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Efficacy and Safety of an 8-Week Antiviral Therapy for Chronic Hepatitis C with Ravidasvir and Sofosbuvir

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Introduction. Hepatitis C virus (HCV) genotype 3 is associated with accelerated progression of liver disease; therefore, individuals infected with this genotype represent a clinically significant subgroup of patients. Despite the high efficacy of direct-acting antivirals, the optimal duration of therapy remains a subject of debate.
Aim. To evaluate, in a real-world clinical setting, the efficacy and safety of an 8-week treatment regimen consisting of ravidasvir (200 mg) and sofosbuvir (400 mg) once daily in treatment-naive patients with chronic hepatitis C virus genotype 3 (HCV-3) infection and F0–F2 liver fibrosis (according to the METAVIR score).
Materials and methods. This prospective, single-cohort, observational study (ClinicalTrials.gov, NCT07316842) enrolled 30 patients with HCV-3; the final per-protocol analysis included 29 patients who completed the full course of antiviral therapy and were available for the assessment of sustained virological response 12 weeks after treatment cessation (SVR12). The diagnosis of HCV-3 was verified in accordance with the Clinical Guidelines "Chronic Hepatitis C", approved by the Scientific and Practical Council of the Ministry of Health of the Russian Federation. The mean age of the patients was 40.4 ± 7.1 years, and 65.5 % were men. The stage of liver fibrosis was determined by transient elastography using the FibroScan device (Echosens, France). The distribution of fibrosis stages was as follows: F0 — 44.8 %, F1 — 48.3 %, and F2 — 6.9 %. The primary endpoint was the achievement of SVR12, while the secondary endpoints included the achievement of aviremia 4 weeks after antiviral therapy completion (SVR4), viral load dynamics, changes in ALT and AST activity during treatment, as well as the safety and tolerability of the antiviral therapy.
Results. In patients with HCV-3 and F0–F2 liver fibrosis (according to the METAVIR score), SVR12 was registered in 28 out of 29 patients (96.6 %; 95% CI: 82.8–99.4). SVR4 was achieved in 24 out of 25 patients with available data (96.0 %; 95% CI: 80.5–99.3). The median viral load decreased from 8.3×10^5 IU/mL at baseline to an undetectable level after 4 weeks of treatment and remained at this level at the time of SVR12 assessment. The median ALT activity decreased from 115.2 to 18.0 U/L, and AST activity decreased from 66.0 to 23.3 U/L ($p < 0.001$ for both parameters). No serious adverse events or treatment discontinuations due to adverse events were registered.
Conclusion. The shortened 8-week antiviral therapy regimen with a combination of ravidasvir (200 mg) and sofosbuvir (400 mg) once daily in patients with HCV-3 without advanced liver fibrosis demonstrates high efficacy and a favourable safety profile in this cohort.
Keywords: chronic hepatitis C, hepatitis C virus genotype 3, ravidasvir, sofosbuvir, 8-week antiviral therapy, sustained virological response
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Эффективность и безопасность 8-недельной противовирусной терапии хронического гепатита С равидасвиром и софосбувиром

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Введение. Генотип 3 вируса гепатита С (HCV) ассоциирован с ускоренным прогрессированием заболевания печени, в связи с чем инфицированные им лица представляют собой клинически значимую подгруппу пациентов. Несмотря на высокую эффективность прямых противовирусных препаратов, оптимальная длительность терапии остается предметом обсуждения.

Цель: оценить в условиях реальной клинической практики эффективность и безопасность 8-недельной схемы терапии равидасвиром (200 мг) и софосбувиром (400 мг) 1 раз в сутки у ранее не получавших противовирусную терапию пациентов с хроническим гепатитом С, инфицированных генотипом 3 HCV (ХГС-3), при фиброзе печени F0–F2 (по шкале METAVIR).

