Real-world clinical characteristics and treatment patterns of patients with metabolic dysfunction-associated steatohepatitis in Germany

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BACKGROUND

- Metabolic dysfunction-associated steatohepatitis (MASH) is a chronic, progressive disease characterized by fatty liver, liver cell injury, and inflammation. MASH can progress from liver fibrosis to cirrhosis as well as hepatocellular carcinoma.
- The global MASH prevalence is estimated to be 5% of the general population and 16% of the metabolic dysfunction-associated steatotic liver disease population.[1-2]

OBJECTIVES

- To understand the clinical characteristics and disease journey of patients with MASH in Germany, and to assess the need for novel treatments to prevent disease progression.

METHODS

Study design

- Data were drawn from the Adelphi Real World MASH Disease Specific Programme (DSP)™, a cross-sectional survey, with retrospective data collection of physicians and their patients with MASH in France, Germany and Italy between January and May 2024. The DSP methodology has been described, validated, and demonstrated to be representative and consistent over time.[3-6]

Inclusion and Exclusion criteria

- Physicians were eligible to participate if they were a primary care physician or specialist* who was personally responsible for the clinical management of patients with MASH and saw a minimum of five (primary care physicians) or ten (specialists) patients per month.
- Patients were eligible if they were ≥18 years old, were being managed for MASH, did not have another form of liver disease** and were not participating in a clinical trial for MASH at the time of data collection.
- Physicians reported patient demographics and clinical characteristics.

Data analysis

- Fibrosis severity was physician-stated based upon recent tests and assessments (e.g. lab tests [blood or urine], liver composite tests [LCTs], liver imaging scans and/or liver biopsy).
- Patients were grouped by physician-stated fibrosis severity at data collection into F0-F1, F2-F3 and F4 and were compared using Spearman's Rho and Kruskal-Wallis.

RESULTS

Survey population

- Overall, data were collected from 65 physicians reporting data on 587 patients with MASH.
- Patients were grouped by physician stated fibrosis severity at the time of data collection as F0-F1 (n=344), F2-F3 (n=236), and F4 (n=7).

Demographics

- For F0-F1, F2-F3 and F4, respectively:
  - the mean age (± standard deviation [SD]) was 54.7±10.2, 55.8±10.2 and 61.7±7.4 years.
  - The proportions of females was 40.7%, 36.4% and 28.6%.
  - The mean body mass index (BMI) was 32.1±4.0kg/m^2, 32.3±4.1kg/m^2 and 29.2±5.5kg/m^2 - **Table 1**.

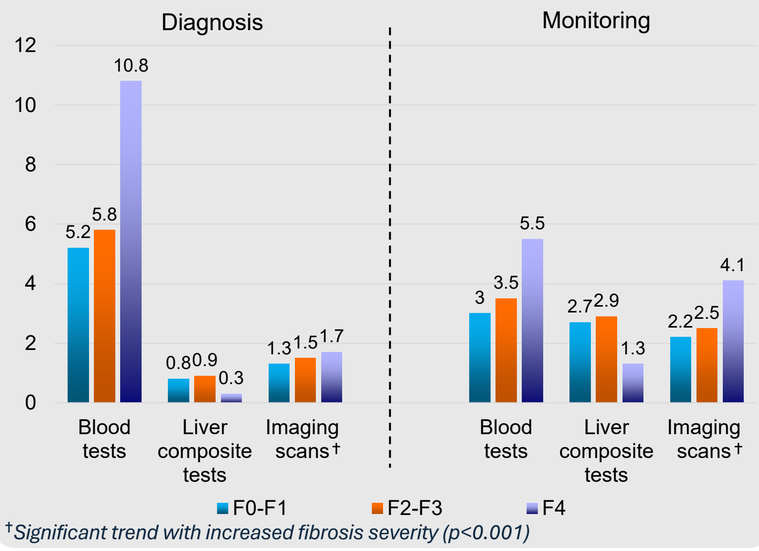
Tests to diagnose and assess MASH

- As fibrosis severity increased, patients had more tests to aid diagnosis (r=0.13, p<0.01), especially imaging scans (r=0.18, p<0.001).
- In the two years prior to the survey, for F0–F1, F2–F3, and F4 patients, respectively:
  - the mean number of LCTs was 2.7 ± 2.6, 2.9 ± 3.3, and 1.3 ± 0.6.
  - the mean number of imaging scans was 2.2 ± 1.2, 2.5 ± 1.6, and 4.1 ± 3.4 (r = 0.10, p < 0.05).
  - the mean number of blood tests was 3.0 ± 1.8, 3.5 ± 2.3, and 5.5 ± 3.8 (r = 0.10, p < 0.05) – **Figure 1**.
  - The proportion of patients who had a liver biopsy to assess MASH was 5.1%, 13.0% and 42.9% (p<0.0001)

TABLE 1. Demographic and clinical characteristics of patients with F0-F1, F2-F3 and F4 MASH.

