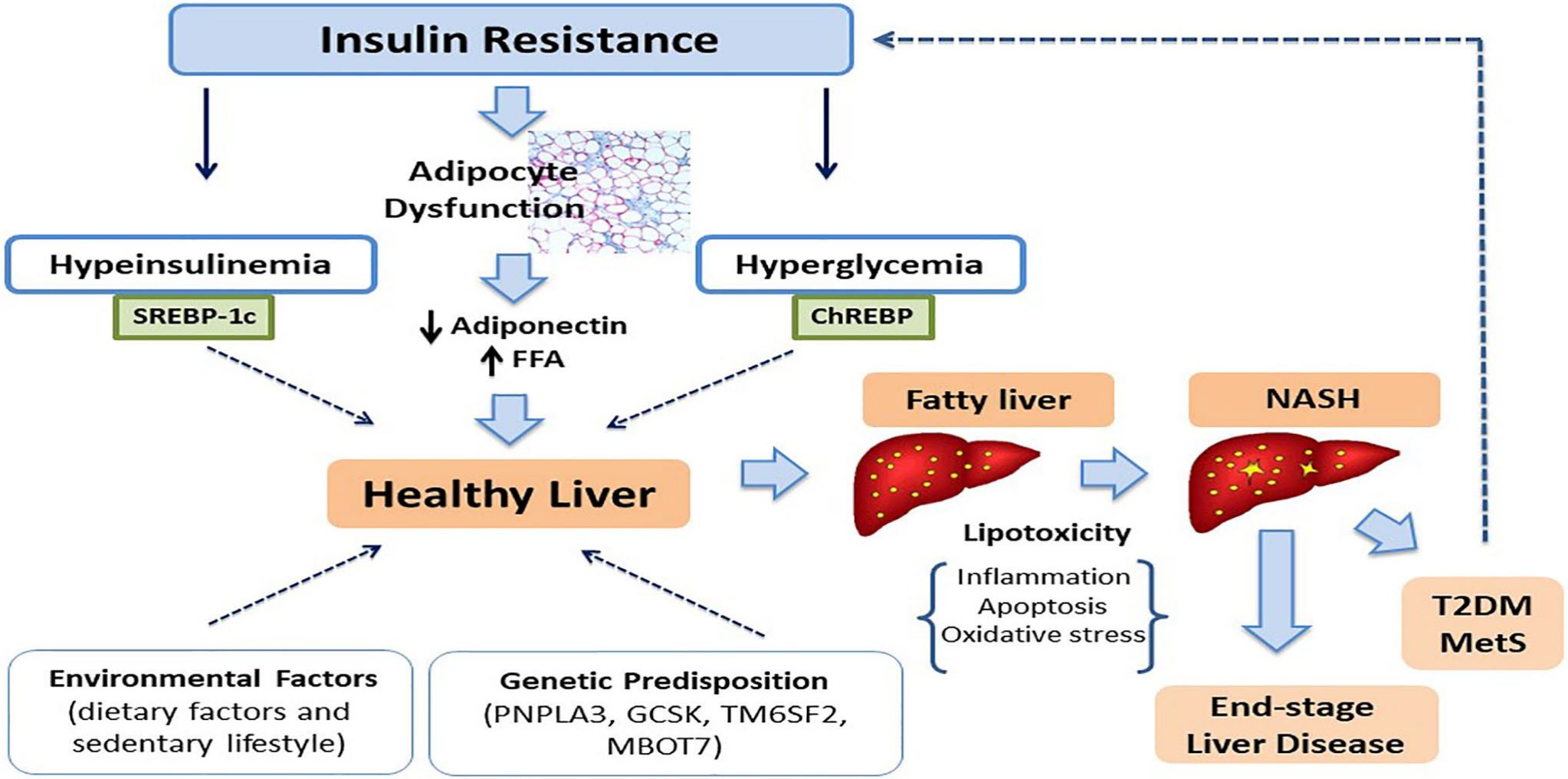
*Cardiometabolic criteria

Adult Criteria	Pediatric Criteria
At least 1 out of 5:	At least 1 out of 5:
☐ BMI ≥ 25 kg/m² [23 Asia] OR WC > 94 cm (M) 80 cm (F) OR ethnicity adjusted	☐ BMI ≥ 85th percentile for age/sex [BMI z score ≥ +1] OR WC > 95th percentile OR ethnicity adjusted
☐ Fasting serum glucose ≥ 5.6 mmol/L [100 mg/dL] OR 2-hour post-load glucose levels ≥ 7.8 mmol/L [≥140 mg/dL] OR HbA1c ≥ 5.7% [39 mmol/L] OR type 2 diabetes OR treatment for type 2 diabetes	☐ Fasting serum glucose ≥ 5.6 mmol/L [≥ 100 mg/dL] OR serum glucose ≥ 11.1 mmol/L [≥ 200 mg/dL] OR 2-hour post-load glucose levels ≥ 7.8 mmol [140 mg/dL] OR HbA1c ≥ 5.7% [39 mmol/L] OR already diagnosed/treated type 2 diabetes OR treatment for type 2 diabetes
☐ Blood pressure ≥ 130/85 mmHg OR specific antihypertensive drug treatment	☐ Blood pressure age < 13y, BP ≥ 95th percentile OR ≥ 130/80 mmHg (whichever is lower); age ≥ 13y, 130/85 mmHg OR specific antihypertensive drug treatment
☐ Plasma triglycerides ≥ 1.70 mmol/L [150 mg/dL] OR lipid lowering treatment	☐ Plasma triglycerides < 10y, ≥ 1.15 mmol/L [≥ 100 mg/dL]; age ≥ 10y, ≥ 1.70 mmol/L [≥ 150 mg/dL] OR lipid lowering treatment
☐ Plasma HDL-cholesterol ≤ 1.0 mmol/L [40 mg/dL] (M) and ≤ 1.3 mmol/L [50 mg/dL] (F) OR lipid lowering treatment	☐ Plasma HDL-cholesterol ≤ 1.0 mmol/L [≤ 40 mg/dL] OR lipid lowering treatment

