NICOLAUS COPERNICUS UNIVERSITY IN TORUŃ

Quality in Sport. eISSN 2450-3118.

Journal Home Page
https://apcz.umk.pl/QS/index

ZAPALSKA, Magdalena, KRUPSKA, Barbara Izabela, MALEC, Julia Anna, KULIG, Lidia, WŁODARCZYK, Franciszek, WOŹNIAK, Weronika Maria, WIELEBA, Marcin, WINIARSKA, Zuzanna, WITCZAK, Katarzyna Wiktoria, and WIERCIOCH, Eliza. Hepatitis C Virus Infection in Pregnant Women – Current Treatment Practices. Quality in Sport. 2026;54:70418. eISSN 2450-3118. https://doi.org/10.12775/QS.2026.54.70418

The journal has been awarded 20 points in the parametric evaluation by the Ministry of Higher Education and Science of Poland. This is according to the Annex to the announcement of the Minister of Higher Education and Science dated 05.01.2024, No. 32553. The journal has a Unique Identifier: 201398. Scientific disciplines assigned: Economics and Finance (Field of Social Sciences); Management and Quality Sciences (Field of Social Sciences).
Punkty Ministerialne z 2019 - aktualny rok 20 punktów. Załącznik do komunikatu Ministra Szkolnictwa Wyższego i Nauki z dnia 05.01.2024 Lp. 32553. Posiada Unikatowy Identyfikator Czasopisma: 201398. Przypisane dyscypliny naukowe: Ekonomia i finanse (Dziedzina nauk społecznych); Nauki o zarządzaniu i jakości (Dziedzina nauk społecznych).
**The authors declare that there is no conflict of interest regarding the publication of this paper.
Received: 30.03.2026. Revised: 03.04.2026. Accepted: 05.04.2026. Published: 09.04.2026.**

Hepatitis C Virus Infection in Pregnant Women – Current Treatment Practices

Magdalena Zapalska

ORCID https://orcid.org/0009-0007-5777-2959

E-mail magda.zapalska1@gmail.com

Medical University of Lublin, Poland

Barbara Izabela Krupska
ORCID https://orcid.org/0009-0002-5755-9377
E-mail: bkrupska07@wp.pl
Medical University of Lublin, Poland

Julia Anna Malec
https://orcid.org/0009-0002-2564-2889
E-mail: jmalec17@wp.pl
Medical University of Warsaw, Poland

Lidia Kulig
https://orcid.org/0009-0008-0709-574X
E-mail lidia.kulig01@gmail.com
Medical University of Warsaw, Poland

Franciszek Włodarczyk
https://orcid.org/0009-0005-0754-4558
E-mail fwlodarczyk576@gmail.com
Medical University of Lublin, Poland

Weronika Maria Woźniak
https://orcid.org/0009-0007-4906-7125
E-mail weronika7801@gmail.com
Medical University of Lublin, Poland

Marcin Wieleba
https://orcid.org/0009-0006-9815-4340
E-mail marcin.wieleba09@gmail.com
Medical University of Lublin, Poland

Zuzanna Winiarska
https://orcid.org/0009-0002-3177-4271
E-mail zuzawiniarska22@gmail.com
Medical University of Lublin, Poland

Katarzyna Wiktoria Witczak
https://orcid.org/0009-0008-5622-208X
E-mail kasiawitczak310@gmail.com
Medical University of Lublin, Poland

Eliza Wiercioch
https://orcid.org/0009-0004-0044-301X
E-mail eliza.wiercioch2001@gmail.com
Medical University of Lublin, Poland

Corresponding Author:
Magdalena Zapalska
magda.zapalska1@gmail.com

ABSTRACT

Hepatitis C Virus (HCV) is a single-stranded RNA virus with hepatotropic potential classified within the Flaviviridae family. HCV infection still remains a global problem, which is why World Health Organisation (WHO) initiated a global strategy to achieve the elimination of the infections caused by hepatitis C virus (HCV) and hepatitis B virus (HBV) by 2030. According to the WHO, about 50 million people were chronically infected in 2025. Available data suggest that the number of seropositive births fluctuates between 2,2 to 5,5 million every year worldwide. The therapy of hepatitis C during pregnancy continues to be a challenge, in light of the risk of theratogenic effects this treatment may carry. The aim of this review is the analysis of current treatment practices and the future of therapeutic process among pregnant women suffering from hepatitis C.

