

International round-table meeting
Prevention and control of Viral Hepatitis in the Russian Federation:
lessons learnt and the way forward
October 25 – 26, 2018, Moscow, Russia

EASL Recommendations on Treatment of Hepatitis C 2018 through the prism of Russian realities

S.N. BATSIKH

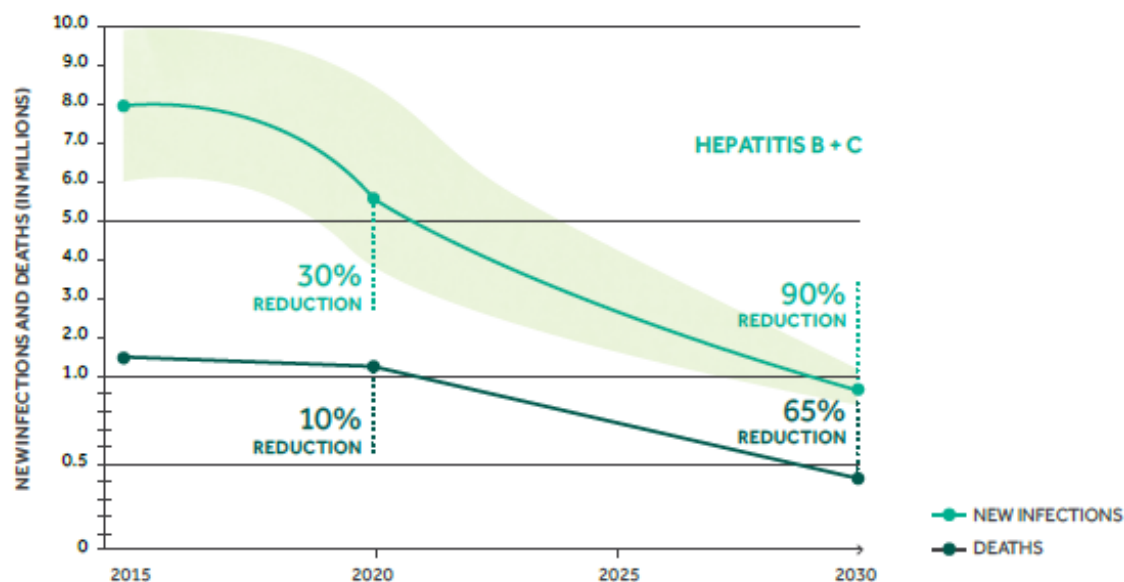
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GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS 2016–2021

TOWARDS ENDING VIRAL HEPATITIS

GOAL

Eliminate viral hepatitis as a major public health threat by 2030.



EASL Recommendations on Treatment of Hepatitis C 2018^{*}European Association for the Study of the Liver^{*}

Summary

Hepatitis C virus (HCV) infection is a major cause of chronic liver disease, with approximately 71 million chronically infected individuals worldwide. Clinical care for patients with HCV-related liver disease has advanced considerably thanks to an enhanced understanding of the pathophysiology of the disease, and because of developments in diagnostic procedures and improvements in therapy and prevention. These European Association for the Study of the Liver Recommendations on Treatment of Hepatitis C describe the optimal management of patients with acute and chronic HCV infections in 2018 and onwards.

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Introduction

Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide.¹ The long-term natural history of HCV infection is highly variable. The hepatic injury can range from minimal histological changes to extensive fibrosis and cirrhosis with or without hepatocellular carcinoma (HCC). There are approximately 71 million chronically infected individuals worldwide,^{1,2} many of whom are unaware of their infection, with important variations according to the geographical area. Clinical care for patients with HCV-related liver disease has advanced considerably during the last two decades, thanks to an enhanced understanding of the pathophysiology of the disease, and because of developments in diagnostic procedures and improvements in therapy and prevention.

The primary goal of HCV therapy is to cure the infection, i.e. to achieve a sustained virological response (SVR) defined as undetectable HCV RNA 12 weeks (SVR12) or 24 weeks (SVR24) after treatment completion. An SVR corresponds to a cure of the HCV infection, with a very low chance of late relapse. An SVR is generally associated with normalization of liver enzymes and improvement or disappearance of liver necroinflammation and fibrosis in patients without cirrhosis. Patients with advanced fibrosis (METAVIR score F3) or cirrhosis (F4) remain at risk of life-threatening complications. However, hepatic fibrosis may regress and the risk of complications such as hepatic

failure and portal hypertension is reduced after an SVR. Recent data suggest that the risk of HCC and liver-related mortality is significantly reduced, but not eliminated, in patients with cirrhosis who clear HCV compared to untreated patients and non-sustained virological responders, especially in the presence of cofactors of liver morbidity, such as the metabolic syndrome, harmful alcohol consumption and/or concurrent hepatitis B virus (HBV) infection.³⁻⁶ HCV is also associated with a number of extra-hepatic manifestations and viral elimination induces reversal of most of them with reduction of all-cause mortality.¹⁰⁻¹⁶