Материалы и методы. В проспективное однокогортное наблюдательное исследование (ClinicalTrials.gov, № NCT07316842) включили 30 пациентов с ХГС-3, в финальный анализ вошли 29 пациентов (per protocol), получивших полный курс противовирусной терапии и доступных для оценки устойчивого вирусологического ответа через 12 недель после завершения лечения (УВО-12). Диагноз ХГС-3 верифицировали в соответствии с клиническими рекомендациями «Хронический вирусный гепатит С», утвержденными Научно-практическим советом Министерства здравоохранения РФ. Средний возраст пациентов составил 40,4 ± 7,1 года, 65,5 % пациентов — мужчины. Стадию фиброза печени устанавливали методом транзиентной эластографии на аппарате FibroScan (Echosens, Франция). Распределение по стадиям фиброза печени: F0 — 44,8 %, F1 — 48,3 %, F2 — 6,9 %. Первичной конечной точкой являлось достижение УВО-12, вторичными — достижение авиремии через 4 недели после завершения противовирусной терапии (УВО-4), динамика вирусной нагрузки, изменение активности АЛТ и АСТ во время лечения, а также безопасность и переносимость противовирусной терапии.

Результаты. У пациентов с ХГС-3 и фиброзом печени F0–F2 (по шкале METAVIR) УВО-12 был зарегистрирован у 28 из 29 больных (96,6 %; 95% ДИ: 82,8–99,4). УВО-4 достигнут у 24 из 25 пациентов с доступными данными (96,0 %; 95% ДИ: 80,5–99,3). Медиана вирусной нагрузки снизилась с 8,3 × 10^5 МЕ/мл исходно до неопределяемого уровня через 4 недели лечения и сохранялась на этом уровне к моменту оценки УВО-12. Медиана активности АЛТ снизилась со 115,2 до 18,0 Ед/л, активность АСТ — с 66,0 до 23,3 Ед/л (для обоих показателей $p < 0{,}001$). Серьезные нежелательные явления и отмена терапии из-за нежелательных явлений не зарегистрированы.

Заключение. Сокращенный, 8-недельный, режим противовирусной терапии комбинацией равидасвира (200 мг) и софосбувира (400 мг) 1 раз в сутки у пациентов с ХГС-3 без выраженного фиброза печени в данной когорте демонстрирует высокую эффективность и благоприятный профиль безопасности.

Ключевые слова: хронический гепатит С, вирус гепатита С генотип 3, равидасвир, софосбувир, 8-недельная противовирусная терапия, устойчивый вирусологический ответ

Финансирование: подготовка и публикация данной статьи осуществлены при финансовой поддержке ООО «Авиафарма» (ГК «ХимРар»). Спонсоры не оказывали влияния на дизайн исследования, сбор, анализ и интерпретацию данных, написание статьи, а также на принятие решения о публикации рукописи.

Конфликт интересов: авторы декларируют наличие финансовой поддержки от коммерческих организаций (ООО «Авиафарма», ГК «ХимРар») для проведения данного исследования и подготовки публикации. За исключением указанного финансирования, авторы заявляют об отсутствии иных конфликтов интересов, способных повлиять на объективность представленных научных данных. Мнения и выводы, изложенные в статье, принадлежат исключительно авторам и не обязательно отражают официальную позицию или политику компаний-спонсоров.

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Introduction

Chronic infection caused by the hepatitis C virus (HCV) remains a significant global health problem associated with the progression of liver fibrosis, the development of cirrhosis, liver failure, and hepatocellular carcinoma, as well as increased mortality related to liver diseases. Despite the revolutionary achievements brought by the introduction of direct-acting antiviral agents, which ensure the achievement of a sustained virological response (SVR12) in more than 95 % of patients, optimizing the duration of therapy remains an important task in terms of improving treatment accessibility, patient adherence, and the overall effectiveness of HCV elimination programs [1, 2].