Rinella M, et al. Hepatology. 2023

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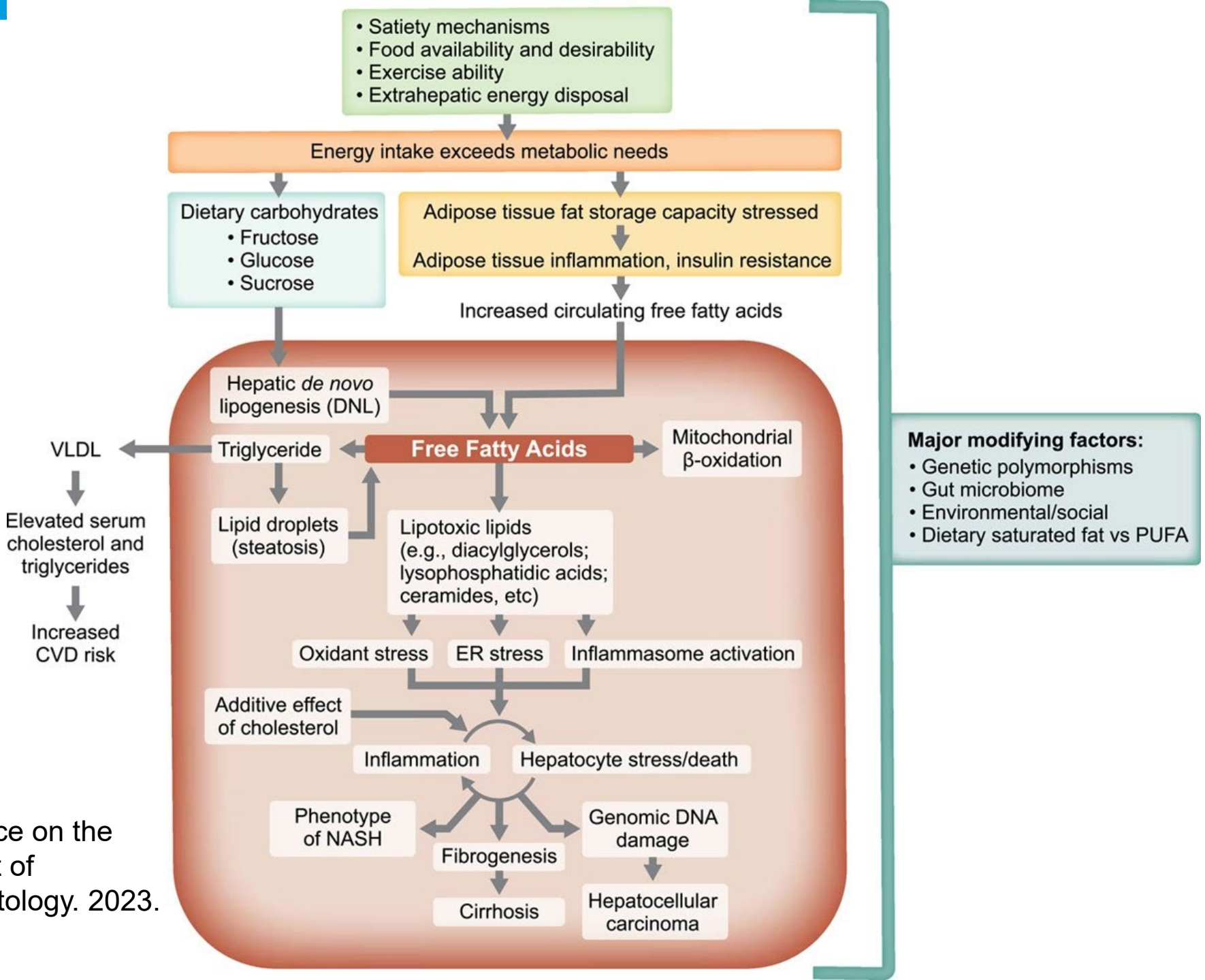
INSULIN RESISTANCE STRONGLY ASSOCITED WITH OF NAFLD / NASH



Scapaticci S, et al. Frontiers in Endo. 2021

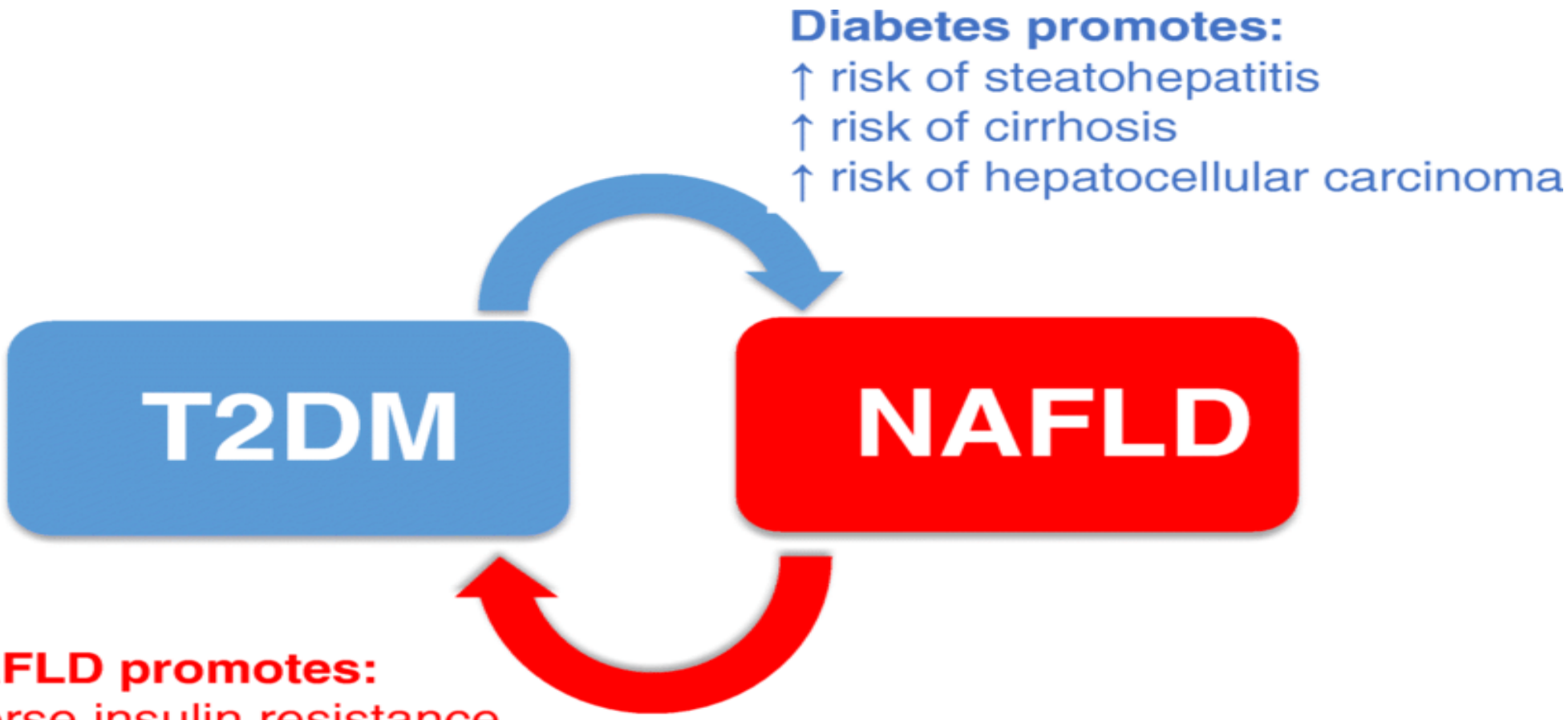
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PATHOGENIC DRIVERS OF NAFLD (MASLD)



Rinella et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023.

T2DM AND NAFLD ARE INTERCONNECTED



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Budd & Cusi. Curr Diab Rep. 2020

