Assessing the Feasibility of a German Electronic Hepatology Network Database as a Real-World Data Source for Steatotic Liver Disease Research

RWD160

Karolin Weber [1], Milica Matijevic [1], Tobias Heidler [1], Mohammed Dagher [2], Dennis Häckl [3], Michael Schultze [2], Marc Pignot [2], Ingolf Schiefke [4]

1 WIG2 GmbH – Scientific Institute for Health Economics and Health System Research, Leipzig, Germany
2 ZEG Berlin GmbH, Berlin, Germany
3 Leipzig University, Leipzig, Germany
4 GREENBAY research GmbH, Leipzig, Germany

Introduction

- Metabolic Dysfunction-Associated Steatotic Liver Disease (**MASLD**) is a leading cause of chronic liver disease, affecting 23% of adults in Germany, and up to 30% of the global population [1]. Its progressive form, Metabolic Dysfunction-Associated Steatohepatitis (**MASH**), affects 4-5% of adults in Germany [2] and can progress through hepatic fibrosis to cirrhosis, increasing the risk of end-stage liver disease and hepatocellular carcinoma (HCC) [3].
- Despite the high prevalence of MASLD and the high risk of its progression to MASH, both conditions remain substantially underdiagnosed: according to expert consensus, around 75% of MASH patients in Germany are undetected [1]. This is largely attributable to the asymptomatic nature of early-stage disease and the constraints of ICD-10-GM-based coding [2], which captures diagnoses alone without the laboratory or imaging data explaining fibrosis severity. Consequently, complementary real-world data (RWD) sources are needed to provide information on disease severity and progression that is not routinely captured in claims data alone.

Objectives

- to characterize MASLD and MASH patients within a German Electronic Health Record (EHR) network of over 50 general practitioners and specialists (gastroenterologists and hepatologists);
- to assess the EHR network's potential as a complementary RWD source for a comprehensive steatotic liver disease research.

Methods

Data Source

The EHR network provides daily-updated data for more than 240,000 patient cases annually. Alongside demographic data, it captured diagnostic test results, medication details, comorbidities, and repeated measurements of routinely collected **liver-related biomarkers**, including alanine aminotransferase (ALT), gamma-glutamyltransferase (GGT), bilirubin (BILI), prothrombin time (Quick), platelet count (PC), and alpha-1 antitrypsin (A1AT).

Study Design & Population

The study cohort comprised of patients with MASLD and MASH, monitored in period 2019-2025. Patients with diagnosis of viral hepatitis, toxic, autoimmune, inherited metabolic, or cholestatic liver diseases, alcoholic liver disease, or HIV infection were not included.

Database Characterization

Abnormalities were determined relative to the laboratory-reported normal range for each result. **Thrombocytopenia** was classified based on PC in Gpt/L as mild (100 ≤ PC < 150), moderate to severe (PC < 100). **Advanced fibrosis risk** was stratified as low (FIB-4 < 1.3), indeterminate (1.3 ≤ FIB-4 < 2.67), or high (FIB-4 ≥ 2.67), assessed at the earliest value (baseline) and, in the ΔFIB-4 subset, the most recent value (follow-up).

Fibrosis stage (F0–F4) was determined by transient elastography–based liver stiffness measurement (LSM) in kPa, using the following cutoffs: F0–F1 (LSM < 7.5 kPa), F2 (7.5 kPa ≤ LSM < 10 kPa), F3 (10 kPa ≤ LSM < 14 kPa), F4 (LSM ≥ 14 kPa). **Cirrhosis** was classified as excluded (LSM < 12.1) or not excluded (LSM ≥ 12.1).

Results

Liver Biomarkers

Abnormalities of BILI, GGT, ALT, and thrombocytopenia were significantly more frequent in MASH than MASLD (p_{adj} < 0.001); whereas A1AT deficiency was comparable (p_{adj} > 0.9).

Liver Stiffness Measurement

Nearly all MASLD patients (99.6%) fell within F0–F1, whereas 5.7% of MASH patients had F4 stage. F3 was rare overall (4 of 2,392 patients), occurring exclusively in MASH.

LSM-based cirrhosis criteria were met in 6.3% of MASH versus 0.05% of MASLD patients (p_{adj} < 0.001), consistent with the overall pattern of greater disease severity in MASH.