The use of shortened antiviral therapy (AVT) regimens is considered a promising strategy aimed at simplifying treatment and scaling up HCV elimination programs, especially in resource-limited settings and areas with restricted access to medical care. The feasibility of reducing AVT duration to 8 weeks has been convincingly demonstrated for several regimens across various viral genotypes

and patient categories, primarily in treatment-naive individuals. At the same time, for certain regimens, including those based on HCV polymerase inhibitors, such as the combination of ravidasvir and sofosbuvir, the treatment duration in most cases remains 12 weeks. This is particularly relevant for patients infected with HCV genotype 3 (HCV-3), which is traditionally considered the most difficult to treat, especially in the presence of advanced liver fibrosis, hepatic steatosis, and the HCV Y93H mutation associated with reduced sensitivity to AVT. These data established a clinical and methodological rationale for investigating shortened treatment regimens in strictly defined cohorts of patients with HCV-3.

Ravidasvir (a next-generation pangenotypic NS5A inhibitor) has demonstrated high antiviral activity, a favorable pharmacokinetic profile, and good tolerability in combination with sofosbuvir across several studies. This drug is characterized by high affinity for NS5A, resistance to mutations (including Y93H), and, consequently, potent suppression of HCV replication. In phase II–III trials, including STORM-C-1, the combination of ravidasvir and sofosbuvir for 12 weeks ensured the achievement of SVR12 in approximately 97 % of patients with various HCV genotypes, including those with compensated liver cirrhosis. At the same time, despite the absence of corresponding instructions in the clinical guidelines of leading professional societies, the results of randomized trials suggest the potential feasibility of shortening the duration of ravidasvir and sofosbuvir therapy to 8 weeks without a loss of efficacy; however, the volume of evidence in this area remains limited and primarily relates to carefully selected cohorts [3, 6, 7].

HCV-3 remains of high clinical interest due to its association with faster progression of liver fibrosis and lower AVT efficacy compared to infection with other HCV genotypes. In this regard, the development of simplified and shortened treatment regimens for this category of patients is of important clinical and epidemiological significance. In this context, real-world data allow for supplementing the results of randomized clinical trials and evaluating the efficacy of AVT in routine medical practice, where patient populations are less selective and more heterogeneous [8].

The aim of this prospective observational study was to evaluate the efficacy and safety of an 8-week treatment regimen consisting of ravidasvir and sofosbuvir in treatment-naive patients with HCV-3 and METAVIR fibrosis stages F0–F2. The primary endpoint was the rate of SVR12 achievement, while the secondary endpoints included the assessment of virological response at weeks 4 and 8 of AVT and 4 weeks after its completion (SVR4), the dynamics of biochemical parameters, and the safety profile of the therapy.

Patients and methods

Study design

This was a prospective, single-cohort, observational study conducted in a real-world clinical setting. The study did not provide for any additional diagnostic or therapeutic interventions beyond the routine management of patients with chronic hepatitis C (CHC).

Patients

Adult patients with a confirmed diagnosis of CHC, infected with genotype 3, and having METAVIR fibrosis stages F0–F2 determined by transient elastography no earlier than 3 months prior to the initiation of therapy, were sequentially enrolled in the study (Table 1).

Inclusion criteria:

- age 18 years and older;
- confirmed diagnosis of CHC-3;
- METAVIR liver fibrosis stages F0–F2 based on transient elastography data;
- initiation of ravidasvir and sofosbuvir therapy within routine clinical practice;
- signed informed consent for the use of anonymized data.

Exclusion criteria:

- coinfection with hepatitis B virus or human immunodeficiency virus;
- presence of other significant liver diseases (including autoimmune liver diseases, primary biliary cholangitis, primary sclerosing cholangitis, hemochromatosis, and hepatocellular carcinoma);
- severe pathology of other organs and systems;
- prior AVT;
- pregnancy or breastfeeding;
- conditions, in the opinion of the treating physician, capable of affecting adherence to therapy (e.g., substance abuse);
- concomitant diseases requiring ongoing concurrent medical therapy.

