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

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INTRODUCTION

- Metabolic dysfunction-associated steatohepatitis (MASH) is a chronic, progressive disease characterized by fatty liver, liver cell injury, and inflammation.
- 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]
- MASH can progress from liver fibrosis to cirrhosis, as well as hepatocellular carcinoma. Increased fibrosis severity is also known to be associated with higher comorbidity burden.
- There is need to further understand the impact of advancing fibrosis on both hepatic and extrahepatic complications.

OBJECTIVES

- To understand the clinical characteristics, disease journey and healthcare resource utilisation (HCRU) of patients with MASH in Italy 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. 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 75 physicians reporting data on 562 patients with MASH.
- Patients were grouped by physician-stated fibrosis severity at the time of data collection as F0-F1 (n=235), F2–F3 (n=282) and F4 (n=45).

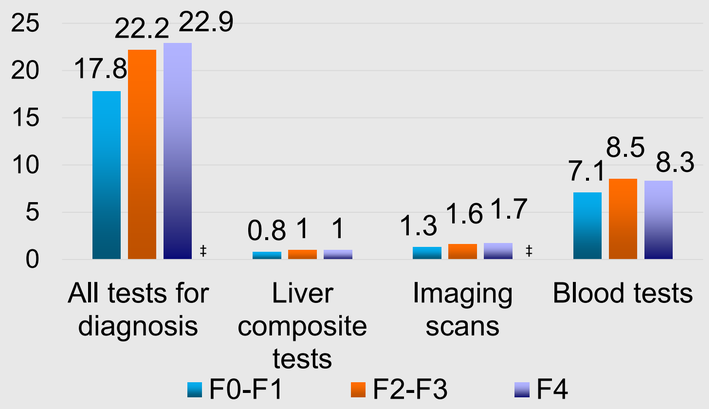
Demographics

- For F0-F1, F2-F3 and F4, respectively:
  - the mean age (± standard deviation [SD]) was 55.7±11.1, 56.8±11.7 and 66.2±10.2 years.
  - the proportions of females was 28.9%, 37.9%, and 47.7% .
  - the mean body mass index (BMI) was 32.5±5.7 kg/m^2, 31.8±5.3 kg/m^2 and 32.0±5.1 kg/m^2 – **Table 1**.

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

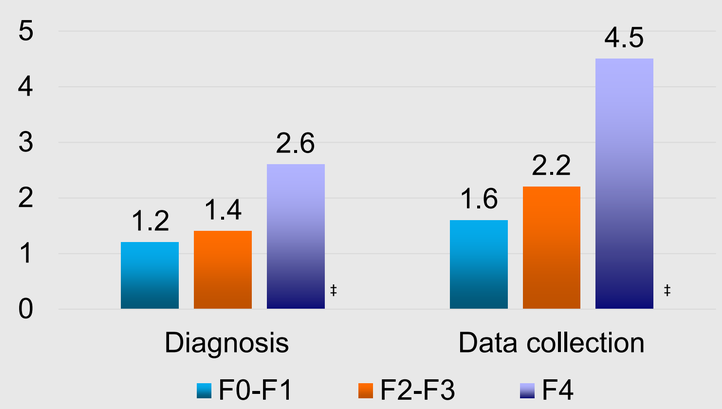
	F0-F1	F2-F3	F4	Rho	P-value
Overall, n	**235**	**282**	**45**		
Patient age, years	55.7±11.0	56.8±11.7	66.2±10.2	0.15	0.0003
Patient sex, male, n, n (%)	235 167 (71.1)	280 174 (62.1)	44 23 (52.3)		0.019
Patient BMI, kg/m^2, n, mean±SD	235 32.5±5.7	282 31.8±5.3	43 32.0±5.1	-0.07	0.0502
Number of days since MASH diagnosis, n, mean±SD	225 483.9±550.8	258 631.3±778.1	39 989.5±1206.0	0.13	0.0033
Number of hospitalisations in last 12 months for:					
MASH, n, mean±SD	219 0.1±0.2	249 0.1±0.4	43 2.1±7.5	0.21	<0.0001
MASH-related comorbidity, n, mean±SD	219 0.1±0.3	249 0.1±0.5	38 0.4±0.7	0.11	0.0117
Number of nights spent in hospital (last five hospitalisations), n, mean±SD	31 2.7±2.4	61 2.9±3.9	37 5.6±5.1	0.22	0.012
Charlson Comorbidity Index, n, mean±SD	230 2.1±0.4	263 4.3±0.8	43 4.5±0.9	0.88	<0.0001

FIGURE 1. Mean number of tests conducted to aid diagnosis



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

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.

