Metabolic dysfunction-associated steatohepatitis (MASH) prevalence in Germany – results from a claims analysis

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Introduction

- Metabolic dysfunction-associated steatohepatitis (MASH) is the most advanced of metabolic dysfunction-associated steatotic liver disease (MASLD) that can lead to severe complications, including liver cirrhosis and hepatocellular carcinoma. These conditions impose a significant burden on both patients and healthcare systems.

- An estimated 4% of the German population is affected by MASH as of 2016[1], with an increasing global prevalence of the disease[2]. Despite its rising prevalence, MASH often remains underdiagnosed and undercoded due to the asymptomatic nature of the disease and the invasive requirements of liver biopsy for confirmatory diagnosis[3-7].

- The actual diagnosed and coded prevalence/incidence of MASH in Germany is not well characterized. Further leading to challenges in characterizing the disease and the cost of care, as information on follow-up and management of many patients is lacking.

Aim

- This study aimed to estimate the coded prevalence and incidence of MASH in Germany, as well as to characterize these patients in terms of age and sex.

Method

- A retrospective analysis was conducted using statutory health insurance (SHI) claims data from the InGef sample database, representing 4.7% of the German population and 5.4% of the German SHI population.

- The study period spanned from January 1, 2020, to December 31, 2022.

- Prevalence and incidence figures were analyzed for the year 2022, identifying MASH patients by International Statistical Classification of Diseases and Related Health Problems, 10th Revision, German Modification (ICD-10-GM) diagnosis code K75.8 "Other specified inflammatory liver diseases [Nonalcoholic steatohepatitis NASH]".

- For inclusion, this diagnosis had to be recorded at least once in the inpatient sector (as primary or secondary discharge diagnosis) or at least twice in different quarters in the outpatient setting (verified diagnosis) during 2022.

- Incident patients were defined as those who had a diagnosis-free period of two years (2020-2021).

- Patients with evidence of alcohol use disorder or alcohol-associated liver disease during the study period were excluded based on the corresponding ICD-10-GM codes.

Results

- 3,609,469 individuals from the InGef sample database were included in the analysis sample between 2020 and 2022.

- Of these, 3,719 prevalent MASH patients were identified in 2022.

- This corresponds to a one-year coded prevalence rate of 103.03 patients per 100,000 individuals, or 0.10%.

- The coded incidence rate was determined to be 15.71 patients per 100,000 individuals, equivalent to 0.02%.

- The average age of coded prevalent patients was 59.90 years, with 49.3% being female, while coded incident patients were slightly younger, averaging 55.69 years of age.