GENETIC VARIANTS ASSOCIATED WITH NAFLD AND PROGRESSION TO NASH

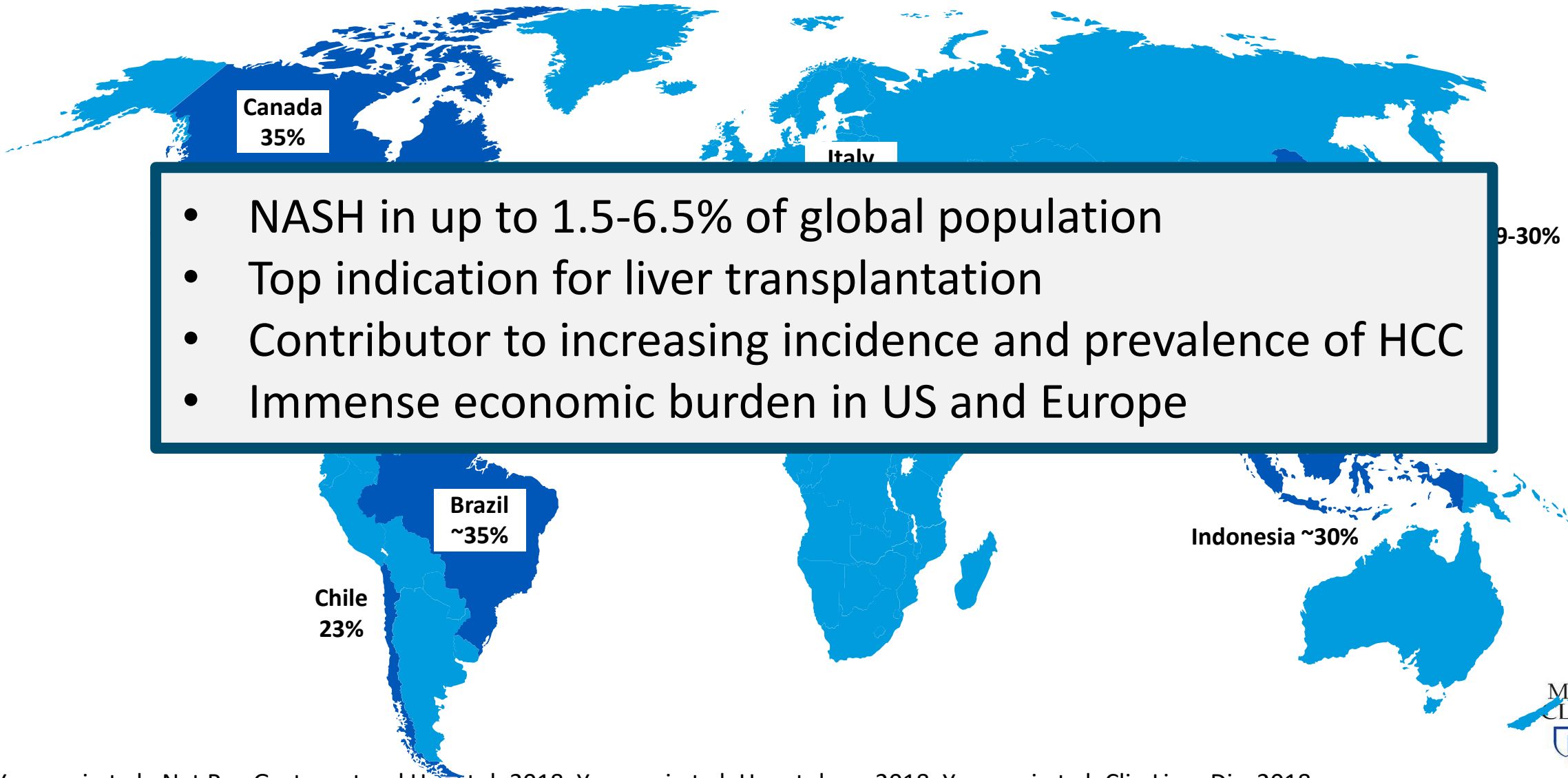
	Variant	Function	Variant Effect	Phenotype
PNPLA3	rs738409	Lipid droplet remodeling	Impaired mobilization of Fas from lipid droplets	↑NAFLD, NASH, fibrosis, and HCC
TM6SF2	rs585542926	VLDL secretion	Decreased VLDL secretion, hepatic triglyceride accumulation	↑NAFLD, NASH, and fibrosis
GCKR	rs1260326	Regulation of de novo lipogenesis	Increased de novo lipogenesis	↑NAFLD, NASH, and fibrosis
MBOAT7	rs641738	Remodeling of phosphatidylinositol	Increase hepatic inflammation	↑NAFLD, NASH, fibrosis, and HCC
HSD17B13	rs72613567	Unknown, localized to hepatocyte lipid droplets	Decreased HSD17B13 and PNPLA3 production	↓NASH and fibrosis

PNPLA3: patatin-like phospholipase domain-containing protein 3.
TM6SF2: transmembrane 6 superfamily member 2.
GCKR: glucokinase regulatory protein.
MBOAT7: membrane-bound O-acyltransferase domain containing 7.

Danford CJ, et al. *J Biomed Res*. 2018;32:389-400.
Eslam M, et al. *J Hepatol.* 2018;68:268-279.
Kovalic AJ, et al. *J Clin Exp Hepatol*. 2018;8:390-402.
Abul-Husn NS, et al. *N Engl J Med*. 2018;378:1096-1106.
Barbara M, et al. *Hepatobiliary Surg Nutr*. 2018;7:372-381.

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NAFLD (MASLD) Is Endemic—A Global Epidemic



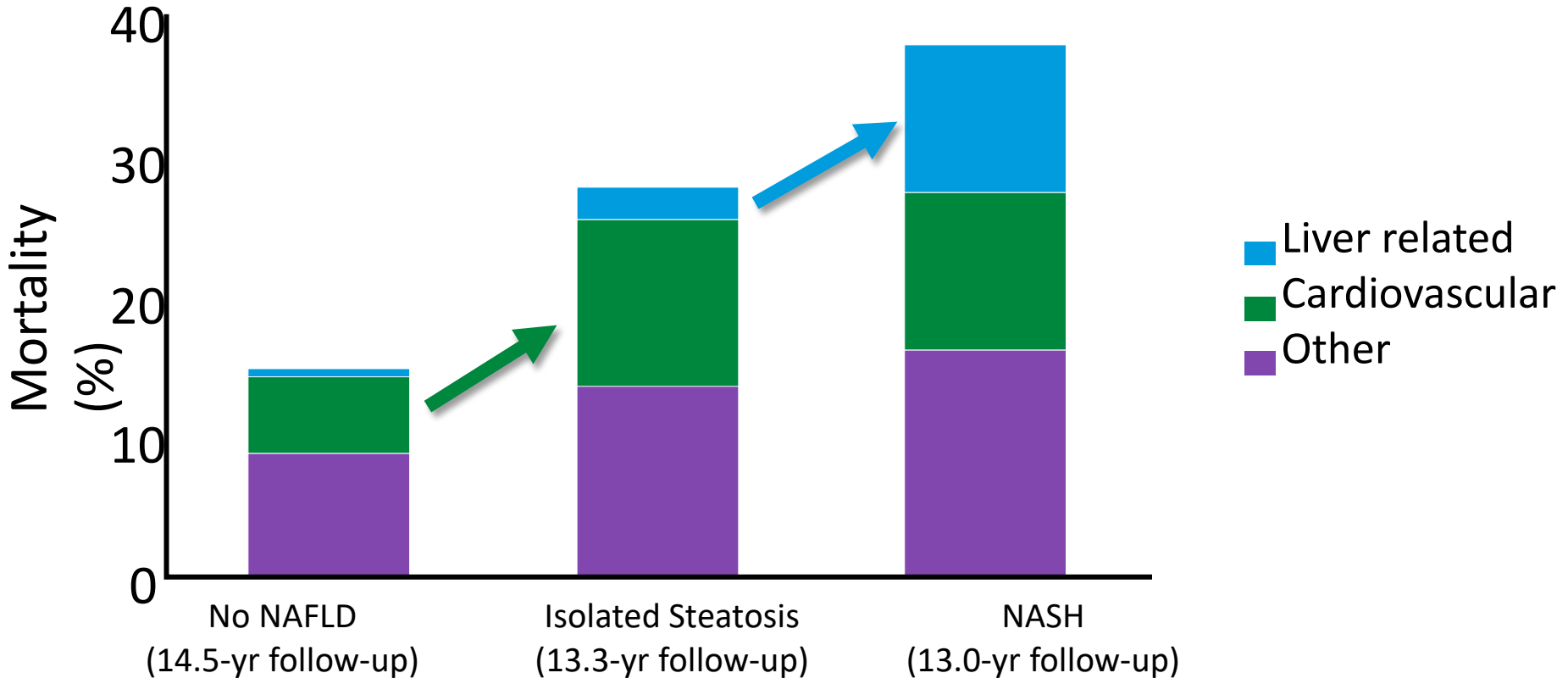
- NASH in up to 1.5-6.5% of global population
- Top indication for liver transplantation
- Contributor to increasing incidence and prevalence of HCC
- Immense economic burden in US and Europe

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Younossi et al. Nat Rev Gastroenterol Hepatol. 2018; Younossi et al. Hepatology. 2018; Younossi et al. Clin Liver Dis. 2018

MORTALITY RISK ASSOCIATED WITH ISOLATED STEATOSIS AND NASH

- Analysis of all-cause mortality in 6 separate studies among patients without NAFLD vs with and without NASH
  - NAFLD determined by ultrasound; NASH determined by liver biopsy



Bril. Endocrinol Metab Clin N Am. 2016;45:765.

