

Insights from a Delphi Panel

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BACKGROUND

- Metabolic dysfunction-associated fatty liver disease (MASLD), which was previously termed nonalcoholic fatty liver disease (NAFLD), is a leading cause of chronic liver disease on a global scale. [1]
- Metabolic dysfunction-associated steatohepatitis (MASH), formerly referred to as nonalcoholic steatohepatitis (NASH), represents an advanced stage of MASLD. It is distinguished by histological characteristics including the swelling of hepatocytes and inflammation within the lobules. It can progress to liver fibrosis and cirrhosis and may also lead to the development of hepatocellular carcinoma (HCC). [2]
- It is estimated that approximately 30% of the global population is affected by MASLD. [3] In Germany, the prevalence was projected to be around 23% for MASLD and 4% for MASH in 2016 according to a model that was built based on prevalence data for obesity and type 2 diabetes. [4]
- The aim of this study was to generate insights on MASH diagnosis, management and current treatment options in Germany.

METHODS

Delphi method

- A three-round survey, integrating the methodologies of a Delphi panel with a standard expert survey, was conducted to generate consensus on defined study questions (**Figure 1**). The survey was web-based, allowing panelists to complete it online.
- The study period spanned from the start of the first survey round in February 2024 until the completion of the third round in May 2024.

Participants

- In consultation with a Thought Leader (TL), 17 national specialists with expertise in MASH diagnosis and management were identified and invited via email. Of these, twelve experts, including gastroenterologists, hepatologists and diabetologists, agreed to participate in the online questionnaire.
- These participants included hospital and office-based physicians located across Germany.

RESULTS

Definitions, Epidemiology, and Diagnosis

- Hepatic fibrosis was identified as the most critical prognostic factor for MASH with 66.7% of the experts having ranked “presence of hepatic fibrosis” as very important.
- Experts estimated that approximately 75% of MASH patients in Germany remain undiagnosed (**Figure 2**). In the second panel round this mean value was confirmed by 83.3 % of the panelists.