Treatment

Patients with CHC-3 received a combination of the antiviral drugs ravidasvir (200 mg) and sofosbuvir (400 mg) once daily for 8 weeks. Alterations to the antiviral therapy were not regulated by the study protocol. Concomitant therapy was permitted at the discretion of the treating physician, taking into account potential drug-drug interactions. The primary endpoint of the study was the achievement of SVR12, expressed as the absence of detectable HCV RNA 12 weeks after the completion of therapy. Secondary endpoints included the evaluation of

Table 1. Baseline characteristics of patients with CHC

Parameter	Value
Patients enrolled in the study	30
Patients in the efficacy analysis	29
Age, years (*Me* ± SD)	40.4 ± 7.1
Men, *n* (%)	19 (65.5 %)
Women, *n* (%)	10 (34.5 %)
HCV genotype	Genotype 3 in all patients
Treatment-naive, *n* (%)	29 (100.0 %)
Fibrosis F0, *n* (%)	13 (44.8 %)
Fibrosis F1, *n* (%)	14 (48.3 %)
Fibrosis F2, *n* (%)	2 (6.9 %)
Baseline viral load, mean	1.22×10^6 IU/mL
Baseline viral load, *Me*	8.30×10^5 IU/mL

SVR4 achievement, virological response during treatment, viral load dynamics, changes in biochemical parameters, and treatment safety. RNA genotyping of the hepatitis C virus was performed using AmpliSens HCV-1/2/3-FL test systems (Russia). Quantitative determination of HCV RNA using Vector-Best reagents (Russia) with a sensitivity of 15 IU/mL was performed immediately before the first dose of antiviral drugs, at weeks 4 and 8 of AVT (response at the end of treatment), as well as 4 and 12 weeks after completion of AVT (SVR4 and SVR12, respectively). Evaluated biochemical parameters included alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, alkaline phosphatase, gamma-glutamyl transpeptidase, creatinine, glucose, uric acid, creatine phosphokinase, and other parameters as indicated. Assessment of the liver fibrosis stage was carried out by transient elastography using a FibroScan device (Echosens, France).

All adverse events occurring during the treatment and follow-up periods were registered.

Ethical aspects

The study was conducted in accordance with current legislation and international guidelines for non-interventional studies, including the principles of Good Pharmacoepidemiological Practice. All patients signed an informed consent for the use of their anonymized data. The study protocol and related documents were reviewed and approved by an independent ethics committee prior to the initiation of the work. The study was registered in the ClinicalTrials.gov registry (identification number: NCT07316842).

Statistical analysis

Baseline characteristics and treatment outcomes were described using descriptive statistics. Categorical variables are presented as absolute values and proportions (percentages), while continuous variables are expressed as means with standard deviation or medians, depending on the nature of the data distribution. The rate of SVR achievement was calculated with 95 % confidence intervals (95 % CI) using the Wilson method. Changes in laboratory parameters over time were analysed using the non-parametric Wilcoxon signed-rank test. The analysis was performed on the available population; missing data were not imputed.

Results

A total of 30 patients were enrolled in the study. One patient was lost to follow-up and was not included in the efficacy analysis. Thus, the population available for analysis consisted of 29 patients (per protocol), of whom 65.5 % were men. The mean age of the patients was 40.4 ± 7.1 years. The distribution of liver fibrosis stages was as follows: F0 — 44.8 %, F1 — 48.3 %, and F2 — 6.9 %.

The rate of SVR12 achievement was 96.6 % (28/29; 95 % CI: 82.8–99.4), while that of SVR4 was 96.0 %. The median viral load decreased to an undetectable level as early as 4 weeks into therapy and remained at this level at all follow-up stages (Table 2). The single patient who failed to achieve SVR12 had resistance-associated substitutions in *NS5a* (T62 and H93), with no mutations detected in *NS5b*. Due to the absence of concomitant drug therapy, an analysis of drug-drug interactions in patients within this study was not conducted.