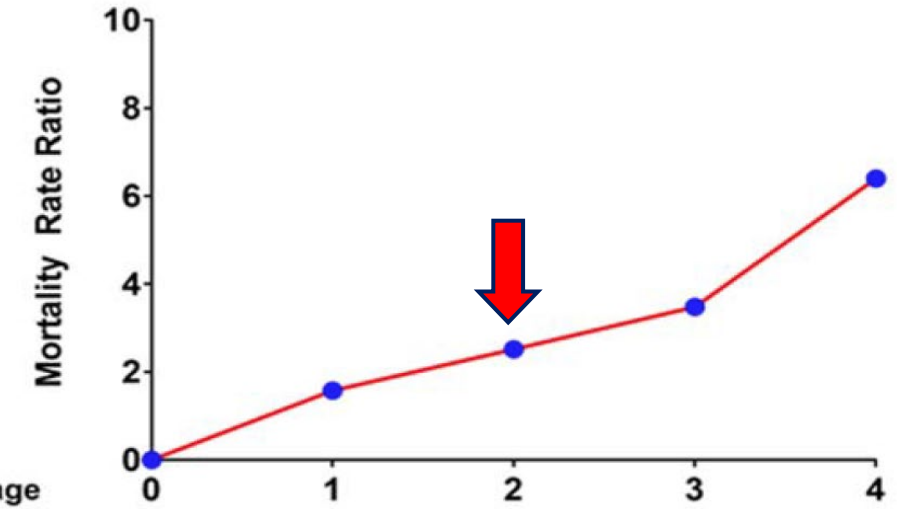
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Severity of liver fibrosis is associated with long-term outcomes

Increased risk of mortality by fibrosis stage in NAFLD: systematic review and meta-analysis

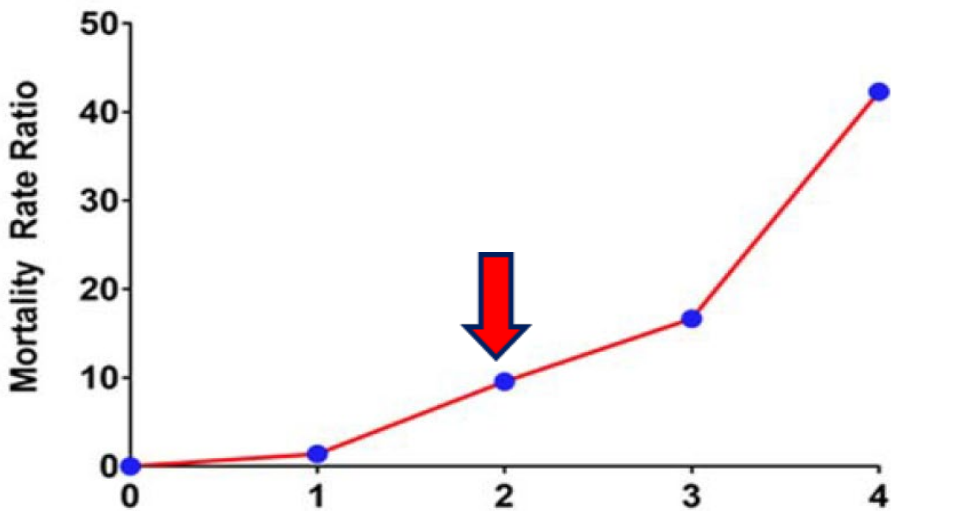
Five studies including 1,495 NAFLD patients equating to 17,452 patient-years follow-up[1]

All-cause mortality



Fibrosis Stage	0	1	2	3	4
Mortality Rate Ratio (95% Confidence Interval)		1.58 (1.19-2.11)	2.52 (1.85-3.42)	3.48 (2.51-4.83)	6.40 (4.11-9.95)
Mortality Rate (per 1,000 PYF)	15.2	17.1	27.9	36.0	45.8

Liver-related mortality



	0	1	2	3	4
		1.41 (0.17-11.95)	9.57 (1.67-54.93)	16.69 (2.92-95.36)	42.30 (3.51-510.34)
	0.30	0.64	4.28	7.92	23.3

MRR=mortality rate ratio; NAFLD=non-alcoholic fatty liver disease; PYF=patient years of follow-up.

1. Dulai P et al. *Hepatology.* 2017;65(5):1557-1565. 2. Mezale D et al. *Non-Alcoholic Steatohepatitis, Liver cirrhosis and Hepatocellular Carcinoma: The Molecular Pathways, Liver Cirrhosis-Update and Current Challenges*. doi:10.5772/intechopen.68771.

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PRIMARY RISK FACTORS FOR METABOLIC DYSFUNCTION ASSOCIATED FATTY LIVER DISEASE (MASLD)

- Central obesity (waist circumference > 102 cm ♂ and 88 cm for♀ women)
- Overweight / obese status (BMI ≥ 30 kg/m^2)
- Insulin resistance
- Impaired glycemic control (fasting glucose > 100 mg/dl)
- Type 2 diabetes mellitus
- Hypercholesterolemia
- Hypertriglyceridemia
- Low HDL cholesterol
- Hypertension
- Hypothyroidism
- Polycystic ovarian syndrome

About 75% of patients with lean NAFLD (BMI < 25 kg/m^2 have at least 1 feature of metabolic syndrome

Rinella M, et al. Hepatology 2023

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OTHER CAUSES OF NAFLD

NOT ASSOCIATED WITH METABOLIC SYNDROME

Nutritional	Protein-calorie malnutrition, Total parenteral nutrition Rapid weight loss	
Medications	Glucocorticoids Estrogens Tamoxifen Amiodarone Methotrexate	Zidovudine Valproic acid Tetracycline Aspirin Diltiazem
Toxins	Petrochemicals Phosphorus *Amanita phalloides* mushroom poisoning *Bacillus cereus* toxin	
Infections	Human immunodeficiency virus Hepatitis C (genotype 3) Small bowel bacterial overgrowth	
Other Conditions	Wilson Disease Celiac Disease Reye's syndrome Acute Fatty Liver of Pregnancy	

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WHEN TO CONSIDER TESTING FOR OTHER CAUSES OF HEPATIC STEATOSIS AND STEATOHEPATITIS

Condition	Clinical scenario	Diagnostic test	Treatment
Hypobetalipoproteinemia	Low LDL, low triglycerides, fat malabsorption	ApoB level, genetic testing (MTTP, PCSK-9)	Low-fat diet, fat-soluble vitamin supplementation
LAL deficiency	Markedly elevated LDL-C and low HDL-C, elevated triglycerides, xanthelasma, hypersplenism, advanced fibrosis in young age, predominately microvesicular steatosis on liver biopsy	Enzyme assay, genetic testing	LAL replacement
Nutrient deficiency (eg, carnitine, choline)	Anorexia, short bowel, bypass surgeries	Nutrient levels	Supplementation
Wilson disease	Younger age, neuropsychiatric symptoms, low alkaline phosphatase, low ceruloplasmin	24-h urine copper; quantitative copper on liver biopsy	Chelation
Celiac disease	Iron deficiency, abdominal pain, bloating, vitamin D deficiency, bone loss, diarrhea, dermatitis herpetiformis	Tissue transglutaminase IgA, duodenal biopsy	Gluten-free diet

Abbreviations: ApoB, apolipoprotein B; HDL-C, high-density lipoprotein cholesterol; IgA, immunoglobulin A; LAL, lysosomal acid lipase; LDL-C, LDL cholesterol.

