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Steatotic Liver Disease: New Nomenclature and Its Localization in the Russian Federation

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Aim: localization of the new nomenclature of steatotic liver disease in Russian clinical practice.
Key points. In 2023, international consensus decided to introduce a new nomenclature for steatotic liver disease. The article discusses the reasons for the change in nomenclature and the new terms adopted: steatotic liver disease, metabolic dysfunction-associated steatotic liver disease, metabolic dysfunction and alcohol associated steatotic liver disease. Adapting new terms to Russian healthcare poses a certain problem. The results of voting by Russian doctors on the introduction of new terms and their optimal translation are presented. A comparison of existing classifiers with new terms was carried out and the formulation of diagnoses was discussed taking into account the new nomenclature.
Conclusions. Adaptation and implementation of new nomenclature into clinical practice is an important and complex task, in which it is necessary to maintain a balance between a progressive concept and the interests of practical healthcare.
Keywords: steatotic liver disease, non-alcoholic fatty liver disease, metabolic dysfunction-associated steatotic liver disease, metabolic dysfunction-associated steatohepatitis, metabolic dysfunction and alcohol associated steatotic liver disease
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Жировая болезнь печени: новая номенклатура и ее адаптация в Российской Федерации

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Цель: адаптация новой номенклатуры жировой болезни печени к российской клинической практике.
Основные положения. В 2023 г. международным консенсусом принято решение о введении новой номенклатуры жировой болезни печени. В статье обсуждаются причины изменения номенклатуры и принятые новые термины: жировая болезнь печени, метаболически-ассоциированная жировая болезнь печени, метаболически-ассоциированная жировая болезнь печени в сочетании с употреблением избыточного количества алкоголя, жировая болезнь печени специфической этиологии. Определенную проблему представляет адаптация новых терминов к российскому здравоохранению. Приведены результаты голосования российских врачей, посвященного внедрению новых терминов и их оптимальному переводу на русский язык. Проведено сопоставление действующих классификаторов с новыми терминами и обсуждены формулировки диагнозов с учетом новой номенклатуры.

Выводы. Адаптация и внедрение в клиническую практику новой номенклатуры являются важной и сложной задачей, при выполнении которой необходимо соблюсти баланс между прогрессивной концепцией и интересами практического здравоохранения.
Ключевые слова: жировая болезнь печени, неалкогольная жировая болезнь печени, метаболически-ассоциированная жировая болезнь печени, метаболически-ассоциированный стеатогепатит, метаболически-ассоциированная жировая болезнь печени в сочетании с употреблением избыточного количества алкоголя
Конфликт интересов: авторы заявляют об отсутствии конфликта интересов.

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Background

The concept of disease nomenclature is a wide list of generally recognized names used by doctors for correct and uniform designation of pathological conditions. As medical science develops, the disease and condition nomenclature expand due to new terms being included. Their full list is subject for revision due to regular revisions of the International Statistical Classification of Diseases and Related Health Problems (ICD). In 2023 the international consensus decided to introduce a new nomenclature for steatotic liver disease (SLD). There is a specific background for the above [1].

To begin with, the concept of non-alcoholic fatty liver disease (NAFLD) should be considered as a chronic disease where lipid accumulation in more than 5 % of hepatocytes (steatosis) is detected in the absence of other readily identified reason for steatosis (alcohol abuse, some drugs, fasting, monogenic diseases, etc.) [2]. NAFLD covers a pathological spectrum from simple steatosis to steatohepatitis and cirrhosis [3]. Steatosis (simple steatosis) and non-alcoholic steatohepatitis (NASH) are two different conditions (phenotypes) with different prognosis [3, 4].

The term non-alcoholic steatohepatitis (NASH) was first proposed by J. Ludwig et al. in 1980 in an article titled "Nonalcoholic steatohepatitis: Mayo Clinic experiences with a hitherto unnamed disease", to highlight that this until then unnamed disease is similar to alcoholic liver disease (ALD) but develops without exposure to alcohol [5]. Subsequently, the disease was named "nonalcoholic fatty liver disease", and NASH began to be considered as its progressive variant. Also, for steatosis without inflammation, the term fatty liver disease was used.

Despite their imperfection, the terms NASH/NAFLD have been existing for about 40 years. NASH/NAFLD diagnosis criteria implied strict exclusion of the alcohol factor in the genesis of the diseases [5].