These EASL Recommendations on Treatment of Hepatitis C are intended to assist physicians and other healthcare providers, as well as patients and other interested individuals, in the clinical decision-making process, by describing the current optimal management of patients with acute and chronic HCV infections. These recommendations apply to therapies that have been approved by the European Medicines Agency and other national European agencies at the time of the publication.

Methodology

These EASL recommendations have been prepared by a panel of experts chosen by the EASL Governing Board. The recommendations are primarily based on evidence from existing publications and presentations at international meetings. In the absence of such evidence, the experts' personal experiences and opinions have been considered. Wherever possible, the level of evidence and recommendation are cited. The evidence and recommendations have been graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.¹⁷ The strength of recommendations reflects the quality of underlying evidence. The quality of the evidence in the recommendations has been classified into one of three levels: high (A), moderate (B) or low (C). The GRADE system offers two grades of recommendation: strong (1) or weak (2) (Table 1). Thus, the recommendations consider the quality of evidence: the higher the quality of evidence, the more likely a strong recommendation is warranted; the greater the variability in values and preferences, or the greater the uncertainty, the more likely a weaker recommendation is warranted. The recommendations have been approved by the EASL Governing Board.

Diagnosis of acute and chronic hepatitis C

Anti-HCV antibodies are detectable in serum or plasma by enzyme immunoassay (EIA) in the vast majority of patients with HCV infection, but EIA results may be negative in early acute

^{*} Clinical practice guidelines panel: Chair: Jean-Michel Pawlotsky; EASL governing board representative: Francesco Negro; Panel members: Alvaro Agüero, Marina Berenguer, Olav Dahlborg, Geoffrey Dusheiko, Rosa Marrero, Massimo Piro, Walter Vidanes.

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EASL Recommendations on Treatment of Hepatitis C 2018

Indications for treatment: who should be treated?

Recommendations

- All patients with HCV infection must be considered for therapy, including treatment-naïve patients and individuals who failed to achieve SVR after prior treatment (A1).
- Treatment should be considered without delay in patients with significant fibrosis or cirrhosis (METAVIR score F2, F3 or F4), including compensated (Child-Pugh A) and decompensated (Child-Pugh B or C) cirrhosis, in patients with clinically significant extra-hepatic manifestations (e.g. symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B-cell lymphoma), in patients with HCV recurrence after liver transplantation, in patients at risk of a rapid evolution of liver disease because of concurrent comorbidities (non-liver solid organ or stem cell transplant recipients, HBV coinfection, diabetes) and in individuals at risk of transmitting HCV (PWID, men who have sex with men with high-risk sexual practices, women of childbearing

age who wish to get pregnant, haemodialysis patients, incarcerated individuals) (A1).

- Patients with decompensated (Child-Pugh B or C) cirrhosis and an indication for liver transplantation with a MELD score ≥ 18 –20 should be transplanted first and treated after transplantation (B1).
- If the waiting time on a liver transplant list is more than 6 months, patients with decompensated (Child-Pugh B or C) cirrhosis with a MELD score ≥ 18 –20 can be treated before transplantation, although the clinical benefit for these patients is not well established (B2).
- Treatment is generally not recommended in patients with limited life expectancy due to non-liver-related comorbidities (B2).

EASL Recommendations on Treatment of Hepatitis C 2018

People who inject drugs and patients receiving opioid substitution therapy

Recommendations

- PWIDs should be routinely and voluntarily tested for anti-HCV antibodies and HCV RNA. PWIDs who are HCV RNA-negative should be tested for HCV RNA annually and following any high-risk injecting episode (**A1**).
- PWIDs should be provided with appropriate access to OST and clean drug injecting equipment as part of widespread comprehensive harm reduction programs, including in prisons (**A1**).
- All PWIDs who are infected with HCV have an indication for antiviral therapy, as DAA-based therapies are safe and effective in HCV-infected patients receiving OST, those with a history of injecting drug use and those who recently injected drugs (**A1**).
- HCV treatment should be offered to HCV-infected patients in prison (**B1**).
- Pre-therapeutic education should include discussions of HCV transmission, risk factors for fibrosis progression, treatment, reinfection risk, and harm reduction strategies (**B1**).
- In patients on OST, DAA-based anti-HCV therapy does not require methadone or buprenorphine dose adjustment (**A1**).
- Harm reduction, education and counselling should be provided to PWIDs in the context of HCV treatment to prevent HCV reinfection following successful treatment (**B1**).
- Following SVR, monitoring for HCV reinfection ideally through bi-annual, at least annual HCV RNA assessment should be undertaken in PWIDs with an ongoing risk behaviour (**A1**).
- Retreatment should be made available, if reinfection is identified during post-SVR follow-up (**A1**).