Matherials and methods. The literature review was conducted using databases: Scopus and Pubmed. The review included the recent years publications and analysis of six different clinical trials focused on the safety and efficacy of the HCV infection treatment during pregnancy with Direct-Active Antivirals (DAAs).

Results. According to the results of analyzed in this review clinical trials it can be concluded that DAAs therapy is effective. Various combinations of DAAs, including Sofosbuvir/Velpatasvir and Sofosbuvir/Ledipasvir showed similar therapeutic potential and safety for women and their newborns.

Conclusions. More clinical trials in larger groups of pregnant patients should be performed to understand the effectivenes and safety of the DAAs therapy among women in pregnancy. Available results of conducted research show that Direct-Active Antivirals are well-tolerated and they reduce the risk of mother-to-child-transmission of the HCV.

Keywords: HCV, DAA, hepatitis C, pregnancy, sofosbuvir, velpatasvir

Introduction

Hepatitis C Virus (HCV) is a single-stranded RNA virus with hepatotropic potential. HCV is classified within the Flaviviridae family, genus Hepacivirus. Infection with this virus leads to acute or chronic hepatitis (Martinello M. et al.2023). According to the World Health Organisation (WHO) 50 million people are chronically infected as of 2025 (Topi et al. 2024). Chronic hepatitis is associated with severe complications such as liver cirrhosis, hepatic encephalopathy and hepatocellular carcinoma (Martinello M et al. 2023). Direct-Acting Antivirals (DAA) registration in the therapy of HCV infection has fundamentally transformed the treatment process.

Viral structure of the Hepatitis C Virus

HCV belongs to the Flaviviridae family, that is grouped into Hepacivirus, Pestivirus and Flavivirus, Viral genetic material is composed of single-stranded RNA, and its particle consists of a lipoprotein envelope, that is surrounded by a capsid. The core protein constitutes the protein coat (Sallam M. and Khalil R. 2024). There are eight identified HCV genotypes. In Europe, Australia, central and East Asia, North America and South America genotype 1 predominates. Genotype 3 is the most prevalent HCV genotype in India and Pakistan, and genotype 4 in Egypt, central and sub-Saharan Africa (Martinello M. et al.2023).

HCV transmission and replication cycle

Viral transmission occurs through the exposure to blood infected with HCV. It can be also spread by vertical transmission, from mother to newborn and also through the sexual contacts (Martinello M. et al.2023). Replication starts with the RNA transcription, after that, the polyprotein is formed. The creation of the viral replication complex is related to intracellular membranes. New molecules are produced and the virus is released from the infected cell (Sallam M. and Khalil R. 2024).

Clinical manifestation of the infection

Acute HCV infection is asymptomatic in most cases. Symptoms that may be presented are jaundice, fever, nausea, vomitting, musculoskeletal pain, headache and generalise discomfort. Chronic infection leads to the inflammation and fibrosis of the liver. Long-term inflammation process is responsible for the development of the hepatocellular carcinoma. Elevation of alanine aminotransferase and aspartate aminotransferase is commonly associated with hepatitis C (Martinello M. et al.2023)

Diagnosis

Unexplained liver abnormalities should be a motivation to start a two-step HCV testing algorithm. The process begins with anti-HCV antibodies detection, the aim of this step is the identification of the past or current HCV infection. Serologic testing is carried out using Enzyme Immunoassays (EIAs) (Rios J. et al. 2024). Positive serologic results must undergo verification with HCV RNA quantitative and qualitative nucleid acid testing.

