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PATIENT CHARACTERISTICS AND CHANGES IN LIVER FUNCTION LABORATORY TESTS AMONG RESMETIROM TREATED PATIENTS IN A REAL-WORLD MASH POPULATION

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RESONANCE
Real-World Evidence of Resmetirom Advancing Outcomes, Natural History, Assessment, and Clinical Effectiveness

INTRODUCTION

- Metabolic dysfunction-associated steatohepatitis (MASH) is characterized by hepatic steatosis, inflammation, and hepatocellular injury, with potential progression to advanced fibrosis, cirrhosis, and liver-related complications.
- Resmetirom (brand name Rezdiffra) was approved in the United States (US) in March 2024 for adults with noncirrhotic MASH with moderate to advanced liver fibrosis (F2-F3).[1]
- Real-world evidence is needed to characterize early users, treatment continuity, and lab changes following initiation.

AIM

To describe baseline characteristics and changes in hepatic and cardiometabolic laboratory measures among adults initiating resmetirom in routine US clinical practice.

METHODS

Study design and data source

- This was a descriptive and retrospective study using Optum's de-identified Market Clarity Data (Optum® Market Clarity) with a study period from March 14, 2023 through March 31, 2026.

Study population and eligibility

- The study included adults with ≥1 paid prescription claim for resmetirom on or after March 14, 2024 (first paid claim=index date) and with continuous medical and pharmacy enrollment in the 12-month pre-index period (zero gap allowance).
- Patients with record of ≥1 diagnosis for non-MASH liver conditions, cirrhosis-related complications, or heavy-metal exposures in the 12-month pre-index period were excluded.

Study outcomes and statistical methods

- Baseline demographics and clinical characteristics were summarized using descriptive statistics.
- Changes in hepatic and cardiometabolic biomarkers were evaluated between baseline (365 days on/before index) and follow-up (365 days post-index ±45 days).
  - Mean within-patient changes were evaluated using paired t-tests among patients with measurements at both baseline and follow-up.
  - Mean within-patient absolute value percentage change was reported.

RESULTS

Baseline characteristics

- A total of 2,732 patients met the inclusion criteria; mean age was 61.4 years (SD, 12.9) and 62% were female (**Table 1**).
- Among patients with body mass index (BMI) information (n=412), mean BMI was 34.0 kg/m2 (SD, 6.2); when assessed categorically, the majority (1,598/1,954; 82%) had a BMI ≥30.0 kg/m2.
- Over half of patients were obese (n=1,637; 60%) or had type 2 diabetes (n=1,429; 52%).
- At baseline, 35% of patients (n=956) were prescribed glucagon-like peptide 1 receptor agonists (GLP-1 RAs).

Table 1. Baseline Characteristics

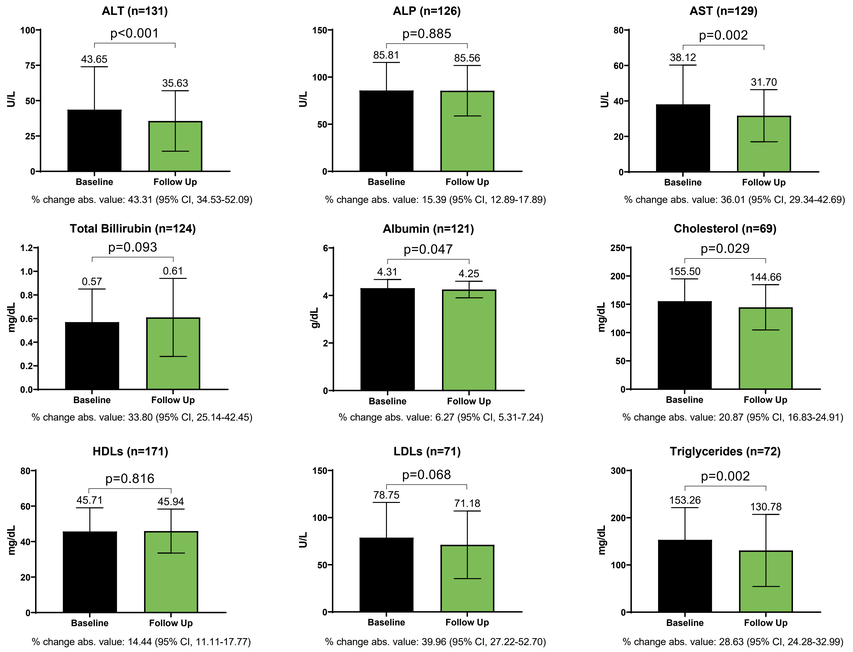
Characteristic, N (%)	Resmetirom Cohort N=2,732
Age, mean (SD)	61.4 (12.9)
Female	1,685 (61.7%)
Payor	
Commercial	940 (34.4%)
Medicare	1,561 (57.1%)
Medicaid	224 (8.2%)
Unknown	7 (0.3%)
BMI, categorical	**n=1,954**
<25.0 kg/m^2	48 (2.5%)
25.0 - <30.0 kg/m^2	308 (15.8%)
≥30.0 kg/m^2	1,598 (81.8%)
BMI, continuous	**n=412**
Mean (SD), kg/m^2	34.0 (6.2)
Select Comorbidities	
Hyperlipidemia	2,031 (74.3%)
Hypertension	1,943 (71.1%)
Obesity	1,637 (59.9%)
Type 2 diabetes mellitus	1,429 (52.3%)
Cardiometabolic risk factors	
0	193 (7.1%)
1	342 (12.5%)
2	605 (22.1%)
3+	1,592 (58.3%)
Baseline medication use	
Hyperlipidemia/dyslipidemia medications	
Statins	1,655 (60.6%)
Other lipid medications	580 (21.2%)
GLP-1s	956 (35.0%)
Follow-up days, mean (SD)	280.8 (186.4)

