roshapharma

xeliver®

Resmetirom

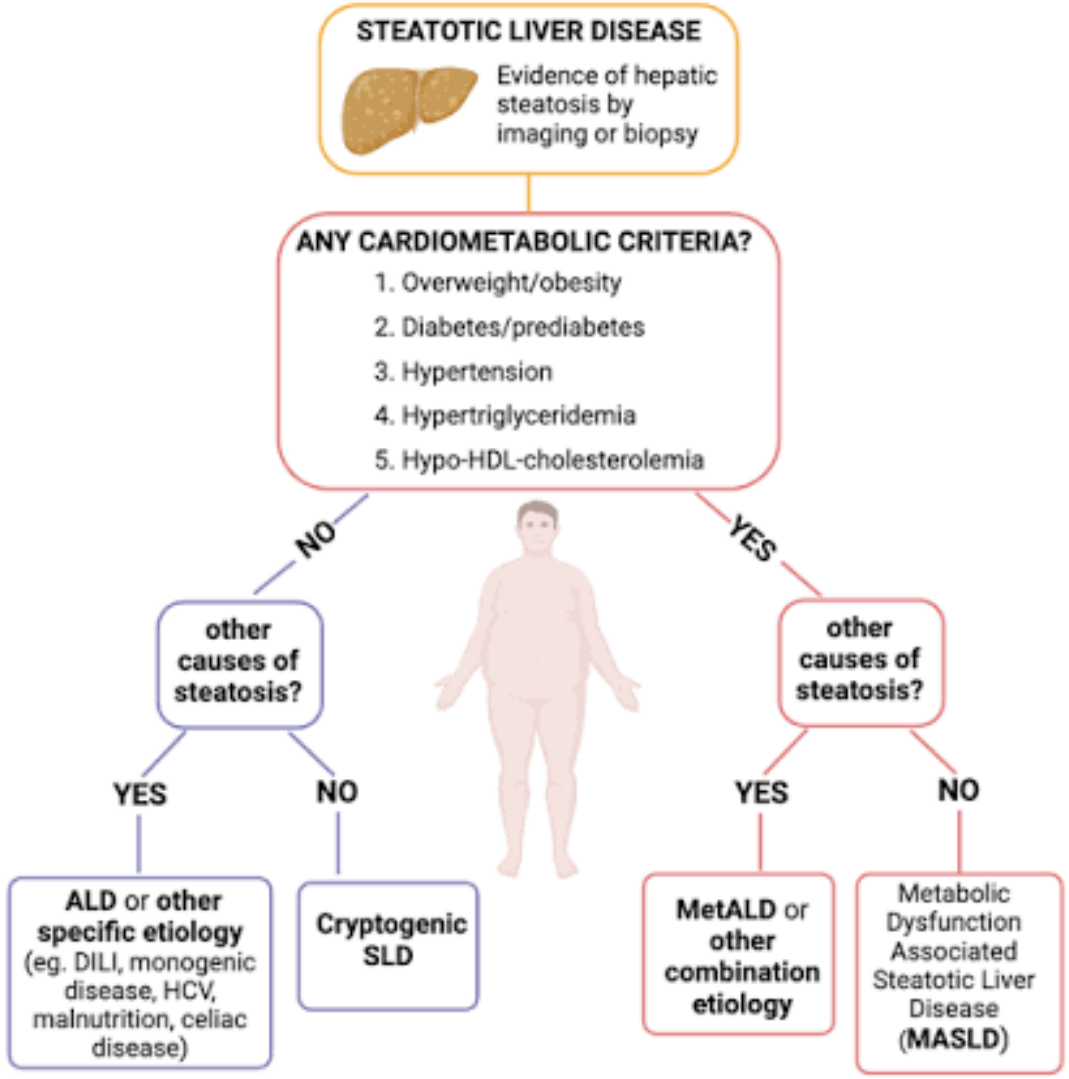
The silent savior of liver

What is MASLD?

MASLD is characterized by hepatic steatosis in the presence of at least one cardiometabolic risk factor:

- **Overweight/obesity or Abdominal Obesity**
- **Impaired Glucose Metabolism**
- **Hypertriglyceridemia**
- **Hypertension**
- **Low HDL-cholesterol**

Appropriate consideration of alcohol intake and other causes of steatotic liver disease is required.



"Long-term prognosis of lean MASLD: evidence from three population-based prospective cohorts." *Gut* vol. 75,4 772-785. 6 Mar. 2026

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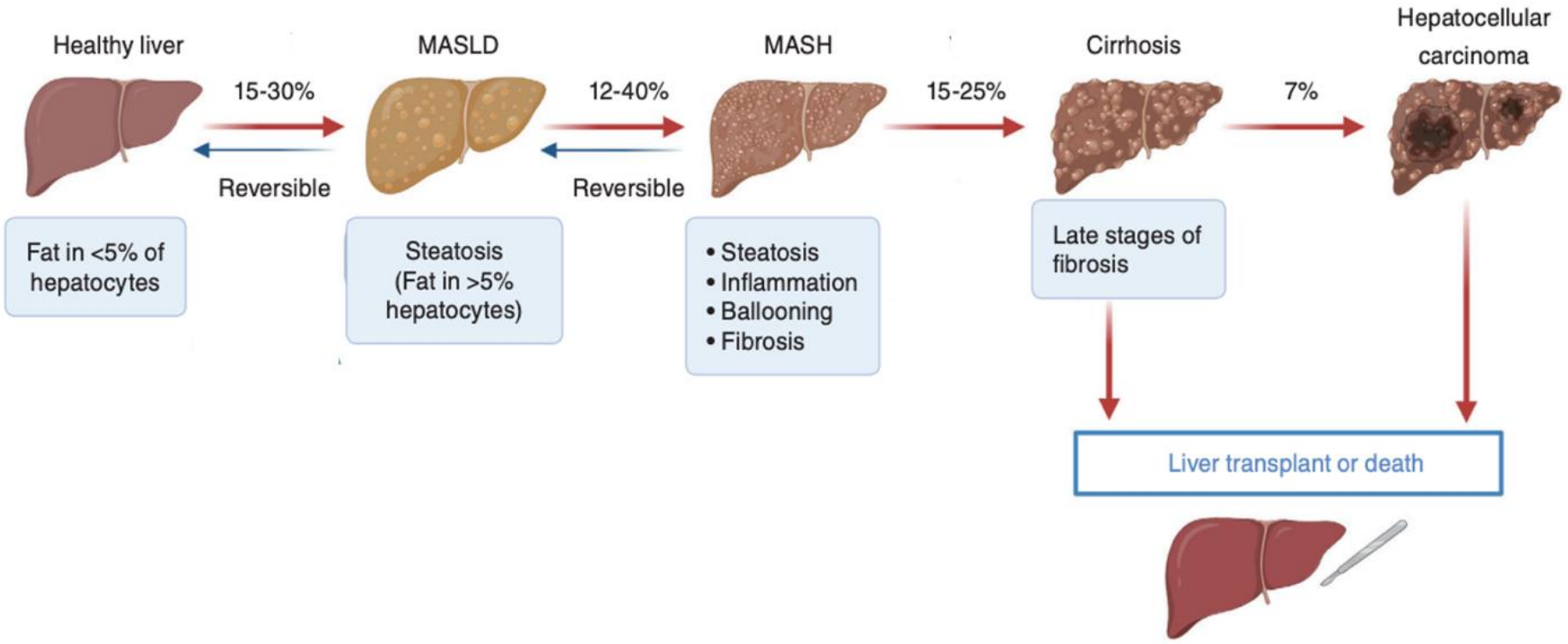
The Spectrum of MASLD

MASLD encompasses a broad spectrum ranging from simple steatosis to MASH, advanced liver fibrosis, cirrhosis, liver transplantation, and liver-related mortality.



Current understanding of the progression and regression of MASLD

iLIVER. 2024

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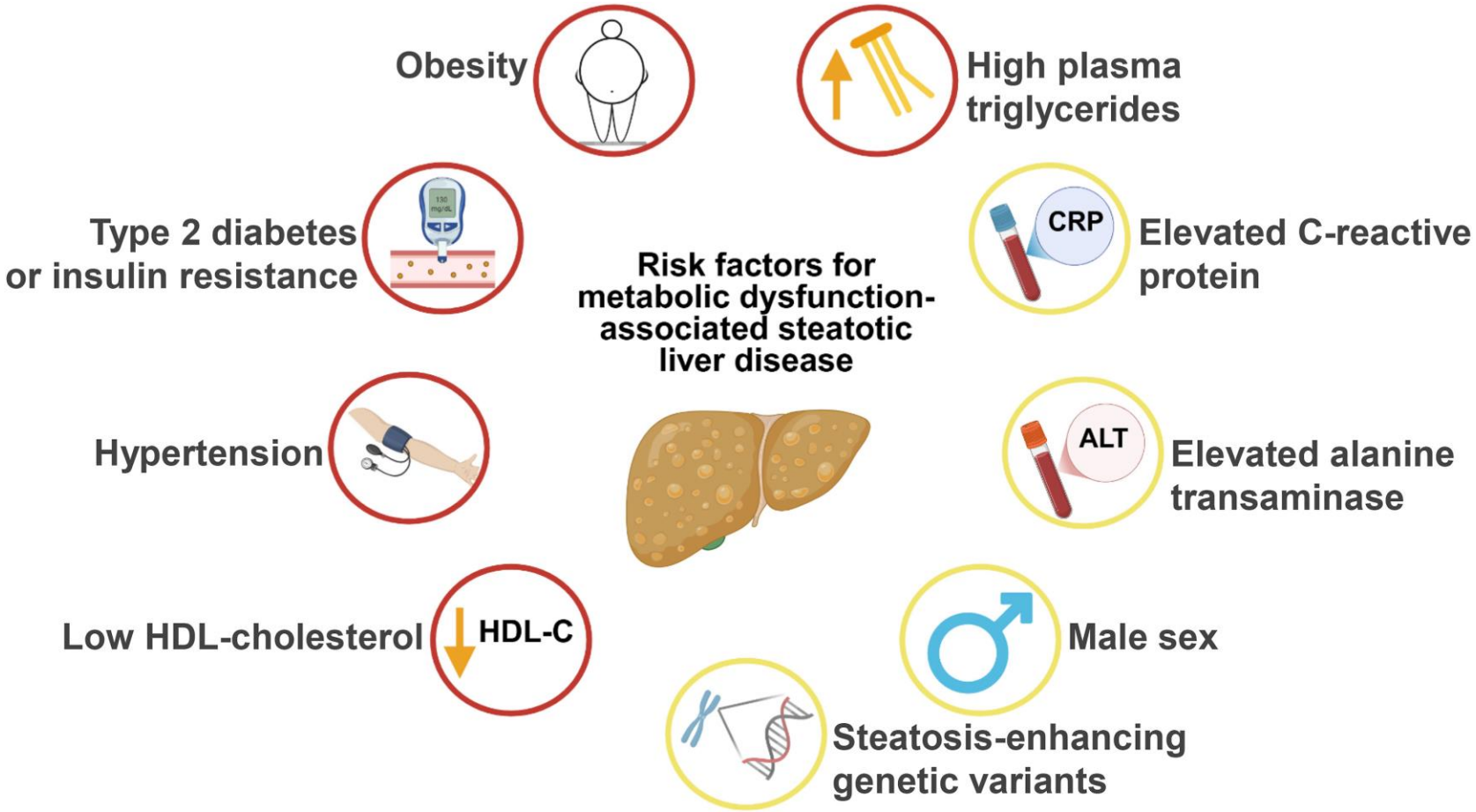
MASLD and Cardiometabolic Risk Factors

MASLD is a multi-system metabolic disease, closely linked to obesity, type 2 diabetes, hypertension, and other metabolic disorders.



Metabolic dysfunction-associated steatotic liver disease, cardiometabolic risk factors, and cardiovascular disease. Atherosclerosis, 2025; 411

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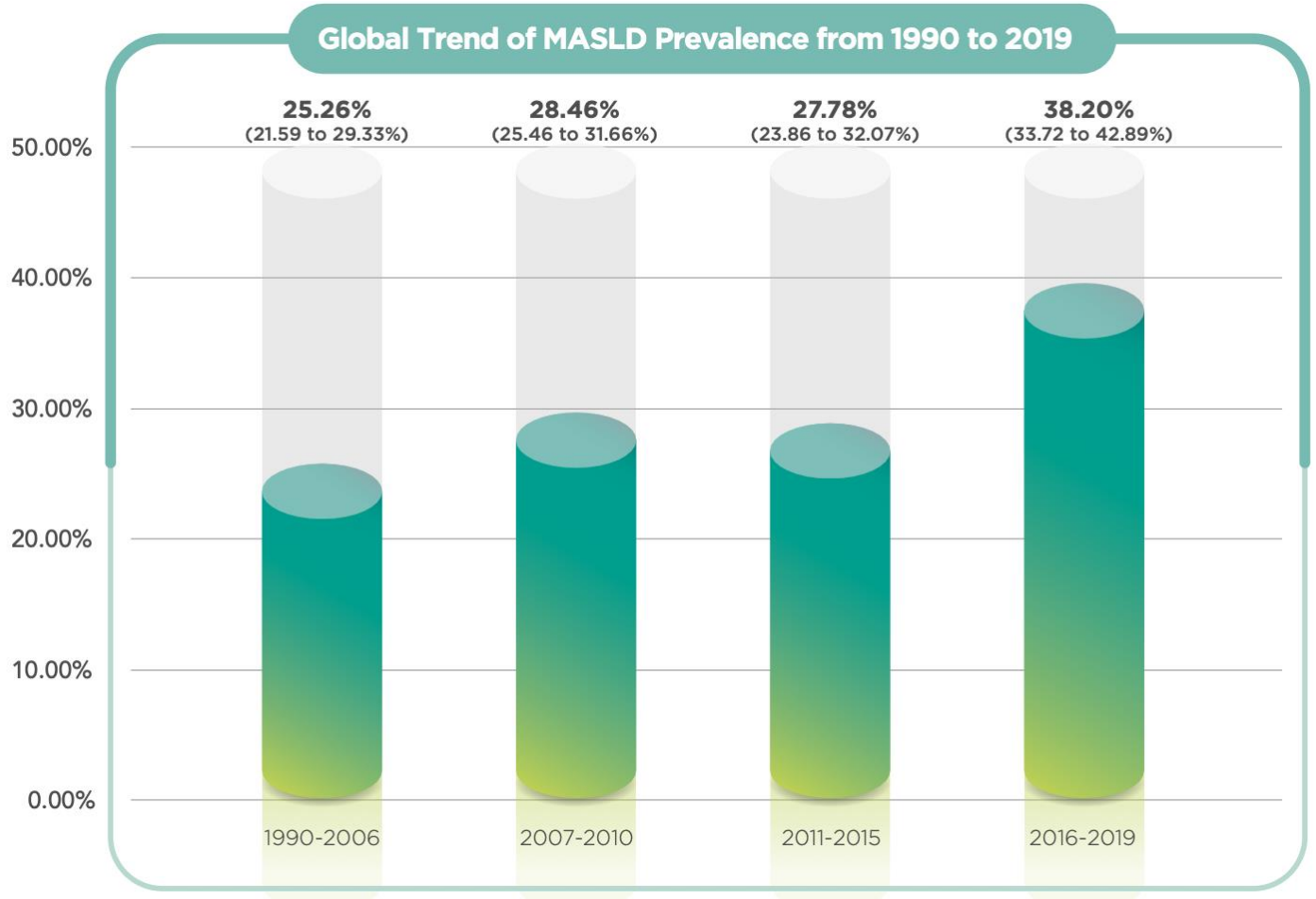
MASLD/MASH; An Uprising Global Health Challenge