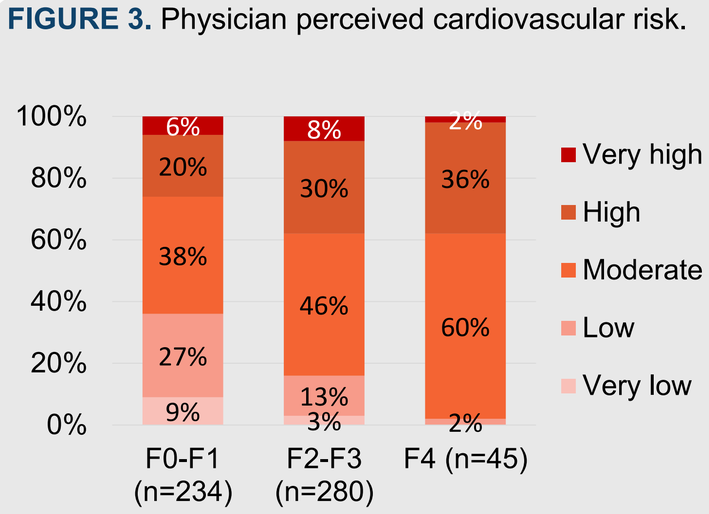


FIGURE 4. Physician perceived hepatocellular carcinoma risk

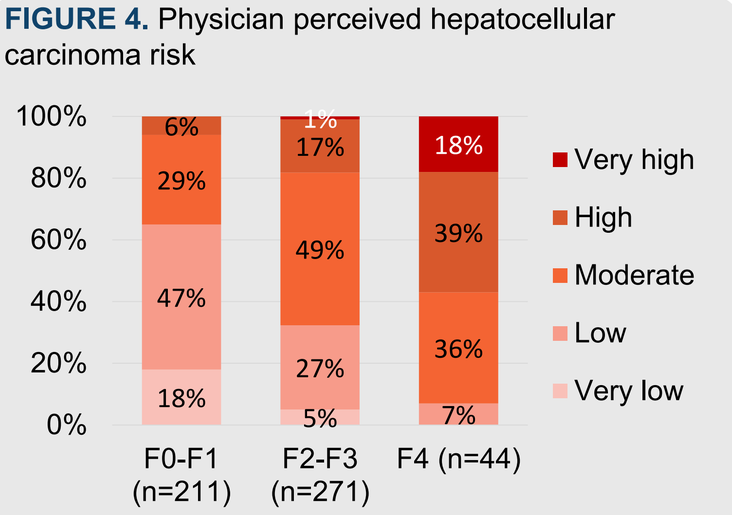
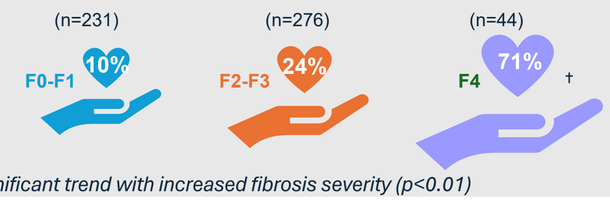


FIGURE 5. Proportion of patients with a caregiver



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

Tests to diagnose MASH

- Increased fibrosis severity was associated with more diagnostic tests (r=0.19), LCTs (r=0.12), imaging scans (r=0.20) and blood tests (r=0.11; all p<0.05) – **Figure 1**.

Clinical characteristics

- Increased fibrosis severity was also associated with more symptoms at diagnosis (r=0.19) and at time of data collection (r=0.26) as well as presence of fatigue, general weakness and sleep disturbance at data collection (all p<0.05) – **Figure 2**.
- Charlson Comorbidity Index (r=0.88 – **Table 1**), perceived cardiovascular risk (r=0.22 – **Figure 3**), and risk of hepatocellular carcinoma (r=0.43 – **Figure 4**) increased with fibrosis severity, as did the requirement for a caregiver (**Figure 5**), all p<0.01.

Healthcare resource utilisation

- In the 12 months prior to data collection, hospitalisations due to MASH (r=0.21) and due to MASH-related comorbidities (r=0.11) increased with fibrosis severity, as did time spent in hospital (r=0.22; all p<0.05) – **Table 1**.
- Increased fibrosis severity was associated with more treatments prescribed to target MASH-associated comorbidities (r=0.13, 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 demonstrates the substantial clinical and HCRU impact of advancing fibrosis in patients with MASH in Italy. These findings underscore the urgent need for effective therapeutic strategies to prevent disease progression and reduce risk of liver and other systemic health complications to reduce healthcare burden and improve patient outcomes.

* gastroenterologists, hepatologists 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; 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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