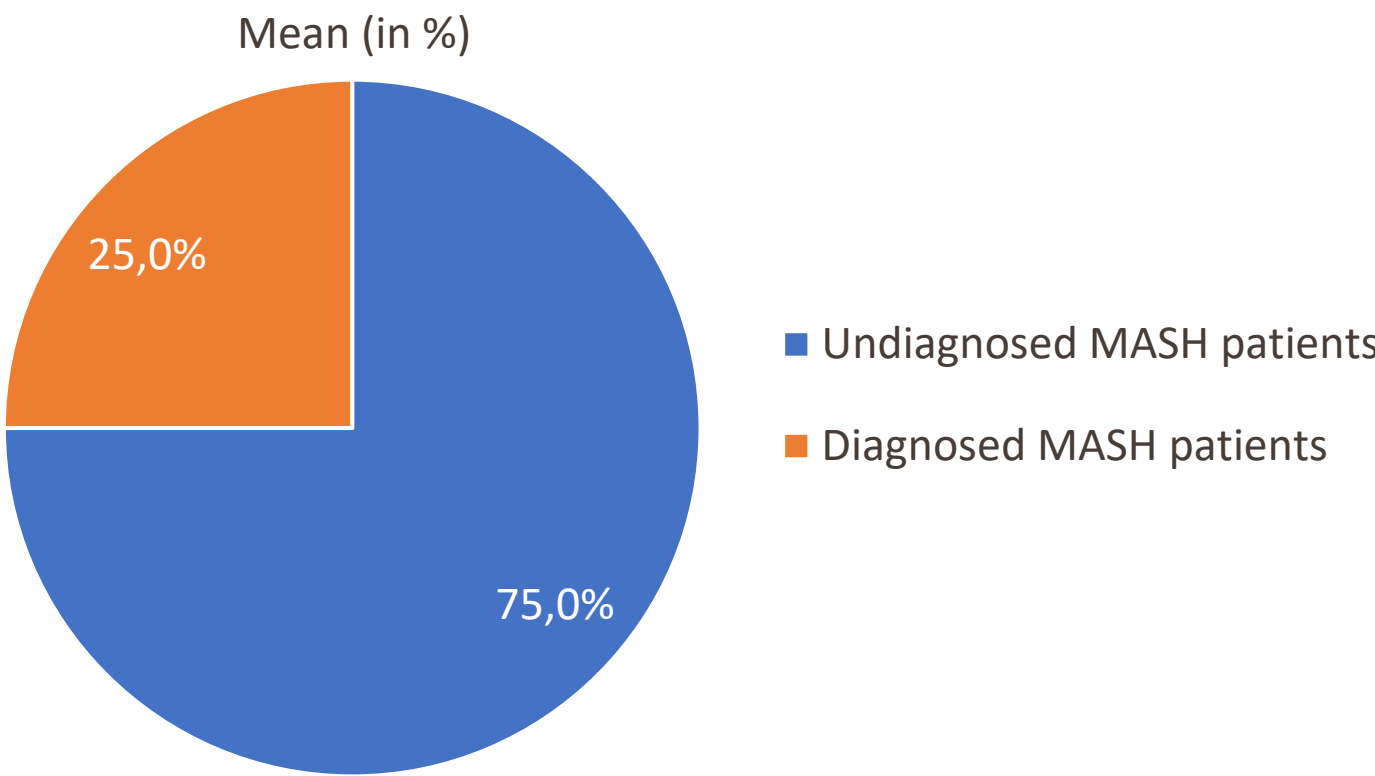


Figure 2. Proportion of diagnosed and undiagnosed MASH patients

- On average, the experts receive 62.5% of their patients through referrals from general practitioners. The average referral rates from endocrinologists and gastroenterologists/hepatologists are similar, at 18.3% and 17.1%, respectively (**Figure 3**).
- With 73.3% of referral reasons on average, the major reason for patients being referred to the expert’s clinics/practices is an elevated/abnormal liver function test (LFT) observation (**Figure 4**).