Worldwide Prevalence of MASLD

Global MASLD prevalence increased from 25.26% in 1990 to 38.20% in 2019 (p<0.001), **expecting it to reach 55.4% by 2040.**



Metab Target Organ Damage. 2024;4:35
Clin Mol Hepatol 2022;28:841-850.

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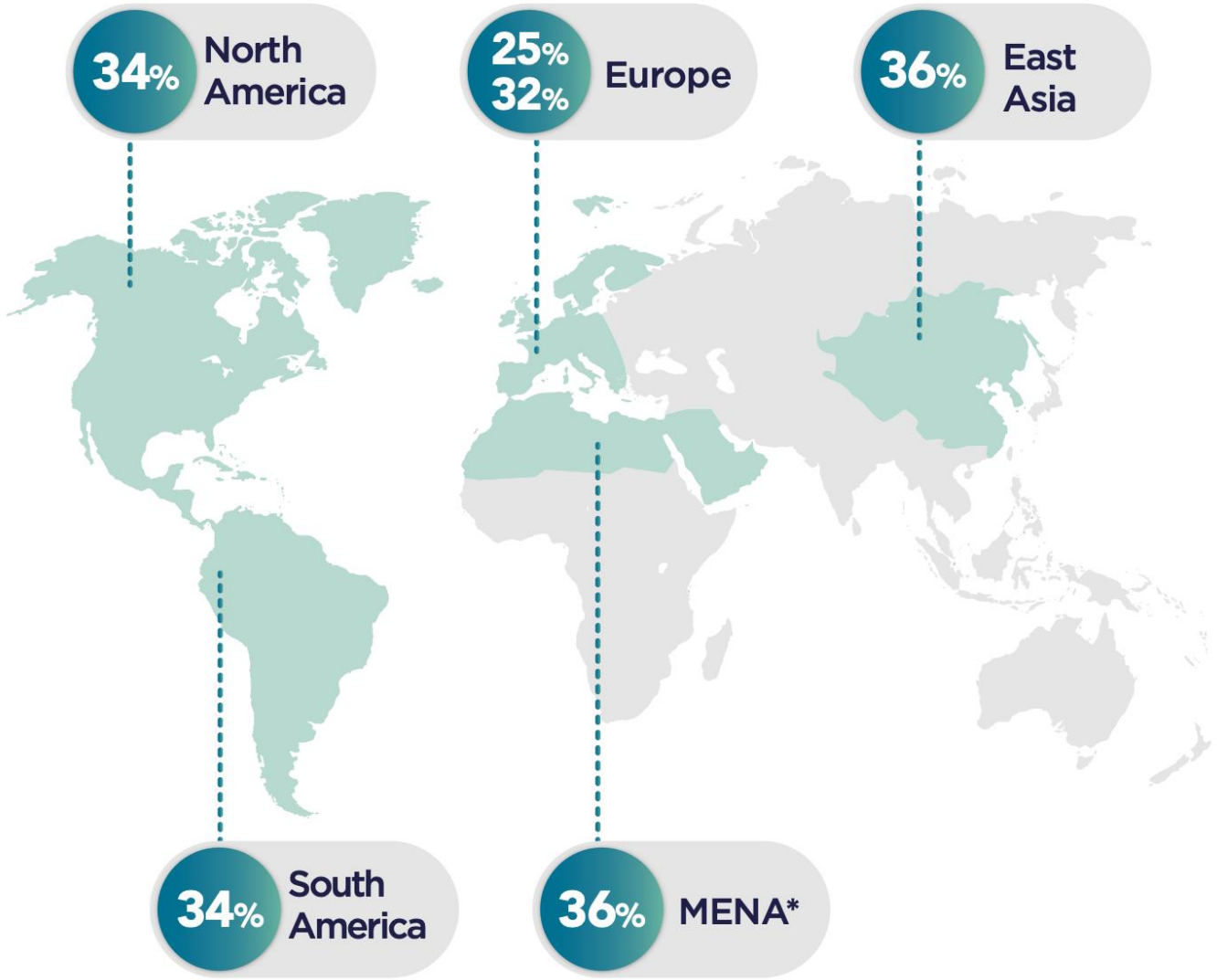
MASLD/MASH; An Uprising Global Health Challenge

Prevalence of MASLD estimations around the world



Hepatology vol. 77,4 (2023): 1335-1347

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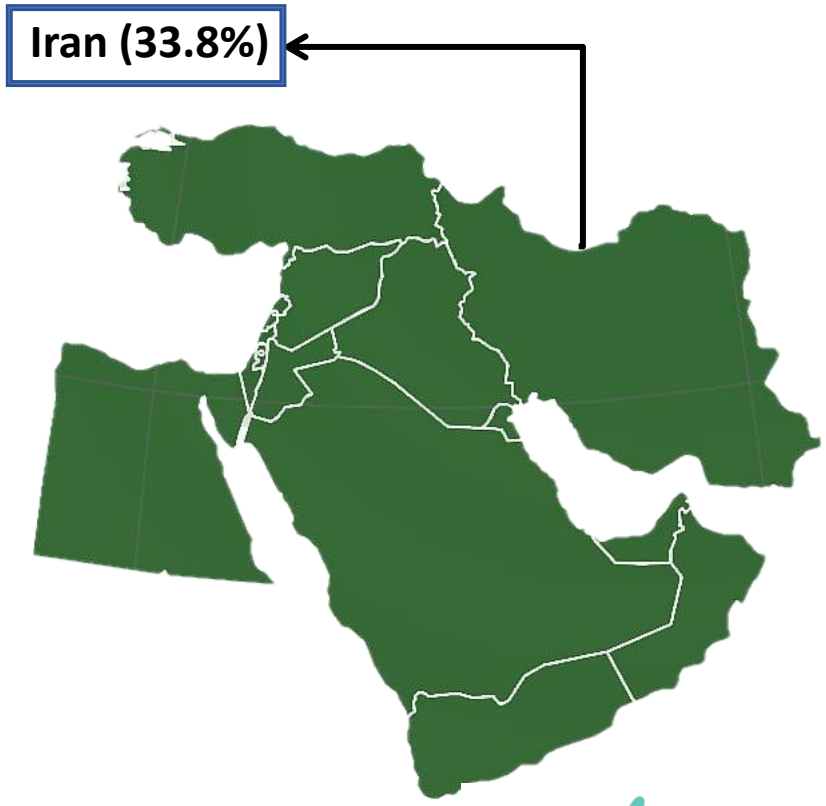
MASLD/MASH; An Uprising Global Health Challenge

Prevalence of MASLD in Iranian population

- The MENA countries expected to have the highest number of MASLD cases are Egypt, followed by Türkiye and **Iran (33.8%)**.



The **global disease burden** paired with the **public health impact** from clinical outcomes highlights the critical need for the development of highly effective, well-tolerated, and safe pharmacotherapy.

Liver international : official journal of the International Association for the Study of the Liver vol. 44,4 (2024): 1061-1070.
Alimentary pharmacology & therapeutics vol. 34,3 (2011): 274-85.

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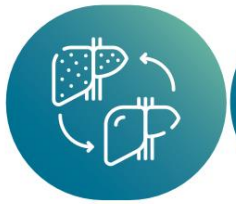
MASLD/MASH; A Massive Burden on Healthcare System

MASLD progresses to metabolic dysfunction-associated steatohepatitis (MASH) at a rate of 12-40% with a significant risk of:

Cirrhosis

Hepatocellular carcinoma (HCC)



Liver transplantation

And Liver-related death

MASH is responsible for most liver-related morbidity, mortality and transplant demand, with prevalence rising alongside obesity and type 2 diabetes worldwide.[2,3]

Frontiers in cell and developmental biology vol. 12 1433857. 16 Jul. 2024, doi:10.3389/fcell.2024.1433857
Journal of hepatology vol. 73,1 (2020): 202-209
Clinical and molecular hepatology vol. 31,3 (2025): 753-770

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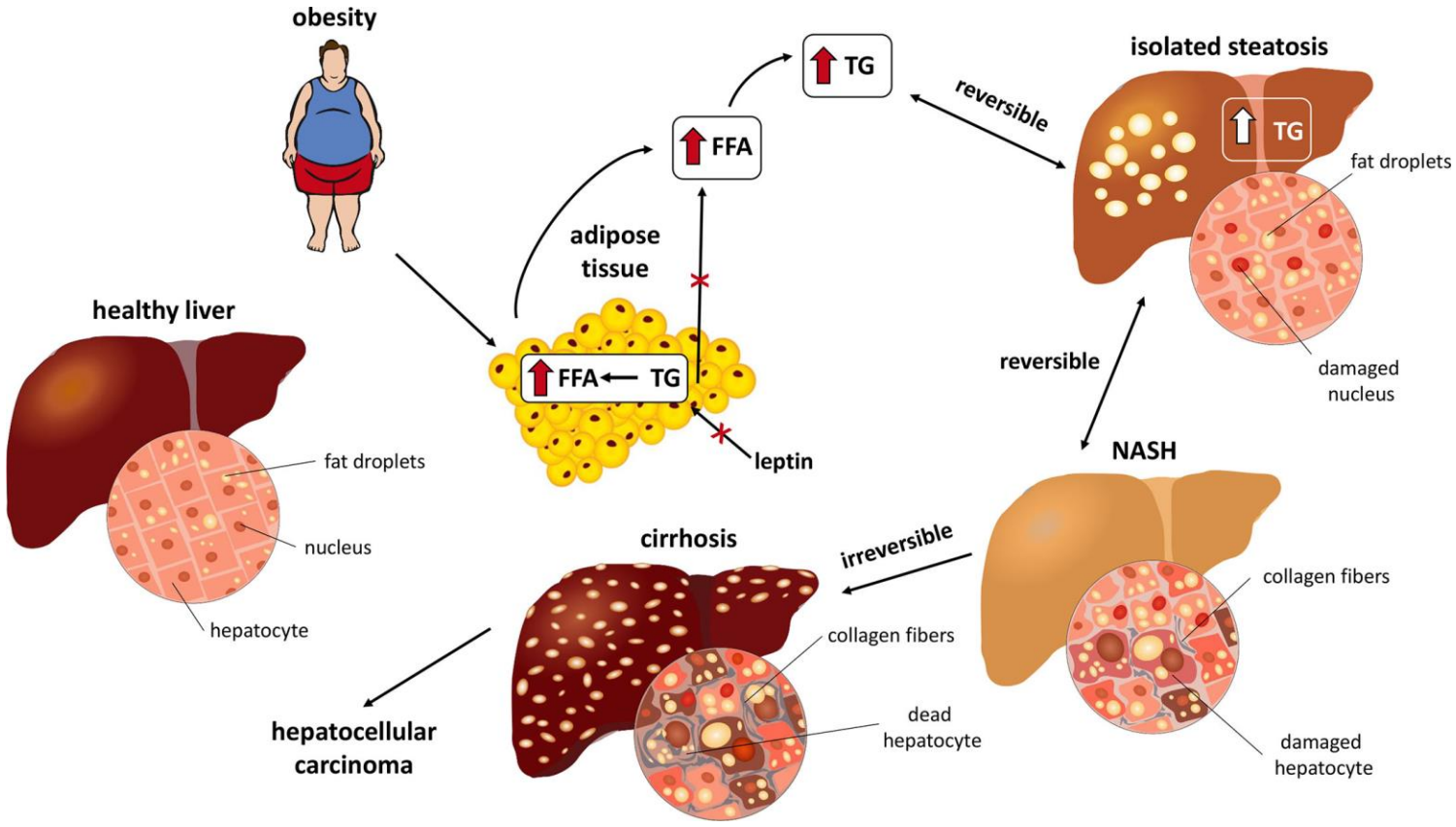
MASLD/MASH Pathophysiology

- MASLD originates from underlying metabolic dysfunction and insulin resistance, driving excess fat accumulation in the liver.
- As the disease advances, lipotoxicity triggers persistent inflammation and hepatocellular injury, paving the way toward MASH and progressive fibrosis.