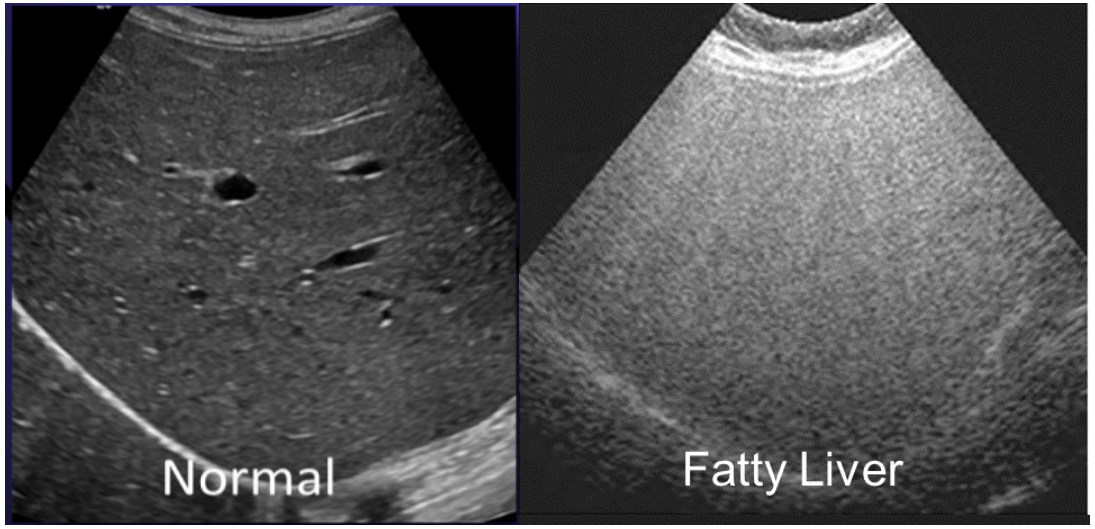
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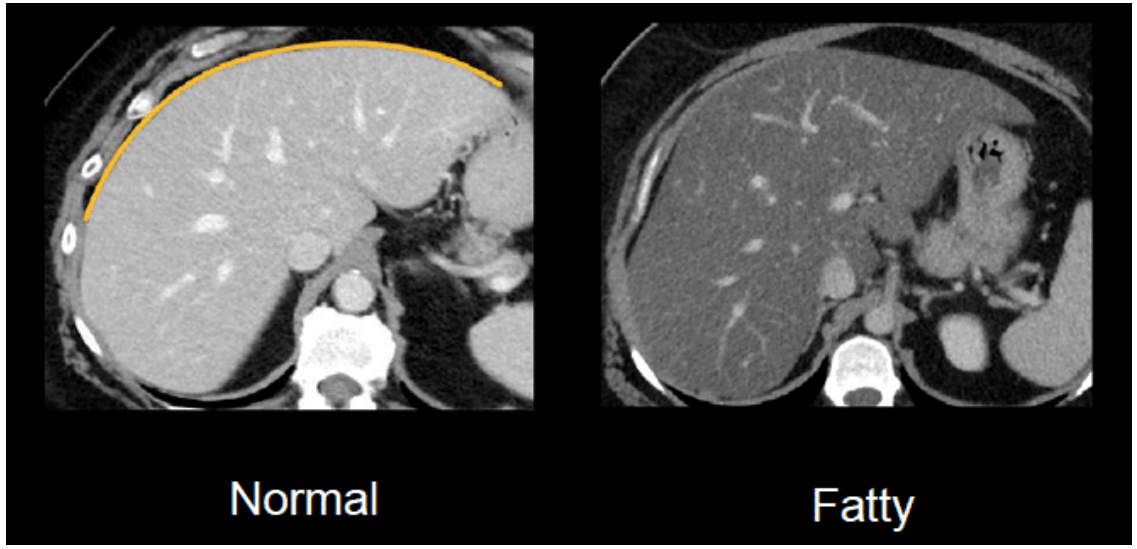
NAFLD - CLINICAL PRESENTATION

- Usually asymptomatic, occasionally RUQ discomfort
- AST and ALT<5X normal (classically ALT>AST)
  - 75% may have normal ALT or AST
  - True normal ALT and AST (< 20 U/L ♀ and < 30 U/L ♂)
- Alkaline phosphatase and GGT < 3 x ULN
  - Rarely, alkaline phosphatase may be increased with normal aminotransferases.
- Normal albumin, bilirubin, INR (unless advanced disease)
- Hyperlipidemia, hyperglycemia
- Elevated ferritin in ~30%. No need to check HFE gene unless transferrin saturation is high or ferritin > 1000 ng/ml.
- ANA (>1:160) or smooth muscle antibodies (>1:40) can be present in up to 40% of patients with NAFLD, without histologic evidence of AIH

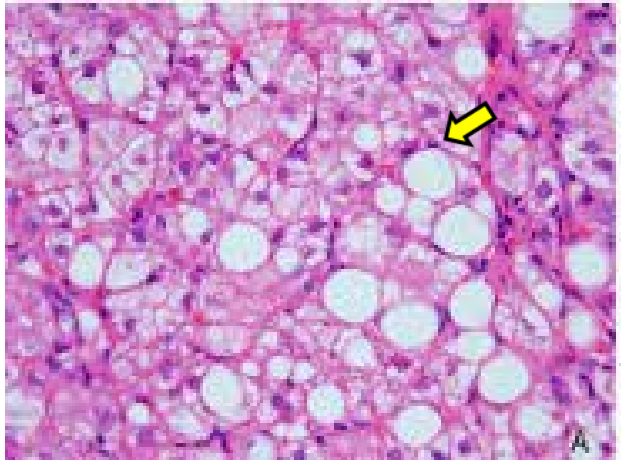
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RADIOLOGIC & HISTOLOGY FEATURES