High treatment efficacy was observed across all liver fibrosis subgroups: F0 — 100 % (13/13), F1 — 92.8 % (13/14), and F2 — 100 % (2/2). The only case of relapse was recorded in a patient with fibrosis stage F1. The rate of SVR12 achievement was comparable between men and women, at 100 % (19/19) and 90.0 % (9/10), respectively. The only case of failure to achieve

Table 2. Virological response to antiviral therapy

Parameter	Result
SVR12 rate	28/29; 96.6 % (95% CI: 82.8–99.4)
Virological relapse	1/29; 3.4 %
SVR4 rate	24/25; 96.0 % (95% CI: 80.5–99.3)
Median HCV RNA at baseline	8.30×10^5 IU/mL
Median HCV RNA at week 4	0 (undetectable level)
Median HCV RNA at the end of therapy	0 (undetectable level)
Median HCV RNA at SVR12 assessment	0 (undetectable level)

Table 3. SVR12 rates according to liver fibrosis stages

Subgroup	SVR12, *n*/N	Proportion
Fibrosis F0	13/13	100.0 %
Fibrosis F1	13/14	92.8 %
Fibrosis F2	2/2	100.0 %
Men	19/19	100.0 %
Women	9/10	90.0 %

SVR12 was registered in a female patient. The differences in the SVR12 achievement rate between men and women do not appear to be statistically or clinically significant given the limited sample size (Table 3).

Against the background of combined AVT with ravidasvir and sofosbuvir, a rapid, statistically significant ($p < 0.001$) decrease in transaminase levels to normal values was noted: the median ALT activity decreased from 115.2 to 18.0 U/L, and AST activity decreased from 66.0 to 23.3 U/L. The most pronounced changes were observed during the first 4 weeks of therapy (Table 4).

Safety of AVT

No serious adverse events were registered during AVT with ravidasvir and sofosbuvir. The reported adverse events were mild and transient, resolved spontaneously, and did not require treatment discontinuation. The most common of these included headache, fatigue, and dyspepsia.

Discussion

The obtained results are consistent with international data and confirm the feasibility of using a shortened AVT regimen in patients with minimal liver fibrosis while maintaining high treatment efficacy (Table 5).

In this prospective, real-world clinical study, the 8-week therapy with sofosbuvir and ravidasvir demonstrated high efficacy in treatment-naive patients with CHC-3 and METAVIR liver fibrosis stages F0–F2. The SVR12 rate was 96.6 %, with a rapid decrease in viral load to an undetectable level observed in most patients as early as 4 weeks into AVT. The obtained data indicate that in patients without advanced fibrosis, the 8-week treatment regimen with sofosbuvir and ravidasvir can provide a virological response rate comparable to the results of standard 12-week regimens.

The results of the study are consistent with published data on 12-week sofosbuvir and daclatasvir therapy in patients with CHC-3. In the ALLY-3 study, 12-week AVT with sofosbuvir and daclatasvir ensured the achievement of SVR12 in 96 % of patients with CHC-3 without cirrhosis and was characterized by good tolerability [9]. The efficacy of ravidasvir and sofosbuvir in patients with minimal and mild liver fibrosis (METAVIR stages F0–F2) with a shorter treatment duration

Table 4. Biochemical response to antiviral therapy

Parameter	Baseline	SVR12	*p*
ALT, U/L	115.2	18.0	<0.001
AST, U/L	66.0	23.3	<0.001

Table 5. Efficacy comparison of ravidasvir-containing regimens

Study	Treatment regimen	Population	SVR12
NCT07316842	ravidasvir/sofosbuvir (8 weeks)	CHC-3, F0–F2	96.6 %
STORM-C-1 [3]	ravidasvir/sofosbuvir (12 weeks)	All HCV genotypes, F0–F4	97.0 %
EASE [10]	ravidasvir/sofosbuvir (8 weeks)	F0–F3	93.4 %