Nature medicine 24.7 (2018): 908-922

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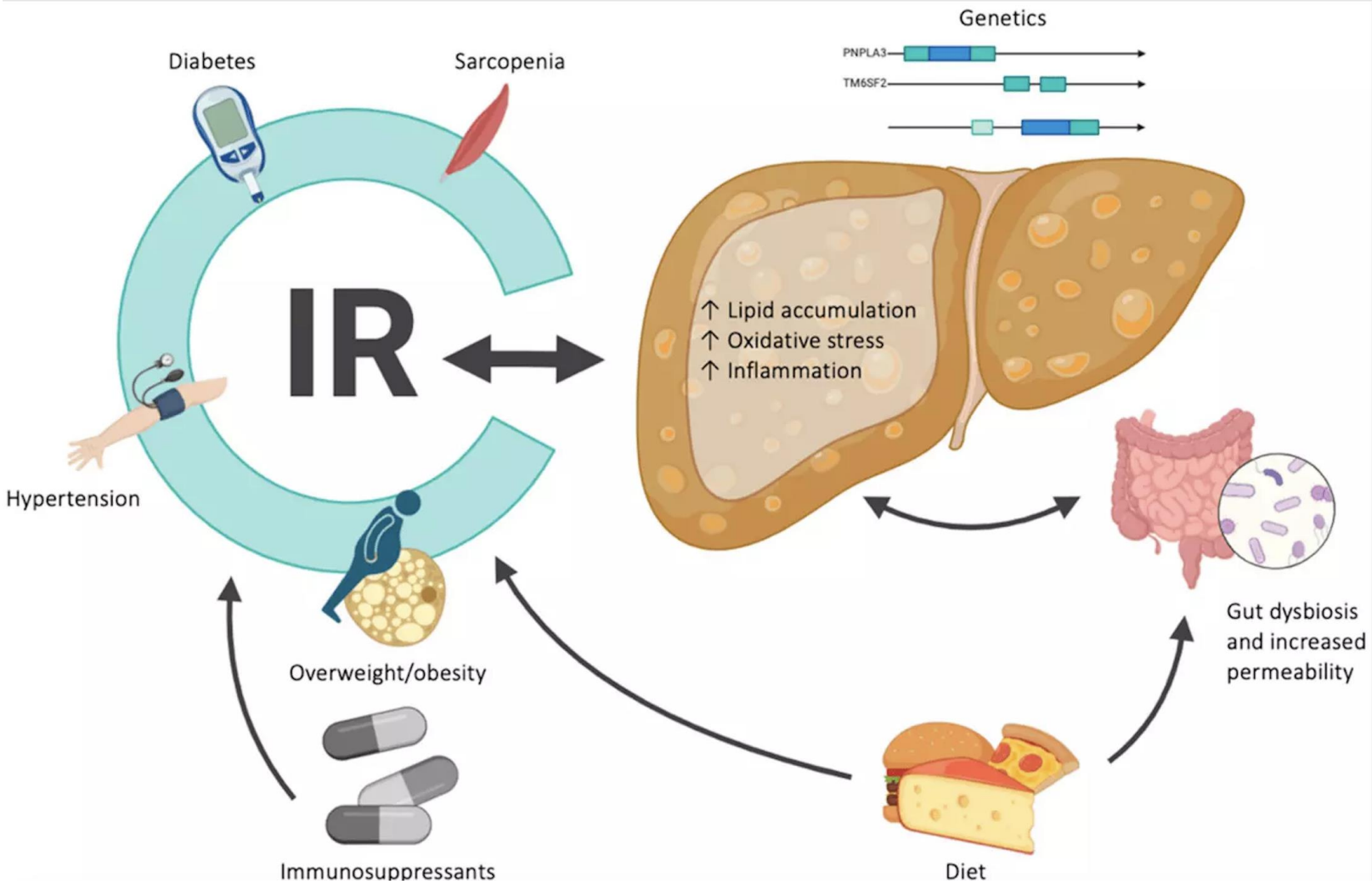
Multifactorial Pathogenesis of MASLD

- Insulin resistance acts as a central driver linking cardiometabolic risk factors, obesity, sarcopenia, genetic susceptibility, diet, and gut dysbiosis to hepatic lipid accumulation, oxidative stress, inflammation, and liver injury.



Nature medicine 24.7 (2018): 908-922

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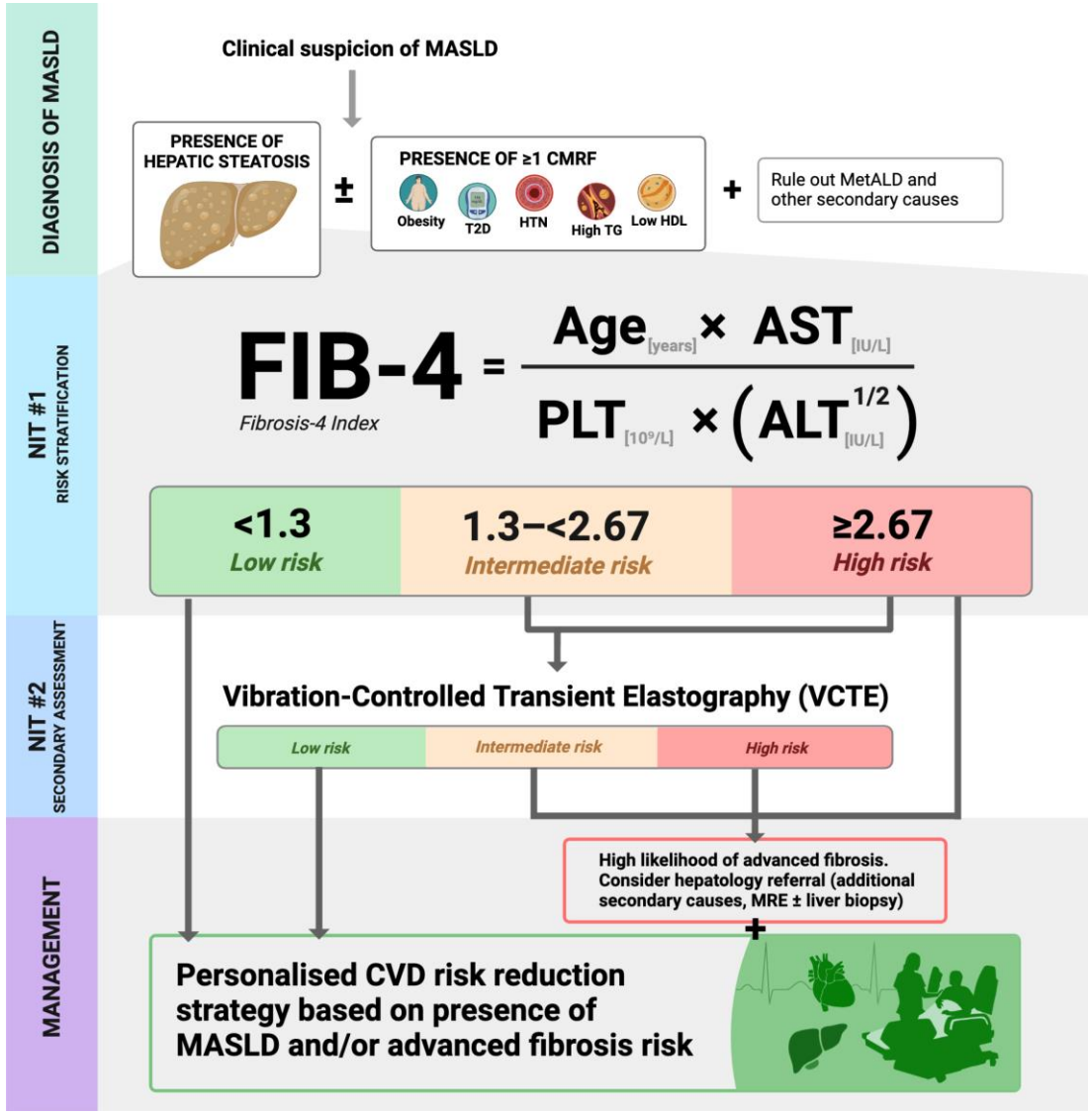
Screening High-Risk Patients for Advanced MASLD Fibrosis

- Patients with hepatic steatosis and cardiometabolic risk factors—particularly obesity, type 2 diabetes, hypertension, hypertriglyceridemia, or low HDL—should undergo stepwise fibrosis risk assessment.

- FIB-4 is recommended as a first-line non-invasive test, followed by VCTE in patients with intermediate or high risk, to identify those who may require evaluation for liver-directed therapy.



"Cardiovascular-Liver-Metabolic Health: Recommendations in Screening, Diagnosis, and Management of Metabolic Dysfunction-Associated Steatotic Liver Disease in Cardiovascular Disease via Modified Delphi Approach." *Circulation* vol. 151,1 (2025):

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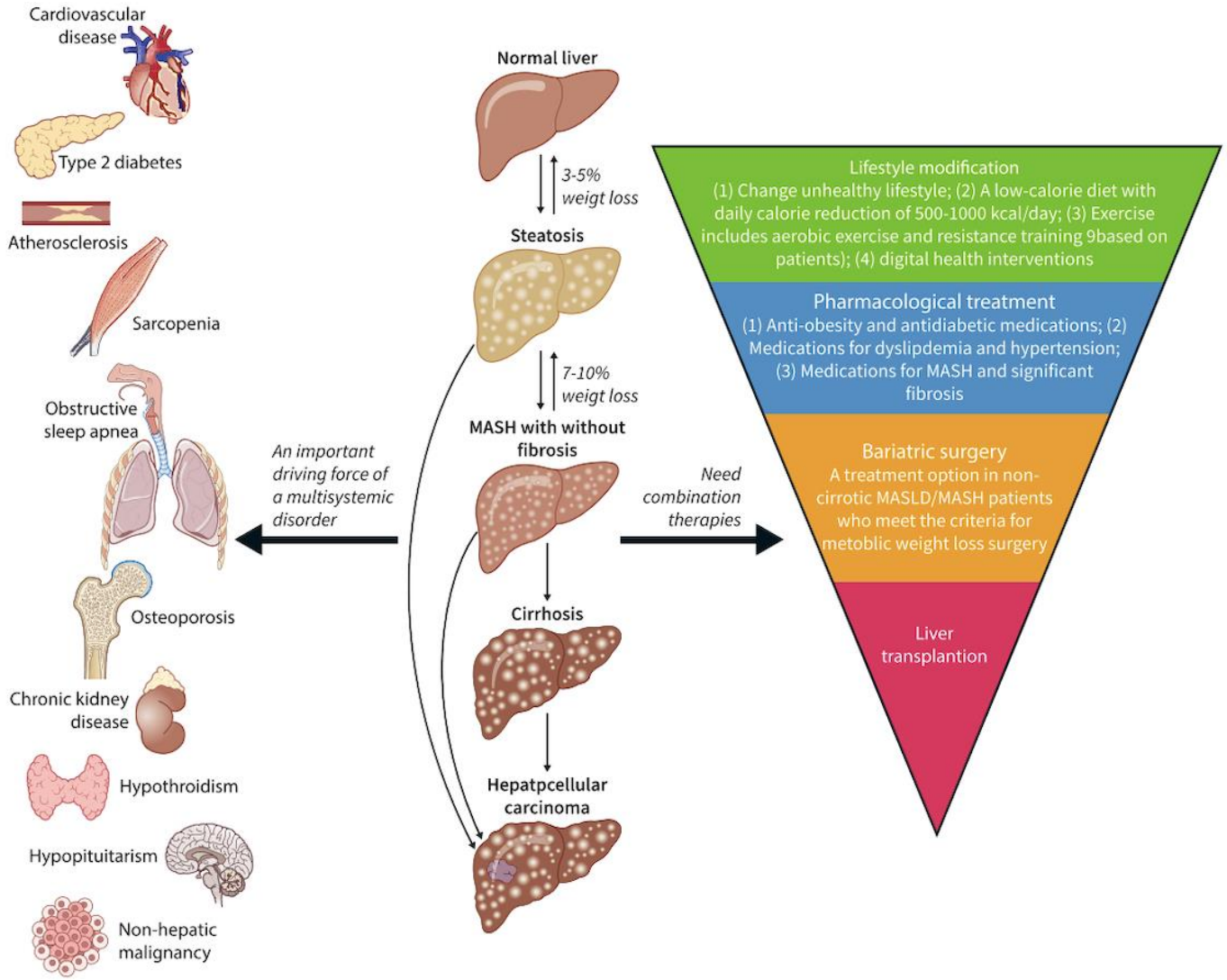
Therapeutic Management of MASLD

- The management of the underlying metabolic drivers of the disease by lifestyle modification and weight loss is the cornerstone of the treatment of MASLD/MASH.
- For MASLD patients with overweight/obesity, a weight loss of 3-5% can reduce steatosis, while a 7% weight loss can lead to MASH regression, and a 10% weight loss may result in fibrosis regression.



