

Real-World clinical characteristics and healthcare resource utilisation of patients with metabolic dysfunction-associated steatohepatitis in France

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INTRODUCTION

- 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, disease journey and healthcare resource utilisation (HCRU) of patients with MASH in France 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)TM, a cross-sectional survey, with retrospective data collection of physicians and their patients with MASH in France, Germany and Italy. Data collection occurred between January and May 2024. The DSP methodology has been described, validated, and demonstrated to be representative and consistent over time.^{3, 4, 5, 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, clinical characteristics and HCRU.

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 74 physicians reporting data on 698 patients with MASH.
- Patients were grouped by physician stated fibrosis severity at the time of data collection as F0-F1 (n=240), F2-F3 (n=369) and F4 (n=89).

Demographics

- For F0-F1, F2-F3 and F4, respectively:
 - the mean age (± standard deviation [SD]) was 54.6±11.1, 56.6±11.4 and 64.9±10.0 years.
 - The proportions of females was 50.8%, 40.9%, and 41.6% – **Table 1**.
 - The mean body mass index (BMI) was 31.5±6.0 kg/m², 32.0±4.8 kg/m² and 33.9±7.6 kg/m² – **Table 1**.

CONCLUSION

This study demonstrates the substantial clinical and HCRU burden associated with MASH in France. Advancing fibrosis severity was associated with greater clinical and economic burden, underscoring the need for effective targeted therapeutic strategies to prevent further progression and associated complications of liver damage to improve patient outcomes.

RESULTS

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	240	369	89		
Patient age, years, mean±SD	54.6±11.1	56.6±11.4	64.9±10.0	0.23	<0.0001
Patient sex, male, n (%)	118 (49.2)	218 (59.1)	52 (58.4)		0.0471
Patient BMI, kg/m ² , n, mean±SD	238 31.5±6.0	368 32.0±4.8	88 33.9±7.6	0.11	0.0053
Number of days since MASH diagnosis, n, mean±SD	198 959.9±1226.8	289 923.7±1089.4	67 1363.2±1140.1	0.09	0.028
Number of hospitalisations in last 12 months for:					
MASH, n, mean±SD	203 0.0±0.3	317 0.1±0.3	78 0.5±1.1	0.24	<0.0001
MASH-related comorbidity, n, mean±SD	200 0.1±0.3	312 0.2±0.6	76 0.3±1.0	0.10	0.0167
Number of nights spent in hospital (last five hospitalisations), n, mean±SD	23 2.7±4.0	80 4.1±7.7	46 6.7±6.6	0.30	0.0002
Charlson Comorbidity Index (CCI), n, mean±SD	230 2.1±0.5	362 4.3±0.7	87 4.4±0.9	0.82	<0.0001