Later on, it became clear that steatosis and steatohepatitis are heterogeneous and are associated with metabolic dysfunction in the vast majority of cases but can also develop due to other and additional causes (excessive alcohol consumption, drug-induced liver injuries, etc.), which was not taken into account in the then-current nomenclature. The terms "non-alcoholic fatty liver disease" and "non-alcoholic steatohepatitis" themselves are based on exclusionary rather than affirmative definitions. There is an understanding of the possibility of a combined genesis of steatosis and steatohepatitis [1, 6, 7]. All the above resulted in the need to revise the SLD nomenclature. The main objectives of the new nomenclature are to give a clear definition of SLD and its forms (including specific nosologies), enhance awareness of the population, stimulate changes in healthcare policy, identify individuals from risk groups, diagnose diseases and ensure access to medical care [1].

In 2020 the concept of metabolic dysfunction associated fatty liver disease (MAFLD), that is, fatty liver disease associated with metabolic dysfunction, was proposed, and its criteria were developed, which included type 2 diabetes mellitus, obesity and cardiometabolic risk factors [6].

But the international medical community was not satisfied with the lack of a common view on diseases occurring with steatosis and steatohepatitis. Consensus on nomenclature and diagnostic criteria was needed.

New nomenclature for steatotic liver disease

The work on the nomenclature was conducted under the aegis of the American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL) in cooperation with the Latin American Association for the Study of the Liver (ALEH),