	F0-F1	F2-F3	F4	Rho	P-value
Overall, n	**344**	**236**	**7**		
Patient age, years, mean±SD	54.7±10.2	55.8±10.2	61.7±7.4	0.07	0.0969
Patient sex, male, n (%)	204 (59.3)	150 (63.6)	5 (71.4)		0.5016
Patient BMI, kg/m^2, mean±SD	32.1±4.0	32.3±4.1	29.2±5.5	0.01	0.724
Number of days since MASH diagnosis, n, mean±SD	324 482.1±569.3	193 526.6±697.0	7 1135.1±981.9	0.03	0.5358
Hospitalisations in last 12 months, n, mean±SD	337 0.1±0.0	231 0.2±0.0	7 0.4±0.0	0.11	0.0073
Number of comorbidities, n, mean±SD	316 3.1±1.7	216 3.5±2.0	6 4.7±1.6	0.10	0.0201
Charlson Comorbidity Index, n, mean±SD	343 2.1±0.3	236 4.2±0.7	7 4.7±0.8	0.95	<0.0001
Comorbidities, n (%)					
Dyslipidaemia	201 (58.6)	135 (57.2)	3 (42.9)		0.6826
Hypertension	157 (45.8)	135 (57.2)	5 (71.4)		0.0142
Type 2 diabetes	169 (49.3)	115 (48.7)	3 (42.9)		0.9406
Obesity	110 (32.1)	74 (31.4)	3 (42.9)		0.8095

FIGURE 1. Mean number of tests conducted to aid diagnosis and for monitoring.



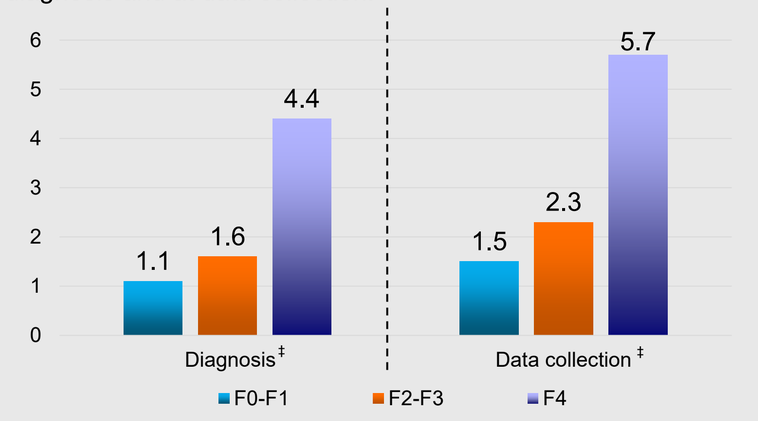
†*Significant trend with increased fibrosis severity (p<0.001)*

TABLE 2. Test Results

Reported as n, mean±sd

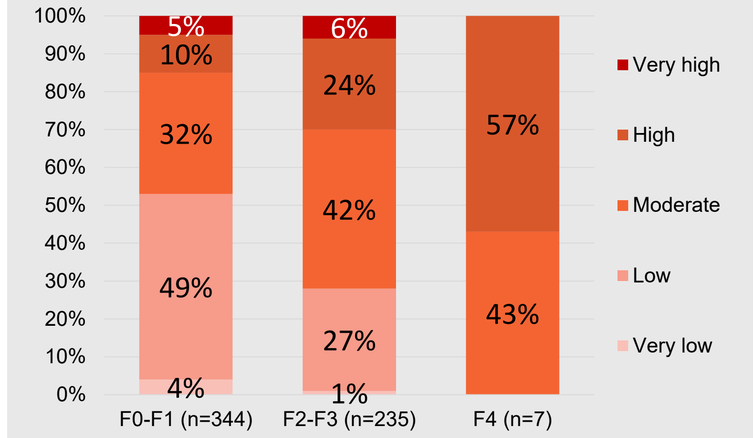
	Diagnosis		Data collection	
	All patients	F2-F3	All patients	F2-F3
Blood pressure, mmHg, n, mean±SD				
Systolic	260 140.5±12.6	111 141.9±11.4	N/A	N/A
Diastolic	268 84.4±9.3	111 85.7±8.4	N/A	N/A
HbA1c, %, n, mean±SD	250 6.9±1.0	97 6.9±0.9	136 6.7±1.0	48 6.7±1.1
Lipids, mg/dL, n, mean±SD				
LDL	128 132.5±43.5	52 131.1±44.8	82 119.8±36.8	26 121.9±38.0
HDL	105 85.1±51.0	42 74.3±46.4	58 85.1±45.2	15 75.7±48.3
Triglycerides	131 223.2±105.1	52 226.6±64.9	83 180.9±120.5	21 170.1±38.8

