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Real-world healthcare resource utilisation of patients with metabolic dysfunction-associated steatohepatitis in combination with cardiometabolic comorbidities in Italy

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Introduction: Metabolic dysfunction-associated steatohepatitis (MASH) is a chronic, progressive disease estimated to affect 4.58% of the Italian population leading to advanced fibrosis, cirrhosis and hepatocellular carcinoma.[1] Current pharmacotherapy primarily focuses on cardiometabolic risk factors, including obesity and type 2 diabetes (T2DM), while targeted liver-directed therapies are emerging. Real-world evidence describing the clinical burden and management of MASH across fibrosis stages are limited.

Objective: To characterise the cardiometabolic comorbidity burden among patients with MASH in Italy and how this may influence treatment selection across fibrosis (F) stages.

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 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[2, 3, 4, 5].
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 PwM 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, prevalence of cardiometabolic risk factors, fibrosis stage and current treatment for their consulting patients with MASH at the point of data collection.

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 into F0-F1, F2-F3 and F4. Cardiometabolic risk factors (CRFs) included: obesity, T2DM, dyslipidaemia, and arterial hypertension

* Hepato-gastroenterologists, 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

ABBREVIATIONS:
BMI: body mass index; CCI: Charlson Comorbidity Index; DSP: Disease Specific Programme; GLP-1: Glucagon-like peptide-1 (GLP-1) receptor agonists: LCT: liver composite test; MASH: Metabolic dysfunction-associated steatohepatitis; PwM: Patients with MASH; SD: Standard Deviation; T2DM: Type 2 Diabetes Mellitus

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- HW and JJ are all employees of Adelphi Real World
- YK, MD, MI and PB are all employees of Madrigal Pharmaceuticals

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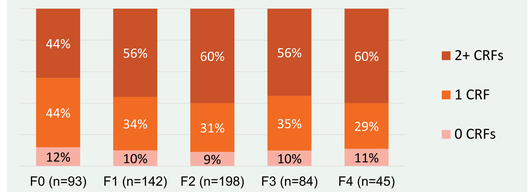
Results:
Survey population: Overall, 75 physicians reported data on 686 patients with MASH (PwM) of which 562 had a physician stated fibrosis stage. Patients were classified as F0 (n=93), F1 (n=142), F2 (n=198), F3 (n=84) and F4 (n=45).
Demographics: For F0, F1, F2, F3 and F4, respectively: mean age (± standard deviation [SD]) was 57.1±11.9, 54.8±10.4, 58.0±11.8, 58.7±11.5, and 66.2±10.2 years. The mean body mass index (BMI) was 32.4±7.2, 32.6±4.6, 31.8±5.7, 31.6±4.3 and 32.0±5.1 kg/m2 – **Table 1**.

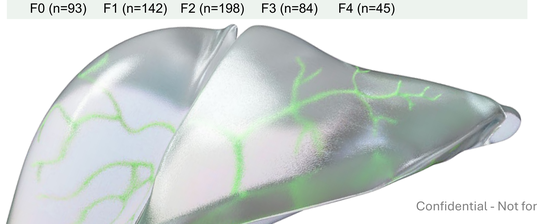
TABLE 1. Demographic and clinical characteristics of patients with F0, F1, F2, F3 and F4 MASH.

	F0	F1	F2	F3	F4
Overall, **n**	**93**	**142**	**198**	**84**	**45**
Patient age, years, mean±SD	57.1±11.9	54.8±10.4	56.0±11.8	58.7±11.5	66.2±10.2
	93	**142**	**198**	**84**	**45**
Patient sex, male, n (%)	56(60%)	111(78%)	120 (61%)	54 (64%)	23 (51%)
n,	**93**	**142**	**198**	**84**	**43**
Patient BMI, kg/m^2, mean±SD	32.4±7.2	32.6±4.6	31.8±5.7	31.6±4.3	32.0±5.1
n,	**90**	**135**	**185**	**73**	**39**
Number of days since MASH diagnosis, mean±SD	464.2± 743.5	496.9± 565.5	599.0± 777.2	713.1± 779.6	989.5± 1206.0
n,					
Hospitalisations in last 12 months, mean±SD	**88** 0.2±0.5	**132** 0.1±0.5	**177** 0.2±0.6	**72** 0.5±0.9	**43** 2.5±7.5
n,					
Number of comorbidities, mean±SD	**93** 2.5±2.2	**137** 2.9±2.0	**191** 3.4±2.4	**72** 3.9±2.3	**43** 3.7±3.0
n,					
Charlson Comorbidity Index (CCI), mean±SD	**93** 2.1±0.4	**137** 2.2±0.5	**192** 4.2±0.5	**72** 4.5±1.2	**43** 4.5±0.9
Physician-perceived cardiovascular risk, n (%)	**93**	**141**	**197**	**83**	**45**
Low risk	37 (39.8)	44 (31.2)	37 (18.8)	4 (4.8)	1 (2.2)
Moderate/High risk	50 (53.8)	85 (60.3)	131 (66.5)	53 (63.9)	33 (73.3)
Established CV event	4 (4.3)	6 (4.3)	20 (10.2)	16 (19.3)	6 (13.3)