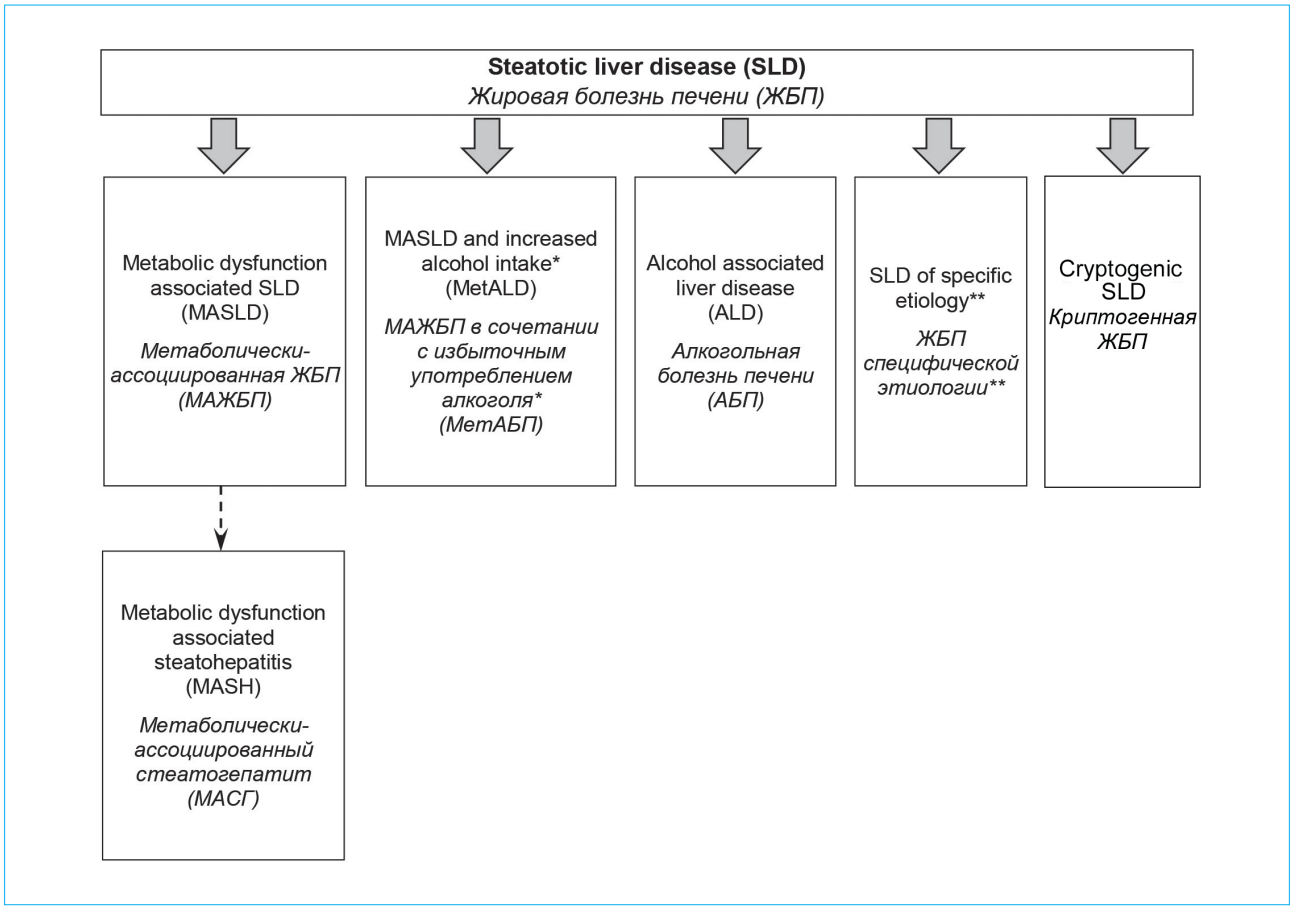

Figure 1. New nomenclature for steatotic liver disease and its subclassification (Rinella M.E. et al., with modifications) [1]. * Excessive alcohol intake: 140–350 g per week of ethanol for women and 210–420 g per week for men, 20–50 g per day of ethanol for women and 30–60 g per day of ethanol for men; ** SLD of specific etiology includes: monogenic diseases (lysosomal acid lipase deficiency, Wilson's disease, inborn errors of lipid metabolism, etc.), certain phenotypes of drug-induced liver damage, other diseases

Рисунок 1. Новая номенклатура жировой болезни печени и ее субклассификация (по M.E. Rinella et al., с изменениями) [1]. * Избыточный прием алкоголя: 140–350 г в неделю этанола для женщин и 210–420 г в неделю для мужчин, 20–50 г в день этанола для женщин и 30–60 г в день этанола для мужчин; ** ЖБП специфической этиологии включает: моногенные болезни (дефицит лизосомной кислой липазы, болезнь Вильсона, врожденные ошибки метаболизма липидов и прочее), отдельные фенотипы лекарственного поражения печени, другие заболевания

involving specialists from all over the world, including hepatologists, gastroenterologists, pediatricians, endocrinologists, pathologists and experts in public healthcare and obesity as well as representatives of the industry, regulatory authorities and patient organizations. In total, 236 experts from 56 countries participated in the work on this issue using the Delphi consensus method, which was published in 2023: "A multisociety Delphi consensus statement on new fatty liver disease nomenclature" [1].

The use of a unifying umbrella term was approved: steatotic liver disease (SLD), within which specific diseases and groups of diseases are distinguished (Fig. 1).

SLD are classified as:

– metabolic dysfunction associated steatotic liver disease (MASLD);

– alcoholic liver disease (ALD, alcohol associated steatotic liver disease);

– metabolic dysfunction and alcohol associated steatotic liver disease, MetALD);

– steatotic liver disease of specific etiology;

– cryptogenic steatotic liver disease [1].

The overwhelming majority of international experts determined that inclusion of "metabolic dysfunction" in the name helps both patients and healthcare professionals to better understand the nature of the disease. The majority of the responders (95 %) believed that the metabolic dysfunction

associated steatohepatitis (MASH), should be still identified as it has prognostic meaning, while its resolution is the primary goal in clinical practice and serves as the main criterion of clinical studies results efficacy [1]. A new notion has been introduced — MetALD [1]. New criteria for MASLD have been proposed [1], which we will discuss below.

Localization of new nomenclature in Russia

A certain problem lies in the adaptation and integration of the new nomenclature into the Russian medical environment, the correct translation of English terms into Russian. Thus, the authors of the new nomenclature replaced the term "fatty" with "steatotic" in order to eliminate the stigmatization of the patients. In English, the word "fatty" can have a non-medical offensive meaning for a person, similar to the Russian word «жирный» applied to a person with excess body weight. This is especially true for adolescents. In Russian-language medical literature and clinical practice, the term «жировой» has been used for many years, and its meaning coincides with the English term of Greek origin "steatotic" but does not have a second common offensive meaning. Another example: when developing new international nomenclature, the abbreviation MAASLD for liver injury due to metabolic dysfunction and excessive alcohol consumption was rejected, since it is consonant with the abbreviation for American Association for the Study of Liver Diseases, AASLD, but this perception is absent in Russian.