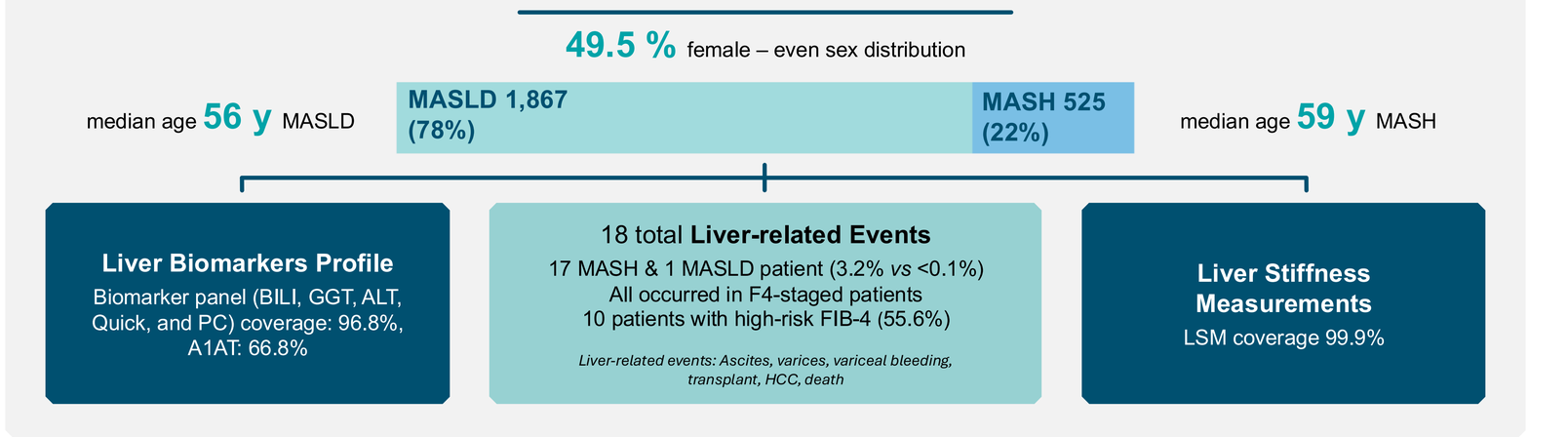
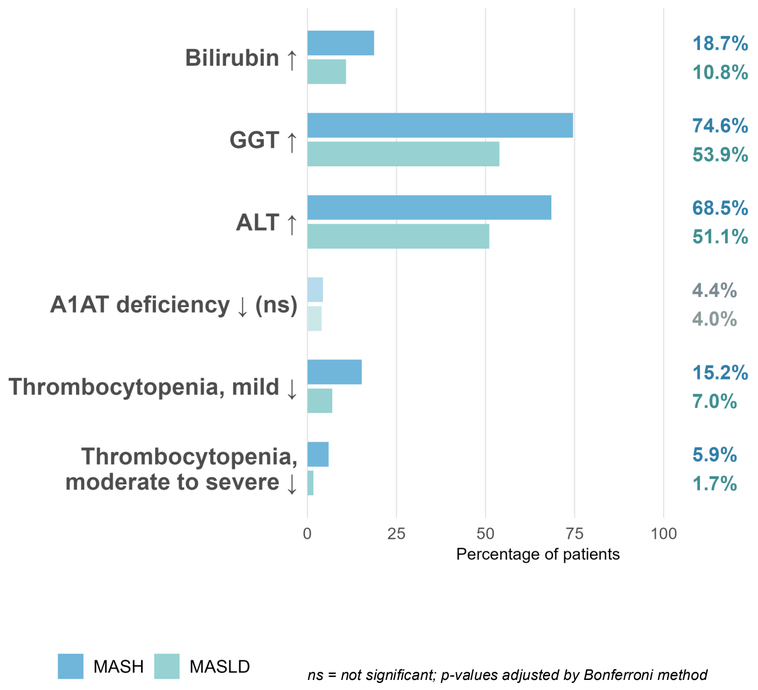
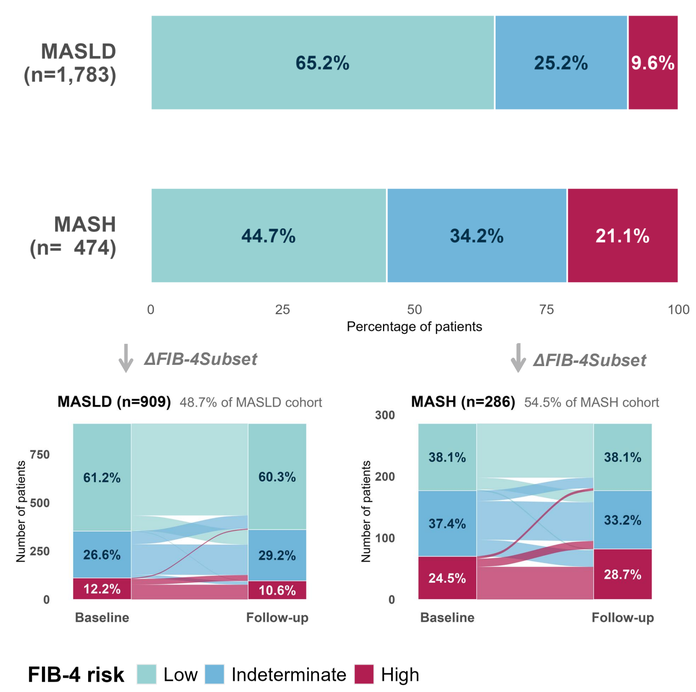