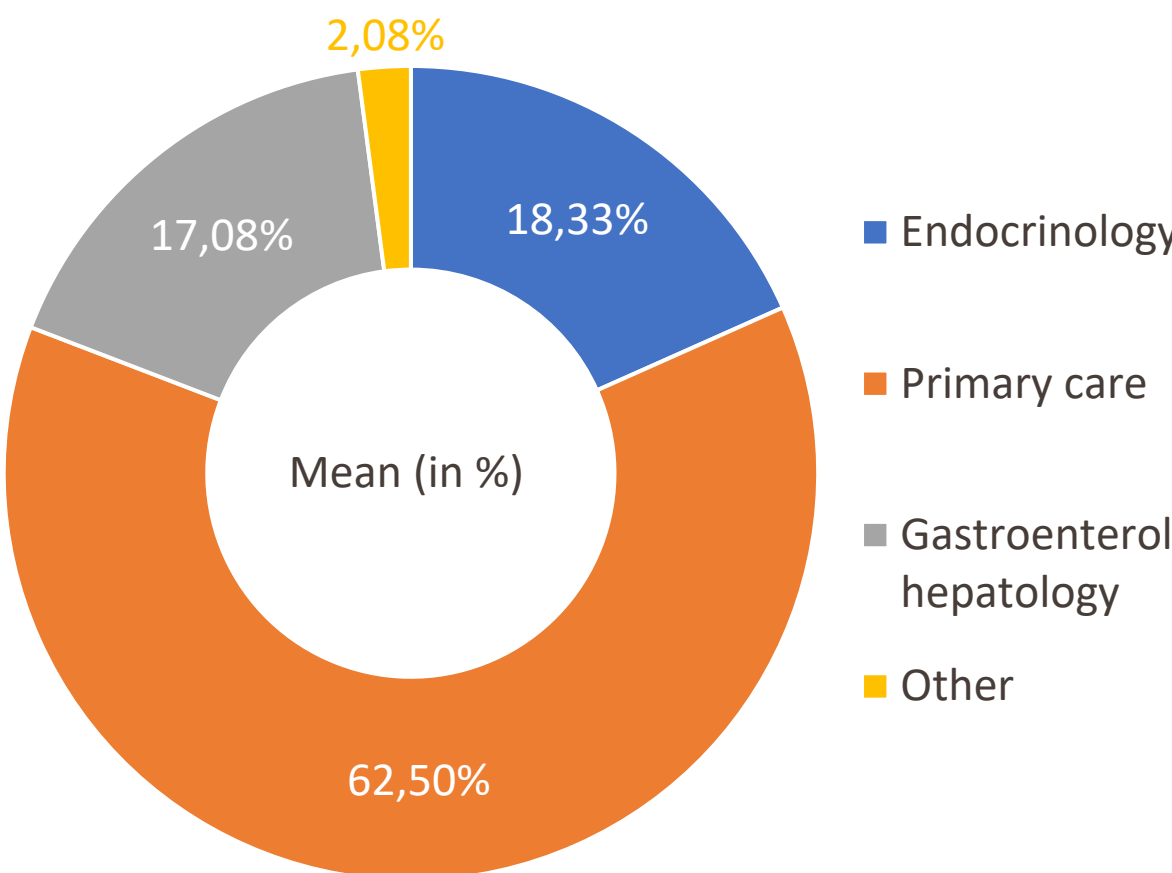


Figure 3. Referral route

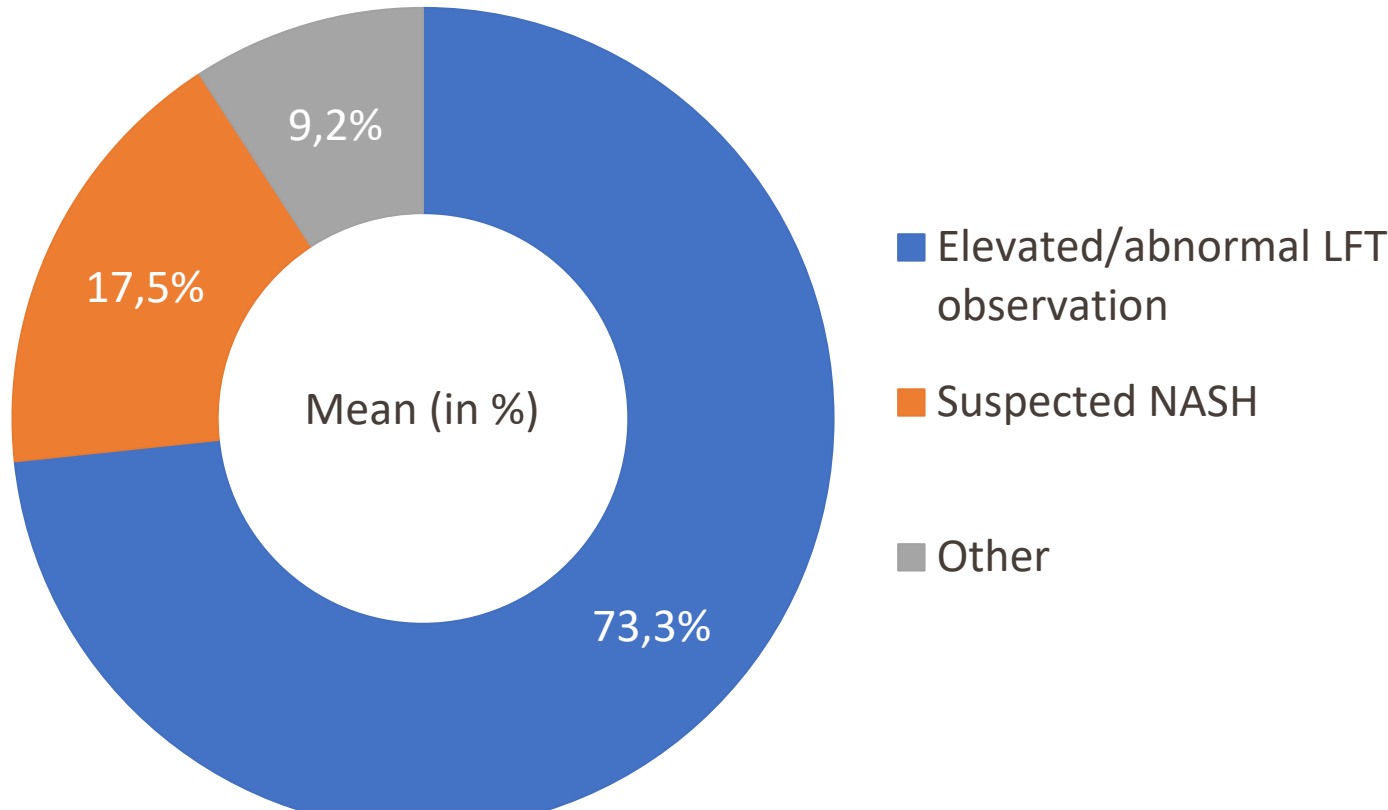


Figure 4. Reasons for referral

Diagnosis of MASH

- The primary methods for diagnosing MASH patients included the use of fibrosis scores, liver enzyme tests, other serological tests, and Vibration-Controlled Transient Elastography (VCTE) liver stiffness measurement (LSM). However, steatosis and activity scores, as well as Magnetic Resonance Elastography (MRE), were reported to be either unavailable or inaccessible to 42% of the panelists (**Figure 5**).

- They completed the survey without knowledge of the identities and responses of other participants.