- ...
- Употребляющие инъекционные наркотики лица должны быть обеспечены доступом к заместительной опиоидной терапии и чистым оборудованием для инъекционного употребления наркотиков ..., в том числе в тюрьмах
- Всем употребляющим инъекционные наркотики лицам, инфицированным HCV, показана противовирусная терапия ПППД
- Лечение должно быть предложено HCV-инфицированным пациентам в тюрьме
- ...



EASL Recommendations on Treatment of Hepatitis C 2018

Table 3. HCV DAAs approved in Europe in 2018 and recommended in this document.

Product	Presentation	Posology
Pangenotypic drugs or drug combinations		
Sofosbuvir	Tablets containing 400 mg of sofosbuvir	One tablet once daily
Sofosbuvir/velpatasvir	Tablets containing 400 mg of sofosbuvir and 100 mg of velpatasvir	One tablet once daily
Sofosbuvir/velpatasvir/voxilaprevir	Tablets containing 400 mg of sofosbuvir, 100 mg of velpatasvir and 100 mg of voxilaprevir	One tablet once daily
Glecaprevir/pibrentasvir	Tablets containing 100 mg of glecaprevir and 40 mg of pibrentasvir	Three tablets once daily
Genotype-specific drugs or drug combinations		
Sofosbuvir/ledipasvir	Tablets containing 400 mg of sofosbuvir and 90 mg of ledipasvir	One tablet once daily
Paritaprevir/ombitasvir/ritonavir	Tablets containing 75 mg of paritaprevir, 12.5 mg of ombitasvir and 50 mg of ritonavir	Two tablets once daily
Dasabuvir	Tablets containing 250 mg of dasabuvir	One tablet twice daily (morning and evening)
Grazoprevir/elbasvir	Tablets containing 100 mg of grazoprevir and 50 mg of elbasvir	One tablet once daily

DAA, direct-acting antiviral; HCV, hepatitis C virus.

 - drugs not registered in the Russian Federation

The choice in Russia is poorer than in Europe,



but this is a choice from what is available!

EASL Recommendations on Treatment of Hepatitis C 2018

- If cirrhosis can be reliably excluded by means of a non-invasive marker in treatment-naïve patients, the combination of glecaprevir and pibrentasvir can be administered for 8 weeks only (A1).
- Generic drugs can be used, provided that quality controls are met and guaranteed by the provider (A1).
- Possible drug-drug interactions should be carefully checked and dose modifications implemented when necessary (A1).
- Given the high SVR12 rates expected with these regimens across all groups of patients if adherent, checking SVR12 12 weeks after the end of treatment is dispensable (B1).
- Patients with high-risk behaviours and risk of reinfection should be tested for SVR12 and yearly thereafter whenever possible (B1).
- In patients with advanced fibrosis (F3) or compensated cirrhosis (F4), post-SVR surveillance for the diagnosis of HCC and linkage to care must be provided when treatment for HCC is available (A1).

- Дженерики могут использоваться при условии, что контроль качества обеспечивается и гарантируется поставщиком

Criminal Code of the Russian Federation



Статья 238.1. Обращение фальсифицированных, недоброкачественных и незарегистрированных лекарственных средств, медицинских изделий и оборот фальсифицированных биологически активных добавок

(введена Федеральным законом от 31.12.2014 N 532-ФЗ)

Article 238.1. Circulation of counterfeit, substandard and unregistered medicines, medical devices and turnover of counterfeit dietary supplements

(introduced by Federal Law dated December 31, 2014 N 532-FZ)

