# Impact of cardiovascular, renal and metabolic comorbidities on activity and health-related quality of life in patients with metabolic dysfunction-associated steatohepatitis in Canada, France, Germany and Italy

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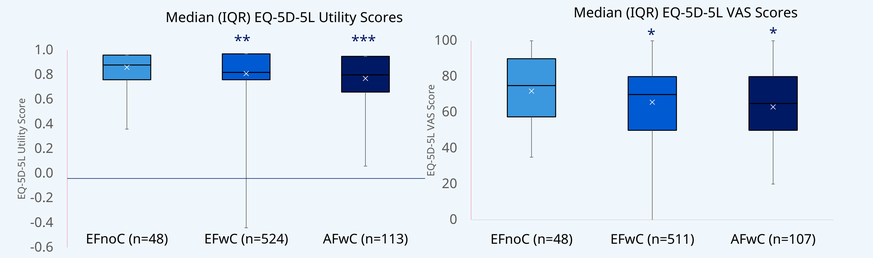
# Patients with MASH and additional cardiovascular, renal and metabolic comorbidities report lower health-related quality of life compared to patients without additional comorbidities

**Key result**

**Figure 1:** EQ-5D-5L utility scores and VAS scores in EFnoC, EFwC and AFwC patients




*= p<0.05, **=p<0.01, ***p<0.001, x indicates mean.

*VAS = visual analogue scale, CVRM= cardiovascular, renal and metabolic, EFnoC = early fibrosis (fibrosis stage 0-2) without additional CVRM comorbidities, EFwC = early fibrosis with ≥1 additional CVRM comorbidity, AFwC = advanced fibrosis (fibrosis stage 3-4) with ≥1 additional CVRM comorbidity*

## Aims

- Previous studies suggest that physical health and health-related quality of life (HRQoL) is likely to be poorer in patients with metabolic dysfunction-associated steatohepatitis (MASH)[1] compared to the general population.
- MASH is strongly associated with cardiovascular, metabolic and renal (CVRM) comorbidities, such as obesity and type 2 diabetes mellitus,[2] requiring the presence of at least one of five cardiometabolic risk factors for diagnosis[3].
- There is currently limited understanding as to how additional CVRM comorbidities in patients with MASH impact HRQoL[4].
- This study aimed to describe the impact of CVRM comorbidities on HRQoL, daily activities and patient burden in patients with MASH in Canada, France, Germany and Italy.

## Methods

- Data were drawn from the Adelphi Real World MASH Disease Specific Programme (DSP)™ , a cross-sectional survey of physicians and their patients with MASH in Canada, France, Germany and Italy from January – May 2024. The DSP methodology has been described,[5,6] validated,[7] and demonstrated to be representative and consistent over time.[8]
- Physicians reported patient demographics, clinical characteristics and healthcare resource utilisation (HCRU).
- 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.

*Specialists included endocrinologist/diabetologists, gastroenterologists, hepatologists, hepato-gastroenterologist and internal medicine specialists.
** Liver disease was defined as: alcohol-related liver disease, primary biliary cholangitis, viral hepatitis, autoimmune hepatitis, Wilsons's disease, alpha-1-antitrypsin deficiency or hemochromatosis.

## Methods

- Patients were stratified by physician-stated fibrosis stage and presence of additional cardiovascular, renal and metabolic comorbidities: early fibrosis (fibrosis stage 0–2) without comorbidities (**EFnoC**); early fibrosis with ≥1 additional comorbidity (**EFwC**); and advanced fibrosis (fibrosis stage 3–4) with ≥1 additional comorbidity (**AFwC**).
- Additional cardiovascular, renal and metabolic comorbidity status was defined as those with ≥1 of the following comorbidities: obesity (Body Mass Index (BMI) ≥ 30); type 2 diabetes mellitus; metabolic syndrome; dyslipidaemia; hypertension; renal disease; cardiovascular disease; myocardial infarction; congestive heart failure; periphery artery disease; cerebrovascular disease; stroke; transient ischaemic attack; stable angina; unstable angina; hypertension.
- Patients self-reported HRQoL via the Non-alcoholic steatohepatitis Clinical Hepatology Evaluation and Classification Key (NASH-CHECK), EQ-5D-5L (German tariff) and the Work Productivity and Impairment (WPAI) questionnaire.
- The NASH-CHECK measures HRQoL across six symptom scale scores and three HRQoL scale scores from 0–10; with higher scores indicating more severe symptoms and higher HRQoL impact.[9]
- The EQ-5D-5L measures general health across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Utility scores range from 1 (full health) to below 0 (a health state equivalent to death). Visual Analogue Scale (VAS) scores range from 0–100%, where 100% indicates best imaginable health.[10]
- The WPAI measures work and activity impairment during the seven days prior to data collection across four domains: absenteeism, presenteeism, and overall work impairment and impairment to daily activities. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity.[11]
- **EFwC** and **AFwC** patients were compared using pairwise statistics against the **EFnoC** control after entropy balancing on patient age and sex.

## Key results

- Overall, 247 physicians: 62 primary care physicians, 103 gastroenterologists, 6 hepatologists, 27 hepato-gastroenterologists, 41 endocrinologist/diabetologists and 8 internal medicine specialists completed 2,221 PRFs for patients with MASH who met the fibrosis stage and comorbidity definitions.