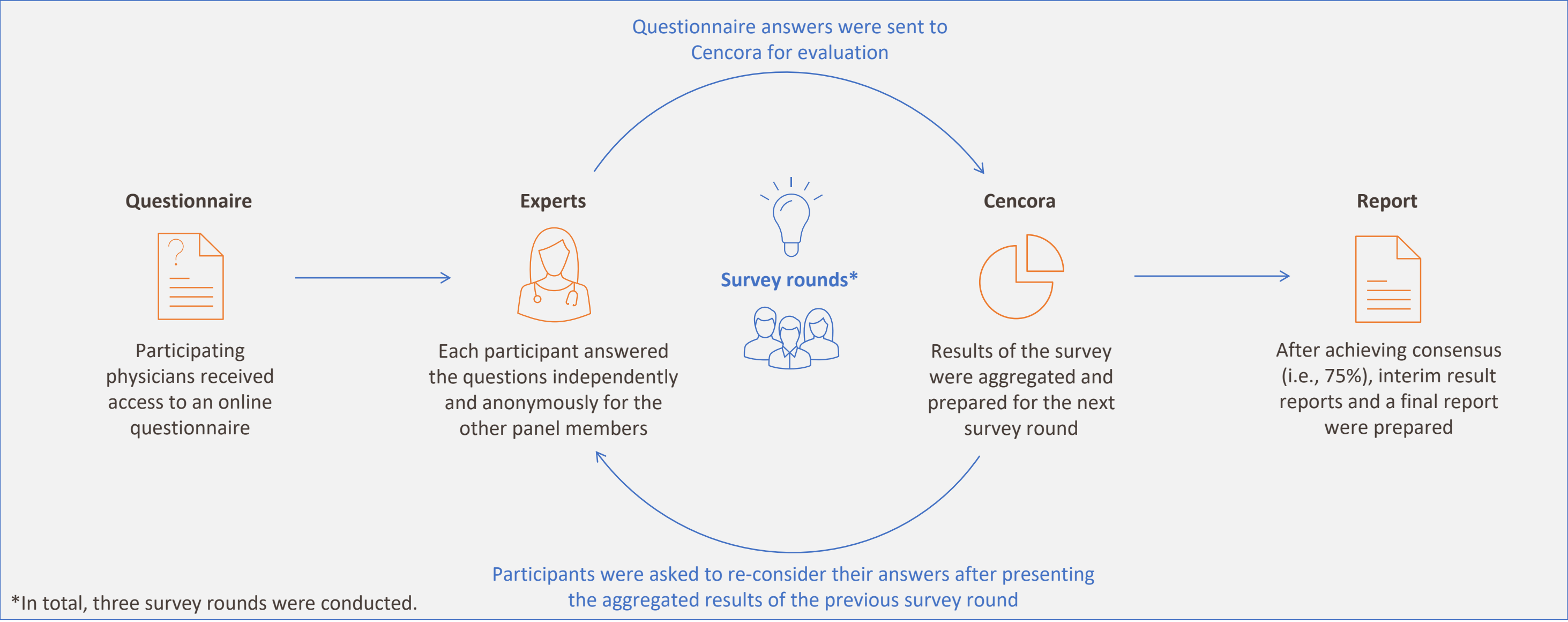


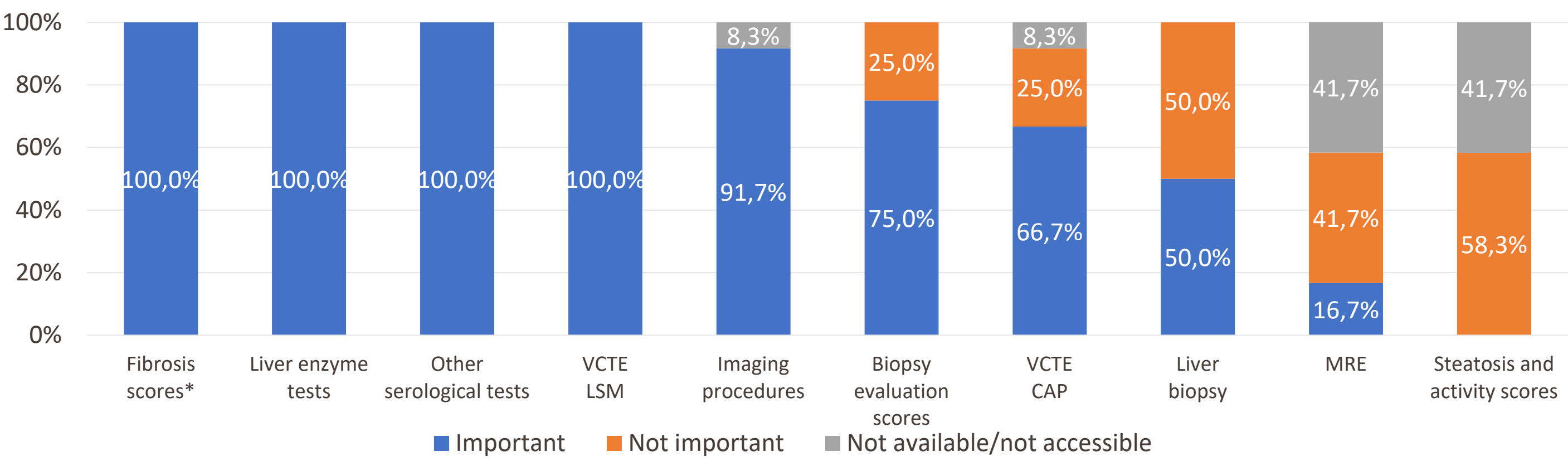
Figure 1. Delphi method

Consensus

- Consensus questions were defined as 75% participant agreement according to the Delphi method. Four of the questions were consensus questions.
- Results from each round were consolidated by calculating the arithmetic mean of all answers. Only questions with less than 75% agreement advanced to the third round, where a new mean value was calculated based on the second round's answers. In the third round, participants could agree or disagree with the new mean, and if they disagreed, they provided an alternative value.

Questionnaire

- The questionnaire comprised 36 exploratory and consensus questions.
- The topics addressed in the survey included various MASH-related topics referring to definitions, epidemiology, diagnosis, current treatments, comorbidity management, pharmaceutical therapy, and patient education. Additionally, panelists were asked to provide details about their workplace, specialty and number of patients treated.



*Please note, fibrosis scores include the following: NAFLD fibrosis score, FibroTest, BARD-Score, FIB4 Index, Enhanced Liver Fibrosis (ELF) panel.

Figure 5. Importance of selected approaches to diagnose a MASH patient in clinical practice

Current treatment and monitoring strategies

- Current treatment strategies predominantly emphasize lifestyle modifications and the management of comorbidities such as diabetes and cardiovascular diseases, with 100% of the panelists indicating this approach, as there are limited pharmaceutical options available, owing to a lack of approved medications for MASH.
- Non-invasive methods, such as VCTE (e.g., to measure liver scarring or fibrosis), were preferred over invasive procedures such as liver biopsy for diagnosis and monitoring MASH. Liver biopsy/histology is only used in 8.3% of MASH patients to measure treatment success.