EASL Recommendations on Treatment of Hepatitis C 2018

Recommendations

- Patients with decompensated (Child-Pugh B or C) cirrhosis should be treated in experienced centres with easy access to liver transplantation and close monitoring during therapy is required, with the possibility of stopping therapy with evidence of worsening decompensation during treatment (A1).
- Patients with decompensated (Child-Pugh B or C) cirrhosis, without HCC, awaiting liver transplantation with a MELD score <18–20 should be treated prior to liver transplantation. Treatment should be initiated as soon as possible in order to complete a full treatment course before transplantation and assess the effect of SVR on liver function, because significant improvement in liver function may lead to delisting in selected cases (A1).
- Protease inhibitors-containing regimens are contraindicated in patients with decompensated (Child-Pugh B or C) cirrhosis (A1).
- Patients with decompensated (Child-Pugh B or C) cirrhosis, without HCC, awaiting liver transplantation with a MELD score <18–20 can be treated with sofosbuvir and ledipasvir (genotypes 1, 4, 5 and 6), or with sofosbuvir and velpatasvir (all genotypes), with daily weight-based ribavirin (1,000 or 1,200 mg in patients <75 kg or ≥75 kg, respectively) for 12 weeks (A1).
- In patients with decompensated (Child-Pugh B or C) cirrhosis without HCC awaiting liver transplantation with a MELD score <18–20 treated with sofosbuvir and ledipasvir with ribavirin, or with sofosbuvir and velpatasvir with ribavirin, ribavirin can be started at the dose of 600 mg daily and the dose subsequently adjusted depending on tolerance (B1).
- Patients with decompensated (Child-Pugh B or C) cirrhosis with contraindications to the use of ribavirin or with poor tolerance to ribavirin on treatment should receive the fixed-dose combination of sofosbuvir and ledipasvir

(genotypes 1, 4, 5 or 6), or the fixed-dose combination of sofosbuvir and velpatasvir (all genotypes), for 24 weeks without ribavirin (A1).

- The higher risk of adverse events reported in patients with decompensated cirrhosis awaiting liver transplantation necessitates appropriately frequent clinical and laboratory assessments during and after HCV therapy (B1).
- Patients with decompensated cirrhosis without HCC awaiting liver transplantation with a MELD score ≥18–20 should be transplanted first, without antiviral treatment. HCV infection should be treated after liver transplantation (B1).
- Patients with decompensated cirrhosis without HCC awaiting liver transplantation with a MELD score ≥18–20 can be treated before transplantation if the waiting time on the transplant list exceeds 6 months, depending on the local situation (B2).

○ - drugs not registered in the Russian Federation

Sofosbuvir

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

МИНЗДРАВ РОССИИ
ИНСТРУКЦИЯ ЛВ-003527 - 250316
СОГЛАСОВАНО

по медицинскому применению лекарственного препарата

СОВАЛЬДИ

Регистрационный номер:

Торговое название: Совальди

Международное непатентованное наименование: софосбувир

Лекарственная форма: таблетки, покрытые пленочной оболочкой

СОСТАВ

1 таблетка содержит:

действующее вещество: софосбувир 400,0 мг;

вспомогательные вещества:

Ядро таблетки:

маннитол 360,0 мг, целлюлоза микрокристаллическая 356,0 мг, кроскармеллоза натрия 60,0 мг, кремния диоксид коллоидный 6,0 мг, магния стеарат 18,0 мг;

Оболочка таблетки:

Опадрай II желтый 36,0 мг, содержащий: поливиниловый спирт (40,0%), титана диоксид (23,33%), макрогол (20,20%), тальк (14,8%), краситель железа оксид желтый (1,67%).

ОПИСАНИЕ

Капсулообразные таблетки, покрытые пленочной оболочкой желтого цвета, с гравировкой "GSI" на одной стороне и «7977» на другой.

ФАРМАКОТЕРАПЕВТИЧЕСКАЯ ГРУППА: противовирусное средство

Код АТХ: J05AX15.

ФАРМАКОЛОГИЧЕСКИЕ СВОЙСТВА

Фармакодинамика

ПРОТИВОПОКАЗАНИЯ

- Повышенная чувствительность к софосбувиру или любому другому компоненту препарата;
- Беременность;
- Детский возраст до 18 лет (эффективность и безопасность не установлена у данной популяции);
- Почечная недостаточность тяжелой степени тяжести ($КК < 30$ мл/мин) или терминальная стадия почечной недостаточности, когда необходимо проведение гемодиализа (безопасность не установлена у данной популяции пациентов);
- Сочетанное инфицирование вирусами гепатита С и В (ВГС/ВГВ) (отсутствуют данные о применении препарата Совальди у данной популяции пациентов);
- Декомпенсированный цирроз печени (эффективность и безопасность не установлена у данной популяции пациентов);
- У пациентов, получающих мощные индукторы Р-гликопротеина (например, рифампицин, зверобой продырявленный [*Hypericum perforatum*], карбамазепин и фенитонин, фенobarбитал, окскарбазепин).