"Cardiovascular-Liver-Metabolic Health: Recommendations in Screening, Diagnosis, and Management of Metabolic Dysfunction-Associated Steatotic Liver Disease in Cardiovascular Disease via Modified Delphi Approach." *Circulation* vol. 151,1 (2025):

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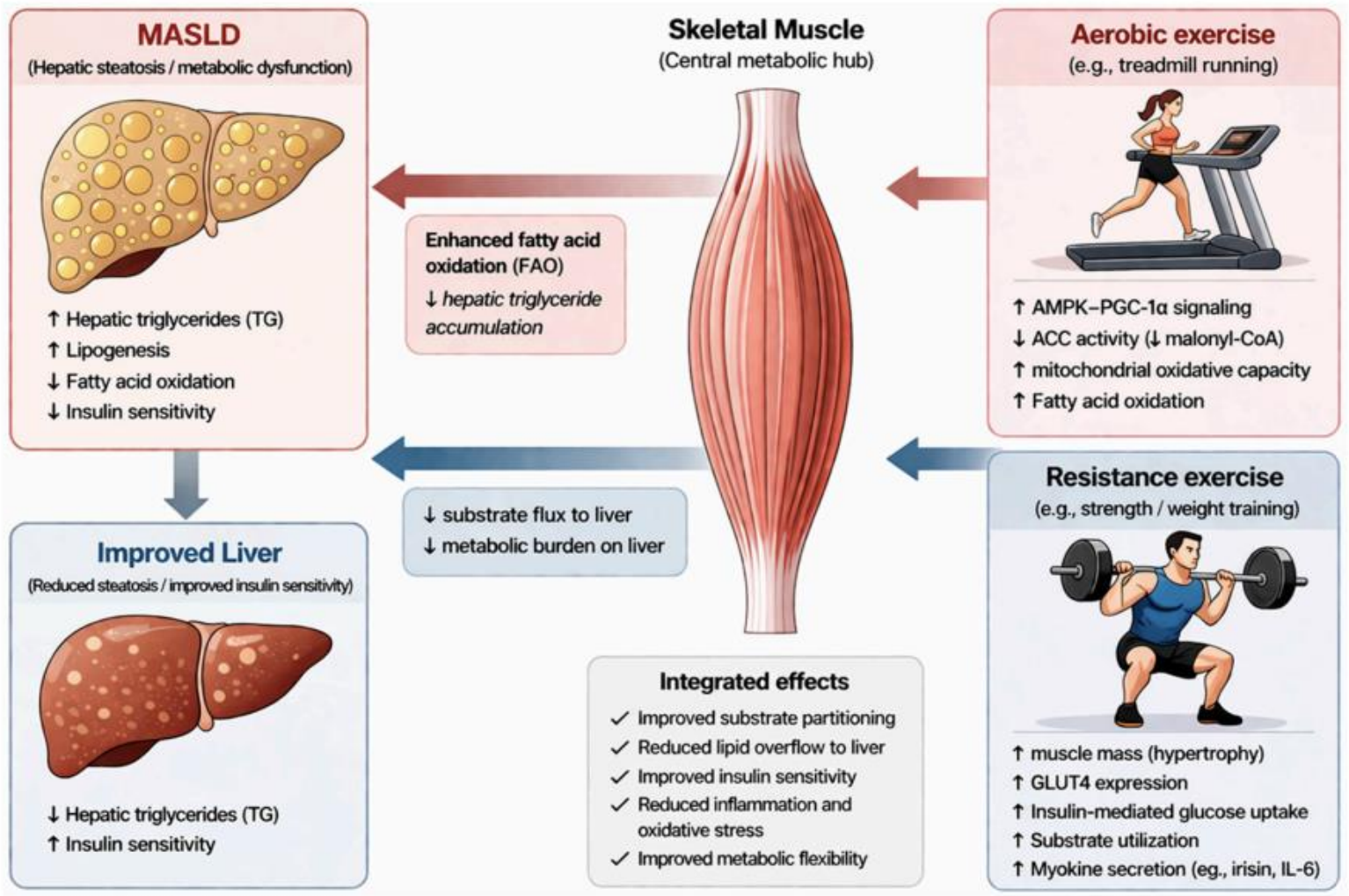
Lifestyle Recommendations in MASLD Management

- Patients should be encouraged to follow a Mediterranean-style diet rich in vegetables, fruits, legumes, nuts, olive oil, fish, and lean protein, while limiting sweets, refined carbohydrates, processed foods, fast food, sugary drinks, red and processed meat, and excess salt.

- Regular physical activity should be individualized based on the patient's ability and lifestyle, with a general target of at least **3 hours of moderate-intensity aerobic exercise per week** to support weight loss and metabolic improvement.



Roh H-T, Bae J-Y. Exercise as a Metabolic Therapy for MASLD: Beyond Weight Loss Toward Sustainable Exercise Strategies. *Medicina*. 2026

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The Evolving MASH Therapeutic Landscape

Drug class	Representative agents	Key evidence/development status	Major limitations/safety concerns
PPAR agonists	Pioglitazone, elafibranor, lanifibranor, saroglitazar	Pioglitazone: histological benefit; elafibranor: phase 3 failure; lanifibranor: positive phase 2; saroglitazar: approved in India	Weight gain, edema, class heterogeneity
FXR agonists	Obeticholic acid	Phase 3 fibrosis benefit but not fully approved	Pruritus, dyslipidemia
THR-β agonists	Resmetirom	FDA approved (2024)	Generally well-tolerated
GLP-1 receptor agonists	Liraglutide, semaglutide	Semaglutide: FDA approved (2025)	Gastrointestinal effects
FGF21 analogs	Pegozafermin, efruxifermin	Early trials: improved fibrosis/metabolic markers	Confirmatory trials needed
Antioxidants	Vitamin E	Efficacy in non-diabetic patients	Long-term cardiovascular/oncologic safety concerns
Failed targeted therapies	Selonsertib, cenicriviroc	Phase 3 failure or no MASH resolution	Single-pathway limitations

Tirzepatide	GIP/GLP-1 dual agonist	Phase 3	Reduced liver fat by 8.1% over 52 weeks in T2DM patients; improved ALT, AST, GGT
Retatrutide	GCGR/GIPR/GLP-1R triple agonist	Phase 3	Significant body weight loss in obese patients; improved liver health markers in preclinical models

Yu, Jiang, and Yong Peng. "The immunometabolic mechanisms and therapeutic targets of metabolic dysfunction-associated steatohepatitis." *Frontiers in medicine*. 20 May. 2026,

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FDA and EASL Guideline recommendations

Xelivex® is the first FDA-approved medication for the treatment of MASH with moderate to advanced liver fibrosis.

- **Xelivex®** can be considered for treatment of adults with MASH and moderate to advanced liver fibrosis (consistent with F2-F3) based on latest AASLD guidelines.

- Based on EASL guidelines, adults with non-cirrhotic MASH and significant liver fibrosis should be considered for targeted treatment with **Xelivex®**, demonstrating resolution of MASH and fibrosis with acceptable safety and tolerability.

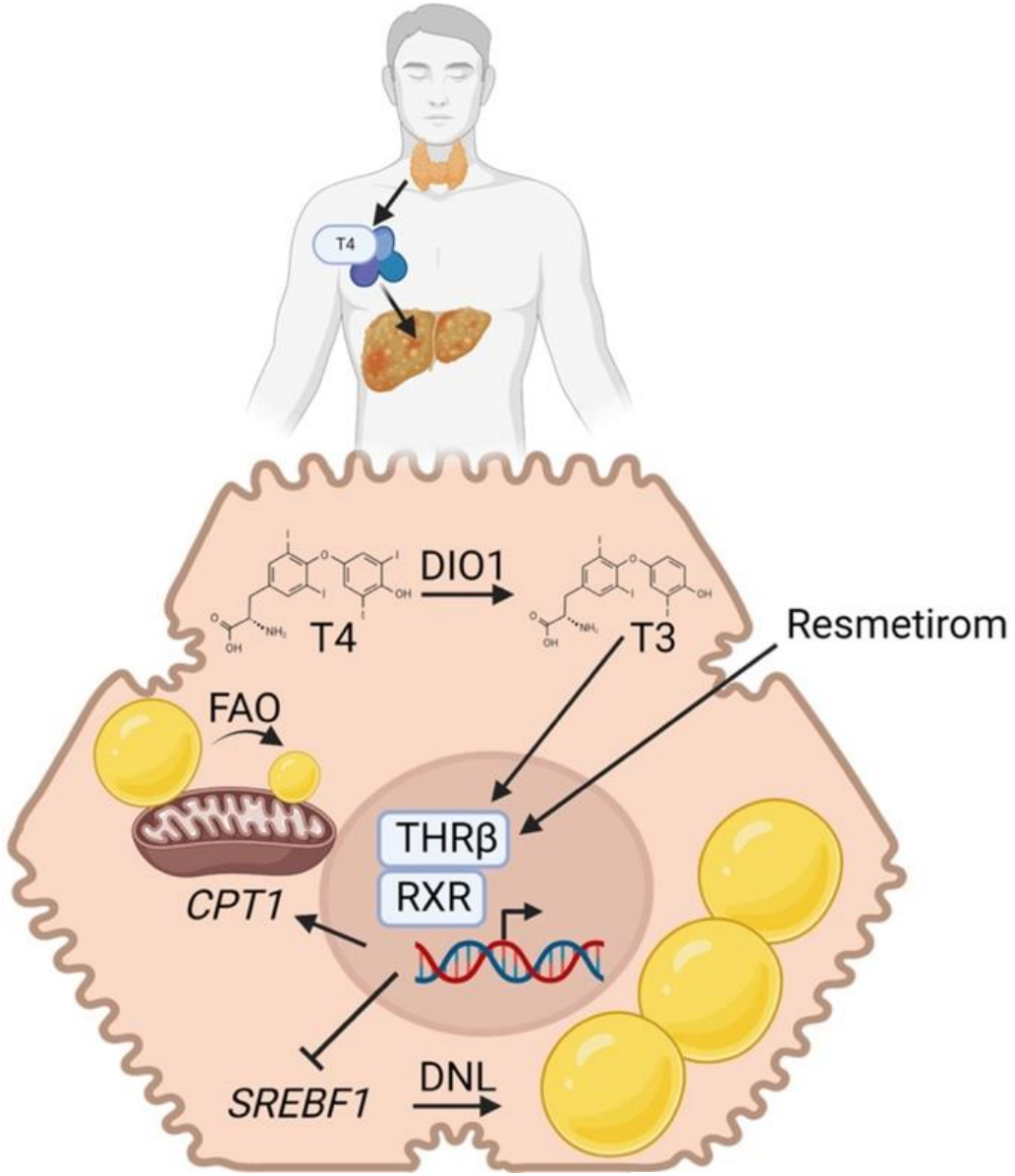
AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

EASL™
The Home of Hepatology

Nature reviews. Gastroenterology & hepatology vol. 15,1 (2018): 11-20.
Hepatology 81(1):p 312-320, January 2025.

Xelivex® Mechanism of Action

Xelivex® is a liver-directed, orally active agonist of thyroid hormone receptor (THR), improving lipid metabolism, glucose homeostatsis, and inflammation.

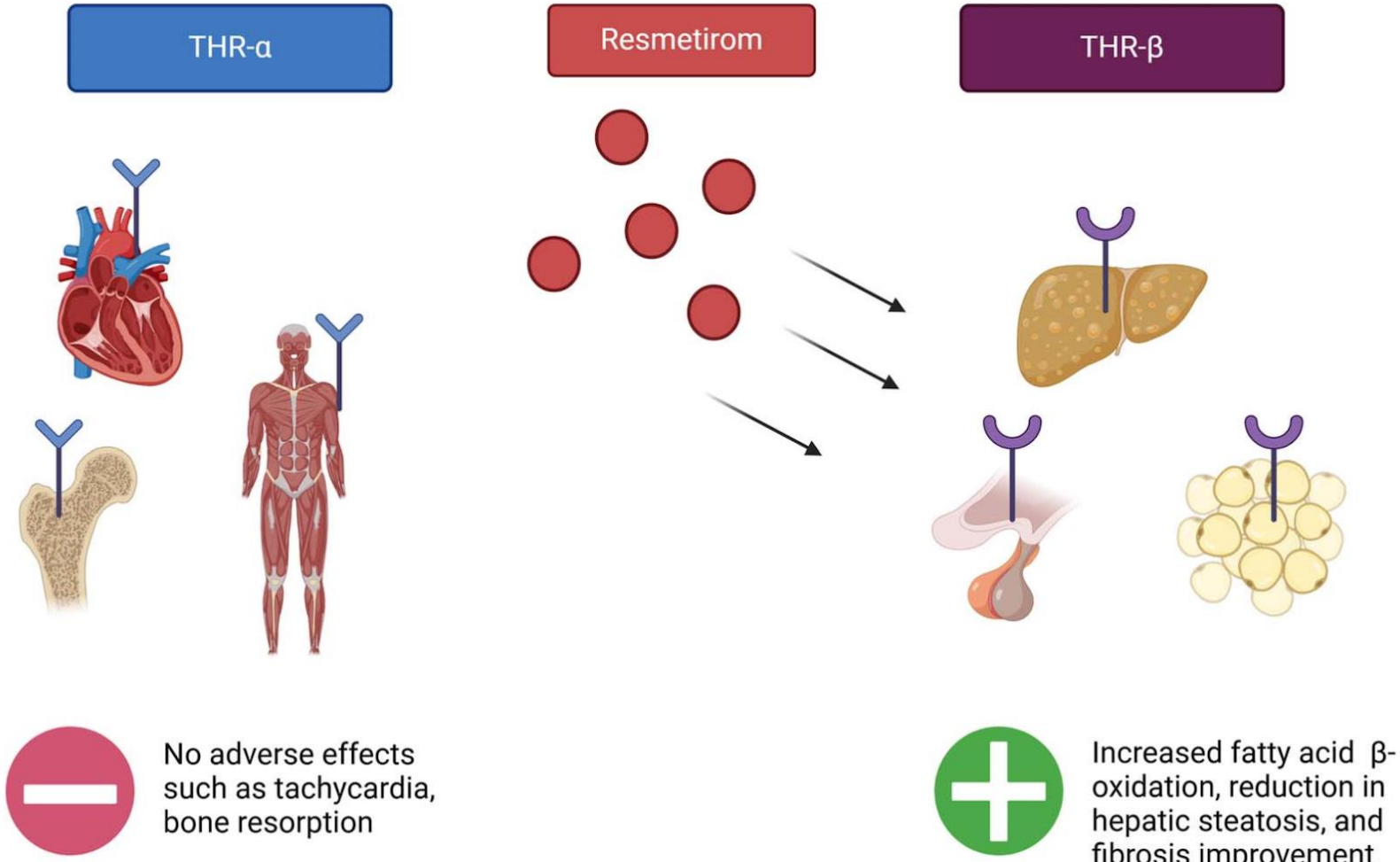


J Med Chem 2014; 57: 3912–23

xelivex® Resmetirom

Selectivity of Xelivex® and Its Effects on Different Organs

Xelivex® selectively targets hepatic THR-β receptors, minimizing THR-α–mediated extrahepatic adverse effects such as tachycardia and bone resorption.