Abbreviations: BMI, body mass index; GLP-1s, glucagon-like peptide-1 receptor agonists

Changes in hepatic and cardiometabolic biomarkers

- At 12 months, patients with paired measurements had mean decreases in ALT of 8.0 U/L, AST of 6.4 U/L, total cholesterol of 10.8 mg/dL, and triglycerides of 22.5 mg/dL. All four changes were nominally statistically significant (**Figure 1**).
- The within-patient absolute value percentage change for these biomarkers was 43.31% for ALT, 36.01% for AST, 20.87% for cholesterol, and 28.63% for triglycerides.
- Sample sizes ranged from 69 to 131 across these outcomes.

Figure 1. 12-month changes in hepatic and cardiometabolic biomarkers



Abbreviations: ABS, absolute; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CI, confidence interval; g/dL, grams per deciliter; HDLs, high-density lipoproteins, LDLs, low-density lipoproteins; mg/dL, milligrams per deciliter; SD, standard deviation; U/L, units per liter.

LIMITATIONS

- There was no comparator group. Laboratory changes were assessed using uncontrolled pre-post comparisons and cannot be attributed solely to resmetirom.
- There was selective laboratory availability. Only a minority of initiators had measurements at both baseline and 12 months, and patients undergoing repeated testing may differ systematically from the overall cohort.
- Concurrent treatment with GLP-1 receptor agonists, statins, diabetes therapies, weight change, and other clinical management may have contributed to laboratory changes.
- Limited generalizability: Continuous medical and pharmacy enrollment selects patients with stable insurance and may limit applicability to uninsured or intermittently insured populations.

CONCLUSIONS

- In this early real-world cohort, adults initiating resmetirom had substantial cardiometabolic burden, including high prevalences of obesity, type 2 diabetes, hypertension, and hyperlipidemia.
- Among selected patients with paired laboratory measurements, mean ALT, AST, total cholesterol, and triglycerides decreased from baseline to 12 months. ALP, bilirubin, HDL, and LDL did not change significantly, while albumin decreased slightly.
- These uncontrolled available case findings are exploratory and require confirmation with longer follow-up and comparative analyses.

REFERENCES

1. US Food & Drug Administration. FDA approves first treatment for patients with liver scarring due to fatty liver disease. 2024. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-liver-scarring-due-fatty-liver-disease.

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ABBREVIATIONS

ALP, alkaline phosphatase; **ALT**, alanine aminotransferase; **AST**, aspartate aminotransferase; **BMI**, body mass index; **F2–F3**, fibrosis stages 2–3; **FDA**, Food and Drug Administration; **g/dL**, grams per deciliter; **GLP-1 RA**, glucagon-like peptide-1 receptor agonist; **HDL**, high-density lipoprotein; **kg/m²**, kilograms per square meter; **LDL**, low-density lipoprotein; **MASH**, metabolic dysfunction-associated steatohepatitis; **mg/dL**, milligrams per deciliter; **PDC**, proportion of days covered; **U/L**, units per liter; **US**, United States

DISCLOSURES

MB serves on advisory boards or steering committees for Boehringer Ingelheim, Boston Pharma, CurveBio, Fibronostics, GSK, Madrigal, Merck, Novo Nordisk, Surrozen, and Theratechnologies Medical, and received research funding from Histoindex, Pfizer, and Siemens. **EB**, **CG**, and **AC** are employees of Genesis Research Group which received funding from Madrigal to conduct this study. **DVV** is an employee of IQVIA and was employed by Genesis Research Group at the time of the study. **JPM** is an employee of Petauri and was employed by Genesis Research Group at the time of the study. **BT**, **NA**, **FL**, and **JOD** are employees and shareholders of Madrigal.

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