Pharmaceutical therapy

- Familiarity with various pharmaceutical treatments in clinical trials varies considerably, with 75% of participants being eager to adopt new therapies as soon as they become available.

Comorbidity management

- Experts indicated that high rates of comorbid conditions are prevalent among MASH patients. In the second panel round all experts agreed that 82.1% of MASH patients suffer from obesity, 66.3% from metabolic syndrome and 63.8% from hypertension. 91.7% of the experts agreed that more than half of the patients suffer from Type 2 diabetes (57.1%), and dyslipidemia (56.3%) (**Figure 6**).

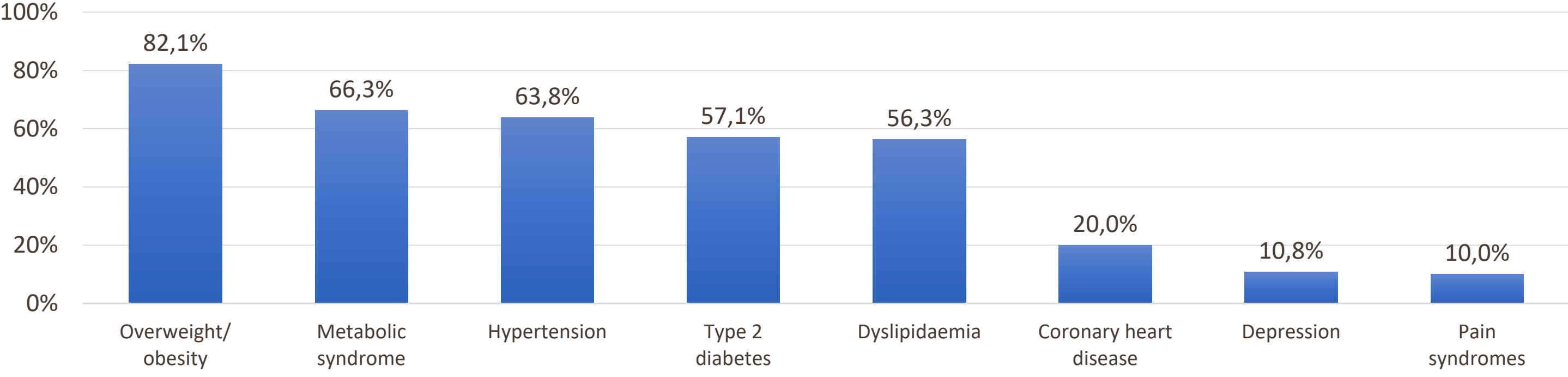


Figure 6. Comorbidities among MASH patients

Patient education

- Over half of the experts (58,5%) noted a gap in patient education during initial consultations, with many patients lacking sufficient knowledge about MASH. One third of the experts miss brochures on the disease, comorbidities and therapy options.

CONCLUSIONS

- The study highlighted significant challenges in managing MASH in Germany, particularly the absence of approved pharmaceutical treatments.
- Although liver biopsy is considered the most reliable method for confirming MASH, half of the panelists deemed it unimportant, highlighting a potential misalignment regarding the role of liver biopsy.
- There is a need for improved patient education to enhance understanding and management of MASH.
- With the absence of an approved pharmacotherapy for MASH, emphasizing lifestyle modification is crucial for the effective management of MASH.
- Management of comorbid conditions remains essential until more targeted therapies become available.

ACKNOWLEDGMENTS

We would like to thank the survey panelists for their valuable contributions to this research. Additionally, we would like to thank Jesse Fishman for his contribution to the design of the study.

DISCLOSURES

Madrigal Pharmaceuticals Inc. provided the funding for this research, which was conducted by Xcenda GmbH, part of Cencora Inc.. Prof. Tacke and participating panelists received consulting fees from Madrigal Pharmaceuticals Inc. for the study.

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