CONTRAINDICATIONS:

- ...
- ...
- ...
- Decompensated cirrhosis (efficacy and safety not established in this patient population)
- ...

EASL Recommendations on Treatment of Hepatitis C 2018

Treatment of special groups

HBV coinfection

Recommendations

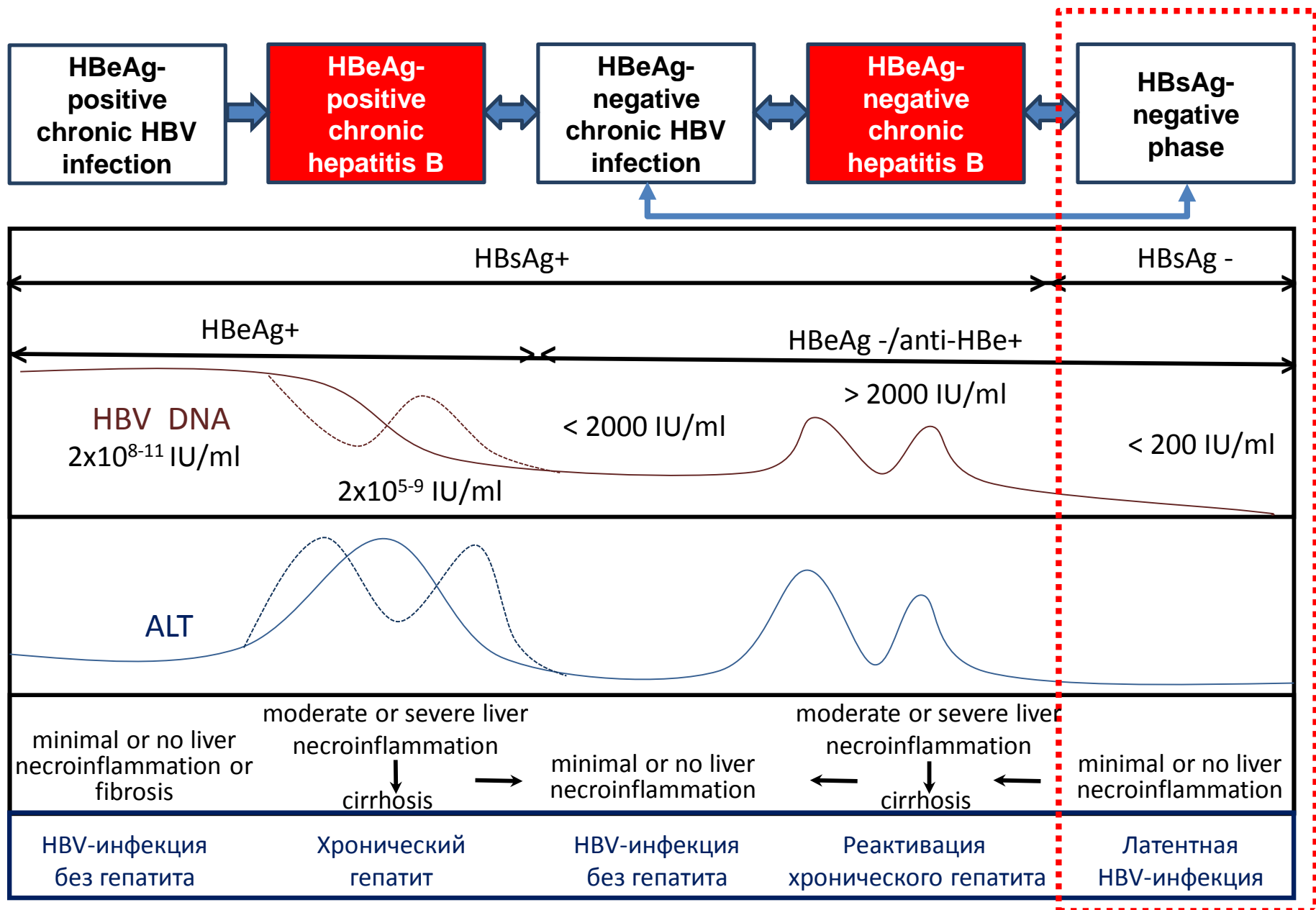
- Patients with HBV-HCV coinfection should be treated with the same anti-HCV regimens, following the same rules as HCV monoinfected patients (**B1**).
- Patients coinfecting with HCV and HBV fulfilling the standard criteria for HBV treatment should receive nucleoside/nucleotide analogue treatment according to the EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection (**A1**).
- Patients who are HBs antigen-positive should receive nucleoside/nucleotide analogue prophylaxis at least until week 12 post anti-HCV therapy and be monitored monthly if HBV treatment is stopped (**B1**).
- In patients who are HBs antigen-negative but anti-HBc antibody-positive, serum ALT levels should be monitored monthly, HBs antigen and HBV DNA should be tested if ALT levels do not normalise or rise during or after anti-HCV therapy, and nucleoside/nucleotide analogue therapy should be initiated if HBs antigen and/or HBV DNA are present (**B1**).
- HBs antigen-negative, anti-HBc antibody-positive patients undergoing anti-HCV treatment should be monitored monthly for ALT and tested for HBs antigen and HBV DNA in case of ALT elevation (**B1**).