When translating terms into Russian, one should keep in mind the Federal Law dated February 28, 2023 No. 52 "On Amending the Federal Law "On the State Language of the Russian Federation", according to which the use of words and expressions that do not comply with the norms of the present-day Russian literary language is unacceptable [8].

Translation of the new nomenclature into Russian is widely discussed in the medical community. At the initiative of the Russian Scientific Liver Society (RSLS), in 2023 general practitioners and gastroenterologists were surveyed on-line on the choice of an optimal translation of English terms from the new nomenclature into Russian. Over 300 doctors participated in the survey. The options for the translation of English terms were offered by the Chief Gastroenterologist of the Ministry of Health of the Russian Federation, President of the Russian Society of Liver Studies, Academician V.T. Ivashkin. In this article, we used only the terms which the majority of survey participants voted for.

Over 75 % of the voters supported the use of the unifying term "steatotic liver disease" (SLD). For the translation of new SLD nomenclature and its subclassification, almost 75 % of Russian doctors who voted spoke out for the term "metabolic dysfunction associated steatotic liver disease", abbreviated as MASLD (in Russian, "метаболически-ассоциированная жировая болезнь печени", МАЖБП), which complies with the currently used term "non-alcoholic fatty liver disease", abbreviated as NAFLD (Fig. 2A). A similar point of view has been expressed regarding the term "metabolic dysfunction associated steatohepatitis", abbreviated as MASH, (in Russian, "метаболически-ассоциированный стеатогепатит", МАСГ) which complies with the currently used term "non-alcoholic steatohepatitis", abbreviated as NASH (Fig. 2B).

During the survey among Russian doctors, about 90 % of them accepted singling out other types of SLD (Fig. 1) and such Russian-language terms as: alcoholic liver disease (ALD); SLD of specific etiology (expanding the reason for liver injury in the diagnosis); cryptogenic SLD (when a full examination of the patient failed to establish the cause for SLD).

Criteria for metabolic-associated steatotic liver disease (MASLD)

The medical community considered it reasonable (95 % of votes) to use the new optimized diagnostic criteria for MASLD (current term NAFLD) in Russian practice:

1. Hepatic steatosis identified by visual diagnostic methods (ultrasound or other methods) or histologically during liver biopsy in combination with one or more of the cardiometabolic risk factors listed below.

2. Cardiometabolic risk factors/risk for MASLD (NAFLD in current terminology):

— body mass index > 25 kg/m^2 (Caucasian) or 23 kg/m^2 (Asian) or waist circumference > 94 cm (men), 80 cm (women), or other ethnic equivalent parameters;

— fasting glucose > 5.6 mmol/L, or postprandial glucose > 7.8 mmol/L, or HbA1c > 5.7 %, or type 2 diabetes mellitus, or treatment of type 2 diabetes mellitus;

— blood pressure ≥ 130/85 mmHg or special antihypertensive medical treatment;

— plasma triglycerides ≥ 1.70 mmol/L or lipid-lowering treatment;

— plasma HDL cholesterol < 1.0 mmol/L (men) and < 1.3 mmol/L (women) or lipid-lowering treatment [1].

If in the course of patient examination, the doctor has not identified any of the above cardiometabolic risk factors, but their diagnostic concept suggests MASLD (NAFLD according