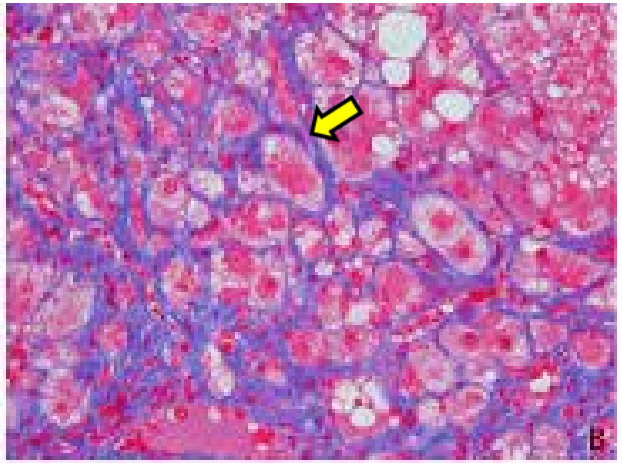




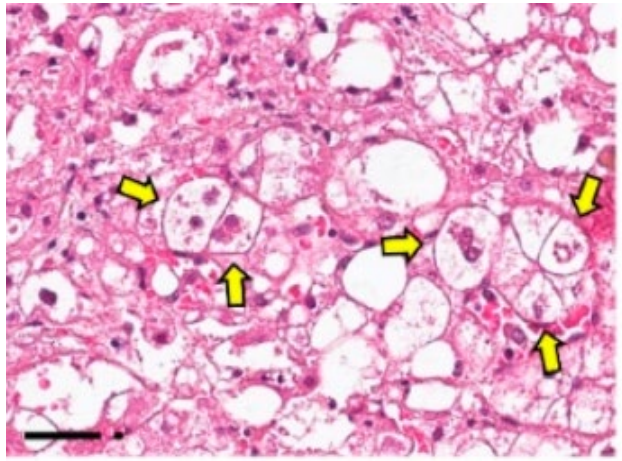
Steatosis



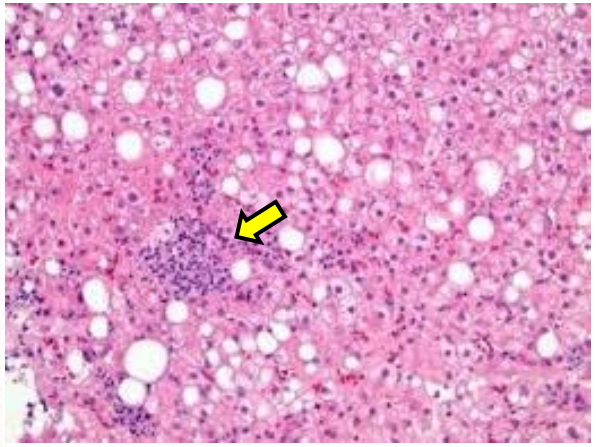
Pericellular
“chickenwire” fibrosis



Ballooned hepatocytes



Lobular inflammation



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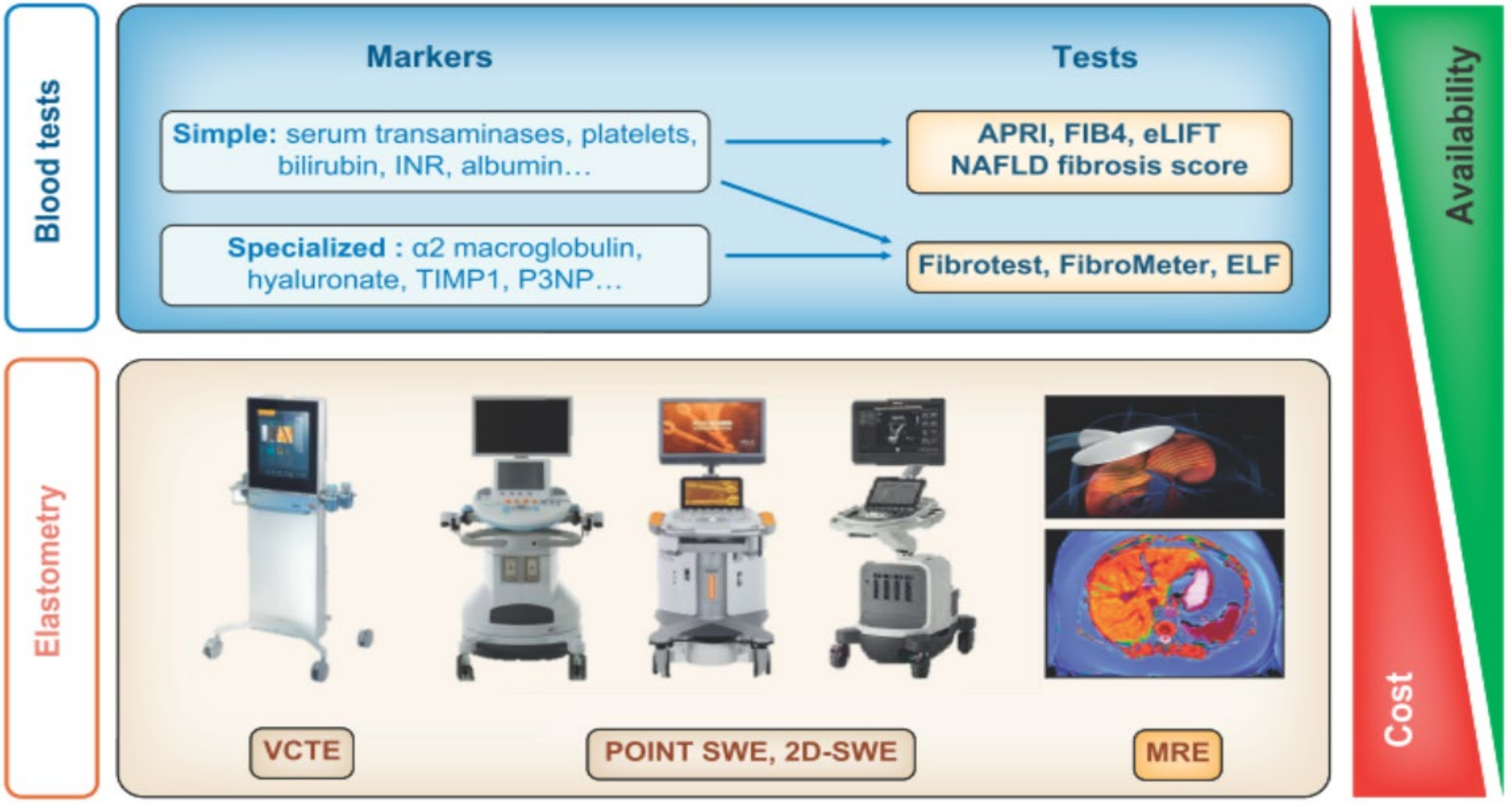
WHO TO SCREEN FOR ADVANCED FIBROSIS IN HIGH-RISK POPULATIONS

Screening Recommended	Prevalence of advanced fibrosis, %
Type 2 diabetes mellitus	6-19
Medically complicated obesity	4-33
NAFLD in context of moderate alcohol use	17
First-degree relative of a patient with NAFLD/ NASH-related cirrhosis	18

Prevalence of NAFLD in background population 0.9-2.0%

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NON-INVASIVE TESTS FOR FIBROSIS



Bousier J, J Hepatology Reports. 2021

PERFORMANCE CHARACTERISTICS OF NON-INVASIVE PREDICTORS OF ADVANCED FIBROSIS IN NAFLD

	F3-F4	F4	Externally Validated
Serum-based tests			
Non-proprietary			
APRI	0.74	0.75	++++
BARD	0.78	0.75	++++
FIB-4	0.90	0.82	++++
NAFLD fibrosis score	0.85	0.86	++++
Proprietary			
ELF	0.86	0.86	+++
Fibrometer	0.94	0.94	+
FibroTest	0.80	0.91	++
HepaScore	0.81	--	+

Vilar-Gomez E, et al. *J Hepatol.* 2018;68:305-315.

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ADVANTAGES/ DISADVANTAGES OF IMAGING BIOMARKERS

	Transient elastography	Magnetic resonance elastography	Shear wave elastography (ARFI, 2D-SWE)
AUROC F3-4	0.85-0.88	0.96	0.95
Point-of-care	Yes	No	No
Cost	$	$$$	$$
Failure rate	3-27%	0-2%	2-13%?
Precision of measurement	±26%	±19%	Limited data
Quality criteria	Well-defined	Well-defined	Not well-defined
Confounders	Obesity, steatosis, inflammation	Iron overload	Limited data
Other information	Steatosis (CAP) ?spleen	Steatosis (PDFF) NASH, ?spleen	Evaluation of liver and spleen