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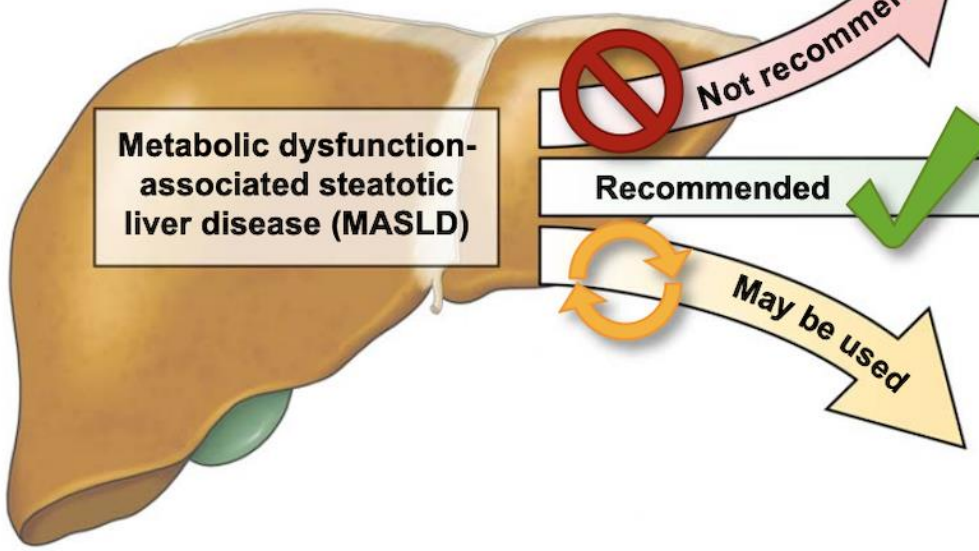
J Med Chem 2014; 57: 3912–23

Selection of Patients for Xelivex® Therapy



- Cirrhosis, including LSM via VCTE >20 kPa or MRE >5 kPa
- Concomitant active liver disease
- Excess alcohol use (>20/30 g/d in women/men)
- Active thyroid disease

Imaging-based NILDA	VCTE: LSM 8 kPa - 15 kPa[a] MRE: LSM 3.1 kPa - 4.4 kPa[a]
Liver histology	MASH with F2-F3[b]

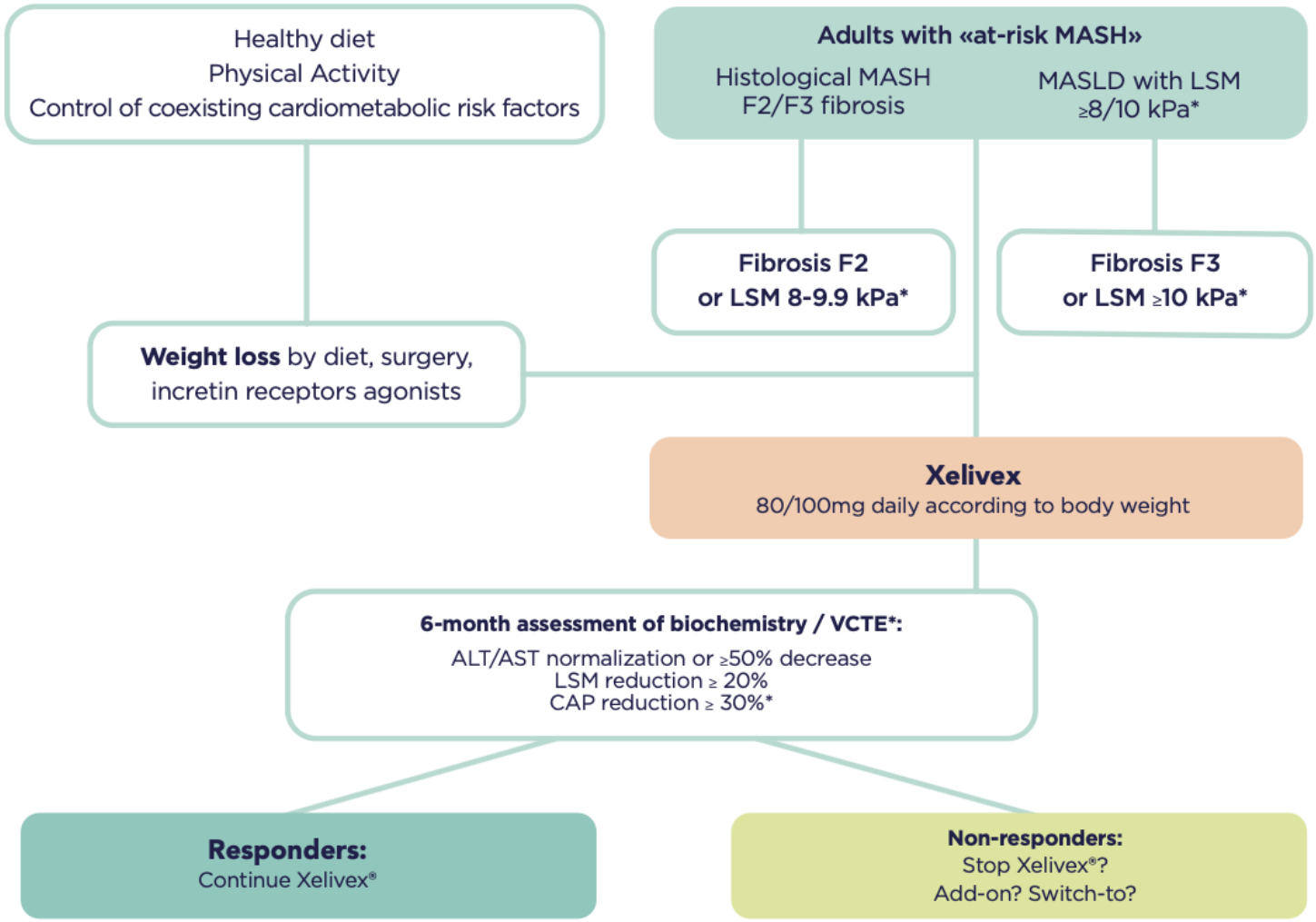
- Individualized decisions by a specialist experienced in liver fibrosis for:
  - LSM values outside the recommended ranges
  - Other NILDA data consistent with F2-F3[c]

[a] Modified from the AASLD NILDA guidelines.[5]
[b] Liver biopsy is not routinely recommended for staging of MASH.
[c] Imaging-based NILDA is preferred, eg, shear wave elastography (applying local standards for F2-F3) versus enhanced liver fibrosis score (9.2-10.4). The latter range is based on the interquartile range from the MAESTRO trial data; no recommendations are available from the AASLD NILDA guidelines.[6]

xelivex® Resmetirom

"Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance." *Hepatology (Baltimore, Md.)* vol. 81,1 (2025)

Xelivex® Treatment Algorithm For At-risk MASH



Diabetologia vol. 67,11 (2024): 2375-2392.

xelivex® Resmetirom

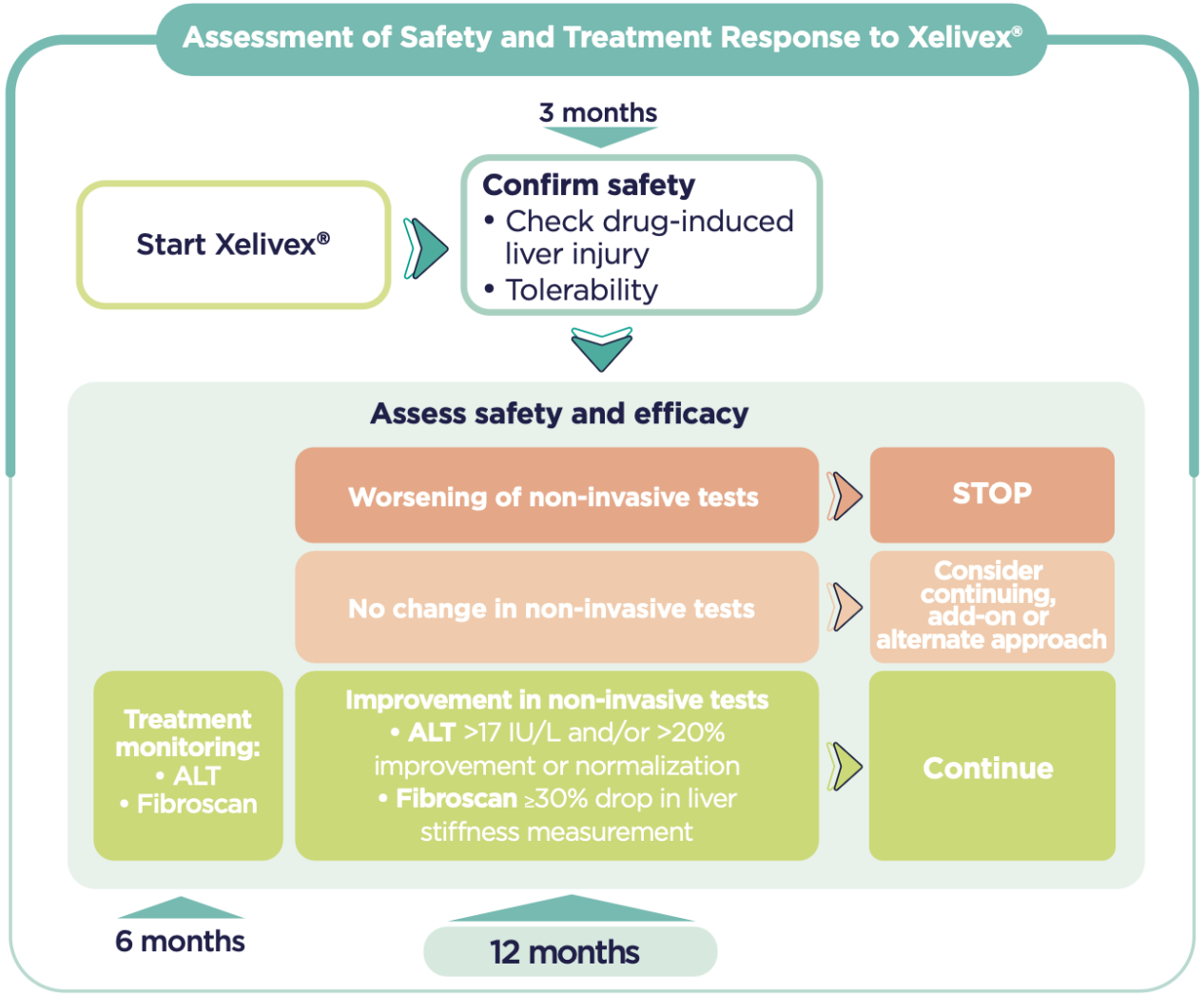
Safety and Efficacy Assessments within The First Year of Treatment with Xelivex®

	Safety/Efficacy assessments	Safety assessments		Efficacy assessments	
Timeframe	**Hepatic function panel[a]**	**Thyroid function[b]**	**Lipid profile[c]**	**Noninvasive measurement of liver stiffness[d]**	**MRI-PDFF[e]**
Before treatment initiation	✓	✓	✓	✓	Consider
3 months	✓				
6 months	✓	✓	✓		
12 months	✓	✓	✓	Repeat if imaging NILDA was used at baseline	Consider repeating if baseline data are available

xelivex® Resmetirom

"Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance." *Hepatology (Baltimore, Md.)* vol. 81,1 (2025)

Xelivex® Duration of Treatment



Diabetologia vol. 67,11 (2024): 2375-2392.

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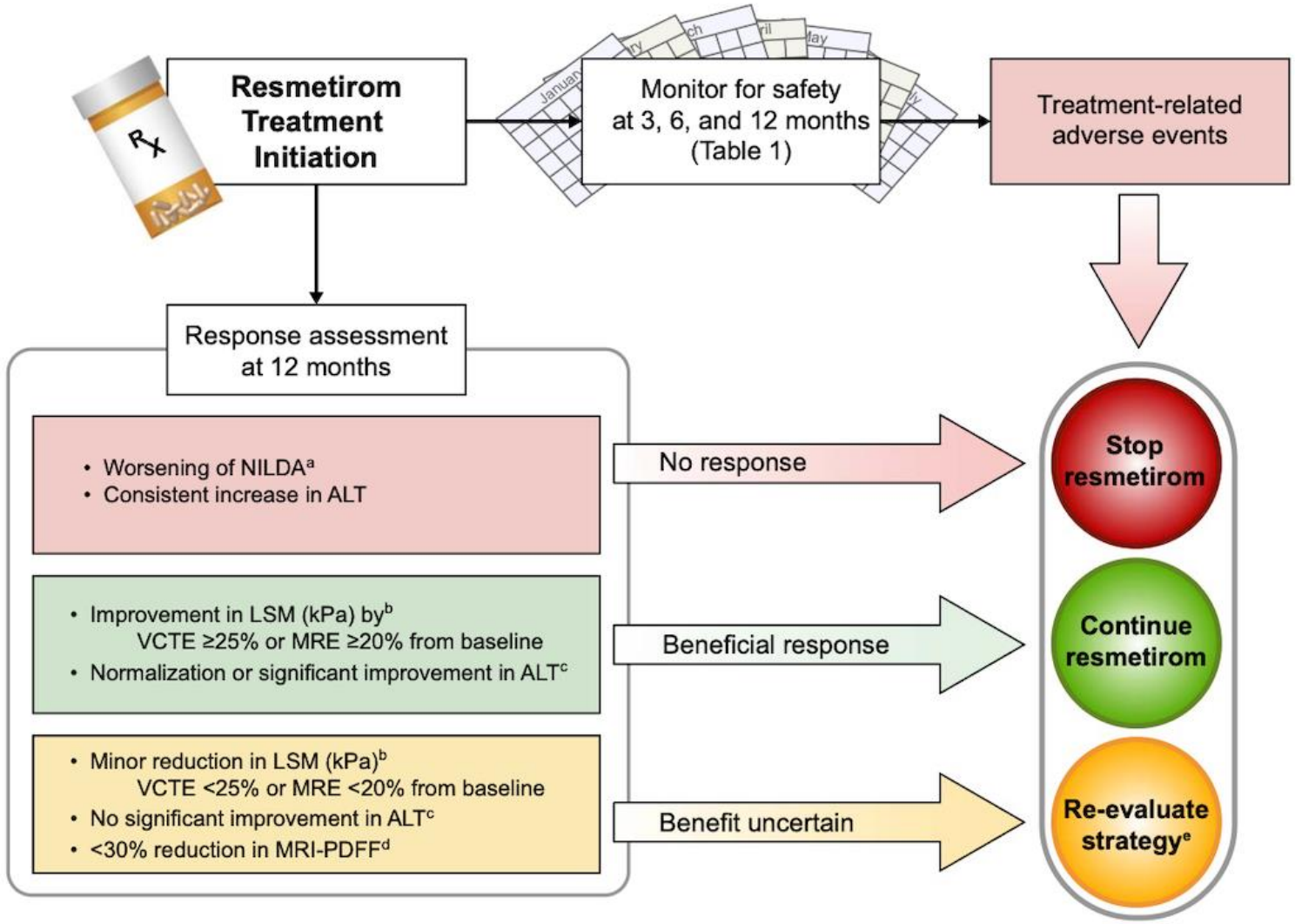
Assessment for Treatment Outcome in Patients Receiving Xelivex®



"Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance." *Hepatology (Baltimore, Md.)* vol. 81,1 (2025)

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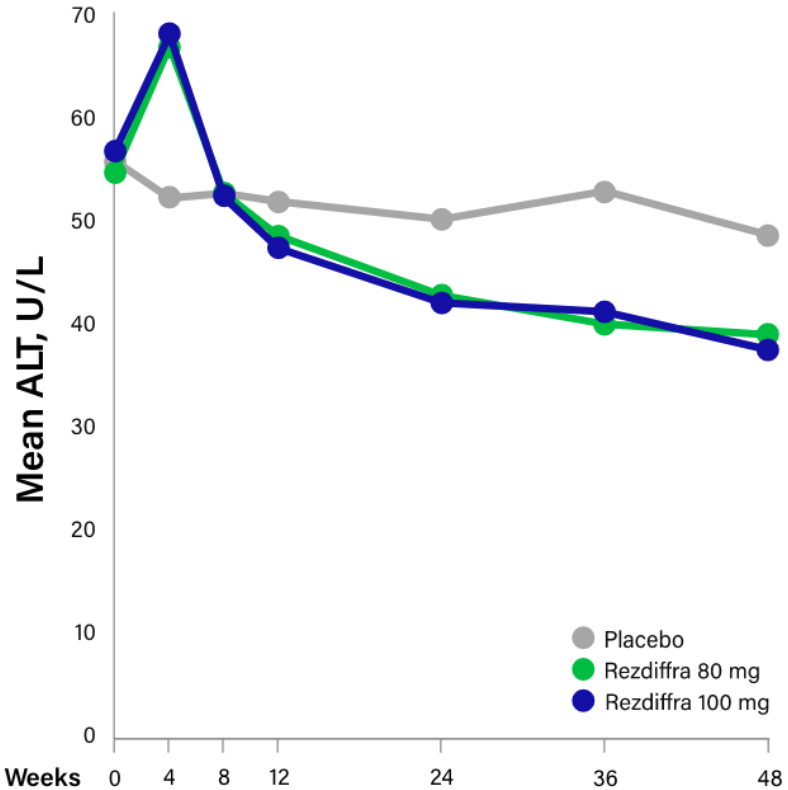
Early Period of Treatment with Xelivex®

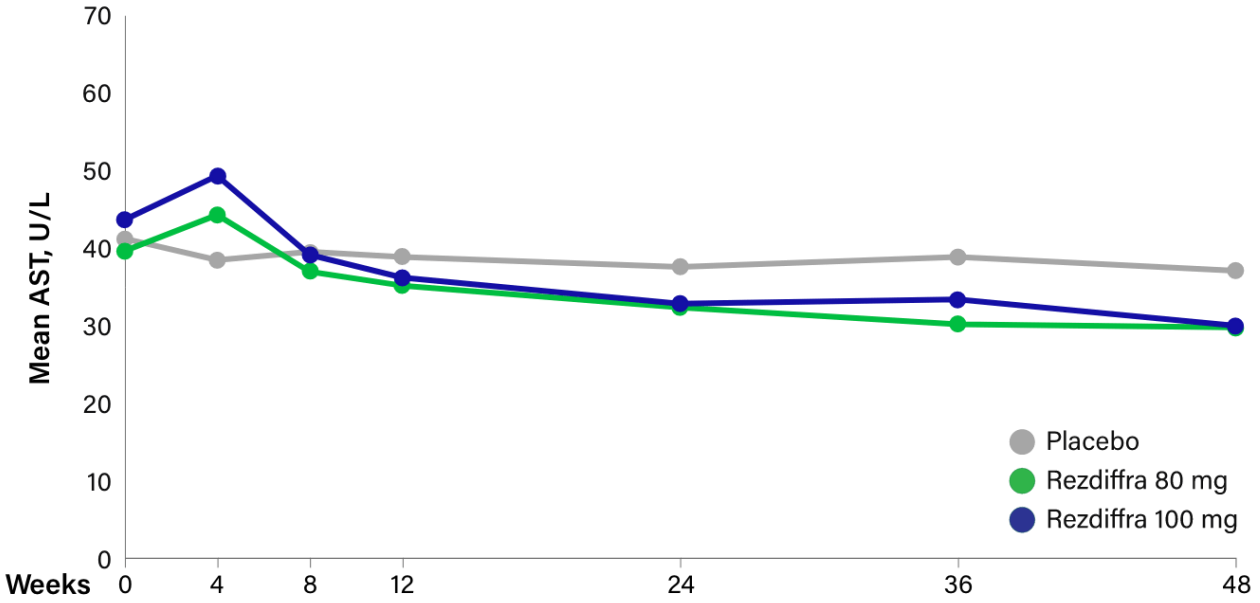
Slight increases (<1.5*baseline) of liver enzymes may be observed in the first 4 weeks, which returned to baseline around 8 weeks after initiation.

Alanine aminotransferase (ALT) laboratory curves[1]



Weeks	0	4	8	12	24	36	48
Placebo n=294	286	274	281	269	264	259	
Rezdiffra 80 mg n=298	285	280	273	269	260	252	
Rezdiffra 100 mg n=296	287	272	262	262	250	236	

Aspartate aminotransferase (AST) laboratory curves[1]



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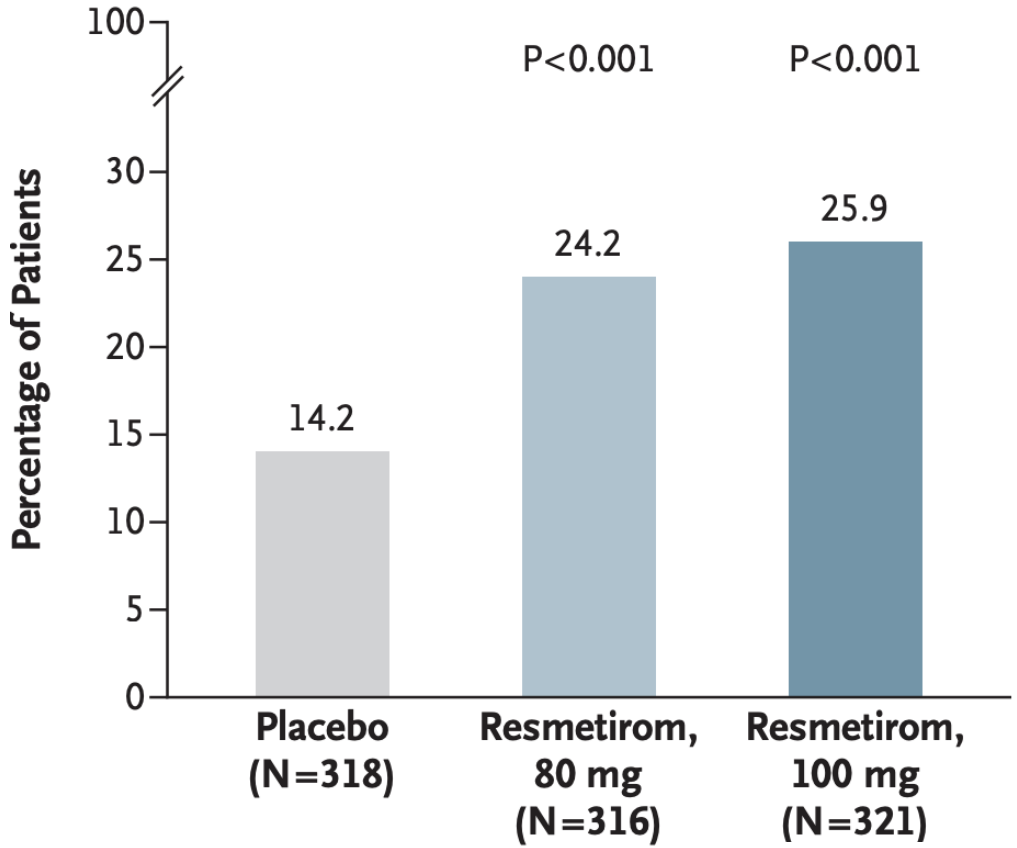
Rezdiffra 80 mg n=298	285	280	273	269	260	252	
Rezdiffra 100 mg n=296	287	272	262	262	250	236	

xelivex® Resmetirom

Maximum Liver Fibrosis Improvement by Xelivex®

Xelivex® significantly improves liver fibrosis by at least one stage.

Xelivex® showed effective fibrosis regression, with ≥1-stage improvement observed in 24-26% of patients.



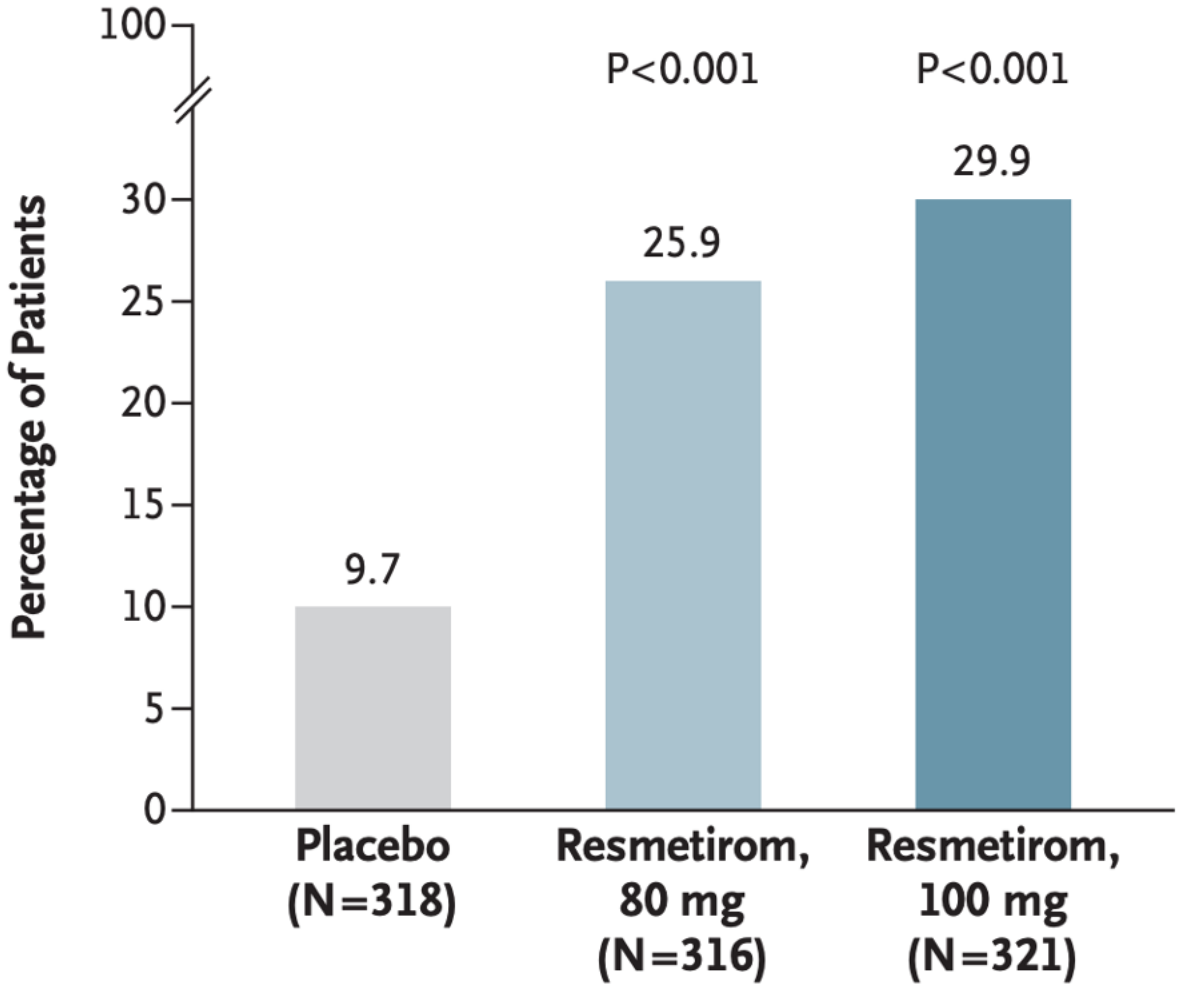
The New England journal of medicine vol. 390,6 (2024): 497-509.

xelivex® Resmetirom

Xelivex® demonstrated significant resolution of MASH after a period of 52 weeks.