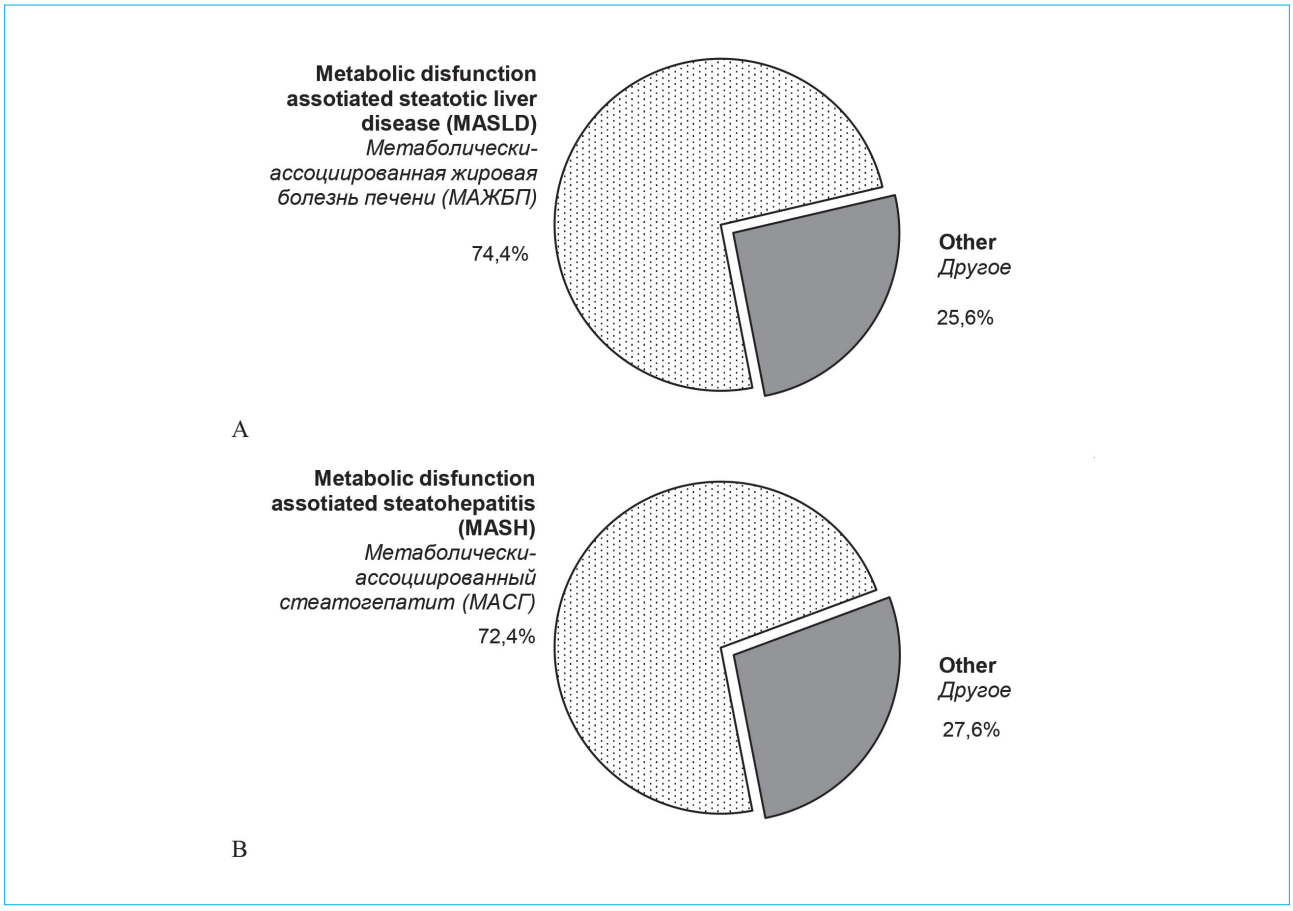

Figure 2. Results of voting by Russian doctors on the translation and implementation of the new nomenclature of steatotic liver disease

Рисунок 2. Результаты опроса российских врачей по переводу и внедрению новой номенклатуры жировой болезни печени и ее субклассификации

to current terminology), they may expand the examination scope and additionally perform a HOMA-IR test (Homeostasis Model Assessment of Insulin Resistance) and oral tests to assess glucose tolerance [1]. Positive results shall confirm the doctor's diagnosis.

When adopting a new SLD nomenclature, the international experts actively discussed if its introduction shall influence the implementation and development of new diagnostic and treatment methods. Data from a cohort of patients participating in the European project Liver Investigation Testing Marker Utility in Steatohepatitis (LITMUS) were analyzed, which demonstrated that 98 % of patients with NAFLD from the register comply with the MASLD criteria. Thus, almost all the patients previously diagnosed with NAFLD have MASLD according to the new concept. Moreover, preserving the term and clinical definition of steatohepatitis provides succession and validity of the previous data from clinical studies in patients with NASH, which can be extrapolated to the individuals classified as having MASLD or MASH according to the new nomenclature [1].