Occult hepatitis B virus infection

- **Definition:** Presence of HBV DNA in the liver (with detectable or undetectable HBV DNA in the serum) of individuals testing HBsAg negative by currently available assays.

When detectable, the amount of HBV DNA in the serum is usually very low (< 200 IU/ml)

Natural history of chronic HBV infection



Hepatitis B Virus Reactivation Associated With Direct-Acting Antiviral Therapy for Chronic Hepatitis C Virus

A Review of Cases Reported to the U.S. Food and Drug Administration Adverse Event Reporting System

Susan J. Bersoff-Matcha, MD; Kelly Cao, PharmD; Mihaela Jason, PharmD; Adebola Ajao, PhD; S. Christopher Jones, PharmD, MS, MPH; Tamra Moyer, PhD, MPH; and Allen Brinker, MD, MS

Background: Direct-acting antiviral agents (DAAs) are used increasingly to treat hepatitis C virus (HCV) infection. Reports were published recently on hepatitis B virus (HBV) reactivation (HBV-R) in patients with HBV-HCV co-infection. Hepatitis B virus reactivation, defined as an abrupt increase in HBV replication in patients with inactive or resolved HBV infection, may result in clinically significant hepatitis.

Objective: To assess whether HBV-R is a safety concern in patients receiving HCV DAAs.

sign: Descriptive case series

^aing: U.S. Food and Drug Administration (FDA) Adverse Reporting System (FAERS).^b: 29 patients with HBV-R receiving HCV DAAs.**vements:** Clinical and laboratory data

The FDA identified 29 unique reports of HBV-R in pa-
tients receiving DAA from 22 November 2013 to 15 October
2014. Of these, 15 cases resulted in death and 1 case in liver transplan-
tation. In whom HBV-R developed were heterogeneous
V genotype, DAAs received, and baseline HBV
baseline. 9 patients had a detectable HBV viral

load, 7 had positive results on hepatitis B surface antigen (HBsAg) testing and had an undetectable HBV viral load, and 3 had negative results on HBsAg testing and had an undetectable HBV viral load. For the remaining 10 patients, data points were not reported or the data were uninterpretable. Despite provider knowledge of baseline HBV, HBV-R diagnosis and treatment were delayed in 7 cases and possibly 7 others.

Limitations: The quality of information varied among reports. Because reporting is voluntary, HBV-R associated with DAAs likely is underreported.

Conclusion: Hepatitis B virus reactivation is a newly identified safety concern in patients with HBV-HCV co-infection treated with DAAs. Patients with a history of HBV require clinical monitoring while receiving DAA therapy. Studies would help determine the risk factors for HBV-R, define monitoring frequency, and identify patients who may benefit from HBV prophylaxis and treatment. DAAs remain a safe and highly effective treatment for the management of HCV infection.

Primary Funding Source: None

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For author affiliations, see end of text.

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170 million persons worldwide have chronic hepatitis C virus (HCV) infection (1), including 2.7 million in the United States (2). The infection is in about 75% to 85% of HCV-seropositive persons. Chronic HCV infection results in 10% to 20% of patients and is the leading cause of liver disease, cirrhosis, and hepatocellular carcinoma in the United States. Approximately 10,000 persons die each year of HCV-related liver disease in the United States (3).

atment regimens were cumulative drug effects, and only patients had a sustained virologic response defined as the absence of virus 12 weeks after com-

availability of newer direct-acting antiviral (DAA) agents for HCV, patients now achieving SVR (7, 8), with a sustained virologic response is associated with a reduction in all-cause and liver-related mortality, including hepatocellular carcinoma, and hepatic de-

in the United States, acute hepatitis B virus (HBV) infection occurs primarily among injection drug users and men who have sex with men. Approximately 2% to

6% of U.S. adults with HBV infection become chronically infected (11). An estimated 850 000 to 2.2 million persons in the United States have chronic HBV infection, and an additional 5000 to 8000 become chronically infected each year (11). Worldwide, HBV is a major cause of liver disease, ranging from acute to chronic hepatitis, cirrhosis, and hepatocellular carcinoma.