FIGURE 1. Mean number of tests conducted to assess MASH

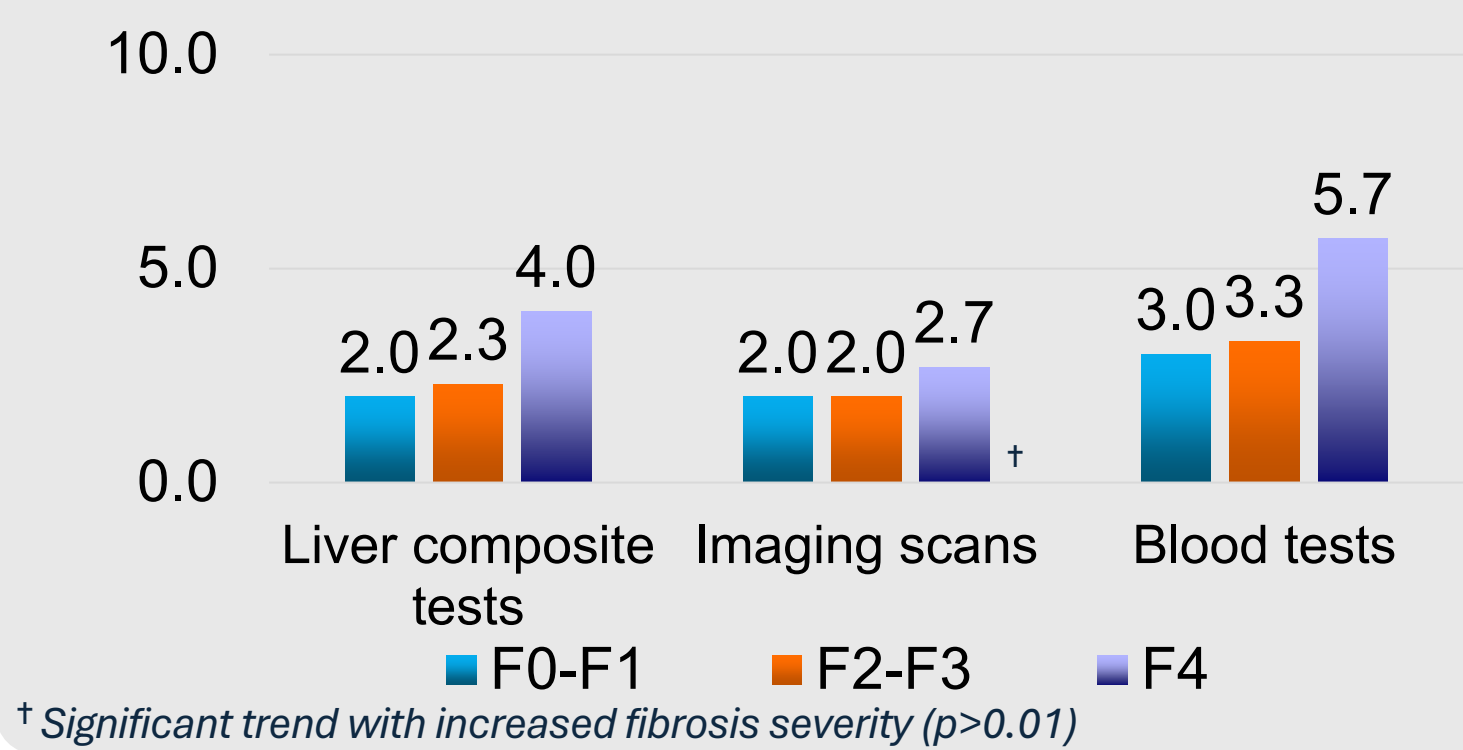
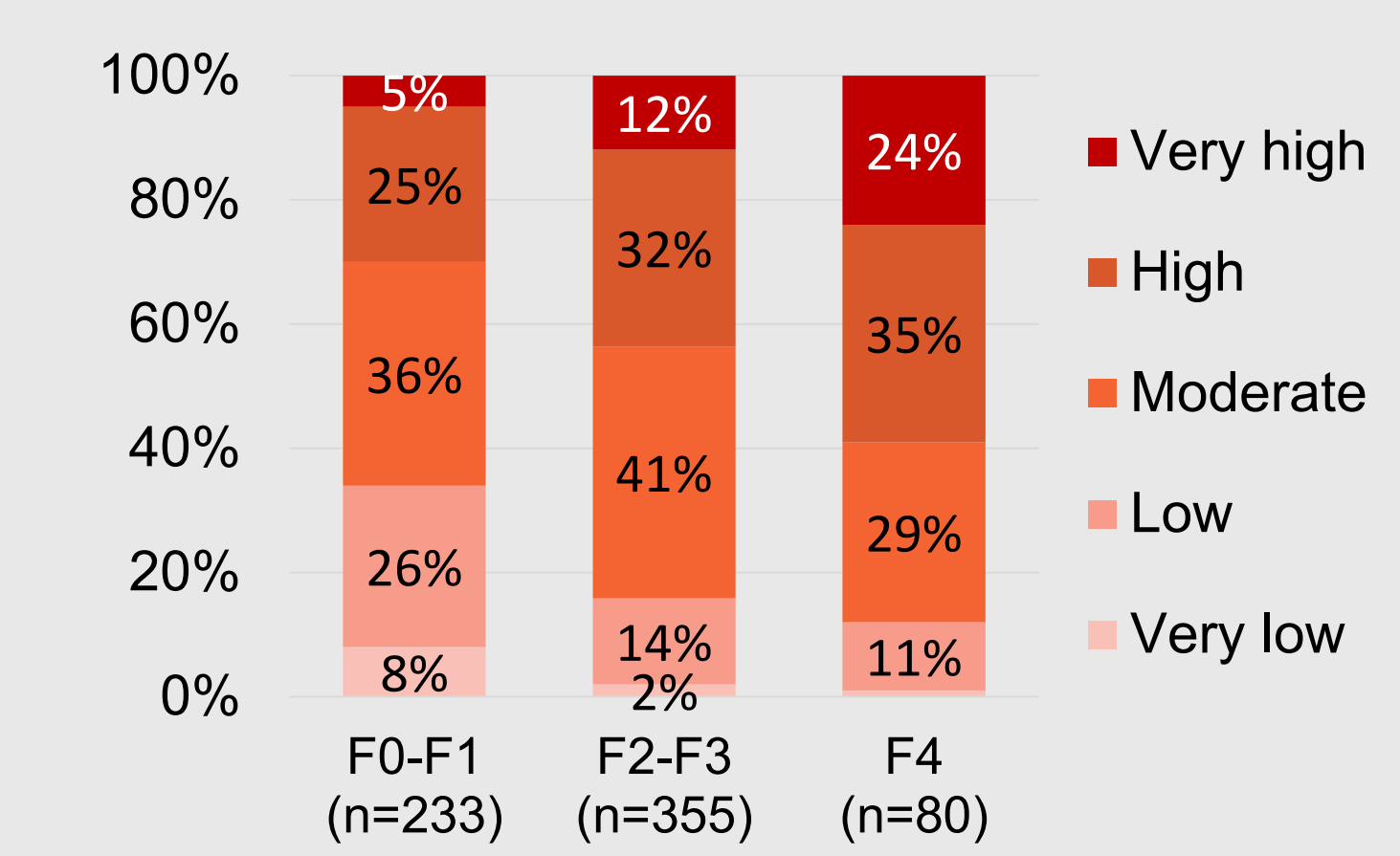