Epidemiological data

According to WHO, 50 million people all over the world are chronically infected as of 2025. 21% of them are of reproductive age (Wasuwanich P. et al. 2024). Available data shows that between 2,2 and 5,3 million HCV annual seropositive births are reported worldwide. A cohort analysis of data collected between 1990 and 2021 on HCV infection among women aged 15-49 showed an incidance rate of 5,46 per 100000 for acute HCV infection and 29,92 per 100000 for chronic HCV infection (Kushner et al. 2022).

The influence of HCV infection on the pregnancy course

Retrospective cohort study performed in Canada included a total of 2170 pregnancies in 1636 women infected with HCV. Analyzing the results it can be concluded that pregnant women who

were HCV RNA positive had an increased risk of preterm birth, intrahepatic cholestasis of pregnancy and post-partum hemorrhage (Rios J. et al. 2024).

Perinatal transmission

Mother-to-child-transmission (MTCT) is the mayor clinical consequence associated with HCV infection. The risk of perinatal transmission is 7,2%, and it reaches a level of 12,1% among people co-infected with HIV. About 30% of the HCV vertical transmissions occur between 24,9 and 36,1 week of pregnancy (Mariné-Barjoan E. et al. 2007). The chance of MTCT increases when HCV viremia reaches the concentration greater than 10^6 IU/ml. Also, the antepartum hemorrhage is likely to increase the risk of the perinatal transmission. There is no strong evidence that breastfeeding and delivery method increase the risk of MTCT (Ghamar Chehreh ME et al. 2011). The infection resolves spontaneously among 65,9% of perinally-infected infants, whereas 3,9% of them have persistent viremia at the age of 5 (Wasuwanich P. et al.). Current estimates indicate that 5-12% of them develop liver fibrosis and 5% suffer from liver cirrhosis 10-20 years after the delivery (Fauteox-Daniel S. et al. 2017)

Screening

In the past testing recommendations were risk-based which is why the screening included women in reproductive age and pregnant women. According to this policy, the testing involved women who had a history of drug using, HCV-positive sexual partners, sexually-transmited infections or hemodialysis. In 2019 American Association for the Study of Liver Diseases and the Infectious Diseases Society of America decided to recommend a routine HCV screening among pregnant women (Wasuwanich P. et al.). Polish Society of Gynecologists and Obstetricians recommend routine HCV screening at 10 weeks of gestation.

Delivery guidelines

A study was conducted in six hospitals in France and included 214 mother-infant pairs. According to the results, there were no significant differences in the risk of infection among infants born by vaginal delivery and cesarean section (Ghamar Chehreh ME et al. 2011). A meta-analysis of eight studies that involved 641 mother-and-child pairs also showed no statistically meaningful risk increase related to the mode of delivery (Conte D. et al. 2000). These studies confirm the validity of the current Department of Health and Human Services (DHHS) guidelines which suggest that the delivery method should be guided by clinical HIV status.

Breastfeading and HCV infection

Analyzing most studies it can be concluded that breastfeeding does not raise the risk of MTCT, however the chances of transmission are greater when breastfeeding is accompanied by bleeding from nipples (Bhattacharya D. et al. 2023)(Hartley et al. 2024).

Previous treatment strategy

In 1990s the first HCV infection treatment was implemented. The therapy included pegylated interferon-α2b and Ribavirin with sustained virologic response (SVR) achieving 40-50% efficacy. However, this drug combination remains theratogenic, leaving pregnant women with HCV infection with no effective treatment available (Dutra K. et al. 2025).