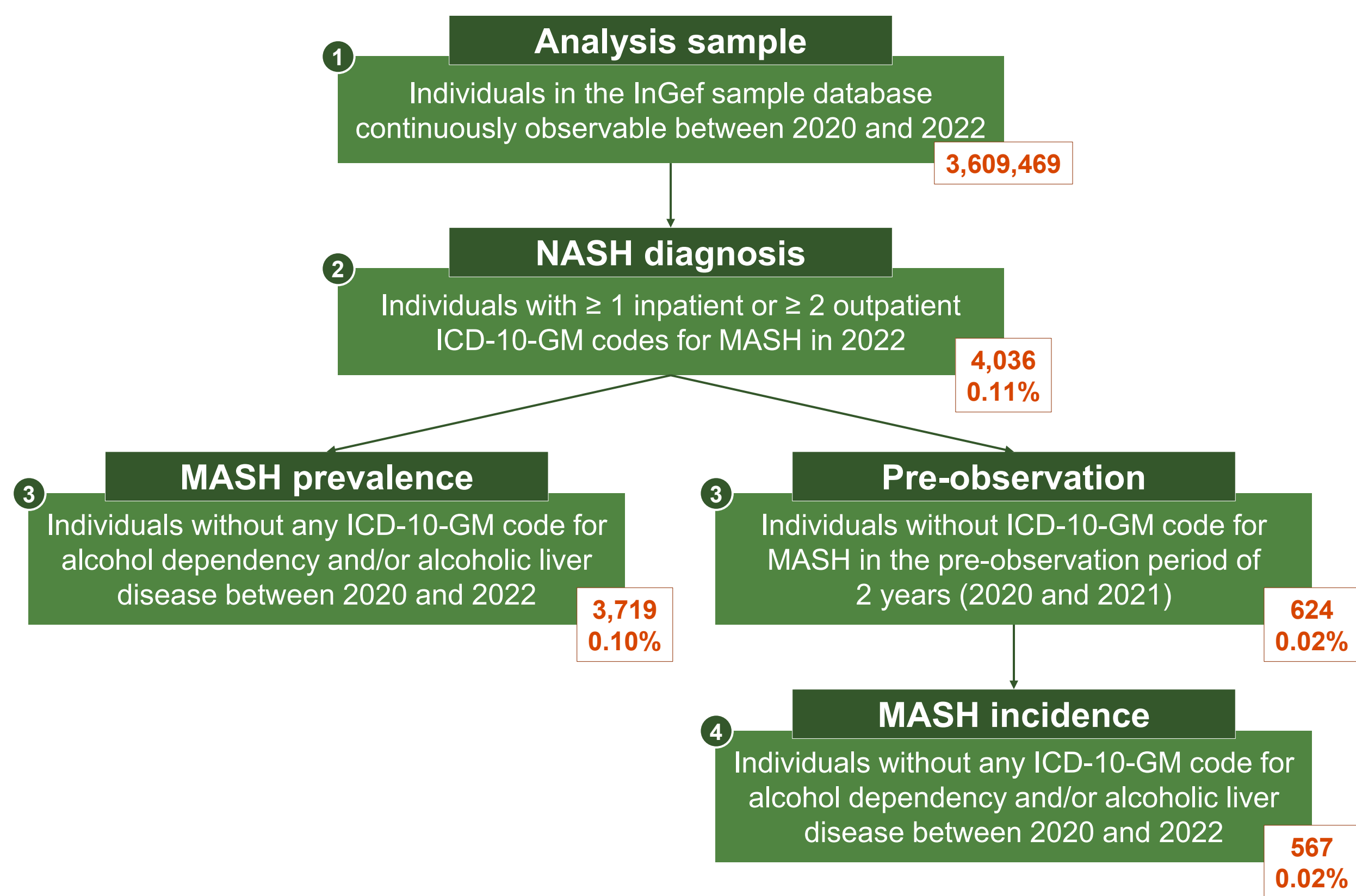**Figure 1** Identification of MASH prevalence and incidence in 2022

Table 1 Age and gender distribution of prevalent and incident coded MASH patients in 2022

Age and sex	Prevalent MASH patients						Incident MASH patients					
	Male		Female		Total		Male		Female		Total	
	n, summary measures	%	n, summary measures	%	n, summary measures	%	n, summary measures	%	n, summary measures	%	n, summary measures	%
Age distribution												
Mean	56.51		63.39		59.90		51.99		59.58		55.69	
SD	15.06		14.10		14.99		16.90		16.61		17.17	
Min	1		2		1		4		2		2	
Q1	47		56		51		41		52		45	
Median	57		65		61		53		59		57	
Q3	67		73		71		63		70		68	
Max	92		97		97		87		97		97	
Age groups												
0-17 years	16	0.85	12	0.65	28	0.75	8	2.75	5	1.81	13	2.29
18-29 years	75	3.98	29	1.58	104	2.80	21	7.22	10	3.62	31	5.47
30-39 years	157	8.33	68	3.71	225	6.05	39	13.40	12	4.35	51	8.99
40-49	310	16.45	147	8.01	457	12.29	46	15.81	32	11.59	78	13.76
50-59	508	26.96	396	21.58	904	24.31	80	27.49	82	29.71	162	28.57
60-69	442	23.46	541	29.48	983	26.43	55	18.90	58	21.01	113	19.93
70-79	261	13.85	415	22.62	676	18.18	29	9.97	46	16.67	75	13.23
≥ 80 years	115	6.10	227	12.37	342	9.20	13	4.47	31	11.23	44	7.76
Total	**1,884**	**100.00**	**1,835**	**100.00**	**3,719**	**100.00**	**291**	**100.00**	**276**	**100.00**	**567**	**100.00**