FIGURE 3. Physician perceived cardiovascular risk.



Tests to assess MASH

- Increased fibrosis severity was associated with more tests/scales/scans to assess MASH (r=0.11, p<0.01); including LCTs (r=0.12; p<0.05), imaging scans (r=0.12, p<0.01) and blood tests (r=0.09) – **Figure 1**.
- Proportion of patients who had a liver biopsy to assess MASH also increased with fibrosis severity (p<0.05).

Clinical characteristics

- Increased fibrosis severity was also associated with more symptoms at diagnosis (r=0.12, p<0.01) and at time of data collection (r=0.21, p<0.0001) as well as presence of fatigue, general weakness and sleep disturbance at data collection – **Figure 2**.
- Charlson Comorbidity Index (r=0.82 – **Table 1**), perceived cardiovascular risk (r=0.25 – **Figure 3**), risk of hepatocellular carcinoma (r=0.43 – **Figure 4**) and history of major adverse cardiovascular events increased with fibrosis severity (all p<0.001)

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

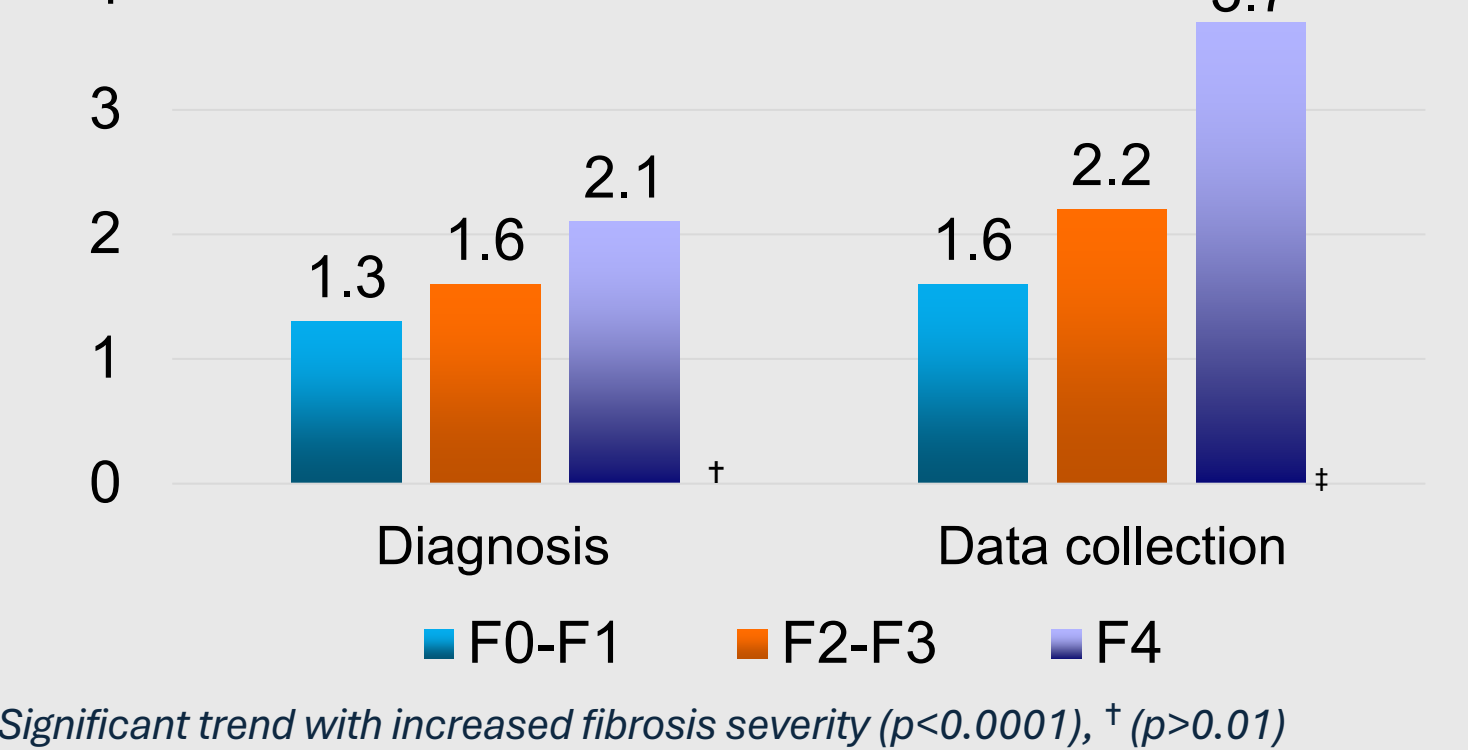