Metabolic dysfunction and alcohol associated steatotic liver disease (MetALD)

Distinguishing of a new form of SLD called "metabolic dysfunction and alcohol-associated liver disease (MetALD)" is of great interest. Attention should be paid to the doses of alcohol suggested for this type of liver injury, which are lower than 60 g of ethanol per day for a man and 50 g of ethanol per day for a woman. In this situation, the dose of alcohol consumed by a patient has crucial significance (Fig. 3).

According to the opinion of more than 90 % of international experts who have generated the new nomenclature, daily consumption of 30 to 60 g of ethanol by patients with MASLD (NAFLD according to current terminology) influences the natural course of the disease and can change the response to treatment. Russian doctors who participated in the survey absolutely agree with the

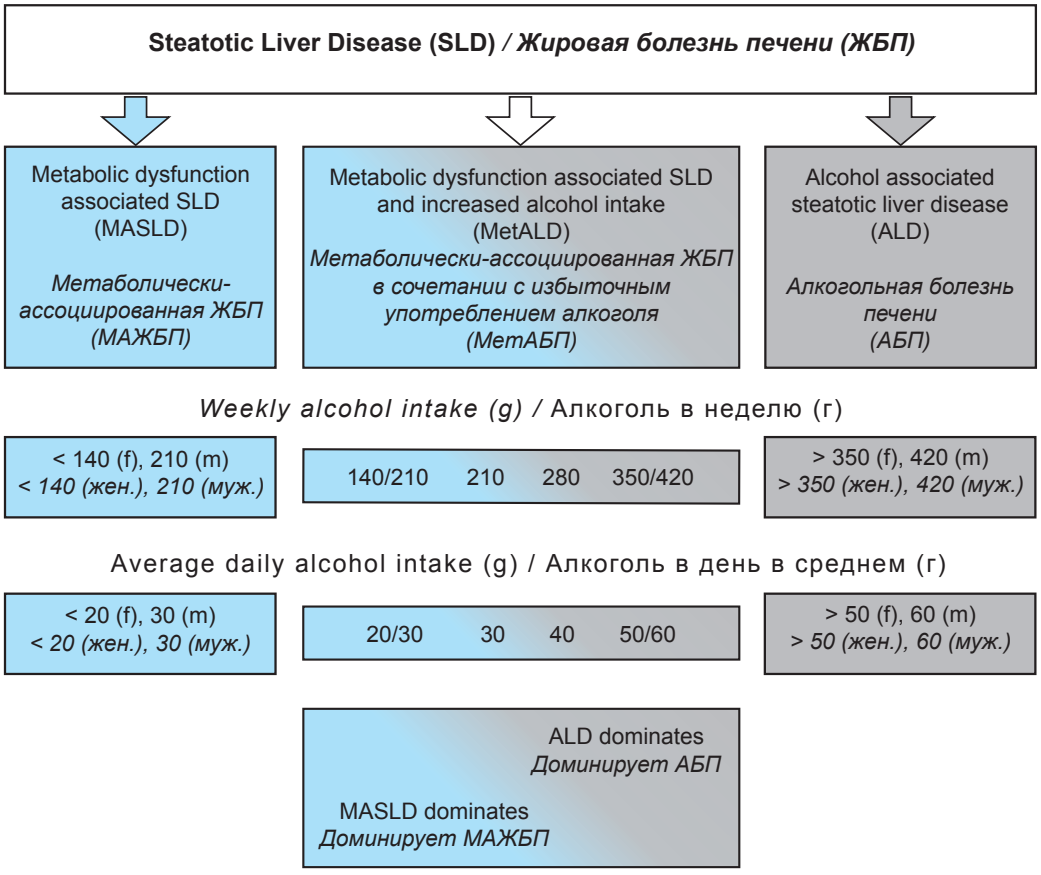

Figure 3. Metabolic dysfunction and alcohol associated steatotic liver disease (MetALD) (M.R. Rinella et al., with modifications)

Рисунок 3. Метаболически-ассоциированная жировая болезнь печени в сочетании с избыточным употреблением алкоголя (МетАБП) (по M. E. Rinella et al., с изменениями)

relevance and singling out of this form of liver injury. Most of them (65 %) supported the use of the term "metabolic dysfunction-associated and alcohol-associated liver disease" and its abbreviation MetALD. Inside the MetALD group, there are subgroups of patients in whom the contribution of metabolic and alcohol factors will vary [1]. In such patients, the features of liver injury pathogenesis, the contribution of each pathophysiologic factor to it and the nature of therapy require studying.