FIGURE 2. Mean number of symptoms present at diagnosis and at data collection.



‡ *Significant trend with increased fibrosis severity (p<0.0001)*

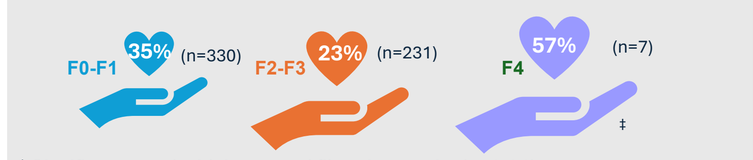
FIGURE 3. Physician perceived cardiovascular risk.



Clinical characteristics

- Increased fibrosis severity was also associated with more symptoms at diagnosis (r=0.18, p<0.001) and at time of data collection (r=0.22, p<0.001) – **Figure 2**.
- Overall, the most common symptoms at diagnosis were fatigue (32.5% of F0–F1, 46.5% F2-F3 and 85.7% F4), sleep disturbance (19.1%, 25.4%, 28.6%) and general weakness (16.6%, 23.3%, 57.1%). These were the most common at data collection also: fatigue (39.0% of F0–F1, 55.4% F2–F3, 85.7% F4); sleep disturbance (24.1%, 33.1%, 28.6%); and general weakness (20.2%, 33.9%, 71.4%).
- Increased fibrosis severity was associated with higher Charlson Comorbidity Index (r=0.95 – **Table 1**), cardiovascular risk (r=0.28 – **Figure 3**), hepatocellular carcinoma risk (r=0.37), more treatments prescribed for MASH-associated comorbidities (r=0.20) and history of major adverse cardiovascular events (all p<0.05).
- Blood pressure, HbA1c, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglyceride levels reported at diagnosis and data collection shown in **Table 2**.
- The number of patients considered by physicians to be a candidate for novel MASH therapy also increased as fibrosis severity increased (p<0.05).

FIGURE 5. Proportion of patients with a caregiver***



‡ *Significant trend with increased fibrosis severity (p<0.01)*

Limitations

- While minimal inclusion criteria governed selection of participating physicians, participation was influenced by willingness to complete the survey.
- Patients were actively consulting, which limits the generalisability of the results to all patients with MASH.
- Recall bias, a common limitation of surveys, may have affected physician responses to questions. However, physicians had access to patient medical records reducing risk of recall bias.

CONCLUSION

This study demonstrated a substantial clinical and HCRU burden in Germany. Advancing fibrosis stage was associated with increased clinical and economic burden, underscoring the need for targeted therapies to prevent further liver damage and associated complications, and in turn, these may improve outcomes in patients with MASH.

* gastroenterologists, hepatologists, internal medicine specialists or endocrinologists/diabetologists

** For example, Alcohol-related liver disease, Primary Biliary Cholangitis, Viral hepatitis and Autoimmune hepatitis, Wilson's disease, alpha-1- antitrypsin deficiency or hemochromatosis

*** Caregiver status: Physicians were asked to state whether the patient had any additional support/care as a result of their MASH above and beyond what would be expected for a person of their age

ABBREVIATIONS

BMI: body mass index; DSP: Disease Specific Programme; HDL: high-density lipoprotein; LCT: liver composite tests; LDL: low-density lipoprotein; MASH: Metabolic dysfunction-associated steatohepatitis; SD: standard deviation

DISCLOSURES AND ACKNOWLEDGEMENTS

- HW, LA, EQ and RS are all employees of Adelphi Real World
- YK, MD and MI are all employees of Madrigal Pharmaceuticals
- KT is a former employee of Adelphi Real World

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