Hepatitis C treatment in pregnant women

The invention and approval of Direct-Active Antivirals (DAAs) have fundamentally reshaped the whole therapeutic process. It is suggested that DAAs should be considered as a treatment for HCV infection during pregnancy after considering all the advantages and disadvantages of this strategy (Kushner T et al. 2022). The U.S. Food and Drug Administration (FDA) registered pan-genotypical DAAs comprising glecaprevir/pibrentasvir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir. Ledipasvir/sofosbuvir were originally approved in 2014 and the combination of these two is used and covers genotypes 1, 4, 5 and 6. DAAs are categorized as pregnancy class “B” using FDA classification. Caterory “B” drugs have not demonstrated an increased risk to the fetus in animal studies, however there are no evidence-based research on the DAAs therapy in pregnant women. To avoid the fetal organogenesis disruption, the treatment should be initiated in late pregnancy due to the fact that most DAAs are documented to cross the placental barrier. The optimal time to start the therapy may be at around between 24. and 28. week of pregnancy. Glecaprevir had shown the lowest transfer into breast milk, however the others, including sofosbuvir, ledipasvir, velpatasvir and pibrentasvir, had demonstated high concentration in breast milk (Freriksen JJM. et al. 2019).

Direct-Active Antivirals’ pharmacological mechanism of action

DAAs show three different mechanisms of action. Non-structural protein 5A (NS5A) inhibitors, such as ledipasvir, pibrentasvir and velpatasvir inhibit the lipoprotein’s creation of the replication complex inside of the Golgi apparatus. As a result the transport and release of viral particles out of the hepatocyte is blocked. Non-structural protein 5B (NS5B) inhibitors,

including sofosbuvir, integrate into the RNA-dependent RNA polymerase. As a consequence of this action the nucletides cannot be added to the RNA chain. NS3/4 protease inhibitors, for example glecaprevir, suppress the replication process of positive single-stranded RNA into the negative single-stranded RNA in hepatocytes, this action prevents the multiplying process of HCV (Hartley C. et al. 2024).

DAAs therapy in pregnancy

1. **A study conducted in Women's Liver Clinic included 23 pregnant women at an average age of 30 years. 65% of them were unaware of HCV infection (Kushner T. et al. 2022).**

The clinical management started with evaluating all the pros and cons of using DAAs. The combination of drugs used in the study was: sofosbuvir/ledipasvir and sofosbuvir/velpatasvir. Glecaprevir/pibrentasvir were chosen for the postpartum period. 65% of women included in this research opted for treatment initiation. Finally, eight women received treatment during pregnancy and seven during postpartum. Only two study participants who were administered treatment in pregnancy and five who were treated in postpartum attended their follow-up visit. The concentration of alanine aminotransferase (ALT) were measured before and after the therapy. Median serum ALT level before treatment was 42 U/L and after – 14 U/L. The administration of DAAs among pregnant women and those in postpartum was well tolerated and significant benefits to maternal and child health were observed. HCV eradication may reduce the risk of mother-to-child-transmission and also the chances to present the intrahepatic cholestasis of pregnancy symptoms.

2. **The multi-site, prospective, open-label, collaborative PK study was conducted in two Australian hospitals (Giles et al. 2025).**

The age of the study participants ranged from 18 to 45. All five pregnant study participants' medical histories were reviewed and many laboratory tests were taken, including HIV, hepatitis B, and syphilis infection testing. The treatment with DAAs tested in this research – sofosbuvir/velpatasvir (SOF/VEL) was introduced between 22 and 24+6 weeks' of pregnancy. The doses used in the research were: 400 milligrams for sofosbuvir and 100 milligrams for velpatasvir daily. Three visits were performed: the first at 25+0 to 26+6 weeks of gestation, the second at 29+0 to 31+6 weeks' and the third at 33+0 and 34+6 weeks'. Blood samples were

collected from participants during each visit and the SOF/VEL concentrations were measured. Mothers underwent HCV RNA tests at the end of the treatment and twelve weeks after. The aim of these tests was to evaluate the effectiveness of the DAAs therapy. Newborns were observed for twelve months after the delivery and they underwent HCV RNA test after they turned 6 months. According to the results SOF/VEL therapy was well-tolerated, no meaningful side effects and severe neonatal complications were observed. The treatment provided was effective, at the end of the therapy maternal HCV PCR tests were negative in 80% of study participants upon completion of treatment and in 100% at 12 weeks after. Two of five neonates had a negative HCV RNA test at 6 months, and the other three were lost to monitoring.