FIGURE 4. Physician perceived hepatocellular carcinoma risk

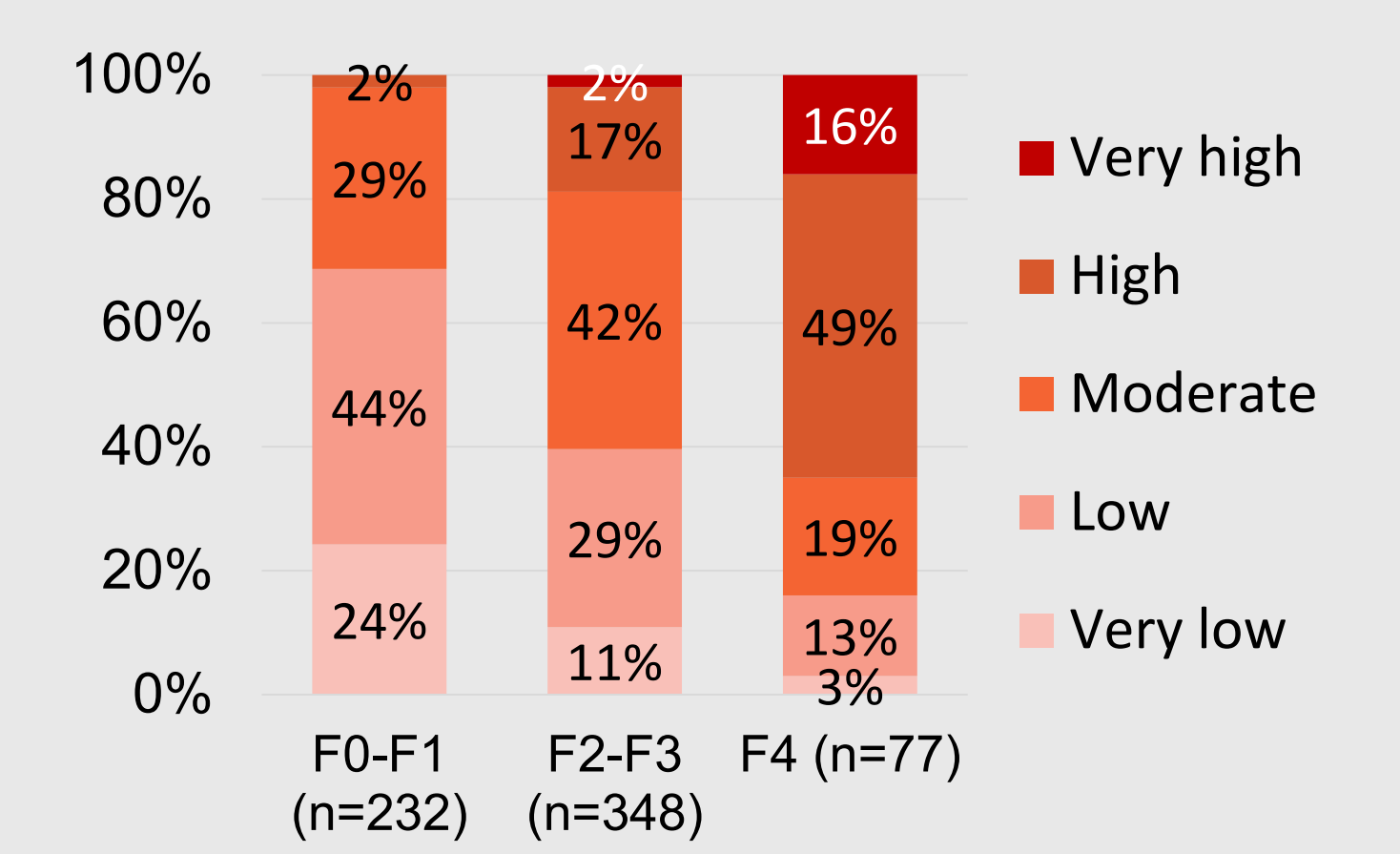
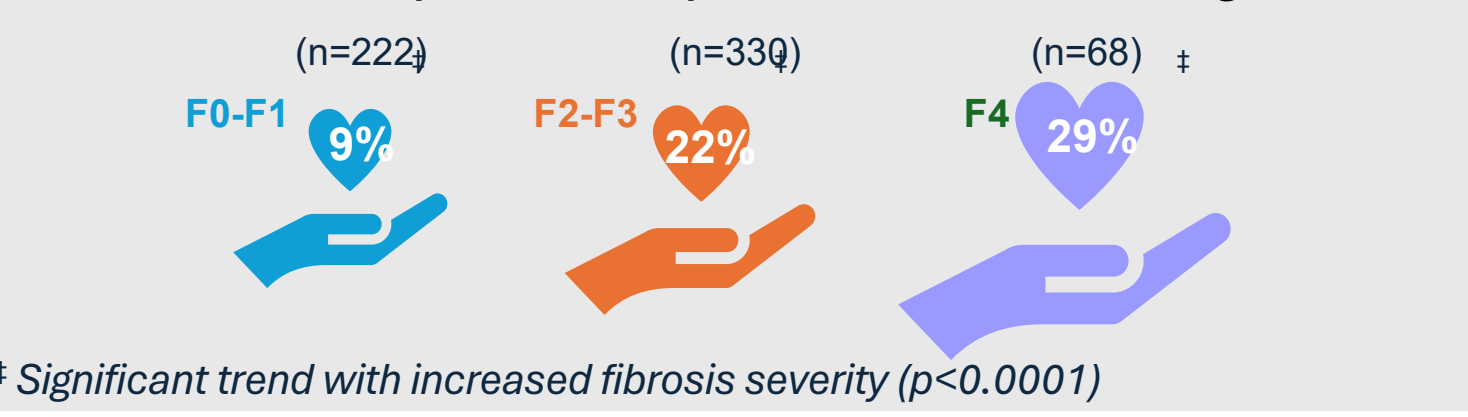


FIGURE 5. Proportion of patients with a caregiver***



Healthcare resource utilisation

- In the 12 months prior to data collection, hospitalisations due to MASH (r=0.24) and due to MASH-related comorbidities (r=0.10) increased with fibrosis severity, as did time spent in hospital (r=0.30; all p<0.05) – **Table 1**.
- Increased fibrosis severity was also associated with more consultations with hepato-gastroenterologists (r=0.22, p<0.001).
- Patients were also more likely to be prescribed treatments to target MASH-associated comorbidities as fibrosis severity increased (r=0.08, p<0.05).

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.

* hepatogastroenterologists, 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; CCI: Charlson Comorbidity Index; HCRU: healthcare resource utilisation; LCT: liver composite test; 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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