was found to be similar to the efficacy level of 12-week AVT with sofosbuvir and daclatasvir, with the SVR12 achievement rate being 96.6 %. The obtained results also correspond to the data on the efficacy of 12-week AVT with sofosbuvir and ravidasvir in the STORM-C-1 study [3]. The combination of ravidasvir (200 mg) and sofosbuvir (400 mg) was administered for 12 weeks in patients without cirrhosis and for 24 weeks in those with cirrhosis; an interim analysis showed high efficacy of the regimen regardless of the HCV genotype. According to the STORM-C-1 study, the overall efficacy of AVT with sofosbuvir and ravidasvir was 96.8 %, and for patients with CHC-3, it was 97 %. Similar data were obtained in the EASE study, in which the efficacy of 8-week AVT with ravidasvir and sofosbuvir in patients with CHC without liver cirrhosis was comparable to that of the 12-week regimen: the SVR12 achievement rate was 93.42 % in the 8-week group and 93.46 % in the 12-week group, which confirms the fundamental feasibility of reducing the duration of sofosbuvir and ravidasvir therapy in patients without cirrhosis [10]. The results of the present study supplement these data by focusing on CHC-3 in Russian real-world clinical practice.

An analysis of patient subgroups with CHC-3 and minimal or mild liver fibrosis enrolled in the present study demonstrated a high rate of SVR12 achievement regardless of the fibrosis stage, gender, or baseline viral load. The only case of failure to achieve SVR12 was registered in a female patient with fibrosis stage F1 according to the METAVIR score. However, due to the small sample size, these results should be considered descriptive; the study lacked sufficient statistical power to detect significant differences between the subgroups.

The rate of achieving a sustained virological response 4 weeks after treatment completion (SVR4) deserves a separate discussion. In clinical practice, this parameter is not considered a definitive marker of cure and has no independent prognostic value, since the evaluation of SVR12 remains the international standard for treatment efficacy. In the present study, despite the high rate of SVR4 achievement (96.0 %), certain patients with detectable viremia at the early stages of treatment subsequently achieved SVR12. This observation is consistent with data from clinical trials of antiviral drugs, which show that the presence of detectable HCV RNA during treatment is not necessarily associated with a failure to achieve SVR12. Thus, the interpretation of HCV RNA PCR test results during treatment requires caution, and decisions regarding the need for repeat antiviral therapy should not be based on these data in the absence of other clinical grounds.

Thus, the results of the present study support the hypothesis that in patients with CHC-3 and early stages of fibrosis, the duration of AVT with ravidasvir and sofosbuvir can be shortened to 8 weeks without a decrease in efficacy. Consequently, if its efficacy is confirmed by randomized clinical trials, this treatment regimen can be considered a potentially promising therapeutic strategy for CHC-3 patients without advanced liver fibrosis. Reducing the duration of the course offers important practical advantages, such as improving patient adherence and lowering the cost of AVT. This is particularly important for healthcare systems where drug availability and the organizational simplicity of treatment are key factors in scaling up hepatitis C elimination programs. Furthermore, the regimen is characterized by a favourable safety profile and the absence of serious adverse events requiring treatment modification.

The present study has several limitations. It was a single-center, single-cohort, observational study without a randomized control group; therefore, a direct conclusion regarding the non-inferiority of the 8-week regimen compared to the 12-week therapy is not possible. The sample size was limited, which widens the confidence intervals and reduces the precision of subgroup estimates. The study included only treatment-naive patients with CHC-3 and METAVIR liver fibrosis stages F0–F2; consequently, the results cannot be extrapolated to patients with advanced fibrosis or liver cirrhosis, other HCV genotypes, significant comorbidities (including HIV infection), or those with a history of prior AVT. Finally, as in any real-world study, selection biases, incomplete data, and variability in laboratory monitoring are possible.

Conclusion

The results of the conducted study (identification number: NCT07316842) demonstrate the high efficacy and favorable safety profile of an 8-week AVT regimen with ravidasvir and sofosbuvir in treatment-naive patients with CHC-3 and minimal or mild liver fibrosis (METAVIR stages F0–F2). The SVR12 achievement rate of 96.6 % registered in the study provides a strong rationale for further investigation into the efficacy of this shortened treatment regimen in larger multicenter randomized trials, with the subsequent update of clinical guidelines for the management of CHC.

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