Although estimates vary regarding the prevalence of HBV-HCV co-infection, it is common in geographic areas where both infections are endemic and in populations at high risk for both viruses because of their common routes of transmission (12, 13). The prevalence of HBV co-infection in 2 U.S. Veterans Affairs patient cohorts with chronic HCV infection was as high as 42% to 67% (14-17).

Hepatitis B virus reactivation (HBV-R) is defined as an abrupt increase in HBV replication in a patient with inactive or resolved HBV infection (18). Although HBV-R may occur spontaneously, it is more frequent in patients with immunodeficiency due to HIV (19), autoim-

See also:

Editorial comment 1

Hepatitis B virus reactivation among hepatitis C patients treated with direct-acting antiviral therapies in routine clinical practice

Elisabetta Loggi, Stefano Gatto, Alessandra Scuteri, Giovanni Grandini, Pietro Andreone

ARTICLE INFO

Keywords:
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Disseminating and/or
Repeating
Repeating C
Repetition

ABSTRACT

[illegible]

the whole, reactivation of HBsAg in the presence of anti-HBc is a more frequent event than the development of a protective status in previously HBsAg-positive patients [3,5].

On the other hand, the immunosuppressive therapy characterized by cyclosporin A and prednisone, which is given to HLA-Ag positive patients, may be responsible for the development of HLA-Ag positive patients. Reactivation can occur after the withdrawal of immunosuppressive therapy [19]. The reactivation of HLA-Ag positive patients has been reported in one of the described case reports [9]. The reactivation of HLA-Ag positive patients may be related to the immunosuppressive therapy that required liver transplantation.

case reports [7,8].
activation led to fulminant hep-

1. Background

The introduction of this treatment of chronic hepatitis C (CHC) drug has revolutionized the treatment of CHC patients, with

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These authors contributed equally to the work.

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EASL Recommendations on Treatment of Hepatitis C 2018

Simplified treatment of chronic hepatitis C with pangenotypic drug regimens in patients without cirrhosis and in patients with compensated (Child-Pugh A) cirrhosis

- If cirrhosis can be reliably excluded by means of a non-invasive marker in treatment-naïve patients, the combination of glecaprevir and pibrentasvir can be administered for 8 weeks only (A1).
- Generic drugs can be used, provided that quality controls are met and guaranteed by the provider (A1).
- Possible drug-drug interactions should be carefully checked and dose modifications implemented when necessary (A1).
- Given the high SVR12 rates expected with these regimens across all groups of patients if adherent, checking SVR12 12 weeks after the end of treatment is dispensable (B1).
- Patients with high-risk behaviours and risk of reinfection should be tested for SVR12 and yearly thereafter whenever possible (B1).
- In patients with advanced fibrosis (F3) or compensated cirrhosis (F4), post-SVR surveillance for the diagnosis of HCC and linkage to care must be provided when treatment for HCC is available (A1).