Fig 1: Laboratory abnormalities



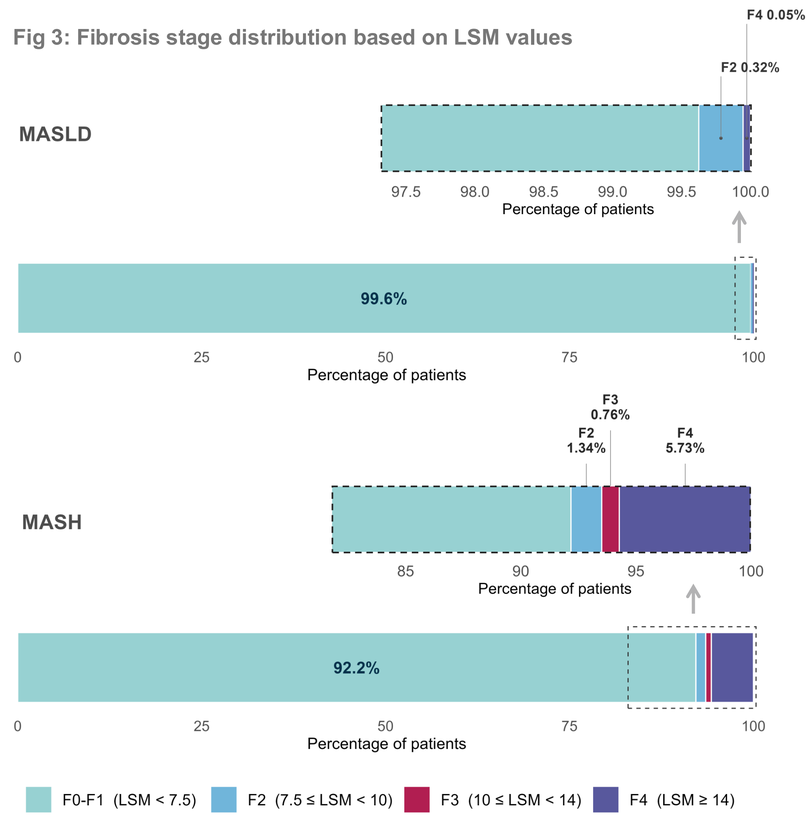
ns = not significant; p-values adjusted by Bonferroni method

Fig 2: Advanced fibrosis risk



ΔFIB-4 Subset comprised 1,195 patients (50.0%) with both a baseline and follow-up FIB-4 value (median interval between measurements was 32.3 months, IQR 15.3–54.8)

Fig 3: Fibrosis stage distribution based on LSM values



Key findings

- **High LSM (99.9%) and biomarkers panel (96.8%) coverage** highlight this network's strength for non-invasive fibrosis assessment.
- **MASH** shows consistently **higher liver disease burden than MASLD** across fibrosis stage, cirrhosis, advanced fibrosis risk, and the frequency of abnormal liver-related biomarkers.
- All 18 liver-related events (17 MASH and 1 MASLD) exclusively occurred in F4-staged patients; FIB-4 flagged high risk of advanced fibrosis in 9 of these 17 MASH cases and the single MASLD case.
- In ΔFIB-4 Subset, FIB-4 risk more often worsened in MASH and more often improved or stayed stable in MASLD.

Conclusion

Steatotic liver disease carries a substantial and rising burden, highlighting the need for clinical data to complements claims-based insights. This GP/specialist EHR network addresses that gap, providing detailed clinical and laboratory data that enable a more comprehensive understanding of MASLD and MASH.

Limitations

Low A1AT coverage (66.8%) likely underestimates true A1AT deficiency prevalence in this cohort.

References

[1] Kim Y. et al. Liver International 45, 8 (2025) DOI: 10.1111/liv.70225
[2] Tacke F. et al. Journal of Comparative Effectiveness Research 15, 8 (2026) DOI: 10.57264/cer-2026-0092
[3] Younossi Z. et al. Clinical Gastroenterology and Hepatology, 24, 1016-1034 (2025) DOI: 10.1016/j.cgh.2025.09.002