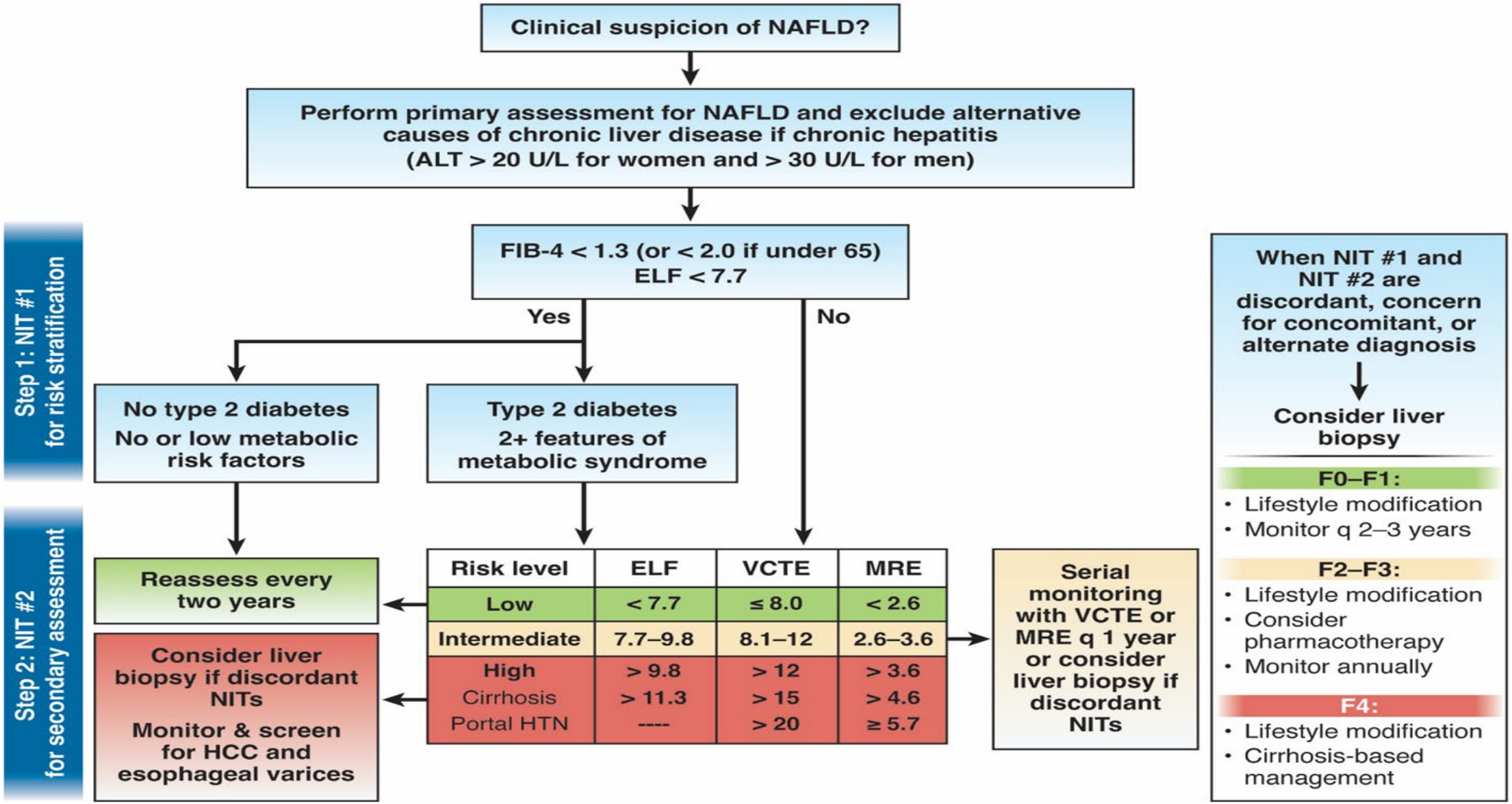
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WHEN TO CONSIDER A LIVER BIOPSY

- Consider liver biopsy
  - NAFLD patients at increased risk of having steatohepatitis and/or advanced fibrosis
  - Suspected NAFLD patients where competing etiologies for hepatosteatosis and the presence and/or severity of coexisting chronic liver diseases cannot be excluded without a liver biopsy
- Non-invasive assessments that may be used to identify those at risk for steatohepatitis and/or advanced fibrosis
  - Presence of metabolic syndrome, NAFLD score or FIB-4, or liver stiffness measured by VCTE or MRE

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PUTTING IT ALL TOGETHER



Wattacheril J & Abdelmalek M, et al. Gastroenterology. 2023

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QUESTION

A 55-year-old Asian man with type 2 diabetes and hypertension was referred to the hepatology clinic with elevated liver aminotransferases ALT at 58 U/L and AST 49 U/L with normal synthetic function. Platelet count is 203×10^9/L. He does not drink alcohol and his liver etiology screen was negative for viral hepatitis, autoimmune or metabolic liver diseases and malignancy. His BMI is 27 kg/m^2 with truncal obesity. He takes ramipril, metformin and glipizide and no other prescribed or non-prescribed substances. Liver ultrasound demonstrated bright echotexture. The fibrosis-4 index for liver fibrosis (Fib-4) score is indeterminate and he is referred for transient elastography (FibroScan) which shows a liver stiffness of 9.0 kPa.

•*Which of the following is the next stage in his management?*

a) Bariatric surgery.
b) Behavioural and lifestyle counselling.
c) Obeticholic acid
d) Pioglitazone
e) Vitamin E

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ANSWER

A 55-year-old Asian man with type 2 diabetes and hypertension was referred to the hepatology clinic with elevated liver aminotransferases ALT at 58 U/L and AST 49 U/L with normal synthetic function. Platelet count is 203×10^9/L. He does not drink alcohol and his liver etiology screen was negative for viral hepatitis, autoimmune or metabolic liver diseases and malignancy. His BMI is 27 kg/m^2 with truncal obesity. He takes ramipril, metformin and glipizide and no other prescribed or non-prescribed substances. Liver ultrasound demonstrated bright echotexture. The fibrosis-4 index for liver fibrosis (Fib-4) score is indeterminate and he is referred for transient elastography (FibroScan) which shows a liver stiffness of 9.0 kPa.

•*Which of the following is the next stage in his management?*

a) Bariatric surgery.
b) Behavioral and lifestyle counselling.
c) Obeticholic acid
d) Pioglitazone
e) Vitamin E

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NAFLD MANAGEMENT

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CURRENT TREATMENT OF NASH IS PATIENT CENTERED--INDIVIDUALIZED THERAPY

NO FDA APPROVED TREATMENT FOR NAFLD/NASH



Tackle Overweight Obese Status

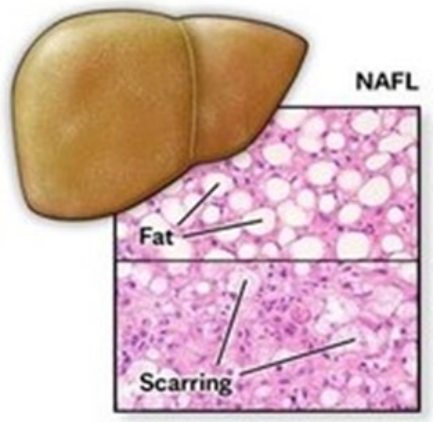
Weight loss
Exercise
Mediterranean Diet

Co-Factors Dietary Modifiers

↓ Alcohol
Stop Smoking
↓ Fructose
↑ Coffee

Address EACH Co-Morbidity

Obesity
Diabetes
Dyslipidemia
Hypertension
Sleep apnea



Managing NAFLD and NASH: *Lifestyle Interventions*

Diet

- **Decreasing caloric intake** by ≥30% improves insulin resistance & hepatic steatosis
- **Mediterranean diet** improves steatosis
- **Coffee** (caffeinated, filtered) ≥ 3 cups/day decreases NAFLD mortality
- **Alcohol:** Minimize; none for those with advanced fibrosis

Exercise

- Physical activity **≥150 min/week** decreases serum aminotransferases
- Moderate exercise **≥5 times/week** is associated with greatest benefit for long-term NAFLD prevention and improvement