Figure 2 Development of MASH coded prevalence and incidence per 100,000 individuals and % from 2019 to 2022
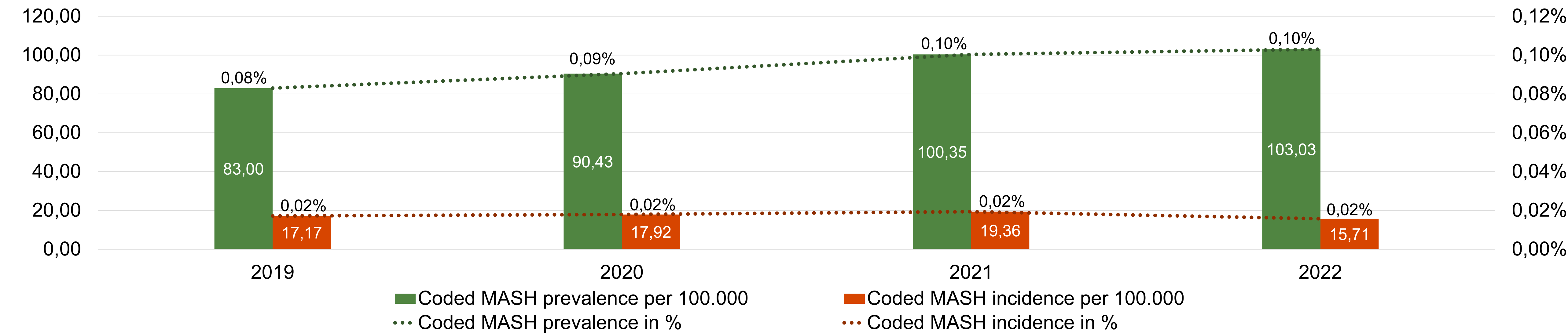
Limitations

- This study relied on ICD-10-GM based coding and lacks potentially relevant clinical information on patients. We are also unable to identify fibrosis staging or confirm disease states due to lack of lab and imaging results in the data.

Conclusions

- Despite an increasing trend in the coded prevalence of MASH, the results of this study suggest that there is a significant underdiagnosis and undercoding of MASH in the German healthcare system, when comparing the prevalence rate to available literature (4% vs. 0.1%). This discrepancy suggests the need for healthcare providers to increase awareness and use non-invasive tests for risk stratification and diagnosis of MASH patients.

References

1. Younossi ZM et al. The global epidemiology of nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH): a systematic review. *Hepatology* 2023; 77(4):1335-47.
2. Estes C et al. Modeling NAFLD disease burden in China, France, Germany, Italy, Japan, Spain, United Kingdom, and United States for the period 2016-2030. *J Hepatol* 2018;69(4):896-904.
3. Tacke F et al. Updated S2k Clinical Practice Guideline on Non-alcoholic Fatty Liver Disease (NAFLD) issued by the German Society of Gastroenterology, Digestive and Metabolic Diseases (DGVS). *Z Gastroenterol* 2022; 60: e733–e801.
4. Roeb E et al. Amendment "New nomenclature for MASLD (Metabolic Dysfunction Associated Steatotic Liver Disease)" to the S2k guideline "Non-alcoholic fatty liver disease" (v.2.0 / April 2022) of the German Society of Gastroenterology, Digestive and Metabolic Diseases (DGVS). March 2024 - *AWMF register number: 021 – 025*.
5. Gerhardt F, et al. Biopsy rate and nonalcoholic steatohepatitis (NASH) in patients with nonalcoholic fatty liver disease (NAFLD). *Scand J Gastroenterol* 2020;55(6):706-11.
6. Khalifa A, Rockey DC. The utility of liver biopsy in 2020. *Curr Opin Gastroenterol* 2020;36(3):184-91.
7. Tincopa MA, Loomba R. Non-invasive diagnosis and monitoring of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. *Lancet Gastroenterol Hepatol* 2023;8(7):660-70.

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