For instance, according to the Russian experts, for NAFLD with an associated risk factor such as excessive alcohol consumption, ademetionine [9, 10] should be prescribed, which is used in the treatment of ALD and NAFLD according to Russian Clinical Guidelines [11, 12]. Singling out MetALD shall allow to conduct future studies and evaluate the drug in this particular patient category.

Other subtypes of steatotic liver disease

There is a number of reasons for SLD development [13]. Therefore, an overwhelmingly important part of the new nomenclature is the identification of its other variants: classic ALD; SLD of specific etiology. The latter includes monogenic diseases (for example, lysosomal acid lipase deficiency, Wilson's disease, hypobetalipoproteinemia and others), some phenotypes of drug-induced liver injuries and other conditions accompanied by steatosis and steatohepatitis (such as viral hepatitis C, malnutrition, celiac disease) [1]. It shall undoubtedly facilitate the doctors' understanding of the provision that steatosis and steatohepatitis are typical pathological processes which result from various causes and require differential diagnosis of liver diseases (Fig. 4).

In our opinion, some incompleteness of the new nomenclature lies in the fact that SLD

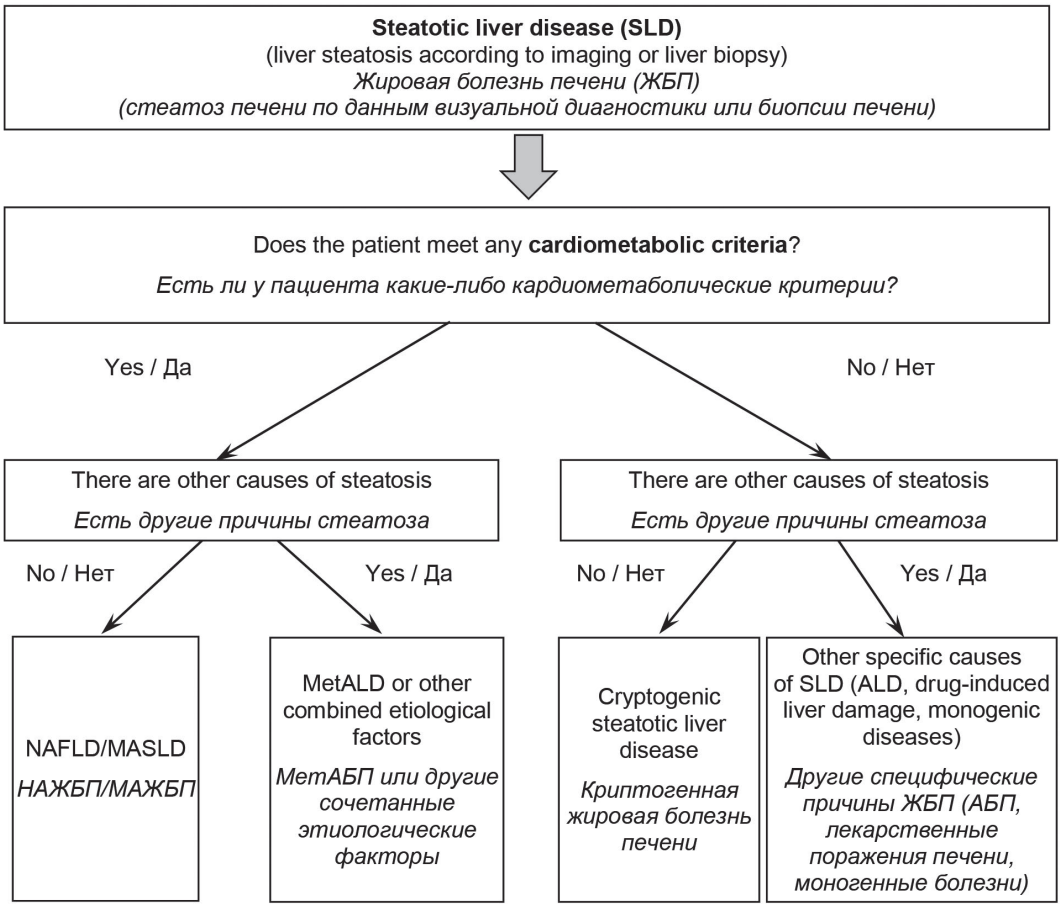

Figure 4. Algorithm for differential diagnosis of steatotic liver disease (M.E. Rinella et al., with modifications) [1]: SLD — steatotic liver disease; NAFLD — non-alcoholic fatty liver disease; MASLD — metabolic-associated steatotic liver disease; ALD — alcoholic liver disease; MetALD — metabolically associated fatty liver disease in combination with excessive alcohol consumption

Рисунок 4. Алгоритм дифференциальной диагностики жировой болезни печени (по M.E. Rinella et al., с изменениями) [1]: ЖБП — жировая болезнь печени; НАЖБП — неалкогольная жировая болезнь печени; МАЖБП — метаболически-ассоциированная жировая болезнь печени; АБП — алкогольная болезнь печени; МетАБП — метаболически-ассоциированная жировая болезнь печени в сочетании с употреблением избыточного количества алкоголя

of a specific etiology is not divided into two fundamentally different groups of diseases. If one of them is present, steatosis/steatohepatitis is the primary morphological manifestation of the disease obligatory damaging the liver (for example, lysosomal acid lipase deficiency, Wilson's disease, drug-induced liver injuries). In other cases, the process is optional, essentially secondary to the underlying disease, or is a complication thereof (for example, celiac disease, inflammatory bowel disease, certain endocrinopathies).

But it should be noted that according to the authors of the international consensus, the nomenclature offered by them is not conclusive and static, but rather allows its further clarification as new data on the pathophysiologic basis and risk factors for SLD emerge.

New nomenclature and current classifiers

The matching of the new nomenclature with existing classifiers (currently, ICD-10, in the near future, ICD-11) is a complicated issue [2, 14, 15].