3. **An open-label single-site PK evaluation study of SOF/VEL therapy administrated in eleven pregnant women was conducted between November 2020 and July 2022 (Chappell C. et al. 2025).**

Participants aged between 18 and 39 were between 23 and 25 weeks of gestation. All of them received a twelve weeks' treatment with 400 milligrams of sofosbuvir and 100 milligrams of velpatasvir per day. 24-hour visits were carried out at three, six and nine weeks of treatment. Each visit included blood-samples collecting and HCV RNA test. Ten study participants completed the study and delievered. Two of them were lost to follow-up. Eight of them completed the sustained virologic response, which means that twelve weeks after the end of the treatment they had no detectable viral load. Nine of eleven participants experienced side effects. Adverse events observed: headache, nausea, vomiting, fatigue, heartburn. Two of eleven infants delivered preterm: at 35 and 36 weeks of gestations. Three of eleven participants suffered from postpartum hemorrhage, two experienced hypertensive disorder of pregnancy, and none of trial participants had gestational diabetes or cholestasis of pregnancy.

4. **An open-label, phase 1 study was conducted from October 2016 to September 2018 in pregnant women with genotype 1 HCV infection (Chappell C. et al. 2020).**

The aim of the study was to analyze the differences between pharmacokinetics of ledipasvir and sofosbuvir among pregnant and non-pregnant women. Nine pregnant participants between 23 and 24 weeks of gestation were included. The treatment administered was 90 milligrams of ledipasvir with 400 milligrams with sofosbuvir for twelve weeks. During the whole therapeutic process three visits were carried out: at 25-26, 29-30 and 33-34 weeks' gestational. All nine

participants and all nine infants completed the study. Based on the analysis of the results, it was concluded that Ledipasvir/Sofosbuvir treatment showed no significant difference between pregnant and not-pregnant women. The pharmacokinetic parameters did not differ significantly in pregnancy with non-pregnant participants. All pregnant participants showed undetectable viremia at the third visit in 33 and 35 weeks of pregnancy. Only one of them had detectable viral load at delivery, however she also presented the highest viremia at the beginning and declared opioid using during the treatment. Nine participants had an undetectable level of HCV RNA twelve weeks after the end of the treatment. Side effects were observed in five of nine participants, including: nausea, vomiting, diarrhea, fatigue. Eight of nine newborns were delivered at term (>37 weeks of gestation), one was delivered at 36+6 because of gestational hypertension. The control sampling in infants conducted during the twelve-month follow-up showed no detectable HCV RNA among all nine neonates.

5. **A single- center, observational, prospective study was conducted from March 2016 to February 2019 a at the Sher-I-Kashmir Institute of Medical Sciences, Srinagar, India (Yattoo GN et al. 2023).**

Participants included were 26 volunteers at the age of 21-39 years during the second and third trimester of pregnancy. They received sofosbuvir/ledipasvir (SOF/LDV) therapy for twelve weeks. Administered doses were 400 milligrams of sofosbuvir and 90 milligrams of ledipasvir. HCV RNA tests were performed four weeks after the treatment started, at the end of the therapy (week twelve) and twelve weeks after. Infants were tested for IgG anti-HCV 6 months after the delivery using enzyme-linked immunosorbent assay (ELISA), and positive results were verified using HCV RNA PCR. 26 of 26 participants presented rapid and sustained virologic response. Four of twenty six newborns were seropositive for anti-HCV, whereas the HCV RNA remained undetectable. No significant adverse drug reactions were registered. The most common side effects were nausea, headache and fatigue. Fetal adverse events were not observed. No intrauterine, peripartum and neonatal deaths were documented.