Cardiometabolic risk factors:
- Overall, over half of PwM had ≥2 cardiometabolic risk factors (CRFs) – **Figure 1.**

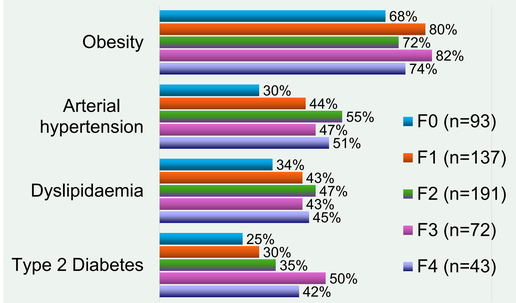
FIGURE 1. Number of cardiometabolic risk factors in PwM.





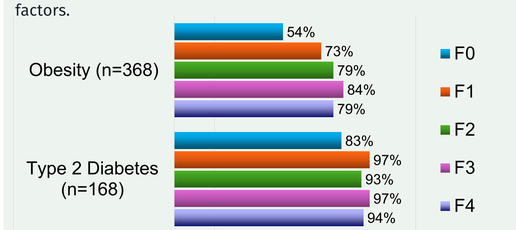
- Obesity was the most common comorbidity, affecting three-quarters of patients, while T2DM was present in over one-third – **Figure 2**.
- Around a quarter of patients had both obesity and T2DM (F0=15%, F1=27%, F2=24%, F3=32%, F4=29%).

FIGURE 2. Cardiometabolic risk factors in PwM



Treatment for cardiometabolic risk factors
- Pharmacological treatment rates were high. Nine out of ten patients were on a prescribed treatment for T2DM and three quarters were on a prescribed treatment for obesity – **Figure 3.**

FIGURE 3. Proportion of PwM on treatment for cardiometabolic risk factors.



- Statins, metformin, GLP-1 receptor agonists (GLP-1s) and other cardiovascular medications were the most common treatments prescribed – **Figure 4**.
- GLP-1 use was most common in patients with both obesity and T2DM – **Figure 5.**

FIGURE 4. Treatment prescribed for cardiometabolic risk factors

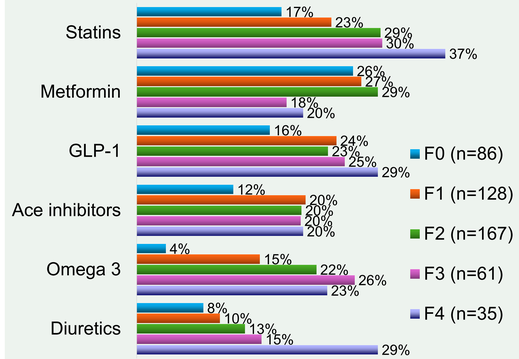
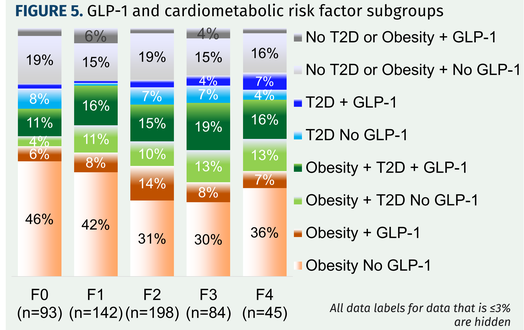


FIGURE 5. GLP-1 and cardiometabolic risk factor subgroups



All data labels for data that is ≤3% are hidden

Conclusion:
- **This data highlights the substantial cardiometabolic burden among PwM in Italy, particularly obesity and T2DM, which frequently coexist and increase with fibrosis severity.**
- **Pharmacotherapies are more commonly prescribed in patients with F2/F3 disease and those with multiple cardiometabolic risk factors. These data highlight the need for novel treatments to manage MASH as MASH continues to persist in PwM despite being treated for their comorbidities.**

Limitations
- While minimal inclusion criteria governed selection of participating physicians, participation was influenced by willingness to complete the survey.
- Physicians provided data for a consecutive series of patients to avoid selection bias, however patients who visited their physician more frequently had a higher likelihood of being included in the survey which limits generalisability of the results to all patients with MASH.
- Recall bias, a common limitation of surveys, may have affected physician responses. However, physicians had access to patient medical records reducing this risk.

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