The issue of the terms that should be used in official medical documentation was discussed with

the Chief Gastroenterologist of the Ministry of Health of the Russian Federation, Academician V.T. Ivashkin. In his opinion, in these cases it is necessary to use the current terminology adopted in the Russian Federation, non-alcoholic fatty liver disease. This is due to the fact that in the Russian Federation, doctors use ICD-10 codes from Clinical Guidelines on management of patients with this liver disease, which have as well been approved by the World Health Organization (WHO) [11, 12, 14, 15]. New terminology allows for a better understanding of the essence of the disease and allows for more meaningful planning of clinical studies. It can dominate in scientific research when its results are published in specialized medical literature. We must adopt optimized diagnostic criteria for NAFLD (MASLD) and reflect them in Clinical Guidelines; a large group of specialists is currently working on this task. We should focus on MetALD as a special form of SLD. In medical documentation we can specify the diagnosis as "steatotic liver disease of double etiology: due to metabolic dysfunction and excessive alcohol consumption", coded K76.0. In this case, the doctor must understand exactly the threshold amount of alcohol under discussion and should carefully study the patient's alcohol consumption history. ALD should be coded according to its phenotypes, using ICD-10, without changes. When coding a SLD of specific etiology, for example, Wilson's disease, appropriate ICD-10 codes and diagnoses should be used, while the form of its manifestation (e.g., hepatic steatosis) can be additionally recorded either in the diagnosis or in the patient's medical documentation. The term "cryptogenic SLD" implies ruling out all the known causes for its development. If no complete examination to establish the reason for SLD has been performed, the term "SLD unspecified" coded K76.0 should be used.

In general, genuinely new things always benefit medical science and practice. The most important is to maintain certainty in the wording of the diagnosis and clarity in understanding the disease pathogenesis.

Conclusion

The new SLD nomenclature is undoubtedly a step forward: it can improve the understanding and prognostic assessment of the patient's condition by healthcare professionals, contribute to the improvement of diagnosis and differential diagnosis, and the development of treatment options. At the same time, the introduction of any new terminology and classification raises a number of problems for the professional community. Adapting and introducing the nomenclature proposed in 2023 into Russian clinical practice is undoubtedly an important and complex task, the implementation of which requires to maintain a balance between the new progressive concept and the interests of practical healthcare.

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