6. **A multicenter, single arm study of Sofosbuvir/Velpatasvir (SOF/VEL) – phase 4 of clinical trial (NCT05140941).**

Participants included will be between 20+0 and 30+0 weeks of gestation and they will receive the SOF/VEL therapy for twelve weeks. Dose combination given consists of 400 milligrams of sofosbuvir and 100 milligrams of velpatasvir. Pregnant women will take one dose of SOF/VEL

treatment for 84 days daily. The follow-up program assumes six maternal and three infant visits. The aim of the study is to check the maternal HCV viremia twelve weeks after the end of SOF/VEL therapy, and also to review if preterm deliveries were noticed. Other endpoints are: the verification if maternal and infants adverse events were reported, what is more to determine whether neonatal intensive care unit admission was required. The study started in April, 2024 and will be finished in June, 2026.

Discussion

The review of five different clinical trials suggest that Direct-Active Antivirals therapy in pregnant women presented high efficacy. All pregnant participants presented rapid and sustained virologic response after twelve weeks of treatment. Despite the administration of different drug combinations, including sofosbuvir/ledipasvir and sofosbuvir/velpatasvir, the results showed similarities. Several studies observed that there were no vertical transmissions among participants. Taken together, these trials show no significant adverse drug reactions. Similar side effects were observed in every study performed, including nausea, headache, fatigue and vomiting. Future studies should include larger groups of patients. Further investigation is required to clarify if the DAAs therapy can be administered during postpartum and breastfeeding.

Conclusions

World Health Organization's program about combating hepatitis B and C to reach elimination by 2030 should motivate us to focus on mother to child transmission of HCV. Increased detection of HCV in early pregnancy may create an opportunity for us to reduce the HCV viremia and minimalize the risk of MTCT. The efficacy of treatment with DAAs is very high and all trials included in this review presented no detectable HCV RNA among newborns. According to the conducted studies DAAs therapy is safe for pregnant women, fetus and newborns. More clinical trials in larger groups of patients are necessary.

Data bases

References used in the review were found in databases: Pubmed, Scopus.

Limitations

The main limitation of this review was the research conducted on small groups of patients.

Disclosure

Conceptualization: Magdalena Zapalska, Lidia Kulig, Barbara Izabela Krupska, Julia Anna Malec, Marcin Wieleba

Methodology: Magdalena Zapalska, Marcin Wieleba, Franciszek Włodarczyk, Katarzyna Wiktoria Witczak

Software: Zuzanna Winiarska, Eliza Wiercioch, Weronika Maria Woźniak, Katarzyna Wiktoria Witczak

Check: Magdalena Zapalska, Marcin Wieleba, Franciszek Włodarczyk

Formal analysis: Julia Anna Malec, Weronika Maria Woźniak, Franciszek Włodarczyk, Barbara Izabela Krupska

Investigation: Magdalena Zapalska, Barbara Izabela Krupska, Lidia Kulig

Resources: Magdalena Zapalska, Katarzyna Wiktoria Witczak, Zuzanna Winiarska, Julia Anna Malec

Data curation: Weronika Maria Woźniak, Franciszek Włodarczyk, Marcin Wieleba

Writing-rough preparation: Magdalena Zapalska, Lidia Kulig

Writing-review and editing: Weronika Maria Woźniak, Eliza Wiercioch, Marcin Wieleba

Project administration: Magdalena Zapalska

Author's Contribution

All authors have read and agreed with the published version of the manuscript.

Funding

This research received no external funding.

Institutional Review Board Statement

Not applicable.

Informed Consent Statement

Not applicable.

Data Availability Statement

Not applicable.

Acknowledgments

Not applicable.

Conflict of interest

Authors declare no conflicts of interest.

Declaration of the use of generative AI and AI-assisted technologies in the writing process

In preparing this work, the author(s) used ChatGPT for language improvement and grammatical correction. After using this tool/service, the author(s) have reviewed and edited the content as needed and accept full responsibility for the substantive content of the publication.

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