Xelivex® significantly decreased NAS* in nearly 27.9% of patients in comparison to placebo.

*NAS, NAFLD Activity Score

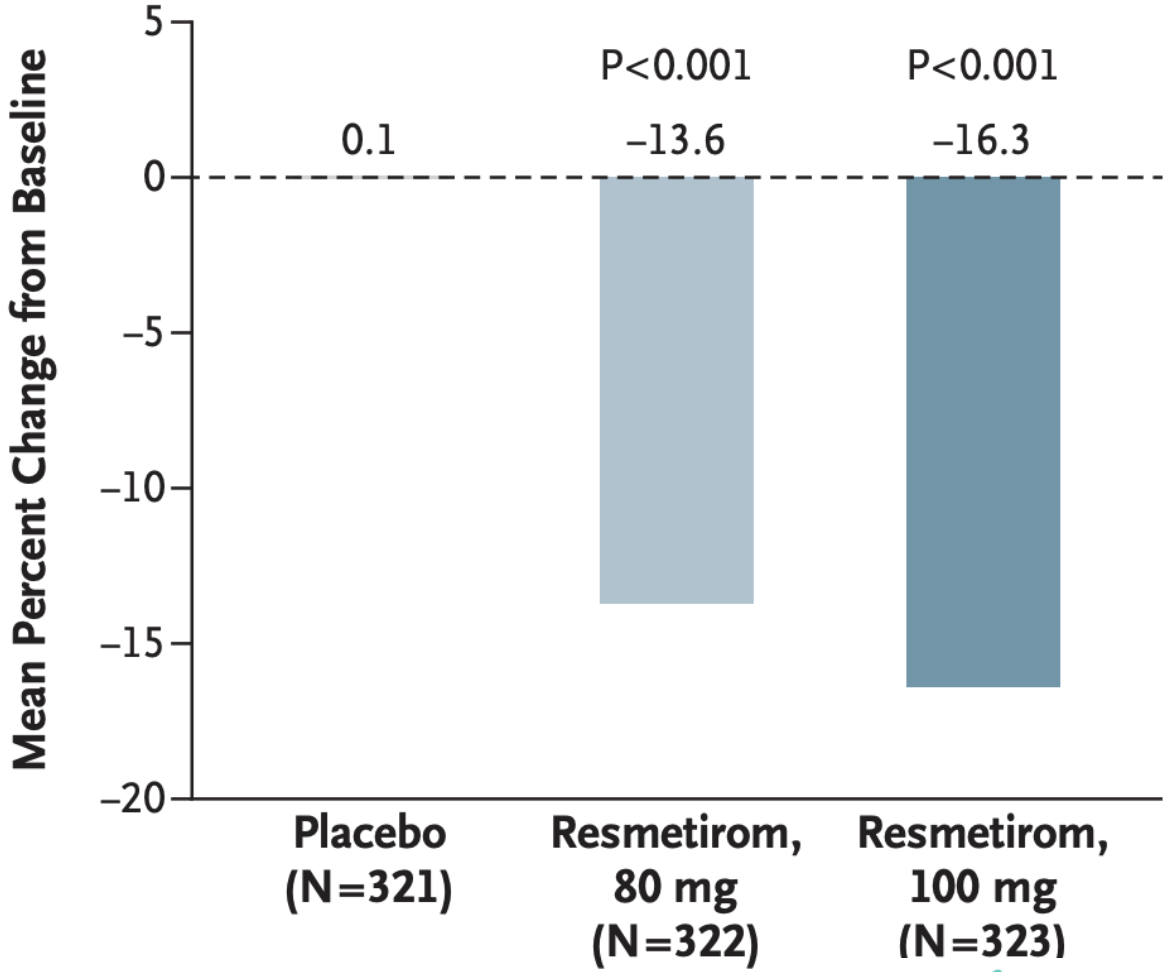


The New England journal of medicine vol. 390,6 (2024): 497-509.

xelivex® Resmetirom

Xelivex® expressed outstanding LDL level reduction after 24 weeks of treatment.

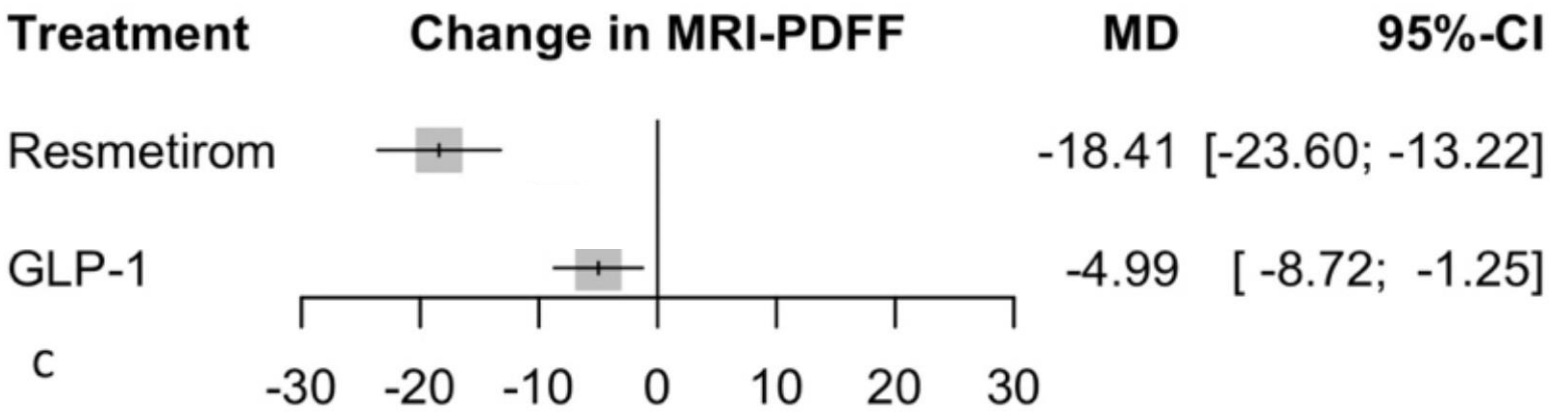
Xelivex® effectively reduced LDL levels (-13.6 to -16.3%) after 24 weeks of treatment.



The New England journal of medicine vol. 390,6 (2024): 497-509.

xelivex® Resmetirom

Xelivex® showed significant reduction in liver fat vs. GLP-1 agonists.



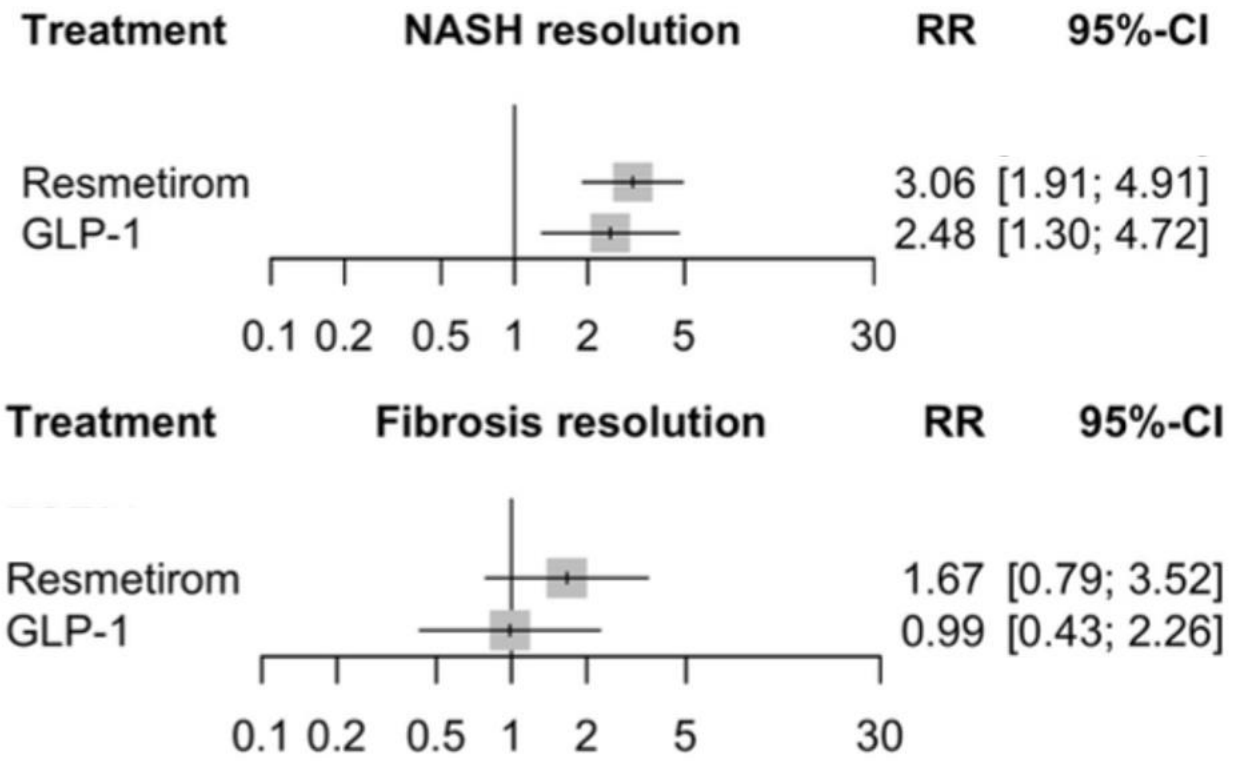
Xelivex® achieves the greatest reduction in hepatic fat content, with a mean decrease of −18.41%—more than double the effect observed with GLP-1 agonists.

Biomedicines vol. 12,10 2328. 14 Oct. 2024

xelivex® Resmetirom

Xelivex® demonsrates stronger NASH resolution than GLP-1 agonists, with a more favorable trend toward fibrosis improvement.

Xelivex® shows a higher relative risk of NASH resolution than GLP-1 agonists, with an RR of 3.06 vs. 2.48, and a more favorable performance in liver fibrosis improvement.

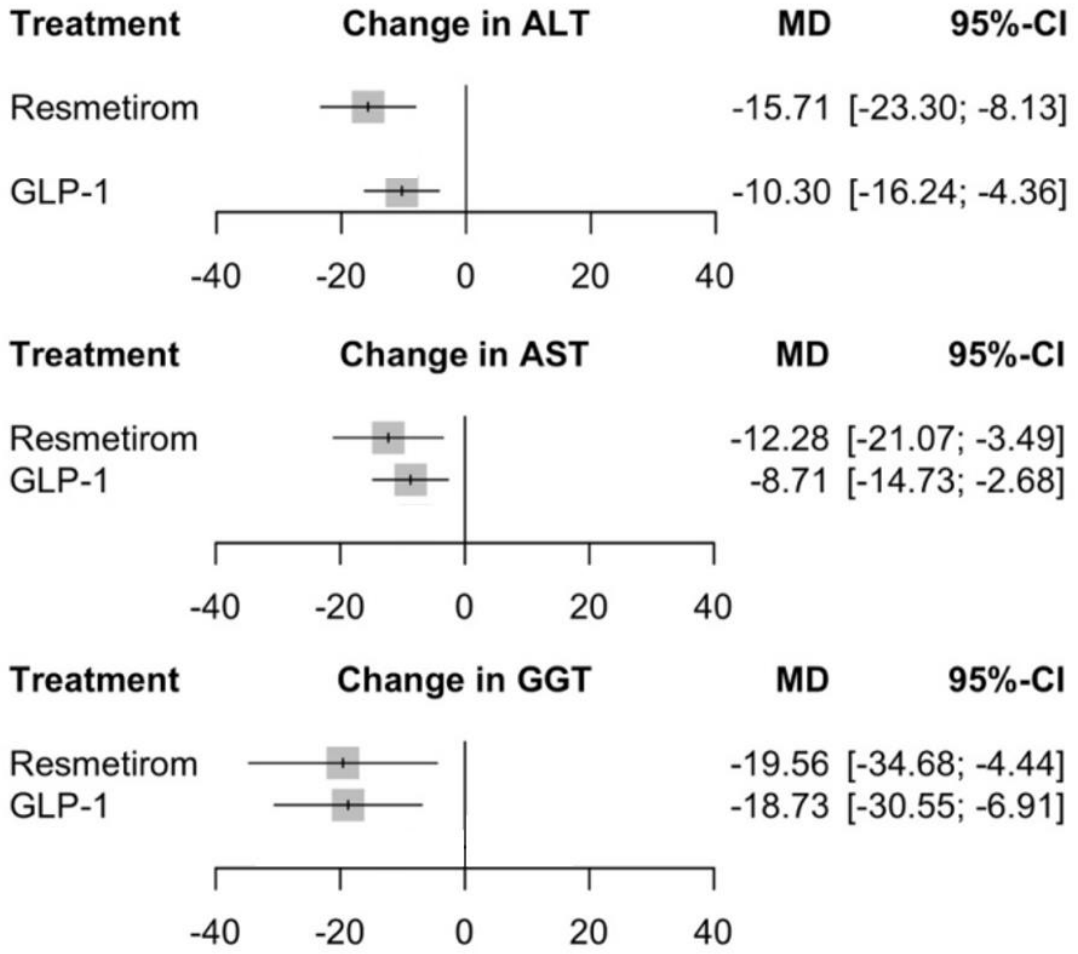


Biomedicines vol. 12,10 2328. 14 Oct. 2024

xelivex® Resmetirom

Xelivex® delivered significant reduction of liver enzymes, compared with GLP-1 agonists.

Xelivex® reduced ALT, AST, and GGT levels more effectively than GLP-1 agonists.