**Table 1:** Physician-reported patient demographics

| | EFnoC (n=170) | EFwC (n=1575) | AFwC (n=478) |
|---|---|---|---|
| Mean (SD) age, years | 50.6 (10.8) | 54.7 (11.3) | 60.4 (11.6) |
| Sex, Female, (%) | 46.5 | 40.9 | 37.2 |

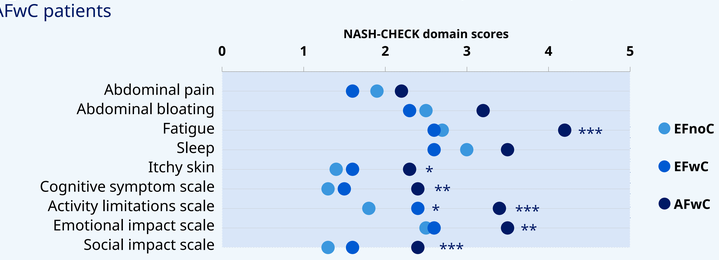
*EFnoC = early fibrosis (fibrosis stage 0-2) without additional CVRM comorbidities, EFwC = early fibrosis with ≥1 additional CVRM comorbidity, AFwC = advanced fibrosis (fibrosis stage 3-4) with ≥1 additional CVRM comorbidity, SD = Standard Deviation*

- Mean (SD) EQ-5D-5L utility scores were lower **for EFwC** and **AFwC** patients (0.85 [0.16] and 0.81 [0.18]; both p<0.01) than **EFnoC** patients (0.90 [0.12]).

## Key results

- Mean (SD) VAS scores were also lower for **EFwC** and **AFwC** patients than **EFnoC** patients (65.7% [19.3%] and 63.1% [19.6%] vs 71.9% [20.3%]; both p<0.05; **Figure 1**).

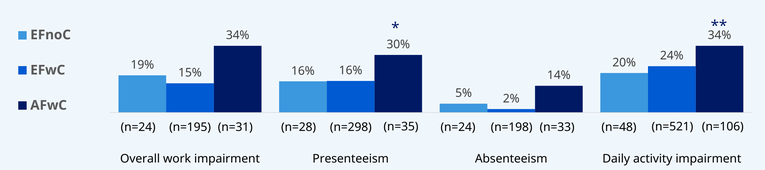
**Figure 2** Differences in NASH-CHECK domains in EFnoC patients compared to EFwC and AFwC patients




**p<0.05, **p<0.01, ***p<0.001*
*EFnoC, EFwC and AFwC patient bases - Itchy skin, Cognitive symptom scale, n=48, n=527 and n=116; Activity limitations scale, Sleep n=48, n=526, n=116; Abdominal pain n=47, n=527, n=116; Abdominal bloating n=47, n=525, n=116; Fatigue, n=47, n=528, n=116; Emotional impact scale, n=47, n=517, n=113; Social impact scale, n=48, n=520, n=115.*
*EFnoC = early fibrosis (fibrosis stage 0-2) without additional CVRM comorbidities, EFwC = early fibrosis with ≥1 additional CVRM comorbidity, AFwC = advanced fibrosis (fibrosis stage 3-4) with ≥1 additional CVRM comorbidity*

- **AFwC** patients reported significantly higher impact on HRQoL in six of the nine NASH-CHECK domains (Fatigue, Itchy skin, Cognitive symptoms, Activity limitations, Emotional impact and Social impact) than **EFnoC** patients (all p<0.05; **Figure 2**).
- The greatest significance between **AFwC** and **EFnoC** was seen in the Activity Limitations Scale (3.4 [2.2] vs 1.8 [1.8]; p<0.001), Fatigue (4.2 [2.8] vs 2.7 [2.3]; p<0.001) and Cognitive Symptom Scale (2.4 [2.4] vs 1.3 [1.6]; p<0.01) domains.
- **EFwC** patients reported significantly greater activity limitations compared to **EFnoC** patients (2.4 [1.9] vs 1.8 [1.8]; p<0.05).
- **AFwC** patients reported a higher presenteeism and daily activity impairment score than **EFnoC** patients via the WPAI (p<0.01; **Figure 3**).

**Figure 3:** Mean WPAI scores in EFnoC, EFwC and AFwC patients




**= p<0.05, **=p<0.01, ***p<0.001*

*EFnoC = early fibrosis (fibrosis stage 0-2) without additional CVRM comorbidities, EFwC = early fibrosis with ≥1 additional CVRM comorbidity, AFwC = advanced fibrosis (fibrosis stage 3-4) with ≥1 additional CVRM comorbidity, WPAI = Work Productivity and Impairment*

## Summary and Conclusion

- Both **AFwC** and **EFwC** patients reported a lower HRQoL than **EFnoC** patients, as demonstrated by lower EQ-5D-5L utility and VAS and higher NASH-CHECK scores.
- Advanced fibrosis and additional comorbidities also impacted daily activities and presenteeism.
- These findings highlight the need for improved management strategies in patients with MASH and additional CVRM comorbidities.
- This also highlights the critical need for improved recognition of comorbidities, and appropriate intervention, to improve patient outcomes.

## Limitations

- While minimal inclusion criteria governed the selection of participating physicians, participation was influenced by willingness to complete the survey.
- Participating patients may not reflect the general MASH population as the DSP only includes patients who are consulting with their physician.
- Patient diagnosis of MASH was based on the judgement of the respondent physician and not a formalised diagnostic check. This is representative of real-world physician classification of patients.
- Due to low base size patients with advanced fibrosis with no additional CVRM comorbidities were not included in the analyses
- The absence of advanced fibrosis patients without additional comorbidities limits the extent that the impact of comorbidities can be investigated.

## Disclosures

- ES, HW, KT and EQ are employees of Adelphi Real World.
- RO is an employee and shareholder in Novo Nordisk, A/S.

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The Adelphi Real World DSP is a fully owned Adelphi product, of which Novo Nordisk is one of multiple subscribers.
Presented at the ISPOR 2025 16th May 09:00-11:30AM, Montreal Canada

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