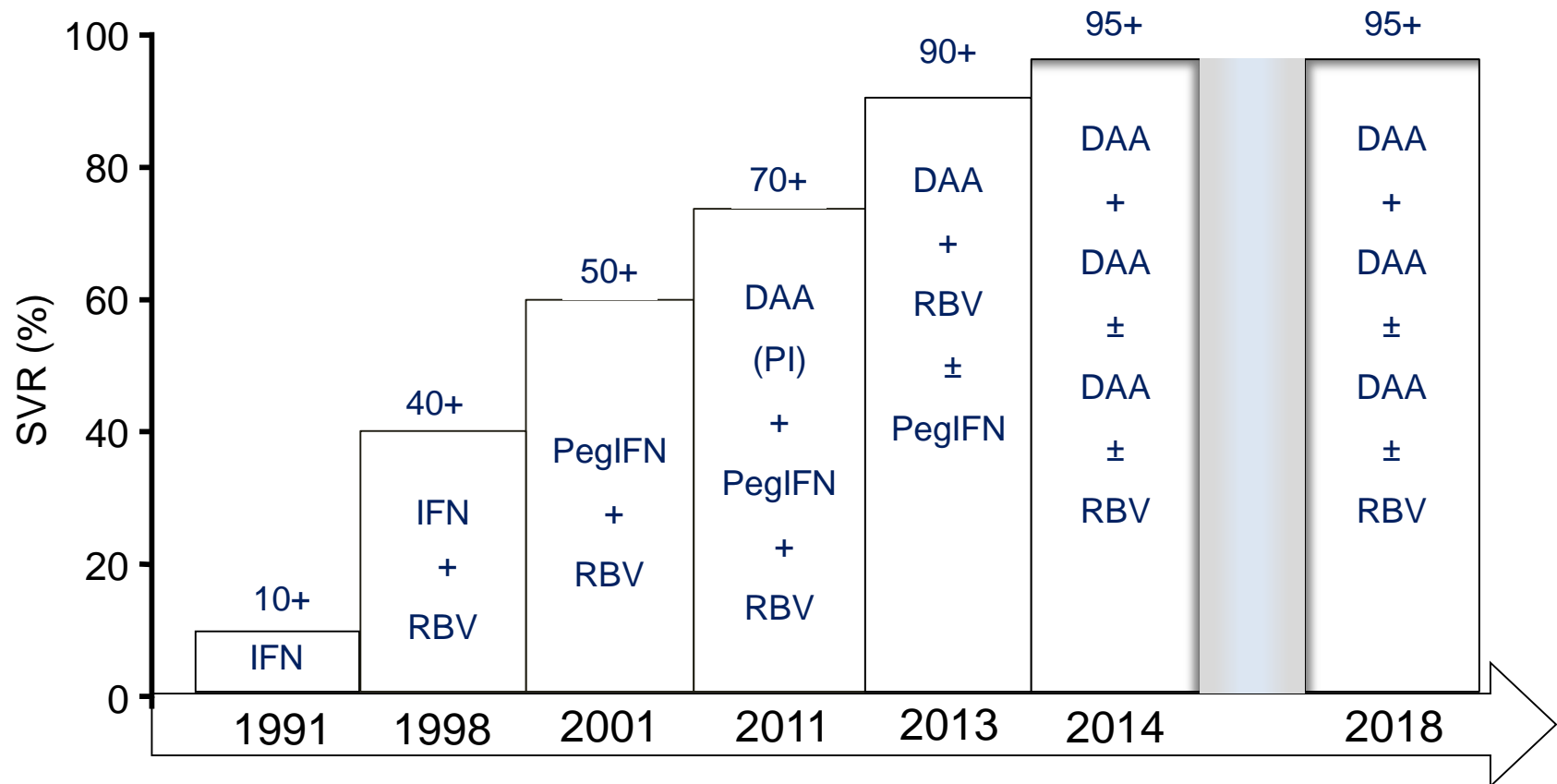
Учитывая высокие показатели УВО12, ожидаемые при этих режимах во всех группах пациентов, если они привержены лечению, **проверка УВО через 12 недель после окончания лечения необязательна**

Recommendations

- A sensitive molecular method with a lower limit of detection ≤ 15 IU/ml should be used to monitor HCV RNA levels in serum or plasma (A1).
- In low- or middle-income countries and in specific settings in high-income countries, a qualitative HCV RNA assay with a lower limit of detection $\leq 1,000$ IU/ml (3.0 Log₁₀ IU/ml) can be used to provide broad affordable access to HCV diagnosis and care (B1).
- Measurement of HCV core antigen levels in serum or plasma by EIA can be used as an alternative to HCV RNA level measurement to monitor treatment efficacy when HCV RNA assays are not available and/or not affordable (A1).
- In patients treated with an IFN-free regimen, HCV RNA or HCV core antigen levels should be measured at baseline and 12 or 24 weeks after the end of therapy (to assess SVR12 or SVR24, respectively) (A1).
- In some parts of the world, given the high SVR12 rates expected with DAA-based regimens, checking SVR may be dispensable, except in patients with high-risk behaviours and risk of reinfection (B2).

В некоторых частях мира, учитывая высокие показатели УВО12 **при использовании схем на основе ПППД, проверка УВО необязательна**, за исключением пациентов с рискованным поведением и риском реинфекции

Treatment of HCV Infection



IFN, interferon- α ; PegIFN, peginterferon- α ; RBV, ribavirin; DAA, direct-acting antiviral; PI, protease inhibitors;
SVR, sustained virological response

Conclusion

- Russian specificity impacts on the use of EASL Recommendations on Treatment of Hepatitis C in real clinical practice
- Российская специфика накладывает отпечаток на использование рекомендаций EASL по лечению гепатита С в реальной клинической практике
- Only serious work on harmonization of domestic standards with the best international ones will allow to solve the problem of controlling HCV infection in Russia
- Только серьезная работа по приведению в соответствие отечественных стандартов с лучшими международными образцами позволит приблизиться к решению задачи по контролю над HCV-инфекцией в России