Weight Loss

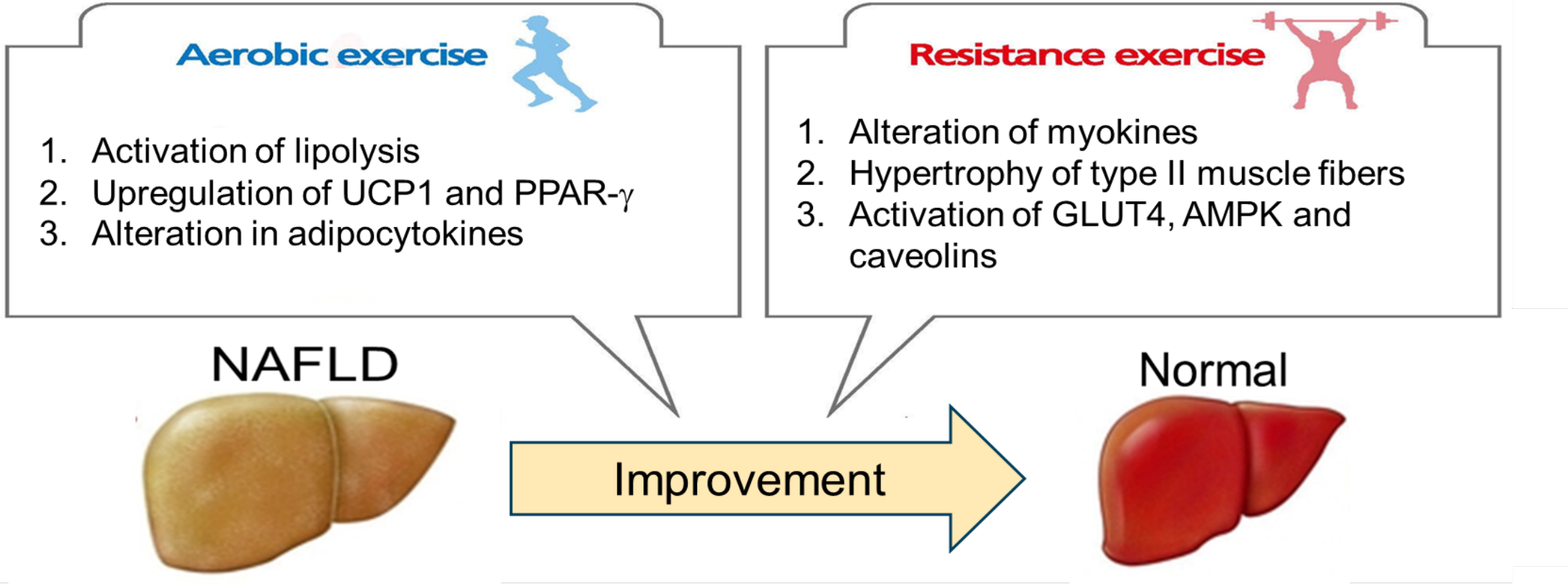
- Losing **≥5%** of body weight improves HS
- Losing **≥7%** body weight improves NASH
- Losing **≥10%** body weight improves all features of NASH and potentially fibrosis

Diet and exercise counseling and/or structured obesity management programs are recommended for patients with NAFLD

Kirk E, et al. *Gastroenterology*. 2009;136(5):1552-1560; Haufe S, et al. *Hepatology*. 2011;53(5):1504-1514; Sung KC, et al. *J Hepatol* 2016;65:791-797; Musso G, et al. *Diabetologia*. 2012;55(4):885-904; Vilar-Gomez E, et al. *Aliment Pharmacol Ther*. 2017;45(2):332-344; Poole R, et al. *BMJ* 2017;359:j5024.

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EXERCISE IN NAFLD (MASLD)



4.8 METs, 40min, 3x/wk x 12 wk

3.5 METs, 45 min, 3/wk x12 wk

Similar metabolic changes, similar reduction steatosis (12-17%), less energy expended in resistance group.

Adapted from Hashida et al. J Hep 2016

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EXISTING PHARMACOLOGICAL TREATMENTS FOR PATIENTS WITH BIOPSY-PROVEN NASH

No FDA-approved treatments specific for NASH

Not Recommended:

- Insulin sensitizers (metformin)
- Ursodeoxycholic acid
- Omega-3 fatty acids
- Obeticholic acid
- Herbal supplements

Insufficient Evidence:

- Dipeptidyl peptidase-4
- Statins
- Silymarin/ milk thisle
- SGLT-2 inhibitors

Recommended:

- **Vitamin E** (rrr α-tocopherol) at 800 IU/day for 12 months in patients without T2DM decreases aminotransferases, improves NASH
  Concerns: prostate cancer, hemorrhagic stroke

- **Pioglitazone** in patients with or without T2DM reduces NAS, improves fibrosis and hepatocellular injury
  Concerns: weight gain, bladder cancer, bone loss in women

- **Do not** stop statins or ACE-inhibitors—use to treat CV risk .

- **GLP-1 receptor agonists** (semaglutide) consider for its approved indications (T2DM/obesity) in patients with NASH, as it confers a CV benefit and improves NASH.

- If fibrosing NASH, consider **clinical trials**

Chalasani N et al. Hepatology. 2018;67:328.; EASL, EASD, EASO. J Hepatol. 2016;64:1388; Eslam M et al. Hepatol Intern. 2020:14:889; Rinella et al. Hepatology. 2023.

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PHARMACOLOGIC TREATMENT

- Vitamin E: First-line therapy for biopsy proven NASH without diabetes
  - Improves NASH parameters in 40% of patients
  - No effect on fibrosis
  - Concerns regarding bleeding, prostate cancer

- Pioglitazone: Can be for biopsy-proven NASH with or without diabetes
  - Improves NASH parameters in 30-50% of patients
  - No effect on fibrosis
  - Concerns regarding CHF, weight gain, bladder cancer, bone loss

- There are multiple clinical trials with investigational agents

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BARIATRIC SURGERY

- Effectively treats all metabolic parameters and induces > 20% weight loss
- Resolves NASH in 90% patients at 1 year with fibrosis regression in at 5 years.
- Meta-analysis of 21 studies, N=2,374 patients

Outcome	Improvement
Steatosis	88%
NASH	59%
Fibrosis	30%

- No randomized studies comparing to lifestyle modifications or medical therapies

2023 AASLD Guidelines: “Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves NAFLD or NASH in the majority of patients without cirrhosis and reduces mortality from CVD and malignancy.”

Fakhri T Surg Obes Relat Dis 2019; Lassailly et al. Gastroenterology 2020; Rinella M, et al. Hepatology. 2023.

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QUESTION

56 yo man with NASH cirrhosis has failed to achieve significant weight loss with moderate-intense lifestyle interventions (<10%). He is interested in bariatric surgery. BMI is 39 kg/m^2. He has no prohibitive cardiopulmonary comorbidities.

He has no history of ascites, encephalopathy, variceal bleeding or jaundice. MELD-Na score is 8. Platelets are 165. Imaging shows cirrhosis without splenomegaly or ascites.

You advise:

A) Against surgery due to high risk in the context of cirrhosis

B) Against surgery because he does not meet criteria by BMI

C) To proceed with bariatric surgery

D) Confirmation of cirrhosis with elastography

E) More testing with HVPG

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ANSWER

56 yo man with NASH cirrhosis has failed to achieve significant weight loss with moderate-intense lifestyle interventions (<10%). He is interested in bariatric surgery. BMI is 39 kg/m^2. He has no prohibitive cardiopulmonary comorbidities.

He has no history of ascites, encephalopathy, variceal bleeding or jaundice. MELD-Na score is 8. Platelets are 165. Imaging shows cirrhosis without splenomegaly or ascites.

You advise:

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D) Confirmation of cirrhosis with elastography

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BARIATRIC SURGERY IN NASH CIRRHOSIS

- Bariatric surgery can lead to improvement in liver disease severity and prevent further progression to decompensation
- Should be considered in *carefully selected* patients, at experienced surgical centers:
  - compensated cirrhosis
  - preserved synthetic function (low MELD)
  - absence of significant portal hypertension (HVPG>15 mmHg)
    - *those with HVPG 10-15 or non-bleeding esophageal varices should be assessed on a case-by-case basis*
  - absence of significant comorbidities

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QUESTIONS & DISCUSSION



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