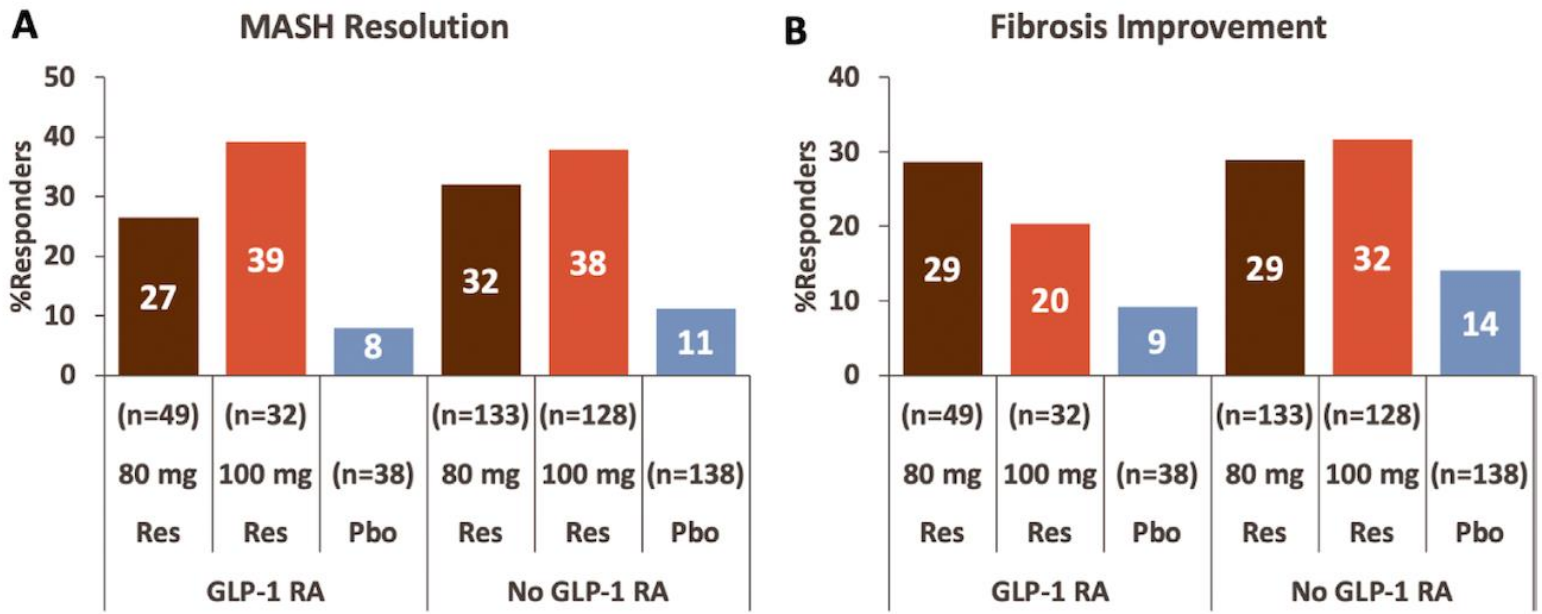


Biomedicines vol. 12,10 2328. 14 Oct. 2024

xelivex® Resmetirom

Xelivex® showed consistent histological benefits in both patients receiving and not receiving GLP-1 receptor agonists.

Fibrosis improvement was also observed with Xelivex®, supporting its liver-directed efficacy regardless of concomitant GLP-1 RA use.



Biomedicines vol. 12,10 2328. 14 Oct. 2024

xelivex® Resmetirom

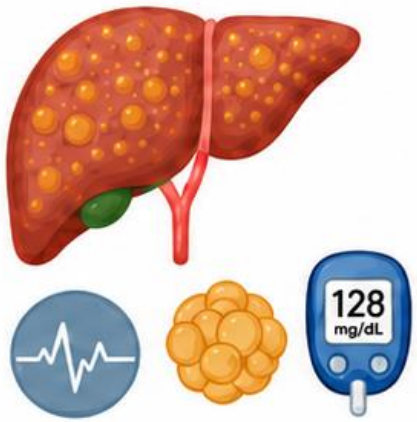
Early real-world effectiveness of resmetirom in adults with metabolic dysfunction-associated steatohepatitis and moderate-to-advanced fibrosis

Abstract No. 174 | Clinical Science | MASLD: Therapy

BACKGROUND

Resmetirom is a THR-beta agonist approved in the US in 2024 for adults with noncirrhotic MASH and moderate-to-advanced fibrosis.

Aim: assess early real-world effectiveness in US practice.



METHODS

1) Single-arm retrospective cohort

2) Latica real-world database

3) Adults with >=1 resmetirom prescription

4) 712 patients included | mean treatment duration: 5.7 months

Common risk factors: hypertension 77%, obesity 71%

RESULTS

Clinically meaningful improvements over ~6 months

FAST score	ALT	LSM by VCTE
↓ 0.18 (n=28)	↓ 13.6 U/L (n=330)	↓ 2.2 kPa (n=70)

Response thresholds met

FAST	ALT	VCTE
42.9% (≥0.22 reduction)	46.7% (≥17 U/L or ≥20% reduction)	41.4% (≥30% reduction)

Subgroup observations

- Statin and non-statin users showed similar overall trends.
- Lipid markers improved in both groups.
- GLP-1 concomitant users and non-users showed similar ALT/AST declines and slight BMI reduction.
- LSM decline was greater with GLP-1 concomitant use: −3.2 vs −1.9 kPa.
- CAP declined in both groups: −39.5 vs −43.9 dB/m.

Treatment-related AE discontinuation: ~2%
Most common reason: diarrhea

CONCLUSION

In this real-world analysis, resmetirom was associated with **clinically meaningful improvements** in blood and imaging biomarkers over approximately 6 months, suggesting early effectiveness consistent with the 52-week MAESTRO-NASH trial.

Larger cohorts with longer follow-up are needed to assess long-term outcomes.

Discontinuation due to treatment-related adverse events was uncommon.

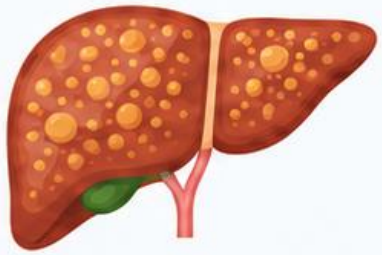
***Source**: study abstract provided by user*

Real-world effectiveness of one year of Resmetirom treatment in at-risk metabolic dysfunction–associated steatohepatitis

Abstract No. 3697 | Clinical Science | MASLD: Therapy

BACKGROUND

Resmetirom, a selective thyroid hormone receptor-β agonist, has shown histologic efficacy in MASH. Real-world treatment response data remain limited.



Aim: To assess hepatic and metabolic responses to at least 1 year of resmetirom using noninvasive tests (NITs).

METHODS

- Retrospective real-world study
- Adults with presumptive F2/F3 at-risk MASH
- Outpatient hepatology practice
- 599 patients prescribed resmetirom (Mar 2024–Jul 2025)
- 331 completed ≥52 weeks
  - Excluded: GLP-1/GIP analog users (n=268)
- **Final analysis: n=204**

Assessments: aminotransferases, fibrosis scores (e.g., FIB-4, FAST), VCTE/CAP, lipid parameters, tolerability

Baseline characteristics (n=204)

Mean age	55 years
Male	42%
Mean BMI	37.7 kg/m²
T2DM	49.5%
Dyslipidemia	33.8%
Hypertension	54.9%

RESULTS (After 52 Weeks of Resmetirom)

62.7% achieved ≥1-stage reduction in liver fibrosis by VCTE

Mean VCTE kPa reduction	⬇ 32.2%
Mean CAP reduction	⬇ 21.1%

AST	⬇ −12.5 IU/L
ALT	⬇ −22.44 IU/L

Lipid Parameters

Total cholesterol	⬇ −24.36 mg/dL
LDL-C	⬇ −26.19 mg/dL
Triglycerides	⬇ −68.6 mg/dL
HDL-C	⬆ +5.5 mg/dL

8% discontinued due to adverse events

CONCLUSION

In real-world clinical practice, 52 weeks of resmetirom was associated with **significant improvements in liver fibrosis, steatosis, liver enzymes, and cardiometabolic parameters** in patients with at-risk MASH.

Therapy was generally **safe and well tolerated,** supporting the effectiveness of resmetirom in routine care.

Source: *study abstract provided by user*

Twelve-month changes in liver function enzymes and lipids in patients receiving resmetirom

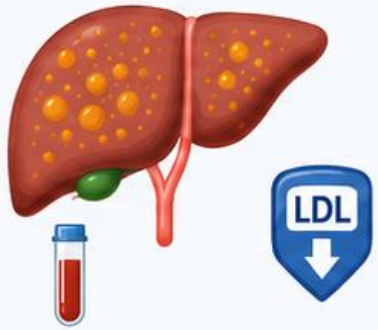
Abstract No. 840 | Clinical Science | MASLD: Therapy

BACKGROUND

Resmetirom is a THR-beta selective agonist.

Approved in the US in March 2024 for adults with noncirrhotic MASH and moderate-to-advanced fibrosis.

Aim: assess 12-month changes in ALT, AST, and LDL-C in routine practice.



METHODS

- Retrospective cohort study
- Truveta deidentified EHR + medication dispensing data
- Adults ≥18 years initiating resmetirom on/after Mar 14, 2024
- Follow-up through Oct 17, 2025
- Outcomes: ALT, AST, LDL-C at baseline and 12 months
- Analyses stratified by T2D and GLP-1 use

N=728 with 12-month follow-up

- Mean age 58 years
- 36% male
- 52% T2D
- 30% GLP-1 use

RESULTS

Key 12-month changes

ALT	AST	LDL-C
64.5 → 43.1 U/L	50.1 → 35.4 U/L	93.9 → 85.4 mg/dL
↓ -21.5 U/L	↓ -14.7 U/L	↓ -8.5 mg/dL
$p < 0.01$	$p < 0.01$	$p < 0.05$
$n=222$	$n=222$	$n=85$

Subgroup observations

- ALT and AST declines were similar regardless of T2D status or GLP-1 use.
- LDL-C reductions were similar in T2D and non-T2D patients.
- LDL-C reduction was smaller in baseline GLP-1 users: -1.0 vs -11.9 mg/dL (small subgroup).

CONCLUSION

- Mean liver function tests decreased over 12 months in patients receiving resmetirom.
- Improvements in ALT and AST were observed irrespective of T2D or GLP-1 use.
- LDL-C decreased overall; reductions were smaller in baseline GLP-1 users.
- Further research should evaluate additional non-invasive measures and longer-term outcomes.

Source: *study abstract provided by user*

Dosage and Route of administration

	<100 kg Body Weight	≥100 kg Body Weight
Dosage	xelivex® 80 QD	xelivex® 100 QD
Concomitant Use with Clopidogrel	xelivex® 60 QD	xelivex® 80 QD

Contraindications

- Concomitant use with a strong CYP2C8 inhibitor (e.g., gemfibrozil) is not recommended.

Xelivex® is an oral, once-daily tablet that can be taken with or without food.

FDA Prescribing Information – 2024

xelivex® Resmetirom

Safety considerations

Pregnancy

- There are no available data on Xelivex use in pregnant women.

Breastfeeding

- There is no information regarding the presence of Xelivex in human or animal milk, the effects on the breast-fed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Xelivex and any potential adverse effects on the breastfed infant from Xelivex or from the underlying maternal condition.

Geriatric Use

- Trials have shown numerically higher incidence of adverse reactions in adults aged 65 years or older than younger adult patients.

Renal Impairment

- Despite the similar dosage of Xelivex in patients with mild to moderate renal impairment and patients with normal renal function, there is lack of data regarding Xelivex use in severe renal impairment.

Hepatic Impairment

- Avoid use of Xelivex in decompensated cirrhosis. Child-Pugh Class B or C (moderate to severe impairment) may increase the risk of adverse reactions, while there is no need for dosage adjustment in patients with Child-Pugh Class A (mild impairment).

- The safety and effectiveness of Xelivex have not been established in patients with MASH cirrhosis.

Statins

- It is recommended to keep statin at the minimum effective dosage when used concurrently.

xelivex® Resmetirom

FDA Prescribing Information – 2024

First in Iran, Trusted by thousands

- Rosha Pharmaceutical Company, the first manufacturer of the first FDA-approved liver-directed therapy for MASLD in Iran.
- More than **4,000 patients** currently under treatment; the highest coverage of fatty liver patients under treatment in Iran
- In 12 months, **over 500 physicians** trusted Xelivex®.
- **One year** of successful presence in Iran's pharmaceutical market
- **68% of patients** experienced at least one stage improvement in liver fibrosis after 6 months with Xelivex®.

Key Messages

- Xelivex is the first FDA-approved medication for the treatment of MASH with moderate to advanced liver fibrosis.

- Xelivex is a liver-directed, orally active THR agonist, improving lipid metabolism, glucose homeostatsis, and inflammation.

- Xelivex showed effective fibrosis regression, with ≥1-stage improvement observed in 24-26% of patients.

- Xelivex significantly decreased NAFLD activity score (NAS) in nearly 27.9% of patients in comparison to placebo.

- Xelivex effectively reduced LDL levels (-13.6 to -16.3%) after 24 weeks of treatment.

- **Xelivex** achieves the greatest reduction in hepatic fat content, with a mean decrease of −18.41%—more than double the effect observed with GLP-1 agonists.
- **Xelivex** demonstrates a superior efficacy compared with GLP-1 agonists achieving >30% hepatic fat reduction with a high relative risk.
- **Xelivex** is an oral, once-daily tablet that can be taken with or without food.
- **Xelivex** is administered using weight-based dosing, with 80 mg for patients <100 kg and 100 mg for those ≥100 kg.
- **Xelivex** should be avoided in decompensated cirrhosis and severe hepatic impairment, while dose reduction is required when co-administered with Clopidogrel.

xelivex®
Resmetirom

xelivex®

Resmetirom

60,80,100 mg | F.C. Tablet

XELIVEX, the Silent Savior of Liver

Thank you!